The Evaluation of Light Cure Baseplate Material.

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This thesis is the original work of the author.

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Abstract

The study was undertaken to evaluate light cure resin as an alternative to a current self cure material. Light cure materials are supplied by the manufacturer ready mixed in the form of sheets, rope or gel as opposed to the raw chemicals which have to be mixed before or during use.

Laboratory tests showed that, on average the two light cure resins tested deflected more, had a significantly lower impact resistance and had a significantly harder surface than the self cure material.

From the dental technician's point of view light cure materials are easier to adapt and a good reproduction of the fitting surface is achieved. In the gel form the material can be adapted in layers to achieve the desired thickness but care must be taken to avoid internal voids caused by over adaption. It can be adapted trimmed and polished significantly quicker than the conventional self cure powder and liquid. The main disadvantage of light cure materials is the fine dust produced when trimming as opposed to the shavings with conventional acrylics.

The light cure material which performed better in the laboratory tests (Thixotec) was compared with the conventional self cure resin (Orthoresin) in a clinical study. A total of 25 patients participated between January 1994 and March 1996. A series of questionnaires was completed at various stages of treatment. The results showed that there was no significant difference in the patients' acceptance of the two materials. Although there were more breakages to the light cure material the number was small.

Light cure resin, therefore, has considerable potential for wider use in orthodontics by virtue of its less toxic handling properties and its comparable clinical performance to self cure resin.

Chapter 1 : Introduction

The fabrication of modern dental appliances with acrylic resin involves the use of various chemicals which may give rise to problems both to the operator and / or the patient, if the procedure is not carried out according to the manufacturer's instructions. Even if these instructions are followed there is still a chance of minute traces of residual monomer being present in the baseplate of the finished appliance. The operator must also be vigilant when handling these chemicals as there is a hazard warning on all containers. The risk to both patient and operator must be minimised to ensure that no harm occurs to either.

When an appliance is manufactured in the dental laboratory raw chemicals are mixed together and cured by various methods depending on the material selected. These chemicals presently consist of monomers and polymers of methyl methacrylate in both self cure and heat cure forms. The raw chemicals are either mixed or sprayed to saturate the polymer granules which are then activated by a chemical activator in self cure resins, or by exothermic heat when using heat cure acrylics. When mixing heat cure materials the chemicals are dispensed into a mixing vessel in measured quantities. Polymer absorbs the monomer and when the saturation of the chemicals is complete the mixture is stirred and left to go through various stages - "damp sand", "stringy", until a dough stage is reached. The material is then handled with gloved hands and packed into a mould. The mould is then placed in a water bath or an oven to be processed where care must be taken that the interior of the mould does not exceed 100.3 degrees Celsius, the boiling point of monomer, or porosity will occur. Short cures take about 30 minutes and longer cures can take up to 10 hours duration.

With self cure materials the monomer and polymer can either be mixed or sprayed. With the spray method polymer is dispensed onto the model or mould and then saturated with monomer. This procedure is repeated until the operator has added enough material. The mould is then placed in a pressure pot partially filled with water, at 45 to 55 degrees Celsius, which must cover the mould for 8 - 10 minutes. The pot is then pressurised to 2 Bars. The correct time, temperature and the pressure ensures complete polymerisation and a porous free acrylic. Monomer fumes are evident until the material has been processed, therefore all the time the operator is using unprocessed material they are at risk from these chemicals. The use of these materials in the laboratory necessitates the use of special extractor units to remove the harmful fumes of the monomers from both self and heat cure acrylics. These materials have a flash point of 15 degrees Celsius, so care must be taken that there are no naked flames in close proximity to the working area.

These materials even when processed correctly have residual monomer present in the appliance to varying degrees. The residual monomer which is present in the finished appliance leaches out into the water after completion in the storage area. Although the free radicals of monomer go into solution very quickly, if there is some residual monomer present when the appliance is inserted into the patient's mouth it is not unusual for a patient to complain about the strange taste of a new appliance. Is there a better alternative to using these potentially harmful chemicals?

Light cure materials were introduced in the early 1980's and they were demonstrations round the country publicising these new materials with impressive presentations. The material seemed to have a great potential being ready-mixed and supplied in sheets, rope and gel. It has a very low

odour, which could mean a less hazardous material and also a less inflammable material. A number of years have now passed since the introduction of these first light cure systems and a number of modifications have been made. Light cure is an attractive material as it can be used without an extractor system when moulding and adaption is taking place. It could have the advantage of eliminating the costly filters used in the current extraction systems. Being able to use the material without harmful fumes may lead to a safer working environment. The material is supplied ready mixed and could save time, as mixing and spraying is eliminated, and more accurate adaptation is possible. To have all round access when building up an appliance is a great asset and could lead to greater accuracy when constructing appliances. It also makes the material more user friendly as it can be used on normal bench surfaces, although it would be advisable to adapt the material in a specific area of the laboratory in the interests of good practice, hygiene and safety regulations.

Light cure materials are currently used in the clinic and all the necessary equipment for curing is available. However it would be an advantage if the laboratory materials could be cured with the same spectrum of light. Most appliances need some degree of modification during a course of treatment and as there are very few practices or clinics with their own laboratory services attached it would be an advantage if light cure laboratory materials could be cured using a surgery light cure gun. Modifications could be then undertaken near the chairside.

Light cure materials have been in use in a clinical environment for a number years but now their use is becoming more widespread in the laboratory field. These materials, because of the activator, use a light source and this can give

the operator a degree of control over the working time. Their use in orthodontics at the present time is limited. Possibly at present the greatest use of light cure materials is for the construction of individual or special trays.

The technique for using light curing material for orthodontic appliances is the same procedure for all self cure appliances i.e.. fabrication of the wire work, coat the model with a separating agent, soak the model (optional) then apply the resin.

Light cure is a new breed of highly sophisticated acrylic resins supplied ready mixed as a gel, sheet, and rod or rope form.

A number of questions regarding this new material require to be answered e.g.

Will the material be operator and patient acceptable?

What are the advantages and disadvantages?

Will its properties be as good as currently used materials?

Chapter 2 : History

2.1 Introduction

Removable orthodontic appliances, also referred to as active plates, and functional appliances can be removed from the mouth by the patient, whereas fixed appliances are cemented or etched to the teeth and normally remain *in-situ* until the course of orthodontic treatment is completed.

2.2 Removable appliances

Nearly all removable appliances have a *Baseplate* which supports the wire framework of the appliance and which is constructed from an appropriate material. A variety of materials has been used for this purpose since the inception of such appliances. However modern day materials have superior properties to those used in the past.

The baseplate serves several functions:-

i) To link all the wires into a common area.

ii) To provide anchorage, by means of embracing a number of teeth, against which the reaction to active movement of teeth can be resisted.

iii) To provide an area where functional components such as Anterior Bite Planes and Posterior capping can be added to the appliance design.

iii) To extend the muscular area of the oral cavity when using functional appliances to stimulate or redirect growth.

Accurately formed baseplates play an important role when moving or retaining teeth when using removable appliances. Colyer (1900) he states that *"The movement of teeth by mechanical means is accomplished by the use of certain forces acting from a fixed base known as "the point of delivery." The*

resistance of the point of delivery or anchorage must be greater than that of the tooth or teeth to be moved. This is essential, and is frequently overlooked. The point of delivery is usually obtained from the resistance of the teeth ***by the means of a well fitting plate."***

He goes on to say " *The successful working of a regulation plate (orthodontic appliance) depends mainly on the* ***fit*** *and great care should therefore be taken in obtaining a model of the mouth".*

The baseplate material has continually changed over a period of time with improvements taking place to existing materials and some new materials appearing on the market from time to time.

2.3 Gold and Dental Alloy

The first removable orthodontic appliances in the early part of the 19th century were made from gold or dental alloy but with the introduction of vulcanite a much better fitting appliance could be obtained. Vulcanite then almost entirely superseded metals as the main material for appliances. It had a better fit and the bite was more easily adjusted, (Colyer, 1900).

2.4 Vulcanite

In New York in 1831 sulphur was dissolved in turpentine and rubber solution resulting in a hard rubber surface. Gurthie could not think of a use for his latest discovery. However eight years later Charles Goodyear discovered the phenomenon of vulcanisation by heating caoutchouc, or raw rubber, with sulphur and produced a soft rubber. Then in 1843 Thomas Hancock discovered that if different amounts of the same raw materials were used a hard rubber could be obtained. Goodyear studied the process and obtained a patent in 1851. The production of vulcanite about 1866 to 1879 was protected

by various patents and all dentists were forced to obtain a licence before selling vulcanite dental appliances. There were objections to paying the licence fee which ended with the tragic murder of Josiah Bacon, a licence collector, by Dr Samuel Chalfant in a San Francisco hotel. Dr. Chalfant was supported by the dental profession, headed by Dr S.S. White, during his trial to try and reduce the severity of his sentence. He became a martyr and served a term in prison. Subsequently the dental profession was freed from the necessity of having to obtain a licence before using vulcanite material. All the newspapers and dental periodicals reported the incident at the time, (Shell, 1938).

Hard rubber was called by a variety of names but the term vulcanite was favoured by the dental profession. This name was derived from the fact that the material is obtained by vulcanisation - heating with sulphur. The distinction between soft and hard rubber is the sulphur content. Soft rubber contains 2 -5 parts sulphur to a 100 parts of raw rubber where as hard rubber contains between 25 -47 parts of sulphur to 100 parts of raw rubber. Early rubber came from the wild rubber areas in South America , Africa and Mexico, and in 1934 the majority of the rubber came from plantations mainly centred in Southeast Asia as plantation rubber succeeded the wild variety.

Vermilion, the colouring agent for vulcanite, is derived from Mercuric sulphide (HgS). It is a fine bright scarlet powder, permanent in air, odourless and tasteless as well as being insoluble in water, alcohol, and various acids. When pure it is used as a pigment and its resistance to chemical action makes it particularly valuable as organic colourants are usually destroyed by the heat of vulcanisation. Although vermilion has a poisonous mercury base it has not had to any clinical problems attributed to it. The main problems with vulcanite

arise from its rough and porous surface, the difficulty in keeping it clean and the poor conduction of heat. The service from hard rubber appliances could not be exceeded by any of the non metallic materials available at that time (1930's). It had excellent permanence of colour, retention of shape, and was easily repaired, although there was a slight chance of warpage if incorrectly vulcanised and could be porous if slightly over-vulcanised.

Early orthodontic retainers were fabricated from gold wire and vulcanite. They were used by Hawley and others around 1914. Orrin Remensnyder's rubber gum massaging appliance, called a Flex-O-Tite, was introduced in 1923. He went on to patent the device in 1928 with which he described minor tooth movements. Later with his second patent he used the term "orthodontic appliance" for a one piece rubber device, (Remensnyder, 1926). Vulcanite positioning retainers were used by Kesling and others from around 1943, (Ponitz, 1971).

From a technician's view perhaps vulcanite's greatest advantage was when the appliance was being devested since wires, clasps and components could be removed without fear of damage from embedding plaster as it was very soft due to the high pressures and temperatures of vulcanisation, up to 90 lbs per square inch and 168 degrees Celsius, (Anderson, 1956).

2.5 Cellulose or Pyroxylins

Billiard balls were made from elephant ivory and when the world supply was insufficient to meet the demand synthetic celluloid was developed in 1868 by Hyatt. He treated cotton cellulose with nitric acid and obtained cellulose to make substitute ivory billiard balls. Cellulose or pyroxylins were introduced as dental materials as early as 1871 but neither the billiard balls nor the dental

material was satisfactory, (Shell, 1938). It was supplied as a blank and was moulded into shape by heating and compressing. Unfortunately the strains set up during moulding were later released slowly and the dental appliance tended to warp. If layering occurred during the moulding it tended to open up after a short period as the material did not join together to form a homogeneous mass. It absorbed water which decreased its strength. Patients complained (Anderson, 1956) of the smell and taste of the camphor plasticiser which volatilised during wearing and left a brittle structure but in many other fields celluloid was indispensable. It fell into disuse for a few years before being revived in the mid 1930's. They were the first synthetic plastics to be developed. Cellulose was heated with nitrate acid to form cellulose nitrate. The acid was removed and the product washed with alcohol and impregnated with camphor. Cellulose nitrate is inflammable. Colouring of cellulose is limited to organic materials and can be produced almost colourless. They are soluble in alcohol, decompose in acids or alkalis, swell when placed in warm water and also slowly harden with age.

2.6 'Bakelite'

'Bakelite' was the first example of a condensation resin based on phenol formaldehyde. The chemical changes which occur during condensation, render the material hard and infusible. 'Bakelite' is a thermosetting resin and once moulded its shape cannot be changed by heat or pressure. It was first produced in 'Bakeland' in 1916 in a form suitable for moulding and marked the beginning of a new plastics industry, (Anderson, 1956).

2.7 Phenol Formaldehyde

These resins were prepared by heating phenol and formaldehyde in the presence of a catalyser, fillers of flour, mica, asbestos, wood and many other materials were used to modify the physical properties. They were difficult to colour and had a high resistance to heat deformation and oxidation, (Shell, 1938).

These materials were very hard, and brittle. Although their strength could be quite high in small areas their deformation was not as high. The moulding process was complicated when applied to dental techniques using plaster moulds. These moulds had to be dry as moisture had to be excluded from the resin during condensation. Failures with this material could be attributed to poor processing of the dental appliances, as some appliances lasted a number of years and over this time gave a satisfactory service, (Anderson, 1956).

2.8 Vinyl Resins

Before 1928 vinyl and styrol resins were almost valueless commercially but since then vinyl resins have become one of the outstanding chemical groups in industry. They are inert and thermoplastic and have been used in the production of long playing phonograph records because of their hardness and permanence, (Shell, 1938).

These materials have a very low resistance to flexural fatigue and upper dental appliances repeatedly fractured in the midline area. They were difficult to mould and did not flow very well. A hard stone mould was required to prevent breakages during moulding and required a temperature of 140 degrees Celsius and even at this temperature they did not flow well. Vinyl resins are very resistant to water and maintain their original physical

properties, even under damp conditions like those found in the oral cavity.
Vinyl resins have been used as additives to acrylic resins in order to improve their physical properties and reduce the dimensional changes due to water absorption, (Anderson, 1956).

2.9 Acrylic Resins

Acrylic resin first became available as a highly plasticised blank which was softened by heat and injected into a mould. In 1935 Kulzer in Germany patented an idea of moulding fine grains of polymer which were softened and joined together by the addition of monomer. The soft mixture could then be squashed into a plaster mould and then polymerised (processed) *in-situ.*

Acrylic resins were rapidly developed during the early years of Second World War when the use of natural rubber for dental vulcanite was prohibited.
Today acrylic resins are still the most frequently used dental base materials for dentures and appliances.

In 1936 acrylic resins were introduced in the monomer / polymer form and only minor changes have taken place since then. Although different methods and pigmentation have been developed the basic material remains very similar to the original Paladon material introduced in 1936, (Anderson, 1956).

Since 1937 steel wire and and acrylic retainers have been used extensively, (Ponitz, 1971).

2.10 Orthodontic Resins

Several types of acrylic came on the market and the change from vulcanite to acrylic took place over a period of years as the acrylic materials became more

acceptable. The first acrylics were very basic materials and had a better colour than the vulcanite rubbers which had been previously used. The early acrylics had no cross linking agent and it was common to get crazing of the material. Crazing consists of small cracks formed by the relaxation of surface stress. The modern concept is that crazing is an actual mechanical separation of the polymer chains or groups of chains under tensile stress, (Phillips, 1991). These cracks can vary in size from readily visible to microscopic, and may also indicate the start of a fracture. Care had to be taken when repairing these materials. Any stress present within the old acrylic when contacting the monomer would craze the old material which would appear as small cracks along the stress lines. The acrylic would be very weak in this area and would be very easily broken. This problem was eliminated with the introduction of cross linking agents and the acrylics entered a new era.

The self cure acrylic also made several advances during this period. Early materials had a tendency to be porous and discoloured but this was eventually eliminated as the acrylics advanced over the years. Initially denture base resins were used for orthodontic appliances but as advances were taking place in acrylic resins these resins were modified to make it possible to process the resin directly on the model using a spray technique. The spay technique also described as the "salt and pepper technique" (BSI 6747:1987) is when monomer and polymer is dispensed on to the surface of the model alternately as the build up progresses, until there is a sufficient coating of acrylic. Self cure acrylics used in this way may be prone to problems such as a weaker baseplate, poorer fit due to contraction, and a potentially greater risk of residual monomer compared to heat cure resin. The main problem with all acrylics is that they have to be used within a fume extractor unit due to the material being highly inflammable and an irritant to the skin. Acrylics are well

accepted by the patient as the material seems to be kind to the tissues. This is a characteristic of the material which cannot be measured, tested or reproduced in the laboratory environment. Only clinical trials will test this asset.

2.11 Thermoplastic Blanks

The technique was pioneered by W.C. Godwin and others who produced at a modest cost a large number of mouth guards for athletes.

In 1963 Shanks first showed how thermoplastic blanks could be formed for mouth guards and transparent retainers using a machine. Cellulose acetate butyrate, polyurethane, polyvinylacetate-polyethylene polymer and latex were the most frequently used materials, (Ponitz, 1971). By the 1970's there was a more comprehensive range of materials; methacrylate, polyvinyl, polycarbonate. All these blanks are supplied in 95mm or 125mm diameter disks and vary in thickness from 0.5 mm to 3 mm, (Roberts et al., 1976).

2.12 Light Cured

In 1970 Michael Buonocore introduced a method of sealing pits and fissures for caries prevention using ultraviolet light which was reported in the Journal of the American Dental Association. Buonocore went on to say that Ultra Violet technique was being studied for use on a larger clinical scale, including Prosthodontics and Orthodontics. He even mentioned cementing plastic brackets directly onto labial surfaces of teeth, (Buonocore, 1970).

Despite problems during its introduction (3.3.3) the light cure system has been in use for several years now. In the clinic it is now used routinely for aesthetic fillings both in the anterior and posterior quadrants. Later the etch and bond system for orthodontic fixed brackets and bands was introduced.

The extraoral light cure system "Triad" for dental laboratories was introduced by DeTrey in 1983.

This was superseded in the 90's with a second generation system "Triad 2000" a powerful curing unit and Triad System materials which according to the manufacturers are pliable, premixed and cure on command with no waste, mess or monomer odour.

2.13 Future

There are new materials being developed all the time but it is only by testing these materials that decisions can be made to see if they have a potential market. There are now Micro Wave curing systems being tested. What material will we be using in the future? Hopefully a material that has patient acceptability, does not fracture, and is safer for the technician to use.

Chapter 3 : Review of the Literature

3.1 Introduction

To ensure the success of orthodontic treatment with removable appliances the patient must enjoy wearing their appliances as far as that is possible. The movement of teeth can be an uncomfortable experience for the patient so that the non active components should not give rise to functional problems.

As new materials were developed the properties of dental appliances surely improved. Well, according to the patients this was not always the case. When cellulose materials were used in the 1930's Anderson (1956) reported "the patients complained of the constant smells and tastes" which was caused by the camphor volatilising after a period of wear. Cousins (1962) indicated that porosity was a problem with the current self cure materials and Petit et al. (1985) reported that "removable retainers and orthopaedic appliances are coated with saliva and millions of organisms"

On the safety side most of the current materials have many disadvantages - for example some must only be used with extraction units as they contain carcinogenic materials in the uncured material (Manufacturers Product Information Sheets). Employees are at risk when they use these and other chemicals, (Kanerva et al., 1993).

Regardless of the material used to construct a dental appliance most involve the use of chemicals and all chemicals have a risk factor. There must be a balance to be able to give the patient the best possible appliance and to minimise as much as possible the risk in the dental laboratory .

3.2 Current Materials

3.2.1 Acrylic

Various materials have come and gone over the years but acrylic has been with us for the last forty years. Despite the problems encountered with acrylic resins they have remained the most popular choice of material .

There have also been problems with acrylic resin as there is always free radicals of monomer. Sometimes the patient complains of a strange taste when appliances are fitted or after a repair has been completed. When an appliance has been processed the chains are incomplete and leave free radicals of monomer which leach out during storage or into a saliva solution after the appliance is fitted. It was reported by Smith et al. (1955) that there was residual monomer in acrylic baseplates and he linked the problem to the denture causing a sore mouth.

On the "product information sheets" supplied with monomer products the material is listed as an "irritant and highly inflammable liquid" which can with inhalation be an "irritant to the respiratory system and excessive exposure to it may cause dizziness and narcosis". The monomer "when mixed with the appropriate powder forms a crossed linked mass which is used intraorally and the product is inert and non toxic". At least the finished product the patient receives is safer.

With the growing awareness of the hazards of monomer fumes and to satisfy the current safety requirements it is recommend to use either a downflow or ordinary extraction unit with carbon filters and checked regularly to satisfy Control of Substances Hazardous to Health (COSHH) regulations.

With the introduction of these new regulations all laboratories must conform to COSHH, and these regulations also apply to manufacturers who must have product information sheets available for each product.

3.2.2 Pressure Moulding

Methyl methacrylate used as a liquid / powder variant has all the problems previously mentioned, (1.2.1) so some manufactures supply blanks for pressure moulding.

Pressure moulding seemed to be a solution as the blanks were supplied ready to use. The blanks were manufactured from methacrylate, polycarbonate, and polyvinyl. This technique required the use of self cure acrylic resin to cover the component tags. These blanks were placed on a heating element and when soft were adapted to the surface of the model using air pressure. As the material was sucked down or blown down with a vacuum unit a problem still existed with deep vaulted palates but Roberts and Knapp (1976) described a technique of using "Modified Removable Appliances". They placed self cure in the vault of deep palates to prevent undue stretching of the blanks and modified "gum shield type of appliances".

The use of these appliances was limited and they also used methyl methacrylate self cure resin though in minute quantities and still involved the use of monomer extraction fume cabinets.

According to Lewis et al. (1986) "Thermoplastic resins are also being used for retainers which eliminates the free monomer problem but are very difficult to modify".

The majority of operators who use this system limit it to Hawley retainers and very simple removable appliances.

3.2.3 Acrylic Free

The Sarhan type retainer seemed the answer to all the problems associated with methyl methyacrylate but this "acrylic free retainer" was completely made from wire. "The Hawley retainer consisting of two Adams clasps, a labial bow, and an acrylic baseplate is the most commonly used appliance". "However if not properly cleaned, the baseplate could become unhygienic, may cause allergic reactions in some patients, and can cause speech problems, at least initially because of its bulk. As a result may not be tolerated by some patients", (Sarhan et al., 1993).

He had attempted to bridge the gap with this appliance and had tried to eliminate the problems of the current materials. Kolstad et al., (1983) and Brin et al., (1984) reported on non acrylic appliances but unfortunately they were only suitable for retainers.

3.3 Light Cure

3.3.1 Introduction

Light activated materials when initially introduced (Buonocore, 1970) were not without their problems. Rock (1974) and Birdsell et al. (1977) both expressed concern about the harmful effects of near ultra violet radiation which resulted in the modification of the curing units. The use of light curing materials has increased by leaps and bounds on the clinical side and is now used routinely in conservation for fillings and in orthodontics for the placement of fixed brackets using the acid etch technique.

The application of the light cure technique for the construction of appliances in the laboratory has had slow progress. Laboratory light cure materials were introduced in 1983 and since then various reports have indicated "Preliminary studies of VLC (Visible Light Cure) resins have produced promising results; however additional research is necessary to completely define qualities of this material", (Ogle et al., 1986). "Light curing is an exciting innovation", (Lewis et al., 1986). "The application of Triad VLC resin material to the practice of orthodontics is very promising", (Lewis et.al., 1988).

Light cure material since its introduction has still not made a great impact on the laboratory side of the market despite having the potential of a user friendly system. Possibly the most common use for light cure materials at the present time is for custom made trays.

3.3.2 Applications

De Trey introduced visible light cure material (VLC) for use in the dental laboratory. The material was supplied in sheets and rope and was initially marketed as a prosthodontic material which could be used for orthodontic appliances.

The system was developed to construct any type of custom made dental appliance which was previously made from acrylic resin. The material is produced in sheets, rope and gels in a variety of colours. The sheets are packaged in regular pink fibred and light pink fibred, also "Trans Sheets" in colourless and pink shades. There is also a colourless gel material which flows and blends for maximum control and minimum of trimming. These gels are available in clear, pink, blue and red with the "Provisional Material" available in tooth coloured material, ivory extra light, ivory medium, ivory dark

and enamel for crowns, bridges and veneers. "Custom Tray", a material for the fabrication of custom made or special trays is produced in blue to visually contrast impression materials.

Other manufacturers also supply light cure materials e.g. Kulzer have a crown and bridge system.

Cale (1986) described the technique using the light cure pink acrylic sheets designed for dentures for constructing orthodontic appliances. He listed the advantages as having no odour compared to self curing acrylic and the light curing "acrylic seems to have no residual taste or less than that of other appliances". He went on to say that having too few types of light curing acrylic materials available was a disadvantage.

Light cure was evaluated for the reconstruction of the spine in experimental rats and such procedures are used for the reconstruction of vertebra in humans. They investigated its use in spinal surgery because of its superior strength, accurate fit and ease of manipulation, (Alsawaf et al., 1991).

3.3.3 Curing Source

The application of photo-polymerization in dentistry began with pit and fissure sealants in the 1970's (Buonocore, 1970) and rapidly extended to resin based restorative materials (previously known as dental composites). "Because these early materials contained photosensitizers such as benzoin methyl ether with the absorption maxima near 340 nm (nanometer), radiation sources such as the high pressure Hg lamps were required for successful polymerisation", (Cook, 1982).

During the next few years after the introduction of the light cure system there were several articles indicating the possible dangers of ultraviolet radiation, (Rock, 1974). An article on an electronic device used to polymerise sealants and composite resin suggested that clinicians take the appropriate precautions to avoid potential hazards to themselves and the patients. These devices had an absence of shielding on the probe, (Birdsell et al., 1977).

Concern was also expressed regarding the possible biological damage to the eye and oral mucosa, (Rock, 1974) and (Birdsell et al., 1977). It is well established that ultra violet radiation produces tissue damage and is the mechanism responsible for suntanning and sunburn in fair races. The light receptor of the eye is particularly venerable to eye damage as in the case of arc welders who can get ophthalmic flash damage from the light source if not fully protected. "The tissue damage produced by ultra violet radiation depends on the intensity and the duration of the exposure", (Rock, 1974) and Birdsell et al.,1977 drew attention to the "Harmful effects of near-ultraviolet radiation used for polymerisation of a sealant and a composite resin" . The manufacturers took action and modified the units.

The next move was towards the "white light" system which is in the blue region of the visible spectrum. The visible light activated composites usually contain di-ketone initiators such as camphoroquinone and a reducing agent such as tertiary amine to produce radicals after controlled irradiation by visible light to iniate polymerisation. The camphoroquinone initiator is activated by wavelengths in the range of 400 -500 nanometers.

The light source for the laboratory is contained in the upper area of the curing unit which emits an intense light centred in the blue 400 - 500 nanometer cure

area of of the visible light spectrum.

The depth of cure varies with the intensity of the curing unit and the time. Ortman (1986) states that hand held units give a partial cure to a depth of 1-2 mm whereas Lewis et al., (1986) say deep curing of 5-6 mm is possible with a curing unit and a shielded high intensity light centred in the 400-500 nanometer cure band of visible light.

3.3.4 Composition

The material is similar to light curing composite restorative materials but uses organic filler instead of inorganic. The filler is made of acrylic beads of varying sizes and a matrix of urethane dimethacrylate with enough micro fine silica to control the handling characteristics. The photo-intitator camphoroquinone activates the amines that initiates the polymerisation of high molecular weight acrylic monomers within the matrix. To achieve complete curing of the material it must be covered with an air barrier coating before the final placement in the curing unit, (Lewis et al., 1986) and (Ortman, 1986).

The monomer problem is not totally solved as it would be difficult to obtain a resin that will completely polymerise. The degree of polymerisation with light cure materials seems to correlate with the amount of filler present in resin, the lower amount of filler the more complete polymerisation that will be achieved, (Barron et al., 1992).

3.3.5 Safety

The main advantages with the light cure systems is the material can be cured on command and there is no residual monomer present in the completed prosthesis and appliance.

A report in "Contact Dermatitis" (Kanerva et al, 1993) indicates the problems

that can exist if good practice in handling materials is not adhered to. The number of cases reported in the publication in the 1970's was relatively low partly because of the awareness of the sensitising capacity of acrylates and perhaps because methyl methacrylate itself is not very sensitising. It also reports that dental personnel had become sensitised to composite resins and dentine primers but they had seen only a few who worked with prosthesis. "This may change, however, since more complex acrylic mixtures, including light cured acrylics, have now come into use" and went on to say, "Light cured acrylics are similar in composition to dental composite resins. These acrylics contain more potent acrylic sensitisers than methyl methacrylate. Accordingly, dental personnel may face a higher risk of sensitisation than previously".

