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An evaluation of the Bicon Implant System using  
short implants:

Patient experience and implant success  
in the short term.

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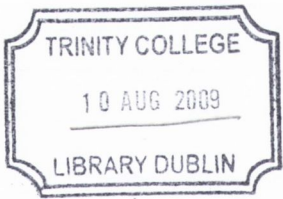
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## Summary

The aim of this study was to evaluate the success of short Bicon implants, patient experience in relation to implant placement and patient satisfaction with treatment in the short term.

45 hydroxyapatite coated short Bicon implants were placed in 25 patients and followed up for 3 to 6 months following restoration with Integrated Abutment Crowns (IAC). Implants ranged in length from 5.7mm to 8mm and in width from 4.5mm to 6mm. Implant survival and success rates were evaluated in addition to plaque and gingival health, interproximal papilla presence, marginal bone levels, and Integrated Abutment Crown aesthetics. Patient anxiety was assessed using the Spielberger State Trait Anxiety Inventory. A Health Related Quality Of Life (HRQOL) instrument was used to assess patient pain experience and interference with daily activities. Patient satisfaction was evaluated using a questionnaire. The interplay between these patient related factors was analysed. A comparison was made between clinician satisfaction ratings with the final restoration and the patient's satisfaction.

A 98% implant survival and success rate was found. 71% of patients demonstrated no marginal bone loss, 29% of patients had an average of 0.44mm loss. There was a significant relationship between the submergence depth of the implant and bone loss at 3 to 6 months following restoration. IAC surfaces demonstrated a tendency to accumulate plaque however 2 independent examiners found 67% and 86% of implants respectively to have no adjacent gingival inflammation. Interproximal papillae were absent in only 12% of cases. Patient anxiety levels were moderate pre-surgery. State anxiety levels significantly correlated to trait anxiety levels. The worst pain was experienced on day one despite higher analgesic requirements and worse post op sequelae on day two. Interference with daily activities reduced over 7 days. Satisfaction and overall experience scores were high but showed a slight tendency to negatively correlate with pain and interference scores. The correlation between patient satisfaction and clinician satisfaction with the IAC was weak.

In conclusion, short Bicon implants restored with IACs are a viable treatment option in the short term. Patient pre surgical anxiety levels can be predicted from trait anxiety. Patients will experience pain, postoperative sequelae and interference with daily activities following surgery however the majority of these will have decreased by day 4. Patient satisfaction with implant therapy was generally high.

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# **Chapter 1:**

## **Introduction**

The concept of osseointegration, first described by Brånemark in the 1960's, has provided both the partially and fully edentulous patient with the possibility of restoring their dentition using a structural and functional union between ordered living bone and the surface of a load bearing implant. It is this concept that has revolutionised dental rehabilitation and provides the clinician and patient with dental implant placement as an option when compiling treatment plans in restorative dentistry today.

Early studies indicated a promising future for implant supported restorations in edentulous jaws. Adell et al. (1981) showed 81% implant stability of fixtures which supported bridges in the edentulous maxilla after 5 to 9 years and a corresponding 91% success rate in the edentulous mandible. Continuous bridge stability was achieved in 89-96% of the upper and 100% of the lower jaws over 1 to 9 years despite the loss and replacement of fixtures. Brånemark et al. (1977) demonstrated continuous implant supported bridge stability in 99% of lower and 76% of upper edentulous jaws when consecutive cases were carried out over a 10 year period.

Encouraged by good success rates in the fully edentulous patient, attempts were made to restore the partially edentulous patient using dental implants often restored as single units. Success and survival rates of dental implants in the partially edentulous patient have been shown in many studies to be greater than 95% (Jemt & Lekholm 1993, Bahat 1993, Gentile et al. 2005) and others report success rates of 92 – 94% (Lekholm et al. 1994) over periods up to 5 years. Furthermore, Ekelund et al. (2003) reported an implant cumulative success rate of 98.9% and a corresponding continuous prosthesis function of 100% over a period of 20 years based on the results of a prospective study of 179 implants in 30 patients.

Implant dentistry is constantly being explored leading to changes in overall implant shape or geometry, size, design features, alloys, surface macro and microstructure and implant abutment connections. Today's implant features deviate somewhat from the requirements outlined by Albrektsson et al. (1981) for achieving success in the long-term which included a threaded unalloyed titanium implant of defined finish and geometry. Attempts have been made to demonstrate the benefits of such changes in implant features in terms of overall implant survival and success rates, improved aesthetics and periimplant tissue health, earlier integration, patient satisfaction and ease of implant placement.



The Bicon implant system is a somewhat unique system being a plateau root form press fit implant with sloping shoulders and utilising platform switching at its screwless 1.5 degree Morse taper implant abutment connection. A range of wide short implants are available in this system, the shortest being a 5.7 mm implant which is 6mm wide. This system also offers the option of restoring the implant with an integrated abutment crown consisting of a composite material chemomechanically fused to the underlying titanium abutment featuring a narrow transmucosal neck and a hemispherical base. The implant and abutment consists of titanium alloy. The implant fixture considered in this study was coated with hydroxyapatite. Osteotomy preparation is carried out at very low torque and implant placement is by hand using a mallet to fully seat the fixture to a 3mm submerged position relative to the crestal bone height. The reamers used during the osteotomy preparation gather alveolar bone within the flutes which is then replaced over the fixture head following placement. No irrigation is necessary during osteotomy preparation.

This study aims to evaluate implant success in the short term using short Bicon implants restored with Integrated Abutment Crowns (IAC) in terms of both function and aesthetics. In addition, this study aims to assess the patients' experience in terms of pain following placement of Bicon implants, investigate the influence of anxiety on pain perception and determine the level of patient satisfaction with the outcome of treatment. The ultimate question put to the patient was: "Was it a worthwhile experience for the outcome gained?" The benefit of oral rehabilitation using dental implants ultimately rests with the patient. Assessing the patient's perceived satisfaction with the final outcome following restoration when considering any hardship endured during the placement procedure in addition to the clinical success of the implant, facilitates an evaluation of the success of the implant system from both the patient and the clinician's perspective.

## **Chapter 2:**

### **Literature Review**



The following literature review attempts to address implant design and restoration features of relevance to the Bicon implant system which may have an impact on survival and success rates. In addition factors affecting patient experience of implant placement and satisfaction with the outcome of treatment will be reviewed.

## **2.1 Implant survival and success**

### **2.1.1 Criteria for implant success**

The outcome of dental implant placement can be discussed in terms of survival or success, the former referring to the presence of the implant after a specified time period and the latter referring to the actual success of the implant as a functioning unit. The success of an implant is more difficult to define than survival and leads to some ambiguity which must be remembered when comparing success rates of various studies. Criteria for success have been proposed by several researchers. (Schnitman & Schulman. 1979, Smith & Zarb. 1989)

The most commonly used criteria are those outlined by Albrektsson et al. (1986) despite more recent developments in implant design and surfaces rendering some aspects of these criteria relatively obsolete.

- An individual, unattached implant is immobile when tested clinically
- A radiograph does not demonstrate any evidence of periimplant radiolucency
- Vertical bone loss is less than 0.2mm annually following the first year of service of the implant.
- Individual implant performance is characterized by an absence of persistent or irreversible signs and symptoms such as pain, infections, neuropathies, paraesthesia, or violation of the mandibular canal.
- In the context of the foregoing, a success rate of 85% at the end of a 5-year observation period and 80% at the end of a ten year observation period are minimum criteria for success

An implant which is present within the alveolar bone but non functional or unrestored due to incorrect positioning or, perhaps, unesthetic and mobile due to excessive marginal bone loss are examples of unsuccessful implants and are consequently of no

benefit to the patient despite their existence intraorally. Criteria for success should be included in every study for accurate interpretation of the results.

### **2.1.2 Risk factors related to implant failure**

Account should be taken for factors which influence the success of an implant. Albrektsson et al. (1981) outlined requirements for ensuring osseointegration in the long term. These included threaded unalloyed titanium implants of defined finish and geometry, inserted using a delicate surgical technique and allowed to heal in situ without loading for a period of at least 3-4 months. These specifications have changed somewhat over the last few decades due to changes in implant design and features. In a more recent review, Sennerby & Roos (1998) identified three categories of factors which determine implant success: patient factors such as general health, local health and smoking habits and bone anatomy, implant component factors such as geometry, surface roughness, size, number, location, one or two stage technique, surgical placement technique and time of loading and clinician related factors such as level of experience. Sennerby & Roos (1998) found a higher failure rate associated with cylindrical press fit implants and suggested following review of the literature that rough surface implants were more successful than machined implants. However, the review indicated that the majority of reports on peri-implantitis were associated with rough surface implants. Regarding the number of supporting implants in a prosthesis, the results of the literature search were conflicting. The review also stated that higher failure rates were reported for implant supported prosthesis in the maxilla than the mandible. (Sennerby & Roos, 1998)

McDermott et al. (2003) reported a complication rate of 13.9% when a retrospective cohort study was carried out on a sample group of 677 patients with 2,349 Bicon implants over a median duration period of 13.1 months. 10.2% were inflammatory, 2.7% were prosthetic and 1% was operative. 53% of these complications were considered minor. Using a multivariate Cox model, smoking, the use of 1-stage implant placement procedures and reconstructive procedures were statistically associated with an increased risk for overall complications. Woo et al. (2004) using bivariate analysis revealed the following 4 factors as being statistically or nearly statistically associated



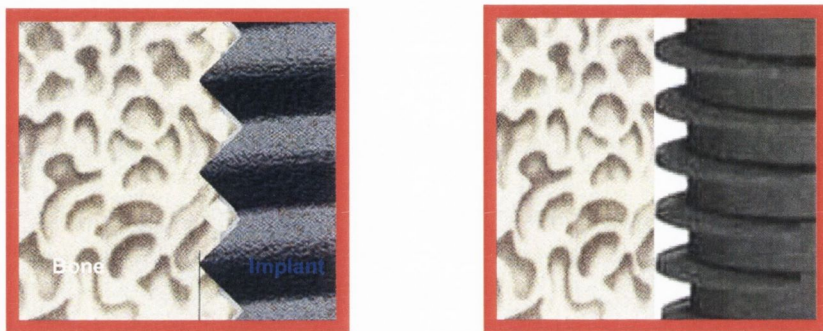
with implant failure; current tobacco use, implant length, implant staging and type of prosthesis.

## **2.2 Bicon Implant design features**

### **2.2.1 Plateau root form implant.**

In response to the surgical trauma of the implant site osteotomy preparation, a sequence of cellular and molecular events is initiated that includes inflammation, repair and remodelling which ultimately results in osseointegration. This tissue healing, bone remodelling and new bone formation is similar to the mechanisms occurring in fracture healing (Hollinger et al. 1996) and bone tissue formation in tooth extraction sockets (Cardiopoli et al. 2003). The first stage of the process, known as osteoconduction, initiates with clot formation and the resulting fibrin meshwork facilitates migration of osteogenic cells to the surface of the implant. The next phase as described by Davies (2003) involves two types of osteogenesis; distance and contact. Davies (2003) speculated that both types of osteogenesis occur during implant osseointegration. In distance osteogenesis new bone forms on the surface of old bone in the peri implant site. In contact osteogenesis new bone forms first on the implant surface and results in de novo bone apposition to the implant surface. Hence there are two types of bone growth occurring around a dental implant undergoing osseointegration; appositional bone growth and intramembraneous bone growth. Following the osteogenesis stage, the bone undergoes mineralization, maturation and remodelling. Implant surface characteristics have a part to play in facilitating ossteoconduction, attachment and retention of the fibrin meshwork to the implant surface during bone formation (Davies, 2003). Similarly, implant geometry affects the pattern of healing response. The predominant type of osteogenesis is determined by the closeness of fit of the implant surface area to the osteotomy site. For example, a threaded implant fits tightly to the adjacent bone and hence does not allow colonisation of its surface by osteogenic cells. Osteogenesis occurs at the surface of the adjacent prepared bone which undergoes necrosis, repair and remodelling. (Sykaras et al. 2000) Osteotomy preparation for a plate, rod or screw design implant is normally carried out in such a way as to achieve maximal fit and fill of the osteotomy site with the implant itself allowing only appositional bone growth from the bone side of the existing microgaps. (Fig 2.1) In

contrast to these implant designs, plateau, fin and porous designs are generally placed into osteotomy sites with a tight fit existing only at the tips of the fins or plateaux. This creates larger spaces between the fins which allow intramembranous bone growth to occur in addition to appositional bone growth. (Fig 2.1) The spaces fill with woven (callous like) bone. (Lemmons, 2004) This form of bone growth occurs at a faster rate (30 to 50  $\mu\text{m}$  per day, Roberts & Garetto, 1998) than appositional bone growth (0.7 - 1 $\mu\text{m}$  per day Bloebaum et al. 1994).



**Fig 2.1. Appositional bone growth at a screw design implant with maximal fit and fill of osteotomy site and intramembraneous bone growth at a plateau design implant with close contact between the implant and bone occurring only at the tip of the plateaux.**

Establishment of primary stability is one of the pre-requisites of implant success (Berglundh et al. 2003). Somewhat less initial stability is afforded by the plateau or finned implant design due to the reduced surface area that is in close contact with bone at implant placement. However, the deposition and growth of woven bone within the open spaces between the fins potentially allows for faster bone healing and earlier integration with mature haversian type bone. (Berglundh et al. 2003) A delicate balance between these two types of bone growth is required. A recent in vivo study (Leonnard et al. 2007, Under review) using a beagle dog model investigated the bone healing process around unloaded plateau root form and screw root form endosseous dental implants. The healing was examined at four different time points over a twelve week period and a histomorphometric analysis of bone to implant contact, bone area fraction occupancy and mineral apposition rates was carried out. This study demonstrated the prominent



role of woven bone in the bone healing process around plateau root form implants. Bone to implant contact and bone area fracture occupancy were in fact comparable for both implant designs and increased over time. No similar attempts have been made to date to measure and compare the degree of integration in a human model at various time points using different implant designs.

### **2.2.2 Hydroxyapatite surface**

Albrektsson et al. (1981) appreciated the potential impact of surface topography, chemical composition, charge and wettability on osseointegration. Following investigation of the design and surface characteristics of 13 different commercially available dental implant systems Wennerberg et al. (1993) concluded that to expect to achieve the same clinical results with such variability among the systems would be without justification. Brunski et al. (2000) stated that the ideal implant surface biomaterial should not disrupt and preferentially enhance the general processes of bone healing regardless of implantation site or bone quality and quantity.

