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Three-Dimensional Breast Assessment by Multiple Stereophotogrammetry after Breast Reconstruction with Latissimus Dorsi Flap

Helga Henseler M.D.

Thesis submitted for the degree of Doctor of Philosophy to the Faculty of Medicine, University of Glasgow

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and in

Glasgow Dental Hospital & School

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Summary

Introduction

Numerous methods exist for the assessment of the female breast. Traditionally, a subjective approach was taken for surgical planning and evaluation of the postoperative outcome. Several objective methods have been developed to support this procedure, among which are laser scanning, MRI, mammography, ultrasound and photography. Recently, 3D imaging technology has been developed.

Material & Method

3D breast assessment by multiple stereophotogrammetry was examined. A custom-made imaging system with eight digital cameras arranged in four camera pods was utilised. This system was used for breast capture, resulting in eight images obtained by the cameras. The merging of these images and 3D image construction was carried out by C3D software and the volume assessment of the 3D images was made using breast analysis tool (BAT) software, developed by Glasgow University.

A validation study was conducted. Nine plaster models were investigated and their volume determined by 3D stereophotogrammetry and water displacement method. Water displacement was considered to be the gold standard for comparison. The plaster models were specially made in order to represent a variety of shapes and

sizes of the female breast. Each plaster model was examined 10 times by each method. Further, the volumes of the breasts of six female volunteer live models were investigated by the same two methods and the results compared. A special focus was placed on the reproducibility of the assessment. Each live model was captured with the 3D capture system three times at two different time points after retaking a special pose in a custom-made positioning frame. Altogether, each live model was measured three times with BAT software.

A patient study was conducted in 44 patients after unilateral immediate breast reconstruction with Latissimus dorsi flap and no contra-lateral surgery. Each patient underwent 3D imaging with the multiple stereophotogrammetry system. During capture, the special pose in the custom-made positioning frame was taken by the patient's leaning forward almost horizontally with the upper body for the breasts to rise off the chest wall to enable full breast coverage by the cameras. 3D images were constructed with C3D software and volumes measured with BAT. For each patient, one 3D image was constructed and measured four times with BAT software. In addition to the volume determination, a shape analysis was conducted. For this purpose, 10 landmarks were determined according to recommendations in the literature. Two landmarks, sternal notch and xiphoid, were marked, forming an imaginary midline between each other and four landmarks on each breast, i.e. the medial and lateral ends of the infra-mammary fold, and the most prominent and most inferior breast points were utilised for symmetry assessment between the right and left breasts. Each landmark was recorded four times by the operator on the 3D image and three-dimensional coordinates obtained. By assessment of the left and right breasts a breast asymmetry score was calculated.

Firstly, breast asymmetry was assessed objectively on the 3D images through the centroid size, which was determined as the square root of the sum of squared Euclidian distances from each landmark to the centroid. The centroid was the geometric mean of the landmarks. Secondly, asymmetry was assessed through breast volume by application of BAT software. Thirdly, asymmetry was examined through the landmarks themselves by investigation of the mismatch of the landmark configuration of one breast and its relabelled and matched reflection. The non-operated and reconstructed sides were compared and landmarks were recorded by the operator in three dimensions in four repeated tests. A decomposition of the total landmark asymmetry into its factors was conducted by fixation of the surface of the non-operated side and translation, rotation and scaling of the surface of the reconstructed side.

For comparison, a subjective breast assessment was conducted by six expert observers who rated the results after breast reconstruction by subjective qualitative assessment of the symmetry in 2D images of the same 44 patients in six poses. For this purpose the Harris scale was utilised, providing a score of 1 to 4 for poor to excellent symmetry.

Results

The results revealed that differences in the obtained volumes in the plaster models were not significant. In contrast, differences in the breast volumes measured in the live models were significant. The examination of the reproducibility revealed that overall reproducibility obtained by stereophotogrammetry was better than that obtained by water displacement. No correlation between breast size and reproducibility of the measurements was found.

The results of the patient study demonstrated that the reproducibility of the landmarks was within 5 mm. There was a non-significant difference of the centroid sizes between both breasts. There was a significant difference of the volumes between the two breasts, with the non-operated side being larger than the reconstructed side. Volume was considered to be a more accurate measure for comparison of both breasts than centroid size as it was based on thousands of data points for the calculation as opposed to only four points of the centroid size. The statistical analysis of the landmark data provided a mathematical formula for determination of the breast asymmetry score. The average asymmetry score, derived by landmark assessment as the degree of mismatch between both sides, was 0.052 with scores ranging from 0.019 (lowest score) to 0.136 (highest score). The decomposition of the landmark-based asymmetry revealed that location was the most important factor contributing to breast asymmetry, ahead of intrinsic breast asymmetry, orientation and scale.

When investigating the subjective assessment, the inter-observer agreement was good or substantial. There was moderate agreement on the controls and fair to substantial intra-observer agreement.

When comparing the objective and subjective assessments, it was found that the relationship between the two scores was highly significant.

Conclusion

We concluded that 3D breast assessment by multiple stereophotogrammetry was reliable for a comparative analysis and provided objective data to breast volume, shape and symmetry. A breast asymmetry score was developed, enabling an objective measurement of breast asymmetry after breast reconstruction. 3D breast assessment served as an objective method for comparison to subjective breast assessment.

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Henseler, H., Khambay, B., Bowman, A., Smith, J., Siebert, P., Oehler, S., Ju, X., Ayoub, A., Ray, A.: **Investigation into accuracy and reproducibility of a 3D breast imaging system using multiple stereo cameras**, *JPRAS*, , 2011; 64 (5): 577-582

Henseler, H., Smith, J., Bowman, A., Khambay, B., Ju, X., Ayoub, A., Ray, A.:
Investigation into Variation and Errors of a 3D Breast Imaging System using
Multiple Stereo Cameras, *JPRAS*, online with editors, October 2011

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List of Posters

Henseler, H.: **Validation of 3D imaging system using multiple stereo cameras.** Presented at 14th International Congress of the International Confederation for Plastic, Reconstructive and Aesthetic Surgery (IPRAS), June 26th-30th, 2007, Berlin, Germany

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Henseler, H.: Validation of a 3D multiple stereo camera system, reproducibility of breast assessment in the live model. Presented at the 40th Annual Conference of the German Society of Plastic, Reconstructive and Aesthetic Surgery (DGPRAEC) and the 14th Annual Conference of German Aesthetic Plastic Surgeons, September 10th to 12th, 2009, Hanover, Germany

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Henseler, H.:**The importance of the pose in 3D imaging of the breast.** Presented at the 42nd/ 49th Annual Conference of the German/ Austrian Society of Plastic, Reconstructive andSeptember 29th to October 1st, 2011, Innsbruck, Austria

Literature review

Introduction

Breast cancer is now the most common cancer in the UK (48). Each year more than 45000 women are diagnosed with breast cancer, the equivalent of more than 100 women a day. The lifetime risk of developing breast cancer is 1 in 9 for women in the UK. Worldwide, more than a million women are diagnosed with breast cancer every year. Breast cancer is now the second most common cause of death from cancer in women after lung cancer, but more women are surviving breast cancer than ever before.

Breast reconstruction is the rebuilding of a breast and is a crucial part of breast cancer treatment (71). The need for, and the value of, breast reconstruction is universally accepted. It involves using autologous tissue or prosthetic material to construct a natural-looking breast (64). Breast reconstruction is a large undertaking that usually takes multiple operations. Several surgical methods of breast reconstruction exist, but which technique produces the "best" result in terms of shape and symmetry still needs to be assessed. The surgeon strives for, and the patient desires, breast symmetry, which is considered to be a feature of beauty (93). The ideal reconstruction is the creation of a mirror image of the unaffected breast, a degree of symmetry which may or may not be fully achieved (33; 66;

117). In breast conserving therapy, breast symmetry is judged as perfect if the operated breast does not differ in size and shape from the contra-lateral side (32).

To date, the evaluation of breast symmetry and shape has been mostly subjective (18). Poor accuracy, predictability, reproducibility and inter-observer agreement were among the problems associated with the method of subjective breast assessment (17).

Very few methods exist objectively to record the complex three-dimensional structure of the breast even though the assessment of the shape of the breast is of great importance in surgical planning, assessment of the quality of reconstruction and follow-up after treatment (83). The assessment of a complex three-dimensional structure like the breast should ideally be carried out with a three-dimensional measurement technique (75).

Among the methods to record the breast are laser scanning, magnetic resonance imaging (MRI), computerized axial tomography (CT), 3D ultrasonography and Moiré topography. Nevertheless, all these methods have their limitations. The utilisation of two cameras for three-dimensional imaging, known as stereophotogrammetry, was first described for clinical use in 1967 (14).

The advances in 3D stereophotogrammetry have been used to capture facial morphology (3). Lately this technique was also been applied in the field of the assessment of breast reconstruction. However, this new application has yet to be validated. To date, no extensive, reliable and repeatable validation of measurements with a multiple stereo camera system has been carried out and additional validation trials have been considered necessary (93).

The review of the literature is divided in three parts. It initially describes various objective methods of 3D capture of the body. Many of these methods have been applied to investigate the face. The review continues by presenting methods of breast assessment in general, which include subjective as well as objective methods. Finally, the review extends to various, modern and more specific methods of breast assessment by 3D imaging that have been developed recently, for example 3D multiple stereophotogrammetry, to examine the female breast.

1.1 Methods of 3D capture

1.1.1 Multiple Stereophotogrammetry

Stereophotogrammetry is a process in which two cameras are utilised together as one camera pod and was first described in 1967 by Burke& Beard (14). The authors conducted a preliminary investigation into the accuracy of a simplified system for contour mapping by photography through the application of a dual purpose stereo camera and plotting instrument. The stereo camera recorded in stereo a pair of photographs of a posed face and the mapping instrument plotted contour maps of that face. Initially the technique was only used for facial examination and it was refined over the years.

Three-dimensional imaging, also called stereoscopy or stereoscopic photography, is defined as any technique capable of recording three-dimensional visual information or creating the illusion of depth in an image (14). Two images of the same object are blended into one, giving a three-dimensional appearance to the single image. By presenting a slightly different image to each eye, the illusion of depth is created. This was first invented by Sir Charles Wheatstone in 1838 (132).

Photogrammetry has been described as a process of obtaining measurements by means of photographs (38). It involves the determination of geometric properties from photographs.

An investigation into the clinical applicability of a 3D stereophotogrammetry system utilised custom made software for a system called "C3D clinical" (92). The C3D system was created through collaboration between the Turing Institute and the University of Glasgow, Dental School. Overlapping images of the facial surface of a patient were captured using TV cameras, calibration information was added and a 3D model of the patient was obtained. Examples of the application of the system in maxillofacial surgical planning and dental cast archiving were provided. The authors felt that the system was easy to use at a fast capture time and provided high measurement accuracy of distances angles and areas. It was concluded that widespread utility regarding shape and appearance analysis of a patient could be achieved. A measurement comparison and systematic investigation of the system accuracy was still outstanding.

The potential of 3D imaging was discovered when 3D imaging was applied to archiving dental study casts (4). A stereo pair of video cameras and special textured illumination was utilised for capture of a dental plaster cast. Two pairs of images with normal illumination and with textured illumination were obtained. C3D software was used for 3D built up. An estimate of the accuracy of the computer generated cast based on past experience was given, of about 0.2mm.

3D imaging by speckle texture projection photogrammetry was introduced and application of the C3D system was developed for human body capture (111). C3D was described as a 3D sensing technique and was based on white light speckle texture projection photogrammetry. The author cited the advantages of the method over other non-contact optical measurement techniques. He cited the geometric simplicity of the capture hardware, well understood calibration methods leading to higher accuracy of measurements, full field capture with high capture speed, inexpensive hardware, reliability of the system and software as the principal component as advantages. Limitations were seen in the measurement resolution dependent on the cameras, difficulties of integration of large numbers of cameras that are required for full field coverage, the need for texture illumination for featureless surfaces as well as the computer intensive data analysis. For depth sensing C3D was based on a certain camera to projector to camera baseline configuration. Each point imaged with one camera matched a corresponding point imaged with the other camera and this process was called stereo matching. A patented software algorithm was used, and a disparity map obtained whose values mapped each pixel coordinate in the x and y direction. Image capture was conducted with two monochrome and one colour camera. Calibration was given a special consideration. Illumination was conducted with special texture flash projectors and white light flashes. From the disparities, the range values were recovered after projection of a notional ray from each corresponding pair of pixels. Their intersection in 3D space was computed, a process called space intersection. This resulted in a point cloud in X, Y and Z space. The point cloud from one stereo pair of cameras comprised 2.5 D information whereas the one from two or more stereo pairs of cameras provided 3D information. A five-pod system was utilised. A surface was computed by a known marching cubes algorithm (82). The principle of the application was explained, examples were given but no systematic study was presented.

The accuracy of 3D stereophotogrammetry for achieving dental study models was formally examined by conducting a comparison between direct measurements on dental study models and measurements on the computer generated threedimensional images (7). For this purpose, 22 dental study models were measured directly using an Orthomax Vernier calliper for determination of the distances between six anatomical dental landmarks. The same study models were also captured by 3D stereophotogrammetry and images digitally stored. On the computer-generated 3D image the same points were digitised and the distances between the points calculated. Intra-observer error was assessed by repeating the measurements eight times. The Euclidian distance matrix analysis of the morphometric features, which is a method of analysis of all possible inter-landmark distances, was applied. Statistical analysis of the two sets of measurements by application of a two sample t-test was conducted. The average difference was 0.27 mm and was not statistically significant (p<0.05). The intra-observer variation in measuring the same points was not statistically significant. The accuracy of the method was judged satisfactory for 3D storage of dental study casts.

The application of 3D stereophotogrammetry with the C3D software system for clinical use was investigated (38). A review was presented of other available methods for 3D assessment of the face. Among these were 3D cephalometry, morphoanalysis, CT-assisted 3D imaging, stereolithography, 3D laser scanning, Moiré topography, 3D facial morphometry and 3D ultrasonography. Disadvantages of these methods were seen as exposure to radiation, long capture time and cumbersome equipment. The C3D system that was presented consisted of stereo pairs of monochrome digital cameras and a third central colour camera to capture

skin texture. Illumination was conducted with special texture flash projectors and white light flash. The process of 3D imaging was described that evolved from the monochrome 2D images of each camera pod, disparity models and confidence map, 2.5 D range models of each camera pod to the final 3D image of the face. With the C3D system 30 landmarks on 10 3D models were identified three times and assessments conducted with a new software system, facial analysis tool. The reproducibility of landmark identification was high for 20 of the chosen points at standard deviations around the landmark centroids of ≤ 0.5 mm.

Hood aimed to determine the degree of facial asymmetry in children with cleft lip and/ or palate (47). A study of 20 children with unilateral clefts and 20 controls was conducted. Stereophotogrammetry images with the C3D imaging system were obtained prior to repair and 3, 6 and 12 months post repair. Twenty-eight anatomical landmarks, which had unique 3D co-ordinates in space, were identified on 3D models. 3D configurations were generated and mirror images obtained. These landmark configurations were aligned by Procrustes analysis. Procrustes analysis is a mathematical method of manipulating configurations of landmarks for comparison independently of size and position (90). It is used for size and shape measurements in morphometrics, derived from the Greek words "morph" (shape) and "mentron" (measurement). Firstly the configurations were aligned to a common size, then reflected, rotated and translated to achieve a best fit. Mean square distances between original landmarks and their mirror images for each 3D configuration were calculated and expressed as the asymmetry score. The results revealed that asymmetry scores in the controls were stable. Children with unilateral cleft lip and palate were more asymmetric than those with unilateral cleft lip. Improvement in asymmetry scores in children with unilateral cleft lip and palate were based on improvement in nasal form after surgery but this was not so in children with unilateral cleft lip. It was concluded that facial asymmetry scores should be differentiated from lip and nose asymmetry scores. The study outlined the benefit of the application of the C3D imaging method in objectively recording facial asymmetry.

The validity of the three-dimensional imaging technique was examined (3). A fullface alginate impression was taken in twenty-one children with cleft lip and a stone cast was made on which five anthropometric points were marked. After digitisation of each cast, the 3D co-ordinates of the five points were obtained using a validated co-ordinate measuring machine (CMM, Ferranti). This machine uses a probe to sense the object to measure. Each cast was then scanned in four different positions with a computerised stereophotogrammetry (C3D) system. Landmarks were digitised on the computer screen by three examiners and their co-ordinates extracted. After alignment of the co-ordinate systems of both methods, C3D and CMM, a comparison was conducted using partial Procrustes analysis. Operator error was found to be within 0.2mm of the true landmark co-ordinates. The C3D system error was determined at an accuracy of 0.4 mm. The registration error revealed an average displacement of points over the 21 casts at four positions of 0.79 mm (median 0.68). The 3D imaging system was judged as reliable at a fast capture time of about 50 milliseconds for monochrome and coloured stereo images.

The application of 3D imaging in orthodontics was presented (40; 41). The generation of 3D models in three steps was discussed in terms of "modelling", describing the physical properties of an object, displayed as a wire- framed or polygon mesh and additional texture mapping with application of a surface layer of pixels, to secondly "shading" and lightning of the 3D model and finally to "rendering" describing the conversion of anatomical data in a life-like 3D object. Examples of displaying the face as well as the teeth were given. The future of orthognathic surgical planning was seen in a combination of CT-based maps and stereophotogrammetry to create an integrated 3D model. Software for this purpose was presented, but no systematic study.

Facial symmetry was examined before and after orthognatic surgery (39). Fortyfour patients, divided in three different groups according to surgical method, were included. 3D images were taken following a standardised protocol. A two pod capture system was used, capturing the face from bilateral antero- lateral position, C3D software was applied and images translated into virtual reality modelling language and measured with facial analysis tool software. Landmarks were digitised on the 3D images, the landmark configuration was mirror imaged over an arbitrary plane and a superimposition of the original on the reflected configuration conducted. With Procrustes analysis, the asymmetry was assessed by calculation of an asymmetry score from the squared distances between both configurations. This resulted in objective comparability of the three different surgical methods regarding symmetry improvement and assessment of longitudinal changes. The validity of the new method of 3D stereophotogrammetry for the assessment of facial volumetric changes after orthognatic surgery was further examined (42). The validation was conducted on a lifelike plastic female dummy head as well as on a live male subject head. 29 landmarks were marked with a permanent ink pen on the dummy model as well as on the live model's face before capture with a clinical 3D imaging system (C3D). The model was exported as a Virtual Reality Modelling Language Model, file size 2 to 5 megabytes displaying a mesh made out of mesh nodes and triangles. Thirty facial silicone specimens were made displaying the nasal and periorbital regions in different shapes to simulate different facial deformities. These specimens were applied on the dummy head and their volume determined by stereophotogrammetry and water displacement method. 3D manipulation software (facial analysis tool) was used to calculate the volume of each specimen on the 3D image and three different algorithms tested for this purpose. The landmarks were utilised for registration of the models before and after application of the silicone specimen and superimposition of the images for assessment with ordinary Procrustes alignment. The live subject was also examined with and without silicone patches. Student t- test was applied. The results revealed that one of the three algorithms in the facial analysis software presented the least error and that the error in the live subject was increased. The authors concluded that facial expression should be standardised and that the method was valid for the use in the 3D assessment of orthognathic surgical outcome.

The options and limitations of three-dimensional stereophotogrammetry were discussed and a comparison with laser scanning conducted (128). No systematic

study was presented, but experience was reported. 3D imaging technologies were discussed in terms of their application of indirect anthropometry in comparison with direct anthropometry. Limitations of the indirect method were seen. A restriction of the field of vision of any 3D imaging technology was criticised. Measurement error was judged as being caused by difficulties in landmark location, inconsistent measurement procedures and faulty equipment. The authors were of the opinion that the measurement error needed to be investigated by testing accuracy (degree of congruence between new and established techniques), reproducibility (collecting data in a consistent manner), precision (multiple observers/ repeated measurements) and bias (systematically over- or underestimating values). Tests by commercial manufacturers were criticised as being conducted under idealised conditions, lacking examinations for precision and bias and being influenced by a conflict of interest. The lack of large databases presenting normal population data on 3D surface anthropometry was seen as a problem. The main difference to laser systems was regarded as being their longer capture speed. The existence of synchronous 3D photogrammetry systems versus sequential systems regarding 3D data points and colour/texture information was mentioned. An explanation was given for the terminology "modularity" describing the option to add further cameras. Software requirements were quoted as user-guided rotation and surface renderings, application of landmarks on the images and recording of their x-, yand z-coordinates, measurement options for linear distances, capture angles, calculation of surface arcs and areas as well as volume calculation. The superimposition of images and customer dependent application were cited. The recommendation was made extensively to test any system before purchase.

A comparison of two commercially available methods of 3D stereophotogrammetry by the Genex and by the 3dMD system and a comparison with direct anthropometry using a digital calliper for the investigation of the face was conducted and published one year later (129). The limitations and considerations from the anthropometric perspectives were discussed. On 18 manneguin heads, 12 linear distances were measured twice by each method. The results revealed that overall mean differences were small for all methods and of little practical importance. Adequate landmark identification was seen as critical and therefore training was recommended, particularly in indirect anthropometry. Measurement error was regarded as a problem and the lack of large normal databases as a control of the 3D data was seen as a disadvantage. No difference in the quality of the software for both 3D systems was seen. The results suggested that calliperderived measurements on the dummy models were as precise as those made with the two 3D methods. Intra-observer error for all methods was equally distributed, inter-observer error was not assessed. It was recommended that software should be customised. Weinberg (2006) advised extensive testing of any system before purchase.

The validation and accuracy of a three-dimensional imaging system (Di3D), Dimensional Imaging, Glasgow, was assessed (133). Accuracy was described as a mean error measurement when comparing measurements of a real object to a three-dimensional digital model. A clinically irrelevant difference was understood as one of less than 1.0mm for the head. The investigation was conducted with the application of 4 digital cameras with 8 mega pixels and 50 mm lenses. Di3D capture and reconstruction software was applied. The head, face and neck of a mannequin were imaged after red paint was brushed on to provide texture. 18 anatomical landmarks on the mannequin's head were located and marked with a fine pen, leaving dots of less than 0.5mm in size. Firstly, 10 repeated captures and measurements were made of the mannequin's head facing the cameras with reconstruction of the surface data, calculation of the mean and differences of the 10 surfaces and so providing mean error and variance of the measurements. Secondly, physical linear landmark distances were measured manually with a digital Vernier calliper on the mannequin's head and compared to the colourcoded software measurements on the textured three-dimensional image: Reproducibility was examined for assessment of the extent of human error. Thirdly, the system's field of view was examined by analysing a sphere modelling the patient's head. A meter ruler was imaged vertically and horizontally as well as a bowling ball representing the mannequin's head at a fixed distance of 90 cm. The proportion of it being captured and the angle of coverage with the camera system were assessed and the radius of the bowling ball was compared with the radius of the digitised image.

The results for the first test showed a mean error in three-dimensional surface measurements of 0.057 mm and high reproducibility of measurements (variance of 0.0016 mm). The second test presented a mean error in linear distance measurements of 0.62 mm. The third test revealed a complete coverage of the field of view of 170° horizontally and 102° vertically. The authors concluded that their approach of utilising a mannequin's head for assessing a three-dimensional imaging system was sufficient to assess accuracy and reproducibility of measurements and that the validation of the system was achieved.

The validation and reproducibility of a high resolution three-dimensional imaging system (Di3D) was further examined (70). A 2 pod stereo camera system with 4 cameras was utilised. 12 adult plaster casts that were derived from alginate impressions of live models' faces were captured. Before capture, 10 landmarks were placed onto the plaster casts using a fine dental probe, leaving an indentation that was marked with ink. All casts were captured after being securely positioned on a tripod and a 3D model was built with Di3D software. The landmarks on each three-dimensional image were digitised on the computer screen by one observer recording the three positional coordinates of each landmark. For comparison, an Axiom coordinate measuring machine, CMM (Aberlink Itd., Glouchestershire, Uk), was utilised as this is regarded as the gold standard. This machine applied a stylus touch probe for measuring the threedimensional coordinates of the landmarks of known accuracy. Two observers recorded the landmark coordinate data for each plaster cast on two occasions, providing four sets of data of coordinates for each plaster cast from which the mean measurement was calculated. The operator error, which was the error derived by repeatedly placing landmarks on the three dimensional image, was assessed. For quantification of this error, the Euclidian distance was calculated between repeated digitised sets of landmarks on each of the 3D models for each cast from each capture. Therefore, two sets of distances, one from each capture session, were produced. The reproducibility error was evaluated from repeating the capture of the casts on two different occasions, which provided two sets of coordinates from each capture session that were averaged. This led to two 3D configurations that were compared through ordinary Procrustes Analysis (OPA) with matching, translation and rotation. The Euclidian distance between the two sets of coordinates was calculated. The Di3D system error was the error

associated with the system calculated through the four sets of coordinates for each landmark, two sets from each capture session. By this, the threedimensional global positions of the landmarks on the three-dimensional images were obtained, which then could be compared with those obtained by CMM. Comparison was conducted with ordinary Procrustes analysis after alignment of the coordinates obtained by both methods, translation and rotation. The operator error was small at 0.07 mm, the reproducibility error of the Di3D system was low at 0.13 mm, the Di3D system error derived by the mean distance between the CMM and Di3D landmarks was 0.21 mm and therefore less than the 0.4 mm system error previously reported by Ayoub (2003) with the C3D system (3). The result of the Di3D system was judged as clinically acceptable and offered considerable improvement in stereophotogrammetry for facial capture and analysis. The work presented an important and well-conducted study making a valuable contribution to the field of validation and assessment of the reproducibility of a threedimensional imaging system.

1.1.2 Laser

A laser is defined as a device that emits coherent light radiation, usually with the help of crystals (50). The term "laser" is an acronym for "Light Amplification by Stimulated Emission of Radiation" (36). The underlying process for laser action, stimulated emission, was first described theoretically by Albert Einstein in 1917. A patent application was processed in 1958 by Arthur Scharlow and Charles Hard Townes, but was later challenged by Gordon Gould (36).

A laser produces an intense beam of coherent light (54). The word light is used in a broader sense, referring to electromagnetic radiation of any frequency, not just the visible spectrum. There are infrared lasers, ultraviolet lasers, X-ray lasers and others. Typically a laser emits coherent radiation in a narrow, low divergence beam, with a narrow wavelength spectrum.

A laser scanner is an optical scanner that serves as an input device using a light beam to scan codes, text, or graphic images (54). A laser scanner can be utilised for 3D scanning to analyse a real world object or environment to collect data on shape and appearance. It is a non-invasive method which produces surface coordinates which are stored in computer memory (38).

In a medical context, a laser has been described as a device using light from a collimated source aperture that scans the patient (120). The reflected light from the surface being scanned is used to generate a surface topographical image. The scanning process takes a few seconds and the surface shape obtained is converted into a lattice of thousands of points. The shortfalls of the method when scanning humans are the slowness of the method leading to distortion and the need for eye closure and holding the breath for torso scanning and limitations in surface texture capture (38).

A Minolta Vivid 910 laser scanning system was utilised to investigate the accuracy and precision of three-dimensional assessment of the facial surface with a 3D Laser Scanner (77). For the validation of the method, a comparison of data obtained by manual measurements with a digital calliper on a dummy model with those obtained by laser scanning was utilised. 162 distance measurements taken manually between landmarks and repeated by each of two observers were examined. The results revealed that less than 7% of data provided with the scanner were outside a range of error of 2 mm compared to the manual measurements. It was concluded that the accuracy was sufficient for clinical practice.

The application of a laser scanner for the examination of the face was investigated with the aim of establishing a measurement protocol (76). Five male volunteers were examined in a variety of settings regarding camera and laser numbers as well as position, recording angles and head positions of the test subjects. 48 landmarks were applied either before scanning on the face or after scanning on the virtual face model and a comparison conducted between manually taken data between landmarks tagged on the faces and those applied on the virtual models. Three examiners repeated the measurements ten times with the scanner: 10 different virtual face models with and without texture were examined. The results revealed that 50% of the inter-landmark distances deviated by more than 2mm between the manual and virtual data. Measurement precision could be increased by shortening capture time, stabilising the subjects` head positions and when landmarks were drawn on the virtual model rather than on the life model before scanning. Shaded pictures provided more measurement precision than textured ones.

Some laser scanners are called photonic scanners. Photonics is the science and technology based on the controlled flow of photons or light particles (127). It is the optical equivalent of electronics and the two technologies coexist in such innovations as optoelectronic integrated circuits. Photonic devices include laser and photo detectors, data storage, using optical disks and holograms, data transmission by optical fibre optic devices, telecommunications, optical switches and light modulators. Photonics deals with generating, controlling and detecting photons, mainly in the visible and infrared but also in the ultraviolet, long-wave infrared and far infrared spectrum. A photonic scanner is a device that transmits information using light beams. Images or text are converted into digital information that can be stored as a computer file and processed by graphics software. The first transistor was created in 1948 and photonics was an outgrowth of the first practical semiconductor light emitters invented in the early 1960s at General Electrics, MIT Lincoln laboratory. Photonics as a field emerged in 1960 with the invention of the laser and later provided the infrastructure for the internet.

1.1.3 Moiré topography and contour photography

Moiré topography is a method of three-dimensional morphometry in which contour maps are produced from overlapping interference fringes created when an object is illuminated by beams of coherent light issuing from two different point sources (49). The name derives from the French word for "watered" (57).

Moiré topography uses grid projections during exposure for the creation of standardised contour lines of a surface (81). It was further described as a lightsectioning technique for three-dimensional facial measurements with the utilisation of telecentric lenses for the elimination of divergence. The accuracy and reproducibility of contour photography was assessed using firstly, a polystyrene model head with life-like facial contours Secondly, 12 mature, carefully-posed subjects were examined and wax bite impressions were taken on two occasions in centric occlusion and in protrusive positions. Inter-landmark distances were calculated and compared to direct measurement of the polystyrene model as well as of the live models. Results revealed less than 1 mm errors for measurements between facial landmarks by direct measurements and contour photography in the polystyrene model. In the live models, three distances in the middle third of the face from the external canthi to the nose tip varied less than 1mm over time and changes from centric occlusion to protrusive bite were similar. The greatest variations were from external canthi to the angles of the mouth. The authors concluded that facial movement, problems in landmark identification and measurement errors were disadvantages of the method. Advantages were seen as being relatively inexpensive equipment, low cost attached to each contour plot and easy training. In comparison with stereophotogrammetry, the accuracy of the method was seen as inferior, more so in the lateral than in the medial facial area. A standardisation of the head position was suggested for improvement of the reproducibility of contour photography.

A system using moiré stripes was presented and examined on 60 Japanese high school students for facial analysis (69). Facial photography was conducted with the moiré camera, moiré stripes were entered into a computer and automatic analysis of facial dimensions conducted. The faces were examined with the utilisation of three horizontal transverse sections. Mean and standard deviation in male and female subjects for each section were assessed. Differences between the sexes in regard to the central region of the face were analysed, as well as those between right and left side of the face. For comparison a circular cylinder was photographed under the same conditions as the students. For analysis of the moiré photographs, the centre of each strip was traced and X, Y and Z coordinates of 400 points on each stripe put into a coordinate reader and entered in the computer. The facial form was stored as a mesh. The examination of the precision of the method revealed similar results for right and left values for the circular cylinder. In the students there were significant differences for both sides of the face and for both genders. The height difference between right and left side of the upper lip was more than 1mm. Based on these results the authors were of the opinion that it should be permissible to accept a 1 mm difference between the two sides of the upper lip in cases of lip repair in cleft lip and palate patients.

A projection moiré system is a further development of the shadow moiré system to overcome the one dimensional presentation (116). The shadow moiré system was originally utilised in the aeronautical industry and the projection moiré system later in medicine. For the validation of a projection moiré system a comparison with nine mathematically defined geometrically formed specimen was performed that were fabricated to match alveolar ridge defects pre- and postoperatively. Six "A" specimens had a rectangular form, while three "B" specimens had a more complex 3D surface. The nine specimens were formed using commercially available aluminium alloy and a milling machine. The true volume of the mathematical defined form was assessed with a mechanical 3D coordinate measuring machine or by a software-controlled milling machine. The absolute and relative variability of the volume measurements were obtained. The optical moiré system utilised a phase shift technique for the comparison of pre- with postoperative images. The systematic error of the moiré measurements was examined when comparing the data of the moiré system with the mathematical calculation data of the nine specimens. The data for the B specimen showed less accuracy than for the A specimen, which had a lower relative systematic error. The systematic error of the moiré system with the mathematic error. The systematic error of the moiré system with the moiré system was less than 2.8 %. The variability of the measurements was within 2.2 %.

Further experience has been gathered and discussed with the moiré method delivering 3D information of the face (38). The importance of the exact positioning of the object for examination by Moiré topography and contour photography was stressed in the literature as a small change in head or body position produced a large change in fringe pattern. A disadvantage was seen in obtaining 3D information on surfaces with sharp features so that application only on smooth surfaces was recommended.

1.1.4 MRI

Magnetic resonance imaging (MRI) is defined as a diagnostic scanning technique which gives precise images of internal tissues by analysing its response of being bombarded with high-frequency radio waves within a strong magnetic field (58). It makes use of nuclear magnetic resonance to produce images of particularly the soft tissues of the human body. It is a medical imaging technique primarily used in radiology to visualise the structure of the body that does not show up well on x-rays. MRI is a valuable imaging method displaying the anatomy in detail and revealing minute abnormalities and changes.

The images of the body can be generated in any plane as slices or as 3D constructs. As the soft tissue contrast is greater than that of computed tomography, MRI is particularly useful in neurological, musculo-skeletal, cardiovascular and oncological imaging. With the powerful magnetic fields, the nuclear magnetisations of atoms in the body are aligned and radiofrequency fields are applied for systematic alteration of this alignment of the magnetisation. As the nuclei return to their previous state after each radio wave pulse, they produce radio signals which are detectable by the scanner. Through manipulation of these signals through magnetic fields enough information is created to build up the image of the body. Advantages are the lack of exposure to harmful x-ray radiation. Disadvantages are the cost and slowness of the method. Limitations are that it is unsuitable for application with patients with pacemakers or those suffering from claustrophobia.

The application of the MRI imaging method evolved in medicine in early 1980, when it was pioneered by Elias Zerhouni, an American radiologist. In 2003, Paul Lauterbur, an American chemist and Peter Mansfield, a British physicist, won Nobel prizes for its further development (58).

1.1.5 3D Ultrasonography

Ultrasound in medicine utilises high frequency sound (ultrasonic) waves to produce images of structures within the human body (55). 3D ultrasound is a method that delivers a three-dimensional reflection picture that is transformed into digital information and was developed from 2D ultrasound technique. Originally the method was first developed by Olaf von Ramm and Stephan Smith at Duke University in 1987 and patented. Due to the poor transmission and distortion of ultrasound waves as they pass through air a contact probe was required. Disadvantages were time needed for the examination, learning curve of the examiner, the need for a compliant patient and soft tissue distortion through use of the probe.

3D ultrasonography as a diagnostic medical imaging technique has found a use to visualise muscles, tendons and organs and further, in obstetrics to visualise the foetus (31).

A method of 3D ultrasound that used a special applicator for 3D data generation, as well as an early case report of a clinical application in oral and maxillofacial surgery, was described. (46). Data were obtained from several parallel ultrasound slices. A swinging probe, a rotating section probe or a rotating parallel probe for scanning was utilised. It was possible to visualise head and neck lymph nodes after subtraction of overlying tissue.

The application and value of 3D ultrasound in the field of 3D imaging was later discussed (38). It was stressed that the 3D ultrasound system provided the 3D coordinates of surface landmarks that were chosen but not the 3D image itself.

3D ultrasound was further applied in gynaecology for the determination of gynaecological structures and the reliability and validity of the method was investigated (31). The author utilised a Volusen 530 D ultrasound machine (Kreuz Technik, Austria) for trans-abdominal and trans-vaginal scanning. In twenty eight women, admitted for hysterectomy, preoperatively a trans-abdominal and transvaginal ultrasound image of the cervix was obtained. Three cases had to be excluded due to body habitus. After hysterectomy the true cervical volume was determined by water displacement. A comparison was conducted with the computer generated three-dimensional volumes that were calculated using 10 equidistant slices. Two examiners conducted the examination blinded to the true volumes and repeated the examination. Intra- and inter-observer reliability was examined. No significant differences were found between the two ultrasound methods of cervical volume examination. Comparing the two ultrasound methods with the true volume, both methods performed equally poorly. Intra-observer reliability was good, while inter-observer reliability was good for trans-vaginal images but poor for trans-abdominal images. The validity and reliability of 3D volume estimation of the non pregnant cervix was judged as poor.

The same Volusen 3D ultrasound system was enhanced with modern software and a further study on the inter-observer reliability and validity was conducted (102). Two observers were given a single three-dimensional ultrasound dataset of three phantom objects of different sizes and shapes that were water-filled of known volume. True volumes were established by water displacement technique. Different techniques of 3D ultrasound were applied, rotational and conventional. The rotational technique of volume calculation relied on the rotation of a dataset through 180° about a central axis defined by the application of two callipers. In the conventional technique of volume calculation, a series of slices was taken through the volume of interest while the outlining of contour was conducted in another plane. The two observers measured each all six data sets using the rotational and conventional technique. Intra- and inter-reliability was assessed. The first method of rotational measurements of volume achieved a higher degree of reliability and validity but all techniques were highly reliable and valid to within 4% of the true volumes. Volume calculation from three-dimensional ultrasound data sets in the in vitro setting was judged as reliable and valid. Nevertheless the number of objects examined was small and a larger study with objects of different shapes and sizes should confirm the results.

1.2 Methods of assessment of the female breast

1.2.1Subjective approach

Subjective breast assessment based on the votes of experts was developed after radiation therapy for stages I and II carcinoma of the breast and a four-point Harris scale was introduced (43). Cosmetic results were analysed after application of primary radiation therapy to 29 patients presenting with 31 biopsy proven stage I and II breast cancers. The 29 patients were selected from a group of 80 patients that were treated with primary radiation therapy. From this group, all patients who were alive without disease were considered eligible to be included in the study which was a group of 46 patients. From this group, all patients who were able to see the authors during an evaluation period were included in the study which amounted to 29 patients. Two of the 29 patients had bilateral cancer so that 31 breasts were evaluated by at least one of the authors and photographed. Scoring for the adverse effects of the radiation therapy based on: 1. the extent of fibrosis; 2. skin changes, and; 3. match-line effect was performed. The match-line effect was defined as a localised area of fibrosis and skin change between adjacent radiation fields. The score that was suggested was: 0- none, 1- slight, 2moderate, 3- severe adverse effects. All photographs were subjectively reviewed by the authors and an overall cosmetic score, the Harris score, was given: 1. excellent- treated breast nearly identical to untreated breast; 2. good- treated breast slightly different than untreated; 3. fair- treated breast clearly different from untreated but not seriously distorted, and; 4. poor- treated breast seriously distorted. A scoring for the judgement of the aesthetic result of the biopsy was suggested and was: 0- scar unapparent, 1- scar apparent, 2- major tissue loss. The study revealed that the cosmetic outcome relied firstly on the extent and location of the breast cancer biopsy, secondly on the time and dose of the radiation therapy and thirdly on the technique of the radiation therapy. The study, conducted in 1979, presented ground-breaking work on the subjective assessment of the overall aesthetic outcome after biopsy and radiation therapy in breast cancer patients. The intra- and inter-observer error of the scoring method was not assessed. The suggested Harris score is still cited in the literature.

The question how subjective breast assessment would be influenced by the choice of observers was investigated regarding the evaluation of the aesthetic outcome in breast cancer conservative treatment (16). The observers' skills were assessed by evaluation of the inter-observer agreement. In 55 women, postoperative photographs were taken in four views, face with arms up and down, left and right side with the arms up, after unilateral breast cancer treatment. 5 controls without breast treatment were added. 13 observers were divided into three subgroups: experienced, medium experienced and inexperienced. The observers had to detect the 5 controls as well as the operated side in the patients and accuracy in doing so was individually assessed. The aesthetic results were subjectively judged as excellent, good, fair and poor by the observers. Inter-observer agreement in each group was assessed with the kappa statistic and the groups were compared. The results revealed that inexperienced observers performed significantly worse than experienced observers when identifying patients, controls and side of treatment. The inter-observer agreement was significantly greater in the group of

the experienced observers in comparison to those of the medium and inexperienced observers. The authors concluded that experience in breast cancer conservative treatment should be a requirement for the subjective evaluation of aesthetic results.

Subjective breast assessment and inter-observer agreement by 24 experts from 13 countries evaluating photographs of 60 women after breast conserving therapy was examined (17). The consensus of the experts over the aesthetic evaluation of conservative breast cancer treatment was investigated. Photographs were taken in four positions: patient facing forward and arms down, facing forward and arms up, from the left side with arms up and right side with arms up. The images were recorded on CD and posted to all observers. The classification of the overall aesthetic result was conducted according to the Harris scale as excellent, good, fair and poor. Observers were divided into subgroups according the gender, age, number of cases treated a year and number of publications. Inter-observer agreement was assessed with the kappa statistics. A kappa score equal to 0 was considered to indicate poor agreement, 0.01-0.20 slight agreement, 0.41-0.60 moderate agreement, 0.61-0.80 substantial agreement, 0.81-0.99 almost perfect and 1.00 perfect agreement.