They also described how dental technicians are the ones who handle methacrylates most often for the production of orthodontic appliances and other dental prosthesis. (Kanerva et al, 1993)

3.3.6 Problems

One of the problems encountered previously was the reproduction of the fitting surface using the sheet type materials. It was difficult, if not impossible, to achieve a good reproduction of the fitting surface or model surface. This problem was highlighted in the Journal of Prosthetic Dentistry, (Tan et al., 1989). In an effort to achieve a good reproduction a vacuum unit (Drufomat) was used to blow down a sheet of light cure material using a sheet of rubber dam to prevent any undue thinning of the light cure sheet. This technique worked reasonably well apart from still trapping air voids on the fitting surface. Even with careful hand adaption the problem still existed. Unfortunately a good reproduction of the fitting surface is vital to ensure the patient has a

comfortable appliance. The sheet material has very good handling properties and virtually no aroma. On the surface the sheet material adapts very well and allows preliminary trimming to be completed. This trimming consists of the back edge and round the collets of the teeth with a LeCron / Ash 5 or a plastic bladed instrument which prevent the light cure adhering to the blade of the instrument. After the preliminary trimming has been completed the appliance is placed in a light curing unit to initiate the curing cycle.

The monomer problem is not totally solved as it would be difficult to obtain a 100% monomer conversion. The degree of monomer conversion varies with the amount of filler. The degree of polymerisation seems correlate with the amount of filler present in resin, (Barron et.al., 1992).

3.4 Summary

The quest for suitable baseplates should be sought as an article by Kerr (1984) reported that the breakage of a baseplate "is expensive in terms of time and resources and may frustrate the rapid achievement of treatment goals" he went on to say that in this study the baseplate breakages amounted to 57% of the appliances repaired in the hospital laboratory over the period of the twelve month study.

The potential for this material that has virtually no aroma, can be trimmed and then cured on demand could revolutionise appliance construction.

Chapter 4 : Aims of the study

The aims of this study are to:- "evaluate light cure resin baseplate material" and to assess the following:-

1 To test the physical properties of light cure resin baseplate material. *(study 1)*

2 To evaluate the reaction of patients to the use of light cure resin as a baseplate material. *(study 2)*

3 To compare both of the above with self cure acrylic resin.

4 To make a personal assessment as to the handling properties of light cure resin baseplate material in the laboratory.

Chapter 5 : Material Tests - Study One

5.1 Materials

Four light cure materials were donated by a dental suppliers for testing.
All the light cure materials were supplied in toothpaste style tubes filled with a 'gel' material.

The gel material was selected because of the problems of achieving a good reproduction of the fitting surface when adapting the sheet light cure material. The manufacturers recommend hand adapting these sheet materials to the model and because of the method of curing it cannot be kept under pressure.

Defects on the fitting surface when using light cure sheet materials are a common problem, (Tan et al, 1989).

The materials were tested on some sample appliances to assess the quality and how easy they were to work with at the bench before commencing on the laboratory tests.

5.1.1 Material 'A' "Thixotec"

This material was supplied in clear and rosa (red) in alloy coloured tubes. The material adapted easily from the tube onto to the model. The material could be manipulated round the wires and formed into an even thickness with ease.

The material settled into a smooth surface without moving from the adapted position (did not slump). This smoothness could be an asset to the gel materials as finishing time could be reduced. Additional layers up to 3 mm could be added until the required thickness was achieved, (6.8.3). The

adaptation round the collets was close and accurate. The fitting surface had no air voids and the reproduction was good.

This material was included in the baseplate evaluation study.

5.1.2 Material 'B'

This material was supplied in clear and in white coloured tube.
The clear material adapted easily from the toothpaste style tubes onto the model. The material did not slump and was easily adapted round the wires. The only difference between Material 'A' and 'B' at this stage was the top surface.

On material 'B' the surface was ridged as opposed to the smooth surface of material 'A'. Several techniques were employed to try and smooth the surface e.g.

i) Leaving the material to settle after adaption,
ii) Using instruments to smooth the surface of the adapted material,
iii) Wiping the surface with a small paint brush to smooth the adapted material,

The last technique (iii) was the most successful of the methods tried.
The technique of using a paint brush seemed to have the potential of moving these light cure gels and was used very successfully later in the study, (6.8.3.).

After processing there was no change on the surface as it was still rough.
By having a ridged surface the trimming time could be longer and this could be a disadvantage.

Material 'B was included in the baseplate evaluation study.

5.1.3 Material 'C'

Material 'C' was a gel supplied in white tubes and was coloured blue. When this material was adapted to the sloping surface of the model it slid back to the base and the vault of the palate. This resulted in 2 mm thickness and the material barely covered the wires slumping into the base of the palate which gained in thickness to approximately 6 mm.

There was no evidence of voids when curing this 6 mm mass of material as encountered with material 'A', (6.8.3).

A few different techniques were used to try to eliminate the problem of slumping e.g.

i) Reducing the amount of material applied.

ii) Angling the model, etc.

The problem of slumping persisted and the material was eventually removed from the study.

5.1.4 Material 'D'

Material 'D' was a yellow gel supplied in white tubes. It did not flow as well as the other light cure gels but it did not slump like some of the other materials. It was easy to achieve an even thickness of material. The top surface settled to a smooth surface and gave the impression this material would supersede the others.

When material 'D' was cured it still looked good until it was removed from the model. When cured the fitting surface had a pointed roughness as if it had lifted partially in the vault of the palate.

From a material that adapted and flowed extremely well, round the wires and in between the teeth, after the material was cured the fitting surface had lifted from the model and formed stalagmites or stalactites depending on how the appliance was held.

The surface reproduction was very poor which rendered the material unsuitable and was immediately discarded from further testing.

5.1.5 De Trey's Orthoresin

The control material would be the current material used in the department for the fabrication of all the self cure removable appliances.

A standard pack of Orthoresin was bought from the usual suppliers and in line with current I.S.O. standards with a batch number and a use by date. All the appliances were constructed from an 850gm standard pack with monomer. The Orthoresin from this pack had an expiry date of 00/02.

5.2 Materials Selected for Testing

Light cure materials 'A' and 'B' were selected as they were the most consistent materials during the initial study tests. On adaptability light cure materials 'A' and 'B' performed better than the other gel materials. They did not slump and reproduced the fitting surface more accurately.

The following tests were then conducted on these materials

i) Transverse deflection

ii) Impact

iii) Hardness

These tests were selected to assess the stiffness, the ability of the materials to withstand a sudden shock and the hardness of the surface finish .

5.3 Method

A test specimen plate had to be made in metal or resin to the dimensions according to the British Standards Publications (BS 2782, 1984 and BS6747, 1987, and BS2487, 1989). These patterns would then be used for the production of test specimen moulds. The test specimen moulds would then be used to produce test specimen plates a raw unfinished moulded plate. The test specimen plate would then be prepared and finished to the dimensions required for each test specimen. These test specimens and specimen strips would now in a suitable form for testing.

5.4 Preparation of the patterns.

5.4.1. Transverse Deflection

A piece of perspex 5 mm thick was cut to 65 mm long and 40 mm wide. This was then marked on the reverse side 1 mm less than the previous side to give measurement of 64 mm x 39 mm. This resulted in a rectangular piece of perspex which had tapering sides to permit easy removal of the test specimen plate after the mould had been made.

5.4.2 Impact

A 7mm thick piece of perspex was shaped to 61 mm long x 46 mm wide and 60 mm long x 45 mm wide on the reverse which gave a test specimen plate with tapering sides to enable the fabrication of a mould for the construction a test specimen plates from which the test pieces would eventually be formed.

5.4.3 Hardness

A piece of perspex 39 x 39 mm and 1.5 mm thick was shaped and the edges slightly chamfered 1.00 mm less on the other side to permit easy removal of the test specimen plate from the mould.

5.4.4 Preparation of test specimen moulds.

A glass slab 150 mm x 100 mm was used as a base for the preparation of the patterns of the test specimen plates which would be used for the production of Kaffir 'D' moulds. The piece of perspex was secured to the glass slab using a very thin cohesive film of Vaseline between the two materials to prevent movement during the production of the moulds. A wall of cardboard was then attached to the glass slab leaving approximately a 2 cm space between the perspex and the cardboard wall. A 100 gm of Kaffir 'D' to 30 ml of water ratio was vacuum mixed for 30 seconds and gently vibrated into the mould to a depth of 15 mm. This was left to set for one hour and the perspex preparation specimen plate was removed. The taper on the sides of the plate is to allow easier removable and no breakage of master mould.

The perspex specimen was removed from the Kaffir 'D' mould and the exercise repeated to produce another mould in case any damage occurred when the actual samples were removed. This exercise was repeated for the production of each mould.

5.4.5 Preparation of the test specimen plates.

Using this mould at least two specimen plates would be required for each material, Orthoresin, Light Cure 'A', and Light Cure 'B' materials. The mould was coated with De Trey's C.M.S. a sodium alginate separating medium to prevent acrylic and Light Cure sticking to the Kaffir 'D' plaster mould.

5.4.6 Orthoresin

The Orthoresin specimen plates were produced using the spray technique to build up the self cure acrylic. The mould was filled level and then the specimen was processed as specified by De Trey's manufacturers instructions for 8-10 minutes with a water temperature of 45 -50 degrees Celsius and

pressurised to 2 bars. No problems were encountered when producing the Orthoresin specimens.

5.4.7 Light Cure

Two types of light sources were supplied with the materials donated by the manufacturer, a Xenon strobe light unit (Fig. 6.9) and a Blue light box. The Xenon strobe light unit had two settings. The first one gave a 30 second cycle and the other a 3 minute cycle. This was the unit recommended by the manufacturer for the light cure materials supplied and cured the material successfully. The other unit - Blue light box had two settings of 3 and 5 minutes but even after four cycles, with all the light cure materials supplied, the materials still had the same consistency as when they were adapted. The nanometer range was not marked on the Blue Light Box but the Xenon Strobe unit has a range of 400 to 500 nanometers so light cure materials should only be used with the appropriate light curing unit.

The light cure specimens posed particular problems as the recommended maximum thickness at which this material can be processed is 3 mm and the mould has a depth of at least 5 mm. In an effort to fill the mould with one layer and to eliminate curing layers of light cure material two methods were tried.

i) The mould was filled and the material processed with the curing unit set at one for 30 seconds. This resulted in the top surface and the base being processed but it left left a void in the middle.
ii) The mould was refilled and reprocessed at the setting two for 3 minutes.

Again the top surface and the base were processed but it still left a void in the middle.

The light cure gel material cures from the top and from the base of the material which leaves a liquid in the middle. This eventually creates a void in the centre of the material. It was reported that light cure materials could deep cure to a depth of 5 - 6 mm (Lewis et al., 1986) but light cure gel materials will only cure in layers to a maximum thickness of 3 mm or voids may appear. The samples were then produced by layering to a maximum of 3 mm layers The material was then processing to the manufactures instructions, tacking at one and processing at two. The specimen was then processed on the reverse side which is a common practice with light cures.

5.5 Preparation of test specimen strips.

5.5.1 Transverse deflection

Two test specimen plates were prepared from different mixes for each of the materials - Light Cure 'A' and 'B' and Orthoresin.

Each plate was carefully sawn lengthwise using a Sample Cutting Machine (5.6.1) into three equal strips measuring 64 mm x 11 mm x 3.5 mm. This would allow for a millimetre all round to enable the correct size to be achieved when preparing the test sample.

These strips were then prepared on a sample preparation machine (Fig. 5.4) using various grades of silicone carbide paper and finishing with a P1200 grade. The sample preparation machine was fitted with a speed controller to reduce the revolutions in order to prevent the overheating of the samples.

Cold water was sprayed constantly on to the rotating wheel to prevent overheating and to act as a lubricant.

Six test specimen strips were prepared with dimensions of 64 mm long and 10 mm wide and 2.5 mm thick. The toleration on the width and thickness was +/- 0.03 mm.

5.5.2 Impact

Two test specimen plates for each material, Light Cure 'A' and 'B' and Orthoresin, were prepared from a mould 60 mm long and 40 mm wide by 7 mm deep from different mixes of material.

From each plate not less than 5 test specimens were prepared from each plate with final dimensions of 50 mm long and 6mm wide and 4 mm deep with a tolerance of +/- 0.02 mm. The test specimen strips were prepared on a sample preparation machine (Fig. 5.4).

These specimens were notched according to Method 359 Type B notch. The sample was measured and the position of the notch marked. A 1.00 mm needle file was used to cut the notch to a depth of .8 mm. The radius was shaped to 45 degrees using a needle file. The depth of the notch was tested using the micrometer (Fig. 5.3) and a piece of straight 0.8mm wire.

5.5.3 Hardness

Two test specimen plates for Light Cure 'A' and 'B' and Orthoresin were made from a test specimens mould and the samples were prepared on a sample preparation machine (Fig. 5.4) to the finished dimensions of 38.5mm long and 38 mm wide and 1.00 mm +/- 0.02 mm thickness and obtained from different mixes of material.

5.5.4 Conditioning of Test Specimen Plates

All the test specimen plates were stored in distilled water at 37 +/- 2 degrees Celsius for 7 days. The samples were removed and placed in water at 23 +/- 2 degrees Celsius for 1 hour prior to testing.

5.6 Equipment

5.6.1 Sample cutting machine

Each test specimen plates was divided into a number of strips as required for each test using a Microbiology Sample cutting machine with a circular diamond disc cutter which was water cooled and had a digitally variable speed controller. The cutting speed of 350 rpm was used to ensure no physical damage occurred to the sample strips.

5.6.2 Nene M3000 Testing Machine

The transverse deflection tests were carried out using a Nene M3000 Testing Machine using a 500N load cell. The samples were placed equidistantly on the steel bars of the 'U' shaped table and the plastic rod with a steel rod on the base attached to the load cell was lowered onto the sample, (Fig. 5.1). Individual samples were tested with a load of 15 and 30 N's. The Nene testing was linked to a computer which calculated the data which was then printed out on graph paper. The data was then analysed and load figures for 15 and 30 Newtons were then realised, (Fig. 5.5).

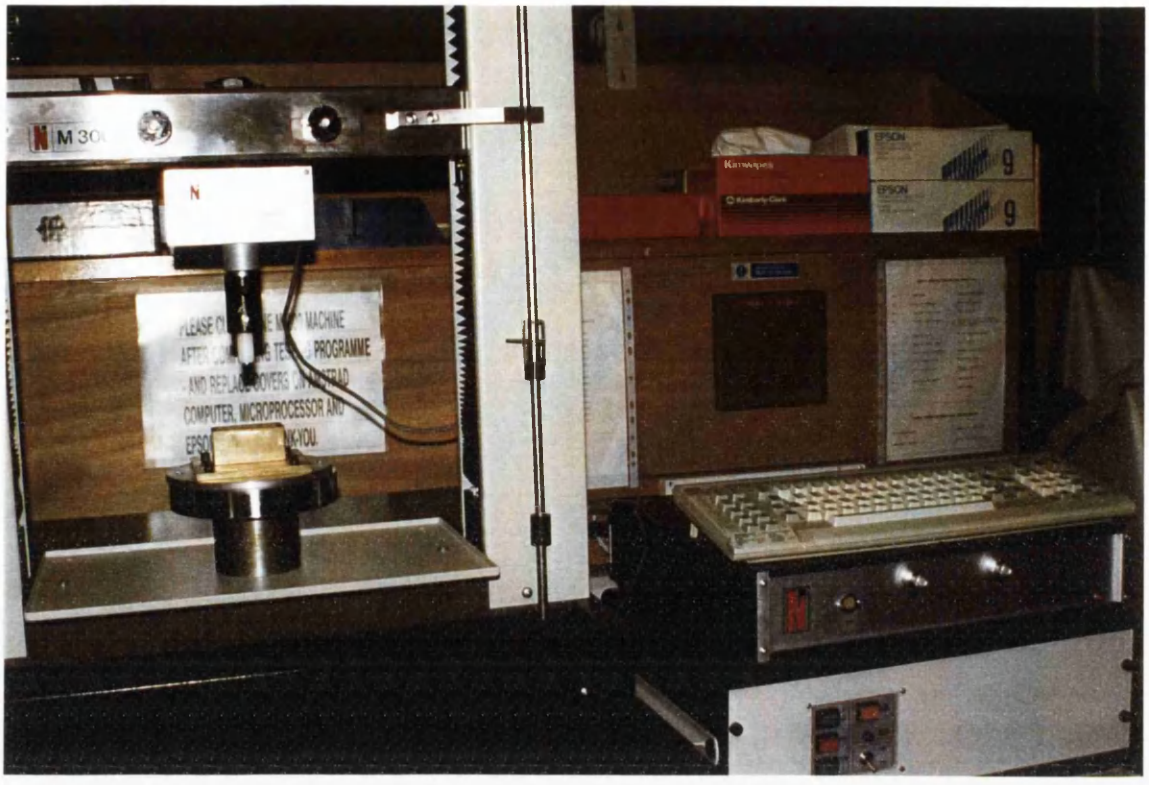


Figure 5.1 Nene M3000 Testing Machine

5.6.3 Charpy Impact Tester

The Hounsfield Charpy Impact Tester (Fig. 5.2) was used for the impact tests.The machine is designed to measure the breaking of a notched test piece. This indicates the resistance of the material to stress concentration. This is considered an important test because moulded, machined and punched plastics generally embody sections where stress is concentrated when subjected to forces or accidental impact and usually ultimately fail at these areas.

The test specimens must be of the same size for comparable results and the cross section of the test piece should be comparable to the average thickness of the manufactured product.

5.6.4 Making a test.

A tup was selected and placed on the tester. The arm was positioned in the raised position and the pointer moved to its stop position. The machine was now checked by releasing the tup without a test piece. It should register zero on the dial. Any deviation in this figure should be adjusted by the operator.

The notched test specimen was aligned squarely with the pin and against the anvil heads of the testing instrument. The pin for aligning the notched test specimen was now dropped to allow the test to be commenced. The tup was released and the pointer would register a reading on the dial. The reading should ideally be between 0.35 and 0.7. The graduations between zero and 0.35 and above 0.7 were coarsely graduated whereas the area between 0.35 and 0.7 was finely graduated. The dial reading was now calculated using the tables supplied with the testing machine and the size of the tup used in the test. The same tup had be used for all the tests and if the sample failed to fracture it had be rejected to eliminate any errors.

Extra test specimen plates which did not meet the specified dimensions were used to determine the size of the tup which would be used for the actual tests.

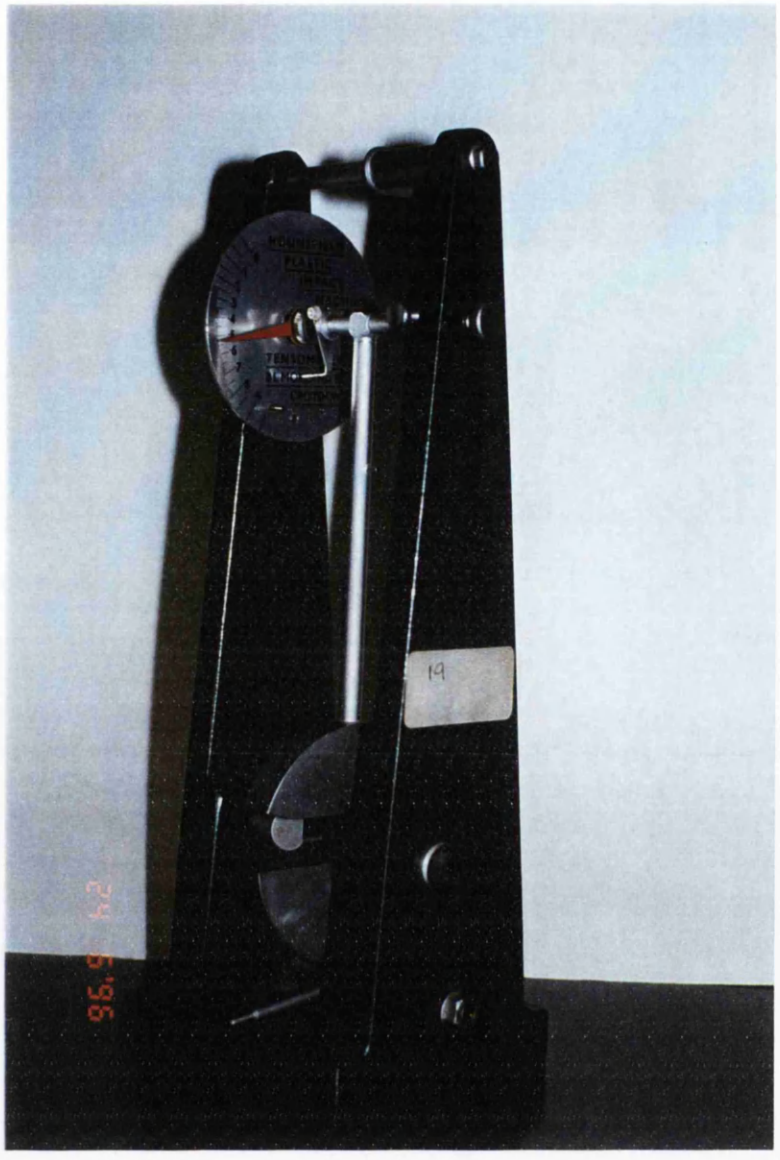


Figure 5.2 Hounsfield Charpy Impact Tester

5.6.5 Leitz Miniload Knoop Micro Hardness Tester

The hardness tests were conducted on a Leitz Miniload Knoop Micro hardness Tester. The tester was linked to a printer and the results were analysed to produce the graphs, (Fig. 5.10).

A minimum of two test specimen plates for each material was prepared from the Kaffir 'D' mould. These samples did not need sectioning as they were tested using prepared specimen plates with final dimensions of 38 x 38 millimetres and 1 millimetre plus / minus 0.02 thick.

5.6.6 Digital Micrometer

An engineer's digital read out micrometer was used to measure the dimensions of the samples. This precision instrument which can accurately measure to 0.001mm and was very easy to use. It consisted of a measuring area and two knurled rotating nobs. The micrometer was closed and the display was zeroed. Then the micrometer could then measure the samples in inches or millimetres and these values could be changed at the touch of a button. The British Standards Institute publications uses millimetres as the standard. The micrometer was set to millimetres and zero checked before starting a batch of samples. The nob was rotated towards the sample until it clicked. The digital display indicated the dimensions to 3 points on the millimetre scale. The tolerance allowed varied between plus / minus .02 for Impact and plus / minus .03 millimetres for Transverse Deflection tests.

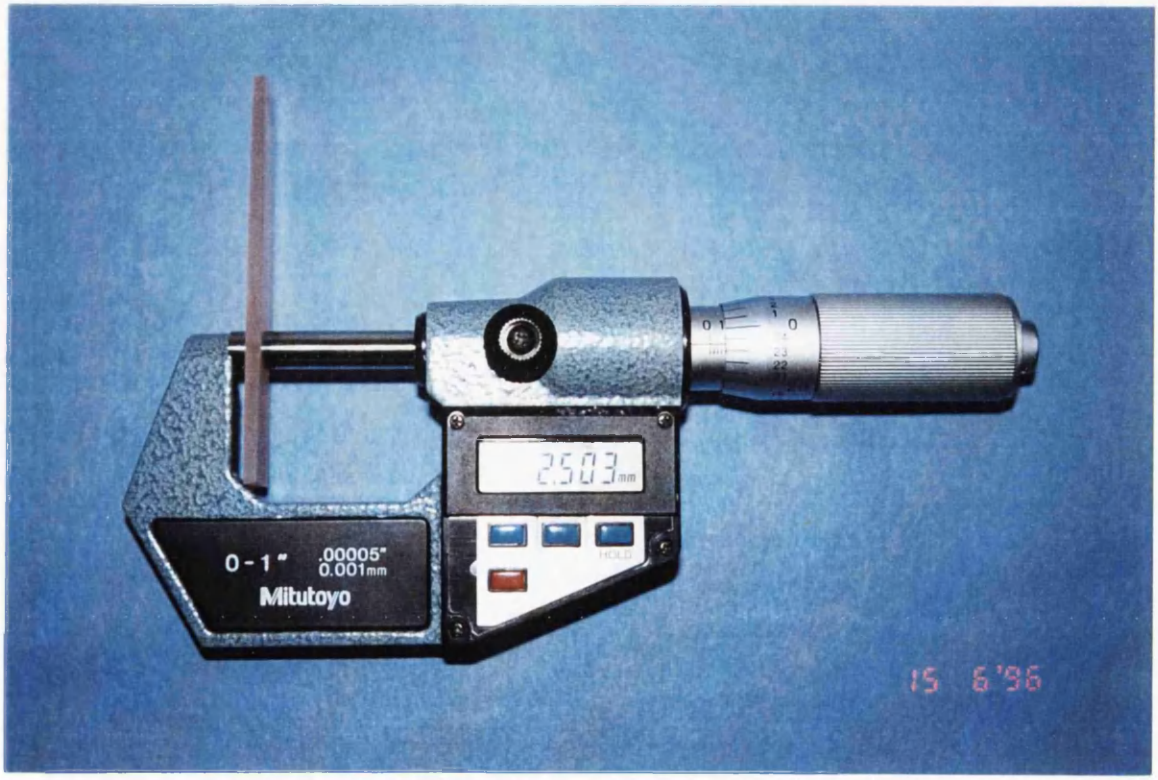


Figure 5.3 Digital Micrometer with sample

5.6.7 Sample preparation machine

This machine had a metal plate to which various grades of silicone carbide self adhesive disks could be attached to the metal rotating plate. A speed controller varied the rotation of the disk which had be slow to avoid damage to the samples. A spray of cold water continuously wet the rotating disk to keep the sample cool and prevented any alteration to the physical properties of the sample.

Figure 5.4 Sample Preparation Machine

5.7 Results

The results from the tests were analysed and entered in a Macintosh Claris Works spreadsheet programme. The results of all the test specimen plates were calculated and averaged. The data was then used with Claris Works Charts programme to produce the following graphs, (Figs. 5.5, 5.8, 5.10). Statistical analysis of the data was executed with the PC Minitab Version 9.

A one-way analysis of variance with the Tukey sub-command was executed on the data for the following results on Transverse Deflection, Impact and Hardness. (Figs. 5.6, 5.7, 5.9, 5.11)

5.7.1 Transverse deflection

A total of six test specimen plates were tested for each material and the results were printed on graph paper by the printer linked to the Nene M3000 testing machine. Each result was analysed and a value produced for each sample.

The results for all the materials were consistent considering the samples were made from different batches of material.

Light cure material 'A' had a greater deflection than the the other materials at 15 N's and 30 N's. This material was the most flexible of the materials and the deflection was approximately twice as much as the self cure material tested. Although this material was more flexible it was still suitable for a baseplate material, (Fig. 5.5).

Light cure material 'B' deflected slightly less than the self cure material. The deflection of this material was more comparable to the current self cure materials, (Fig. 5.5).

Self cure materials have been used for over forty years and although their properties have improved considerably since their introduction the light cure materials will be compared to the present self cure material.

The graph (Fig. 5.5) shows at 15 N's light cure material 'A' has a greater deflection than light cure material 'B' and the self cure material which have comparable results. When the load was increased to 30 N's light cure material

'A' showed considerably more deflection than light cure material 'B' and the self cure material whose results were approximately comparable.