Currently available implant system surfaces consist of titanium or titanium alloys of various degrees of roughness which have had a variety of surface modifications or hydroxyapatite (HA) coatings with a titanium bulk substructure. Increasing surface roughness of both commercially pure titanium and titanium alloy implants using techniques such as sand blasting and/or large grit acid etching has been shown in numerous experimental studies (Buser et al. 1991, Ericsson et al. 1994, Wennerberg et al. 1997, Cochran et al. 1996) and in literature reviews (Cochran, 1999, Esposito et al. 2008) to achieve earlier osseointegration and a greater bone to implant contact. In a more recent study Abrahamsson et al. (2004) investigated the sequence of events during the early phases of tissue integration at turned and roughened surfaces (SLA) in a canine model. The study showed a higher rate and greater extent of osseointegration at the roughened surface compared to the turned surface which remained superior for the duration of the study (12 weeks).

Long-term clinical studies comparing various degrees of surface roughness between similar implant designs and geometry are few, leading to inconclusive evidence on the role of surface composition and texture on the bone to implant interface. (Brunski et al. 2000) Cochran, (1999) attempted to overcome this problem by carrying out a meta



analysis of human clinical studies which evaluated implants placed in patients and followed longitudinally. It was concluded that in general, roughened surfaces provided an advantage in terms of success over smooth surface implants as did hydroxyapatite coated implants when studies were compared with specific indications or patient groups. However, high success rates were achieved with all surfaces and results were comparable for single restorations. Success rates were greater in the mandible irrespective of surface roughness however success rates were comparable between the mandible and maxilla for hydroxyapatite coated implants. Cochran (1999) highlighted the difficulty in identifying the advantage of different surface compositions in terms of clinical success in human studies due to the fact that clinical evaluation criteria such as mobility, pain, and associated radiolucencies may not be precise enough to detect differences due to implant surface characteristics. In addition, few implants failed when placed in similar conditions leading to the necessity for a very large sample group to have an adequate number of failures.

In addition to increasing the surface roughness of titanium implants and hence improving the mechanical bond at the implant bone interface, attempts have been made to improve the osteoconductive capability of the implant surface and the creation of a chemical bond between the implant and bone by using a bioactive hydroxyapatite coating. Despite numerous evidence of earlier osseointegration, improved bone to implant contact and greater interfacial strength, (Block et al. 1989, Watson et al. 1998) controversy exists over the long-term impact of hydroxyapatite coating on implant survival and success. Concern is due to the dissolution of the coating over the long-term, causing a late separation of the bone to implant contact and the potential for greater plaque accumulation on the hydroxyapatite surface compared to a titanium surface. In an attempt to limit the effect of potentially greater plaque accumulation on rough surfaces some systems have incorporated a smooth collar into their implant design.

An eight year clinical retrospective study of press fit titanium plasma sprayed and press fit hydroxyapatite coated cylindrical implants was carried out by Wheeler (1996) and survival rates based on implant removal for any reason were determined using life table analysis. The study showed a higher initial survival rate for HA-coated implants than for titanium plasma sprayed (TPS) implants. However this was not statistically

significant and after 4 years the survival rates of HA coated implants were significantly lower than TPS implants. In addition, the greater failure rate initially in the TPS group was non-inflammatory whereas the late failures which were predominantly inflammatory related were in the HA group. These resulted in periimplantitis lesions with rapid and aggressive breakdown in periimplant bone and soft tissue. Cumulative survival rates up to 8 years were 92.7% for TPS and 77.8% for HA coated systems. However, the low number of implants at risk beyond 6 years was too small to make the difference between the survival rates of the two surfaces statistically significant. It has been proposed that HA coated implants are of benefit in soft bone and hence can improve success rates in the maxilla, however this was not the case in the study carried out by Wheeler et al. (1996).

Block et al. (1996) carried out a 10 year observation of hydroxyapatite coated cylindrical implants placed in the posterior mandible and found, by using a life table analysis, a cumulative survival rate of 0.793. Criteria for success were based on less than 2.5mm bone loss and a functioning implant. Poorer success was found using 8mm long implants especially in the second molar region and the authors attributed mechanical problems such as overload and inflammation due to plaque accumulation as reasons for implant failure. No implants were lost after 5 years in patients who were followed up for 10 years. In an earlier study carried out by Block et al. (1994) HA coated implants placed in the anterior mandible in compact bone had good success regardless of length. Block et al. (1992) in a prospective review of one system with a HA coated implant reported a cumulative 5 year success rate of 91.74%. Golec et al. (1992) in a 5 year retrospective study of 3,093 Calcitite HA-coated Integral implants reported a survival rate of 97% of implants placed and 98.5% success of restored implants. The authors emphasised the absence of a failure at the HA-metal interface in this study. The study also demonstrated equivalent success rates in the maxilla, mandible and extraction sockets. Morris et al. (1998) reported on a total of 2,795 Spectra-System implants which were placed in all bone types in all jaw regions. The implants were cylinder, grooved, screw and basket designs with HA or non coated surfaces. Cumulative survival rates from placement to 36 months were 97% for HA coated designs and 86.5% for non coated designs. Jeffcoat et al. (2003) showed success rates of 97.9% for HA coated threaded implants compared to 95.2% for machined titanium threaded implants over 5 years in a randomised controlled clinical trial.



Furthermore, 99% of HA coated cylindrical implants had less than 2mm of bone loss. In a prospective study where 429 HA coated cylindrical implants were placed in 121 patients and followed for 5 to 7 years a cumulative survival rate of 95% at 7 years was found (McGlumphy et al. 2003). Mean bone loss was 1.2mm in the mandible and 1.4mm in the maxilla at 5 years. It has been reported that when examined, *in vivo* cases of HA coating-titanium interface fractures as a cause of implant failure are rare. (Biesbrock et al. 1995)

Contrary to such evidence, in a critical review of previous studies Albrektsson, (1998), denounced the use of HA coated implants. This conclusion was based on experimental studies carried out by Gottlander et al. (1992) which demonstrated no difference histomorphometrically in direct bone contact between HA coated implants and uncoated controls and, in the author's opinion, a lack of good quality long term clinical results supporting the use of such implants. These doubts are also reflected in a 3 to 6 year clinical study of overdentures supported by HA coated implants (Watson et al. 1998) in which short term success rates were high but due to progressive bone loss, concern over the long term steady state of these implants was indicated. The authors implicated implant size, opposing dentition, existing periodontal disease, smoking and bone quality as contributing factors to the failures of the implants. In a recent prospective study (Binahmed et al. 2007) 114 HA coated implants were followed for 10 years and showed inferior long term survival rates (82%) than reported survival rates in the literature for threaded titanium implants. (Adell et al. 1990, Ekelund et al. 2003)

There is great diversity in the quality of hydroxyapatite coatings on commercially available implants which must be remembered when discussing success and failure in relation to such coatings. Factors affecting quality include the source and type of HA, substrate specifics, temperature specifics, coating processes and quality of coating environment. As HA content, crystallinity and uniformity of composition and adherence increases the potential for dissolution of the coating decreases (Golec et al. 1992).

The method of coating hydroxyapatite on the titanium implant surface causes an alteration in its chemical composition resulting in a reduced crystallinity and the creation of other calcium containing compounds such as amorphous calcium phosphate, alpha tricalcium phosphate, beta tricalcium phosphate, tetra calcium phosphate and

calcium oxide. The presence of these compounds increases the solubility of the coating. This dissolution is beneficial in early stages due to its osteoconductive effect because it releases ions into the adjacent tissue interface. However at later stages it may jeopardise osseointegration at the surface of the implant due to loss of the coating. Crystallinity of hydroxyapatite varies greatly among commercially available coatings in addition to its mass, surface area and porosity. Various processes have been developed in an attempt to improve the crystallinity of the coating such as heat treatment of the implant surface following deposition of the coating, post plasma spray leaching of the soluble phases, optimisation of the plasma spraying process parameters and a high pressure hydrothermal process. This final process, referred to as the MP-1<sup>TM</sup> process which was developed to improve the crystalline HA content of the Calcitite® plasma sprayed coating, has been shown *in vitro* to convert a typical plasma-sprayed coating of 75% crystalline HA into a coating of approximately 95% crystalline HA without causing a reduction in the shear strength of the coating (Burgess et al. 1999). Furthermore, an *in vivo* study demonstrated that this high HA crystallinity does not affect short term osseointegration despite reduced soluble components (Burgess et al. 1999).

In another study, cylindrical implants of sand-blasted CP titanium and HA coated titanium of varying crystallinity were inserted into the canine femur for up to 26 weeks. Morphometric analysis and a pull out test were carried out. The implants were also examined under scanning electron microscope and light microscope. The findings showed no significant difference between the percentage of bone contact and interfacial attachment strength between HA coated implants with different crystallinity content. However, when compared to uncoated implants, HA coated implants had a significantly higher bone to implant contact and interfacial strength. It must be noted that findings in this study did indicate a reduction in coating thickness over time and this was most noticeable at the low crystallinity coatings (Chang et al. 1999). The authors concluded that the crystallinity did not have any impact on osseointegration but was of importance in terms of long term stability of the coating which is in agreement with the conclusions drawn by Lee et al. (2000) in a meta-analytic review on the survival of hydroxyapatite-coated implants.



### **2.2.3 Implant abutment connection**

Ideally, the abutment carrying the prosthetic restoration should remain secured to the implant fixture throughout the life of the implant unless it is necessary to remove it for prosthetic reasons. This connection varies among implant systems. Some are using a screw retained abutment and others are using a taper – integrated screw or a purely tapered interface fit. Complications such as screw loosening or screw fracture can often be the cause of implant failure. (Ekfeldt et al. 1994, Wannfors & Smedberg, 1999)

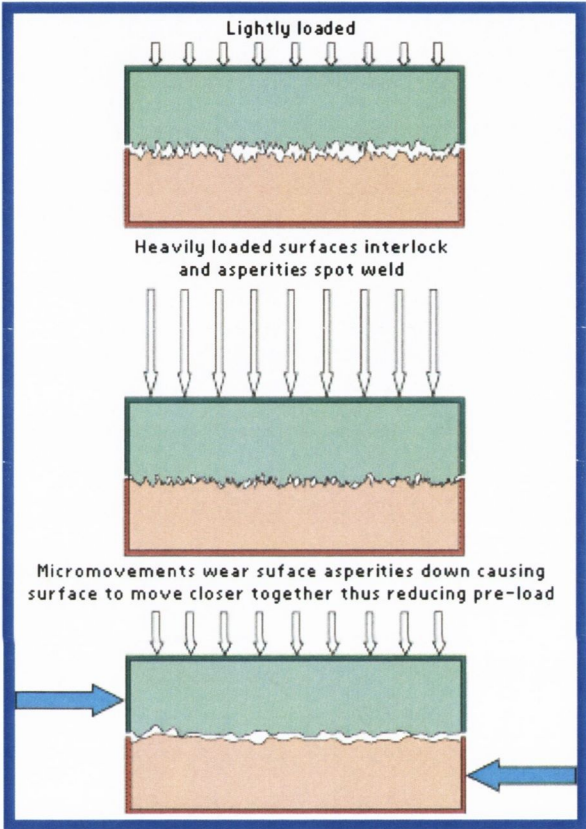
#### **2.2.3.1 Implant abutment connection stability**

Occlusal forces on dental implant abutments vary in magnitude and direction and are different for single unit restorations compared to multiunit restorations. The effect of these forces on the implant abutment connection stability is also different. Axial occlusal force is compressive for a single tooth restoration but in a multiunit restoration this force could become tensile. When using tapered interface abutment connections tensile forces and loosening torques should be avoided or design features incorporated to minimise their effects. Conversely in screw retained abutments compressive forces and loosening torques can be problematic.

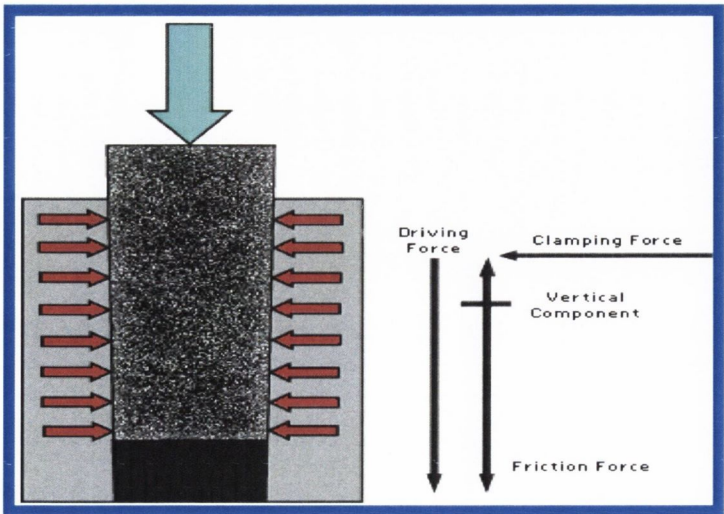
The tensile force (pull out force) is linearly proportional to the insertion force and to the insertion depth. A small taper angle and long contact length improves the safe range of insertion forces which is difficult to control as such abutments are inserted by means of non standardised tapping by the clinician. Inadequate insertion force could lead to abutment loosening and excessive force could lead to plastic deformation of the implant and abutment. The efficiency of the tapered connection is defined as the ratio of the pull out force to the insertion force. Taper angle and friction coefficient affect the efficiency of the connection. Taper angle is less subject to uncertainties and the smaller the angle the greater the efficiency. The Bicon implant system uses a purely Morse tapered 1.5 degree implant abutment connection with a small tapered angle over a long contact length potentially facilitating a highly efficient and successful implant abutment connection (Bozkaya & Muftu, 2004).

A locking taper, like a screw, relies on friction for retention, however the assembly force applied by tapping the tapered abutment into the matching well in the fixture creates a clamping force which is almost lateral to the axis of the implant. The plane of

friction is perpendicular to the axis of the implant, therefore unlike the screw connection there should be minimal wear of the interlocking surface asparities responsible for the integrity of the implant abutment connection when the implant is subjected to lateral forces or moments about the abutment. (Fig 2.2 & Fig 2.3)

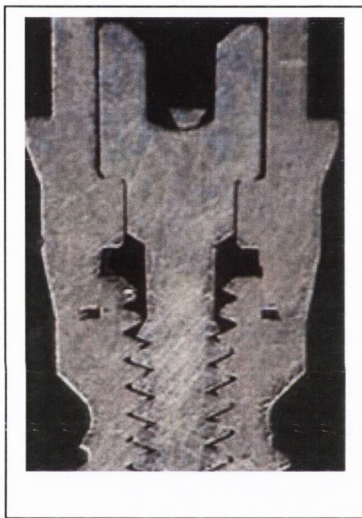


**Fig 2.2: Preload is lost as asparities break off due to lateral forces**

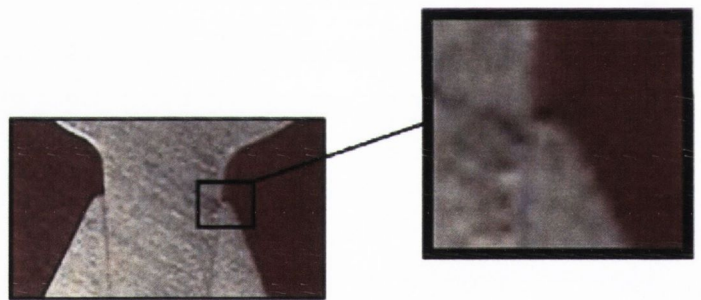


**Fig 2.3: Retaining forces in locking taper implants**

In addition, the Bicon system uses a titanium alloy (Ti-6Al-4V) which is stronger than commercially pure titanium. The outcome is a 'gap free' (gap of 0.5 microns or less) cold weld connection with less potential for loosening when engineering principles are considered than the screw connection. The high force applied when tapping the abutment into place causes breakdown of the surface oxides on the two opposing surfaces resulting in fusing of the surface asperities and the creation of a cold weld which will disengage only in the presence of adequate torque. (Keating, 2001)



**Fig 2.4: Screw joint showing gaps**



**Fig 2.5: Locking taper - gap free implant abutment interface**

### **2.2.3.2 Implant abutment connection microgap**

A microgap presence between implants and abutments has been implicated as a potential location for bacterial colonisation and subsequent leakage into the surrounding tissues even in gaps as small as 10  $\mu\text{m}$  or less. Most implant system protocols result in the placement of the implant abutment connection at the crest of the alveolar ridge which could potentially result in bone resorption in response to an inflammatory reaction due to the presence of a microbial colony which could exist undisturbed within the microgap even in the presence of meticulous plaque control (Jansen et al, 1997).



