AN ASSESSMENT OF PATIENTS TREATED WITH IMPLANT RETAINED MANDIBULAR OVERDENTURES

G. D. Gee BSc BDS

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This work contains no material which has been accepted for the award of any other degree or diploma in any university or other tertiary institution and, to the best of my knowledge and belief, contains no material previously published or written by another person, except where due reference has been made in the text.

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SUMMARY

Literature Review

The loss of teeth has been a common dental experience for man since the earliest times. Historically, the loss was partial rather than complete, and if treated, the rationale was aesthetic rather than functional. Beginning in the late 1700's and continuing through to the late 1900's the incidence of edentulism has increased dramatically. Through a combination of dental disease, aggressive surgery, and a longer life span, the rate of complete edentulism has climbed to between 10 to 20 per cent of the adult population in most developed societies. The restoration of function, in addition to form, became increasingly important with the loss of all teeth. Improvements in materials, particularly the advent of porcelain and acrylic, largely solved the problem of providing an aesthetic restoration. Improvements in technique, such as impression taking and the use of articulators, led to better fabricated prostheses. Functionally, however, dentures remained a barely adequate replacement for the natural dentition.

The changes that occur on the loss of teeth impact profoundly on form and oral function. Changes in extra- and intra-oral form are due principally to residual ridge resorption (RRR), which is the outstanding feature of the post-extraction milieu. RRR can result in dramatic morphological changes in the edentulous jaw with changes in the maxilla-mandibular relationship, and changes in muscle attachments and sulcus depth. Changes in form may be due to RRR, but changes in function are derived mainly from loss of the periodontal ligament. The periodontal ligament has a pivotal role in supporting and retaining the natural dentition in bone, as well as having important neurosensory inputs into masticatory control. Hence, ligament loss results in a very significant functional deficit. This deficit is most obvious in the mandible. Here the denture bearing area is approximately half that of the maxilla and continuing bone loss produces a dramatic decrease in denture support and retention and

superficial muscle attachments undermine denture stability. Thus, the successful restoration of the edentulous mandible presents one of the great challenges in clinical dentistry.

The rationale for treatment of the edentulous mandible is the restoration of form, essentially by compensating for the loss of teeth and the ravages of RRR, and the restoration of function, essentially by compensating for the loss of the periodontal ligament. Whereas the loss of form can largely be restored with porcelain and acrylic, the restoration of function has proven to be much more problematic.

Contemporary treatments of the edentulous mandible which seek to restore function may be classified into three categories: conventional removable denture treatment on an existing tissue foundation, conventional removable denture treatment on a surgically improved tissue foundation, and removable and fixed denture treatment on an implant foundation.

Conventional removable denture treatment on an existing tissue foundation relies heavily on denture support, stability and retention for satisfactory function. Unfortunately, two factors militate against this triad of denture elements so important to function. The first factor is ongoing RRR. Regardless of how well a denture is fabricated ongoing RRR will insidiously undermine the denture foundation. The second factor is the mucosa. In the dentate, the medium by which bone provides support, stability and retention is the periodontal ligament, whereas in the edentulous it is the mucosa. Where the ligament is resilient enough to withstand the functional load, very often the mucosa is not. Hence, conventional denture therapy may restore adequate form but often it cannot restore adequate function.

Although clinical experience demonstrates that most patients can cope with conventional removable dentures, this is more a testament to their stoicism than to the adequacy of their prostheses. All edentulous patients realise the functional deficiencies of their dentures and many remain actively dissatisfied with conventional therapy.

The desire to overcome the functional deficit has seen major developments in preprosthetic surgery, particularly in the use of implants.

Augmentative treatment whether relative, absolute or both can improve the denture foundation but does not change the load bearing status of the mucosa. Although augmentation can improve ridge form, jaw relations and soft tissue profiles, a number of problems especially relapse and neurosensory loss limit its routine prescription. Augmentation can restore form by compensating for bone loss but does not address the problems of continuing RRR and loss of the periodontal ligament. Hence, functional improvements after enlargement of the denture foundation are generally marginal.

Implant therapy can largely compensate for the loss of the periodontal ligament and help prevent ongoing RRR. Complication and failure rates are much lower than for reconstructive preprosthetic surgery and generally the surgery is less traumatic.

Dental implants have a long and controversial history and it is only in recent times that this treatment modality has been accepted into the mainstream of dental practice. The acceptance of implants as an efficacious prosthodontic therapy has in large part been due to the discovery and development of osseointegration by Professor P. I. Branemark. Based on 30 years of clinical research osseointegration does appear to provide predictable and long term implant success.

The use of implants overcomes the two fundamental problems of conventional denture treatment. RRR is stabilized by implant use and so intra- and extra- oral form are preserved. Secondly, the implant becomes the means by which bone supports the functional load and so the mucosa is unloaded. Further, because the implant is fixed in bone it can provide the necessary prosthetic stability and retention required for satisfactory and comfortable function. Although the implant cannot compensate for the neurosensory deficit caused by ligament loss, studies on masticatory efficiency have shown that the chewing ability of patients with implant

supported prostheses approaches that of the dentate and is much superior to that of complete denture wearers. Hence, the implant is a very adequate replacement for the periodontal ligament providing the necessary prosthetic support, stability and retention for satisfactory function.

There are two broad categories of prosthesis available for use with implants in the treatment of the edentulous: the implant borne prosthesis and the implant and tissue borne prosthesis. Totally implant borne prostheses, whether fixed or removable, completely unload the mucosa. The success of implant borne prostheses is well substantiated in the literature with minimal bone loss in the underlying jaw after loading, considerable improvements in function, and importantly, high patient satisfaction. Although these treatments are very successful, they are also complex and expensive. For a large proportion of the edentulous group, i.e. the economically disadvantaged, such treatments are often out of reach. For this group a simpler and less expensive implant option is required. The simplest and perhaps least expensive option for the troublesome edentulous mandible is the two implant retained overdenture. This is an implant and tissue borne prosthesis.

Present Study

The efficacy of the implant and tissue-borne mandibular prosthesis is not well established in the long-term. Reports on efficacy, simplicity and cost-effectiveness of the treatment are somewhat contradictory with some studies noting good clinical success for a simple and relatively inexpensive restoration, whereas others record reservations about long-term efficacy and cost-effectiveness considering ongoing bone resorption and maintenance problems.

The objectives of this study were to assess the efficacy of mandibular overdentures retained by two endosseous implants and to compare three overdenture retention systems.

The efficacy of implant overdenture treatment was evaluated by a patient and clinical assessment of denture function, comfort and retention, and an assessment of peri-implant tissue health including: plaque, calculus and gingival bleeding indices; crevice depth; implant mobility and radiographic changes in bone.

The three retention systems were compared with respect to patient and clinical assessments of denture function, comfort and retention.

The null hypothesis for the study states that, "There is no perceived improvement in mandibular denture function, comfort and retention provided by the use of two Integral implants and overdenture attachments, and that there is no difference in using either clip, O-ring or ball attachment systems".

Within the constraints of a study with a sample size of 24 patients followed up for 18 months only the results demonstrate that a two-implant retained overdenture can provide significant improvements in denture function, comfort and retention. Of the attachments systems used (clip, O-ring and ball) no one was superior to any other. The study also demonstrated that overdenture treatment can result in high levels of prosthetic maintenence due to ongoing ridge resorption and support problems.

Twenty three of the 24 implants placed were still functioning at the end study and were generally in good health with favourable gingival bleeding, crevice depth and tissue height indices, negligible mobility and minimal bone loss.

CONTENTS

LIST OF FIGURES

LIST OF TABLES

1. INTRODUCTION

1.1 Historical Perspective

Since the beginning of man the loss of teeth has seemed an inexorable result of the life experience. Whether through oral disease such as caries or periodontitis or through trauma, accidental or induced, very few humans have lived a long life without losing teeth.

The problem of replacing teeth vexed the minds of our ancestors as much as it does that of the modern dental practitioner. In their texts on the history of dentistry, Hoffmann-Axthelm (1981), and Ring (1985), trace the development of prosthetic reconstruction including many examples of ingenious and skillfully crafted dental prostheses from ancient times.

With a life expectancy in ancient times of approximately half that of the biblical three score and ten years, most individuals died in at least a partially dentate state. Hence, most of the early examples of tooth replacement utilized remaining teeth as abutments in some form of bridgework. An exception to this mechanistic approach was found in Honduras in 1931. Three pieces of shell were embedded in the mandible to restore missing incisors. Dated to about 600AD, it is the earliest evidence of attempts at endosseous alloplastic implantation.

The rationale for tooth replacement in the ancient world was mainly aesthetic rather than functional for most of the prostheses that have survived from that period restore anterior spaces. Further, there is no mention of prosthetic reconstruction in the comprehensive medical literature of antiquity, although other dental problems are covered widely. Hence, the denture was not considered a functional device but rather the product of artisans, essentially for adornment.

It was not until 1692 and the publication of Professor Antonius Nuck's work 'Operationes et Experimenta Chirurgica' that function, specifically mastication, appears in the

literature as a rationale for edentulous reconstruction. In addition to extolling the virtues of hippopotamus teeth as a base material for denture construction, Professor Nuck stated that "if all the teeth are missing in the mandible, a one piece row of teeth should be carved and inserted in such a fashion that it moves together with movements of the mandible, and thus grinds the size of food in the mouth". This is the first mention in the dental literature of the prosthetic management of the edentulous mandible, and corresponds with the rise of edentulism in Europe.

The Renaissance renewed the process of objective assessment of the natural world begun by the Greeks. With advances in anatomical knowledge, surgery became an important treatment modality for many afflictions. Aided in part by the carnage of European wars, the skill of surgeons improved greatly in the 15th and 16th centuries. The rise of surgery with improvements in technique and instrumentation heralded a new era in the dental condition of Homo Sapiens, for the incidence of edentulism began to increase rapidly as the popularity of tooth extraction as a treatment for dental malaise increased. As far back as the 1430's Savonarola in his remedies of the carious tooth had warned against "rash and foolhardy operators who always want to pull teeth immediately". Unfortunately, although other treatment modalities existed they were limited and of no real value.

Edentulism was then, and remains today, a significant social problem. The solution to this problem has evolved as prosthetic techniques, and perhaps more importantly, prosthetic materials have improved over the centuries.

1.1.1 Technique

Pierre Fauchard is considered the father of modern dentistry. His two volume work 'Le Chirurgen Dentiste, on Traits des Dents' was the first useful textbook devoted entirely to dentistry. His writings on prosthetics were comprehensive and detailed, so much so, that

Fauchard believed they were detrimental to his own financial interest as a practising dentist. He advocated the use of human teeth, ivory, hippopotamus bone and walrus tusks in prosthesis construction. The dentures he made either rested by their own weight on the lower jaw or were retained by spring devices. Fauchard's denture base, like the teeth, were non-anatomical and so did not conform to the tissues of the jaws. It was not until the publication of "Abhandbing vond den Zahren" (Treatment on the Teeth) by Phillip Pfaff in 1756 that an impression technique for recording the anatomy of the jaws was described. Pfaff used sealing wax softened in hot water for his impression and also took a check bite by having the patient bite into the wax if any natural teeth remained. Thus, this was also the first description of an occlusal record. Pfaff poured his wax impressions in plaster and used this model to fabricate his dentures. Not until 1820 when Delabarre recommended the use of impression trays was Pfaff's method bettered.

Better impression methods led to the next great advance in prosthetics, although it occurred more by serendipity than science. In the late 18th century the move westward to North America was gaining momentum. One emigrant from France, Jacques Gardette, a former naval physician, settled in Philadelphia in 1784. In the earlier 1800's he constructed a full upper denture for a female patient but did not add the usual supporting springs to the mandible because the patient wanted to accustom herself to the prosthesis first. He did not see the patient until some months later and was surprised to see the denture firmly in place. His son Emil reported "the principle upon which the artificial piece thus adhered to the gums at once suggested itself to his mind, and suction, or atmospheric pressure was henceforth depended upon in numerous cases of the same kind." One imagines he had less success with mandibular prostheses. Nevertheless, the principle of 'suction' and hence accurate and optimal tissue coverage had been established.

Although Pfaff was the first to suggest a bite registration be used in the fabrication of dentures eighty four years passed before James Cameron, a Philadelphian, patented the first dental articulator for mounting models using such a registration. Whereas Cameron's articulator allowed only hinge movements, an articulator patented later the same year by Daniel T. Evans provided for lateral and forward movements. The first truly useful articulator was made by William Arlington Gibson Bonwill, yet another Philadelphian, in 1864. Based on a balanced three-point contact occlusion it set the standard for all articulators that followed.

1.1.2 Materials

Ivory, bone, wood and of course human teeth had been used as prosthetic materials since ancient times and continued in use well into the 19th century. Human teeth were harvested from hospitals, cemeteries, executioners and chiefly, the battlefield. Indeed, up to the Crimean War of 1853-56 'battlefield hyenas' were still active. Discolouration and odour were major problems with the porous materials and all being organic they suffered the same fate as their predecessors and decayed or decomposed on prolonged exposure to the oral environment.

The first reported artificial mineral teeth were manufactured for a Parisian apothecary, Alexis Ducharteau in 1774. Although he successfully made and was satisfied with his own porcelain prosthesis he could not repeat that success for others and the porcelain denture lapsed into oblivion for 12 years. In 1788, just one year before the French Revolution began another Parisian, Nicolas Dubois de Chemant, resurrected Duchateau's idea and claimed it as his own. In 'Dissertation sur les Avantages des Nouvelles Dents ets Nateliers Artificials' (A Dissertation on Artificial Teeth) he describes his porcelain dentures as 'incorruptibles et sans odeur' (imperishable and odourless) and a major advance on the decomposing and smelly prostheses of bone or ivory and natural teeth. Dubois' 'incorruptibles' combined advances in

dental materials with advances in the prosthetic techniques of impression taking and use of plaster models. Thus fabricated, these prostheses did indeed withstand the rigours of the oral cavity better than any previous denture.

Porcelain teeth were first fired in North America in 1817. However, it was a Philadelphian jeweller Samuel Stockton who first produced the teeth in large numbers. Starting in 1825 he was soon manufacturing half a million teeth a year and was forced to take on two nephews as assistants. Samuel Stockton White served a six year apprenticeship at six dollars per week but left the business when his request for a raise of one dollar per week was refused by his uncle. He began producing his own improved teeth in 1844 founding the SS White Company which still serves dentistry today. Another company of that era which survives to this day is the British firm Ash, Sons and Co. Founded by Claudius Ash in 1837, the company was the first to produce truly high quality artificial teeth. The Ash and SS White companies monopolised the world market in artificial teeth until the end of the 19th century.

With the mass production of artificial teeth the only obstacle that stood in the way of an affordable, aesthetic and long-lasting prosthesis was a cheap durable denture base. Ivory and bone were organic and porous thus caries and odour were a problem. Guillemeare had recommended a plastic material made from wax, olive tree resin, martix powder, ground coral and pearls. Whether this material could have resisted mastication is questionable, however, it is the first known attempt to replace bone and ivory as base materials. Despite such attempts hippopotamus teeth remained the preferred base and as late as 1861 no fewer than 1,100 of these creatures were slaughtered each year to supply the denture market. Fortunately, salvation for the hippopotami was at hand for in 1851 Charles Goodyear succeeded in hardening the resin of the rubber tree and by 1864 the Goodyear Dental Vulcanite Company was founded. The material was durable but not cheap for the company mercilessly exacted a licence fee from any dentist who used the product. This lead to the sensational murder of the

company treasurer, Josiah Bacon in 1879. Bacon had pursued a dentist who refused to pay the licence fee, Samuel Chalfant, through three states. Finally tracked down to San Francisco, Chalfant was hauled before the courts and humiliated by Bacon. Driven to distraction by Bacon's vows to destroy him, Chalfant shot the treasurer in a hotel. From that time the company took a more tolerant view of non fee-paying dentists and by 1881 American dentists were able to use Vulcanite without paying a licence fee..

Other materials such as colloidin (1859), aluminium (1866), celluloid (1870), and vinylite (1932) were tried as denture bases but only the methacrylic esters were able to endure. Developed by Walter Bauer in Germany in the 1920's the methacrylates were first marketed in England in 1935. By 1936 the Kulzer Company had produced a liquid-powder system that soon dominated the market. Methyl methacrylate continues to this day as the dominant denture base material.

These advances heralded the modern era with modern dental materials of acrylic and porcelain and modern techniques for recording jaw form and function.

The materials and techniques of traditional and indeed contemporary denture therapy struggle to compensate for the loss of teeth, so great are the changes that occur when a jaw is rendered edentulous. These changes can be particularly severe in the lower jaw and make successful restoration of the edentulous mandible one of the most difficult of clinical problems to solve.

2. THE EDENTULOUS MANDIBLE-

THE PROBLEM

The restorative problem with the edentulous mandible is that when the permanent dentition is lost the changes which occur can be so profound as to render prosthodontic treatment palliative rather than curative. Because they impact so heavily on treatment outcomes a short review of these changes is warranted.

The extra and intra-oral changes can be broadly categorized into changes in form or morphology and changes in function or neuromuscular activity. Whereas changes in neuromuscular activity occur principally due to loss of the periodontal ligament on extraction of teeth, changes in morphology occur after teeth extraction due to resorption and remodelling of bone. This resorptive and remodelling process is the most dramatic feature of the post-extraction milieu.

2.1 Residual Ridge Resorption (RRR)

RRR is a chronic, cumulative, localized disease of bone remodelling. The rate of RRR varies not only between individuals but within the same individual at different times. The residual alveolar ridge undergoes continual internal and external remodelling after the extraction of teeth. This remodelling inexorably reduces the size of the ridge (most rapidly within 6 months to 2 years post extraction) continuing on throughout life and resulting in the loss of vast amounts of jaw structure (Tallgren, 1972).

As dentures rely on the bony support of the residual ridge for stability, retention and comfort, the continuing loss of bone means that even well made dentures will in time become unsatisfactory and require replacement. Kalk et al. (1990) estimate the incidence of edentulism in most populations is between 10-20 per cent. Thus, there are hundreds of millions of

individuals throughout the world who suffer the consequences of what Atwood (1971) terms 'this major oral disease entity'.

Edentulism, as discussed, began to rise in the 1700's as the incidence of caries increased, and surgical technique and instrumentation improved. Hence, for over 200 years RRR has been growing towards its present status as a 'major disease entity'. It is therefore surprising that the true cause of RRR is still not known. Atwood (1979) states "...the cause of RRR is either a factor not yet fully elucidated or else a combination of several factors: i.e. a multifactorial disease." Among the factors indicated in this process are local factors such as excessive loading from dentures, biochemical resorptive agents triggered by micro-organisms and the availability of viable bone cells. Systemic factors such as hormonal excess or deficiency are also known to contribute.

2.2 Morphological Changes

The morphological changes that result from RRR occur both outside and inside of the mouth. Extra-orally, changes in facial support and rest height, and changes in the temporo-mandibular joint (TMJ) may be evident. Intra-orally, changes in jaw anatomy and jaw relations, muscle attachments, sulcus depth, tongue size as well as mucosal changes can occur.

2.2.1 Extra-oral

Facial Support

The loss of support afforded by the dentition has a marked effect on facial appearance. Involution of lips and cheeks together with deepening of nasolabial grooves, loss of labio-mental angle, decrease in horizontal labial angle and a narrowing of the lips, all combine to produce the typical appearance of premature ageing seen in the edentulous individual (Scher, 1979).

Rest Face Height

Tallgren (1967) showed that after the extraction of teeth, face height decreased due to residual ridge resorption (mainly in the mandible) with a resultant forward and upward mandibular rotation producing prognathism. This study supported earlier work which showed that face height was not a constant, but adaptable to changes in occlusal height (Atwood, 1956). Hence, on removal of teeth a marked decrease in face height can occur.

Temporomandibular joint

Structural alterations can take place in the TMJ throughout life with the articular surfaces undergoing a slow and continuous remodelling. Zarb and Thompson (1970) demonstrated that degenerative changes in the joint due to dysfunction can occur in the edentulous as well as the dentate individual. Oberg et al. (1971) indicated that such degenerative joint changes were more common in denture wearers.

2.2.2 Intra-oral

Ridge anatomy

Cawood and Howell (1991) derived a pathophysiological classification of alveolar anatomy based on the study of 300 dried skull (Figure 1). The six anatomical classes were described as:

Class I	-	dentate.
Class II	-	post extraction.
Class III	-	rounded ridge, adequate height and width.
Class IV	-	knife edge ridge, adequate height, inadequate width.
Class V	-	flat ridge, inadequate height and width.
Class VI	-	depressed ridge with varying degrees of basal bone loss, that may be extensive but follows no predictable pattern.

The main conclusions arising from this study were:

- Basal bone does not change shape significantly unless subjected to harmful local effects such as the overloading of ill-fitting dentures.
- Alveolar bone changes shape significantly.
- In general, changes of shape of the alveolar bone follow a predictable pattern.
- The pattern of bone loss varies with site. Anterior mandibular (anterior to mental foramina) bone loss is mainly horizontal from the labial aspect. Posterior mandibular (posterior to mental foramina) bone loss is mainly vertical.
- Anterior maxillary bone loss is mainly horizontal from the labial aspect. Posterior maxillary bone loss is mainly horizontal from the buccal aspect.
- Stage of bone loss can vary anteriorly and posteriorly and between jaws.

A classification of ridge anatomy widely used in the implant literature was proposed by Lekholm and Zarb (1985). They suggested five groups of residual jaw shape or bone quantity and four groups of residual jaw bone quality (Figures 2a and b).

Bone Quantity:

A. Most of the alveolar ridge is present.

B Moderate residual ridge resorption has occurred.

C Advanced residual ridge resorption has occurred and only basal bone remains.

D Some resorption of the basal bone has started.

E. Extreme resorption of the basal bone has taken place.

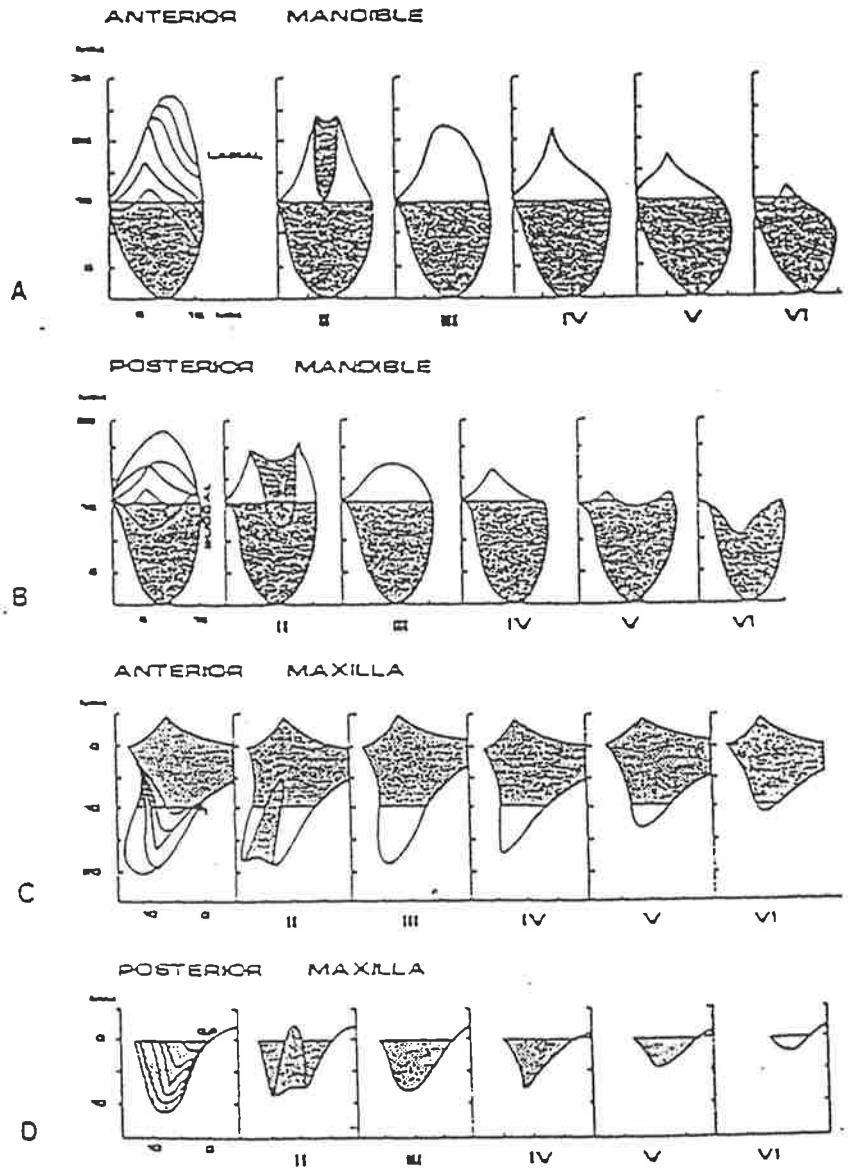
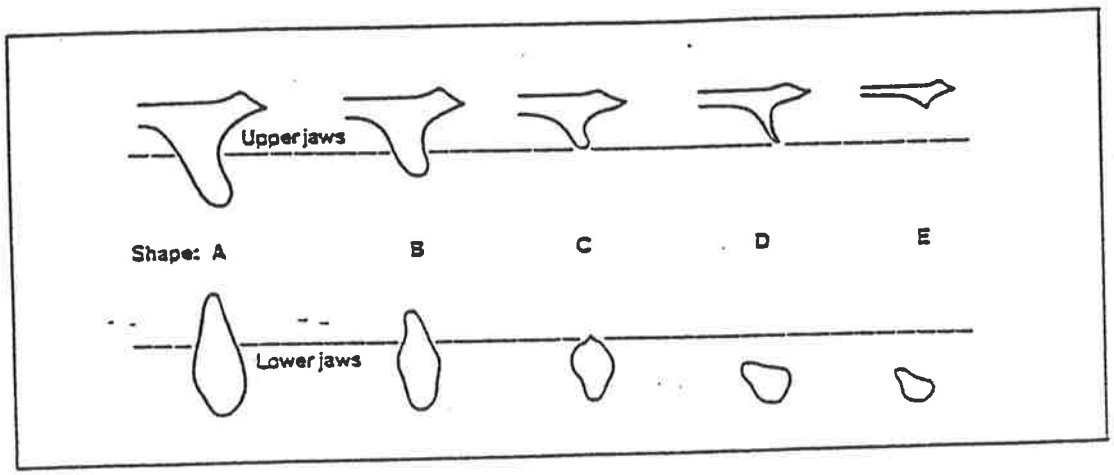


Figure 1. Classification of alveolar resorption in the edentulous jaws (Cawood & Howell, 1991).



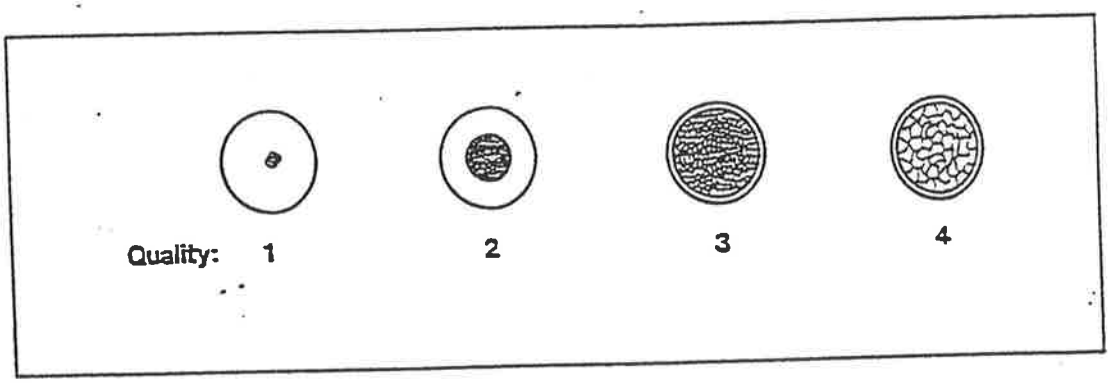


Figure 2a and b. Classification of residual jaw bone quantity (top) and quality (bottom). The dotted lines indicate the approximate demarcation between alveolar and basal bone (Lekholm and Zarb, 1985).

Bone Quality:

1. Almost the entire jaw is comprised of homogenous compact bone.
2. A thick layer of compact bone surrounds a core of dense trabecular bone.
3. A thin layer of compact bone surrounds a core of dense trabecular bone of favorable strength.
4. A thin layer of cortical bone surrounds a core of low density trabecular bone..

In the edentulous mandible, apart from an overall loss of bone mass, RRR may result in sharp and uneven residual ridges, prominent mylohyoid ridges, and prominent genial tubercles.

Inter-arch Changes

These changes may be summarised as:

Sagittal changes	-	maxillary and mandibular arches become shorter.
Coronal changes	-	maxilla becomes narrower and mandible becomes broader producing a reverse overjet.
Vertical changes	-	inter-arch distance increases but a shortening of the lower face by auto-rotation of the mandible compensates and produces a prognathic jaw.

Muscle Attachments

RRR results in muscle attachments becoming more superficial as demonstrated in Figure 3.

Sulcus Depth

As the height of the residual ridge decreases and muscle attachments become more superficial the sulcus depth becomes less.

Mucosal Changes

Qualitative and quantitative changes occur in the mucosa of the edentulous patient. Cawood and Howell (1988) have shown that between Class I and Class VI there is a significant decrease in the amount of attached and unattached gingiva.

Qualitative changes in the epithelium include greater acanthosis, elongated rete pegs, parakeratosis and/or increased non-keratinization. Connective tissue changes essentially involve a thinning with increased density of crestal tissue. The response of these tissues to

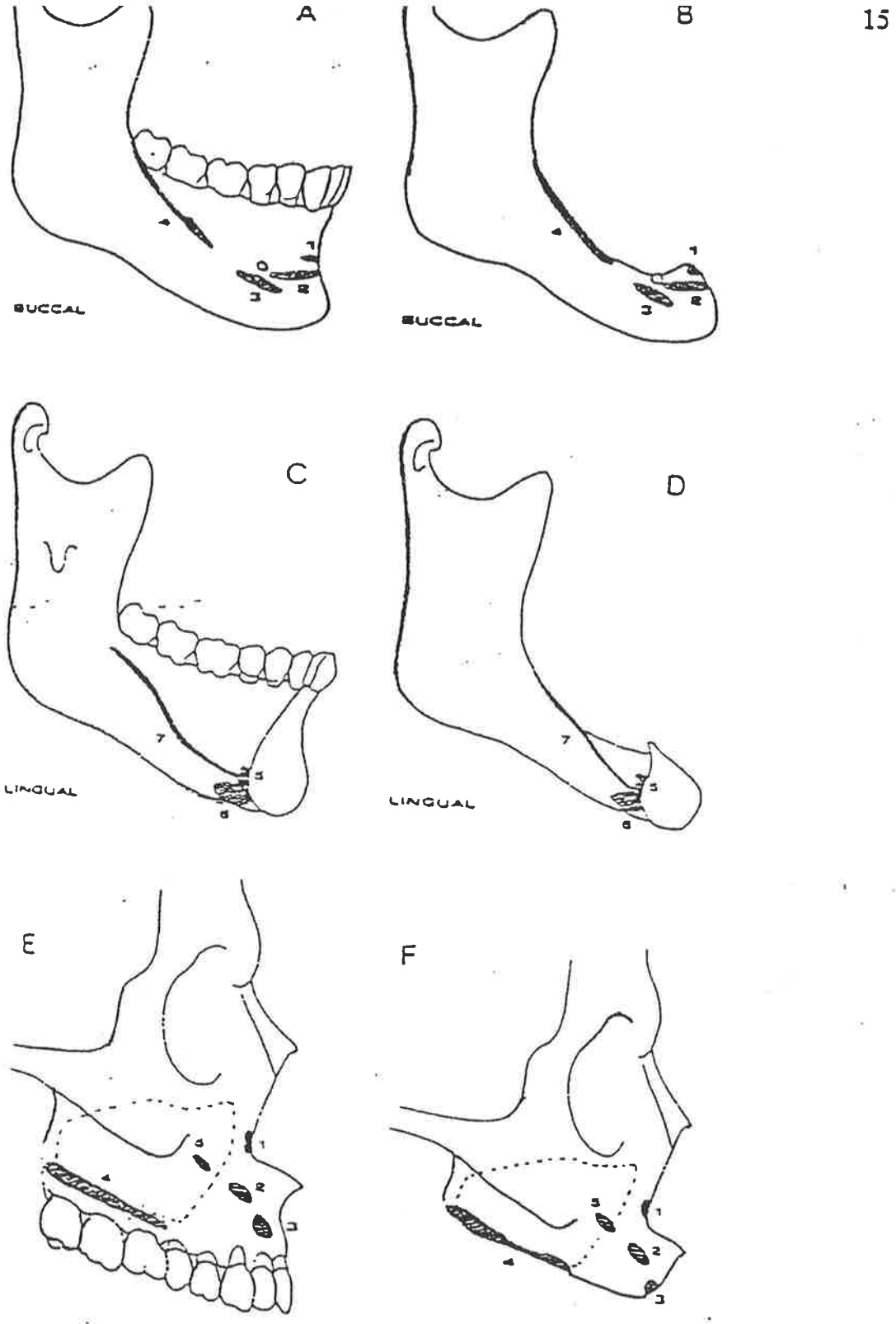


Figure 3. Attachment of the circum-oral and floor of mouth musculature, showing how they become increasingly superficial as bone loss progresses. A: dentate mandible (Class 1), buccal aspect; B: edentulous mandible (Class V), buccal aspect: 1-mentalis, 2-depressor labii inferioris, 3-depressor anguli oris, 4-buccinator; C: dentate mandible, lingual aspect; D: edentulous mandible, lingual aspect: 5-genioglossus (superior) and geniohyoid (inferior), 6-digastric (anterior belly), 7-mylohyoid. E: dentate maxilla (Class 1), buccal aspect; F: edentulous maxilla (Class V), buccal aspect: 1-dilator naris, 2-compressor naris, 3-depressor septi, 4-buccinator, 5-levator anguli oris (Cawood & Howell, 1991).

denture wearing is contentious. Krajicek et al, (1984) in a histological study of 37 autopsy cases could find little difference in the epithelium, connective tissue and bone of denture and non-denture wearers. Kapur and Shklar (1963), and MacMillan (1972), maintained that the tissue response to dentures is an individual one and need not necessarily be degenerative. Other authors (Ostlund, 1958; Boucher et al, 1975) believe mucosal changes border on the pathologic but without obvious inflammation. Hence, as with RRR, individual variation is large with some mucosal tissues exhibiting little change on loading while others show degenerative change.

Enlarged Tongue

Muscular hypertrophy of the tongue is a common sequela of patients who have been without dentures for a long time. The tongue, no longer bounded by teeth and taking on more of the masticatory load, enlarges (Boucher et al, 1975).

2.3 Neuromuscular Changes

The sensory innovation of the periodontal ligament, the mucosa, the muscles of mastication and tongue, and the temperomandibular joint are all important in the process of perception which assists oral function (Crum and Loiselle, 1972). Although changes in the mucosa, muscles and TMJ will affect the perceptive input in the edentulous case, the loss of the periodontal ligament has by far the greatest effect. The loss of the ligament with its proprioceptive feedback mechanism results in the loss of dimensional proprioception (Kawamura and Michman, 1960) and tactile sensitivity to load (Wilkie, 1964). The loss of proprioception also results in decreased accuracy of closure (Mohl and Drinnan, 1979). Further, mandibular displacement and velocity are decreased resulting in diminished masticatory function (Karlsson, 1979; Jemt, 1981). The periodontal ligament is also the means

by which the teeth are supported by and retained in bone. Hence, loss of the ligament has severe repercussions on dentition support and retention as well as neuromuscular control.

In summary, profound changes occur on edentulism. Changes in form come about due mainly to RRR. Extra-orally there is a collapse in facial height and contour. Intra-orally, ridge height and form is diminished, jaw relations change, muscle attachments become more superficial, sulcus depth decreases, the tongue may enlarge, and the quantity and quality of the mucosa may be compromised. Changes in function come about due mainly to the loss of the periodontal ligament. Loss of support and retention together with decreased mandibular velocity and displacement, accuracy of closure and sensitivity to load combine to produce a significant impairment in oral function.

3. THE EDENTULOUS MANDIBLE-

THE SOLUTION

How then do we compensate for the loss of teeth and the profound changes that result? Is a cure possible or is palliation the reality?

Historically, the restoration of form was the priority with less emphasis on function. The production of porcelain and acrylic teeth in a multitude of shapes, sizes and shades together with a tinted denture base of methyl methacrylate largely solved the problem of providing an aesthetic prosthesis. Further, these materials in compensating for the loss of teeth and supporting tissues could restore facial contour and occlusal vertical dimension. Hence, the problem of restoring form was mostly solved early this century. The restoration of adequate and comfortable function has proven a much more difficult problem to solve and though recent developments offer real promise, many questions remain as to their long term efficacy.

Contemporary treatments of the edentulous mandible which seek to restore function may be broadly classified into three categories: (1) conventional removable denture treatment on an existing tissue foundation, (2) conventional removable denture treatment on a surgically improved tissue foundation, and (3) removable and fixed denture treatment on an implant foundation.

3.1 Removable Denture Treatment on an Existing Tissue Foundation.

It is not intended in this introduction to give a detailed account of the techniques for traditional denture treatment of the edentulous mandible. Rather, a brief synopsis of the guiding treatment principles is appropriate. The principles which ensure functional success in complete denture therapy relate to a triad of denture factors namely: support, stability and retention. This precis is based on the review Jacobsen and Krol (1983).

3.1.1 Denture Support

Support is the resistance to vertical movement toward the ridge. In the dentate, bone provides support via the periodontal ligament. In the edentulous, bone provides support via the mucosa. Thus, denture support is a function of the resistance and resiliency of the tissues loaded in denture use.

In the mandible the primary stress bearing areas are the buccal shelf and the pear-shaped pad. This pad is formed after the most distal molar is extracted and is the most distal extension of the keratinized masticatory mucosa. The mandibular residual ridge crest is generally reserved as a secondary stress bearing area due to the presence of cancellous bone and the often profound resorptive changes that occur in this region. The lingual and anterior ridge slopes do not usually contribute to denture support as the alveolar mucosa in these regions is thin and does not tolerate pressure well. Finally, the area overlying the mental nerve should not be loaded if neural dysaesthesias are to be avoided. Hence, good denture support can be achieved by using impression techniques which accurately record those tissues most able to tolerate functional loading without discomfort.

3.1.2 Denture Retention

Retention is the resistance to displacement away from the ridge. In the dentate, the periodontal ligament provides tooth retention. In the edentulous, denture retention is provided by physical factors and neuromuscular control. A denture that is easily unseated during mastication or speech can be a great embarrassment to a patient. Thus, retention is important for the psychological comfort of the patient.

Commonly listed physical factors important in retention include: adhesion, cohesion, surface tension, gravity, intimate tissue contact, border seal, and atmospheric pressure. These

physical factors are of more significance in the maxilla due to the greater surface area involved. Achieving adequate physical retention with the mandibular prosthesis is usually a major problem. A movable floor of mouth, tongue and jaw reduce the border seal achievable, and a small surface area limits the possible retentive effects of atmospheric pressure. Although physical factors are important in denture retention, by far the most important factor is neuromuscular control.

Brill et al. (1959) demonstrated a dramatic decrease in mandibular denture retention when the oral mucosa of experienced denture wearers was anaesthetized. Neuromuscular control is so important because it becomes the dominant retentive factor over time. In a new or rebased denture intimate tissue contact is achievable and so physical retention can be high. However, as the supporting tissues change over time this contact diminishes and so does good physical retention. Fortunately, during this period most patients develop the neuromuscular skills which provide long term retention of their denture prosthesis. For those patients with poor neuromuscular control, a lack of adequate denture retention can be a serious and embarrassing problem.

3.1.3 Denture Stability

Stability is the resistance to horizontal and rotational forces. In the dentate, bone via the ligament provides stability. In the edentulous a number of factors are involved including:

- The relationship of the denture base to the underlying tissue,
- The relationship of the denture external surface and border to surrounding orofacial musculature,
- The relationship of the occlusal surface to the underlying ridge and opposing teeth, and
- Neuromuscular control

Relationship of Denture Base to Tissues

Optimal stability can only be achieved when those tissues that best resist horizontal forces are properly recorded and related to the denture bases. Boucher et al., (1975) emphasise that the maximum use of all bony foundations where the tissues are firmly and closely attached to bone, particularly those at right angles to the occlusal plane, will achieve stability. In the mandible these areas are the lingual slope and residual ridge. As the lingual slope of the mandible approaches 90 degrees to the occlusal plane it is very effective in resisting destabilizing forces. Thus maximum flange extension in this area is a priority and should be accommodated by appropriate impression techniques. The functional mobility of the floor of the mouth limits the stabilizing potential of this region as does the nature of the alveolar mucosa. Thin and intolerant to pressure, the mucosa often requires relief and so intimate tissue contact may be lost and stability decreased.

The stabilizing effect of the residual ridge depends on ridge arch form, shape and height. Arch forms that are square or tapered resist rotation better than ovoid arches. Ridges that are large, square and broad resist lateral forces better than small, narrow and tapered ridges.

Relationship of External Surface and Border to Orofacial Musculature

This relationship can either diminish or enhance denture stability. The polished denture surface should freely accommodate the musculature of the tongue, lips and cheek as this relationship is crucial to denture stability. Moreover, proper muscle molding at the final impression will ensure optimal border extension with no encroachment on muscle attachments which may lead to denture dislodgement.