Consensus was obtained by the Delphi method (45). The Delphi method is a subjective method to achieve systematically a consensual opinion in a group of examiners with reference to a research question. It is defined as a multistage procedure of opinion collection. Consensus is achieved if a certain percentage of examiners share the same opinion.

In Cardoso's study on inter-observer agreement, consensus was considered to have been reached when 50% or more of the experts provided the same classification. During several subsequent rounds feedback sheets with the consensual cases were distributed and non-consensual cases were decided upon again and revision opinion requested. Inter-observer agreement was fair between the experts working in different geographical areas and also fair when assessing the subgroups of experts. First round consensus was reached in 77% of the cases and second round consensus in 98% of the cases. In conclusion subjective breast assessment of conservative breast cancer treatment was just fairly reproducible between expert observers from different geographical areas. Intra-observer agreement was not evaluated. For studies in which a low level of agreement was sufficient, the authors felt that obtaining consensus was a suitable method.

The validity of a software programme, called BCCT-Core, for objective aesthetic assessment of breast cancer conservative treatment was examined and comparison conducted to subjective breast assessment (18). Twelve observers conducted a subjective judgement using the Harris scale on 30 digital photographs of patients. The photographs were taken in four positions: face with arms down, face with arms up, left side with arms up and right side with arms up. The photographs were rated as excellent, good, fair and poor. The rating was conducted at least one year after surgery or radiotherapy. Then the same twelve observers examined the BCCT.-Core software with application of a scale and reference points to the photographs. It was agreed that if at least two-thirds of observers provided the same classification this was considered as a consensus. The remaining cases were evaluated after open discussion. The software

performed an automatic assignment to a given class, once scale and reference points in the photograph had been selected by the observers. Subjective agreement between observers, between each observer and the consensus and between results by computer software achieved by each observer and the software and the consensus were evaluated. Kappa statistics were utilised, a kappa score of 0 indicated poor agreement, 0.01-0.2 - slight agreement, 0.21-0.4 fair agreement, 0.41-0.6 - moderate agreement, 0.61-0.8 – substantial agreement, 0.81-0.99 - almost perfect agreement, and 1 - perfect agreement. Inter-observer agreement was fair to moderate, agreement between the observers and the consensus was also fair to moderate, results for computer software achieved by each observer were consistent, but three participants failed to complete the assessment: agreement between software and consensus was substantial in the first 17 cases but in the cases overall only fair. Agreement was improved by reducing the four-point Harris scale to a three-point scale by merging the two middle classes together. In this case the results produced by the software showed good agreement with subjective expert votes. In conclusion the authors stated that the BCCT software provided a consistent evaluation of the appearance. The software produced similar results when used by the non-experts. However there were many limitations of the approach. These were due to a small study sample and poor accuracy and reproducibility of subjective judgement.

Cardoso further investigated factors determining aesthetic outcome after conservative breast cancer treatment based on the subjective consensus method (19). Photographs of 120 women were taken under standardised conditions at least one year after conservative unilateral breast cancer surgery with and without

axillary therapy and with radiotherapy. These images were sent to experts from 13 different countries and subjectively assessed as excellent, good, fair and poor. A retrospective data collection in view of patient characteristics, tumour- and treatment factors was conducted. The correlation between these factors and the overall aesthetic outcome was investigated by uni- and multivariate analysis. In 113 cases consensus with the Delphi method was obtained. In the group of the patient characteristics, younger and thinner patients, with lower body mass indexes and premenopausal status showed better cosmetic results. In the group of tumour and treatment related factors, larger surgically excised specimens, visible scarring, chemotherapy and long follow up periods were related to less aesthetic results. The only factors that were identified after multivariate analysis to determine the aesthetic outcome were the BMI and scar visibility that showed significant association with the cosmetic result after conservative breast cancer treatment.

A comparison of subjective versus objective approach was investigated by examining the question whether a single, face only photographic view was sufficient for the aesthetic evaluation of conservative breast cancer treatment (20). For objective assessment, a software programme, BCCT, was utilised that relied on photographs with the patient facing forward only. For subjective assessment, 150 patients were photographed at least one year postoperatively in four positions, face with arms down, face with arms up, left side with arms up and right side with arms up. The photographs, taken by a digital camera with four megapixels, were subjectively evaluated by a panel of experts using both the face-only and four-view assessment. The classification of results was conducted according to the Harris scale as excellent, good, fair and poor. By the Delphi method a consensus opinion was reached when 50% of observers provided the same classification on the aesthetic result. The agreement between the consensus and the BCCT software evaluation was calculated. The three experts who had the highest number of answers coincident with the final consensus were identified as those with the best evaluations of the panel of experts. Face-only view photographs of the 150 patients were subsequently arranged in a different order and send to these three experts. Their individual agreement between the face-only view, four-view photographs and consensus was evaluated. Results were compared to the software. There was a moderate agreement between the software and the consensus. The highest value of agreement from the three experts was between the four-view evaluation and consensus and matched the software agreement. The highest value of agreement from the three experts, between the face view evaluation and the consensus was only fair. Performance of the software based on a single, face-only view was considered equal to that obtained by the three experts using a four-view evaluation. The agreement in face-only view of the experts was only fair. It was concluded that the software evaluation provided sufficient information for accurate assessment of the aesthetic outcome of breast cancer conservative treatment in face-only view. The reason for this was seen as it being based on many factors besides simply asymmetry.

The majority of breast assessment still relies on a subjective approach, often with utilisation of subjective scales. The problem of high inter-observer discrepancies with subjective breast assessment remains a subject for discussion in the literature. This led to the question of the applicability of the use of subjective scales for prospective trials. A solution was suggested in form of a software programme for objective breast assessment (32). An excellent inter-observer reproducibility in the evaluation of the cosmetic outcome of breast surgery with the use of this software programme, called breast analysis tool (BAT©), developed by one of the authors (W.L.), was described. It was claimed that the study presented a newly invented breast symmetry index (BSI) for the first time based on this software. This symmetry index was calculated by subtracting size and shape between both breasts from the frontal and side view photographs. The breast was considered symmetric if it did not differ in size and shape to the contra-lateral side. In this case the breast symmetry was considered perfect. The digital photographs of 27 patients were examined with this software. A prospective randomised trial with analysis by patients, 5 experts and 5 non-experts was conducted. A 2 dimensional 2cm X 2cm scale adjacent to the breast was utilised for calibration. Initially jugulum and nipples were marked and the circumference between both breasts in front and side view determined. The analysis on the computer was conducted by application of the software versus subjective breast assessment with the Harris scale. There was a BSI frontal, side and total index derived and the results were given in percentage of differences. Values smaller than 30% were regarded as good, while those larger than 30% indicated a poor appearance. Linear regression analysis was performed as a statistical test for the correlation. Pearson Correlation was utilised for calculation of significant differences. Interobserver agreement was excellent at r=0.9, p<0.05.The software accuracy was tested on five drawings of breast dummy models. Distances that were measured with the software were compared with those measured by hand. The accuracy of the software tested against manual measurements was excellent and correlated nearly 100%. Inter- observer reproducibility was excellent. There was a significant correlation between the subjective vote of experts and the BSI frontal and total index but not side index. For non-experts this correlation was much lower. There was no correlation between BSI index and patient's view. It was concluded that the BSI index was able to give a significant differentiation between good and bad results. No information was given about the qualifications or number of examiners testing the software accuracy. The software presented in the paper provided only a 2D analysis. According to the authors, the 3D version of the software still needed to be developed.

In a review of literature a subjective approach in the judgement of breast conserving therapy was negatively criticised (134). A lack of standardisation in the evaluation of cosmetic results was described. Poor reproducibility of subjective methods of cosmetic evaluation even performed by experts was mentioned. BAT and BCCT.-Core software were discussed and limitations quoted. The design of new software that included patient, tumour and treatment characteristics for the application of postoperative quality control was recommended.

For assessment of congenital asymmetry, a comparison of subjective and objective assessment was conducted (88). The subjective assessment was based on a pre- and postoperative photographic analysis of 24 patients by a panel of observers as well as by patients providing symmetry scores. The two panels of observers were made up of an independent group of 10 university personnel and a group of 7 surgical staff, including the surgeon conducting the operation. The observers subjectively evaluated the symmetry of the patients` photographs using

visual, linear analogue scales, 10 cm long. Patients subjectively scored on a fivepoint scale from 5= very pleased to 1= very unhappy. Additionally, they judged their own breast symmetry on a visual, linear analogue scale 10 cm long. Objective breast assessment was conducted by linear measurements of the nipple position. The nipple position was determined by measuring the distance of nipple to sternal notch, nipple to midline, angle subtended by the nipple-sternal notch line and midline and centre of nipple to infra-mammary fold. Breast volume was also determined using stereophotogrammetry with a two-pod system called Body Map. A point-scoring system for documentation of differences in linear measurements and angle measurements of the left and the right breasts was utilised. Derived from this point- scoring system a qualitative judgement of the result as excellent, good, fair and poor was established. Linear differences of less than 1 cm and angle measurements of smaller than 2.5° lead to a score of 4 points, of 1 to 1.5 cm and 2.5° to 5° to a score of 3 points, of 1.5 to 2 cm and 5° to 7.5° to a score of 2 points and of more than 2 cm and more than 7.5° angle difference to 1 points. A total score of 16 points was judged as excellent, of 12 to 16 points as good, of 8 to 12 points as fair and of 4 to 8 points as poor. The results revealed that there was a significant difference between the preoperative symmetry scores by the panels of observers and their postoperative scores and so provide a quantitative documentation of the improvement in symmetry through surgery. There was an excellent correlation of the symmetry assessment of the 2 panels of observers. The results of the subjective patient assessment revealed that their expectations to a large extent were realised. A good correlation was found between the panel's estimates of symmetry and that of the patients. Patient satisfaction was significantly correlated with the degree of perceived symmetry but poorly correlated with volume estimates or linear measurements. In contrast, the mean

panel determined symmetry was strongly correlated with volume estimates and linear measurements. The author argued that visual assessment was the subject of bias. The usefulness of an objective measurement system of breast asymmetry was stressed. The study lacked focus on patient posing and error assessment.

A literature review on assessment of breast aesthetics was conducted and articles on subjective ratings, direct physical measurements, measurements on photography and assessment by three-dimensional imaging examined (72). The author expressed the opinion that a widespread use of subjective rating scales was not found due to a lack of precision and low intra- and inter-observer agreement. Four articles on this subject that based the subjective judgement on four or five point scales, partly with additional subscales were quoted and discussed. The subject population varied from 14 to 76 photographs of patients after either breast conservation or breast reconstruction surgery. The findings described low observer agreement, low reliability, low to moderate reliability of the subscales and lack of internal consistency and reproducibility. No original study was presented but a literature review was provided.

Another study on subjective breast assessment examined the effects of radiation therapy on pedicled transverse rectus abdominis musculo-cutaneous (TRAM) flap breast reconstruction on 199 patients with 232 flaps (21). By subjective approach the overall aesthetic appearances were assessed by blinded reviewers who graded the aesthetic results by comparing the right breast with the left one year after completion of treatment. Patients were grouped in five groups according to timing of reconstruction and radiation therapy. The overall aesthetic result was examined according to the Harris scale. Further, a judgment in subscales was added to three categories evaluating the volume of the breast mound, placement of the breast mound and infra-mammary fold. The results revealed that there was no difference in the subscale analysis and the summed subscale scores for the various groups. There was a statistically significant difference for the global score in favour of the group with immediate reconstruction without radiation. Smoking and radiation at any time negatively influenced the global cosmetic score. Interrater reliability showed some degree of reliability for the total subscale and fair agreement for the global score among the judges. There was no difference in TRAM flap complications in any of the groups that received radiotherapy. The study presented an excellent examination by subjective approach. In line with clinical experience, immediate reconstruction without radiation showed the best results. It has to be noted that the timing of radiation did not lead to a difference in the aesthetic results and that the inter-rater reliability was only fair.

Subjective assessment in clinical practice has often been conducted by surgeons and not by patients (27). The study aimed at the evaluation of a subjective instrument for breast assessment based on seven appearance criteria which were derived from several pilot investigations that contributed to a "judge scoring sheet".

Four surgeons subjectively assessed photographs of 59 cases of breast reconstruction by transverse rectus musculo-cutaneous flaps. The assessment was repeated after 30 days. 36 patients in this group evaluated their own photographs. This assessment was repeated by 30 patients after 30 days. The photographs included frontal and lateral views. The seven evaluation criteria

included breast positioning, which was subdivided into vertical versus horizontal axis-, defects of the breast, breast masses, abnormalities, concavities or convexities, breast projection, breast shape, defined as the degree of resemblance with the naturally teardrop-shaped breast, quality of the infra-mammary fold, quality of the medial contour of the breast and overall appearance. A multiple criterion scale was utilised for grading that relied on explicit descriptions of the meaning of each score and that attributed several criteria to each of the seven main points of interest. In order to focus the assessment on these seven criteria and to eliminate the influence of symmetry, the images included only the side of the reconstructed breast which was assessed. The patients scored the breast according to eight criteria that included the previous seven criteria and one additional one to assess their overall satisfaction with the entire reconstructive experience on a "patient self-scoring sheet". Before the evaluation, the patients were instructed on the use of this instrument. The results revealed high internal consistency of the instrument used by both patients and surgeons, but the result was even better for that of patients. Reproducibility of the test on each aesthetic sub-item was better among patients than surgeons. Inter-rater agreement was poor among patients and surgeons. There was poor correlation among surgeonbased evaluation of aesthetic sub-items and patients` overall appearance or satisfaction. The study concluded that patient input should be included in the evaluation of breast reconstruction. The study provided a valuable instrument for aesthetic breast assessment. The findings of poor inter-observer agreement among experts have been reported frequently (17). Interestingly, this study described less reliable internal consistency among experts. The conclusion that patient input should be included in the evaluation of breast reconstruction might contribute to future assessments.

A study on the reliability of a rating system was conducted (126). The study aimed at the retrospective evaluation of the aesthetic results after TRAM flap reconstruction (44). The reliability of the rating system was examined and patient satisfaction ratings obtained.

Twenty patients who had undergone TRAM flap breast reconstruction after mastectomy were included. The patients were selected consecutively from two different hospitals. All breast reconstruction operations were conducted in two steps with the first one being the reconstruction and the second being further ipsior contra lateral surgery to achieve breast symmetry. For this purpose, contralateral surgery, including mammaplasty, flap lipectomy or flap liposuction, was conducted. The same surgeon performed all procedures. The results were assessed after 3, 6 and 12 months according to two methods: firstly, following a rating grade from 0 to 10. In this method the patients` own assessments and the one of two senior plastic surgeons, who were not involved in the patients` treatment, were obtained; secondly, results were assessed following a subscale method containing five breast features. These five features for scaling were breast volume, breast shape, placement of the breast, infra-mammary fold and breast scars, which were judged in three categories of aesthetic appearance. Both raters judged pre- and postoperative photographs independently. No access to previous ratings was given. Friedman's analysis of variance was utilized for comparison of the differences between the evaluations by grades and for intra-rater testing. Kappa statistics were utilised for assessment of the agreement in the inter-rater test. Intra- and inter-rater agreement was found to be poor to fair in the majority of the subscales. Looking at the overall grades a significant difference was found between the evaluation of the patients and the raters at 3 and 6 months. Moreover, at month 12 the results revealed that one rater gave significantly lower ratings than the patients and the other rater at $p \le 0.001$. The level of satisfaction with the results among the patients was higher than among the raters. It should be noted that the patient group was small and that there was no randomisation of the patients. Further, the patients were selected from two different hospitals and were heterogeneous, undergoing several types of ipsi- or contra-lateral surgical procedures.

A comparison of different scales for subjective breast assessment was conducted on postoperative photographs of 50 patients (87). The study investigated three methods of subjective breast assessment. The first method was a classic fourpoint scale based on qualitative measures according to the Harris scale: excellent (4), good (3), fair (2) and poor (1). To each of these four categories additional descriptive criteria were added for clarification. These were termed: no discernible difference between the two sides, minimal identifiable differences between the two sides, obvious asymmetry, but without contour distortion, major aesthetic flaws in treated breasts. The second method was a five- point subscale by Garbay, which was assessed. This subscale examined the volume of the breast, the contour (shape) of breast, the placement of the breast, the infra-mammary fold and the breast scars. Each of these five subscales was judged in three categories, called zero, one and two and further descriptive criteria were added such as, for example, marked, mild or no asymmetry. The third method relied on a visual analogue scale following the description by Malata (88). This was based on a 10 cm line anchored at the left end by a photograph of an unreconstructed mastectomy scar and on the right end, a photograph of a normal pair of breasts to clarify the two extremes of breast aesthetics. The rater was supposed subjectively to mark a point between these two extremes subjectively judging the degree of aesthetic result after reconstruction. As the linear scale was a continuous method of evaluation, additional categorisation was introduced, one with four and one with five categories, to achieve a qualitative assessment. For this purpose the scale was divided into lengths of 2.0 or 2.5 cm.

Fifty women undergoing breast reconstruction were randomly selected and postoperative photographs assessed. Standardised anterior and lateral photographs were used. Three plastic surgeons rated the photographs according to the three scales. A repeat rating was conducted after four weeks. Intra- and inter-rater reliability was assessed.

Wide variation in the subjective judgments was found, going from poor to good for the three methods, with the second method, the subscales, showing the highest reliability. The scales with the least explicit rating criteria led to the lowest reliability. The visual analogue scale was the least reliable. The authors concluded that inter-rater reliability for the four-point and visual analogue scale was unacceptable. Explicit rating criteria reduced the differences between raters and separation into subscales improved the reliability of the results.

A concern in this study is the mixed level of expertise of the raters that may have influenced the subjective breast assessment. There was further heterogeneity in the patient group and method of breast reconstruction.

An investigation into the evaluation and comparison of aesthetic results and patient satisfaction with bilateral breast reduction was conducted (103). Two different techniques of breast reduction procedures with inferior pedicle and with

bilateral vertical pedicle after McKissock were compared. The aesthetic results, complication rates and patient satisfaction were investigated. Homogeneity of two patient groups was examined regarding demographic data and mean resection weight.

Group one (inferior pedicle technique) comprised 24 patients and was recruited from a public hospital and selected from all available women. Patients with concomitant disease or further surgery were not included. Group two (McKissock technique) comprised 27 patients recruited from a private hospital and randomly chosen from a pool of 70 patients. A patient questionnaire with 43 questions was provided and patients conducted a subjective ranking on a scale from 1 to 10 with 1 being the worst. Through this questionnaire pre- and postoperative symptoms of complaints were subjectively judged by the patients of the two groups. Further, patients subjectively judged functional and cosmetic results. The later was judged firstly as an overall evaluation and secondly according to five sub-criteria. One surgeon and one medical intern in the role of an observer subjectively judged the overall aesthetic result on a scale of 1 to 10. Complication rates for the surgical technique of both groups were recorded.

The results revealed that the aesthetic results were quoted as good or excellent in both groups. Complication rates also showed similar results. The comparison between the results of both, the surgeon and the observer, with the patients` evaluation revealed that no significant difference was found between those of the observer and the patients. The surgeon`s evaluation in one group was significantly higher than the one of the patients` but not than that of the observer. Regarding the aesthetic results, complication rates and patient satisfaction, no differences between the groups were found. One of the main limitations of this article was the small sample size and the inconsistent randomisation of the patients. A single surgeon and a single observer conducted the evaluation. Intra-observer errors were not assessed. Surprisingly, the paper reported that aesthetic evaluation in one group scored higher with the surgeon than the patients and nevertheless it was stated that no differences regarding the aesthetic results were found

Aesthetic outcomes in patients undergoing breast conservation therapy for the treatment of localised breast cancer were examined to clarify the need for specialist plastic surgical consultation for this patient group (5). In order to answer this question the study investigated aesthetic changes after conservative breast therapy and attempted to judge if the level of the changes was sufficient to warrant specialist consultation. Twenty-one patients undergoing breast conservative therapy for breast reconstruction were examined and 11 patients without breast cancer were used as a control group. The control group comprised patients that were evaluated for augmentation, reduction or mastopexy procedures. Standardised postoperative photographs in five views, frontal, oblique right and left and side right and left were taken. Eight reviewers, four surgeons, two nurses and two medical students evaluated the photographs on a single occasion, grading a breast asymmetry score by subjective approach following a standardised questionnaire. For this purpose, breast size, ptosis, nipple-areola position, shape, scar appearance, contour deformity and skin changes were assessed. The resulting score ranged from -3 to 6 for each breast. For the resulting total breast asymmetry score, the difference between the two breasts was calculated and ranged from 0 to 9. A higher score reflected a greater degree of asymmetry. 2SD

above the sample mean were considered as significant. A 15-item questionnaire concerning treatment related changes was given to patients.

The average treatment-related score was 1.93 for the breast conservative patients. 35% demonstrated significant changes in comparison to the control group. All patients noted asymmetry but 86% were nevertheless satisfied with the treatment outcome.

The author concluded that in view of the significant asymmetry that was caused by breast conservation therapy, a specialist consultation on reconstruction was warranted. There was heterogeneity in the patient group, with different stages of disease and different tumour sizes for removal and breast conservation therapy. There was also heterogeneity in the group of the examiners and in the group of patients utilised as a control sample. Overall, the sample group was small. Patient enrollment data showed that only one tenth of the patients could be recruited for this study leading to the question of possible selection bias. Intra- and inter-observer error were not assessed.

Aesthetic breast assessment was investigated in a retrospective study in patients undergoing breast reconstruction by TRAM flap surgery (115). Pre- and postoperative photographs from 100 patients of one senior surgeon were taken from the archives. All but one patient underwent unilateral reconstruction. Twentysix photographs were selected in order to obtain a broad range of outcomes, from poor to excellent. Inclusion criteria required that the nipple areola complex was reconstructed. The photographs that were examined showed the breast in anterior, posterior, and side views. The group of investigators included 5 physicians and 12 non-physician evaluators utilising a visual analogue scale survey. None of the evaluators had previously seen a TRAM flap. Initially, six patient photographs were evaluated as a trial to clarify the task before the real study was conducted by evaluation of the remaining 20 patient photographs. The overall aesthetic breast appearance was scored as well as aesthetic subunits investigated. A visual analogue scale ranging from 0 to 100 mm was utilised for the judgment of the overall aesthetic appearance of the breast reconstruction. Further, breast volume, symmetry, contour, nipple-areola complex, infra-mammary fold, scar quality, skin paddle quality, appearance and breast position were scored on additional analogue scales. Four evaluators repeated the survey after four weeks.

The results revealed that there was a high degree of correlation between the overall score and the subunit scores. Inter-rater reliability was quoted as poor. Intra-rater reliability was excellent between overall and mean subunit score, showing that the overall score presented an excellent correlation to the mean of various subunit scores. Symmetry, contour and breast positioning were determined as the most important components of breast reconstruction. Altogether, 12 of the 17 evaluators completed the visual analogue surveys. Differences between physician and non-physician scores were not given. The authors concluded that they were able to derive a set of aesthetic rules from their investigation and that methodical application of these rules would maximise the reliability of assessing the aesthetic outcome.

The number of cases that were studied was small. There was no randomisation of the patients and heterogeneity in the group of the assessors that contained physicians and non-physicians as well as in the group of patients that underwent unilateral and bilateral reconstruction. Non-experts were utilised for breast assessment in this study.

The choice of observers for the evaluation of aesthetic results in breast cancer patients was the focus of a study on subjective breast assessment (16). Interobserver agreement of three different groups of observers with different levels of experience judging surgical results under aesthetic considerations was examined.

Photographs were taken of 55 women undergoing conservative unilateral breast cancer treatment. Five women without breast disease served as controls. Thirteen observers had the task of distinguishing the patients from the controls and the operated from the un-operated breasts. Classification of the photographic images was grouped as excellent, good, fair or poor. The accuracy of the evaluation of each observer was examined as well as the inter-observer agreement by utilizing kappa statistics in each of the three observer groups. The results revealed that inexperienced observers were significantly less successful in identifying controls, patients and side of operation. Inter-observer agreement with regard to judgment of aesthetic results was significantly better in the group of the experienced observers. In conclusion, the authors recommended that previous experience should be necessary to judge aesthetic breast results.

A review of the literature regarding subjective versus objective breast assessment and patient self assessment was conducted. The aesthetic appearance of the breast after breast conservation therapy after primary breast cancer was investigated (1). The Harris scale was cited as the most popular grading system for subjective assessment. The limitation of the use of photography for subjective assessment was criticised due to the fact that important factors for breast assessment were missed that would have been available during live assessment. Patient self-assessment was considered to be important but it was noted that patients tended to judge more positively than professional observers. Factors that could possibly influence the cosmetic outcome were discussed and the authors reported contradictory findings of the influence of age and breast size and weight. Further, the literature review revealed that factors such as tumour size or location and treatment factors had an influence on the aesthetic appearance according to the subjective judgment of several authors.

Breast symmetry and the need for secondary surgical procedures after breast reconstruction were examined (95). Expander/implant reconstruction versus autologous reconstruction were analysed without regard to the 3D photography that was considered in a previous study. A retrospective study of 382 women undergoing breast reconstruction over a four-year period was performed. The following information was recorded: the total number of women, type of reconstruction, either autologous or with implant, unilateral or bilateral, immediate or delayed. Symmetry assessment was based on subjective judgment by the patient or surgeon based on five parameters. These were symmetry in volume and contour after initial reconstruction, the need for secondary procedures and symmetry in volume and contour after the procedure. Minimum follow-up was 11 months, mean follow up 21 months. The results revealed that initial volume symmetry was observed more often after autologous reconstructionthan implant reconstruction, whereas the opposite was true for initial contour symmetry. Final

volume and contour symmetry were found more often after autologous reconstruction in which secondary procedures were also conducted more often. Altogether four times more ipsi-lateral than contra-lateral secondary procedures were performed. Among these were skin and fat excision breast reduction, mastopexy, implant augmentation and exchange. More delayed reconstructions led to the need for secondary procedures than immediate ones. A retrospective study was performed based on the subjective approach of judgment on a limited number of parameters. Limited information was given as to how symmetry was subjectively judged. The time of follow up was short. No gold standard for comparison was utilised, no reproducibility of data tested, no differentiation between the judgment of the patient and the surgeon was given.

Standard photography, a two-dimensional method of capture, has been utilised in the plastic surgical clinical practice for many years (33; 66; 79). Photographic analysis is generally based on the display of a three- dimensional structure in a two-dimensional image, which is a major limitation of the technique. Accurate assessment of the breast concerning volume, shape and symmetry is therefore difficult with this technique.

In the study conducted by Kroll (1992) subjective breast assessment by photography was conducted by four judges (79). They retrospectively graded 325 photographs of post-mastectomy breast reconstruction as excellent, good, fair or poor. Three different types of breast reconstruction by Transverse Rectus Abdominis Muscle (TRAM) flap, tissue expansion and Latissimus Dorsi (LD) flap were compared. An evaluation concerning symmetry, shape, ptosis and scarring and the overall result was conducted. Further, the failure rate was recorded. For

immediate breast reconstruction, the TRAM flap was the most successful technique aesthetically. The failure rate was highest with tissue expansion, which also was less aesthetically successful in obese patients. Methods with autologous reconstruction provided more consistent success.

Rohrich (2003) utilised standard photography for his study to investigate the incidence of breast and chest wall asymmetry in breast augmentation patients (104). In his frequently cited paper he described an examination of 100 randomly selected patients who attended his clinic for breast augmentation consultation. Four experts subjectively examined standardised three-view pre-operative photographs and documented the existence of asymmetry in a retrospective analysis. The patient was standing upright with the arms down and the photographs were taken from the front and from each side. The assessment was carried out once. Nipple position and size, chest wall asymmetry, breast mound asymmetry, volume, base constriction and infra-mammary fold position were documented. Significant asymmetries in all parameters were found. The study revealed some inconsistencies in the recordings among the four examiners. 88% of patients showed at least one parameter of breast asymmetry and 65% had more than one parameter. Intra- and inter-observer errors were not further assessed.

A retrospective study on factors determining the shape and symmetry in immediate breast reconstruction was conducted with the application of 2D photography (64). Five plastic surgeons, blinded to the nature of the procedure,

undertook a photographic analysis on 62 patients that were undergoing skinsparing mastectomy and immediate reconstruction. For reconstruction either autologous tissue (TRAM or LD flap) or implant surgery was used. Patients with a two-stage procedure and preoperative radiotherapy were excluded from the study. Clinical factors such as mastectomy incision, parenchyma appearance, skin envelope, nipple areola complex placement, scarring, bulk and position of the flap or implant, flap necrosis and complications were noted in the 2D photographs. Following evaluation by Mann Whitney U test, it was concluded that autologous reconstruction produced better results than breast reconstruction by implants. According to the examination, the skin-envelope appeared to be the most important factor affecting the aesthetic outcome of breast reconstruction, whereas the shape of the tissue filling the skin envelope was less important. In implant reconstruction sub-muscular placement led to poorer results. The lack of replacement of the nipple areola complex led to a decrease in size and surface area of the reconstructed breast. The volume of the breast reconstruction affected the appearance of the projection. The patient group was heterogeneous. There was a lack of explanation of the method of this study in terms of the judgment that was made subjectively by the five plastic surgeons. Patient posture was not standardised. Intra- and inter-observer errors were not assessed, nor the reproducibility or reliability. It remained unclear how conclusions were reached. The breast was described as a cone made of skin envelope and breast parenchyma with the nipple areola complex sitting the apex of the cone but no further explanation was provided as to how this knowledge would affect the reconstruction.

Clinical photographs in five views were utilised for the assessment of aesthetic outcomes of breast cancer treatment. The aim of the study was to conduct objective measurements on photographs by measuring ptosis and to compare the results to subjective judgments (71). Ptosis refers to the natural hanging of the breast, which is determined by the extent to which the nipple is lower than the infra-mammary fold. An experienced plastic surgeon selected preoperative photographs of 52 patients undergoing breast reconstruction surgery. Eight observers, 5 experienced and 3 new, marked landmarks on the photographs of 10 patients, who had been selected to represent a wide range of aesthetic characteristics. The landmarks that were manually identified on the images were the sternal notch, lateral end of infra-mammary fold, lowest point of the breast and the nipple. The x and y coordinates for each point were documented with the help of MATLAB® software programme. Measurements were taken from inter-landmark distances in oblique and lateral photographs and repeated three times at 5minutes intervals. Subjective assessment on all 52 patients using a four-point scale was conducted two weeks apart, stating which grade of ptosis, 0= none, 1= minor, 2= moderate, 3= major, was visible. The position of the nipple in relation to the lateral end of the infra-mammary fold was judged. Measurements were repeated three times at 2-weeks intervals. A comparison of the results with subjective ratings was conducted using a linear regression model. The subjective rating showed excellent intra-observer agreement but lower inter-observer agreement. The objective scale showed stable intra- and inter-observer agreement for expert and novice observers. A high level of correspondence between the objective measures and subjective ratings was found.

1.2.2 Objective approach

The objective approach in breast assessment is a new development of recent years. In order to increase accuracy and reproducibility of measurement processes different techniques of objective assessment were examined. Historically, images of the human body have been utilised on multiple occasions by doctors at all periods. Early methods relied on 2D display. In the modern era, the capture of the human body in a realistic way emerged as a possibility. More recently, 3D capture methods that more closely represented the three-dimensional features of the area of interest have been examined. Human body capture for documentation and teaching purposes, surgical planning and assessment of the outcome developed an increasing importance.

1.2.2.1 Mammography, 2D breast capture

Mammography is a well-established procedure for the assessment of the breast. The soft tissue structure of the breast can be examined and displayed on X-Ray film, presenting a 3D structure on a 2D film. The accuracy and reproducibility of mammographic examination for breast volume calculation has been examined (68). The validation was performed by comparing results of mammographic volume measurements with pathologic specimen of mastectomy tissue. The volumes of 32 mastectomy specimen were evaluated by pathologic examination through recording of the breast weights. The weighted samples were divided into four groups of tissues based on the percentages of fat and water visible in the preoperative mammograms. The more water that was documented, the denser the tissue that was measured, as the densities of fat (0.916g/ml) and the density of water (1.000g/ ml) differ. Using these tissue densities, the weights of the mastectomy specimen were converted into volumes. For this purpose, the preoperative mammograms were reviewed by a single radiologist and the parenchymal pattern were classified into the four groups: in pattern A (<10% dense tissue) the breast was assumed to be composed entirely of fat (0.916 g/ml); in pattern B (10-49% dense tissue) the breast was assumed to be composed of 66.7% of fat and 33.3 % of water (0.944gr/ml); in pattern C (50-98% dense tissue) the breast was assumed to be composed of 33.3% of fat and 66.7% of water and; in pattern D (≥90% dense tissue) the breast was assumed to be composed entirely of water (1.000g/ ml). In utilising these tissue densities and converting the mastectomy weights into mastectomy volumes, a 1000g pattern B breast would, for example, have a volume of 1059 ml.

Two radiologists independently measured preoperative breast height and width on mammograms in anterior posterior and oblique projection. Compression thickness was recorded on the craniocaudal and mediolateral oblique projections. With these three figures the volume was calculated by utilising six different formulas described by Keddy and Brebner in 1980 and also based on a computer algorithm. For determination of accuracy, a linear regression analysis was performed. The results revealed that the most accurate method for calculating breast volume was the method that assumed a half elliptic cylinder shape for the compressed breast in the craniocaudal projection. Measurements in craniocaudal projection turned out

to be more reproducible than those in mediolateral oblique view. Inter-observer variability was low. The paper concluded that breast volume can be accurately and reproducibly determined by using mammograms, measuring in the craniocaudal view and knowing the compression thickness. However, the accuracy of total breast volume measurement by mammography has some limitations as the back wall of the breast during compression was not recorded. This missing anatomical area of the breast reduces the validity of mammography as a method for total breast volume determination. Further, by the subjective approach the tissue densities were recorded, grouped and utilised for volume measurements, which could lead to error in the calculation. The use of mammography exposes the patient to radiation and therefore the application has to be considered carefully. In the research setting, though, it is possible to obtain the necessary measurements without radiation as the compression thickness can be applied and recorded without X-ray exposure, which is also true for the two linear measurements that are necessary for the formula of breast volume calculation. The patient undergoing mammography takes a position standing upright with the breast pulled forward for compression into the machine, which changes the position of the natural breast and could influence volume calculation.

Breast volume measurements obtained from mammograms were compared with those obtained from thermoplastic moulding, magnetic resonance imaging, water displacement and anatomic measurements (13). Twenty breasts and ten women were assessed. The study group was selected from patients who attended the breast clinic and had a mammography showing benign conditions. All patients underwent all modalities of breast volume measurements apart from one patient who declined examination with MRI: Eight of the ten patients were premenopausal and were examined during the menstrual cycle. Breast volume measured with mammography was calculated from measurements in a craniocaudal direction by the mathematical formula of a cone $(1/3\pi rh)^2$. R was half the length of the base of the breast and h was the distance from the nipple to the base. Volume was obtained from MRI by adding the sum of individual sagittal slices together. Thermoplastic cast volume was measured by the negative replica of the breast that was filled with water. Volume was obtained by water displacement according to the Archimedes principle by use of a calibrated container which was filled with water and in which the breast was immersed. Anatomical measurements of linear distances between 4 landmarks were utilised by application of a mathematical formula previously described in a study on Chinese women. The statistical analysis calculated regression lines of the different methods. Regression coefficients and correlation coefficients were produced. The correlation coefficient that was obtained for volume assessment by mammogram was 0.48 for MRI, 0.82 for thermoplastic moulding, 0.83 for anatomic measurements and 0.61 for the Archimedes principle of water displacement. The authors concluded that thermoplastic moulding was a good method for comparison breast volume measurements mammograms. Thev of to stated that measurements to with thermoplastic moulding were superior previous measurements of mastectomy specimens due to the possibility of obtaining a 3D impression of the breast shape with moulding. Anatomic measurements were not seen as favourable because of arguments over the mathematical formula to be used. MRI was seen as costly and water displacement as difficult to perform. Mammography was seen as uncomfortable for the patient but of diagnostic value. Data on patient recruitment were missing. Accuracy was not tested, intra- and inter-observer error not assessed. Different anatomic areas of the breast were compared.

1.2.2.2 Arthur Morris device

Historically this device was built to measure the volume of the breast by application of a plastic cylinder with a stamp pressing down onto the breast (91). The author described it as a portable mammometer in the form of an oversized syringe. The plastic cylinder of 14.5 cm in diameter was calibrated in millilitres. Calibration was conducted by water displacement. Unlike a syringe, the open end of the cylinder was curved to fit the contour of the chest wall. The second part was the base of the cylinder that fitted onto the non-curved part of the cylinder. The third part was a piston to fit inside with a concave end to fit the contour of the breast. While the patient was lying on her back, the breast was eased into the cylinder, the piston was inserted until it fitted closely to the breast and the volume was measured directly through the markings on the cylinder. Application in breast reduction and augmentation patients was described. Two different devices, for small and large breasts were created and much appreciation by the patients was obtained, according to the inventor. No further investigation was presented. The accuracy and reproducibility of the measurements were not assessed. For the time of the invention the device presented a creative way forward to address the difficult problem of total breast volume measurement.

1.2.2.3 Grossman Roudner device

The Grossman Roudner device is cited in the literature on many occasions and consisted of a plastic cone that was applied to the breast (37). The device was a round plastic cut along the line of the radius. The principle of this device was that it utilised an adjustable conical geometric form with a scale on it that was put onto the breast so that the volume could be read from the scale at the overlapping edges. The device could be sterilised and easily packed. Application was in a semi-recumbent position of the patient with the breast filling the inside of the adjustable cone. The authors were of the opinion that they were able to measure accurately within 5 ml. Reliability and reproducibility were not tested and no systematic study presented.

The cost effectiveness of the Grossman Roudner device versus plaster casting and MRI for breast volume was determined (22). The examination was conducted on five women with different breast sizes who were measured with each technique three times. The Grossman Roudner device was laid upon the breast and the volume was read directly on the device. The plaster casts, which were obtained from breast impressions, were filled with a butter-sand mixture and the volume was determined under application of water displacement method. The breast volume that was calculated from the MRI was assessed by examining the single image slices that were obtained by this method and analysis was conducted using ANALYSE bio-imaging software. By application of mean and standard deviation and power analysis the number of subjects necessary to detect a 5% change in volume with 80% power and alpha of 0.05 was determined. The number of subjects that were examined was multiplied with the price per test for cost calculation. The measurements revealed good reproducibility in all techniques. The volume measurements in the same subject that was examined with the Grossman Roudner device revealed a result of about half the volume in comparison to that obtained by MRI. The plaster cast measurements were consistently found to be between the two other techniques. The authors concluded that the results revealed that the Grossman Roudner device was the most cost effective and the MRI the most expensive. A comparison of the results to a gold standard in breast volume measurement that could serve as a reference for the measurements was not utilised. The accuracy of the three techniques was not assessed. The test for reproducibility was based on three results in five women only; therefore the study group was small. The conclusion regarding cost effectiveness relied on reproducibility without knowledge of the accuracy of the method.

1.2.2.4 Tegtmeier device

The Tegtmeier device is a tool for the volume measurement of the breast, a mammometer (119). The author believed that his device was a quick, accurate, dry and versatile tool for use in breasts of up to 600cc. The mammometer was composed of a plastic measuring chamber in the form of a breast with a flexible diaphragm to fit to the breast at the bottom. On top of it a graduate cylinder that

functioned according to water displacement principle was mounted. First, the zero point of the device was found while it was rested on a stand that simulated the chest wall minus breast tissue. Then the device was put onto the breast of the patient and the amount of water displaced was read in the graduation cylinder. A single patient's measurements were described in the publication and data provided of the preoperative volume of the right and left breasts of this patient, the volume of the mastectomy specimen on either side and finally the volume of the reconstructed breast after implant reconstruction on either side. Accuracy and reproducibility were not tested. No further study was presented.

1.2.2.5 Tezel device

The Tezel device (123) was utilised for breast volume measurement by water displacement based on the Archimedes principle. The device was made out of three parts: a container, a pliable plastic bag and a rubber stopper. Into the container a 2cm hole was made through which an empty plastic bag was pulled through. A rubber stopper was utilised to close this hole. The container had to be large enough to accommodate the full breast. A photograph of the device was published that showed that the plastic container of a breast implant served as the container of this device. The device was placed on the breast while the patient was lying on her back. The stopper was removed and the plastic bag was filled with water while the breast filled part of the container. The volume of the water that was filled in was recorded. The application was not only for mastectomy patients

or breast asymmetry patients but also for patients wishing to undergo augmentation surgery. In this last group, the plastic bag was placed once over the naked breast and once over the breast with a brassiere that was filled with a sponge. The differences were measured, which equalled the implant volume required. The advantage was that by application of this device the patient did not get wet. Further, the authors cited its simple use, low cost and applicability during surgery as positive aspects. The reliability and reproducibility of the device were not tested.