Several implant systems have adapted their implant design to reduce or eliminate this gap such as the tapered implant abutment connection of the Ankylos system and the Bicon system. The Astra system also uses a conical implant abutment interface. However in an *in vitro* study carried out by Jansen et al. (1997) where thirteen different implant abutment connections from nine different systems were tested for microgap size and microbial leakage from within the connection, a good marginal fit (less than 10  $\mu\text{m}$  with a median value of under 5  $\mu\text{m}$  for all systems) did not prevent microbial leakage. Brogini et al. (2003) investigated the effect of submerging or non submerging 2 piece implants and the effect of one and two piece non submerged implants on the composition of inflammatory cells immediately adjacent to the implant (i.e. the presence or absence of a microgap in the vicinity of the crestal bone). The implants used were specifically developed for the study and not a commercially available system. This study showed that when a microgap (i.e. in a 2 piece implant) is present at the crest of the alveolar bone there is an intense inflammatory infiltrate and a sustained neutrophil accumulation ultimately resulting in promotion of osteoclast resorption of periimplant crestal bone. This process occurred in both the submerged and non submerged surgical protocols (i.e. one or two stage surgery).

Hermann et al. (2001) using a canine mandible histometrically evaluated crestal bone changes following placement of 2 piece non submerged implants after an unloaded period of 3 months. 3 different microgap sizes between implant components were investigated. In addition, welded and screw connections were compared regarding adjacent crestal bone resorption. In agreement with Jansen et al. (1997) the size of the microgap proved non significant. However when the welded and screw connections were compared, Hermann et al. (2001) demonstrated that potential movements in the non welded connections significantly influenced crestal bone changes. Similar results were found by King et al. (2002) using the same study design but evaluation of crestal bone changes were radiographical.

It has been hypothesised that the location of the microgap has an effect on crestal bone resorption. Heijdenrijk et al. (2006), compared crestal bone resorption in patients with two piece submerged, two piece non submerged and one piece non submerged implants, with differences in the microgap location i.e. at the crestal ridge, a few millimetres coronal to the crestal ridge or absent (one piece). In contrast to the above studies, it was

shown that there was no difference in crestal bone loss between the groups and yearly bone loss recorded over a period of five years was within acceptable limits. It must be noted however that no radiographs were available for analysis prior to restoration and functional loading of the implants. Therefore no knowledge of differences in early pre load bearing on bone resorption differences between the implants can be gained. This study also differs from those of Hermann et al. (2001) and Broggini et al. (2003) in that the implants were functionally loaded. Therefore crestal resorption due to functional stress and bone remodelling may be of greater significance than the location or presence of a microgap at this stage.

In addition Heijdenrijk et al. (2006) demonstrated, following microbiological sampling, that the presence of potential periodontal pathogens around implants cannot be directly associated with peri implant bone resorption or implant failure. Despite numerous studies showing an association between plaque accumulation, pathogenic microbial change in the periimplant area and inflammation of the gingival tissues (Berglundh et al. 1992, Leonhardt et al. 1992, Ericsson et al. 1992) none of these studies demonstrated a progression to periimplantitis. Animal studies using ligature induced periimplantitis following undisturbed plaque accumulation, demonstrated marked attachment loss and bone resorption (Lindhe et al. 1992, Schou et al. 1993, Lang et al. 1993, Ericsson et al. 1995, Tillmanns et al. 1997) which would suggest a causal relationship between pathogenic bacteria and periimplantitis, however this could be due to the creation of a deeper pocket by the mere presence of the ligature and resultant bacterial colonisation of the created pocket or a foreign body reaction to the ligature (Quirynen et al. 2002). Clinical studies demonstrate higher levels of anaerobic or pathogenic bacteria to be associated with failing implants. (Mombelli et al. 1987, 1988, Leonhardt et al. 1999) However to date no direct causal relationship has been demonstrated (Quirynen et al. 2002). Marginal bone loss due to occlusal over load can result in deep periimplant pocket creation which then creates a harbour for pathogenic bacteria. Two possible causes for on going marginal bone loss would then coexist. In a review of the literature relating to infectious risks for oral implants Quirynen et al. (2002) emphasised the controversy regarding the cause of ongoing marginal bone loss following initial successful integration and highlighted the interplay between various factors such as the host defence mechanism, the duration of infection, implant system design rendering it



more or less susceptible to occlusal overload and surface characteristics subjecting it to greater or less plaque accumulation or bacterial aggregation.

Thus, the impact of bacterial leakage from the microgap at the implant abutment connection on subsequent crestal bone resorption is somewhat controversial. Persson et al. (1996) could not demonstrate a correlation between the degree of internal implant contamination and marginal bone loss. However, as mentioned earlier the use of a one piece implant system or the welding of a two piece system has been shown to undergo less periimplant crestal bone loss than two piece systems with a microgap.

The Bicon implant system by virtue of its Morse taper implant abutment connection potentially eliminates or reduces the effect of micromotion or microbial leakage on crestal bone resorption. In addition, the system's protocol for placement of the fixture in a 3mm submerged position removes the connection from the crestal bone area. Dibart et al. (2005) demonstrated the hermetic nature of the implant abutment connection in the Bicon system in an *in vitro* study. This study investigated both bacterial passage from outside the implant abutment connection to within and the reverse using ten wide body implants (5 x 11mm implants with 3mm wells) and 10 abutments (with 3mm posts). The implant-abutment interface was examined by scanning electron microscope (SEM). A 120µm wide chamfer present in the coronal portion of the implant creates a crevice when assembled with the abutment post, the bottom of which is less than 0.5µm which does not allow bacterial penetration. This gap is somewhat smaller than recordings of microgaps in other systems; 2 to 4µm in the Astra system (Norton, 2006), 5 µm in the Branemark system, (Todescan et al. 2002) and could explain the lack of microbial movement between the internal surface of the connection and the adjacent periimplant tissues which has been shown to occur in other implant systems (Quirynen et al. 1993, 1994, Steinebrunner et al. 2005) Steinebrunner et al. (2005) attributed some of this leakage to be due to micromovement about the connection when the implant is in function. The study carried out by Dibart et al. (2005) did not investigate microleakage during function. The metal to metal cold welding in the Bicon 1.5 degree locking taper implant abutment connection constitutes the hermetic seal (Muftu et al. 1997) and minimises micromovement.



## **2.3 Crestal bone loss**

An early study by Adell et al. (1981) described early crestal bone loss and quantified it as an average of 1.2mm during the first year followed by a reduced rate of 0.05 to 0.13mm per year thereafter when measurements were taken from the first thread. Other studies show similar bone loss of approximately 1mm during the first year and substantially less from then onwards (Quirynen et al. 1992). Evidence of such crestal bone loss after initial implant placement has been so commonly noted that it is often used as a criterion for implant success (Albrektsson et al. 1986) but it must not be forgotten that due to emergence of newer implant system designs the relevance of such early accepted crestal bone loss may no longer be valid.

Various studies have been carried out to identify the cause of this bone resorption, however no definitive answer has been found. Several factors have been suggested to participate in the stimulation of the resorption process such as flap reflection during surgical placement of the fixture, implant osteotomy, microgap at the implant abutment connection, micromovement of the abutment components, bacterial invasion, biological width establishment and stress factors (Misch, 2004). In addition studies have shown that implant design, the junction between smooth and rough surfaces and local bone quality have an impact on crestal bone resorption (Chun et al. 2000, Bozkaya et al. 2004). Elimination or reduction of crestal bone resorption is one of the goals of implant dentistry when attempting to achieve successful long-term osseointegration (Albrektsson et al. 1986).

### **2.3.1 Surgical procedure**

Periosteal reflection and implant osteotomy although potentially related cannot be a primary causative factor in the localised early bone loss seen around implants as it does not explain why bone loss is greater during the first year or why it does not occur until after second stage surgery.

### **2.3.2 Biological width**

Peri implant biological width establishment as described by Wallace (1994) seems like a plausible cause of early bone resorption however there is no establishment of

attachment of a junctional epithelium directly into the surface of an implant similar to the fibre attachment to root cementum which diminishes the relevance of potential hard and soft tissue remodelling to a level beneath the implant abutment connection as a factor in early bone resorption. (Misch, 2004) In addition, bone resorption is seen in association with one piece implant systems. (Misch, 2004) However, bone resorption occurs following exposure of the implant and connection of the abutment implying that biological width establishment does have a part to play in early bone resorption but the question is to what extent. It must be noted also that resorption to the first thread is of a different magnitude depending on the implant design and greater resorption is seen in poorer quality bone.

### **2.3.3 Functional stress**

The final and perhaps most plausible cause of crestal bone resorption is stress which is created in the crestal area when the implant is in function. Misch (2004) described this bone modelling and remodelling as being controlled by the mechanical environment of strain and that stress contours form a V or U shaped pattern with the greatest magnitude in the area of first contact when two materials of different elastic moduli are united with one material loaded. This has been shown by finite element analysis. Resorption in this situation may be due to microfracture of bone or strain in the overloaded zone and a reduction of the blood supply to the crestal area. As the density of the bone increases it is more capable of resisting resorption. During the first year weaker bone resorbs as stress/strain is pathologic and outside physiologic limits. However as the density improves these forces are within physiologic limits allowing bone to remodel. This is further supported by evidence showing less crestal resorption when implants are placed in the anterior mandible which is an area of greater bone density.

### **2.3.4 Implant design**

Implant designs such as taper, platform switching, implant abutment connection, thread pitch and depth and presence, absence or location of a smooth collar may reduce or exacerbate crestal bone resorption in response to functional load. (Chun et al. 2000, Hermann et al. 2001, O' Sullivan et al. 2004, Bozkaya et al. 2004, Lazarra et al. 2006) Bone is weaker to shear forces. This could explain the greater resorption down from the smooth collar to the first thread, the point at which, in many designs represents a change from shear to compressive loads (Misch, 2004). In an *in vitro* study evaluating the load



transfer characteristics of five different implants in compact bone with different amounts of load, finite element analysis results indicated that for moderate levels of occlusal loads (100 to 300N) compact bone was not overloaded by any of the 5 systems investigated (Ankylos, Astra, Bicon, Nobel Biocare, ITI). However when more extreme occlusal loads were applied the effect of overload was evident and the degree varied among the systems demonstrating the impact of different implant geometries. The Ankylos and Bicon implants were superior in terms of resistance/reduction of occlusal overload in compact bone in response to compression. The authors attributed this to the narrowing cross sections at the top of the cortical bone of these implants which were in contrast to the widening cross sections of the other systems investigated. (Bozkaya et al, 2004)

### **2.3.5 Platform switching**

Platform switching is a theory developed in recent years in an attempt to limit postrestorative crestal bone level resorption. This theory involves the use of a narrower abutment than the fixture width and a horizontal inward repositioning of the implant-abutment interface. Lazzara et al. (2006) reported on radiographic observations made over a 13 year period and showed evidence of reduction and in some cases elimination of crestal vertical bone loss adjacent to implants restored using the platform switching concept. The authors attributed this result to be due to the increased surface area created by the exposed implant seating area which resulted in less necessity for crestal bone resorption in order to create an adequate soft tissue seal and an inflammation free connective tissue zone coronal to the implant bone interface as outlined by Ericsson et al. (1995) and Berglundh & Lindhe, (1996). In addition, the inward shift of the implant abutment connection away from the implant bone interface could limit the negative implications of the connection such as microbial leakage from the microgap, inflammation and micromovement. Clinical case reports demonstrated these conclusions. (Canullo et al. 2007, Degidi et al. 2008)

Degidi et al. (2008) reported a similar effect in a case report with histological and histomorphometrical evaluation of one of three implants which was removed after 4 weeks of integration with immediate loading for psychological reasons. Bone was present 2mm above the implant shoulder when examined under low power magnification.



In further support of platform switching, Maeda et al. (2007) demonstrated using finite element analysis the potential biomechanical advantage of moving the stress concentration area at the implant abutment connection away from the cervical bone-implant interface however the authors also hypothesised that stress could be increased around the abutment or abutment screw leading to potential fracture when a narrower abutment to implant width is used. Longitudinal evidence of the stability of this implant abutment connection when using the theory of platform switching is lacking.

## 2.4 The short implant



**Short Implant**  
6.0 x 5.7mm

Limited bone height or encroachment on anatomic structures such as the maxillary sinus and the inferior dental nerve and mental foramen render implant placement in the posterior maxilla and mandible difficult in many cases. Several studies have been carried out to investigate the survival rates of short dental implants and many have shown similar longevity and success rates to those of longer implants. (Table 2.1 & 2.2)

However, some studies have shown increased failure rates associated with shorter implants (Friberg et al. 1991, Jemt et al. 1993, Bahat, 1993) although this failure did not occur in some cases until after loading which would suggest unfavourable biomechanics when considering the crown root ratios. Other authors have demonstrated the irrelevance of such ratios and have shown success with crown implant ratios greatly exceeding the traditionally acceptable crown root ratio of 0.5:1 and a minimum of 1:1. A retrospective study carried out by Schulte et al. (2007) demonstrated a survival rate of 98.2% after a mean follow up time of 2.3 years using single unit Bicon implants which had crown to implant ratios ranging from 0.5:1 to 3:1. Moreover, the crown to implant ratios of the failed implants (n=16) were similar to those that were successful and in function (n=873). The mean crown to implant ratio was 1.3:1. Implant failure in this study was defined as implant removal. Another study carried out by Rokni et al. (2005)

investigating the impact of implant length, surface area and crown to implant ratio on implant success and crestal bone levels using sintered porous-surface tapered root-form press-fit implants (Endopore dental implant system) showed that crown implant ratio and implant surface area using this system had no effect on crestal bone level stability. However, long implants and splinted implants showed greater crestal bone loss than shorter non splinted implants. The mean crown to implant ratio in this study was 1.5. This implant design relies on bone ingrowth and 3D mechanical interlocking rather than bone to implant surface contact for implant stability and integration. This was a retrospective study using clinical data from two previous prospective clinical trials. Misch (2006) however, identified an increased crown height relative to a short implant to be a risk factor in the failure rate of short implants and suggested methods to employ to attempt to reduce biomechanical stress in the presence of this risk factor.

