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AN ASSESSMENT OF POSTERIOR COMPOSITE RESTORATIONS IN A NON-ADULT POPULATION.

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SUMMARY

Composite restorative resins were introduced initially as replacement to alumino-silicate and methylmethacrylate anterior restorative materials. However, success of these new materials created a demand for an aesthetic posterior composite as an alternative to amalgam. Unfortunately, early trials showed that the anterior materials were inadequate in the new clinical situation (e.g.excessive material loss).

Since the early trials, posterior composite materials have been greatly modified and are now claimed to be much improved than the original formulations.

Prior to the beginning of the investigations described in this thesis, clinical testing of such materials had been carried out in trials involving child and adult patients, and had not shown comparable results either within, or across age groups.

Loss of material from the composite resins (i.e. wear), had been noted, particularly when used in the posterior situation. Assessment of the quantity of wear had been estimated by various means, but little accurate wear measurement had been reported in relation to clinical trials.

The aim of the present work was to test two posterior composite restorative materials (Herculite and Occlusin)

against a non-gamma 2 dental amalgam, in a pragmatic clinical study and to measure the material loss.

A non-adult group i.e. ages ranging from 7 - 18 years, was chosen, as subjects of this age had not been reported on previously. Furthermore, their dental occlusion is in a state of development which could affect the wear pattern of a composite material. A clinical assessment system (USPHS) was adopted, and the restorations graded over a two year period.

Replica casts were made at each assessment stage and used for evaluation. A stereo-microscope capable of measurement in three-dimensions, was employed to assess material loss.

As with other studies over such a relatively short clinical time-span, caries incidence was not a factor. in any of the three study groups. However, the trial showed that neither composite material performed entirely satisfactorily in the posterior restorative situation. Occlusal marginal adaptation of the composite, Occlusin, was assessed to be significantly better, whereas the retention of anatomical form was significantly better with the composite, Herculite. As both these parameters could be regarded as measures of material wear, the clinical trial findings did not indicate clearly a better performance of either material.

The surface roughness of Herculite was found to be significantly lower than that of Occlusin with the former maintaining its surface smoothness over the two year period.

The percentage of perfect margins for all three materials, identified by stereomicroscopy at baseline, was low and dropped further over the two years. Wear was quantified by measuring both the step discrepancies at the cavo-surface margin and the length of cavo-surface margin involved. Each composites exhibited wear over the two year period and, on average, was similar to that reported by other workers, although the involvement of the cavo-surface margin for Herculite was lower over the study interval possibly indicating a slower wear rate. Each wear parameter was correlated separately with the restoration and tooth areas.

The relationship between the two study phases i.e. field and laboratory, of each materials' performance was poor, with no material's field trial assessment grades showing an agreement of greater than 65% with the laboratory results. This agreement was even poorer when the Alpha grades alone were compared, where the Amalgam and Occlusin correlation fell to approximately 25%, while Herculite maintained a 50% level over the two years.

This low relationship indicated that neither assessment parameter on its own would give the overall view of any materials effectiveness.

The pragmatic structure of the study was chosen deliberately to place the trial materials in as robust a clinical situation as possible. This type of trial is worthwhile but, from the current project, the balance between an explanatory and pragmatic approach must be established to reduce the variability reported here, while still permitting a "real-life" assessment of clinical materials.

Additional studies using the modification suggested above must be undertaken to test new formulations of restorative materials, but these must be accompanied by accurate indirect measurement of the materials' performance for a complete overview.

The length of such a clinical trial might well be reduced as the indirect assessment technique employed in this thesis may indicate changes much earlier than would be clinically apparent. This would be particularly important as new materials or new formulations of established materials are being introduced with increasing frequency to the dental profession.

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DECLARATION

This thesis is the work of the author under the direction of his supervisors.

CHAPTER 1

Literature Review

1.1 Introduction

This review will consider the development of dental posterior composites and their classification. Criteria for assessment of the clinical performance of the materials will be discussed as will the number of examiners required for an assessment procedure.
Application of such assessments to paedodontic and adult surveys will be considered and methods of quantifying the wear of composites, detailed.

1.2 Development of Posterior Composites

Bowen (1) defined a composite restorative material as a man-made three dimensional combination of at least two chemically different materials with a distinct interface separating the components.
Composite resin restoratives have helped to provide more stable and aesthetic restorations in anterior teeth than those previously available i.e. silicates and unfilled acrylic resins.

These anterior composites have a wide range of shades which, together with their ability to adapt -in part- to tooth colour, made matching the tooth shade more straightforward. They also proved themselves to be more durable than other materials. The aesthetic success of these anterior restoratives led to a demand for composite resins that could be used in posterior teeth as a possible replacement for dental amalgam.
However, such change of purpose required a distinct advance in the formulation of composite resin materials to enable them to cope with the heavier occlusal loading in posterior teeth. Nevertheless, the rate of posterior composite development has been rapid, as has the appearance of these materials on the dental market.

Clinical trials have been carried out on a number of posterior composites. Studies on early products showed either a high degree of material loss, or occlusal wear, but the more recent formulations have indicated they may be a substitute for amalgam.
Clinical trials have, in the main, been tightly controlled and involved either children under 8 years of age - where the deciduous or first molars were restored, or adults - where the material has been used as (a) the primary restorative material, or (b) an amalgam replacement.

Modern composite resins are a development of the unfilled methacrylates introduced in 1948, and commonly used throughout the 1950's. The early restorative materials exhibited a number of significant disadvantages e.g. high polymerisation shrinkage, as reported by Smith (2); poor colour stability noted by Caul(3), and a history of pulpal effects due, in part, to the presence of free monomer reported by Grossman (4), and Kramer (5).
The development of the acrylic resins continued in the late 1950's and early 1960's, but never attained any major share of the dental restorative market as the Bis-GMA resin-based restoratives had by then become available.

Composite materials were based on a resin which was a reaction product of Bis-phenol A and Glycidyl Methacrylate. This resin was patented by Bowen (6), and exhibited distinct advances over the original, filled methylmethacrylate formulations.

Craig (7), Assmussen (8), Smith (9), Jones (10) and Ruyter (11), all documented adequately the development, chemistry and composition of the restorative composite material, and a clinical overview of their status was reported by Phillips (12), and Leinfelder (13). Jacobsen (14) supported their use, but again emphasised the

associated problems, particularly dimensional change and abrasion resistance. Lewis (15) and Sulong & Aziz (16), reviewed aspects of posterior composite wear, and Kreulen & van Amerongen(17), methods of measurement. All, in effect, suggested that clinicians should be more conscious of the shortcomings of the materials and investigate them in carefully planned surveys.

Early restorative composites were either two-paste systems, or paste-liquid presentations using chemical initiation. Later products used ultra-violet light initiation, where the application of UV light (340-380 nanometres) for 30-60 seconds, released free radicles which allowed the setting reaction to take place. Although this system gave the operator control over the setting reaction, it was considered to be potentially harmful, and was withdrawn from commercial use until proper filtration was incorporated into the apparatus. Visible light (350 - 510 nanometres) initiation is now the most commonly used, as it permits greater control of composite manipulation.

1.3 Classification of Composite Resin Materials

A classification of composites was proposed by Lutz & Phillips (18), who suggested four main divisions, based on the size and types of filler particles.

(i) Traditional composite resins

Traditional composite resins were filled originally with heavy metal glasses ground to size - the average being approximately 100 μm. This type of filler tended to be harder than the resin matrix, hence finishing was difficult, and the particles were subject to "plucking". The more modern fillers are now smaller, softer and more rounded, giving an improved inorganic filler content. The newer materials also incorporate silane bonding, have better shelf-life, handling characteristics, wear resistance and radiopacity.

(ii) Hybrid composite resins

With these products, the resin is reinforced with microfillers to provide better viscosity and wear resistance. The composite contains inorganic macrofillers together with pyrogenic silica. The surface finish is better than the "traditional" composite, but is not ideal.

(iii) Homogeneous microfilled composite resins

Here, the resins are filled with directly admixed microfillers of 0.04 μm size. These smaller fillers are invisible to the observer and provide good surface finish. The homogeneity lessens the problem of "plucking", thus maintaining a good surface.

(iv) Heterogeneous microfilled composite resins

These composites contain directly admixed microfillers and microfiller complexes of three possible types;

i) splintered pre-polymerised
ii) spherical polymer-based
iii) agglomerated

These products provide good finishing,and wear resistance but some have shown a greater degree of contraction setting than others.

Leinfelder (19) proposed a simpler classification and divided composites into four groups, in terms of the magnitude of the particles:

(i) conventional - particles sizes ranging from 30-50 μm,
(ii) intermediate - particles sizes ranging from 1-5 μm,
(iii) fine - particle size of 0.5 μm,
(iv) microfine - particle size no greater than 0.05 μm.

The composite clinical trials to be discussed, will be reviewed using the Leinfelder classification (19);(20). It is a simpler classification than others, particularly

as some of the newer materials only provide information on particle size, and but none relating to the derivation of the incorporated particles.

1.4 Clinical Assessment

Jacobsen (21) has noted that the number of clinical trials of new dental materials has increased over the last fifteen years, in contrast to the situation whereby early products appeared on the market with no trial-related research support.

Schwartz & Lellough (22) were the first to recognise that all clinical trials were not of a similar nature. They considered there were two types of clinical trial, and adopted the terms "explanatory" and "pragmatic".

Discrimination between the two trial types was discussed by O'Mullane (23) who suggested that clinical research should be considered as a two-stage situation. Firstly, a material should be subjected to laboratory testing, followed by an explanatory clinical trial whereby the new product would be assessed under ideal situations, in a closely supervised clinical environment. In this way it should then be possible to report on a material's properties as tested under the best possible conditions.

The second stage of assessment suggested by O'Mullane (23), was that of the community, or pragmatic trial.

In this case, the material would be subjected to real-life situations. There would be no close supervision, and the material's performance in the more "robust" environment of general usage could be monitored. Products could then be recommended if they performed well in both explanatory and pragmatic trials.

Jacobsen (24) supported O'Mullane's suggestion that the explanatory trial required to be set-up with variables as closely controlled as possible, in order that the material itself could be assessed without influence of any extraneous factors. The pragmatic trial, on the other hand, would show its performance in the everyday conditions experienced in general dental practice.
Downer & Mitropoulos (25) also defined explanatory and pragmatic trials, pointing out the aims and benefits of both. They emphasised that the experimental clinical trial (explanatory) should be conducted in conditions designed to give an agent the best chance to show its properties, and must involve pre-selection of trial subjects - in contrast to the pragmatic type.
Wilson (26) detailed the advantages of the explanatory trial, stating that this trial type provided a good database, and indicated methods for improving the material tested. However, he further commented that the pragmatic trial, performed in "the real world", although

showing wider variation of results, produced evidence of the material's effectiveness when used in more robust situations.

It can be argued that the true success of a dental restorative material may only be gauged by its performance in the day-to-day clinical situation. Thus, while the properties of a product can be measured by material scientists using a range of tests, no matter how sophisticated these may be, they can only provide a guide to the eventual clinical performance of a material when used to restore a patient's teeth.

Ryge (27) commented in 1972, that most accepted materials in use at that time, had been studied extensively under laboratory conditions, whilst little practical information was available on their long-term success within the mouth.

He noted also, that dentists had little scientific back-up to guide them when deciding which new materials to use, as most information was in the form of unrefereed product testimonials.

Cvar & Ryge (28) commented that practising dentists were placed in the position of choosing restorative materials with little practical clinical information on their performance over time within the oral environment.

Practitioners have a number of sources of information about new products, these are:

i) journals, both refereed and unrefereed,
ii) information gained from attendance at courses,
iii) other colleagues' experiences,
and
iv) information from suppliers or manufacturers.

Unfortunately, many of the reported "clinical assessments" are over short time-periods; manufacturers wish to have their new materials on the market as soon as possible, in order to gain a return on the investment. Hence there is a distinct paucity of clinical data regarding the long-term performance of materials in the robust atmosphere of general dental practice.

1.5 Clinical Trials

Assessments of the performance of composite are mainly of the explanatory type of design. Indeed, none of the major studies reported in the literature since 1970 has been undertaken using the field trial (pragmatic) approach. Only in the pragmatic study of three composite materials did Mair et al (29) detail that the general dental

practitioners placed the restorations, without detailed protocol guidance.

It is essential that research into the value of new dental materials is based, not only on laboratory and closely related trials, but relates also to the clinical users, by utilizing the pragmatic approach suggested by O'Mullane (23). This is essential if the dental practitioner is to feel that the academic- or hospital-based operator working in an explanatory trial mode, is not working in a "protected" environment and producing results inapplicable to general practice.
The explanatory trial type can provide indicative "best performance" results, whereas the pragmatic trial can give results more related to every-day life in general dental practice.

The following may be regarded as essential components for any clinical trial:

i)- the new material must be compared with an established material,

ii)- the restoration must be placed by a clinician,

iii)- randomisation for both material and placement position,

iv)- the material assessment must reflect the clinical entities being investigated.

and should the trial be of an explanatory nature

v)- the protocol should reduce the operator variability to a minimum, by giving explicit instructions

1.6 Assessing the Value of New Restorative Materials

Self-, or peer-review was seen by Schonfeld (30) as a means of ensuring the best possible treatment and rehabilitative care is made available to the patient. This type of review is not a new concept, and Schonfeld quoted from McCluggage's History of the American Dental Association (31) where, it was reported, a survey had been instituted in 1846 in which its members were asked to note clinical failures, and their considered cause of such faults. However, no guidelines were given by the Association as to the criteria to be employed for judgement. Schonfeld (30) commented that any survey must be based on guidelines or standards, otherwise self-evaluation criteria would be devised by each individual practitioner.

That dentists vary in their perception of which criteria should be assessed, and the level of assessment, has been demonstrated by Elderton (32). Diverging

interpretation of set criteria and the high rate of inter-and intra-examiner variation could also cause the results of any assessment system to be questioned (33);(34).

For many years, subjective decisions have been used to assess the quality of dental restorations. It has been stated that the use of objective assessment methods with good repeatability, would allow the quality of restorations to be more closely and accurately defined (32).

Subjective decision-making was recognised as a problem in the marking of dental students' examination papers and a formalised evaluation procedure was introduced by Natkin & Guild after troublesome inconsistencies in marking were discovered(34). The system was based on the principle that a pass grade could only be downgraded when certain errors were recognised. The errors were given a separate weighting for the degree of seriousness.

This systematic evaluation and grading procedure did improve the reliability.

Swallow et al (33) stated that a major problem of using subjective criteria was the difficulty in employing them on a wider scale outwith those of the original workers.

These authors went on to suggest alternatives:

i) the use of objective measurements as suggested by Elderton (32).

ii) the use of pairs of examiners as suggested by Ryge & Snyder (35).

and

iii) accept that intra- and inter-examiner variation exists, and measure the variation from the standard.

However the authors pointed out that condition - (i) would be time-consuming, difficult to use in field trials, and would be subject to a reduced variability. Nevertheless, while condition - (ii) could be a solution, the assessors had to be trained and agree, although this only increased concordance without improving the objectivity of the observations.

Finally condition - (iii) was judged the most desirable.

1.7 Cvar/Ryge Clinical Assessment System

The development of assessment criteria was reviewed by Ryge (27) and Ryge & Snyder (35), their rating system being based on a clinical operational approach

paralleling the decisions taken by any dental practitioner. Other criteria which had been used previously were limited because:

i) they were visually developed for a particular research setting and were inappropriate for other trials,

and

ii) they lacked written specificity for the assessment and were therefore, of reduced value to others.

Ryge and Snyder (35) considered the first major decision a dentist had to make when assessing a restoration was - whether or not it was satisfactory? From this basic two-way decision, the criteria were expanded to four operational categories, two associated with the satisfactory decision - restoration met all standards and the restoration was satisfactory but should be observed at next visit and two connected with the not satisfactory decision - restoration should be immediately replaced and the restoration should be replaced for prevention of further damage. These four operational categories had specific criteria developed for each one, to make it easier for an assessor to evaluate the restoration.

The system was refined further, to present the appraiser with a cascading series of bi-polar decisions which would

guide him to judge the final level of assessment for each criterion.

The key element of the success of the Cvar/Ryge assessment system (28) are briefly described in the following sub-sections.

1.7.1 Training

Prior training for examiners using the system, with practice examinations and discussions, was considered essential for its success, to ensure examiner variability would be reduced to a minimum. The inter- and intra-examiner agreement level required was 85%. Where there was a disagreement, both examiners had to re-examine and agree to a rating level before assigning a ranking.

Cvar & Ryge (28) commented that it was difficult to train examining dentists to realise that the examination was governed by set criteria, and was not intended as an examination of a specific patient for the formulation of a treatment plan.

1.7.2 Criteria

The criteria adopted for any investigation must be well - defined and subject to no misinterpretation (36). The

original system was established to review the performance of amalgam restorations, but further criteria have been developed from the original four clinical parameters to allow its use with other materials.

The criteria chosen by what is now the United States Public Health Service (USPHS) system to judge and reflect the clinical acceptability of any new product are:

Colour match,

Cavo-surface discolouration,

Anatomic form,

Marginal adaptation,

and

Caries development

all of which will be described and discussed in more detail later in this thesis.

The above system has been adopted widely as a standard form of clinical assessment, as direct comparison of different trials could be possible, particularly as both the criteria and the examiners had been standardised previously.

1.8 Alternative Assessment Systems

1.8.1 California Dental Association System

An alternative system to that employed by USPHS was introduced by the California State Dental Association (CSDA) in 1977.

The criteria were:

i) Marginal discoloration,

ii) Occlusal over- and under-contouring,

iii) Occlusal height reduction,

iv) Colour mismatch,

v) Marginal caries,

and

vi) Fracture and Visible crevice formation.

This scoring routine did not utilise the cascade decision system of the USPHS, but the presence of a number of nominated clinical entities was noted. However no value was assigned to any clinical fault observed.

A trial using these guidelines suggested by the CSDA was reported on the success of a conventional composite used to restore shallow minimal cavities at two and six years (37);(38). It was concluded that the material was too technique-sensitive to be used as an amalgam replacement.

1.8.2 Gibson & Derkson Assessment System

This totally individual system was used by Gibson et al (39) to compare a non-gamma 2 amalgam and a conventional composite (Adaptic). Here, permanent molars of children had modified cavities prepared for the composite.

The criteria adopted were:

i) Sound restoration,
ii) Rough margin,
iii) Chipped margin,
iv) Caries,
v) Occlusal wear,
vi) Surface discolouration,
vii) Marginal stain,
and
viii) Restoration replaced or Restoration lost.

Ratings were based on evidence of any one of the criteria being present without grading the degree of fault. Unfortunately, it is difficult to relate this unique system to results of other trials, as there was no method of fault grading employed. After two years 46% of Amalgam and 42.6% of composite restorations were considered sound. The workers noted that the greatest defect of the composite restorative material was the

occlusal wear especially in larger cavities. The authors commented that results did not suggest composite was superior to amalgam.

Finally, Derkson et al (40) used a system similar to that described by Gibson et al (39). However, this also contained shortcomings, as faults were not decided on in a cascade method as Cvar/Ryge.

1.9 Clinical Examiner Numbers

Single examiners have been used in many clinical investigations. For example, in epidemiological caries studies (41), the effect of fluoride rinsing, reported upon by Rugg-Gunn et al (42);use of fluoride tablets by Stephen and Campbell (43); Downer et al (44) and Mainwaring & Naylor (45) documented the use of fluoride dentifrice; the potential value of fluoridated milk and detailed fissure sealant trials have been reported by Stephen et al (46);(47).

Ryge & Snyder (35) detailed methods of assessing the quality of restorations provided by dental auxiliaries utilizing either one or two assessors. The authors did not, however, comment on the advantages or disadvantages of using one or two examiners, nor did they make any

observation as to why they adopted a two-examiner system for their own clinical examination procedures.

Support for the comment of Swallow et al (33) that the use of two examiners only leads to an increase in the concordance and not an increase in objectivity between examiners, is illustrated by Cvar & Ryge's (28) insistence that there should be a baseline requirement of 85% intra- and inter-examiner agreement. Concordance is further emphasised by asking the two examiners to agree on a common rating, when a jointly agreed result could not be reached.

1.10 Clinical Assessment in Paedodontics

Paedodontists have adopted the USPHS system in many trials of restorative materials.

A two year study of 3-8 year olds, comparing a carvable composite to amalgam, was reported by Tonn & Ryge (48) and the criteria used were those suggested by Cvar & Ryge (28). Here, the use of composite materials was considered a possibility as the wear rate of deciduous enamel was faster than adult enamel, and closer to that of some composites. The material remained colour stable for the two years, with all restorations retaining the top (Alpha) rating. The amalgam control returned a 72%

level for anatomic form, whereas the composite restorations had only 18% retaining Alpha anatomic form. The marginal integrity of both materials was commented on as poor, particularly as they had been placed under a strict protocol. As a result, the authors concluded that the new material could not be recommended as an amalgam replacement for restoration of primary molars.

A three year study, using the USPHS system to assess two types of conventional composites and a high copper amalgam to restore primary molars, was carried out by Nelson et al (49). The colour match and the cavo-surface marginal discolouration were graded similarly at two years, but one year later, there was a significant difference with a marked colour change and cavo-surface marginal staining. The maintenance of anatomical form of the composite restorations was not dissimilar at two years but significantly different at the three year evaluation, as opposed to the amalgam control.
However, in contrast to the two year study of Tonn et al (48), it was concluded that the test composite would be suitable as a restorative material for a limited three year period for primary molars, despite the failure in anatomic form.

A twelve month study was conducted by Paquette et al (50) to compare modified and conventional cavity designs restored with two composites. The formulations used contained conventional fillers, with particle size range from 1-50 μm. The USPHS system was employed not only to assess the clinical trial, but also to judge a series of colour photographs of the restorations. Restorations in the modified class II cavities failed significantly more frequently than did the others ($p < 0.01$), suggesting a lack of sufficient retention and resistance form. Colour match was considered good over the period, as was the incidence of cavo-surface marginal discolouration. The anatomical form was retained and there was little downgrading of marginal adaptation. However the authors commented that the trial time was too short, as most changes had been noted by other workers as occurring after a 12 month period. Hence they could only recommend the composites for clinical use over a twelve month period.

In a trial by Oldenburg et al (51), two experimental microfilled composites were tested over two years in class I and class II restorations of three different designs, on 4-8 year old children . As there was a high number of class II restorations placed, the researchers included another criterion in the system i.e. axial

contour. Conventional cavities with bevels were found to be more successful than the modified designs. Unfortunately the colour match deteriorated significantly but the anatomical form showed no change. The cavo-surface discolouration and the marginal integrity deteriorated very little over the two years, nor was there any significant change to axial contour. No comment or recommendation for use was made.

The clinical acceptability of the material was reported after four years (52) when a note was made of the high acceptability of the composite materials as expressed by the patients. However, the colour match was judged to have dropped significantly over the time span. Marginal integrity deteriorated also during the trial period, although the cavo-surface margin staining was not significant. There was a reversal of the ratings for wear at four years, with the Alpha ratings showing an improvement, but it was suggested that this was due partly to exfoliation and wear of the deciduous teeth showing a lowering of the rating values to that date.

The performance of a microfilled light-cured material was compared with a non-gamma 2 amalgam in a mix of permanent and primary molars by Oldenburg et al (53). At two years, the colour match of the composite had dropped in rating. The marginal discolouration was maintained at

a significant level over time. Marginal integrity was slightly better in primary teeth, but wear was greater in the composite than the amalgam restorations, particularly in permanent teeth.
For primary teeth, there was little to choose between the light-cured material and amalgam, except for the anatomical form, when using the USPHS scoring system.