The principle of a harmonious balance between denture surfaces and orofacial musculature has been termed the neutral zone concept. This concept proposes the dentures (teeth and base) be positioned in a functionally generated neutral zone where the muscular forces of the lips, cheeks and tongue are balanced and hence stability enhanced. Although a prosthesis which is functionally rather than anatomically positioned may have enhanced stability, an aesthetically compromised restoration may result. This may be particularly so where RRR has been extensive and placement of the arch in the neutral zone leaves it some distance from the position once occupied by the natural arch.

Relationship of the Occlusal Surfaces

Denture occlusions may be balanced or not. An occlusion balanced throughout excursive movements seeks to minimize dislodging forces by ensuring multiple points of contact distribute the functional load. An unbalanced occlusion seeks to minimize denture dislodgement during unilateral excursive tooth contacts by directing forces towards the ridges. For example, some monoplane occlusal schemes position 0-degree teeth slightly lingual to the mandibular ridge to direct forces to the lingual side of the lower ridges during working side contacts.

Neuromuscular Control

Neuromuscular control is crucial not only to denture retention but also to stability. Every dentist has experienced the patient who has functioned satisfactorily with old, ill-fitting and unstable dentures. Such patients learn to alter their muscular function to accommodate a poorly fitting prosthesis. Oral sensory perception and motor coordination differ among patients, with some able to develop the conditioned reflexes to manipulate even an unsatisfactory prosthesis while others cannot control the best made dentures. Certainly age is

a factor with Brill et al, (1960) demonstrating that older patients have more difficulty adjusting to new complete dentures. This probably results from progressive cerebral atrophy and highlights the importance of central mechanisms in neuromuscular control.

In summary, denture stability is dependent on: tissue factors such as mandibular ridge and muscular anatomy; denture factors such as flange design and occlusal schemes; and finally and most importantly, neuromuscular control.

Although clinicians have been generally successful in treating the edentulous patient with complete dentures there is still a significant number of patients of all age groups who remain dissatisfied with removable prostheses (Agerberg et al. 1981; Blomberg, 1985; Weinstein et al. 1988). This dissatisfaction is generally related to function and comfort rather than appearance (Gordon et al. 1988). Misch and Misch (1991) surveyed denture satisfaction in 104 patients seeking implant treatment. Approximately 80 per cent expressed general satisfaction with their existing prostheses. However, when more specific questions on denture function and comfort were asked satisfaction rates dropped. Only 49 per cent of patients were satisfied with masticatory ability and 62 per cent had some problems with speech. Stability was considered satisfactory in 65 per cent of maxillary dentures compared to only 38 per cent of mandibular dentures. Finally, 68 per cent of upper dentures were comfortable compared to 37 per cent of lowers.

Depletion of the residual ridge, a thin and non-resilient mucosa together with changes in neuromuscular control combine to decrease the necessary support, stability and retention required for long-term successful prosthodontic treatment. Herein lie the two major shortcomings of conventional denture therapy: treatment does not prevent RRR, and the dentition is supported and retained by way of an unsuitable medium - the mucosa.

The most innovative modern techniques which attempt to overcome these shortcomings are surgically orientated. Generally, these pre-prosthetic surgical procedures either enhance the denture bearing areas or make use of dental implants.

3.2 Removable Denture Treatment on a Surgically Improved Tissue Foundation

The aim of reconstructive pre-prosthetic surgery is to improve the effectiveness of prosthodontic treatment. This surgery seeks to reconstruct denture foundations ravaged by RRR. Surgical intervention to improve the denture foundation by increasing surface area and improving surface topography endeavours to improve prosthetic support, stability and physical retention. The tissue foundation can be surgically improved either by relative or absolute enlargement.

A review of preprosthetic reconstructive surgery to enlarge the denture bearing area is outside the scope of this study. However, it is worth noting that the trauma involved in this surgery is significant and the long-term success equivocal. Relapse and neural damage are prime complications with vestibuloplasty and biological augmentations (Tideman et al. 1986; de Koomen, 1977 and 1979), whereas the more successful alloplastic augmentations suffer principally from dehiscence and displacement (Block and Kent, 1984; Peterson, 1987). Significantly, post-operative patient satisfaction and functional ability is not well reported in the literature and one suspects improvements in these parameters may not be great. This should not surprise, for although these surgical techniques will enable the fabrication of a superior denture, there are many studies which report that clinically improved dentures do not necessarily result in improved oral function (Jemt and Karlsson, 1980; Gunne et al. 1982; Lindqvist et al. 1985). Augmentation, like conventional therapy, does not prevent ongoing RRR nor does it change the means by which the functional load is accommodated. Essentially, it is because the mucosa is not a good medium for support, stability and retention that these

procedures meet with such questionable success. Thus, this surgery may well compensate for changes in form in the short- to medium-term, but it cannot adequately compensate for changes in function. As a result, many patients remain dissatisfied with removable prosthodontics regardless of how good the tissue foundation is or how well the prosthesis is fabricated.

3.3 Removable and Fixed Denture Treatment on an Implant Foundation.

If the employment of mucosa and an existing or improved tissue foundation cannot always restore oral function- what can? The functional changes which occur on edentulism are due mainly to the loss of the periodontal ligament. The ligament supports and retains the natural dentition and has an important sensory input into the neuromuscular control of oral function. Thus, compensating for the loss of the periodontal ligament may well solve the problem of restoration of function. Of the contemporary treatments available only implant therapy offers some hope in this regard. Implant therapy is not new, it has a long and often controversial history. Only in recent times have implants been accepted into the mainstream of dental practice.

3.3.1 Historical Overview

As noted in earlier Chapter 1, the first recorded attempts at alloplastic implantation were those of the Mayans in South America at about 600AD. Although transplantation of teeth became popular in the medieval era, alloplastic implantation did not truly begin until the 19th century. Balkin (1988) in an historical review noted the following major developments in endosteal (within bone), subperiosteal (on bone) and transosteal (through bone) implants.

In 1809 Maggilio implanted gold root forms into extraction sockets and after a healing period restored the root with a crown. Harris in 1887 was the first to produce an artificial

socket in which he placed a lead covered platinum post supporting a porcelain crown. Berry in 1888 was the first to discuss biocompatibility of implant materials when he suggested the use of lead over wood, tin and silver because it was considered 'safe' and well tolerated in the body.

Endosteal implantations continued in much the same manner using porcelain, gutta percha, rubber and gold until Greenfield between 1910 and 1913 documented two important developments in technique. In the first carefully documented record of an implant procedure, Greenfield stressed the importance of sterility during implant placement. In addition, he stressed that once his iridio-platinum wire basket implant was placed and splinted it should be left undisturbed and unrestored for a period of between 2 to 3 months to allow bony ingrowth to occur. Thus, Greenfield was the first to record the importance of immobility in the implant, noting that the bony core in the centre of the implant assured solidity. This protocol has an uncanny similarity to the two-stage surgical implant procedures of today.

Leger-Dorez pioneered the use of internal screws in implants when he developed an expandable artificial root implant much like a concrete expansion bolt in 1920.

The 1930's previewed the modern era of implant therapy with the work of Venable, Strock, Dahl, and Gershkoff and Goldberg. In 1937 Venable developed 'Vitallium' a cast cobalt-chromium-molybdenum alloy. This advance in materials science foreshadowed the innovative implant procedures of the following decades.

In the 1940's Strock developed endodontic and endosteal or endosseous implants using Vitallium. Importantly, he also carried out tissue response studies in dogs, noting evidence of bony apposition to the implants. This was the first histological evidence of a physical connection of bone to implant, a phenomenon later to be termed osseointegration by Branemark.

Endosseous implant design rapidly evolved through the 1940's, 50's and 60's. In 1947 Formiggini developed the single helix wire spiral implant of stainless steel or Tantulum. Zepponi improved Formiggini's implant by producing a cast spiral implant and Chercheve introduced a double helix design together with the first proper surgical armamentarium.

The 1950's and 60's were dominated by the work of Linkow. In 1963 he introduced the Vent-Plant implant (Vent-Plant Corporation, Philadelphia, PA, USA), similar in design to the contemporary Core-Vent and ITI Swiss Hollow Basket implants and not dissimilar to Greenfield's 1913 design. Linkow's best known design, the Linkow blade, was the first blade implant developed. Introduced in 1967 the Blade-Vent implant (Ultimatics Inc, Springdale, AR, USA) dominated the market until the early 80's. In 1965 Roberts developed a variation on the endosseous theme with the ramus frame implant for mandibular restoration.

Subperiosteal implants which are placed on rather than in bone were developed by Dahl in Sweden in the 1940's. Gerschkoff and Goldberg pioneered Dahl's method in the United States using a standard jaw impression for frame fabrication. In 1951 Lew introduced the direct bone impression with a two stage surgical procedure. Bodine's butterfly implant of the 1950's began the design trend to greater bone coverage which continued to the 70's with the recommendation of James to use the buccal surfaces of both mandibular rami for framework support. James has also been in the forefront of computed tomography (CT) scanning in subperiosteal therapy. CT scans can be used to generate jaw models thus eliminating the direct bone impression surgical stage.

Transosteal or through bone implants were developed by Small in the mid 1960's. The bone plate and mandibular staple of Small were followed in 1983 by the transmandibular implant of Bosker.

The history of implant dentistry has not been without controversy. Most of the early work in the field occurred outside of academic institutions in the area of private practice and

was considered 'fringe' dentistry. Those practising implantology were often severely criticized by other members of the profession for placing devices which had not undergone adequate developmental nor biological investigation in controlled animal and human trials. Thus, Zarb (1983) stated "...many patients have suffered unnecessarily from the well intentioned application of human experimentation without genuinely informed consent".

In 1978 the NIH-Harvard Conference reviewed the popular implants of the day and attempted to form a consensus on implant efficacy (NIH-Harvard Consensus Development Conference). A strategy for introducing a disciplined approach to implant evaluation was proposed and included:

- a definition of success and efficacy including subjective and objective criteria, and
- four categories for implant adoption :
    - unrestricted use
    - use with guide-lines
    - clinical trials use
    - human application contraindicated

The conference concluded that on the basis of the data presented none of the implants evaluated could justify an 'unrestricted use' classification. This finding reinforced the views of many that implant therapy was not a valid treatment modality and did indeed amount to human experimentation.

Unfortunately this conference did not review the work of Per-Invar Branemark published the previous year. Based on 26 years of scientific and clinical research, Branemark's 1977 watershed publication introduced the concept of osseointegration - a concept that was to revolutionize implantology and finally bring implants in from the cold (Branemark, 1977). With the reporting in 1981 of 15 year results on a sample of 2768 implants placed into 410 jaws of 371 patients, a review of the Branemark implant became a priority (Adell et al. 1981).

Zarb (1983) introduced the Swedish research to collective scientific scrutiny in Toronto in May 1982.

The Toronto conference stimulated tremendous interest in implants, and with the growth of the science of biomaterials, implant usage exploded in the late 1980's and early 1990's. In 1985 the estimated number of implants used in the US was 24,500 by 1990 this had reached 65,000 and by 1992 the estimate was 300,000 placements per year (Worthington, 1988).

The concept of osseointegration has led this phenomenal surge and has spawned many other systems beside Branemark's. Kawahara developed the Bioceram single crystal alpha aluminium oxide implant (Kyocera Corporation, Kyoto, Japan.) in the early 1970's. In 1974 Kirsch introduced the IMZ implant (Interpore International, Irvine, CA, USA) and the ITI Swiss Hollow Basket (Institute Straumann, Waldenberg, Switzerland) began development.

Most cylindrical endosseous implants were developed following the acceptance of the Branemark implant (Nobelpharma AB, Goteborg, Sweden) in 1982. Niznick introduced the two stage Core-Vent implant in 1982 (Dentsply/Implant Division, Encino, CA, USA). Steri-oss (Denar Corporation, Anaheim, CA, USA), Flexiroot, and the Screw-vent/Swede-vent implants were all introduced in 1982 based on the Branemark implant. The first implant coated with hydroxyapatite, the Integral implant (Calcitek Corporation, Carlsbad, CA, USA), was introduced in 1984, with many other systems following not long after with their own HA designs.

Regardless of material, design or technique all implant systems must comply with certain scientific principles if long-term predictable success is to be achieved.

3.3.2 The Scientific Basis for Implant Treatment

Developments in one area of basic science have been instrumental in increasing implant interest and usage. Biomaterials is the scientific study of materials which are compatible with living tissues. Developments in this field have led to the discovery of a biological seal of gingival tissues around the implant neck and of a stable interface between implant and bone. These two processes and their importance to implant longevity have been among the most controversial issues in implant dentistry.

3.3.2.(a) The Biological Seal

Lavelle (1981) postulated a mucosal seal was important for implant success because it provided a barrier against the ingress of bacteria and toxins into the tissue/implant space.

James and Schultz (1974) were the first to systematically study this seal phenomenon. They demonstrated the presence of hemidesmosomes associated with crevicular epithelial cells and the presence of a cuticle like substance on the implant surface which appeared to facilitate gingival epithelium attachment.

McKinney et al (1984) positively identified the regeneration of attached gingiva and the formation of a sulcus lined with crevicular epithelium. McKinney theorized that fibroblasts produce glycosaminoglycons which coat the implant surface. The regenerating epithelial cells produce the basal lamina together with hemidesmosomes and laminin which tack the basal lamina to the cells. Finally, fibronectin produced by fibroblasts and new capillaries 'glue' the basal lamina to the glycosaminoglycan coat on the implant. Thus the mucosal seal is formed.

Because all implants, regardless of type, have a transmucosal element the formation of an effective biological seal against bacteria, toxins and oral debris was seen as crucial to implant longevity. However, Ten Cate (1985) believes the formation of an epithelial seal is irrelevant to implant success or failure. Based on theoretical considerations he postulates that

the connective tissue response to an implant is much more likely to be the critical factor. If there is inflammation in the connective tissue, for example due to infection or overloading, then connective tissue breakdown will occur with subsequent epithelial migration and eventual implant loss. If Ten Cate's theory is correct then the interface between implant and bone and not the gingival junction may be the crucial element in implant longevity.

A stable gingival attachment is essential to tooth longevity and periodontal indices are important indicators of the health of this attachment. For implants, however, there is evidence to suggest that periodontal-type indices may be poor indicators of implant success (Bauman et al, 1992; van Steenberghe and Quirynen, 1992; and Albrektsson and Zarb, 1993). Hence, the health of the gingival or mucosal seal may not be, as Ten Cate suggests, a critical determinant in implant survival.

3.3.2.(b) Implant-Bone Interface

No other area of implant science has generated as much controversy as the nature of the implant-bone interface in successful implants. Debate has literally raged in implant journals at times dropping to the level of personal attack (Niznick, 1987 and Weiss, 1987). On one side, the proponents of fibro-osseous integration believe that only a connective tissue 'ligament' can provide a stable interface under functional load. On the other, the proponents of osseointegration believe that only a direct anchorage to bone will ensure implant longevity.

Fibro-osseous Integration

Weiss (1987) defines fibro-osseous or fibro-osteal integration at the light microscopic level as "an interposition of an osteogenic peri-implant ligament between well differentiated bone and an implant interface which has been functionally loaded for at least six months". Weiss believes that any biocompatible material implanted and left unloaded will achieve

osseointegration. However, as the implant is loaded from hypo through to hyperfunction the nature of the implant tissue interface changes from osseous to soft tissue. Thus he defines 'first range' functional forces to be physiological and consistent with the maintenance of osseointegration. 'Second range' forces although greater are still physiological but consistent with the maintenance of fibro-osseous and not osseo- integration. Finally, 'third range' forces are defined as non physiological and incompatible with either fibro-osseous or osseo-integration. Weiss and many traditional implantologists believe fibro-osseous integration is the preferred implant interfaces for it alone can resist 'second range' functional forces due to the shock absorbing role of the peri-implant 'ligament'. Fibro-osseous integration occurs via hypofunctional or protected healing where the implant is not totally submerged and left unloaded. Further the patient is restored within weeks rather than after months as with the two stage osseointegration technique.

Osseointegration

Osseointegration was defined by Branemark (1977) as the direct contact between haversian bone and implant at the light microscopic level. Presently, this type of attachment appears to be the most predictable and long lasting connection between implant and host tissue.

Albrektsson et al. (1981) studied the implant bone interface in fixtures that were removed after 30 months of satisfactory clinical function. Scanning and transmission electron microscopy revealed direct bony contact with no intervening fibrous tissue. The border between titanium and bone consisted of a proteoglycan layer a few hundred angstrom units thick. When studied at the ultra-structural level no fibrous tissue separation between bone and implant was seen. Collagen filaments were always separated from titanium by a proteoglycan layer of at least 200 angstrom units thickness. This layer was partly calcified and in direct

continuity with the implant surface at resolution of 30-50 A. The achievement of bony anchorage appears to depend on a number of factors including: (1) biocompatibility of the material used, (2) control of surgical trauma, (3) condition of the tissue bed, and (4) implant loading (Branemark et al, 1985).

Biocompatibility

Bone reacts differently depending on the implant material used. If an incompatible material such as copper is used then a thick connective tissue capsule is formed and rejection is rapid. Less toxic materials such as some stainless steels may be enveloped by a thin connective tissue layer, however, this usually thickens resulting in loosening and eventual loss of the implant. Compatible materials such as Vitallium and gold are usually surrounded by immature bone and this indicates a less than complete acceptance of the material which in turn will lead to rejection. Well oriented haversian bone around an implant is an indication of tissue acceptance and hence good biocompatibility. Materials exhibiting such biocompatibility include titanium and certain ceramics. The unique biocompatibility of titanium is based on the tightly adherent oxide layer which forms on the metal's surface.

Control of Surgical Trauma

Surgical trauma to bone should be minimized to limit the extent of the tissue necrosis caused during the cutting of bone. Particularly important is temperature control during cutting as bone temperatures greater than 47^{o}C will cause hard tissue necrosis. Slow speed cutting and use of copious irrigation is essential.

Condition and Site of the Tissue Bed

The optimum hard tissue bed is one free from infection and of adequate quantity and quality to enable integration. Although important, the quantity of bone is not a critical factor in osseointegration for, as noted previously, ridge augmentation is possible. The quality of bone, however, may be an important factor.

Type IV bone has been associated with much higher failure rates than other bone types. Jaffin (1991) in a study of 1,054 Branemark fixtures reported failure rates of 4 per cent in the maxilla, 10 per cent in the anterior mandible, and 44 per cent in the posterior mandible in Type IV bone. Conversely, Bahat (1993) reported only slightly higher failutre rates in Type IV bone when compared to Types II and III (5.5 per cent versus 4.6 per cent).

Directly related to bone quality, the site of the tissue bed is another important determinant in achieving osseointegration. Zarb (1987) defines Zone I as the edentulous space in the anterior segment of the dental arches which crosses the midline. Zone II are the edentulous spaces posterior to Zone I. Virtually all of the Swedish clinical evidence on osseointegration is based on implants in Zone I. Zone I in the mandible has enjoyed the greatest success in terms of implant longevity due in part to ease of access and the ability to immobilize the implant by engaging the inferior cortical plate. Zone II in the mandible is a less favoured site due to bone quality, the presence of the inferior dental canal and problems of surgical access.

Implant Loading

Dead bone as found in the border zone around a freshly placed implant is a poor anchorage base for a prosthesis. The months following implantation are crucial to the replacement and remodelling of bone in this zone. Overloading during this period may disrupt the bone formation and remodelling process and result in a connective tissue interface. A

period of at least 3 months is required for initial callus formation and bony substitution leading to implant stability. Bony remodelling continues on loading after the 3 month period with McKinney et al. (1987) suggesting that the implant may, in fact, be completely surrounded by connective tissue 2 to 4 months after loading. They suggest that bony regeneration then occurs with direct contact of bone to the now loaded implant being re-established. These results based on histological studies are interesting and indicate that osseointegration is not a static all or none process but dynamic, ongoing and dependent on, among other factors, the forces applied to the implant.

The confusion surrounding the definition of osseointegration resulting from histological studies prompted Albrektsson and Zarb (1993) to state, "Various histologically based definitions of osseointegration have not reached a more general consensus because of difficulties in properly defining the resolution level of the direct bone-to-implant contact and/or the proportion of a bony contact necessary to call the implant osseointegrated. Furthermore, it must be conceded that the histologically based definition does not necessarily reflect the clinical performance, or vice versa, because of the continuum of biomechanical response that a clinical definition demands. A convenient working clinical definition is more useful at this stage, and the authors are of the opinion that the term osseointegration is currently best defined as: A process whereby clinically asymptomatic rigid fixation of alloplastic materials is achieved, and maintained, in bone during fuctional loading."

In some respects histological findings and the above definition are compatible with many of the contentions of the 'fibro-osseous integrationist' and so the precise nature of a successful implant-bone interface remains obscure. Certainly, more research is required on what is still an incompletely understood phenomenon. Because histological research results have been somewhat confusing and ultimately it is the clinical outcome which is important, it has been clinical results which have been used to gauge the efficacy of implant treatment.

3.3.3 Clinical Basis For Implant Treatment

The 1978 NIH Consensus Development Conference on Dental Implants endorsed the need for longitudinal and controlled prospective clinical trials. This endorsement resulted from a review of the retrospective implant studies presented at the conference; studies which lacked randomization, controls, uniformity in patient and site selection, surgical and prosthetic methodology, evaluation of data, and clear definitions of success. Although the conference sought to introduce a disciplined approach to implant evaluation; standardized prospective clinical trials and data assessment are only now becoming more common in implant dentistry.

Historically, survival rate has been used to assess implant efficacy. However, this is a measure of implant mortality only without any measure of morbidity. Hence, a failing implant associated with bone loss, infection and pain would not be assessed as a failure until actual removal from the jaw. In their 1986 review, Albrektsson et al. set the following success criteria for implant use:

- The individual, unattached implant is immobile when tested clinically;
- A radiograph does not demonstrate any evidence of peri-implant radiolucency;
- The mean vertical bone loss is less than 0.2 mm annually following the implant's first year of service;
- No persistent pain, discomfort, or infections is attributable to the implant; and
- That, in the context of the above, a success rate of 85 per cent at the end of a 5 year observation period and 80 per cent at the end of a 10 year period be the minimum criterion for success.

Albrektsson and Zarb (1993) recently altered the criteria to distinguish between anterior and posterior zones of the jaws in terms of percentage success. They suggested success percentages for zone I to be 90 per cent at 5 years and 85 per cent at 10 years, and in

zone II to be 85 per cent at 5 years and 80 per cent at 10 years. The authors did not change the bone loss criteria despite concerns over the relevance of the standard to clinical success. For example, Quirynen et al (1991) have stated, "It is the conviction of the authors that no firm limit can presently be established for unacceptable annual bone loss".

Chaytor (1993) reviewed the data from the Toronto study which used the above criteria and in which 8 of the 274 implants placed failed after stage 2 surgery. All 8 failures were first diagnosed on the basis of mobility and none were removed because of excessive horizontal bone loss in the absence of mobility. Further, excessive bone loss in one year did not signify excessive loss thereafter. Chaytor observed that in this study clinical judgement appeared to overrule the research-based criteria. He concluded that removal of an implant, based on bone loss in a single year, was not appropriate as it may deprive patients of years of implant service. In addition, remedial procedures for implants with associated bone loss have been shown to be successful and so an ailing implant may not necessarily be a failing implant (Meffert, 1992).

Bone loss is particularly pertinent to treatment of the edentulous. The deficit in form and to some extent function on edentulism is due in large part to the ravages of RRR. Hence, any therapy which helps to maintain the ridge without detriment (which can occur with augmentation procedures) would greatly assist in the overall management of the edentulous problem. While implants may impede RRR, continued bone loss may occur and at varying rates.

Ahlquist et al (1990) observed higher marginal bone loss in patients with minor RRR before implant placement than in patients with prior moderate to severe RRR. They suggested that the different rates of bone loss may be related to the difference in alveolar and basal bone. Certainly the findings of Cawood and Howell (1991) in the edentulous jaw demonstrated that alveolar bone can change shape significantly whereas substantial changes in basal bone do not

occur unless subjected to harmful local effects such as the overloading of ill-fitting dentures. Hence, different bone loss criteria may be required for implants in alveolar and basal bone.

Because of these concerns, annual bone loss should be used as a relative indicator of implant health and the need for remedial treatment, rather than an absolute indicator of implant failure and the need for removal.

Regardless of these considerations Albrektsson's criteria significantly upgrade the 1978 NIH Conference recommendation of five years functional service in 75 per cent of cases. Standardized success criteria are important in implant evaluation for stringent criteria would enable an earlier and more thorough evaluation of implant systems and better comparisons between systems. Otherwise, as Shulman (1988) states "Nothing short of a ten year life-table statistic from a prospective clinical trial- e.g. Kaplan-Meier, would provide... the efficacy data... to scientifically assess and compare implants." On the basis of adequate success criteria and/or Shulman's ten year survival statistic, how successful are implant systems?

3.3.3.(a) Fibro-Osseous Integrated Endosseous Implants

Blade implant systems are not well documented. Although James (1988) reported 90 per cent ten year and 75 per cent eighteen year results,.generally blades fall short of Albrektsson's 80 per cent, ten-year threshold and exhibit mobility and peri-implant radiolucency. Smithloff and Fritz (1987) studied 49 implants in 32 patients over 15 years. Twenty implants were lost to follow up and three were removed. Of the 26 surviving to 15 years, half were in clinical health while 13 were not, with 5-8mm pockets and extensive bone loss. Estimates of the success rate were between 42-66 per cent with a raw survival rate of 87 per cent. Kapur et al. (1989) in a prospective study at 5 different centres in which 114 patients received fixed partial dentures and 118 patients received removable partial dentures noted a 5-

year survival rate of 84 and 74 per cent respectively. If, however, Albrektsson's criteria are applied then 45 per cent of implants displayed unacceptable bone loss.

3.3.3.(b) Osseointegrated Endosseous Implants

The Branemark Implant

Albrektsson's criteria are met by the Branemark implant. This implant achieved a 93 per cent mandibular and an 84 per cent maxillary functional survival rates for 5-12 years. (Adell et al. 1981). In a replica study by Swedish centres, the group reported 99 per cent survival for mandibular fixtures for 5-8 years and 85 per cent, 5-7 year survival for maxillary fixtures (Albrektsson et al. 1988) . Other follow-up studies have reported similar results. Kondell et al. (1988) reported a 99 per cent mandibular success rate (average follow-up 3 years on 440 fixtures) and a maxillary success rate of 84 per cent (average follow-up 2 years on 350 fixtures). Meito et al. (1989) reported a success rate of 99 and 89 per cent in the mandible (247 fixtures) and maxilla (145 fixtures) respectively over a 0-36 month follow-up period. Van Steenberghe et al. (1989) reported an 87 per cent implant success in the maxilla (n=40) and a 92 per cent success in the mandible (n=93) for a follow-up of 6-36 months. In the longest running study, Adell et al. (1990) reported minimal survival rates for fixtures in the maxilla to be 78 per cent, and in the mandible 86 per cent, at 15 years. In another replica study, the Toronto group reported an 88 per cent survival rate at the end of a 5-10 year observation period (Zarb and Schmitt, 1991). Most of the results for this implant relate to the edentulous jaw and in particular Zone I of the mandible.

The Branemark studies are notable for the very large numbers involved, the high integration rates, long term bone maintenance under loading, minimal bone loss at failure, excellent longevity at 5-15 years, and extensive replication in Sweden and internationally.

The Tubingen Aluminium Ceramic Implant

This implant is used mainly for single unit restorations. Albrektsson and Sennerby, (1991) in a review of studies on this implant noted success rates of 80 to 90 per cent over a 0-5 year follow-up. They also reported problems of implant fracture in load bearing situations.

The Core-Vent Implant

Severe bone resorption has been reported around this implant (Moy, 1987; Malmquist and Sennerby, 1990). Moy reporting on 101 implants followed for 2 years noted a 50-60 per cent success rate whereas Malmquist and Sennerby could only report a 9.3 per cent rate on 47 implants followed for 2-4 years. Patrick et al. (1989) published much improved success rates (96-98 per cent) for 1732 consecutively placed Core-Vent implants over a 64 month observation period. However, mobility and bone loss assessments were not possible due to cemented bridges and the poor quality of radiographic data presented. Thus, uncertainty remains concerning these factors with the Core-Vent implant.

The IMZ Implant

The various designs and surface coatings make data assessment difficult for this implant. Kirsch and Ackerman (1989) reported a 97.8 per cent success rate with 3088 implants in 1401 patients. Although the success rate was very high and the numbers large, patient control was questionable and accurate bone height evaluations were not reported. Bone loss of nearly 3mm (average follow-up 5.5 years) was noted by Albrektsson and Sennerby (op cit) in a study by Flemming and Holtje (1988) of 39 implants. Chan et al (1995) reported a 96 per cent success rate in 65 mandibular overdenture patients treated with 154 implants for 1 to 6 years.

The ITI Implant

This is an unusual osseointegrated system as the implant is allowed to immediately penetrate the mucosa from the time of placement. This single-stage procedure does not appear to disturb bony anchorage (Buser et al. 1988). Like the IMZ, design changes to the ITI implant make data assessment difficult. However, Albrektsson and Sennerby, (op. cit.) note that this implant is one of the best documented implants in current usage with success rates of the order of 85 to 92 per cent reported for a follow-up of 0-8 years.

Hydroxyapatite coated endosseous implants

Research has shown that a chemical reaction occurs between HA and bone and that the interface formed is stronger than HA or bone alone (Krauser, 1988). Meffert et al. (1987) defined this "direct biochemical bond to a surface that is significant and confirmed at the electron microscope level" as biointegration. Biointegration, via a HA surface coating, results in enhanced bone to implant healing and increased bone to implant contact (Block et al. 1987). Finally, the mean interfacial strength between HA and bone is 5 to 8 times greater up to 18 months than between commercially pure titanium and bone (Cook et al, 1987).

One problem with HA coating is inconsistencies in coating quality. Not all HA coatings are the same, and quality variation can be large. Coat failure may occur if the coating quality is not high. Denissen et al. (1989) reported 16 such failures in an 11 year study of 71 implants. How serious a long-term problem coat failure is, remains to be established. Other problems cited with HA-coated implants are susceptibility to bacterial infection and long-term instability (Johnson, 1992). Notwithstanding these concerns implants with high quality coatings have achieved good clinical results.

Kent et al. (1990) reported 5-year results of a prospective study with 740 Integral implants in 215 patients and noted a 91.74 per cent cumulative survival rate. However, 12 per

cent of implants were defined as morbid, i.e. requiring adjunctive therapy to relieve symptomatic problems. Golec and Krauser (1992) in a 5-year retrospective study of 3093 Integral implants reported a survival rate of 97 per cent. The authors noted that of the 3093 implant inserted 830 were placed in the posterior mandible and 862 in the posterior maxilla. Hence, the majority of implants were placed in areas which demonstrate the lowest success rates in non-HA osseointegrated systems, i.e. Zone II.

Weyant and Burt (1993) in an excellent article reviewed survival rates of 2098 implants in 598 patients up to a maximum of 5.6 years. The sample included pure titanium implants and 'other' implants of which over 90 per cent were HA-coated. The implant-specific survival rate was 89.9 per cent compared to a patient-specific rate of 78.2 per cent. The odds of having a second implant removed were 1.3 times greater if the patient had already had one implant removed. Thus systemic factors must affect the survival of all implants within a given patient and may lead to multiple failures. Interesingly, pure titanium implants had better short term survival rates but worse long-term survival rates when compared to coated implants. When considering the claimed advantages of HA coating i.e. a faster and stronger bond to bone, reverse results may have been expected.

The most recent results were published following a symposium on HA-coated implants in Philadelphia, USA in June 1993. Block and Kent (1993) reported on 1,374 Calcitek implants over 7-8 years. The authors contended that success rates of 89 per cent for the development period and 97 per cent for the most recent 3-4 year study period were superior to results published in a similar manner by Adell et al (1990) on the Branemark implant. Lozada et al, (1993) reported a 97 per cent survival rate for 62 HA-coated blade implants and 98-99 per cent survival rate for 745 root form implants for periods of up to 7 years. Finally, Guttenberg (1993) recorded a cumulative survival rate of 96.5 per cent for up to 88 months for 690 Calcitek implants.

The mean observation period for these studies is less than Shulman's 10 year target and although survival rates look promising, unless they are sustained to, and past 10 years a question mark will remain over the long-term survival of HA-coated implants.

3.3.3.(c) Transmandibular Implants

Small and Misiek (1986) reported a cumulative success rate of 94.6 per cent for 5 years and 90.9 per cent for more than 10 years, in a retrospective study of the staple implant in 1516 patients. However, moderate to major bone loss and mobility were observed in 10 per cent of cases. The Bosker transmandibular implant has been favourably reported by its inventor in a 12-year follow-up study with only 6 failures in 368 patients (Bosker and Van Dijk, 1989). Additional studies by Powers et al. (1989) and Maxson et al. (1989), although of only 2-5 year duration, appear to verify Bosker's results. Arvier et al. (1989) reported an 86 per cent success rate in a study of 43 implants inserted over 4 years. Three implants were removed due to infection and three due to mandibular fracture. The insertion of these implants is surgically more traumatic than endosseous placements and failure in any one part of the implant usually results in total implant loss and prosthetic failure. Hence, the system is less forgiving than endosseous systems where failure in one implant need not eventuate in prosthetic failure.

3.3.3.(d) Subperiosteal Implants

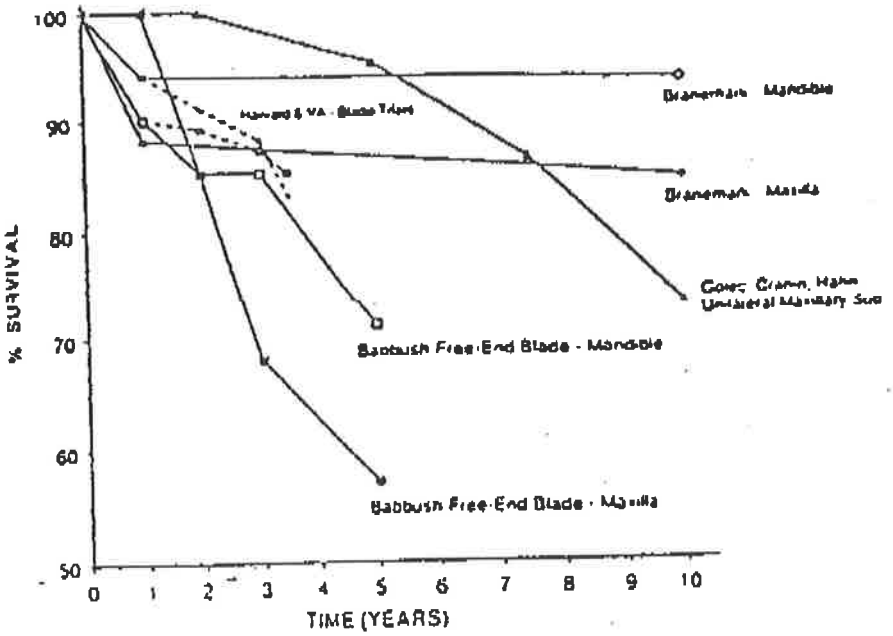
In controlled survival studies, Bodine and Yanase (1985) reported success rates of 93 per cent at 5 years, 64 per cent at 10 years, and 50 per cent at 15 years for full mandibular subperiosteals. James et al. (1988) reported a 78 per cent success rate at 13 years for similar restorations. Also reported were success rates for maxillary implants of 92 per cent for unilaterals and 80 per cent for full subperiosteals. Golec (1989) in a 10-year review of 202 mandibular subperiosteal implants reported a 99 per cent success rate at 5 years and a 95.5 per

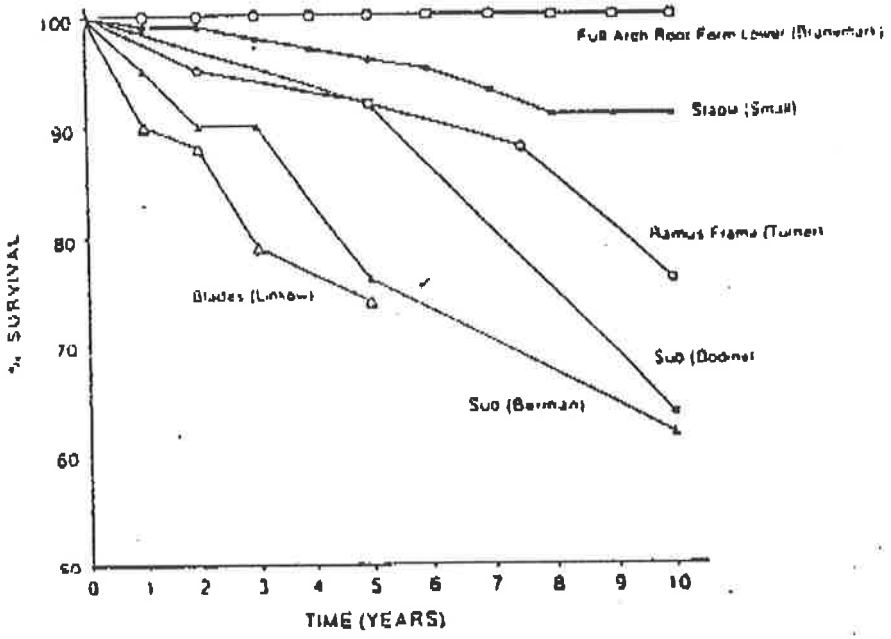
cent rate at 10 years. He defined success as "a clinically functioning patient who is free from symptoms" and noted that 9 implants failed and 33 required interceptive treatment, including strut removal and HA grafting. Golec also noted design changes over the period of the study, particularly those brought about by the advent of HA. For the last four years of the study all implants were HA coated which resulted in direct bony anchorage. Although Golec alluded to superior results with HA coating no comparative data was presented. Subperiosteal implants are most suited to cases where a lack of bone volume may preclude the placement of endosseous implants without augmentations. Like transmandibular implants, subperiosteals are not as flexible as endosseous systems, however they are a very good option in the treatment of severely resorbed jaws.

In conclusion, implants can be a predictable and successful long-term treatment modality. However, not all systems have the long-term results which would guarantee such an endorsement. Presently, only the Small's transmandibular staple and the Branemark implant have the 10+-year survival data that meet Albrektsson's criteria for success. Based on 5-7-year data, some subperiosteal implants (ad modum James, Golec, and Bodine & Yanase), the Tubingen ceramic implant, the ITI implant, and the Integral implant are acceptable systems for clinical use.

On the question of which is a more successful interface: fibro-osseous integration or osseointegration, the results favour the latter. Shulman (1988) drew up survival curves for various implant systems based on data from controlled and uncontrolled, prospective and retrospective studies, and life-table and nonlife-table data (Figures 4a and b). He noted important differences in survival patterns between fibro-osseous integrated and osseointegrated implants. Implants with a connective tissue interface are steadily lost at a rate of approximately 3 per cent per year. Loss of bone anchored implants is concentrated in the first

year and then falls off thereafter to below 1 per cent per year. These results seem to support Zarb's contention that fibro-osseous integrated implants are generally not long-term restorations but create an illusion of longevity by failing slowly (Zarb, 1988).





Figures 4a and b. Survival curves for single implant (top) and complete arch reconstructions (bottom) with various implant systems (Shulman, 1988)

3.3.4 Prosthetic Management

Prosthetic reconstruction of the edentulous mandible using implants can be achieved in two ways. The prosthesis is either implant supported or is implant and tissue supported.

3.3.4.(a) Implant Supported Prostheses

Implant supported prostheses may further be subdivided into:

Fixed - prosthesis of teeth (+/- soft tissue methacrylic analogue) and metal frame fixed directly to implants, and

Patient removable - removable overdenture retained by implant supported attachments or precision metal superstructure.

The major determinants of whether a prosthesis should be fixed or removable are: patient's wishes, aesthetics, phonetics, number of implants required, and hygiene factors. Aesthetically, the amount of RRR is important for if this is minimal, a fixed prosthesis can be fabricated with a metallic framework supporting the prosthetic teeth without a soft tissue analogue, i.e. the traditional fixed bridge. If ridge reduction is moderate then compensation for lost tissue is required and the bulk of the prosthesis comprises teeth and acrylic resin replacing the missing soft tissues. This prosthesis may be fixed or fixed-removable. When ridge reduction is great, it is no longer possible to compensate for tissue loss in a fixed prosthesis without severely compromising aesthetics, phonetics and hygiene. This is not such a great problem in the mandible but certainly is in the maxilla in a patient with a high smile line. In such cases a fixed-removable or an overdenture are the only options.

As noted previously, most of the Swedish research on the Branemark system was carried out on edentulous jaws, particularly the mandible, and most of the prostheses were fixed. Hence, there is long term data which demonstrates very high prosthetic success of implant supported restorations in the mandible. For example, Adell et al (op. cit.) reported 15

years of continuous prosthesis stability in 99 per cent of mandibles treated. The prosthetic success was much higher than the survival rates for individual fixtures (86 per cent), for the loss of a fixture did not necessarily mean the loss of the prosthesis (Figures 4a and b). Multi-centre evaluations in Sweden report very similar results (Albrektsson, 1988). Further, in the longest running Branemark implant study outside of Sweden, the Toronto study, Zarb and Schmitt (op. cit.) noted 42 out of 43 (41 fixed, 2 overdenture) successful mandibular restorations after 10 years. Treatment satisfaction was very high with patients reporting subjective but dramatic improvements in comfort and function.

In a comparative study of 32 removable complete dentures and 32 fixed prosthesis, Lindquist (1987) showed that chewing capacity improved markedly on insertion of a fixed mandibular prosthesis and continued to improve up to 3 years later. The 2 to 3 time increase in bite force and decrease in chewing time noted by Lindquist supported earlier work by Jemt (1985).