1.2.2.6 Water displacement technique

The Archimedes principle is a physical law of buoyancy which proposes that a body immersed in a fluid is acted upon by a force that is created by the displacement of the fluid equal to the weight of the body (56). If the body is immersed in water the displaced volume and weight will be the same as when the body is immersed and free floating. In other words, the volume of the displaced fluid is therefore equivalent to the volume of the object fully immersed in the fluid. The Archimedean method for breast volume measurement by water displacement was reportedly applied as early as 1970 and involved a female patient who was bending over a bowl filled with water and breast volume was calculated according to the amount of water displaced (109). It was reported that three pieces of equipment were needed, a wide-mouth container with enough depth to submerge the breast fully, a second container underneath for water collection, and a

calibrated cylinder for measurement. It was recommended that ink dots be placed on the skin to help the patient better to repeat the immersion, which should be done slowly while the patient is kneeling on her bed or over a table. It was felt that including the chest wall into the measurement would overestimate the volume by 60 to 70 cc. The application of the method was recommended for patients presenting with breast asymmetry in particular and was judged as an objective assistance tool for the inexperienced surgeon or occasional operator. The author described that the measurements were repeated in each patient to ensure accuracy of the method. No study was presented, accuracy and reproducibility were not assessed, but examples were described.

To date water displacement has found clinical application in arm lymphoedema measurement following breast cancer surgery (118). A study was conducted on patients who had breast cancer surgery, including axillary dissection. Nineteen patients with and 22 without arm lymphoedema and 25 control subjects were examined. Two examiners took circumferential tape measurements at specified distances on the arms measured from the fingertips as well as relating to anatomic landmarks and compared these to measurements by water displacement method. Volumes obtained by circumferential tape measurements had high validity compared to those obtained by water displacement and were slightly larger. As expected, differences between patients with and without arm lymphoedema were found. Volumes based on calculation from anatomical landmarks were reliable, valid and more accurate than those obtained from circumferential measurements based on distances from fingertips.

The volume of a pedicled TRAM flap in 28 patients was measured intraoperatively by immersion of the flap into a box that was closed with a lid. Then through a small opening this box was filled with warm saline solution for volume measurement according to the Archimedes' Principle (25). The weight of the pedicled flap was measured with a spring balance. The authors found that the volume of the reconstructed breast displayed a closer relationship with the volume of the net pedicled TRAM flap than with its weight. The difference of the maximal chest circumferences (the index of the breast volume) displayed a positive correlation with the difference of the volumes and weights between the mastectomy specimen and the net TRAM flap but this relationship was closer for the volume (r= 0.677) than for the weight (r= 0.618). The authors stated that this finding was contrary to that of Sheamoun and Hartrampf (44), which was that the weight, in grams of breast tissue that was removed, was proportional to the volume in cubic centimetres. Intra- and inter-observer error in this study was not examined, accuracy and reproducibility were not investigated and the study group was small and heterogeneous.

1.2.2.7 Direct anthropometry

In the plastic surgical field, linear measurements on the breast are utilised routinely. Usually only simple measurements of the nipple position are conducted. Penn's work on nipple to sternal notch, nipple to nipple and nipple to midclavicular point in women with "aesthetically perfect" breasts (100) has attracted widespread notice in the plastic surgical community and his publication has been cited as a landmark paper in the literature (113). The author stated his aim as establishing standards of normality of breast shape. One hundred and fifty healthy volunteers were measured in a standing position with arms at the sides, then, 20 were selected as being aesthetically perfect: these were then regarded as normal. The publication provided a literature review on breast anatomy as well as a discussion of breast reduction surgery but no exact description on the method of breast measurements that were obtained. The author concluded that the standards in plastic surgery should aim for aesthetically attractive proportions after surgery, which included that the nipples should be at the same level on either side. Penn felt that it should be within the capacity of plastic surgery to produce a final breast modelling that would satisfy the strictest aesthetic criteria. He presented a desirable nipple to sternal notch distance and nipple to mid-clavicular point distance of 8.5 inches each and called these the normal breast measurements. It should be noted that the study group that was presented was purposely selected for aesthetically perfect breasts. Therefore, the study did not represent the distribution of breast shapes in the normal population but it can be correctly stated that it represented the breast shapes of ideal appearance.

Smith examined normal breast parameters of the population regarding breast volume and anthropomorphic parameters (113). Fifty-five women, aged 18 to 31 were recruited and questioned on systemic illnesses, breast pathology and bra size. Linear distances were measured on the breast according to several landmarks that were drawn on anatomical points in relation to the nipple position. The five distances that were measured were: lateral breast crease to nipple, axilla

to nipple, nipple to midline, nipple to infra-mammary fold and nipple to the lowest point of the breast. Based on these measurements, breast volume in cc was calculated. As gold standard for comparison, volume measurements of the breast were taken using the plaster of Paris impression technique. Statistical analysis was performed from the 5 linear distances obtained and the mean and standard deviation were evaluated. A highly significant difference was found between the right and left breast regarding three of the inter-landmark distances: axilla to nipple, nipple to midline and lowest point of the breast to the nipple. Distances were longer on the left than on the right side. The calculation of the volumetric differences between the right and left breasts did not reach statistical significance. The calculation of the breast volume based on the five linear distances was insufficiently explained. The study group was not randomised as the patients were recruited from advertisements, were young with ideal rather than normal or average breasts and therefore did not represent the normal population. Intra- and inter-observer errors were not assessed. The results of the patient questionnaire were not provided. Nevertheless, the study presented some valuable contributions to land-marking and linear distance measurements.

Westreich (1997) defined aesthetically perfect breasts as those without ptosis for which no aesthetic procedure would be indicated (131). In his study on anthropomorphic breast measurements in 50 women with aesthetically perfect breasts, multiple linear distances were described that were directly measured with tape measure between torso parameters. The correlation between these parameters was studied and breast volume assessed by linear regression analysis. For volume determination, a mathematical formula was established. Nine parameters showed a significant correlation between the linear measurements and breast volume. Among these distances were the sternal notch to nipple as well as nipple to nipple, which were detected as most significantly correlating with breast volume. A mathematical formula was presented based on these two linear distances for the calculation of breast volume. The volume obtained by this method was compared with breast volume measurement with the Grossman Roudner device (37). In the clinical application the author found that most women desired a higher volume than the one calculated. The study added some valuable contributions to the field but lacked a clear structure, making it difficult to comprehend the method and results that were only partly described in the discussion section of the study. A comparison to linear distance measurements by other authors was given but results have to be interpreted carefully due to the different material and methods of the studies. The results of the volume comparison with the Grossman Roudner device were not specified, nor were accuracy and reproducibility tested.

A literature review regarding the assessment of breast aesthetics examined anthropometry as one of four measurement methods. The paper quoted the necessity of large-scale studies to validate anthropomorphic measures (72). The author stated that breast symmetry had been typically determined by calculating the differences in measured distances on the breast mound and nipple areola complex. Several pragmatic limitations of anthropometry were discussed based on the difficulty of quantifying the breast projection because of the underlying curvature of the chest wall and mobility of subcutaneous tissues. It was felt that for the validation of anthropomorphic measures prospective studies across multiple institutions with multiple observers were required but that the relation to subjective scales was doubtful. The benefit for routine clinical practice was considered to be limited. Beyond the literature review that was provided, no original study was presented.

A method of assessing female morphology and clinical application was evaluated and reference to key landmarks was given (12). Measurements were taken of 60 subjects who were content with their breast shape out of the normal population. Subjects were recruited from patients attending the Plastic Surgery unit without a history of breast surgery or disease and from medical students. Thirty women had one or more children, while 30 were nulliparous. The aim was to obtain reference data for breast shape with normal diversity in weight and height and to gain insight into possible factors that could influence these measurements. With the person sitting upright, key landmarks on the breast were identified and marked. These landmarks were the nipple (N), the medial (M), the lateral (L), extents of the inframammary crease and its most inferior point (IC) and the lowest point on the breast, the base (B). The mid-humeral and mid-clavicular points were also measured and patients` height and weight obtained. Each landmark was obtained in horizontal and vertical values. Symmetry was assessed by subtraction of right to left measurements. Further, for 25 women requesting breast reduction and 6 women requesting augmentation, measurements were obtained. The results revealed that vertical positions of landmarks migrate inferiorly with increasing age and inferior laterally with increasing weight, except at the medial end of the inframammary crease. Areola diameter decreases with age and increases with weight. Only for one measurement, the horizontal displacement of the lowest point on the infra-mammary fold, a significant difference was found for right and left measurements. The proportion of subjects with breast asymmetry for individual measurements was greater than anticipated. Breast reduction patients showed more differences in comparison to the normal population and augmentation patients fewer differences. BMI in reduction patients was significantly above and in augmentation patients below that of the normal population. The authors concluded that the presented method of morphometric measurements of the female breast was simple and reproducible.

There are few publications that assess the question of how much breast asymmetry is actually visible with the human eye. Two authors expressed their expert opinion that a difference of \pm 50 grams of breast tissue was not clinically detectable (112; 125).

Turner investigated the possibility of predicting bra cup size after reduction mammaplasty, as he criticised the lack of a standardised protocol (125). Seventyfive consecutive patients undergoing breast reduction surgery were studied. A study on brassiere sizes was conducted with application of tape measurements for the circumference underneath the arms, around the maximum breast projection and at the level of the infra-mammary fold Breast volume measurements were determined preoperatively and six weeks postoperatively by application of a mathematical formula by Regnault and Daniel (1984). Measurements were taken pre- and postoperatively and a comparison conducted between the predicted and actual reduction weight. For the prediction, different formulas were utilised and compared as well as modified formula being developed. A sample t-test was used to determine the differences between the formulas and true volume, which were not significant for two of the formulas. As a prelude to the study, the author accepted that during bilateral breast reduction a weight of \pm 50 g of breast tissue is not usually clinically detectable. No further systematic examination to this prelude was conducted.

Sigurdson examined the development of a formula to determine breast volume in hypertrophic patients based on linear measurements of the breast (112). In 101 women breast volume was obtained with water displacement by a modification of the technique of Tezel. Tetzel's method was based on a water-filled plastic bag that was put in a clear empty box and positioned on the breast. The volume was determined by subtracting the volume of the plastic bag from the total container volume. Eleven anthropomorphic measurements were obtained in a total of 202 breasts. For determination of the formula by Sigurdson, the linear distances were measured with a tape measure and a multiple stepwise linear regression calculation was used to determine predictive variables. Patients were standing upright. By utilisation of a regression model, two linear measurements were found to be valuable for the formula. These two linear measurements incorporated variables of the breast base circumference as well as a vertical measurement in the midline of each breast from the infra-mammary fold to a point determining the projection of the fold to the anterior surface of the breast. The formula derived accounted for 89% of the variability in breast volumes. The results provided a rough idea about the volume but did not correlate well with bra size. Sigurdson subjectively defined symmetrical breast volume as a volume difference of less than 50 cc between the right and left breasts in a given patient. However, no further systematic study on this assumption was presented. It was based solely on clinical experience.

A comment was published in view to Sigurdson's study citing the lack of reproducibility of anthropomorphic measurements and the lack of observerindependence (29). It was criticised that by the application of water displacement method for breast volume determination the posterior breast delimitation was defined as a planar level, which was regarded as inaccurate. It was suggested to use three-dimensional surface imaging instead and the opinion was voiced that by using special software the thorax wall curvature was calculable.

1.2.2.8 Plaster casting

Plaster casting is an old technique that has been extensively described (15). In a study of 47 female volunteers the measurement of breast volume by plaster casting was examined. Reliability of the method was assessed. Each subject applied a thin coating of Vaseline to the area to be examined and fast setting plaster strips were added. After drying, the plaster negatives were filled with sand of known density up to a level that was judged subjectively at the level of the curvature of the chest wall. Sand density was examined on 20 samples and ranged from 1,435 to 1.487 gram ml⁻¹. The volume of each cast was calculated by dividing the sand weight by the density (volume = weight/density). To test the reliability of the casting method, duplications of casts were made on 34 volunteers

standing upright. To test the sand filling method, the filling of 30 casts with sand was conducted twice. To test positional effects, 15 women were casted standing upright as well as in a prone position. The results of the reproducibility of the tests revealed reliable individual differences at r=0.97 with a standard deviation of \pm 45.7gr equalling an error of \pm 10.2% (1SD/ mean) x 100. Altogether 10% of the error that was obtained was due to the casting method and 5% was due to the sand filling. There were no differences observed between volumes determined in upright and prone positions.

Breast volume was assessed by casting 15 volunteers in an upright position (30). The reproducibility of the technique was investigated. Twenty healthy volunteers were examined by application of thermoplastic sheets that were moulded to the breast and chest wall. Based on previous research experience, the breast boundaries were delineated on the casts according to a subjective approach with free-hand marking by the operator. A negative replica of the breast was created and filled with water and the volume of each cast was measured three times. Each breast was further examined twice with plaster casting so that altogether four casts and 12 measurements for each person were conducted. The coefficient of variation was utilised to calculate the precision of the method by dividing the precision by the mean. The formula was p=square root of sum of squared differences between double tests divided by two times the number of pairs for analysis. The standard deviation between the three repeated water measurements was 1.6% which equalled a percentage of the mean volume of 2.9%. The coefficient of variation between the two corresponding casts and therefore independent measurements of one breast was 6%. Accuracy of breast volume

1.3 Methods of 3D breast capture

1.3.1 MRI

Recording of 3D structures with MRI is possible for all body parts. However, the technique is costly and time-consuming and considered invasive when contrast agents are used. During the capture of the breast the patient is usually positioned horizontally in a prone position with the breast hanging downwards which results in gravitational forces different from the upright position and this will influence the outcome.

A study of the estimation of breast volume and its variation during the menstrual cycle using MRI and stereology was presented (65). Stereology was defined as the study method of three-dimensional properties of objects usually observed two dimensionally. Three main objectives were examined: first, to adapt methods of MRI and stereology for breast volume estimation, second, to determine variation of breast volume during the menstrual cycle and third, to assess asymmetry between left and right sides. The stereological method for estimating volumes when using the MRI is called the Cavalieri method. This method requires the scanning of the structure of interest with a series of parallel planes that are a certain distance apart. The study was conducted on 15 healthy female volunteers aged 22 to 44. The first day of the menstrual cycle was taken as day one. All women had regular cycles and none took contraceptives. The MRI images were taken in a prone

position with the breast suspended in a breast coil. The scanning resolution was chosen to meet the needs of the study before the images were transferred to ANALYSE software (Mayo Foundation, Minnesota). Point counting by aid of a square grid was utilised for volume calculation. The number of points was recorded. The volume was computed based on mathematical calculation and the use of S-Plus software (Stat.Sci, Washington). Imaging was repeated on three different occasions. Statistical tests included analysis of variance (ANOVA) for testing significant differences. Breast volume was regarded as a random variable based on the individual (15 women) or the breast (two sides) or the time of cycle (three observations, during menses, during ovulation, and pre-menses). The coefficient of error (CE) was assessed. The results showed that the CE on volume estimation through point counting was less than 3%. There was a significant difference in the volume measurement of the three different captures in the same women during different times of the cycle. The volume during ovulation was the smallest, the premenstrual volume the largest. The overall variation in volume was 76 cc contributing to 13.6% of the total volume. There was no significant difference between the volume of the left (561cc) and right (567cc) breasts. The presented study was methodically sound and provided valuable new information. Manual assessment of breast volume by point counting of each MRI currently appears to be one of the best methods to record total breast volume most accurately. Nevertheless, there is the potential for some measurement error due to the subjective assessment of breast borders which was not examined in this study. There was no comparison of point counting on axial and sagittal MRI slices and possible differences between these. Intra- and inter-observer errors were not assessed. For the purpose of volume assessment of the breast MRI is a time- and cost-intensive method and could be utilised as a non-invasive technique with good

participant tolerance. Overall, the authors have to be praised for the study that they presented.

Kovacs (2005) utilised MRI as method of comparison for the validation of 3D breast volume assessment by laser scanner (73). The aim was to investigate precision and accuracy of breast volume measurement. Five observers utilised 2 dummy models (n= 200) to standardise the 3D laser scanning application. Laser scanning was used in 6 test subjects and 10 patients (n= 2220). MRI was utilised for comparison of the volume data. The results revealed that the mean breast volumes obtained with both methods significantly correlated. Inter-observer data did not differ significantly. Measurement precision was highest with the dummy models and lower with the live models. It was found to be less good preoperatively than postoperatively. High agreement was found between the chest wall curvature that was found with the MRI examination, which was considered to be the true curvature and that, which was interpolated by 3D scanning data. It was concluded that breast volume assessment with 3D surface imaging was sufficiently precise and accurate. A well-designed study was presented that investigated a valuable question. MRI was considered as the gold standard for comparison but validation of MRI for total breast volume measurement was not presented. Further assessment of the agreement of MRI with a method of comparison would be interesting.

A study on breast tumour volume was conducted (99). The aim was to establish the value of MRI in predicting tumour-recurrence free survival (RFS) in patients undergoing neo-adjuvant chemotherapy and to compare the predictive value of MRI with prognostic indicators. The authors hypothesised that measurements of tumour volume by calculation of automated segmentations of MRI images offered more accurate images of tumour extent than diameter measurements. Treatment success was to be measured by detection of tumour size changes. The study involved 62 women of an average of 48.6 years old. All the women had confirmed invasive breast cancer and had undergone neo-adjuvant chemotherapy. Four women were omitted from the analysis. Follow-up time ranged from 9.5 to 80 months. MRI examination with contrast medium and processing was performed similarly for all patients. Tumour diameter and number of positive lymph nodes according to the pathology report were recorded and the variables for clinical response observed. RFS was documented after physical examination and mammography 6 and 12 months postoperatively. A univariate Cox proportional hazards analysis was used to identify variables associated with RFS. The results of this analysis showed that the initial breast cancer volume that was measured by MRI was the strongest predictor for RFS. However, no details were given on randomisation of patients. It remained unclear if MRI acquisition and processing was performed according to a standardised protocol. The reproducibility of the measurements was not assessed. The examination was limited to breast tumour volume.

1.3.2 CT

To date, capture of breast tissue with CT mainly has mainly had a place in the evaluation of breast cancers due to the problem of patient exposure to radiation.

Cone-beam CT presented a further development in the area of X-ray application for breast tumour assessment without the need for breast compression (26). Cone-beam CT scans an object using a cone of x-ray beams along a circular orbit. A study compared breast tumour detection by 2D mammography and 3D conebeam CT. The two techniques were described in detail by the authors and the literature was reviewed. The authors voiced their opinion that mammography classically suffered from a lack of accuracy in the presentation of a threedimensional breast tumour due to spatial superimposition of the tissues. Breast tumour detection was described as based on the display of tissue intensity through image processing and segmentation. To obtain a breast representation mammography was seen as one of the many methods of breast imaging. Stereo mammography with the application of two images and tomography with the application of many images were introduced to increase the accuracy and add volumetric information by utilisation of a sequence of projection images. Conebeam CT provided rapid data collection on tumour volume through breast mass segmentation and measurement. For the study, a physical object, which was a malignant breast surgical lump from a patient, was scanned by utilisation of x-ray beams. A 3D digital breast image was obtained. Breast mass segmentation in different tissues concerning density and spatial geometry was performed and the volume was calculated. The x-ray source was set at 50 kVp, 288 projection images were obtained and breast volume was calculated according to a conebeam algorithm. The tumour was cut into slices and the digital images analysed. The tumour's visibility was enhanced by rotation and colouring. With the volumetric data the authors then simulated x-ray mammography through computing of projection images. The authors concluded that they believed that volumetric representation in three dimensions provided a more accurate tumour detection than in two dimensions and therefore judged the three-dimensional technique of cone-beam CT for breast tumour detection as superior to the two-dimensional technique of mammography for the same purpose.

Two well-established techniques were described by the authors. However, no direct comparison was made. The experiment that was presented was limited to one single breast specimen that was utilised for the testing of only one of the discussed methods. The scientific proof for the authors' conclusion for the superiority of three-dimensional imaging was not presented; instead, the authors' belief was given. The spatial superimposition problems in mammograms were quoted as an explanation for the limited tumour detection capability and the inferiority of the technique. Projection images through mammography were simulated in the experiment but not measured. Accuracy and reproducibility were not tested and error was not examined. Breast tumour or breast volume calculation through equations and algorithm were mentioned but not further analysed. The application of this technique was restricted to breast tumour assessment and did not find a place in objective assessment of total breast volume.

1.3.3 Ultrasound

3D ultrasound in the breast is a well established technique for the purpose of cancer detection and description (130). 2D, 3D and 4D ultrasound applications are

available. The diagnostic algorithm for advanced US technology involves several indications, as there is lesion detection by the 2D method, lesion analysis, measurement, volume calculation and documentation by the 3D method and elasticity and mobility analysis by the 4D method. For early cancer detection, advanced 2D US systems are currently still utilised. 3D and 4D ultrasound techniques have been influenced by contrast resolution imaging and speckle reduction imaging techniques. With 3D ultrasound the shape of a lesion, its orientation, margin, rim, echogenicity, vascularity and other features can be demonstrated. Static 3D US systems offer the possibility of long axis distance measurements and volume calculations. These systems find utilisation in the follow-up of breast conservation therapy. Very modern ultrasound systems rely on high frequency linear transducers, full digital data management and high resolution including contrast resolution imaging. Tomographic ultrasound is used for a slice by slice documentation of different investigation planes. Further, panoramic view techniques demonstrate the localisation of a lesion within the breast and offer the option to reproduce the position of the lesion. The ultrasound method has not so far been routinely used for total breast volume assessment and does have very limited use in surface and shape analysis. Limitation of the application of ultrasound in capturing breast morphology lies in the fact that the method involves a surface deformation by application of a contact probe and that surface texture is not recorded.

1.3.4 Phase shifting Moiré system

Phase shifting moiré topography (Intek Plus Co, Ltd) was utilised for the 3D capture of 37 women's breasts (80). The study aimed to determine accurate surface data for womens` breasts through determination of a reliable boundary for the purpose of application in the manufacture of form-fitting clothes such as brassieres. The women that were examined were grouped into two groups of 9 and 28 members according to the average radius of breast curvature of the lower breast fold being either skewed (n=9) or symmetrical (n= 28). 3D Images were taken by a CCD camera with halogen light source. A measurement protocol for the determination of a reliable breast boundary of the breast was assessed. Participant posture was standardised to the cameras in exhalation until the end of the scanning. For determination of the upper breast boundary a folding line method was applied that was obtained by pushing the breast upwards and inwards. The folding line when pushing the breast upwards appears due to the fact that the posterior boundary of the breast holds a loose connection to the pectoralis muscle while the outer skin holds a somewhat tight connection to the mammary gland. With additional determination of several reference points on the breast the breast volume and shape were examined. The shape parameters that were examined were five reference points for calculation of the global average curvature of the under breast curve. It was concluded that the global average radius of the curvature of the bottom breast line was found useful as a shape parameter for designing a brassiere. The method of the study was not sufficiently explained, leaving the reader to assume it from the results that were presented. The scientific ground for the multiple reference points that were suggested was not explained.

Data on different breast sizes, intra- and inter-observer error were absent and accuracy and reliability of measurements were not assessed.

1.3.5 Laser scanning

Kovacs (2006) examined the optimisation of 3-dimensional Imaging with laser scanners (74). Two dummy models with small and large breasts without ptosis were scanned from various angles and landmarks were placed on the surface. Inter-landmark distances were examined by laser scanner and direct tape measurements. Five test individuals were also examined. Images were taken with the test persons standing upright and elevating the arms. The results showed a good correlation between the inter-landmark distances obtained by laser scanner and direct tape measurements. Reproducibility of the capture as well as different scanner set-ups were examined. Precision, understood as measurement quality, was determined after calculation of the coefficient of variation from 20 repeated measurements in each woman. It was best for imaging of the thorax with two linked scanners and two tilted shots at 10 degrees upward and downward. Best measurement precision was achieved with the larger dummy model with landmarks placed before imaging. In the test persons, best precision was achieved with two connected scanners and when determining the landmarks before taking the images at 30 degree angles from left and right and 10 degree pointing upwards. The results of the dummies were superior to those of the live models. The limitation of the technique was the imaging of ptotic breasts in an upright position, as this would represent the majority of breast shapes, but which was not examined.

The accuracy of a Minolta Vivid 910 Laser Scanner for the investigation of the breast was examined and new aspects described (75). Five observers examined two dummy models, six test subjects and 10 patients. The two dummy models were investigated by marking on the 3D models and breast volume was calculated. Each observer conducted 120 computations per dummy and breast. The 6 human test subjects were examined by one observer following the dummy model protocol. The upper border of the breast was determined by the folding line method (80). This method determined the upper border of the breast by the examiner manually pushing the breast upwards when the woman was in an upright position, so that a natural demarcation became visible towards the surrounding subcutaneous fat tissue. One of the test subjects was also examined by all observers and measurements repeated 10 times. The 10 patients that were planned for breast reduction and augmentation procedures were examined before and after the operations. Ten breast volume measurements on the 3D models were repeated by each observer for each patient's breast. Comparisons between implant size or reduction weight were conducted. To assess the validity of the method, a comparison of breast volume measurements of the 6 test subjects and MRI scans was carried out; these were regarded as the gold standard. Intra- and inter-observer errors were assessed. Different software packages were used to compare the posterior breast volume delimitation that was interpolated with 3D scanning and the real thorax wall curvature that was obtained with MRI. Mean and standard deviation of the overlaid 3D model volumes were examined. The results revealed that the mean deviation of the breast volume measurements of one test subject by all observers was significantly higher than for the dummy models. The mean measurement precision that was obtained in patients preoperatively was less exact than postoperatively. Inter-observer differences were not statistically significant. The mean breast volume obtained by 3D Laser imaging and MRI significantly correlated. The author concluded that breast volume measurement with 3D laser scanning was precise and accurate. Notably, the subjects' posture during examination in the MRI was horizontal, lying on the abdomen, but vertical, standing upright, during laser scanning. This may impact on measuring breast volume and assessing breast shape. Different breast shapes were not highlighted in this study. Further explanation as to the comparison of posterior breast volume delimitation would add to the study.

A comparison between breast volume measurement techniques using threedimensional laser surface imaging and three classical techniques was conducted (78). The classical techniques were thermoplastic casting, direct anthropometry and MRI. Six participants took part in the study. They all presented of young age, low body mass index and young breast shape without ptosis. The reproducibility of measurements with 10 repeats of each method as well as the inter method correlation were examined. In imaging with a laser scanner, the participant was standing upright and scanned once. One observer repeated 10 measurements by marking the breast region on the 3D image and calculation of volume through a software algorithm. In imaging with MRI the participant was in prone position and imaged once. One observer repeated 10 volume measurements which were accomplished with a 3mm layer thickness through Easy vision software. In thermoplastic casting the participant was upright but seated and a plaster impression was taken once. The impression was filled with water. Measurements were repeated 10 times. In direct anthropomorphic measurements the participant was upright and measured 10 times. One observer applied a formula for volume calculation for each of these measurements once. Reproducibility, tested with the coefficient of variation, was best with MRI, followed by laser scanning, anthropometric measurements and thermoplastic casting. MRI showed the best agreement with three-dimensional laser scanning according to the test of the Pearson coefficient of correlation and linear regression analysis. Both these techniques relied on a curved chest wall as posterior border of the measurements in contrast to thermoplastic casting and anthropomorphic measurements. Kovacs concluded that the technique of laser scanning was a simple promising method carrying the potential for routine breast volume measurements. As a critique it has to be said that posture was not standardised as laser scanning was conducted upright whereas MRI examination was conducted in prone position of the patient. The sample group was small and consisted of selected young volunteers without breast ptosis.

The same type of laser scanner found widespread use by other authors. In one application the scanner that is containing a camera (Konica Minolta Vivid 910, Ramsey, NJ) was mounted on top of a tripod (120). This scanner was then levelled to the height of the breast and breast images were taken from five different positions. Then the tripod with the scanner on top was lowered to the ground and five further inferior views were captured. For lightning, fluorescent lights were utilised. The patient was standing upright with the arms to the side.

Landmarks were placed on the breast before scanning. For volume calculation an individual chest wall template was created for each patient by application of a computer algorithm. The borders of the breast were defined as superiorly where the breast projected from the chest wall, medially and laterally following the extent of the infra-mammary fold (IMF) and inferiorly at the lowest pole of the breast. Computer software provided data analysis and image merging. By matching the 3D image with the chest wall template volume calculation was performed. No systematic study was presented but potential clinical applications were outlined.

In the application described by Eder, the capture was made with two lasers that were connected at 30° angle and pointing upward at 10° angle. (28). The patient was standing upright with the arms downwards and the patient's position remained unchanged. An alternative capture method involved a single scanner that was moved around the patient. Landmarks were placed on the breast before capture with a single shot. The author expressed his opinion that changing the position of the patient would lead to difficulties in merging the different images to a single 3D image. Similarly to Tepper's study, which was commented upon by Eder, a software algorithm was utilised to create the chest wall for the volume calculation. No data were presented but a reference given to the studies that were previously published by Kovacs and himself. Eder discussed breast symmetry analysis and suggested superimposing post- to preoperative images in the case of breast augmentation surgery to quantify surgical changes for verification of breast symmetry. Besides linear, surface and volume measurements, further investigations for quantitative documentation of changes of breast morphology were suggested. For visualisation of the changes, he proposed a grey scale histogram and a superimposition of each breast by mirror image. The shortfalls of the laser scanning were seen in the slowness of the method and inability to capture soft tissue texture resulting in difficulties of landmark identification. Eder noted that there was no generally agreed method of symmetry assessment of the breast.

A quantitative analysis of the reconstructed breast using a 3D laser light scanner was carried out on 51 patients (66). Three groups of patients were evaluated after breast reconstruction with rectus abdominis flap, latissimus dorsi flap or expander implant. Shape, volume and symmetry were examined. For analysis a moiré pattern was utilised based on the interference pattern of light that was utilised like a topographic map similar to those known from engineering. The breast was divided into four zones according to the projection of the breast. Zone 4 was located around the nipple areola complex showing the area with the most projection. Breast symmetry was evaluated through calculation of differences in horizontal and vertical cross sectional areas. A mirror image of the normal breast was superimposed on the reconstructed breast. Differences in the obtained moiré patterns were determined to quantitatively compare the breasts. The surface area ratios were taken for comparison. The surface area ratio was understood as the surface area of the reconstructed breast divided by surface area of the normal breast and then multiplied by 100. The moiré pattern was also used for volume assessment. The absolute breast volume and its ratio in % of the operated breast divided by normal breast multiplied by 100 was calculated. To assess the degree of asymmetry further a horizontal and vertical cross section of the breast was examined and superimposition of the images utilised. Intra-group data were analysed by Kruskal Wallis test and inter group data by Scheff F test. Symmetry was best for latissimus dorsi reconstruction followed by rectus abdominis flap and tissue expander. The latissimus dorsi flap showed nearly ideal volume, whereas the tissue expander showed an over correction and the rectus abdominis flap an under-correction of volume. Surface area showed remarkable differences for all three techniques. The latissimus dorsi flap showed a lack of shape (= height and width) in zone three and zone four which also could be found in the rectus abdominis flap to a greater degree. In third place was the tissue expander with a remarkable difference in shape particularly in zone four. In conclusion, with the laser light scanner, shape, volume and symmetry could be quantitatively analysed. The latissimus dorsi flap and then the tissue expander. The authors recommended this technique of 3D laser scanning as easy quick and accurate. The paper provided a valuable contribution to this field of research.

The clinical value of 3D imaging by laser scanner (Konica Minolta Vivid 910) was further examined in a prospective study on 12 volunteer patients (106). The patients were recruited from cases scheduled for unilateral mastectomy and reconstruction with tissue expander/ implant by one of two senior authors. Ten patients completed immediate reconstruction, two delayed reconstruction. 3D images were taken preoperatively, at the end of tissue expansion and finally after exchange of the expander against a permanent implant. For scanning, the patient was standing upright and turned to the scanner at five different angles. Then the scanner was lowered to the floor and five additional images were taken. The 10 images were merged into one 3D model by help of 3D computer software (Geomagic Studio 9). Breast asymmetry was calculated by the following equation: the absolute value of the left breast volume minus right breast volume divided by the volume of the larger breast and multiplied by 100. The results revealed that symmetry had improved from 88% preoperative to 95% post-operative. The authors concluded that 3D imaging pre-operatively created a target breast volume, helped to guide tissue expansion and was a valuable technique for the assessment of the outcome after breast reconstruction. The sample group of this study was small and heterogeneous. The study lacked data on breast volume measurements and comparison with a control group. Intra- and inter-observer error, accuracy and reproducibility were not assessed.

The intra-operative application of three-dimensional imaging by laser scanning during breast surgery was examined and two case reports presented (117). A Minolta 3D laser scanner was utilised and the reflected light was captured by a CCD camera. After transferring the digital information to a host computer a textured three-dimensional image was obtained. Evaluation was conducted by using the software RUGLE 3 (Meditec, Kyoto, Japan). In breast reconstruction patients, laser scanning was conducted during the operation while the position of the newly reconstructed breast was not jet finalised. Scanning took 2 seconds, and analysis 15 to 20 minutes. Upper and lower breast boundaries were marked and between these surface lines breast surface was calculated and the breast volume obtained. Shape differences between both breasts were demonstrated by assessing linear distances between the nipple and the jugular notch as well as by colour coding after mirror imaging of one breast on the other and substraction from each other. In the first patient, intra-operatively, the breast and implant volume

were calculated after scanning. In the second patient, the volume of a pedicled abdominal muscle flap was measured and intra-operatively symmetry of the breast assessed. The sample size of two cases was small. Accuracy and reproducibility of the method were not assessed.

For breast surgery, a method was developed by application of a laser scanner (Konica Minolta Vi 900) and customised software tool BSA (breast shape analyser) in order to determine a set of parameters to estimate the shape of the natural and reconstructed breast (23). These parameters were surface measurements, angles, curvature, symmetry, infra-mammary fold and shape. Seven female volunteers were imaged when positioned in a chair leaning 45° backwards with the upper body and three views in 45° on each side obtained by rotation of the chair. Breast surface was segmented in four quadrants with utilisation of landmarks. The proposed method relied on geometrical planes (bilateral symmetry plane, meridian plane and equatorial plane) so that significant clinical angles could be calculated. Total surface area, linear distances and angles (breast divergence and ptosis) between different planes in vertical and horizontal direction were measured and three cases in particular presented. A colour scale to represent breast curvature was applied. Contour lines were utilised for graphic demonstration of the curvature of the thoracic surface. The study resulted in a graphic demonstration of breast curvature either as a spheroid (positive curvature) or hyperboloid (negative curvature). The authors concluded that previously mentioned parameters could be estimated well by laser scanning. They further felt that the graphic demonstration of the breast curvature was the most innovative result of the study. The authors expressed their opinion that the validation of 3D imaging of the breast was challenging. The study group that was presented was small and case reports provided. Further systematic assessment of the proposed curvature as a measure of volume distribution would be helpful.

The 3-dimensional photonic scan (3-DPS) technique, formerly used by the fashion industry, was investigated and validated in terms of the accuracy for the measurement of body volume, circumferences, length and percentage of body fat (127). For comparison tape measurements and underwater weighing of the full body (UWW) were conducted. The photonic scanner consisted of a laser beam that measured more than 2 million points on the body and so created an image of the patient's dimensions from top to toe. When laser light points projected on the surface of an object they were reflected and a 3D image was created by application of high speed digital cameras and triangular mathematics. Scanning took 5 seconds; 92 subjects were investigated. The body composition in view to the amount of fat tissue was obtained through calculation of an equation which is referred to. Each unit consisted of a laser source and a digital camera. 3DPS gave slightly but significantly higher measurements for body volume than UWW and those measurements that were obtained with tape measure of body circumferences. However, the comparison of the detected amount of body fat was not significantly different for 3DPS and UWW. The study group concluded that 3DPS measured body volume, circumferences and length rapidly and accurately. The test individuals needed to wear a minimum of clothing for optimal scanning results and a standardisation in posture and breathing were regarded as essential.

An objective analysis by 3D imaging for the analysis of operative changes after breast augmentations was conducted and a series of 28 breast images in 14 patients was investigated (122). After 3D images were obtained, once before and after the operation, the software constructed a customised chest wall template for each patient. From this chest wall template the 3D breast models were extracted as polygon models and the 3D data analysis was conducted. The total breast volume was measured and additionally a horizontal split plane (XZ plane) was placed through the lateral border of the infra-mammary fold for division of the breast into an upper and lower pol. Sagittal sections were taken through the nipple to investigate the projection which was called the anterior posterior (AP) distance. Further the angle of the upper breast pole at the chest wall was measured and called the internal angle. Further surface distances were measured between the nipple to sternal notch and nipple to infra-mammary fold. The results revealed that total breast volume changed in correlation with the implant size. The volumetric distribution of breast volume between the upper and lower breast area remained about the same. The AP projection increased significantly by 23.3mm, but this was 21% less than expected based on the implant dimensions. The internal angle of the breast projection increased significantly as did the sternal notch to nipple distance. The study presented an objective investigation into the changes associated with augmentation surgery. Further details to the technical setup of the 3D imaging system would have been helpful; instead reference to previous publication was given.

This previous publication by Tepper explained that 3D imaging was conducted by laser scanning method (121). The anatomical changes after breast reduction surgery were objectively investigated by application of a V910 Konica Minolta scanner and Studio 9 Geomagic software. Images were taken in thirty patients in upright position at several angles with the subjects facing the camera. Further images were taken with the cameras at the subject's knee level and 3D images were merged together. Topographic colour maps were used for analysis of 3D models. A customised chest wall template was created and breast boundaries subjectively defined. The breast was removed and the software filled in the remaining curvature. Between the chest wall and the surface a closed object was created. The chest wall template was used to overlay on preoperative images. Breast reduction procedures resulted in significant changes in breast projection with the maximal point of projection being elevated. Possible data loss in the inferior breast fold was not assessed. It was claimed that special fluorescent lighting eliminated shadowing resulting in increased accuracy. Further investigation into this claim has yet to be conducted. Reproducibility was not assessed.

1.3.6. 3D imaging with a single digital camera

Three-dimensional imaging devices were built containing a single digital camera for capture and construction of topographic surface maps of certain body parts such as the breast (33). The images contained quantitative data in X, Y and Z axes in space which were evaluated by software programmes for an accurate and objective 3D image built up. In a study with 100 patients, 3D imaging was conducted with the utilisation of a single Genex Rainbow 3D camera (Genex Technologies, Inc., Kensington, Md.) and Genex software for breast assessment. The patients were assigned to five groups for breast augmentation, breast reconstruction, asymmetry correction, breast reduction and mastopexy procedures. One case report from each group was described in the publication and the experiences of the author provided. The author expressed his opinion that three-dimensional imaging in breast surgery has several uses and great clinical potential. Beyond the five case reports, no systematic study was presented and no further information of the application of the 3D imaging system provided.

The role of three-dimensional imaging for improving outcomes of breast reconstruction surgery was further investigated under utilisation of this single Genex Rainbow 3D camera (94). A study was performed involving 382 women undergoing breast reconstruction during a four-year period. 334 women completed the examination and were included in the study. These women were divided into two groups. One group of 33 women was established on the basis of the use of 3D photography. The other group for comparison consisted of 301 women who did not undergo 3D photography. The women in both groups underwent multiple different methods of breast reconstruction utilising autologous and non-autologous tissue. Breast symmetry was assessed subjectively in terms of volume and contour after the initial reconstruction and after secondary procedures with and without 3D photography. The subjective assessment was based on visual and photographic assessment of the breast. The assessment of breast volume was based on the calculations provided by the computer that was linked to the camera. The need for secondary procedures to obtain final symmetry was documented. The study was performed by a single surgeon and a single photographer. The patients undergoing 3D imaging were all marked at specific landmarks on the chest with the intention of achieving reproducible breast volumes. The statistical tests that were applied to evaluate the data were not specified. The patient group undergoing 3D photography showed initial symmetry for volume in 73 % and for contour in 27% of cases; secondary procedures were necessary in 70% of cases. Final symmetry for volume was achieved in 88% and for contour in 79%. The group without 3D photography showed initial symmetry for volume in 57% and for contour in 34% of cases; secondary procedures were necessary in 50 % of cases. Final symmetry for volume was achieved in 80% and for contour in 71% of cases. Altogether, reconstructions with autologous tissue achieved more symmetry than with implant reconstructions. The study concluded that there was no significant difference in final volume and contour symmetry between the two groups with and without 3D imaging. Surprisingly, the authors came to the conclusion that 3D photography was of limited use. However, the study design was insufficient to merit this statement. There was no randomisation of the patients and 48 patients were excluded for no clear reasons. Intra- or inter-observer errors were not examined. The method of subjective assessment was not clarified. A wide range of reconstructive procedures were compared. There was insufficient information as to how symmetry was judged. Figures for symmetry were astonishingly high and examples of photographs contradicted statements of symmetry achieved. The reproducibility of data was not examined. Importantly, insufficient information was provided on the method of 3D capture.

The surface area of the breast was measured by application of an optical grid that was projected onto the breast and two images were captured, that were merged to one 3D image (124). These images were obtained by a video camera that was positioned cranial and caudal to the patient who was in a prone position on a special table with the breast hanging downwards. For validation of the method simple geometrical shapes were analysed, volume, surface and projection assessed and results revealed excellent correlation in all parameters (r>0.995, $p<10^{-14}$). In the subjects, comparison with plaster casts revealed also excellent correlation (r>0.992, $p<10^{-11}$). It was concluded that this optical method measured volume and surface with accuracy.