Several studies indicated bone quality to be perhaps of greater importance than implant size (ten Bruggenkate et al. 1998, Tawil et al. 2003). In a study carried out by Romeo et al. (2006) all of the implants which failed were placed in low-density trabecular bone. Two failed implants out of 532 short implants were reported by Anitua et al. (2008) one of which was placed in type IV bone and the other may have fractured due to cantilever overload. Similarly, Lekholm et al. (1994) found poor bone quality to be associated with higher implant failure rates.

Implant design and surface microstructure has been implicated to compensate for shorter implant length and the implant-bone interface has been suggested to play an important role in implant success. (ten Bruggenkate et al. 1998) Earlier studies which showed higher failure rates when short implants were placed investigated implants with less surface roughness than hydroxyapatite coated, sand blasted acid etched or titanium plasma sprayed surfaces.

Misch et al. (2006) listed three risk factors that increase stress and may contribute to the failure of short implants; an increased crown height, higher bite forces and bone density. In addition, the following methods were suggested to reduce and eliminate such stress when using shorter implants; eliminate cantilevers on the prostheses, exclusion of lateral forces on the prostheses, splinting of multiple implants, use of rougher implant surfaces to increase the bone to implant contact and increasing implant thread number

and depth. Misch et al. (2006) reported implant success with short implants while following such principles.

Gentile et al. (2005) using the Bicon implant system studied the success of 172 implants of which 26% were 6mm in length and 5.7mm in diameter. 43.6% were placed in the posterior mandible and 34.3% were placed in the posterior maxilla. 47.5% were placed in poor quality bone (Type 4). 51.9% were HA coated, 30.9% were TPS and 17.3% were uncoated. In contrast to the study by Misch et al. (2006), most implants (92.8%) were restored as single units. In this study the difference between the 1 year survival between the 6 by 5.7mm and non 6 by 5.7mm implant groups was not statistically significant. Implant staging alone was found to be statistically associated with implant failure, a 2 stage approach showing an 80% less failure rate than a 1 stage approach. Implant size was not associated with failure. However it must be noted that this study had a small sample size and a short follow up period.



| Researchers                       | Study type        | Implants features                            | No., Type, location, restoration                                                                                           | Survival/success                                                                                                                      | Conclusions                                                                                                |
|-----------------------------------|-------------------|----------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|
| Jemt, T.,<br>Lekholm, U.,<br>1993 | Prospective study | All lengths, shortest 7mm<br>regular widths, | 259 standard Branemark, 94 prosthesis, 62% supported by > one implant. Average bone quality: type3, Both jaws              | Overall 5 year implant cumulative survival rates: 97.2%, 100% prosthesis survival. 70% of implants lost were 7mm                      | Higher failure rate for short implants                                                                     |
| Bahat, O. et al.,<br>1993         |                   | All lengths, shortest being 7mm              | 1 to 9 Nobelpharma implants in 213 patients in posterior maxillae. Mean follow up post loading: 30.3 months. Multiple unit | Overall failure rate; 4.8% Slightly higher failure: Type IV bone Failure rate of 7mm implants: 9.5%, all others: failure rate of 3.8% | Only statistical significant variable was implant length: higher failure rate associated with 7mm implants |
| Lekholm, U. et al, 1994           | Prospective study | All lengths and widths                       | 442 Branemark implants in partially edentulous maxilla and mandible, supporting multiple unit prosthesis                   | Cumulative implant success rates: 92% for maxillae and 94% for mandibles                                                              | Most failures were represented by the standard implants and implants placed in type IV bone                |

**Table 2.1: Studies denouncing the use of short implants**

| Researchers                 | Study type                             | Implants features                                                                                     | No., Type, location                                                             | Survival/success                                                                                                   | Conclusions                                                                                                                         |
|-----------------------------|----------------------------------------|-------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| Teixeira et al, 1997        | Retrospective study                    | L: 8 or 11mm W: 3.75 or 4mm, HA                                                                       | 67implants Mandible only, single/multiunit restorations                         | Overall cumulative survival:<br>94% at 5 years for 67 implants (90% were 8mm long)                                 | Good predictability of short HA coated implants in the posterior mandible                                                           |
| Ten Bruggenkate et al, 1998 | Prospective multicentre clinical trial | Length:6mm, TPS, hollow cylinder, hollow screw, solid screw, regular. width                           | 218 Strauman implants<br>Single/multiunit<br>Both jaws                          | Cumulative survival rate:<br>94% after 6 years                                                                     | Short implants promising but few study were single units or bridges only on 6mm implants                                            |
| Tawil G., et al, 2003       | Prospective study                      | Length: 6, 7, 8, 8.5 and 10mm,<br>Width 3.3, 3.75, 4, 5mm Machined surface                            | 269 Screw type Branemark implants<br>Both jaws<br>single/multiunit restorations | Survival rate: 95.8% (after replacing 8 lost implants).<br>No statistical difference between the lengths or widths | Bone quality critical. Short implants good alternative if low quantity but good bone quality                                        |
| Griffen et al, 2004         | Retrospective study                    | Length: 8mm<br>Width: 6mm in diameter, HA coated                                                      | 168 Steri-Oss implants Posterior both jaws                                      | Success : 100%<br>Follow up:34.9 months after loading                                                              | Simple and predictable treatment alternative                                                                                        |
| Gentile M. A. et al, 2005   | Retrospective cohort study             | Length: 6mm<br>Width 5.7mm                                                                            | Bicon implants, Short: 45, Non “6x5.7” : 127 TPS/HA Both jaws                   | 1 year survival<br>Short: 92.2%<br>Control: 95.2% Overall: 93.9%<br>Difference not significant                     | Short implants can be a clinically acceptable option                                                                                |
| Arlin, M. L., 2006          | Prospective case series                | Length<br>Test: 6 or 8mm<br>Control:10-16mm                                                           | 630 Strauman implants                                                           | 2 year survival rates:<br>6mm – 94.3%,<br>8mm – 99.3%,<br>Control – 97.4%                                          | Outcome of short implants comparable to longer implants                                                                             |
| Mish, C. E., 2006           | Multicenter retrospective case series  | Length: 7 or 9mm<br>Stress reduction by splinting and mutually protected or canine guidance occlusion | 745 implants in posterior regions supporting 338 restorations                   | Overall implant survival before restoration – 99.2% after restoration up to 5 years – 100%                         | Short implants viable to support fixed restorations in posterior jaws Reduction of biomechanical stress at bone interface necessary |
| Romeo, E., 2006             | 3 to 14 year longitudinal study        | Lengths: 8/ 10mm<br>Width: 3.75, 4.1, 4.8<br>TPS/ Sand blasted, single or multi units                 | 223 Strauman implants in anterior and posterior regions of both jaws            | 14 year cumulative survival rate:<br>8mm = 97.9%,<br>10mm = 97.1%                                                  | A mix of implant sizes had no affect on implant success rates.                                                                      |
| Anitua E., et al, 2008      | 5 year retrospective study             | Length: 7 to 8.5mm<br>Width: 3.3 to 5mm<br>Acid etched and bioactive surfaces                         | 532 implants single and multiunit posterior of both jaws                        | Implant survival rate:<br>99.2% mean follow up of 31 +/- 12 months                                                 | Short implants can be safe and predictable when strict protocols followed                                                           |

**Table 2.2: Studies advocating the use of short implants**

## 2.5 The Wide Implant

Achieving maximal implant surface area to bone contact does not necessarily require a long implant. A 6 by 8mm implant was used in a study carried out by Griffen et al. (2004) in which it was reported that the surface area of this implant was 254mm squared which was slightly less than the average root surface of a mandibular canine but equal to the surface area of a 3.75 by 18mm implant. The authors in this study however, proposed a minimal ridge height of 6mm to achieve initial stability and at least 1mm thickness of the buccal and lingual plates.

Some studies indicate that increasing the diameter of an implant has a positive influence on implant survival and success (van Steenberghe et al. 1990, Bahat, 1996). However contrary to this theory, Ivanoff et al. (1999) and Eckert et al. (2001) showed a lower survival rate to be associated with wider diameter implants. Both studies used the Nobel Biocare system. Ivanoff et al. (1999) suggested a learning curve, poor bone quality and changed implant design to be possible causes of the higher failure rate. Clinicians in this study were experienced in implant placement but were inexperienced in the use of wider implant fixtures. It should be noted however, that this study was retrospective and 45% of the implants were used for rescue purposes in low quantities of poor quality bone. Also, the majority of wide implants placed were less than 10mm in length. In addition, 2 patients accounted for 6 out of 17 failed implants in the 5mm diameter implant group. In this study no relationship could be observed between implant failure and jaw type or bone quality and quantity. The authors attributed this to the low number of failed implants in the study which was 26 out of 299.

A recent retrospective study (Degidi et al. 2007) investigating survival and success of wide implants ( 5 to 6.5mm) of varying lengths (8 to 15mm) and various makes indicated wide implants to be a viable treatment option other than as rescue implants and showed no difference between the different implant designs. The survival rate in this study was 98.4% over a mean follow up time of 30 months. The majority of implants in this study were placed in type II and III bone of adequate quantity. However, when implant success was investigated by assessing changes in crestal bone height, statistics showed small implant diameter and short implant length to be



associated with a lower crestal bone resorption. In addition, the authors indicated wide implant fixtures to be contraindicated in anterior areas with narrow alveolar crests.

The proposed benefits of using wider implants especially in posterior areas include improved tolerance of occlusal forces (Huang et al. 2005) and the provision of a wider base for molar prosthetic restoration facilitating a better emergence profile and easier oral hygiene control. Davarpanah et al. (2001) described some of the biomechanical advantages of the wide implant. The seating surface of the prosthesis increases with increasing implant diameter while risk of fracture decreases. Force exerted on the abutment retaining screw can be reduced by 20% and 33% with 5 and 6mm diameter implants. In a retrospective study carried out by Krennmair et al. (2004) a survival rate of 97.3% in the maxilla and 100% in the mandible for wide diameter Frialit-2 implants was found over a mean post loading time of 41.8 months. No short wide implants were used and all placements were planned to be wide fixtures from the outset. The authors partially attribute the success to these factors.

## 2.6 Integrated abutment crown



**Fig 2.6: The Integrated Abutment Crown**

The restoration of missing teeth with functional and aesthetic replacements in harmony with the surrounding dentition while maintaining the health of existing oral structures is the ultimate goal of implant dentistry. The Bicon implant system offers a unique method for single tooth restoration known as the Integrated Abutment Crown (IAC). This is a cementless restoration with the implant abutment and the crown material fused as one unit. A light cured highly filled composite resin known as Ceramage® (Shofu Dental Corporation) is chemomechanically bonded to the coronal portion of a titanium alloy abutment.

Ceramage® (Shofu Dental Corporation) is a zirconium silicate restorative material. It is a progressive fine structure (PFS) filling of more than 73% and the organic polymer matrix provides good flexural strength, elasticity and polishability. The manufacturers claim a flexural and compressive strength beyond 140 MPa, abrasion resistance of opposing dentition, transmission and diffusion of light with a refractive index similar to natural teeth, good colour stability over 5 years, good viscosity and modelling properties, good polishability with minimal effort and a microstructure which resists plaque accumulation. In addition, scanning microscopy comparison of conventional composite and Ceramage® demonstrates the difference in microstructure between the two materials; Ceramage® had a homogenous structure compared to inconsistent particle size between the glass-fillers and matrix in conventional composite. The following is a list of specific properties of Ceramage® :

|                                        |      |
|----------------------------------------|------|
| Vickers Hardness (MPa)                 | 726  |
| Flexural Strength (MPa)                | 146  |
| Modules of Elasticity (GPa)            | 10.7 |
| Compressive Strength (MPa)             | 354  |
| Indirect Tensile Strength (MPa)        | 62   |
| Polymerisation Shrinkage (Vol. %)      | 2.5  |
| Toothbrush Abrasion (%)                | 0.43 |
| Enamel Abrasion of the Antagonist (µm) | 3.2  |
| Working time (min.)                    | >30  |

Typical conventional composite materials have compressive strengths of 260 MPa, yield stress of 260 MPa, Tensile strength of 45 MPa, flexural strength of 110 MPa, modulus of elasticity of 12 GPa and hardness values of 60 (VHN). Porcelain has been shown to have hardness values of 450. Enamel has a Vickers Hardness value of 350. (McCabe & Walls, In Applied Dental Materials 8<sup>th</sup> Edition, Blackwell Publishing)

### **2.6.1 Advantages of IAC**

The IAC design eliminates the need for screw or cement retention of the crown to the abutment and hence the potential for inflammation of the gingival tissues and periimplant bone loss due to excess cement (Wannfors & Smedberg, 1999, Pauletto et al. 1999, Weber et al. 2006) or screw related problems such as screw loosening or fracture, limited access for screw placement, interference with occlusion, weakening of coronal structure and compromised aesthetics.

Research has demonstrated the presence of marginal gap discrepancies when using both screw retained and cement retained restorations, the magnitude of the gap using the latter method varying depending on the luting cement used (Keith et al. 1999). In the IAC system there is no microgap between the crown and abutment in the critical gingival sulcus area which could act as a harbour for potential pathogenic bacteria and allow unfavourable loading characteristics due to compression of the casting and rocking of the framework (Hebel & Gajjar, 1997). However, the strength of the chemomechanical bond between the crown material and the underlying titanium alloy has yet to be demonstrated in long term studies.

One of the reasons why the use of screw retained crowns became popular was due to easy retrievability in the event of necessary crown removal. Although the coronal restoration and abutment of an IAC are one unit and thus inseparable, retrievability is still possible by removing the abutment crown unit as a whole from the Morse taper connection to the implant fixture. This action is not always necessary however, due to the fact that IACs facilitate chair side adaptation and intraoral modification of the restoration when necessary.

Advantages of composite restorations that apply to the IAC restoration include the “shock absorbing properties” of resin materials which have been shown to reduce impact force on implants by about 50% when compared with porcelain and gold (Gracis et al. 1991) and a wear rate similar to tooth enamel which reduces opposing natural tooth wear. Recent research has demonstrated similar wear rates between “modern” ultra fine compact filled composite resin materials and human tooth enamel (Mehl et al. 2007). However, during treatment planning care must be taken to consider the opposing dentition because if this is, in fact, porcelain then excessive wear of the IAC could occur



resulting in occlusal destabilisation (Gracis et al. 1991, Yip et al. 2004). In addition, as mentioned above, chair side modifications of the coronal restoration are possible.