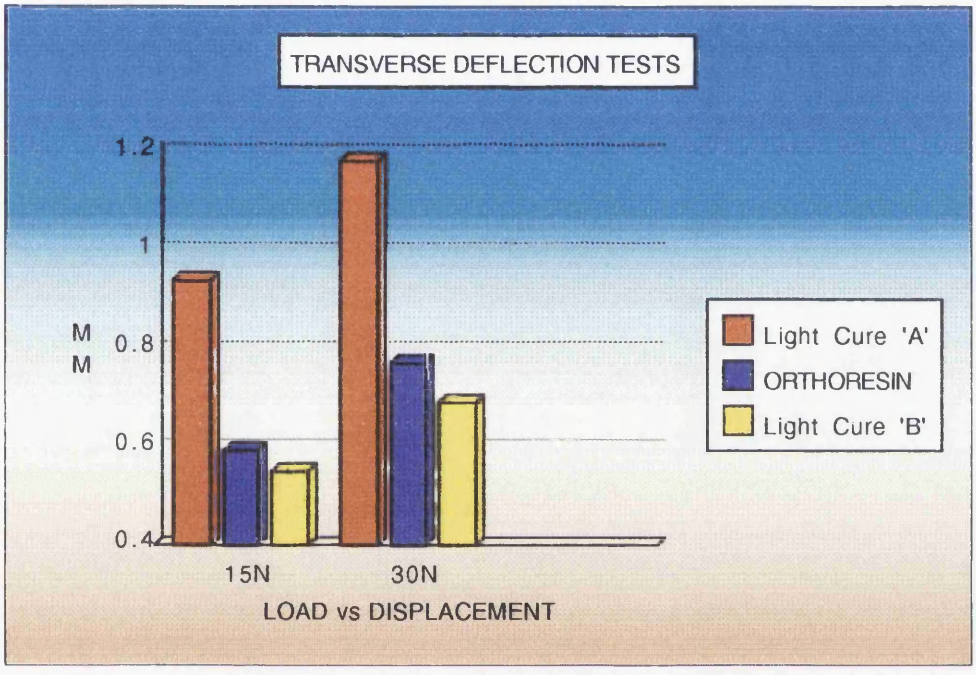


Figure 5.5 Transverse Deflection

5.7.2 Statistical Analysis on Transverse Deflection

The deflection of light cure material 'A' is significantly greater than light cure material 'B' and Orthoresin, when a load of 15 N and 30 N were applied to the samples. (Figs. 5.6, 5.7)

```
ANALYSIS OF VARIANCE ON 15kn
SOURCE      DF        SS         MS         F         p
C2           2    0.5501     0.2751     13.98     0.000
ERROR       15    0.2952     0.0197
TOTAL       17    0.8454

                                        INDIVIDUAL 95% CI'S FOR MEAN
                                        BASED ON POOLED STDEV
 LEVEL       N      MEAN      STDEV  ---------+---------+---------+-------
LC 'A' 1     6    0.9423     0.2124                      (-----*-----)
  'O' 2      6    0.5523     0.0538   (-----*-----)
LC 'B' 3     6    0.5942     0.1050     (-----*-----)
                                      ---------+---------+---------+-------
POOLED STDEV =    0.1403                    0.60      0.80      1.00

Tukey's pairwise comparisons

    Family error rate = 0.0500
Individual error rate = 0.0203

Critical value = 3.67

Intervals for (column level mean) - (row level mean)

               1         2

     2    0.1798
          0.6002

     3    0.1380    -0.2520
          0.5584     0.1684
```

Figure 5.6 Analysis of Variance on 15 N.

```
ANALYSIS OF VARIANCE ON 30kn
SOURCE      DF        SS         MS         F         p
C4           2    0.8338     0.4169     18.61     0.000
ERROR       15    0.3361     0.0224
TOTAL       17    1.1699

                                        INDIVIDUAL 95% CI'S FOR MEAN
                                        BASED ON POOLED STDEV
 LEVEL       N      MEAN      STDEV  --------+---------+---------+--------
LC 'A' 1     6    1.1848     0.2332                     (----*-----)
  'O' 2      6    0.6942     0.0501   (----*----)
LC 'B' 3     6    0.7725     0.1017      (----*----)
                                      --------+---------+---------+--------
POOLED STDEV =    0.1497                   0.75      1.00      1.25

Tukey's pairwise comparisons

    Family error rate = 0.0500
Individual error rate = 0.0203

Critical value = 3.67

Intervals for (column level mean) - (row level mean)

               1         2

     2    0.2664
          0.7149

     3    0.1881    -0.3026
          0.6366     0.1459
```

Figure 5.7 Analysis of Variance on 30 N.

5.7.3Impact

Ten specimen plates prepared according to Method 359 with type B notches were tested on an Impact Testing Machine (5.6.2). The samples were positioned on the instrument and a tup released and the readings calculated using the tables supplied with the Impact Testing Machine. The light cure material 'A' specimens had a very low impact resistance compared to the self cure material. The rejected specimen plates were used to evaluate which size of tup would be required to carry out the tests. A preliminary test was carried out on a self cure sample and when the same tup was used on light cure material 'A' sample the tup size had to be reduced to accommodate both materials due to the low resistance of the light cure material 'A'.

The impact resistance of material 'A' was very low compared to the conventional self cure material and light cure material 'B' when tested using the prepared test specimen plates. The graph (Fig. 5.8) shows how little energy was required to break the specimen plates of the light cure material 'A' compared to the greater energy required to break the self cure and light cure material 'B' test specimen plates.

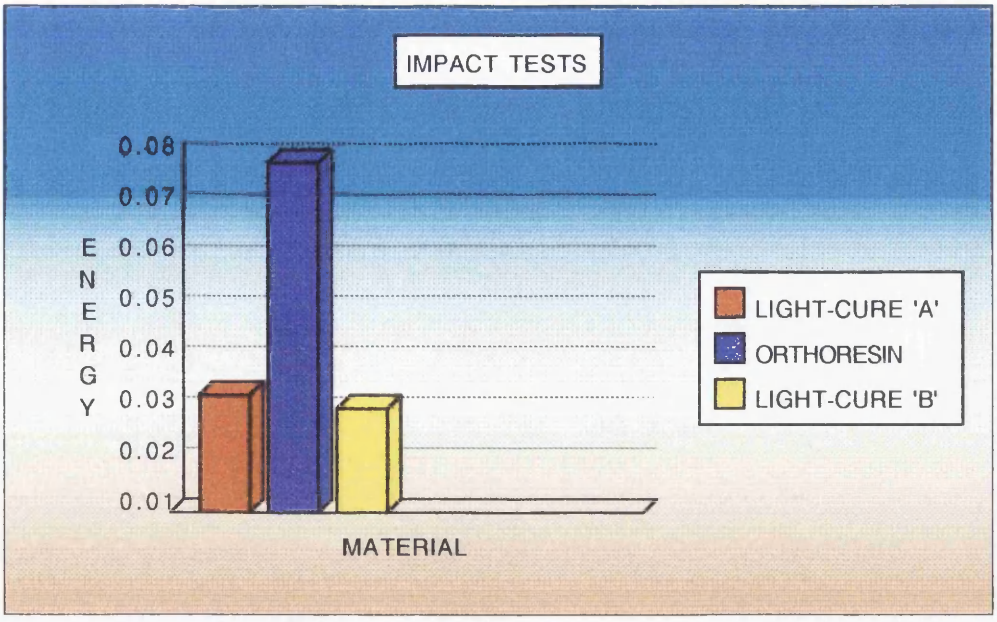


Figure 5.8 Impact Tests

5.7.4 Statistical Analysis on Impact

The average energy on impact is significantly greater for self cure than light cure 'A' or 'B'. (Fig. 5.8)

```
ANALYSIS OF VARIANCE ON Impact
SOURCE      DF         SS          MS          F          p
C6           2  0.0074759   0.0037380      89.03      0.000
ERROR       12  0.0005038   0.0000420
TOTAL       14  0.0079797

                                          INDIVIDUAL 95% CI'S FOR MEAN
                                          BASED ON POOLED STDEV
 LEVEL       N       MEAN      STDEV      --------+---------+---------+--------
LC 'A' 1     5   0.032880   0.003349        (--*---)
LC 'B' 2     5   0.030420   0.005994      (--*--)
   'O' 3     5   0.078960   0.008877                              (--*---)
                                          --------+---------+---------+--------
POOLED STDEV = 0.006480                         0.040     0.060     0.080

Tukey's pairwise comparisons

    Family error rate = 0.0500
Individual error rate = 0.0206

Critical value = 3.77

Intervals for (column level mean) - (row level mean)

                1          2

     2 -0.008464
        0.013384

     3 -0.057004 -0.059464
       -0.035156 -0.037616
```

Figure 5.9 Analysis of Variance on the average energy on Impact

5.7.5 Hardness

A series of indents were made on each of the two samples for each material using the Leitz Miniload Knoop Micro Hardness Tester. The materials were tested on both sides. The self cure material registered the largest indent which renders its surface as the softest. Both light cure materials registered a much lower indent with light cure material 'B' as the hardest material. Light cure 'A' came in between the other two materials, (Fig. 5.10). The surface hardness indicates whether a material can be resistant to food and bacteria adherence and whether the material can take a good surface finish.

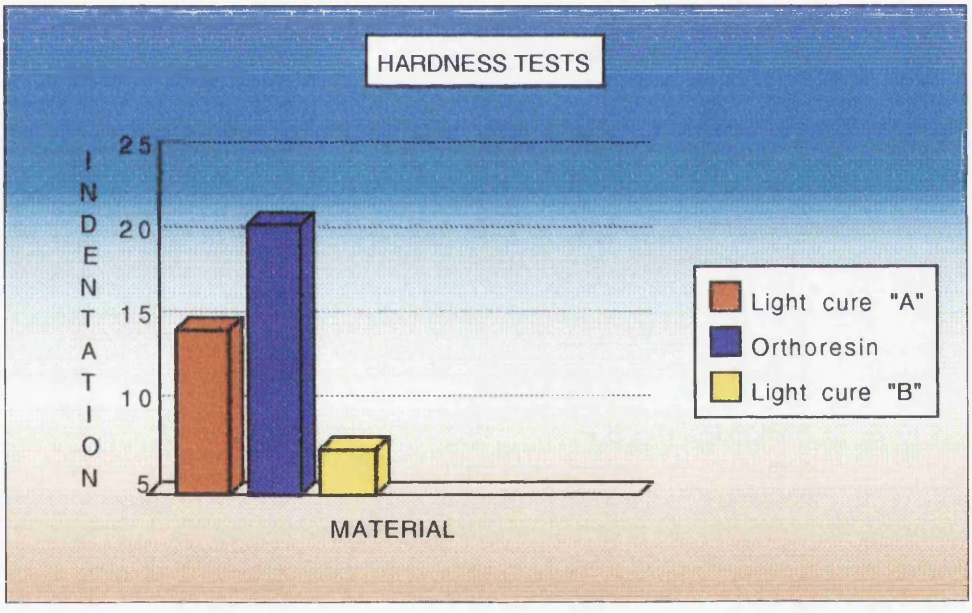


Figure 5.10 Hardness Tests

5.7.6 Statistical analysis for hardness

The average hardness of light cure 'B' is significantly greater than light cure 'A' which in turn is significantly greater than self cure, (Fig. 5.11).

```
ANALYSIS OF VARIANCE ON Hardness
SOURCE     DF        SS        MS        F        p
C8          2    438.03    219.02   105.63    0.000
ERROR      12     24.88      2.07
TOTAL      14    462.92

                                        INDIVIDUAL 95% CI'S FOR MEAN
                                        BASED ON POOLED STDEV
 LEVEL      N      MEAN     STDEV  --------+---------+---------+--------
LC 'A' 1    5    14.618     1.110               (--*--)
  'O' 2     5    20.924     2.212                          (--*--)
LC 'B' 3    5     7.692     0.308   (-*--)
                                    --------+---------+---------+--------
POOLED STDEV =    1.440              10.0      15.0      20.0

Tukey's pairwise comparisons

    Family error rate = 0.0500
Individual error rate = 0.0206

Critical value = 3.77

Intervals for (column level mean) - (row level mean)

               1         2

     2    -8.734
          -3.878

     3     4.498    10.804
           9.354    15.660
```

Figure 5.11 Analysis of Variance on the average hardness

5.8 Discussion

The light cure materials were easy to adapt from the toothpaste style tubes but material 'A' settled to an extremely smooth surface as opposed to the rough surface encountered with material 'B'. With both of these gel materials care had to be taken when adapting as the optimum thickness seems to be a maximum of 3 mm otherwise voids will occur as the material cures on the surface and the base leaving an initial liquid area and eventually a void within the material.

The material tests showed the light cure materials properties varied from the current materials in use at the present time. One of the light cure materials was slightly more flexible as the tensile deflection tests indicated. This flexibility may counteract the lower impact resistance when compared to self cure materials. The low impact resistance may be a problem and could lead to a

higher percentage of fractures of the base plate. Orthodontic base plates normally consist of wire components embedded in a base plate and these wires could act as protection in the event of an appliance receiving a sudden blow e.g. dropped when cleaning. The surfaces of the light cure materials were almost twice as hard as the current self cure materials which could give a more durable and cleaner appliance with less resistant to bacteria and easier cleaned.

The self cure materials have been in use for a number of years and although the light cure materials are ready mixed and have a low odour their properties vary from the current materials.

5.9 Materials Selected for Evaluation

Four materials were received for evaluation and two were eliminated because of poor working qualities, (5.1.3 & 5.1.4). Two materials, light cure 'A' and 'B', were subjected to physical and mechanical tests with the control self cure material. Light cure material 'B' was eventually rejected because of its rough surface when adapting the gel material, (5.1.2). The inability to achieve a smoother surface before curing would lead to greatly increased finishing times.

For the clinical trials (Study 2) the characteristics of light cure material 'B' (Thixotec) with its better handling properties (5.1.1) was selected for evaluation with the control self cure material Orthoresin.

Chapter 6 : Clinical Trial - Study Two

A: Fabrication of Appliance

6.1 Selection

Patients for inclusion in the trial were selected consecutively from those requiring a removable appliance in the undergraduate student clinic. The appliances were to be standard removable appliances. No functional or fixed appliances were to be included in the survey. The patients were given a patient information sheet (see appendix) outlining the purpose of the clinical trial. After their agreement to take part in the trial alginate impressions were then taken and sent to the University Orthodontic Laboratory together with the appliance design.

6.2 Models

The impressions were poured in a standard 100 gms of Kaffir 'D' to 30 ml of water to produce a workable mix of British Gypsum Kaffir 'D' plaster. This was then vacuum mixed for 30 seconds using a Whip Mix Continental Vacuum Mixer. The Kaffir 'D' mix was vibrated into the impressions and when the mix was sufficiently firm the impressions were inverted to form the base and the gross excess of Kaffir 'D' removed. Study models if required can be poured from the same impressions but the model from the first pour must be used for the appliance. The models were trimmed using a model trimmer. The bases of the study models should be of uniform height and symmetrical outline and should come into occlusion when placed on their bases, posterior angle and buccal angle, (Adams, 1995).

6.3 Design

A design sheet accompanied the work box which had been designed jointly with the lecturer and an undergraduate student. The only stipulation was that the appliance had to be a removable appliance. This was one of the reasons the student undergraduate clinic was selected. Any type of removable appliance design could be constructed and would test the material fairly quickly under varying conditions as all appliances could exhibit different problems.

6.4 Construction

The removable appliances would be constructed in either Thickotex light cure resin or De Trey's Orthoresin self cure acrylic resin. Thickotex light cure material was selected from the pilot study of light cure materials received for the trial, (5.5.1).

The appliances were allocated alternately as they entered the laboratory to ensure no preference was given to either material so to ensure the materials were given a fair test. The patients' work boxes were recorded in a table on a computer using the programme Word 2.1, as soon as they were delivered to the laboratory. The patients were unaware as to which material they were receiving.

Computer Details :-

i) The patients box number.

ii) Date of impression.

iii) Date of insertion.

iv) Type of appliance.

v) Material to be used for construction.

vi) Record of any repairs.

vii) Survey forms.

viii) When this stage of treatment was completed.

All the above details were all entered into the computer programme. This provided a record of the progress of the appliance which was constantly updated.

6.5 Types

All types of removable appliances were accepted to ensure the materials were given a reasonable test both in the laboratory and during the clinical trial.

The range of appliances consisted of :-

i) Moving teeth mesially / distally using springs or retractors.

ii) Moving teeth palatially using buccal springs

iii) Various types of screw plates

iv) Lower appliances

v) Habit appliances

vi) Space maintainers

vii) Hawley retainers

The baseplates varied in thickness depending on the type of appliance but an effort was made to keep the appliance as delicate as possible. The variance in the thickness of the baseplate of each appliance could indicate the advantages or disadvantages and enable the problem areas to be recorded . The different types of appliances would indicate if these materials would be suitable for every day use.

6.6 Wire work

The wire component construction used the same technique whether the appliance was being constructed in self cure or light cure resin.

All the wire work of the appliances were constructed from stainless steel wire supplied by K.C. Smith. The active components were constructed first. Any springs requiring blocking out was completed in Tenactin modelling wax. After the active components - finger springs, buccal retractors, labial bows, screws etc, and the fixation components Adams clasps, three-quarter clasps, fitted bows, recurved bows for anchorage etc, were constructed. They were sealed using modelling wax on the buccal side of the model.

All the tags of the wire components had to have a space of 0.5 to 1.00 mm to allow the baseplate material to completely flow under all the tags during the adaptation of the material, (Fig. 6.1).

Failure of the baseplate material to flow completely under the wire components could lead to the wire tags becoming detached from the baseplate, which could lead to appliance failure and / or cause trauma to the tissues. Another factor was that the appliance would be unable to transmit the force onto the specified area required for the movement of the teeth. It was also possible that the component could become detached during the course of treatment.

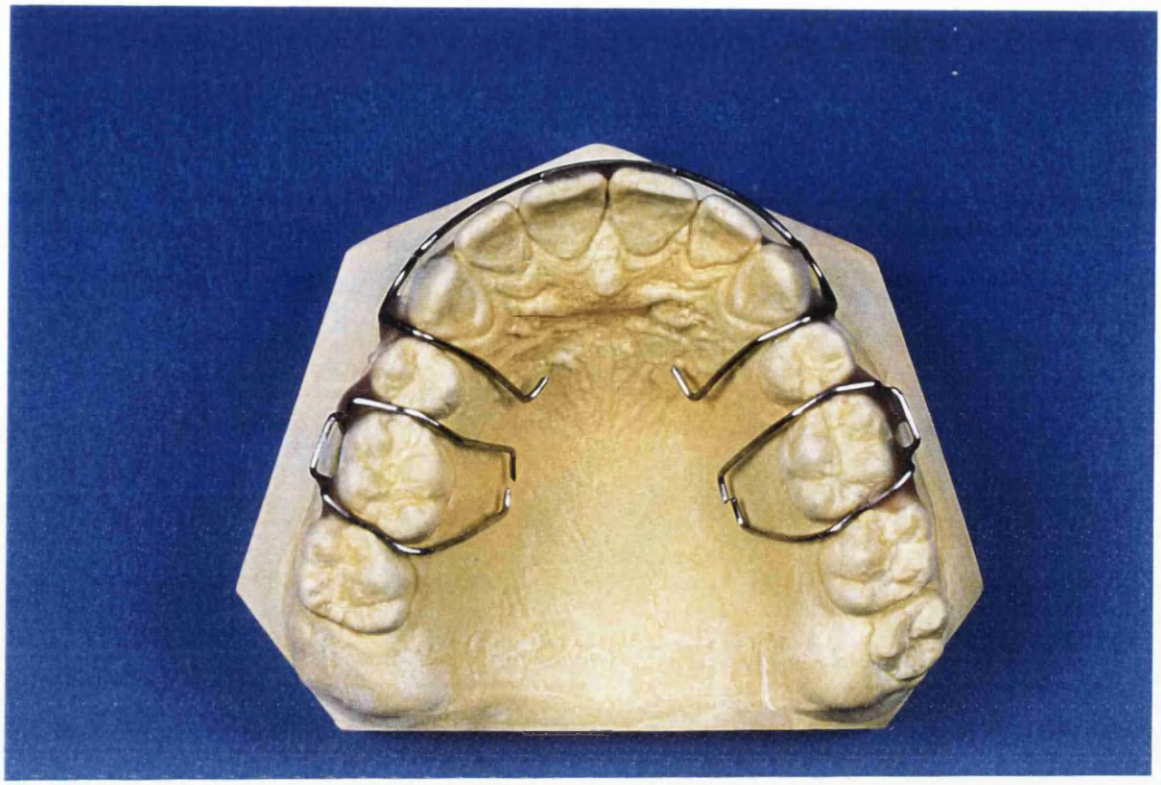


Figure 6.1 Wire Work

6.7 Model preparation

The model was now divided into two areas :-

a) The palatal area

b) The labial and buccal areas.

There can be exceptions to this theory e.g.. posterior capping, incisor coverage.

The model had to be blocked out separating the two areas so that the baseplate material was contained within the specified area during the adaption of the material.

The baseplate material must not damage the model surface and be easily removed after processing. Therefore a sealer must be used to prevent the

baseplate material adhering or damaging to the surface of the model.

Ideal Properties of a Sealer :-

i) Prevent the baseplate material sticking to the surface of the model.

ii) Prevent the drying out of the baseplate material into the porous model.

iii) Should allow close adaption of the baseplate material.

iv) Should not contaminate the baseplate material.

v) Should not interfere with the setting of the baseplate material.

There are two types of sealer in use at the present time :-

i) Sodium alginate a water based solution which reacts with the surface of the plaster model to form a calcium alginate layer. This layer is very thin and coats the surface evenly. When the sodium alginate coating dries it is indistinguishable from the original model surface apart for a slight colour change.

ii) The other type has a Vaseline type consistency which is painted on the surface of the model. Care must be taken to ensure an even coating.

Sodium alginate has been used throughout the study of the baseplate material. It has been diluted with 50% water to increase the flow and provide a very thin layer on the surface of the model. Sodium alginate because of its viscosity can form a gel when setting between the wires and the model. By lowering the viscosity with water the sealer was much thinner and soaked into the model quicker preventing the fore mentioned problem. The separation of the baseplate materials and the model was not effected by this modification to the sodium alginate separating material.

Dry models have to be soaked in water :-

i) If the models have to be immersed in water during the processing cycle.

ii) Because it is normally easier to remove appliances from damp models.

With the light cure technique it was not necessary to soak the model but all models were very slightly damp when the material was adapted as it prevented the separating medium (sodium alginate) from drying out.

With the self cure technique the model and acrylic were submerged in a pressure pot which was partially filled with warm water during the processing procedure. To prevent the baseplate material incurring voids due to the air being expelled during the models immersion in the pressure pot the model had to be soaked before adaption of the baseplate material.

Only the base of the model was placed in water to allow the water to percolate from the base to the surface of the model. This prevented the water lifting the separating medium (sodium alginate layer) from the surface of the model.

6.8 Light Cure

6.8.1 Equipment and Tools :-

i) Tube of light cure gel

ii) Small good quality paint brush.

iii) Vaseline or a light barrier paste.

iv) Light curing unit (Zeon Strobe).

v) Laboratory hand piece.

vi) Acrylic rotary trimmers.

vii) Polishing unit.

viii) Felt cones, mops, brushes etc.

ix) Pumice and Acrylic Gloss polishing block.

6.8.2 Light cure material

The light cure material was supplied in sheets, rolls approximately 5mm in diameter and tubes of ready mixed gel. The ready mixed gel material had been used for all the light cure appliances which were part of the evaluation study.

The model was prepared as previously described.

6.8.3 Adapting the light cure

The light cure gel material was supplied in soft metal toothpaste style tubes with a pointed nozzle. (Fig. 6.2)

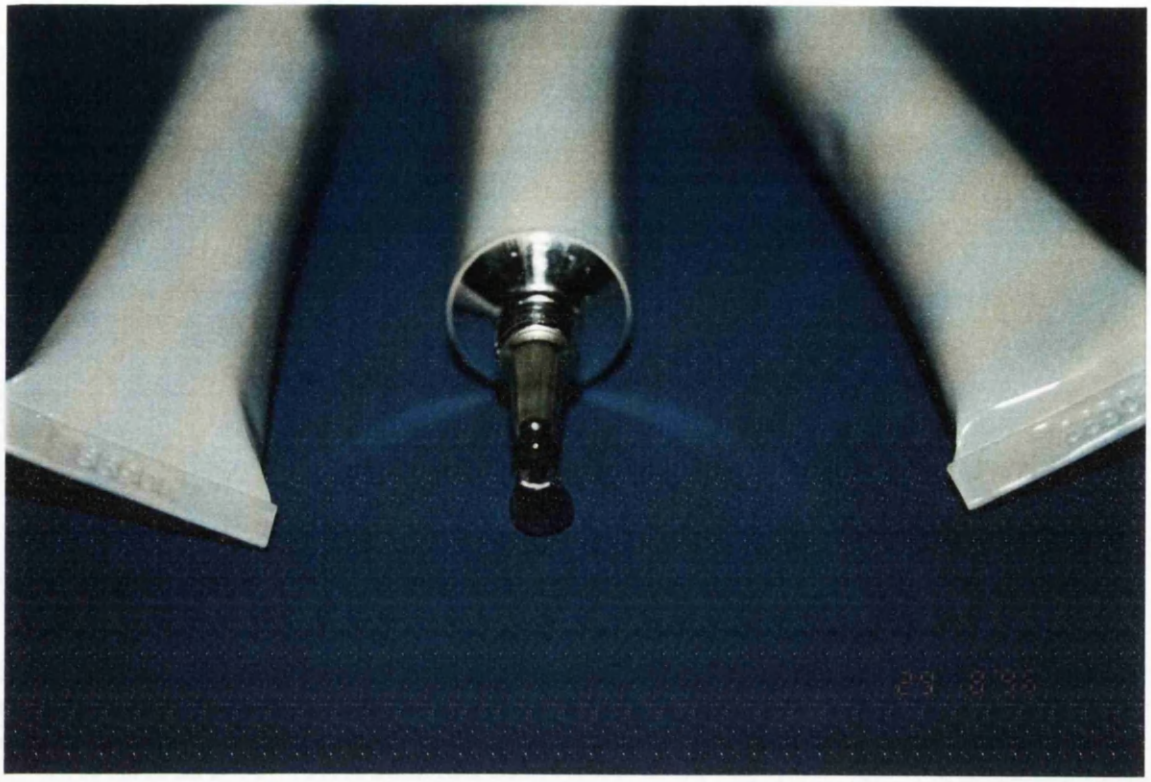


Figure 6.2 Tubes of Gel

The nozzle was positioned approximately .5mm from the model surface and the tube was gently squeezed. The best area to start was the most posterior wire tags. The gel material was squeezed round the wire tags forcing the material under the wires, (Fig 6.3). The procedure was continued round the tags up to the gingival margins and then along to the next wire tag and the procedure was repeated again, (Fig. 6.6.4). When the opposite side of the model at the posterior border was reached the application of the material was stopped. A small paint brush was taken and used to pull the light cure material up around in between the teeth. (Fig. 6.5) Finally the vault of the palate was filled and the brush was again used to shape the extension of the baseplate. The uncured light cure material surface would, if left for a few seconds, settle and form a smooth surface. The material would not slump even if left longer but had this amazing characteristic of flowing or settling into an even surface.