Apart from improved function, the most notable finding of the study was the small amount of bone resorption (well within Albrektsson's criteria) even after 6 years. Chaytor et al (1991) reported similar data from the Toronto study. Thus, implants can help prevent RRR and so assist in the maintenance of extra and intra-oral form.

Implant-supported overdentures have some advantages over a fixed prosthesis including: cheaper costs, easier hygiene, better aesthetics in cases of severe RRR, and less implants required in a less rigid and stress-broken system. It has been generally assumed that fixed prostheses provide better function and patient satisfaction than overdentures. However, one recent within-subject crossover study of 16 patients concluded that there was no significant clinical difference in function or satisfaction between mandibular fixed bridges and long bar overdentures, with no tendency for patients to choose one over the other (de Grandmont et al. 1992; Feine et al. 1992).

In conclusion, there is much evidence to show that therapy with implant-supported prostheses can maintain form and dramatically improve function.

3.3.4.(b) Implant and Tissue Borne Overdentures

In the mandible, as few as two anterior implants may be all that is required to overcome functional difficulties. In such cases, denture support is provided by the primary tissue bearing areas of the buccal shelf and pear-shaped pad posteriorly and by the implants anteriorly. The implants, coupled with a suitable attachment system, will provide the necessary denture retention and stability necessary for prosthetic success.

The attachments used will depend on clinical requirements and many systems are available including bar, stud, ball and magnetic attachments. Bar attachments splint the implants and provide good anterior support as well as stability and retention. They are ideal where implant alignment is not good. Adequate vertical space is required to accommodate the bar and examples include the Dolder, Hader, Andrews and Ceka bars.

Less vertical space is required for stud or O-ring attachments, which are not splinted. This method of attachment provides good stress breaking and excellent retention and stability. However, such a system should not be used with non-parallel implants or excessive wear of the female retainer will occur and unnecessary forces will be applied to the implants on removal and placement of the prosthesis. Examples of stud attachments include the Dalla Bona, Gerber and Ceka.

Ball attachments with resilient soft tissues provide excellent stability and retention. The soft liner is intimately associated with the tissue and its massaging action is claimed to produce a very good tissue response. As with stud attachments, implant alignment is important if undue stresses are not to be placed on the implants and soft liner tears are to be avoided.

Magnetic attachments may provide good retention but this can be lost in function when intimate contact between magnet and keeper is broken. These attachments do not provide horizontal stability and corrosion and wear can affect long term retention (Finger and Guerra, 1992).

Only in recent years has the volume of literature on implant-tissue borne prostheses approached that of implant borne prostheses.

Naert et al (1988) studied mandibular overdentures supported by two or three Branemark implants in 44 patients over a period of 2.5 years. A 97.7 per cent success rate for both overdentures and individual implants was recorded with adverse soft tissue reactions the most common complication.

Mericske-Stern (1990) reported on 62 mandibular overdentures retained by 137 endosseous (ITI) implants. Five implants were lost over the study period of 6 to 66 months, 3 before loading. In the 56 patients restored with just two implants and an overdenture, only one implant failed (in that case, the patient had adjusted to a denture retained and stabilized by one implant and refused a replacement of the failed implant). Hence no prosthesis failed due to implant loss, with all patients reporting satisfaction with their dentures.

Naert et al. (1991) reported on 80 mandibular overdentures retained by two Branemark implants over 4 years. No implants were lost after loading, and marginal bone loss about the implants was within Albrektsson's criteria. Patients generally reported satisfactory function and comfort. However, one patient did not wear the overdenture, six complained of continuing pain and chewing problems, and two were not happy with an overdenture, having originally requested a fixed prosthesis. The problems of pain were related to sharp residual ridges or superficial mental foramina. Hence, a partially tissue borne overdenture will not

necessarily overcome all support-related problems. The main prosthetic complications included fracture of opposing dentures (10 per cent) and loose screws (5 per cent).

Kirsch (1991) reported 2 implant failures out of 17 in maxillary overdentures and 6 out of 365 in mandibular overdentures over 11 years. No discrimination was made between implant supported and implant-tissue supported overdentures.

Ensquist et al. (1988) reported on a multicentre overdenture study involving 11 Swedish centres and 89 patients. The overall failure rate of the 339 Branemark implants inserted was 20 per cent, with a 30 per cent failure rate in the maxilla and 6 per cent in the mandible. It should be noted, however, that in 64 per cent of the cases treated, overdenture therapy was the only option either due to failure of a fixed prosthesis or inadequate bony anatomy to support a sufficient number of fixtures for a fixed prosthesis. Failures did not seem to be related to the retention system used (bar-clip with and without extensions, and separate stud attachments). Soft tissue hyperplasia was the most common complication encountered.

Block et al. (1990) studied 90 patients restored with overdentures supported by 168 Integral implants for up to 56 months. Of the 175 mandibular implants inserted, five were removed for psychiatric reasons (2.8 per cent). Eleven of 68 maxillary implants were removed (16 per cent); 5 due to infection and 6 due to patient requests following repeated abutment fractures.

Ensquist (1991), in a six year prospective study on 39 patients, noted 18 of 37 implants (48 per cent) failed under maxillary overdentures (7 before loading, 4 after loading) and 7 of 51 implants (14 per cent) failed under mandibular overdentures (all before loading). Nearly all overdentures were implant and tissue supported with 27 on 2 implants (6 maxillary, 21 mandibular), 10 on 3 implants (7 maxillary, 3 mandibular) and only 1 on 4 implants (maxillary). Two attachment systems were utilized: a bar system with clips (22) and separate stud

attachments (16), (Nobelpharma AB, Sweden). Four lost implants supported bars and seven lost implants supported studs.

Zarb and Schmitt (1991) in a study over 6 years of 33 patients with 35 edentulous arches treated with 104 implants noted a 12 per cent failure in the maxilla and 5 per cent failure rate in the mandible. A Dolder bar was utilized for 29 arches (6 maxillae, 23 mandibles), magnets in 2 mandibles, custom designed frameworks in 2 mandibles and in one maxilla and mandible the abutments were left unattached. The authors reported that clinical observation and patient reports indicated a complete resolution of each patient's prosthetic problems. However, also noted was the level of maintenance required. Although abutment problems and complications were minimal, the prosthesis and attachment systems required greater maintenance. Some patients needed relining of their mandibular distal extension areas which indicated resorptive change and frequently the opposing denture also required relining. The authors note that prosthodontic maintenance tends to be ignored and is poorly referred to in the literature in favour of the impressive stabilization achieved by osseointegration. Maintenance required and noted in the study included:

Tightening of prosthetic screws,

Tightening of Dolder bar clip,

Tightening of magnetic keeper screws,

Modification of acrylic flange to prevent food trap under Dolder bar, and

Adjustment and/or relines of posterior acrylic resin saddles.

Parel (1991) in an overdenture study of 45 Branemark implants in 15 patients over nearly 5 years recorded no failures in free standing attachments and 2 failures in splinted abutments. No further data were given.

Geering and Mericske-Stern (1991) reported on a 5.5 year retrospective study of 67 patients with 149 implants supporting mandibular overdentures. Five patients with 12 implants

were lost to recall and of the remaining 137 implants 2 failed in function (1.4 per cent failure rate). A clip-bar or a Dalbo attachment was used for denture retention. When the periodontal parameters of plaque index, bleeding index and probing depth were related to retention devices, no obvious differences could be detected. The authors concluded that two implants could provide very satisfactory retention for mandibular overdentures.

In a 3.5 year study of 86 overdenture patients using 196 Branemark fixtures, Quirynen et al (1991) recorded a 1 per cent failure rate in the mandible (2 of 184 fixtures) and no failures in the maxilla (12 fixtures). The authors contrasted their results with those of Ensquist et al (op. cit.) and suggested that the very different failure rates were probably due to different overdenture designs and the different resorption patterns in their respective populations. A bar-clip attachment system was used almost exclusively in the Quirynen et al study (79 of 86 cases) and the authors believe that this system which connects two fixtures by a straight bar parallel to the hinge axis offers two advantages: (1) there is distal mucosal support as the overdenture can rotate about the bar and, (2) the fixtures are mainly loaded axially. More importantly, only 5 per cent of the population in the Quirynen study had extremely resorbed jaws. In accordance with the classification of Lekholm and Zarb (1985), mean jaw bone quality and quantity were respectively; 2.5 and 4.6 for the maxilla, and 2.2 and 2.4 for the mandible. In the Ensquist study, 56 per cent of patients had extremely resorbed jaws with a further 8 per cent being failed fixed prosthetic cases.

The periodontal parameters measured in this study included: plaque index, gingivitis index, probing depth, height of gingival margin, fixture mobility, and marginal bone height. The authors noted that although the plaque index was high, the gingivitis and probing depth were comparable with recordings about "fairly healthy natural teeth". The height of the gingival margin decreased about 1mm during the study period, an observation consistent with that seen about abutments supporting fixed prostheses (Adell et al, 1986). The change in

marginal bone height (1mm in the first year, 0.05-0.1mm annually thereafter) was also comparable to that which occurs about fixtures supporting fixed prostheses (Adell et al, 1986; Lekholm et al, 1986; and Cox & Zarb, 1987). Mobility was measured by means of a Periotest device ™ (Siemens, Germany). Periotest values ranged from -3 to +4.5, which were consistent with an earlier study by the same group (Teerlink et al, 1991).

The prosthetic parameters of implant supported overdentures in this same group of patients were reported by Naert et al (1991). No relationship could be demonstrated between changes in marginal bone height and (1) absence of incisal contact, (2) presence of a balanced occlusion, and (3) interabutment distance. The presence of a balanced occlusion and incisal contact did not seem to remain stable with time. However, the authors noted that no certain conclusions could be drawn due to the errors inherent in recording these parameters. Complications were mainly related to attachment systems. Corrosion, extreme wear and rapid loss of retention with Jackson™ magnets eventually precluded their use in the study. O-ring box fracture occurred twice on eight attachments during the first five months of function. Loose gold screws occurred in 5 per cent of lower overdenture cases. Opposing full upper dentures fractured in 10 per cent of cases and one chrome-cobalt reinforced lower overdenture also fractured. These results support the findings of earlier work which indicated that bite force levels with overdentures can be considerable (Haraldson et al, 1988). Only six overdentures required relining during the four year study period. Although the authors believe that this was due to decreased bone resorption under the bar-overdenture when compared to resorption under a conventional full denture, no supporting data were presented. The authors also indicated that patients complained about less retentive upper dentures, but again presented no supporting data. Other patient reactions were reported on, with a median response of 8 on a rating scale of 1 to 9 for overdenture comfort, function and appearance.

In an 18 month study, McNamara and Henry (1991) reported on 13 patients treated with nine mandibular and four maxillary overdentures supported by 52 Branemark implants. No failures occurred in the 36 mandibular fixtures, while 2 of 16 maxillary fixtures were lost (6 per cent failure rate). In accordance with the classification of Lekholm and Zarb (1985), mean jaw bone quality and quantity were both 3 for maxilla and mandible. Reporting patient response on a 1 to 9 scale, the authors recorded an 8.4 score for general satisfaction, 8.3 for retention, 7.7 for chewing, 8.5 for speech and 9.4 for appearance. Complications following Stage I surgery included haematoma (2 cases) and paraesthesia (2 cases). All patients had problems with clips loosening and in four cases the clips fractured. The use of magnets was discontinued due to corrosion and loss of retention. In contrast to Naert et al (1991) but in agreement with Zarb and Schmitt (1991), the need for overdenture relining was highlighted. All required early relining, with some being relined twice within the 18 month observation period. One suggestion for the increased resorptive change was an increased bite force. The authors concluded that the need for relining was a major problem in relation to long-term stability and efficacy of treatment. The improvement in function due to increased retention and stability resulted in increased anterior temporalis muscle activity and it was suggested that combined with the effects of parafunction, Cranio-Mandibular Dysfunction (CMD) may increase in some cases.

Johns et al (1992) reported on a prospective study of overdentures involving 9 international centres. One hundred and thirty three patients were restored with 117 Branemark implants in the maxilla and 393 implants in the mandible. A total of 21 implants were lost in the maxilla (18.8 per cent), and 11 in the mandible (3.8 per cent). Surgical complications included: fractured mandible (1 patient), mental paraesthesia (19 patients), oedema (17 patients), haematomas (18 patients), and soft tissue penetration (7 patients). Prosthodontic complications included: 7 fractured dentures (3 maxillary, 4 mandibular), 15 clip fractures (6

maxillary, 9 mandibular), 15 relines (8 maxillary, 7 mandibular), 2 fractured bars (mandibular), and 43 clips were tightened one or more times (8 maxillary, 35 mandibular). Gingival height about abutments did not change significantly over time. Mean marginal bone loss during the first year was 0.4mm mesially and 0.6mm distally for the maxilla, and 0.3mm and 0.2mm for the mandible.

Donatsky (1993) studied 25 patients with mandibular atrophy restored with overdentures and ball attachments supported by 93 Branemark implants over 12 to 27 months (median observation period of 18 months). Jaw bone quantity ranged from moderate ridge resorption to extreme resorption of basal bone. Jaw bone quality was rated as good in most patients. Three implants failed (3.2 per cent failure rate) but all prostheses remained functional. Both surgical and prosthetic complications were observed to be minor and reversible.

A 5-year comparative study of 59 overdenture patients restored using two different implant systems was reported by Mericske-Stern and Zarb (1993). Two stage Branemark implants (total: 68) were used in 25 patients and single stage ITI implants (total: 74) in 34 patients. After 5 years the success rates for the different systems were very similar (Branemark: 91.2 per cent, and ITI: 92.2 per cent). Soft tissue evaluation showed that health was maintained in both groups with few complications. No prosthetic assessment was reported.

Naert et al. (1994) studied 36 patients restored with splinted and unsplinted abutments for mandibular overdentures for up to 24 months (mean= 12.4). They reported no fixture failures and no significant difference in the clinical performance of the ball, magnet and clip attachments including changes in marginal bone height, crevice depth, Periotest™ values (Periotest™: Siemens AG, Benshiem, Germany) and patient satisfaction.

Cune et al (1994a) reported on 429 patients restored with implant-retained overdentures over a period of up to 36 months. Cumulative implant survival after 36 months was 70.7 per cent for the maxilla and 96.7 per cent for the mandible. Complications were generally minor and mostly restricted to the health of the peri- implant tissue. Oral hygiene was often inadequate and resulted in bleeding and hyperplasia about the implant neck. As a result, additional surgical treatment was required in 15 patients. The authors noted that considerable prosthetic maintenance was required and combined with concerns over hygiene necessitated regular check-ups.

Chan et al (1995) noted a 96 per cent success rate in 65 mandibular overdenture cases treated with 154 IMZ implants for 1 to 6 years. Despite poor hygiene (plaque recorded on 68 per cent of abutments) only 17 per cent exhibited bleeding on probing. Maintenance was a problem also noted in this study, particularly with the stress-absorbing element (IME) of the system.

The need for regular prosthetic maintenance was noted by Jemt et al (1992). In following 92 maxillary overdentures over 1 year they noted 22 per cent of metal clips fractured and a 19 per cent incidence of acrylic repairs. Tolman and Laney (1992) reviewed 353 patients over 6.5 years and observed many problems with overdenture O-ring, bar and magnetic attachments. Walton and MacEntee (1993) reported that 78 per cent of problems reported by 29 patients with implant prostheses were associated with removable dentures. Most of these problems were related to fractured acrylic resin or denture teeth. The same authors (1994) retrospectively evaluated maintenance in 156 patients restored with implant prostheses. Seventy one overdentures averaged almost three times as many adjustments (2.1 per overdenture) and twice as many repairs (1.9 per overdenture) as fixed prostheses. Overdenture adjustments included contour adjustments (50.7 per cent), component tightening (25.3 per cent), and occlusal adjustments (14.7 per cent). Repairs included loose or lost clip

(31.4 per cent), relines (27 per cent), fractured clip (8.8 per cent), fractured tooth (7.3 per cent), fractured resin (5.8 per cent), and fractured framework (5.1 per cent).

On the functional improvement with overdentures, Jemt (1986) reported significant increases in mandibular velocity with two implant borne overdentures. Improvement was not as great as for fixed prostheses but occurred more rapidly (over 2 months as opposed to 3 years for fixed restorations). Improvements in masticatory function were also reported by Haraldson et al (1988a,b) who noted increases in bite force and McNamara and Henry (1991) who noted improvements in masticatory muscle activity.

Thus, it appears that where stability and retention are the major problems with a conventional mandibular denture, and adequate support is available posteriorly, then a implant-tissue borne prosthesis is a very satisfactory restoration.

Although a few sequelae of continued RRR in the maxilla and posterior mandible, such as the need for reline, are noted in some of the above studies, no mention is made of the possibility of Combination or Anterior Hyperfunction Syndrome in cases of mandibular overdentures opposing a complete maxillary denture. This syndrome described by Kelley (1972) may occur in partially-dentate cases when only the mandibular anterior teeth are retained and a complete maxillary and a mandibular removable partial denture (RPD) are worn. The syndrome is characterized by:

- resorption of the anterior region of the maxillary residual ridge with or without a resultant redundant fibrous ridge,
- pneumatisation and downgrowth of the maxillary tuberosities,
- development of palatal papillary hyperplasia,
- resorption of the posterior mandibular residual ridge,
- extrusion of the mandibular anterior teeth,

- development of epulis fissuratum in the maxillary anterior vestibule,

- poor prosthesis adaptation,

- a posterior slope to the orientation of the occlusal plane,

- anterior repositioning of the mandible,

- periodontal changes about the remaining natural teeth, and

- loss of vertical dimension.

Shen and Gongloff (1989) found evidence of Combination Syndrome in 24 per cent of 150 patients with maxillary dentures opposed by mandibular anterior teeth.

A traditional approach to preventing the syndrome was the use of a maxillary overdenture with the retention of maxillary anterior tooth roots. Another approach suggested by Keltjens et al (1993) is the placement of an implant in each of the posterior edentulous areas of the mandible to provide support and retention to the distal extensions of the RPD. They suggest that this will reduce RRR in the posterior mandible and improve force distribution to the maxillary denture. Thus it is hoped that Combination Syndrome will be prevented.

The implant-tissue borne mandibular overdenture opposing a complete maxillary denture is analogous to the clinical situation which results in the Combination Syndrome. Theoretically, therefore, the Syndrome may be expected to occur with implant-tissue borne mandibular overdentures, particularly in cases where much of the residual ridge is composed of more labile alveolar bone.

Maxson et al (1990) in a prospective 2 year study of 13 edentulous patients treated with a transmandibular implant-retained overdenture found evidence of Combination Syndrome. This included: loss of posterior mandibular ridge height, epulis fissuratum, loss of vertical dimension of occlusion and anterior occlusal prematurities.

Barber et al. (1990) studied bone loss in 15 patients treated with a transmandibular implant opposing a full upper denture for an average of 34 months. They found a mean

vertical bone loss in the anterior maxilla of 0.43 mm (SD 1.36) per year. This was consistent with the bone loss described by Kelley in his 1972 study. The authors noted that regular occlusal adjustments may have minimized the bone loss that can occur due to anterior occlusal prematurities that result from tooth wear and posterior mandibular ridge resorption. They therefore stressed the need for regular and long-term prosthetic recall.

Jacobs et al (1992) compared posterior mandibular ridge resorption in 3 groups of patients restored with different prostheses: a 2 implant-retained mandibular overdenture (30 patients), an implant-supported fixed mandibular prosthesis (25), and complete dentures without implant support or retention (85). The mean observation times were 24 months, 28 months, and 12 months respectively. Minimal posterior mandibular ridge resorption was observed in the fixed prosthesis group. Although resorption was evident in the complete denture group, most resorption occurred in the overdenture group. After the 6 month post-extraction remodelling phase, bone resorption in the overdenture group was 2 to3 times that of the complete denture group. When patients had been edentulous for more than 10 years no difference between these two groups was observed. They therefore counselled caution in the prescription of an overdenture in a young or recently edentulous patient.

Despite the resorption noted in the overdenture group, few relinings were seen to be needed during the 3 year observation period. The authors explained that resorption in the anterior maxilla may well have masked posterior mandibular ridge resorption with progressive tilting of the dentures.

Jacobs et al (1993) studied maxillary bone resorption in 44 patients prosthetically restored as in the previous study. They did not find a pattern of resorption in the maxilla complementry to that found in the mandible in the previous study. Instead a more pronounced annual bone resorption in complete denture wearers compared to overdenture wearers was

observed. The resorption in overdenture patients was limited but ongoing and slightly lower than that observed in the fixed prosthesis group.

This report is not necessarily inconsistent with the previous study for most of the 44 patients had been edentulous for more than 10 years and as observed in the 1992 study differences between the groups were more marked up to 10 years and diminished thereafter. Moreover, there was no indication that the 44 patients in this study were part of the larger 1992 study population of 140.

In summary, there is clinical evidence to support the theoretical contention that Combination Syndrome can occur in overdenture patients. The high risk groups are the recently edentulous where minimally resorbed ridges mainly composed of alveolar bone are more susceptible to the increased and differential loading conditions imposed by overdenture treatment.

3.3.5 Patient Satisfaction with Implant Prostheses

Kent (1992) reviewed the literature on the psychological and social effect of osseointegrated implant treatments. He noted that the main reason for seeking implant treatment was dissatisfaction with an existing prosthesis. Kiyak et al (1990) noted that fear of surgery was the most important reason given for not proceeding with implant treatment.

Kent reviewed both retrospective and prospective studies when assessing the psychological and social effects of implant treatments.

In a retrospective study, Blomberg (1985) reviewed 189 patient responses to implant treatments over 13 years. The results were positive with 90 per cent of men and 80 per cent of women reporting that their prosthesis had become an integral part of them and that their psychic health and self-esteem had improved.

Kiyak et al (1990) evaluated 39 patients on six occasions from first stage surgery to six months after prosthesis insertion. Patient problems and a range of psychological profiles were assessed including body image and self-esteem. Problems decreased significantly over the assessment period and body image improved. There was no change in self-esteem.

The only study to include a control group was reported by Kent and Johns (1991). Patients who decided to enrol in an implant program completed a questionnaire designed to evaluate psychologic distress, self-esteem and functional status. At surgical assessment some patients were excluded due to anatomic limitations and this group became the control group. All patients were contacted 2 years later (at least 6 months after implant prosthesis insertion) and the same questionnaire completed. The results indicated a dramatic improvement in the treatment group. Functional symptoms declined by 90 per cent whereas there was no change in the control group. The treament group experienced a significant decrease in psychological distress whereas the control group recorded a significant increase. No change in self-esteem was reported in either group.

Kent concluded that "...retrospective and prospective studies alike provide support for the claim that osseointegrated implants can have positive effects on well-being and quality of life."

Studies investigating patient satisfaction after implant overdenture treatment are scarce. De Grandmont et al (1992) and Feine et al (1992) compared patient satisfaction with fixed and overdenture prostheses and concluded that there was little difference between the groups with satisfaction for both groups being high. Walton and MacEntee (1994) reported no difference in patient satisfaction between fixed and removable prostheses with 86 per cent of both groups indicating that they were very satisfied with treatment. Hence, it may be that the results of patient satisfaction studies cited could well be applied to overdenture treatments.

Many of the overdenture studies cited in the previous section contain elements of or comment on patient satisfaction. In all such studies patient satisfaction is reported as high even though maintenance requirements are generally reported as also being high.

Cune et al (1994b) reported on patient satisfaction in 303 patients, 246 of whom were treated with implant overdentures (95 per cent in the mandible). In terms of a reduction in denture complaints the authors concluded that implant overdenture treatment was very effective. Although patients were generally fairly satisfied with the opposing denture (usually the upper) when asked specifically about possible improvements, 20 per cent replied that the maxillary denture now needed improvement. The authors suggest that dissatisfaction with maxillary dentures was caused by higher patient expectations of dentures following successful implant treatment in the mandible. They did not believe that dissatisfaction was caused by decreases in maxillary denture stability and retention.

Conversely, Haraldson et al (1988a,b) reported that an increase number of maxillary denture complaints following mandibular overdenture treatment was caused by larger dislocating forces on the maxillary denture due to increases in bite force.

Hence, patient satisfaction with mandibular implant overdentures is high but questions remain about maxillary denture performance and maintenance problems following treatment.

4. OBJECTIVES

The objectives of the study were to assess the efficacy of mandibular overdentures retained by two endosseous implants and to compare three overdenture retention systems.

The efficacy of implant overdenture treatment was evaluated by a patient and clinical assessment of denture function, comfort and retention, and an assessment of peri-implant tissue health including: plaque, calculus and gingival bleeding indices; crevice depth; implant mobility and radiographic changes in bone.

The three retention systems were compared with respect to patient and clinical assessments of denture function, comfort and retention.

The null hypothesis for the study states that, "There is no perceived improvement in mandibular denture function, comfort and retention provided by the use of two Integral implants and overdenture attachments, and that there is no difference in using either clip, O-ring or ball attachment systems".

5. MATERIALS AND METHODS

The protocol for this study is based on that of Hawker (1987). Although Schaff's original protocol was designed principally for the rehabilitation of head and neck cancer patients, it has been utilized in the treatment of the edentulous and partially edentulous implant patients at the Adelaide Dental Hospital since 1987. The study was approved by the Ethics of Human Experimentation Committee of The University of Adelaide and by the Board of Directors of the South Australian Dental Service.

5.1 Materials

Calcitek™ instrumentation, implants and related components were used exclusively in the study. Details of these items and other prosthetic materials used appear at Appendix A.

5.2 Method

One partially dentate and twenty three completely edentulous individuals who experienced chronic problems managing a full lower denture formed the population in this study. Due to the difficulty in recruiting sufficient edentulous patients within the time available for the study, the partially dentate patient was included; the inclusion considered unlikely to effect the overall findings of the study.

Patient selection required that appropriate conventional prosthodontic treatment had been exhausted before enrolment in the study was considered. All patients were drawn from the waiting list of the Maxillofacial Clinic of the Adelaide Dental Hospital.

Patients had to be willing to return for routine reviews following treatment and had to have an appropriate level of physical and emotional health to complete the two year period of the study. No patient was excluded on the basis of these criteria.

Prospective patients were provided with an information sheet (Appendix B) and were fully informed of the benefits and risks of implant treatment. All patients drawn from the waiting list volunteered to be part of the study and all completed a consent form (Appendix B). Base line data, treatment and follow-up protocols are detailed below. Table 1 summarises the age and sex data of the population all of whom were treated with implant retained overdentures in the mandible only.

Table 1. Age and sex of mandibular overdenture patients

Age (years)		Sex	
Mean	Range	Male	Female
59	36-71	6	18

5.2.1 Medical History

Although no patient was excluded from the study on health grounds a high incidence of compromised systemic health was noted in this patient group (Table 2).

Table 2. Number and distribution of health problems

Medical Condition	Number of Patients
Cardiovascular disease	12
Psychological problems	6
Arthritis	4
Diabetes	1
Allergies	9
Smokers	5

5.2.2 Dental History

The patients enrolled in the study had been treated at the ADH for an average of 3 years (range: 1-9 years). Patients had been referred to the Maxillofacial Clinic after conventional treatment by staff prosthodontists had failed to remedy chronic problems with the lower full denture. Of the patients referred for implant consultation, 5 had requested or inquired about implant treatment. Table 3 details the population's denture history.

Table 3. Denture history

	Maxilla (Mean and range)	**Mandible** (Mean and range)
Years edentulous	24 (7-43)	21 (5-43)
Years with present dentures	4 (1-15)	4 (1-15)
Number of dentures	5 (1-15)	5 (1-15)
Number of relines/rebases	3 (0-15)	3 (0-15)

5.2.3 Examination Findings

An examination form (Form D) was completed for each patient and the salient examination findings are listed in Table 4, 5 and 6.

Table 4. Examination findings

Finding	Number of Patients
Occlusion:	
-Class I	23
-Class II	1
TMJ problems:	14
-joint pain	7
-clicking/crepitus	6
-deviation on opening	9
-limited opening	2
Poor neuromusc coordination	6
Parafunction	12
Poor salivary flow	2
Oral hygiene:	
-good	17
-fair	5
-poor	1

Half of the population showed signs of parafunctional activity and/or TMJ problems. This qualitative assessment was used to screen out any severe TMD problems and at the time of treatment no patient had symptoms of joint or muscle pain. Six patients demonstrated poor neuromuscular coordination and another two poor salivary flow.

When assesssing bone quantity and quality the classification of Lekholm and Zarb (1985) was used. The assessment for bone quantity was made from radiographs and clinical observation. Bone quality was assessed from radiographs and, in the case of the mandible, was verified at the time of implant placement.

Table 5. Maxillary bone quality and quantity (classification of Lekholm and Zarb, 1985)

	Bone Quantity					
Bone Quality	**A**	**B**	**C**	**D**	**E**	**Total**
1	0	0	0	0	0	**0**
2	0	3	0	0	0	**3**
3	1	13	4	0	0	**18**
4	1	0	0	0	1	**2**
Total	**2**	**16**	**4**	**0**	**1**	**23**

Generally the maxilla demonstrated moderate with some advanced RRR with a thin layer of compact bone and a good density of cancellous bone. The mandible showed more resorption ranging from moderate through advanced to the loss of some basal bone. Bone quality was generally good with a homogeneous to thick layer of compact bone being present in most cases.

Table 6. Mandibular bone quality and quantity (classification of Lekholm and Zarb, 1985)

	Bone Quantity					
Bone Quality	**A**	**B**	**C**	**D**	**E**	**Total**
1	0	0	3	6	1	**10**
2	0	3	3	2	0	**8**
3	0	5	1	0	0	**6**
4	0	0	0	0	0	**0**
Total	**0**	**8**	**7**	**8**	**1**	**24**

5.3.4 Diagnosis

All patients enrolled in the study were considered prosthodontic failures due to their inability to adapt to a mandibular denture. Table 7 lists the diagnoses of the population's maladaptive condition. From the numbers listed it can be seen that many patients had more than one possible cause for their problems with dentures.

Table 7. Diagnoses of maladaptive condition

Diagnosis	Number of patients
Inadequate alveolus	17
Parafunction	12
Poor neuromuscular coordination	6
Psychological	3

5.3.5 Treatment Planned

Each patient was treatment planned for 2 implants in the anterior mandible. Three retention systems were used:

- Ball attachment with Molloplast™ soft liner (Figure 5),
- O-ring attachment (Figure 6), and
- Dolder bar (Figure 7).

Hence, each attachment system was to be used on 8 patients. A random allotment of attachment systems was planned. However, five patients who were wearing lower dentures with Molloplast™ soft liners were reluctant to give them up and so they were restored with the ball system. All other patients were randomly assigned a retention system.

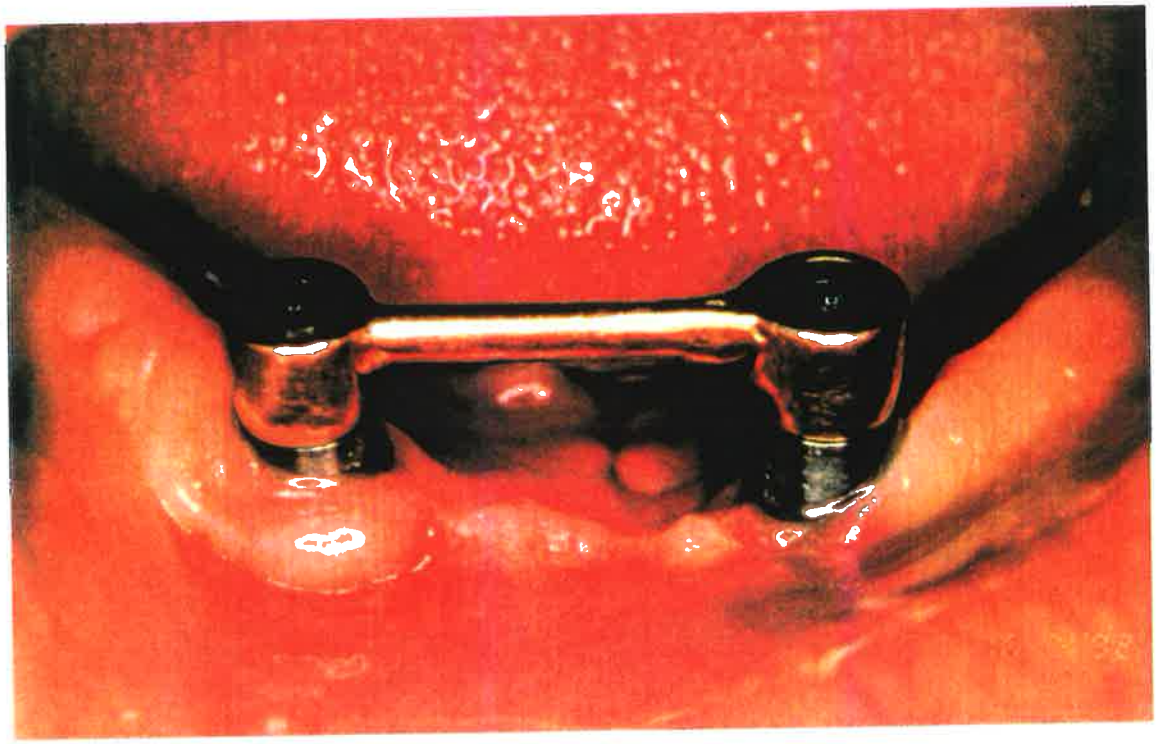


Figure 5. Clip Attachment

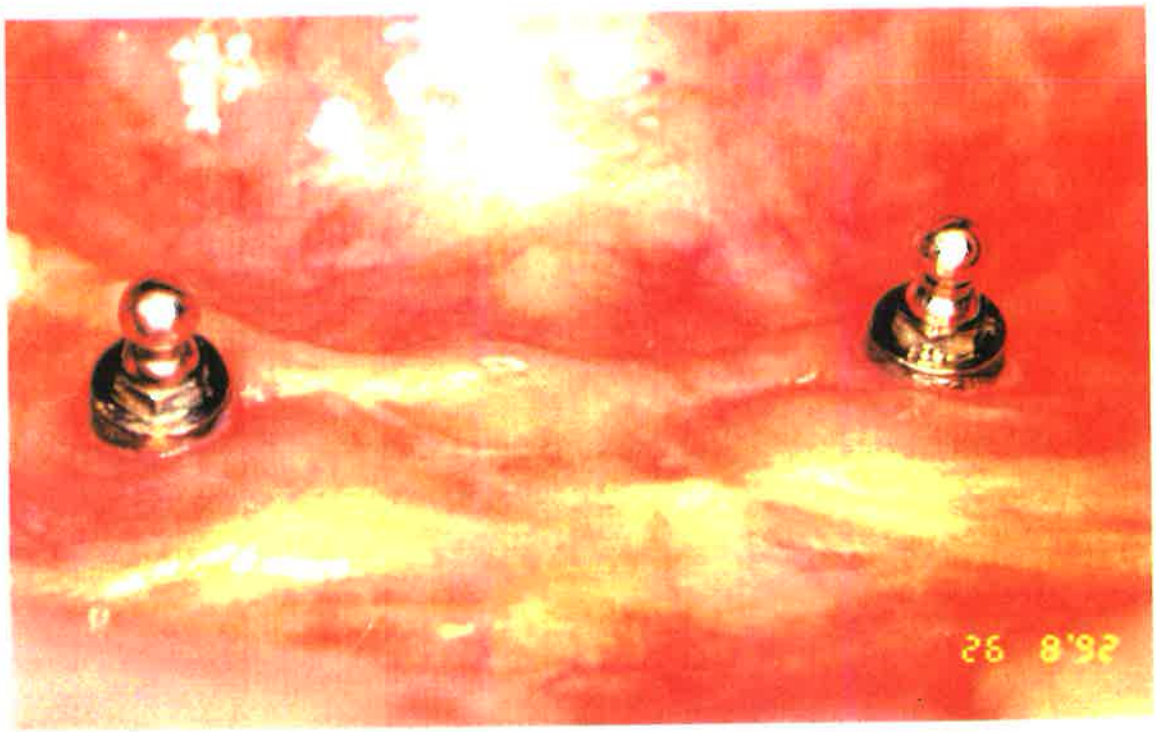


Figure 6. O-ring Attachment

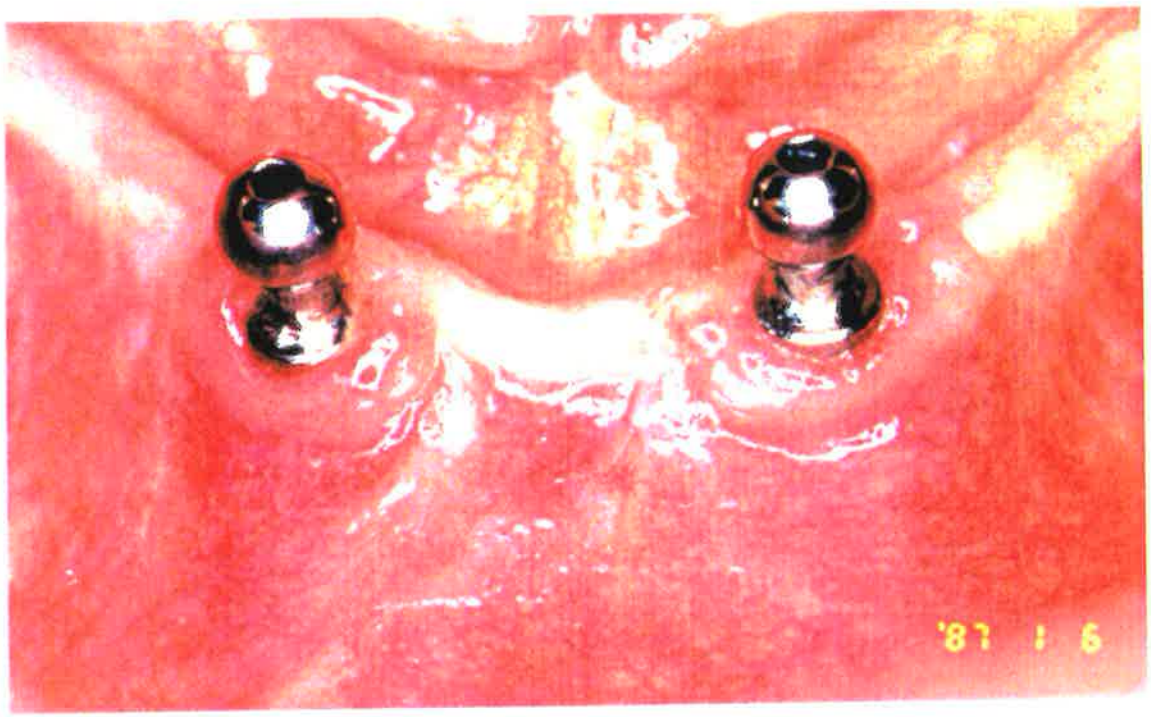


Figure 7. Ball Attachment

4.3.6 Surgical Protocol

All surgical procedures were carried out by or under the direction of Dr P. Duke (Consultant Oral Surgeon, Adelaide Dental Hospital). All surgery was undertaken in the Oral Surgery Clinic, Adelaide Dental Hospital.

Stage I - Implant Placement

Implants were placed under aseptic surgical conditions using the Calcitek™ surgical armamentarium. Full thickness muco-periosteal flaps were raised via a mid-crestal incision in the anterior mandible. Implant crypts were prepared at the crest of the ridge in the lateral incisor/canine area and the implants inserted 1 mm below the crest where possible. No surgical stents were used. The overlying tissue was then replaced and closed with interrupted black silk

sutures. In 18 cases, placement was carried out under a combination of intra-venous sedation (Midazolam, Roche™; Fentanyl, Astra Pharmaceuticals™; Diprivan, ICI™) and local anaesthesia (Lignocaine hydrochloride and Bupivacaine hydrochloride, Astra Pharmaceuticals™), while in 6 cases local anaesthesia alone was used. Post-operative antibiotics (Amoxycillin, SB pharmaceuticals™) and analgesics (Paracetamol/Codeine, Sterling Pharmaceuticals™) were prescribed.

Calcitek Integral™ implants were used exclusively in the study. The length, diameter and total number of implants used is recorded in Table 8.

Table 8. Length and diameter of implants placed

Length (mm)	Diameter (mm)	Number
8	4	6
10	4	14
13	4	16
15	4	12

Bone quality was evaluated at the time of placement and Table 9 compares this surgical assessment with the radiographic assessment obtained at the time of initial examination. In 8 cases bone quality was reassessed to a lower grade at the time of surgery.

Table 9 Comparison of radiographic and surgical assessments of mandibular bone quality

Bone Quality	Radiograph	Surgery
1	10	6
2	8	9
3	6	8
4	0	1

Stage II - Implant Exposure

Stage II took place approximately 3 months post-implantation and involved uncovering of the implants and placement of temporary gingival cuffs.

5.3.7 Prosthetic Protocol

Dr P.B. Hawker (Senior visiting specialist in maxillofacial prosthodontics, Adelaide Dental Hospital) supervised the prosthetic treatments which were carried out by hospital specialists, hospital dentists and the author. All post-insertion assessments and treatments were carried out by the author.

At the time of the initial consultation, the patient's existing dentures were assessed and if considered unsatisfactory were remade prior to Stage II surgery. The overdenture retention system to be used with the final prosthesis was also selected at that time.

Following implantation the denture was soft-lined with Coe-Comfort™ and delivered. The soft liner was replaced at 1 week intervals until primary healing was complete. Thereafter, a Coe-Soft™ liner was used and renewed at two or three weekly intervals until Stage II surgery.