In a two year study by Roberts et al (54) to compare a conventional composite and amalgam, the colour match was observed to degrade over time but the cavo-surface discolouration did not extend into the depth of the marginal discrepancy. The change in anatomic form for both the amalgam and the composite was not rated as significant. Marginal adaptation change for both composite and amalgam was also insignificant, and the authors supported the use of such materials in childrens' primary teeth.

A light-cured intermediate-sized filled composite material was investigated by Tonn & Ryge (55) in 3-8 year olds. At two years the colour match was rated as "good", but cavo-surface discolouration gradually increased. The anatomical form grading decreased in quality. Marginal integrity was also considered good. It was concluded that the light-cured material functioned well at the one

and two year stage, but no advice was given as to its further use.

A four year follow-up study of these experimental materials was reported by Tonn & Ryge (55). At that time, colour-match was not considered different, although the marginal discolouration did degrade, albeit not significantly. Marginal adaptation of the experimental material lowered over the period, and the anatomic form of the composite did drop for the first three years, but was given an improved rating at the four year stage. As a result, the authors concluded that the material had worked effectively during the study period.

Bevan & Braham (56) reported on the handling properties of a fine-sized composite (new ultra-small particle hybrid) using the USPHS system, and it was noted that handling characteristics were regarded as good, and the aesthetic qualities "excellent". However no long-term report of the material's clinical capabilities was mentioned.

Another paper relating to the use of this formulation was published by Eidelman et al (57), where two restoration techniques of primary molars were compared. Results showed little in the way of wear, marginal integrity or cavo-surface discolouration, the main point

of concern being the interproximal discrepancies at the gingival margin.

1.11 Clinical Assessment in Adult Dentistry

1.11.1 Introduction

It is only since specific criteria have been widely adopted to highlight the performance of a number of restorative materials' clinical parameters, that it has been possible to compare directly one formulation with another, and one material within a number of different clinical situations.

It is difficult to relate the different trials using composite restoratives directly to each other, due to the speed of improvement of the materials, and their appearance on, and disappearance from the dental product market.

For this discussion, comments on such trials will be grouped by generic composite type and by duration of study.

1.11.2 Conventional Composite Materials

In 1971, Phillips et al (58) reported on the placement of class II posterior restorations using one of the original conventional materials and comparing it to an

amalgam control. After one year, no caries was detected and the amalgam performed significantly better in relation to anatomic form. The authors stated this assessment slippage of anatomical form for amalgam i.e. Alpha to Bravo, although judged to be significant, should be regarded as"slight". This was in contrast to Osbourne et al (59) who noted that the anatomic form had decreased significantly in their study at the one year examination. Here comment was made that no composite restorations required replacement due to wear. The marginal integrity of the composite was significantly better than amalgam, which showed "ditching", as had been observed by Osbourne et al (59) . There was a colour change but it was considered acceptable. The cavo-surface margin discolouration exhibited only 49% free of stain at the study end.

Phillips et al(60), in their two year report of the material, stated significant evidence of wear was noted i.e. Alpha ratings down to 45%. This finding was supported by Osbourne et al (59) and Leinfelder et al (61). Marginal adaptation showed an increase in faults, but the difference between the two materials was not now considered significant, in contrast to the data of Osbourne et al (59) and Leinfelder et al (61), where the composite maintained its baseline level while the amalgam

deteriorated over the same period. Colour-match dropped in the Alpha grading to 36% but was judged as acceptable, whereas the results of Osbourne et al (59) showed the material improving with age. These data contrast to those of Leinfelder et al (61) who found the colour-match decreased at the first year but was kept at that level at two years, albeit they were considered outwith the normal range.

A disappointingly low return rate of only 35.5% of total baseline restorations was available for the three year report (62), and such a low number makes the interpretation of results questionable.

Nevertheless, significant changes in the composite ratings' colour-match and cavo-surface discolouration were noted. While the marginal adaptation remained at a higher level than did that of the amalgam, the anatomic form of the composite was so poor, it was suggested its routine use for class II restorations was not advised.

The observations that amalgam preserved better anatomical form was evidenced further in the trial of Eames et al (63) involving composite, amalgam and silicate cements, with the amalgam and composite being placed in class I and class II situations. Although this study did not use

USPHS criteria, the composite was judged superior in its marginal adaptation quality, thus supporting the findings of the earlier works. In addition, caries was not reported as a problem in any of the studies.

1.11.3 Small Particle Composite Materials

The performance of more modern materials in clinical studies, will be reviewed in relation to each criterion used in the assessment.

1.12 Colour Match

1.12.1 Introduction

One of the decided advantages of composites is the ability they have to blend to the colour of the enamel, although it could be argued that too close a match might increase the difficulty in finishing a composite restoration. However, maintenance of good colour-match is essential to reduce the need for replacement due to intrinsic colour degradation which, in turn, would undermine the patient's appreciation of such materials as compared to amalgam.

1.12.2 Intermediate Composite Materials

Colour-match assessment in any clinical evaluation procedure must be entirely subjective. The colour match of all four U V-cured composite materials examined by Wilder et al (64);(65) at their three and five year evaluations, were considered "excellent".

In the first year report by Wilson et al (66) on a new composite material, it was specifically stated there was a deliberate mismatch in colour between the tooth and the restoration at baseline ; only 6.8% of restorations examined at twelve months had worsened. This situation did not change significantly at the three year stage where 10.9% were considered below Alpha rating (67). By five years the percentage decline was stated as 7% (68). Such an "improvement" might, in-part, be due to a slight shift in the borderline decisions made by examiners, or could be due to the reduction in overall numbers being reflected in the percentage figure.

Robinson et al (69), in another trial of the same formulation (Occlusin), described a 2.5% colour deterioration at three years. This trial was also reported on by Rowe (70) at the five year stage, when the satisfactory colour-match situation had declined to only

23%, in contrast to the reports by Wilson and co-workers (68) for this time-span.

Colour-matching ability of four of the six composites tested by Tyas et al (71), showed an increasing darkening, whereas the remaining two composites maintained a closer match.

The good colour-matching ability of Fulfil was also described by Boksman et al (72), where 76% of resins placed were graded as a close match to tooth substance at three years. Confirmation of this success was reported in three and five year studies by Sturdevant et al (73);(74), where the composite remained unchanged, as an experimental composite's ratings reduced.

A self-curing composite material was assessed by Brunson et al (75) and showed an increasing number of Alpha ratings changing to Bravo, at the three year evaluation (88%-71%).

1.12.3 Microfine Composite Materials

The colour-matching abilities of two chemical, and three light-cured materials were given by Heymann et al (76), where two were filled with microfine - and three were

filled with conventional - sized particles.
There was a wide variation in colour-matching with results ranging from an 85% Alpha rating for Visio-radiopak, to a low of 43% for Nimetic Dispers. Throughout, no clear distinction was made between the light- and the chemical- cured materials, but of these two materials, one was microfilled and the other conventional filled.
Of the three materials assessed by Feller et al (77), only one continued to show Alpha ratings at three years.

1.13 Cavo-surface Discolouration

1.13.1 Introduction

Discolouration of the interface between a cavity margin and a restoration is suggestive of cavo-surface margin breakdown, and may lead to early crevice formation. This margin stains more easily and is regarded an unaesthetic. Thus it may lead the patient to lower their acceptance of the tooth-coloured material, and ask that the restoration be replaced.

1.13.2 Intermediate Composites Materials

Derkson et al (40) stated that approximately 5% of the restorations placed using a conventional composite showed

cavo-surface discolouration at a three year examination. Wilson et al (66) reported a higher discolouration rate at first year, 8.5% having deteriorated. However, this proportion rose markedly to 29.1% at year three, and to 52% at year five. The authors stated this discolouration occurred mainly in the occlusal region of the restorations, rather than in the proximal boxes.

The trials conducted by Robinson & Rowe (69), and subsequently by Rowe (70), showed a significantly higher proportion with cavo-surface staining (50% approximately). This remained basically unchanged after five years, which equated well with the results of Wilson (68).

In another trial of the same material, Cunningham et al (78) found 32% of restorations exhibited staining at the three year interval i.e. similar to the findings of Wilson et al (67), but lower than those of Robinson & Rowe (69).

In contrast, Boksman et al (72) reported 4% staining of the cavo-surface margin at three years. This rating was not observed by Sturdevant et al (73) where the tested composite exhibited 12% staining at three years, with only 3% being recorded for the experimental material, the respective five year data being 5% and 8% (74).

All composites under trial by Tyas et al (71), including the material tested by Boksman et al, showed increasing discolouration of the margins at three years (72). In contrast, Brunson et al (75) concluded that the staining in their study was restricted to around the 5% level.

1.13.3 Microfine Composite Materials

Heymann et al (79) stated that the microfilled materials tested had a greater incidence of marginal staining, whereas the work of Feller et al (77) did not support these conclusions - three composites exhibiting only minimal reduction in Alpha gradings.

1.14 Marginal Adaptation

1.14.1 Introduction

The integrity of "fit" of a restorative to a cavity margin is essential to protect the dentine - pulp complex. Any deficiency in the interface would indicate

(i) a fracture of the material which had been supra to the margin;

(ii) a gap between tooth and restoration produced by setting contraction;

or

(iii) a deficiency due to wear or loss of the material through abrasion of the material, all of which reduce the life-expectancy of a restoration.

1.14.2 Intermediate Composite Materials

No marginal adaptation problems were reported by Wilder et al (64) at the three year stage of their study and no comment was made in relation to adaptation in their five year report (65).

Wilson et al (66) described a low fault level of 1.7% at the first year. However, this had increased to 21.8% at three years, particularly in relation to occlusal surfaces of class I and II restorations. The rise in the marginal adaptation decline continued through to the five year assessment, when 40% of occlusal surfaces and 32% of proximal surfaces were faulted.

The reports of Robinson & Rowe (69) described a 31% deterioration of the adaptation at three years (15% in molars and 14% in premolars), which was significantly better than that for amalgam. In the five year report (70), the significant difference was maintained.

Boksman et al (72), using a light-curing material, reported a 4% lowering of gradings at three years. Surprisingly, a 100% Alpha rating was given at three years by Sturdevant et al(73) but, taken in relation to the work of Boksman and co-workers (72), this may well be a real value.

The five year data, relating to the same composite, indicated 95% of remaining restorations were still Alpha rated, However, an experimental material used for comparison did not perform as well, with a three year level of 96%, and a five year level of 91% (73);(74). With respect to a self-cure material, P-10, a 4% drop in Alpha ratings was recorded at three years

1.14.3 Microfine Composite Materials

Feller and his co-workers (77) reported at three years that one material had recorded 85.7% success - 8% better than the amalgam control.

1.15 Anatomical Form

1.15.1 Introduction

The maintenance of anatomical form is equated with wear resistance. This particular criterion has long interested researchers and clinicians, as loss of

anatomic form is an important factor with implications for the maintenance of occlusal relationships.
However, while wear of restorations can be assessed clinically, it is difficult to measure directly.

1.15.2 Intermediate Composite Materials

The only comment made by Wilder et al (64) about the four UV materials they assessed, was that three performed better than the fourth material, in relation to the number of Alpha ratings. There was some generalised loss of material when reviewed clinically, but three rated greater than 87% Alpha at three years, whereas the fourth scored as 47% Alpha, although this was not supported by indirect measurement.

Derkson et al (40) showed that 20 of 94 composite restorations exhibited occlusal wear at three years, but no details were published as to the degree of involvement.

In contrast, Wilson and his co-workers (66) reported on the same composite at yearly intervals, and at the one year stage no restoration was rated as having deteriorated. Their excellent data were continued at three years with an approximate 2% level of decline (67).

By five years, 34% were noted deficient but the extent of grade slippage was not given (68).
Robinson & Rowe (69) found no significant difference in the wear between the test composite and amalgam, with around 7% decline - i.e. higher than did Wilson et al (67) . The five year data by Rowe (70) produced a 26% loss, not dissimilar to that of Wilson et al (68).

The study carried out by Boksman et al (72), reported that 100% of restorations had retained their occlusal form over three years.
The same material was again tested, but only 49% of the restorations examined were given Alpha grades at three years (73), and 59% at five years by Sturdevant et al(74). This apparent rise in Alpha grades was related possibly to a fall in the number of the restorations available for re-examination.

Brunson et al (75), stated that wear of the restorations using a chemically cured composite increased gradually over the three years' test period to a level where only 59% were rated Alpha.

1.15.3 Microfine Composite Materials

In this category of composites, only one of the materials tested by Feller et al (77) performed better than amalgam at the one and two year interval, and was equal to it at three years.

1.16 Indirect Methods of Wear Assessment

1.16.1 Introduction

The clinical assessment techniques adopted to record the performance of restorations intra-orally have allowed researchers to monitor materials over a period of time. However, none of the systems adopted has been able to quantify accurately the material loss observed over the trial period, nor have they been able to show if the wear rate was consistently linear.

It is essential to have meaningful information on restoration wear, as this is a key factor in a material's ability to maintain occlusal relationships.

This section will consider the different "extra-oral" systems for monitoring the performance of filling materials, with particular reference to wear.

1.16.2 Wear

A simple definition has been suggested by Burwell (80) where he explained wear as" the unwanted removal of solid material from rubbing surfaces". He went on to comment that this definition "lumps together" many different phenomena -adhesion, abrasion, corrosion and surface fatigue.

Adhesive wear is found when two solid surfaces rub against each other.

Abrasive wear occurs where one harder surface rubs against another, or where a third hard substance is placed between two softer materials, so causing loss.

Corrosive wear occurs under sliding conditions when one or both bodies are affected by a corrosive environment which produces a surface coating on one or both surfaces, which is then removed by rubbing.

Surface fatigue is mainly related to materials rolling over each other, and gives rise to pitting or flaking.

This definition of wear is supported by the UK Institution of Mechanical Engineers whose definition is quoted by Sulong & Aziz (16), as "the progressive loss of substance from the surface of a body brought about by mechanical action". Their review also divided wear into a number of sub-sections:

adhesive, abrasive, erosive, corrosive and impact.
The definition of wear as it applies to restorative dentistry is difficult. Wear of posterior composite materials has been recognised by clinicians and materials scientists as a major disadvantage for the full acceptance of a material by the profession.
Visible evidence of material loss through wear is easily seen by flattening of the occlusal or anatomical form of a restoration. Several factors have been suggested as responsible for the phenomenon.

Bryant(81) listed a number of major features, depending on the type of composite formulation, that contribute to wear. These were:

i) macrofillers are subject to "plucking,"
ii) hydrolytic degradation of the filler/resin interface,
iii) adhesive and cohesive fracture in the occlusal contact area and contact free area,
iv) failure of the bond between the prepolymerised filler material and the resin matrix,
v) porosity - chemically cured materials are more porous and are more prone to wear,
and
vi) tooth position.

Lambrechts et al(82) suggested two main components of wear in occlusal areas, viz:

a) attrition occurring in the occlusal contact area due to direct tooth contact from the opposing tooth

b) abrasion occurring in the contact free area where the wear is caused by toothbrush abrasion or contact with food. He also added that fatigue could play a part in the wear process.

The low modulus of elasticity of some microfilled materials allowed them to deform under load, so propagating microcracking until the surface was undermined, giving rise to sudden failure. This failure can happen without there being great evidence of wear. The phenomenon also occurred in the hybrid materials where, although they deformed less, the particles acted as crack stoppers but, over time, the surface could be observed as pitted.

Swift (83), in his review, noted that a number of researchers had theorised that composite wear was due to a number of factors, including chemical degradation of the resin matrix due to thermal and mechanical stresses. Microcracking through the action of occlusal forces was again implicated in the breakdown of the composite surface. He also identified, like the previous workers, the failure of the filler/bond/matrix interface and porosity, particularly in chemically-cured materials,

which had been identified as less wear-resistant than the light-cured composites.

Sulong & Aziz (16), in their review paper, commented that the wear problem had curtailed the use of composites in areas under heavy occlusal loads. Hirt et al (84) noted that, in addition to the common wear factors, an extra and almost ignored component was the quality of the resin matrix itself. The wear of microfilled composites was, in the main, regarded as being less than that of conventional composites, and hybrid composites were rated superior in abrasion terms, than were microfilled materials.

Jorgensen et al found that the wear experienced in vitro by conventional resins, was related to filler particles in part protecting the resin matrix, and in part then exposing the matrix, when subsequently lost through plucking(85)Here the matrix became rougher, and this rough surface increased friction, and hence abrasion. Microfilled composites were regarded as softer and therefore more abrasion-susceptible, but the smoother surface and more rounded particles did reduce the abrasion factor. Furthermore, it was noted that the porosity of the composite increased abrasion.

Lutz et al (86) remarked that wear was not even across the surface of restorations, noting it was higher in the area of occlusal contact, as compared to the contact-free

areas. None of the materials tested were as good as amalgam in respect of wear resistance, but a heat-cured composite was better then a light-cured which, in turn, was better than a chemically-cured. Interestingly, the composites were rated as "Alpha" using the Cvar & Ryge system (28), and the authors stated that "evaluating the step formation between the restoration and natural tooth surface with naked eye and sharp explorer may not be an appropriate method to evaluate early performance of modern potential posterior composites". The rate of loss was regarded as low and undetectable, such that they estimated it would take 2.5 years to detect clinically. In the in vitro situation, microfilled materials showed typical 2-bodied abrasion, whereas hybrid materials (with the denser packing of conventional - sized particles) gave a distinct 3-bodied result (102).

1.17 Step Model Wear Assessment System

1.17.1 Introduction

A regime was described by Golberg et al (87) to evaluate ten posterior composite resins. This system used four casts which had distinct steps between the cavo-surface margin and the restoration. The steps were measured by a travelling microscope at 1, 190, 330, and 580 μm, giving a seven step series. A comparison of the clinical

assessment sensitivity and the ranking and indirect wear evaluation system was investigated.

A total ranking scheme was also carried out as reported by Osbourne et al (88). As a result, it was found that the total ranking and the stepped model method (categorical scoring) were more sensitive to clinical change occurring in the composites at the two year stage, than was the clinical assessment method (USPHS).

Inter-operator agreement with the total ranking system was higher than that of the categorical (indirect evaluation) system, but it was suggested that the lack of training in this new approach contributed to these findings.

The system devised by Golberg et al (87) to allow observers to quantify material loss was revised by Leinfelder et al (89);(90). It was reported as easy to use and provided quantitative results that could be related to other trials and materials. A series of casts taken of restored teeth were sectioned and the distance between the cavo-surface margin and the restoration surface measured using a travelling microscope. Of these, six casts were selected with cavo-surface margin deficiencies in steps of approximately 100 μm intervals, giving an eleven step procedure to quantify material loss.

The measurement of wear, by assessing the vertical loss of material, is the basis of the Leinfelder (89);(90) and Moffa & Lugassy (91) systems. However Mair (92) did point out that the assessment should be carried out at several points around the margin to give an average result of material wear. The step system was modified to present the steps joined together in a line to ease assessment. The averaged wear result is difficult to relate to the clinical situation where a large step discrepancy will register on probing, but this is not necessarily so with the smaller steps. The modified step system was used and a loss of 225 μm was reported at three years. Such loss of substance differs from that of conventional composites. Sluiceways,through which food passes, and buccal and lingual extensions, are areas where composites are more susceptible.

1.17.2 Intermediate Composite Materials

A three year trial of four ultra-violet light-cured composites (90) was subjected to clinical assessment employing categorical scoring using the stepped model system reported earlier (89);(90), and a rank ordering system (88). The authors commented that although the USPHS system did use standardised criteria, it lacked the preciseness of direct measurement as quantification was

required, the clinical assessment system being regarded as purely conceptual in nature. The models were examined three times by three separate clinicians and, of the two indirect means tested, the rank ordering system offered the possibility of greater sensitivity in earlier wear discrimination than did the direct system. As a result, the average wear reported in the trial was 178 μm.
From these studies, the authors commented on the limitations of ranking, although they felt that

(i) it did give early warning of change,
(ii) it provided the ability to make multiple direct comparisons between objects,
(iii) the rankings were only valid with other materials within the ranking procedure - thus comparisons were difficult,

and

(iv) rankings do not lead to quantitative results.

Hence, many workers now include model-based quantitative data along with their clinical observations.
Wilder et al (64) did not report any quantitative results of the trial of UV composites at year three but detailed their three and five year assessments together. The loss of material was nearly linear over the five year

span, a finding which was not supported by other investigations.

Using the USPHS system, little wear had been observed for the first three years with a rapid rise for the last two, whereas the above quantitative results showed a small steady increase. The total wear over the period of the trial was approximately 0.25 mm.

The USPHS system was used by Leinfelder et al(93)who reported on nine posterior composite resins which were tested at 0.5, 1, 2 and 3 years. The assessment was paralleled with an indirect evaluation of wear using the stepped cast system. The direct system was found to be incapable of detecting a cavo-surface discrepancy until it was greater than 150-175 μm. This meant that the cavo-surface adaptation could have a step of 100-150 μm remaining undetected until wear of the restoration took the step beyond the 175 μm level i.e. equivalent to a grading change in the direct assessment system from Alpha to Bravo. With careful comparison of the standard casts and the model, the sensitivity of the step cast technique could be as low as 25-50 μm. It was noted that half the wear measured had occurred in the first six months. Taking this forward, it was claimed possible to predict closely the wear for a three year period.

In the first year report of the posterior composite

material (66), no measurements were provided by the authors. However, at the third year interval, these were not undertaken by the authors themselves but were reported as 192+/-30 μm at the occlusal contact area, and as 81+/- 30 μm at the contact-free area.

The five year report (68) gave an overall measurement of the wear encountered using the stepped model system as 97+/-67 μm. The authors stated that the difference between the two measurements i.e. the third year and fourth year, could be explained by the first work being carried out by laser interferometry, and the four year results having been obtained by the more directly applicable Leinfelder stepped model system. Here the wear differential between molars and premolars was highlighted. The fifth and final account gave the overall wear at 154+/-97 μm, with 238 μm at the point of heavy occlusion (68).

Robinson & Rowe (69), and Rowe (70) also described the three and five year deterioration in occlusal form of the same material. The three year outcome was 70+/-36 μm, and at five years was 129+/-59 μm, although these were assessed on only 19 restorations. This five year data set was well below the figures reported by Wilson et al (67);(68), but no explanation was given by the authors

regarding the difference, although both were participating in a multi-centre trial where the average wear at three years was given as only 76+/-45 μm (94).

Boksman et al (72), in a three year report, gave the average rate of wear in the first year as 57 μm. At the second year, it was noted at 47 μm and, by the third year, at 31 μm i.e. 135 μm in toto. This rate of wear, they remarked, was compatible with a enamel wear rate of 82 μm over two years, as reported by others.

In a further study of the same material, Sturdevant et al (73) produced results which closely matched those of Boksman et al (72), with a three year wear rate of 145+/-5 μm, the experimental material giving a slightly higher reading at 164+/-10 μm. However, this three year rate of wear had not occurred evenly, as half was measured in the first six months with a subsequent decrease over years one to three. This finding was again in agreement with Boksman and his fellow workers (72). The authors hypothesised this early loss could be explained by the surface being affected by micro-cracking at the time of finishing the composite.

Although the average for the five year wear rate was within the ADA specifications (250 μm), the range of results for this material was 0-438 μm.

Tyas et al (71) carried out wear estimation using S E M and the stepped models. At two years, the wear rates measured were much lower than the outcome obtained by the S E M procedure

At two years Brunson et al (95) found wear at 108+/-91 μm for the composite P-10 i.e. nearly three times that of Tyas et al (71) and at a five years, it was 145+/-77 μm. They commented that the wear rate increased gradually if judged by the USPHS standards, but that it decreased over time if the model estimation system was used.