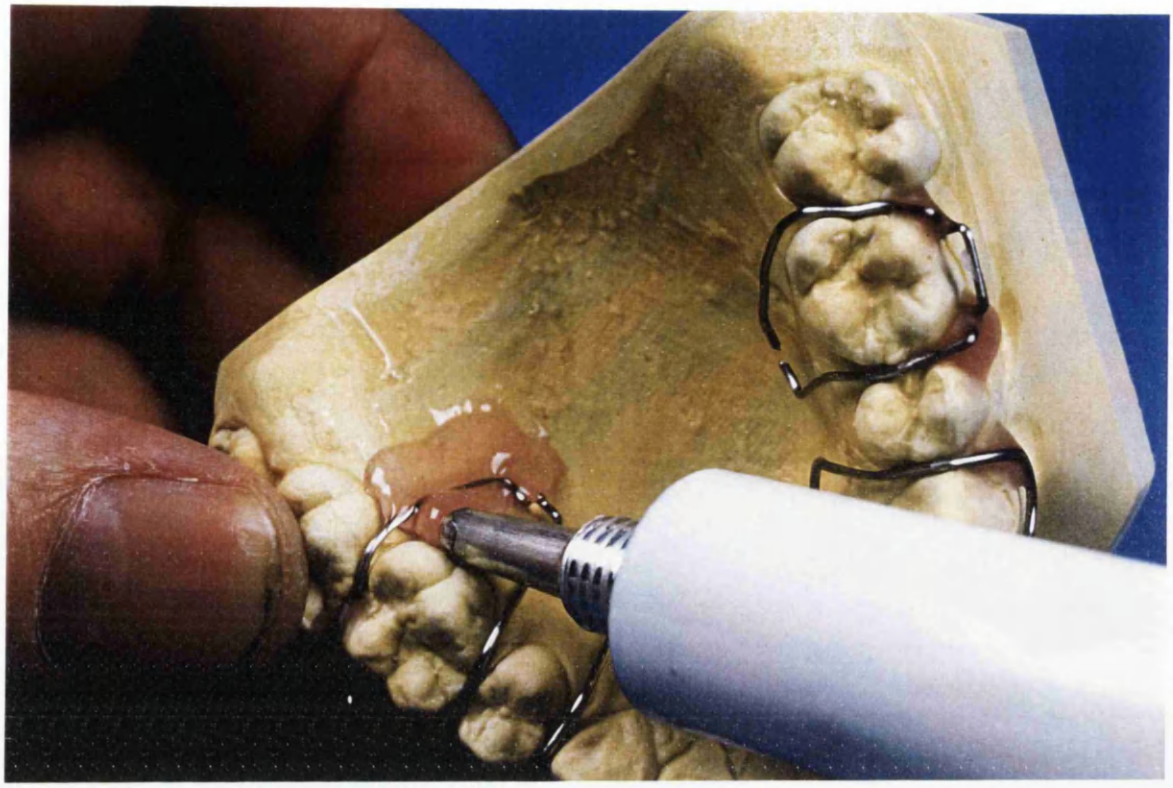


Figure 6.3 Adapting gel around wires

Figure 6.4 Adapting Gel

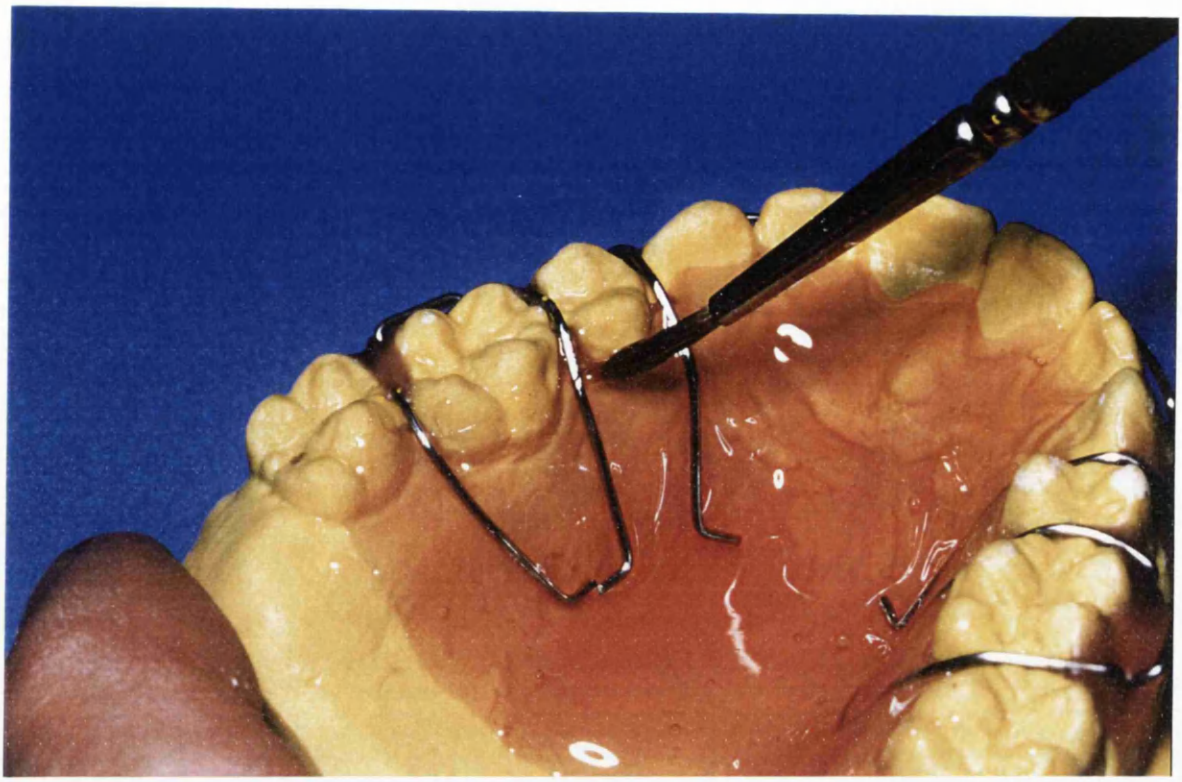


Figure 6.5 Adapting gel using a brush

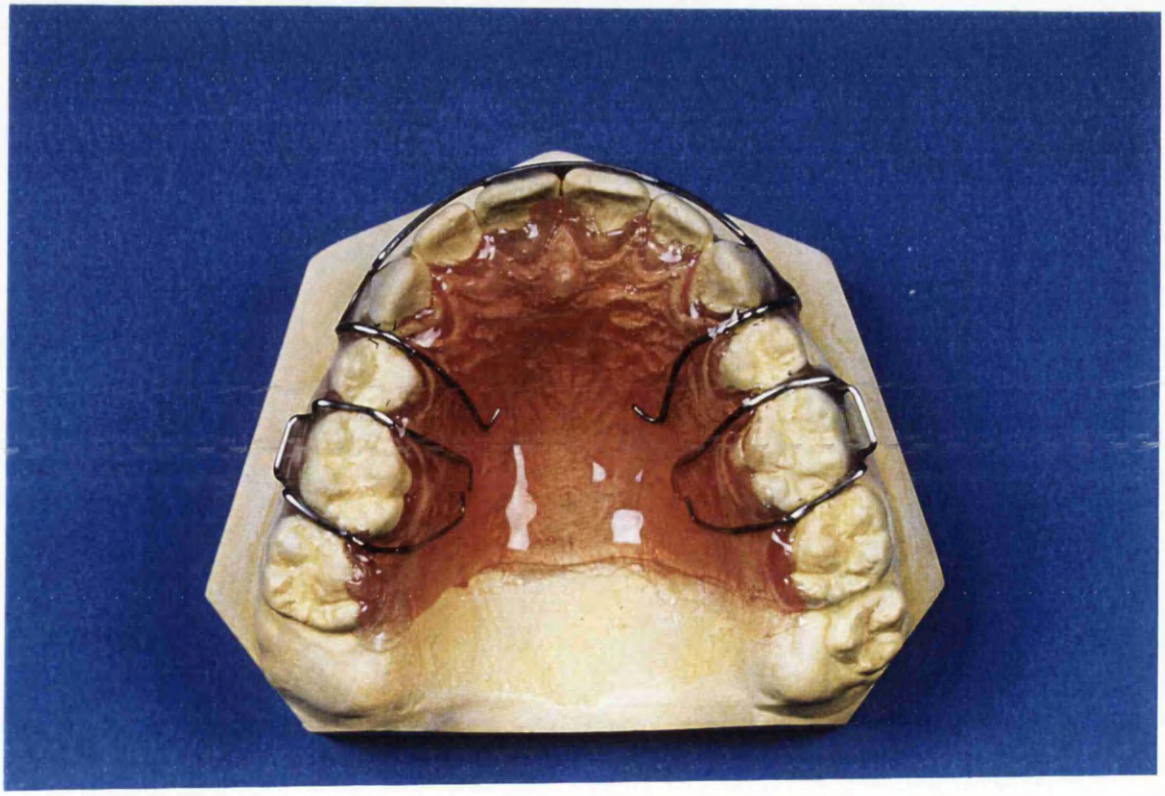


Figure 6.6 Adaption of Gel completed and cured

The thickness of the light cure material could not exceed 2-3mm at any part of the baseplate, otherwise the light cure material could cure on the top surface and on the surface next to the model and leave a void in the middle between the two surfaces of this over adapted material, (Fig. 6.7).

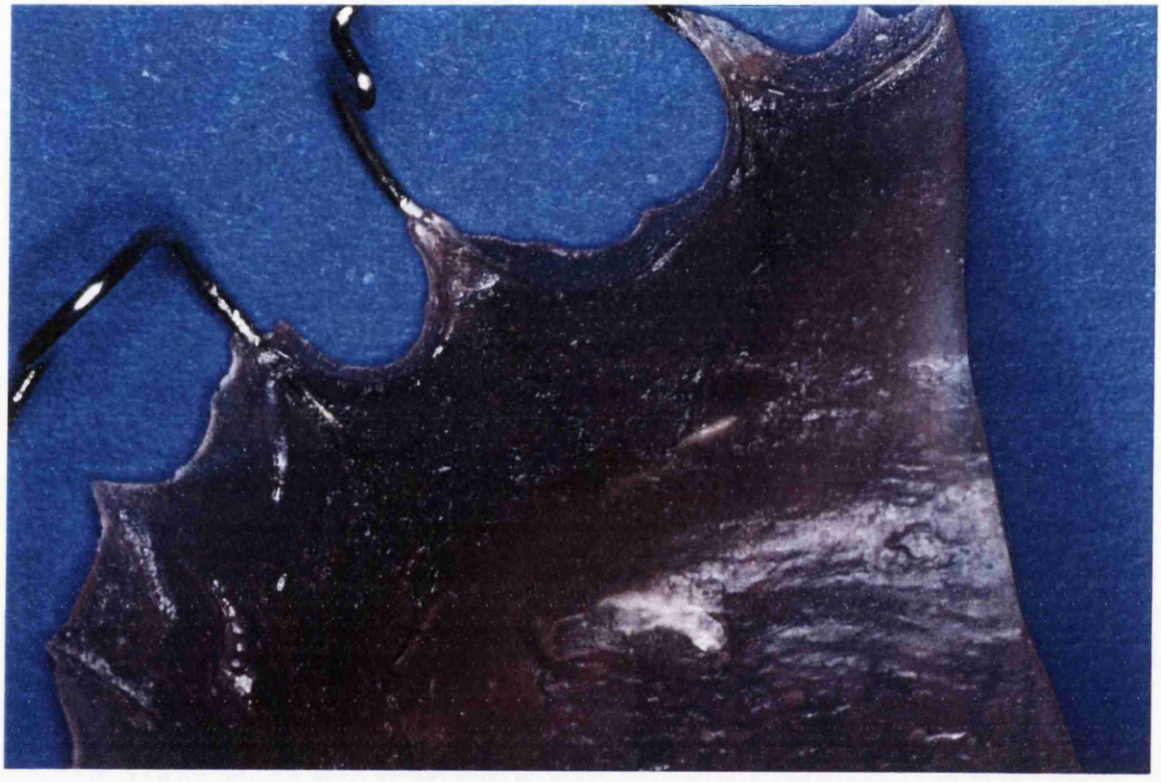


Figure 6.7 Example of a Void

The appliance was then placed into the light curing unit and set at cycle one (see 6.8.4). The strobe unit would operate for 30 seconds then the appliance was removed and checked and inspected for thickness. The appliance was now marked, (6.10.2). If the appliance had a sufficient thickness of material the final curing cycles could proceed. If the thickness was not sufficient, the surface could not be touched as the oxide or dispersion layer could get contaminated. The dispersion layer allowed more light cure gel to be added to the existing cured material. A further layer of gel was added to thin areas but to

achieve a extremely smooth finish the brush was used to coat the whole appliance. This technique prevented any demarcation areas between original and newly adapted material. Any baseplate additions e.g.. anterior, posterior and inclined bite planes could be made by adding the gel and curing in layers until the desired thickness was achieved, (Fig. 6.8).

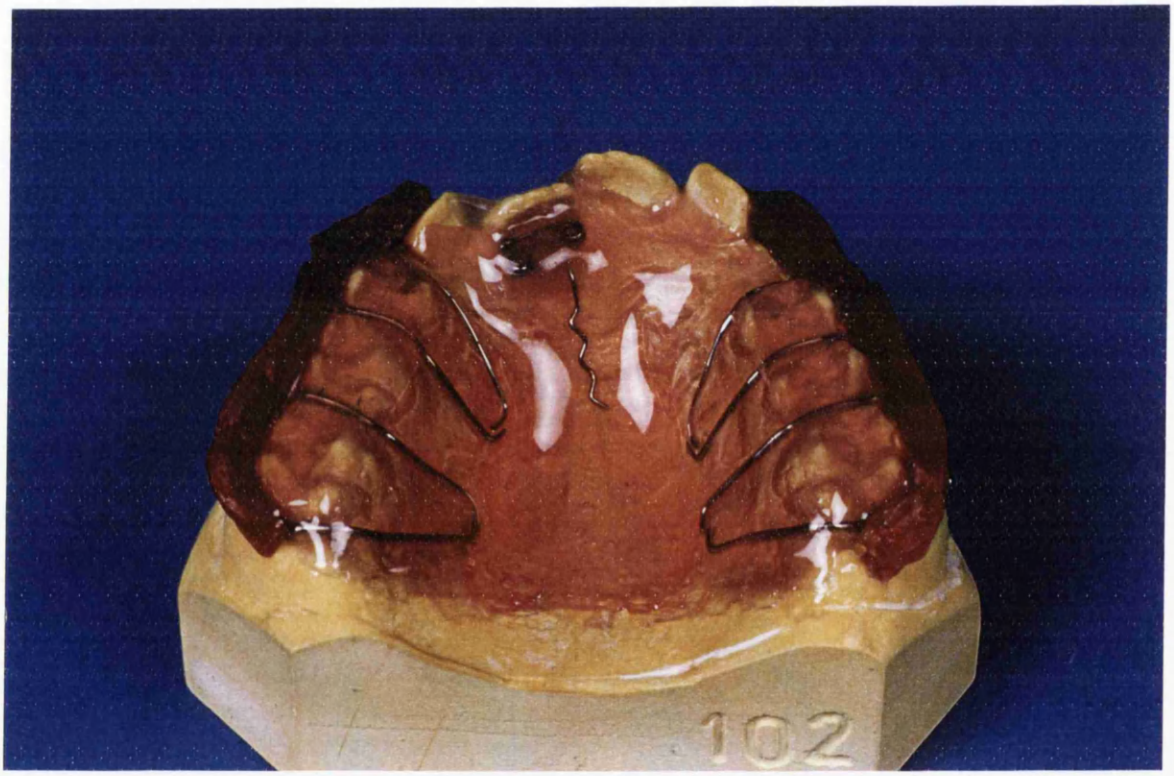


Figure 6.8 Layered gel for posterior capping

Problems were encountered when curing appliances with expansion screws, because the light cure gel underneath the expansion screws remained as a gel due to the light not penetrating the underside of the metal screw.This problem could be solved by either using a surgery light gun and tacking the light cure gel when positioning the screw or by tilting the appliance in the light box to allow the light waves to reach the gel under the screw. Only then could

the rest of the build up continue as previously described.

6.8.4 Curing Unit

The unit consisted of a small box large enough to accommodate a plane line articulator or an occluder complete with models, (Fig. 6.9). The curing unit had a Zeon Strobe light unit complying to 400 - 500 nanometres range of the light spectrum. This was the ideal part of the light spectrum to ensure the material was cured. There were two timing cycles incorporated within the unit, Cycle 1 = 30 seconds duration, Cycle 2 = 3 minutes duration.

Figure 6.9 Light Curing Unit

6.8.5 Curing Cycle

Number one setting on the light curing unit switched on the Zeon Strobe and exposed the appliance for 30 seconds. This setting was useful for tacking the light cure gel.

The second cycle on the light curing unit switched on the Zeon Strobe and exposed the appliance for 3 minutes. This setting was used for final curing of the appliance.

6.8.6 Final Curing

To seal the surface of the dispersion layer and get a complete cure an air barrier coating could be used. Vaseline was an alternative material. These materials sealed the surface and prevented the air coming into contact with the surface thus ensuring the surface cured completely. The surface was coated with a thin layer of air barrier coating and the appliance was replaced in the curing unit for a further cycle at number two. The appliance was removed from the model and the fitting or contact surface was cured in the same manner as the previous side.

The appliance was boiled out to remove the wax in the same manner as other appliances.

6.8.7 Fitting Surface

The reproduction of the fitting surface using light cured gel material was extremely good. The light cure gel material flowed under the wires easily when adapting and all the wires had a complete covering of baseplate material after curing, (Fig. 6.10). All the detail of the model surface was also recorded with no voids on the baseplate material surface. There was a problem of surface voids encountered in a previous study using the light cure

sheet materials, (Tan et al., 1989). The gel light cure material flowed extremely well onto the model surface surface and gave an excellent reproduction when the baseplate material was cured, (Fig. 6.10)

Figure 6.10 Surface Reproduction with Gel

The fit against the model surface was also better than self cure resin. A light cure and a self cure appliance was sectioned and checked visually for closeness of adaption to the model, (Fig. 6.11). The light cure material gave a much closer adaption to the model surface as opposed to the self cure material.

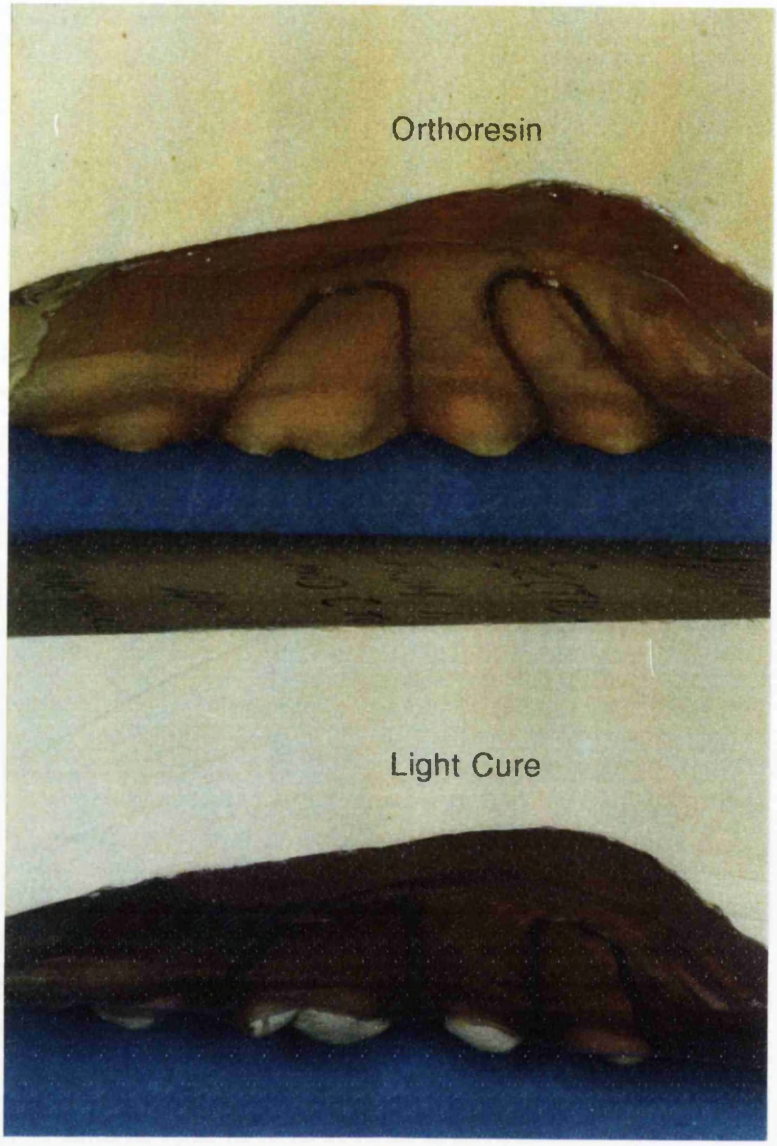


Figure 6.11 Sectioned Models

6.8.8Trimming

The only trimming that might be necessary with a light cure appliance was the back edge and round the collets. Light cure appliances could be trimmed up fairly quickly due to the accurate adaption process resulting in less trimming. Standard steel rotary trimmers and Tungsten carbide burs could be used for the trimming of light cure resins.The only problem with the material was the fine dust given off during abrading. Even with a dust extraction unit it was advisable to wear a dust face mask due to the fineness of the dust. The only consolation was that the appliances constructed in light cure resin only

required a little trimming compared to self cure acrylic.

6.8.9 Polishing

Light cure materials had a harder surface compared to selfcure materials and also had a smoother surface after the curing. They also required a minimum of trimming, (6.8.8).

The standard procedure for polishing acrylic appliances was used for light cure materials, and because of the former took less time, (6.9.9).

The appliance was then washed thoroughly with soap and water; rinsed and dried; checked and sealed in a plastic bag with the patient's name and number.

6.8.10 Additions or Repairs.

The dispersion layer had to be introduced on completely cured or used appliances so that new material could be added. A thin layer of gel was painted on the surface after trimming and cured at cycle one, then the build up was continued and the standard curing cycles were used.

6:9 Orthoresin

6.9.1 Equipment and Tools

i) Orthoresin monomer and polymer

ii) Dispensing bottles for monomer and polymer.

iii) Pressure pot.

iv) Hot plate to maintain the correct curing temperature.

v) Laboratory hand piece.

vi) Acrylic rotary trimmers.

vii) Polishing unit

viii) Felt cones, mops, brushes etc

viiii) Pumice and Acrylic Gloss polishing block.

The Orthoresin Polymer was supplied in an 850 gm tub with a use by date of '2000'. The monomer was supplied in 250 ml tins with a use by date of '1998'.

All the control appliances which were part of the evaluation study were constructed in Orthoresin, the favoured material for a number of years and this self cure material was used for the majority of the department's appliances with a small amount being constructed in heat cure acrylic resin.

6.9.2 Wire work

The model was prepared as previously described, (6.6).

6.9.3 Model preparation

The preparation of the model was the same (6.7) except that only sodium alginate could be used and the model had to be soaked.

6.9.4 Adapting the Orthoresin

All acrylic material have be used within an extractor fume cupboard for chemicals with the appropriate filters. These fume extractors could either be cabinets or down flow units. The down flow units were becoming more popular since it had been reported that monomer fumes were heavier than air and fell to a lower level.

The Orthoresin polymer and monomer was decanted into 50 ml spray bottles to enable easier handling. The monomer bottles had a piece of 0.5 mm i.d. stainless steel tubing inserted into the nozzle to enable the monomer to be controlled when dropped. The polymer bottle also had a nozzle which was cut

to 1.25 mm diameter. This diameter allowed a free flow of polymer.

The model had to be tilted to access a horizontal part and a thin layer of polymer sprayed onto the surface. The monomer was dropped onto the polymer until the polymer granules were saturated with monomer and the process was repeated until a sufficient layer was built up on the model and over the wires.

As the granules of polymer had a large surface area which could be wetted this reduced the tendency of the material slumping when using the spray technique for adapting. The model was then tilted to access another horizontal area of the model and the process repeated until the baseplate was completed. Any baseplate additions such as anterior, inclined bite planes and posterior capping had all to be built up at this stage. The build up of appliances using Orthoresin could be completed in one visit. However if too little material was applied second and subsequent visits would be necessary.

6.9.5 Pressure Pot and Hot plate

These items of equipment were required for successful processing of self cure acrylic resin. Huggett (1978) reported in a survey that the range of curing temperatures varied from 27 to 80 degrees Celsius and only 6% of the respondents used a thermostatic hotplate. The curing times also varied from 4 to 30 minutes and the pressure from 20 to 70 pounds per square inch (p.s.i.).

Self cure acrylic resin was required to be placed in water at a temperature of 45 - 55 degrees Celsius to ensure the polymerisation cycle was completed. The self cure acrylic had also to have pressure of 2 bars applied to the surface of the resin to prevent the occurrence of porosity due to insufficient pressure

being applied to the surface during the processing procedure.
The pressure pot and the thermostatic hot plate ensured that the acrylic was maintained at a steady temperature, pressure and correctly processed according to the manufactures instructions.

6.9.6 Curing Cycle

The self cure acrylic resin was required to be processed at the correct temperature and pressure for 8 - 10 minutes to ensure the acrylic resin was completely polymerised.

After the appliance had been processed it was removed from the pressure pot; the wax was boiled off and the appliance carefully removed from the model. The appliance was now ready for trimming.

6.9.7 Trimming

The posterior or lingual borders had to be trimmed first. The acrylic was then blended onto the teeth, except where there was anterior or posterior planes or capping. The rest of the appliance could then be shaped to give a uniform thickness, if that was possible, considering there would be springs or screws present. Steel rotary trimmers and Tungsten Carbide burs were used at a maximum speed of 18000 rpm for the shaping and trimming of self cure appliances. Higher speeds could cause the acrylic to soften and coat round the bur.

Large granules of polymer which assisted in the wetting during the build up create a rough surface which had to be smoothed. This required the whole surface of the appliance to be trimmed with the acrylic trimmers otherwise it would be difficult to get a reasonable polish.

The appliance was now marked, (6.10).

Acrylic silicone rubbers could be used at a maximum of 15,000 rpm over all the trimmed areas of acrylic to smooth the surface further before proceeding to the next stage - polishing.

6.9.8 Polishing

Pumice acted as an abrasive and smoothed the surface further in the finishing procedure. Pumice was then used with a calico mop to smooth the large areas of the palate or lingual areas of the appliance while cones, metal centre white brushes and palate brushes were used for access into the vault of the palate and other integrate areas of the appliances. The appliance was rinsed and dried then checked for scratches and rough areas. The surface had to be smooth, mat and non polished.

If any surface roughness was present the appliance had be repumiced and rechecked. The appliance was now ready for the final polish using a white soft swansdown mop with a minute amount of acrylic gloss compound wiped onto the revolving mop. The appliance was applied to the revolving mop to impart the high lustre on the the self cure acrylic surface.

The appliance was then washed thoroughly with soap and water, rinsed and dried, checked and sealed in a plastic bag with the patients name and number.

This is the standard procedure for polishing of all acrylic appliances.

6.9.9 Additions or Repairs.

Repairs and additions to the Orthoresin appliances were achieved using the same material.

The appliance was repositioned on the original model if available or if the model was not suitable the appliance were stuck together with sticky wax and a new model poured. Coltene Laboratory Putty was used in areas where a plaster model could cause distortion due to baseplate undercuts or wire work. The appliance was removed from the model and the broken area trimmed to leave a 1mm gap between the broken pieces. This area was then chamfered approximately 2-3 mm from the broken edge.

Self cure acrylic resin was then mixed in a silicone dappens dish and applied to the gap between the broken pieces. This technique prevented acrylic resin seeping under the edges onto the fitting surface of the appliance ensuring the appliance fit was not detrimental. After sealing the gap the acrylic was sprayed on using the same technique as described in section, (6.9.5).

The acrylic was processed and cured as described earlier.
After processing the appliance was removed; the wax boiled off; trimmed and polished.

6.10 Appliance Marking

Some form of simple marking system had to be devised to ensure the appliances were controlled and monitored in the clinic and the laboratory, (Fig. 6.12).

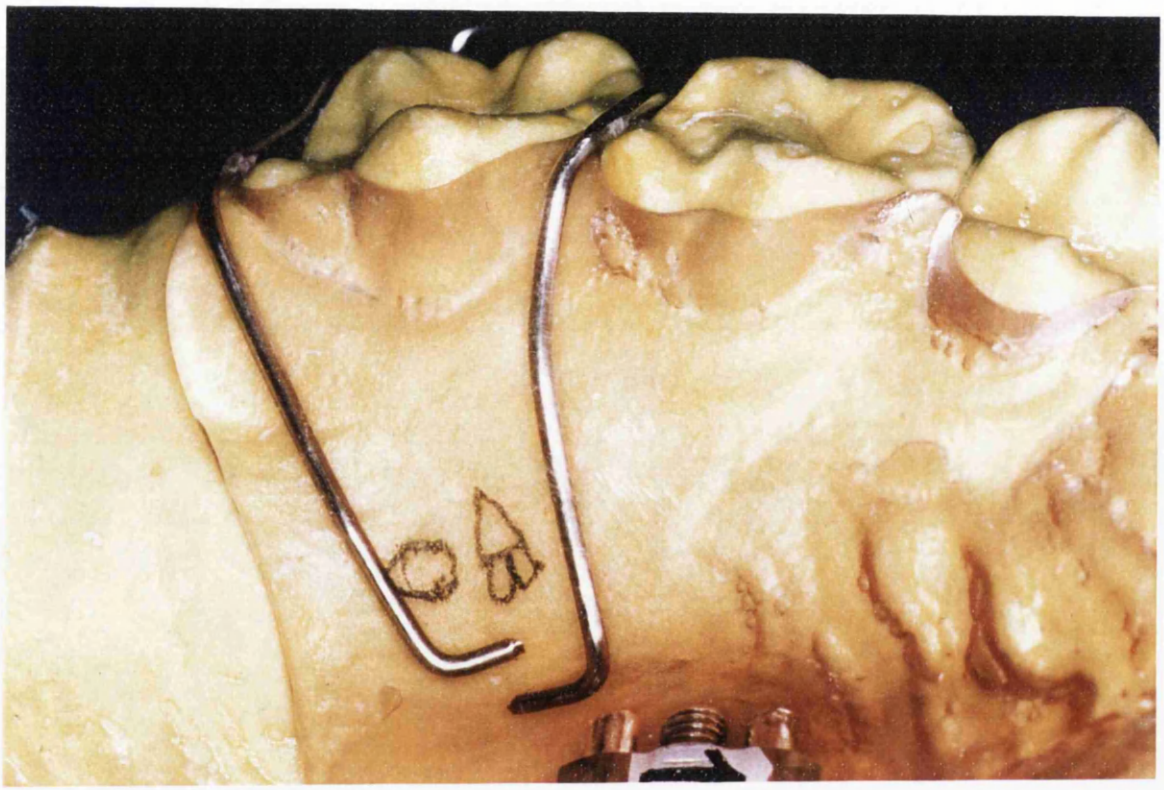


Figure 6.12 Marked Orthoresin Appliance

6.10.1 Reasons for marking

i) The appliances were to be part of a clinical evaluation study of the materials.

ii) Appliances after insertion had to be recognised in the clinic

iii) All repairs and additions had to be returned to the laboratory where they were constructed for the repairs etc. so any faults could be recorded.

iv) In case any study appliance was sent to the Trust laboratory by mistake.