1.3.7 Multiple Stereophotogrammetry

An early investigation into breast volume measurement of 248 women using biostereometric analysis was conducted in 1987 using stereophotogrammetry (86). Two wide-angled stereo cameras (Kelsh K-460, Danko Arlington Kelsh, Inc., Baltimore, Md.) were used; these were equipped with a vacuum film plane and fibre optic terminations for enabling fiducial marks on film. The two cameras were mounted next to each other on a double rail support with a surface contrast optical projector in the middle. This served as source of illumination and projection of a contrast pattern on the photographed surfaces on Kodak film. Total volume and volumetric differences between breast pairs were studied and compared to clinical parameters such as handiness, subjective perception of breast size, age and menstrual status. The authors reported that their technique involved first a data acquisition, then a reduction of the stereophotographs to a series of coordinates that were subjected to mathematical algorithms and finally a graphical and numerical analysis. The 248 women were chosen randomly from those attending the hospital for mammographic examination and who did not show any pathology nor had any history or examination of malignancy. For data collection, the women lay in a prone position on a table with two openings for the breasts to be placed through. The stereo camera system was positioned underneath the table taking the images while gravitational forces pulled the breasts down to separate the breast tissue from the chest wall. By application of a modified stereoplotter (Kern PG-2, Stereoplotter, Kern Instrument Co., Aarau, Switzerland) the data reduction was performed from the exposed photographs to three-dimensional coordinate locations for a series of points lying on the surface of the breasts. These points, representing the surface of the breast, were recorded as contour lines lying parallel to the frontal plane of the subject. The contour lines were repeatedly scanned and the plotter operator recorded a series of coordinates presenting the breast boundary. Then a read-out of all coordinates was sent to an IBM 3033 computer for determination of volumes and volume distributions. The mathematical algorithm that was utilised for data analysis was previously described by Sheffer et al (1985; 1986) and included isolation of coordinates, interpolation of an approximate breast curve and computing of all areas of contours. Volume differences were expressed as the percentage of the volume of the smaller of the two breasts. Statistical tests included a trimmed mean technique for exclusion of extreme scores and a chi square test for correlation of volume with clinical factors like age, handiness etc. Breast volumes showed a wide range from 21.5 to 1331.5 ml. The author reported that subjective perception of breast size correlated well with objective measurements. No correlation was documented between handiness and breast size. No dominance of breast size on one side was described. No significant correlation was found between total breast volume and

volume asymmetry. The overall volume asymmetry was judged as relatively small, as in 87.5 percent of subjects it was less than 100 ml. On the other hand 99.6 percent of women showed some degree of asymmetry. The authors described stereophotogrammetry as simple, non-contact, non-invasive, accurate and rapid. In 1987 the authors published a new and emerging technique and presented a valuable contribution to the field including the standardisation in posture of the prone position to obtain the measurements. No information on the method of subjective breast assessment was provided and no clarification how the conclusion of the simplicity of the technique derived from the study. Accuracy and reproducibility were not investigated and capture speed was not mentioned.

A further early examination of objective breast assessment was published in 1994 based on a two-camera prototype system and computer-based software called the Body Map system (10; 88). For full breast coverage, a stereo camera configuration with a projector in the middle was required. Congenital breast asymmetry in 24 patients was investigated and objective measurements and subjective judgements compared. The body map system relied on the illumination of a non-flat surface like the breast with structured light to obtain a unique pattern of light distortion. The analysis was based on the image of the distortion (i.e. photograph) together with the original slide, that together formed a stereo pair from which the coordinates of the projected grid lines on the surface could be determined. There was a good correlation between the patient's visual estimates of symmetry and those of two observer panels, who further provided a mean panel symmetry score that was strongly correlated with the quantitative estimates. Based on this study, the author voiced the opinion that the role of stereophotogrammetry in the assessment of the results of breast surgery still needed to be established.

The validation of 3D imaging of the breast was described by use of a new 3dMD system that consisted of 12 synchonized cameras arranged in 6 pods at standard distance, but at varying angles (84). Fourteen patients were examined and 3D images were taken on 19 breasts prior to skin-sparing mastectomy. The true volume of the mastectomy specimen was measured intra-operatively with the water displacement technique. This was compared to volume measurements on the 3D images taken preoperatively, which were assessed twice under application of 3dMD software by two examiners, who were unaware of the intra-operative assessments. Landmarks were placed on the images. A Coons patch, which is an area generated by computer software on the breast equivalent with the chest wall base, was applied. With software calculation, volume between this patch and the breast surface was obtained. An examination was conducted twice by each rater. Bland-Altman statistical analysis was used to compare the results of the two different measurement techniques. Intra-rater test was evaluated by t- test, interrater test was evaluated by intra-class correlation. In addition, an evaluation of 10 patients and 20 breasts was conducted. Nipple to sternal notch distances were measured with tape and compared to measurements on 3D imaging by two raters, who calculated these distances once. The examination of the accuracy of the volume measurements derived by Bland Altman analysis revealed a mean of -2.6% and -1.8% and a standard deviation of 13% and 16% for the two raters respectively. Reproducibility after intra- and inter-rater test was judged as good, the coefficient of reproducibility was 0.8; p< 0.24 for rater 1 and 0.92; p<0.28 for rater 2; differences were not significant, tested by t-test. In the inter-rater test the reliability coefficient was 0.975; p< 0.025, therefore the level of agreement between the two raters was highly significant. The test for accuracy of the linear measurements revealed a mean of - 6% for both raters and a standard deviation of 6.6% and 6.9% respectively. The intra-class correlation was 0.968. Shape analysis, based on linear measurements, was judged as showing a good level of agreement in the inter-rater test. The reproducibility was not determined for the linear measurements. Based on the assumption that a clinical acceptable limit of 10% difference from the mean could be regarded as satisfactory accuracy, then 85% of all measurements of both raters fell into this range. The benefit of the method offering lifelike images was demonstrated. Unfortunately, the sample size was small. A breast volume calculation by the software of being within about 2% of the buoyancy measurements appears to be impressive. A few linear measurements for shape analysis are insufficient. There was a lack of data regarding the configuration of the 6-pod camera system with 12 cameras, patients posture and clinical application. The title: Validation of 3D imaging of the breast was misleading, as the study by Losken solely investigated the 3dMD system, but no other 3D imaging methods.

An objective evaluation of the extent of natural breast asymmetry by 3D stereo photogrammetry was presented by the same author. The previously described 3dMD system was utilised. The study aimed to quantify the differences in breast size and shape (83). Eighty-seven women without a history of breast cancer, breast disease or previous breast surgery were examined. Recruitment was conducted from women undergoing screening mammography. Data were recorded on age, parity, body mass index, ethnicity and bra size. The linear distance between nipple and sternal notch was calculated with the computer after 3D imaging. To determine the degree of asymmetry, the left and right breast images were superimposed. The distance between two surfaces was calculated in mm by the computer using a colour histogram for shape analysis. To quantify the degree of asymmetry, the mean root square (RMS) from the measurements by the computer in mm was used. The RMS was a measure of the magnitude of a set of numbers. To calculate RMS all the measurements of surface distances by the computer were taken, the values were squared, the average of these squares was determined and finally the square root was taken. For comparison a subjective evaluation by four reviewers was added; they rated the perceived breast asymmetry by determining 0 = none, 1 = mild, 2 = moderate, 3 = markedasymmetry. The results showed that there was a difference in the average nipple to notch distance of the right to left breast. In two-thirds of the cases this distance was longer in the left breast. The measurements of the mean distances between two breast surfaces in mm showed that on average the left breast was larger. The RMS was significantly higher in patients with a larger BMI, chest wall and cup size. On the other hand, age, parity and ethnicity did not have an impact on breast asymmetry. Concerning shape, the authors stated most patients had a combination of asymmetries. The most common pattern identified, was that the breast was larger in one location and smaller in other locations, most commonly larger laterally and smaller medially. The subjective evaluation revealed that 46 patients from 87 had no or mild asymmetry, 32 had moderate and 9 patients had marked asymmetry. 90 % of the patients had mild to moderate asymmetry. The authors concluded that there was a good correlation between subjective and objective evaluation and that the results showed that natural breast asymmetry existed. Based on the superimposition of the images, the authors claimed that differences in breast size, shape and contour could be successfully determined.

The paper lacked the details of the camera set up, posing of patients and the method of nipple to notch and surface distances determination. Further information of the exact processes that were involved in size, shape and contour calculations that determined the asymmetry assessment would have helped in understanding the method. Nevertheless, the presented study provided valuable information in a new field of research.

Kovacs (2005) commented on the article by Losken, agreeing on the importance of 3D imaging as a recognised technique (73). A sound and careful validation was recognised as being important for 3D imaging technology to achieve applicability in every day clinical life. The limits of the 3D technology were seen in the fact that volume calculation was dependent on a closed surface by software-driven simulation of the chest wall, which could open the possibilities to differences in the volume calculation. Kovacs criticism was that Losken's study relied on front and lateral thorax wall views only, restricting the significance of the method to a comparative analysis. Alternatively, a 360-degree scan was suggested or a method in which the rear demarcation of the breasts was determined by the extension of the thorax wall level. In the latter case, the surface behind the breast was computed by interpolation of the surface curvatures. It was suggested that anatomical boundaries were considered for the volume calculation and the criticism was made that the skin demarcation of the cranial breast border in Losken's article was not clearly described. For the cranial border, the folding line method by Lee, which relies on emerging upper skin folds when shifting the breast upwards, was recommended. Reference to own work was given. Kovacs pointed out the possibility of varying learning curves among examiners in terms of the precision and accuracy of the measurements of breast volume and shape. He felt that further validation work was required on the applied software and evaluation protocol before the method could be introduced into clinical practice. Overall, the comments represented the opinion of an expert with experience in the field.

Another comment on Losken's work on validation was provided and acknowledgement given to his contribution to objective breast assessment and choice of method of comparison for total breast volume determination by utilisation of the water displacement method in mastectomy specimens (96). The author described his own experience with a 2-pod stereophotogrammetry system (Genex 3D camera) and the observation of a significant variability in the calculation of breast volume. Reasons for this variability were seen in the individual utilising the cameras and determining the breast landmarks. The author proposed that a single individual should therefore be responsible for placing the landmarks and obtaining the 3D images. Contrary to Losken, who placed the landmarks on the 3D computerised image, Nahabedian placed them on the patient prior to obtaining the 3D image. Nahabedian offered his opinion of the superiority of Losken `s approach as it seemed to have improved the reproducibility of the technique. Nahabedian discussed further the clinical purpose of 3D imaging in general, which he felt was still uncertain. It was pointed out that with increasing breast size and ptosis the breast borders become more obscured and landmark determination becomes less precise. Nahabedian felt that the issue of a suspension of the breast needed to be solved to improve the applicability of the method in ptotic breasts. A standardisation of posture was advised. Further, he pointed out that with an increase of the thickness of the subcutaneous breast tissue an increase in the degree of miscalculation has to be expected. The author gave his opinion on the clinical potential of 3D imaging in the future in terms of the ability to quantify breast symmetry, but pointed to remaining technical obstacles at present.

An alternative application in the field of radiotherapy has been investigated in terms of the standardisation of patient positioning for breast tumour marking with a commercial 3D surface imaging system (108). A 2-pod stereo camera system with 2 cameras (Vision RT, London) was utilised fixed to the ceiling aiming downwards at a patient positioning table. A phantom model and 4 healthy male volunteers were examined. The study aimed to test the accuracy and precision of the system. Volunteer position was standardised as supine on the table with the arms raised above the head. A surface image of the model by triangulation and merging was taken and compared to a pre-registered reference model. Surface reconstruction was performed in expiration as this was considered to be the most stable and reproducible volunteer position. Fourteen images were taken and compared to each other in terms of the stability of the surface model. In the volunteer model, respiratory movements were considered and alignment accuracy assessed. Through transformation the set-up of the future patient was corrected. The suggested setup with this camera system was compared to a marker based optical system and the results proved to be consistent. The authors concluded that the results demonstrated that the camera system provided highly accurate setup conditions in the phantom and healthy volunteer model. A further investigation with patients was suggested. The study provided a possible application for multiple stereophotogrammetry in the positioning of breast cancer patients for radiotherapy. This has to be differentiated from plastic surgical approach in assessing breast volume, shape and symmetry in the female breast.

A clinical retrospective study of a three-dimensional digital evaluation of breast symmetry after breast conservation therapy was conducted in 23 patients with utilisation of the same 3dMD camera system (3Q corporation) as previously described by Losken (93). 12 camera lenses arranged in a three-dimensional array for facial or chest wall analysis were utilised. A superimposition of the treated onto the non-treated breast by application of the software for surface area and volume differences was conducted by bisecting the thorax down the midline on the three-dimensional image. The surface was analysed through mesh interpolation and division into random, individual dots. This was compared to the reference surface that is also meshed and assigned with points before the differences between the associated points were summated to obtain the individual differences leading to the total volume difference, which is designated as the root mean square (RMS) providing an asymmetry score. Patients` posture was standardised as standing upright, arms to the sides as well as arms to the hips. A control group of 35 healthy subjects was utilised for comparison. Mean asymmetry score was 3.02 for the control group and -.59 for the breast conservation therapy group. A positive correlation was found between amount of removed breast tissue and asymmetry. The study presented a valuable contribution to a new field of objective breast assessment by multiple stereophotogrammetry. Further details on the camera configuration and comments on experiences in ptotic breast shapes would have contributed to the study.

Summary

This chapter described how stereophotogrammetry as a method of objective 3D imaging evolved and found a clinical application in the field of facial capture. Reports on the validation and clinical use of the method were published. The chapter ends with the presentation of recent attempts at the application of multiple stereophotogrammetry for 3D capture of the breast. An overview is given of various methods of breast assessments that have been tried over the years and which include objective 2D and 3D methods. Traditional subjective judgements were also presented. Laser scanning has evolved as one of the more recent and advanced objective methods for 3D breast capture, in addition to stereo-photogrammetry, which provides most promising lifelike images. Studies on the assessments of accuracy and reproducibility of multiple stereophotogrammetry for 3D breast capture were presented and recent clinical application of the method was illustrated. Nevertheless, overall there has been a paucity of publications of independent assessments of the method to date.

2 Materials and Methods

Introduction

This chapter describes the 3D imaging system of multiple view stereo cameras that was used. The approach we took to achieve the validation of this prototype system is presented. A pilot study with plaster and live models and volume measurements by 3D imaging and water displacement method for comparison is illustrated. Accuracy and reproducibility as well as errors were investigated. A patient study of patients after unilateral immediate breast reconstruction by Latissmus dorsi flap is described. It is illustrated how the patients were captured postoperatively and 3D images were constructed and measured. Breast asymmetry was objectively assessed and possible contributing factors to asymmetry were investigated, as were errors. A comparison was conducted by expert observers of subjective assessments using 2D patient images.

2.1 Part I – Pilot Study - Validation

2.1.1 Study Design

A prospective study was designed to measure the volumes of plaster breast models as well as the breast volumes of volunteer live models by 3D imaging that was conducted with multiple view stereophotogrammetry. The results were compared with those obtained by water displacement.

2.1.1.1 Aim of Study

The aim of the study was to assess the validity of a 3D breast imaging system based on multiple stereophotogrammetry (Fig 2.1). The accuracy and the reproducibility of the system in recording breast volume were evaluated.



Figure 2.1 3D breast imaging system based on multiple stereophotogrammetry

2.1.2 Subjects and Objects

Plaster and live models were assessed and volume measurements conducted.

2.1.2.1 Plaster Models

The study was conducted on nine specially shaped plaster models (Fig 2.2), seven models in the shape of a breast, two models in the shape of a hemisphere.



Figure 2.2 Nine plaster models resembling different breast shapes and sizes

Each breast shape was achieved by using rubber bowls of different forms (Fig 2.3) and additional free-hand moulding using pink coloured putty of a polysiloxane condensation-type elastomer ("lab putty", Coltene). All models were manually textured and painted in flesh colour without gloss (Crown Paints).



Figure 2.3 Rubber bowls for the molding of plaster models

The different breast shapes were intended to resemble a human breast with or without ptosis. Two sports balls, one small and one large, were utilised to construct two plaster models in the form of a hemisphere (Fig 2.4).



Figure 2.4 Two plaster models in the shape of a hemisphere

All models but one were made with a flat back wall and fixed to a flat wooden board of matching texture and paint (Fig 2.5).

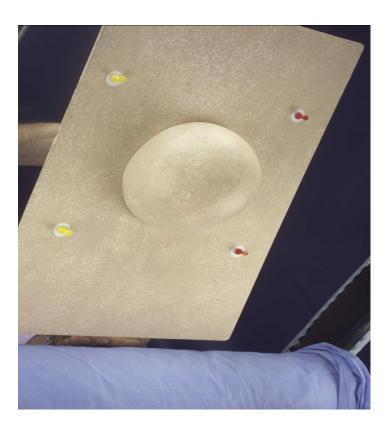


Figure 2.5 Plaster model mounted to wooden board

One model with curved back wall was attached to a plaster torso (Fig 2.6).



Figure 2.6 Plaster model mounted to plaster torso



The plaster models were each uplifted for 3D capture (Fig 2.7).

Figure 2.7 Plaster model uplifted for 3D capture

Capture was conducted once using the multiple stereophotogrammetry system. Each plaster model was placed at the centre of the four camera pods and simultaneous images from all cameras were captured. After capture, a 3D model was built and measured 10 times with BAT software (Fig 2.8).

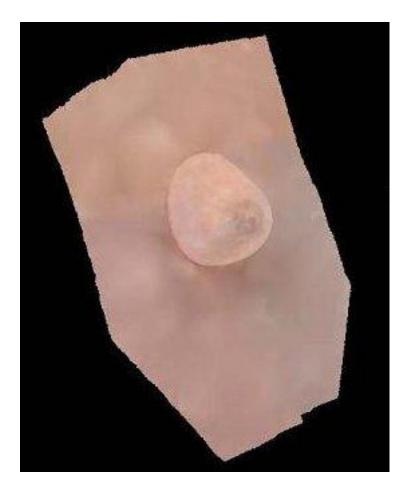


Figure 2.8 3D image of plaster model

2.1.2.2 Live Models

This study was conducted on six volunteer live models with different breast shapes, with and without ptosis and of different sizes. The breast was captured with the stereophotogrammetry system and this was repeated six times for each model (Fig. 2.9).

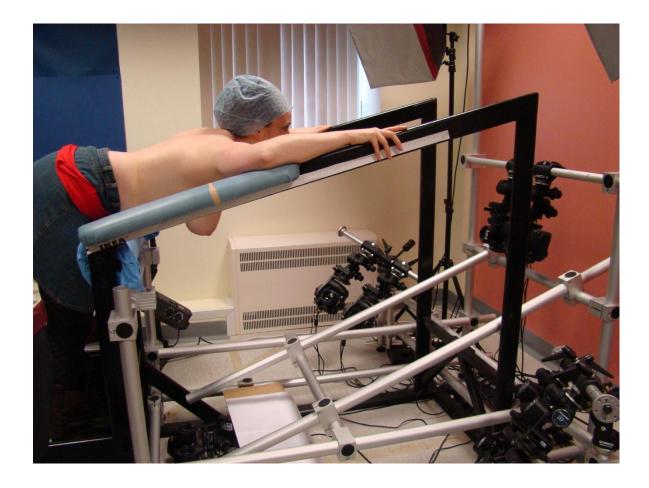


Figure 2.9 Live model captured by 3D multiple camera system

2.1.3 Materials

2.1.3.1 Water Displacement Method

To conduct comparative volume measurements and ascertain the volume of the plaster models, Archimedes` principle of buoyancy was used. According to Archimedes` principle, the weight of the displaced fluid is directly proportional to the volume of the displaced fluid, on the assumption that one gram equals one cubic centimeter of water volume at a temperature of 20° C. The plaster models were completely emersed.

2.1.3.1.1 Measurements of Plaster Models

Water displacement for volume assessment was conducted using a scientific scale (Ohaus, Navigator [™]) that was levelled by adjusting the feet and calibrated (Fig 2.10).



Figure 2.10 Water displacement system for plaster models

A plastic bowl was positioned on the top of the scale and a metallic rig was glued into this bowl to serve as a stand for a smaller bowl, which was used for the immersion of the plaster models that were used in the study. The smaller bowl was filled with water at room temperature and was levelled off with a flat, clear board to avoid the inclusion of air bubbles. The object to be measured was inserted into the small bowl. The water which overflowed from the small bowl was collected in the large bowl underneath and then removed using a pipette and syringe. Then the object was removed from the small bowl. The weight of the water collected in the small bowl before and after the overflow was calculated and was considered to be equal to the weight of the immersed object, on the assumption that one gram of the plaster model equaled one cc of water volume. The volume measurement was repeated 10 times for each model.

2.1.3.1.2 Measurements of Live Models

For the examination in the live models a modified system of water displacement for breast volume assessment was built in order to accommodate larger breasts and meet the demands of the application in the live subject (Fig 2.11).



Figure 2.11 Water displacement system for live models

This system consisted of a modified, wooden table of low height in which a central hole was cut. With the aid of a wire hanger a plastic bowl was hung into this hole, which was filled with water. The live model knelt in front of this table and slowly and fully immersed her breast into the bowl containing the water, resting her body on the table which stopped further immersion (Fig 2.12).



Figure 2.12 Live model fully immersing her breast into water

The water overflowed and was collected in a second bowl underneath. The weight of the overflow was recorded on the aforementioned scientific scale and considered as being equal to the breast volume. Each live model repeated the examination six times.

2.1.3.2 The 3D Imaging System

2.1.3.2.1 Stereophotogrammetry

The process of capturing a numeric representation of the breast in 3D and then extracting the required breast surface area and volume information comprised the following steps (6; 92; 111):

- Acquisition of four stereo-pairs of images covering the required field of view of both breasts.
- Processing each of the four stereo-pairs of images depicting the breasts to generate four corresponding 3D surface models.
- Integration of the four individual surface models into a single continuous 3D model of both breasts.
- 4. Analysis and interpretation of the integrated breast model comprising semiautomated breast boundary and chest wall estimation to allow each breast to be segmented as a closed volume. The surface area and internal volume of the segmented breast could then be measured automatically.

2.1.3.2.2 The Camera System

The sets of stereo-pair images required to construct the 3D model of the breast were acquired by means of a four pod, eight-camera system, which was developed by researchers in the University of Glasgow in collaboration with Dimensional Imaging Ltd. (Glasgow, UK). High resolution digital cameras (Kodak Company, Rochester, USA) were utilised (Fig 2.13).



Figure 2.13 Eight high resolution digital cameras used in camera system

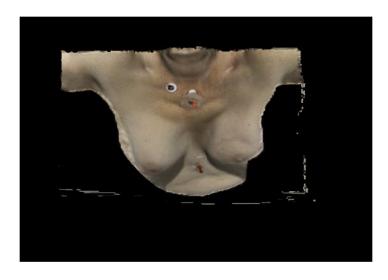
The principal task in the design of the image capture system was the configuration of the cameras to capture the complex structure of the breasts in order to be able to generate the complete surface of both breasts in 3D. The capture system needed to deal with the gross variation in breast sizes. A wide range of breast sizes posed challenges due to the variation in subject-to-camera distances which influenced the depth of field and camera focus necessary to ensure satisfactory 3D measurement precision. Breast capture was conducted simultaneously from the right, left, front and inferior view where each one of the four camera pods was positioned (Fig 2. 14 a, b, c, d).



Figure 2.14 a Capture of the breast from the right side



Figure 2.14 b Capture of the breast from the left side



2.14 c Capture of the breast from the front



2.14 d Capture of the breast from below

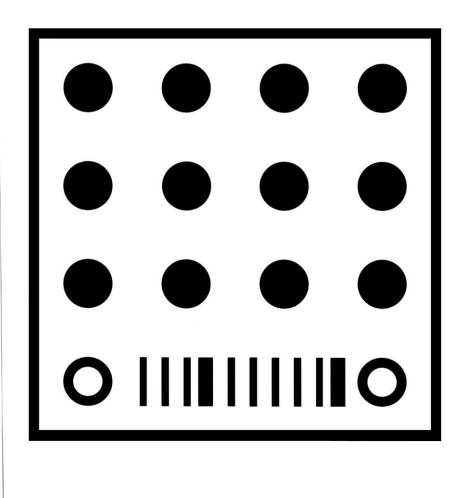
2.1.3.2.3 Posture for 3D Image Capture

The posture was standardised to achieve the greatest possible accuracy and reproducibility of the capture and resulting processes. Each subject had to position herself in a wooden positioning frame which served for stabilisation of the body. While standing on an adjustable standing board with the hips resting against a hip roll, the subject bent forward with the upper body to an almost horizontal position with the arms stretched out, resting on supporting arm boards with the head lifted upwards. The breast lifted off the chest-wall, hanging downwards and was located at the centre of the focus of the four camera pods. In this position any obscuration of the lower breast fold and resulting data loss was avoided.

2.1.3.2.4 Calibration

Prior to image capture the cameras were calibrated to enable metric 3D measurements to be obtained and also to allow the coordinate frames of each

stereo-pair of cameras to be aligned within a single measurement space. The imaging system was calibrated to allow simultaneous accurate localisation of the geometry of the breast by all the cameras. The calibration procedure used a specific calibration target that was imaged in a variety of different positions to allow simultaneous image capture by each one of the stereo camera pairs as well as by each combination of them (Fig 2.15).



In total, approximately 50 different target captures were necessary to calibrate the system. The calibration data were then attached to each subject's images in order to construct each 3D model correctly. The final images could be built at low or high resolution. This was dependent on the requirements in regard to the planned usage of the images.

2.1.3.2.5 Image Capture Software

The use of stereophotogrammetry involved image capture, model construction and image measurements. Image capture was carried out using commercially available software (Di capture, Dimensional imaging). The software served to recover the simultaneously captured images from the eight calibrated cameras at a capture speed of approximately 1.5 milliseconds. Post-capture software, developed by the Computing Science department, University of Glasgow, was used to convert the files into integrated 3D models.

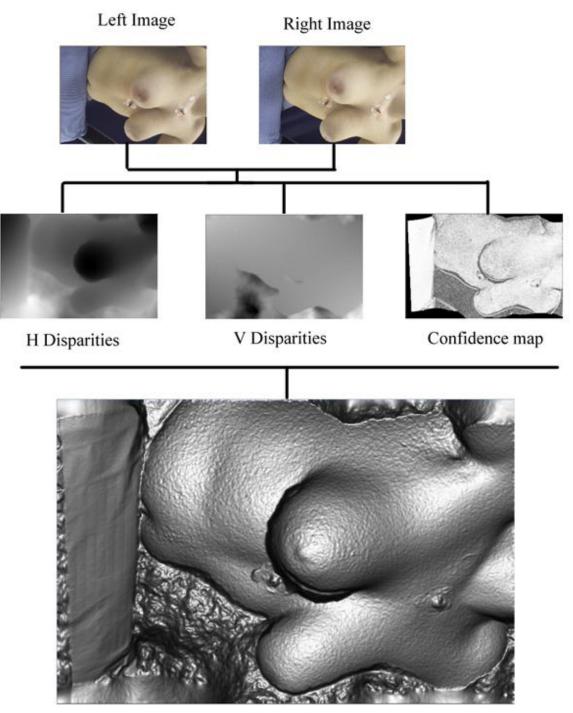
2.1.3.2.6 Background and Lighting

The multiple stereophotogrammetry system was located at the Canniesburn Plastic Surgery Unit at the Glasgow Royal Infirmary where a self-coloured (blue) back ground was used. Several images were captured of the same object or subject and the best quality images were selected and edited; extraneous background material, which was not required to build the 3D model, was removed. The blue background was employed to allow automated segmentation of the background and thereby facilitate subsequent image processing operations. Lighting was done with four white light studio flashes that were located on the right and left sides of the capture system and that were adjusted in their position according to the skin colour of the photographed subject and the amount of light needed.

2.1.3.2.7 3D Model Construction

The images were then processed using three-dimensional reconstruction software, C3D (67; 111). The C3D stereophotogrammetry software system was used to construct the 3D model of the breast from the four sets of stereo-pairs based on an image matching algorithm.

The sequence of three-dimensional model construction was previously described for facial capture (38; 39). The same method was applied for the capture of the breast with the difference that for the face, two camera pods were used and for the breast, four camera pods. The camera configuration was redesigned to cater for breast capture in a forward-leaning pose. At the start of the 3D imaging built-up process disparity and confidence maps were constructed from the images of each camera pod in two dimensions (x, y). The disparity map was built in horizontal and vertical directions and aligned the corresponding points of the two cameras. The confidence map presented the goodness of the disparity map and indicated where the image registration between the two cameras had succeeded or failed (Fig 2.16).



Range image

Figure 2.16 3D model construction

(image provided by Xiangyang Ju)

The photogrammetry process converted the disparity map, which was computed for each camera stereo-pair; into a 2.5D range map (F-model, displayed as a "silver" image in C3D) by means of the calibration method. The 2.5 D model is a simplified 3D surface representation derived from as single stereo-pair of images that was further developed into a true 3D model after merging the images of all four camera stereo-pairs together. The range-map represented an image-like data structure for storing 3D data. Every pixel of the range-map represented the distance measured from the camera perspective centre to the corresponding world surface location observed on the camera imaging plane. After further processing, each range-map was transformed into a "point cloud" comprising (X, Y, Z) coordinates in the "world-space" (111). Any excess of data outside each point cloud was removed by a process called masking to improve of the quality of the images. The "world-space" point clouds constructed from each camera pod were merged together to form an integrated 3D model by means of the C3D software using the "marching cubes algorithm" (82), which was extensively modified to achieve the integration of the multiple camera views. A self-correction method of the 3D reconstruction from the multi-view stereo images was recently developed to improve image quality by repair of the 3D surface damaged by depth discontinuities (67).

The solid model was the initial presentation of the 3D model in grey colour and with a smooth surface. The wire-framed model was an alternative representation which was created by the conversion of the 3D model into a single triangulated polygon mesh. Photorealistic visualisation with a "textured" surface was achieved by placing a layer of pixels ("texture mapping") onto the model. The process involving image merging and texture mapping is known as photorealistic rendering. A life-like 3D model of the object was thereby generated.

The 3D model was exported from C3D software as a Virtual Reality Modeling Language (VRML) model in a file size between 5 to 20 megabytes.

2.1.3.2.8 Volume and Landmark Measurements

The 3D model obtained was loaded and displayed using the breast analysis tool software (BAT), developed at the University of Glasgow (97) (Fig 2.17).

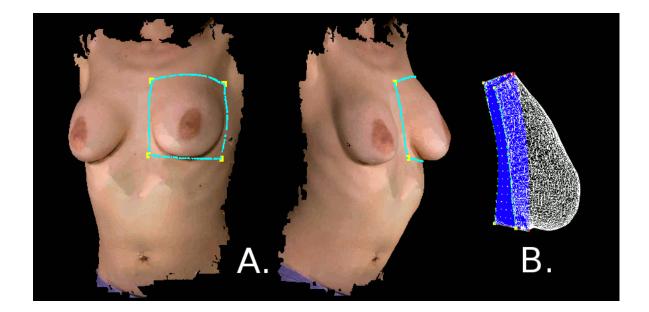


Figure 2.17 3D breast model displayed in BAT software with breast segment

(image provided by Susanne Oehler)

In order to determine the volume of the breast, four landmarks were placed at the extremities of the breast segment, creating a rectangular surface patch. The software then created an artificial chest-wall on the selected breast segment, based on the use of a "Coons patch" (6). The shape of the generated chest-wall patch was controlled by the curvature of the edge lines delimiting the breast segment. These edge lines corresponded to an approximation of the "geodesic

path", the shortest line, on the surface of the model between each of the initially placed edge points, i.e. these lines followed the shape of the torso. A modification was the application of a "pseudo-geodesic path", which was the shortest surface intersection with a plane, which was "anchored" by two points to allow free rotation and to find the shortest intersection pathway (98). The segmentation method and chest-wall generation methods were key factors in the volume measurement procedure of the breast analysis tool software.

The software programme enabled model rotation, translation and magnification. The 3D model could be visualised either as a wire-framed, a grey-shaded and a photorealistic model simultaneously in three different viewing windows (Fig 2.18).

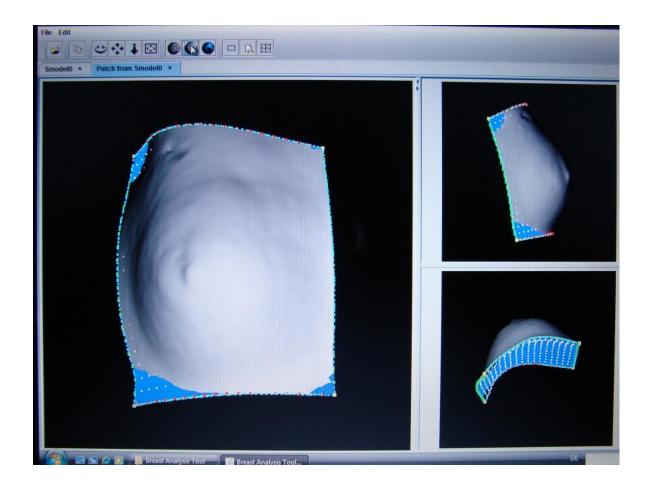


Figure 2.18 3D breast segment displayed in three different viewing windows

2.1.3.2.9 Systematic Differences

The statistical analysis was based on the method by Bland and Altman for assessing the agreement between two methods (8). Mean, standard deviation and the systematic differences between the data generated by each method were examined. The differences between the breast volumes generated by 3D imaging and water displacement for the plaster and live models were identified. Water displacement served as the gold standard for the measurements. Additional geometrical volume calculations were conducted in the two plaster models in the shape of a hemisphere (13).

2.1.3.2.10 Reproducibility

The reproducibility of the measurements in the plaster models after ten repeated tests and in the live models after six repeated tests was examined. Special focus was placed on the investigation of the reproducibility of the 3D breast measurements in the live models, as described in the error study. Factors that may have been contributing to the variability were assessed and it was also investigated if a possible correlation could be found with the breast size.

2.1.4 Error Study in Plaster and Live Models

2.1.4.1 Posing-, Capture- and Measuring-Up Error

The reproducibility of 3D measurements in the live models was examined in more detail. The capture was conducted at two different time points, with three captures on each occasion when the live model was recaptured to determine the variation of the pose (Posing Error). Each of the live models was captured six times (Capture Error). Each capture resulted in a 3D image, so that for each of the live models six 3D images after six captures were obtained. On each of these 3D images the operator used the BAT software to calculate the breast volume three times separately and the mean of these three measurements was then used for comparison with the measurements by water displacement. Overall, 18 BAT measurements were obtained for each live model (Measuring-Up Error).

2.1.4.2 Factors Contributing to Variability

The cause of the variability of the 3D imaging results was examined - was it from a genuine volume difference of the models' breasts, the repositioning in the rig on the two separate occasions, the individual captures of the models or the operator's use of the BAT software for the volume estimation? A linear mixed-effects model was fitted to differentiate between these factors. This statistical model assumes an overall mean and investigates how far the results deviate from this mean for each model, pose, capture and measurement.

2.1.4.3 Correlation of Size and Variability

A possible correlation was investigated between the size of the plaster models and the reproducibility of the measurements determined by 3D imaging and water displacement.

It was assessed whether there was a correlation between the live model's breast size and the variability of the measurements determined by 3D imaging and water displacement.

The Pearson correlation coefficient was assessed to investigate this correlation between size and reproducibility, measuring the strength of the linear dependence between two variables X and Y, giving a value between +1 and -1. A value of 1 implied that a linear equation described the relationship between X and Y perfectly and all data points were positioned on a line for which Y increased as X increased. A value of -1 was similarly connected to the decrease of Y with an increase of X. A value of 0 implied that there was no linear correlation between the variables.

2.2 Part II - Patient Capture

2.2.1 Study Design

A prospective evaluation was conducted by 3D imaging in patients to examine breast volume, shape and symmetry after unilateral breast reconstruction.

2.2.1.1 Aim of Study and Null Hypothesis

The study aimed to achieve an objective evaluation of breast symmetry. The null hypothesis was that there was no difference in volume between the reconstructed breast and the opposite side.

2.2.1.2 Ethical Approval

Ethical approval was granted ahead of the clinical application of the multiple stereophotogrammetry system for 3D imaging as well as 2D imaging at the same occasion. Approval comprised the study in a patient group after unilateral breast reconstruction at the Canniesburn Plastic Surgery Unit at the North Glasgow Health Trust and was obtained from West Glasgow Ethics committee. Indemnity cover was granted by Glasgow University. Patient consent was secured.

2.2.2 Subjects

49 Patients were examined by 3D capture.

2.2.2.1 Inclusion Criteria

- unilateral immediate breast reconstruction after mastectomy with the aid of transposition of the latissimus dorsi (LD) muscle flap,
- patients` age between 37 and 67 years,
- no surgery to the contra-lateral breast and
- no chemotherapy or radiotherapy in the last 6 months.

Based on the findings of their case notes, 49 patients were initially identified, who consented to take part in the study.

2.2.2.2 Exclusion Criteria

- malfunction of one camera during capture,
- one case of bilateral breast reconstruction,
- two cases of delayed breast reconstruction and
- one case of a chest wall resurfacing

Five cases were excluded from the study in due course and 44 patients were finally included in the study.

2.2.3 Materials

2.2.3.1 Assessment of Case Notes

The case notes of patients who underwent breast reconstruction between 2005 and 2008 at the Canniesburn Plastic Surgery Unit were examined and a group of patients with uniform features was identified. Altogether, 355 case notes were reviewed. A homogeneous group of patients was chosen after unilateral breast reconstruction with latissimus dorsi flap.

2.2.3.2 The 3D Imaging System

The 3D imaging system was described in the section of the Pilot study (2.1.3.2).

2.2.3.3 Patient Image Capture

Prior to the patient capture session, the 3D multiple stereophotogrammetry system was calibrated. The patient was marked with two plastic ECG lead pads which were attached superficially to the skin. The superior lead was positioned at the point of the supra-sternal notch (i.e. the jugulum, the groove between the collar bones) and the inferior lead at the xiphoid (i.e. the bony extension at the lower end of the sternum) (Fig 2.19).



Figure 2.19 Patient with two ECG lead pads at supra-sternal notch and xiphoid

These two lead pads served as landmarks to define an imaginary midline of the chest. A paper sticker with a number representing the order of the patient in the study was attached at the height of the right clavicle. The patient's identity was concealed in all captures; the breast was the only anatomical region that was captured.

Three captures for each patient were obtained simultaneously by all cameras of the stereophotogrammetry equipment. All patients took the previously described body posture in the positioning frame. The captures were assessed immediately and subjectively with the help of preview software, Di Capture (Dimensional Imaging) to ensure that full coverage of both the reconstructed breast and the other breast had been achieved in the eight images of each capture.

2.2.3.4 3D Image Construction

The best of the three captures in the preview was chosen for the construction of the 3D image of the breast. The 3D image construction was achieved with the C3D software as previously described and image surface quality was improved by self-correction software.

2.2.3.5 Choice of Landmarks

The decision on the choice of surface landmarks was made following established literature on landmark placement on the breast (12). Following anatomical criteria an upper midline point at the sternal notch and a lower midline point at the xiphoid were chosen. Due to lack of a clear upper border of the breast no specific point was defined in this area. The sub-mammary fold was utilised to define the lower breast border and the medial and lateral ends of this fold were marked. Finally, the most prominent point and the most inferior point of the breast were identified (Figure 2.20). Ten surface landmarks were identified and 3D landmark coordinates obtained.

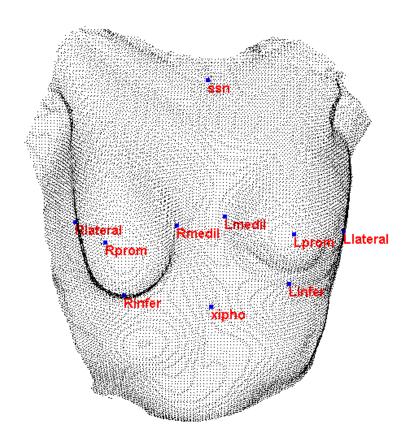


Figure 2.20 Ten surface landmarks on 3D breast image

(image provided by Joanna Smith)

2.2.3.6 Landmark Identification

The following methods were adopted to reduce errors associated with landmark identification:

- 1. Immediate repeated digitisation of each landmark on the same occasion
- 2. Further immediate repeated digitisation on separate occasions

- 3. Utilisation of multiple windows, which displayed the breast from different partitions and directions simultaneously
- Magnification facility to identify anatomical features and aid in digitising landmarks

2.2.3.7 Operator Training

The operator was trained in the placement of the landmarks on 10 randomly selected cases. In each case, repeated digitisations were carried out on the same occasion and then repeated five days later.

Training was also conducted in breast volume measurement on 10 randomly selected cases. For this purpose, four corner landmarks were placed around the 3D breast image to create a rectangular surface patch with the breast in the middle. In each case repeated breast volume measurements were carried out on the same occasion and then repeated five days later.