Patients were instructed on an appropriate oral hygiene regime including the removal of dentures overnight.

At Stage II surgery the lower denture was relieved over the temporary gingival cuffs and a Coe-Comfort™ liner placed. When healing was complete the cuffs were replaced by permucosal abutments and an impression taken. Once fabricated, the modified lower denture was delivered along with the appropriate retention system.

5.3.8 Follow-up

Twenty four patients each received 2 implants in the anterior mandible. One male patient failed to attend any reviews after the provision of his dentures and was withdrawn from the study. Another male patient moved overseas after his first year review but has remained in contact with the researcher. After two years of function the patient continues to complete documentation on denture satisfaction and has reported satisfactory implant health after professional evaluation.

All 22 remaining patients attended the last review process.

Due to time constraints imposed by the MDS program, this study reviewed treatment from 5 to 24 months post-prosthesis delivery, with a mean observation time of 18 months. Further annual reviews are being undertaken in the Maxillofacial Clinic under the direction of Dr P.B.Hawker.

5.4 Documentation

Documentation used in the study appears at Appendix B. Documentation used and assessment times are listed below.

	Record	Data Collection
	Patient Information Sheet	At initial assessment.
Form A1	Patient Consent Form	At initial assessment.
Form A2	Health Questionnaire	At initial assessment.
Form B	Denture Assessment - Patient	At initial assessment and 1,3,6,12, 18,24 etc month post-delivery.
Form C	Denture Assessment - Clinician	At initial assessment and 1,3,6,12, 18,24 etc month post-delivery.

Form D	Consultation Form	At initial assessment.
Form E1	Stage I Surgical Form	Implant placement.
Form E2	Stage I Postsurgical Form	
Form F1	Stage II Surgical Form	Implant uncovering.
Form F2	Stage II Postsurgical Form	
Form G	Clinical Evaluation Form	At prosthesis delivery and 1,3,6, 12,18,24 etc month post-delivery.

The documentation suggested by Hawker has been modified and expanded to incorporate many of the recommendations of the proposed National Implant Registry (Fagan, 1991).

5.4.1 Form B

The 'Denture Assessment - Patient' form was based on that developed by Gukes et al (1978) and used by Toolson (1983) and Misch (1991). The visual analog scale was completed by the patient prior to treatment and at every review after overdenture insertion. Hence, patient satisfaction pre-treatment and at varying intervals post-treatment could be compared.

To simplify the assessment, questions were grouped into four categories: function, comfort, retention and dysfunction. The average score for each category was calculated for each assessment and plotted over the study period. Questions were grouped into categories as follows:

•Function-	questions 3,4,5.
•Comfort-	questions 6,7,8,9,12,15,16,17,18,19.
maxillary comfort	questions 6,7,12,16,17,18.
mandibular comfort	questions 8,9,15,16,17,19.

•Retention-		questions 10,11,13,14.
	maxillary retention	questions 10,11.
	mandibular retention	questions 13,14.
•Dysfunction-		questions 20,21.

Questions were evaluated individually where responses showed significant variation over the period.

Question 23 assessed patients' expectation before treatment and question 25 assessed attitudes after treatment.

5.4.2 Form C

The 'Denture Assessment - Clinician' form was completed by the author prior to treatment and at every review after overdenture insertion. As for Form B, the denture factors assessed were function, comfort, retention and dysfunction. The number of negative, ie 'no' responses per denture factor e.g. function, was divided by the number of questions per factor to provide a score which could be plotted over the observation period and compared to the patient assessment score. The questions used to evaluate denture factors were as follows:

•Function-	muscular balance	questions 13,14,15,16,32,34.
	occlusal balance	questions 21,22,24,25.
•Comfort		questions 1,2,3,6,7,35.
	maxillary comfort	questions 1,3,6,35.
	mandibular comfort	questions 2,3,7.
•Retention		questions 9,10,11,12.
	maxillary retention	questions 9,11.
	mandibular retention	questions 10,12.
•Dysfunction		questions 27,28,33,35.

Any problems with the dentures themselves or problems caused by the dentures were noted on this form together with any remedial treatments.

5.4.3 Form E

The 'Stage I Surgical Form' was completed at the time of implant insertion and noted surgical details including any complications. The postsurgical form was completed at suture removal and weekly thereafter until healing had occurred.

5.4.4 Form F

The 'Stage II Surgical Form' was completed at the time of implant exposure and noted surgical details including any complications. The postsurgical form was completed at suture removal and weekly thereafter until healing had occurred.

5.4.5 Form G

The clinical performance of the implants was assessed using a protocol modified after McKinney and Roth (1982) and Fagan (1991). The following parameters were evaluated:

- Peri-implant indices
    - Plaque and calculus
    - Gingival bleeding
    - Crevice depth
    - Tissue height
- Mobility Index
- Marginal bone levels

In addition, any complications involving or associated with the implants or abutments were noted on this form.

5.4.5. (a) Peri-implant Indices

There is conjecture as to whether all periodontal-type indices apply around oral implants (van Steenberghe and Quirynen, 1992). Albrektsson and Zarb (1993) stated that these indices are poor indicators of implant success, while Bauman et al (1992) recommended their continued use until further research clarified their true value. As the indices are accepted indicators of general oral health they were included in the study.

Plaque and Calculus Index. The index (Ramfjord, 1959) was used to measure the supra- and subgingival plaque and calculus accumulations at the implant neck. It was used as an indicator of oral hygiene compliance by the patient and as an indicator of the overall oral health status. The highest reading for the implant was recorded.

Grade	Clinical Impression
0	No plaque, no calculus.
1	Plaque can be scraped off but is not visible to the clinician; or supragingival calculus extending no more than 1mm below the free gingival margin.
2	Visible plaque within the gingival crevice or on the implant and gingival margin; or subgingival calculus extending more than 1mm into the crevice or moderate amounts of supragingival and subgingival calculus.
3	Heavy accumulation of plaque within the crevice or on the implant and gingival margin; or heavy accumulation of supra- and subgingival calculus.

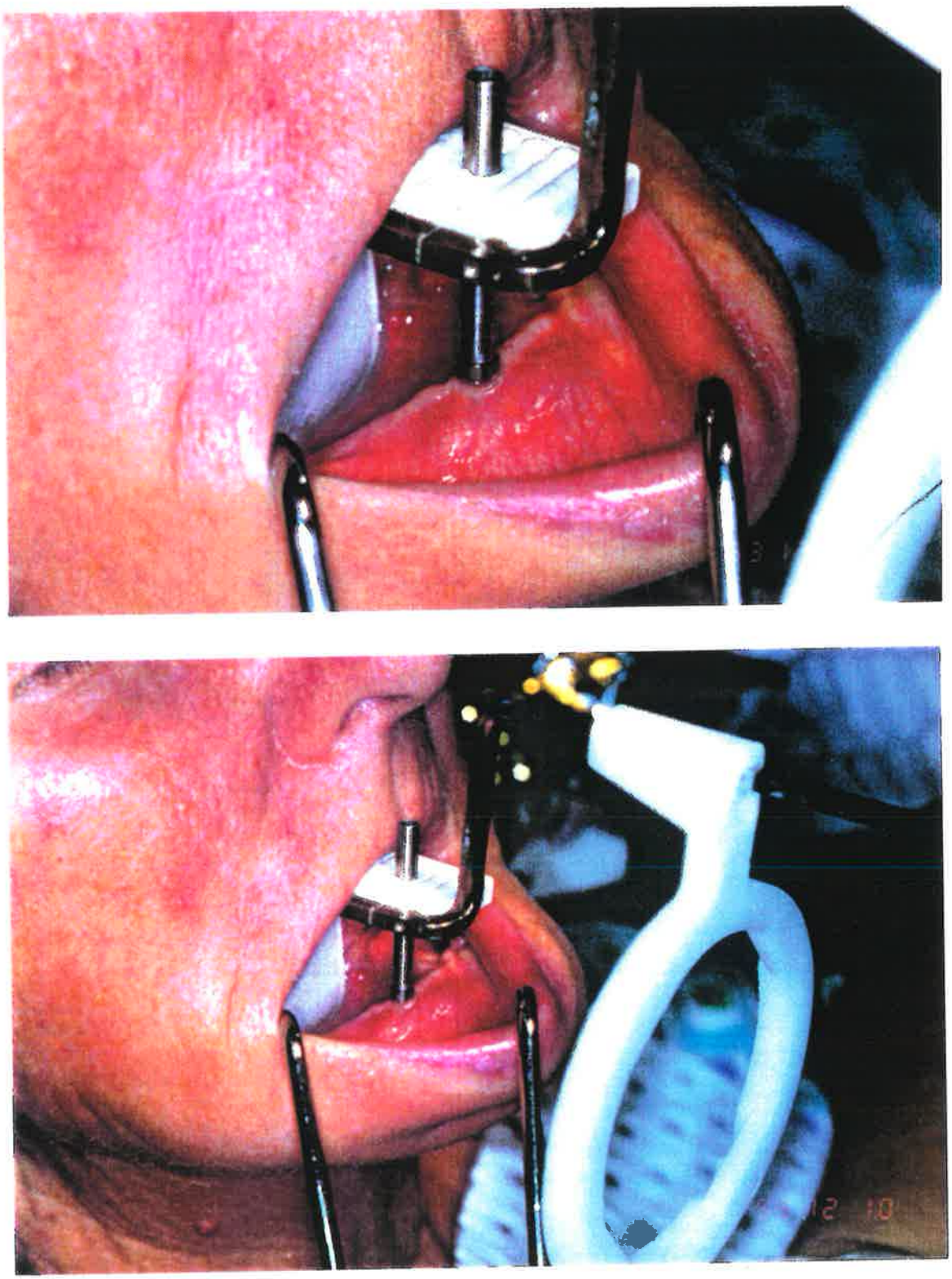


Figure 8a and b. Radiographic positioning jig (top) and aiming rod (bottom).

6. RESULTS

6.1 Surgical Results

The surgical results include all findings at implant placement, implant uncovering and post-operative reviews.

The average number of appointments for surgery and reviews was 8 (range 5-17). These numbers include a second surgery for implant placement for a patient in whom one implant was found to have failed at uncovering.

6.1.1 Implant Placement

Complications noted at implant placement are summarised in Table 10. Inferior border perforations were common and resulted from the location and angulation of prepared sites. In the edentulous mandible there is only a very narrow band of attached gingiva at the crest of the ridge. To gain a gingival attachment about the eventual abutment (without grafting), the implant were located below a mid-crestal incision. With increasing RRR the crest becomes more lingually placed and so implants located at the crest are more likely to perforate the lingual plate, particularly if they are proclined rather than vertical or retroclined. Pain was associated with all inferior border perforations.

Equipment complications were also common. Drilling in dense cortical bone blunted spade drills and jamming often resulted. Irrigation lines leaked and internally irrigated drills blocked. Only one pilot drill fractured in the 48 sites prepared.

Table 10. Complications at implant placement

	Number of patients (and sites)
Inferior border perforation	9 (17)
Pain at surgery	9 (18)
Equipment complications	9 (18)
-jamming drills	9 (18)
-irrigation problems	8 (13)
-broken drills	1 (1)
Poor adaptation to site	4 (6)

Table 11 summarises all post-surgical complications following implant placement. Wound dehiscence with resultant slow or poor healing occurred in half of the patients within one week of implant placement. This complication was principally related to the suturing technique utilised. The interrupted suturing technique used initially did not prevent the opposing pull of the mentalis and genioglossus muscles from parting the wound. When vertical mattress sutures were used, dehiscences did not eventuate. A total of 3 implant cover or healing screws became loose in two patients with associated pain and poor healing. One screw which exfoliated was replaced and the other two loose screws were retightened. Healing then proceeded uneventfully.

The average number of appointments for implant placement and reviews was 4 (range 3-9).

Table 11. Complications following implant placement

	Number of patients
Poor/slow healing	12
Haematoma	2
Infection	1
Dehiscence	12
Loose/lost cover screw	3
Inferior border pain	6

6.1.2 Implant Uncovering

At implant uncovering measurements of the bone levels adjacent to the implants were made as a base line reference for later radiographic evaluation of changes in marginal bone levels over time.

One implant was found not to be integrated at uncovering and was removed. This failure occurred in the only patient to experience a post-operative infection following implant placement. Following a healing period of 3 months a further implant was placed at the failure site and this implant achieved successful integration. The only other finding of note at uncovering was the number of loose cover screws. Fourteen of the 48 implants placed were found to have loose cover screws at exposure. This was in addition to the 3 screws which caused post-operative problems as outlined above.

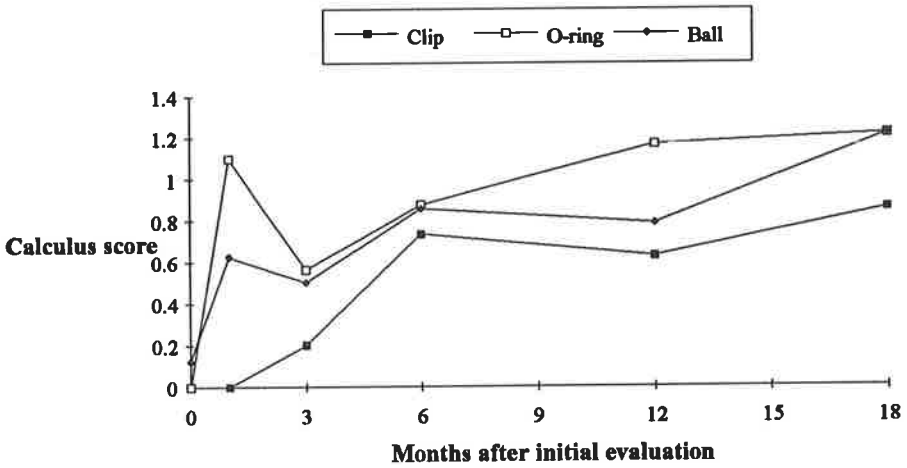
Post-exposure problems were minor and generally involved some tissue irritation related to the temporary gingival cuffs. Table 12 summarises the problems noted at, and following implant uncovering.

Table 12. Complications at, and following implant exposure

	Number of patients (and sites)
Exposure	
Failed implant	1 (1)
Loose cover screw	10 (14)
Post-exposure	
Poor/slow healing	7 (13)
Swelling	2 (3)
Ulceration	2 (3)
Hyperplasia	2 (3)
Infection	1 (1)

The average number of appointments for implant uncovering and reviews was 4 (range 2-8).

Figure 12. Calculus Scores per Attachment System

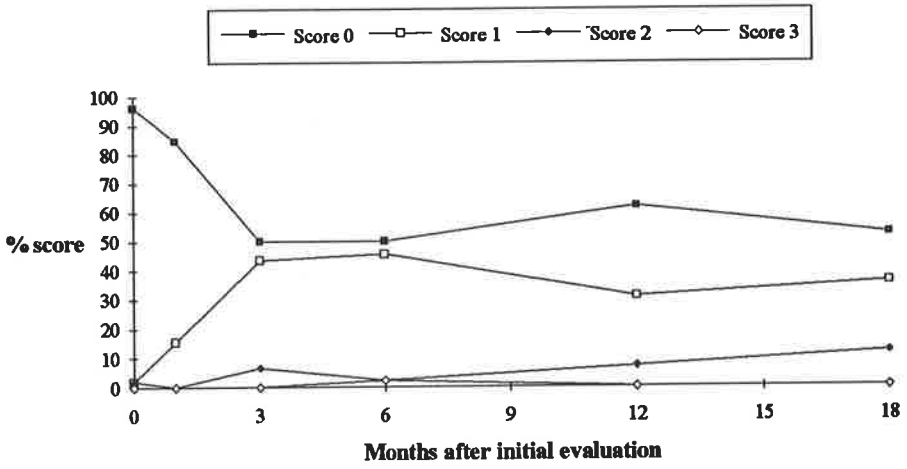


6.2.2 Gingival Bleeding

Percentages of bleeding scores 0 to 3 over the study period were tabulated (Table 17) and the results depicted in Figure 13. Bleeding on gentle probing about abutments (Score 2 or 3) was uncommon averaging between 2 and 12 per cent over the period. In most assessments no bleeding occurred on probing and the tissue colour was normal (50 to 96 per cent of abutments over the period). From the 3 month to the final evaluation between 31 and 45 per cent of abutments displayed erythematous contiguous gingiva but no bleeding on probing.

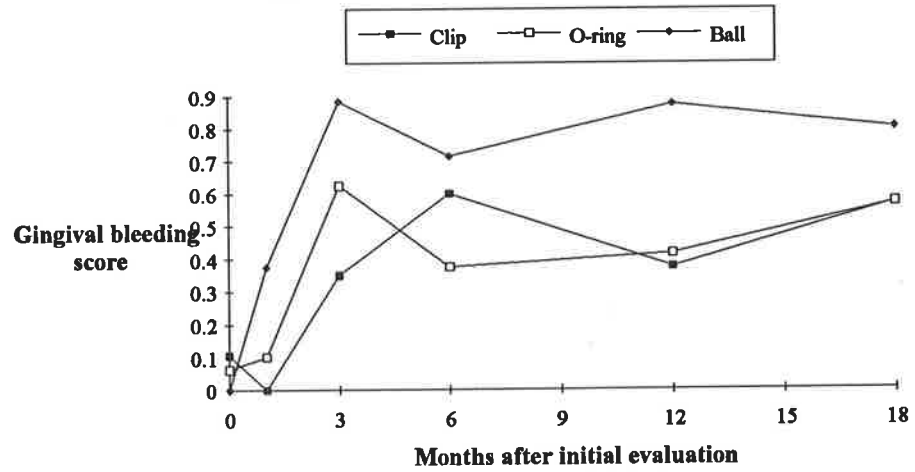
Hence, although minimum to moderate plaque accumulations occurred on about three quarters of the abutments over the period this did not seem to have any significant impact on gingival health with no gingival bleeding occcurring about 88 per cent of abutments.

Figure 13. Distribution of Gingival Bleeding Scores



The lack of a relationship between plaque and gingival bleeding was reinforced when the bleeding score per attachment system was calculated as shown in Table 18 (Score x frequency of score/ total number of scores). Figure 14 shows that the relative bleeding score for ball attachments was graphically higher than for clip and O-ring attachments despite the plaque scores being generally similar. There was no evidence of peri-implant mucositis.

Figure 14. Gingival Bleeding Scores per Attachment System

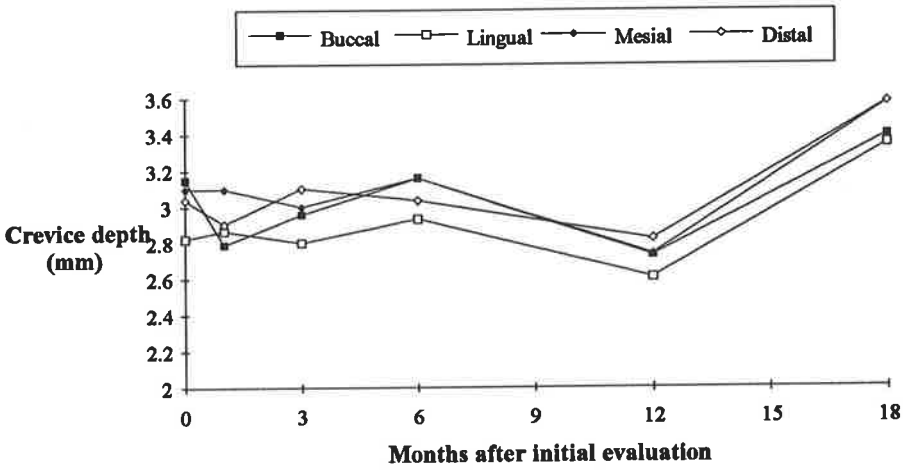


6.2.3 Gingival Crevice Depth

Crevice depth results are shown in Table 19 and Figure 15. For the first 6-months crevice depths were relatively constant ranging between 2.8 and 3.2 mm. At the 12 month assessment a general decrease in depths occurred followed by a general increase in depths at

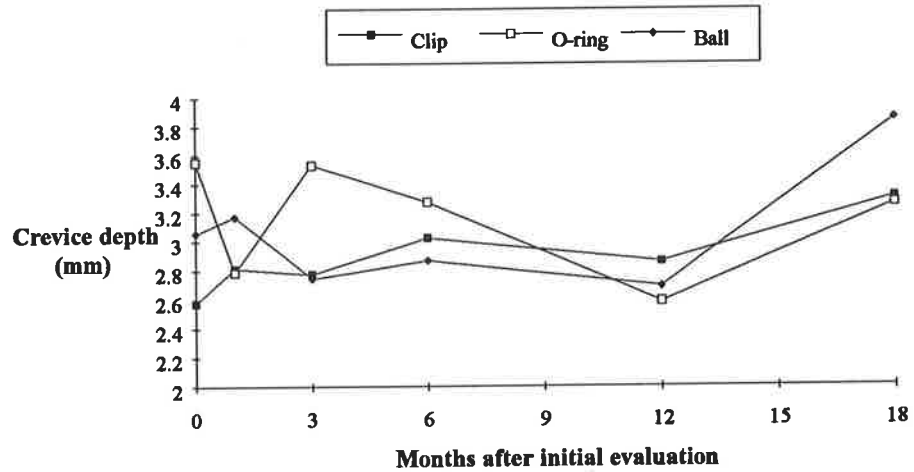
the final evaluation. Such changes represent a true measurement differential of less than one mm and within the errors inherent in measurement taking are not significant. There was no evidence of peri-implantitis.

Figure 15. Gingival Crevice Depth



An average of the scores from the four measurement sites for each attachment system was calculated (Table 20) and then graphed (Figure 16). The results were consistent with the overall findings, demonstrating a differential of less than 1mm between attachments systems at any review period.

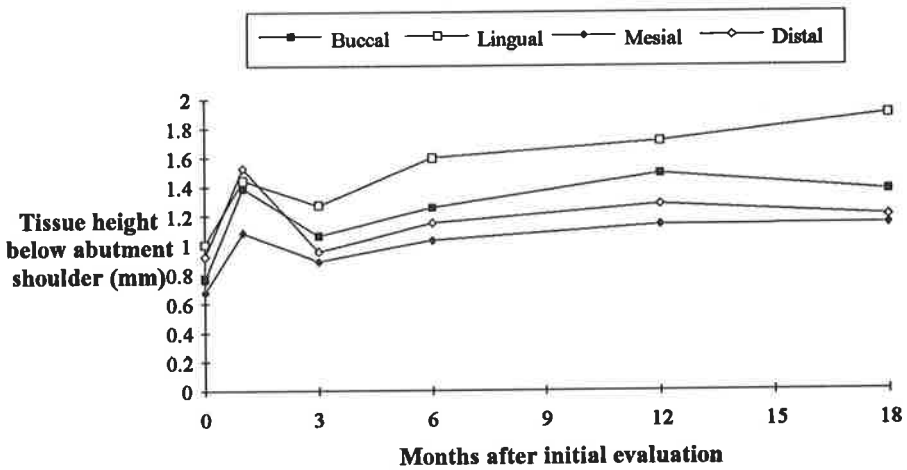
Figure 16. Gingival Crevice Depth per Attachment System



6.2.4 Tissue Height

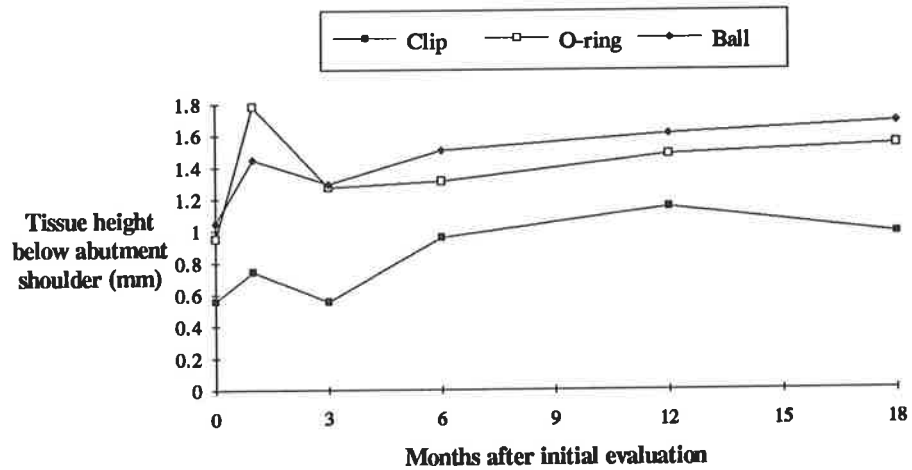
Tissue height was measured relative to the attachment shoulder so that increasing scores denoted decreasing tissue height and decreasing scores, increasing tissue height and possible hyperplasia. The overall results for the four measurement sites showed an initial decrease in tissue height followed by an increase then a final and sustained slow decrease (Table 21, Figure 17).

Figure 17. Tissue Height



The above results were mirrored when tissue height by attachment system was evaluated (Table 22, Figure 18). Only the clip attachment showed any variation to the overall pattern with a slight increase in tissue height at 18 months.

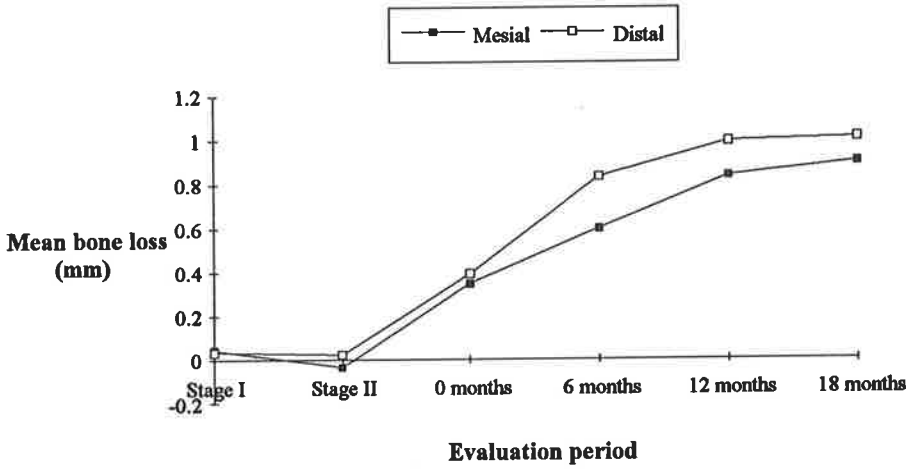
Figure 18. Tissue Height per Attachment System



6.2.5 Bone Loss

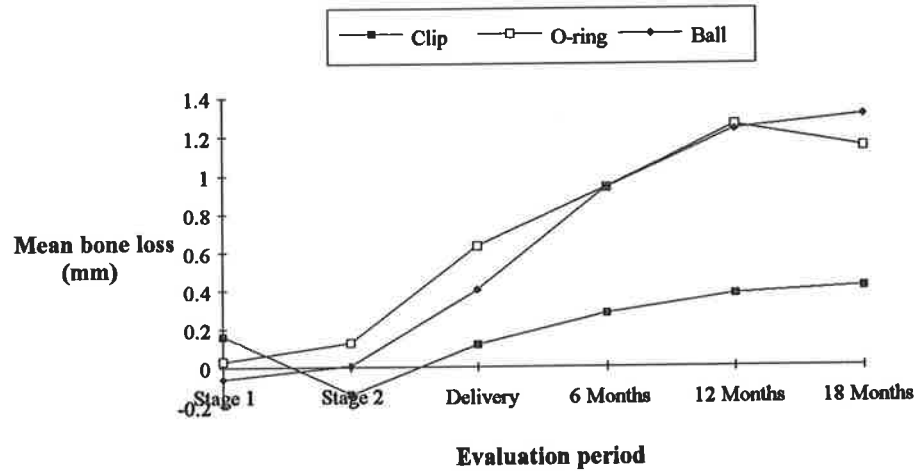
Overall bone measurement results (Table 23, Figure 19) demonstrated a steady loss of marginal bone up to the first year then a gradual plateauing up to the 18 month final evaluation. The average mesial bone loss in the first year was 0.88 mm, while the distal bone loss was 0.99 mm.

Figure 19. Bone Loss



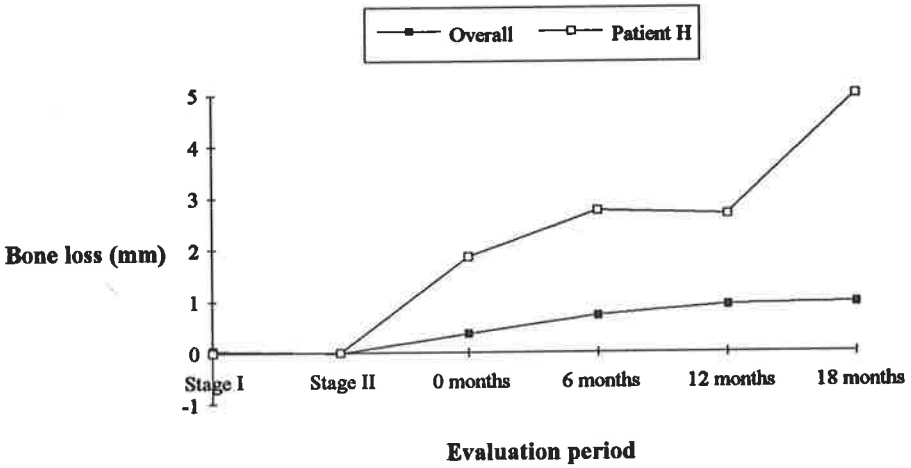
To assess bone loss per attachment system, the mesial and distal scores were averaged (Table 24). The results showed a graphic difference between the splinted clip attachment and the unsplinted O-ring and ball attachments (Figure 20). The average loss at 18 months was 0.41 mm for the clip and 1.14mm for the O-ring and 1.31 mm for the ball.

Figure 20. Bone Loss per Attachment System



Eight patients exhibited bone loss above the average but by no more than 2mm. An exception to this occurred in one patient (ball attachment) who recorded an averaged loss of 6.2mm at 24 months (Figure 21). . Examples of radiographs taken are shown at Annex D

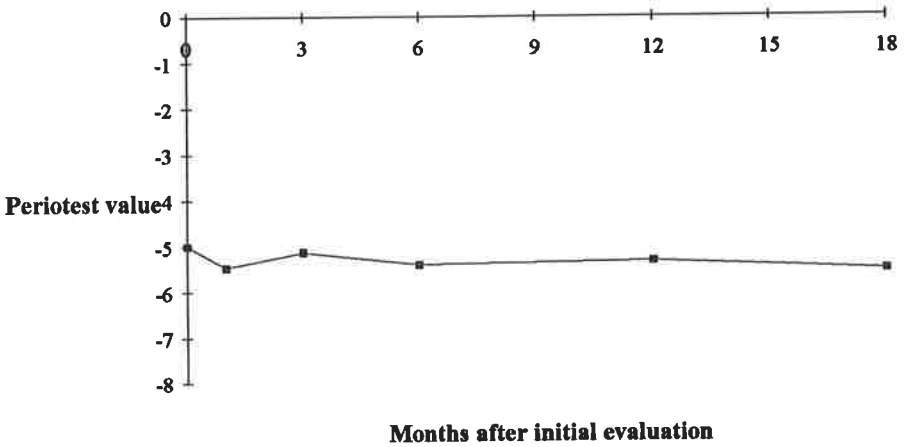
Figure 21. Bone loss - Patient H



6.2.6 Periotest Values

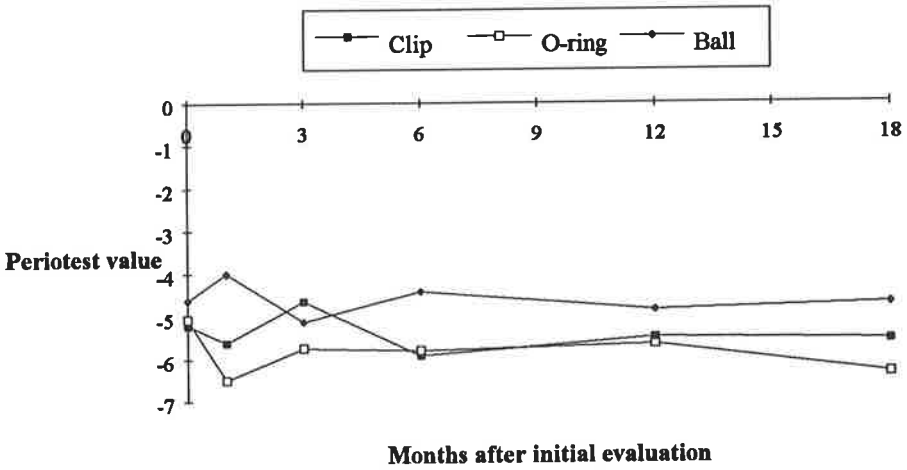
Overall Periotest values remained very consistent throughout the observation period with the average score decreasing from -5 at delivery to -5.55 at 18 months (Table 25, Figure 22).

Figure 22. Periotest Values



When assessed by attachment system the differences were minor with the clip and O-ring attachments scoring marginally better than the ball attachment (Table 26, Figure 23). Periotest values increased in only one patient (Patient H) over the period, from a minimum PTV of -2 to a maximum of +1. This change in PTV's was associated with significant bone loss (0 to 6.2mm over 24 months).

Figure 23. Periotest Values per Attachment System



6.2.7 Peri-implant Correlations

Correlation tests were carried out on 18 month data to determine whether relationships existed between some of the important parameters measured.

Oral Hygiene

Chi square analysis showed that no significant relationship existed between the initial assessment of oral hygiene status (assessed as good/fair/poor in Form D) and the attachment system used ($\chi 2=8.57$, d.f.=4, $p=0.73$).

Chi square analysis of oral hygiene to plaque, calculus and bleeding scores for each attachment system is shown in Table 27. Surprisingly, no relationship was obvious between the initial assessment of oral hygiene status and plaque and calculus scores. Nor was any relationship evident between oral hygiene and O-ring and Ball bleeding scores, whereas a

correlation was noted between oral hygiene and bleeding scores for the Clip system with poorer hygiene relating to higher bleeding scores.

Periotest Values

The relationship of PTV's to retention system, implant length, bone quality and parafunction is shown in Table 28. ANOVA testing showed no significant relationship between the above variables.

Bone loss

The relationship of bone loss to retention system, implant length, bone quality, bone quantity, oral hygiene and parafunction is shown in Table 29. ANOVA testing showed no significant relationship between the above variables.

A standard linear regression analysis showed no correlation between bone loss and periotest scores ($R = 0.15$, $p = 0.47$).

6.3 Prosthetic Results

After the initial patient examination and denture assessment, 26 new dentures were made (12 uppers and 14 lowers) and 12 were relined (8 uppers and 4 lowers).

Prosthetic results are detailed below. Baseline data was recorded at initial assessment (not at delivery of the prostheses) and is designated as time '0' in both tables and graphs. Reviews were then recorded at 1, 3, 6, 12, 18 and for some patients 24 months post-delivery. All tables relevant to prosthetic results are contained in Appendix C.

The average number of prosthetic appointments was 16 (range 4-24) which included an average of 4 reviews (range 2-5).

Prosthetic results were divided into a patients' and a clinician's assessment of denture function, comfort, retention and dysfunction.

6.3.1 Patient Denture Assessment

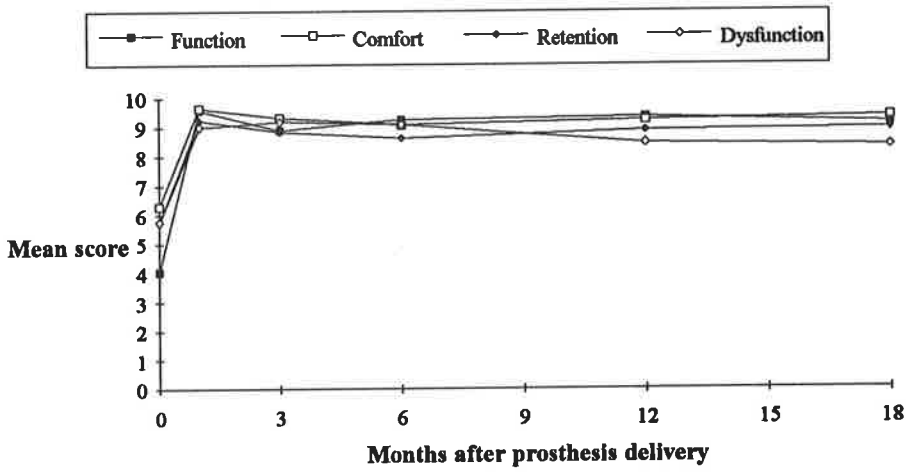
6.3.1 (a) Patient Expectations of and Overall Satisfaction with Treatment

Prior to overdenture delivery, the patient's expectation of implant treatment was evaluated via Questions 23-24 of Form B. On a scale of 0 (no improvement) to 10 (great improvement), the mean score for expected improvements in retention was 9.3, for chewing 9.1, for speaking 7.9, and for appearance 4.9. Thus, most patients had high expectations of treatment.

Overall patient assessment of function, comfort, retention and dysfunction is shown in Table 30 and Figure 24. Mean scores for function rose from 4.04 at initial assessment to 9.59 at 1 month then plateaued out to finish at 9.13 at the final 18 month assessment. Evaluations of comfort, retention and dysfunction followed a similar pattern rising from 6.29 to 9.34, 5.73 to 8.93 and 5.75 to 8.33 respectively. Hence, patients were generally very satisfied with improvements in denture function, comfort and retention with a treatment outcome close to their pre-treatment expectations.

The dysfunction score demonstrated the smallest improvement and the greatest standard deviations. Thus, some patients continued with dysfunctional problems despite an overall improvement for the group.

Figure 24. Patient Denture Assessment over study period



Question 25 of Form B assessed patients' feelings about their treatment and about themselves after therapy.

All patients thought the treatment was worth the trouble and this did not change over the study period.

At each review all patients said that they would repeat the treatment even though some reported that it had been more difficult and/or painful than they thought it would be.

All were happier with their dental health after treatment.

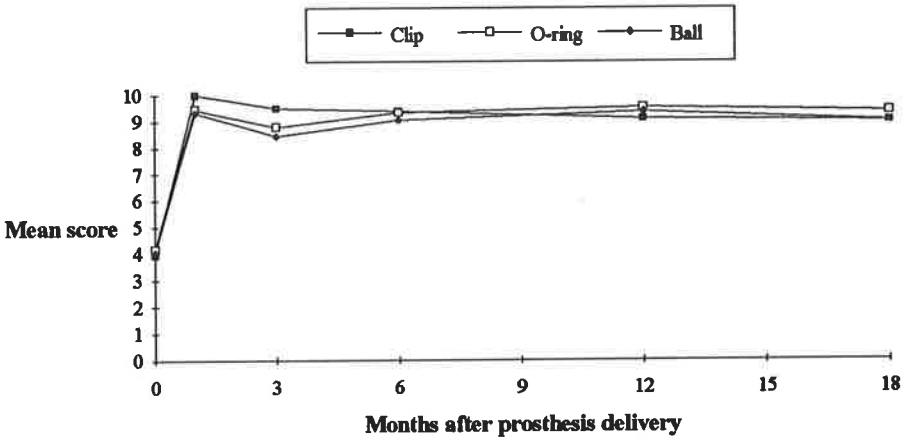
All patients said that they would recommend the treatment.

Sixteen patients said that they were more confident and generally felt better about themselves after treatment.

6.3.1.(b) Overall Patient Assessment by Attachment System

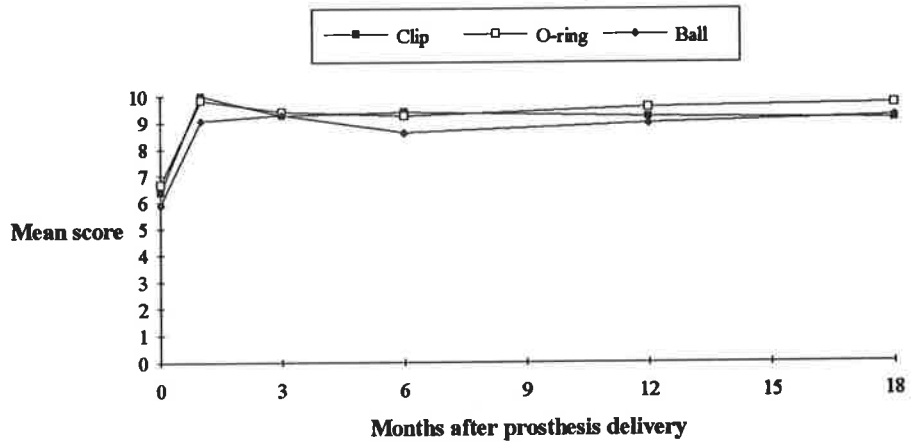
Patient assessment of function, comfort and retention by attachment system is shown in Tables 31, 32, 33 and Figures 25, 26, 27. At the end of the observation period there was very little difference between the retention systems with each demonstrating significant improvements in scores.