6.10.2 Light Cure Appliances

The appliance were constructed as described in section (6.8) to a stage where light cure was still being applied. The appliance was marked using a 0.5mm lead pencil with the type of material the appliance was manufactured from and the technician who made the appliance. The mark was then covered with a layer of light cure material and placed in the curing unit for processing. The lead pencil mark was sealed in an envelope of light cure resin to ensure complete safety from contamination in the oral environment.
If desired the mark could also be placed according to (6.10.1) using light cure resin.

6.10.3 Orthoresin Appliances

The appliance were made according to section (6.9) up to the stage just before polishing.

With a large round bur a depression was made in the palate near the posterior border of the appliance. A finger had to be positioned on the fitting surface and if heat was felt when trimming the acrylic was becoming thin and it would be inadvisable to reduce the baseplate material any further. The approximate dimensions of the trough had to be 10 mm x 5 mm x 0.5 to 1 mm deep. A 0.5 mm lead pencil was used to mark the base of the trough indicating the material from which the appliance was constructed and a mark made to indicate the technician who constructed the appliance although only one was involved at this stage. A small amount of self cure was sprayed into the marked trough and left slightly proud. The appliance was placed in the pressure pot and processed; removed and the small area retrimmed and smoothed. The appliance was ready for polishing, (6.9.9).

6.11 Delivery

The appliances were checked in the laboratory against the following criteria :-

1) Appliance conformed to the prescription.

2) Active components - a) components had an adequate range of movement.
   b) could move freely without interruptions.
   c) light wires had to have safety ends.
   d) all wire free ends had to be smoothed.
   e) wire had to follow the contour of the tissue where appropriate.
   f) coils had to be situated in the correct position.
   g) all active components had to be passive.

3) Adam's Clasps - a) The bridge of the clasp stood clear of the tooth.
   b) Arrowheads sloped to match the contour of the gum.
   c) Sides of each arrowhead were parallel.
   d) Arrowheads had not to touch adjoining teeth.
   e) Bridge had to lie halfway between tooth height and gum surface.
   f) Wire fitted closely over contact areas and where there was no adjacent tooth, wire had to cross on or above contact area.
   g) Tags on the lower appliance had to allow trimming without interfering with wire (lingual undercuts).

The baseplate criteria was followed precisely to ensure all appliances were constructed to a uniform standard.

4) **Baseplate** -

a) Baseplate had to be smooth and have no rough areas.

b) All wire tags had to be covered with acrylic.

c) Baseplate had to blend onto teeth - no troughs.

d) All margins and edges had to be smooth and rounded.

e) Anterior bite platforms / Posterior capping suitable for intended purpose.

f) The baseplate material had to have sufficient strength to suit its intended purpose.

When all the criteria was met the appliances was washed and sealed in a polythene bag and marked with the patient's name and number. The patient's computer laboratory record was then checked and updated logging the type of appliance, material used for construction, date of delivery.

The patients box containing study model records and the newly completed appliance were then delivered to the clinic to await the patient's next appointment.

6.12 Time

During the construction of the appliances the time was recorded for each stage of production of the twenty five appliances included in the study.

6.12.1 Build up

The self cure appliances were recorded from the start of the build up of the monomer and polymer onto the model and stopped when the build up was completed. The light cure appliances time started when the cap was removed from tube of gel and stopped when each stage of the build up was completed. Light cure material took longer to build up the appliance to the desired shape. Some appliances needed more than one layer but only the build up times were recorded as other work could be undertaken during curing cycles. The average light cure appliance took approximately two and a half minutes longer to complete the adaption of the baseplate material, (Fig 6.13).

6.12.2 Trimming

The appliances had the wax boiled off and no time was recorded for this stage as there is no difference in the procedure for both light cure and self cure materials. The trimming time started at the bench when trimming commenced. The light cure appliances recorded the shortest time for this stage as they could be adapted more accurately during the build up stages. These appliances only required to be trimmed round the collets and the back edges. Anterior and posterior bite platforms might require slightly more trimming. The self cure material required slightly more trimming time due to the nature of the material as it had to be slightly over built and also resulted in a rough granular surface, (6.9.8). This surface had to be trimmed all over to ensure a smooth surface was achieved before proceeding to the polishing stage. The self cure resins required a longer trimming time compared to light cure materials for the appliances used in this study, (Fig. 6.13).

6.12.3 Polishing

The light cure materials again recorded a shorter time. These materials were easier to trim and polish as the material adapted to a smooth surface during the initial build up of the appliance, (6.8.3). These materials took on a reasonable polish using conventional polishing materials for self cure. The self cure appliances recorded a slightly longer time as the whole of the appliance had to be thoroughly polished but again the average time difference was only over a minute, (Fig. 6.13).

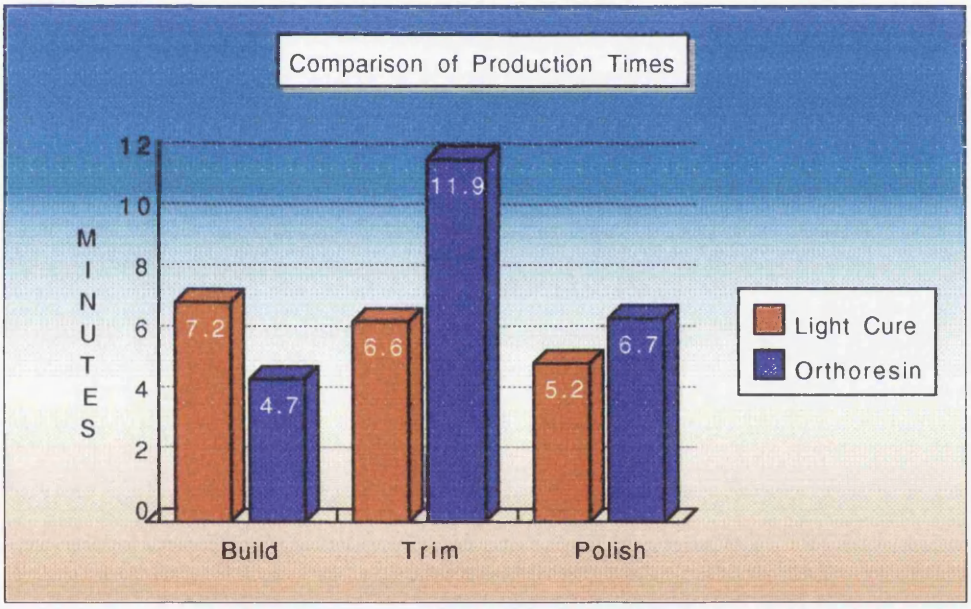


Figure 6.13 Average production times for each stage

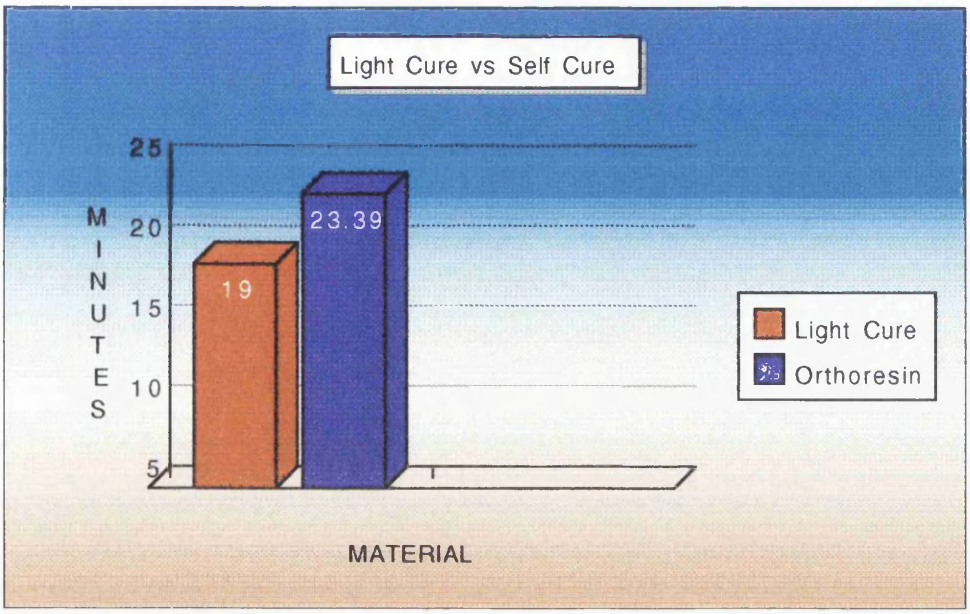


Figure 6.14 Average baseplate production times

6.13 Statistical Analysis

A two-sample t-test was performed to determine the differences in adapting the baseplate material (build), trimming the baseplate material (trim) and polishing the baseplate material (polish). The p-value 0.0000 indicates there is a statistical difference in the materials for build and trimming (Fig. 6.15 and 6.16) but no statistical difference in the polishing, (Fig. 6.17).

```
TWOSAMPLE T FOR Build
C24    N      MEAN      STDEV    SE MEAN
1 'LC' 14      7.27       1.09       0.29
2 'O'  11      4.77       1.25       0.38

95 PCT CI FOR MU 1 - MU 2: ( 1.50,  3.49)

TTEST MU 1 = MU 2 (VS NE): T= 5.24  P=0.0000  DF=  19
```

Figure 6.15 Two sample t-test for adapting the materials

```
TWOSAMPLE T FOR Trim
C26    N      MEAN     STDEV   SE MEAN
1 'LC' 14     6.68      1.12      0.30
2 'O' 11     11.98      1.60      0.48

95 PCT CI FOR MU 1 - MU 2: ( -6.50,  -4.10)

TTEST MU 1 = MU 2 (VS NE): T= -9.34  P=0.0000  DF=  17
```

Figure 6.16 Two sample t-test for trimming the materials

```
TWOSAMPLE T FOR Polish
C28    N      MEAN     STDEV   SE MEAN
1 'LC' 14     5.25      1.49      0.40
2 'O' 11      6.77      1.13      0.34

95 PCT CI FOR MU 1 - MU 2: ( -2.61,  -0.44)

TTEST MU 1 = MU 2 (VS NE): T= -2.91  P=0.0081  DF=  22
```

Figure 6.17 Two sample t-test for polishing the materials

A two-sample t-test for the combined times of build, trim and polish (Fig. 6.18) indicates there is a statistical difference in production times between the materials.

```
TWOSAMPLE T FOR B,T,& P
C31    N      MEAN     STDEV   SE MEAN
1 'LC' 14    19.00      2.79      0.75
2 'O' 11     23.39      2.77      0.84

95 PCT CI FOR MU 1 - MU 2: ( -6.72,  -2.05)

TTEST MU 1 = MU 2 (VS NE): T= -3.91  P=0.0008  DF=  21
```

Figure 6.18 Two sample t-test for the combined times of build, trim and polish

6.14 Conclusion

Light cure material was easier to adapt and took a slightly shorter time to complete the orthodontic appliances constructed during the course of this study, (6.12.2). Although the time difference was small the material being used was also being used for the first time. The main disadvantage of light cure materials was the fine dust produced when trimming the appliances. The dust was a very fine powder as opposed to the shavings produced when trimming self cure materials. This fine powder could be a distinct disadvantage to the widespread use of light cure materials. When using these light cure materials it might be advisable to use a protective face dust mask as well as an efficient dust extraction unit at the laboratory bench.

The self cure material was familiar and very user friendly and also easy to adapt, trim and polish. The main disadvantage with self cure materials was that they had to be used within an extractor unit because of the hazardous nature of the monomer and polymer fumes and volatility.

The average time taken to adapt either light cure gel or self cure monomer and polymer materials, trim and polish the appliances differ by only a few minutes with the appliances used in this study.

Chapter 7 : Clinical Trial - Study 2

B : Patient Questionnaires

7.1 Patient Selection

The undergraduate clinics were selected because the students receive an introduction to removable appliance therapy as part of their undergraduate B.D.S. course. Patients booked on these sessions were selected for undergraduate teaching and were mainly patients who required non fixed treatment. This clinic seemed the ideal place to recruit patients to take part in a baseplate evaluation study.

7.2 Method for Study 2

A series of four questionnaires to be completed by each of the twenty five patients' enrolled in the study.

7.3 Discussion of material

Thirty six patients were enrolled in the study and four light cure and seven self cure patients had to be deleted from the study due to the following reasons.

a) failure to continue treatment.
b) patients emigrating.
c) form not returned.

The sample consisted of twenty five patients who attended for orthodontic treatment at the Glasgow Dental School in the period from January 1994 to March 1996. All the subjects required removable appliance therapy using either upper or lower appliances. Functional appliances and laboratory made

fixed appliances were excluded from this study.

There were 14 subjects in the light cure group and 11 in the self cure group and the appliances were allocated on an alternate basis. The mean age and range as well as the proportion of males and females in the two groups is presented in Table 7.1

	Light Cure	Self Cure
Male	6 (43%)	6 (55%)
Female	8 (57%)	5 (45%)
Total	14	11

Mean Age	14.7	15.1
Std. Deviation	4.30 years	4.38 years
Minimum	9 years	10 years
Maximum	23 years	24 years

Table 7.1 Descriptive Statistics of Sample

7.4 The Questionnaires

The questionnaires were adapted from a previous study by Stewart (1994) on " An Evaluation of Patient Experiences and Adaption to the Wearing of Fixed and Removable Orthodontic Appliances". The original questionnaires were part of a longitudinal series of five questionnaires developed and compiled in German by Professor Dr. H.G. Sergl (an orthodontist) and Dr. U. Klages (a

psychologist) in Mainz, Germany. These questionnaires were subsequently translated into English for use with the former study.

Numerous studies had been involved in determining the predictors of patient cooperation and associating patient variables with levels of cooperation during treatment. The range of feelings or "sensations" were examined by Stewart (1994) as opposed to the treatment variables of previous studies.
The questionnaires used for the "Stewart Study" were then adapted to include specific questions regarding the baseplate of the orthodontic removable appliance to suit the present study on baseplate evaluation.

The questionnaires of Stewart included thirteen questions. In this study one question was deleted and an additional three questions were added to specifically invite comment about the baseplate. The following questions were added to the questionnaire :-
"My appliance had a strange taste", "My appliance is comfortable" and "My appliance feels smooth".

Responses to the questions were sought on a scale; not at all, a little, much, very much and would give an indication of any differences between the patients' perception of the appliances assuming that all the appliances were correctly fitted and adjusted.

7.4.1 Questionnaires

Questionnaire 1

The questionnaire was composed of questions to indicate the patient's emotional well being at that visit, together with some descriptive details about the patient and the appliance prescribed, (see appendix).

Questionnaire 2

This questionnaire was composed of seven identical daily record sheets, one to be filled in at the end of each of the first seven days of appliance wear. The patient recorded his / her experience with and feelings about the removable orthodontic appliance (brace). The patient recorded for example whether the appliance was tight, comfortable or had a strange taste and attempted to quantify its severity on the form with a four point, Likert-type format. Each item's response was scored for 'not at all', 'a little', 'much', and 'very much' respectively, (see appendix).

Questionnaire 3

The questionnaire was composed of a daily record sheet identical to questionnaire two and a series of nine questions adapted from a measure used by Clemmer & Haynes (1979). Questions one to five evaluated the patient's general attitude and questions six to nine assessed the patient's appliance attitude. A general assessment of the patient's emotional well-being could also be assessed from this questionnaire, (see appendix).

7.5 Data

Several subjects had to be excluded from the study during the period of data collection due to failure to return for continued care and failure to complete the questionnaires appropriately.

Not all the information collected in the completed set of questionnaires was used in the study.The relevant responses were scored and were employed as a basis for statistical analysis.

7.6 Statistical analysis of data

Statistical analysis of the data was executed with Minitab version 9.

In performing the chi-square tests and Fisher Exact tests for differences between sample groups (Tables 7.2 to 7.16), cells with small expected values were amalgamated with their neighbours.

7.7 Procedure

If the prospective candidates indicated an interest they were given a "Patient Information Sheet for the *Evaluation of Orthodontic Baseplate Material Study*", (see appendix). It explained how we would like them to take part in a survey to evaluate orthodontic base materials (the pink or clear part of the appliance). The patient would be required to fill in questionnaires at the start and end of treatment and if they were unfortunate enough to break their appliance during the course of treatment they would be required to fill in a single sheet questionnaire, (see appendix).

The next part described the "Background to the study" on how the fabrication of the appliance involved the use of chemicals to construct the pink or clear area and although they were safe when processed for patient use, they could be harmful to the technicians during the manufacturing of the appliance. However the manufacturers are continually improving their materials and we would like to evaluate various areas from laboratory construction to patient acceptability.

A brief description was given on how results of the study would affect the patient, the laboratory technician who constructed the appliance and how it would enable us to determine which was the most acceptable material for future appliances.

The information sheet ended with a "Thank you for your anticipated

cooperation".

When compiling the information sheet there was an effort to provide the information in patient friendly language e.g. appliances became braces etc.

If the patient and parent or guardian (if the patient was under 18) agreed to take part in the survey they were then asked to fill in a "Consent Form" (see appendix) in which they freely and voluntary agreed to participate in a clinical research study on "The Evaluation of Orthodontic Baseplate Material". The form went on to state their treatment would be carried out in an entirely normal manner and that the only additional element would be the completion of some questionnaires. They were also assured that any information obtained from the questionnaires would not be disclosed without their permission to any other party in a manner which would reveal their identity. (see appendix)

The impressions were then taken in alginate impression material; immersed in cidex disinfectant for 5 minutes; placed in self seal polythene bags and marked "disinfected".

The lecturer and student had discussed and designed the removable appliance to be constructed by the laboratory and filled out a laboratory work card. The laboratory work card showed the design in diagram and text format to enable the laboratory to construct a custom made appliance for each patient.

The impressions and the completed laboratory work card were now placed in the patient's record box and sent to the laboratory to enable the completion the next stage - the construction of the removable orthodontic appliance.

This technique was described in Chapter 6.8 & 6.9

After the appliance had been constructed and returned to the clinic the next stage was the insertion of the appliance. The appliance work card would show the type of material the appliance was constructed from e.g.. Light cure or Orthoresin.

The appliance was now inserted and the patient asked to fill in the "Appliance Insertion" form. (see appendix)

This form obtained the following information - the patient's name, box number, date of insertion and also the material the appliance was manufactured from e.g. Light cure or Orthoresin. There were tick boxes to indicate the type of appliance e.g. an active appliance or a retainer and also if the patient had previously worn an orthodontic appliance or a dental plate. A few physiological questions were also included.

Before the patient left the clinic they were given seven blue "Daily Record Sheets", (see appendix). A separate sheet was to be filled in daily during the first week after receiving their new removable appliance. The questionnaire consisted of fifteen questions to be answered by ticking the relevant boxes :-

i) not at all

ii) a little

iii) much

iv) very much

These were linked to a series of questions to access the patient's experience with the appliance. Materials which have excellent working properties and look good do not always comply with the patients acceptability of an appliance. It must be remembered that patient acceptability was one of the most important aspects in patient compliance when wearing orthodontic appliances during treatment.

At the patients' next visit they returned the completed questionnaire to the clinic. The forms would all be collated when the survey was completed in approximately six to twelve months. Their treatment was the same as all the other patients attending the department except that they were required to complete survey forms at the end of each current phase of treatment.
In the event of a repair the patient was required to complete a survey form (see appendix) indicating the cause of the breakage and whether it occurred in or outside the oral cavity and whether it affected the wire, resin or both. The repair survey form also had a diagram and the site of repair recorded.

7.8 Repairs

The size of the study did not give a good indication on repairs. Information regarding the circumstances of appliance breakage was recorded as shown in repair forms, see appendix. The only repairs that were recorded involved light cure appliances. There were no recorded breakages to Orthoresin appliances. There were four recorded breakages to the light cure appliances :-

Appliance one

The resin was fractured on the patient's right in the premolar / molar region. It occurred out of the mouth when the patient was cleaning the appliance. The appliance was not dropped and something did not fall on it. The repair was completed and returned in a approximately thirty minutes.

Appliance two

There were a few pieces of resin missing round the collets which fractured whilst the patient was watching television. This was the first repair to the light cure appliances and in an area which should be trouble free. The appliance was repaired and gave no further problems.

Appliance three

There was a complete mystery surrounding what happened to this appliance. The patient had no recollection of how the appliance broke. It possibly was in the mouth but could not remember. There was a fracture in the midline of the palate approximately a centimeter long. The appliance was repaired and returned in approximately thirty minutes. Another fracture occurred to this appliance a month later when the patient was eating hard food. The resin had fractured from the first premolar region to the posterior border. The appliance was repaired and caused no further problems.

Although all the repairs occurred to light cure appliances it does not give the material a good test. The percentage of repairs occurring to the light cure appliances was 28%. In a previous twelve month survey on repairs to orthodontic appliances there were 57% of fractures which involved the resin, as opposed to the 43% of the wire elements, (Kerr, 1984).

7.9 Results on patient experiences and patterns of adaptation to wearing light cure and self cure resin appliances.

Tables 7.2 to 7.16 were cross tabulations of the scores for the light and self cure appliance groups for each of the sensations studied.

Chi-square tests were conducted on the scores and because of the small sample size and p-values obtained a further procedure was conducted called the "Fisher Exact Test" to verify the presented results, (Tables 7.2 to 7.16).

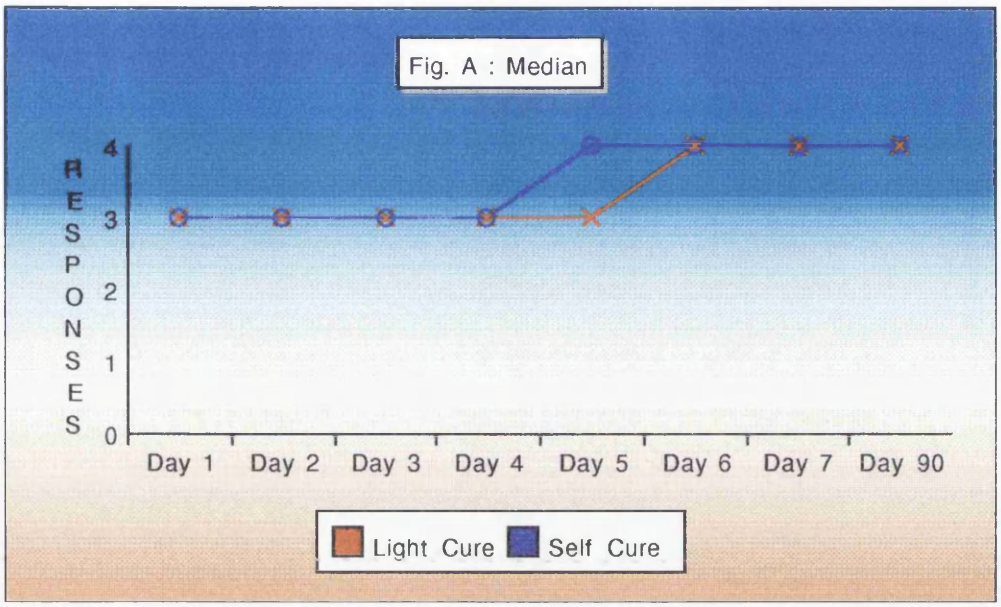
Figures 7.1 to 7.15 were plots of the medians and percentages of "much' and 'very much" responses for the two groups over the days for each of the fifteen sensations.

		Not at all	A little	Much	Very much	
Day 1	LC O	0 0	4 4	5 5	5 2	p = 1.00
Day 2	LC O	0 0	1 2	9 7	4 2	p = 0.813
Day 3	LC O	0 0	1 4	7 5	6 2	p = 0.191
Day 4	LC O	0 0	2 2	6 4	6 5	p = 1.00
Day 5	LC O	1 0	1 0	8 4	4 7	p = 0.607
Day 6	LC O	1 0	1 1	4 1	8 9	p = 1.00
Day 7	LC O	0 0	1 1	5 1	8 9	p = 1.00
Day 90	LC O	0 0	4 0	1 1	9 10	p = 0.158

p - values are not statistically significant.

Table 7.2 ***"I felt comfortable with my appliance"***

A comparison of scores for Light Cure and Orthoresin



Response Scores

4 Very much
3 Much
2 A little
1 Not at all

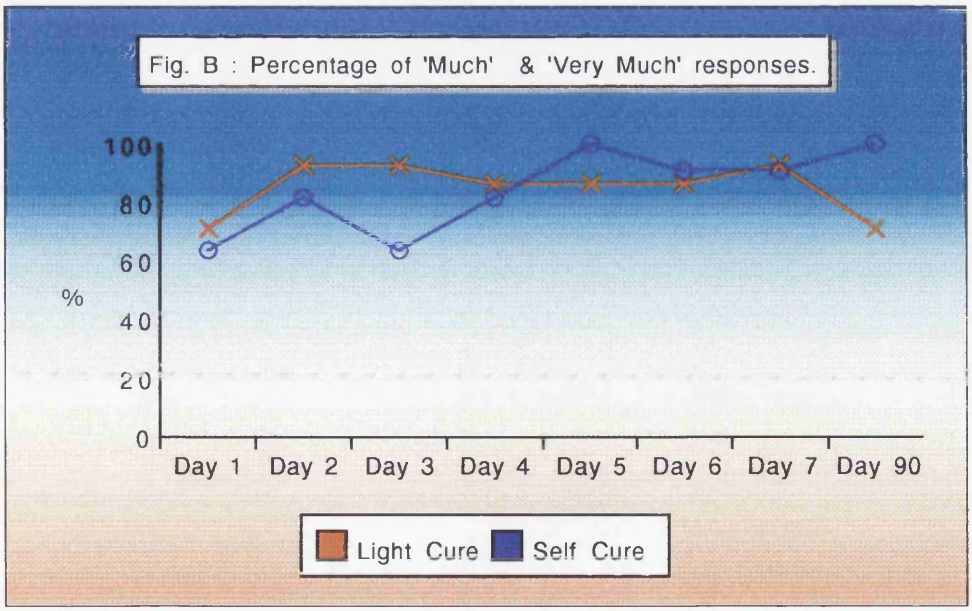


Figure 7.1 A and B ***"I felt comfortable with my appliance"***

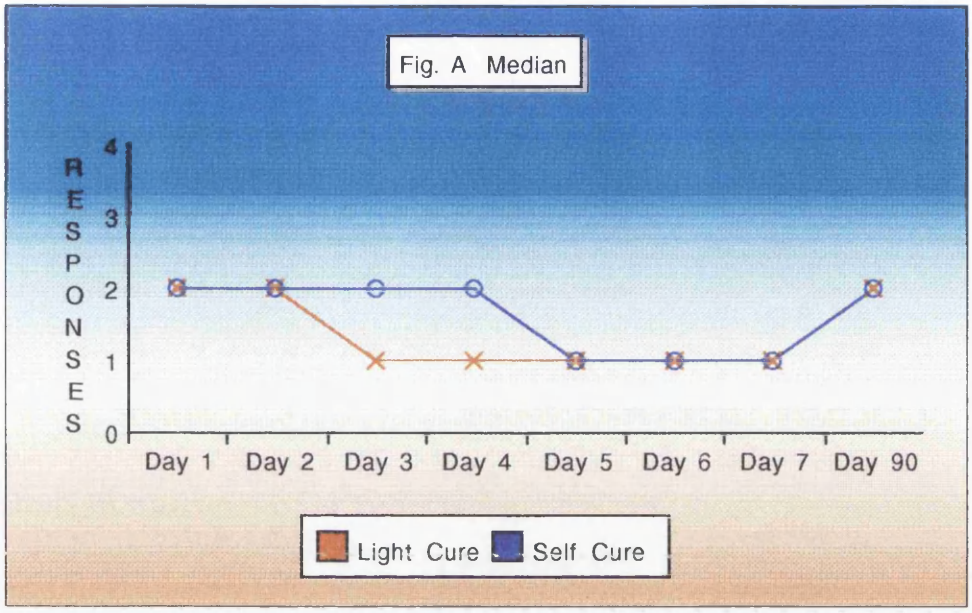
Median and percentage plots for Light Cure and Orthoresin appliance groups.