1.17.3 Microfine Composite Materials

The combination of the direct and indirect method of evaluation was also employed in the assessment of two auto-cured and three light-cured materials over two years (76). The USPHS system did not reveal any differences in wear but the indirect method showed that wear was related to particle size.

No statistical difference in wear occurred between the light- and chemically-cured materials using the direct (USPHS) and indirect method (90) but, in the discussion, the authors commented that an indirect method gave more quantitative results and were more sensitive to detecting

wear over time. Of the materials, the two microfilled specimens proved to be more wear resistant.

1.18 Moffa and Lugassy Model Wear Assessment System

Another quantifiable system was devised by Moffa & Lugassy (91). This was based on 18 standards with holes of varying known depths cut into one end of This technique gave a larger number of depth steps than the Leinfelder system (90) and could be regarded as more accurate to read, in that the steps were sharper and well defined .

1.18.1 Comparison of the Leinfelder, and the Moffa-Lugassy Wear Assessment Systems

In a comparison of these systems Taylor et al (96), stated the technique of Moffa & Lugassy identified lower values of depth than the Leinfelder model-based measuring technique. Here, it was pointed out that the minimal step Alpha-Bravo transition identified by the M-L system was 97 μm as distinct from that of Leinfelder, which registered 199 μm. However, the authors could not come to any decision as to the reason for the large divergence between the two methodologies, but pointed out that the Leinfelder system, based as it was on models and not cut

cylinders, may be more clinically applicable and easier to read.

However the use of pre-calibrated casts was regarded as a significant improvement in quantifying restoration wear.

1.19 Methods of examining Wear in in-vitro situations

1.19.1 Scanning Electron Microscopy

Kusy & Leinfelder (97) described wear patterns of the early macrofilled composites after three years as a simple bowling out of the composite in the class I situation, leaving a meniscoid shaped occlusal surface with exposed cavity walls. The filler particles were described as exposed, as the resin wore away until the particles were "exfoliated". There was no mention of any differentiation between occlusal contact areas and contact-free areas.

The consequence of wear after 2 and 4.5 years was examined using S.E.M. by Xu et al (98);(99). Again, macrofilled particles of the first generation composites were seen to protrude from the resin surface for up to 12 months but, when plucked, the voids left increased in size and cracks around the fillers increased. The microfilled composites' uneven surfaces were seen at 12

months, but at 24-54 months, cracks were observed running between the matrix and organic filler particles with some cavitation. These authors commented that the fatigue resistance of modern composites required to be enhanced.

In 1980, O'Brian & Yee(100) examined 10 specimens from restorations removed from patients. Unfortunately no mention was made of the age of the restorations, but their observations of matrix cracking, loss of particles, wear of polymer and exposure of entrapped bubbles, were in accord with Xu et al (98);(99).

Abell et al (101) examined replicas of a class I restoration using a conventional material over a seven year period, and again particles were exposed and lost. The rate of wear was measured at 0.08 - 0.16 μm per day. They also noted that it declined after seven years, possibly due to the "shielding effect" of the now high surrounding enamel. There was no comment on the wear rate varying with specific periods of time.

1.19.2 Profilometry

Quantification of the loss of composite and amalgam in vivo was reported by Lutz (86). In these studies, copper plated models from silicone impressions of

restorations undertaken using a conventional, intermediate composite and an amalgam were made at one, seven and thirteen months. Tracings were taken via profilometry across the occlusal surface. The tracing records were analyzed by computer program and the extent of wear calculated. An intermediate material performed equally well as the non-gamma 2 amalgam, both in relation to attrition and abrasion areas, and in the abrasion area alone. The conventional composite was considered to be inadequate for class I and II restorations.

Profilometry (102) was used to measure the in- vivo and in vitro wear of a number of composites of differing formulations at 7 and 180 days.

The in vitro testing was carried out using the slider pin and disc system. The in vivo wear was measured by a modified profilometer using copper plated models of the restorations.

Here, two areas of interest in relation to occlusal wear were measured for the in vivo situation i.e. the occlusal contact area (O.C.A.) and the contact free area (C.F.A.). None of the composites tested showed comparable wear resistance to the amalgam control. Wear in the O.C.A.was 2.5 times greater than the C.F.A.. The researchers' conclusion was that in vitro, slider-on-disc wear tests

demonstrated surprisingly good correlation with the *in vivo* situation for amalgam and microfilled materials.

This system was used by Hirt *et al* (84) on experimental materials at 1, 3 and 6 months. Again the O.C.A. wear was higher than that of the C.F.A.. Profilometry tracings were also used to assess the surface roughness (Rice *et al* (103)).

1.19.3 Volume Loss of Restorative Material

Metal Coping Technique

Volume loss of a conventional composite was evaluated at 3, 6, 9 and 12 months by measuring the amount of fine-bodied silicone impression material trapped under a metal coping constructed at baseline over the occlusal surface (104). Minimal material loss was reported at 12 months, although the precision of the figures reported was only at a 13% level.

Volumetric loss from the occlusal surfaces of microfilled light cured and hybrid chemical-cured composites was investigated by Vrijoef (105);(106). Cast silver caps of each occlusal surface restored were constructed at baseline, and the volume of light bodied silicone material taking up the space of the worn composite was

calculated. The highest rate of loss was observed during the first six months i.e. similar to the observations of Leinfelder (93) in relation to the timing of this fast rate of wear. The wear rate found in this study related well to other results, in that conventional composites lost material at a higher rate than the micro-filled, which themselves were at a higher rate than amalgam.

An innovative method of quantifying the volume loss on abrasion of a composite material with a toothbrush was described (107). In this investigation, the micrographs showed that toothbrush surface abrasion characteristics were in relation to the size of the inorganic filler particles, with the hybrid material eventually acquiring a surface as rough as conventional composite through time. Aker (107) employed S E M techniques as part of an investigation of the surface of composites when tested for toothbrush abrasion. In this work, conventional composites lost less material over the fifteen hours of toothbrushing than did other formulations.

1.19.4 Two-body Abrasion Tests

(a) Slider and Pin Type

Powers et al (108) carried out two-body abrasion test

employing a single pass sliding test on two light- and seven-chemically cured composites. These results were compared with a clinical/laboratory examination of 54 class II restorations, with the height discrepancy from the cavo-surface margin to the restoration surface being measured. The correlation between the in vitro and in vivo methods was considered high with the authors stating that these in- vitro tests could be used as a predictor for in vivo wear.

Lutz et al (102) compared the in vivo wear of composite by measuring indirectly using a profilometer on plated dies from 7 and 49 day old restorations which had been undertaken using homogeneous, heterogeneous microfilled and hybrid composites. In vitro wear tests were completed utilising a slider on disc procedure, and the older samples showed greater wear resistance. The authors concluded there was surprisingly good correlation between in vitro and in vivo testing for amalgam and microfilled composites.

Further pin on disc wear testing was reported and compared four light-cured microfilled, one self-cured microfilled, three light-cured conventional filled and one self-cured composite. The microfilled materials performed significantly better than the conventional sized composites in relation to wear rates.

These were measured again by profilometry (103).

Leinfelder et al (109) used a modified pin and slider system with an intermediate polyethylene tape between the pin and the composite. The technique mimicked marginal fracture, localised wear and generalised loss.
Two-bodied abrasion tests were carried out using a number of conventional and microfilled composites. These materials were then tested for abrasion resistance against amalgam, glass ionomer cermet, porcelain and bovine enamel, where Embong et al (110) reported that composites with the larger particles performed better than those microfilled materials in the wear tests. They also tested the surface roughness of the abraded specimens with a profilometer, but did not publish any relevant data.

(b) Sectioned Wheel to Wheel Abrasion
The relationship of in vitro and in vivo tests was further examined by Finger & Theimann. Here, two cylinders were rotated against each other to mimic clinical wear (111). One cylinder had windows cut in it to carry samples of the test materials, and the other had a scaled steel surface. In all, 25 materials were assessed. During contact, a slurry containing poppy seeds was flowed between the contact surfaces.

Wear was again measured by profilometry.

The quantitative results were compared with those reported by Lambrechts et al (112). The surface morphology of the in vivo and in vitro samples were found to be similar, and the authors offer the system as a predictor of occlusal wear.

A two wheel system with windows similar to that of Finger & Thieman in concept, was employed by De Gee et al (113), to measure abrasion resistance of a non-gamma 2 amalgam, a conventional and four microfilled composites. Millet and polymer particles were used to act as the abrasion slurry interface. The pattern of wear proceeded in a similar manner to in vivo wear with concentric wear and exposed walls, but the wear was also relative to the type of slurry employed.

1.20 Laser

A highly sophisticated technique for measuring material wear was reported (Atkinson et al (114)) and used by Williams et al to detail wear of class I and class II restorations (115). This employed laser interferometry and was regarded as the most advanced method of its time. Subsequently Mair et al (29) used this technology to measure the attrition occurring on a number of composites placed in vivo. These workers found that attrition i.e.

direct wear on composite material, could be 3.5 times greater than abrasion, i.e. wear of the composite effected by a third body intervening between two teeth, with the material P-30 having the highest such wear of the materials tested.
This equated with other reports of O.C.A.and C.F.A. wear.

1.21 Stereophotography

Stereophotography of two composites was the method adopted by Eick et al (116). By incorporating a locating bite splint to accurately fix the position of two cameras, in vivo photographs were recorded. Here, it was claimed that a reduction of 50% in both assessment time and patient discomfort could be achieved. The stereo-photographs were examined with the aid of a computer - graphics program to produce volumetric measurements.

1.22 Modified Dentures

An innovative test regime was described by Mitchem et al (117) using specially modified first molars in full lower dentures. Here four materials were placed in the hollow occlusal surfaces of the metal formed molars, which were opposed by zero degree acrylic teeth. Throughout the

experiment, patients continued with their normal eating and oral hygiene regimes, and the resulting occlusal composite surfaces were examined again using a profilometer. Results at the 6 month interval showed that microfilled composites performed better than conventional ones. This test regime was again reported by the same workers three years later when they used a series of different composites with similar results (118). It was stated, that although the test regime was unusual, it could be used as an appropriate method for wear testing. As mentioned earlier, Xu et al (98);(99) used restorations placed in dentures and examined them by SEM.

In a study conducted by Bloem et al (119), specially modified molar denture teeth were again used to measure wear of a number of composites. The composites were placed in the occlusal surfaces of the modified lower molar metal teeth. These teeth occluded against chrome cobalt cusps of the upper molars. Wear was calculated using a computer-based mapping procedure devised by the Michigan Computer Graphics Coordinate Measuring System. This was considered as a possible model to predict wear, even although it was an early report and the materials had yet to be fully rotated to all positions before full material loss could be calculated and directly compared.

1.23 Computer Mapping

Roulet et al (120) employed computer technology to develop a mapping system to assess the quantity of occlusal wear by digitising the occlusal surface. The researchers commented that the system was highly accurate and was able to determine early signs of wear, after three months under clinical conditions. This computer stored the parameters of the area to be scanned, thus allowing the same area to be compared at a later date. The accuracy of the system was claimed to be +/-0.67 μm. Repositioning was within 0.022 degrees, with an increase in measuring error of only 1.6 μm.

Another computer-based mapping system was described by Lambrechts et al (112) to enable comparative studies of changes in the occlusal surface of teeth filled with composite and amalgam over a period of years. Replicas of the in vivo situation were made. The repositioning/re-orientation regime was based on a negative model of the occlusal surface taken at the baseline;this negative location device, together with the use of reference points, was used to realign the subsequent models to within 1 μm. They found that the wear of conventional composites was unsatisfactory as was the microfilled

composite at the O C A, i.e. in attrition, but the hybrid composite showed a higher wear resistance.

A computer-based mapping system based on that of Lambrechts et al (112) was adopted to establish the wear rate of four composites. Each tooth to be measured had three locating points ground into the occlusal surface in order to ensure the accurate relocation of subsequent models (121). The occlusal surface of the baseline model was mapped accurately in three dimensions, and this compared with those collected at later dates. No significant difference was observed in abrasion or attrition rates at the 12 month period for the four composites collectively. However the abrasion and attrition rates differed significantly for each individual material at the 6 and 12 month period.

Occlusal mapping was also described (122) to quantify the wear on denture teeth using the Reflex Microscope (123) and a main frame computer- driven contour interpolation package. This measuring system did not involve actual contact with the occlusal surface of the model as distinct from the system used by Braem et al (121). Occlusal maps of the baseline and subsequent test samples were created, and the volume of material lost calculated.

Further occlusal computer mapping was carried out by Delong et al (124) who produced contour maps by tracing a stylus across the restoration surface so allowing calculation of volume difference.

1.24 Fracture Mechanics

A completely novel approach to the prediction of wear was claimed to be achieved by a fracture mechanics approach which measured the crack velocity (125). By so doing, these workers could rank materials in toughness order of wear resistance. However, the authors commented that both a static and a dynamic test would be required to be more reliable.

1.25 Radioactive Tracers

A ^{90}Sr beta transmission gauge was devised by Moores et al (126) to measure the change in length of resin samples subjected to wear.

The authors stated that this type of assessment was within +/-3% of the measurements from a micrometer gauge.

1.26 Conclusion

In spite of the extensive work, both laboratory- and clinically-based, that has been undertaken, there would seem to be the need for further clinical assessment. This should be carried out in a population, where the use of the newer composite materials may be beneficial, particularly in their ability to perform as suitable restoratives especially in relation to material wear or loss of occlusal surface substance.

A non-adult patient population will be used as this age group would bridge the gap between previously reported studies of the composites used in the restoration of childrens' first permanent molars, and those undertaken in the adult population. Results of childrens' studies have been equivocal as to the suitability of the composites tested for adoption as a permanent material. While this could also be said of studies carried out in adults, much of the doubt expressed to date could be due to the multiplicity of materials investigated.

Wear has been of paramount concern in work undertaken with both child and adult populations and has been assessed <u>in vivo</u>, but this has not provided quantitative data. <u>In vitro</u> measurement has been carried out by a variety of means but measured wear from models has been detailed only rarely.

As a result of the conclusions drawn from the literature review, the purpose of the work reported in this thesis is to examine clinically, in a field trial, two formulations of composite resins along with a non-gamma two amalgam control. Wear is also to be measured *in vitro* using a stereomicroscope to overcome the objections of step series comparisons, and enable comparison of *in vivo* and *in vitro* wear assessment to be made.

CHAPTER 2

Field Study - Materials and Methods

2.1 Introduction

In the work to be described, the use of clinicians working outwith a Dental Hospital and School environment was considered important, as the majority of previous clinical research on composite materials has been undertaken using the explanatory trials methodology. The results of such rigidly controlled studies may not mirror the performance of the materials in general practice.

In the current investigation, five community dental officers and a dental therapist from the Greater Glasgow Health Board volunteered to participate in this pragmatic study of two composite formulations. They were based in clinics throughout the Health Board area, the communities served being in zones of low socio-economic status where the community dental services provided the majority of dental care.

The use of tooth-coloured restorative materials for posterior fillings, instead of amalgam, must be considered to have great potential in attracting and retaining young patients. However, it is clearly

important to test such materials to ensure their longevity and appropriateness. The early failure of these materials could lead to the possibility of young people becoming disenchanted with dentistry.

2.2 Patient Selection

The patients were within the age range 8-17 years i.e. older than the population reported with restorations placed in deciduous and first permanent molars and younger than the adult age range usually considered. This span was chosen as there was a lack of information about the performance of composites in the permanent teeth of such a group.
No special restrictions were placed on the operators in their choice of patients.

2.3 Materials used in the Field Trial

Of the composite materials developed for use for posterior restorations, two were chosen, these to be tested against an established amalgam control. The composites were:

(1) Occlusin (ICI)[1] -a intermediate material using hybrid particle sizes,

and

(2) Herculite (Kerr)[2] -a fine particle material composite with particle size < 0.5 um, while the amalgam selected was: Sybralloy (Kerr)[3] -a non-gamma 2 amalgam.

Occlusin, an intermediate hybrid filler particle-type was chosen for this trial as it had, at that time, been recently introduced to the dental market. Herculite was selected as the second composite as it had been produced as a fine-particle sized filled material which claimed to be polishable, and to retain its surface characteristics.

Amalgam has been used commonly as a control material in such investigations following the principles of Ryge (127) who suggested that any new product should be compared with a known one. High copper amalgam has been employed by the dental profession as it reduced the gamma-2 phase of the set amalgam, so diminishing the corrosion by-product. This increased the edge strength

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[1] ICI Macclesfield UK.

[2] Kerr, Romulus,USA

[3] Kerr,Romulus,USA

and decreased the ditching problem of standard amalgam formulations. In this study, Sybralloy was chosen as the control formulation.
All materials used were supplied via the investigator, and all manufacturers' instructions were included in the packaging provided for the operating clinicians.

2.4 Clinical Protocol

The clinical protocol was discussed at an introductory meeting of participants and their dental surgery assistants (Appendix 1).

The aim of the protocol was that it should not be proscriptive, but the decided intention was to allow and encourage the operators to continue to use their own caries diagnostic standards, and to use radiographs, if and when they deemed it necessary.

The clinicians were encouraged to continue to prepare the cavities in their usual way, with no emphasis placed on the production of modified or minimal design preparations. It was considered essential that the operators did not feel they themselves were under examination, in order to ensure the materials were used in an unconstrained manner.

2.4.1 Cavity Design

In day-to-day situations, composites will be used by many clinicians, either as the material of first choice, or as a replacement for amalgam restorations. However, none of the clinicians in this field trial were to select teeth which required replacement restorations.
As these products were to be placed by operators who, in the main, had been exposed to "traditional" conservative dentistry teaching concepts, the composites would be placed in clinical situations which would normally be associated with amalgam as the choice restorative material, and amalgam-type preparations would be cut. Undoubtedly, this situation will prevail for a number of years until the newer cavity designs pervade the dental profession, and the caries rate declines.

Although operators were not restricted in respect of the cavity form, there was one exception i.e. no cavity which involved the coverage or replacement of a cusp was to be included in the trial. This was to conform, both to the manufacturers' guidelines and the American Dental Association's recommendations (128);(129).

The clinicians were asked to follow the manufacturers' instructions regarding the enamel preparation by acid

etching, and also in the use of the dentine bonding agent supplied for the composites.

2.4.2 Base or lining regime

With respect to the lining regime, instructions were regarded as important as to the use of a base or sub-base to ensure the continued vitality of a tooth. Each operator was advised to use a setting calcium hydroxide material as the base and, in a deep cavity situation, to use the calcium hydroxide material as a sub-base with a structural base of phosphate material. Any cavity, where there was doubt as to possible pulpal exposure, was not to be included in the trial.

2.4.3 Material Selection

Each clinician was supplied at the beginning of the investigation with 3 sets of 4 envelopes, each envelope of the set contained the name of each material. There were twelve envelopes in toto.

The set was mixed fully and the topmost envelope indicated the material to be used for the first patient involved. After use, it was to be placed at the bottom of the selection series and a fresh envelope taken for the next patient in the trial.

All restorations for a patient had to be of one material only for the period of the study, and baseline recruitment to the trial was over a nine-month period.

2.4.4 Material Placement

Placement of the materials generally followed that of an amalgam technique for all cavities. The class II situation required accurate location of a metal matrix band, accompanied by good placement of a wooden wedge. The band had to be burnished to the contact point of the adjacent tooth to make the contact as tight as possible. All the materials used were packable, and the instructions recommended the composites should be packed in layers of not more than 2 mm before applying the curing light.

Carving of the occlusal surface had then to be undertaken before finally curing the material, leaving only minor adjustment of the occlusion.

2.4.5 Clinical Assessment

For clinical assessment, each operator was contacted and appointments made to examine the restorations placed to that date. At baseline, these were examined no later

than six weeks after their final finishing.

The assessment was carried out by one examiner (SWS) at base-line, one year and two year intervals, in the Community Clinic where the restorations had been inserted.

A 10% random sample was re-examined to check for examiner reproducibility, a minimum period of two weeks after original scoring, and four weeks after the final assessment.

2.4.6 Assessment Form

Experimental data were to be collected on an assessment form, which was divided into two sections :

(i) To collect general patient information,

(ii) To code the assessment of the criteria for each restoration placed. (Appendix 2)

2.4.7 Clinical Recording Routine

For clinical recording, the patient was seated in a dental chair in the semi-supine position and the operatory light used to illuminate the mouth.

The tooth and the restoration under study were dried with a cotton wool roll, and the restoration examined with a sharp, sterile probe and mirror. The code for each criterion was recorded immediately on the form, if a composite was involved, the examiner was not informed which tooth-coloured material had been used for the patient until that particular assessment had been completed.

2.5 Assessment System

The clinical scoring system adopted was based on that used by the United States Public Health Service, although the original criteria were modified for this trial as detailed below.

The Marginal Adaptation and Caries criteria were expanded to include the proximal box area. In addition, Surface Roughness and Interproximal Contact were new additions to the criteria of Cvar & Ryge (28).

The criteria assessed were:

i) Marginal Adaptation

ii) Anatomical Form

iii) Caries

iv) Surface Roughness

v) Interproximal Contact

vi) Colour Match

vii) Cavo-surface Discolouration

2.6 Criteria Recording

2.6.1 Marginal Adaptation

Marginal adaptation is considered to be a function of the continuing quality of the restoration, and of the material's ability to act as a tooth restorative over a period of time. Poor adaptation can lead to the accumulation of plaque, and so increase the potential for recurrent carious attack.

Marginal adaptation was assessed by passing the probe across the cavo-surface margin of the tooth and the restoration, in both the tooth-to-restoration and restoration-to-tooth directions. This margin-passing was repeated not less than 50 times along the accessible margin of the restoration at each assessment. Note was made of any discrepancy detected and in what direction,

after which the appropriate code was recorded.
By so doing, the technique differed from the original system reported by Cvar & Ryge (28) who noted the presence of a marginal discrepancy, but with no differentiation as to directional assessment. In the situation where tooth-coloured material had been placed, the finishing of the material to the tooth surface/cavity margin can be difficult to achieve, due to the closeness of colour-match between the tooth and restorative material.

It was considered that the criteria adopted by the USPHS system, i.e. exposure of dentine or the base, and the mobility of the restoration, were too severe criteria to adopt, as any restoration would have been replaced by the practitioner before these situations would have applied. The assessment of marginal adaptation is used as a measure of a materials' ability to resist wear, with one of the following codes being recorded:

ALPHA	No observable catch detected,
BRAVO	A catch (or catches) in a restoration-to-tooth direction,
CHARLIE	A catch (or catches) detected in the tooth-to-restoration direction,

DELTA	A catch in both directions across the margin,
ZEBRA	Any other finding.

This same examination was completed for any proximal box involved in the restoration, and the appropriate grading given.

2.6.2 Anatomical Form

The maintenance of the anatomical form is a measure of a material's ability to maintain the tooth in its relation both within the arch and with respect to the opposing arch. Excessive wear will allow the tooth to move, drift or over-erupt.
The assessment of anatomical form is considered to be a measure of the material's resistance to wear. The situation where the material was inadequately contoured and left superior to the contour of a tooth was given an additional score.

To measure this criterion, the probe was passed along and across the surface of the restoration and the tooth in many directions. The contour of the restoration, and its conformity with the remaining occlusal tooth shape and contour, was assessed as detailed below:

ALPHA	The restoration followed the main occlusal or proximal contour of the remaining tooth, and the cusp form and ridge form were such as to be continuous with the natural tooth,
BRAVO	The restoration contour was under-contoured or flattened, and so did not follow the original occlusal contour,
CHARLIE	The restoration contour was in excess of what had been the original contour of the tooth,
DELTA	The material was fractured or missing,
ZEBRA	Any other finding.

2.6.3 Caries

The presence of caries at the margin of the restoration could be considered as the ultimate criterion in consideration of long-term success.