Figure 25. Patient Denture Assessment of Function per Attachment System



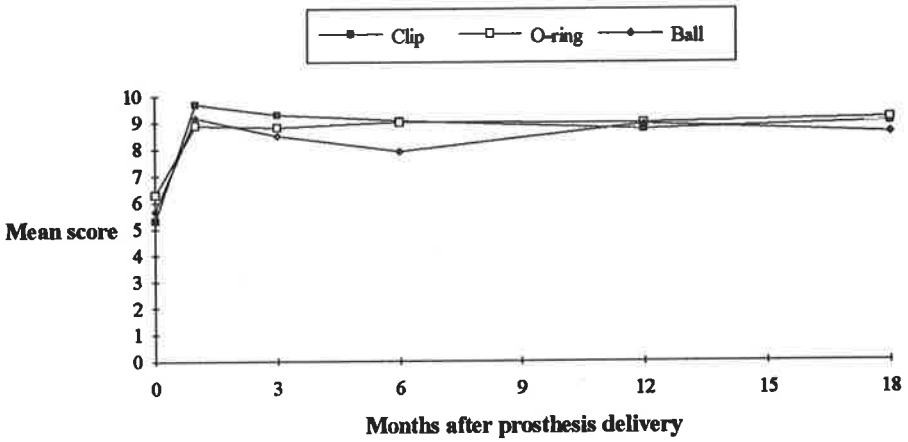
Functional scores improved by 125 per cent for both clip and O-ring and 123 per cent for ball attachments. Statistical analysis using ANOVA showed no significant difference between the three retention systems at 18 months (Mean = 9.13, S.D.= 1.42, Degrees of Freedom = 2, F value = 0.17, Probability = 0.85).

Figure 26. Patient Denture Assessment of Comfort per Attachment System



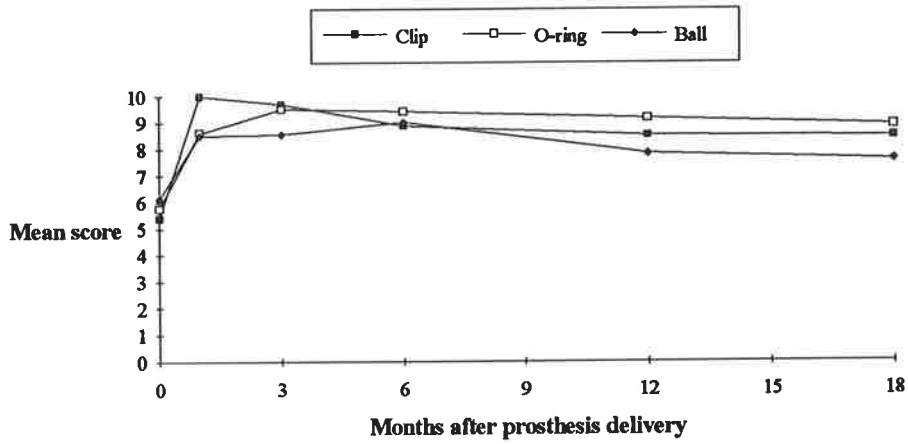
Comfort scores improved by 56, 45 and 43 per cent for ball, O-ring and clip attachments respectively.

Figure 27. Patient Denture Assessment of Retention per Attachment System



Retention scores improved by 70, 50 and 45 per cent for clip, ball and O-ring.

Figure 28. Patient Denture Assessment of Dysfunction per Attachment System

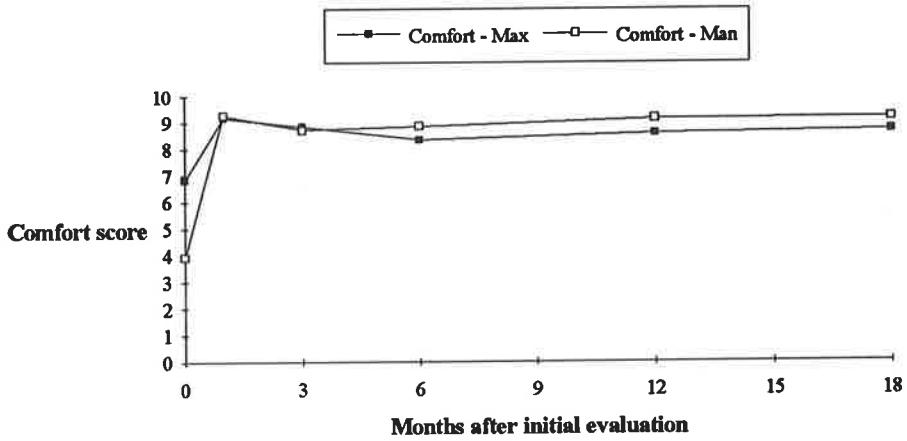


Assessment of dysfunction showed greater variation between the groups with ball attachments demonstrating the poorest score (Table 34, Figure 28). Clip and O-ring scores improved by 56 and 54 per cent respectively whereas ball scores improved by 23 per cent. Statistical analysis using ANOVA showed no significant difference between the three retention systems at 18 months (Mean = 8.33, S.D.= 2.70, Degrees of Freedom = 2, F value = 0.43, Probability = 0.66).

6.3.1.(c) Patient Assessment of Comfort by Arch and Attachment System

To demonstrate differences in comfort scores in each arch, patient assessment was further analyzed by arch and then by arch and attachment system (Tables 35, 36 and 37).

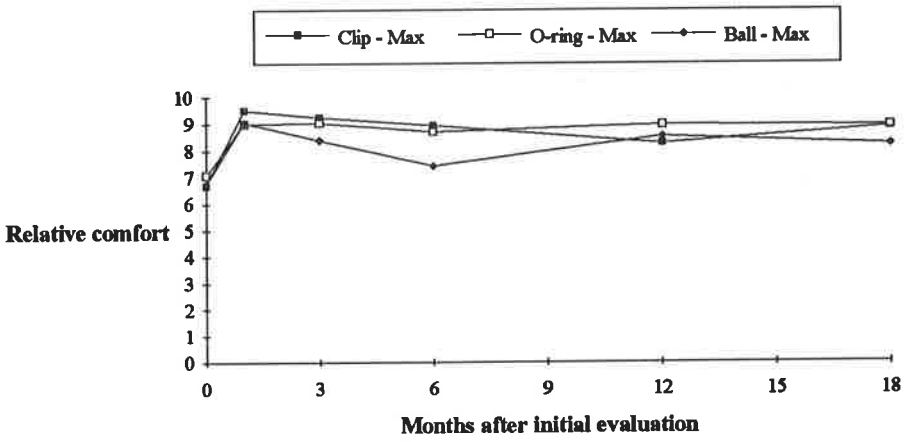
Figure 29. Patient Denture Assessment of Maxillary and Mandibular Comfort



When evaluated by arch, mandibular comfort rose from a low score of 3.92 to a high 9.15 illustrating a pronounced improvement in comfort over the observation period (Figure 29). Maxillary comfort rose from a high base score of 6.82 to 8.67. Hence, over the 18 month period the mandibular comfort score rose by 133 per cent compared to a maxillary score increase of only 27 per cent. Where at initial assessment the maxillary arch was the more comfortable at the final observation the mandibular arch was the more comfortable.

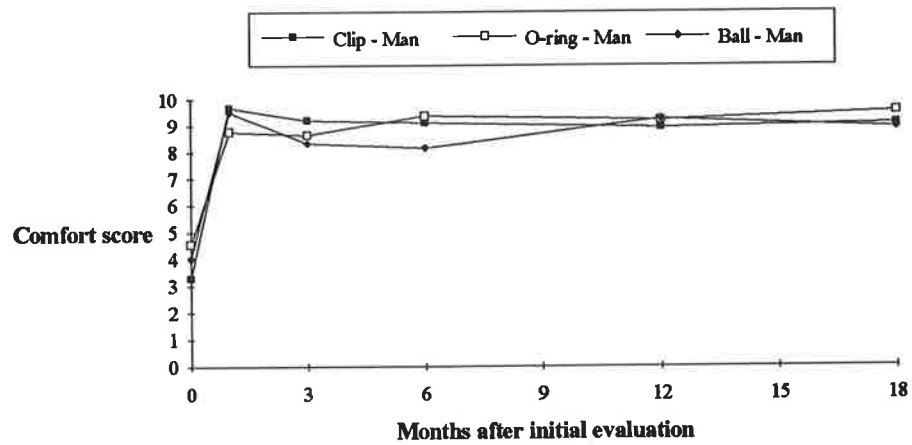
When asked about possible improvements in treatment, 7 patients suggesting improving the upper denture.

Figure 30. Patient Denture Assessment of Maxillary Comfort per Attachment System



Patient evaluation of maxillary comfort by attachment system is shown in Figure 30. The clip score improved from 6.68 to 8.85 (32 per cent), the O-ring from 7.06 to 8.89 (26 per cent) and the ball from 6.74 to 8.21 (22 per cent). Thus, the clip and the O-ring systems scored similarly and slightly higher than the ball attachments. Statistical analysis using ANOVA showed no significant difference between the three retention systems at 18 months (Mean = 8.67, S.D.= 1.69, Degrees of Freedom = 2, F value = 0.35, Probability = 0.71).

Figure 31. Patient Denture Assessment of Mandibular Comfort per Attachment System



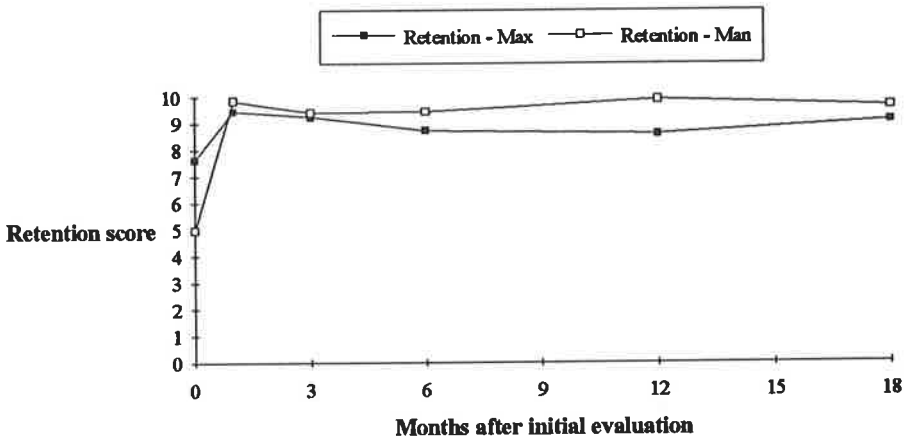
A similar pattern was evident when the assessment of mandibular comfort by attachment sytem was analyzed (Figure 31). The clip recorded a 176 per cent improvement from a baseline score of 3.27, the O-ring a 109 per cent improvement from a 4.54 baseline and

the ball a 120 per cent improvement from a 4.01 baseline. Hence, the best raw scores were recorded by the O-ring and the worst by the ball system, with the clip recording the greatest improvement in comfort scores.

6.3.1.(d) Patient Assessment of Retention by Arch and Attachment System

As for comfort, patient assessment of retention was further analyzed by arch and then by arch and attachment system (Tables 38, 39 and 40).

Figure 32. Patient Denture Assessment of Maxillary and Mandibular Retention



A dramatic increase in mandibular retention from a score of 4.96 to 9.63 dwarfed a much smaller rise in maxillary retention of 7.61 to 9.06 from pre-delivery to final assessment (Figure 32). Hence, patients recorded a 94 per cent improvement in mandibular retention compared to a 19 per cent improvement for maxillary retention after 18 months. Where the maxillary denture was easily the more retentive pretreatment, after treatment the mandibular denture became so.

Figure 33. Patient Denture Assessment of Maxillary Retention per Attachment System

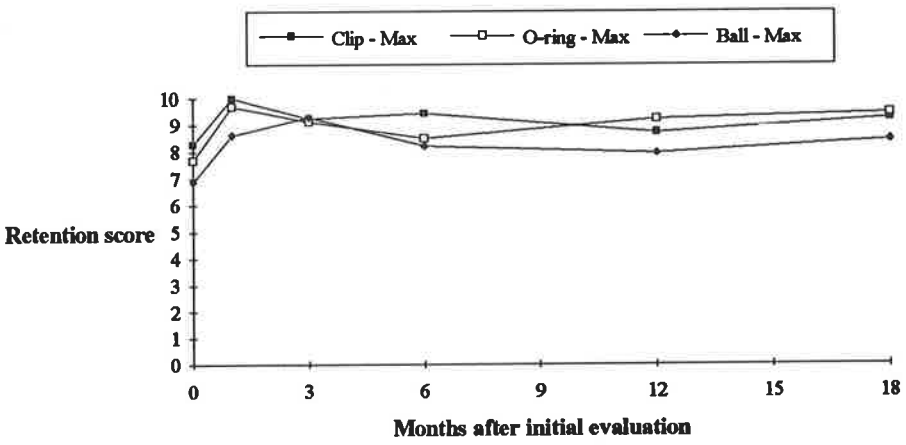
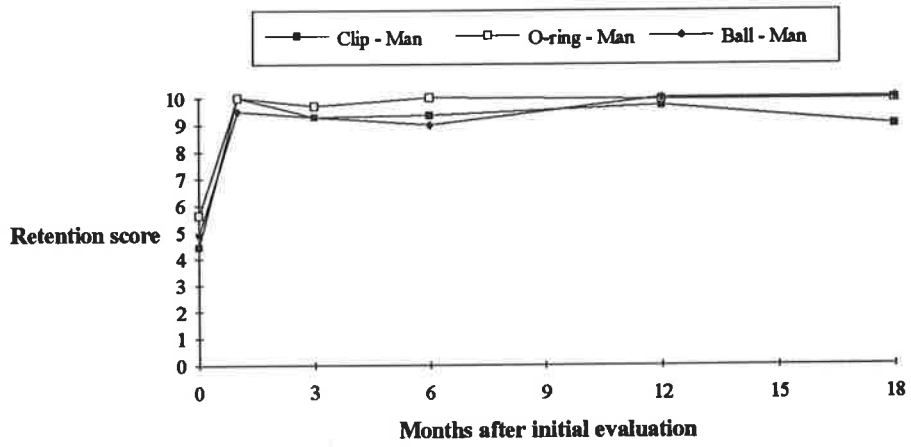


Figure 33 compares maxillary retention by attachment system and exhibits a familiar pattern with clip and O-ring attachments recording comparable and higher scores than ball attachments. Statistical analysis using ANOVA showed no significant difference between the three retention systems at 18 months (Mean = 9.06, S.D.= 1.55, Degrees of Freedom = 2, F value = 0.86, Probability = 0.44).

Figure 34. Patient Denture Assessment of Mandibular Retention per Attachment System



When mandibular retention was analyzed by attachment system, no clear preference was evident at 12 months but the O-ring and ball groups scored better than the clip at 18 months (Figure 34). Statistical analysis using ANOVA showed no significant difference

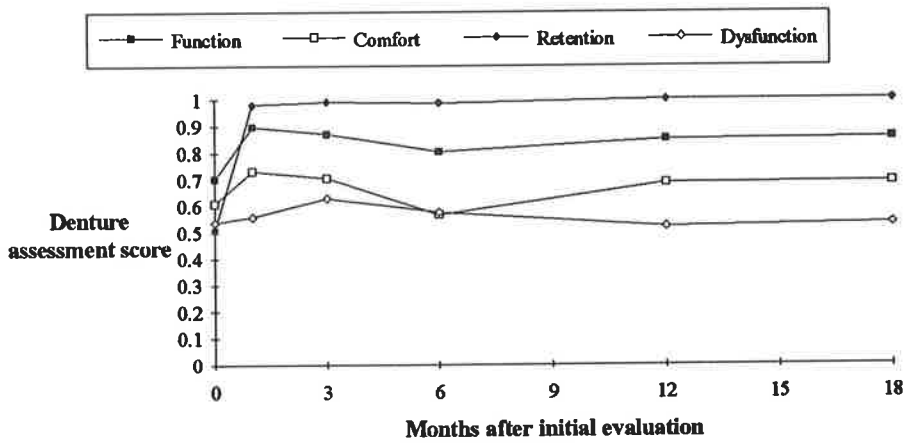
between the three retention systems at 18 months (Mean = 9.63, S.D.= 1.37, Degrees of Freedom = 2, F value = 0.33, Probability = 0.29).

6.3.2 Clinical Denture Assessment

6.3.2.(a) Overall Clinical Assessment

The overall clinical appraisal of denture function, comfort, retention and dysfunction is shown in Table 41 and Figure 35.

Figure 35. Clinical Denture Assessment of Function, Comfort, Retention and Dysfunction



An improvement in function (28 per cent) was noted at the first review after insertion of the overdenture, thereafter the functional score fell away over the 3 and 6 month reviews before improving to finish 23 per cent above the score recorded at the initial examination (0.70 to 0.86).

The comfort score improved by 20 per cent immediately after delivery then weakened and at 6 months had fallen to below the initial score indicating increasing comfort problems as patients became more experienced with their prostheses. The comfort scores improved at the 12 month review and flattened out to finish at slightly better than the score recorded at the inital examination (0.61 to 0.69). Hence, at the 18 month review overall denture comfort had improved marginally (13 per cent) according to the observer.

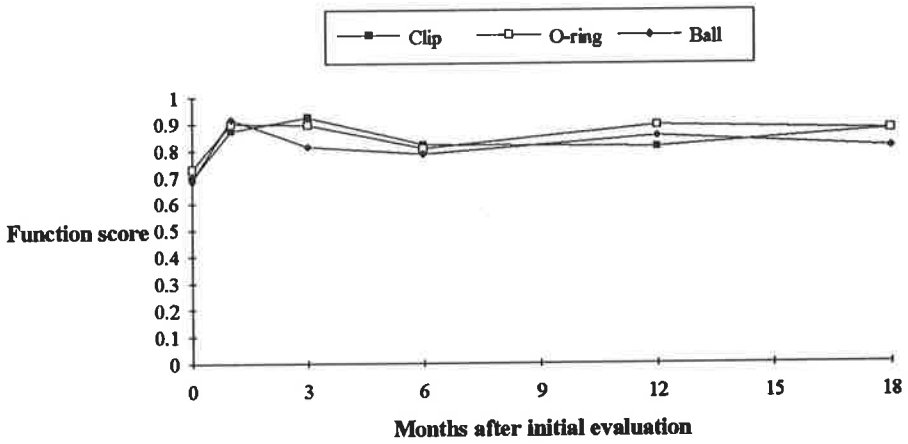
Retention scored worst at initial examination (0.51) but dramatically improved after delivery (0.98), a 92 per cent improvement which was sustained over the observation period with very few negative responses recorded.

The initial dysfunctional score (0.54) was similar to that of retention and although the score improved up to 3 months, the improvement was marginal and fell away in the ensuing 15 months to end virtually where it started (0.53). Thus, despite an initial improvement, dysfunctional problems remained largely unchanged after 18 months.

6.3.2.(b) Overall Clinical Assessment by Attachment System

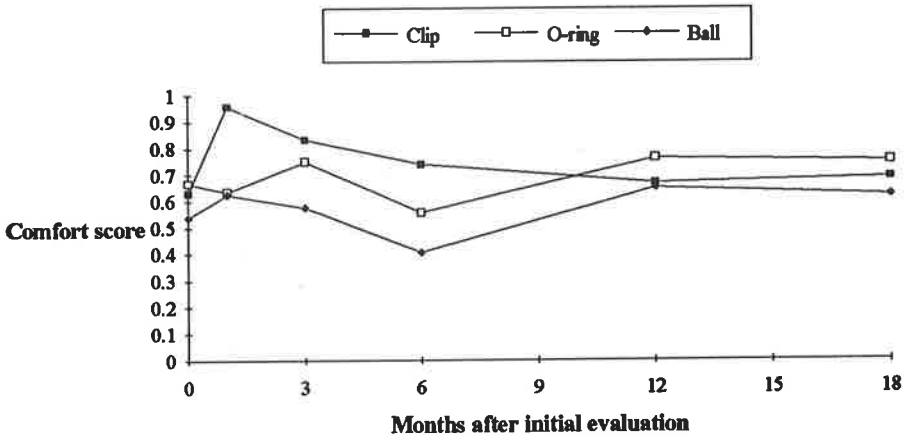
The clinical assessment scores of function, comfort, retention and dysfunction by attachment system are shown in Tables 42, 43, 44 and 45 and in Figures 36, 37, 38 and 39.

Figure 36. Clinical Denture Assessment of Function per Attachment System



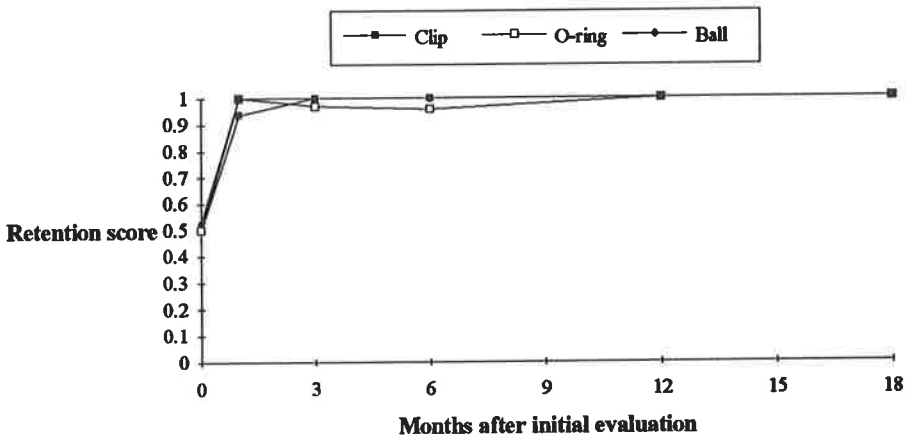
Functional scores for clip and O-ring were very close throughout the study period and marginally superior to ball attachment scores (Figure 36). A trend very similar to the patient assessment. Statistical analysis using ANOVA showed no significant difference between the three retention systems at 18 months (Mean = 1.85, S.D.= 0.06, Degrees of Freedom = 2, F value = 4.05, Probability = 0.03).

Figure 37. Clinical Denture Assessment of Comfort per Attachment System



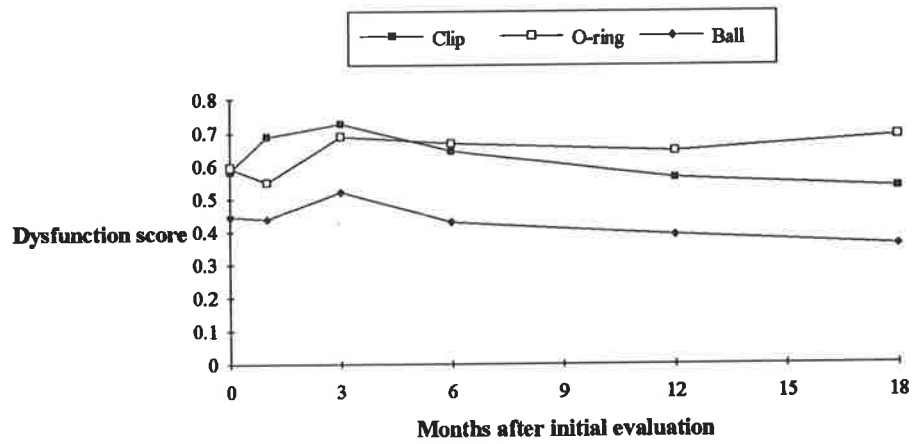
The trend was not so apparent when the comfort scores of the different attachment systems were graphed (Figure 37). The scores were more varied with the clip scoring highly at the first review before falling to finish about 10 per cent above the initial score at 18 months. The O-ring score fell at the first review, rose and fell at the second and third reviews before rising and stabilising at a score 14 per cent above the original. The ball score was again the poorest, but coming off the lowest base did eventually rise to record a 15 per cent improvement at 18 months. When compared to the patient assessment of comfort where the different attachment systems scored closely throughout the study period, the clinical assessment showed far greater variation between retention systems at different reviews. Notwithstanding, the final scores were still reasonably close with the O-ring scoring better than clip than ball.

Figure 38. Clinical Denture Assessment of Retention per Attachment System



The clinical assessment of retention showed very little variation between the scores of each system (Figure 38). All showed a dramatic and sustained improvement (100 per cent) which was the general trend apparent in the patient assessment.

Figure 39. Clinical Denture Assessment of Dysfunction per Attachment System



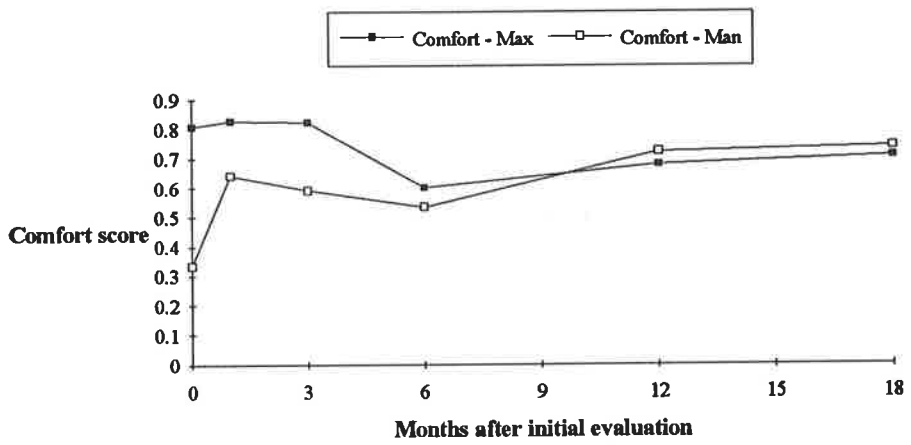
The clinical dysfunctional scores followed a similar pattern to the comfort scores with a wider variation apparent than in the patient assessment (Figure 39). The ball group scored the poorest from the lowest base with a final score 18 per cent worse than the initial score. The clip group showed some improvement over the first three reviews then fell away to end some 10 per cent worse off at the final assessment. Only the O-ring group showed any longer-term improvement with a 17 percent increase over the initial score at 18 months. Statistical analysis

using ANOVA showed no significant difference between the three retention systems at 18 months (Mean = 1.40, S.D.= 0.28, Degrees of Freedom = 2, F value = 0.95, Probability = 0.42).

6.3.2.(c) Clinical Assessment of Comfort by Arch and Attachment System

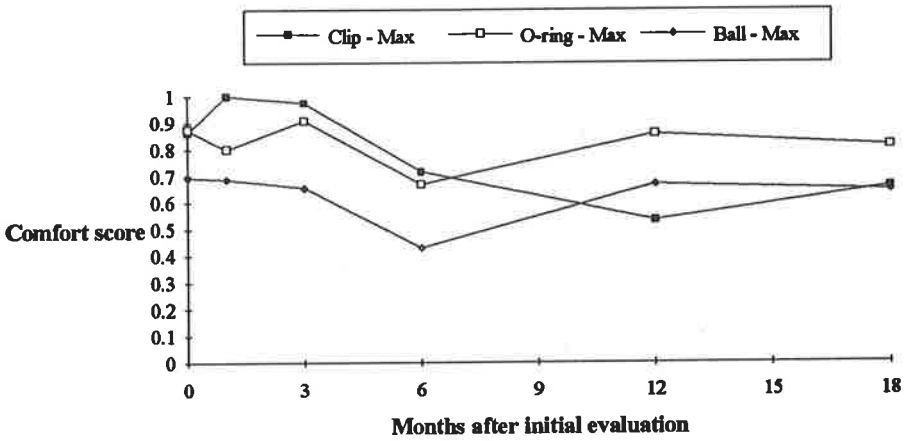
As for the patient assessment of comfort the clinical assessment was further analyzed by arch and then by arch and attachment system (Tables 46, 47 and 48).

Figure 40. Clinical Denture Assessment of Maxillary and Mandibular Comfort



When evaluated by arch, mandibular comfort rose from a low score of 0.33 to a high of 0.74 demonstrating a 124 per cent improvement in comfort over the observation period (Figure 40). At the same time maxillary comfort fell from a high base score of 0.81 to 0.71 - a 12 per cent drop in comfort. The clinically assessed mandibular comfort improvement was comparable to the 133 per cent improvement recorded in the patient assessment. Although the maxillary scores of patient (27 per cent increase) and clinical (a 12 per cent decrease) assessments were not as comparable, the overall trends were i.e. where at initial assessment the maxillary arch was the more comfortable at the final observation the mandibular arch was the more comfortable.

Figure 41. Clinical Denture Assessment of Maxillary Comfort per Attachment System



Clinical evaluation of maxillary comfort by attachment system is shown in Figure 41. Comfort improved at the 1 and 3 month reviews for the clip system, then fell away significantly at the 6 and 12 month reviews before recovering slightly to show an overall 24 per cent drop in score over the study period (0.86 to 0.66). The O-ring score fluctuated up and down relative to baseline over the study period before finishing 6 per cent below baseline at 18 months (0.87 to 0.81). From the lowest baseline, the ball system score fell away to the 6 month review before recovering to show a 7 per cent drop in comfort at 18 months (0.69 to 0.64). Hence, the O-ring recorded the highest raw score and the ball system the lowest at the end of the study but all systems showed falls in maxillary comfort with the clip recording the greatest fall. Statistical analysis using ANOVA showed no significant difference between the three retention systems at 18 months (Mean = 1.58, S.D.= 0.36, Degrees of Freedom = 2, F value = 0.49, Probability = 0.62).

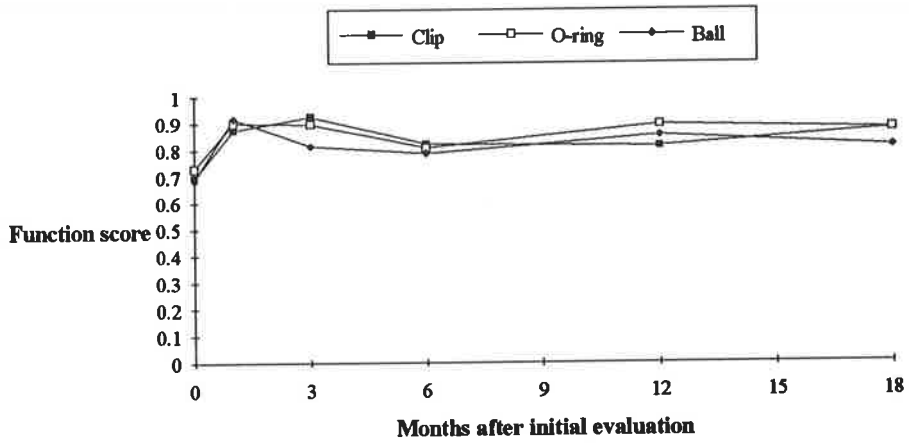
Retention scored worst at initial examination (0.51) but dramatically improved after delivery (0.98), a 92 per cent improvement which was sustained over the observation period with very few negative responses recorded.

The initial dysfunctional score (0.54) was similar to that of retention and although the score improved up to 3 months, the improvement was marginal and fell away in the ensuing 15 months to end virtually where it started (0.53). Thus, despite an initial improvement, dysfunctional problems remained largely unchanged after 18 months.

6.3.2.(b) Overall Clinical Assessment by Attachment System

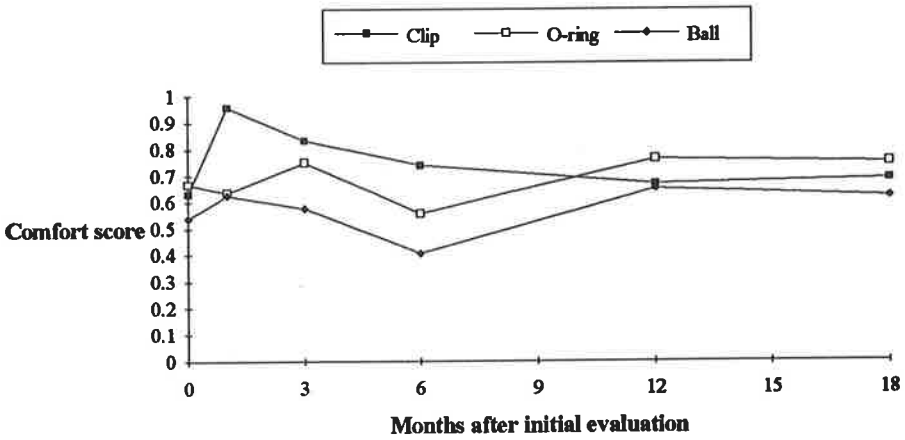
The clinical assessment scores of function, comfort, retention and dysfunction by attachment system are shown in Tables 42, 43, 44 and 45 and in Figures 36, 37, 38 and 39.

Figure 36. Clinical Denture Assessment of Function per Attachment System



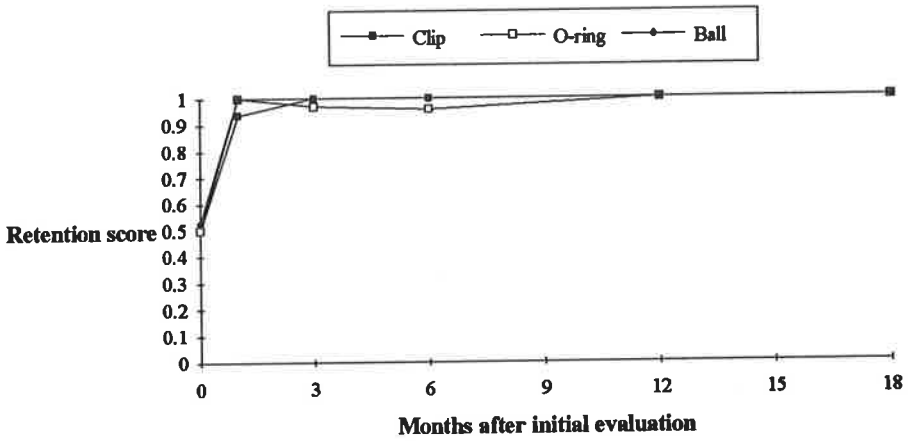
Functional scores for clip and O-ring were very close throughout the study period and marginally superior to ball attachment scores (Figure 36). A trend very similar to the patient assessment. Statistical analysis using ANOVA showed no significant difference between the three retention systems at 18 months (Mean = 1.85, S.D.= 0.06, Degrees of Freedom = 2, F value = 4.05, Probability = 0.03).

Figure 37. Clinical Denture Assessment of Comfort per Attachment System



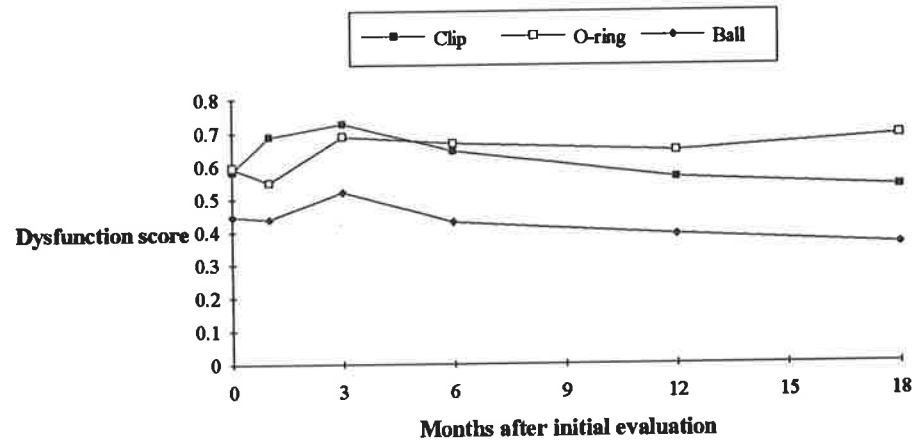
The trend was not so apparent when the comfort scores of the different attachment systems were graphed (Figure 37). The scores were more varied with the clip scoring highly at the first review before falling to finish about 10 per cent above the initial score at 18 months. The O-ring score fell at the first review, rose and fell at the second and third reviews before rising and stabilising at a score 14 per cent above the original. The ball score was again the poorest, but coming off the lowest base did eventually rise to record a 15 per cent improvement at 18 months. When compared to the patient assessment of comfort where the different attachment systems scored closely throughout the study period, the clinical assessment showed far greater variation between retention systems at different reviews. Notwithstanding, the final scores were still reasonably close with the O-ring scoring better than clip than ball.

Figure 38. Clinical Denture Assessment of Retention per Attachment System



The clinical assessment of retention showed very little variation between the scores of each system (Figure 38). All showed a dramatic and sustained improvement (100 per cent) which was the general trend apparent in the patient assessment.

Figure 39. Clinical Denture Assessment of Dysfunction per Attachment System



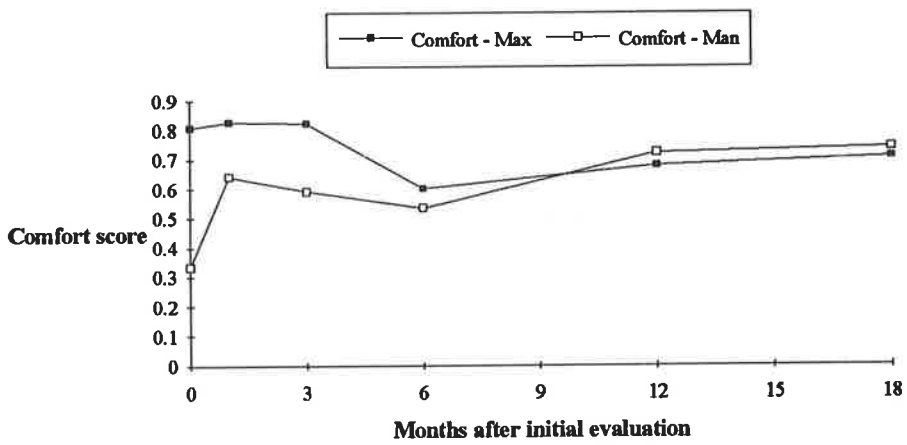
The clinical dysfunctional scores followed a similar pattern to the comfort scores with a wider variation apparent than in the patient assessment (Figure 39). The ball group scored the poorest from the lowest base with a final score 18 per cent worse than the initial score. The clip group showed some improvement over the first three reviews then fell away to end some 10 per cent worse off at the final assessment. Only the O-ring group showed any longer-term improvement with a 17 percent increase over the initial score at 18 months. Statistical analysis

using ANOVA showed no significant difference between the three retention systems at 18 months (Mean = 1.40, S.D.= 0.28, Degrees of Freedom = 2, F value = 0.95, Probability = 0.42).

6.3.2.(c) Clinical Assessment of Comfort by Arch and Attachment System

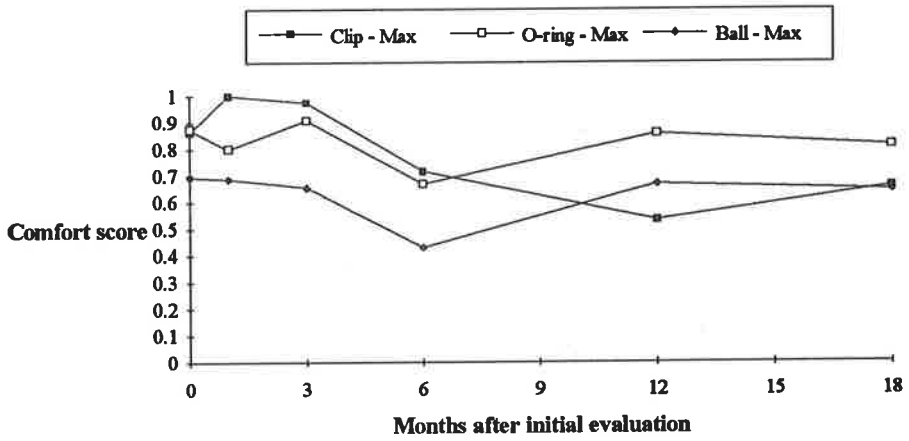
As for the patient assessment of comfort the clinical assessment was further analyzed by arch and then by arch and attachment system (Tables 46, 47 and 48).

Figure 40. Clinical Denture Assessment of Maxillary and Mandibular Comfort



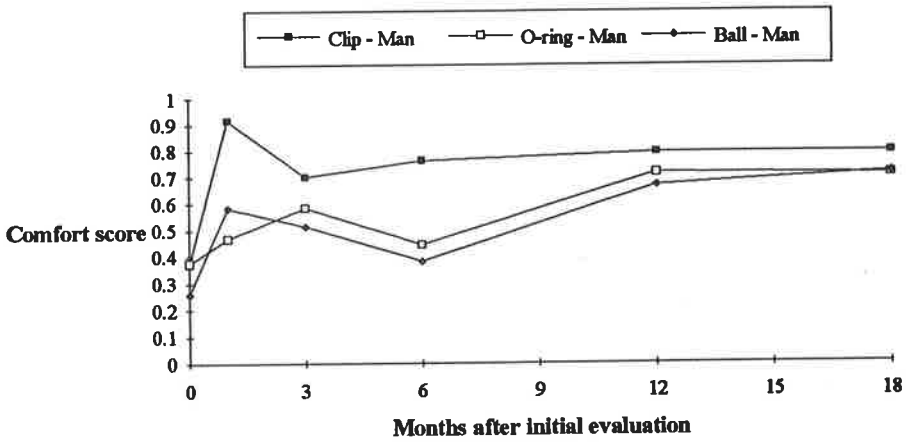
When evaluated by arch, mandibular comfort rose from a low score of 0.33 to a high of 0.74 demonstrating a 124 per cent improvement in comfort over the observation period (Figure 40). At the same time maxillary comfort fell from a high base score of 0.81 to 0.71 - a 12 per cent drop in comfort. The clinically assessed mandibular comfort improvement was comparable to the 133 per cent improvement recorded in the patient assessment. Although the maxillary scores of patient (27 per cent increase) and clinical (a 12 per cent decrease) assessments were not as comparable, the overall trends were i.e. where at initial assessment the maxillary arch was the more comfortable at the final observation the mandibular arch was the more comfortable.

Figure 41. Clinical Denture Assessment of Maxillary Comfort per Attachment System



Clinical evaluation of maxillary comfort by attachment system is shown in Figure 41. Comfort improved at the 1 and 3 month reviews for the clip system, then fell away significantly at the 6 and 12 month reviews before recovering slightly to show an overall 24 per cent drop in score over the study period (0.86 to 0.66). The O-ring score fluctuated up and down relative to baseline over the study period before finishing 6 per cent below baseline at 18 months (0.87 to 0.81). From the lowest baseline, the ball system score fell away to the 6 month review before recovering to show a 7 per cent drop in comfort at 18 months (0.69 to 0.64). Hence, the O-ring recorded the highest raw score and the ball system the lowest at the end of the study but all systems showed falls in maxillary comfort with the clip recording the greatest fall. Statistical analysis using ANOVA showed no significant difference between the three retention systems at 18 months (Mean = 1.58, S.D.= 0.36, Degrees of Freedom = 2, F value = 0.49, Probability = 0.62).