		Not at all	A little	Much	Very much	
Day 1	LC	3	8	3	0	p = 1.00
	O	0	8	2	1	
Day 2	LC	5	5	4	0	p = 1.00
	O	3	6	2	0	
Day 3	LC	8	2	4	0	p = 0.158
	O	1	10	0	0	
Day 4	LC	9	1	3	1	p = 0.4898
	O	3	7	1	0	
Day 5	LC	10	0	4	0	p = 0.4898
	O	9	1	1	0	
Day 6	LC	9	1	4	0	p = 0.4898
	O	8	2	1	0	
Day 7	LC	8	2	3	1	p = 0.158
	O	9	2	0	0	
Day 90	LC	4	5	5	0	p = 0.7139
	O	3	6	2	0	

p - values are not statistically significant.

Table 7.3 ***"My appliance exerted tension"***

A comparison of scores for Light Cure and Orthoresin



Response Scores

4 Very much
3 Much
2 A little
1 Not at all

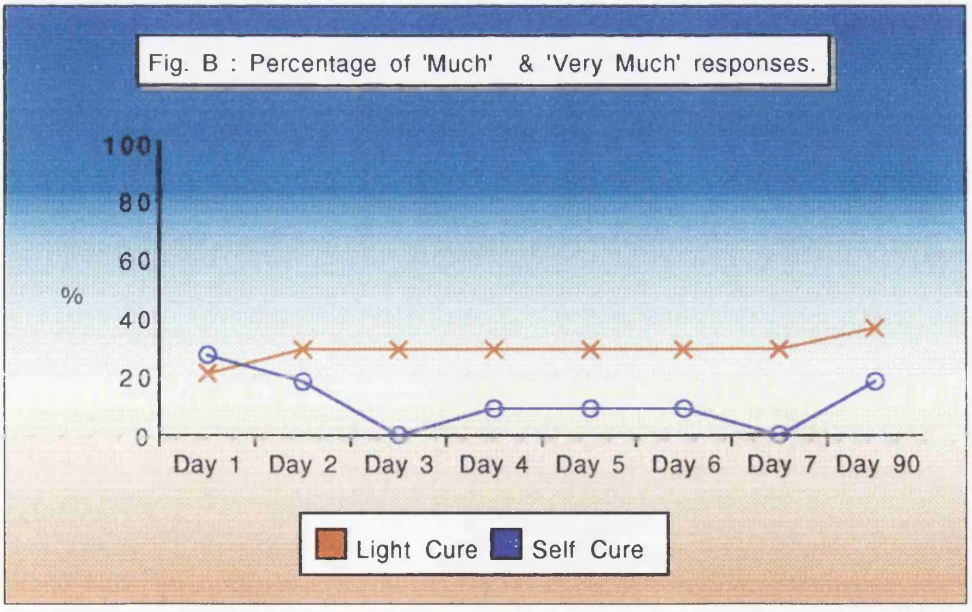


Figure 7.2 A and B ***"My appliance exerted tension"***

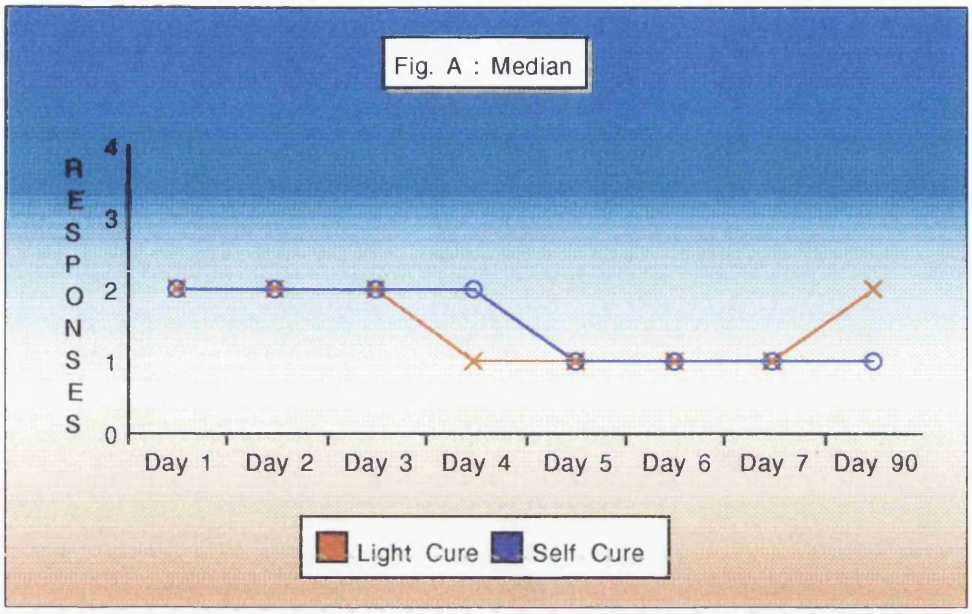
Median and percentage plots for Light Cure and Orthoresin appliance groups.

		Not at all	A little	Much	Very much	
Day 1	LC O	5 3	5 7	4 1	0 0	p = 0.4898
Day 2	LC O	6 2	4 7	2 2	2 0	p = 0.904
Day 3	LC O	8 4	2 4	4 3	0 0	p = 1.00
Day 4	LC O	10 3	0 7	3 1	1 0	p = 0.4898
Day 5	LC O	8 9	3 2	3 0	0 0	p = 0.317
Day 6	LC O	9 9	1 2	3 0	1 0	p = 0.4898
Day 7	LC O	8 9	2 2	3 0	1 0	p = 0.158
Day 90	LC O	5 7	5 2	4 2	0 0	p = 0.904

p - values are not statistically significant.

Table 7.4 ***"My appliance exerted pressure"***

A comparison of scores for Light Cure and Orthoresin



Response Scores

4 Very much
3 Much
2 A little
1 Not at all

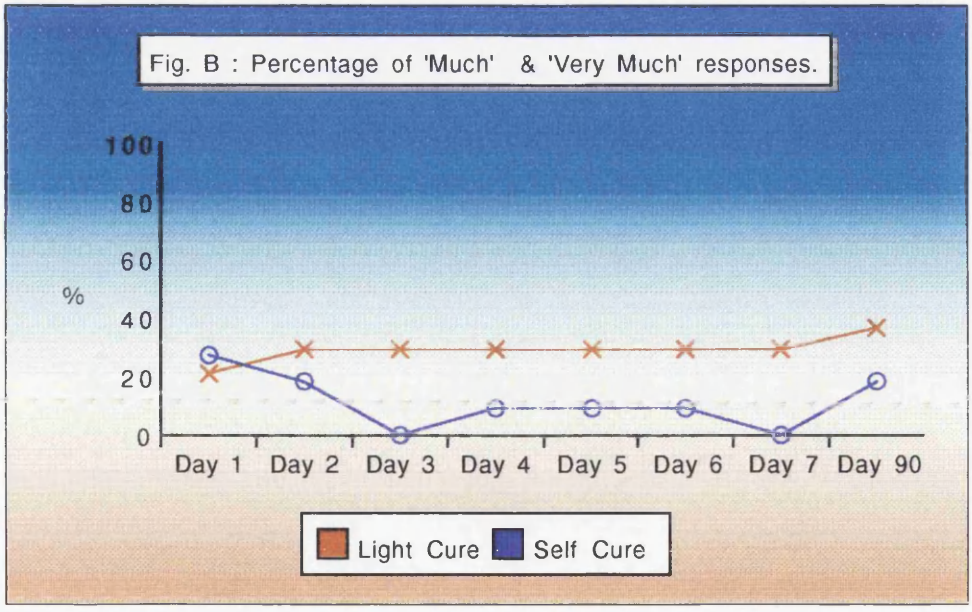


Figure 7.3 A and B ***"My appliance exerted pressure"***

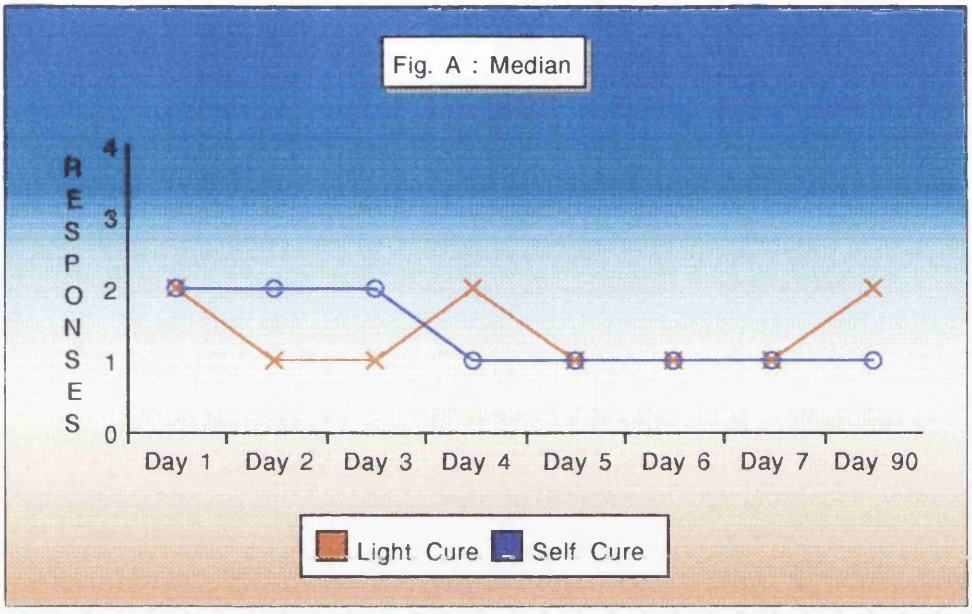
Median and percentage plots for Light Cure and Orthoresin appliance groups.

		Not at all	A little	Much	Very much	
Day 1	LC O	4 2	6 5	4 2	0 2	p = 1.00
Day 2	LC O	8 3	2 6	4 2	0 0	p = 0.904
Day 3	LC O	9 2	2 8	3 1	0 0	p = 0.791
Day 4	LC O	7 6	6 5	1 0	0 0	p = 1.00
Day 5	LC O	9 9	5 2	0 0	0 0	p = 1.00
Day 6	LC O	9 9	3 2	2 0	0 0	p = 0.607
Day 7	LC O	11 9	0 2	3 0	0 0	p = 0.317
Day 90	LC O	6 6	6 4	2 1	0 0	p = 1.00

p - values are not statistically significant.

Table 7.5 ***"My appliance felt tight"***

A comparison of scores for Light Cure and Orthoresin



Response Scores

4 Very much
3 Much
2 A little
1 Not at all

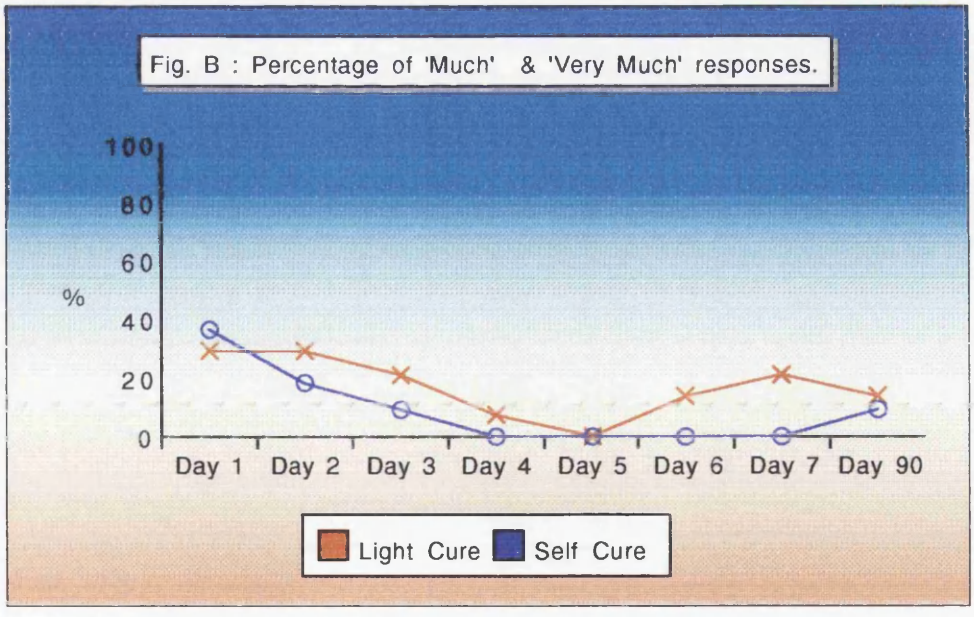


Figure 7.4 A and B ***"My appliance felt tight"***

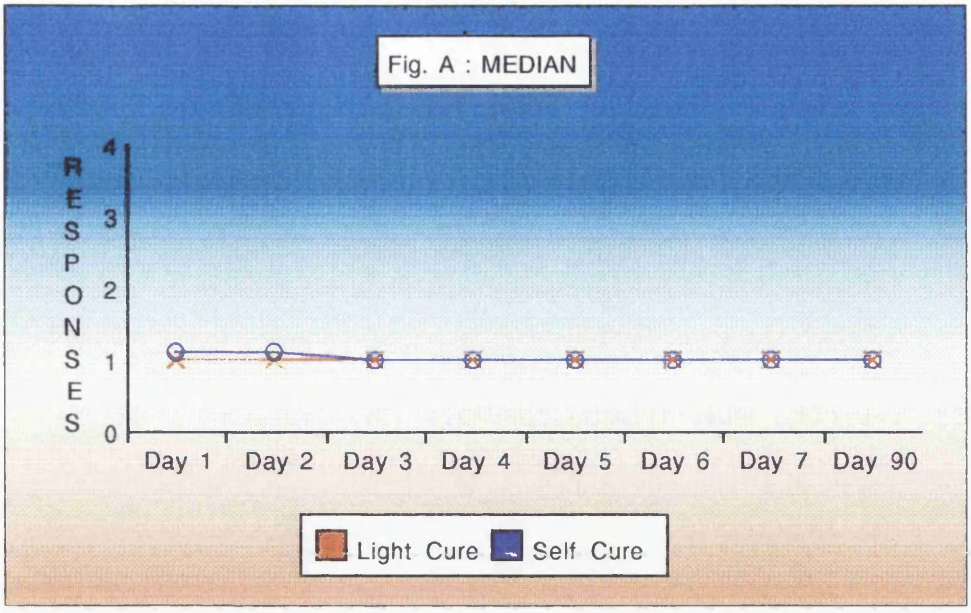
Median and percentage plots for Light Cure and Orthoresin appliance groups.

		Not at all	A little	Much	Very much	
Day 1	LC O	12 6	2 4	0 0	0 1	p = 0.88
Day 2	LC O	14 8	0 2	0 1	0 0	p = 0.88
Day 3	LC O	13 11	1 0	0 0	0 0	p = 1.00
Day 4	LC O	13 11	1 0	0 0	0 0	p =1.00
Day 5	LC O	13 11	0 0	1 0	0 0	p = 1.00
Day 6	LC O	13 10	0 1	1 0	0 0	p = 1.00
Day 7	LC O	13 11	0 0	1 0	0 0	p = 1.00
Day 90	LC O	13 11	1 0	0 0	0 0	p = 1.00

p - values are not statistically significant.

Table 7.6 *"My appliance had a strange taste"*

A comparison of scores for Light Cure and Orthoresin



Response Scores

4 Very much
3 Much
2 A little
1 Not at all

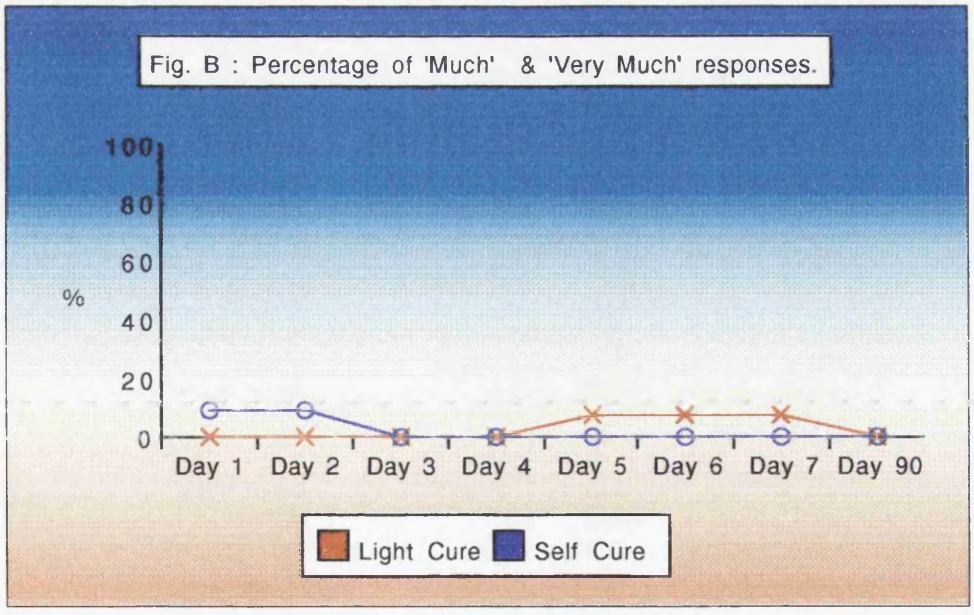


Figure 7.5 A and B ***"My appliance had a strange taste"***

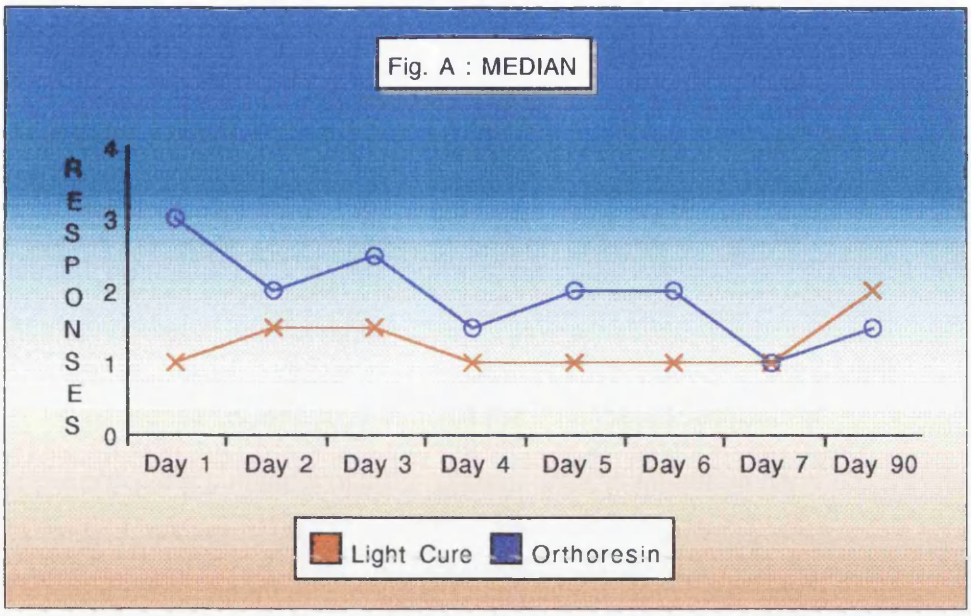
Median and percentage plots for Light Cure and Orthoresin appliance groups.

		Not at all	A little	Much	Very much	
Day 1	LC O	9 1	1 4	2 4	2 2	p = 0.366
Day 2	LC O	7 1	5 6	1 2	1 2	p = 0.417
Day 3	LC O	7 4	5 4	1 2	1 1	p = 1.00
Day 4	LC O	9 6	3 2	1 2	1 1	p = 0.765
Day 5	LC O	9 5	4 3	0 2	1 1	p = 0.417
Day 6	LC O	9 5	4 4	0 2	1 0	p = 0.813
Day 7	LC O	8 7	5 3	0 1	1 0	p = 1.00
Day 90	LC O	3 6	9 5	1 0	1 0	p = 0.607

p - values are not statistically significant.

Table 7.7 ***"My appliance interfered with speaking"***

A comparison of scores for Light Cure and Orthoresin



Response Score

4 Very much
3 Much
2 A little
1 Not at all

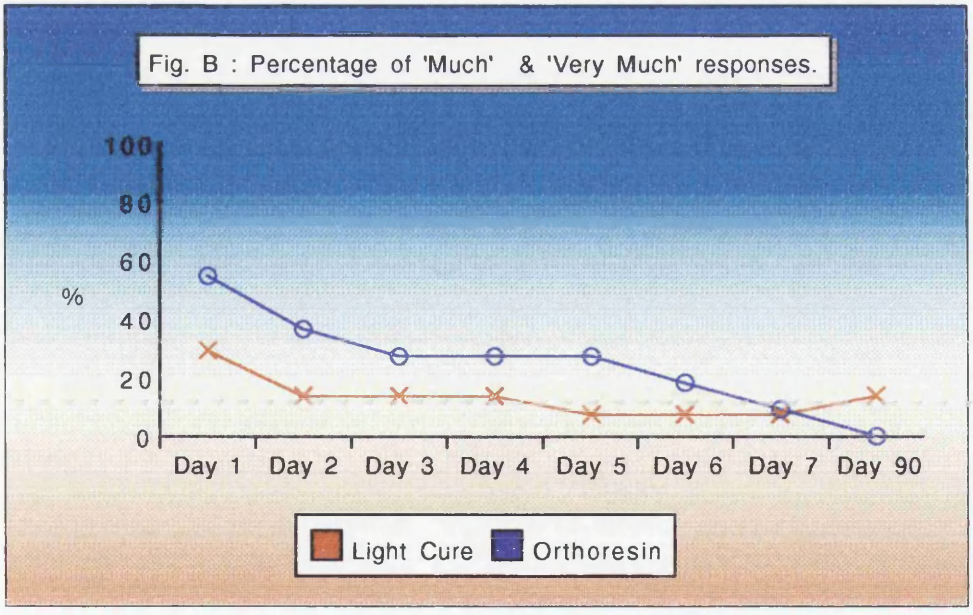


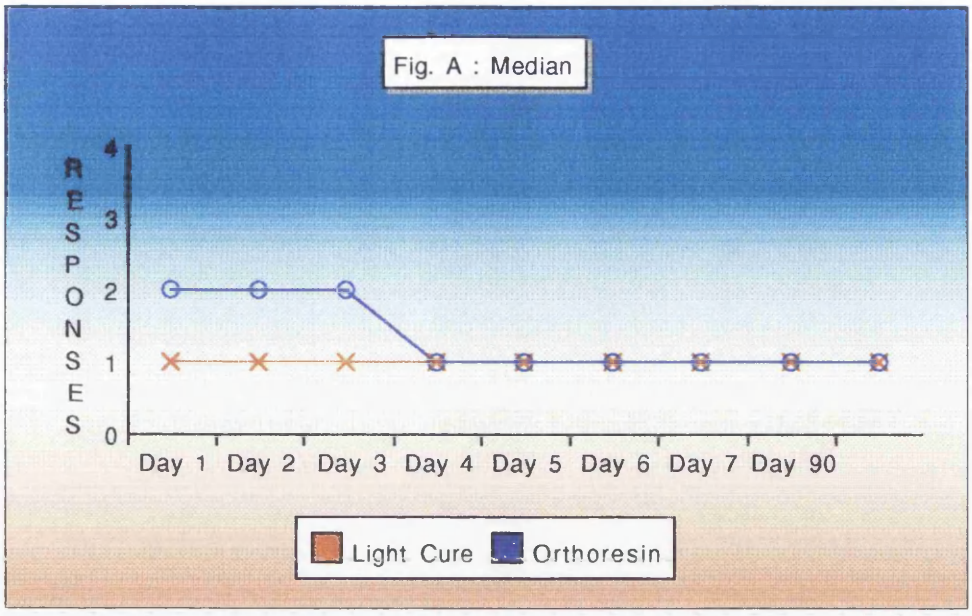
Figure 7.6 A and B ***"My appliance interfered with speaking"***
Median and percentage plots for Light Cure and Orthoresin appliance groups.

		Not at all	A little	Much	Very much	
Day 1	LC O	11 2	0 6	1 3	2 0	p = 1.00
Day 2	LC O	10 4	3 5	0 1	1 1	p = 0.813
Day 3	LC O	11 4	2 4	0 2	1 1	p = 0.417
Day 4	LC O	11 8	2 2	0 1	1 0	p = 1.00
Day 5	LC O	11 8	2 3	0 0	1 0	p = 1.00
Day 6	LC O	12 9	1 2	0 0	1 0	p = 1.00
Day 7	LC O	12 9	1 1	0 0	1 1	p = 1.00
Day 90	LC O	10 11	2 0	1 0	1 0	p = 1.00

p - values are not statistically significant.

Table 7.8 ***"My appliance interfered with swallowing"***

A comparison of scores for Light Cure and Orthoresin



Response Score

4 Very much
3 Much
2 A little
1 Not at all

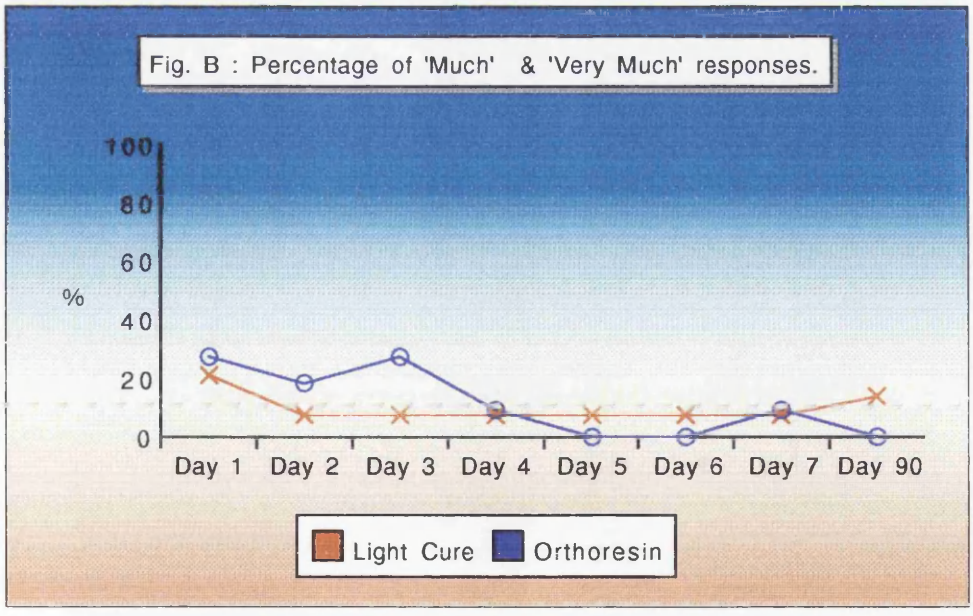


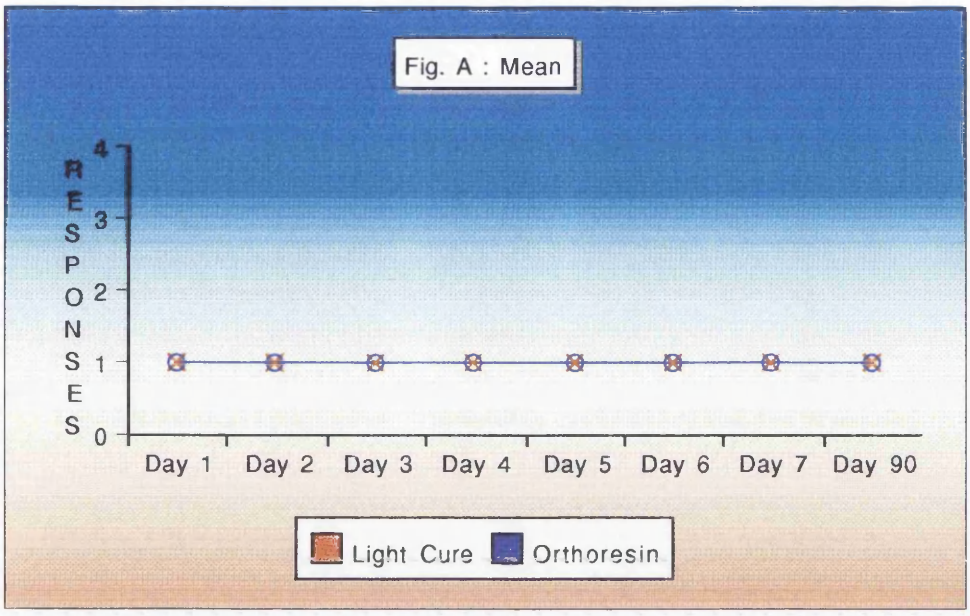
Figure 7.7 A and B ***"My appliance interfered with swallowing"***
Median and percentage plots for Light Cure and Orthoresin appliance groups.