2.2.3.8 Landmark Digitisation in Patient Images

Following the same method as in the 10 test cases, all 3D images of the 44 patients were examined and the landmark placement conducted twice by the same observer at five-day intervals. The reproducibility of the landmark coordinates was investigated and comparison between the right and left sides of the breast was made.

2.2.3.9 Volume Measurements

Similarly to the landmark digitisation all three-dimensional images of the 44 patients were examined for breast volume assessment twice, on two occasions. All images of the breasts were measured with the application of BAT software.

2.2.3.10 Data Storage and Archiving

The data of all images were saved after being coded with a unique identifier. Personal details were stored separately from the 3D data and confidentiality was carefully maintained. Data after 3D capture were stored on the hard drive of a personal computer as well as on an additional external hard drive. The x, y and zcoordinates of each landmark were saved as a text file for statistical analysis and served in the examination of breast shape.

2.2.4 Error Study in Patients

The reproducibility of landmarks was assessed. The breast asymmetry score was calculated and factors contributing to it were examined.

2.2.4.1 Reproducibility of Landmark Digitisation

The reproducibility of the landmark coordinates was examined for all 44 patients` 3D breast image models. For each 3D image an original configuration of landmarks was created and utilised for assessment.

The average distances from the mean, also called Euclidian distances, for each of the x, y and z-coordinates for all 10 landmarks within a certain day (tests 1 and 2) were calculated.

The average Euclidian distances for each of the x, y and z-coordinates for all 10 landmarks when landmarked on different days and using the average landmarks on each day (tests 1 and 2 versus tests 3 and 4) were calculated.

The average Euclidian distances for each of the x, y and z- coordinates for all 10 landmarks when landmarked on different days and using only the first set of landmarks (test 1 and test 3) were calculated.

The average Euclidian distances over the x, y and z-coordinates for all 10 landmarks when landmarked within a certain day (test 1 and test 2) were calculated.

The average Euclidian distances over the x, y and z-coordinates for all 10 landmarks when landmarked on different days and using the average landmarks on each day (test 1 and test 2 versus test 3 and test 4) were calculated.

The average Euclidian distances over the x, y and z-coordinates for all 10 landmarks when landmarked on different days and using the first set of landmarks (test 1 and test 3) were calculated.

The average Euclidian distances over the x, y and z-coordinates for all 10 landmarks using the mean of all 4 sets of landmarks (tests 1, 2, 3 and 4) were calculated. In addition to the overall mean distance the standard deviation was calculated.

In summary, the error was quantified by comparing results within a day (test 1 and test 2), by comparing the average of the two simultaneous measurements between two days (tests 1 and 2 versus tests 3 and 4), by comparing the first test of each of two separate days (test 1 and 3) and by comparing the average of all four measurements (tests 1, 2, 3, and 4).

2.2.4.2 Measurement of Breast Asymmetry

The two first landmarks, the supra-sternal notch and the xiphoid, provided the option to create a midline, so that a mirror image (reflected landmark configuration) from each side of the breast was generated. This enabled a superimposition of the original landmark configuration on the reflected one and a statistical analysis using the morphometric method.

The statistical method chosen was Procrustes Analysis, (see more details underneath), which provided a comparison of two point clouds in the threedimensional space, a landmark based method for shape analysis with good visual output (90). This involved superimposition of the images in two steps: translation and rotation. Translation meant that the images were moved to have the same geometric centres. Rotation was added to find the best fit between all landmarks.

Linear distances between the original and reflected landmark configuration were calculated. The mean of these distances was derived, which provided information on the individual asymmetry score of the breast. In a case of perfect symmetry this score would have been zero. An increasing score indicated increasing asymmetry.

Further, mean and standard deviation were calculated for all three landmark coordinates around their centroids, (see more details underneath), and the overall reproducibility of each landmark was investigated. The centroids were calculated as the square root of the sum of squared distances of a set of landmarks from their centroids (or average point). It calculated the distances of each point from the average point and combined them to give a measure of the size of an object. Data were documented on a metre scale.

2.2.4.2.1 Procrustes Analysis

Procrustes analysis is a statistical method for the analysis of shape. Shape is defined as the form of an object minus the size. The analysis of size and shape is called geometric morphometrics after the Greek words " morph", indicating shape and "mentron", indicating measurement. Procrustes analysis, as a tool in morphometrics, is derived from a legendary Greek mythical character Procrustes,

the stretcher, who presented a "one size fits all method". Procrustes converted his victims uniformly to one size to fit in his iron bed.

In Procrustes analysis the difference in shape between two objects is examined through superimposition of their landmark configurations. These are derived from landmark coordinates in x, y and z direction forming a figure. Three steps are followed: translation, rotation and scaling. In Euclidean Geometry a translation entails moving every point a constant distance in a specified direction. Euclidean Geometry is a mathematical system attributed to the Alexandrian Greek mathematician Euclid and was described in Euclid's textbook on geometry: "The Elements". In Procrustes analysis translation refers to a process in which the geometric centroid is found and the centroids of two landmark configurations are superimposed. Then a rotation is performed to reduce the squared differences between landmarks. In geometry a rotation is a transformation in a plane or in space that describes the motion of a rigid body around a fixed point. A rotation is different from a translation, which has no fixed points. A rotation is also different from a reflection, which "flips" the body, which it is transforming. Scaling further improves the matching between homologous landmarks to find the same size, a process that can also happen at the beginning of the analysis. The Procrustes residual is then calculated by evaluating the distances between the corresponding landmarks of the two matched configurations.

The application of Procrustes analysis so far was implemented for the assessment of craniofacial growth. With utilisation of 3D landmark configurations an examination was available for 3D cephalometric records, 3D facial expressions in cleft lip and palate patients, in faces of children with non cleft features and in normal faces. The application for the shape analysis of the breast is new. We chose the Procrustes analysis as it led to an objective asymmetry score for the quantitative analysis of the difference in shape between the two breasts. The Procrustes analysis was conducted with a statistical software "R" (Peter Dalgaard: Introductory Statistics with R, Springer, 2002; http://cran.r-project.org). For the calculation of the shape analysis professional mathematical support by the Department of Statistics at Glasgow University was obtained and a software package, named "shapes", within "R" was utilized.

2.2.4.2.2 Centroid Size

The centroid is the geometric centre of a figure. In a two dimensional figure it is the point in which all straight lines which divide the figure in two equal parts would intersect. In a three dimensional figure, the centroid of a convex object, such as the breast, always lies inside the object. The centroid of a non-convex object can be found outside the object. The centroid is understood as the "average" point of a set of data. In shape analysis the centroid is calculated as the arithmetic mean of all points of a shape. The term "centroid size" is reflecting the size of an object but not the volume.

To obtain the centroid size firstly landmarks are determined on the object or shape of interest. A landmark is a point of correspondence which matches across all objects. These are usually points of anatomical significance and they are used to conduct statistical shape analysis. Landmark based coordinate data for the centroid determination were utilized. The distance from each landmark to the centroid of the landmarks was calculated. These data were then squared, and the square root of the sum of these squared distances was then obtained as our size measurement. The centroid size is calculated as the square root of the sum of squared Euclidian distances from each landmark to the centroid. The unit of the centroid size is metres. This is in contrast to the unit of volume, cc.

The term centroid size is used in morphometrics, which refers to the quantitative analysis of the form/ shape of an object. Length, widths or surface measurements provide a multitude of data for shape analysis, many of which are correlated to each other, but only a few present independent variables. In shape analysis usually the relative data are of interest rather than the absolute figures. Therefore the calculation of the centroid size on its own does not give as much information as the comparison of two centroids sizes for the analysis of shapes. Finding enough data to describe the shape of an object of interest can be difficult to achieve as these data have to be consistent in all individuals who are analyzed, so that landmark configurations can be obtained.

In our study the centroid was the average point of the coordinate data of four landmarks on each breast. Having obtained this average point the distances from each landmark to this point was calculated. The data were squared and the sum for all four landmark distances was calculated. Finally a square root transformation was conducted and the centroid size was obtained. The statistical software "R" was used by the Department of Statistics at Glasgow University for the analysis.

2.2.4.3 Effects of Factors on Breast Asymmetry

The overall asymmetry was further assessed for the subcomponents: location, orientation and scaling. The location effect was calculated by moving the

reconstructed landmarks into the same position as the unreconstructed ones so that they obtained the same centroids. During this procedure we allowed the landmarks of the reconstructed breast to move in all three dimensions to ensure that both sets of landmarks had the same centroids. This procedure involved using a translation matrix that moved the points from one location to another. The distances between the two sets of points were calculated again and the amount of improvement (decrease) in the score that was gained provided an answer as to how much the location affected the overall asymmetry score. The orientation effect described how much an object was aligned in space and therefore how much it was rotated. By application of Procrustes matching, the best rotation in order to match the sets of points was found. The distances between the sets of points were then calculated again and the improvement was understood as being the effect the orientation of the breast had on asymmetry. Finally, the effect of scaling was assessed by multiplying the landmarks on the reconstructed breast by a scale factor so that they gained the same centroid size as the landmarks on the unreconstructed breast. The improvement in the asymmetry score was understood as the scaling factor which described the size effect.

The effects that various pre-existing factors of the patients contributed to the breast asymmetry that was determined after breast reconstruction were also examined. The factors that were investigated were age, body mass index (BMI), parity, chest- wall size and bra cup size. The patients were grouped according to the factors that they displayed; for example they were grouped into two age groups of under and over 50 years of age, body mass index of under and over 25, chest-wall size of under and over 36 and bra cup size of under and over a B cup. The factor parity was divided into four groups with 0, 1, 2 and 3 or more children. A t-test statistic was used.

2.3 Part III - Subjective Breast Assessment

2.3.1 Study Design

A prospective study was conducted by 2D imaging in patients after breast reconstruction for assessment of the aesthetic appearance of the breast following a standardised grading system by expert observers.

2.3.1.1 Aim of Study

The study aimed to obtain subjective data for comparison with the objective data by 3D imaging.

2.3.2 Subjects

Forty-nine patients were examined by 2D imaging and images of 44 patients, the same group as previously examined (2.2.2.2), were included in the study. Further 2D images of six volunteers without breast surgery were added.

2.3.2.1 Panel Composition

Six expert assessors were chosen from among consultants in plastic surgery who routinely undertook breast reconstructive procedures.

2.3.2.2 Calibration of Expert Assessors

A calibration session of the expert assessors was conducted to reach a general agreement on the method of scoring of each parameter aiming to minimise the differences between the experts. Several 2D patient images were presented in standardised poses to show a poor and an excellent result, which represented the extreme ends of the scale to facilitate the scoring process. Further images featuring fair and good results and various aspects of subjective assessment were discussed. This procedure was repeated several times to agree on the variables to be considered during scoring. Scarring and colour differences between the two breasts were not considered as factors in the assessment. Two training sessions were attended.

2.3.3 Materials

2.3.3.1 2D Imaging

A single digital camera (Sony, DSC - H9) was utilised for the capture of a series of 2D images in the patients. The camera was fixed on a tripod to avoid loss of image quality. The distance and position of each subject to the camera for capture was kept constant at 1.5 metres by markings on the floor regarding camera and patient position. 2D Capture was conducted in the patients after unilateral breast reconstruction. Altogether six images of each patient's breast were obtained. The position was: 1. patient facing forward with the arms down; 2. patient facing forward with the arms up at the sides with the shoulders at a 90-degree angle; 3. patient facing 45 degrees to the left, arms down; 4. patient facing 45 degrees to the right, arms down; 5.patient facing all the way to the side, arms down and 6.patient facing all the way to the other side, arms down (Fig 2.21 a, b, c, d, e, f). This particular set-up of the posture of the patients was recognised as the standard for 2D clinical hospital photography records.



Figure 2.21 a 2D image of patient facing forward, arms down



Figure 2.21 b 2D image of patient facing forward, arms up



Figure 2.21 c 2D image of patient facing 45 degrees to the left, arms down



Figure 2.21 d 2D image of patient facing 45 degrees to the right, arms down

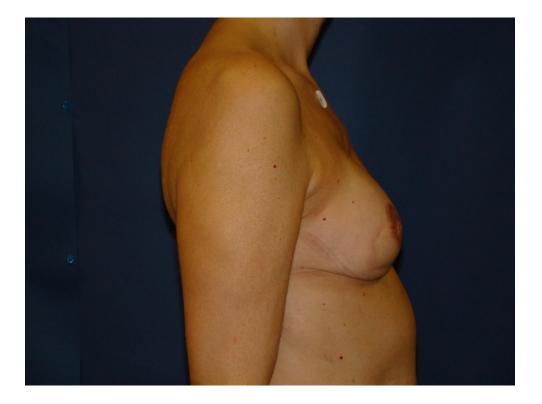


Figure 2.21 e 2D image of patient facing all the way to the left, arms down

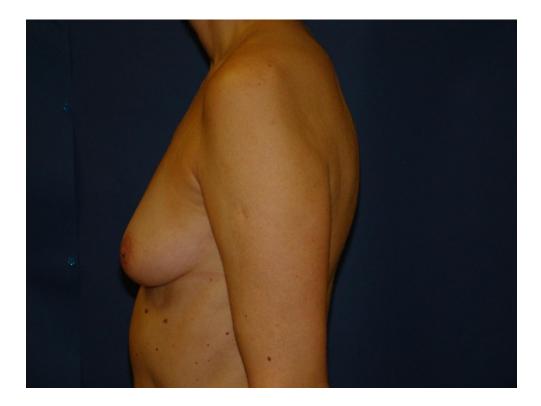


Figure 2.21 f 2D image of patient facing all the way to the right, arms down

2.3.3.2 Scoring Method

Scoring was conducted for each of the following parameters: breast volume, breast shape and symmetry. Breast volume and shape were judged for the reconstructed breast in comparison to the non-operated side as well as in isolation, while symmetry was judged for breast appearance of the reconstructed breast in relation to the opposite side. Therefore, for each case five different scores were recorded. Scoring was conducted separately and independently.

2.3.3.3 Grading Scale

For subjective breast assessment a standard and frequently cited grading scale, the Harris scale, which describes a four-point grading system, was utilised (43). The Harris scale was originally established for judgment of the breast after breast cancer treatment. It consists of the following scores and descriptions: a score of 1 for a poor result, treated breast seriously distorted; a score of 2 for a fair result, treated breast clearly different than untreated; a score of 3 for a good result, treated breast slightly different than untreated and; a score of 4 for an excellent result, treated breast nearly identical to untreated breast.

2.3.3.4 Image Storage and Archiving

Images were stored on a Sony memory stick and transferred to a personal computer. The 2D images of all patients that were included into the study were inserted in a PowerPoint (Microsoft) presentation and given on encrypted memory sticks to the expert assessors who were conducting the subjective assessment.

2.3.4 Error Study for Subjective Assessment

The Power Point presentation was created following a special protocol. Besides the images of the breasts of the 44 patients, further images of the breasts of 6 healthy live model volunteers without any surgery were randomly inserted into the presentation. In addition, repeated images of 10 patients out of the 44 cases were added and also randomly inserted. The full data set comprised of 60 cases.

2.3.4.1 Inter-Observer Agreement

The inter-rater agreement was measured with the consideration that observers sometimes agree by chance. The kappa statistic was used, as it takes this into account and therefore it is a more robust measure than simple percent agreement calculation. If the raters are in complete agreement, then K= 1. If there is no agreement among the raters and other than what would be expected by chance, then K \leq 0.

2.3.4.2 Agreement on Controls

The kappa statistic also was utilised to assess the subjective ratings on the 6 cases that served as controls without any surgery and that were inserted into the group of 44 cases of patients after breast reconstruction.

2.3.4.3 Intra-Observer Agreement

The intra-rater agreement was assessed through the use of 10 cases that were repeated from the 44 patient cases that were presented to the assessors. The kappa statistic was used to calculate how strongly the observers agreed on these repeated cases among themselves.

2.4 Part IV – Objective and Subjective Breast Assessment

For assessment of the agreement between subjective and objective scores, a linear model was fitted. This compared the average of the 6 subjective scores for each case according to the scoring method (2.3.3.2) to the calculated asymmetry score. The subjective scores were considered as the explanatory variable and the objective scores as the response variable. The subjective score was an impression of how symmetric the chest was overall. The subjective global asymmetry score was used and a comparison with the objective global asymmetry score was conducted.

In a further examination, a comparison between the subjective score for breast volume in comparison between both breasts was established with the objective asymmetry score for the scaling component.

When removing the effects of location, orientation and scaling, the objective intrinsic asymmetry score was obtained. The average subjective score for breast shape of the reconstructed breast in comparison to the unaffected side and for breast shape in isolation was compared against this objective intrinsic asymmetry score.

The average subjective score for breast shape in comparison as well as in isolation was compared against the objective volume difference.

The average subjective score for breast volume in comparison as well as in isolation was compared against the objective volume difference.

2.4.1Effect of subjective influence on objective landmark-based analysis

Three-dimensional imaging is a new objective method of the assessment of the female breast. The objective analysis is conducted by software algorithm based on the placement of landmarks. However, to date the placement and digitization of landmarks on the 3D images is done manually, by subjective judgment of the experienced operator and it will require further software development to advance this method into an automated, solely software-based process.

Therefore, in the current study the effect of the subjective influence of the operator on the objective analysis was investigated and if this effect amounted to be significant. Firstly the reproducibility of the landmark placement by the operator by repeating the digitisation four times was investigated (2.2.3.8; 2.2.4.1). Based on the results of this investigation the landmark with the greatest variation and therefore least reproducibility was chosen and purposely shifted away from its originally chosen position in the x-, y- and z-directions over all cases. The effect on the asymmetry score by comparison of the original scores to the adjusted scores was examined. A graphical display by scatter plot was chosen. A paired sample ttest was conducted to assess if the effect was significant.

Summary

To assess the validation of the 3D imaging system, a pilot study was conducted with nine plaster and six live models and breast volumes, which were measured by the 3D imaging method. For comparison, the water displacement method as a gold standard for volume assessment was chosen. Accuracy in the plaster models as well as reproducibility in the live models was investigated and errors were calculated. To assess breast asymmetry in patients, a uniform patient group after unilateral breast reconstruction by Latissimus dorsi flap was examined. A comparative analysis between the reconstructed and unreconstructed breast in each patient was conducted. Breast volume, shape and symmetry were objectively investigated. Breast volume was calculated with BAT software. To conduct shape and symmetry analysis 10 landmarks were digitised on the 3D images and their 3D coordinates were used for measurements. Procrustes analysis was utilised as a landmark based method for shape analysis. For this purpose, the centroid of the configuration, which was understood as the average point for a set of landmarks, was calculated. For comparison, a subjective assessment of breast volume, shape and symmetry in the same patients was conducted. The Harris score was chosen for the subjective judgment by expert observers on 2D images of these patients. Possible errors of the patient study were examined.

3 Results

Introduction

The chapter describes the findings of the validation of the prototype 3D imaging system that was used in the pilot study. The results of the accuracy and reproducibility assessment as well as of the error study are presented. The results of the validation study were sufficient to allow the utilisation of the system for a clinical study on patients after unilateral breast reconstruction to conduct a comparative assessment with the non-operated side. Patients were successfully captured and 3D breast images constructed. The variation of the repeated digitisation of 10 landmarks on the 3D images was presented. The centroid, the average point, of the landmark configuration of each 3D image was calculated. The results of the breast assessment through centroid size, volume and landmarks are illustrated. Based on the landmarks, a breast asymmetry score was calculated. The individual components that contributed to this score were presented which were the intrinsic asymmetry as well as factors down to location, orientation and scaling. The asymmetry score obtained objectively was compared with the subjective breast assessment by subjective scoring.

3.1 Part I – Pilot Study - Validation

3.1.1 Systematic Differences

The systematic differences for plaster and live models that were measured by two different methods, 3D imaging and water displacement, were assessed and results compared. The agreement between the methods was established.

3.1.1.1 Plaster Models

The volume of nine plaster models was examined by 3D stereophotogrammetry and water displacement. The overall mean of the plaster volume measurements was 477.18 cc for 3D stereophotogrammetry and 466.06 cc for water displacement, resulting in an overall mean difference of 11.12 cc (Table 1).

Plaster Model (number)	1	2	3	4	5	6	7	8	9
Water displacement (cc)	364.60 ± 3.89	434.70 ± 2.41	579.00 ± 2.36	231.10 ± 3.96	433.40 ± 2.07	591.60 ± 1.96	596.60 ± 5.13	100.40 ± 2.01	863.1 ± 6.62
Three dimensional Imag. (c	354.40 ± 6.77	422.30 ± 2.41	613.40 ± 7.96	209.50 ± 0.85	465.1 ± 1.2	610.50 ± 4.14	620.70 ±9.52	96.10 ± 0.74	902.6 ± 6.5
Total volume difference (cc)	10.2	12.4	34.4	21.6	31.7	18.9	24.1	4.3	39.5
Mean (waterdispl. + 3D) (c	359.5	428.5	596	220	449	601.5	609	98	883
% diff. (total diff / mean)	0.031	0.03	0.057	0.1	0.071	0.032	0.039	0.041	0.045

Table 1 Volume measurements in nine plaster models by water displacementand 3D imaging

For assessment of the systematic differences, the mean volumes of each plaster cast were used and graphically displayed (Fig 3.1).

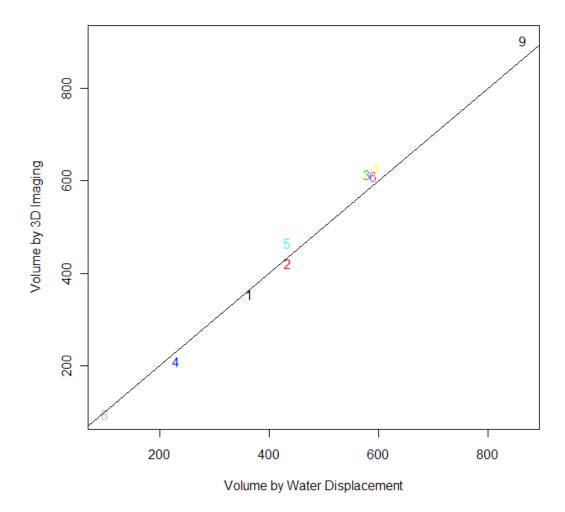


Figure 3.1 Volume measurements of plaster models by water displacement and 3D imaging with line of equality

Nearly all data points lay close to the line of equality, suggesting that the two methods gave quite similar results. An additional mathematical calculation (13) was conducted in the two plaster models in the shape of a hemisphere and confirmed the results at 98 cc for plaster model 8 and at 884 cc for plaster model 9.

Further, it appeared that in the smaller plaster casts the volumes obtained by water displacement method were greater than by 3D imaging and in the larger plaster casts the opposite seemed to be the case. This observation was formally tested by fitting a regression model and evaluating whether the slope of the line of the best fit (i.e. the coefficient for water displacement) was found to be greater than 1. A value of 1 indicates that the model perfectly fits the data. A value outside 1 can occur when the agreement between two values is obtained. A value of slightly greater than 1 in our study was confirmed to be the case, as the 95% confidence interval for this coefficient was found to be (1.02, 1.14).

In all cases, the discrepancy between the volume that was measured by water displacement and by 3D imaging did not exceed a total of 40 cc. The relative differences that were calculated in each case as the difference divided by it's particular mean, varied between 3% and 10%. The average relative difference was 5%. The average volumes determined by water displacement and 3D imaging were compared with a paired-sample t-test. This revealed that the difference between both methods was not statistically significant at p= 0.189; the 95% CI for the difference was (-6.732, 28.976). The mean standard deviation of the volume measurements was 3.38 for water displacement and 4.45 for 3D imaging.

The agreement between both methods was assessed by the Bland Altman method (8). It was found that all data points were positioned between the limits of agreement, which were calculated as the mean difference $\pm 2x$ the standard deviation of the differences (d $\pm 2s$) (Fig 3.2). This suggested that it was valid to replace the water displacement method by 3D imaging following the study on the specially-shaped plaster models, provided that differences within 46 cc would be clinically acceptable.

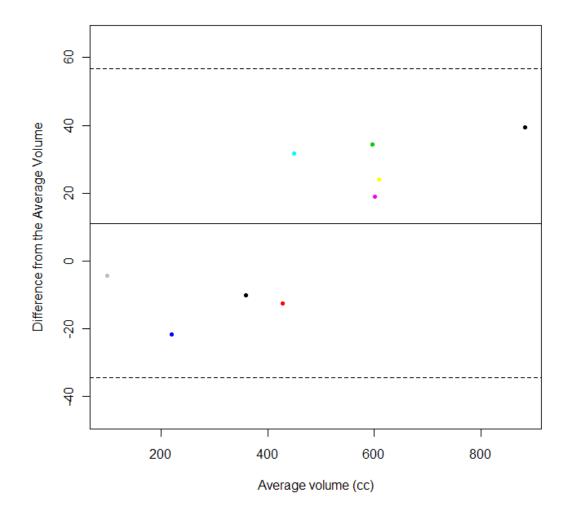


Figure 3.2 Bland Altman graph with limits of agreement for both measurement methods in plaster models

3.1.1.2 Live Models

The breast volume of six volunteers was examined by 3D stereophotogrammetry and water displacement. When comparing both methods of measurements in the live models, the overall mean breast volume was 687.19 cc for water displacement and 480.14 cc for 3D stereophotogrammetry, resulting in a mean difference of 207.05cc (Table 2).

Live Model (number)	1	2	3	4	5	6
Water displacement (cc)	1083.08 ± 34.60	1128.42 ± 32.37	390.33 ± 21.52	295.00 ± 12.81	220.42 ± 24.02	1005.92 ± 141.64
Three dimensional imaging (cc)	618.93 ± 62.61	854.23 ± 42.09	206.57 ± 12.10	176.28 ± 22.64	89.17 ± 28.08	935.68± 25.23
Total volume differences (cc)	464.15	274.18	183.77	118.72	131.25	70.23
Mean (water displ. + 3D) (cc)	851	991	298.5	235.5	154.5	971
% diff. (total diff/ mean)	0.55	0.28	0.62	0.5	0.85	0.07

Table 2 Breast volume measurements in six live models by water displacement and 3D imaging

The discrepancy between both methods exceeded 400cc, with relative differences ranging between 7% and 85% with an average relative difference of 47.7%. When assessing the systematic differences of the breast volumes in the live models, the data points did not lie close to the line of equality (Fig 3.3). In all cases the measurements for water displacement were larger than those for 3D images. Again, the differences between the two methods were formally tested. The paired-sample t-test revealed that the differences were statistically significant at p=0.017, while the 95% CI for the difference was (56.12, 357.98).

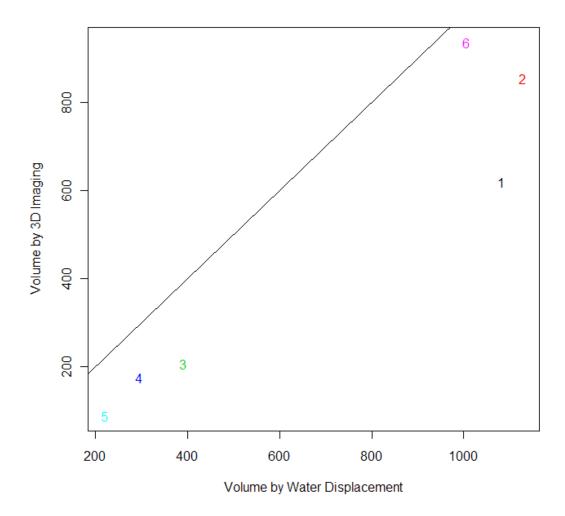


Figure 3.3 Volume measurements of live models by water displacement and 3D imaging with line of equality

Using the Bland Altman method to assess the agreement, the differences were again all within the limits of agreement (Fig 3.4). However, this time the bands were far wider and the margin of error was 281.88, which would be far less clinically acceptable.

Based on the finding that there was a significant difference between the measurements that were obtained by each method, there arose the possibility that

this difference was a constant one, i.e. that water displacement produced a volume that was X cc higher than 3D imaging due to some systematic difference. By fitting a regression model, a strong relationship between the two variables was found. The 95% confidence interval for the coefficient of 3D imaging was (0.93, 1.23). As this confidence interval contained one, it was a plausible suggestion that the discrepancies between the two methods were constant. The coefficient for the intercept showed what this constant difference was likely to be and it's 95% CI was (82.01, 254.88).

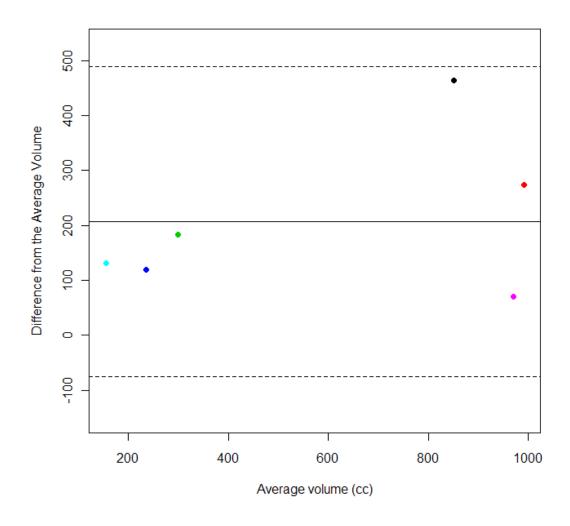


Figure 3.4 Bland Altman graph with limits of agreement for both measurement methods in live models

3.1.2 Reproducibility of 3D Measurements

Overall, the volume measurements were found to be more reproducible by 3D stereophotogrammetry than by water displacement, with standard deviations of 36 units/ cc and 62.6 units/ cc respectively. This finding was largely due to live model 6 however, as she had a greatly increased standard deviation for water displacement. In direct comparison, we found that four out of the six live models had lower standard deviations by water displacement method and therefore more reproducible results than by stereophotogrammetry; however, overall the opposite was true. The lack of reproducibility highlights the technical difficulties of the water displacement method.

3.1.3 Investigation of Errors

3.1.3.1 Posing-, Capture- and Measuring-Up Error

The posing error of breast capture of six volunteer live models, between two sets of three captures each was investigated and found not to be significant at 95% CI (-77.3;11.9), p-value of 0.119; mean standard deviation over six live models for pose 1 was 7.6%, for pose 2 it was 4.9% and for both together it was 6.25%.

The capture error derived from six repeated captures in six live models revealed a mean standard deviation over all six models of 11.5%.

The measuring-up error after 18 measurements with BAT software in six live models revealed a mean standard deviation over all six models of 12.8%.

3.1.3.2 Variability

A global approach was taken to investigate further the errors of the measurements. For this purpose the reproducibility of the 3D imaging measurements was assessed by decomposing the variation into components attributable to different effects. A linear mixed effects model was used. The results as obtained for each model, pose, capture and individual measurements with BAT software revealed that by far the largest component of variability was due to the differences in the model (st.dev. of 369.73). The next largest contribution to the variation was the one due to pose, even though this was only a small fraction of the contribution of the model (st.dev. of 32.95). This was closely followed by differences between individual BAT measurements (st.dev. of 28.32) and several captures (st.dev. of 19.43), both of which gave respectively smaller contributions to the variation. The interval estimates for the variability of each of the components was graphically displayed firstly with the model component and secondly without it (Fig 3.5 a, b).

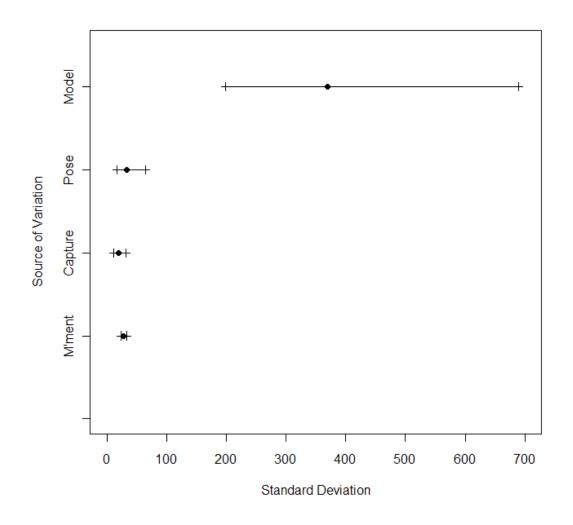


Figure 3.5 a Four components contributing to variability of measurements:

live model per se, pose, capture and BAT measurements

A mathematical representation of this linear mixed effects model would be:

Volume = overall mean + model + pose + BAT replicate + capture

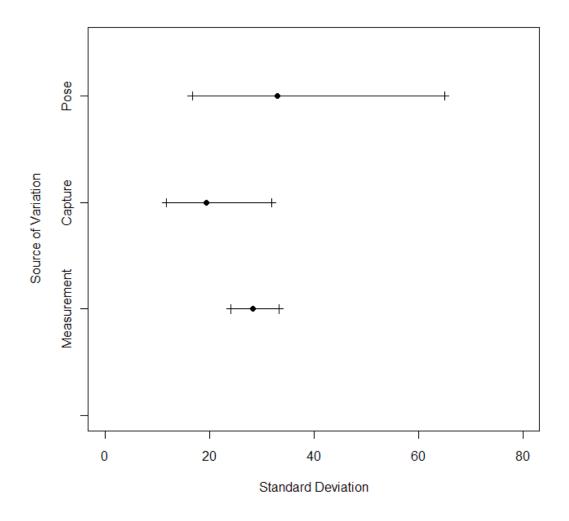


Figure 3.5 b Components contributing to variability of measurements without live model

The overall mean from the data was 480.14 cc and the standard deviations for the model, pose, BAT replicate and capture were 369.73, 32.95, 28.32 and 19.43 respectively. Through the application of this model a useful way was found to examine the errors, as the model treats all of the variables (pose, capture etc) as random effects.

3.1.3.3 Correlation of Size and Variability

The investigation of a possible correlation between breast size and the reproducibility of the measurements using regression analysis provided the following results:

3.1.3.3.1 Plaster Models

Water displacement: 95% CI for correlation coefficient = (-0.24, 0.87). p=0.168. Not significant.

BAT: 95% CI for correlation coefficient = (0.08, 0.93). p = 0.033. Significant.

Combined water displacement and BAT: 95% CI for correlation coefficient = (0.21, 0.84). p = 0.007. Significant.

3.1.3.3.2 Live Models

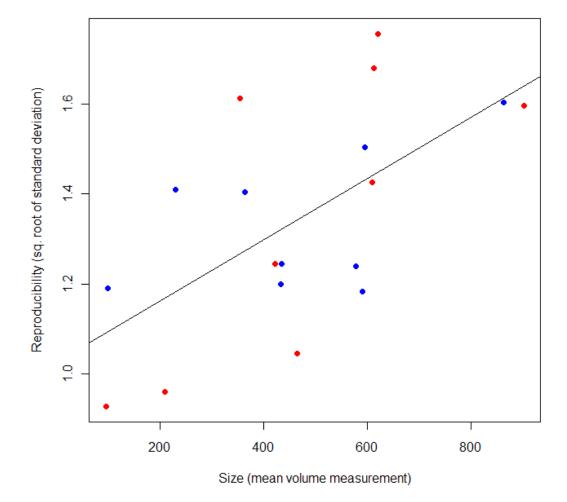
Water displacement: 95% CI for correlation coefficient = (-0.46, 0.94). p = 0.244. Not significant.

BAT: 95% for correlation coefficient = (-0.55, 0.93). p = 0.342. Not significant.

Combined water displacement with BAT: 0.95% CI for correlation coefficient =

(-0.06, 0.85). p = 0.074. Not significant.

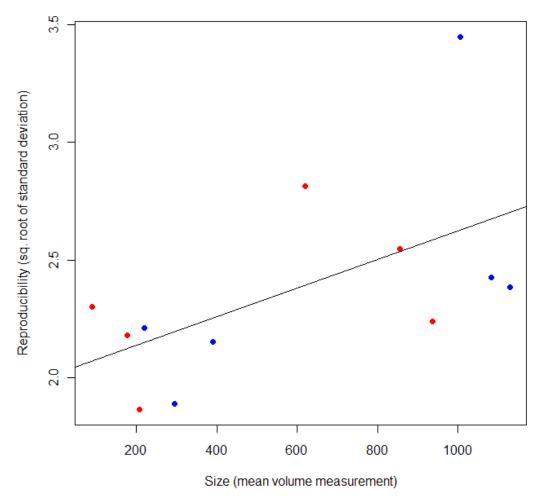
These findings revealed that there was no strong correlation between the size of the breast and the variability of the measured volume (measurement error) within the live models. Due to the sample size consisting of only six cases, some uncertainty remained concerning the detection of a relationship. When combining the results of both methods, the significance of the relationship increased in both the plaster and live models, to a significant level in the plaster models. The combined plots are graphically displayed for plaster and live models (Fig 3.6, Fig 3.7). The lines of the best fit through the data are also shown. Their upward slope suggests that the larger the breast, the more variable the results (i.e. the poorer the reproducibility). However, the p-value for the live models revealed that the relationship was not strong enough to be significant.



Correlation between size and reproducibility (Plaster Models)

Figure 3.6 Correlation between size (mean volume measurements) and

reproducibility (sq root of standard deviation) in plaster models



Correlation between size and reproducibility (Live Models)

Figure 3.7 Correlation between size (mean volume measurements) and reproducibility (sq. root of standard deviation) in live models

3.2 Part II - Patient Capture

The extent of breast asymmetry in patients after mastectomy and breast reconstruction was investigated. Forty-four patients were included in the study. They were aged between 37 and 67. The date of surgery was between 2003 and 2008.

3.2.1 Assessment of Breast Asymmetry

All patients had undergone immediate, unilateral breast reconstruction with a Latissimus dorsi flap. Breast capture and 3D image build-up was conducted with the multiple stereo camera system as previously described. Breast asymmetry assessment was based on data derived from landmark data or overall surface measurements.

3.2.2 Reproducibility of Landmarks

On all 3D breast images, ten landmarks were digitised four times and the averages of these data-sets was used for the analysis. The first two landmarks indicated the midline and the other four were recorded on each breast. Each landmark was documented with three coordinates. It was found that the mean reproducibility of the landmarks was within 5mm, ranging from 0.61mm to 4.85mm (Table 3, reproducibility of landmarks).

The average distance was obtained from the mean distance of each of the four repeated points for each landmark to their centroid. Average results for all 44 cases were calculated.

Landmark	Average Distance (mm)	Standard Deviation		
ssn	0.610	0.704		
xipho	0.794	0.869		
Lprom	1.753	2.234		
Rprom	1.984	2.782		
Lmedial	2.393	2.761		
Rmedial	2.488	2.980		
Linfer	3.249	4.385		
Llateral	4.352	4.908		
Rlateral	4.865	5.619		
Rinfer	4.850	7.450		

Table 3 Reproducibility of landmarks

3.2.3 Assessment of Breast Reconstruction through Centroid Size

The unreconstructed breast versus the reconstructed side was assessed and the centroid size for both was calculated. The centroid size was obtained as the square root of the sum of squared Euclidian distances from each landmark to the centroid. It was found that the average centroid size of the reconstructed breast was 0.113 (metres) and of the unreconstructed breast was 0.115 (metres). Therefore, the size of the reconstructed breast was slightly smaller than the one on the unreconstructed side, but not significantly (Fig 3.8). The graphic display shows the line indicating equality of the two breast sizes as a reference.

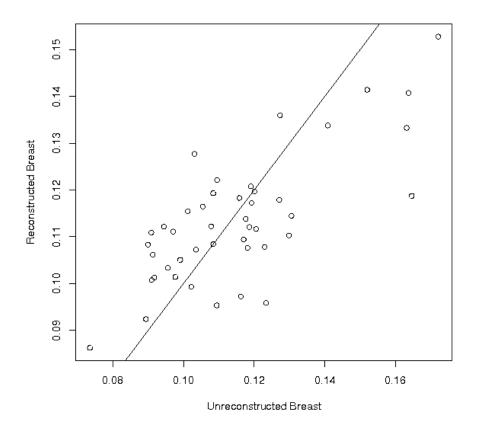


Figure 3.8 Assessment of breast asymmetry through centroid size

The size differences were more pronounced between the reconstructed and unreconstructed breast in the larger breasts. This means that the larger the unreconstructed side, the less satisfactory the match that was achieved by Latissimus dorsi flap transposition for breast reconstruction.

3.2.4 Assessment of Breast Reconstruction through Volume

For the breast volume calculation, breast analysis tool (BAT) software by Glasgow University was utilised. Breast volume was obtained by determination of breast surface and calculation of a dorsal chest-wall by software algorithm. Each volume of the reconstructed side, as well as the unreconstructed breast for each patient was calculated four times and average results were used. It was found that overall the within-person standard deviation was 21 units/cc of breast volume. For comparison of the reconstructed with the unreconstructed side a graphic display was used (Fig 3.9). The unreconstructed breast tended to show considerably higher breast volumes in most cases than the reconstructed breast and again differences in the larger breasts were more pronounced. This impression from the graphic display was confirmed by the statistical test. A paired sample t-test was utilised and found differences between both sides of the breast highly significant at p< 0.0001, a mean difference of 179.8cc (95% CI = 103.5, 250.0). Breast volume measurement was a far more detailed procedure than the centroid size measurement as it was calculated by thousands of surface points as opposed to only 4 data points for the centroid size calculation. Therefore, the findings of the volume measurements based on a surface mesh of 3D data were more accurate than using individual landmarks and their centroids. Overall it was found that there was a significant size difference between the reconstructed and unreconstructed breasts.