The Bicon implant fixture is placed 3mm below the crestal bone level and 5mm below the gingival margin in aesthetic areas. The narrow neck of the abutment with a hemispherical base allows maximum space for periabutment soft tissue bulk and underlying alveolar bone while providing the potential for optimal emergence profile of the coronal restoration without concern over subgingival margin placement. However, Keith et al. (1999), suggested that as the depth of the implant restoration interface increases the likelihood of trapping gingival tissues and incomplete seating of the prosthesis increases.

### **2.6.2 Disadvantages of the IAC**

The disadvantages of the Integrated Abutment Crown system include higher roughness values when compared with all-ceramic materials which could facilitate greater plaque accumulation and a higher rate of surface staining. Plaque accumulation causes gingival inflammation (Löe, 1965) which may or may not lead to bone loss and periodontal destruction depending on other factors such as patient susceptibility to periodontal destruction. Inflammation of the periimplant soft tissue has also been demonstrated in the presence of poor oral hygiene and plaque accumulation (Berglundh et al. 1992). Bone loss and periimplant destruction can ensue from plaque accumulation as shown by Schwarz et al. (2007). The provision of a plaque resistant surface is one of the qualities of the ideal restorative material. Research has shown that the distribution pattern of plaque on different surfaces of crowns is the same as on natural teeth e.g. greater plaque accumulation on interproximal surfaces. However, the composition of the plaque and the amount varies depending on the crown material and surface roughness (Adamczyk & Spiechowicz. 1990). Lower plaque accumulation is a well accepted advantage of porcelain crowns and indeed studies have shown porcelain to be even less plaque retentive than natural enamel (Chan & Weber, 1986). Such research has implicated acrylic and gold restorations to have high plaque retentive characteristics. When plaque accumulation on various composite filling surfaces was investigated using SEM, voids and depressions between the composite material matrix and filler particles were seen which may provide retentive features for plaque. Hence, the polishability of composite materials is an important feature (Weitman & Eames, 1975). Plaque accumulation on

composite resin fillings has been shown to be higher than that on natural teeth within the same subject (Larato, 1972) and accumulation increases with increasing age of the filling material (Dijken van et al.1987). However, Dijken et al. (1987), failed to show a statistically significant difference in an *in vivo* study between the amount of plaque accumulation on conventional, hybrid and microfiller type composites when a 7 day experimental gingivitis study was carried out.

Sorensen et al. (1989) identified three factors that mediate plaque accumulation and influence gingival health at the tissue-restoration interface of crown systems. These factors were surface roughness, marginal fit and contour of crown margins.

## **2.7 Patient Experience**

Unfortunately, for many the dental experience is often perceived as an endurance one must bear in the pursuit of oral health, adequate function and pleasing aesthetics. Pain or the anticipation of a painful event evokes varying levels of anxiety in patients. Patient satisfaction is perhaps due to the actual experience during treatment, whether this is as painful as anticipated or not, being deemed worthwhile, in their opinion, in terms of the benefit or outcome of treatment.

### **2.7.1 Pain**

Pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage (Merslay & Bogdük, 1994). By virtue of this definition, to evaluate pain using simple assessment tools would lead to incorrect conclusions due to the omission of the behavioural and psychosocial aspects inherent in the individual's perception of pain. (Gracely et al, 1978)

An ideal pain assessment tool should be reproducible, easy to use, applicable to different patients and different groups and free from subjective and objective bias. Generally assessment tools may be categorised into observer-dependent or patient self-reporting scales, the latter being the more ideal method e.g. McGill pain questionnaire. Ideally the tool should be able to provide an absolute measure of pain rather than a relative one e.g. a visual analogue scale (VAS) merely achieves a relative measure of

pain intensity in an individual patient which has no relevance to a different person's measure of suffering with a similar pain.

#### **2.7.1.1 Visual analogue scales (VAS)**

This is a simple, reproducible and sensitive method of pain assessment and can provide a numerical value for the severity of pain.

A VAS is usually measured on a straight and horizontal line which is 10cm in length. One end of the line is marked no pain and the other is marked as the worst possible pain imaginable. The patient is then asked to draw a mark to intercept the line to illustrate their current level of pain. This mark denotes a numerical value for the severity of pain. It is important to explain to the patient what is required of them to prevent any misunderstanding. This should be carried out by the same clinician each time to avoid any potential change in influences on the patient's response. Visual analogue scales are also useful to measure patients' satisfaction with treatment. Unfortunately the VAS assessment tool fails to take into account the multi-dimensional nature of pain.

#### **2.7.1.2 Verbal pain scales**

Verbal pain scale methods attempt to overcome the shortcomings of VAS in terms of the multi-dimensional nature of pain. An example of such a tool is the McGill pain questionnaire. Patients are given a list of 102 words that were obtained from clinical literature and have been put into three main classes and 20 subclasses. The three main classes look at:

1. Sensory qualities of pain in terms of temporal, spatial, pressure, thermal and other qualities.
2. Affective qualities in terms of tension, fear and autonomic properties,
3. Evaluative words describing the subjective intensity of the total pain experienced.

Patients are asked to select one word from each sub-class to describe their pain. The main disadvantage of this method is the length of time it takes to complete the questionnaire.



### **2.7.1.3 Psychosocial assessment of pain**

Finally, in keeping with the definition of pain, a psychosocial assessment of pain should be carried out to determine the severity of pain in terms of impact on basic functioning during daily life, a patient's beliefs and misconceptions concerning the meaning of their pain and health related quality of life issues. Shugars et al. (1996) developed a method to measure patient's perceptions of their experiences after the surgical removal of third molars. Shugars et al. (1996) identified the need for condition specific health related quality of life measures to improve the sensitivity of such tools to evaluate patients experience during specific treatments such as third molar extractions. Based on work of previous researchers (Torrance et al.1987, Bader & Shugars, 1995) which identified dimensions of overall well being and the specific dimensions of dental outcomes, preliminary categories were selected for the collection of data. These were oral function, general function, pain and other symptoms. Thus, the developed self-administered instrument consisted of 14 items representing the four dimensions. Visual analogue scales and five-point Likert-type scales were incorporated to collect the data. A modified version of this assessment tool could be of benefit in evaluating patients' experience during implant placement and has been used effectively as such in a study carried out by Al Hashem et al. (2006).

### **2.7.2 Anxiety**

Pain is closely associated with factors such as stress and anxiety and when anxiety exists, it has been shown that one is more perceptive of the painfulness of a procedure (Eli et al. 2003). Anxiety has been described as an unpleasant subjective bodily state that acts as an alerting reaction and coping mechanism to some impending event (Gale 1972). The anticipation or the expectation of the severity of pain to be experienced during a particular procedure or event can influence the final interpretation of the stimulus to a positive or negative extent (Humphries & Ling, 2000). In addition, in a review of the literature Sokol et al. (1985) reported that individuals who show generally higher anxiety states in their daily lives (trait anxiety) tend to be more sensitive and reactive to pain. Causes of dental anxiety include previous traumatic experiences, vicarious learning, preparedness and personality (Kleinknecht et al. 1973, Eli et al. 1997, Locker et al. 2001, Chadwick B. L. 2002). Scott et al. (1982) reported that the vast majority of 609 undergraduate students investigated regarding dental anxiety were at least somewhat anxious while undergoing dental treatment however there was a wide

range of levels of anxiety. This variation in fear reactions to dental treatment has been shown by others (Kleinknecht et al.1973). Spielberger (1970) defined two types of anxiety; state anxiety and trait anxiety. State anxiety was defined as a transitory emotional state or condition of human organisms that is characterized by subjective, consciously perceived feelings of tension and apprehension, and heightened autonomic nervous system activity. It may fluctuate over time and can vary in intensity. Trait anxiety was defined as relatively stable individual differences in anxiety proneness and refers to a general tendency to respond with anxiety to perceived threats in the environment.

### **2.7.2.1 Assessment of Dental anxiety**

**Physiological:** This measure of anxiety involves the gathering of 'hard' data such as heart rate, salivary cortisol content and Galvanic skin response. However there are unavoidable problems with this method of anxiety assessment such as the requirement for monitoring equipment and the patient's reaction to being monitored. For this reason it is beneficial to take resting measures also.

**Behavioural:** This is an observational measurement of a patient's anxiety whereby the clinician or observer rates the patient's anxiety using various scales which have been developed such as Frankl's Behaviour Rating Scale. As a method of anxiety assessment this tool is fraught with difficulties, namely lack of clear definitions of categories of behaviour, time consuming and technical difficulty attaining correct sampling of behaviour as in some cases, especially in children, the behaviour observed may be learned as opposed to anxiety induced.

**Self-report:** This method involving the use of questionnaires is widely used and is a relatively efficient method of anxiety level assessment. The data can be collected relatively quickly and many different aspects of anxiety can be deduced from the questionnaires. Examples of this method include the Dental Anxiety Scale (DAS) developed by Corah (1969) and the Spielberger State Trait Anxiety Inventory which was developed by Charles D. Spielberger, (1970). The STAI comprises two separate self-report questionnaires for measuring state and trait anxiety which ask the patient to evaluate how they feel at that moment in time (e.g. pre-op) and how they generally feel respectively. The state anxiety questionnaire investigates feelings of apprehension,



tension, nervousness and worry which are all important components of Spielberger's definition of state anxiety. Scores on this scale increase in response to physical danger and psychological stress and decrease as a result of relaxation training. Similar questions are posed in the Trait anxiety questionnaire however they refer to general situations. In addition to identifying specific personality traits such as high neurotic anxiety, scores from this scale are also useful for evaluation of the immediate and long-term outcome of psychotherapy, counseling, behaviour modification and drug-treatment programs.

The STAI has been widely used in medicine, dentistry, education, psychology and other social sciences and has proved to be an invaluable tool in evaluating patient anxiety, the affect of anxiety on other emotions and behavior and in developing treatment strategies.

### **2.7.3 Pain and anxiety related to dental implant placement**

Limited research has been carried out on the pain associated with dental implant placement, the associated anxiety inflicted on the patient and the interplay between them. Al-Khabbaz et al. (2007) and Hashem et al. (2006) both reported similar results which showed the pain associated with implant placement to be mild to moderate and that this pain decreased postoperatively over time with peak intensity occurring during the first 24 hours. Highest anxiety levels were reported on the day of surgery (Hashem et al. 2006). No research to date has been carried out on pain reported by patients during and following placement of the Bicon implants which utilizes a slightly different placement method than most other implant systems in that the reamers are used at low speed with no irrigation and the implant is hand placed and tapped into its final position using a mallet. In addition, no study has attempted to evaluate the patients' opinion regarding their satisfaction with the outcome of treatment when the pain and anxiety endured during the 'experience' is taken into consideration.



## 2.8 Patient satisfaction

Despite extensive implant related published literature very few studies have evaluated patient centered outcomes of implant supported restorations. Of these, the vast majority deal with edentulous patients restored with implant supported overdentures or fixed prosthesis. There is limited evidence of the level of patient satisfaction following placement and restoration of a single unit implant restoration.

Pjetursson et al. (2004) carried out a 10 year prospective study investigating patients' satisfaction following implant therapy using both detailed questionnaires and visual analogue scales (VAS). The questionnaire addressed aspects of function and chewing comfort, phonetics, aesthetics, oral hygiene practices, general satisfaction and cost. More than 90% of the patients reported complete satisfaction with chewing function and 70% reported their chewing function to be identical to chewing with natural teeth. 97% of the patients using the questionnaire data were satisfied or very satisfied with the aesthetic appearance of their restorations and this was confirmed by a mean VAS score of 93. 90% of the patients would be willing to undergo implant therapy again if necessary. Overall, the patient centered treatment outcome was very good. In addition, this study demonstrated a good correlation between the results from the categorized statements and the VAS. The authors advocate the use of either a questionnaire or VAS alone or in combination as adequate methods for evaluation of patient satisfaction with implant dentistry.

Evidence has indicated that personality traits have an effect on patient centered outcome in terms of satisfaction with implant dentistry. Hantash et al. (2006) used the Dental Impact on Daily Living questionnaire to assess the impact of implant restoration on the quality of life for patients and combined this with specific personality traits in an attempt to identify predictors of patient satisfaction with implant therapy. The results indicated a significant negative relationship between neuroticism and satisfaction. The authors suggested a value in attempting to predict the level of satisfaction expected to be achieved with implant restoration prior to embarking on a specific treatment plan.

### **2.8.1 Patient satisfaction compared to clinician rating of restoration**

Two recent studies compared patient satisfaction ratings with clinician's opinion of the esthetic outcome of single tooth implant restorations (Palmer et al. 2007, Chang et al. 1999). Chang et al. (1999) reported a median VAS value of 96% when patients were asked to indicate their esthetic appreciation of their implant-supported single crown despite the clinical evaluation which revealed pertinent differences between the appearance of the peri-implant soft tissue topography and restoration appearance and that of the contralateral natural tooth. The authors concluded that such differences in crown and soft tissue appearance between implant supported single tooth restorations and contralateral natural teeth were of minor importance for the patient's appreciation of the esthetic outcome of the implant therapy. Palmer et al. (2007) evaluated patients' response to a questionnaire in which they were asked to rank from 1 to 6 their satisfaction with the crown shape and colour, gum shape and colour, ability to eat and talk, comfort, ease of care and any additional problems they may have had. The patients' satisfaction questionnaire indicated a universal maximum satisfaction (rating 6) with the appearance of the crown and soft tissue. However, the clinician's rating was somewhat lower ranging from a median of 5 for gum shape to 5.5 for crown shape and crown and gum colour. The authors concluded that single tooth restorations have a high chance of fulfilling patient's aesthetic and functional expectations. This study also demonstrated an improvement in soft tissue appearance over time and indicated that at least 12 months should have passed before assessment of clinical parameters on the appearance of periimplant soft tissue should be carried out. Similar evidence was given by Jemt et al. (1997).

## **2.9 Research specific to the Bicon Implant system**

To date, there is limited published research on the clinical success of the Bicon implant system. However some scientific evidence of the attributes of specific design features of this system have been reported. These have been discussed more extensively earlier and include *in vitro* evidence of the hermetic seal between the implant abutment connection (Dibart et al. 2005), the success of the short implant irrespective of the crown root ratio (Schulte et al. 2007) and the evaluation of load transfer characteristics of the Bicon implant in compact bone (Bozkaya et al. 2004).