Figure 42. Clinical Denture Assessment of Mandibular Comfort per Attachment System

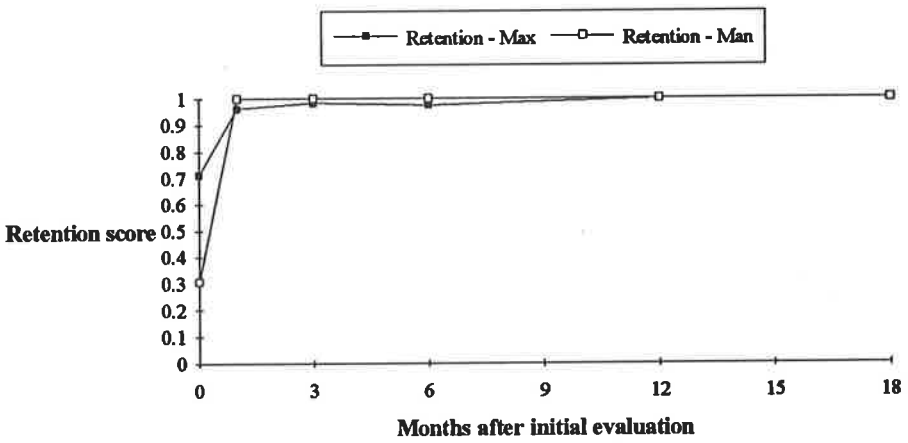


The assessment of mandibular comfort by attachment system showed a 114 per cent improvement from a baseline score of 0.37 for the clip, an 89 per cent improvement from a baseline of 0.37 for the O-ring and a 176 per cent improvement from a baseline of 0.26 for the ball system (Figure 42). Thus, the clip recorded the highest final raw score and the ball the largest improvement in score. Statistical analysis using ANOVA showed no significant difference between the three retention systems at 18 months (Mean = 1.74, S.D.= 0.28, Degrees of Freedom = 2, F value = 0.20, Probability = 0.82).

6.3.2.(d) Clinical Assessment of Retention by Arch and Attachment System

As for comfort, the clinical assessment of retention was further analyzed by arch and then by arch and attachment system (Tables 49, 50 and 51).

Figure 43. Clinical Denture Assessment of Maxillary and Mandibular Retention



Mandibular retention improved dramatically from a score of 0.31 to 1.00 compared to a much smaller rise in maxillary retention of 0.71 to 1.00 from pre- to post- delivery assessment (Figure 43). Hence, the clinical evaluation recorded a 223 per cent improvement in mandibular retention compared to a 41 per cent improvement in maxillary retention after delivery.

Figure 44. Clinical Denture Assessment of Maxillary Retention per Attachment System

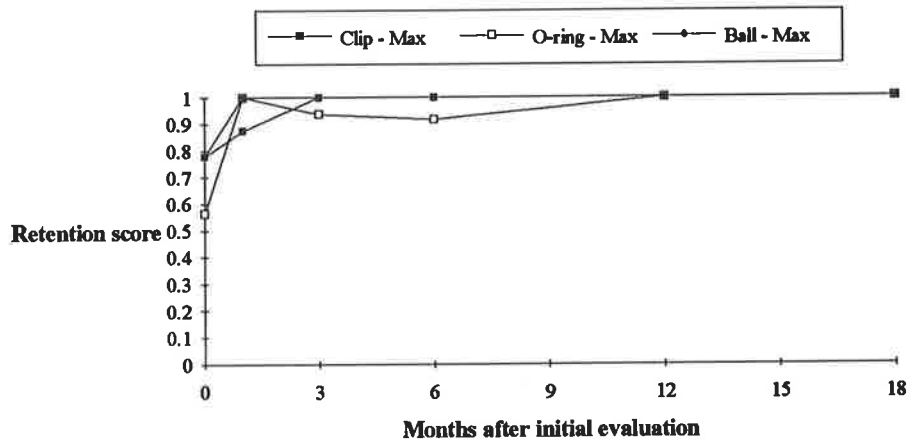
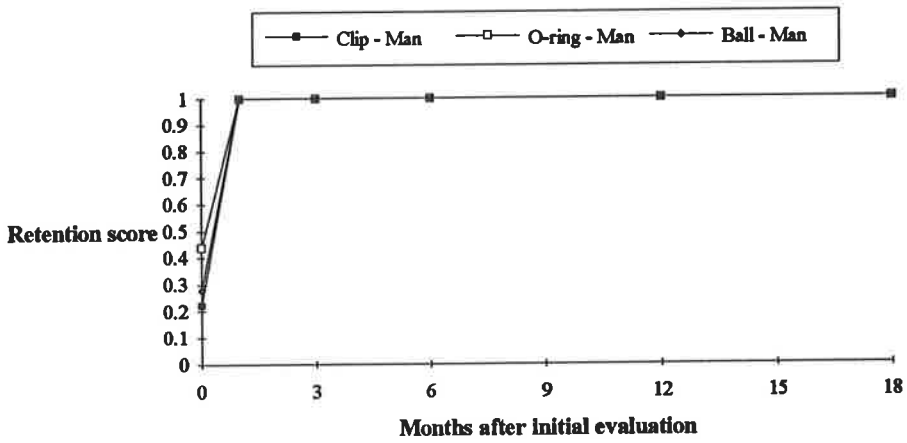


Figure 44 compares maxillary retention by attachment system. The graph shows that attachment systems had little effect on maxillary retention over the study period.

Figure 45. Clinical Denture Assessment of Mandibular Retention per Attachment System



When mandibular retention was analyzed by attachment system, no difference was evident after delivery with all systems retaining the lower denture adequately (Figure 45).

6.3.3 Prosthetic Correlations

Correlation tests were carried out on 18 month data on both patient and clinician assessments of denture use to determine whether relationships existed between some of the important parameters measured.

6.3.3.(a) Patient Assessment

Function

Patient assessment of function was tested against attachment system and pyschological history (question 13 Form A). ANOVA testing showed no significant relationship between the above variables (Table 52).

Comfort

Patient assessment of comfort was tested against attachment system and pyschological history (Table 53). ANOVA testing showed no significant relationship between the above variables.

Maxillary comfort was tested against attachment system, parafunction and bone quantity (Table 54). ANOVA testing showed no significant relationship between the above variables.

Mandibular comfort was tested against attachment system and bone quantity (Table 55). ANOVA testing showed no significant relationship between the above variables.

Retention

Patient assessment of maxillary and mandibular retention were tested against attachment system, pyschological history and bone quantity (Table 56 and 57). ANOVA testing showed no significant relationship between the above variables.

Dysfunction

Patient assessment of dysfunction was tested against attachment system and pyschological history (Table 58). ANOVA testing showed no significant relationship between the above variables.

6.3.3.(b) Clinician Assessment

Function

Clinician assessment of function was tested against attachment system and pyschological history (Table 59). ANOVA testing showed no significant relationship between the above variables.

Comfort

Maxillary comfort was tested against attachment system, parafunction and bone quantity (Table 60). Mandibular comfort was tested against attachment system and bone quantity (Table 61). Further, question 1 of Form C which examined soreness in the upper denture bearing area and question 35 which examined soreness specifically in the premaxillary area were tested against attachment system and parafunction (Table 62 and 63). ANOVA testing showed no significant relationship between the above variables apart from maxillary comfort and Questions 35, and parafunction ($P < 0.01$).

Dysfunction

Patient assessment of dysfunction was tested against attachment system (Table 64). ANOVA testing showed no significant relationship between the above variables.

6.3.4 Prosthetic Maintenance

Prosthetic problems with resultant maintenance were notable factors of overall treatment. The most common prosthetic problems encountered at each review are listed in Table 65. All problems concerned the dentures and not the abutments.

Discrepancies in the occlusion, principally heavy anterior contacts were common. Fractures of the denture bases and teeth (10 of 48 dentures) were surprisingly high as were soft liner problems with the Molloplast liners. Either the liner deteriorated (often with Candida Albicans growths) or it ripped about the abutment. Most of the liner tears occurred where the abutments were not parallel. Component loss figures all relate to the loss of rubber O-rings and as for liner tears usually occurred where the abutments were not parallel. Finally, decreased retention was noted in 29 upper and 12 lower dentures over the assessment period.

Table 65. Post-insertion prosthetic problems

Review (months)	1	3	6	12	18	Total
Occlusion Problems	3	6	5	5	1	20
Fractured U Denture	0	1	0	0	0	1
Fractured L Denture	0	0	1	2	1	4
Fractured Teeth	0	2	0	2	1	5
Soft Liner Problems	0	4	3	3	5	15
Component Loss	2	1	0	1	5	9
↓ U Retention	1	9	9	6	4	29
↓ L Retention	0	1	2	3	6	12

The most common treatments required at each review are listed in Table 66. Three dentures were remade, 16 relined and 9 repaired due to fractures or problems with comfort and retention. Thirty two required some adjustment at review, usually easing of the pre-maxillary area in the upper or posterior area in the lower.

Eight soft liners and 14 O-rings were replaced and 9 clips required tightening. The clip retention system was replaced with O-rings in one patient due to interference of the bar with the lingual frenum. Finally, 20 occlusal adjustments and 5 remounts were required to overcome the occlusal discrepancies noted above.

Table 66. Prosthetic maintenance

Review (months)	1	3	6	12	18	Total
Remake U Denture	0	1	0	0	0	1
Remake L Denture	0	0	1	1	0	2
Reline U Denture	2	2	4	3	1	12
Reline L Denture	0	0	0	1	3	4
U Denture Adjustment	0	2	4	4	4	18
L Denture Adjustment	2	6	1	0	4	14
Remount Dentures	2	1	1	1	0	5
Replace Soft Liner	0	2	2	2	2	8
Replace Retainers	2	2	2	3	5	14
Tighten Clip	0	2	2	1	4	9
Change Attch System	0	1	0	0	0	1
Denture Repair	0	3	1	3	2	9
Occlusal Adjustment	3	6	5	5	1	20

7. DISCUSSION

Although the short duration of this study prevents any definitive conclusions from being made, certain trends are manifest and will be discussed under the headings of: Population; Surgical Considerations; Peri-implant Considerations; and Prosthetic Considerations.

7.1 Population

The population in this study had a high incidence of compromised general and dental health.

Of the eighteen females and six males with an average age of 59 years, half had a history of cardiovascular disease, a quarter a history of psychological problems, and many had multiple health problems. Patients with a history of psychological problems did not have any more denture problems than other patients either during or after treatment. Notwithstanding the state of their health, all patients completed the treatment successfully.

The relatively small sample size and short duration of the study precluded any more meaningful analysis of the influence of medical conditions on overdenture treatment outcomes. Nonetheless, these results are consistent with the general view that there are few medical conditions that absolutely preclude implant treatment. Systemic factors are important in implant success for as Weyant and Burt (1993) noted, patients who lose an implant are more likely to lose another compared to patients who do not suffer a loss. Although there is evidence that factors such as smoking can compromise peri-implant tissue health the importance of systemic factors is yet to be fully elucidated.

The population's dental history was poor. The mean number of years patients were edentulous (24 for maxilla and 21 for mandible) was about double compared to other studies (Quirynen et al, 1991 and Johns et al, 1992). Patients had spent years seeking a solution to their dental problems with some patients having had up to 15 dentures made (mean=5) and 15 relines (mean=3) during their edentulous years. The baseline results for the patients' evaluation of their dentures are illustrative of their dissatisfaction with mean scores for function, comfort and retention being 4.04, 6.29 and 5.73 respectively. This level of dissatisfaction is consistent with that found in pre-treatment groups reported in other studies (Misch and Misch, 1991; Hoogstraten and Lamers, 1987) Hence, and as Kent (1992) noted, patients sought implant treatment because of profound dissatisfaction with their existing prostheses.

It is not surprising that this group experienced such difficulty managing dentures when the examination findings are analysed. Signs of parafunction were evident in half the group while another 6 patients had poor neuromuscular coordination. Hence, 6 patients could not adequately control their lower denture while a further 12 patients exerted parafunctional forces on the mucosa with consequent discomfort problems.

7.2 Surgical Considerations

The surgical procedure for the placement of Integral implants is a relatively straightforward procedure involving preparation of the site and the friction fitting of the cylindrical implant, no thread tapping is required. Despite the simplicity of the procedure, surgical complications at placement, although minor, were common. Perforations of the inferior border of the mandible and equipment complications occurred in about a third of the sites prepared. Jamming drills and blockages of internally irrigated drills were the main technical problems encountered. These complications pointed to some problems with surgical

technique and although no serious sequelae occurred in this study haemorrhage following perforation of the lingual cortex has been reported (ten Bruggenkate et al, 1993). Cune et al (1994) also reported major complications following implant surgery, however most related to transmandibular implants.

Post-surgical complications were also minor and common with half of the population demonstrating delayed or poor healing due to wound dehiscence. Dehiscences were principally due to loss of sutures, a complication noted by McNamara and Henry (1991). When the suturing technique was changed from interrupted suturing to the use of vertical mattress sutures the problem ceased and no further wounds were pulled open by the opposing actions of the genioglossus and mentalis muscles. The common complications that occurred pointed to some shortcomings in surgical technique which was not unexpected considering that most surgery was undertaken by surgical registrars relatively inexperienced in implant surgery.

Another reason for wound dehisence in two patients was the exfoliation of loose implant cover screws. The loss of these screws was in addition to the 14 screws which were found to be loose at Stage II surgery. Hence, 17 or 35 per cent of cover screws either loosened or were lost.

No major surgical complications occurred which is consistent with the very low incidence of such occurrences in other studies (McNamara and Henry, 1991; Johns et al, 1992) and which demonstrates the relative safety of the cylindrical implant surgical technique.

Notwithstanding the number of surgical complications only one implant failed to achieve integration. This failure occurred in the only patient who experienced an infection at an implant site after placement. An implant subsequently placed at the same site 3 months later successfully achieved integration and remained healthy throughout the study period. Thus, 23 of the 24 implants originally placed had achieved osseointegration at stage II surgery; a succcess rate of 95.8 per cent at that time. The loss of one implant despite the rate of surgical

complications experienced, indicates that the Integral implant is resilient to minor surgical abuse and will achieve bony integration in most cases.

7.3 Peri-implant Considerations

Plaque and Calculus Indices

Plaque and calculus indices were generally consistent with other published studies (Naert et al. 1994; Cune et al. 1994) with approximately 20 to 30 per cent of abutments plaque and calculus free over the study period. Considering that abutments were located in the front of the mouth and hence afforded easy access for cleaning, the fact that 70 to 80 per cent scored mild to moderate plaque accumulation in any post 3 month evaluation period indicated that patient oral hygiene was generally only fair. This assessment of oral hygiene is in contrast to the assessment at examination when 17 patients were noted as having good oral hygiene, 5 fair, and only 1 poor. The initial assessment was optimistic as no correlation between this assessment and plaque and calculus scores was found. Gotfredson et al. (1993) reported good oral hygiene in 20 mandibular overdenture patients. However, patients were treated at least 3 monthly by an hygienist. A similar result was reported by Mericke-Stern et al, (1994), again with regular hygienist recalls. Without such follow-up it would appear patients generally do not adequately clean their prosthesis.

When plaque and calculus scores were assessed by attachment system there was no statistically significant difference between the systems, a result consistent with the findings of Geering and Mericske-Stern (1991).

Gingival Bleeding Index

Despite the presence of plaque and calculus on most abutments there was little tissue inflammation evident with no gingival bleeding about nearly 90 per cent of abutments. This

again is consistent with other studies (Quirynen, 1991 et al; Naert et al, 1994; Chan et al, 1995) but contrasts with Cune et al. (1994) who found peri-implant inflammation the most common treatment complication affecting 40 per cent of patients in a population where oral hygiene was noted as poor. Schou et al (1992) also found a correlation between the presence of plaque and gingival inflammation but only when the accumulation of plaque became moderate to heavy.

Ball attachments were associated with higher bleeding scores than clip and O-ring although plaque scores were similar. This does not support the contention that soft liner materials may massage the gingiva and promote gingival health whereas the dead space about clip and O ring abutments would encourage plaque accumulation and gingival inflammation. The opposite appears to be the case.

Gingival Crevice Depth

The mean crevice depth varied by 1mm over the study period (2.6 to 3.6 mm). Quirynen et al (1991) measured a 2.7 to 3.2 mm range. A 0.5mm increase in crevice depth was also recorded by Naert et al (1994) and Mericke-Stern et al (1994).

The accuracy of crevice depth measurements is questionable because delicate probing was required to negotiate the tight cuff about the abutment without probing through the hemidesmosomal attachment. As pain on probing was a common finding at periodic assessments, it may be assumed that the attachment was often breached and hence the crevice depth overestimated. The measurement error alone is enough to explain the minor variation recorded and so no definitive conclusion could be drawn on changes in crevice depth over the study period. When assessed by attachment system a similar inconclusive result was apparent.

Tissue height

Tissue height about abutments decreased by between 0.5-1.0 mm over the observation period. Similar degrees of gingival recession were reported about overdenture abutments by Quirynen et al (1991) and about fixed prostheses abutments by Adell et al (1986).

The tissue receded despite most abutments scoring some plaque over the period. There were no significant changes in tissue height between attachment systems. Hence in this study unlike others (Ensquist et al. 1988; Cune et al. 1994;) tissue hyperplasia was not a problem. Like gingival inflammation, there was no correlation between tissue height and the amount of plaque accumulations on the abutments.

Bone loss

Increases in crevice depth were shadowed by bone loss around implants. Average bone loss in the first year was about 1mm with the rate then plateauing which is in agreement with other published reports (Quirynen et al. 1991; Naert et al. 1991b).

When bone loss was assessed by attachment system there was a graphical but not a statistically significant difference between the splinted and non-splinted attachment systems. Naert et al, (1994) also reported little difference between bone loss about splinted and non splinted overdenture abutments.

Only one patient demonstrated significant bone loss about implants. This fit and strong recently edentulous 67 year old opal miner had a significant parafunctional habit as evidenced by wear and repeated fractures of teeth on his dentures. Although the tissue about the abutments was healthy keratinized gingiva with no signs of inflammation, bone loss was marked. McNamara and Henry (1991) reported that parafunction can increase after the

insertion of a mandibular overdenture. It would seem that the bone loss was not inflammatory in nature but traumatic as a result of this patient's parafunctional habit. Sanz et al. (1991) and Quirynen et al. (1992) reported that fixtures that failed due to overloading were characterised by healthy soft tissue with no signs of inflammation.

Other patients who recorded signs or symptoms of parafunction (half of the population) did not demonstrate the same degree of bone loss. Why this is so is unclear. It may be that the parafunction of other patients (mainly women) was not as severe. It is also worthy of note that this man had been edentulous for 5 years during which time he rarely wore his lower denture because of discomfort. Hence, he had a very good residual ridge (bone quantity: A) composed of alveolar as well as basal bone (bone quality: 3). Other patients had relatively less alveolar and more basal bone. As has been suggested by Alqvist et al. (1990) alveolar bone about implants is more susceptible to resorption than basal bone. Thus it may be that this man's heavy parafunction coupled with the quality of the peri-implant bone resulted in excessive bone loss. It should also be noted that despite his very good maxillary ridge, patient H also developed pre-maxillary discomfort after overdenture delivery.

Periotest Values

Periotest values remained generally constant throughout the study, the mean score decreasing very slightly from -5.0 to -5.55. Only patient H recorded a significant change in score (-2 to +1). Naert et al. (1994) in their study of 36 patients restored with splinted and unsplinted abutments for overdentures also recorded a very slight decrease in PTV's (from a baseline mean of -3.1). Gotfredsen et al (1993) reported a very slight increase in PTV's from -3.8 to -3.7 after 2 years for overdenture abutments. Consistent with the above reports the present study showed no significant difference in PTV's between the attachment systems.

The survival rate for implants on completion of this small study was 95.8 per cent which is consistent with the 97.2 per cent survival rate reported by Block et al (1990) for Integral implants. The survival rate is also consistent with published mandibular overdenture studies for other implant systems (Table 67).

Table 67. Implant success rates for mandibular overdentures.

Implant system	Survival rate (%)	Study
Branemark	97.7	Naert et al (1988)
	99.0	Quirynen et al (1991)
	94.0	Ensqvist et al (1988)
	86.0	Ensqvist (1991)
	95.0	Zarb and Schmitt (1991)
	95.0	Parel (1991)
	100	McNamara and Henry (1991)
	96.2	Johns et al (1992)
	96.8	Donatsky (1993)
	91.2	Mericske-Stern and Zarb (1993)
	100	Naert et al (1994)
	96.0	Cune et al (1994)
ITI Bonefit	96.4	Mericske-Stern (1990)
	98.6	Geering and Mericske-Stern (1991)
	92.2	Mericske-Stern and Zarb (1993)
	94.0	Cune et al (1994)
IMZ	98.4	Kirsch (1991)
	96.0	Cune et al (1994)
Core-Vent	88.0	Cune et al (1994)

7.4 Prosthetic Considerations

Prosthetic Assessment

Although both patient and clinical assessments were subjective, the scoring methodology differed and impeded quantitative comparisons between the two assessments. Patients evaluated outcomes such as eating, speaking, comfort and retention whereas the clinician evaluated elements which contribute to those outcomes such as denture support, retention, stability and occlusion. Nonetheless, similar trends were evident in the two evaluations. In nearly all assessments, patient or clinician, the trend in scores was an initial marked improvement followed by a slight fall then a recovery and stabilisation.

7.4.1 Assessment of Function, Retention, Comfort and Dysfunction

The patient assessed functional score improved by 126 per cent to a score of 9.13 over the period compared to a 23 per cent improvement to 0.86 recorded by the clinician. The final scores showed that patient expectations of functional improvements, although high (pre-treatment: 9.1), were met with patients functioning very satisfactorily with their overdentures. The shape of the graphs for clinical and patient assessment of function were similar, however the difference in percentage improvements suggests that the denture elements evaluated by the clinician were not good indicators of patient function.

The patient assessed retention score improved by 61 per cent to a score of 8.93 over the period compared to a 92 per cent improvement to 0.98 recorded by the author. Hence, there were marked improvements in overall retention. Again patient expectations were largely met (pre-treatment score: 9.3).

McNamara and Henry (1991) and Naert et al. (1991) also used visual analogue scales to measure patient satisfaction. Patients scored an average of 8 (on a rating scale of 1 to 9) for overdenture function and retention which is consistent with the above results.

When assessed by arch the far greater percentage improvements recorded in the clinical evaluation (mandible: 223, maxilla: 41) when compared to the patient evaluation (mandible: 94, maxilla: 19) demonstrated a shortcoming in the clinical assessment. The nature of the patient assessment (a linear scale, 0-10) enabled a more sensitive evaluation of relative maxillary and mandibular retention than did the nature of the clinical assessment (yes/no). Hence, whereas an analysis of the patient assessment was able to show that the mandibular denture became the more retentive denture post-delivery and maintained that superiority over time the clinical assessment did not.

The patient comfort score rose from 6.29 to 9.34 (49 per cent) compared to 0.61 to 0.69 (13 per cent) for the clinical score. No one attachment system was any more comfortable than another in either assessment. Thus the improvements in comfort did not match those in function.

When comfort was evaluated by arch it was apparent in both assessments that marked improvements had occurred in the mandible (patient=133 per cent; clinical=124 per cent) whereas improvements in the maxilla were equivocal (patient= +27 per cent; clinical= -12 per cent). In either assessment it could be concluded that whereas at initial assessment the maxillary arch was the more comfortable at the final observation the mandibular arch was the more comfortable. This result parallels that found for maxillary and mandibular retention.

The finding that clinically assessed maxillary comfort was not as good as patient assessed comfort suggests that discomfort in the maxilla had not reached a level which would

trigger patient complaints. When asked about possible improvements in treatment, 30 per cent of patients suggested improving the upper denture. This is consistent with the findings of Cune et al (1994b) who found that although patients reported satisfaction with upper dentures after overdenture therapy, when quizzed specifically on what improvements in treatment could be made, 20 per cent thought that the upper could be improved. The authors suggested that this finding resulted from higher patient expectations after treatment rather than problems related to the upper denture. Haraldson et al (1988a,b) found an increased number of upper denture complaints after overdenture treatment but they believed these were due to increased bite forces causing discomfort in the maxilla. The findings of the present study support the latter authors.

There was no correlation in either assessment between maxillary comfort and attachment system or maxillary bone quantity. There was a correlation between maxillary comfort and parafunction in the clinical but not the patient assessment. More specifically the correlation was between pre-maxillary comfort and parafunction. So although patients with parafunctional habits did not necessarily report discomfort in the pre-maxilla, discomfort was often apparent when the area was palpated during periodic clinical examinations. This may be a concern for if patients do not complain or if regular and thorough clinical examinations do not take place then more serious sequelae may arise from the causes of clinically detected discomfort.

Half the population of this study had signs or symptoms of parafunction before overdenture treatment. A prime symptom was mandibular discomfort as a result of an unstable and non-retentive lower denture rubbing on the mucosa during parafunction. After overdenture treatment lower denture stabilty and retention was greatly improved and mandibular comfort improved accordingly. However, parafunction did not improve after overdenture treatment according to the clinical assessment where the dysfunctional score

decreased from 0.54 to 0.53. This is in agreement with Haraldson et al (1988a,b) and McNamara and Henry (1991) who reported that parafunction can increase after overdenture therapy. As the upper denture is now the less stable denture, it rubs against the mucosa in parafunction causing maxillary and specifically pre-maxillary discomfort.

Pre-maxillary discomfort was a problem following overdenture insertion despite 26 upper dentures either being remade or relined prior to overdenture delivery. The extent of the problem is highlighted by the fact that a further 12 upper dentures were relined within 18 months of overdenture delivery. In addition, 20 occlusal adjustments were required, mostly to relieve a heavy anterior occlusion in order to decrease the load on the premaxilla.

Naert et al (1991) noted that the presence of incisal contact did not seem to remain stable with time in overdenture patients. Maxson et al (1990) also reported anterior occlusal prematurities and cited this finding as one element of evidence of Combination Syndrome in overdenture patients. The problems with pre-maxillary comfort and the need for relinings and occlusal adjustments in the present study also point to the risk of Combination Syndrome in overdenture patients and in particular in overdenture patients with evidence of parafunction.

It is suggested that the more severe sequelae of Combination Syndrome were not observed in this study due to a combination of factors including: the short period of the study, clinical intervention, and the relative bony stability of the residual ridges.

The short period of this study precluded any of the more long-term complications of Combination Syndrome being observed. The regular recall and immediate attention to problems by way of relines and occlusal adjustments also limited the effects of the syndrome. Barber et al (1990) suggested that clinical intervention could well have decreased the bone loss in the anterior maxilla they noted in overdenture patients and they stressed the need for regular and long-term prosthetic recall.

RRR usually begins to stabilise after 2 years and is very stable after 10 (Tallgren, 1972). As the population in the present study had been edentulous for a mean of 24 years in the maxilla (range: 7-43) and 21 years in the mandible (range: 5-43), it could be concluded that the ridges were relatively stable. Further, Jacobs et al (1992) reported that when patients had been edentulous for more than 10 years there was no difference in posterior mandibular ridge resorption between an overdenture and a complete denture group. Resorption still occurs but not at an accelerated rate.

While the more severe sequelae of Combination Syndrome were not observed in this population as a whole, individuals within the group did show signs that more severe complications could occur if regular follow-up and clinical intervention did not take place.

Recently edentulous patients with parafunction such as patient H are particularly vulnerable. Jacobs et al (ibid) reported that posterior mandibular ridge resorption after a 6 month post-extraction remodelling phase was 2 to 3 times greater in the overdenture group than in the complete denture group. Despite the resorption noted in the overdenture group, few relinings were seen to be needed during the 3 year observation period. The authors explained that resorption in the anterior maxilla may well have masked posterior mandibular ridge resorption with progressive tilting of the dentures. The authors therefore counselled caution in the prescription of an overdenture in a young or recently edentulous patient and the results of the present study support this advice.

Notwithstanding the comfort problems experienced in the maxilla and the implications thereof, most patients were very happy with the treatment outcome. All patients thought that the treatment was worth the trouble and would recommend it. Sixty nine per cent reported that were happier with their dental health, felt more confident, and generally felt better about themselves.

Based on the study by Hoogstraten and Lamers (1987), Kent (1992) suggested that implant treatment can raise patient satisfaction to the level where no further treatment is sought. If patients are satisfied when they no longer seek treatment, then in the present study 70 per cent of patients were satisfied. Thirty per cent were not completely satisfied because they suggested further treatment on the upper denture.

7.4.2 Assessment of Attachment Systems

There was no statistically significant difference in the functional or retention (mandibular and maxillary) scores when assessed by attachment system in either the patient or clinical evaluations. Although there were wider variations in comfort and dysfunction scores when assessed by attachment system, no statistically significant difference in either the patient or clinical evaluations was found.

Notwithstanding the above, some trends were apparent between attachment systems. Generally the ball group recorded the lowest base scores and the clinical evaluation tended to show that the ball group had more comfort and dysfunctional problems than the O-ring and clip groups. This may well relate back to the initial selection of attachment systems where O-rings and clips were alloted randomly but not ball attachments. As noted earlier, patients who had soft liners in their existing dentures were very reluctant to give them up and requested that they be retained. These patients had soft liners because of the severity of their denture problems and as they amounted to 62 per cent (5 of 8) of the ball group, the results for this group may have been skewed.

Whereas the ball group tended to have generally lower comfort scores when assessed clinically, the clip group demonstrated the largest fall in comfort and particularly maxillary comfort over the study period. It may be that the rigid clip system transmits more force to the

upper arch than the stress-broken ball and O-ring systems resulting in more maxillary discomfort.

Although the attachment systems could not be separarted on the basis of the denture factors assessed, they could on the basis of maintenance required. One third of the soft liners were replaced, a more time consuming and expensive exercise than replacing O-rings or tightening clips.

7.4.3 Maintenance requirements

Although no maintenance problems were reported for implant abutments, the maintenance required for both upper dentures and lower overdentures was significant. This finding is not in agreement with Naert et al (1991) who reported minimal maintenance requirements for mandibular overdentures but is consistent with many other published reports (Zarb and Schmitt, 1991; McNamara and Henry, 1991; Johns et al, 1992; Tolman and Laney, 1992; Walton and MacEntee, 1993, 1994).

The requirement for multiple occlusal adjustments and remounts over the study period is indicative of an unstable occlusion, a factor in overdenture therapy noted by Naert et al (1991) and Maxson et al (1990). This instability, as Zarb and Schmitt (1991) suggested and Jacobs et al (1992) showed, is due to ongoing RRR which changes the relationship of the denture bases and results in a heavy anterior occlusion.

The high number of denture adjustments in the pressure areas of overdenture patients ie the pre-maxilla and the lower posterior area is also illustrative of where RRR is taking place. Ongoing changes in the denture foundation necessitated 3 denture remakes and 16 relines (40 per cent of dentures). This compares with the 27 per cent reported by Walton and MacEntee (1994).

The number of denture base or teeth fractures was also high (21 per cent of dentures) which is consistent with the 19 per cent reported by Walton and MacEntee (ibid) but double that reported by Naert et al (1991). This result is indicative of increased bite forces if not parafunction in this group of patients.

With the exception of soft liners the maintenance on attachments systems was not excessive. Fourteen O-rings were replaced; but for non-parallel abutments this figure could have been much lower. Clips required nothing more than occassional tightening over the period in contrast to other studies where the rate of fractured, loose or lost clips had been as high as 40 per cent (Jemt et al, 1992; Walton and MacEntee, 1994).

The high level of denture maintenance in this group reinforces the contention that ongoing RRR and comfort problems in overdenture patients can be significant problems, problems which requires regular and long-term prosthetic follow-up if the worst sequelae of Combination Syndrome are to be avoided.

8. CONCLUSIONS

Within the constraints of a sample size of 24 patients followed up for 18 months only, it was found that:

1. Integral implants can achieve osseointegration in the anterior mandible at rates similar to other cylindrical implant systems despite minor surgical complications and medically compromised hosts.

2. The peri-implant tissue about Integral abutments can remain healthy in the presence of mild to moderate plaque accummulations.

3. Two Integral implants can be used to stabilise and retain a mandibular overdenture with low implant failure rates consistent with other cylindrical implant systems.

4. A two-implant retained mandibular overdenture can provide significant improvements in overall denture function, retention and comfort.

5. Mandibular overdenture treatment largely solves retention and comfort problems in the mandible but such treatment appears to cause discomfort in the pre-maxilla in patients with parafunctional habits.

6. Of the attachment systems used (clip, O-ring or ball) all can provide improved denture function, retention and comfort and no one is superior to any other.

7. Overdenture treatment can result in high levels of prosthetic maintenance due to ongoing RRR and comfort problems.

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APPENDIX A

Materials

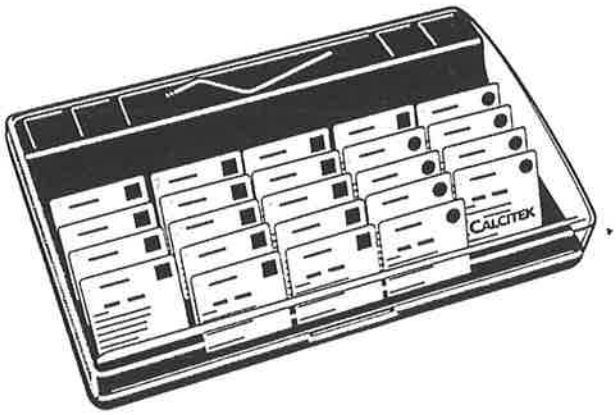
•*Surgical Components-*	Calcitek Corporation, Carlsbad, CA, USA	
Combination Instrumentation Kit		Catalog No. 0325
Integral Implant, 4.00mm	8mm body	Catalog No. 0801
	10mm body	Catalog No. 0802
	13mm body	Catalog No. 0803
	15mm body	Catalog No. 0804
Temporary Gingival Cuff, 4.00mm	3mm cuff	Catalog No. 0680
	5mm cuff	Catalog No. 0682
	7mm cuff	Catalog No. 0688
•*Prosthetic Components-*		
Shouldered Abutment	3mm cuff	Catalog No. 0711
	4mm cuff	Catalog No. 0712
	5mm cuff	Catalog No. 0713
Ball Overdenture Attachment	3mm cuff	Catalog No. 0437
	4mm cuff	Catalog No. 0438
	5mm cuff	Catalog No. 0439
O-Ring Attachment	3mm cuff	Catalog No. 0771
	4mm cuff	Catalog No. 0772
	5mm cuff	Catalog No. 0773

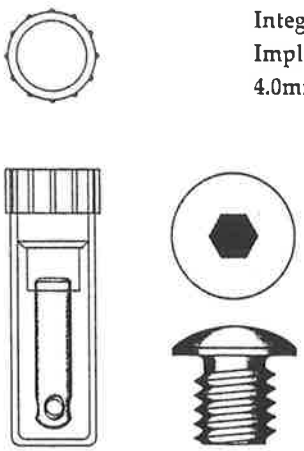
•*Other Prosthetic Materials Used-*	
Lumin-Acryl V acrylic denture teeth	Vita Zahnfabrik H. Rauter GmbH & Co. KG Bad Sackingen, Germany.
Vertex denture Acrylic	Dentimex B.V. PO Box 10 3700 AA Zeist, Holland
Molloplast-B	Regneri GmbH & CO. KG D-7500 Karlsruhe 1, Germany
Coe-Comfort/ Soft	ICI Dental, Alderley House Alderley Park, Macclesfield Cheshire, England

SURGICAL PRODUCTS PRICE LIST

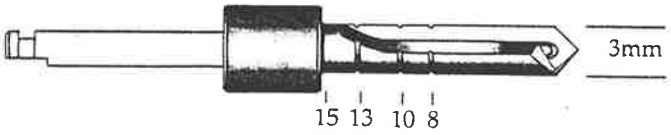
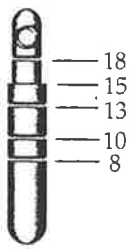
Integral 4.0mm Diameter

Item	Catalog No.	Description	Qty/Pkg
Integral Implant Surgical Kit, 4.0mm	0600	*Contents*	1 kit
		8mm Implant Body with Healing Screw (sterile)	2ea
		10mm Implant Body with Healing Screw (sterile)	2ea
		13mm Implant Body with Healing Screw (sterile)	2ea
		15mm Implant Body with Healing Screw (sterile)	2ea
		Pilot Drill	1ea
		Rosette Drill	1ea
		Intermediate Spade Drill	1ea
		18mm Intermediate Spade Drill	1ea
		Countersink Drill	1ea
		8mm Final Spade Drill	1ea
		10mm Final Spade Drill	1ea
		13mm Final Spade Drill	1ea
		15mm Final Spade Drill	1ea
		18mm Final Spade Drill	1ea
		Drill Extension	1ea
		Parallel Pins	6ea
		Hex Drive Seating Tool Kit	1ea
		Implant Body Tryin	1ea
		Tapper	1ea
		Tapper Tips	4ea
		Implant Body Retriever	2ea
		Tissue Punch	4ea
		Technical Products Manual	1ea
		Product Organizer	1ea
Surgical Instrumentation Kit, 4.0mm	0650	Surgical Instrumentation Kit *Note: Same as listed in the Integral Implant Surgical Kit, excluding implant bodies*	1ea
Integral Implant, 4.0mm	0801	8mm Implant Body with Healing Screw (sterile)	1ea
	0802	10mm Implant Body with Healing Screw (sterile)	1ea
	0803	13mm Implant Body with Healing Screw (sterile)	1ea
	0804	15mm Implant Body with Healing Screw (sterile)	1ea
	0760	Titanium Healing Screw	2ea



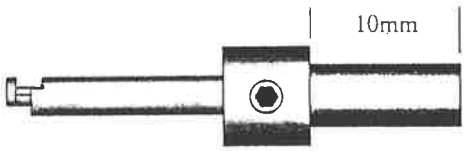
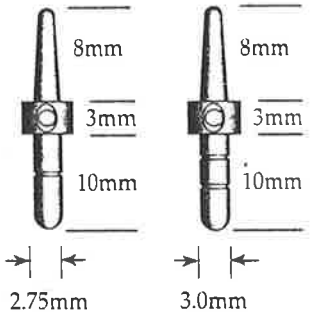
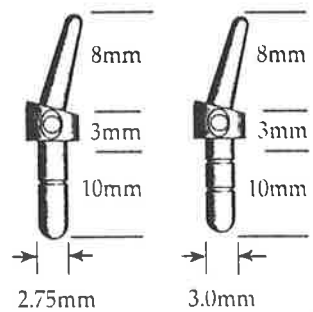


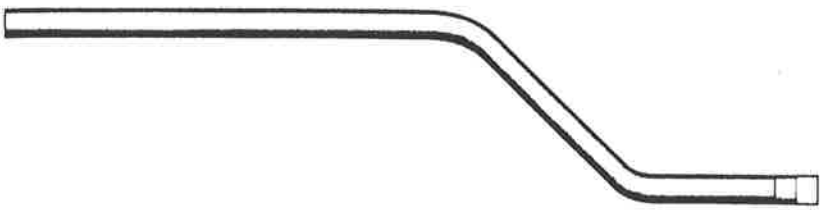
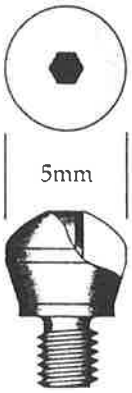
Integral 4.0mm Diameter

Item	Catalog No.	Description	Qty/Pkg
			
Intermediate Spade Drill	0352	15mm Intermediate Spade Drill	1ea
	0351	10mm Intermediate Spade Drill	1ea
			
Countersink Drill	0354	Countersink Drill	1ea
			
Final Spade Drill	0355	8mm Final Spade Drill (Blue Bands)	1ea
	0356	10mm Final Spade Drill (Red Bands)	1ea
	0357	13mm Final Spade Drill (Yellow Bands)	1ea
	0358	15mm Final Spade Drill (Green Bands) *Note: Color bands correspond to drill length also reflected in Autoclave Tray.*	1ea
			
Implant Body Tryin	0798	Implant Body Tryin	1ea

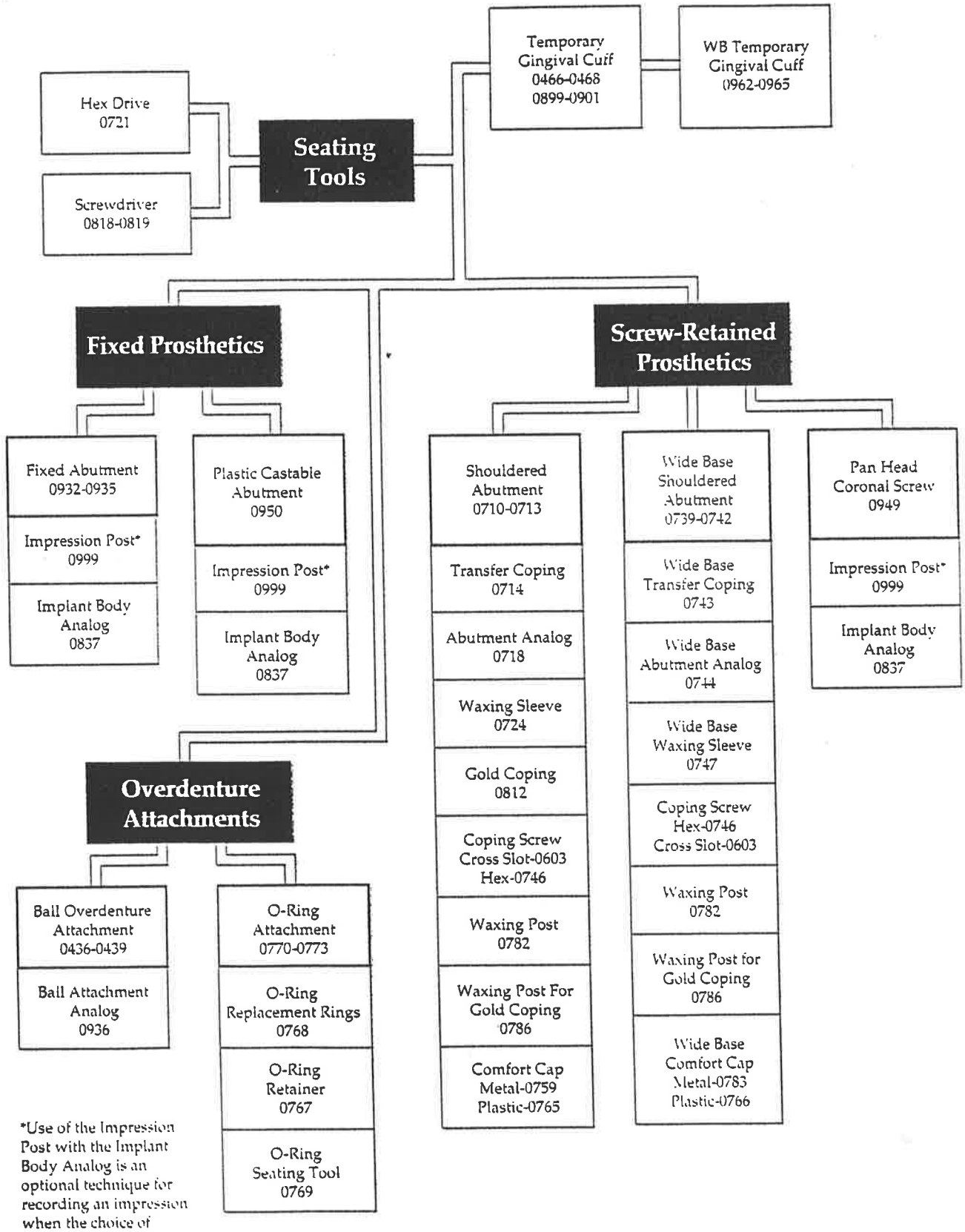
Surgical Products Price List

General Instrumentation

Item	Catalog No.	Description	Qty/Pkg
 Pilot Drill	0201	Pilot Drill	1ea
 Rosette Drill	0202	Rosette Drill	1ea
 Drill Extension	0989	Drill Extension	1ea
 Tissue Punch	0816	Tissue Punch	4ea
 Parallel Pins	0482 0485 0490	3.25mm Parallel Pins 4.0mm Parallel Pins Combination Parallel Pins (each set includes four 3.25mm Parallel Pins and four 4.0mm Parallel Pins)	6ea 6ea 1 set
 Preangled (15°) Parallel Pins	0483 0486	3.25mm Preangled Parallel Pins (15°) 4.0mm Preangled Parallel Pins (15°)	3ea 3ea

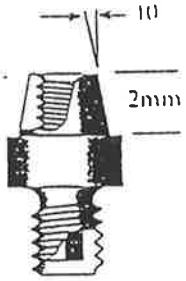
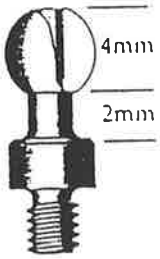
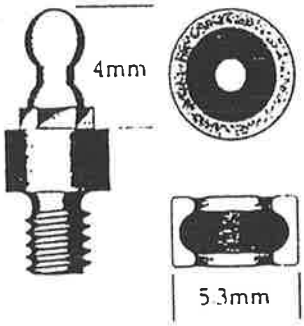
Item	Catalog No.	Description	Qty/Pkg
			
Tapper	0817	Tapper	1ea
	0889	Tapper Tips	4ea
			
Implant Body Retriever	0815	Implant Body Retriever	1ea
			
Temporary Gingival Cuff, Titanium	0466	Temporary Gingival Cuff (2mm)	4ea
	0467	Temporary Gingival Cuff (3mm)	4ea
	0468	Temporary Gingival Cuff (4mm)	4ea
	0899	Temporary Gingival Cuff (5mm)	4ea
	0900	Temporary Gingival Cuff (7mm)	4ea
	0901	Temporary Gingival Cuff (10mm)	4ea
			
Wide Base Temporary Gingival Cuff, Titanium	0962	Wide Base Temporary Gingival Cuff (4mm)	4ea
	0963	Wide Base Temporary Gingival Cuff (5mm)	4ea
	0964	Wide Base Temporary Gingival Cuff (6mm)	4ea
	0965	Wide Base Temporary Gingival Cuff (7mm)	4ea

INTEGRAL 4.0MM SYSTEM
PROSTHETIC COMPONENTS FLOWCHART



*Use of the Impression Post with the Implant Body Analog is an optional technique for recording an impression when the choice of abutment is to be made at a later date.