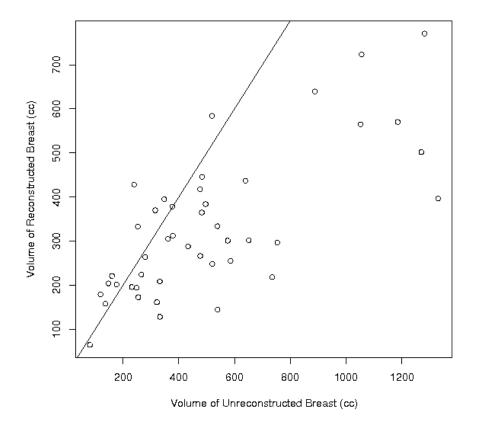


Figure 3.9 Assessment of breast asymmetry through volume

3.2.5 Assessment of Breast Reconstruction through Landmarks

Four landmarks were identified on each breast and an additional two landmarks determined at the midline of the image as previously indicated, so that overall, ten landmarks were measured for each patient. Therefore, four landmarks had natural pairings due to their corresponding positions on the reconstructed and unreconstructed breast (R/L medial, R/L lateral, R/L prom, R/L infer), whilst others were positioned on the midline (ssn, xipho).

Asymmetry was quantified, based on landmark data, as the degree to which a mismatch was identified between a landmark configuration and its relabelled and matched reflection. In ideal conditions of perfect symmetry, the two landmarks at the top and bottom of the midline (ssn, xipho) would serve as a reflection line over which the landmark configuration of the one breast could be exactly superimposed onto that of the other breast. When reflected, the paired points were matched with each other whilst the midline points were matched to themselves.

A perfectly symmetric breast could be matched exactly with its mirror image. Every mismatch contributed to the individual asymmetry score of the person and the degree of mismatch quantified how far the object was from being symmetrical. All landmarks were stored in a (k x m) matrix X, in which k equalled 10 landmarks multiplied with m, which equalled 3 dimensions. Hence, X was the representation of k landmarks in n dimensions. This analysis allowed the shape of the configuration to be assessed in terms of the size or location. Therefore, a mathematical calculation was carried out to increase the simplicity of the reflection and matching process. This involved all columns of the matrix X being centred on O, which was considered as the origin or the centroid. X was further scaled to a size of 1 in involvement of the formula where $||X|| = \sqrt{tr}(X^T X)$.

In order to obtain a reflection of the configuration in the x-plane, X_{R} , the sign of the x-coordinates, was reversed. This reflection was centred on O and matched to the original configuration through a mathematical process named ordinary partial Procrustes algorithm (90; 114). This algorithm identified the rotation matrix Γ that

minimised the distances between two sets of points. The degree of mismatch could then be quantified as the asymmetry score, calculated as:

 $\mathsf{A} = \left|\left|\mathsf{X} - \mathsf{X}_{\mathsf{R}} \mathsf{\Gamma}\right|\right|^2 / k$

The asymmetry score arose from the sums of squares. A square-root transformation was used to reduce skewed appearance. The results in our group of 44 patients were displayed graphically in a histogram (Fig 3.10). For graphic purposes, a square root scale (metre) was chosen on the x-axis because of the square root transformation. The total patient number (no) was displayed on the y-axis. The average asymmetry score was found to be 0.052. The scores ranged from 0.019 to 0.136.

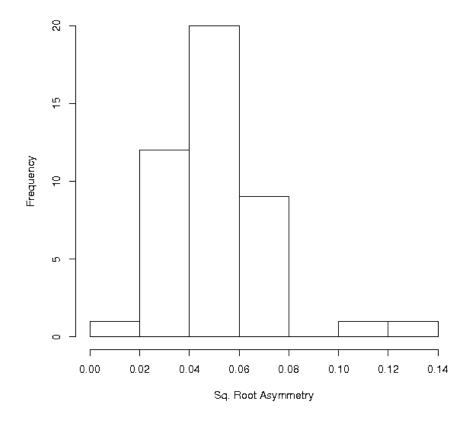
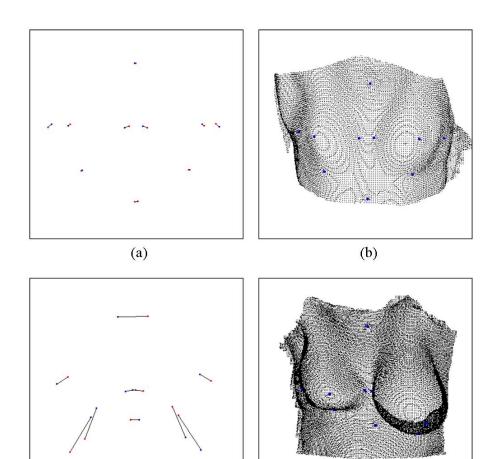


Figure 3.10 Distribution of asymmetry scores in patients

It became apparent that there were two cases with markedly higher asymmetry than the others and these displayed higher square root asymmetry in the histogram of scores. Examples of images and configurations for the cases with the lowest and highest asymmetry scores respectively were displayed (Fig 3.11).



(c)

(d)



3.2.6 Decomposition of Landmark Asymmetry

Further to the previously calculated asymmetry score, which provided an overall judgment of the individual cases, the question was investigated if this score could be decomposed into single factors and what their contribution to this asymmetry score might be. To assess this it was imagined that the part of the surface, that was equivalent to the unreconstructed breast was held fixed, before the reconstructed breast was translated, rotated and scaled to achieve a best match. This procedure would influence the alteration of the overall asymmetry score.

A decomposition of this overall asymmetry score into its single parts was conducted to location, orientation and size of the reconstructed breast. In order to decompose the score, the reconstructed breast was reflected in the plane that was created by ssn, xipho and the centroid of the breast. This resulted in an inversion of the landmarks, which then were rotated around the axis of the midline, between ssn and xipho, until the distance between them and their correspondent landmarks on the unreconstructed breast was minimised. Any asymmetry remaining after these transformations was due to a difference in the actual shape of the breasts, named the "intrinsic asymmetry". A rotation matrix R was required for hinging a point or set of points around a given axis.

The overall asymmetry score between the two configurations of the reconstructed and unreconstructed breasts, when looking solely at the four landmarks on each breast was then recalculated as:

 $A = ||Xu - \tilde{X}_r R||^2$

Xu denoted the landmarks of the unreconstructed breast and \tilde{X}_r the reflected landmarks of the reconstructed breast. This was taken as the global asymmetry score of the breasts.

It was examined how the location of the reconstructed breast affected the asymmetry. This investigation was conducted by application of a translation matrix by which the landmarks of the reconstructed breast were moved in such a way that their centroids were in the same position as those of the unreconstructed breast. The asymmetry score A was then recalculated. The difference was determined between this newly calculated asymmetry score and the global asymmetry score, which provided the degree of asymmetry which was due to the location.

The same examination was repeated for rotation as well as for scaling of the breast by application of the ordinary Procrustes algorithm to find the optimal parameters. Then the effect of both rotation and scaling on the distance between the two configurations was assessed. The remaining asymmetry was considered to be due to a genuine difference in the actual shape of the two breasts, rather than their size, location and orientation.

The remaining shape difference could be considered as the intrinsic asymmetry and was found to be the most influential of the components (Fig 3.12). This intrinsic asymmetry accounted for 35.6% of the overall or global asymmetry. The factor accounting for the second highest degree of asymmetry was location, at 34.6% of the global asymmetry, followed by orientation at 18.8% and scaling at 11.3%, the least influence.

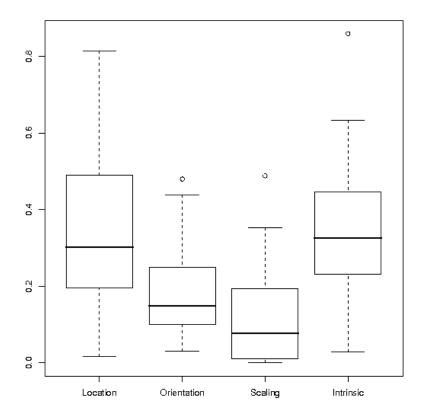


Figure 3.12 Proportions of breast asymmetry accounted for by individual components of asymmetry

The proportion of asymmetry that was accounted for by the individual components of asymmetry for each individual case can be graphically displayed in a repeated measures plot (Fig 3.13) This plot gives a sense of the importance of the different components. As is visible from the plot, there was a variation in pattern among the cases. Cases that were different from the majority are also displayed, one case in particular standing out as having had a very considerable influence from scaling.

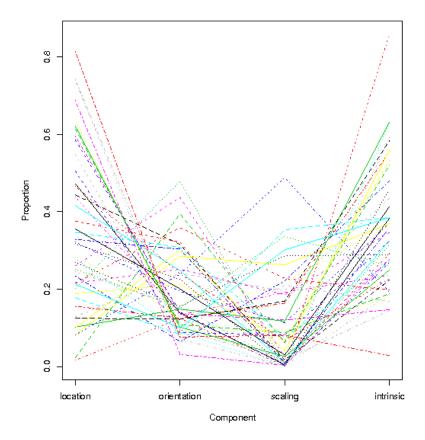


Figure 3.13 Repeated measures plot demonstrating the individual components contributing to asymmetry in each case

3.2.7 Influence of Scaling on Different Landmarks

It was considered that the aforementioned findings could be partly attributed to the nature of the landmarks that were investigated and their influence on the results. The nature of the landmarks was different for the lateral and medial landmarks which were positioned on the chest-wall from the most prominent and inferior landmarks that were positioned on the soft tissue. Therefore, a change in the scale of the breast would not move the lateral and medial landmarks, which were positioned at the edge of the breast on the chest-wall as much as the prominent and inferior landmarks, which would move concomitantly with an increase in the size of the breast. In consequence, scaling of the whole configuration would improve the matching between the inferior and prominent points, but worsen it with the other landmarks. As a result, the size difference between the two breasts would not be as strongly represented as it should be.

3.2.8 Decomposition of Landmark Asymmetry: Separate Scaling

To investigate this problem with scaling further, the previous process was varied in the sense that the configuration was scaled again, but the most prominent and inferior landmarks were scaled separately from the medial and lateral ones. This involved that the medial-lateral line and the remaining two landmarks being scaled individually up to the point where the distances between them and their corresponding landmarks on the unreconstructed breast were minimised. This resulted in a considerable increase of the significance of the scaling factor to 23.1% as a factor contributing to the asymmetry score. The new proportions of asymmetry accounted for by the individual components of asymmetry were again graphically displayed (Fig 3.14). It was obvious that location was now the factor with the most significance at 34.6%, followed by intrinsic asymmetry at 23.4%. This was closely followed by scaling at 23.1% and lastly, at 18.8% orientation was seen to be the least important factor for the overall asymmetry score. It appeared

that this second way of decomposing the asymmetry score was preferable, as it took into account the different characteristics of the landmarks on each breast.

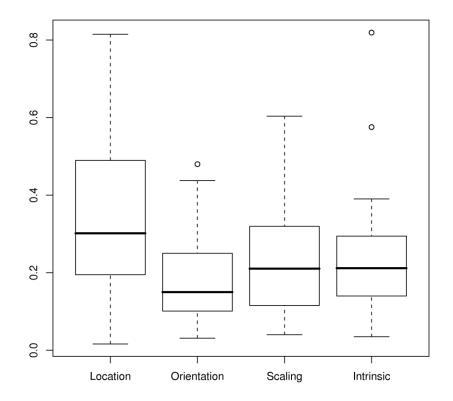


Figure 3.14 Decomposition of landmark asymmetry with separate scaling

3.2.9 Correlation of Unreconstructed Breast Size and Asymmetry Score

There was a significant correlation between the centroid based size of the unreconstructed breast and the asymmetry score, with a p-value of 0.024 (Fig 3.15). This was a positive correlation, an increase in size leading to an increase in asymmetry score with a correlation coefficient of 0.34. This meant that $0.34^2 = 11.56\%$ of the variability in the scores was due to the relationship with the sizes.

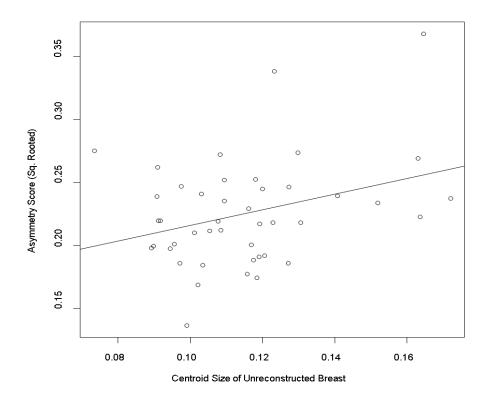


Figure 3.15 Correlation of unreconstructed breast size and asymmetry score

through centroid size

Measuring the volume of the unreconstructed breast using surface data, there was a more significant relationship (p < 0.0001) with a correlation coefficient of 0.556 (again positive) (Fig 3.16).

There were only a limited number of measurements contributing to the centroid based volume, but there was a far larger amount of data that making up the volume measurement due to surface. The latter could therefore be interpreted as that which more closely resembled the true situation of the asymmetry score.

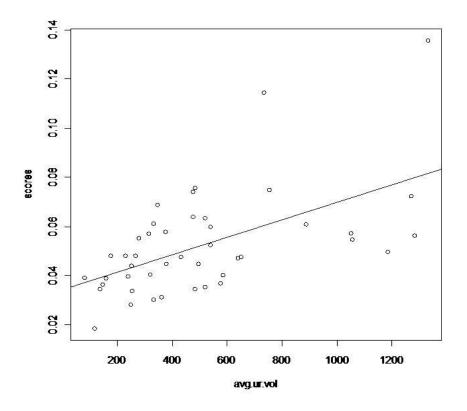


Figure 3.16 Correlation of unreconstructed breast size and asymmetry score through volume

3.2.10 Effects of Factors on Breast Asymmetry

Based on information that was collected from the patients' case notes, the effects of factors on breast asymmetry were investigated. The factors involved were age, body mass index (BMI), parity, chest-wall size and bra cup size (Table 4). It was found that the asymmetry scores for patients in the two age groups (50 years old and over and under 50) were not significantly different; neither was there any significant difference for parity or chest-wall size.

However, there was a significant difference in the factor of BMI, with a p-value of 0.04. BMI was investigated and it was revealed that in the group with a BMI under 25 the mean asymmetry score was 43.64 and in those whose BMI was over 25 it was 61.99. This demonstrated that the slimmer patients had a lower asymmetry score than the larger ones.

The factor of bra cup size was calculated at only slightly above the cut-off point for the significance of 0.05 at a p= 0.062. Nevertheless, this meant that this factor was found not to be significant according to the statistical analysis of our study.

		Number	Mean Score	p-value
Age)			
	≤50	12	48.04	0.294
	>50	32	54.03	.0294
BMI				
	≤25	23	43.64	0.004
	>25	21	61.99	0.004
Pari	ity			
	0	9	44.34	0.098
	1	10	56.22	0.646
	2	15	50.81	0.680
	≥3	10	58.22	0.365
Che	est wall size			
	≤36	33	49.61	0.157
	>36	11	60.78	0.157
Cup	size			
	A-B	14	44.74	0.062
	>B	30	55.97	0.062

Table 4 Factors contributing to breast asymmetry

3.3 Part III – Subjective Breast Assessment

3.3.1 Assessment of Breast Asymmetry by Subjective Score

For comparison to the quantitative analysis, as presented previously, as well as for clinical relevance a subjective evaluation of symmetry as a qualitative measure was carried out. Based on 2D breast images in six different poses of 44 patients, subjective breast assessments were conducted by six expert observers. The images were scored on a scale of 1 to 4, with 1 indicating poor symmetry and 4 indicating excellent symmetric results. The average of the six evaluations was used as the subjective score. We decided that values greater than 3 represented no/very mild asymmetry, values between 2 and 3 represented mild to moderate asymmetry and values of less than 2 represented marked asymmetry. We found that 32.7% of patients demonstrated no to mild asymmetry, 63.3% of patients mild to moderate marked asymmetry.

3.3.2 Inter-Observer Agreement

For measurement of the agreement between observers the kappa statistic was used. A kappa of 1 indicated perfect agreement, whereas a kappa of 0 indicated agreement equivalent to chance. The kappa value calculated for our scores was 0.646, 95% CI: (0.599, 0.694), which corresponded to a good or substantial agreement beyond chance between raters. The p-value was found to be <0.0001, highly significant.

3.3.3 Agreement on Controls

The kappa statistic was also used for assessment of the subjective ratings of the 6 cases serving as controls without any surgery. The magnitude of the statistic was found to be smaller than that of the inter-observer agreement, at a kappa value of 0.505. This revealed that there was only moderate agreement between observers on the cases serving as controls, but this finding could be due to the smaller sample size of 6 control cases instead of the 50 cases used in the assessment of the inter-observer agreement. The kappa statistic that tested the hypothetical probability of chance agreement found in our study that results were highly significant at p < 0.0001.

3.3.4 Intra-Observer Agreement

The results of the intra-observer agreement revealed a fair to substantial agreement of the raters among themselves; however not all the results were found to be significant at p= 0.05 or less. A possible explanation for this finding might be that the small sample size included only 2 sets of 10 ratings (Table 5). The hypothesis to be tested was that there was no difference between the repeated scores for the same observer.

Rater	Карра	Level of agreement	p-value
1	0.355	Fair	0.134
2	0.545	Moderate	0.011
3	0.322	Fair	0.099
4	0.531	Moderate	0.013
5	0.286	Fair	0.159
6	0.643	Substantial	0.005

Table 5 Intra-observer agreement

3.3.5 Raw data of six expert assessors

The raw data of the overall subjective symmetry assessment (2.3) of the six assessors (A-F) were displayed (see below) and the mean and standard deviation calculated. The data file contained altogether sixty cases of 2D images of the breast in the standardized six body postures. The cases-file was derived from 44 patients, six controls without breast surgery and 10 repeated patient-cases (2.3.4). The Harris scale (poor= 1 up to excellent= 4) was used (2.3.3.3; 3.4; Table 7).

	Assess-	Assess-	Assess-	Assess-	Assess-	Assess-	Mean -	St.dev -
Cases	А	В	С	D	E	F	G	Н
1	2	3	3	3	3	4	3	0,63246
2	1	2	2	2	2	2	1,83333	0,40825
3	4	4	4	3	3	4	3,66667	0,5164
4	3	4	3	3	4	3	3,33333	0,5164
5	2	2	2	2	2	2	2	0
6	4	4	4	4	3	4	3,83333	0,40825
7	4	4	4	4	3	4	3,83333	0,40825
8	4	3	3	4	3	4	3,5	0,54772
9	4	4	4	3	3	4	3,66667	0,5164
10	1	2	2	2	1	2	1,66667	0,5164
11	3	4	4	3	3	4	3,5	0,54772
12	4	4	4	4	4	4	4	0
13	2	2	3	2	2	2	2,16667	0,40825
14	1	2	2	2	2	2	1,83333	0,40825
15	4	4	4	4	3	4	3,83333	0,40825
16	4	4	4	3	3	4	3,66667	0,5164
17	3	3	3	3	2	3	2,83333	0,40825
18	3	2	3	3	2	3	2,66667	0,5164
19	4	4	4	4	4	4	4	0
20	3	3	3	3	3	3	3	0
21	3	3	4	3	2	3	3	0,63246
22	3	2	3	3	2	3	2,66667	0,5164
23	3	2	3	2	2	4	2,66667	0,8165
24	1	2	2	2	1	2	1,66667	0,5164
25	4	3	4	3	4	3	3,5	0,54772
26	3	3	3	3	3	4	3,16667	0,40825
27	2	3	3	3	2	3	2,66667	0,5164
28	4	4	3	3	3	4	3,5	0,54772
29	3	3	3	4	2	3	3	0,63246
30	4	3	3	2	3	3	3	0,63246
31	1	2	2	2	1	2	1,66667	0,5164

32	2	3	2	2	1	3	2,16667	0,75277
33	3	4	3	3	3	4	3,33333	0,5164
34	1	2	2	1	1	2	1,5	0,54772
35	3	3	3	3	2	4	3	0,63246
36	3	4	3	3	3	4	3,33333	0,5164
37	3	2	3	3	2	3	2,66667	0,5164
38	4	4	4	4	4	4	4	0
39	1	1	2	1	1	1	1,16667	0,40825
40	4	3	4	4	3	4	3,66667	0,5164
41	4	3	3	3	3	4	3,33333	0,5164
42	3	3	3	3	2	3	2,83333	0,40825
43	3	4	3	3	2	4	3,16667	0,75277
44	2	2	3	2	2	3	2,33333	0,5164
45	3	3	3	3	3	4	3,16667	0,40825
46	4	4	4	4	4	4	4	0
47	3	3	3	3	3	4	3,16667	0,40825
48	2	3	3	3	2	4	2,83333	0,75277
49	4	4	4	3	4	4	3,83333	-
50	4	3	4	4	4	4	3,83333	-
51	1	2	2	2	2	2	1,83333	0,40825
52	4	4	3	3	3	4	3,5	0,54772
53	4	2	2	2	2	3	2,5	0,83666
54	3	3	3	3	3	4	3,16667	0,40825
55	3	3	3	3	2	4	3	0,63246
56	4	4	3	3	4	4	3,66667	0,5164
57	3	3	3	3	2	3	2,83333	0,40825
58	4	4	3	3	3	4	3,5	-
59	3	3	3	3	2	4	3	0,63246
60	4	4	4	3	4	4	3,83333	0,40825
61 -								
mean	3	3,06667	3,1	2,9	2,6	3,38333	3,00833	0,47167
62-								
st.dev.	1,02511	0,82064	0,68147	0,72952	0,88681	0,80447	0,72773	0,19098

Table 6 Raw data by six experts (A-F) scoring altogether 60 cases of 2D images by usage of the Harris scale (1-4); mean and standard deviation, displayed horizontally in row G and H, vertically at position 61 and 62

3.3.6 Null Hypothesis

The null hypothesis that there was no difference in volume between the reconstructed breast and the opposite side was rejected.

The average volume of the reconstructed breast was 330.68cc and of the unoperated side was 507.44cc. The reconstructed breast showed a significantly smaller volume when compared to the opposite side at p<0.0001, a mean difference of 176.8cc and 95%CI (103.5; 250.0).

3.4 Part IV – Objective and Subjective Breast Assessment

The results of the subjective score (1-4), according to the Harris scale (Table 7) were graphically displayed on the x-axis versus the quantitative asymmetry score on the y-axis (metres) (Fig 3.17). The plot showed the line indicating the linear relationship between both sets of data, which was a negative relationship in the sense that an increase in the asymmetry score led to a decrease in the subjective score, equalling poorer symmetry. The result of a regression model that was fitted to the data revealed that the relationship between the quantitative and qualitative scores was highly significant (p< 0.0001), correlation = -0.62, 95% CI (-0.77,-0.40). The R-squared value was 0.3697, which signified that 36.97% of the variance in the asymmetry score was explained by the subjective scores using this model.

Subjective Judgement	Description	Points
Excellent	Treated breast nearly identical to untreated breast	4
Good	Treated breast slightly different than untreated	3
Fair	Treated breast clearly different than untreated	2
Poor	Treated breast seriously distorted	1

Table 7 Harris scale	Table	7 H	arris	scale
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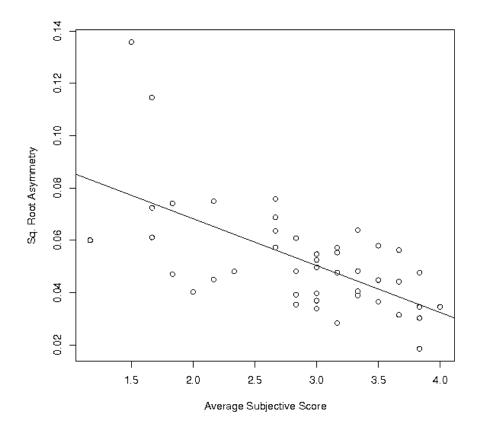


Figure 3.17 Subjective score of breast assessment versus objective asymmetry score

The results of the comparison of the subjective score for volume in comparison between both breasts versus the scaling component of the objective asymmetry score were graphically displayed (Fig 3.18). It was again found that there was a negative relationship, in the sense that an increase in the objective asymmetry score for the scaling component led to a decrease in the subjective score for the volume component only, equalling poorer symmetry. The result of the regression model was that the relationship was very significant at p<0.001.The R-squared value was 0.35, which indicated that 35% of the variance in the asymmetry score was explained by the subjective scores using this model.

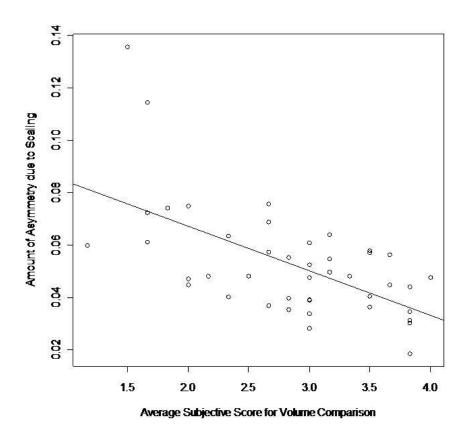


Figure 3.18 Subjective score for volume in comparison between both breasts versus objective asymmetry score due to scaling component

The results of the comparison of the subjective score for shape in the comparison between both breasts versus the objective intrinsic asymmetry score (Fig 3.19) also revealed a negative relationship. The relationship was significant at a p=0.0057. The R-squared value was fairly low at 0.14, which suggested it may not have been a very strong relationship.

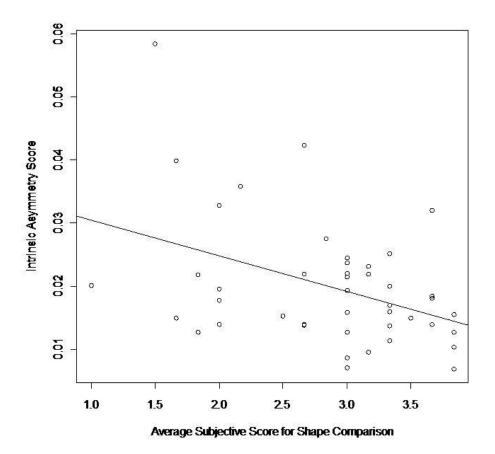
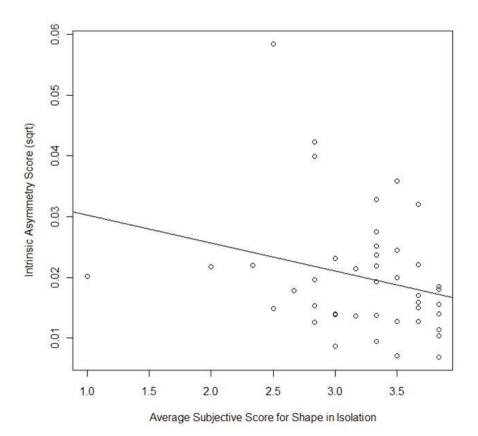
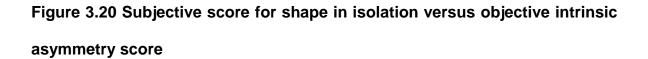


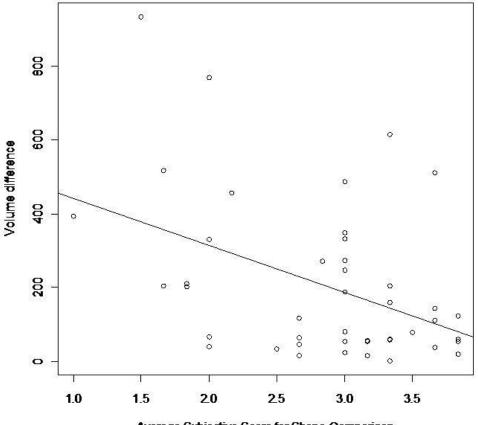
Figure 3.19 Subjective score for shape in comparison between both breasts versus the objective intrinsic asymmetry score

The results of the comparison of the subjective score for shape in isolation versus the objective intrinsic asymmetry score (Fig 3.20) similarly revealed a negative relationship. The relationship was not significant at a p=0.086. The R-squared value was 0.046.





The results of the comparison of the subjective score for shape in the comparison between both breasts versus the objective volume difference (Fig 3.21) revealed a negative relationship. The relationship was significant at a p= 0.0037. The R-squared value was fairly low at 0.16.



Average Subjective Score for Shape Comparison

Figure 3.21 Subjective score for shape in comparison between both breasts versus objective volume difference

The results of the comparison of the subjective score for shape in isolation versus the objective volume difference (Fig 3.22) revealed a negative relationship. The relationship was not significant at a p = 0.25. The R-square value was very low at 0.0081.

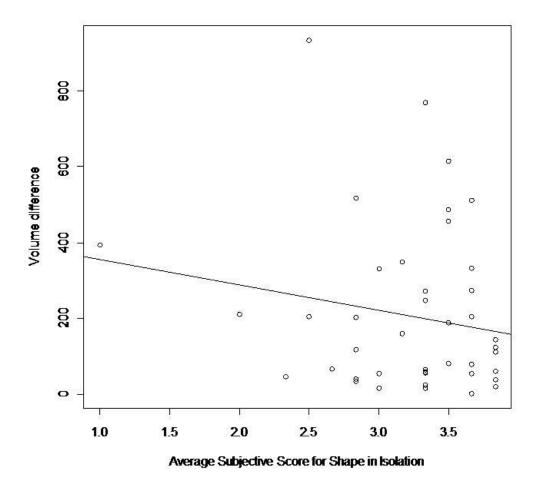
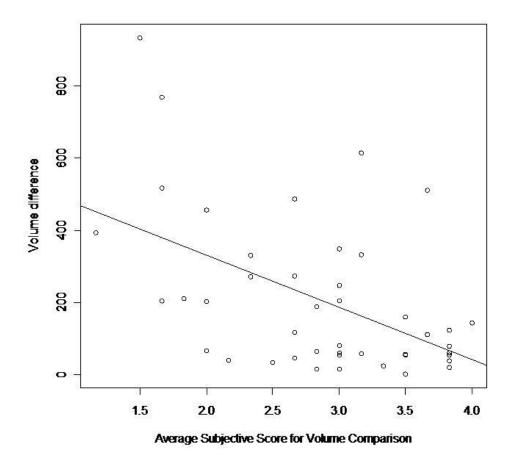
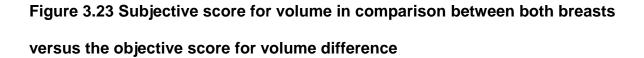


Figure 3.22 Subjective score for shape in isolation versus objective volume difference

The results of the comparison of the subjective score for volume in comparison between both breasts versus the objective volume difference (Fig 3.23) revealed a negative relationship. The relationship was significant at p= 0.00048. The R-square value was 0.24.





The results of the comparison of the subjective score for volume in isolation versus the objective volume difference (Fig 3.24) revealed a negative relationship. The relationship was not significant at p= 0.223. The R-square value was 0.012.

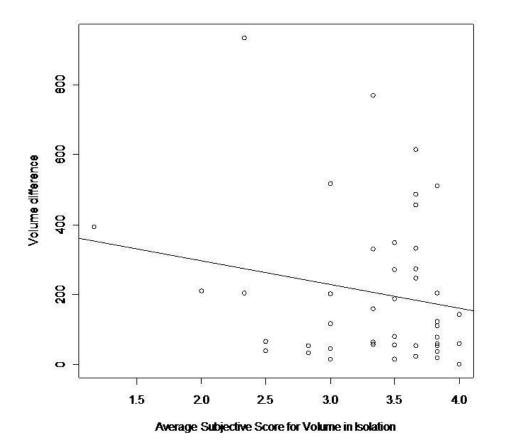


Figure 3.24 Subjective score for volume in isolation versus the objective score for volume difference

3.4.1 Effect of subjective influence on objective landmark-based analysis

The reproducibility in landmark placement was found to be worst in the right inferior landmark (3.2.2, Table 3). The mean reproducibility was found to be within 5mm. Based on this knowledge the right inferior landmark was chosen to examine the effect of the subjective influence by the operator on the objective landmark placement. The landmark was firstly shifted by 5mm and secondly by 1cm away from its originally chosen position in each of the x-, y and z-directions over all cases. Six scatter plots were obtained, which each displayed the original against the adjusted scores.

The paired sample t-tests examined if the difference in means of the two sets of scores was equal to zero.

When the landmark was shifted by 5 mm the difference between the original and newly calculated scores in all three directions was not significant (p= 0.699, p=0.089, p=0.447).

When the landmark was shifted by 1 cm the difference however between the original and newly calculated scores in all three directions was significant (p=0.028, p=0.0006, p=0.023).

Therefore the results of this examination show that the scores are affected by the variability of the landmark placement, but within the levels of reproducibility of 5mm, that was achieved in the study by the operator, the effect was not significant.

Shift of 5mm in x-direction

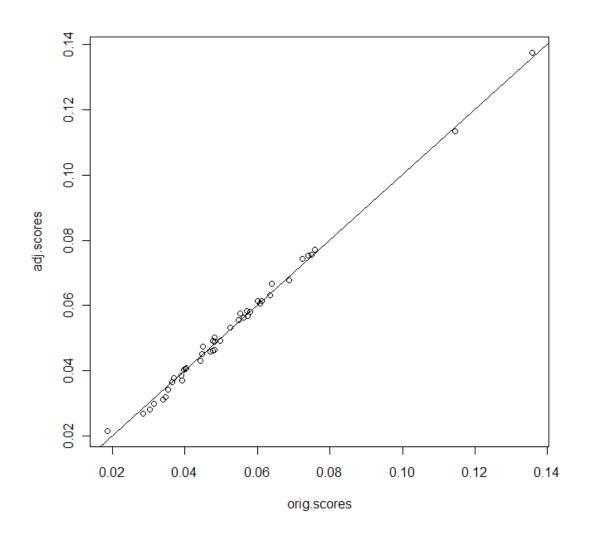


Figure 3.25 Shift of right inferior landmark 5 mm in x-direction

Shift of 5mm in y-direction

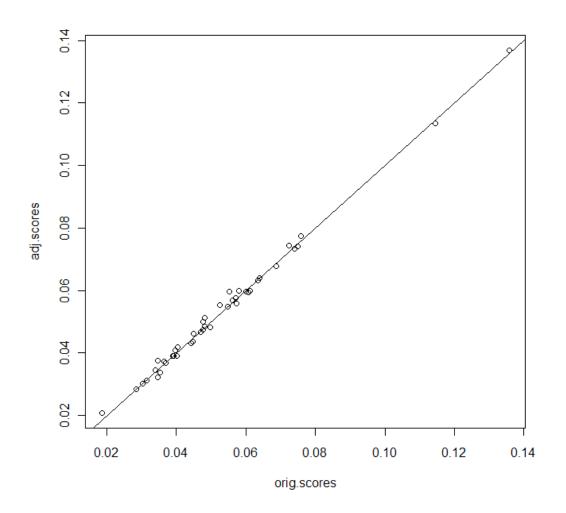


Figure 3.26 Shift of right inferior landmark 5 mm in y-direction

Shift of 5mm in z-direction

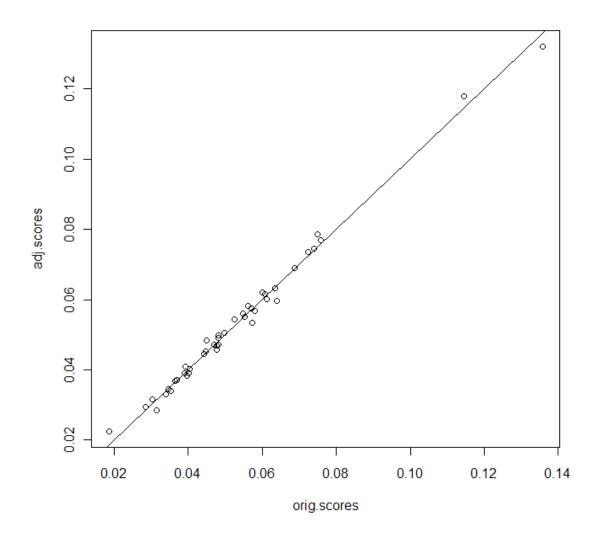


Figure 3.27 Shift of right inferior landmark 5 mm in z-direction

Shift of 1 cm in x-direction

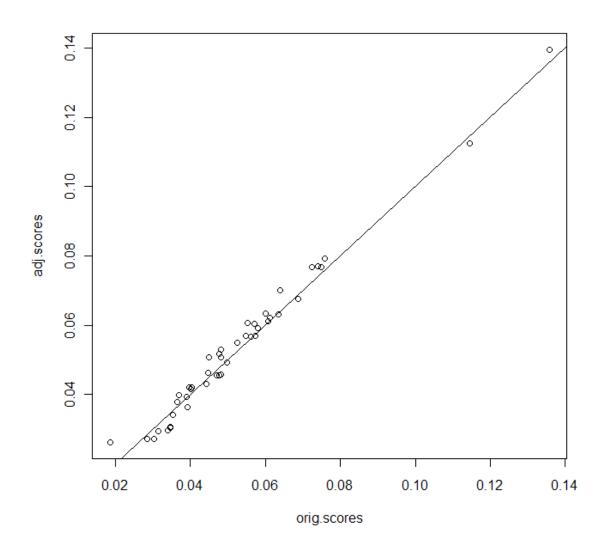


Figure 3.28 Shift of right inferior landmark 1 cm in x-direction

Shift of 1 cm in y-direction

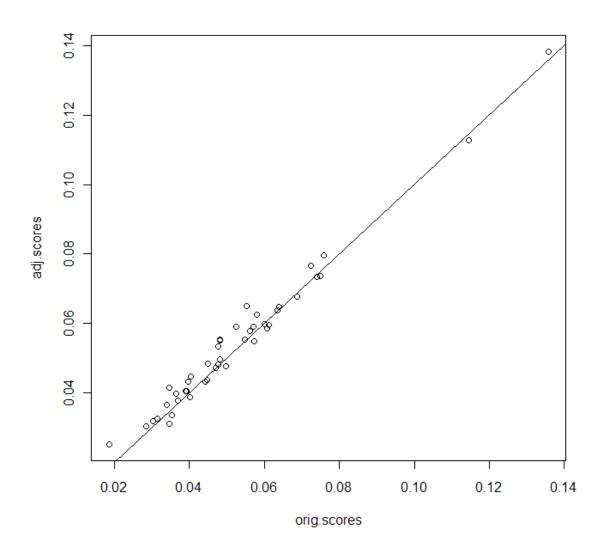


Figure 3.29 Shift of right inferior landmark 1 cm in y-direction

Shift of 1 cm in z-direction

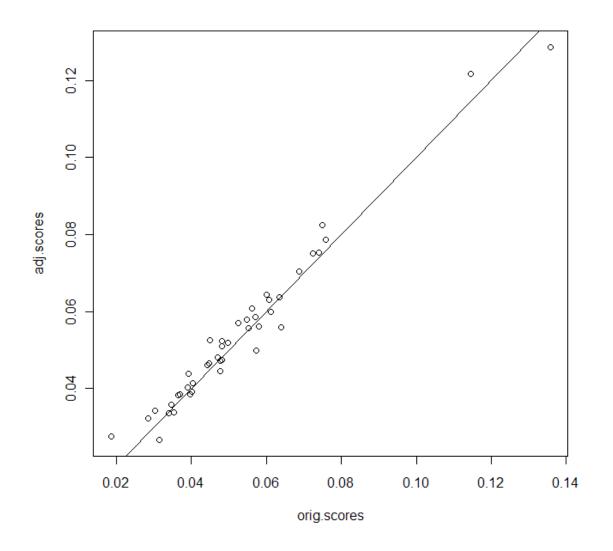


Figure 3.30 Shift of right inferior landmark 1 cm in z-direction

Summary

It was found that the accuracy of the measurements of the volumes of plaster models by the 3D imaging system was satisfactory and that the reproducibility in breast volume assessment in the live models was better than that by water displacement. No strong correlation between breast size and variation of measurements was found. The application in the patient study revealed that when using 10 landmarks for breast asymmetry assessment, the reproducibility for each landmark after four repeated tests was within 5mm. The breast assessment through centroid size revealed that the reconstructed breast was slightly, but not significantly, smaller than the un-operated side. The same was true for volume assessment, but with significant results. The larger the breast, the larger was the mismatch between both sides. The landmark-based assessment provided the mathematically calculated asymmetry score. The breast asymmetry was assessed for various contributory factors such as intrinsic breast asymmetry, location, orientation and scaling of the breast. The most important factor that was determined was the location of the breast before intrinsic asymmetry when different landmarks were scaled separately. It was found that the body mass index played a significant role in breast asymmetry. Patients with a higher BMI displayed greater breast asymmetry after reconstruction. The objective asymmetry score and the subjective score agreed in a linear relationship that was highly significant.

4 Discussion

Introduction

Increasing numbers of women are seeking breast reconstruction following mastectomy (105), as breast cancer is a disease with increasing incidence in the western world (53). It is estimated that over 300000 women each year are confronted with the diagnosis of breast cancer in Europe and over one million women worldwide. The breast cancer incidence has increased by 84% since records began in 1971 in the UK (53). Overall, the incidence of breast cancer has risen about 30% in the past 25 years in western countries (2).