Prospective 4 year prosthetic results of 432 posterior single unit Bicon implants with conventionally cemented prosthetic restorations in posterior edentulous spaces reported cumulative success rates for implant survival of 90% for the maxilla and 96.8% for the mandible (Muftu & Chapman, 1998). Furthermore, the implant-abutment prosthetic success rate was 95.05%. 0.74% of the abutments loosened, 0.5% of the abutments fractured and 2.47% of the crowns experienced porcelain failure. Unfortunately no clear account of the success criteria were included in this study.

A retrospective cohort study of 889 single tooth Bicon implants placed in 294 patients and followed over a mean follow up time of 2.3 years revealed a survival rate of 98.2% (Schulte et al. 2007). Failure was defined as removal of the implant for any reason. This study was investigating the effect of crown implant ratio on implant survival. Therefore, the reported outcomes were merely implant survival and crown: implant ratios.

Gentile et al. (2005) carried out a retrospective study of Bicon implants investigating the 1 year survival estimates and risk factors for failure of 6 x 5.7mm implants. Again, implant failure was defined as explantation for any reason. The results demonstrated an implant survival rate between 92% and 95%.

In a retrospective study carried out by McDermot et al. (2006) to investigate maxillary sinus augmentation as a risk factor for implant failure, the 5 year survival rate for 762 posterior Bicon implants in 318 patients was 87.9% in those who had maxillary augmentation procedures and 88 % in those who had not. In this study tobacco use, implants replacing molars and 1 stage implants were statistically associated with an increased risk of implant failure however preceding sinus augmentation procedures were not. In another study carried out by McDermot et al. (2004) to identify risk factors associated with complications of dental implants the 5 year implant survival rate of 677 Bicon implants in 677 patients was 90.2%. This study was once again retrospective and implant failure was defined as removal of the implant.

At present, no prospective studies exist which aim to investigate the success rates of the Bicon implant system's short wide implants restored with the Integrated Abutment Crown. It must not be forgotten that success of an implant is ultimately the benefit the patient appreciates after having the procedure carried out. Attempts should be made to



quantify this patient experience and satisfaction to ultimately determine the outcome of implant dentistry in terms of the Bicon implant system, facilitate treatment planning and adequately inform patients of what to expect having undergone implant placement and restoration.

# **Chapter 3:**

## **Materials and Methods**

### **3.1 Ethical Approval**

Ethical approval was sought and received from the Faculty Research Ethics Group at the Faculty of health sciences, Trinity College, Dublin following submission of a research protocol and description of the benefit and provision of a worthwhile reason for the proposed study. In addition copies of specifically compiled consent forms and patient information leaflets were submitted. (See appendix 1 and 2)

### **3.2 Patient information and consent forms**

- All patients were given a written and verbal description of the study, the procedures involved and any co-operation needed i.e. attendance at recall appointments for up to 6 months post final restoration
- Consent for participation in the study was signed by all participants.

### **3.3 Sample group**

Patients were selected from the implant waiting list at the Dublin Dental Hospital requiring one or more implants to be restored as single units.

#### **3.3.1 Inclusion Criteria**

- ☒ Partially dentate patients
- ☒ Medically fit and well
- ☒ Patients suitable for treatment under LA
- ☒ Ability to attend at necessary predetermined review appointment dates
- ☒ Patients willing to co-operate with any necessary data recording at home
- ☒ Patients with adequate ridge width to accommodate the width of Bicon's wide fixtures without requiring ridge augmentation

#### **3.3.2 Exclusion criteria**

- ☒ Medical contraindications for implant surgery
- ☒ Any condition requiring long term analgesics
- ☒ Any site requiring pre implant grafting
- ☒ Any site not wide enough to accommodate at least a 4.5mm implant width
- ☒ Treatment plans requiring immediate implant placement or immediate loading



### **3.4 Evaluation of patient experience**

Patient experience was assessed and evaluated using various methods. Data relating to anxiety one week before, immediately before and one week after implant placement, pain experienced for the 7 days following surgery and recovery were recorded. Three to six months following final restoration, patients were asked to complete a questionnaire referring to their satisfaction with the restored implants and over all experience during treatment.

#### **3.4.1 STAI: Spielberger state trait anxiety inventory for adults**

This self administered evaluation of anxiety was given in the form of questionnaires to the patient. (See Appendix 3) Two questionnaires, one referring to ‘general feelings’ and one referring to feelings ‘right now’ were given to the patients one week pre-operatively, on the day of surgery but pre-operatively and one week post-operatively. The patients were asked to give truthful and honest responses to the questions. Patients were reassured that all answers would be kept confidential. Clear instructions were written on the top of each questionnaire and highlighted both visually and verbally by the examiner to ensure that no mistake was made by the patient when answering the state and trait questionnaires. If the subject asked specific questions as to how he or she should respond, the examiner’s response was non committal e.g. “ Just answer according to how you generally feel” or “answer the way you feel right now”. State anxiety forms were administered first because scores on the state anxiety scale could be influenced by the emotional climate that may be created if the trait anxiety scale was given first.

#### Scoring

Each STAI item is given a weighted score of 1 to 4. A rating of 4 indicates the presence of a high level of anxiety for ten specific S-Anxiety items and eleven specific T-Anxiety items such as “ I feel frightened” If a high score is attained for the remaining ten S-Anxiety items and nine T-Anxiety items e.g. “I feel calm” an absence of anxiety is implicated. The scoring weights for the anxiety-present items corresponded to the blackened numbers on the test form. The scoring weights for the anxiety absent items are the apparent numbers reversed i.e. 1=4 The questions relating to anxiety absent

items on the S-anxiety scale are questions numbered 1,2,5,8,10,11,15,16,19,20 and the questions relating to anxiety absent items on the T anxiety scale were questions numbered 21,23,26,27,30,33,34,36,39. The scores were then added for the twenty items that make up each scale. The scores could vary between a minimum of 20 to a maximum of 80.

### **3.4.2 Assessment of pain and function**

A condition-specific Health Related Quality Of Life (HRQOL) instrument for evaluating the short-term outcomes of third molar surgery as developed by Shugars (1996) and based on the work of Torrance et al. (1987) and Bader & Shugars (1995) was used in this study. (See appendix 4) Four preliminary categories of data collection were selected. These were oral function, general function, pain and other symptoms. The oral function category addressed the patient's ability to chew and speak and the general function category determined if the procedure had had an impact on the patients' ability to conduct daily activities such as attending class or going to work, their social life, their leisure activities and their sleep pattern. The pain category recorded the patient's pain experience in terms of pain severity and duration. Finally, the "other symptoms" category noted the occurrence of any common sequelae of surgery such as swelling, bruising, bleeding, nausea, bad taste/breath, food impaction. This HRQOL instrument was self administered and consisted of a Likert-type scale as a response format to specific questions, visual analogue scales and pain relief requirement diaries which addressed items from each of the four categories mentioned above. Identical HRQOL instruments were completed on the day of surgery after the surgery and for the following 6 days.

The visual analogue scale (VAS) consisted of a 10cm line with clearly defined boundaries marked as "no pain" and "worst pain imaginable". The patients were asked to place a mark along the line corresponding to their pain severity and the distance from the no pain end of the line to this mark was measured. This numerical value of pain was then used for statistical analysis.



### **3.5 Patient Satisfaction**

3 to 6 months after final restoration, the patients were asked to fill in a satisfaction questionnaire consisting of questions relating to aesthetics and function of the restored implant. (See appendix 5) The patients were also asked to rate how worthwhile they felt the overall experience had been and whether they would undergo the treatment again. They were asked if they would recommend the treatment to others. Visual analogue scales were used to respond to most of the questions. A few questions required a yes or no answer. Numerical scores were gained from the VAS for each corresponding question.

### **3.6 Relationship between anxiety, pain, interference, and patient satisfaction**

State and trait anxiety scores were then correlated to the levels of pain experienced, interference with daily activities and satisfaction ratings with treatment outcome and overall experience. The pain score was derived from the visual analogue scale and was determined for each patient on each day. An interference score was generated for each patient for each day by adding together each score given by the patient to each individual interference e.g. Sleeping. These scores ranged from 1 (no interference to a maximum of 5 (great interference)). There were 8 daily activities questioned. Each daily interference score could have a minimum score of 8 (no interference with any activity) and up to a maximum score of 40 (great interference in all activities). A total interference score for each patient was generated by adding together each daily interference score for the 7 post operative days. A satisfaction score was calculated by adding the results of the visual analogue scale responses to questions 1, 2 and 3 on the satisfaction questionnaire. Hence the score range was from a minimum of 0 to a maximum of 30. The “worthwhile experience” score for each patient was obtained from the patient’s response to question 8 on the satisfaction questionnaire. This score ranged from a minimum of 0 to a maximum of 10.

### **3.7 Overview of implant placement and restoration procedure**

- 6 x 5.7 mm, 5 x 6mm and 4.5 x 8mm hydroxyapatite coated Bicon implants were placed.



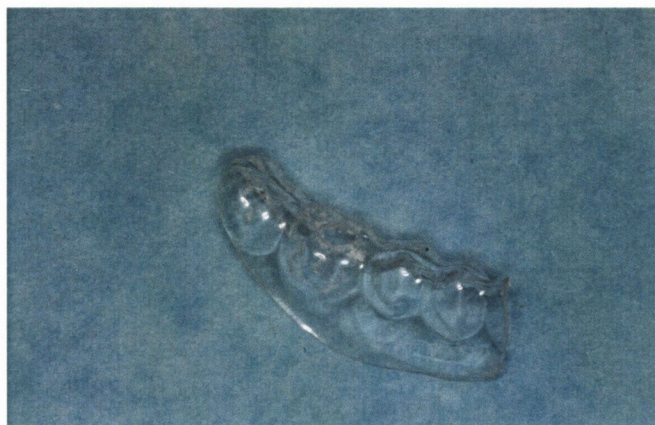
- The implants were submerged and uncovered following a period of three months, thus employing a two stage surgical procedure.
- Implants were placed in both the mandible and maxilla. Due to the width of the implants used no implants were placed in the incisor regions of either jaw.
- No immediate implant placement or prior grafting/soft tissue procedures were carried out as this was one of the exclusion criteria.
- Soft tissue healing was allowed for approximately six weeks following second stage which involved uncovering of the implant and placing of the healing abutment. At the end of this healing period impressions were taken for the definitive restoration.
- The integrated abutment crown which is unique to the Bicon implant system was used to restore the implants as single units.
- Integrated abutment crowns were made at the Bicon Centre in Boston
- Implant placement, and implant restoration was carried out by one operator.

### **3.8 Pre-operative records**

An OPG was taken of all patients and supplemented with a periapical radiograph if necessary. Pre-operative digital photographs were taken. Where necessary impressions were taken for study casts to facilitate provision of a surgical stent. (Fig 3.1 & 3.2)



**Fig 3.1: Wax up with clear acrylic stent**



**Fig 3.2: Clear acrylic stent**

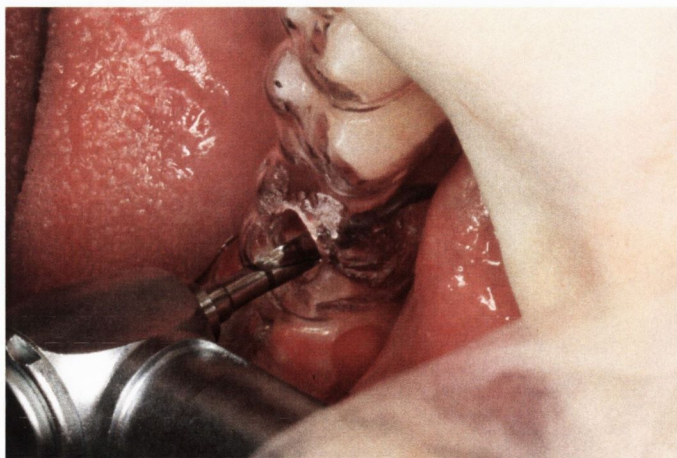
### **3.9 Pre-operative antimicrobials/antiseptics**

A preoperative dose of 3g of amoxicillin was given (no patients were allergic to penicillin in this study) and patients were instructed to rinse with a 10ml solution of 0.2% chlorhexidine mouthrinse for one minute prior to commencing surgery.

### **3.10 Surgical Procedure**

The surgical procedure for osteotomy preparation and implant placement was carried out strictly following the protocol suggested by Bicon.

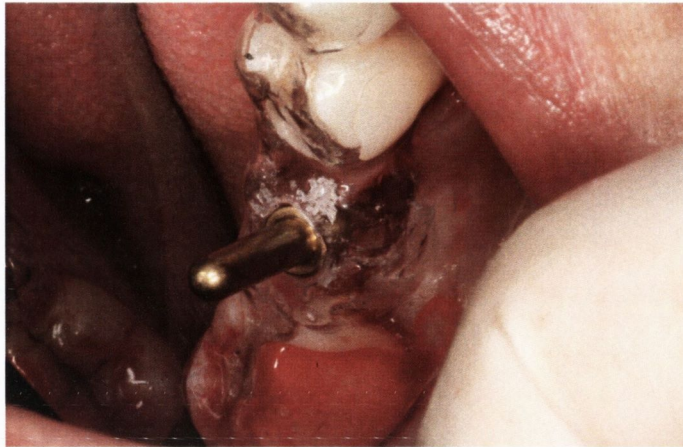
- A mid crestal or slightly palatal crestal incision was made along the edentulous ridge space. The incision was then extended into the buccal and palatal/lingual sulci of the adjacent teeth. Relieving incisions were avoided whenever possible. Buccal and palatal/lingual flaps were elevated in the edentulous space



**Fig 3.3: 2mm pilot drill – initial osteotomy**

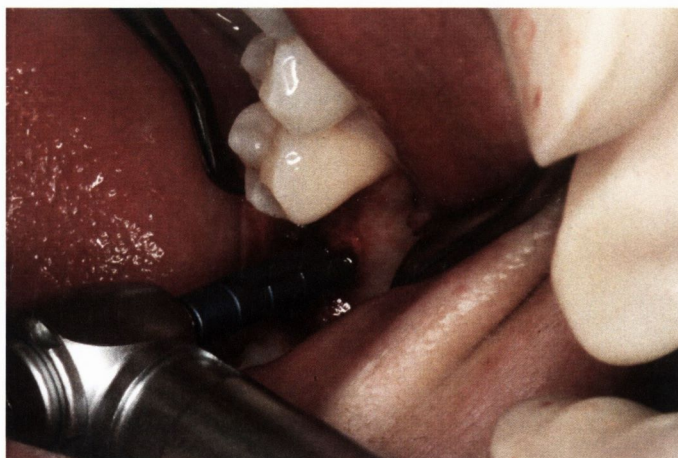


- Pilot osteotomy: A 2mm pilot drill at 1,100RPM with sterile irrigation was used to drill to half the desired depth for fixture placement (Fig 3.3)
- The direction was checked using a paralleling pin (Fig 3.4)