Integral 4.0mm Diameter

	Item	Catalog No.	Description	Qty/Pkg
	Shouldered Abutment (removable*)	0710	Shouldered Abutment (2mm cuff)	1ea
		0711	Shouldered Abutment (3mm cuff)	1ea
		0712	Shouldered Abutment (4mm cuff)	1ea
		0713	Shouldered Abutment (5mm cuff)	1ea
			*Removable refers to screw retained prosthetics	
				
	Ball Overdenture Attachment	0436	Ball Overdenture Attachment (2mm cuff)	1ea
		0437	Ball Overdenture Attachment (3mm cuff)	1ea
		0438	Ball Overdenture Attachment (4mm cuff)	1ea
		0439	Ball Overdenture Attachment (5mm cuff)	1ea
	O-Ring Attachment*	0770	O-Ring Attachment (2mm cuff)	1 set
		0771	O-Ring Attachment (3mm cuff)	1 set
		0772	O-Ring Attachment (4mm cuff)	1 set
		0773	O-Ring Attachment (5mm cuff)	1 set
			(each set includes: 2 O-Ring attachments, 4 black O-Rings and 2 O-Ring retainers)	
		0768	O-Ring Replacement Rings, Black	6ea
	*U.S. Patent 5049072	0767	O-Ring Retainer	2ea

Appendix B

Documentation

Patient Information Sheet

Form A1 Patient Consent Form

Form A2 Health Questionnaire

Form B Denture Assessment - Patient

Form C Denture Assessment - Clinician

Form D Consultation Form

Form E1 Stage I Surgical Form

Form E2 Stage I Postsurgical Form

Form F1 Stage II Surgical Form

Form F2 Stage II Postsurgical Form

Form G Clinical Evaluation Form

South Australian Dental Service
Maxillofacial Clinic

INFORMATION CONCERNING INTEGRAL 'BIO-INTEGRATING' IMPLANT PROSTHESES

We would like to enrol you in a clinical study of an implant system that offers you an opportunity to overcome some of the drawbacks of conventional dentures.

This information is provided so that you might understand the risks and benefits of undergoing treatment employing osseointegrated implants.

Implant prostheses are an alternative to conventional dentures. Where conventional dentures rest entirely on the soft tissue of the gums, implant prostheses can also be supported by the underlying jaw bone. This is achieved by posts through the gums joining the dental prostheses to implants that are strategically placed in the bone. To ensure that the implants are firmly attached to the jaw bone, the implants are specially machined from titanium and coated with hydroxyapatite. Because the hydroxyapatite has the same mineral content as bone, bone grows right up to the implants and it is thought that there is a bonding between the hydroxyapatite and bone. This is what is meant by "Bio-integration".

The direct connection between prostheses and bone allows the forces involved in chewing to be transmitted directly to bone, avoiding pressure on the gums in those areas where implants are placed. Where implants are placed, the normal bone collapse which continues throughout life following extraction of the teeth is markedly reduced.

It is important to remember that implants are not mandatory, that patients rarely have an absolute need for implant prostheses and that most patients should be able to function adequately with conventional dentures. However, if you would like an improvement in your denture retention, comfort and chewing, then the use of implants is one means of achieving this.

Implant Treatment

The proposed study will look at one of the options for treating an edentulous(no teeth) lower jaw i.e. the partial overdenture:

Partial Overdenture - Two implants in the front of the lower jaw support and retain the conventional denture. This treatment gives a much improved retention and resistance to movement of the denture. It lessens the biting pressure on the tissues of the front of the jaw, often an area of chronic soreness with conventional lower dentures. The treatment does not, however, lessen the biting pressure on the tissues further back in the jaw as no implants are placed in this area.

You will be required to complete a confidential medical questionnaire and undergo an x-ray examination of your jaw to determine whether you are a suitable candidate for bone-integrated implants. Not all patients are psychologically suited for implants. However, if there are problems in this regard, then counselling may be arranged with an appropriate specialist.

The prosthodontist will evaluate the prostheses (dentures) in current use and ascertain the reasons why an implant prosthesis is requested. Sometimes other surgical procedures such as grafts or augmentations (addition of material to the bony ridge) may be recommended rather than, or in conjunction with implants.

Summary of Treatment

Final placement of the completed dental implant prosthesis takes on average 4 to 5 months from the date of surgical placement of the implants and involves the joint efforts of a prosthodontist and a surgeon. Treatment involves two surgeries and 3-4 months of healing to reach the stage of the implant posts being ready for the attachment of the prosthesis. It also takes some time for accommodation to the new prosthesis.

Once a patient is accepted for treatment, impressions will be taken of their mouth and the resulting casts related to one another. In many instances where the existing dentures are inadequate, it will be necessary to provide new pretreatment dentures before any consideration of implants. This is to determine if an adequately made prosthesis is all that is needed and also to determine, prior to an implant procedure, the optimal location for the placement of teeth for cosmetic and functional requirements. We are then able to determine if the bone structure remaining can be used to accept the necessary implants to support the desired prosthetic result. Restoration of the opposing natural teeth may be required to enable a suitable bite to be developed. When all the pretreatment work is complete, an appointment for the first surgery will be made.

The Integral bio-integration system of dental implants uses a two stage surgical approach. At the first surgical stage, the surgeon will place two implants at predetermined locations in the jaw. This procedure can be performed under local anaesthetic with intravenous sedation in about 1 hour of surgical time. For those patients who feel uncomfortable about having the treatment under local anaesthesia, a general anaesthetic in a day surgery suite can be arranged. After the implant placement, the surgical site will be sutured closed.

There will be some initial swelling (even bruising under the chin and down the neck) and some post-operative discomfort which usually is controllable with pain medication. Frequently pre-operative medication will be given which will prevent the patient from driving to or from the surgery. Because individuals have different thresholds of pain, the degree of discomfort will vary.

The patient may be without a denture for a week or two while the surgical site heals. After this healing period, the existing denture will be modified and lined with a soft liner. Further appointments with the prosthodontist are required for general monitoring and maintenance. It requires a minimum of 3 months to allow the implanted fixtures to become integrated into the bone. During that time, the patient must be very careful not to do anything which would disturb the surgical site and must report any denture soreness to the prosthodontist.

When healing is complete, the second surgical procedure is performed. The jaw will be anaesthetised with local anaesthetic and a core of tissue over the implant site is removed. In most cases, at this stage it can be seen if the implant has been successful. If an implant does not integrate, it is usually removed and the site used for another implant. There is a slight chance that a site of a removed implant fixture could show deterioration of the bone level and be a poorer denture foundation than before surgery. Sometimes an implant may not be used, but left covered in the jaw and is termed a "Sleeper".

At those sites where the implant appears to be successfully bone-integrated, extensions or posts will be placed from the implant and passed through the gum. After healing these posts will support the final prosthesis. In the meantime a soft lining may be placed in the existing denture which can be worn again.

About two weeks after the second stage surgery, healing will have occurred and the construction of the final prosthesis can begin.

Care of Implants

It is essential to maintain a high level of oral hygiene with implant prostheses. Failure to do so will lead to inflammation of the gum tissue around the posts which occasionally produces excess tissue growth. In some situations minor surgical alteration of the tissue may be required. The prosthodontist will assist in assessing and instructing patients with appropriate cleaning methods.

Possible Problems

Although bone-integrating implants have a lot to offer, patients who contemplate receiving these services should do so knowing that no guarantees are made and that there are some negative aspects which can result.

As stated above some implants do not intergrate and will need to be replaced. This will lengthen the treatment time. Some implants appear to be integrated at the time of the second surgery but are lost later. The chances of this happening are small, especially once an implant has been in function for over a year. Again, such implants may be replaced.

FORM A2: 1☐☐☐☐ : **HEALTH QUESTIONNAIRE**

Patient No:5☐☐☐☐☐☐ **Surname:** ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Date: 23☐☐☐☐☐☐ **DOB:**29☐☐☐☐☐☐ **Sex:M/F** ☐ 36☐

Please circle "yes" or "no" to the following questions. If you are not sure, do not answer.

1. Have you ever had:
   - Rheumatic fever..... yes/no 37☐
   - Heart murmur..... yes/no ☐
   - Heart attack or coronary..... yes/no ☐
   - Angina..... yes/no ☐
   - Heart surgery..... yes/no ☐
   - High or low blood pressure..... yes/no ☐

2. Do you get short of breath on mild exertion or when you lie down? yes/no 43☐

3. Have you ever had a stroke? yes/no ☐

4. Have you had a thyroid problem? yes/no ☐

5. Have you ever had sugar diabetes? yes/no ☐

6. Have you ever had jaundice, hepatitis, or other liver problem? yes/no 47☐

7. Have you ever had hemophilia or other bleeding disorder? yes/no ☐

8. Have you ever had prolonged bleeding after a cut, injury, or tooth extraction? yes/no ☐

9. Have you ever had a sexually transmitted disease? yes/no ☐

10. Have you ever had a blood test for HIV (AIDS)? yes/no ☐

11. Are you in an HIV risk group (ie Homosexual, IV drug user)? yes/no ☐

12. Have you ever had fits, seizures, convulsions, or epilepsy? yes/no ☐

13. Have you ever had a psychiatric illness or nervous condition? yes/no ☐

14. Have you been treated for any allergic condition such as asthma,? eczema or hay fever. yes/no 55☐

15. Have you ever had an adverse reaction to any drug eg Penicillin, Aspirin? yes/no 56☐

16. Have you ever had cancer therapy? yes/no ☐

17. Have you ever had persistent facial or jaw joint pain? yes/no ☐

18. Have you had surgery in your mouth before? yes/no ☐

19. Please list all of the medications or drugs that you are taking at the present time :

Medications	Dosage	
_____	_____	60☐
_____	_____	☐
_____	_____	☐

20. Has there been any change in your general health in the past year? yes/no ☐

21. Have you been treated by a doctor or been in hospital in the past year? yes/no ☐

22. Are you pregnant or think you maybe? yes/no ☐

23. Do you smoke? yes/no ☐
If 'YES', How many per day?_____

24. Do you drink more than 4 standard glasses of alcohol per day? yes/no ☐

25. Is there any other information which you think is relevant? yes/no 68☐

26. High BP? yes/no ☐
27. Asthma? yes/no ☐
28. Hayfever? yes/no ☐
29. Arthritis? yes/no ☐
30. Multiple Sclerosis? yes/no ☐

Signed: ..... 74☐

Referring Dentist: 75☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Patient's Doctor: 87☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Comments:..... ☐
..... ☐
..... ☐

HS (OA) : E / G / F / P - (circle) 102☐

FORM B: 1☐☐☐☐

DENTURE ASSESSMENT - PATIENT

Patient No:5☐☐☐☐☐☐ **Surname:** ☐☐☐☐☐☐☐☐☐☐☐☐

Date: 23☐☐☐☐☐☐ 29☐

Following are a number of statements about your dentures. For each statement, please put an '**x**' on the horizontal line somewhere between Yes and No that best expresses your knowledge and experience at this time.

1. **Are you unhappy with your dentures?**

Yes, I seldom wear them.	Yes, but I wear them most of the time	No, but they have some faults	No, they are very good	☐☐

2. **Are you unhappy with the appearance of your dentures?**

Yes, they are ugly and embarrass me	Yes, they don't look natural but I wear them	No, but I would like to change some things	No, they have a pleasant natural appearance	☐☐

3. **Are you unhappy with your ability to eat and chew?**

Yes, I am able to chew better without my dentures.	Yes, I avoid many foods I would like to eat	No, but I avoid some foods or cook until softer	No, I am able to chew all foods	☐☐

4. **Are you unhappy with your ability to speak with your dentures?**

Yes, it is always very difficult	Yes,it is often difficult	No, but some-times I do have problems	No, I have no difficulty	☐☐

5. **Do your dentures embarrass you socially,eg when eating or speaking?**

Yes, always	Yes, often	Yes, occasionally	No, never	38☐☐

6. **Are you unhappy with the comfort of your upper denture?**

Yes, I seldom wear it.	Yes, it causes many sore spots	No, but occasionally it causes problems	No, it never causes discomfort	40 ☐☐

7. **Do you use comfort liners in your upper denture?**

Yes, always	Yes, often	Only occasionally	No, never	☐☐

8. **Are you unhappy with the comfort of your lower denture?**

Yes, I seldom wear it.	Yes, it causes many sore spots	No, but occasionally it causes problems	No, it never causes discomfort	☐☐

9. **Do you use comfort liners in your lower denture?**

Yes, always	Yes, often	Only occasionally	No, never	☐☐

10. **Are you unhappy with how your upper denture stays in place?**

Yes, it moves so much I seldom wear it	Yes, it often comes loose while eating or speaking	No, but it occasionally comes loose	No, it stays in place all of the time.	☐☐

11. **Do you use denture adhesives in your upper denture?**

Yes, always	Yes, often	Only occasionally	No, never	☐☐

12. **Do you leave your upper denture out because of problems with it.**

Yes, always	Yes, often	Only occasionally	No, never	☐☐

13. **Are you unhappy with how your lower denture stays in place?**

Yes, it moves so much I seldom wear it	Yes, it often comes loose while eating or speaking	No, but it occasionally comes loose	No, it stays in place all of the time.	54 ☐☐

14. **Do you use denture adhesives in your lower denture?**

Yes, always	Yes, often	Only occasionally	No, never	56 ☐☐

15. **Do you leave your lower denture out because of problems with it.**

Yes, always	Yes, often	Only occasionally	No, never	☐☐

16. **Do your dentures hurt if you clench on your back teeth?**

Yes, always	Yes, often	Only occasionally	No, never	☐☐

17. **Do your dentures hurt when you chew?**

Yes, always	Yes, often	Only occasionally	No, never	☐☐

18. **Do you get pain or a burning sensation in the gum under your upper denture?**

Yes, always	Yes, often	Only occasionally	No, never	☐☐

19. **Do you get pain or a burning sensation in the gum under your lower denture?**

Yes, always	Yes, often	Only occasionally	No, never	☐☐

20. **Do the muscles of your face feel tired after wearing your dentures?**

Yes, always	Yes, often	Only occasionally	No, never	☐☐

21. **Do your jaws joints ache after wearing your dentures?**

Yes, always	Yes, often	Only occasionally	No, never	☐☐

22. **Do you have any other problems with your dentures. What are these?**

.....p

Mental nerve soreness..... ☐

Difficulty adjusting to lower denture..... 73 ☐

23. How do you think the following features of your dentures will be effected by implant treatment:

The appearance of your dentures?

Not at all effected | Minimally improved | Much improved | Greatly improved 74 ☐☐

The way your dentures stay in place?

Not at all effected | Minimally improved | Much improved | Greatly improved ☐☐

Your ability to chew?

Not at all effected | Minimally improved | Much improved | Greatly improved ☐☐

Your ability to speak?

Not at all effected | Minimally improved | Much improved | Greatly improved ☐☐

24. Do you think any other changes will occur? What are these?

More socially confident..... 82 ☐

..... ☐

DA: E / G / F / P (circle) ☐

Comments:

..... ☐

..... ☐

---

25. Now that you have functioned with implants:

Do you think the treatment was worth the trouble? yes/no 87 ☐

Would you repeat the treatment? yes/no ☐

Would you recommend the treatment? yes/no ☐

Do you feel better about yourself? yes/no ☐

Are you more confident? yes/no ☐

Are you happier with your dental health? yes/no ☐

Comments:

..... ☐

..... 94 ☐

Signed: .....

FORM C: 1 ☐☐☐☐

DENTURE ASSESSMENT - CLINICIAN

Patient No: 5 ☐☐☐☐☐☐ **Surname:** ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Date: 2 3 ☐☐☐☐☐☐ 2 9 ☐

DENTURE HISTORY

Years edentulous	Max	3 0 ☐☐		Man	3 2 ☐☐
Years with dentures	Max	☐☐		Man	☐☐
Years with present dentures	Max	3 8 ☐☐		Man	4 0 ☐☐
Previous dentures					
Number	Max	4 2 ☐☐		Man	☐☐
No. of Relines/Rebases	Max	☐☐		Man	4 8 ☐☐

Patient presented requesting implant prosthesis: Yes / No ☐

Patient referred for implant prosthesis: Yes / No ☐

5 2 ☐

CURRENT DENTURES

Existing / unmodified denture max / man / both ☐

Relined / new denture max / man / both 5 4 ☐

SUPPORT PROBLEMS (circle Yes/No)

1. **Does firm digital pressure on the upper denture-bearing area elicit pain?**
Yes / No ☐

2. **Does firm digital pressure on the lower denture-bearing area elicit pain?**
Yes / No ☐

3. **Does the patient have pain when the dentures are clenched in centric occlusion?** (Provided centric occlusion has been checked and is correct.)
Yes / No ☐

4. **Does alternate pressure antero-posteriorly or laterally cause rocking of the upper denture base?**
Yes / No ☐

5. **Does alternate pressure antero-posteriorly or laterally cause rocking of the lower denture base?**
Yes / No ☐

6. **Does the patient complain of pain or a burning sensation in the upper denture-bearing areas?**
Yes / No 6 0 ☐

7. Does the patient complain of pain or a burning sensation in the lower denture-bearing areas?

Yes / No ☐ 61

8. Are the ridges narrow or is the mucosa soft and flabby?

Yes / No ☐

RETENTION PROBLEMS

9. Can the upper denture be removed easily from the mouth without resistance?

Yes / No ☐

10. Can the lower denture be removed easily from the mouth without resistance?

Yes / No ☐

11. When the upper denture is seated by firm digital pressure, does it drop when the pressure is removed?

Yes / No ☐ 65

12. When the lower denture is seated by firm digital pressure, does it rise when the pressure is removed?

Yes / No ☐

MUSCULAR IMBALANCE PROBLEMS

13. Does the patient feel that he/she "has a mouthful" and has difficulty in speaking and eating?

Yes / No ☐

14. Does the lower denture rise when the tongue is protruded or when the mouth is opened widely?

Yes / No ☐

15. Does the upper denture resist removal from the mouth but drop when the patient laughs or yawns?

Yes / No ☐

16. Does the tongue become sore at the front despite there being no rough spots in that area?

Yes / No ☐

17. Are the upper teeth set on the ridge regardless of ridge resorption?

Yes / No ☐

18. Are undercuts present on the polished lingual surface of the lower denture?

Yes / No ☐ 72

19. **Do the dentures fail to restore the lips and cheeks to their normal positions?**

Yes / No 73 ☐

20. **Are polished surfaces of the dentures absent which the cheeks, lips and tongue may act against to keep the dentures in place?**

Yes / No ☐

OCCLUSAL BALANCE PROBLEMS

21. **Does the patient wear the dentures comfortably between meals but have to remove them during meals because they move and hurt?**

Yes / No ☐

22. **Do the denture becomes loose only after occlusal contact?**

Yes / No 76 ☐

23. **Are the dentures firm for the first few hours of the day and then become loose or does the patient find a white mucous layer on the fitting surface of the upper denture which is firmer when the mucus is washed off?**

Yes / No ☐

24. **Does the patient tend to retch when the teeth occlude, but not at other times?**

Yes / No ☐

25. **Is there pain with ulceration of the ridge but no obvious cause on the fitting surface of the denture?**

Yes / No ☐

26. **Do the dentures click?**

Yes / No ☐

27. **Does the patient complain of tired masticatory muscles?**

Yes / No ☐

28. **Do the dentures move during grinding?**

Yes / No ☐

MISCELLANEOUS PROBLEMS

29. **Are there any aesthetic problems evident with the patient's dentures?**

Yes / No ☐

30. **Does the patient have denture stomatitis?**

Yes / No ☐

31. **Does the patient have angular cheilitis?**

Yes / No ☐

32. **Is the patient's speech unsatisfactory?**

Yes / No ☐

33. **Are TMJ problems present?**

Yes / No 87 ☐

34. **Is food impaction a problem?**
Yes / No 88 ☐

35 **Are there other problems present?**
Yes / No ☐

Please give details:
Mental nerve compression.....90 ☐
Decreased saliva flow..... ☐
Bruxing..... ☐
Maxillary labial ridge soreness..... ☐

PROSTHETIC COMPLICATIONS

Occlusion problems...Yes:1/No:2 94 ☐
Fractured max denture ☐
Soft liner problems 98 ☐
Retentive component loss 95 ☐
Fractured man denture ☐
Other (describe below) 99 ☐

Decreased retention - max denture..... ☐
Decreased retention - mand denture..... ☐
Tongue space problems..... ☐
Broken teeth..... ☐
.....

TREATMENT REQUIRED

Reline max denture Yes:1/No:2 104 ☐
Remake max denture ☐
Remount dentures ☐
Replace soft liner 110 ☐
Reline man denture 105 ☐
Remake man denture ☐
Replace female retainers ☐
Other (describe below) 111 ☐

Max denture adjustment.....112 ☐
Mand denture adjustment..... ☐
Tighten clip..... ☐
Change attachment system.....115 ☐
Denture repair..... ☐
Adjust occlusion..... ☐
Medication required..... ☐
..... ☐
Combination Syndrome.....120 ☐

DA: E / G / F / P (circle) 121 ☐
for clinical evaluation of dentures use Master Clinical Evaluation Sheet

FORM D: 1☐☐☐☐

CONSULTATION FORM

Patient No: 5☐☐☐☐☐☐ **Surname:** ☐☐☐☐☐☐☐☐☐☐☐☐

Date: 23☐☐☐☐☐☐ 29☐

EXTRA-ORAL EXAMINATION

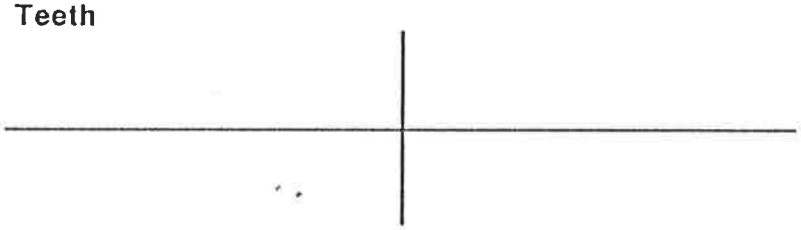
Profile	Normal	Prognathic		Retrognathic		30☐
TMJ	Pain- right	Yes/No	31☐	Crepitus	Yes/No	32☐
	Pain- left	Yes/No	☐	Deviation	Yes/No	☐
	Clicking	Yes/No	35☐	Limited opening	Yes/No	36☐
Muscular Co-ordination	Good	Satisfactory		Poor		☐

INTRA-ORAL EXAMINATION 38☐

Dental Status

Maxilla	Edentulous	Part dentate	Dentate	☐
Mandible	Edentulous	Part dentate	Dentate	☐

Retained Natural Teeth



Bone Quantity - Residual Ridges (Branemark: see Master Clinical Evaluation sheet)

Maxilla	1	2	3	4	5	☐
Mandible	1	2	3	4	5	☐

Bone Quality - radiographic (Branemark classification)

Maxilla	1	2	3	4	☐
Mandible	1	2	3	4	☐

Ridge Relation	Normal	Retrognathic	Prognathic	☐
Interarch Distance	Adequate	Excessive	Limited	☐

Bony Undercuts

Maxilla	None	Slight	Need Surgery	☐
Mandible	None	Slight	Need Surgery	48☐

Tori

Maxilla	None	Slight	Need Surgery	4 9 ☐
Mandible	None	Slight	Need Surgery	☐
Soft Tissue Covering Ridges	Firm	Thick	Hyperplastic	☐
Mucosa	Healthy	Inflammed	Pathologic	☐
Muscle and Frenal Attachments				
	Low	Medium	High	☐
Saliva	Normal	Excessive	Little or Nil	☐
Oral Hygiene	Good	Fair	Poor	☐
Parafunction	Yes/No			☐
Habits	Yes/No			5p7 ☐

Other Tests

OPG
PA's
Casts
Photographs
Other.....
.....
.....

Oral Surgeon's comments:

Bruxism..... 5 8 ☐
Clencher..... ☐
..... ☐
..... ☐
..... ☐

DIAGNOSIS

Implant Rationale

Inadequate alveolus-1	Prosthetic failures-4	6 3 ☐
Parafunction-2	Muscle uncoordination-5	☐
Psychological-3	Other-6	☐

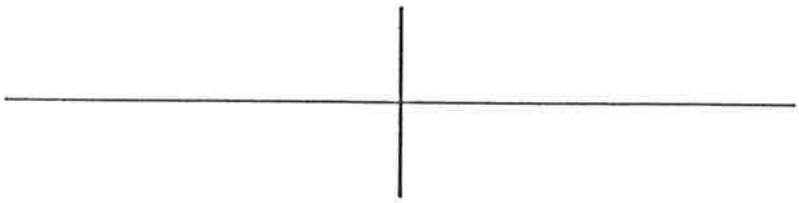
Comment:

..... 6 6 ☐
..... ☐
..... ☐
..... ☐
7 0 ☐

TREATMENT PLAN

7 1 ☐

Intended Implant Sites



General Anaesthetic/Local Anaesthetic + Sedation/LA (circle)

Local Anaesthesia

Xylocaine/Adrenaline
Citanest/Felypressin
Marcain
Other:
.....
.....
.....

Sedation:

IV/oral Diazepam
IV Hypnoval
RA
Other:
.....
.....
.....

Antibiotics:
.....
.....
.....

Analgesics:
.....
.....
.....

Oral Surgeon Comments:

..... ☐
..... ☐
..... ☐
..... ☐

Prosthesis Design

Partially Edentulous

Max	single unit	Overlay	Fixed-detached bridge	Cemented bridge	☐
Man	single unit	Overlay	Fixed-detached bridge	Cemented bridge	☐

Edentulous

Max	Overlay	Fixed-detached bridge	Cemented bridge	☐
Man	Overlay	Fixed-detached bridge	Cemented bridge	☐

Occlusal Relationship

Class I Class II Class III 8 0 ☐

Occlusal Surface (prosthesis)

Acrylic Composite Metal Porcelain 8 1☐

Occlusal Surface (opposing occlusion)

Acrylic Composite Metal Porcelain Natural ☐

Attachments

Clip Magnet O Ring Frictional Other ☐

Pre-implant Treatments Required

Dietary evaluation	OHI	
Restorations	Extractions	Endodontics
Preprosthetic Surgery	Tissue conditioning	Rebase/reline
F / - - / F	P / - - / P	

Other:

Outline Treatment Plan

DA: E / G / F / P (circle) 8 4☐

Dentist:.....

FORM E1: 1☐☐☐☐

STAGE I SURGICAL FORM

Patient No:5☐☐☐☐☐☐ Surname: ☐☐☐☐☐☐☐☐☐☐☐☐

Date: 23☐☐☐☐☐☐ 29☐

* Data contained in boxes 1-28 above, must be entered before **each** column of data below.

Implant site used (FDI)	30	☐☐	☐☐	☐☐	☐☐	☐☐	☐☐	☐☐	☐☐
Bone height (mm: from OPG)		☐☐	☐☐	☐☐	☐☐	☐☐	☐☐	☐☐	☐☐
Bone quality (I-4)	34	☐	☐	☐	☐	☐	☐	☐	☐
Implant type (Integral, Core Vent, Nobelpharma, other) Specify.....		☐	☐	☐	☐	☐	☐	☐	☐
Implant diam (3.25/4mm)		☐	☐	☐	☐	☐	☐	☐	☐
Implant length (8,10,13,15)		☐	☐	☐	☐	☐	☐	☐	☐
Height of implant above crestal bone (0.0mm)	B	38 ☐☐	☐☐	☐☐	☐☐	☐☐	☐☐	☐☐	☐☐
	L		☐☐	☐☐	☐☐	☐☐	☐☐	☐☐	☐☐
	M		☐☐	☐☐	☐☐	☐☐	☐☐	☐☐	☐☐
	D	44 ☐☐	☐☐	☐☐	☐☐	☐☐	☐☐	☐☐	☐☐
or									
Height of crestal bone above implant (0.0mm)	B	46 ☐☐	☐☐	☐☐	☐☐	☐☐	☐☐	☐☐	☐☐
	L		☐☐	☐☐	☐☐	☐☐	☐☐	☐☐	☐☐
	M		☐☐	☐☐	☐☐	☐☐	☐☐	☐☐	☐☐
	D	52 ☐☐	☐☐	☐☐	☐☐	☐☐	☐☐	☐☐	☐☐
Implant altered Yes:1/No:2		☐	☐	☐	☐	☐	☐	☐	☐
Ridge perforation		☐	☐	☐	☐	☐	☐	☐	☐
Jaw fracture		☐	☐	☐	☐	☐	☐	☐	☐
Neurological damage	57	☐	☐	☐	☐	☐	☐	☐	☐
Inf. mand. border perf.		☐	☐	☐	☐	☐	☐	☐	☐
Sinus lift		☐	☐	☐	☐	☐	☐	☐	☐
Perf. sinus/nasal cavity	60	☐	☐	☐	☐	☐	☐	☐	☐
Equip. complication		☐	☐	☐	☐	☐	☐	☐	☐
Unable to seat implant		☐	☐	☐	☐	☐	☐	☐	☐
Poor adaptation to site	63	☐	☐	☐	☐	☐	☐	☐	☐

Ridge augmentation	6 4	☐	☐	☐	☐	☐	☐	☐	☐
Perio tissue damage		☐	☐	☐	☐	☐	☐	☐	☐
Pain at surgery		☐	☐	☐	☐	☐	☐	☐	☐
Excessive bleeding		☐	☐	☐	☐	☐	☐	☐	☐
Jamming drills	6 8	☐	☐	☐	☐	☐	☐	☐	☐
Trephine ridge		☐	☐	☐	☐	☐	☐	☐	☐
Reseat implant		☐	☐	☐	☐	☐	☐	☐	☐
Leaking irrigation hose		☐	☐	☐	☐	☐	☐	☐	☐
Broken drill		☐	☐	☐	☐	☐	☐	☐	☐
Fast drilling	7 3	☐	☐	☐	☐	☐	☐	☐	☐
Anaesthesia	7 4	☐	☐	☐	☐	☐	☐	☐	☐

1.GA /2. LA +IV
3.LA + RA + Oral /4. LA + RA
5.LA + Oral /6. LA
7. .....

Antibiotics Prescribed:
.....
.....
.....

Analgesics Prescribed:
.....
.....
.....

FORM E2: 1 ☐☐☐☐

STAGE I POSTSURGICAL FORM

Patient No: 5 ☐☐☐☐☐☐ **Surname:** ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Date: 2 3 ☐☐☐☐☐☐ 2 9 ☐

Pain (place an **X** along the line indicating pain since implantation/last visit)

Day 1: slight _____ severe 30 ☐☐

Day2: slight _____ severe 32 ☐☐

Day7: slight _____ severe 34 ☐☐

* Data contained in boxes 1-35 above, must be entered before **each** column of data below.

Implant site used (FDI)	3 6 ☐☐	☐☐	☐☐	☐☐	☐☐	☐☐	☐☐	☐☐
Slow healing Yes:1/No:2								
Poor healing								
Haematoma								
Infection	4 1 ☐	☐	☐	☐	☐	☐	☐	☐
Dehiscence								
Paraesthesia/Dysthesia								
Implant removed								
Implant replaced								
Healing screw loose/lost								
Inferior border pain								
Tighten healing screw								
Replace healing screw								
Swelling	5 0 ☐	☐	☐	☐	☐	☐	☐	☐
Other (describe below)								
.....	☐	☐	☐	☐	☐	☐	☐	☐
.....	5 2 ☐	☐	☐	☐	☐	☐	☐	☐

Antibiotics Prescribed:

.....

.....

.....

Analgesics Prescribed:

.....

.....

.....

FORM F1: 1 ☐☐☐☐

STAGE II SURGICAL FORM

Patient No:5 ☐☐☐☐☐☐ Surname: ☐☐☐☐☐☐☐☐☐☐☐☐

Date: 2 3 ☐☐☐☐☐☐ 2 9 ☐

* Data contained in boxes 1-28 above, must be entered before **each** column of data below

Implant site used (FDI) 3 0 ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐

Height of implant above crestal bone (0.0mm)

B 3 2 ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐

L ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐

M ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐

D 3 8 ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐

or

Height of crestal bone above implant (0.0mm)

B 4 0 ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐

L ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐

M ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐

D 4 6 ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐

Implant exposure Yes:1/No:2 ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

Implant left submerged (sleeper) ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

Loss of integration 5 0 ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

Implant removed ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

Implant replaced ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

Surgical complication ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

Loose healing screw ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

Mucosal not gingival attachment 5 5 ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

Other (describe below)

..... 5 6 ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

..... ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

..... ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

..... ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

..... ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

Anaesthesia 6 1 ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

1. GA /2. LA +IV
3. LA + RA + Oral /4. LA + RA
5. LA + Oral /6. LA
7. .....

Antibiotics Prescribed:

.....

.....

.....

Analgesics Prescribed:

.....

.....

.....

FORM F2: 1☐☐☐☐

STAGE II POSTSURGICAL FORM

Patient No:5☐☐☐☐☐☐ **Surname:** ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Date: 2 3☐☐☐☐☐☐ 2 9☐

Pain (place an **X** along the line indicating pain since implantation/last visit)

Day 1: slight _____ severe 30☐☐

Day2: slight _____ severe 32☐☐

Day7: slight _____ severe 34☐☐

* Data contained in boxes 1-35 above, must be entered before **each** column of data below.

Implant site used (FDI) 3 6	☐☐	☐☐	☐☐	☐☐	☐☐	☐☐	☐☐	☐☐
Normal healing Yes:1/No:2	☐	☐	☐	☐	☐	☐	☐	☐
Slow healing	☐	☐	☐	☐	☐	☐	☐	☐
Poor healing	☐	☐	☐	☐	☐	☐	☐	☐
Peri-implant hyperplasia	☐	☐	☐	☐	☐	☐	☐	☐
Pain on percussion	☐	☐	☐	☐	☐	☐	☐	☐
Haematoma 4 3	☐	☐	☐	☐	☐	☐	☐	☐
Infection	☐	☐	☐	☐	☐	☐	☐	☐
Dehiscence	☐	☐	☐	☐	☐	☐	☐	☐
Paraesthesia/Dysthesia	☐	☐	☐	☐	☐	☐	☐	☐
Submerged healing cuff	☐	☐	☐	☐	☐	☐	☐	☐
Loose cuff	☐	☐	☐	☐	☐	☐	☐	☐
Swelling	☐	☐	☐	☐	☐	☐	☐	☐
Ulceration about implant 5 0	☐	☐	☐	☐	☐	☐	☐	☐
Other (describe below)								
.....5 1	☐	☐	☐	☐	☐	☐	☐	☐
.....	☐	☐	☐	☐	☐	☐	☐	☐
.....5 3	☐	☐	☐	☐	☐	☐	☐	☐

Antibiotics Prescribed:

.....

.....

.....

Analgesics Prescribed:

.....

.....

.....

FORM G: 1 ☐☐☐☐

CLINICAL EVALUATION FORM

-Implants

Patient No: 5 ☐☐☐☐☐☐ **Surname:** ☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Date: 2 3 ☐☐☐☐☐☐

Attachment system (1: Clip, 2: Magnet, 3: O-ring, 4: Ball) 2 9 ☐

Review:

1/12	3/12	6/12	12/12
18/12	2/1	3/1	4/1 ☐

Type of Prosthesis:

Max	Single unit	Overlay	Fixed-detached bridge	cemented bridge	☐
Man	Single unit	Overlay	Fixed-detached bridge	cemented bridge	3 2 ☐

* Data contained in boxes 1-32 above, must be entered before <u>each</u> column of data below.