Mastectomy for cancer can severely lower patient quality of life (66). It has been acknowledged that breast reconstruction surgery is a crucial part of breast cancer treatment and can help breast cancer survivors regain a high quality of life (71). The relationship between physical appearance and psychological body image is a central aspect in this regard (72). Surgeons are striving to restore breast volume and shape after breast cancer treatment and to achieve maximum symmetry in comparison to the unaffected side. The symmetry of the breast anatomy appears to be of the utmost importance to the patient. Therefore, an objective outcome measure following breast reconstruction is desirable. With newly developed multiple stereo camera systems, the objective evaluation of breast volume, shape and symmetry, surgical planning and assessment of the outcome is emerging as a possibility. The potential applications in breast surgery could prove invaluable (93).

There is a general lack of reliable methods for total human breast volume measurements which could serve as a method of comparison to 3D imaging.

Recent studies highlighted the options of using MRI to measure breast volume (78). Kovacs demonstrated that breast volume measurements by MRI and by laser scanner produced the best agreement and reproducibility among four methods that were compared. The MRI examination displayed the true anatomical area of the breast that was completely visualised and measured. Advances in MRI technologies offered new options but the methods were costly and lacked validation for total breast volume assessment (70; 83). To date MRI examinations have been mainly used for the assessment of breast tumour volume but not total breast volume. This application might be extended in the future.

One of the most advanced methods to have been used for 3D breast assessment is laser scanning (74; 75; 78). Laser scanning allows an objective breast volume, shape and symmetry analysis. Disadvantages of this method can be seen in the limitation of the display of the surface texture and in the time demands of the scanning process. Laser scanning is a method that does not offer the same natural and real life-like images like multiple stereophotogrammetry, which was used in this study.

For objective breast assessment, other methods such as anthropometric methods have been investigated; these rely on multiple linear inter-landmark distances and traditionally lack accuracy and reproducibility (131). A widespread clinical application did not develop from them. Plaster casting was previously applied for volume measurements, but is uncomfortable for patients and equally, lacks accuracy and reproducibility (78). Ultrasound examinations were used for cancer assessments (130), but not routinely for total breast volume measurements. Mammography examinations provide rough estimations of the total breast volume (68), but do not offer the possibility of a shape analysis. Multiple measurement devices have been developed and tried in the past, but these were not validated and in many cases did not adjust well to the shape of the breast, leading to measurement inaccuracies and imprecision (91; 119; 37). Breast assessments by water displacement have been conducted, but results revealed limited accuracy and reproducibility (123). Sufficient information on breast texture, surface and shape is not provided by the majority of methods. Acceptance by patients is questionable. The clinical application of many of these methods of breast volume and shape measurements has not been routinely established.

To date, breast appearance and symmetry have been mainly subjectively assessed by the application of scoring systems that were applied with the help of 2D photographs or questionnaires. These scoring systems were neither objective, accurate, nor reproducible (72). The judgment of breast aesthetics from photographs is a qualitative, subjective method in contrast to the quantitative, objective method of 3D imaging analysis.

The application of multiple stereophotogrammetry for three-dimensional imaging has been developed and is widely used for the capture as well as assessment of facial morphology and experiences with the validation of systems in this field have been reported (3; 70). However, the application of multiple stereophotogrammetry for breast capture presents challenges different to those encountered with facial capture and analysis. Landmark identification, which is necessary for objective analysis, remains a problem in breast analysis (74).

The concept of mirror imaging for shape and symmetry assessment is not new and is well established in facial surgery (39; 40). The method has also been occasionally applied in the field of plastic and reconstructive breast surgery when 3D imaging methods have been used (88; 83; 66), but a widespread application has to be awaited.

A previous attempt to capture the breast with a multiple stereophotogrammetry system has been reported (84). The 3dMD system with 12 stereo cameras was utilised, but details of the system's configuration were not provided. Losken presented new work on the validation of the 3D imaging method by assessing breast volume on preoperative 3D images and comparing the data with mastectomy specimens that were assessed by water displacement. Nevertheless, by other authors it was criticized that only the front and lateral views of the chest-wall were imaged and only information to relative volume differences between two scans, before and after the operation, seemed to be meaningful (73). Losken also assessed breast shape by assessing linear distances and comparing these with tape measurements, which is a method that does not display the three-dimensional nature of the breast shape. Therefore this approach failed to validate the 3D imaging system for breast shape analysis. In contrast, the shape analysis in our study included data of three dimensions of breast landmarks and therefore truly displayed the anatomical features of the breast.

Losken, in a separate study, investigated the distribution of natural breast asymmetry with the 3dMD imaging system by measuring linear distances and superimposition of the right onto the left breast image and obtaining a colour histogram and surface distances (83). Losken's study group selection was not randomised. The study was based on a comparison of surface distances in mm of the right and left breasts and calculation of the root mean square to obtain an asymmetry score. These two-dimensional measurements failed to conclusively analyse the three-dimensional breast shape and natural breast asymmetry, but nevertheless served the development of the 3D imaging method.

A colleague of Losken, Moyer (93), published his experience of breast shape assessment with the same 3D imaging system. A clinical study was presented and the breast asymmetry score calculated. The patients were captured in an upright body posture which failed to display the infra-mammary fold and details as to the accuracy and reproducibility of the method were not provided.

Apart from these studies to date there has been a dearth of publications on the application of multiple stereo camera systems for breast capture, although some commercial systems with limited applications are available.

Disadvantages of the method are its cost intensity and computational demands. Nevertheless 3D imaging by multiple stereophotogrammetry allows an objective volume, shape and symmetry analysis as well as error assessment.

The 3D imaging system in this study was specially developed to cater for the needs of the extensive breast reconstruction service that is provided by the Canniesburn Plastic Surgery Unit in Glasgow. This unit covers the whole of the population of the West of Scotland and runs a busy breast reconstruction clinic.

Our study is one of the first 3D breast shape analysis methods using a multiple stereophotogrammetry system which considers data of all three dimensions of the breast anatomy.

4.1 Part I - Pilot study - Validation

This study aimed to achieve the validation of the multiple stereophotogrammetry system in measuring breast volume. For this purpose the accuracy and reproducibility of volume measurements were examined. We found that in specially-shaped plaster models the differences in volumes measured with two different methods, multiple stereophotogrammetry and water displacement, did not exceed 40 cc. This difference was less than the volume difference detectable by the human eye, which was reported as 50 cc according to published subjective judgment (112).

The key pieces of the 3D capture system were firstly, the C3D software that was required for the 3D image construction and secondly, the breast analysis tool software (BAT) which was applied to measure breast volume. The complexity of the processes of breast capture and analysis in this study has been described earlier in this thesis. Traditionally, stereophotogrammetry systems were considered as technically cumbersome and computationally intensive. Moreover, the system that we used was not a "turn-key" system but a prototype of a multiple stereophotogrammetry system. The segmentation method and chest-wall generation methods were key steps in the volume measurements of the BAT software. The artificial chest-wall, which was mathematically identified, simulated the natural curve of the chest before measuring the volume. The shape of the generated chest-wall patch was controlled by the curvature of the edge lines delimiting the breast segment. In our investigation we used plaster models with one type of "chest-wall". All but one of the plaster models that we investigated were built with a flat back wall. We assumed that the volume determination was

equally accurate in plaster models with a flat back wall and in those with a curved back wall. It would require further investigation of plaster models with various curved back walls to confirm this hypothesis and validate the software algorithm.

The examination of the spread of the volume measurements in the plaster model study showed a similar level of consistency with either method and differences remained markedly small. The variation with 3D imaging may be due to errors in landmark location using the BAT software. In the live models, 3D imaging emerged overall with better reproducibility than the water displacement method.

Water displacement is an ideal method for recording the volume of an inanimate object, which served the purpose of the first part of the pilot study. In live models, the immersion of the breast is associated with technical difficulties of identifying the chest-wall which was the main reason for the poor reproducibility of the method. A slight variation in depth and possibly in speed of immersion caused a substantial variation of the breast volume determination.

All measurements of breast volumes in the volunteers by water displacement were consistently higher than those obtained by stereophotogrammetry. A possible explanation for this finding could be that water displacement relied on the cooperation of the volunteer and the subjective judgment of the depth of the immersion of the breast. The lack of clear breast boundaries could have lead to over-immersion by the volunteer beyond the anatomical area of the breast and hence have affected the accuracy and reproducibility of the method. An adjustment in height and size of the water displacement system might have improved the reproducibility of the method; however, this assumption would require further investigation. The breast shape contributed to the variability of the measurements in the volunteers. Breasts with a broad base were associated with more measurement variability than tubular breasts due to the differences in the breasts` base to length ratio and ease of immersion. Overall, the use of this method was unreliable for measuring absolute breast volume.

The investigation using the plaster models provided overall satisfactory confidence in the 3D imaging accuracy. Satisfactory reproducibility was confirmed in the live models. Therefore, the necessary requirements for our study were achieved.

In direct comparison, in four out of six volunteers the standard deviation of the repeated measurements by water displacement was less than the spread by the 3D imaging method. This finding might have been due to the fact that when using stereophotogrammetry, the lighting conditions influence the ability of the system to detect skin texture and consequently may have influenced the 3D image construction. White flashes were used in this study and these were adjusted as deemed necessary. The positioning of the breast at the centre of the focus of all cameras was important for complete breast capture and reproducible measurement results. Errors associated with the calibration of the system might also have contributed to the variability of the measurements. As a general rule, the complexity of the calibration is related to the number of camera pods in a multiple stereophotogrammetry system. A precise calibration is crucial for a high-quality 3D image construction. The precision of the calibration process was the main reason for the development of a fixed capture rig, to which all camera pods were mounted, to achieve the utmost stability of the capture system.

It is important to emphasise that in the live models neither 3D imaging nor the water displacement method produced the true and absolute volumes of the breasts, which remained uncertain. This was attributable to the anatomical area that was investigated rather than to features of the capture system. When

conducting total breast volume assessment, a natural breast volume variation due to the monthly hormonal changes has to be considered and this impacts on the measurement accuracy. Even natural breathing may influence the size and shape of the breast.

In obese subjects particularly, the demarcation between chest-wall subcutaneous fat tissue and breast fat tissue that was part of the total breast volume was difficult to establish and the identification of breast boundaries and landmarks in our study remained uncertain.

The limited levels of accuracy and reproducibility of measurements impacted on the overall validity of the 3D capture system in measuring the absolute breast volume. However, 3D imaging overall provided more reproducible data than the water displacement method for recording a relative volume of the breast. This was considered to be useful for a clinical application when the differences between the volumes of reconstructed and unreconstructed breasts are compared. The achieved accuracy and reproducibility of our pilot study was deemed sufficiently valid to conduct a clinical trial involving a comparative analysis between the reconstructed breast and the opposite unaffected side. Therefore, we concluded that 3D imaging with multiple stereophotogrammetry was a useful tool for a comparative analysis of the breast in shape and volume.

The error assessment of our pilot study demonstrated a sufficiently small posing, capture and measuring-up error, a result adding additional weight to the validation of the system.

Our finding that a poor correlation was determined between the reproducibility of breast volume measurements and the size of the breast raised the question as to whether this was representative of the general population. Further investigation with a larger sample size would be required to investigate a possible correlation further.

4.1.1Commercial 3D Breast Capture Systems

Commercial systems including the 3dMD system (3Q Corporation, Vicarage House, 58 Kensington Church Street, London W8 4DB, UK) (51), the Vectra-CR 3D system (Canfield Imaging Systems, 253 Passaic Avenue, Fairfield, NJ 07004-2524, USA) (59), and the Rainbow 3D camera (Genex Technologies, 10411 Motor City Drive, Suite 650, Bethesda, MD 20817, USA) (63) are currently available to capture the breast with the patient in an upright position (33; 84, 93). This patient set-up was also previously applied for a prototype system, the body map system, which is an automated stereophotogrammetric procedure with two stereo cameras and a central slide projector to illuminate a surface with structured light (88). The capture of the ptotic breast in upright position fails to record the infra-mammary fold so that data loss in this region is inevitable. Therefore, in clinical application the adjustment of the patients` posture is essential, especially in patients with ptotic breasts, who constitute the majority of our patients.

The commercially available, modern capture systems present with a fast capture speed and most importantly, with powerful and advanced software for a variety of applications, which are frequently used in the field of aesthetic breast augmentations and the assessment of aesthetic surgery (51; 52; 59; 61; 63). Capture systems should allow a reproducible and comprehensive recording of the

breast without compromising patient safety and should enable a robust analysis of breast shapes and sizes.

There is however, a lack of independent assessments of the application and validation of these systems for 3D breast capture. Systems that are produced for breast capture are valuable and consist of two or three camera pods (51; 59), or even contain more camera pods (51; 61) that are partly angled upwards to limit data loss around the infra-mammary fold. The 3dMD system consists of up to 12 cameras with different configurations. Breast capture with this system was conducted in an upright position; however, the details of the capture errors were not reported (83; 84). The Di3D system which was used in this study can include up to 32 cameras to allow the capture of the human torso (62).

The details of the configuration and the clinical application of the 3D imaging systems that were used for breast capture in patients are limited (33; 93; 94). The configuration of the stereophotogrammetry system in our study involved eight cameras arranged in four pods, as described in detail earlier. This configuration was unique and was crucial to achieving full breast capture.

When promoting 3D systems, manufacturers often quote measurement errors based on their own evaluation of accuracy and reproducibility, which should be viewed with caution (128). Exact information on the systems` assessments is often not provided. It is recommended that prospective users conduct their own validation studies, which cater for their individual needs, before conducting a research project. To achieve the validation of a 3D capture system, a complex investigation that addresses the individual features of the product and application of interest is required. In the future, an independent certification of these systems may be needed. With commercial systems it is noticeable that considerable focus is put on the products' design features rather than on information related to configuration and validation studies. It is advisable that 3D imaging systems demonstrate smooth, cleanable surfaces suitable for a hospital environment but also satisfy safety concerns. A safe covering of the complex wiring and connections of the multiple digital cameras is necessary to avoid accidental risk to patients. Due to the importance of the calibration process, 3D imaging systems should be installed in a fixed rig so that accidental movement of the cameras is avoided. A smooth single-coloured background that enables standardised image capture is essential. This will also facilitate the 3D construction of the captured images.

One method of solving the capture problems associated with breast ptosis was the construction of a patient-positioning frame in which the patients in our study took a specific pose. This frame was custom-made and offered a safe positioning support which helped the patient to lean forward with the upper torso in an almost horizontal position, allowing the breast to lift off the chest-wall for full capture of the infra-mammary fold and the breast as a whole. The standardising of the pose during breast capture helped to minimise position errors and to improve the validity of the assessment of breast size and shape. The importance of the standardisation of the pose was highlighted in our error study. As we found no significant difference between the poses of the first and second set of three breast captures for each live model we concluded that our positioning set-up contributed to the validity of the breast measurements with our system.

4.2 Part II - Patient Capture

The application of a 3D multiple stereophotogrammetry system for breast assessment in patients is a new development and requires specific considerations. The technical features and options of the system need to be matched with the examination question interest. required and of The benefit of а stereophotogrammetry system needs to be judged against other available assessment methods. As a photographic tool, the benefit lies in the presentation of a real image of the breast after capture with complete surface texture, skin colour, scarring etc. In contrast, an assessment of breast tissue underneath the skin surface is not provided by 3D imaging with multiple stereo cameras; therefore the method has limited use for breast cancer detection or evaluation.

The application of a multiple stereophotogrammetry system lies in the field of the assessment of the appearance of the breast as well as in surgical planning and objective measurement of the outcome after breast surgery. The aim of achieving a satisfactory appearance after breast reconstruction procedures has been acknowledged as an important and integral part of surgical care in the management of breast cancer (34; 66; 71). A good aesthetic outcome was recognized as an important endpoint of breast cancer treatment (43; 72; 88). A primary goal in breast reconstruction after mastectomy is to obtain symmetry, shape and size and the role of 3D imaging was investigated (94). The patients of the Canniesburn Plastic Surgery Unit, who voluntarily attended a clinic to undergo breast capture for this research project, repeatedly voiced their gratitude for the treatment of the breast reconstruction and that they were happy to take part in this study. However, the assessment of patients` satisfaction with the surgical

treatment was beyond the scope of this study. The impact of an aesthetically pleasing breast reconstruction on overall quality of life of patients, social functioning and mental health is well documented (11). Breast-conserving treatment, when possible, is known to result in improved quality of life and self– esteem of women undergoing surgical treatment due to breast cancer (32). We hope this study will facilitate the routine use of 3D imaging for the evaluation of the quality of breast reconstruction following cancer ablation.

4.2.1 Assessment of Quality of Breast Reconstruction

The lack of data regarding the distribution of normal breast size and shapes in the population is an obstacle for comparative research studies. To date, the quality of breast asymmetry has mainly been assessed subjectively (104).

Our study focused on a single patient group with homogeneous criteria in whom one breast was reconstructed immediately following mastectomy using the Latissimus dorsi flap technique. We chose this patient group as the Latissimus dorsi flap transposition for breast reconstruction is the most common and reliable surgical procedure for breast reconstruction at the Canniesburn Plastic Surgery Unit. The reconstructed breast was compared with the unaffected breast of the same individual. The benefit of this approach was that capture and measurements errors were similar in both breasts (reconstructed and non-operated sides). Despite the lack of information regarding the magnitude of symmetry between the right and left breast in the general population we assumed that perfect symmetry was the main objective of reconstruction procedures following mastectomy. This concept is in agreement with published data (33; 66). However, an important investigation remains to identify the natural degree of asymmetry or ptosis in the normal population and to revisit the concept that achieving ideal breast shape and symmetry should be always the surgical goal. To date there has been no consensus in the plastic surgical community regarding the question as to whether a breast reconstruction procedure should create a ptotic breast in those cases in which the healthy breast is predominantly ptotic in shape.

Whatever the answer might be, an objective quantification of the degree of mismatch between the reconstructed breast and the unaffected breast is desirable. Until then most plastic surgeons will continue to pursue the goal of achieving a mirror image of the reconstructed breast in relation to the other side, which may or may not be fully achieved. 3D breast imaging is emerging as a new objective tool for the assessment of breast appearance following reconstruction.

4.2.2 Locating and Choosing Landmarks

Currently there is no established method of systematic digitisation of landmarks on the surface of the breast. Brown based his study on anthropometric measurements of 10 anatomical landmarks on the breast (12). The reproducibility of the recording of landmarks on the face has been reported (38). When extending this knowledge to the breast we were faced with different challenges. Firstly, the overall number of landmarks, that seem to be detectable, was limited. Secondly, the position of landmarks was less defined by far on the breast than on the face. Thirdly, due the specific feature of the breast as being a pendulous and movable body part, the identification of the landmark position was less reproducible. Based on the results of our study, we concluded that the reproducibility in locating landmarks on the breast or chest-wall was markedly less than on the face. The reproducibility of landmark digitisation on the breast surface was within 5mm in our study compared to digitisation errors of within 1 mm for identifying facial landmarks (3). However, based on subjective clinical plastic surgical impression, it seemed that 5 mm variation in the identification of landmarks on a female breast was deemed satisfactory. Breast surgeons have traditionally been aware of a certain degree of inaccuracy amounting to a few millimetres when preoperatively marking the breast or postoperatively measuring the outcome. In clinical practice, when breast assessment was conducted by application of tape measurements, the linear distances would often be documented in half centimetres, i.e. the distance "from jugulum to nipple areola complex" would be documented as 20.5 cm. We could not find matching results regarding the reproducibility of the identification of breast landmarks in the literature.

Overall, in our study, the reproducibility of the landmark identification was lowest in the inferior and lateral areas of the breast. In these areas no clear, anatomical point could be determined that would help in the landmark placement. The inferior and lateral breast areas are rather smooth areas and mostly gently curved anatomical zones that make landmark determination difficult. With our capture system we ruled out the possibility that an insufficient capture of the inframammary region was responsible for this finding. This is in contrast to the study by Kovacs, who experimented with different settings and numbers of laser scanners in order to improve the precision of the capture of the obscured infra-mammary fold and lateral breast region in an upright body posture (74).

The digitisation of the landmarks should be conducted after capture on the 3D images as this is the more accurate measure. When marking landmarks on

patients before capture, as conducted by Kovacs (74) the reproducibility of the landmark data might be high, as the digitisations of these pre-marked landmarks can be easily made on the 3D images in repeated tests. Nevertheless, the initial marking before capture could be positioned in the wrong place on the body, which would lead to repeated inaccurate recordings on the 3D images. In contrast, the identification of landmarks on the 3D images, as conducted in our study, after capture, might be less reproducible, but for each repeated test a new evaluation of the landmark position on the 3D image needs to be conducted, which improves the accuracy and reduces the error of the measurements.

We further decided to identify the landmarks on the 3D images after breast capture in order to be able to assess the errors comprehensively and avoid random errors that could not be quantified. We also avoided the need for repeated patient involvement. In our study solely the two midline points were positioned on the patient before capture, as these were positioned on clear anatomic reference points and therefore treated differently to all other landmarks that were digitised directly on the 3D image. Automatic landmark location based on surface geometry might reduce the digitisation errors.

The field of objective breast assessment by application of landmarks and 3D imaging is new and only a small number of study groups have investigated this exciting and innovative subject of analysis. Therefore, in contrast to studies on the face, only a few publications on the 3D imaging method of the breast have been produced. One of these studies is the previously cited study on the optimisation of 3D imaging methods by laser scanner and examined landmarks on breast dummy models (74). It was found that measurements on test individuals had significantly lower precision than those on dummy models. Kovacs used measurements of

distances between landmarks in two dimensions for the analysis. Even though the coordinates of landmarks were identified in three dimensions, only two of these dimensions were used for the assessment of the accuracy and precision of the 3D imaging method and compared to manual tape measurements. In our study the 3D coordinates of the landmarks were fully utilised in all three dimensions in the breast analysis. Our study is one of the first to use all 3D characteristics of the breast and to allow a comprehensive analysis of symmetry, shape and size.

While conducting our study it appeared that the variability of landmark identification was even more pronounced in obese patients in whom the borders between the fat tissue of the breast and the surrounding subcutaneous fat tissue were obscure. The probable difference in the accuracy of the recording of breast landmarks between patients of average weight and obese patients would require further investigation.

Whenever the identification of surface landmarks is required for shape analysis a steep learning curve of the digitisation process needs to be taken into consideration before conducting the actual study. The difficulty of landmark location is particularly pronounced on the upper breast border, so we decided not to use any landmark in this area at all. An attempt to define this area by a "folding line method" was suggested in the literature (73; 80). Nevertheless, no further studies on the folding line method, a method that seems rather rigid and inaccurate, were produced. In contrast to the upper breast border, the lower breast border is more readily defined, although it does not form a perfect half-circle as assumed by Lee (80). We decided to use neither the folding line method at the upper breast nor a perfect half circle approach at the lower breast border but to anatomically-defined landmarks choose to improve the accuracy and reproducibility of the method. We chose to position our landmarks guided by both bony and soft tissue structures instead of assuming that all patients in the study group presented with the same definition of the upper breast border and using imaginary points as described by Kovacs (74).

4.2.3 Positioning of Patients

All patients in our study group managed to take the specific pose in the patient positioning frame that was required for full breast capture. Despite the fact that some patients after breast reconstruction suffered from some restrictions in their shoulder movement, none of our 44 patients failed to take the required pose in which they bent forward with the upper body stretching the arms out and resting these on the side bars of the supporting frame. For some patients with limited shoulder movement, the shoulders were kept in a slightly bent position and breast capture was concluded fully and satisfactorily.

The failure fully to capture the infra-mammary fold in upright body posture is still challenging. Even when arms are raised in order to lift the breast slightly, in markedly ptotic breasts the infra-mammary fold still remains obscure. In patients with larger ptotic breasts, these are usually positioned at the lower lateral chest region in upright body posture The lateral aspects of the breasts and chest-wall region might remain hidden behind the anterior surface of the breast itself, adding to the difficulty of the capture. Kovacs (74) reported that measurement precision in upright body posture was better when the arms were placed behind the back than raised above the head; nevertheless the later arm position was advocated for large ptotic breasts. We would advise adopting our method of bending forward

with the upper body in a patient-positioning frame as the standard for breast capture and shape analysis. The approach that we used by letting the patients bend forward with the upper body presented the solution to the previously discussed problem of breast suspension off the chest-wall in an upright body posture that was thought to be required in ptotic breasts for full capture (94).

4.2.4 Breast Volume, Shape and Symmetry Assessment by Landmarks, Centroids and Surface

Our method of breast volume, shape and symmetry measurement did not entirely depend on the location of landmarks but also considered the whole 3D surface of the breast for analysis. We found that breast symmetry could be measured more accurately when the whole breast surface was utilised in the analysis rather than individual landmarks, a finding that should be considered in future breast symmetry analysis. There is a dearth of publications in the plastic surgical literature regarding the objective symmetry assessment of the breast. The application of the centroid size for differential breast assessment is a novel method in this context (114). The centroid size is calculated as the square root of the sum of squared Euclidian distances from each landmark to the centroid, the average point. The main drawback of the centroid-based analysis in comparison to the surface based assessment was the smaller number of data points that were used. A larger number of landmarks might improve the robustness of the analysis; however, this would require further investigation. Nevertheless, it has to be considered that the recording of further landmarks might not be as accurate as

that of those considered in this study due to the limited number of anatomical reference points on the breast.

For the calculation of breast asymmetry Procrustes analysis was implemented, a method based on the utilisation of landmarks (90). It was originally developed for size and shape measurements in cephalometrics and knowledge was transferred in our study to application on the breast. Procrustes analysis is a new method in the context of breast assessment.

Due to our breast assessment based on four landmarks on each breast leading to the centroid size and the mathematical Procrustes analysis based on the landmark data, the robustness of our analysis was not dependent on the identification of a single, imaginary upper breast landmark for breast asymmetry assessment that was considered to be inaccurate. The landmarks that we used were sufficient to conduct the analysis and draw conclusions from the data. Our surface-based analysis by determination of a breast segment and software interpolation of the chest wall was equally independent from this additional imaginary upper breast landmark.

An important finding of our study was that in the 44 patients the reconstructed side on average turned out to be smaller than the unaffected breast. We objectively demonstrated that there was a size difference between both breasts. Based on the centroid size assessment, this difference was not statistically significant. Nevertheless the clinical significance of the difference should be fully analysed.

In contrast, when comparing differences in volume by BAT software using all surface data, the reconstructed breast was considerably smaller than the non-operated breast and differences were highly significant at p< 0.0001. The results

of the surface-based volume assessment were considered to be a more accurate measure of the size of the breast due to the larger number of data points that were used.

Surgical overcorrection of the breast size would be desirable. However, the magnitude of breast overcorrection is still subjective. As breast symmetry in many cases cannot be achieved by Latissimus dorsi transposition flap surgery, we concluded that this method objectively falls short in it's potential for this purpose. The clinical experience that Latissimus dorsi reconstructions are not ideal for larger type breast reconstructions has been objectively confirmed by this research study. In recent years, the surgical method was extended by inclusion of additional subcutaneous fat tissue surrounding the Latissimus dorsi flap to improve breast symmetry in patients with larger natural breasts (34). It would be of interest to discover the degree of improved symmetry that is achievable with this extended surgical method and whether this can be quantified.

Further, there might be a reduction in muscle bulk over time due to the inactivity of the muscle after breast reconstruction procedures. There might also be fat atrophy and loss of fat with general body weight changes and after chemo- or radiotherapy. This could mislead the surgeon to misjudge the symmetry during surgery as being satisfactory in contrast to what might develop several months later. The 3D imaging method emerges as a potential tool for the quantification of the decrease of muscle bulk over time. The patients can be captured as frequently as necessary without exposing them to harmful radiation. The availability of soft tissues along the Latissimus dorsi muscle varies and seems to depend on the body weight of the patient undergoing breast reconstruction procedures. A sub-grouping of patients according to their body mass indexes might further improve

surgical planning in breast reconstruction with the goal of achieving the best possible symmetry. This study that quantifies the limitations of the Latissimus dorsi transposition flap for breast reconstruction procedures would support the decisionmaking process regarding the type of reconstruction that would be preferable to achieve the best possible results.

In delayed reconstructions the lack of breast skin remains a problem and the different thickness, texture and elasticity of dorsal skin that is transferred anteriorly for breast reconstruction has to be considered. In immediate reconstructions the volume of the Latissimus dorsi flap might fall short of sufficiently filling the skin envelope after mastectomy. An objective and differentiating assessment of breast symmetry following immediate and delayed reconstruction by 3D imaging would require further studies.

4.2.5 Breast Asymmetry Formula

In our study, a mathematical formula based on the sum of squared differences between the original landmark matrix (X) and its reflected counterpart (X_R), that was multiplied with the factor of the rotation matrix (Γ) and divided by the number of landmarks (*k*) was created and facilitated the objective quantification of breast asymmetry (9). This formula for breast asymmetry: A = H·X-X_R Γ H·2/*k* could prove to be a useful tool when aiming to conduct an objective shape analysis. A drawback of this score was the need for specialist camera equipment and the complexity of the calculation of this formula from a plastic surgical perspective as well as the need for professional mathematical support. This method measures global breast asymmetry and considers each landmark in the calculation. The development of a user-friendly software program to carry out this calculation is highly recommended.

The measurement of breast symmetry is crucial to the surgeon, as symmetry is desired by patients and considered to be a sign of beauty. Several authors have stressed that symmetry is an important criteria for aesthetically pleasing breasts (33; 94).

In clinical practice, patients are sometimes unaware of the existence of a certain degree of natural breast asymmetry and demand highly symmetrical surgical results. A measurement tool to quantify objectively the degree of natural asymmetry would assist the surgeon in debating patients` unrealistic expectations.

4.2.6 Factors Influencing Breast Asymmetry

Breast asymmetry can be measured as the degree to which there is a mismatch between a landmark configuration and its relabelled and matched reflection. The two breasts of the same individual were compared in our study. The paired points were matched to each other and the midline points to themselves. In our study the overall "global" breast asymmetry was attributed to four factors: the intrinsic breast asymmetry, location of landmarks, orientation of the breast and the size scale and influence of these was calculated (114).

Our method of individually assessing factors that contributed to breast asymmetry is a novel mathematical approach for breast analysis. Some of the landmarks that we used followed anatomical bony reference points of the breast and were positioned on the chest-wall (medial and lateral breast landmark) and some followed soft tissue features (inferior and most prominent breast landmark). We decided to investigate the landmarks separately to cater for these characteristics. Location was determined to be the most important factor contributing to breast asymmetry.

The finding that the location of the reconstructed breast in comparison to the opposite, non-operated breast seemed to be the most important factor affecting the overall asymmetry score could have implications for the surgical planning of reconstruction procedures. The surgeon should pay particular attention to matching the location of the operated breast as closely as possible to that of the unaffected breast. Clinically, we find that the reconstructed breast is often positioned too high on the chest-wall due to the lack of the inferior skin envelope, which prevents the development of the natural ptosis of the breast. The lower breast fold in breast reconstruction is not always clearly defined, which makes subjective assessment exceedingly difficult. Different surgical approaches have been applied in the past with the goal of enlarging the amount of new skin that is transferred by the reconstruction of the breast or to preserve the amount of skin that can be kept after mastectomy. An objective measurement tool would be of advantage to quantify the surgical outcomes.

According to the results of our study, in patients who underwent an immediate unilateral breast reconstruction with a Latissimus dorsi flap the orientation of the breast seemed to be a factor of lesser contribution to the overall breast asymmetry. Usually the natural axis of a ptotic, non-operated breast points to the lower lateral corner of the chest. This axis might be difficult to detect in reconstructed breasts due to the shortage of the skin envelope and orientation might therefore be one of the less important factors contributing to breast asymmetry.

The question arose as to whether breast asymmetry was influenced by other contributing factors. We did not find a strong correlation between breast asymmetry and other variables of the patients, such as age, parity, and chest-wall circumference. The body mass index was found to be the only significant factor that showed a direct relationship with asymmetry at p = 0.004. Therefore it could be postulated that women with high BMI are likely to have an asymmetric breast reconstruction. This finding could have implications on the acceptance of obese patients for breast reconstruction surgery and it should be discussed whether an optimal weight should firstly be achieved. According to our results, the relationship between breast asymmetry and bra cup size was not significant (p= 0.06), even though the result was just above the cut-off point of 0.05. A possible explanation for this could be that women with larger body weight seemed also to have larger bra-cup sizes, but this impression presented with some considerable variation. Our results on the influencing factors with breast asymmetry were in line with previously published data (83).

Previous evidence that breast cancer patients had more breast asymmetry and larger breasts than age-matched healthy women was reported (110). It has been found that a high degree of breast asymmetry may be a risk factor for breast cancer. An objective measurement tool to assess breast asymmetry as presented in our study seems therefore to be of value.

4.2.7 Requirements and Applications of Multiple Stereophotogrammetry Systems

In 1994, Malata pointed out that there were shortcomings in the clinical application of the body map system, which was a prototype system in stereophotogrammetry and which was investigated for breast analysis (88). These shortcomings were cited as being the need for an experienced operator, the length of data processing, the presence of a subjective element in the data analysis to determine breast boundaries from the camera image and the need to calculate the breast tissue exclusively from the chest wall.

In our study, the prototype of a multiple stereophotogrammetry system that we utilised presented similar challenges. The system also needed an experienced operator, presented a certain length of data processing and showed the presence of a subjective element in data analysis when determining breast boundaries. Nevertheless, the developments in the past fifteen years have targeted these problems by software development and advances in computer science and further improvements in the future might show the full potential of the technique for application in the preoperative planning and surgical outcome assessment. Our study did not solve the problems associated with stereophotogrammetry systems but contributed to gaining experience in the validation and clinical application. We hope that the breast asymmetry assessment, as developed in our patient group after breast reconstruction, will provide a significant improvement in breast analysis. An ideal 3D imaging system should fulfill multiple purposes; it should be easy to calibrate, capture the complete breast surface and produce images of excellent quality.

Modern studies on shape analysis have taken geometric considerations into account. Research has shown that the volume of the breast can be approximated using the measurements of a half-elliptic cylinder (68). Through application of geometrical rules, the breast can be seen to have roughly the shape of a cone. The surface of this cone can be flattened by mathematical calculation so that breast reconstruction procedures can be planned according to mathematical criteria. However, further work will be necessary to continue with this geometric approach and to open this new way of thinking to the plastic surgical practice. A geometrical method would be helpful to serve as a method of comparison to modern 3D imaging technology.

In outcome measures the justification of therapies under current economic constraints are emerging as a new necessity (72). To date, most attempts to justify the value of breast reconstruction procedures have been based on subjective patient questionnaires regarding satisfaction with the operation (126; 27; 95). More recently the quality of life after breast reconstruction was examined (101). Subjective breast assessments lack objectivity in the evaluation of the quality of the surgical outcome (72). Moreover, most patient questionnaires were not assessed for their intra-observer reproducibility (88; 101). The only available objective outcome measure was the number and type of complications that were documented in the case notes and that were retrospectively assessed (21; 24). Formerly there was a lack of a quantitative objective tool to evaluate whether the surgical goal of the reconstruction had in fact been achieved. This need now can be fulfilled by the 3D imaging method.

In times of increased demand for training certifications and quality control measures in hospitals, the application of 3D imaging methods for breast analysis

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should therefore increase. While in the past the surgeons might have been satisfied with their own subjective assessments of surgical outcomes, today the availability of an objective tool for breast analysis would facilitate the accurate evaluation of the quality of breast reconstructions and highlight areas where improvement could be made. An objective method of breast assessment also permits a meaningful comparison of outcome data between different centres offering breast surgical procedures.

It is true that due to the anatomical make-up of the breast with undefined breast boundaries, any breast measurement will always carry a certain degree of error. Nevertheless, an open mind to the approach of modern technologies of breast assessment should be adopted to improve the quality of patients` care.

4.3 Part III - Subjective Breast Assessment

Clinically, reconstructions with unilateral Latissimus dorsi flap often resulted in a smaller breast in comparison to the opposite side (35; 85). In women who presented initially with larger breasts, this method of reconstruction fell short in restoring the breast size (24; 34). This study confirmed these clinical subjective findings.

Subjective breast assessment was conducted in our study based on the appearance of the non-operated and reconstructed breasts in relation to each other and in isolation, as well as in view of the overall symmetry that was achieved following surgery. The parameters that were considered in this assessment were breast size and shape. Other factors such as skin colour, scarring, indentations and hyper-pigmentations were not assessed but might have influenced the assessors when subjectively scoring the overall aesthetic appearance of the breast.

For the subjective assessment we chose the application of the Harris score which is a well established and validated method (43). Previously, assessors with the highest level of experience in breast reconstruction performed best in the subjective evaluation of aesthetic results following breast cancer treatment (16). The assessors of our study who were conducting the subjective breast assessment were all experienced in performing breast surgery.

In our investigation, the calculated Kappa score of 0.646 revealed a satisfactory agreement between the assessors and results were highly significant. Our findings matched formerly published data on inter-observer agreement. Fair agreement when using the Harris scale was reported (17). The slightly better agreement

among assessors in our study group may have been attributable to the calibration session for the assessors that we conducted before the study. It seemed that no calibration session was conducted by Cardoso and experts from different geographic areas were used (17). The differences amounted to a slightly less favourable result in comparison to our study.

This finding was obtained in spite of the application in the study by Cardoso of the Delphi method, which applied several rounds of consensus finding among assessors in the process of subjective judgment. The Delphi method is a structured approach to the analysis of a research question through finding consensus of opinion among a group of experts. In a future study it could be interesting to question the level of agreement among assessors applying the Delphi method preceded by a calibration method under standardised conditions of evaluation and to conduct a comparison with the objective method.

The benefits of the Delphi method can be seen in its low cost and its not requiring the acquisition of any expensive equipment. The disadvantages are the lack of reproducibility of this subjective method and the need for repeated expert involvement.

The results of our study revealed that subjective breast assessment, even when it was conducted by experts, lacked reproducibility, which was in agreement with previous data (72). Kim (2008) voiced the opinion that the lack of a standardised, explicit scale for analysing breast aesthetics was a disadvantage and that a four-or five-point scale was too imprecise. Further research is required to investigate whether the application of a more detailed scale for subjective breast assessment would improve inter- or intra-observer agreement.

Another frequently-used method to evaluate the quality of breast reconstructions is the application of patient questionnaires (107). This approach has its own importance as patients are the ultimate beneficiaries of the advances of surgical technique. Questionnaires can be filled in by patients or doctors and are subjective methods of assessment. The benefits of questionnaires are that they are quick and easy to use and are not intimidating to patients. The use of questionnaires allows doctors to be independent from the professional input of various technicians, which makes them appear desirable. With tighter budgets, the advantage of being of low-cost seems to secure a role for them in future practice. However, the shortfalls of the subjective assessment method are clear due to the lack of accuracy and reproducibility. We hope our study will help doctors and hospital executives to realise the value of the 3D imaging method. The purely subjective method should be a method of the past. Many doctors and scientists who were disappointed with the limitations of the subjective method were previously encouraged to search for alternative routes of breast assessments. The wide range of methods for breast assessment is a clear indication of the ongoing dissatisfaction. Requirements for objective methods of assessments are that they present with a credible validation and could be applied globally. Many of the new objective methods that claimed to be an advance in comparison to previous solely relied on considerable subjective methods nevertheless still subjective professional judgment. However, objective methods should be largely independent from subjective influences. We expect that in the next few years 3D imaging technology will become part of daily surgical life once the difficulties associated with the required computational procedures and cost have been overcome. We hope our study well encourage the public recognition of the value of the 3D imaging method.

4.4 Part IV - Objective and Subjective Breast Assessment

The agreement between two methods, the established subjective assessment and the new objective evaluation, is an important judgment (8). We found significant agreement, which emphasised the value of the new 3D imaging technology. There was a negative relationship between both methods in the sense that an increase in the objective asymmetry score meant a poorer symmetry and correlated with a decrease in the subjective Harris score, which illustrated a poorer result. For the future it would be of interest to know if other surgical techniques could achieve the same level of matching between the subjective and objective assessments.

In our study, when the shape and volume of the breast were subjectively assessed in isolation for each breast, no strong relationship was detected between the objective asymmetry score and the subjective assessment. Therefore, we postulate that it is necessary to look at the breast as a whole and compare the reconstructed side with the non-operated side in order to achieve a balanced view that relates well to objective asymmetry scoring.

A plastic surgical pioneer, Maliniac, previously voiced his opinion on breast assessment (89, 131). Maliniac's statement in 1950 that the surgeon's sense of sculptural form must dictate the ultimate decision as to the replacement and shape of the breast should be changed sixty years later. We postulate in 2010 that the surgeon's subjective breast assessment should be supported by objective 3D imaging method in order to achieve an ideal reconstruction of the breast.

4.5 Part V - Future Research Projects

The 3D imaging method could support the preoperative planning and postoperative assessment of the surgical treatment of the breast as well as the long term follow-up. The method would be an invaluable tool in cases of breast hypertrophy, augmentation and breast asymmetry correction and it could be helpful in deciding on breast resection weight as well as on implant size, dependent on the case. The measurements that are obtained by 3D imaging could be compared with the volumes of mastectomy specimen that are assessed by water displacement. Furthermore, a comparison could be conducted with the certified implant sizes, as given by the manufacturers, when using breast implants for augmentation. This would provide further insight into the accuracy of the volume assessments in the live subject. An investigation into the clinical threshold of breast asymmetry in surgical cases by an objective method is emerging as a possibility.