**Fig 3.4: Paralleling pin – Direction indicator**

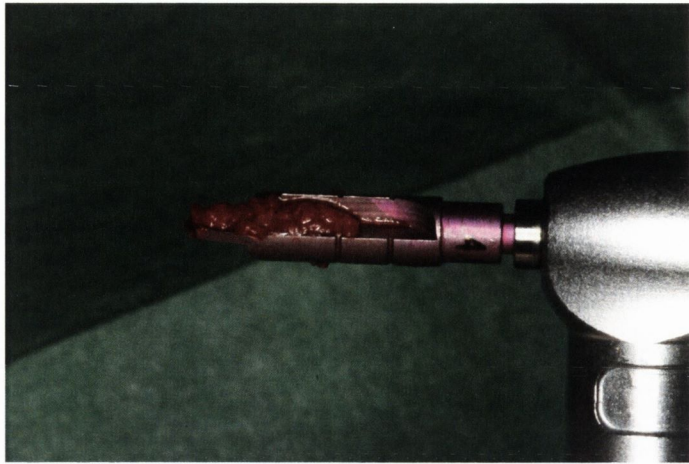
- Drilling was then continued to the full depth facilitating implant placement with the fixture head 5mm below the buccal gingival margin in aesthetic areas, or at least 3mm below the crestal bone level as outlined by the Bicon system protocol, whenever possible.
- Osteotomy preparation was then carried out using latch reamers at 50RPM without irrigation commencing with a 2.5mm diameter latch reamer and increasing in diameter by 0.5mm until the desired implant diameter was reached. (Fig 3.5)



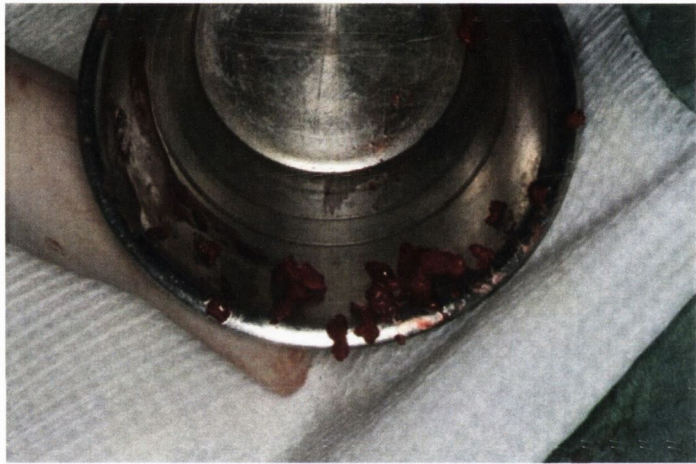
**Fig 3.5: Osteotomy preparation using latch reamer**

- Autogenous bone was collected from the flutes of the latch reamers and placed in a sterile dappen dish. (Fig 3.6 & Fig 3.7)





**Fig 3.6: Bone collection in flute of reamers**

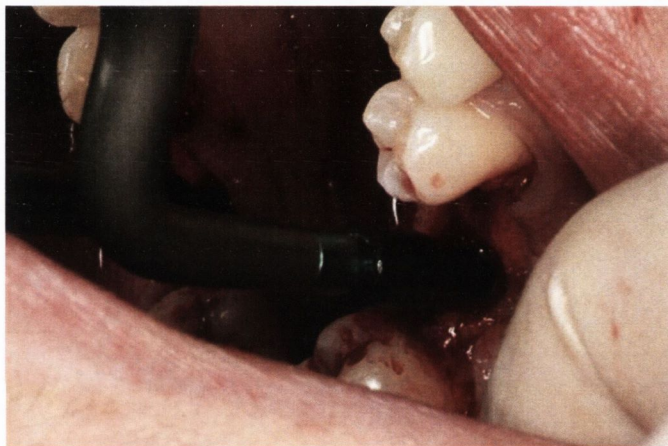


**Fig 3.7: Autogenous bone collected**

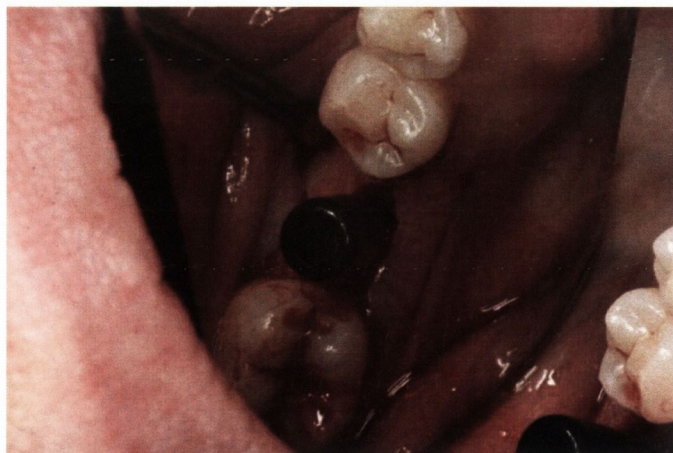
- The osteotomy site integrity was checked and bone shavings were removed.
- The implant was removed from the sealed packing and inserted into the osteotomy site by grasping the healing plug inserter and press fitting the implant in place. The surface of the implant did not touch any other surface before placement in the blood filled socket. (Fig 3.8)



**Fig 3.8: Implant insertion**



**Fig 3.9: Final tapping of implant into place**

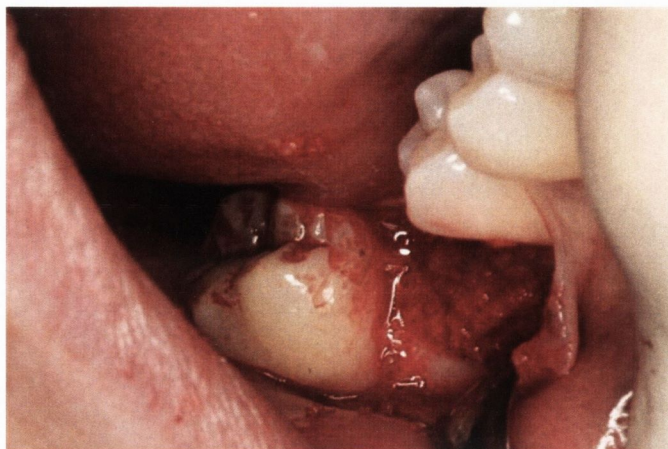


**Fig 3.10: Implant in final position with plastic healing plug**

- Definitive seating of the implant was carried out using a seating tip with straight or offset handles and a mallet and applying a tapping force. (Fig 3.9)



- The incorporated plastic healing plug was trimmed to the level of the crest of the alveolar ridge.
- The collected autogenous bone was replaced around the fixture head (Fig 3.11)



**Fig 3.11: Autogenous bone was replaced around and over the healing plug**

- The site was closed using vicryl or silk sutures. (Fig 3.12)



**Fig 3.12: Primary flap closure at osteotomy site**

### **3.11 Day of surgery, post surgery**

- A Post op x-ray was taken. Non standardised Periapical radiographs using Dentsply Rinn holders were taken. Attempts were made to ensure the film was parallel to the long axis of the implant and the x-ray beam was perpendicular to the film allowing a clear measurement to be made for recording mesial and distal marginal bone height and allowing comparison between later periapical radiographs to be made despite the lack of accurate standardisation of the x-rays. Clear definition of the implant fins indicates an absence of distortion due to incorrect film angulation.



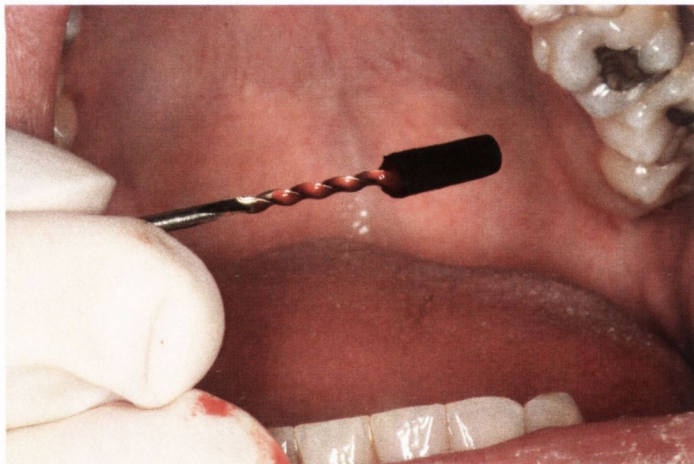
- A prescription of 500mg amoxicillin three times a day for 5 days was given to all patients.
- Note was made of difficulties encountered, location of implant, implant length and width and bone type.
- Post operative instructions were given consisting of a soft diet, analgesics when necessary and oral hygiene instruction.

### **3.12 One week post operatively**

- Sutures were removed and healing checked.
- The implant was then allowed to integrate uninterrupted for 3 months

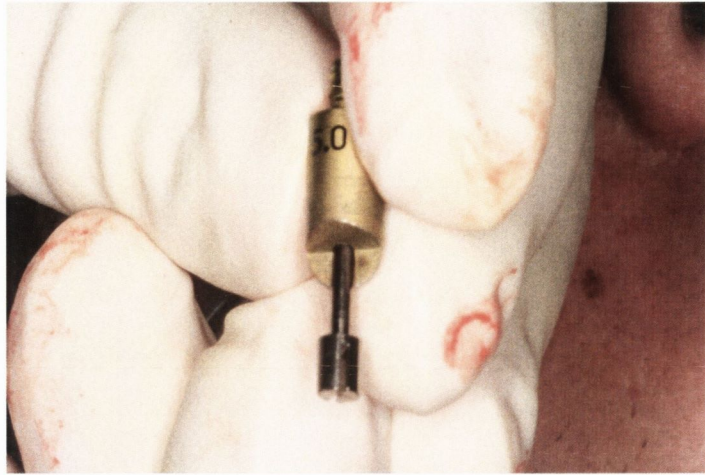
### **3.13 Second Stage Surgery – After 3 months submerged healing**

- A crestal incision was made followed by minimal flap reflection buccally and lingually/palatally
- The black healing plug was located, exposed and removed. (Fig3.13)



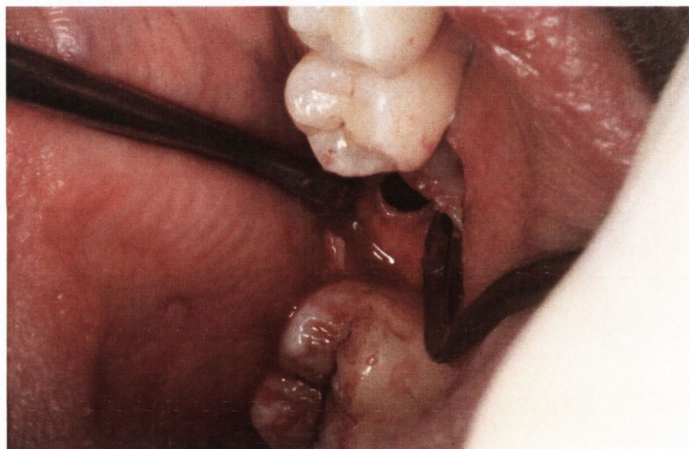
**Fig 3.13: Black healing plug removed**

- A guide pin was inserted into the well of the fixture and integration was evaluated by assessing the presence or absence of mobility of the fixture.
- Any bone or soft tissue preventing seating of the intended abutment was removed using a sulcus reamer. (Fig 3.14)



**Fig 3.14: Socket reamer and guide pin**

- Plastic healing abutments (5x5mm or 5x8mm) were placed and adjusted where necessary. (Fig 3.16)



**Fig 3.15: At second stage with healing plug removed**



**Fig 3.16: Plastic healing abutment seated**

- Soft tissue was replaced and sutured.
- A periapical x - ray was taken.
- Recordings were made of any complications and fixture mobility.
- Soft tissue healing was allowed for 6 weeks.

### **3.14 Impression Taking – 6 weeks post 2<sup>nd</sup> stage**

- The healing abutment was removed.
- An impression reamer was used with a guide pin to remove bone and soft tissue which could prevent the seating of the impression coping.
- The impression coping was inserted and fully seated within the tapered well of the implant using a seating tip and mallet.
- The implant fixture level impression was taken using silicone putty and light body silicone impression material and an open tray method.
- The impression post was removed from the implant and placed in the impression.
- Opposing arch impressions and bite records were taken.
- A shade was chosen using the vita shade guide.
- Digital photographic records were taken using the chosen vita shade tab held against the adjacent teeth and the Bicon shade enhancer.
- The healing abutment was replaced.

### **3.15 Placement of the final restoration – Integrated Abutment Crown**

- The post of the Integrated Abutment Crown was wiped with an alcohol wipe.
- An incisal orientation jig was used to ensure proper anatomical alignment during placement and final seating of the IAC.
- Occlusal and passive interproximal contacts were assessed and adjusted when necessary. Contacts in lateral excursion movements were avoided.
- The integrated abutment crown was fully seated using a seating jig, crown seating tip and 250g mallet while ensuring that tapping was directed along the long axis of the tooth.
- A record was taken of the appointment length and any difficulties encountered.
- Oral hygiene instruction was given to the patient.





**Fig 3.17: Final restoration in place**

### **3.16 Additional Data Recorded for each patient**

- Age of Patient
- Gender of Patient
- Number of implants placed
- Location of implants
- Bone Type
- Smoking habit

### **3.17 Outcome measures**

#### **3.17.1 Plaque and gingival health**

Plaque accumulation on the IAC was evaluated at the 3 to 6 month post final restoration reassessment visit. Using the O'Leary index (1972) a full mouth plaque score was obtained for each patient omitting any porcelain surfaces. The plaque score on the Integrated Abutment Crown was then compared to the full mouth plaque score to determine if the Integrated Abutment Crown was more prone to plaque accumulation than the natural dentition. In addition a score was taken for the % of porcelain surfaces with plaque in any patient with porcelain restorations.

### Plaque index (O’Leary, 1972)

- A disclosing solution was applied to all the teeth.
- 6 surfaces per tooth were recorded which is a slight variation on the 4 surfaces recorded in the original O’Leary index.
- A positive score was obtained if stained soft accumulations were found at the dentogingival junction.
- A full mouth plaque score was then calculated in addition to a mean score per tooth.
- The actual plaque score for the IAC was compared to the mean full mouth plaque score.