		Not at all	A little	Much	Very much	
Day 1	LC O	13 10	0 1	1 0	0 0	p = 1.00
Day 2	LC O	13 10	1 1	0 0	0 0	p = 0.88
Day 3	LC O	13 10	0 1	1 0	0 0	p = 1.00
Day 4	LC O	13 10	0 1	1 0	0 0	p = 1.00
Day 5	LC O	13 10	0 1	1 0	0 0	p = 1.00
Day 6	LC O	13 11	0 0	0 0	1 0	p = 1.00
Day 7	LC O	13 10	0 1	0 0	1 0	p = 1.00
Day 90	LC O	14 11	0 0	0 0	0 0	p = 0.88

p - values are not statistically significant.

Table 7.9 ***"My appliance interfered with breathing"***

A comparison of scores for Light Cure and Orthoresin



Response Score

4 Very much
3 Much
2 A little
1 Not at all

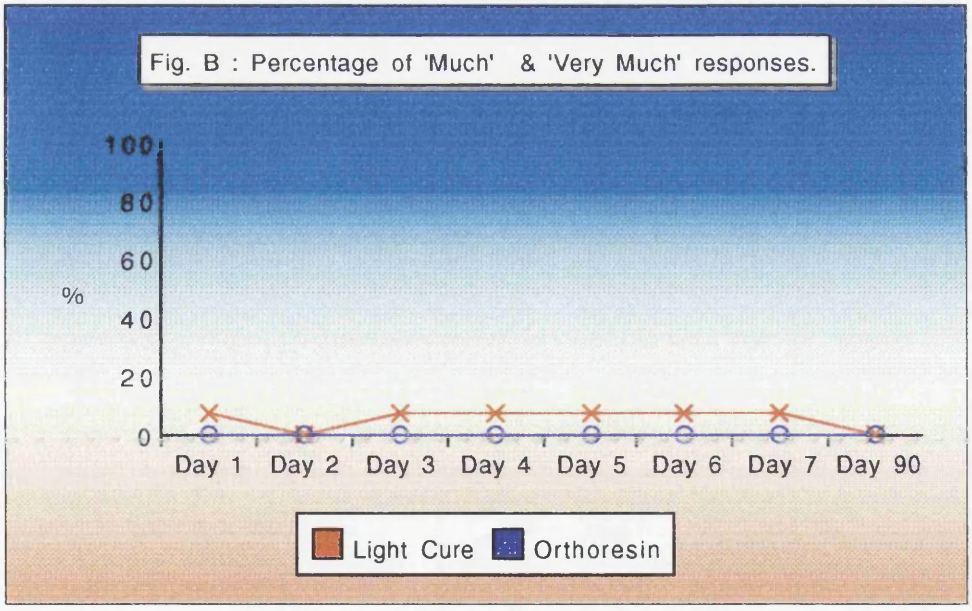


Figure 7.8 A and B ***"My appliance interfered with breathing"***

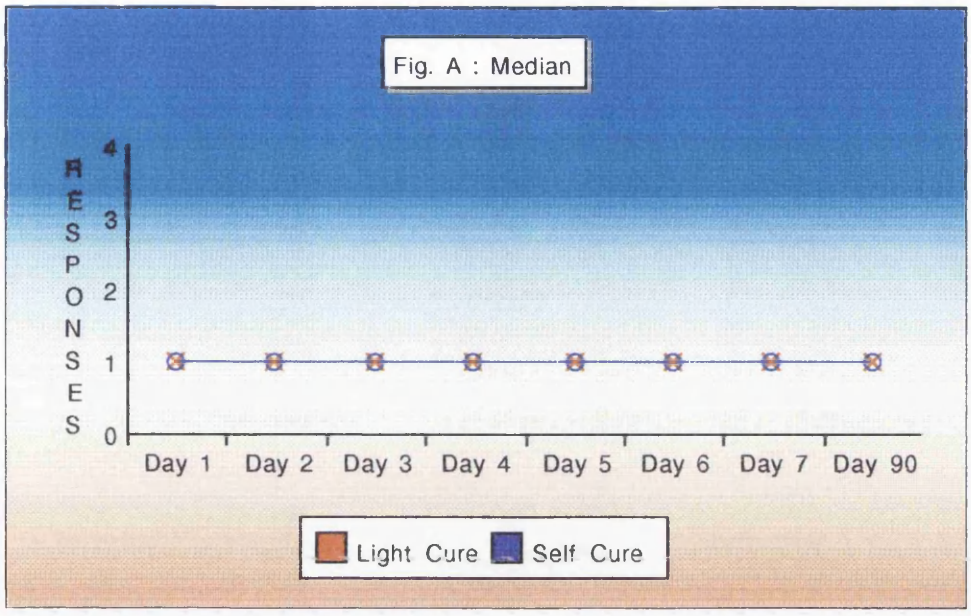
Median and percentage plots for Light Cure and Orthoresin appliance groups.

		Not at all	A little	Much	Very much	
Day 1	LC O	12 7	2 1	0 1	0 2	p = 0.143
Day 2	LC O	13 7	0 4	0 0	1 0	p = 1.00
Day 3	LC O	13 8	0 3	1 0	0 0	p = 1.00
Day 4	LC O	13 9	0 2	0 0	1 0	p = 1.00
Day 5	LC O	13 10	0 1	0 0	1 0	p = 1.00
Day 6	LC O	13 11	0 0	0 0	1 0	p = 1.00
Day 7	LC O	13 11	0 0	0 0	1 0	p = 1.00
Day 90	LC O	13 11	1 0	0 0	0 0	p = 0.88

p - values are not statistically significant.

Table 7.10 ***"My appliance interfered with sleeping"***

A comparison of scores for Light Cure and Orthoresin



Response Score

4 Very much
3 Much
2 A little
1 Not at all

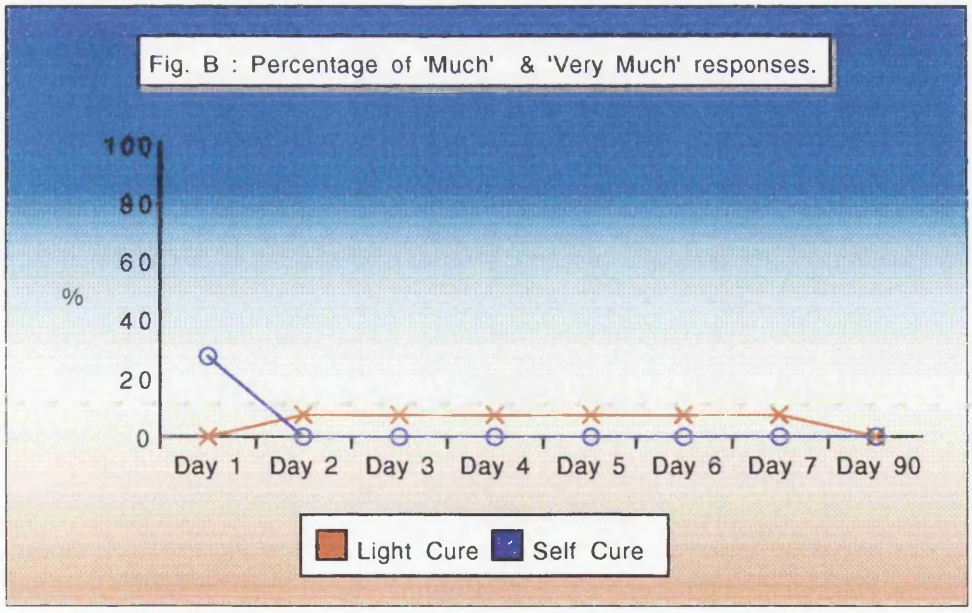


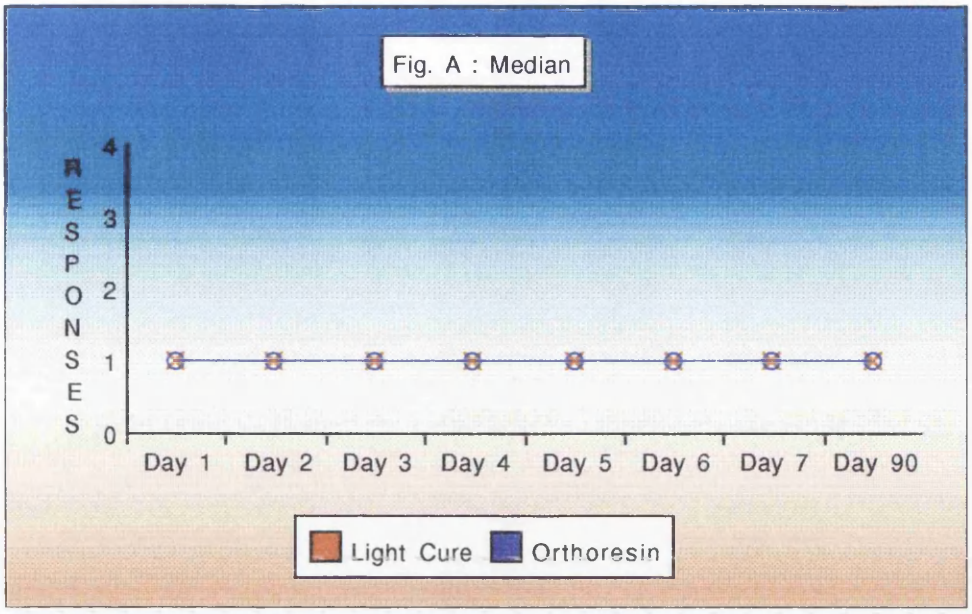
Figure 7.9 A and B ***"My appliance interfered with sleeping"***
Median and percentage plots for Light Cure and Orthoresin appliance groups.

		Not at all	A little	Much	Very much	
Day 1	LC O	12 8	2 3	0 0	0 0	p = 0.88
Day 2	LC O	13 8	1 2	0 1	0 0	p = 0.88
Day 3	LC O	13 10	0 1	1 0	0 0	p = 1.00
Day 4	LC O	13 9	0 2	1 0	0 0	p = 1.00
Day 5	LC O	13 11	0 0	0 0	1 0	p = 1.00
Day 6	LC O	13 10	0 1	0 0	1 0	p = 1.00
Day 7	LC O	13 10	0 1	0 0	1 0	p = 1.00
Day 90	LC O	14 11	0 0	0 0	0 0	p = 0.88

p - values are not statistically significant.

Table 7.11 ***My appliance made me feel disgusted"***

A comparison of scores for Light Cure and Orthoresin



Response Score

4 Very much
3 Much
2 A little
1 Not at all

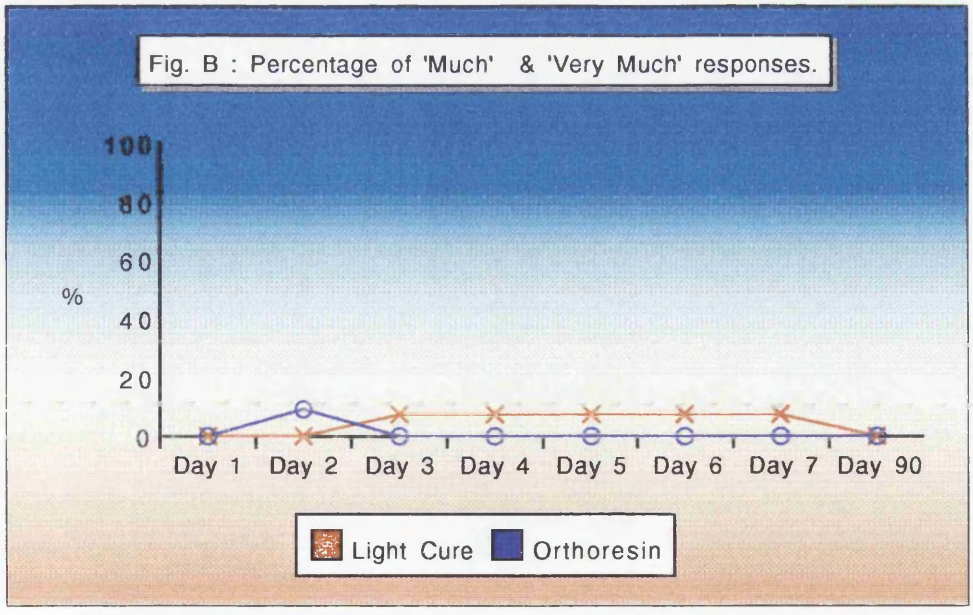


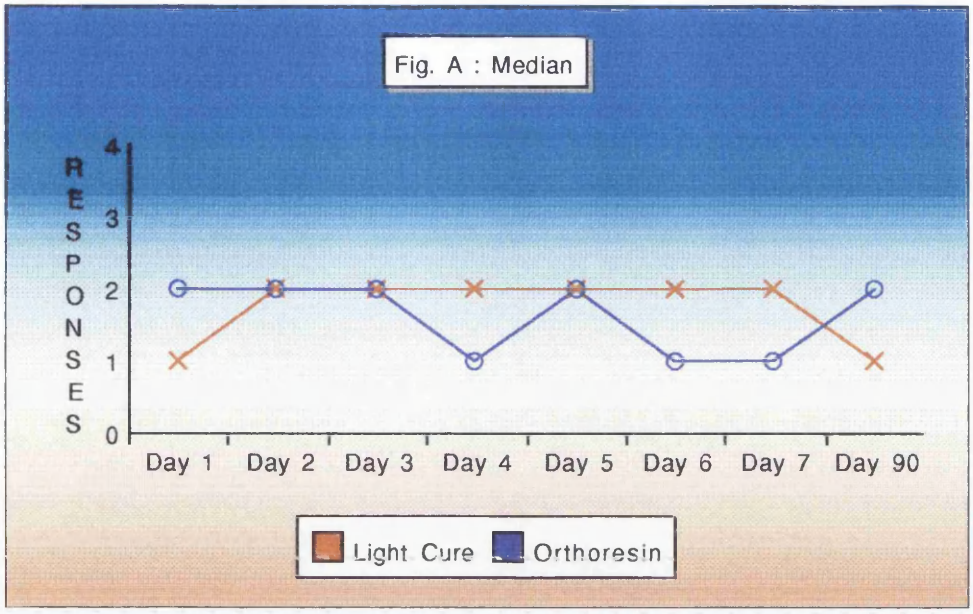
Figure 7.10 A and B ***"My appliance made me feel disgusted"***
Median and percentage plots for Light Cure and Orthoresin appliance groups.

		Not at all	A little	Much	Very much	
Day 1	LC O	8 2	6 6	0 1	0 2	p = 0.143
Day 2	LC O	4 3	7 4	2 1	1 3	p = 0.703
Day 3	LC O	4 3	8 5	1 1	1 2	p = 0.7565
Day 4	LC O	4 6	8 2	1 1	1 2	p = 0.7565
Day 5	LC O	3 5	10 5	0 0	1 1	p = 1.00
Day 6	LC O	4 6	8 4	1 1	1 0	p = 1.00
Day 7	LC O	6 8	7 2	0 1	1 0	p = 1.00
Day 90	LC O	8 5	5 6	0 0	1 0	p = 1.00

p - values are not statistically significant.

Table 7.12 ***"My appliance increased saliva flow"***

A comparison of scores for Light Cure and Orthoresin



Response Score

4 Very much
3 Much
2 A little
1 Not at all

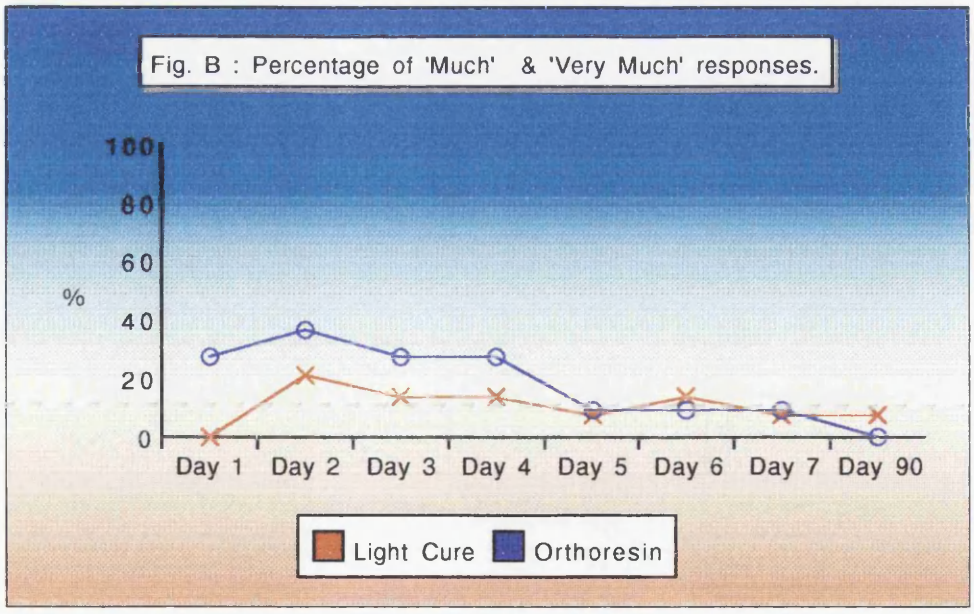


Figure 7.11 A and B ***"My appliance increased saliva flow"***

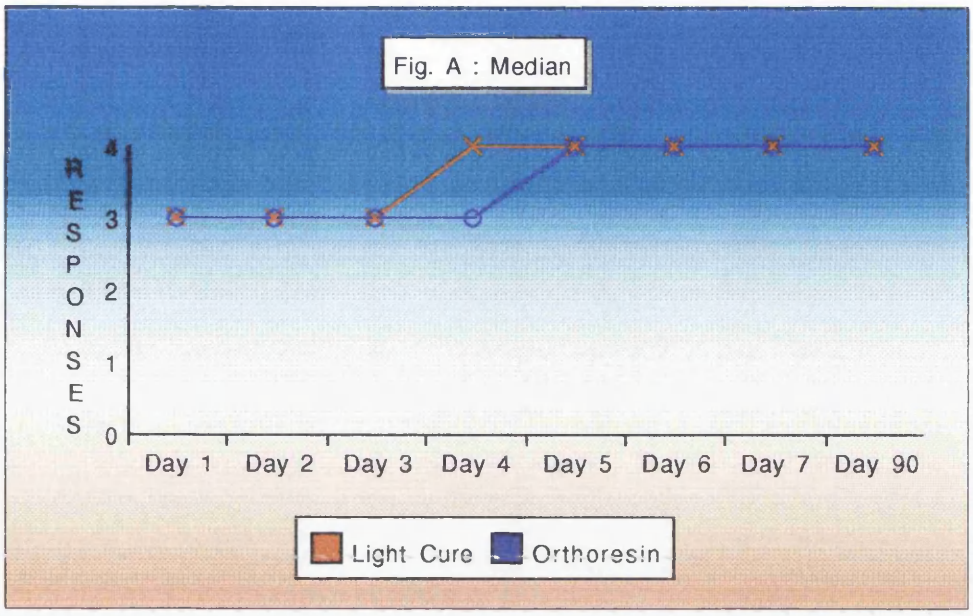
Median and percentage plots for Light Cure and Orthoresin appliance groups.

		Not at all	A little	Much	Very much	
Day 1	LC O	0 0	2 2	7 7	5 2	p = 1.00
Day 2	LC O	0 0	2 2	7 7	5 2	p = 1.00
Day 3	LC O	0 0	2 2	7 7	5 2	p = 1.00
Day 4	LC O	0 0	1 2	6 5	7 4	p = 0.813
Day 5	LC O	0 0	1 0	4 4	9 7	p = 1.00
Day 6	LC O	0 0	0 0	5 2	9 9	p = 1.00
Day 7	LC O	0 0	1 1	3 1	10 9	p = 1.00
Day 90	LC O	0 0	0 0	0 0	14 11	p = 1.00

p - values are not statistically significant.

Table 7.13 ***"My appliance is comfortable"***

A comparison of scores for Light Cure and Orthoresin



Response Score

4 Very much
3 Much
2 A little
1 Not at all

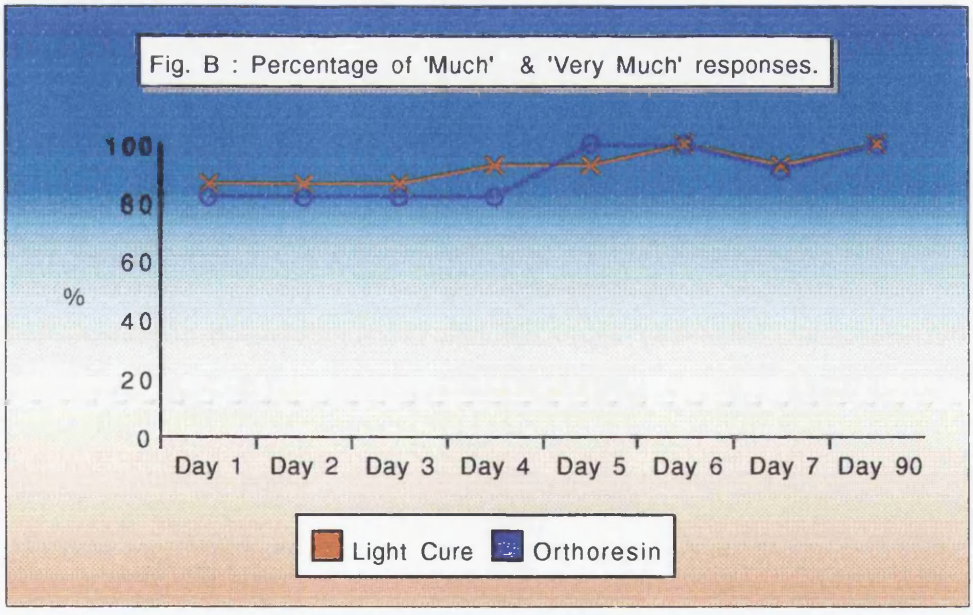


Figure 7.12 A and B ***"My appliance is comfortable"***

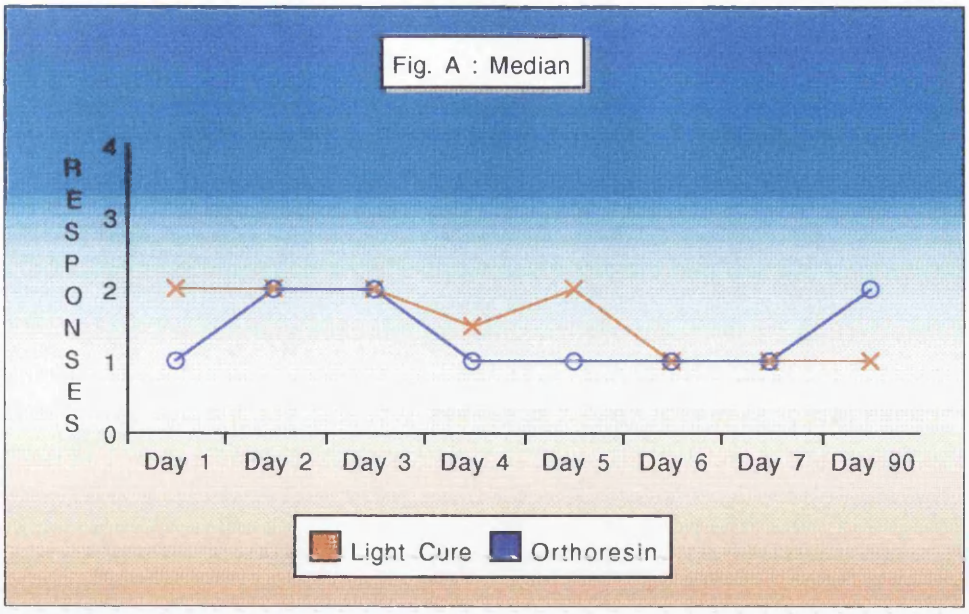
Median and percentage plots for Light Cure and Orthoresin appliance groups.

		Not at all	A little	Much	Very much	
Day 1	LC O	6 7	7 1	0 2	1 1	p = 0.417
Day 2	LC O	2 5	11 2	0 3	1 1	p = 0.191
Day 3	LC O	5 4	7 4	1 1	1 2	p = 0.765
Day 4	LC O	7 8	6 1	0 1	1 1	p = 0.813
Day 5	LC O	7 8	4 3	1 0	2 0	p = 0.317
Day 6	LC O	9 9	4 2	0 0	1 0	p = 1.00
Day 7	LC O	12 7	1 3	0 1	1 0	p = 1.00
Day 90	LC O	9 1	3 7	2 3	0 0	p = 0.7565

p - values are not statistically significant.

Table 7.14 *"My appliance made my teeth feel sensitive"*

A comparison of scores for Light Cure and Orthoresin



Response Score

4 Very much
3 Much
2 A little
1 Not at all

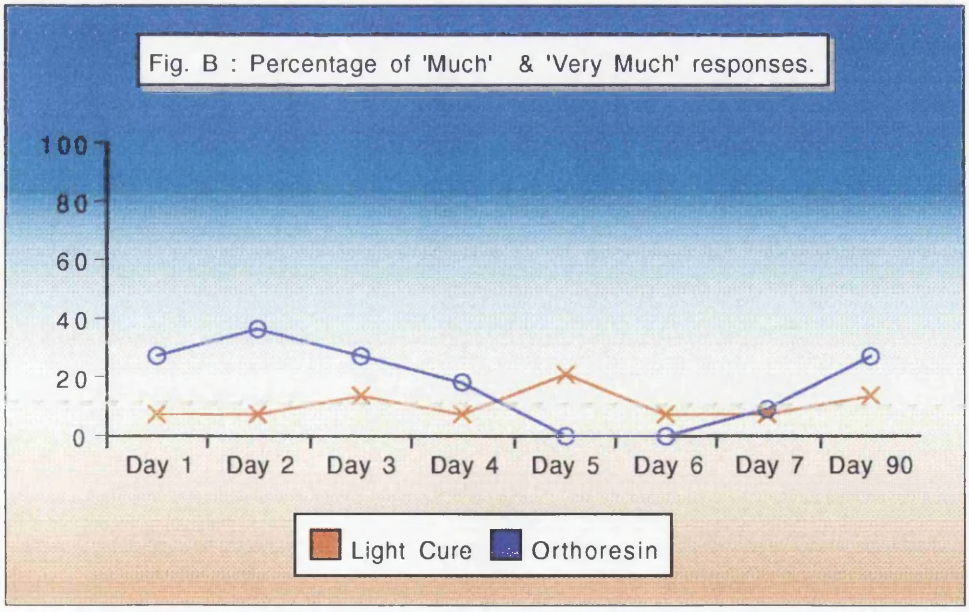


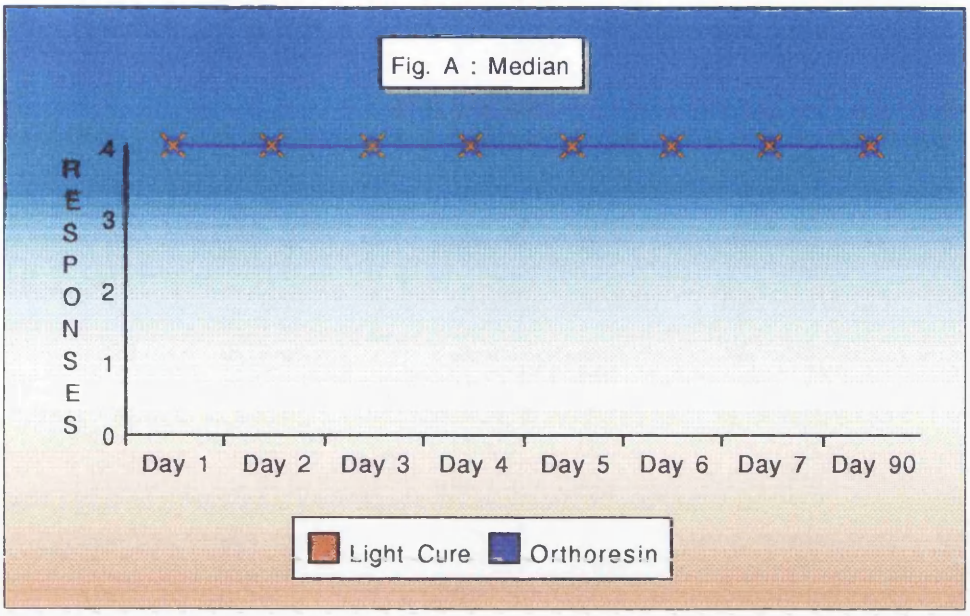
Figure 7.13 A and B *"My appliance made my teeth feel sensitive"*
Median and percentage plots for Light Cure and Orthoresin appliance groups.

		Not at all	A little	Much	Very much	
Day 1	LC	0	0	6	8	p = 0.833
	O	1	0	2	8	
Day 2	LC	0	1	2	11	p = 1.00
	O	0	1	3	7	
Day 3	LC	0	1	3	10	p = 1.00
	O	0	0	2	9	
Day 4	LC	0	1	3	10	p = 0.813
	O	0	2	1	8	
Day 5	LC	0	1	3	10	p = 0.813
	O	0	2	1	8	
Day 6	LC	0	0	5	9	p = 1.00
	O	0	1	3	7	
Day 7	LC	0	1	2	11	p = 0.813
	O	0	2	1	8	
Day 90	LC	0	0	6	8	p = 0.88
	O	0	1	0	10	

p - values are not statistically significant.