The determination of caries at the margin of the restoration was closely defined. Gentle probing of the total accessible cavo-surface margin to detect a catch, rather

than probing for a point of resistance to withdrawal from a catch situation, was advocated by Cvar & Ryge (28).

These standards of caries recognition were also applied to the proximal situation.

The presence of a catch did not of itself signify the presence of caries. The clinical entity of a catch had to be accompanied by one of the following:

(i) softness,

(ii) opacity at the margin of the restoration indicating undermining or decalcification,

(iii) etching or a white spot as evidence of decalcification,

(iv) an area at the margin was also considered carious if the probe did not catch but the conditions (i) and (ii) were satisfied.

The above examination technique was also carried out for any proximal box involved in the restoration and the appropriate code given:

ALPHA	Caries-free situation,
BRAVO	Presence of caries in the occlusal area of the restoration,
CHARLIE	Presence of caries in the proximal box of the restoration,
ZEBRA	Any other finding.

2.6.4 Surface Roughness

The performance of the material in respect of its ability to retain a polish or smooth surface was assessed. Surface roughness may be related to the size and type of particles in a composite, and the quality of the coupling agent in reducing the problem of resin/particle interface bond failure. The difference in the wear rates of the resin and the particles would also contribute to the surface character.

For this judgement, the probe was passed lightly along and across the surface of the restoration many times, in order to estimate the degree of roughness of the restorative material. The categories employed were:

ALPHA	The surface quality of the restoration had a glass-like smooth surface,

BRAVO	The surface quality of the restoration was considered to have a surface similar to fine sandpaper and judged to be capable of re-establishment to a smooth finish,
CHARLIE	The surface quality of the restoration was considered so rough that polishing the restoration would not have restored the smooth surface and would have led to over-carving of the restoration,
ZEBRA	Any other finding.

2.6.5 Interproximal Contact

The potential for wear of composites has been widely reported on the occlusal surface, and wear on the proximal surface would lead to drift of the teeth involved. However, the quality or tightness of the contact between adjacent teeth was assessed. For this, dental floss[4] was employed by holding it between two fingers and passing it through the contact under test.

[4] Sensodyne, Stafford-Miller, Herts, England.

These criteria were applied for this assessment.

ALPHA	Distinct resistance to the passage of the floss between the contact,
BRAVO	No resistance to the passage of the floss.

2.6.6 Colour Match

in the judging of colour match, amalgam restorations were not considered. However, compared to the original assessment situation described by Ryge and Snyder (35) , an additional criterion was introduced to cover the situation where the restoration and the tooth substance differed in colour match. Such a mismatch could be considered by many operators as an advantage, as the restoration margin could be recognised, thus facilitating finishing. In addition, later re-examination could be made easier.

The assessment of colour match was estimated using the dental light for illumination, the restoration being examined by a combination of direct vision and the dental mirror with the following categories pertaining:

ALPHA	The restoration colour was indistinguishable from that of the tooth,
BRAVO	The restoration colour was slightly different from the tooth colour but not displeasing and considered to be within acceptable limits,
CHARLIE	The restoration colour was considered not to be within acceptable limits,
ZEBRA	Any other finding.

2.6.7 Cavo-surface Discolouration

The presence of cavo-surface discolouration can be regarded as an indication of marginal percolation and evidence of potential cavo-surface marginal discrepancy. This could be a portent, either of microleakage or new carious attack. Therefore, the margin of the restoration was examined closely for any indication of discolouration using these criteria:

ALPHA	No discolouration at the cavo-surface margin,
BRAVO	Discolouration present but considered to be less than 10% of the total marginal length,

CHARLIE	Discolouration present but considered to be more than 10% of the marginal length,
ZEBRA	Any other finding.

Chapter 3

Field Study - Results

3.1 Repeatability

Observer reliability was assessed by repeating the assessment for 72 restorations after a one month delay. The percentage match at repeat observations was 92.6% i.e. considerably higher than the 85% required for inter- and intra-examiner agreement by the Cvar & Ryge system (28). Furthermore, no regrading mismatch was greater than one grade away from the original, the distribution of the non-matches being:

Marginal Adaptation	59.4%
Anatomical form	21.9%
Colour match	6.3%
Surface roughness	9.4%
Cavosurface Discolouration	3.1%

3.2 Restoration Numbers in Field Trial

At baseline, Amalgam was inserted into 94 class I and class II cavities in 51 patients. Herculite was placed in 74 class I and II cavities in 36 patients and the

second composite, Occlusin, was placed in 63 class I and II cavities in 29 patients. Within these groupings, there were 18 amalgam, 12 Herculite and 14 Occlusin class II cavities.

At the first year evaluation, 77 amalgam restorations consisting of 65 class I and 12 class II; 64 Herculite restorations made up from 56 class I and 8 class II, and 55 Occlusin restorations - of which 42 were class I and 13 class II design, were evaluated. At the second year examination these numbers had reduced to 65 class I and 12 class II Amalgam; 46 class I and 7 class II Herculite, and 39 class I and 12 class II Occlusin restorations. The distribution of the restorations amongst the patients is shown in **Table 3.1.**

Number of Restorations per Patient

	1	2	3	4	5	6	7	
Amalgam	26	15	8	-	-	-	2	- 94
Herculite	16	12	3	2	1	2	-	- 74
Occlusin	17	4	1	4	-	2	1	- 63

Table 3.1 Detail of the distribution of restorations among the three materials at the trial baseline examination.

As this was a pragmatic study, there was no control of the distribution of the types of cavity restored. The class II numbers are, therefore, small and, as a result only the pooled data i.e. class I and class II will be discussed.

3.3 Statistical Evaluation

The Kruskal-Wallis one-way analysis of variance for ranked data, corrected for ties, was employed. Within the situation where there were only two categories, a Chi-square test was used (77).

3.4 Occlusal Marginal Adaptation

Details regarding the number of grades and percentage distribution are shown in **Table 3.2.**

Occlusal Marginal Adaptation

Amalgam

	Baseline		First Year		Second Year	
Grade	N	%	N	%	N	%
A	40	42.6	20	26.0	16	20.8
B	50	53.2	54	70.1	54	70.1
C	4	4.3	2	2.6	2	2.6
D	0	0	1	1.3	5	6.5
Total	94		77		77	

Herculite

Grade	N	%	N	%	N	%
A	47	63.5	31	48.4	23	43.4
B	27	36.5	33	51.6	30	56.6
C	0	0	0	0	0	0
D	0	0	0	0	0	0
Total	74		64		53	

Occlusin

Grade	N	%	N	%	N	%
A	54	85.7	32	58.2	29	56.9
B	9	14.3	22	40.0	21	41.2
C	0	0	1	1.8	1	2.0
D	0	0	0	0	0	0
Total	63		55		51	

Table 3.2 Detail of numbers and percentages of grades awarded for Occlusal Marginal Adaptation for three materials over two years.

Baseline

Only 42.6% of the Amalgam restorations received Alpha ratings, whereas Herculite Alpha grades were awarded on 63.5% occasions. For Occlusin restorations, Alpha grades were scored for 85.7%.

The performance of the Occlusin, compared to the other two materials at baseline, was found to be significantly better at the $p < 0.001$ level.

First Year

The percentage of Alpha ratings for Amalgam had reduced to 26.0% by this time, and a reduction was also noted for Herculite restorations, with only 48.4% Alpha grades awarded. Occlusin dropped also in the Alpha gradings to 58.2%.

Again, the performance of Occlusin was significantly better than the other materials ($p < 0.01$), although both it and Amalgam had grades of Charlie and Delta scored for some restorations.

Grade Alterations

Amalgam

The grading changes for Amalgam showed that 14 restorations moved from Alpha to Bravo i.e. from a "no catch" situation to a "catch" score in the restoration-to-tooth direction. This downgrading was also seen for

a further two restorations, where one moved from Alpha to Charlie, and one moved from Alpha to Delta. Some degree of improvement was noted in two restorations where the assessments moved the scores from Bravo to Alpha, and in another two from Charlie to Bravo. These changes could have been due to marginal fracture or poor grading.

Herculite

The movement of the grades for this material was much simpler, with 11 restorations going from Alpha to Bravo. There were only three restorations graded Bravo to Alpha, and these findings may have been due to initial wrong grading or the wear of the material "smoothing" out the catch to below 150 um.

Occlusin

This material exhibited 13 restorations graded initially as Alpha, being re-assessed as Bravo. A further one Alpha grade dropped to Charlie, possibly due to a margin of composite which had smoothly overlaid the cavo-surface margin, now having fractured in one area.

Second Year

At the third assessment, the percentage of Amalgam restorations assessed as Alpha again reduced slightly to 20.8%.

This was mirrored both for the Herculite and Occlusin restorations, at 43.4% and 56.9% respectively.
As before, the Occlusin restorations were significantly better than the other two materials ($p < 0.001$).

Grade Alterations

Amalgam

The decline in Alpha scores continued, with six original Alphas now being scored Bravo (one was a reversal of a first year improvement). Superior scores were awarded for three restorations, however, two reverting to a baseline situation.

Herculite

Movement of four restorations was seen from Alpha to Bravo and two showed improvement to Alpha from the Bravo first year scores. However, these had reversed to their original baseline Alpha ratings.

Occlusin

A further two restorations moved away from the ideal to Bravo situation in the one to two year period. However, one improvement to Alpha was again a reversal to its original baseline condition.

3.4.1 Discussion

It has been reported by Leinfelder et al (93) that major loss of composite material through wear occurs in the first 1-6 months of a material's clinical life. The results of the two composites tested here follow this pattern, in that the percentage of Bravo grades increased for Herculite from 36.5%-51.6%, and for Occlusin from 14.3%-40.0%. Amalgam findings paralleled the composite materials in Marginal Adaptation i.e. they declined from base to first year.

The high initial rating of the composite, Occlusin ($p < 0.001$), continued through to the second year. It is possible that the rating of Occlusin might be related to the better sighting or recognition of the margins, because of the poorer colour-match ability. Hence better finishing may have occurred, or else its rougher surface made "step" recognition relatively more difficult to recognise.

The use of marginal adaptation has been adopted as a common measure of composite material wear, possibly as it is easier to recognise clinically the deficiency by probing, although this provides no real guide to the actual amount of wear. Therefore, marginal measurement of the step between the cavo-surface margin and the

surface margin of the composite can give only an indicative result.

In this trial, marginal adaptation was assessed as a clinical entity to try to discern the quality of the margin, and not as a clinical wear measurement. As seen under the measuring microscope (vide infra), the composites' margin maintained close approximation to the walls with no distinct gaps. At worst a "rolled edge" was noted for the fine or microfilled composite, alternatively described by Leinfelder (20) as composite marginal ditching, or by Fukushima et al(130),as cavo-marginal porosity. With amalgam, distinct gaps could be discerned between the material's edge and the margin wall.

The low value of the amalgam occlusal marginal adaptation may be due, in part, to the fact that two of the clinics had a low proportion of baseline "A" grades, possibly indicating that their clinicians did not polish the amalgams as instructed in the protocol (Appendix 1).

However these low amalgam scores were particularly disappointing, especially as a high copper content amalgam alloy was used to reduce marginal corrosion and improve marginal adaptation.

3.5 Proximal Marginal Adaptation

The results of the proximal marginal adaptation grades are shown in **Table 3.3.**

Proximal Marginal Adaptation

Amalgam

	Baseline		First Year		Second Year	
Grade	N	%	N	%	N	%
A	13	72.2	8	66.7	6	50.0
B	2	11.1	2	16.7	5	41.7
C	3	16.7	2	16.7	1	8.3
D	0	0	0	0	0	0
Total	18		12		14	

Herculite

Grade	N	%	N	%	N	%
A	7	58.3	4	55.0	3	42.9
B	5	41.7	3	37.5	4	57.1
C	0	0	0	0	0	0
D	0	0	1	12.5	0	0
Total	12		8		7	

Occlusin

Grade	N	%	N	%	N	%
A	12	85.7	10	76.9	9	75.0
B	2	14.3	2	15.4	2	16.7
C	0	0	1	7.7	1	8.3
D	0	0	0	0	0	0
Total	14		13		12	

Table 3.3 Detail of numbers and percentages of grades awarded for Proximal Marginal Adaptation for three materials over two years.

No significant differences were noted regarding the performance of the materials and considering the low numbers, little can be judged from these results.

3.6 Anatomical Form

The results of the anatomical form scores are detailed in **Table 3.4.**

Anatomical Form

Amalgam

	Baseline		First Year		Second Year	
Grade	N	%	N	%	N	%
A	39	41.5	20	26.0	25	32.5
B	50	53.2	54	70.1	50	64.9
C	5	5.3	3	3.9	2	2.6
D	0	0	0	0	0	0
Total	94		77		77	

Herculite

Grade	N	%	N	%	N	%
A	37	50.0	31	48.4	23	43.4
B	30	40.5	31	48.4	29	54.7
C	7	9.4	1	1.6	1	1.9
D	0	0	1	1.6	0	0
Total	74		64		53	

Occlusin

Grade	N	%	N	%	N	%
A	27	42.9	14	25.5	9	17.7
B	30	47.6	39	70.9	42	82.4
C	9	6.5	2	3.6	0	8.3
D	0	0	0	0	0	0
Total	63		55		51	

Table 3.4 Detail of numbers and percentages of grades awarded for Anatomical Form for three materials over two years.

Base Line

Here, amalgam restorations were assigned 41.5% Alpha grades. A slightly higher level (50.0% Alpha grades) was allocated to the Herculite restorations while 42.9% of Occlusin's were given this rating. However, no significant differences were found between the data pertaining to any of the materials.

First Year

At the first year examination, the performance of Amalgam restorations dropped to 26.0%, whereas, in the Herculite situation a minimal fall was seen to an Alpha level of 48.4%. The performance of Occlusin appeared poorer at year one, with a 25.5% level of Alpha assessments.

Statistical testing indicated a significantly better performance of Herculite over the two other materials ($p < 0.01$).

Grade Alterations

Amalgam

The grades of 11 restorations of this material were re-assessed from Alpha to Bravo. Improvement from Bravo to Alpha rating was seen in two restorations, although these were from an underbuilding situation.

Movement in the other direction i.e. from overbuilt to underbuilt, was observed in only one restoration.

Herculite

The data relating to this material indicated some wear, with four Alpha values moving to Bravo. Further evidence of wear was observed by the regrading of three scores from Charlie to Bravo, and two from Charlie to Alpha. However, six moved from Bravo to Alpha, and one from Bravo to Charlie. This improvement is difficult to explain, but may be due to poor interpretation at the assessment.

Occlusin

Movement of grades for this composite again showed material loss, with 10 changing from Alpha to Bravo, four changing from Charlie (excess material) to Bravo. However, four restorations graded Bravo were re-assessed Alpha, and one Bravo altered to Charlie. As with the similar Herculite situation, it is not easy to explain this apparent improvement. Hence these variations might have been due to according the wrong initial assessment.

Second Year

The reduction in the levels of Alpha ratings continued for both Herculite and Occlusin at the second year

examination (43.4% and 17.7% respectively), whereas the Amalgam restorations increased their percentage Alpha ratings to 32.5%. With respect to Herculite, it maintained its significantly better performance over the two other restorative materials ($p < 0.05$).

Grade Alterations

Amalgam

A single restoration was graded Bravo from Alpha - this being another change back to the original assessment. However, five restorations were scored Bravo from Alpha, with loss of material rated as responsible for the new gradings.

Furthermore, two changed from Charlie to Bravo, whereas one moved Bravo to Charlie. Again, such grading alteration movement has been explained earlier.

Herculite

A further movement of seven grades downwards from Alpha to Bravo, was partly balanced by two moving upwards, one from Bravo to Alpha, and one from Charlie to Bravo.

Occlusin

A small fall of five Alpha grades to Bravo was noted with three scores moving upwards, two from Charlie to Bravo, and one from Bravo to Alpha

3.6.1 Discussion

Again, the amalgam restorations did not perform as would be expected for this type of material, as surely it should have retained form over the relatively short time-span of the study period.

The assessment of anatomical form was particularly subjective, and was made more difficult with tooth-coloured materials. However, the assessment was carried out to estimate if the material had changed in gross form from the baseline, and was not used as a measure of quantifying material loss.

Overall, the major change was a flattening of the surface contour of the two composites. The loss of occlusal form for composites occurred mainly between the base and first year assessment, although Herculite maintained a higher percentage throughout the study period. Furthermore, while the assessment of occlusal form loss was, in effect, estimating material disappearance over the whole of the surface, quantification was possible, and it was interesting to note the difference in assessed performance of the two composite materials. Occlusin was statistically better in marginal adaptation, whereas Herculite was regarded as having retained its anatomical form over the two years. Taking the stand that anatomical form retention is a better indicator of resistance to

wear, Herculite would be ranked as the superior material, whereas the commonly practised regime of using the marginal adaptation score would place Occlusin in the better wear category.

However, this question can only be answered by using indirect measurement techniques, and the introduction of sophisticated computer mapping programs now make it possible to quantify such loss, so resolving the problem of the relationship between clinical wear assessment methods and indirect techniques.

3.7 Caries

The grade distributions for caries scores are as indicated in **Table 3.5.**

Caries

Amalgam

	Baseline		First Year		Second Year	
Grade	N	%	N	%	N	%
A	94	100.0	77	100.0	74	96.1
B	0	0	0	0	3	3.9
C	0	0	0	0	0	0
D	0	0	0	0	0	0
Total	94		77		77	

Herculite

Grade	N	%	N	%	N	%
A	74	100.0	63	98.4	52	98.1
B	0	0	0	0	1	1.9
C	0	0	1	1.6	0	0
D	0	0	0	0	0	0
Total	74		64		53	

Occlusin

Grade	N	%	N	%	N	%
A	63	100.0	55	100.0	49	96.1
B	0	0	0	0	1	2.0
C	0	0	0	0	1	2.0
D	0	0	0	0	0	0
Total	63		55		51	

Table 3.5. Detail of numbers and percentages of grades awarded for Caries for three materials over two years.

There was no evidence of carious involvement associated with any of the restorations during the first year. However, after the second year examination, carious attack was observed in five restorations, two amalgam, one Herculite and one Occlusin restoration.

3.7.1 Discussion

This minimal evidence of caries affecting the restorations placed has been a common finding in most other trials involving composites.

3.8 Surface Roughness

Data relating to surface roughness are listed in **Table 3.6.**

Surface Roughness

Amalgam

	Baseline		First Year		Second Year	
Grade	N	%	N	%	N	%
A	41	43.6	30	39.0	43	55.8
B	53	53.4	47	61.0	34	44.2
C	0	0	0	0	0	0
D	0	0	0	0	0	0
Total	94		77		77	

Herculite

Grade	N	%	N	%	N	%
A	69	93.2	61	96.8	53	100.0
B	5	6.8	2	3.2	0	0
C	0	0	0	0	0	0
D	0	0	0	0	0	0
Total	74		64		53	

Occlusin

Grade	N	%	N	%	N	%
A	16	25.4	3	5.5	1	2.0
B	47	74.6	52	94.6	50	98.0
C	0	0	0	0	0	0
D	0	0	0	0	0	0
Total	63		55		51	

Table 3.6 Detail of numbers and percentages of grades awarded for Surface Roughness for three materials over two years.

Baseline

The percentage of assessments for Amalgam was distributed between 43.6% Alpha and 56.4% Bravo grades. In contrast, 93.2% of all baseline Herculite restorations were rated as Alpha, but the surface roughness of Occlusin was scored particularly low, only 25.4% Alpha grades being awarded for all restorations.

Herculite was significantly better than the other two materials ($p < 0.001$).

First Year

The distribution of Alpha and Bravo ratings for Amalgam at the first year stage moved little from that at the baseline (43.6-39.0%). The Alpha ratings for the Herculite restorations increased slightly to 96.8% while Occlusin gradings dropped to only 5.5% Alpha for all restorations.

Herculite was again significantly better than the other two materials ($p < 0.001$).

Grade Alterations

Amalgam

The main movement, 11 Alpha grades to Bravo, showed surface degrading. Nonetheless, improvement was seen with six restorations regraded Alpha to Bravo.

Herculite

Only two restorations changed to a poorer surface grading, but four improved to Alpha in this assessment period .

Occlusin

A lowering of grading i.e. Alpha to Bravo, indicated degradation of the surface, had occurred in 12 restorations, whereas only two improved.

Second Year

Occlusin data were particularly poor with only 2.0% rated Alpha. Herculite performed significantly better than the other test materials at this evaluation stage, 100% rated Alpha ($p < 0.001$).

Grade Alterations

Amalgam

The surface roughness of Amalgam improved in 14 restorations i.e. Bravo to Alpha, whereas two moved from Alpha to Bravo. Reversal of the grades back to the original was observed, with four moving Bravo to Alpha, while one grade reverted Bravo to Alpha.

Herculite

Improvement was observed with two restorations having

changed from Bravo to Alpha, but these were noted as having dropped from Alpha to Bravo at the first year assessment.

Occlusin

There were only two changes at the second year stage from Alpha to Bravo, but these again reversed the first year situation back to the baseline score.

3.8.1 Discussion

Occlusin surface roughness was rated significantly worse than that of the other two materials at baseline and at the later intervals, because the surface finish was constantly rough. This texture was not gross, but was of the order of fine sandpaper, a characteristic which was retained over the whole of the study period. However, the movement of the Alpha grades to Bravo was much higher from base to first year indicating that a number of surfaces did degrade over this period of time.

In contrast, the surface of Herculite had a smooth glassy feel to the probe, this being retained throughout the trial. It performed significantly better against the other two materials at the base, first and second year examination ($p < 0.001$).

These two findings relate directly to the formulation of both materials and, for Herculite, supports the manufacturer's claim to be a composite with good surface characteristics.
Again the low rating value for amalgam may be due to the failure of some operators to polish these restorations, as only 11% of those placed by two of the clinics were graded Alpha at baseline.

3.9 Interproximal Contact

The quality of interproximal contact was rated 100% Alpha for all class II restorations examined. This finding may relate to the fact that the population age range was 8-17 years. Hence the continual eruption and development of the dentition may have contributed to contact tightness. However, as the numbers involved in this part of the study were not high, the conclusions may not be applicable to a larger population group.

3.10 Colour Match

The results of the grading for colour match in the field study are detailed in **Table 3.7.**

Colour Match

Herculite

	Baseline		First Year		Second Year	
Grade	N	%	N	%	N	%
A	9	12.2	9	14.1	16	30.2
B	65	87.8	55	85.9	37	69.8
C	0	0	0	0	2	2.6
D	0	0	0	0	0	0
Total	74		64		53	

Occlusin

Grade	N	%	N	%	N	%
A	4	6.4	1	1.8	1	2.8
B	56	88.9	54	98.2	49	96.1
C	3	4.8	0	0	0	0
D	0	0	0	0	0	0
Total	63		55		51	

Table 3.7 Detail of numbers and percentages of grades awarded for Colour Match for two materials over two years.

Baseline

Only Herculite and Occlusin were included in this assessment, and their performance was not ideal, with low Alpha ratings for both materials - 12.2% for Herculite and 6.4% for Occlusin. No grades below Bravo were noted for either formulation, and no significant differences were detected between the materials.

First Year

A small change upward in the allocation of Alpha grades for Herculite (14.1%) was seen at this assessment, whereas the Occlusin Alpha ratings dropped to 1.8%. Nonetheless, these data were significant at the 5% level.

Grade Alterations

Herculite

There was minimal change to the grades with just two Alphas dropping to Bravo. However, seven Bravos improved upward to Alpha standard.

Occlusin

Decline was noted in four restorations to Bravo, but improvement was seen with one Bravo raised to Alpha, and three from Charlie to Bravo.