Implant site used (FDI) 3 3 ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐

Sleeper Yes: 1/ No: 2 ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

PERI-IMPLANT HEALTH

Gi'val bleeding(0,1,2,3) 3 6 ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

Plaque(0,1,2,3) ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

Calculus(0,1,2,3) ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

Periotest score 3 9 ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐

Abutment to tissue(0.0mm) B 4 1 ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐

-tissue below abutment L ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐

M ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐

D 4 7 ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐

Abutment to tissue(0.0mm) B 4 9 ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐

-tissue above abutment L ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐

M ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐

D 5 5 ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐ ☐☐

Crevice depth (0.0mm) B 5 7
L
M
D 6 3

Comments

..... 6 5
.....
.....
..... 6 8

RADIOGRAPHY

Cervical cratering Yes:1/No:2 6 9
Peri implant radiolucency

Bone loss (0.0mm):

M 7 2
D

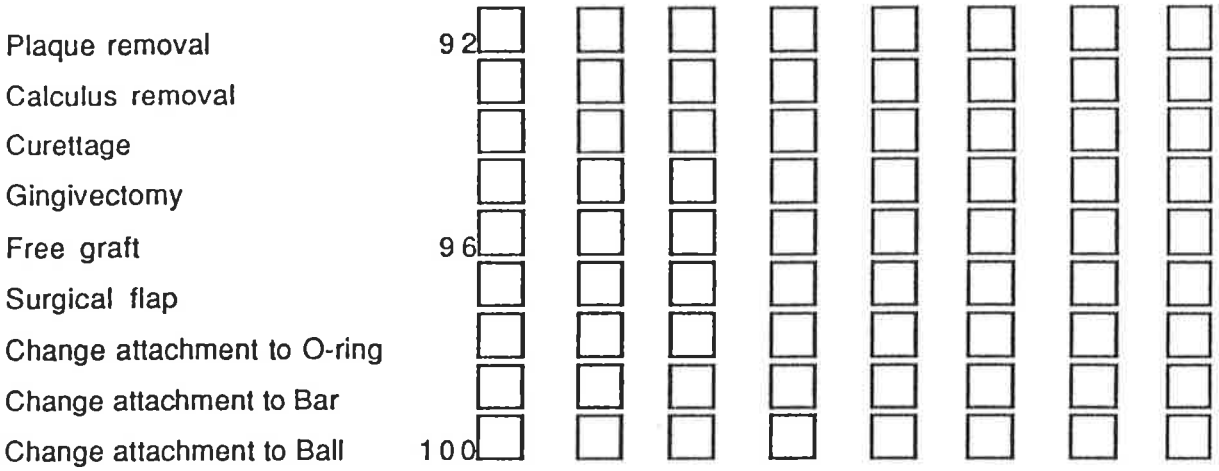
COMPLICATIONS

Implant removed Yes:1/No:2 7 6
Abutment fracture
Implant thread stripped
Screw loosened/lost
Fractured component
Corroded component 8 1
Component replaced
Poor implant angulation
Pain assoc with implant
Pain on probing
Pain on percussion
Sensation loss at implant
Loose abutment
Pathology about abutment 8 9

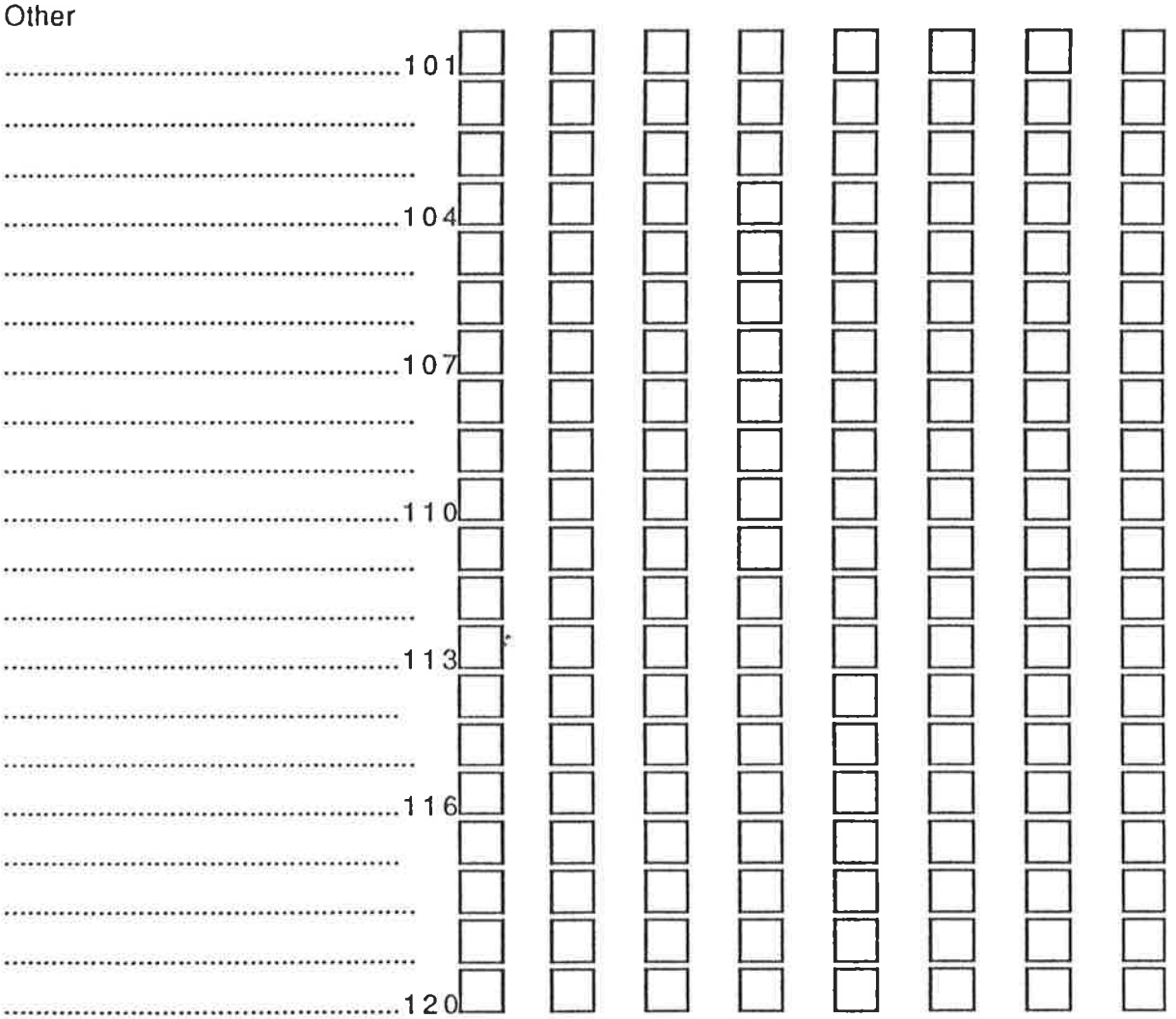
Other

.....
..... 9 1

TREATMENT REQUIRED



Other



Refer to Master Clinical Evaluation Sheet when using this form.

APPENDIX C

Peri-implant and Prosthetic Tables

Table 13. Plaque scores

Months	Score 0	Score 1	Score 2	Score 3
0	46	5	1	0
1	12	2	10	2
3	16	25	19	0
6	10	13	21	0
12	2	17	22	1
18	10	15	17	0

Table 14. Calculus scores

Months	Score 0	Score 1	Score 2	Score 3
0	50	2	0	0
1	16	6	2	2
3	44	8	7	1
6	22	9	11	2
12	14	21	7	0
18	9	20	13	0

Table 15. Relative plaque scores per attachment system

Clip	Score 0	Score 1	Score 2	Score 3	Relative Score
0	17	1	1	0	0.16
1	6	2	0	0	0.25
3	8	5	7	0	0.95
6	5	5	5	0	1.00
12	2	5	8	1	1.50
18	6	2	6	0	1.00
O-ring					
0	14	2	0	0	0.13
1	4	0	4	2	1.40
3	4	8	4	0	1.00
6	4	4	8	0	1.25
12	0	4	8	0	1.67
18	2	5	7	0	1.36
Ball					
0	14	2	0	0	0.13
1	2	0	6	0	1.50
3	4	2	8	0	1.29
6	2	4	8	0	1.43
12	0	8	6	0	1.43
18	2	8	4	0	1.14

Table 16. Relative calculus scores per attachment system

Clip	Score 0	Score 1	Score 2	Score 3	Relative Score
0	19	0	0	0	0.00
1	8	0	0	0	0.00
3	16	4	0	0	0.20
6	7	5	3	0	0.73
12	8	6	2	0	0.63
18	4	8	2	0	0.86
O-ring					
0	16	0	0	0	0.00
1	4	3	1	2	1.10
3	10	4	1	1	0.56
6	10	0	4	2	0.88
12	2	6	4	0	1.17
18	4	3	7	0	1.21
Ball					
0	14	2	0	0	0.13
1	4	3	1	0	0.63
3	18	0	6	0	0.50
6	6	4	4	0	0.86
12	4	9	1	0	0.79
18	1	9	4	0	1.21

Table 17. Gingival bleeding scores

Months	Score 0	Score 1	Score 2	Score 3
0	50	1	1	0
1	22	4	0	0
3	30	26	4	0
6	22	20	1	1
12	26	13	3	0
18	22	15	5	0

Table 18. Relative gingival bleeding scores per attachment system

Clip	Score 0	Score 1	Score 2	Score 3	Relative Score
0	18	0	1	0	0.11
1	8	0	0	0	0.00
3	15	3	2	0	0.35
6	9	4	1	1	0.60
12	11	4	1	0	0.38
18	8	4	2	0	0.57
O-ring					
0	15	1	0	0	0.06
1	9	1	0	0	0.10
3	6	10	0	0	0.63
6	10	6	0	0	0.38
12	7	5	0	0	0.42
18	8	4	2	0	0.57
Ball					
0	16	0	0	0	0.00
1	5	3	0	0	0.38
3	9	13	2	2	0.88
6	4	10	0	0	0.71
12	8	4	2	2	0.88
18	6	7	1	1	0.80

Table 19. Crevice depth scores

Months	Buccal	S.D.	Lingual	S.D.	Mesial	S.D.	Distal	S.D.
0	3.15	1.39	2.82	1.28	3.10	1.55	3.04	1.32
1	2.79	0.99	2.87	0.87	3.10	1.11	2.90	0.80
3	2.96	1.16	2.80	0.91	3.00	1.02	3.10	1.00
6	3.16	1.32	2.93	1.10	3.16	1.14	3.03	1.14
12	2.73	1.00	2.61	0.96	2.74	1.03	2.82	1.15
18	3.39	1.07	3.35	1.24	3.57	1.16	3.57	1.18

Table 20. Crevice depth scores per attachment system

Clip	Buccal	S.D.	Lingual	S.D.	Mesial	S.D.	Distal	S.D.	Mean
0	27.74	12.41	21.84	7.68	26.84	13.15	26.58	13.02	2.58
1	28.75	11.57	22.50	4.63	32.50	12.82	28.75	9.91	2.81
3	25.50	7.42	26.50	11.25	28.50	10.77	30.50	11.46	2.78
6	30.67	9.61	27.67	8.84	32.00	12.22	30.67	9.61	3.03
12	29.06	6.88	25.63	6.02	30.00	7.75	29.69	7.85	2.86
18	32.86	14.37	30.71	16.04	33.93	15.09	34.64	16.81	3.30
O-ring									
0	35.63	18.34	35.50	15.98	37.19	20.73	33.75	17.46	3.55
1	28.50	10.01	28.50	3.37	26.50	8.18	28.00	6.32	2.79
3	38.75	13.60	31.25	9.57	36.56	11.93	34.69	10.72	3.53
6	35.94	17.15	31.25	13.23	33.75	11.62	30.00	11.83	3.27
12	25.83	11.65	26.25	11.10	25.00	11.87	26.25	12.99	2.58
18	31.43	7.45	31.79	12.19	35.36	12.00	31.79	7.23	3.26
Ball									
0	31.88	9.98	28.44	10.91	30.31	10.24	31.56	7.24	3.05
1	26.25	9.16	35.00	11.95	35.00	11.95	30.63	8.63	3.17
3	26.88	9.87	27.08	6.06	26.88	5.86	28.96	7.66	2.74
6	27.50	9.95	28.93	10.22	27.86	10.14	30.36	12.93	2.87
12	26.50	11.80	26.43	11.96	26.36	11.46	28.21	14.06	2.69
18	37.50	8.72	37.86	6.71	37.86	6.71	40.71	7.56	3.85

Table 21. Tissue height scores

Months	Buccal	S.D.	Lingual	S.D.	Mesial	S.D.	Distal	S.D.
0	0.76	1.26	1.00	1.07	0.68	1.09	0.92	0.95
1	1.39	1.10	1.44	1.01	1.08	0.78	1.53	0.93
3	1.06	1.12	1.27	0.96	0.89	0.89	0.95	1.04
6	1.25	1.07	1.60	0.81	1.03	1.01	1.15	1.06
12	1.49	1.08	1.71	0.79	1.14	0.84	1.28	1.09
18	1.37	1.05	1.89	1.04	1.14	1.05	1.20	1.19

Table 22. Tissue height scores per attachment system

Clip	Buccal	S.D.	Lingual	S.D.	Mesial	S.D.	Distal	S.D.	Mean
0	4.68	9.16	7.26	8.79	4.74	7.90	5.68	6.75	0.56
1	8.50	9.97	8.13	11.32	4.38	7.76	8.75	10.26	0.74
3	5.90	9.97	8.85	9.90	3.65	9.18	3.90	8.43	0.56
6	10.53	8.90	15.00	6.70	6.67	10.97	6.13	11.05	0.96
12	11.88	12.37	16.56	6.25	7.19	9.83	10.31	10.87	1.15
18	9.29	11.91	18.57	9.69	7.14	10.14	4.29	12.38	0.98
O-ring									
0	8.94	15.32	10.25	13.73	6.13	15.24	12.69	10.59	0.95
1	18.00	7.15	19.50	8.96	14.50	6.85	19.40	4.90	1.79
3	11.81	12.05	14.75	9.11	9.00	8.44	15.38	9.00	1.27
6	11.69	9.03	16.06	7.88	9.06	8.98	15.63	6.64	1.31
12	17.08	6.89	17.08	7.82	11.25	6.44	13.75	12.45	1.48
18	15.71	8.99	18.21	8.90	11.71	7.83	15.86	8.79	1.54
Ball									
0	9.69	13.76	12.50	9.13	9.56	8.97	10.19	10.44	1.05
1	14.13	14.55	14.38	7.07	12.75	4.98	16.63	9.98	1.45
3	13.75	10.67	14.54	9.12	13.08	6.85	10.33	10.78	1.29
6	15.50	13.63	17.14	9.75	15.57	8.36	12.00	11.83	1.51
12	16.43	11.51	17.71	9.95	15.50	7.67	14.71	9.79	1.61
18	16.07	9.84	20.00	12.86	15.36	12.16	15.71	10.89	1.68

Table 23. Bone loss scores

	Mesial	S.D.	Distal	S.D.
Stage I	0.04	0.25	0.03	0.24
Stage II	-0.04	0.55	0.02	0.57
Delivery	0.35	0.57	0.39	0.66
6 months	0.60	0.85	0.83	1.08
12 months	0.84	1.62	0.99	1.29
18 months	0.90	1.34	1.01	1.41

Table 24. Bone loss scores per attachment system

Clip	Mesial	S.D.	Distal	S.D.	Mean
Stage I	0.18	6.08	0.14	3.63	0.16
Stage II	-0.19	5.98	-0.09	9.17	-0.14
Delivery	0.08	1.60	0.16	2.96	0.12
6 Months	0.23	2.93	0.33	3.00	0.28
12 Months	0.33	4.39	0.43	4.99	0.38
18 Months	0.32	2.83	0.51	4.70	0.41
O-ring					
Stage 1	0.03	6.95	0.03	1.25	0.03
Stage 2	0.04	12.46	0.21	5.60	0.13
Delivery	0.57	7.05	0.69	8.25	0.63
6 Months	0.80	8.05	1.08	10.75	0.94
12 Months	1.10	7.52	1.42	10.02	1.26
18 Months	1.14	7.56	1.14	8.96	1.14
Ball					
Stage 1	-0.06	1.66	-0.06	1.66	-0.06
Stage 2	0.03	7.16	-0.02	6.28	0.01
Delivery	0.41	6.50	0.40	7.28	0.40
6 Months	0.80	11.43	1.08	14.26	0.94
12 Months	1.19	19.52	1.28	18.59	1.24
18 Months	1.24	21.19	1.38	21.85	1.31

Table 25. Periotest scores

Months	Mean	S.D.
0	-5.00	2.15
1	-5.46	1.92
3	-5.13	1.88
6	-5.41	2.11
12	-5.33	1.65
18	-5.55	1.85

Table 26. Periotest scores per attachment system

	Clip	S.D.	O-ring	S.D.	Ball	S.D.
0	-5.21	1.69	-5.06	2.46	-4.63	2.45
1	-5.63	1.77	-6.50	0.53	-4.00	2.39
3	-4.65	1.60	-5.75	1.53	-5.13	2.23
6	-5.93	1.10	-5.81	1.80	-4.43	2.85
12	-5.50	1.15	-5.67	1.30	-4.86	2.28
18	-5.57	1.22	-6.36	1.45	-4.71	2.40

Table 27. Oral hygiene correlations

Score	System	Chi Square	d.f.	Probability
Plaque	Clip	2.29	2	0.32
	O-ring	1.78	2	0.41
	Ball	1.75	2	0.42
Calculus	Clip	1.37	2	0.50
	O-ring	2.94	2	0.23
	Ball	0.84	2	0.66
Bleeding	Clip	16	2	0.0003
	O-ring	2.29	2	0.32
	Ball	1.56	2	0.46

Table 28. PTV correlations

PTV vs	d.f.	F value	Probability
Attachment system	2	3.52	0.03
Implant length	3	1.86	0.15
Bone quality	3	0.58	0.63
Parafunction	1	0.15	0.70

Table 29. Bone loss correlations

Bone loss vs	d.f.	F value	Probability
Attachment system	2	3.91	0.03
Implant length	3	0.58	0.63
Bone quality	3	1.86	0.15
Bone quantity	3	0.68	0.57
Oral hygiene	2	0.52	0.60
Parafunction	1	3.82	0.06

Table 30. Patient assessment of function, comfort, retention and dysfunction

		Function		**Comfort**		**Retention**		**Dysfunction**	
Review (Months)	No. Patients	Score	SD	Score	SD	Score	SD	Score	SD
0	26	4.04	2.55	6.29	2.15	5.73	1.91	5.75	3.60
1	13	9.59	0.49	9.65	0.77	9.22	0.73	9.00	1.87
3	30	8.89	1.47	9.32	0.80	8.85	1.17	9.18	1.55
6	20	9.25	0.93	9.08	1.18	8.63	1.36	9.08	1.40
12	22	9.33	0.91	9.24	0.94	8.88	1.17	8.45	2.16
18	23	9.13	1.42	9.35	1.17	8.93	1.22	8.33	2.69

Table 31. Patient assessment of function per attachment system

Function									
	Clip			O-Ring			Ball		
Review (Months)	No. Patients	Score	SD	No. Patients	Score	SD	No. Patients	Score	SD
0	9	3.93	3.05	8	4.17	2.67	9	4.04	2.18
1	4	10.00	0.00	5	9.47	0.56	4	9.33	0.47
3	10	9.50	0.95	8	8.79	1.18	12	8.44	1.88
6	7	9.38	0.85	6	9.33	0.92	7	9.05	1.11
12	7	9.10	1.42	7	9.52	0.74	8	9.38	0.45
18	8	9.00	2.07	8	9.38	0.93	7	9.00	1.12

Table 32. Patient assessment of comfort per attachment system

Comfort									
	Clip			O-Ring			Ball		
Review (Months)	No. Patients	Score	SD	No. Patients	Score	SD	No. Patients	Score	SD
0	9	6.36	1.77	8	6.66	2.83	9	5.89	1.98
1	4	10.00	0.00	5	9.85	0.34	4	9.06	1.25
3	10	9.28	0.68	8	9.41	0.83	12	9.29	0.92
6	7	9.39	0.76	6	9.25	1.16	7	8.61	1.51
12	7	9.21	1.07	7	9.57	0.73	8	8.97	1.01
18	8	9.13	1.65	8	9.69	0.37	7	9.21	1.22

Table 33. Patient assessment of retention per attachment system

Retention									
	Clip			O-Ring			Ball		
Review (Months)	No. Patients	Score	SD	No. Patients	Score	SD	No. Patients	Score	SD
0	9	5.31	1.97	8	6.29	1.90	9	5.67	1.96
1	4	9.70	0.60	5	8.88	0.91	4	9.18	0.38
3	10	9.30	0.96	8	8.81	0.84	12	8.49	1.45
6	7	9.04	1.22	6	9.00	0.72	7	7.89	1.71
12	7	8.73	1.59	7	8.99	0.83	8	8.93	1.14
18	8	9.01	1.37	8	9.14	1.08	7	8.60	1.33

Table 34. Patient assessment of dysfunction per attachment system

Dysfunction									
	Clip			O-Ring			Ball		
Review (Months)	No. Patients	Score	SD	No. Patients	Score	SD	No. Patients	Score	SD
0	9	5.39	4.30	8	5.75	3.92	9	6.11	2.87
1	4	10.00	0.00	5	8.60	2.61	4	8.50	1.73
3	10	9.70	0.95	8	9.50	1.07	12	8.54	2.03
6	7	8.86	1.57	6	9.42	1.20	7	9.00	1.53
12	7	8.50	1.61	7	9.14	1.22	8	7.81	3.09
18	8	8.44	1.84	8	8.88	2.80	7	7.57	3.52

Table 35. Patient assessment of maxillary and mandibular comfort

Comfort					
		Maxilla		Mandible	
Review (Months)	No. Patients	Score	SD	Score	SD
0	26	6.82	1.93	3.92	2.41
1	13	9.17	0.86	9.27	0.88
3	30	8.84	1.20	8.71	1.53
6	20	8.33	1.61	8.84	1.45
12	22	8.58	1.75	9.12	1.03
18	23	8.67	1.69	9.15	1.03

Table 36. Patient assessment of maxillary comfort per attachment system

Maxillary Comfort									
	Clip			O-Ring			Ball		
Review (Months)	No. Patients	Score	SD	No. Patients	Score	SD	No. Patients	Score	SD
0	9	6.69	2.34	8	7.06	1.91	9	6.74	1.71
1	4	9.50	1.00	5	9.00	1.11	4	9.04	0.34
3	10	9.23	1.00	8	9.02	0.71	12	8.39	1.51
6	7	8.93	1.48	6	8.69	1.14	7	7.40	1.84
12	7	8.26	2.23	7	8.95	1.13	8	8.52	1.91
18	8	8.85	1.69	8	8.90	1.76	7	8.21	1.78

Table 37. Patient assessment of mandibular comfort per attachment system

Mandibular Comfort									
	Clip			O-Ring			Ball		
Review (Months)	No. Patients	Score	SD	No. Patients	Score	SD	No. Patients	Score	SD
0	9	3.28	2.41	8	4.54	2.34	9	4.02	2.57
1	4	9.67	0.67	5	8.77	0.94	4	9.50	0.89
3	10	9.20	1.17	8	8.65	1.33	12	8.33	1.89
6	7	9.10	1.15	6	9.36	0.66	7	8.14	2.03
12	7	8.90	1.51	7	9.19	1.00	8	9.25	0.54
18	8	9.04	1.43	8	9.50	0.53	7	8.88	0.97

Table 38. Patient assessment of maxillary and mandibular retention

Retention					
		Maxilla		Mandible	
Review (Months)	No. Patients	Score	SD	Score	SD
0	26	7.62	2.48	4.96	2.53
1	13	9.46	1.55	9.85	0.43
3	30	9.23	1.12	9.40	1.03
6	20	8.73	1.97	9.43	1.05
12	22	8.59	1.76	9.89	0.43
18	23	9.07	1.55	9.63	1.38

Table 39. Patient assessment of maxillary retention per attachment system

Maxillary Retention									
	Clip			O-Ring			Ball		
Review (Months)	No. Patients	Score	SD	No. Patients	Score	SD	No. Patients	Score	SD
0	9	8.28	1.99	8	7.69	3.17	9	6.89	2.32
1	4	10.00	0.00	5	9.70	0.67	4	8.63	2.75
3	10	9.25	0.83	8	9.13	1.48	12	9.29	1.16
6	7	9.43	0.98	6	8.50	2.32	7	8.21	2.43
12	7	8.71	1.70	7	9.21	1.47	8	7.94	2.03
18	8	9.25	1.17	8	9.44	0.73	7	8.43	2.44

Table 40. Patient assessment of mandibular retention per attachment system

Mandibular Retention									
	Clip			O-Ring			Ball		
Review (Months)	No. Patients	Score	SD	No. Patients	Score	SD	No. Patients	Score	SD
0	9	4.44	2.54	8	5.63	2.76	9	4.89	2.48
1	4	10.00	0.00	5	10.00	0.00	4	9.50	0.71
3	10	9.30	1.16	8	9.69	0.59	12	9.29	1.18
6	7	9.36	1.49	6	10.00	0.00	7	9.00	0.87
12	7	9.71	0.76	7	9.93	0.19	8	10.00	0.00
18	8	9.00	2.28	8	9.94	0.18	7	10.00	0.00

Table 41. Clinical assessment of function, comfort, retention and dysfunction

		Function		Comfort		Retention		Dysfunction	
Review (Months)	No. Patients	Score	SD	Score	SD	Score	SD	Score	SD
0	26	0.70	0.13	0.61	0.22	0.51	0.28	0.54	0.21
1	13	0.90	0.06	0.73	0.24	0.98	0.07	0.56	0.23
3	31	0.87	0.09	0.70	0.23	0.99	0.04	0.63	0.19
6	20	0.80	0.11	0.57	0.29	0.99	0.06	0.58	0.28
12	24	0.85	0.07	0.69	0.28	1.00	0.00	0.52	0.30
18	23	0.86	0.06	0.69	0.26	1.00	0.00	0.53	0.27

Table 42. Clinical assessment of function per attachment system

Function									
	Clip			O-Ring			Ball		
Review (Months)	No. Patients	Score	SD	No. Patients	Score	SD	No. Patients	Score	SD
0	9	0.69	0.11	8	0.73	0.11	9	0.69	0.17
1	4	0.88	0.08	5	0.90	0.07	4	0.92	0.00
3	10	0.93	0.06	8	0.90	0.07	13	0.81	0.10
6	7	0.82	0.11	6	0.81	0.11	7	0.79	0.12
12	8	0.81	0.07	7	0.89	0.04	9	0.85	0.07
18	8	0.88	0.06	8	0.88	0.04	7	0.81	0.04

Table 43. Clinical assessment of comfort per attachment system

Comfort									
	Clip			O-Ring			Ball		
Review (Months)	No. Patients	Score	SD	No. Patients	Score	SD	No. Patients	Score	SD
0	9	0.63	0.22	8	0.67	0.15	9	0.54	0.26
1	4	0.96	0.08	5	0.63	0.27	4	0.63	0.16
3	10	0.83	0.18	8	0.75	0.15	13	0.58	0.24
6	7	0.74	0.32	6	0.56	0.17	7	0.40	0.29
12	8	0.67	0.30	7	0.76	0.19	9	0.65	0.35
18	8	0.69	0.31	8	0.75	0.24	7	0.62	0.25

Table 44. Clinical assessment of retention per attachment system

Retention									
	Clip			O-Ring			Ball		
Review (Months)	No. Patients	Score	SD	No. Patients	Score	SD	No. Patients	Score	SD
0	9	0.50	0.22	8	0.50	0.35	9	0.53	0.29
1	4	0.94	0.13	5	1.00	0.00	4	1.00	0.00
3	10	1.00	0.00	8	0.97	0.09	13	1.00	0.00
6	7	1.00	0.00	6	0.96	0.10	7	1.00	0.00
12	8	1.00	0.00	7	1.00	0.00	9	1.00	0.00
18	8	1.00	0.00	8	1.00	0.00	7	1.00	0.00

Table 45. Clinical assessment of dysfunction per attachment system

Dysfunction									
	Clip			O-Ring			Ball		
Review (Months)	No. Patients	Score	SD	No. Patients	Score	SD	No. Patients	Score	SD
0	9	0.58	0.13	8	0.59	0.23	9	0.44	0.24
1	4	0.69	0.13	5	0.55	0.27	4	0.44	0.24
3	10	0.73	0.14	8	0.69	0.18	13	0.52	0.19
6	7	0.64	0.32	6	0.67	0.20	7	0.43	0.28
12	8	0.56	0.32	7	0.64	0.24	9	0.39	0.31
18	8	0.53	0.28	8	0.69	0.18	7	0.36	0.28

Table 46. Clinical assessment of maxillary and mandibular comfort

Comfort					
		Maxilla		Mandible	
Review (Months)	No. Patients	Score	SD	Score	SD
0	26	0.81	0.25	0.33	0.30
1	13	0.83	0.21	0.64	0.32
3	31	0.82	0.26	0.59	0.32
6	20	0.60	0.37	0.53	0.33
12	24	0.68	0.39	0.72	0.29
18	23	0.71	0.33	0.74	0.28

Table 47. Clinical assessment of maxillary comfort per attachment system

Maxillary Comfort									
	Clip			O-Ring			Ball		
Review (Months)	No. Patients	Score	SD	No. Patients	Score	SD	No. Patients	Score	SD
0	9	0.86	0.25	8	0.88	0.13	9	0.69	0.30
1	4	1.00	0.00	5	0.80	0.21	4	0.69	0.24
3	10	0.98	0.08	8	0.91	0.13	13	0.65	0.32
6	7	0.71	0.42	6	0.67	0.26	7	0.43	0.37
12	8	0.53	0.41	7	0.86	0.28	9	0.67	0.41
18	8	0.66	0.40	8	0.81	0.26	7	0.64	0.32

Table 48. Clinical assessment of mandibular comfort per attachment system

Mandibular Comfort									
	Clip			O-Ring			Ball		
Review (Months)	No. Patients	Score	SD	No. Patients	Score	SD	No. Patients	Score	SD
0	9	0.37	0.26	8	0.38	0.28	9	0.26	0.36
1	4	0.92	0.17	5	0.47	0.38	4	0.58	0.17
3	10	0.70	0.29	8	0.58	0.30	13	0.51	0.35
6	7	0.76	0.25	6	0.44	0.34	7	0.38	0.30
12	8	0.79	0.25	7	0.71	0.30	9	0.67	0.33
18	8	0.79	0.31	8	0.71	0.33	7	0.71	0.23

Table 49. Clinical assessment of maxillary and mandibular retention

Retention					
		Maxilla		Mandible	
Review (Months)	No. Patients	Score	SD	Score	SD
0	26	0.71	0.35	0.31	0.38
1	13	0.96	0.14	1.00	0.00
3	31	0.98	0.09	1.00	0.00
6	20	0.98	0.11	1.00	0.00
12	24	1.00	0.00	1.00	0.00
18	23	1.00	0.00	1.00	0.00

Table 50. Clinical assessment of maxillary retention per attachment system

Maxillary Retention									
	Clip			O-Ring			Ball		
Review (Months)	No. Patients	Score	SD	No. Patients	Score	SD	No. Patients	Score	SD
0	9	0.78	0.26	8	0.56	0.42	9	0.78	0.36
1	4	0.88	0.25	5	1.00	0.00	4	1.00	0.00
3	10	1.00	0.00	8	0.94	0.18	13	1.00	0.00
6	7	1.00	0.00	6	0.92	0.20	7	1.00	0.00
12	8	1.00	0.00	7	1.00	0.00	9	1.00	0.00
18	8	1.00	0.00	8	1.00	0.00	7	1.00	0.00

Table 51. Clinical assessment of mandibular retention per attachment system

Mandibular Retention									
	Clip			O-Ring			Ball		
Review (Months)	No. Patients	Score	SD	No. Patients	Score	SD	No. Patients	Score	SD
0	9	0.22	0.36	8	0.44	0.42	9	0.28	0.36
1	4	1.00	0.00	5	1.00	0.00	4	1.00	0.00
3	10	1.00	0.00	8	1.00	0.00	13	1.00	0.00
6	7	1.00	0.00	6	1.00	0.00	7	1.00	0.00
12	8	1.00	0.00	7	1.00	0.00	9	1.00	0.00
18	8	1.00	0.00	8	1.00	0.00	7	1.00	0.00

Table 52. Function correlations

Function vs	d.f.	F value	Probability
Attachment System	2	0.17	0.85
Psych History	1	3.73	0.07

Table 53. Comfort correlations

Comfort vs	d.f.	F value	Probability
Attachment system	2	0.31	0.76
Psych History	1	0.17	0.68

Table 54. Maxillary comfort correlations

Max Comfort vs	d.f.	F value	Probability
Attachment system	2	0.35	0.71
Parafunction	1	0.02	0.89
Bone quantity	3	1.13	0.36

Table 55. Mandibular comfort correlations

Mand Comfort vs	d.f.	F value	Probability
Attachment system	2	0.27	0.81
Bone quantity	3	1.39	0.28

Table 56. Maxillary retention correlations

Max Retention vs	d.f.	F value	Probability
Attachment system	2	0.86	0.44
Psych History	1	1.87	0.19
Bone quantity	3	0.66	0.59

Table 57. Mandibular retention correlations

Mand Retention vs	d.f.	F value	Probability
Attachment system	2	1.33	0.29
Psychological History	1	1.54	0.32
Bone quantity	3	0.54	0.72

Table 58. Dysfunction correlations

Dysfunction vs	d.f.	F value	Probability
Attachment system	2	0.43	0.66
Psych History	1	0.01	0.92

Table 59. Function correlations

Function vs	d.f.	F value	Probability
Attachment System	2	4.05	0.03
Psych History	1	2.87	0.05

Table 60. Maxillary comfort correlations

MaxComfort vs	d.f.	F value	Probability
Attachment system	2	0.49	0.62
Parafunction	1	9.88	0.009
Bone quantity	3	1.32	0.33

Table 61. Mandibular comfort correlations

Mand Comfort vs	d.f.	F value	Probability
Attachment system	2	0.20	0.82
Bone quantity	3	0.64	0.60

Table 62. Denture bearing area correlations

Upper bearing area soreness vs	d.f.	F value	Probability
Attachment system	2	1.64	0.22
Parafunction	1	2.12	0.16

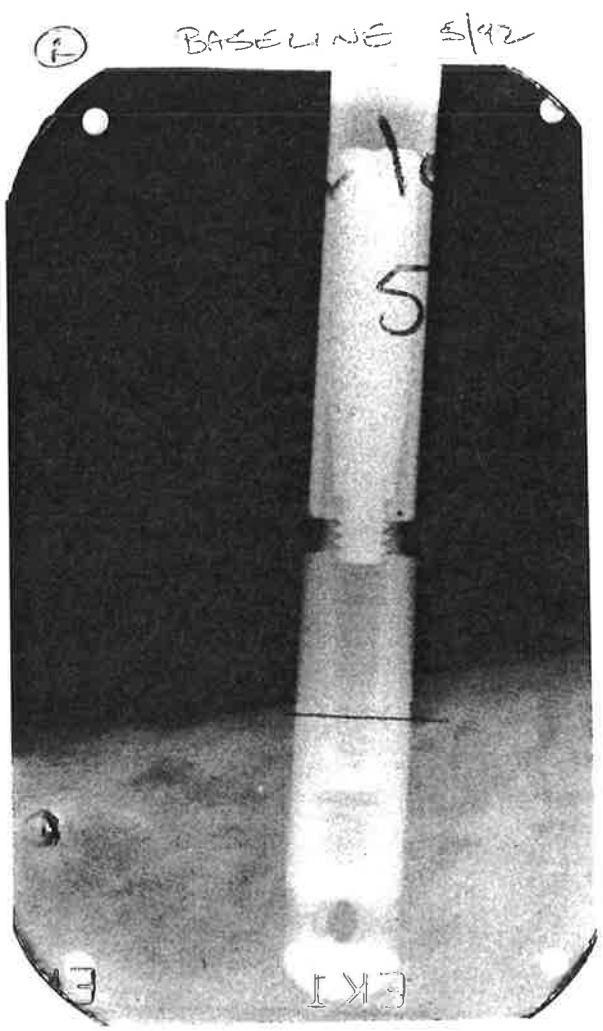
Table 63. Pre-maxillary comfort correlations

Max labial ridge soreness vs	d.f.	F value	Probability
Attachment system	2	1.33	0.31
Parafunction	1	10.02	0.009

Table 64. Dysfunction correlations

Dysfunction vs	d.f.	F value	Probability
Attachment system	2	0.95	0.42

APPENDIX D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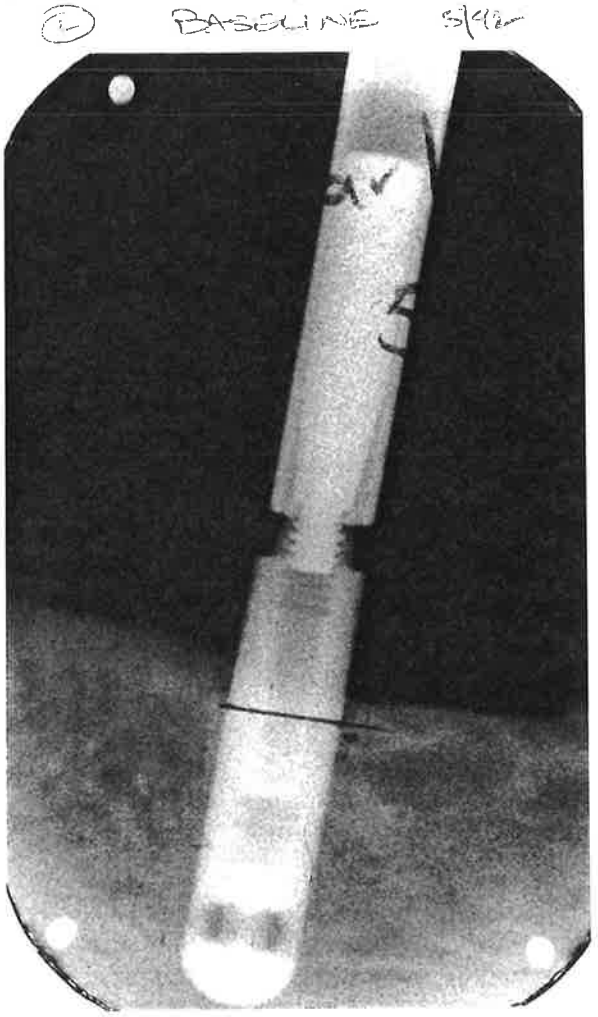
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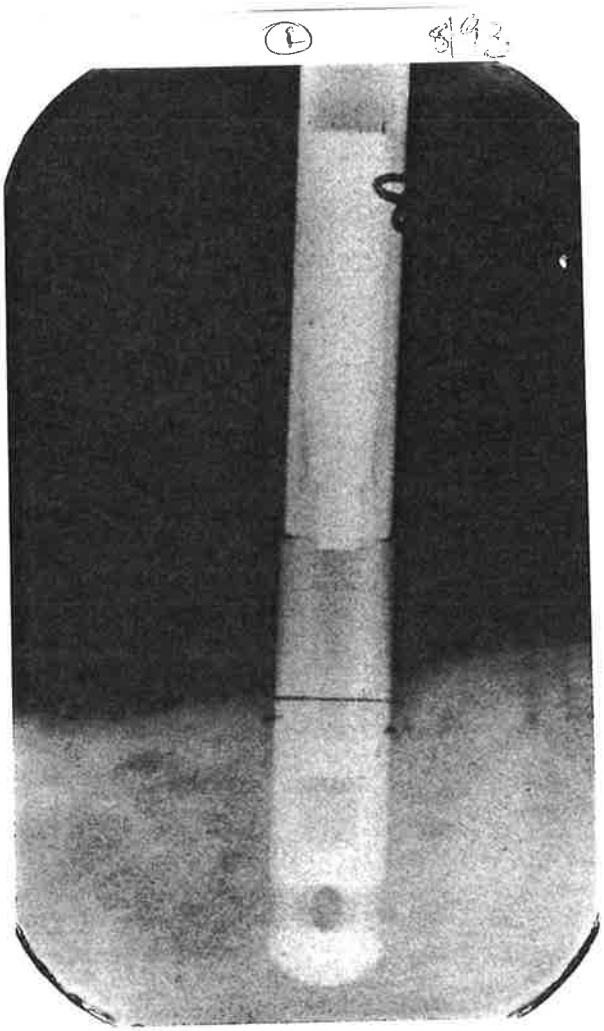
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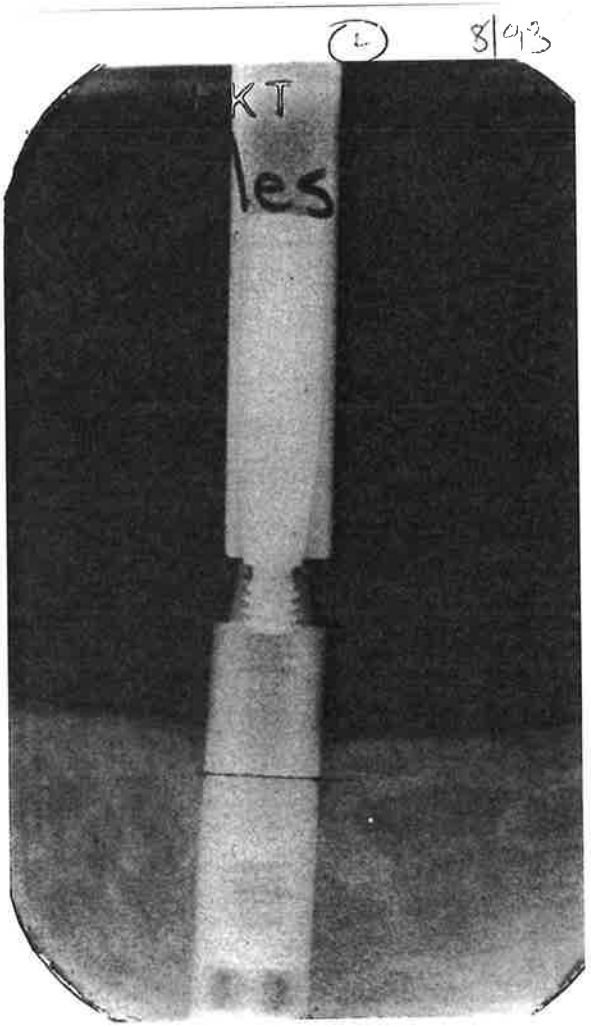
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