A study of the identification and number of landmarks that could be used for breast assessment and their reproducibility would be of interest with the newly defined 3D imaging technology. The upper border of the breast could be examined by a comparison of the 3D imaging method with distances that could be measured from the upper inner border of a mastectomy pocket to the clavicle. The impact of body types and level of obesity on the identification of landmarks could be assessed comprehensively. The possible effect of weight loss or gain on the shape, size and symmetry of the breast could be readily investigated by applying 3D imaging technique and the developed breast analysis tool. The accuracy and reproducibility of the curved chest wall algorithm of the imaging software might be further examined for validation purposes and for this reason 3D imaging could be utilised on a variety of plaster models with differently curved back walls.

Clinical tests of examining the nature of the breast parenchyma by manually pinching it and other methods of assessing the parenchyma with parenchyma density scoring systems have been used to try to predict the volume increase that might be expected following augmentation surgery. 3D imaging and analysis of breast volume pre- and post augmentation would provide valuable predictive data in this group of patients.

Using the developed technology, the question of breast symmetry could be addressed in cases with naturally ptotic breasts. The suitability of Latissimus dorsi flaps in these cases for breast reconstruction procedures requires comprehensive evaluation. It would be of value to investigate whether the accuracy and reproducibility of measurements could be quantified dependent on the body posture of the person that is imaged and to assess if the upright position for breast capture should be abandoned after all.

The presented breast asymmetry score could be established in clinical practice with the help of the 3D imaging method and mathematical calculation. In a clinical study the breast symmetry that can be achieved after reconstruction with a Latissimus dorsi flap versus an extended Latissimus dorsi flap under inclusion of adjacent fat tissue could be compared. The impact of other surgical techniques, i.e. the DIEP flap, for larger breast reconstructions and the effects on symmetry might be questioned. The heights of the nipple areola complexes that can be influenced by various methods could be objectively compared. Recent advances of breast contouring operations by auto fat injections and the effects of fat reabsorption over time on breast shape and volume could be evaluated. The course of post-surgical swelling in comparison to true volume changes of the breast could be longitudinally assessed and volume changes measured for assessment of the newly developed method of breast augmentation by injection of hyaluronic acid. The differences between the laser scanning method and multiple stereophotogrammetry in evaluating breast shape and volume should be studied. 3D imaging method could provide an invaluable future tool for the validation of other breast assessment methods including MRI. In addition, 4D breast imaging might be interesting to the clothing industry to examine the movements of the breast while a person is walking or running and the need and impact of supporting bras.

Changes in the projection and movement of the breast after augmentation surgery and the influences of different body positions on breast shape and orientation warrant full examination. In breast reduction surgery the impact of surgical breast correction on the overall body posture should be questioned and objectively verified.

Recent advances have been made in combining expertise in the field of computeraided engineering with the field of medical 3D imaging and a contact with the automobile industry was initiated (60). Research questions that might be of interest in this context have to be clarified. Research so far has begun in the field of force-feedback applications (haptic modelling), the simulation of soft tissue deformations, biomechanics and the use of virtual reality simulations. Surgeons will rely in their work on the development of these methods by computer scientists, engineers and mathematicians before being able to implement these new methods into their own research projects and clinical practice. The use in clinical practice will involve the utilisation of the 3D imaging method for pre- and postoperative capture, superimposition of images, measurements of volume and shape changes and as a tool to visualise the probable postoperative result. Cooperation between different disciplines, computer scientists, software developers, mathematicians, technicians, designers, trustees, contractors, researchers and medical staff will be essential for future advances.

4.6 Part VI - Clinical Influence of three-dimensional measurements on reconstructive breast surgery

Patients who seek immediate breast reconstructions at the time of their mastectomy frequently do not wish to undergo any kind of surgical intervention on the contra-lateral breast for the purposes of symmetry of shape and/ or size. From a psychological perspective the diagnosis of cancer as such is traumatizing and patients often find it difficult to cope with the idea of having any kind of surgery on the breast that they regard as being essentially normal and part of their own body image. Until the advent of free-tissue transfers such as the transverse rectus abdominis mucle flap (TRAM) and/or the deep inferior epigastric perforator flap (DIEP), it was often difficult to harvest a sufficient amount of soft-tissue and skin to achieve a symmetrical breast mound without surgery on the contra-lateral breast. This was especially true in patients with large and/or ptotic breasts.

In patients who are undergoing skin-sparing mastectomies and immediate reconstructions, the skin envelope requirement can be met with a variety of reconstructive techniques, but the volume requirements pose a reconstructive challenge especially with larger breast sizes.

The autologous Latissimus dorsi flap for immediate breast reconstruction is very popular because of a variety of factors:

1. The operation is lesser in magnitude than free perforator based flaps.

2. The success rate in terms of associated flap-related complications is better.

3. Recovery is also quicker.

However, the objective assessment of breast symmetry revealed that the Latissimus dorsi flap for the immediate breast reconstruction after complete mastectomy did not sufficiently restore the volume of the breast. Breast asymmetry with the un-operated breast was recorded.

To date, at the Canniesburn Plastic Surgery Unit in Glasgow, routinely a skin sparing method for mastectomy and immediate breast reconstruction is used in order to preserve the skin envelop that is crucially important for the appearance of the shape of the breast. The skin sparing method has found acceptance all over the world. Our study revealed that the volume of the Latissimus dorsi flap was too small to fill this envelop. The patient group that we included into the study was recruited between 2005 and 2008, a time during which the method of enlarging the Latissimus dorsi flap by inclusion of additional fat tissue had been well established. However, based on the retrospective evaluation of the case notes, it was difficult to establish in how many cases this extended design had been chosen and to what degree the surgeons used this surgical technique. The amount of fat tissue that was harvested remained unclear.

It would be beneficial to quantify the amount of additional fat tissue in the extended Latissimus dorsi flap technique and the resulting effect on the overall breast symmetry after reconstruction. Currently the problem remains how to exactly and objectively quantify breast volume, shape and symmetry. We assume that even with surrounding fat tissue the method of breast reconstruction with the LD flap still does not provide the volume as deemed necessary.

Based on our results we postulate that 3D imaging should be utilized to objectively compare immediate versus delayed procedures and to compare outcomes across centres. In delayed reconstructions the lack of the skin-envelop is an important factor contributing to the asymmetry to the contra-lateral side. In delayed reconstruction we expect that the Latissimus dorsi flap will provide less good results and will fall short in achieving symmetry with the contra-lateral, un-operated side at even greater extent than in immediate reconstructions. However this assumption should be objectively assessed. A surface measuring method like multiple stereophotogrammetry seems to be ideal in order to achieve this goal.

The 3D breast assessment method provided an unprecedented opportunity to divide the mismatch between the reconstructed breast and the opposite site into four main sub-components: intrinsic breast shape asymmetry, difference in position, orientation and size. The sub-components of intrinsic shape difference and position of the breast were shown to be the factors contributing most to the overall breast asymmetry. This should be taken into consideration during breast reconstruction and should influence the surgical approach. Not only should the shape of the reconstructed breast match the opposite side, but also the position of the breast at its location on the chest wall.

The optimal surgical method for breast reconstruction after complete mastectomies is still disputed. In spite of the fact that for this purpose the TRAM and in recent years the DIEP are well established methods we observed the tendency by surgeons to abandon these methods in favor of the Latissimus dorsi flap reconstruction. The later method was used in a variety of ways, either on its own, with an additional implant, with an extended skin island or with repeated auto-fat injections to augment the lacking volume and shape at a later date. Contra-lateral surgery however was frequently required.

The reasons for the reluctance of many surgeons to choose a DIEP flap for breast reconstruction are probably multiple. They can be seen in the greater surgical difficulties that are entailed with a free-flap reconstruction and the lesser willingness to accept the possibility of a complete flap failure. The necessary surgical skill and the acceptance of the associated risks and complications are greater for a free-flap reconstruction. Theatre time usually is longer. Further problems with donor sites have to be considered, which years ago lead to the abandonment of the TRAM flap and the development of perforator based free micro-vascular methods of breast reconstruction, the most common of which to date is the DIEP flap. However, simple cost and management issues might play a role when methods such as the pedicled Latissimus dorsi flap are favored.

Nevertheless, in spite of the popularity of the Latissimus dorsi flap the quality of the outcome of the breast reconstruction is in no way near to be comparable with the outcome after a free perforator based flap from the abdomen. The DIEP flap has the potential for the best outcome as well as for the worst. Due to the lack of an objective method to quantify the quality of the surgical outcomes this is easily and perhaps purposely overlooked by health service managers in favor of more cost effective procedures. However, neither the patients nor the managers routinely are aware what excellent surgical results are possible with the best technique in contrast to what average results are usually achieved with standard measures. It also appears that the judgment of surgeons in view to advantages and disadvantages of surgical techniques can vary during time or in accordance to their surgical speciality and training. Oncoplastic breast surgeons often have no microsurgical expertise and are therefore only able to offer a limited range of reconstructive options. An interdisciplinary discussion and exchange is required to establish professional opinion. To date, at times TRAM or DIEP flaps were favored, then Latissimus dorsi flaps and currently it seems the Latissimus dorsi flap with additional fat grafting is the method of choice. The later however requires a repeated patient envolvement with consequent cost implications and it has to be awaited how this method will be overall judged in the future. The greater length of the free flap reconstruction method can lead to fatigue in surgeons and lesser willingness to choose this more difficult option.

The quantification of the amount of tissue volume that is needed for a breast reconstruction would be desirable and 3D imaging would be a helping tool in the choice of the reconstructive method. The appropriateness of the Latissimus dorsi flap for breast reconstruction could be decided upon. Currently the Latissimus dorsi method does not seem to be suitable in patients who are looking for perfection or even solely for very good symmetry. We would suggest a follow up study comparing the Latissimus dorsi flap with a DIEP flap reconstruction and evaluate if the objective asymmetry scores match our clinical experience that the DIEP flap is more suitable for the larger types of reconstructions. Can a link be established between the body mass index and the bra size of the patient to the weight of the mastectomy specimen to help in the treatment decision? Alternatively different methods of Latissimus dorsi flaps could be compared, such as these flaps by themselves, flaps with additional surrounding fat tissue, with an additional implant or with additional repeated auto-fat injections for volume augmentations. The study could be extended to other methods for breast

reconstructions such as the TRAM flap, the S-Gap flap or the Gracilis flap that could be objectively examined.

Previous studies have found that symmetry of the breast is a sign of beauty and it seems that this might be of utmost importance to the patient. However, so far it has not been established how much deviation of the goal of symmetry seems to be acceptable to patients and surgeons and how much asymmetry can be found in the natural breast. In contrast to symmetry, ptosis however was not considered to be part of the ideal breast shape. Therefore in cases of extensive ptosis, which usually is not considered to be a sign of beauty, it has to be discussed if a ptotic breast should be the reconstructive goal after mastectomy.

It is important to notice that previous subjective methods of the analysis of clinical results after breast reconstruction tended to be based on visual subjective ranking. However, the subjective scores are difficult to reproduce, especially if the order of photographs is changed. In contrast 3D imaging now provides an objective method for the ranking of clinical results.

With the current measures it is important to consult the patients pre-operatively to establish realistic patient expectations. The instrument of 3D imaging might emerge to a routine use for consultation purposes in breast reconstruction patients, however so far this has not been established yet. To date 3D imaging mostly has been used in the aesthetic sector for the pre-operative simulation of the likely surgical results after breast augmentation.

3D imaging would be a great instrument for surgical planning in order to establish pre-operatively the amount of volume that would need to be produced and the method that would be suitable for the individual patient. Both, the level of patient expectations and the willingness to undergo more extensive surgery will be decisive in the treatment decision.

Not only the planning of surgery could be improved, but also the evaluation of surgical outcomes, as results could be quantified and the degree of post-operative breast symmetry could be determined. The multiple stereo camera apparatus and software in its current state can be very efficiently used for audit purposes providing objective measurement data to volume, shape and symmetry. This application could be used to determine the quality of the results of surgical centres that are providing breast reconstruction services.

Software should be developed to simulate which donor sides might provide the necessary skin and if this area could also be quantified. The assessment of the surface area and shape of the necessary skin island solely is conducted subjectively or by help of linear tape measure. In the majority of cases in delayed reconstructions tissue harvest methods from the abdomen seem to be superior or alternatively expander implant methods could be used if an extended amount of skin needs to be provided in the reconstruction. 3D imaging might emerge as a great helping tool for surgeons in this surgical planning process.

In many cases the goal to achieve a mirror image with the un-operated breast after reconstruction is not achieved. To date there is no cost-effective alternative to achieve good symmetry other than through application of extensive surgical methods and preservation of the skin envelop. The available methods and considerations should be included into surgical training programs to improve the quality of future patient care. We call for a wider application of the perforator flap based methods of reconstructions such as the DIEP flap in contrast to the currently favored method of the Latissimus dorsi flap, which provides less skin and volume. We postulate that the Latissimus dorsi flap is a suitable method for the reconstruction after partial mastectomy and in cases of immediate reconstruction, however not in cases of complete mastectomy and delayed reconstruction except in the cases where the volume requirements are small. This is in line with previous published findings in the literature (66). The DIEP flap seems to be more suitable for the reconstructions where more skin is required. A multi centre study would be helpful to establish this further.

3D imaging would be invaluable in monitoring sequential volume changes of the reconstructed breast following adjuvant treatment such as radiotherapy, chemotherapy or repeated reconstructive procedures such as lipo-modelling in a comparative analysis. To date it is not possible to get an accurate analysis of the absolute breast volume as we cannot model the chest wall. The imaging plane is the surface of the breast and the chest wall is calculated by software algorithm. However, it might be possible to use the shape of the chest wall in patients after mastectomy, who are seeking a delayed breast reconstruction and create a mirror image with the un-operated side. This would assure the obtained measurements with the assumption that the chest wall is symmetrical.

3D photogrammetry has evolved with the advances in digital photographic Technology. Earlier systems used a projected speckle pattern which was used to calculate the shape of the contours on which the pattern was projected. However the advances in digital camera resolution now allows the same recreation of surface contours by looking at the surface texture of the object being investigated without the need for any projected patterns. The resolution of current day digital cameras is sufficiently high to use the texture of the skin such as pores, blemishes or other irregularities to generate a three-dimensional grid model, which can be used for the calculation of shape and volume. With current day developments 3D imaging could therefore be translated into clinical practice.

Summary

Increasing numbers of women are seeking breast reconstruction surgery which was acknowledged as an important part of breast cancer surgery to regain a high quality of life. Therefore an objective outcome measure by 3D imaging with multiple stereophotogrammetry is desirable. The benefit in comparison to other methods can be seen in the presentation of life-like images which can be used for objective volume, shape and symmetry analysis. The investigation of the accuracy and reproducibility revealed that the method was reliable for a comparative analysis of the breast. A clinical study in patients after unilateral breast reconstruction with Latissimus dorsi flap demonstrated that this reconstruction fell short in terms of the symmetry that was achieved, a degree of mismatch that could be quantified. Objective and subjective assessments matched. We judged the method as valuable and expect its future role to expand when problems with capturing the ptotic breast, as demonstrated in this study, are overcome.

5 Conclusions

This study demonstrated that the 3D multiple stereophotogrammetry system was reliable for recording breast shape and the method of analysis was reproducible in the live models. The method was reliable for a comparative analysis of the breast. The breast asymmetry score that was developed for analysis and evaluation of the appearance of the breast after reconstruction proved reliable and meaningful.

The size of the reconstructed breast was on average smaller than the nonoperated breast and this was objectively measured by the 3D breast analysis tool. The location of the reconstructed breast was the most important factor contributing to the overall asymmetry score. The results obtained by the subjective breast assessment method revealed substantial inter-observer agreement and fair to substantial intra-observer agreement, which substantiated the need for an objective assessment method. When the breast was investigated in terms of a comparison between the reconstructed and non-operated sides there was a significant match between the objective 3D breast assessment and the subjective assessment.

System requirements including the complete imaging of the breast surface and availability of software for measurement of volume and shape have been fulfilled. The presented breast asymmetry score supported the process of objective volume and shape analysis.

3D multiple stereophotogrammetry is an objective and reproducible method to quantify breast symmetry for clinical and research purposes. To improve the overall quality of plastic surgical care in modern times, a valuable outcome measure for this service has now emerged as a possibility. The physical and psychological demands of the surgical procedure of breast reconstruction are likely to be lessened through 3D imaging that has the potential to create the gold standard in the assessment.

In the current climate of audit, clinical governance and clinical quality assurance there is a need to develop systems which can produce reliable and standardized data for comparison of results assessing techniques, surgeons and treatment centres. The role of future 3D breast assessment by multiple stereophotogrammetry will expand from current aesthetic applications into the medical sector as soon as the problems of capturing ptotic breasts, as illustrated in this research study, are resolved.

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7 List of Abbreviations and Terms

BAT	breast analysis tool software	
BSI	breast symmetry index	
Capture	3D image taking by system	
C3D	clinical 3D software	
Coons patch	breast segment with chest wall base	
DiCD	digital capture software	
DIEP	deep inferior epigastric perforator flap	
Digitisation	recording coordinates of landmarks on the 3D image	
IMF	infra-mammary fold	
Jugulum	equivalent to sternal notch	
Jugulum Landmark	equivalent to sternal notch anatomical point on bony or soft tissue structure	
-		
Landmark	anatomical point on bony or soft tissue structure	
Landmark LD	anatomical point on bony or soft tissue structure Latissimus dorsi flap	
Landmark LD MRI	anatomical point on bony or soft tissue structure Latissimus dorsi flap Magnetic resonance imaging	
Landmark LD MRI Pose	anatomical point on bony or soft tissue structure Latissimus dorsi flap Magnetic resonance imaging body posture that the subject takes for capture	
Landmark LD MRI Pose Ptosis	anatomical point on bony or soft tissue structure Latissimus dorsi flap Magnetic resonance imaging body posture that the subject takes for capture natural hanging of the mature breast	

TRAM	transverse rectus abdominis muscle flap
3D	three dimensional
2D	two dimensional
Xiphoid	anatomical zone at caudal end of sternum

8 Appendices

- 8.1 Cover letter
- 8.2 Patient information sheet
- 8.3 Consent form, 3D imaging
- 8.4 Consent form, 2D imaging
- 8.5 Publications

Canniesburn Plastic Surgery Unit

Glasgow Royal Infirmary

84 Castle street

Glasgow G4 0SF

Dear Madam,

We would like to invite you to take part in a research project in 3D and 2D breast assessment after breast reconstruction.

Your participation is voluntary. The images will be kept confidential and will not show the face or the name of the participant.

Please find enclosed a patient information sheet and two consent forms for the 3D and 2D capture in case you would agree to participate.

We would be grateful if you would let us know if we would be allowed to contact you.

Please do not hesitate to ask any questions.

Kind regards

Helga Henseler

Consultant Plastic Surgeon and

Breast project researcher

Patient Information Sheet

A study to assess breast volume and symmetry following reconstruction with a latissimus dorsi (LD) flap using 3D stereophotogrammetry

You are invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others, if you wish. Ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this information.

What is the purpose of the study?

The most common method used for reconstruction of the breast following mastectomy is to move a muscle from the back of the shoulder to the breast region. The aim of this investigation is to assess the success of this procedure in reconstructing the breast and achieving a satisfactory shape and size, similar to the unaffected opposite side.

Why you have been invited to take part in this study.

You had this procedure carried out at the Canniesburn Plastic Surgery Unit in the Royal Infirmary.

Do I have to take part in the study?

It is up to you to decide whether or not you would like to take part in this study. If you decide to take part in this investigation, you will be given this information sheet to keep and asked to sign two consent forms.

What will happen if I decide to take part in the study?

If you consent to take part in this investigation, you would be asked to attend at the Canniesburn Unit, Glasgow Royal Infirmary for the breast to be imaged using 3D cameras and standard 2D cameras.

What are the side effects of this imaging?

There are no risks or side effects from these 3D images or 2D images.

What are the benefits of taking part in the study?

You may not have a direct benefit in contributing to this study, however, it would provide us with useful information regarding the success rate of reconstruction of the breast. Based on the findings, the surgical techniques may be fine-tuned and we will be able to provide realistic information regarding the anticipated result of this surgery for future patients.

Will my breast image be kept confidential?

All the information that is collected in this study will be kept strictly confidential. Any information that may leave the hospital for further analysis at the Statistics Department, will have the names and addresses removed so that they cannot be recognised.

What will happen to the results of the research study?

We intend to publish our findings in the medical press. Your image will not be able to be identified from the article. If you are interested, we can provide you with a copy when it is published.

Who is funding the research?

This study is being funded by the researcher's own resources.

Who has reviewed the study?

The study has been reviewed and approved by Greater Glasgow West Research Ethics Committee.

If you need more information or you wish to ask questions before you decide whether you will take part in this investigation, please contact Dr Helga Henseler, Canniesburn Plastic Surgery Unit, Glasgow Royal Infirmary, telephone 0141 211 5717



Version 2, 28.07.08

North Glasgow University Hospitals Division

Patient Consent Form (Adult)

Pilot study: Assessment of breast reconstruction using <u>3D</u> imaging

Patient's name: _____

Date c	of birth:			
			Yes	No
1.	Have you read the information sheet?			
2.	Do you understand the study?			
3.	Did we answer all of your questions?			
4.	Do you want to take part in this study?			
5.	Are you happy for your captured image to be used for publication?			
Who h	ave you spoken to?			
Dr/Mr/	Mrs/Prof			
Do you	u understand that you can change your mind at any time?	Yes 🛛	No	
Signe	d:			 -
Name	(print):			
Signat	ture of witness:			
Name	(print):			



Version 1, 28.07.08

North Glasgow University Hospitals Division

Patient Consent Form (Adult)

Pilot study: Assessment of breast reconstruction using <u>2D</u> imaging

Patie	ent's name:			_
Date	of birth:			
			Yes	No
1.	Have you read the information sheet?			
2.	Do you understand the study?			
3.	Did we answer all of your questions?			
4.	Do you want to take part in this study?			
5.	Are you happy for your captured image to be used for publication?			
Who	have you spoken to?			
Dr/M	r/Mrs/Prof			
Do y	ou understand that you can change your mind at any time?	Yes 🛛	No 🛛	
Sign	ed:			
Nam	e (print):			
Sign	ature of witness:			
Nam	e (print):			

The 14th International Congress of the International Confederation for Plastic, Reconstructive and Aesthetic Surgery June 26 – 30, 2007 - Berlin, Germony

and volume measurement.



Validation of 3D imaging system using multiple stereo cameras

Henseler H.^ 1, Khambay, B.^ 1, Oehler S.^ 1, Siebert P.^ 1, Ray, A.^ 1, Bowman, A.^ 1, Hu H.^2, Ayoub A.^ 1 1 Glasgow / GB, 2 Melbourne/ AU

1. PURPOSE

The need for and value of breast reconstruction is universally accepted. The surgeon strives for and the patient desires breast symmetry. The ideal reconstruction is the creation of a mirror image of the unaffected breast which may not be fully achieved (Figure 1).



Figure 1. Acase showing breast reconstruction after mastectomy

Very few methods exist to record this complex three dimensional structure. At present the majority of the evaluation of breast volume, symmetry and shape is subjective. Nevertheless the assessment of the marghology of this anatomical area is of great importance in surgical planning, assessment of the quality of reconstruction and follow up after treatment.

Recent advances in stereophotogrammetry "3D imaging" have been utilised to routinely capture facial morphology (1,2). Lately this technique has also been applied in the field of breast capture to assess breast reconstruction surgery. However this new application has yet to be validated. To date no extensive, reliable or repeatable validation of measurements with a multiple stereo camera system has been carried out.

The aim of this study is to assess the validity of a system for measuring breast volume using a 3D stereophotogrammetry imaging system (Di3D/C3D).

2. METHODS AND MATERIALS

Six plaster breast models of different shapes, sizes and volumes were constructed and painted to reproduce natural skin colour and texture (Figure 2).



Figure 2. Six plaster breast models of different size, shape and volume

The volume of each plaster cast was measured by 2 different methods: water displacement (gold standard) and 3D stereophotogrammetry.

Each plaster breast was fully immersed in water and the displaced water weighed. According to Archimedes' principle the weight of the displaced fluid is directly proportional to the volume of the displaced fluid. This was repeated 10 times by each of two operators for each plaster breast model. Following this each plaster cast was mounted onto a back board (Figure 3) and captured once using the stereophotogrammetry system (Di3D), the image was landmarked and volume was measured 10 times. The system comprised of 4 pods each with 2 cameras (Figure 4). The imaging system was calibrated using the calibration target and software (C3D).

Figure 3. Plaster breast model secured onto back board for 3D capture.

d Figure 4. Di3D stereophotogrammetry imaging system





Each file was then masked, merged and built to produce a 3D model (Figure 5).



Figure 5. Screen capture of masked, merged and built 3D model

Inner eld of as yet ments displacement and with 3D imaging. Mean and standard deviation displayed.

Figure 6. Close-up of 3D model ready for volume

measurement using Breast Analysis tool

Plaster	Water displacement Examiner 1 (cc)	Water displacement Examiner 2 (cc)	Volume 3D imaging (cc)
breast	Mean ± SD	Mean ± SD	Mean ± SD
Model 1	364.2 ± 3.8	356.0 ± 2.8	374.9 ± 0.2
Model 2	434.3 ± 2.3	426.6 ± 2.5	457.8 ± 0.4
Model 3	578.7 ± 2.2	568.4 ± 2.0	586.7 ± 0.6
Model 4	230.6 ± 3.9	222.1 ± 1.5	241.2 ± 1.4
Model 5	433.1 ± 2.0	423.8 ± 1.8	486.3 ± 1.3
Model 6	591.3 ± 1.9	581.6 ± 3.9	617.9 ± 0.8

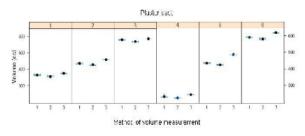
The image (Figure 6) was loaded into the Breast Analysis Tool software developed by the

Department of Computing Science at the University of Glasgow for landmark placement

The systematic differences between the data and the size of the variance were examined.

In each case the volume recorded by examiner 1 with water displacement was consistently higher than the volume recorded by examiner 2. Further, in each case the volume recorded by 3D imaging was consistently higher than the mean volume recorded with water displacement method. This was true for all casts (Figure 7).

Figure 7. Box plot showing three volume measurements for each of the six plaster casts using water displacement (1 & 2) and 3D stereophotogrammetry (3).



The differences in volume measurement with water displacement and 3D imaging was less than 50 cc in most cases which is of limited clinical significance (3). This difference was less than 5% in most cases.

4. CONCLUSIONS

We conclude that the 3D stereophotogrammetry system is valid, reliable and can be utilised for objective assessment of breast reconstruction.

5. REFERENCES

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stagung der DGPRÄC 13. Jahrestagung der VDÄPC 46. Jahrestagung der ÖGPRÄRC 2. bis 4. Oktober 2008 - Haus der Wir





Validation of a multiple stereo camera system for 3D capture of the breast

Henseler, H., Ray, A., Khambay, B., Xiang, Y., Siebert, P., Bowman, A., Ayoub, A., Biotechnology and Craniofacial Science Section

Glasgow University

Introduction

The incidence of breast cancer and the need for mastectomies are increasing. Patients undergoing breast reconstruction following mastectomy may desire breast symmetrisation. The surgeon who is planning the operation aims at creating a mirror image of the healthy breast, although this is not always achieved. There is a wide range of very good to very poor results after reconstruction (Fig. 1 and 2).

A multiple stereo camera system for 3D capture of the breast could help the surgeon in surgical planning and assessment of the outcome. So far, most surgeons relied on a subjective approach for evaluating the quality of the reconstruction following mastectomy.

Three dimensional imaging with multiple stereo camera systems has been utilized for assessment of the breast (Losken, et al., 2005, Moyer, et al., 2008). However the reliability and validity of these systems in measuring breast volume has not been fully assessed.

The team in the West of Scotland based at Glasgow University has developed a new 3D capture system which consists of 4 stereo pairs of

addressed and the validation of the new system was required (Fig. 3). It is our aim to utilize this system to evaluate the quality of breast reconstruction following mastectomy. This presentation is focused on the pilot investigation to evaluate the validity of the system to capture accurately the breast and determine the volume (Fig. 4).

digital cameras. Calibration of this eight camera system had to be



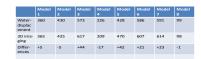
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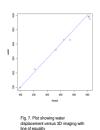
Fig. 3. Calibration target



Results

Table 1. Volume measurements of plaster breast models by waterdisplacement and 3D imaging through C3D and BAT





by water displacement and by 3D imaging did not exceed 50 cc (Table 1).

Figure 7 shows the level of consistency between the two methods used in the study to measure breast volume. The greatest volume difference between water displacement and 3D image was due to incomplete calculation of the infra mammary fold region. This would be avoided by adjusting of the patient's pose at the time of capture.

Conclusion

We conclude that validation of a multiple stereo camera system for 3D breast capture is valid and the breast analysis tool is reliable to measure the breast models.

Reliability in the life model will need further investigation.

References

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Method

The volume of seven different plaster breasts was determined by water displacement and by stereo photogrammetry (Fig. 5 and Fig. 6). The plaster breasts were of varying shape and size. Each plaster model (1 to 6) was mounted on a flat board while model 7 was mounted on a curved back. An eighth model was also included which represented a hemisphere of known dimensions.

Following 3D capture the volume of each three dimensional model was measured using software developed at the University of Glasgow (Breast Analysis Tool). These volume measurements were then compared to those obtained by water displacement.



Fig. 5. plaster breast r



Fig. 6 Water displacement system for plas

Validation of a 3D multiple stereo camera system Reproducibility of breast assessment in the live model



Henseler, H., Khambay, B., Ray, A., Bowman, A., Siebert, J.P., Ayoub, A. **Biotechnology and Craniofacial Sciences Research Group**

Results

40. Jahrestagung der DGPRÄC Deutsche Gesellschaft der Plastischen, Rekonstruktiven und Ästhetischen Chirurgen e.V. 14. Jahrestagung der VDÄPC Vereinigung der Deutschen Ästhetisch-Plastischen Chirurgen e.V. 10. bis 12. September 2009 – HCC Hannover Congress Centrum - Hannover

Introduction

University of Glasgow

Stereophotogrammetry has become an established method for objective volume and shape analysis in the face, recently the method has been used for breast imaging. At present the evaluation of breast shape and size relies on subjective assessment. An objective method for breast evaluation would advance surgical planning and quality control significantly.

Aim

Determine the reproducibility and validity of a multiple stereo camera system to capture 3D breast images in live subjects

Method

The breast was captured using an imaging system made up of eight cameras divided into four pods. This allowed full capture of the breast from the front, right, left and below utilising the four stereo camera pairs. Prior to breast capture the system was calibrated to allow simultaneous accurate localisation of the geometry of the breast by all the cameras.

The study was conducted on six volunteer models. A custom designed rig (Fig 1) was used to minimise posing errors associated with breast capture. Positioning was conducted by leaning forward in the rig in order to allow the breast to lift off the chest wall so that full breast capture was achieved. This was repeated six times to assess the reproducibility of the method.

For comparison a specially built water displacement system for breast volume measurement was utilised (Fig 2). A plastic bowl was filled with water and levelled off with a plastic board, the volunteer fully immersed her breast slowly and carefully into the plastic bowl, water overflew, which was collected underneath and the volume obtained. The method of water displacement was repeated for each model six times to assess the reproducibility of the method.

Figure 1. Volunteer live breast model positioned in rig of camera system





Figure 2. Volunteer live breast model

Each camera pod obtained part of the breast capture through Di3D software (Fig 3).

Figure 3. Images cantured by each of the four camera pods



The images were merged together by C3D software and a three dimensional model was built, which could be viewed either as a textured model (Fig 4) or as a grey shaded model (Fig 5) in three different viewing windows and rotated. Breast volume was measured with breast analysis tool software (BAT) developed by Glasgow University(Fig 6).

Figure 5. 3D breast model

Figure 4. 3D breast model visualised as a textured model

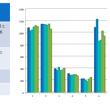


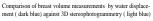


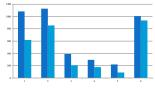


Comparison of breast volume measurements by water displacement against 3D stereophotogrammetry 1128 32.4 220 : 24 1006 : 141.6 1083 34.6 390 ± 21.5 295 : 12.8 854 ± 46.1 207 ± 22.1 176± 22.9 89 ± 29.1 936± 25.9 + SD 851 991 298.5 235.5 154.5 971 ice 464 119 113 274 183 70

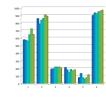
Reproducibility of breast volume nts by water displacement



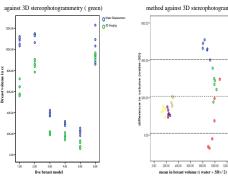




Reproducibility of measurements by 3D stereo photogrammetry



Comparison of water displacement method (blue)



Bland Altman plot of water displacement method against 3D stereophotogrammetry

2.08 3.08 4.08 5.08

3D imaging by multiple stereophotogrammetry in the live subject was more

reproducible than water displacement method for breast volume measurement at a within person standard deviation of 36 units/ cc and 62.3 units/ cc respectively.

The difference between the two groups on average was statistical significant at a p < 0.0001, mean 207.05 cc (95% CI= 156.9, 257.1).

There was no correlation between the size of the breast and the variability of the measured volume.

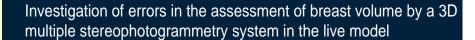
Discussion

In clinical measurement comparison the true measurements often remain unknown. Therefore indirect methods are applied to assess the degree of agreement and investigate the reproducibility of the methods. In our study the differences in breast volumes obtained by the two methods were considerable and the magnitude of the variation was nearly twice as large for the water displacement method than the one for stereophotogrammetry. This could be due to effects of posing of the live model, depth of immersion of the breast into the water, design of the measurement system, breast boundaries and anatomical area

Conclusion

We conclude that the reproducibility of 3D stereophotogrammetry for breast volume assessment is good and validation in the live model has been achieved.





Breast volume



Henseler, H., Ray, A., Khambay, B., Siebert, P., Bowman, A., Smith, J., Ayoub, A.



Biotechnology and Craniofacial Sciences Research Group, Glasgow University

Annual Meeting of German Society of Plastic, Reconstructive and Aesthetic Surgery, 2010, September, 14-18, Dresden, Germany

Aim

Measurement errors in breast volume assessment in live models were investigated under application of a 3D multiple camera system.

Methods

Our 3D multiple stereophotogrammetry system consisted of eight digital cameras, arranged in four camera pods with a stereo pair of cameras each for capture of a subject, who was taking a special pose in a positioning frame (Fig. 1). The breast of six live volunteers was captured simultaneously from the front, right, left and from underneath by each of the four camera pairs. Capture was repeated six times. Especially the view from underneath was considered as important to achieve full breast capture (Fig. 2). Three dimensional images were built (Fig. 3), four corner landmarks around the breast were recorded on the 3D image with breast analysis tool software (BAT) (Fig. 4) and breast volume was measured (Fig. 5).

A special position in a wooden rig had to be taken by each volunteer that was kept during two sets of three captures. This repositioning of the live model provided the posing error.

The six repetitions of the captures provided the capture error.

For each capture one three dimensional model was built and breast volume was measured 3 times; therefore altogether 18 measurements were obtained. This provided the measure up error of the method.

The variability of the results is understood as the error of the measurements.

Figure 1. Volunteer positioning herself in positioning frame of

*** ***

Results

Breast volume

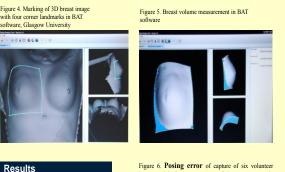


Figure 3. 3D Image built by computer software (C3D, Glasgow University,) after capture

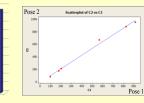








breast models, between two sets of three captures each, not significant at 95% CI (-77.3; 11.9), p-value of 0.119, mean standard deviation over six live models for pose 1 of 7.6%, for pose 2 of 4.9%, for both of 6.25%





Light blue: pose 1, first three Dark blue: pose 2, second th

Figure 7. Capture error derived from 6 repeated captures in six live models

mean standard deviation over all six models was 11.5 %

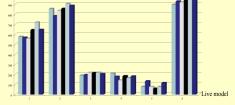


Figure 8. Measure up error after 18 measurements with BAT software in six live models, mean standard deviation over all six models was 12.8%.

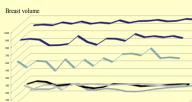
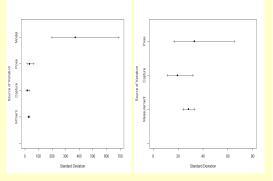


Figure 9a. Variability of the 3D imaging results The largest component is the model itself at a stdey of 369 73

Figure 9b. Variability of the 3D imaging results displayed for the three smaller components, the pose at a stdev of 32.95, the BAT measurements at a stdev of 28.32 and the capture of 19.43.

BAT measurements

14 15 16 17 18



Breast volume = overall mean + model + pose + BAT measurement + capture

Discussion

The investigation of errors is an important step towards the validation of any measurement technique. Errors derive from the variability of the measurements through the assessment of the reproducibility. The analysis of the errors of a 3D capture process was based on a mathematical model, the mixed linear effects model, which proved to be sufficient for the determination of the single components that were contributing to the error assessment.

Conclusions

We conclude that the errors of the 3D multiple stereophotogrammetry system for the measurements of the breast volume in the live model have been successfully assessed and are by far the largest due to intrinsic factors in the live model itself followed by variations in the measurements due to pose, BAT measurements and capture.





The importance of the pose in 3D imaging of the Breast

Henseler, H., Smith, J., Bowman, A., Khambay, B., Ju, X., Ray, A., Ayoub, A. Biotechnology and Craniofacial Sciences Research Group, Glasgow University

Annual Meeting of the German and Austrian Society of Plastic, Reconstructive and Aesthetic Surgery, 2011, September 29th till October 1st, Innsbruck, Austria

Results

Introduction & Aim

3D imaging of the breast has recently emerged as a new method for the objective assessment of the breast. The problem of achieving complete capture of the breast has not been fully solved yet. This is mainly due to the ptotic breast shape, which is visible in the majority of patients; the sub-mammary fold remains obscured when breast capture is conducted in an upright body posture. We aimed to investigate, if full breast capture could be achieved by adopting a special pose during imaging using stereophotogrammetry.

Methods

A prototype 3D imaging system was utilised (Fig. 1). It consisted of eight digital cameras, arranged in pairs on four pods for simultaneous capture of the breast from the front, right, left and from underneath. Before capture the system was calibrated using a target object to allow simultaneous accurate localisation of the geometry of the breast by all the cameras (Fig. 2). The reliability of the system has been previously investigated (1).

A special pose was taken by the subject in a custom made positioning frame (Fig. 3). The volunteers were standing on an adjustable standing step, leaning with the hips against a soft-coated hip roll while stretching forward with the upper body to a nearly horizontal position and reaching with the arms forward to rest on arm boards. By this pose the breast was lifted off the chest wall and kept hanging downwards to enable full breast capture.

To assess the errors of the method and the reproducibility of the pose the breast capture was repeated three times at two different occasions. Each capture provided a 3D image (Fig. 4) which was measured three times with breast analysis tool software (2). Using a custom designed software (Breast Analysis Tool, BAT) the reproducibility of the pose, reliability of the capture and software measurements were investigated and graphically displayed in a lattice plot (Fig. 5).

Fig.1 Multiple stereo camera system



Fig. 3 Volunteer taking pose in 3D imaging system





Fig. 2 Calibration of system

Fig. 4 Pathway of 3D image built-up

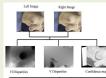
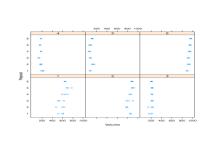




Fig. 5 Reproducibility of the pose, capture and Bat measurements



The investigation revealed that with the help of our custom made positioning frame the complete capture of the breast, even in the ptotic breast shapes, was successful.

The assessment of the reproducibility of breast volume measurements revealed a standard deviation of the pose of 6.25 overall. The posing error between the first and second pose was found not to be significant at 95% CI (77.3; 11.9), p= 0.119.

The standard deviation of the captures was 11.5 and of the breast analysis tool software measurements 12.8, revealing that the pose was the variable with the smallest variation.

Discussion

Commercially available 3D imaging systems, currently on the market for 3D breast capture, tend to capture the patient standing in upright upper body posture (<u>www.3dM.com; www.axisthree.com;</u> <u>www.canfieldsci.com</u>; <u>www.directimensions.com; www.censetech.com</u>).

Capturing the breast from the front however does not record the submammary fold, which remains obscured as the breast rests on the chest wall in upright position. Multiple cameras systems are required to allow a comprehensive capture of the breast for full analysis. Adjusting the pose to lift the breast off the chest wall would facilitate the complete capture of the breast using a 3D imaging system.

Conclusions

Capture of the female breast should be taken when the subject is bending forward with the upper body, so that the sub-mammary fold opens up and full breast capture can be achieved. This is essential especially in ptotic breasts, which represent the majority of breast shapes.

References

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