Second Year

A large improvement of Bravo ratings to Alpha was noted for Herculite, with 30.2% being awarded this score. Occlusin maintained a low level for Alpha grades at this time (2.0%), and these differences were significant at the 1% level.

Grade Alterations

Herculite

Improvement in colour match was continued in 10 restorations, with downgrading in three cases.

Occlusin

For this material, there was minimal change within the scores awarded at this time.

3.10.1 Discussion

Herculite blended into the tooth colour better than did Occlusin, and the data improved between base and first year, then continued through to the second year. On the other hand, Occlusin was not aesthetically unacceptable and displayed some movement to better colour match. However, its capacity to match tooth colour was much less than that of Herculite ($p < 0.01$).

Although the colour match of composite should be close to that of tooth substance, it could be argued it should not be identical, as a slight mismatch might also be clinically beneficial by showing the cavo-surface margins to advantage. Here the performance of the composite, Occlusin, fell into this latter group.

The apparent improvement in colour match recorded in this study has been reported elsewhere by Wilson et al (68) in their Occlusin trial.

3.11 Cavo-surface discolouration

The distribution of grades, numbers and percentages regarding cavo-surface discolouration are shown in **Table 3.8.**

Cavo-surface Discolouration

Amalgam

	Baseline		First Year		Second Year	
Grade	N	%	N	%	N	%
A	93	98.9	76	98.7	73	94.8
B	1	1.1	1	1.3	2	2.6
C	0	0	0	0	2	2.6
D	0	0	0	0	0	0
Total	94		77		77	

Herculite

Grade	N	%	N	%	N	%
A	72	97.3	60	93.8	49	92.5
B	2	2.7	3	4.7	3	5.7
C	0	0	1	1.6	1	1.9
D	0	0	0	0	0	0
Total	74		64		53	

Occlusin

Grade	N	%	N	%	N	%
A	62	98.4	47	85.5	46	90.2
B	1	1.6	6	10.9	3	5.9
C	0	0	2	3.6	2	3.9
D	0	0	0	0	0	0
Total	63		55		51	

Table 3.8 Detail of numbers and percentages of grades awarded for Cavo-surface Discolouration for three materials over two years.

Baseline

All three materials had high baseline Alpha values i.e. Amalgam- 98.9%; Herculite- 97.3% and Occlusin- 98.4%. Furthermore, there was no significant difference in the performance of the three materials over the examination time-scale involved.

First Year

The percentage of Alpha grades for Amalgam was 98.7%. A small change for Herculite Alphas was registered to give a 93.8% level. However, Occlusin dropped 13% to 85.5% for Alphas ratings. This was significant ($p < 0.01$) for Occlusin as compared to Amalgam and Herculite.

Grade Alterations

Amalgam

There were no grade alterations for Amalgam throughout the two year period.

Herculite

Only three movements of grades were noted here - one Alpha to Bravo; one Alpha to Charlie, and one showing improvement of Bravo to Alpha.

Occlusin

The changes of grade were more in a downward direction

with six at Alpha to Bravo, and one Alpha to Charlie, whereas only one grade showed any improvement i.e. Bravo to Alpha.

Second Year

Both Amalgam and Herculite maintained approximately similar levels at this assessment. Occlusin did improve in Alpha rating but this may be due to the loss of restorations with poor cavo-surface margins through non-attendance of patients.

There were no significant differences determined between the results for this criterion.

Grade Alterations

Amalgam

There were only two changes in this criterion from the base to first year - two Alpha awards moved to Charlie. This indicated a minimal involvement in discolouration.

Herculite

Here only two restorations changed, one downwards to Bravo, and one upwards to Alpha i.e. a reversal to the baseline position.

Occlusin

Marginal discolouration was observed to improve in three

situations, but these reversed back to their original status.

3.11.1 Discussion

The two composites maintained a high degree of non-staining at the cavo-surface margin despite the continuing loss of marginal adaptation and actual material. From the observations of the replicas under the measuring microscope, both composite materials did not lose continuity between the cavity wall and the material itself. Minimal marginal ditching was noted, but it was in effect a "rolled edge" of minimal depth, with no gaps or clefts to attract and retain stain or plague.

3.12 Discussion of Field Trial

3.12.1 Occlusal Marginal Adaptation

Conventional Composite

Occlusal marginal adaptation of early composite materials was reported by Phillips et al (58);(60) at first and second year. Here, the Alpha grades were 87.0 % for amalgam and 94.6% for composite ($p < 0.03$) after one year. The two year Alpha ratings were - for amalgam, 76.1%; and for composite 81.5%; with no statistical difference being

shown between the materials. The three year results for Phillips et al (62) remained basically similar, but at a lower significance level. Osbourne et al (59) reported composite marginal adaptation better at $p < 0.05$, this remaining unchanged over the two year period.
Leinfelder (61) compared a number of anterior and posterior composites, and stated that the marginal adaptation was "highly satisfactory" at the two year interval. Eames et al (63) investigated conventional composite and amalgam, but again no significant difference was found between the two materials over the two - three year period.

Intermediate Composite

Wilder et al (65) tested four intermediate sized composite materials, and noted none showed marginal discrepancies over their three and five year trial period. However, it is interesting to note that distinct marginal steps were illustrated and measured as part of the loss of anatomical form, i.e. the equivalent to "wear".

Wilson and co-workers reported yearly on the results of a five year trial with the composite, Occlusin, (66);(131);(67);(132);(68), and stated that the Alpha rating dropped over this time from 98.7% at year 1; to

90.4% at year 2; to 72.7% at year 3; 50% at year 4, and 58% at year 5. The authors commented that the marginal adaptation was affected by restoration size. Another field trial of the same material, by Rowe & Robinson (69), reported there was a highly significant difference at three years for occlusal marginal adaptation in the performance between the composite and amalgam. At five years this difference was reported significantly at the 5% level (70).

The composite later marketed as "Fulfil", was investigated by Boksman et al (72) at the three year interval, when 96% of restorations were graded Alpha. Sturdevant et al (73) reported 88% of the composite restorations (Fulfil) examined at year one had Alpha ratings. This scoring increased to 96% at two years, and 100% at three years for the teeth remaining in the study. However, this cannot be equated with the results reported by them on wear measurement, at levels up to 164 um. A similar high level of marginal adaptation was also reported by Brunson et al (95), with Alpha ratings of 94% at year 1, 98% at year 2, and 96% at year 3.

The results of the present trial follow the pattern of Wilson et al (66) (67) (131), in that the percentage

of margins maintaining Alpha ratings over the trial period decreased over time, but the levels noted in this study are lower than those of others. This may be due, in part, to the pragmatic study design undertaken, and to the "fact" that the margin was assessed for discrepancies, and not to assess wear nor the Anatomical Form.

3.12.2 Anatomical Form

Conventional Composites

Phillips et al (58), in their first year report, stated that the amalgam and composite materials were "essentially equal in terms of anatomical form". Their first year data showed amalgam restorations rated 100% Alpha and composite rated 79%. At two years, these workers commented that 45% of composites continued to rate Alpha, in comparison to the amalgam control (98%), and that this change in anatomical form was due to occlusal wear. The three year report gave only 14.3% of composite restorations an Alpha rating i.e. a significantly poorer relation to amalgam restorations ($p < 0.001$). Osbourne et al (59), in distinction to Phillips et al (58), showed the anatomical form rating of composite restorations to have decreased significantly in the first year of use ($p< 0.001$). This

decrease continued into the second year, but the marginal adaptation did not deteriorate. The findings of Leinfelder et al (61) allocated wear to anatomical form, and reported that all four materials tested had reduced sufficiently to expose dentine.

Anatomical form was better retained with the amalgam than with the composite on trial (Adaptic) in a study by Eames et al (63), where the composite was rated with only 25% at Alpha grades. Here again the composite marginal adaptation was consistently rated higher.

Intermediate Composites

With the advent of the intermediately filled materials, Wilder et al (65) expressed the opinion that although Nuvafil was significantly worse than the other three formulations tested, all could be considered clinically acceptable, with the extent of wear being minimal, and with no marginal discrepancies. This trial was also reported at the five year stage (64);(65) when the anatomical form was stated as equivalent to wear. The materials were again regarded as clinically acceptable, with no significant statistical difference between the four materials.

However none of these rated more than 45% Alpha values, and wear (measured by the Leinfelder step technique) gave a range 145-228 μm.

Wilson and co-workers (66);(131);(67);(132);(68) reported Alpha values at year 1 as 97.4%; 96.2% at year 2, 96.4% at year 3;88% at year 4, and 64% at year 5. The only factor commented on was that the larger restorations showed a slightly higher trend to worsen. Wear, using the Leinfelder step assessment technique, was reported as 238 um at heavy occlusal contact areas, with an overall average rate of 154 +/- 97 μm . Material loss was 166+/-103 μm on molars and 125+/- 72 μm for premolars. The large standard deviation was commented upon.

Occlusin was reported on also by Robinson & Rowe (69) at three years, and by Rowe (70) at the five year interval. After the former period, the composite material showed 92.3% Alpha values and wear was measured at 78 +/-36 μm. At five years, with 66% rated Alpha, no significant difference between the composite and the amalgam control was noted. The wear measured was 129+/-59 μm, a slightly lower finding than reported by Wilson et al (66);(131);(67);(132);(68).

Tyas et al (71) did not comment on the anatomical form per se, USPHS assessment was not used but did measure the wear experienced.

The anatomical form of a composite (Fulfil) was evaluated by Boksman et al (72) as a measure of wear

resistance, and all the restorations were rated at Alpha. This is a surprisingly high assessment at the three year time interval. Again wear, measured by the step technique, was given as 122 μm, although all margins were scored Alpha. This crossover of wear assessment and anatomical form was seen again in the reports of Sturdevant et al (133);(73);(74) at two, three and five year reports. Wear at three years, was given as 145+/-9 μm, but the marginal adaptation was stated to be 100% Alpha. The marginal adaptation at five years was 95% Alpha and the average wear at this interval was 158 μm. The high level of anatomical form retention was not found by Brunson et al (75) investigating P-10, where only 59% of restorations were found to be Alpha rated. However the marginal adaptation was given as 96%, but the average wear measurement was claimed as 192 μm.

Microfine Composites

Microfine materials were tested by Heymann et al (76) over a two year period, and showed a 70-86% range with Alpha grade retention.

No statistically significance difference was reported between the materials.

In the present study, the baseline Alpha level of all three materials was not high. The anatomical form of the

Amalgam and Occlusin dropped by a similar degree. Herculite, on the other hand, maintained anatomical form in the first twelve months. Amalgam sustained its level of gradings over the next twelve months, as did Herculite - but at a higher level, while Occlusin dropped further in the assessment scores. Direct comparison of anatomical form was difficult as, in the majority of other studies, this assessment has been used as, or equated with, wear. The maintenance of anatomical form of Herculite was observed over the trial period, albeit from a lower baseline.

3.12.3 Caries

A very low prevalence of secondary caries has been reported in field trials published to date, and must be considered to be of no real consequence during such relatively short periods.
Indeed such findings were repeated in the present investigation.

3.12.4 Surface Roughness

This criterion was not included in the Cvar/Ryge assessment technique (28). However, its scoring was considered necessary due to the on-going development of

composites, resulting in the introduction of the smaller particle-sized filled materials. These are claimed to reduce the wear and surface roughness observed in earlier formulations. While composite wear has consumed the interest of many workers, the reporting of surface roughness appears to have been ignored in trials other than those on Occlusion.

The ratings for this criterion fell from a first year rate of 98.3% (Alpha grade) to 66% unchanged Alpha at five years, as reported by Wilson et al (68), and Rowe (70).

In the present trial, the high level of Alpha ratings applied to Herculite, and this fine particle material continued to score well throughout the study. Indeed it had a 100% Alpha rating awarded to it at the second year. Occlusin was rated low at base, and slipped between the baseline and first year assessments. However, the low scoring in this study may be due to the formulation of the composite and also to the fact that comparison was made against a fine particle filled material rather than against amalgam, as was the case with Wilson et al (66);(131);(67);(132);(68).

3.12.5 Cavosurface Discolouration

This criterion can be regarded as a indicator of the material's potential to take up marginal stain, so indicating possible initial microleakage and the potential for caries attack.

Conventional Composites

Field trial results vary with the type of material and across generically similar formulations. Phillips et al (58);(60);(62), found 33% Alpha ratings at the three year period, whereas Osbourne et al (59) rated 69.49% Alpha although both were using conventional, early composites formulations.

Intermediate Composites

Both Leinfelder et al (61), and Wilder et al (64), reported high levels of Alpha assessments of margins without staining at two and three years.

The findings of Wilson et al (68); Robinson & Rowe (69), and Rowe (70), generally agreed on the marginal stain level at five years, with approximately 49% of restorations still unstained. Boksman et al (72), using a different intermediate material (Fulfil), again reported a very high level of unstained margins i.e. 96% at three years. This finding was supported by

Sturdevant et al (74) who claimed 95% unstained composite margins at the same time interval.

Microfine Composites

In contrast to the above findings, Heyman et al (76, 79) reported stained margins level, (depending on the composite tested) in 86% of cases.

Marginal staining was minimal at the baseline in the present trial and although there was a small significant change at the first year period, it returned to a non-significant situation at year two.

3.12.6 Colour Match

The colour-matching ability of conventional materials was assessed by both Phillips et al (58);(60);(62), and Osbourne et al (59);(88), who reported a steady fall in the colour-matching ability of these materials. Similar findings were noted by Leinfelder et al (61), although the intermediate materials reported on by Wilder et al (64);(65);(65) over a five year interval, ranged from 93% Alpha, depending on the formulations. Wilson et al (66);(131);(67);(132);(68); Robinson & Rowe (69), and Rowe (70) investigated another intermediate material and showed a high percentage of restorations with marginal

assessment grades unchanged. Nevertheless, a number of composite restorations were rated as having improved their colour matching ability, a feature which was also reported by Tyas et al (71). A colour improvement was also noted by Wilson et al (68) for a small number of Occlusin restorations, an intermediate particle filled material.

The current study did not support the findings of Wilson et al (68) and Rowe (70) on the improvement in colour matching ability of Occlusin. Certainly, the colour match of the material was never rated higher than 6.4% at baseline. However, it must be noted that a potential mismatch was deliberately built in to the formulation of this material (66).

On the other hand, Herculite did show progressive advancement in tooth matching ability, with the significance increasing progressively over the two years studied.

CHAPTER 4

Laboratory Investigation - Materials and Methods

4.1 Introduction

While clinical assessment of restorations provides information on the performance of materials in in-vivo situations, it is impossible to measure accurately the changes occurring to a restorative material in-vivo. Replica measurement does furnish the observer with opportunity to study and measure changes to material remote from the patient and in a more regulated situation.

In-vitro measurement of casts of restorations placed during clinical trials have been undertaken by a number of investigators (76);(93);(69);(70);(73);(71);(67) to measure the wear of restorative materials.

The present investigation was undertaken, over a two year period, to assess the wear or material loss from the two posterior composite materials under study and the amalgam control, together with the relationship of the area of tooth and restoration to the material wear.

4.2 Preparation of the Cast

4.2.1 Impression Material Choice

For cast preparation, the impression material used had to fulfil the following criteria:

(a) Accuracy and Stability;

As impressions were taken in clinics distant from the Dental School, it was essential the impression remained stable and accurate until required for copper plating and subsequent casting of the impression.

(b) Ease of mixing;

The services of a dental surgery assistant could not be guaranteed at all clinics, therefore, handling and mixing of the material had to be simple.

(c) Rapidity of set and pleasing taste and smell;

As impressions were to be taken of restorations placed by community dentists, the young patients might not relate easily to the assessor, thus the material had be in place for minimal time in order to cause least discomfort to the recipient.

(d) Copper-plating compatibility;

Artificial stone surfaces are abraded easily, leading to measurement inaccuracies. Copper plating can afford some degree of protection to the cast surface, and can also show surface abrasion.

A number of classes of impression material were considered viz:-

Reversible and non-reversible hydrocolloid impression materials did not meet a number of the stated requirements, and were not considered.

Polysulphide materials, although accurate and stable over a considerable time, had a distinctly unpleasant smell and took up to ten minutes to set. In addition, the mixing regime was demanding and required two operators to supply the correct delivery consistency. Hence, this class of materials was discarded.

Polyether materials were accurate and had a simple mixing regime, but were not stable over a period of time as they were affected by water. As such, they were deemed unsuitable.

Polyvinylsiloxane impression materials were accurate and stable (134);(135), the setting-time was satisfactorily short. The material, was presented as a two-paste system contained in twin cartridges. To mix, the pastes were simply squeezed through a common tube containing a double helix which immediately mixed the two components (136). This auto-mixing system eliminated mixing discrepancies and reduced the number and size of air inclusions

(137);(138). The material set within 3-5 minutes, which was considered to be within the tolerance level of most patients in the survey.

The medium-bodied presentation of the impression material was used, as the fine-bodied version was considered to have too much flow, and might have caused discomfort to children. Furthermore, the lack of distinct odour was regarded as an advantage, and for these reasons, this material type was chosen for the trial.

4.2.2 Impression Technique

A quadrant impression containing the restoration was adopted as the norm, as it was considered this would be more comfortable for young patients. Quadrant disposable perforated trays[5] were used to carry and support the impression material[6], and both the internal surface and a 1 cm band over the outside edge of the tray, were coated evenly with the recommended adhesive for the material.

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[5] F H Wright, Dundee

[6] Express,3M,Minnisota, USA

For the examination, the patient was seated in the dental chair and the dried restoration was inspected and graded. The quadrant containing the restoration was dried again, either by compressed air jet or cotton wool rolls. Some impression material was rubbed over the occlusal surfaces of the teeth to reduce air inclusions. The impression-filled tray was placed over the quadrant, and held in place until the material had set fully.

The set impression was removed, washed and inspected at the chairside for gross air-blows or air inclusions. The impression was marked with the patient code for future reference, and placed in a polythene bag for transport to the Dental School. Within 24 hours, the impression was inspected again, re-washed to free the surface of any loose debris that might have adhered to the surface during transport and blown dry using medically-pure compressed air.

4.2.3 Copper-Plating Technique

As stated above, improved, hardened dental stones are commonly used as die materials in restorative dentistry. However, their surfaces are susceptible to abrasion, and the surface durability of the casts was important as they had to be stored over a prolonged period without deterioration. Hence, copper-plating the impression

surface was undertaken to provide an accurate, durable surface-coating particularly suitable for measurement (139);(112). However, polyvinylsiloxane impression materials are not electrically conductible without special surface preparation, which was achieved by coating the surface with a fine layer of a conductive material.

Three methods of laying down a conductive layer were considered for the trial:

(a) colloidal graphite

(b) fine copper dust

(c) silver-containing aerosol

(a) Colloidal graphite is a fine suspension of graphite particles in water. This solution was painted over the surface of the impression, the excess gently blown off to leave the surface covered with graphite. This technique did not cover completely, or evenly, the impression surface, as the surface tension of the silicone material repelled the water-based solution. Repeated application of the solution did not guarantee total coating of the surface without leaving gaps or areas where the graphite was applied too thickly **(Fig. 1)**.

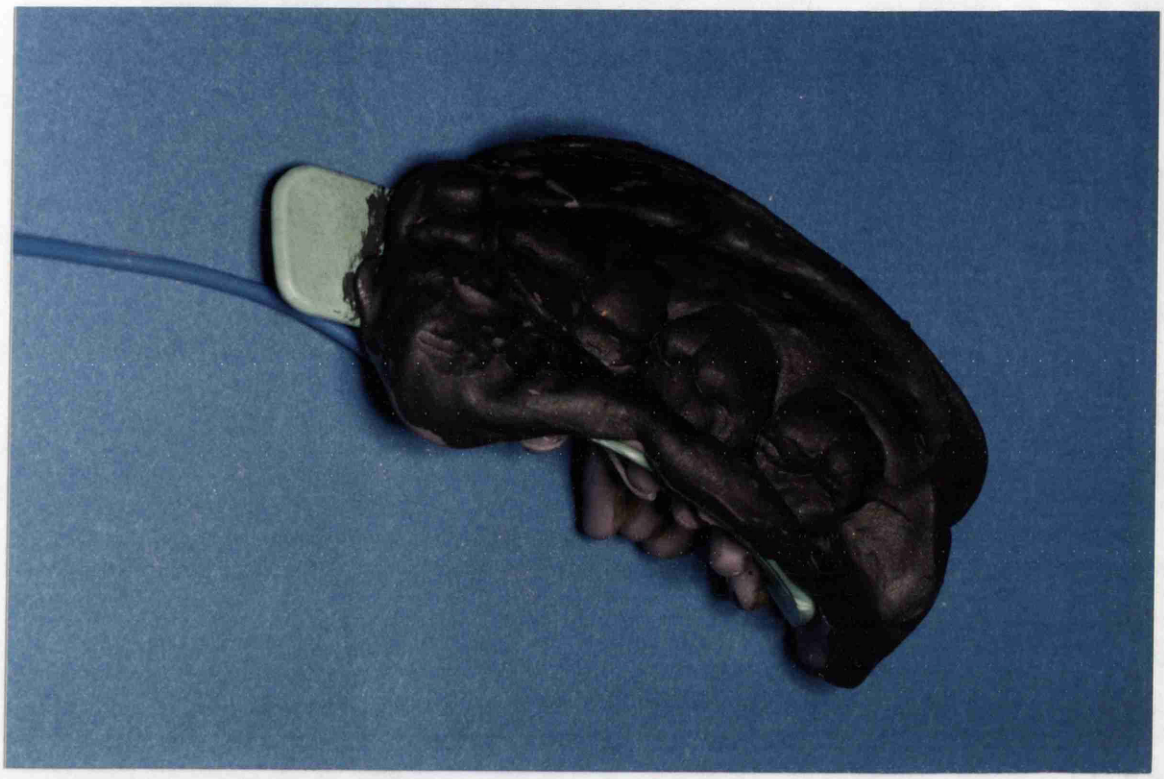

Figure 1. Quadrant impression coated with colloidal graphite.

(b) Super-fine copper particles were brushed vigorously over the dry impression surface and the excess blown off. This technique had to be repeated several times to ensure total covering. The surface was coated more easily than with the graphite method, but it was difficult to confirm that dust had been brushed into the finer details of the occlusal surface **(Fig. 2)**.

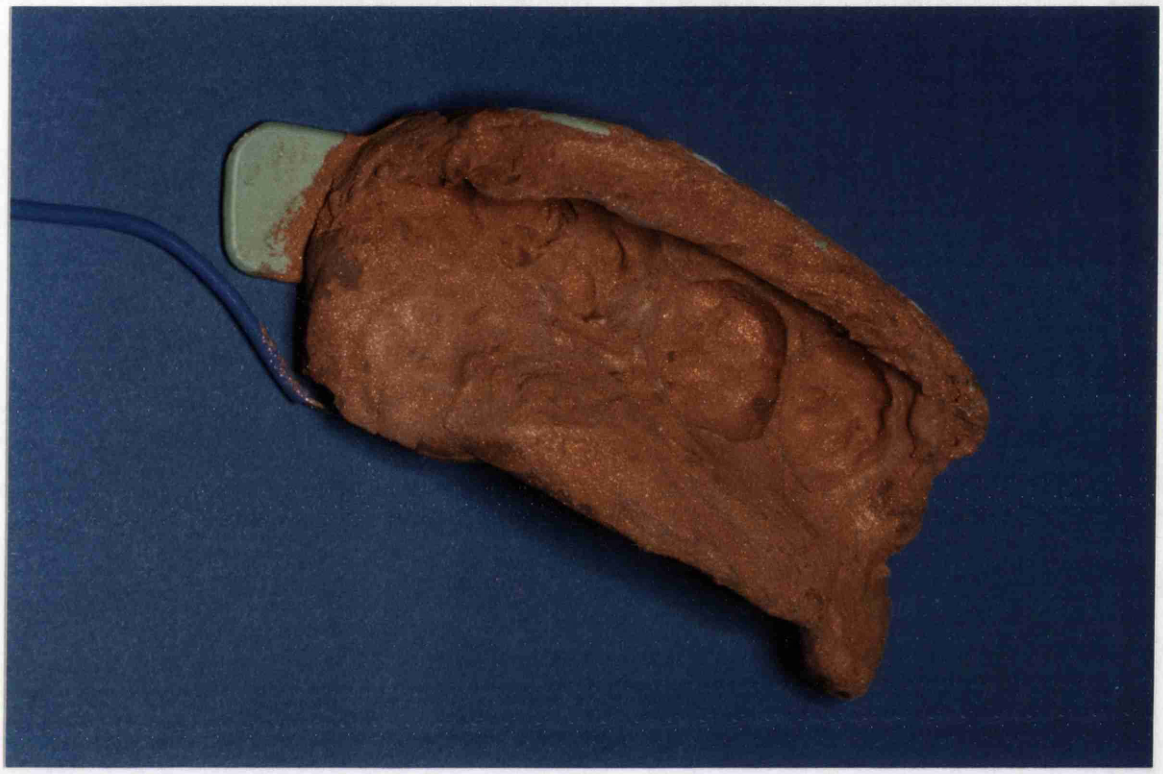

Figure 2. Quadrant impression coated with fine particle copper.