Table 7.15 *"My appliance feels smooth"*

A comparison of scores for Light Cure and Orthoresin



Response Score

4 Very much
3 Much
2 A little
1 Not at all

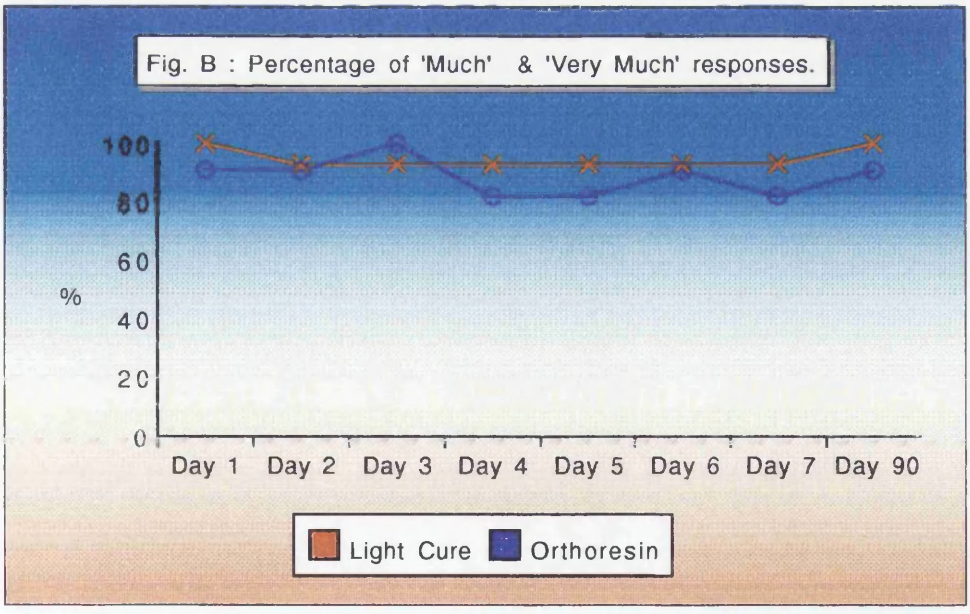


Figure 7.14 A and B ***"My appliance feels smooth"***

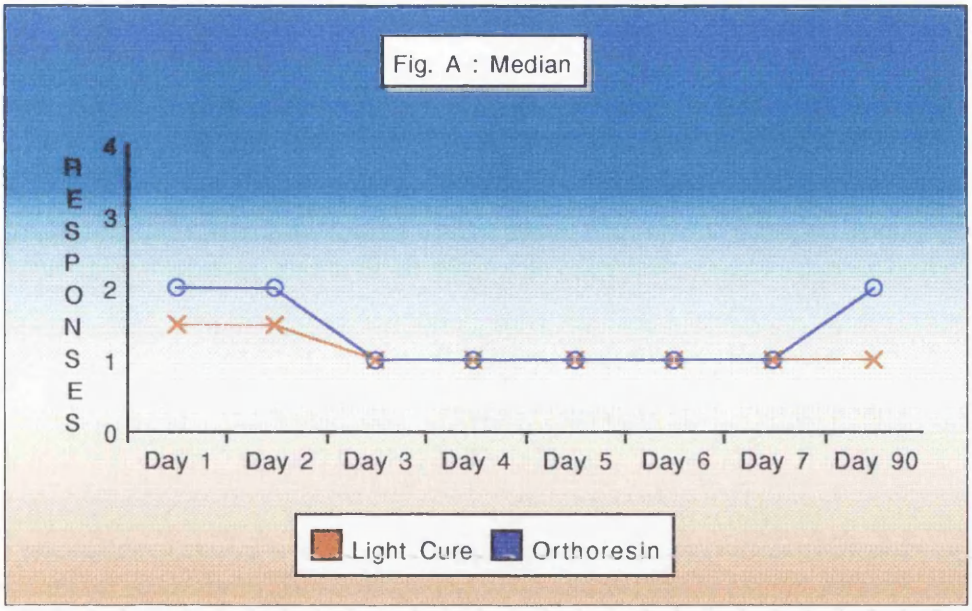
Median and percentage plots for Light Cure and Orthoresin appliance groups.

		Not at all	A little	Much	Very much	
Day 1	LC O	7 5	4 5	2 0	1 1	p = 0.791
Day 2	LC O	7 3	6 6	0 2	1 0	p = 1.00
Day 3	LC O	13 6	0 4	0 0	1 1	p = 1.00
Day 4	LC O	12 8	1 1	0 1	1 1	p = 1,00
Day 5	LC O	8 9	5 1	0 1	1 0	p = 1.00
Day 6	LC O	12 10	1 1	0 0	1 0	p = 1.00
Day 7	LC O	12 9	1 2	0 0	1 0	p = 1.00
Day 90	LC O	11 4	2 7	0 0	1 0	p = 1.00

p - values are not statistically significant.

Table 7.16 ***"My appliance caused pain"***

A comparison of scores for Light Cure and Orthoresin



Response Score

4 Very much
3 Much
2 A little
1 Not at all

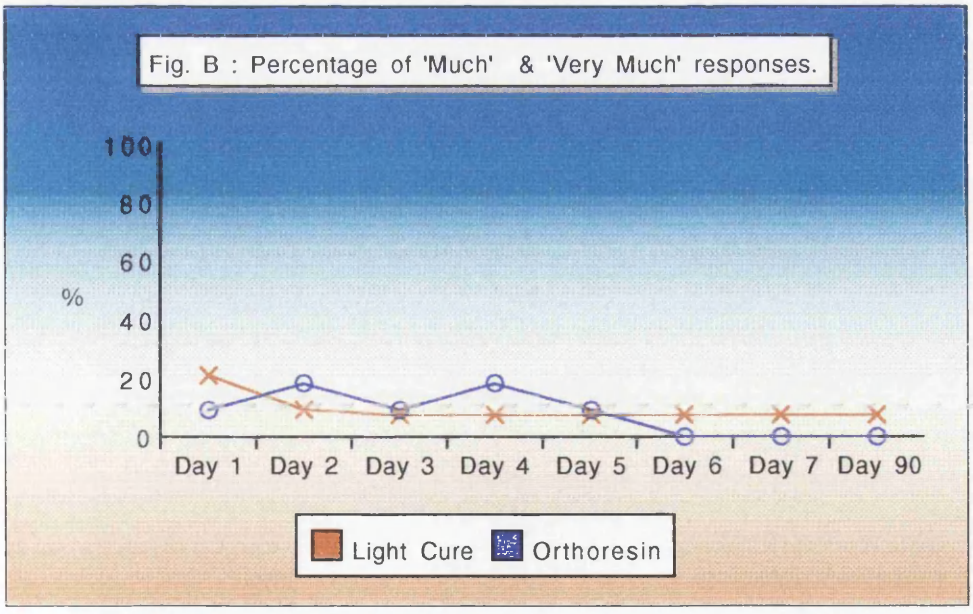


Figure 7.15 A and B ***"My appliance caused pain"***

Median and percentage plots for Light Cure and Orthoresin appliance groups.

Chapter 8 : Results

8.1 Results on patient experiences and patterns of wearing light cure and self cure appliances of "Study Two".

8.2 Introduction

The total number of subjects in each sample group was small. Therefore the male and female subjects were combined into baseplate material groups whose responses formed the basis for statistical analysis.

A two-sample t-test was performed for differences in age of the subjects between the light cure and self cure baseplate material groups. The result is presented on Figure 8.1 and 8.2 and Table 8.1.

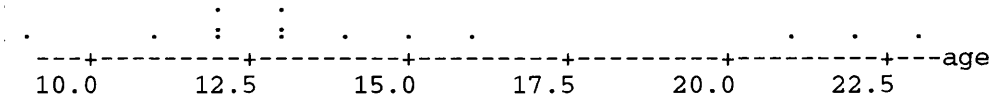


Figure 8.1 Light cure baseplate material subjects.

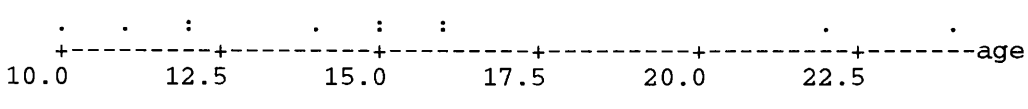


Figure 8.2 Self cure baseplate material subjects.

Appliance	Number	Mean Age	Std. Dev.	S.E. M.
Light Cure	14	14.71 years	4.30 years	1.15 years
Self Cure	11	15.18 years	4.38 years	1.32 years

Two-sample t-test : $t = -0.27$, $p = 0.79$

Table 8.1 Age differences between light cure and self cure baseplate material subjects.

There was no significant difference in age between the two groups.

8.3 Questionnaire Responses

There were no significant difference in the responses of the light cure subjects as compared with the self cure subjects at any stage.

8.3.1 Acceptability of appliance material

The three sensations of taste, comfort, smoothness have been linked as these sensations could possibility effect the patient's acceptance of the baseplate material. The sensation of taste was included as self cure material has been reported (3.2.1) to have free radicals of monomer which can be unpleasant to the patient. Light cure materials also have a dispersion layer (6.8.6) after curing and this could possibly give a sensation of taste if the material was not finally cured. One patient reported a strange taste which decreased and after day two with the self cure appliance and on days five to seven there was a slight taste reported by one respondent with a light cure appliance. The

majority of the patients reported no strange tastes from the baseplate materials.

The comfort of both materials was very well accepted with all patients reporting a comfortable appliance.

Apart from one patient reporting the self cure appliance was not smooth on day one all the patients from day two reported the baseplate materials were smooth.

The light cure material was no worse than and possibly slightly better than the self cure material with the sensations of taste, comfort and smoothness.

8.3.2 Tension, pressure and tightness

The three sensations have been discussed together because of the similarities in the responses. The responses for tension and pressure varied very little from day one to seven and through to day ninety. The light cure appliances' responses to tightness were slightly higher possibly due to the more accurate fit that was obtained from this material.

8.3.3 Speech and swallowing

The two sensations of speech and swallowing affected respondents from both groups on the the first two days which gradually reduced to effect one respondent in each group on day seven. Some light cure respondents indicated that the appliance still interfered with these sensations at day ninety.

8.3.4 Breathing, sleeping, feelings of disgust and appliance wear in public.

From day one to seven only one respondent from each group indicated that their appliance had affected their breathing and by day ninety all respondents reported no difficulty with breathing. On day one only three of the self cure

group reported that appliance interfered with their sleeping while one of the light cure group indicated the same up to day seven. By day ninety no responses were recorded for the appliances interfering with their sleep for both types of material. Only one respondent from the light cure group indicated they had felt disgusted with their appliance but by day ninety all had responded to the "not at all" on the questionnaire.

8.3.5 Increase in saliva flow

The self cure patients experienced a slight increase in saliva flow on the first day. This evened out with a few in both groups experiencing a slight increase by day seven when the saliva increase returned to normal. Only one response reported an increase in saliva flow by day ninety with a light cure appliance.

8.3.6 Pain and sensitivity

The sensations of sensitivity and pain were probably related to the adjustments of the appliance. The responses related to these sensations were during the first three days of receiving the appliance. After these first few days the responses reduced. By day ninety, five responses reported to having sensitive teeth whereas two responses related to having pain.

Chapter 9 : Discussion

A number of light cure materials were supplied and initial tests showed that some of these materials were unsuitable for the commercial construction of orthodontic appliances, (Ch.5). These materials were unsuitable because they either slumped into the vault of the palate or after adaption left a very rough surface.The trimming time of these materials would make it uneconomic for appliance construction. The light cure material selected seemed to have reasonable properties except that the impact resistance was fairly low. The method of supplying the material in a gel form in a toothpaste style tube made adaptation fairly simple. The gel flowed freely from the tube and any large air bubbles could be eliminated with a small good quality paint brush, (6.8.3). Minute air bubbles trapped in the gel material were a problem as it was very difficult to break the surface tension of the bubble. These bubbles must have occurred during manufacture and should have been eliminated. Only a few tubes had this problem. The adaption of the gel material required very little expertise to achieve a good result because of the ready mixed style of the material and its excellent flow characteristics. After adaption the gel also did not slump and settled into an extremely smooth surface. Due to the gel being ready mixed there was very little odour from the material and virtually non inflammable. The curing of the material was straight forward and no undue problems occurred as long as the material was not adapted too thick. The trimming of light cure materials presented the greatest disadvantage as a very fine dust was generated during the trimming procedure, (6.8.8).

During the production of the appliances for the study the time taken for each stage was recorded, (6.12). This time did not include processing times. The build up time for light cure appliances was longer than that for the self cure

appliances. When it came to trimming and polishing the light cure materials fared better and on average the build up, trimming and polishing of light cure appliances was slightly quicker. It must be taken into consideration that light cure materials were not as familiar to the operator as self cure materials and the operator is not a production technician so these times were only for information and guide in judging the materials.

There was only one slight problem at the beginning with a screw appliance as the light did not penetrate underneath the metal but this was soon overcome by changing the technique, (6.8.3). No production problems occurred in any of the appliances supplied to the patients. According to the responses from the patient survey forms the light cure material did no worse, indeed slightly better in a few areas than the self cure material, although no statistically significant differences was elicited.

The problem of residual monomer in the self cure material did not register on the survey forms ("My appliance had a strange taste") possibly because all the self cure appliances were processed using a thermostatic hot plate in conjunction with the pressure pot to ensure complete polymerisation, (6.9.6). The light cure material registered no specific problems in this area either. Both materials also had no specific problems with the comfort and smoothness of the finished appliances.

The light cure materials registered three repairs during the survey while there were no reported repairs to the self cure materials. As the sample size was small it is unfair to draw general conclusions about the robustness of light cure resin in the clinical context.

The results of study showed that although light cure materials have slightly different properties they performed no worse than self cure materials and sometimes better.

Wider clinical testing is required to assess the durability of light cure resin.

Chapter 10 : Summary and Conclusions

10.1 Summary

Heat cure, auto polymerising, (self cure or cold cure) thermoplastic, and light cure acrylic resin are the most commonly used orthodontic baseplate materials. Cured acrylic presents few problems to the patient. However residual monomer is present in a new appliance but these free radicals of monomer go into solution whether it be water or saliva within a short time. In the laboratory acrylic resin has to be sprayed, mixed or packed using a fume extraction unit, either a down flow or a fume cabinet, because of the harmful fumes exhibited by the raw chemicals which are highly inflammable. The monomer fumes are heavier than air and fall towards the floor.

Light cure material, however, has a tremendous potential as a base plate material. The material is supplied in a variety of forms - gel, sheet and rope. The material is virtually non inflammable and has no aroma. A variety of techniques using the different forms of material could be used to build up an orthodontic appliance. The material is simple to adapt but care must be taken on the thickness of the layers - a maximum of three millimeters. The time taken to construct appliances could be reduced as experience of the material increases. This material has also the added advantage of being able to cure on demand especially when building up complex appliances. The material has also one very big disadvantage - the fine powder produced when trimming. Even with a bench equipped with an extraction unit it would be still advisable to use a good face mask to prevent the inhalation of dust. This fine powder is the major problem with light cure materials.

10.2 Conclusions

The laboratory testing of the two selected light cure materials showed

1 The average deflection of material 'A' was significantly greater than material 'B' or Orthoresin at both 15 and 30 Newtons.

2 The impact resistance of Orthoresin was significantly greater than light cure material 'A' or 'B'.

3 Orthoresin was significantly softer than both the light cure materials with light cure material 'B' being significantly harder than light cure material 'A'.

4 Light cure material 'A' recorded a significantly longer time to apply the material than Orthoresin but a significantly shorter time to trim the appliance. Polishing the appliances showed that light cure took significantly less time than Orthoresin to polish. The total time for all procedures was significantly less for light cure material as opposed to Orthoresin.

Clinical testing of Light Cure material 'A' against Orthoresin.

1 There was no statistically significant difference in patient acceptability between the materials.

2 There was a tendency for the light cure material to record better responses in some tests when inserted but this did not continue, where as Orthoresin in some instances recorded poorer responses which improved as treatment progressed.

3 Although there were more breakages of appliances made with light cure material 'A' as compared to Orthoresin the numbers were small (3).

Personal assessment of handling properties showed that

1 Light cure material 'A' was easier to adapt in a uniform thickness which resulted in less trimming when constructing an orthodontic appliance.

2 The light cure material was supplied ready mixed in a dispenser which eliminates the mixing of raw chemicals when applying or mixing the baseplate materials. The light cure material produced only a slight aroma and did not appear to be highly inflammable.

3 Light cure material 'A' was much harder than self cure resin and, possibly due to the fillers used during the manufacturing, a fine dust was evident when trimming. It would be advisable to take precautions when trimming these materials such as wearing a dust mask, as well as using a bench dust extraction unit. The problem of dust is a distinct disadvantage with these materials.

Initial testing of light cure resin showed it to perform comparably to a conventional self cure resin.

More extensive clinical trials now need to be undertaken to prove the worth of the resin as a more user friendly orthodontic material. In the meantime the manufacturers need to give consideration to eliminating the tendency for the formation of fine dust particles on grinding. This could be done by modifying the fillers, taking care not to reduce the current ease of adaptability.

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Appendix

Survey Forms & Literature

Contents **Page**

Procedure for Evaluation of Orthodontic Baseplate Material

1. Enrol patient in study by issuing an information sheet and obtaining a signature on the consent form.

2. Place a sticker on the case notes to indicate patient is part of a study.
   Insert a *Yellow* 'Procedure' form in the case notes.
   All laboratory work should be sent to Mr. J. Brown G28 (if possible)

3. Send impression and appliance design sheet to Mr. J. Brown G28

4. Appointment for insertion of appliance -
   a) Fill out Questionnaire *(Green)*
   b) Insert appliance
   c) Patient is given *(Blue)* Questionnaire to complete daily for the first 7 days.

5. Next Visit - Patient returns *(Blue)* Questionnaire

6. Three Months - Patient completes *(Yellow)* Questionnaire.

7. Next Visit - Patient returns *(Yellow)* Questionnaire

8. End of this stage of treatment - Patient fills in *(Pink)* Questionnaire.

Repairs

It is most important that a survey form is filled in for every repair however minor.
Please forward all repairs to Mr.J.Brown Room G28

Red Folder - Repair survey forms *(White)*
a)Orthodontist fills in top part of *(White*) Survey Form.
b) Patient Fills in area below line.

For more information contact - Prof. Kerr ; Dr. Millet ; P. Taylor or J. Brown ext. 9661

Patient Information Sheet for the

"Evaluation of Orthodontic Baseplate Material Study"

In an effort to give the patient the best possible treatment and using materials which are safer for the technicians who make your removable braces we would like you to take part in a survey to evaluate orthodontic base materials (the pink or clear part of your brace).

How can you help? -

You will be required to fill in questionnaires at the start and end of treatment and if you are unfortunate to break your brace during the course of treatment we would require you to fill in a single sheet questionnaire.

Background to the study -

The fabrication of your brace involves the use of chemicals to construct the pink or clear area which is safe when processed for patient use. Manufacturers are continually improving their materials and we would like to evaluate various areas from laboratory construction to patient acceptability.

Results -

From this study the results of you the patient and the laboratory who constructs the brace will enable us to determine which is the most acceptable material for your future brace (if you need one) and also create a safer working environment for the technical staff who construct the braces.

Thank you for your anticipated cooperation

JB94 (11)

CONSENT FORM

* Delete

I Parent* / Gardian* of ..... freely and voluntary agree to participate in a clinical research study on
"The Evaluation of Orthodontic Baseplate Material "

I have read the accompanying information sheet. The nature and purpose of the study has been explained to me by ..... and I have had the opportunity to ask questions and I understand fully of what is being proposed.

I recognise that I may receive no benefit from the study. I accept that there may be no risks associated with the proceedure which are not directly attributed to neglience on the part of those undertaking the proceedures.

I understand that I am free to withdraw my consent at any time without prejudice to me or my dental care.

I have been assured that any information obtained from me willnot be disclosed without my permission to any other party in a maner which will reveal my identity.

Signature : .....
Date : .....

I confirm that I .....have / has explaned explained the nature and purpose of the of the "The Evaluation of Orthodontic Baseplate Materials Study " and the proceedure in respect of which consent has been given by the above named.

Signature : .....
Date : .....

JB94 (10)

Clinical Survey Form For Appliances
(Evaluation of Orthodontic Base plate Material Study)

AT APPOINTMENT WHEN INSERTING APPLIANCE

Date: / /199 L.C.❑ / O.❑

Patients name : ..... Sex. M / F

Box No. .....

Active appliance Yes❑ / No❑

Retainer Yes❑ / No❑

The appliance is inserted and the patient is asked **"Are you concerned about wearing this brace ?"**

Not at all	☐
A little	☐
Much	☐
Very much	☐

Is this your first brace? Yes❑ / No❑

Is this your first dental plate? Yes❑ / No❑

Brief details : .....

.....

Please indicate your agreement on the following statements.

My physical fitness today is :

Very good	☐
Good	☐
Bad	☐
Very bad	☐

My mood today is :

Very good	☐
Good	☐
Bad	☐
Very bad	☐

In the last few days I have been thinking about my teeth :

Never	☐
Sometimes	☐
Often	☐
Very often	☐

JB94 (1)

Clinical Survey Form For Appliances
(Evaluation of Orthodontic Base plate Material Study)

Please fill in one form at the end of each day for the first 7 days after the start of treatment

DAILY RECORD SHEET **DAY ONE**

		not at all	a little	much	very much
1	I felt comfortable with my appliance				
2	My appliance exerted tension				
3	My appliance exerted pressure				
4	My appliance felt tight				
5	My appliance had a strange taste				
6	My appliance interfered with speaking				
7	My appliance interfered with swallowing				
8	My appliance interfered with breathing				
9	My appliance interfered with sleeping				
10	My appliance made me feel disgusted				
11	My appliance increased saliva flow				
12	My appliance is comfortable				
13	My appliance made my teeth feel sensitive				
14	My appliance feels smooth				
15	My appliance caused pain				

Further remarks: .....

.....

.....

Patient's name : ..... Box No. .....

Date: / /199 L.C.❑ / O.❑ JB94 (2)

Clinical Survey Form For Appliances
(Evaluation of Orthodontic Base plate Material Study)

THREE MONTHS AFTER START OF TREATMENT - PATIENT FORM

		agree very much	agree a little	disagree a little	disagree very much
1	It was not my idea to have orthodontic treatment				
2	I am glad I have started my orthodontic treatment				
3	I like my teeth now than before treatment				
4	I would recommend orthodontics to some of my friends				
5	My orthodontist is very nice				
6	I dislike my orthodontic appliance				
7	My appliance is difficult for me to wear				
8	It bothers me to wear my appliance in public				
9	It bothers me to wear my appliance at home				

Please indicate your agreement on the following statements.

My physical fitness today is :

Very good	
Good	
Bad	
Very bad	

My mood today is:

Very good	
Good	
Bad	
Very bad	

In the last few days, I have been thinking about my teeth :

Never	
Sometimes	
Often	
Very often	

Patients name: ..... Box No. ..... L.C.❑ / O.❑ JB94 (4)

Clinical Survey Form For Appliances
(Evaluation of Orthodontic Base plate Material Study)

MY EXPERIENCE WITH THE APPLIANCE

Please tell us how you felt about your appliance generally since your last appointment ..... weeks ago.

		not at all	a little	much	very much
1	I felt comfortable with my appliance				
2	My appliance exerted tension				
3	My appliance exerted pressure				
4	My appliance felt tight				
5	My appliance had a strange taste				
6	My appliance interfered with speaking				
7	My appliance interfered with swallowing				
8	My appliance interfered with breathing				
9	My appliance interfered with sleeping				
10	My appliance made me feel disgusted				
11	My appliance increased saliva flow				
12	My appliance is comfortable				
13	My appliance made my teeth feel sensitive				
14	My appliance feels smooth				
15	My appliance caused pain				

Further remarks: .....

.....

.....

Patient's name : ..... Box No. .....

Date: / /199 L.C.❑ / O.❑ JB94 (3)

Clinical Survey Form For Appliances
(Evaluation of Orthodontic Base plate Material Study)

END OF THIS STAGE OF TREATMENT - PATIENT FORM

		agree very much	agree a little	disagree a little	disagree very much
1	It was not my idea to have orthodontic treatment				
2	I am glad I have started my orthodontic treatment				
3	I like my teeth now than before treatment				
4	I would recommend orthodontics to some of my friends				
5	My orthodontist is very nice				
6	I dislike my orthodontic appliance				
7	My appliance is difficult for me to wear				
8	It bothers me to wear my appliance in public				
9	It bothers me to wear my appliance at home				

Please indicate your agreement on the following statements.

My physical fitness today is :

- Very good ☐
- Good ☐
- Bad ☐
- Very bad ☐

My mood today is:

- Very good ☐
- Good ☐
- Bad ☐
- Very bad ☐

In the last few days, I have been thinking about my teeth :

- Never ☐
- Sometimes ☐
- Often ☐
- Very often ☐

Patients name: ..... Box No. ..... L.C.☐ / O.☐ JB94 (5)

Clinical Survey Form For Repairs to Appliances
(Evaluation of Orthodontic Base plate Material Study)

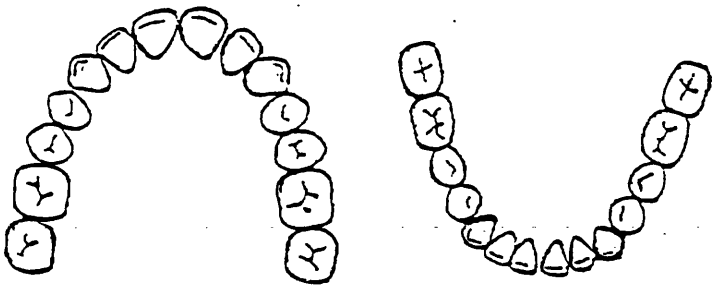
Date : / /199 Time : : Time returned : :

Patients Name : ..... Box No. .....

Material : Orthoresin ❑ Light cure 'A' ❑

Location of Repair (mark on diagram)

Location of Repair :
Wire ❑
Resin ❑
Both ❑



Questions the patient : ✓ the appropriate boxes

What was the reason for the appliance breaking ?

Did it break puting it in ? Yes❑ No❑ / Taking it out ? Yes❑ No❑

Did it break in the mouth?

Yes ❑

⬇

Were you eating? Yes❑ No❑
Was it during a meal? Yes❑ No❑
Were you eating a snack? Yes❑ No❑
Were you eating sweets? Yes❑ No❑
Were you eating fruit ? Yes❑ No❑
Was the food -
hard Yes❑ No❑
average Yes❑ No❑
soft Yes❑ No❑
chewy Yes❑ No❑
Other (brief description) : .....
.....
.....

No ❑

⬇

At chairside Yes❑ No❑
Brief description : .....
.....
.....
.....
Were you cleaning your appliance ? Yes❑ No❑
Did you drop it ? Yes❑ No❑
Did something drop on it? Yes❑ No❑
Other (brief description) : .....
.....
.....
.....
.....

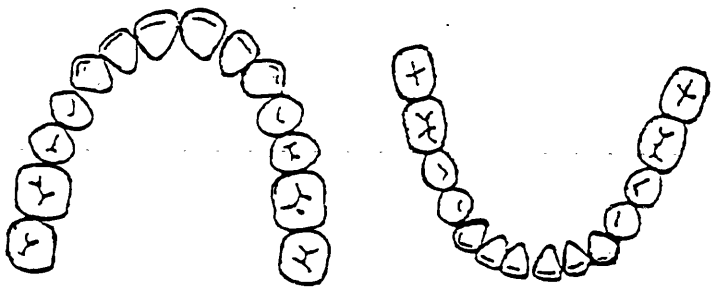
JB94 (6)

Laboratory Survey Form For Repairs to Appliances made with Light Cure Material'A' and Orthoresin
(Evaluation of Orthodontic Baseplate Material Study)

Date : / /199 Time : : Approx time for repair : mins.

Patients Name : ..... Box No. .....

Location of Repair (mark on diagram)



Baseplate Material :

Light Cure ❑
Orthoresin ❑

Type of repair :

Wire ❑
Resin ❑
Both ❑

Other (brief description) - .....
.....
.....
.....

General Condition of appliance :

Good (good surface finish; no missing or broken areas) ❑
Average (no missing or broken areas: lost surface polish) ❑
Poor (missing or broken areas; lost surface polish) ❑

Other (brief description) - .....
.....
.....
.....

JB94 (8)