(c) The impression surface was coated using a silver-containing aerosol spray to produce an electrically-conductive layer of silver.[7] The impression was continually rotated to the spray head to ensure an even coating of all the surface, after which it was allowed to

[7]Galvo Spray,DETAX,Karl Huber KG,D-7500,Karlsruhe 1,Germany

dry. As this last method gave the best surface results, it was the one adopted for the trial **(Fig. 3)**.

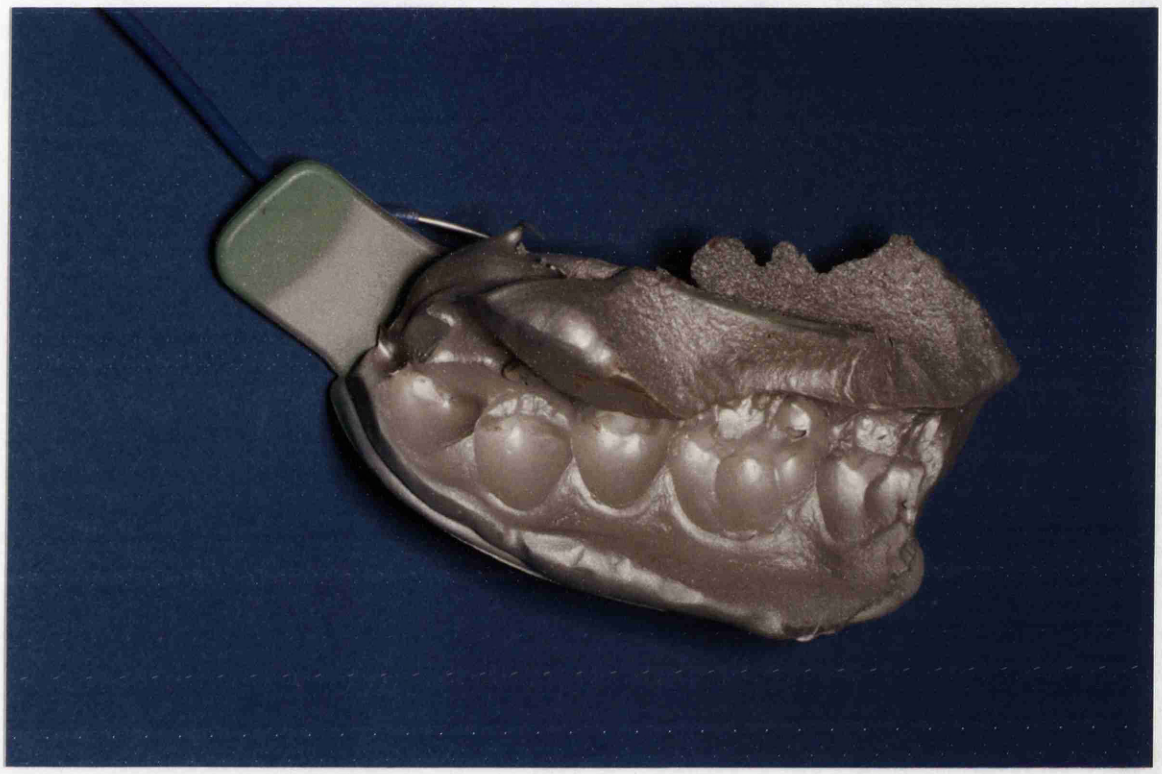

Figure 3. Quadrant impression coated with silver.

Single strand plastic covered wire, (20 cms x 1 mm diameter) was selected, and 15 mm bared at each extremity. One end was pierced through the tray and completely through the body of the impression material, in an area away from the restored tooth. The impression was turned over and the wire turned back on itself and

re-pierced into the impression surface, to lock it in position and to ensure good electrical contact to the silver coating.

The impression surface was sprayed and covered with a fine coating of silver, and the surface inspected for completeness, then set aside to dry.

The coated impression was lowered into the copper sulphate solution of the plater bath[8] until it was covered completely (Appendix 3). The current was switched on and the other bared free end of the wire applied to a terminal. A deflection of the ammeter then indicated a current flowing, thus confirming good contact with the conductive coat over the impression surface. This procedure was repeated for each of six coated impressions which were firmly attached to the terminal, immersion checked and the current adjusted to 0.2 amps for an 18 hour period to give an approximately 54 µm thickness of copper deposited on the impression surface.

Thereafter, the plated impression was removed from the bath, washed in running water to remove the acidic copper sulphate solution from the surface, which was then examined for areas of incomplete plating.

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[8] Bego,Galvo. Bremen,Germany

Two possible causes for incomplete coverage were:

(a) no conductive coat over an area

(b) the impression was angled to the copper cathode in the plating bath such that a part of the impression was in a "shadow" i.e. not in direct line to the copper source , so prohibiting copper deposition.

Each satisfactory copper-coated impression was filled with a mix of artificial stone[9], inverted, based and allowed to set.

The impression was prised off the stone cast carefully, the coated surface examined and the cast trimmed. The cast was coded with the patient's number and stored for later measurement. Any unsatisfactory plated cast was discarded and the impression re-processed through the system.

Less than 3% of total models required re-processing to produce satisfactory casts.

The impression technique, copper plating and the cast fabrication were repeated at each assessment period for each restoration.

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[9]Kaffir D,British Gypsum, U.K.

4.3 Measurement Technique

A Reflex Microscope **(Fig. 4)** was used to measure the casts.[10]

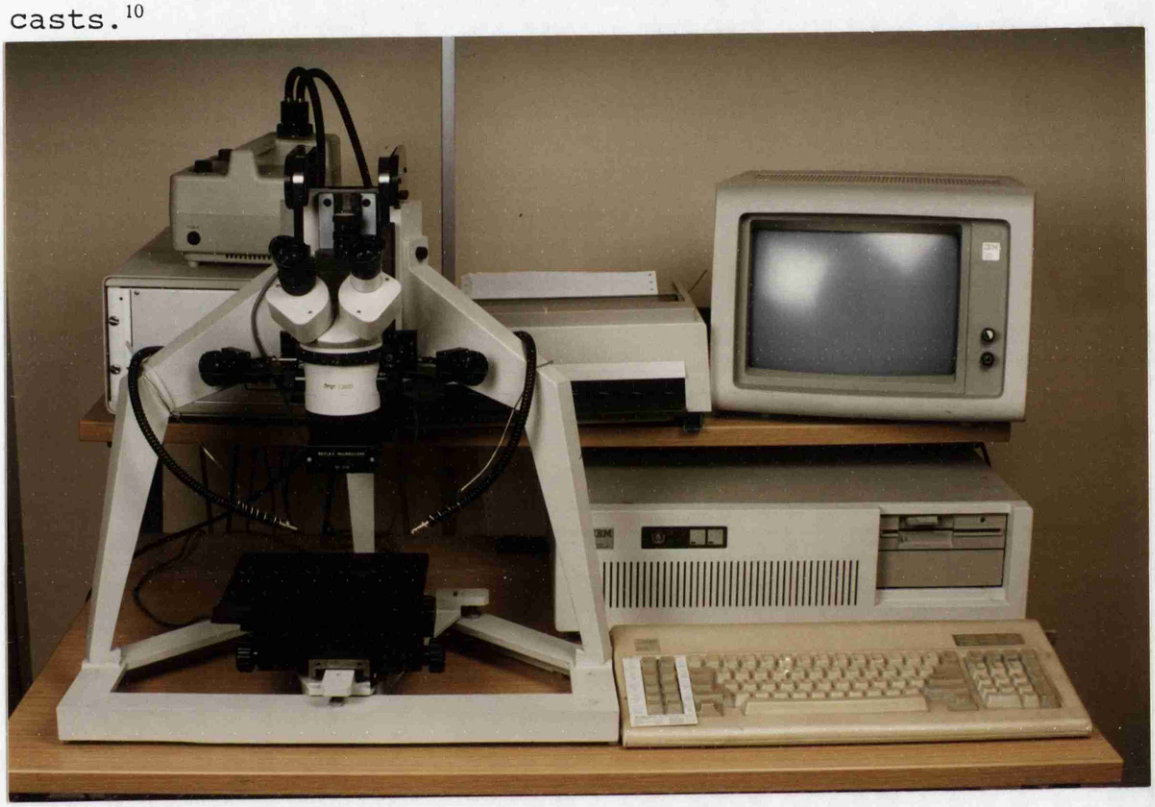

Figure 4. Reflex microscope and supporting computer hardware.

The development of the microscope system has been reported by its developer (123), as it is capable of registering coordinates of points in the X-, Y- and Z-axes. The microscope measuring system was based on a semi-silvered mirror on which the operator observed the

[10]Reflex Instruments,Somerset,U K

object reflected. The measuring mark (a 5 μm light dot created by a light emitting diode) was also projected on to the mirror. This mark could be placed optically on to the object, thus eliminating any parallax problems. The X-, Y- and Z- co-ordinates were automatically recorded using linear displacement transducers and the three axes co-ordinates registered by the computer.
The accuracy of the microscope, as quoted by the manufacturer, was 2 μm in the X- and Y-axes, and 4 μm in the Z-axis.
As the measuring point cannot be moved physically in the X- and Y-axes, translation was achieved by moving the microscope stage supporting the object. The stereo-microscope moved in the Z-axis as the observer re-focused, so taking the measuring mark with it and thus registering the Z-axis co-ordinates. The computer software supplied to accompany the microscope allowed measurement of a number of parameters e.g. distance between two points; angle between three points; mid-point between two points; planes formed by three points; angles between two planes; and area of any surface projected on to a flat plane.

The main advantage of this method was that it recorded the spatial position of points on an object, without actually touching the object.

Further details of the microscope were documented by Adams et al (122) where they reported the accuracy as 3 μm in the X- and Y- axes, and 10 μm in the Z- axis. The authors commented that the intra- and inter-observer differences were 0.1 μm in the X- and Y-axes and 4.5 μm in the Z-axis. However, these data were considered to have minimal consequence when measuring tooth wear loss over an area 7.2 sq.mm.

Repeatability tests, both using known standards and models, are reported later.

4.3.1 Cast Alignment

Orientation Procedure

The casts of any restoration were recovered at the three assessment periods, each restoration's cast series had to be measured in the same spatial position relative to each other, in order that the separate measurements could be compared, as the cast-pouring technique did not guarantee the exact spatial position of one cast relative to another.

The principle of "least squares" fit was used to re-orientate and subsequently match the co-ordinates of models from the baseline and the two models from the other assessment periods. These co-ordinates were registered by the Reflex Microscope and computed. The

program required a minimum of three points on the baseline model to be registered in the X-, Y- and Z-axes using the microscope. These points had to be common to all casts from the same patient series. They were identified, under the microscope, only when all models of each restoration were available for measurement. Anatomical features were chosen, e.g. small indentations, scores and incremental lines.

Adams et al (122) described the mathematical procedures. Here, two three-dimensional co-ordinate systems, one based on a plane defined by three reference marks on the baseline or reference model, and one based on the coordinates from a subsequent model, were regarded as two independent orthogonal systems. Three-dimensional spatial transformation of the microscope coordinates of the second model on to the previously established reference baseline coordinate system of the first, was undertaken to relate baseline and subsequent measurements, i.e. from the reference microscope co-ordinates, a three-dimensional plane was fixed and the second plane "overlaid" for best "fit". Adams et al (122) went on to describe a possible solution to the three-dimensional transformation, viz:

"The problem to be solved is, that if X, Y, and Z are rectangular co-ordinates referred to one set of axes and

X(1), Y(1) and Z(1) are coordinates of the same point referred to a set of axes rotated with respect to the first set then:

$$\begin{matrix} x \\ y \\ z \end{matrix} = R^{t} \begin{matrix} x(1) \\ y(1) \\ z(1) \end{matrix}$$

where R is the orthogonal matrix representing the rotation of axes".

The measurement regime required the operator to follow a previously entered measurement plan, initially recording, in three axes, the three common points for registration, and then all further points for measurement required to complete the measuring plan. Thereafter, calculation of the distances, areas, etc. were completed within the computer program.

The next cast in the assessment series was positioned on the microscope measuring table and the three common registration points for this cast recorded, The computer calculated the spatial orientation difference between the original or baseline position, and that of the second. The program supplied the observer with a listing of the calculated "residuals" between the original and the second model, i.e. the calculated positional difference between the sets of reference points. The operator was

offered an opportunity to re-register the three alignment points on the second cast to reduce the "residuals". This was carried out only if the "residuals" were more than 10 μm in any axis. The registration of the measuring points for the plan was completed for this model and the required results calculated.

The measurement procedure was repeated for all other casts in the patient series, again relating these to the casts series' baseline position.

DeLong (124), like Scott (123), used a least squares fit to accurately relate the profiles of the base and subsequent models, Lambrechts et al (112) used a baseline impression for location of the second and subsequent models, whereas Braem et al (121) used diamond indentations, as registration points, into the occlusal surface of the tooth to be measured.

Other specially written computer programs (112);(124);(140) to measure various parameters have been employed to ensure direct comparability.

4.3.2 Measurement Plan

To measure the cast, a list of the points on the surface was formulated, to allow a series of measurements to be calculated using the computer software program. This measurement plan was used for all the field trial casts.

The measurements were:

(a) Step Deficiency

To ensure the maximum step height was measured, three separate step height assessments were carried out in an area considered to show the greatest deficiency.

In this way the largest step fault was recorded for further evaluation.

The light point was adjusted in all three axes and "placed " on the cavo-surface margin in the area of greatest step. The point was then registered in the computer, and a second point was identified on the restoration surface immediately below that on the cavo-surface margin. This was also recorded and the distance between the points subsequently calculated.

(b) Involved Cavo-surface Margin

The length of each cavo-surface margin associated with the step discrepancy was measured by tracking the light point along the involved cavo-surface margin.

(c) Cavo-surface Margin Length

The cavo-surface margin of the restoration was identified and was measured in a similar manner to that described for the involved cavo-surface margin.

(d) Area of Tooth

The area of the tooth's occlusal surface was estimated by tracing the measuring point along the periphery of the occlusal surface. The periphery was defined, for this study, as a line joining the cuspal tips of the tooth along the highest edge of the inward sloping surfaces. The area calculated was that enclosed by the line when the enclosed surface was projected on to a flat plane.

(e) Area of Restoration

The area of the restoration was assessed by tracing the light point around the periphery of the restoration and the result computed as per tooth area.

Items (a) and (b) were repeated for any further discrepancies along the cavo-surface margin.

These two related zones (d),(e) were calculated in a similar manner. A "true" area comparison of the results was not possible, but comparison of areas and the ratio of the two areas was possible, as they were calculated similarly and could be directly related.

The step deficiency and involved cavo-surface margin will be statistically assessed along with the area of the restoration and tooth, to try to establish a link between these elements of wear and the size of the restoration and tooth.

Chapter 5

Laboratory Investigation - Results

5.1 Accuracy of Measurement by the Observer

(a) Standard Situation

Evaluation of measurement accuracy was carried out at the start of the laboratory evaluation. A light microscope measurement graticule **(Fig. 5)** was used to determine the accuracy in the X- and Y-axes.

A machined stepped brass block **(Fig. 6)** was utilised to allow measurement in the Z-axis. Each step had been previously measured using a digital micrometer.

Figure 5. Light microscope graticule.

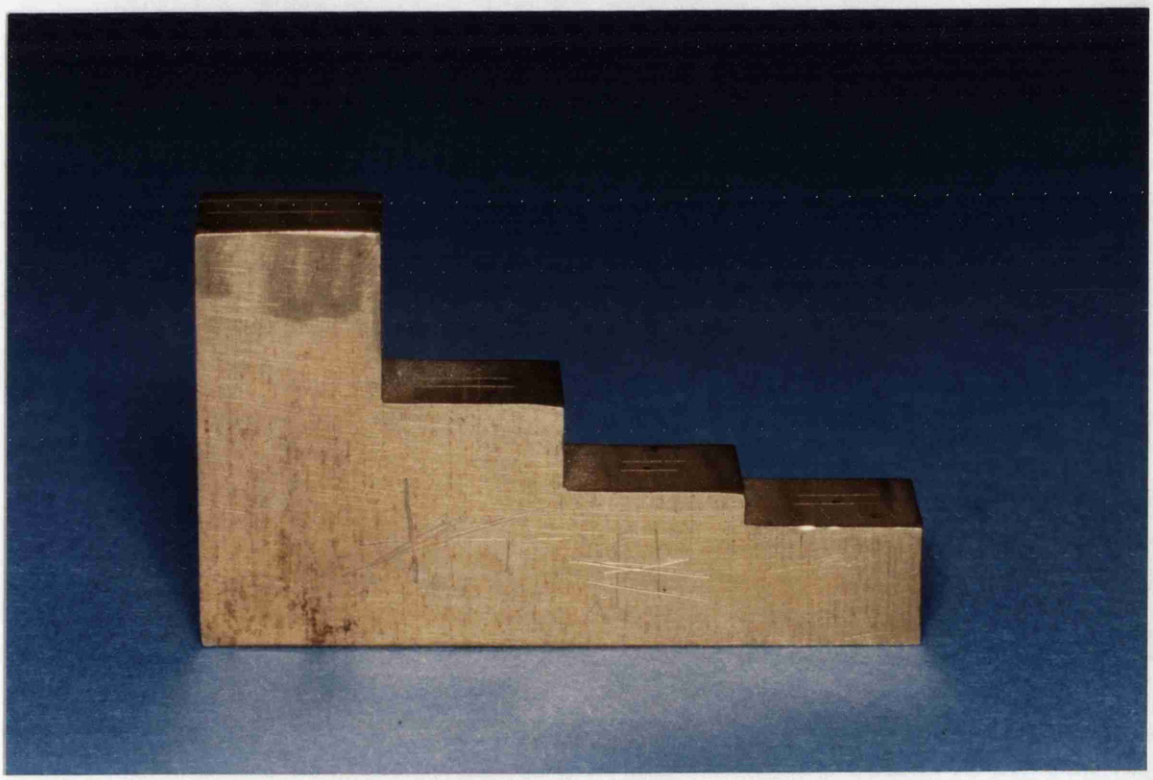

Figure 6. Machined brass step.

The measurements in the X-, Y- and Z-axes were repeated 15 times for each situation over a number of days and are shown in **Table 5.1.**

(b) Clinical Trial Cast

A randomly selected cast was subjected to repeated measurement. The length of the maximum step (assessed as described earlier), the length of the involved margin and the total cavo-surface margin, were measured using the regime described above. The results are shown in **Table 5.1.**

	Mean Length (μm)	**Axis**	**St/Dev**
Standard	3000	X-Y	+/- 1
Standard	2504	Z	+/- 8
Model	333	X-Y-Z	+/- 15
Model	7144	X-Y-Z	+/- 73
Model	15432	X-Y-Z	+/- 131

Table 5.1 Repeatability measurements (x15) in all three axes of two standard and three model situations.

(c) Residuals

The effect of the "residuals" between the original cast position and the second and subsequent casts, was investigated by repetition of the measuring regime on a single cast series. The results are seen in **Table 5.2.** The difference in lengths from the original model situation to the second model placement was less than 0.1%. This low measurement difference was retained if the "residuals" were kept under 10 μm for the three registration points.

Mean Length (μm) +/-S.D.

Position 1	Position 2
7068 +/- 8	7071 +/- 13
5053 +/- 13	5049 +/- 5
6561 +/- 4	6562 +/- 8

Table 5.2 Repeatability measurements (x15) of two casts from the same series in two different positions.

5.2 Cast Measurement

The percentage of models available for measurement was approximately 82% of the total Class I restorations examined in the field study at the two year period.

Each cast of the restoration was assessed on a minimum of two occasions, and all measurements recorded for further analyses.

5.3 Comparison of Size of Restorations

The average cavo-surface marginal length for the restorations placed in the three materials was 18245 (s.d. +/-6385) μm for Amalgam, 19279 (s.d. +/-7102) μm for Herculite, and 20964 (s.d. +/-6429) μm for Occlusin. The average area of the restorations cut for the three materials was 13345 (s.d.+/-7304)sq μm for Amalgam, 14077 (s.d.+/-7156)sq μm for Herculite, and 16203 (s.d +/-8327)sq μm for Occlusin.

5.4 Step Discrepancy

The complete absence of any cavo-surface margin step discrepancy indicated perfect adaptation of the restoration to the tooth surface at the cavo-surface

margin. The percentage of perfect margins observed microscopically is given in **Table 5.3.**

Perfect Cavo-surface Marginal Adaptation

	Baseline	Year One	Year Two
	%	%	%
Amalgam	30.5	22.0	5.1
Herculite	35.1	35.1	8.1
Occlusin	38.5	35.8	7.7

Table 5.3 Detail of percentage of perfect (zero) cavo-surface margins for the three materials over the two years.

As will be noted, the baseline examination showed a low level of marginal perfection for all materials. The "zero" level dropped at the first year assessment in the case of Amalgam and Occlusin, whereas Herculite maintained its baseline level. By the second year, all three materials showed a distinct drop to single percentage figures.

A Chi-square test was carried out for all three assessment periods for the three models. At baseline, there was no significant difference in the performance of the three materials. At the first year appraisal, again

no significant difference was observed between the materials, nor did any show a significant difference in performance at the last report stage.

The distribution of "zero" step discrepancies i.e. perfect margins, was considered in relation to the area of the restoration and the occlusal area of the tooth. The distribution of these restorations where the restoration : occlusal tooth area ratio was less than 0.50 was

Amalgam	50.0%
Herculite	46.2%
Occlusin	73.3%

Each step around the periphery of the cavo-surface margin was identified and the greatest height measured as described above **(Table 5.4.)**.

Height of Step Discrepancy of each Material at each assessment stage (+/- S.D.).

	Baseline	Year One	Year Two
	μm	μm	μm
Amalgam	233+/-236	365+/-332	439+/-378
Herculite	178+/-180	280+/-328	299+/-284
Occlusin	193+/-185	238+/-216	356+/-222

Table 5.4. Detail of average step discrepancies for each material over two years.

The baseline level of step faults was disappointingly high for all materials. All showed a rise in average step deficiencies at the first year assessment period, with Occlusin increasing least over this time interval. In the second period, all three materials' deficiencies increased, with Herculite showing the smallest. Overall, it also showed least increase in average step fault.

The differences in step faults were calculated for all restorations, for baseline - first year and for first - second year intervals, for all three materials.

A Kruskal-Wallis non-parametric analysis was carried out for the two intervals, and showed no material performed significantly better than the others, for either evaluation interval.

5.5 Step deficiencies under 150 μm

Leinfelder et al (93) have reported that, clinically, it was not possible to detect a cavo-surface step fault, if that fault was less than 150 μm in height. The percentage of zero margins and those under 150 μm that would, therefore, have been accepted as "clinically perfect" are shown in **Table 5.5.**

Cavo-surface Marginal Adaptation with step discrepancies under 150 μm.

	Baseline	Year One	Year Two
	%	%	%
Amalgam	42.4	28.8	15.3
Herculite	51.4	51.4	48.6
Occlusin	43.5	33.8	12.8

Table 5.5. Detail of percentage of cavo-surface margin steps under 150 μm for the three materials over two years.

The extra level of " non-detectable margins" that a clinician might well report during the examination of any restorations placed was illustrated by comparison of the figures within **Table 5.3.** and **Table 5.5.**

It is evident that Amalgam performance fell over the two years. However, the potential acceptability level at the two year stage was nearly three times more than that of the "zero" state situation. Occlusin did, to some extent, follow the fall shown by the Amalgam restorations, although the base - first year drop was slightly higher. The final level of "non-detected margins" was higher than that of the "zero" situation. Herculite, in comparison, maintained a near baseline level of non-detected margins throughout the time of the study.

Using a Chi-square test, there was no statistical difference in the performance of the three materials at the baseline and first year assessment periods. At the second year assessment, however, Herculite did achieve a significantly better performance effectiveness ($p < 0.01$) over the other two materials.

5.6 Involved Cavo-surface Margin

The length of margin involved with each step around the restoration was measured. The average length of the margins for the three periods is shown in **Table 5.6.**

Involved Cavo-surface Margin (+/-S.D.)

	Baseline	Year One	Year Two
	μm	μm	μm
Amalgam	3661+/-3863	5176+/-4731	6569+/-4712
Herculite	1888+/-1651	2553+/-1917	3493+/-2073
Occlusin	2017+/-2486	3172+/-3566	4790+/-3111

Table 5.6 Detail of average involved cavo-surface margins for each material over the two years.

All materials started again from a higher than ideal baseline position, continued wear was observed for all materials by the increase in cavo-surface margin involvement over the two year period.

For all materials, a Kruskal-Wallis non-parametric analysis was carried out on the differences of the lengths calculated for baseline - first year, and first year - second year periods.

Here, no material was found to perform better than any other.

Herculite involvement did increase less than the other two materials, which might indicate (although not significantly) a slower cavo-surface margin involvement and hence a slower rate of material wear.

5.7 Area of Restoration and Tooth in Relation to Wear

The relationship of the size of the restoration and the size of the tooth to wear has been reported. Composite wear had been found to be greater in large restorations relative to tooth size i.e. large restoration in a premolar, or where composites had been placed in molar teeth (39);(68);(141);(78).

Regression analysis was carried out for each material at the three assessment intervals for the accepted indicators of wear i.e. step discrepancy and involved margins against (a) the area of the tooth, (b) area of the restoration and (c) the tooth/restoration area ratio, in order to find any relationship.

There was no significant relationship noted at any assessment period for any wear indicators in relation to the area of restoration or tooth, for all materials tested.

5.8 Comparison of Field Trial Results and Laboratory Measurement

The clinical detection, or appreciation, of step discrepancies has been shown to be difficult if the step is less than 150 μm in height (93). The examination of the cavo-surface margin by probe passing would register only as a fault if it was substantial and fell under the path of the probe. Consequently, absolute reliability for fault detection cannot be guaranteed by clinical means alone.

The USPHS assessment system required an 85% intra- and inter-examiner agreement after training, and prior to undertaking a clinical appraisal. The study reported in this thesis had an examiner repeatability of 93.5%, with slippage of +/- one grade. The results of the field trial reported above were, therefore, robust enough to stand comparison with those of other workers.

Occlusal Marginal Adaptation equated with the microscope measurement of step discrepancies. The occlusal marginal adaptation clinical assessment scores were compared with the step discrepancy heights for the restorations measured in the laboratory trial. All step faults of 150 μm and less were considered to be equivalent to Alpha grade, and all remaining microscope results were

regarded as comparable to all other clinical trial scores.

Occlusal Marginal Adaptation (**Table 3.2.**) showed Occlusin to perform significantly better, whereas the results indicating zero marginal discrepancies did not show any material to be statistically superior (**Table 5.3**). However, when the clinically undetectable margins,i.e. under 150 um, were considered **(Table 5.5)**, Herculite was statistically better, in contrast to the field trial results at the second year.

The agreement between the field trial and the laboratory results for each assessment period are illustrated in **Table 5.7.** and **Table 5.8.**

Agreement of Clinical Grades with the Laboratory Measurement

		All Grades %	A Grades %
Amalgam	(n=55)	62.4	41.3
Herculite	(n=38)	47.4	46.0
Occlusin	(n=35)	56.3	37.5

Table 5.7. Overall agreement of the percentage of clinical grades awarded at the Clinical trial with the measurements at the Laboratory investigation over two years, for the three materials.

	All Grades			A Grades		
	Base %	1 Year %	2 Year %	Base %	1 Year %	2 Year %
Amalgam	61.0	62.8	61.1	54.5	46.2	9.1
Herculite	43.2	52.1	48.6	47.8	50.0	37.5
Occlusin	53.8	50.0	46.2	38.2	33.3	16.6

Table 5.8. Detail of the agreement of the percentage of clinical grades awarded at the Clinical trial with the measurements at the Laboratory investigation for each of the assessment stages, for three materials over two years.

Over the two years, Amalgam overall grades awarded were more closely in accord with the microscope results. However, the recognition of the perfect margin situation was increasingly poor.

The all grade results for Herculite increased over the two years but at a lower level than for Amalgam, whereas Occlusin grades dropped only slightly. The performance of the two materials differed when the Alpha grades comparisons were considered. Here, Herculite maintained a higher level of match, although not consistently, throughout the two years. Occlusin, on the other hand, dropped steadily.

5.9 Discussion

The restorations in this trial were inserted in non-adult patients with the majority placed in class I format in molars. Although the operators were not fully familiar with modern conservative restorative procedures, the bulk of the restorations inserted did not exceed one half of the occlusal surface area as illustrated:

Amalgam	59.3%	restorations below half size
Herculite	59.4%	" " " "
Occlusin	66.6%	" " " "

These restorations, therefore, could not be classified as "large", or comprising a large percentage of the occlusal surface area. Indeed, a direct relationship of tooth and restoration size to composite wear, was not observed.

Reasons for non-measurement

A number of reasons for model non-measurement were:

a) non co-operation from patients

b) poor impression surface,

c) poor copper-plating

(a) Non co-operation

The number of children refusing to co-operate with the impression regime was minimal. However, the main problem was the maintenance of a dry working field as, for many children, this was their first experience of any impression technique. This was responsible for most of the rejection numbers due to air or saliva affecting the surface.

(b) Poor impression surface

The set impression surface was checked on removal for air blows or inclusions, but only on subsequent microscopic examination of the copper-plated cast, were various

deficiencies observed which restricted, in some part, the measuring regime.

(c) Poor copper plating

This regime was least problematic, in that the impression preparation and subsequent plating were, in the main, technically successful.

5.9.1 Accuracy of Measurement

Repeatability and Residuals

The results illustrated in **Table 5.1.** showed a low standard deviation of measurement in the X- and Y- axes with the standard deviation slightly higher in the Z-axis. The standard deviation for model measurement was higher than the "standards", but was still acceptably low. The greater the involvement of the Z- axis, the relatively higher was the standard deviation for any situation.

The increase in the standard deviation for model measurement was indicative of the more complex 3-D movement required.

The protocol adopted in relation to "residuals" resulted in a minimal difference in measurement, providing a good foundation for confidence in the repositioning regime.

5.9.2 Wear

Wear has been assessed by measurement of the step produced when the restorative material moved down the wall of the cavity as the material was worn or lost. This loss involved also a greater length of cavo-surface margin being exposed, thus step discrepancy and involved cavo-surface margin could both be regarded as indicators of wear.

Retention of anatomical form must be considered, in addition, as a further indicator of the material's wear resistance. However, this was difficult to assess in-vivo.

Herculite performed better, apart from Occlusal Marginal Adaptation, than the other two materials in the clinical trial. In the laboratory investigation, Herculite showed indications of slower material wear e.g. a lower step discrepancy level; a higher level of margins under 150 μm, and slower involvement of the cavo-surface margins. Although only in one circumstance were the results significant, the trend could be regarded as supporting the clinical findings of superior Anatomical Form retention.

Amalgam performance was unexpected. This material was particularly selected to maintain a high quality marginal

adaptation level but the high level of step fault and cavo-surface marginal involvement, together with the observation of gap formation in many of the amalgam restorations, indicated poor effectiveness.

The presence of a large percentage of perfect margins (or margins under 150 μm), clinically equivalent to a nil recognition of marginal discrepancy, could be equated with a lower level of wear i.e. a high number of Alpha grades in the clinical examination with regard to occlusal marginal adaptation and anatomical form retention scores. Further low wear indicators were low average step fault height and low length of cavo-surface marginal involvement.

Occlusin was found to be significantly better in regard to Marginal Adaptation whereas in the laboratory analysis Herculite, which performed better in anatomical form retention, did give indication, although not significantly, of slower step formation **(Table 5.4 and 5.5)** and cavo-surface involvement. However, no significant difference was recorded for these two indicators except for one period, so direct linkage between clinical and laboratory findings could not be established.

Herculite did, on average, show better results, both in the step fault and involved marginal length parameters, perhaps indicating that the wear rate of Herculite could be better than that of Occlusin.

Further possible support for this proposition is given in **Table 5.9.** where the ratio of the involved margin length to the total cavo-surface margin length for the three materials over the trial period was calculated.

	Baseline	Year One	Year Two
Amalgam	0.21	0.29	0.39
Herculite	0.12	0.15	0.22
Occlusin	0.11	0.14	0.25

Table 5.9. Detail of ratio of the involved cavo-surface margin to the total cavo-surface margin over two years.

Although there was no significant difference for the materials, here again Herculite's wear-affected margin was again slightly less than that found for Occlusin. The low level of perfect margins observed at the baseline examination for all three materials cannot be due to the wear of the restorative materials, therefore poor cavity

management and/or material handling must be the prime factor(s). However, none of the materials maintained even this low performance status over the trial period but, in contrast to the baseline situation, this could be related to the materials' composition.

The high average step deficiencies found at baseline were taken as the start point to calculate the amount of material lost in the base - first year and first - second year intervals. The average material loss was for Amalgam 132 μm for the first interval, and 74 μm for the second; for Herculite - 102 μm for the first and 19 μm for the second, and for Occlusin - 46 μm for the first interval and 118 μm for the second one. Other workers, using a variety of composites, have reported the step fault measurement as equivalent to material loss. Brunson (75) commented on P-10 composite at the two year period where wear was recorded at 108 +/-91 μm. Heymann et al (76) reported on six composites over a similar time scale and these results varied from 111 -199 μm see **Table 5.10.**

Leinfelder et al (90) examined four composites and stated the wear ranged from 152 -273 μm over a three year period **(Table 5.10)**. In the same year, Leinfelder et al (93) gave the wear for a second series of composite materials

over two years as ranging from 86 - 178 μm **(Table 5.10)**.

Occlusin was also reported to have lost 56 μm in the first year. Furthermore, its wear was measured by Rowe (70) in a five trial, at 25.8 μm annually. Sturdevant et al (73) reported on the wear of four composites at three years with loss varying from 111-199 μm, as illustrated in **(Table 5.10.)**.

Wilson et al (67) stated that Occlusin wear at three years was 192 +/- 30 μm.

Average Wear of Composites

	Two Years		Three Years	
	µm		µm	
Visiofil	199	*	Estilux	152 **
Nimetic	198	*	Nuvafil	210 **
Visioradiopak	150	*	Uviofil	213 **
Visiodispers	113	*	Nuvafil	273 **
Nimeticdispers	111	*		
Fulil	86	#		
X-55	103	#		
H-120	131	#		
P-10	140	#		
P-30	178	#		
Nuvafil	140	#		

Table 5.10. Detail of average wear of composites at two and three years, as reported by those researchers identified by reference number.

* Heymann *et al* (76)

** Leinfelder *et al* (90)

\# Leinfelder *et al* (93)

Herculite composite showed the typical high rate of material loss over the first twelve month period similar to that reported by Leinfelder et al (19). There was a smaller increase in its wear over the second twelve months. Occlusin composite's wear pattern was not seen to follow the Leinfelder pattern, in that the material loss was less in the first year than in the second.
The average total wear result for Herculite composite was 161 μm, and for Occlusin 152 μm, - both of which compared well with the results of other investigations.
Differential wear has been described by Lutz et al (102). Lambrechts et al (82) and Wilson et al (67) where two areas of the occlusal surface were mentioned i.e. the area where the opposing cusp contacted - Occlusal Contact Area (OCA) and the area unaffected by direct occlusal forces - Contact Free Area (CFA). In the trial reported here, only two OCA's were observed, both related to Herculite restorations. This low OCA incidence might be due to the fact that;

(a) composite carving at baseline was overdone taking the material out of occlusion,

(b) the composite wear was too rapid, so any OCA could be removed quickly,

(c) the age of the patients involved was in the range where the occlusion was in a developing

state, hence the OCA would not have been a constant situation.

Marginal adaptation was observed to be different for Amalgam and composites. Marginal gaps were noticed in 73% of the amalgam restorations at baseline, 76% at year one and 91% at year two in association with the marginal steps. Few marginal gaps were observed for the composites, with the material maintaining close adaptation to cavity walls. Ditching was reported by Leinfelder (20) where he described a "rolled" or "ditched" edge close to the cavity wall. He stated this was related to microfilled materials and to areas of high stress, although he did not define that situation. In this trial, the ditching condition was observed, but no estimation of occlusal load could be made.

5.9.2 Comparison of Laboratory Results with the Field Trial

The higher level of agreement for Amalgam, than for the other two materials, both re the overall situation and the three assessments, might be due to the fact that Amalgam was the most commonly used restorative material. Thus recognition of margins and marginal faults might well have been easier subjectively, because of its

familiarity of use. In addition, the distinct colour difference may have made marginal recognition simpler.

Herculite correlation reached only 47.4% for all grades, and 46.0% for Alpha scores. Low relationship scores for Occlusin were noted (56.3% for total grades; 37.5% for Alpha ratings). Possible causative factors for this difference were the two main contrasting features between Herculite and Occlusin i.e. (a) colour match, and (b) filler type. With respect to (a) Occlusin was reported as being deliberately slightly mismatched to tooth substance. This should have made cavo-surface margin recognition easier but this was not found to be so. Regarding (b) Herculite filler particles were stated to be smaller and softer to maintain a smoother surface, and this was confirmed in the field trial. However, this surface might well have aided recognition of the marginal faults as compared to Occlusin as the fine sandpaper effect of the surface might have masked an imperfect margin so leading to a higher recognition of perfect margins.

A further explanation for the low relationship between the clinical assessment and the laboratory measurement might be that the field trial was carried out, with time constraints, in an "uncontrolled" clinical environment

with patients unknown to the assessor, while the laboratory measurement had good lighting, magnification, and no time penalty. These factors might have contributed to the difficulty of carrying out the former assessment in a pragmatic atmosphere, as against the laboratory, where control was easier.

Lack of any catch to probing at the cavo-surface interface has been taken as "clinical perfection", providing clinical evidence of no potential for pathology. This "clinical perfection" does not confirm the absence of a catch, as the probe might not have passed over a catch area or, as Leinfelder et al (93) have stated, where step faults up to 150 μm in height could go undetected by the clinician. Even in the circumstances where a catch is recognised, the clinician will assess the extent of the fault as well as the immediate oral environment and, therefore, its potential for both development and/or continuation of further pathology.

With respect to the large standard deviations observed in relation to step discrepancies and involved cavo-surface margins, these were a reflection of the varying size of the restorations and the differing performance of the various operators.

Finally, it could be argued that highly exact indirect measurement is of little consequence for the general

dental practitioner who is more interested in a material's gross performance, and concerned little with the minutia. However, this would be a dangerous attitude for any profession to adopt, and the investigation and possible confirmation of a material's best performance in a clinical environment, supported by laboratory studies, will only enhance the delivery of dental care and advance the status of the profession.

FINAL DISCUSSION and CONCLUSION

Assessment of new materials in a clinical environment was necessary and a pragmatic trial allowed these products to be assessed in a "real-life" situation. This trial exerted minimal control on the operators, and results showed poor handling of the materials and poor understanding of the materials' properties leading to a low level of perfect restorations, even at baseline. However, tighter control of the operators would have reduced the trial's effectiveness and removed one of the basic concepts to be tested i.e. the assessment of the situation faced by a practitioner when presented with a new material for use in everyday practice.

The larger particle material, Occlusin, did show a better performance level in regard to occlusal adaptation. The smaller particle-filled composite restorative (Herculite) did show a slower wear rate though not significant. Nevertheless it did perform as expected in that it held its surface finish to a better degree than did the other composite material (Occlusin).

Caries was not a significant factor in this trial with respect to any of the materials studied over the two year period, as has been reported by others undertaking similar work.

Marginal discolouration of the materials varied over the time-span whereas Herculite's colour-matching ability was significantly better than that of Occlusin.
Unfortunately, the laboratory investigation undertaken supported the poor baseline performance of all three materials found via the field study.
Wear of the two composites was similar, on average, to that shown by other studies. However, the wear parameters employed i.e. step discrepancy; involved cavo-surface margin; and from the field trial, anatomical form and occlusal marginal adaptation, did not indicate clearly any one material to be significantly better than the other.
Hence all the above findings did not provide any clear indication that these materials should be adopted as the restorative of choice for use in the younger age group under study.

The lack of correlation of wear with size of tooth or restoration, might be due to the age range of the chosen cohort where occlusal relationships are not fully developed. However, as stated above, this clinical factor did not appear to reduce the wear as measured.

With respect to the time-scale of the clinical (and commercially-related) events, the last patients were

accepted into the trial for the two study year period in late 1987. Unfortunately, further analyses of the two composite materials was not possible, as Occlusin was withdrawn from the British market in 1988-9 and Herculite was superseded with an improved version, Herculite HR in 1986-7. In view of the findings in this trial, perhaps these marketing decisions were not injudicious.

The use of the stereomicroscope to measure the clinical wear experienced by the composite materials understudy was innovative, but required all models of the series to be available before any laboratory-based measurement could take place. Thus, there was inevitably a delay in the verifying the observations, even with respect to the quality of baseline restorations.

The correlation between clinical wear indicators and the microscope results, did not relate directly. This must cast doubt on field trials which comment on the amount of wear experienced, but which are not supported by any indirect wear assessment system.

As to the future, clinical judgement is a universally adopted method of quality measurement for both the clinician and the material under test. However, any system must assess and measure, both directly and indirectly, as many wear parameters as is feasible, in

order to provide clear evidence of the amount and nature of the wear process and to ensure that correlation of the direct and indirect systems is high. By so doing, guidance may be provided for both the clinician and product manufacturers to the ultimate benefit of the patients treated with these newly emerging restorative materials.

The results of the previous explanatory trials have shown some composites in poor light as compared to the amalgam control, whereas the findings of this pragmatic study were that the composites and the amalgam control performed equally well.

The importance of the pragmatic trial format is the removal of tight protocol constraints associated with the more widely reported explanatory trial. This clinical study style is a more robust method of assessing the clinical performance of restorative materials, so therefore, should become employed more routinely , both by the manufacturers and researchers, to ensure that the new materials introduced to the dental market can be evaluated readily in a situation as akin to general usage as possible.

General practitioners are not in a position to asssimilate the findings of a number of explanatory trials nor will they place great reliance on results with which they cannot relate to their own situation.

Accordingly, the operators in a clinical trial must be allowed, and encouraged, to use their existing clinical diagnostic and clinical methods and should be selected to eliminate any possible bias due to age, training.

It is essential that the pragmatic design of a clinical trial holds true to the concept. It is to easy to dilute the significance of the findings of the trial by the introduction of proscriptive rigid protocols or the use of research-based clinicians.The pragmatic trial, as has been suggested, has its place alongside the explanatory trial, where it will augment the findings but from a different perspective.

There has been no obvious reason for the paucity of pragmatic trial effort, except that, with the effectiveness of the trial being dependant mainly on the efforts of those undertaking the clinical work, researchers feel that too much is at risk.

This is too easy a limitation on the potential of the pragmatic trial to provide the necessary link between the Hospital/School based study and that which is practitioner based.

APPENDICES

Appendix 1

Clinical Protocol

The patients for this posterior restoration trial must be within the age group 8-17 years

Carious lesions will be charted by the participating community dental officers who will then decide on the restorative strategy. Bitewing radiographs will normally be taken as an aid to diagnosis of caries.

Before the cavity is prepared the operator will:

a) check the personal details and enter them on the Data Collection Form,

b) Record the tooth to be treated on the Trial Record Chart,

c) Note if local anaesthesia was given,

d) If this is the patient's first entry to the trial the operator will select an envelope from the supply.

These envelopes contain the names of the restorative materials randomly arranged. The choice of the material will be recorded on the chart and this material will be used for all subsequent restorations for that patient when in the trial.

b) Composite: For composite restorations a lining of setting calcium hydroxide e.g."Life" must be placed. Where necessary this lining may be supplemented by a structural lining of phosphate cement.
This lining must be placed BEFORE any etchant is applied.

Placement of the Restorations

a) Amalgam: In class II cavities, a Siquivland matrix band of the appropriate width will be used together with properly placed wooden wedge(s). The type of amalgam will be "Sybralloy" and will be used according to the manufacturer's instructions.
The amalgam will be condensed with packers appropriate to the size of the size of the restoration. The matrix band will be burnished against the adjacent tooth to ensure a well-placed contact point.
In class I and class II situations, the amalgam will be over-packed and carved back to the contours of the tooth. The occlusion will be checked with articulating paper and the patient only dismissed if the operator is satisfied that the occlusion is correct in all excursions of the mandible. The amalgam will be polished using, initially, steel finishing burs, and followed by either polishing paste or " Brownies and Greenies".

b) Composites: The margins of the cavity will be etched using a gel etchant, taking care not to etch the adjacent tooth. A Siquivland matrix of appropriate width will be placed around the tooth and wooden wedge(s) placed, the band will be burnished to the adjacent tooth to ensure a well-placed contact point.

In both the Class I and class II situations, the cavity must be etched,washed and dried according to the instructions of the manufacturer. It is essential that the cavity remains dry. Once the operator is satisfied that there is the typical frosty white appearance, the composite may be placed in the cavity. A bonding material will be placed across the cavity and cured before the composite is placed.

Both the composite materials "pack" better than some of the original posterior composites, but the operator must ensure that the material is "packed"well into the cavity. The maximum depth of cure is 2 mm, thus the cavity will be filled in successive layers. The cavity will be over-packed and the material shaped to the contours of the tooth before final cure. The restoration will be finished using ultra-fine diamonds,finishing strips and ultra-fine Soflex discs. The occlusion will be checked similarly to amalgam. Final adjustment may be carried out after 24 hours.

Appendix 2

Data Collection Form

RESTORATION PROJECT Detailed Study

Patient's Name.....Date of Birth.....

Address..... Date.....

.....

CLINIC [1 2] I.D.NO [3 4 5 6] ... Sex (1 Male (2 Female [7]

Age Group [8] Age [9 10 11 12] Operator [13 14] Filling Material [15]

****

Exam type [16] Examiner [17]

****

Tooth	Marg/l Adapt/n	Anat Form	Caries	Surface Rough/s	Interp Contact	Colour Match	C/S Discol	Tooth Cont	Non-Eval.
18 19	20 21	22	23	24	25	26	27	28	29
30 31	32 33	34	35	36	37	38	39	40	41
42 43	44 45	46	47	48	49	50	51	52	53
54 55	56 57	58	59	60	61	62	63	64	65
66 67	68 69	70	71	72	73	74	75	76	77
78 79	80 81	82	83	84	85	86	87	88	89

Appendix 3

Copper Plating Solution

Distilled Water	1925.0 ml
Copper Sulphate .$5H_2O$	288.0 mgm
Concentrated Sulphuric Acid	177.1 ml
Ethanol	7.7 ml

BIBLIOGRAPHY

1. Bowen RL, Barton JA, Mullineaux AL. Composite Restorative Materials Publication 354. Washington, U S A: National Bureau of Standards, 1972: 93-100.

2. Smith DL, Schoonover IC. Direct filling resins;dimensional changes resulting from polymerisation shrinkage and water sorption. J.Amer.Dent.Assoc. 1953;46:540-544.

3. Caul HJ, Schoonover IC. The colour stability of direct filling resins. J.Amer.Dent.Assoc. 1953;47:448-452.

4. Grossman LI. Pulp reaction to the insertion of self-curing acrylic resin filling materials. J.Amer.Dent.Assoc. 1953;46:265-269.

5. Kramer IRR, McLean JW. The response of the human dental pulp to self-polymerising acrylic restorations. Brit.Dent.J. 1952;92:255-261:281-287:311-315.

6. Bowen RL. Dental filling material comprising vinyl silane treated fused silica and a binder consisting of a reaction product of bisphenol and glycidyl methacrylate. U.S.Patent No. 3,006,112; 1962

7. Craig RG. Chemistry,composition,and properties of composite resins. Dent.Clin.Nth.Amer. 1981;25:2:219-239.

8. Assmussen E. Clinical relevance of physical chemical and bonding properties of composite resins. Oper.Dent. 1985;10:61-73.

9. Smith DC. Posterior composites dental restorative materials: materials development. Netherlands:Ed. Peter Szule, 1985: 47-60.

10. Jones PA, McCabe JF, Spence D. Some properties of current composite materials. J.Dent. 1977;5:2:85-92.

11. Ruyter IE, Sjovik IJ. Composition of dental resin and composite materials. Acta Odontol.Scand. 1981;39:133-146.

12. Phillips RW. Past, present, and future composite resin systems. Dent.Clin.Nth.Amer. 1981;25:209-219.

13. Leinfelder KF. Composite Resins. Dent.Clin.Nth.Amer. 1985;29:359-371.

14. Jacobsen PH. The current status of composite restorative materials. Brit.Dent.J. 1981;150:15-18.

15. Lewis G. In vivo occlusal wear of posterior composite restorations. Oper.Dent. 1991;16:61-69.

16. Sulong MZAM, Aziz RA. Wear of materials used in dentistry: A review of the literature. J.Pros.Dent. 1990;63:342-349.

17. Kruelen CM, van Amerongen WE. Wear measurements in clinical studies of composite resin restorations in the posterior region: a review. J.Dent.Child. 1991;51:109-122.

18. Lutz F, Phillips RW. A classification and evaluation of composite resin systems. J.Pros.Dent. 1983;50:480-488.

19. Leinfelder KF. Wear patterns and rates of posterior composite resins. Int.Dent.J. 1987a;37:152-157.

20. Leinfelder KF. Current developments in posterior composite resins. Adv.Dent.Res. 1988a;2:155-121.

21. Jacobsen PH. The clinical evaluation of amalgam alloys. Brit.Dent.J. 1984;157:436-439.

22. Schwartz D, Lellough J. Explanatory and pragmatic attitudes in therapeutic trials. J.Chronic.Dis. 1967;20:637-648.

23. O'Mullane DM. Efficiency in clinical trials of caries preventive agents and methods. Comm.Dent.Oral Epidemiol. 1976;4:190-194.

24. Jacobsen PH. Design and analysis of clinical trials. J.Dent. 1988;16:215-218.

25. Downer MC, Mitropoulos CM. Improvement in selection of study participants. J.Dent.Res. 1984;63:(Special Issue):742-755.

26. Wilson NHF. The evaluation of materials; Relationships between laboratory investigations and clinical studies. Oper.Dent. 1990;15:149-155.

27. Ryge G. Biological evaluation of dental materials. National Bureau of Standards; Special Publication 354:1972;191-200.

28. Cvar JF, Ryge G. Criteria for the clinical evaluation of dental restorative materials. U.S.D.H.E.W. Monograph 1973;No.790-244.

29. Mair LH, Vowles RW, Cunningham J, Williams DF. The clinical wear of three posterior composites. Brit.Dent.J. 1990;169:355-359.

30. Schonfeld HK. Peer review of quality of dental care. J.Amer.Dent.Assoc. 1969;79:1376-1382.

31. McCluggage RW. A history of the American Dental Association; a century of health service. 1959.

32. Elderton RL. Assessment of the quality of restorations. A literature review. J.Oral.Rehab. 1977;4:217-226.

33. Swallow JN, van Groenestijn MAJ, Maase-de Waal CJ, Mileman PA. Examiner variability in the assessment of dental restorations. Comm.Dent.Oral Epidemiol. 1978;6:256-263.

34. Natkin E, Guild RE. Evaluation of preclinical laboratory performance: a systematic study. J.Dent.Educ. 1967;31:152-161.

35. Ryge G, Snyder M. Evaluating the clinical quality of restorations. J.Amer.Dent.Assoc. 1973;87:369-377.

36. Ryge G. Clinical criteria. Int.Dent.J. 1980;30:347-358.

37. Leifler E, Vaprio M. Proximo-occlusal composite restorations in primary molars: a two-year follow-up. J.Dent.Child. 1981;48:411-416.

38. Vaprio M. Proximo-occlusal composite restorations in primary molars: a six year follow-up. J.Dent.Child. 1985;52:435-440.

39. Gibson CB, Richardson AS, Patton RE, Waldron R. A clinical evaluation of occlusal composite and amalgam restorations: one- and two-year results. J.Amer.Dent.Assoc. 1982;104:335-337.

40. Derkson GD, Richardson AS, Waldman R. Clinical evaluation of composite resin and amalgam posterior restorations: three year results. J.Canad.Dent.Assoc. 1984;6:478-480.

41. Rugg-Gunn AJ, Holloway PJ. Methods of measuring the reliability of caries prevalence and incremental data. Comm.Dent.Oral Epidemiol. 1974;2:287-294.

42. Rugg-Gunn AJ, Holloway PJ, Davies TGR. Caries prevention by daily fluoride mouthrinsing. Brit.Dent.J. 1973;135:353-360.

43. Stephen KW, Campbell D. Caries reduction and cost benefit after 3 years of sucking fluoride tablets daily at school. Brit.Dent.J. 1978;144:202-206.

44. Downer MC, Holloway PJ, Davies TGH. Clinical testing of a topical fluoride caries preventive programme. Brit.Dent.J. 1976;141:242-246.

45. Mainwaring PJ, Naylor MN. A four year trial to determine the caries inhibiting effect of calcium glycerophosphate and sodium fluoride in calcium carbonate base dentifrices containing sodium monofluorophosphate. Caries Res. 1983;17:267-276.

46. Stephen KW, Kirkwood M, Main C, Gillespie FC, Campbell D. A clinical comparison of two filled fissure sealants after one year. Brit.Dent.J. 1981;150:282-284.

47. Stephen KW, Boyle IT, Campbell D, McNee S, Boyle P. Five-year double-blind fluoridated milk study in Scotland. Comm.Dent.Oral.Epidemiol. 1984;12:223-229.

48. Tonn EM, Ryge G, Chambers DW. A two year clinical study of a carvable composite resin used as class II restorations in primary molars. J.Dent.Child. 1980;47:405-413.

49. Nelson GV, Osbourne JW, Gale EN, Norman RD, Phillips RW. A three year clinical evaluation of composite resin and a high copper amalgam in posterior primary teeth. J.Dent.Child. 1980;47:414-419.

50. Pacquette DE, Vann WF, Oldenburg TR, Leinfelder KF. Modified cavity preparations for composite resins in primary molars. Paed.Dent. 1983;5:246-251.

51. Oldenburg TR, Vann WF, Dilley DC. Composite restorations for primary molars: two year results. Paed.Dent. 1985;7:96-103.

52. Oldenburg TR, Vann WF, Dilley DC. Composite restorations for primary molars: results after four years. Paed.Dent. 1987;9:136-143.

53. Oldenburg TR, Vann WF, Dilley DC. Comparison of composite and amalgam in posterior teeth of children. Dent.Mater. 1987a;3:182-186.

54. Roberts MW, Moffa JP, Broring CL. Two year clinical evaluation of a proprietary composite resin for the restoration of primary molars. Paed.Dent. 1985;7:14-18.

55. Tonn EM, Ryge G. Two year clinical evaluation of light cured composite resin restorations in primary teeth. J.Amer.Dent.Assoc. 1985;111:44-48.

56. Bevan FL, Braham RL. Clinical evaluation of the handling properties of Herculite in posterior primary teeth. Amer.J.Dent. 1989;2:17-20.

57. Eidelman E, Fuks A, Chosack A. A clinical, radiographic and SEM evaluation of class 2 composite restorations in primary teeth. Oper.Dent. 1989;14:58-63.

58. Phillips RW, Avery DR, Mehra R, Swartz ML, McCune RJ. One year observations on a composite resin for class II restorations. J.Pros.Dent. 1971;26:68-77.

59. Osbourne JW, Gale EN, Ferguson GW. One-year and two-year clinical evaluation of a composite resin vs.amalgam. J.Pros.Dent. 1973;30:795-800.

60. Phillips RW, Avery DR, Mehra R, Swartz ML, McCune R.J. Observations on a composite resin for class II restorations: two year report. J.Pros.Dent. 1972;28:164-169.

61. Leinfelder KF, Sluder TB, Sackwell.C.L., Strickland WD, Wall.J.T. Clinical evaluation of composite resins as anterior and posterior restorative materials. J.Pros.Dent. 1975;33:407-416.

62. Phillips RW, Avery DR, Mehra R, Swartz ML, McCune RJ. Observations on a composite resin for class II restorations: Three year report. J.Pros Dent. 1973;30:891-897.

63. Eames WB, Strain JD, Weitman RT, Williams AK. Clinical comparison of composite, amalgam, and silicate restorations. J.Amer.Dent.Assoc. 1974;89:1111-1117.

64. Wilder AD, May KN, Leinfelder KF. Three year clinical study of UV-cured composite resins in posterior teeth. J.Pros.Dent. 1983;50:26-30.

65. Wilder AD, May KN, Leinfelder KF. Five year clinical study of composite resin posterior teeth. J.Dent.Res. 1984;63:Abstract 1497:337.

66. Wilson NHF, Wilson MA, Smith GA. A clinical trial of a new visible light cured composite restorative - initial findings and one year results. Quintess.Int. 1985;4:281-290.

67. Wilson NHF, Smith GA, Wilson MA. A clinical trial of a visible light cured posterior composite resin restorative material: three year results. Quintess.Int. 1986;17:643-652.

68. Wilson NHF, Wilson MA, Wastell DG, Smith GA. A clinical trial of a visible light cured posterior composite resin restorative material: five year results. Quintess.Int. 1988;19:675-681.

69. Robinson AA, Rowe AHR, Maberley ML. A three year study of the clinical performance of a posterior composite and a lathe cut amalgam alloy. Brit.Dent.J. 1988;164:248-252.

70. Rowe AHR. A five year study of the clinical performance of a posterior composite resin restorative material. J.Dent. 1989;17:s6-s9.

71. Tyas MJ, Truong VT, Goldman M, Beech DR. Clinical evaluation of six composite resins in posterior teeth. Aust.Dent.J. 1989;34:147-153.

72. Boksman L, Jordan RE, Suzuki M, Charles DH. A visible light-cured posterior composite resin: results of a 3-year clinical evaluation. J.Amer.Dent.Assoc. 1986;112:627-631.

73. Sturdevant JR, Lundeen TF, Sluder TB, Leinfelder KF. Three year study of two light cured posterior composite resins. Dent.Mater. 1986;2:263-268.

74. Sturdevant JR, Lundeen TF, Sluder Jr. TB, Wilder AD, Taylor DF. Five year study of two light cured posterior composite resins. Dent.Mater. 1988;4:105-110.

75. Brunson WD, Bayne SC, Sturdevant JR, Robertson TM, Wilder AD, Taylor DF. Three year clinical evaluation of a self-cured posterior composite resin. Dent.Mater. 1989;5:127-132.

76. Heymann HO, Wilder AD, May KN, Leinfelder KF. Two-year clinical study of composite resins in posterior teeth. Dent.Mater. 1986;2:37-41.

77. Feller RP, Ricks CL, Matthews TG, Santucci EA. Three year clinical evaluation of composite formulations for posterior teeth. J.Pros.Dent. 1987;57:544-550.

78. Cunningham J, Mair LH, Foster MA, Ireland RS. Clinical evaluation of three posterior composite and two amalgam restorative materials: 3-year results. Brit.Dent.J. 1990;169:319-323.

79. Heymann H, Leonard R, Wilder A, May K, Leinfelder K. Five year clinical study of composite resins in posterior teeth. J.Dent.Res. 1987;66:Abstract 480:166.

80. Burwell JT. Survey of possible wear mechanisms. Wear 1957;1:119-141.

81. Bryant RW. Posterior composite resin restorations - a review of clinical problems. Aust.Pros.J. 1987;41-50.

82. Lambrechts P, Braem M, Vanherle G. Evaluation of clinical performance for posterior composite resins and dentin adhesives. Oper.Dent 1987;12:53-78.

83. Swift EJ. Wear of composite resins in permanent posterior teeth. J.Amer.Dent.Assoc. 1987;115:584-588.

84. Hirt T, Lutz F, Roulet JF. In vivo evaluation of occlusal wear of two experimental composites versus amalgam. J.Oral Rehab. 1984;11:511-520.

85. Jorgensen KD, Horsted P, Janum O, Kroch J, Schultz J. Abrasion of class I restorative resins. J.Dent.Res. 1979;87:140-145.

86. Lutz F, Imfield T, Meirer C, Firestone AR. Composites versus amalgam - comparative measurements of in vivo wear resistance: 1 year report. Quintess.Int. 1979;3:77-87.

87. Goldberg AJ, Rydinge E, Santucci EA, Racz WB. Clinical evaluation methods for posterior composite restorations. J.Dent.Res. 1984;63:1387-1391.

88. Osbourne JW, Phillips RW, Gale EN, Binon PP. Three year clinical comparison of three amalgam alloy types emphasizing an appraisal of the methods used. J.Amer.Dent.Assoc. 1976;93:784-789.

89. Leinfelder KF, Barkmeier WW, Goldberg AJ. Quantitative wear measurements of posterior composite resins. J.Dent.Res. 1983;62:Abstract 194:671.

90. Leinfelder KF, Taylor DF, Barkmeirer WW, Goldberg AJ. Quantitative wear measurement of posterior composite resins. Dent.Mater. 1986;2:198-201.

91. Moffa JP, Lugassy,AA, Calibration of evaluators utilising the M - L occlusal loss scale. J.Dent.Res. 1986;65:Abstract 1197:302

92. Mair LH. The measurement and analysis of clinical abrasion - a modified approach. Dent.Mater. 1990;6:271-275.

93. Leinfelder KF, Wilder AD, Teixeira LC. Wear rates of posterior composite resins. J.Amer.Dent.Assoc. 1986a;112:829-833.

94. Wilson NHF, Norman RD. Five-year findings of a multiclinical trial for a posterior composite. J.Dent. 1991;19:153-159.

95. Brunson WD, Wilder AD, Sturdevant JR, Robertson TM. Three year clinical evaluation of a light polymerised resin in posterior teeth. J.Dent.Res. 1987;66:Abstract 476:166.

96. Taylor DF, Bayne SC, Sturdevant JR, Wilder AD. Correlation of M-L, Leinfelder, and USPHS clinical evaluation techniques for wear. Dent.Mater. 1990;6:151-153.

97. Kusy R P, Leinfelder KF. Pattern of wear in posterior composite restorations. J.Dent.Res. 1977;56:544.

98. Xu H, Wang Tong, Song Shiqing. Wear patterns of composite restorative resins in vivo; observations by scanning electron microscopy. J.Oral Rehab. 1985;12:389-400.

99. Xu H, Wang Tong, Vingerling PA, Shiqing Song. A study of surfaces developed on composite resins in vivo during 4.5 years; observations by SEM. J.Oral Rehab. 1989;16:407-416.

100. O'Brian WJ, Yee J. Microstructure of posterior restorations of composite resin after clinical wear. Oper.Dent. 1980;5:90-94.

101. Abell AK, Leinfelder KF, Turner DT. Microscopic observations of the wear of a tooth restorative composite in vivo. J.Biomed.Mats.Res. 1983;17:501-507.

102. Lutz F, Phillips RW, Roulet JF, Setcos JC. In vivo and in vitro wear of potential posterior composites. J.Dent.Res. 1984;63:914-920.

103. Rice SL, Bailey WF, Wayne SF, Burns JA. Comparative in vitro sliding wear study of conventional, microfilled, and light-cured composite restoratives. J.Dent.Res. 1984;63:1173-1175.

104. Dennison JB, Powers JM, Charbeneau GT. Measurement of in vivo wear on posterior composite restorations. J.Dent.Res. 1980;59:Abstract 202:

105. Vrijoef MMA, Hendriks FHJ, Letzel H. Loss of substance of dental composite restorations. Dent.Mater. 1985;1:101-105.

106. Vrijoef MMA, Letzel H, Hendriks FHJ. A method to determine the loss of substance of dental restorations. J.Oral Rehab. 1985;12:9-16.

107. Aker JR. New composite resins:comparison of their resistance to toothbrush abrasion and characteristics of abraded surfaces. J.Amer.Dent.Assoc. 1982;105:633-635.

108. Powers JM, Ryan.MD, Hosking DJ, Goldberg AJ. Comparison of in vitro and in vivo wear of composites. J.Dent.Res. 1983;62:1089-1091.

109. Leinfelder KF, Beaudreau RW, Mazer RB. An in vivo device for predicting clinical wear. Quintess.Int. 1989;20:755-761.

110. Embong A, Glyn-Jones J, Harrison A. The wear effects of selected composites on restorative materials and enamel. Dent.Mater. 1987;3:236-240.

111. Finger W, Theimann J. Correlation between in vitro and in vivo wear of posterior restorative materials. Dent.Mater. 1987;3:280-286.

112. Lambrechts P, Vanherle G, Vuylsteke M, Davidson CL. Quantitative evaluation of the wear resistance of posterior dental restorations: new three-dimensional measuring technique. J.Dent. 1984;12:252-267.

113. De Gee AJ, Pallav P, Davidson CL. Effect of abrasion medium on wear of stress-bearing composites and amalgam in vitro. J.Dent.Res. 1986;65:654-658.

114. Atkinson JT, Groves D, Lalor MJ, Cunningham J, Williams DF. The measurement of wear in dental restorations using dual source contouring. Wear 1982;76:91-104.

115. Williams DF, Cunningham J, Lalor MJ, Groves D, Atkinson JT. Laser techniques for the evaluation of wear in class II restorations. J.Oral Rehab. 1983;10:407-414.

116. Eick JD, McGarrah RD, Lamb RD, Cardone M. Application of stereophotogrammetry to measure wear of posterior composites. J.Dent.Res. 1984;63:Abstract 1482:335.

117. Mitchem JG, Gronas DG. The in vivo evaluation of wear of restorative resin. J.Amer.Dent.Assoc. 1982;104:333-335.

118. Mitchem JG, Gronas DG. The continued in vivo evaluation of the wear of restorative resins. J.Amer.Dent.Assoc. 1985;111:961-964.

119. Bloem TJ, McDowell GC, Lang BR, Powers JM. In vivo wear: Part II: Wear and abrasion of composite restorative materials. J.Pros.Dent. 1988;60:242-249.

120. Roulet JF, Reich T, Lutz F. High precision occlusal mapping system for measuring wear of posterior composites. J.Dent.Res. 1983;62 (Special Issue): Abstract 457:220.

121. Braem M, Lambrechts P, van Doren V, Vanherle G. In vivo evaluation of four posterior composites: quantitative wear measurements and clinical behaviour. Dent.Mater.1986;2:106-113.

122. Adams LP, Joosie CH, Thomas CJF. An indirect in vivo method for quantification of wear of denture teeth. Dent.Mater. 1989;5:31-34.

123. Scott PJ. The reflex plotters: measurements without photographs. Photogramm.Rec. 1981;10:435-446.

124. Delong R, Pintado M, Douglas WH. Measurement of change in surface contour by computer graphics. Dent.Mater. 1985;1:27-30.

125. Truong VT, Tyas MJ. Prediction of in vivo wear in posterior composite resins: a fracture mechanics approach. Dent.Mater. 1988;4:318-327.

126. Moores GE, Glentworth P, Harrison A. Measurement of the rate of wear of dental composite resins by a ^{90}Sr beta particle transmission gauge. J.Biomed.Mater.Res. 1983;17:843-853.

127. Ryge G. Clinical evaluation of adhesive restorative materials. Data Gathering. Adhesive Dental Materials-II. U.S.D.H.E.W. 1964;258-265

128. Council on Dental Materials. Expansion of the acceptance program for dental materials, instruments and equipment: composite resin materials for occlusal class I and class II restorations. J.Amer.Dent.Assoc. 1981;102:349-350.

129. Council on Dental Materials. Posterior Composite Resins. J.Amer.Dent.Assoc. 1986;112:707-709.

130. Fukushima M, Setcos JC, Phillips RW. Marginal fracture of posterior composite resins. J.Amer.Dent.Assoc. 1988;117:577-583.

131. Wilson MA, Wilson NHF, Smith GA. A clinical trial of a visible light-cured posterior composite resin restorative: two-year results. Quintess.Int. 1986;17:151-155.

132. Wilson NHF, Wilson MA, Smith GA. A clinical trial of a visible light cured posterior composite resin restorative material: four year results. Quintess.Int. 1988;19:133-139.

133. Sturdevant JF, Sluder TB, Lundeen TF, Wall JT, Wilder AD. Two year clinical study of a visible light cured posterior composites. J.Dent.Res. 1985;64:Abstract 1600:352.

134. McCabe JF, Wilson HJ. Addition curing silicone rubber impression materials. Brit.Dent.J. 1978;145:17-20.

135. Marcinak CF, Draughn RA. Linear dimensional changes in addition curing silicone impression materials. J.Pros.Dent. 1982;47:411-413.

136. Keck SC. Automixing: A new concept in elastomeric impression material delivery systems. J.Pros.Dent. 1985;54:479-483.

137. Chong YH, Soh G, Wickens JL. The effect of mixing method on void formation in elastomeric impression materials. Int.J.Prosthodont. 1989;2:323-326.

138. Chong YH, Soh G, Lim KC, Teo C-S. Porosities in five automixed addition cured silicone elastomers. Oper.Dent. 1991;16:96-100.

139. Lambrechts P, Vanherle G, Davidson C. An universal and accurate replica technique for scanning electron microscope study in clinical dentistry. Microscopia Acta 1981;85:1:45-58.

140. Lang BR, Bloem TJ, Wang R-F, Jaarde M, Kowalski CJ. An in vivo experiment to test composite resin wear using the latin-square analysis. Int.J.Prosthodont. 1991;4:529-538.

141. Leinfelder KF. Posterior composite resins. J.Amer.Dent.Assoc. 1988;117:(Special Issue):21E-28E.

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