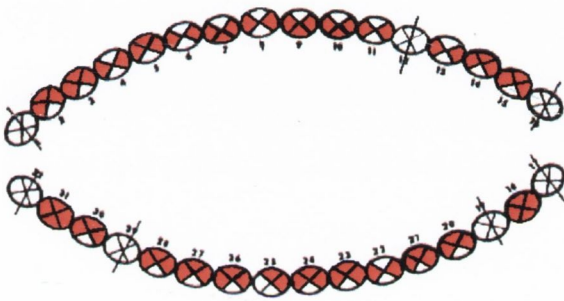


Fig 3.18: O’Leary plaque score method

### Gingival index (Lobene, 1986)

- 4 sites per tooth were assessed; buccal, lingual and interdental
- Scale: 0: absence of inflammation
  - 1: mild inflammation (slight change in colour, little change in texture of any portion of marginal or papillary unit)
  - 2: mild inflammation (involving entire marginal/papillary unit)
  - 3: moderate inflammation – glazing, redness edema and/or hypertrophy of the marginal or papillary unit
  - 4: Severe inflammation – marked redness, edema and/or hypertrophy of the marginal or papillary unit, spontaneous bleeding

Periimplant probing pocket depths were not recorded due to the design of the Bicon implant and the integrated abutment crown which consists of a narrow neck connecting

the hemispherical base of the abutment to the submerged fixture making a true and reproducible probing pocket depth unobtainable.

### **3.17.2 Papilla presence**

The presence or absence of papilla at 6 months following restoration was noted. The lack of a contact point was recorded when relevant.

Papilla Index – Jemt

- 0 = No papilla present
- 1 = less than half papilla present
- 2 = At least half papilla present but not to contact point
- 3 = Papilla entirely fills the area to the contact point and is in harmony with the adjacent papilla
- 4 = Papilla is hyperplastic

A score of 5 in the present study indicated a non applicable site i.e. where there was no adjacent tooth or contact point present.

### **3.17.3 Assessment of IAC aesthetics**

Integrated abutment crown aesthetics were assessed by two independent examiners using the modified United States Public Health Service criteria which evaluated the IACs for marginal gap, colour match, surface texture and anatomic form. (Table 3.1) The examiners were calibrated prior to the examination of the patients in the study.



| Variable        | 0          | 1                | 2               |
|-----------------|------------|------------------|-----------------|
| Marginal gap    | No catches | Catch            | Grossly open    |
| Anatomy         | Correct    | Incorrect        | Defective       |
| Surface texture | Smooth     | Dull             | Rough or pitted |
| Colour Match    | Excellent  | Minimal mismatch | Severe mismatch |

**Table 3.1: Table used when assessing Integrated Abutment Crowns**  
**Ryge G, Cvar JF (1971): Criteria for the clinical evaluation of dental restorative materials. US Public Health Service publication**

Values of 0 (alpha) and 1 (bravo) are considered clinically acceptable. Values of 2 or higher require further treatment. For color match, an unrestored tooth in close proximity served as the comparison.

A clinician satisfaction score was obtained for each restoration by adding the scores for all categories (marginal gap, anatomic form, surface texture and colour match) obtained from each clinician. The clinician satisfaction scores were compared to patient satisfaction scores and a correlation co-efficient was determined.

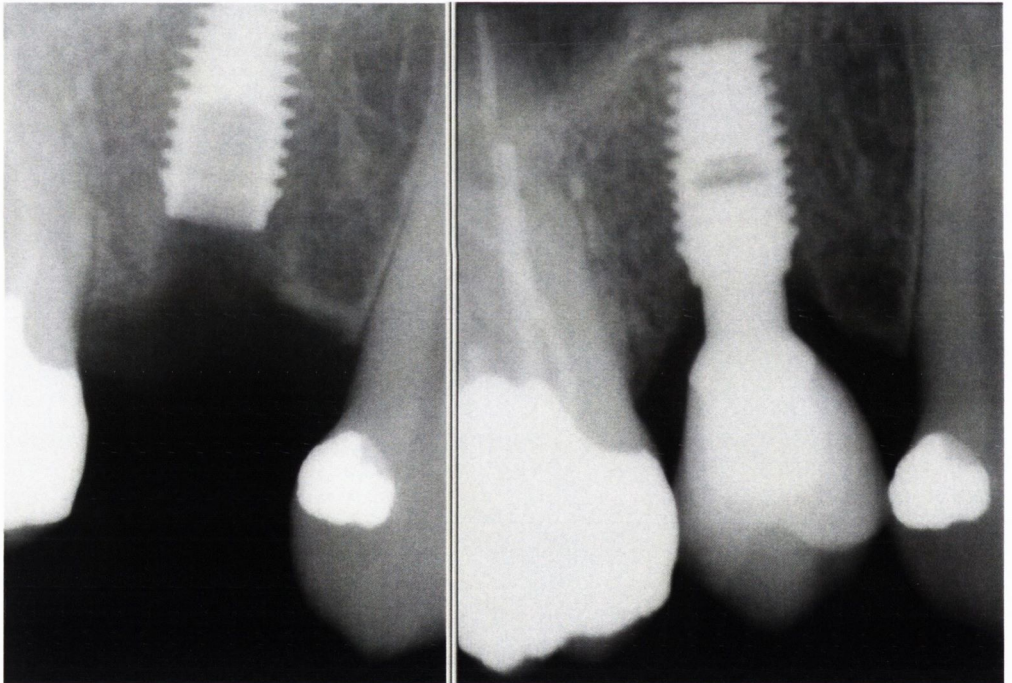
**3.17.4 Marginal bone heights and Radiographic assessment**

Periapical x-rays were taken immediately post operatively, at 2nd stage and at 3 to 6 months after final restoration. The following was determined:

- Absence of pathology
- A measurement of bone coverage from the first plateau to the head of the fixture was taken at each time point and bone loss or gain compared to the bone level immediately post operatively was determined. Measurements were taken from the mesial and distal aspects of each fixture and averaged.

- A measurement of the extent of submergence of the fixture was obtained from the x-ray taken immediately postoperatively. This measurement was taken from the head of the fixture at both the mesial and distal aspects to the crest of the alveolar bone immediately above this point. Mesial and distal scores for each implant were averaged to obtain a single submergence measurement for each tooth
- The x-rays were taken conventionally and scanned into the Planmeca Digimaxis software which enabled their magnification to facilitate accurate measurement. The magnification factor was considered in the measurements.
- Calibration of measurements:  
(ME):  $ME = AIL/MIL$

The digital measurement was multiplied by the margin of error



**Fig 3.19 Radiographic assessment of depth of submergence and marginal bone loss at 3 to 6 months following final restoration**

### **3.17.5 Implant mobility**

Implant mobility was determined by tactile sense at second stage by placing the guide pin in the well of the fixture.

Any adverse symptoms or complications occurring during the study period were recorded.

### **3.17.6 Implant survival and success**

An overall implant survival rate was calculated for the follow up time of 3 to 6 months after final restoration. This rate considered strictly the presence or absence of an implant in the mouth.

Implant success was based on the criteria described by Albrektsson et al, (1986)

- An individual, unattached implant is immobile when tested clinically
- A radiograph does not demonstrate any evidence of periimplant radiolucency
- Vertical bone loss is less than 0.2mm annually following the first year of service of the implant.
- Individual implant performance is characterized by an absence of persistent or irreversible signs and symptoms such as pain, infections, neuropathies, paraesthesia, or violation of the mandibular canal.
- In the context of the foregoing, a success rate of 85% at the end of a 5-year observation period and 80% at the end of a ten year observation period are minimum criteria for success

In addition, IAC aesthetics as rated by both the clinician and the patient and overall patient satisfaction were taken into consideration when assessing implant success.



## **Chapter 4:**

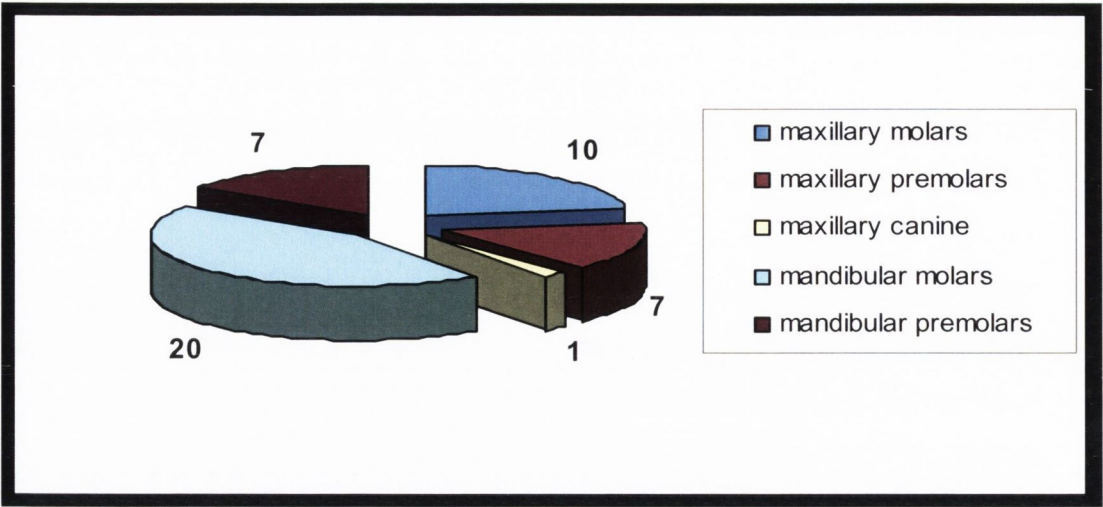
### **Results**

## **4.1 Study group.**

26 patients fulfilling the inclusion criteria who were on the implant waiting list at the Dublin Dental Hospital were initially included in the study. There were 21 females and 5 males. One male was unable to remain in the study due to an unrelated serious illness which developed shortly after second stage surgery. This patient had to indefinitely postpone further treatment. The implant in this patient was not restored. During the study period, one patient had a severe exacerbation of ulcerative colitis during which the patient was hospitalised and received high doses of steroids, two patients became pregnant and one patient developed trigeminal neuralgia which was not associated with the region of implant placement. The average age of the patients in the sample group was 43.9 years. The youngest patient was 27 years old and the eldest was 64 years old at the time of implant placement. There were 10 smokers and 15 non smokers.

## **4.2 Implants placed**

Excluding the patient removed from the study, 45 implants were placed in a total of 25 patients with a mean of 1.8 implants per patient. However 5 implants were placed in one patient, 12 patients had one implant placed, 8 patients had 2 implants placed and 4 patients had 3 implants placed. 18 implants were placed in the posterior maxilla and 27 implants were placed in the posterior mandible. (Fig 4.1) Only one implant was placed in the canine area and no implants were placed in incisor areas due to the requirement for wide ridges to accommodate the width of the implants which were placed.

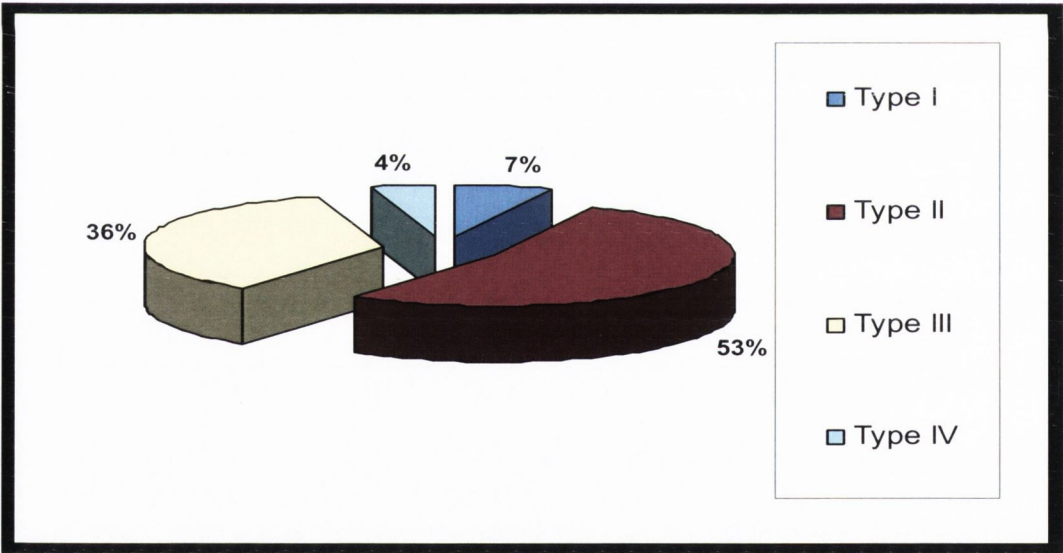


**Fig 4.1: Location of implants placed**

Short, wide hydroxyapatite coated Bicon implants were placed. Twenty seven 4.5x8 mm implants, fifteen 5x6mm implants and three 6x5.7mm implants were placed. All implants were restored using Integrated Abutment Crowns.

**4.3 Bone Type**

The implants were placed most commonly (53% of sites) in Bone type II (n=24).



**Fig 4.2: Bone Type**

**4.4 Implant survival**

One implant failed, 4 months after restoration giving an implant survival rate of 98% at 3 to 6 months post final restoration. No signs of inflammation or periimplantitis were present at previous check visits and the implant appeared integrated at second stage. However, the patient attended the Dental Hospital complaining of implant mobility. The



implant had been placed in the canine area in Type III bone. The patient was a smoker and had previously been treated for aggressive periodontitis which had rendered her partially edentulous. There was a vertical deficit of bone which resulted in an increased crown:implant ratio.

#### **4.5 Implant success**

At second stage, which was 3 months following implant placement all fixtures appeared integrated when tested clinically. At the final follow up appointment 3 to 6 months following placement of the final restoration, no implants were mobile, there were no associated radiographical pathologies, and no signs or symptoms of pain, infection, neuropathies, violation of the ID canal or paraesthesias. 98% of implants (n=44) remained in function for the duration of the study period.

#### **4.6 Marginal Bone Loss/Gain: Radiographic assessment**

Radiographic assessment immediately post operatively revealed an average implant submergence of 1.8mm. Four implants appeared to be placed very slightly supracrestal. One of these implants was placed in the mandible in type I bone and difficulty preparing the osteotomy site had been recorded. Another two of the implants were placed in mandibular type II bone and difficulty had been experienced when attempting to fully seat the implant. These four implants had incomplete bone coverage from the first plateau to the head of the fixture radiographically immediately postoperatively. 71% of implants (n=32) demonstrated no bone loss between the fixture head to the level of the first plateau when compared to the bone level immediately following implant placement. Only one implant demonstrated greater than 1mm marginal bone loss. This implant had bone loss of 3.2 mm with the bone level at 2<sup>nd</sup> stage being at the level of the 2<sup>nd</sup> plateau. Minimal bone loss over the following 6 months was observed. The implant remained in function with no mobility for the duration of the study period. Inflammation was absent. This patient had an extended period of illness shortly after implant placement which required high doses of steroid medication over several months. Excluding this implant, the average bone loss at 3 to 6 months following loading was 0.44mm in 29% of the implants. Three implants demonstrated bone gain from implant placement to 3 to 6 months post restoration. All of these implants had been placed supracrestally. Other implants may also have gained additional bone height

over the study period but due to the fact that the measurement of bone coverage from the first plateau to the head of the fixture if the ideal 3mm submerged placement was carried out would be maximal from the outset no further gain in bone height could be accounted for.

Paired t-tests indicated a statistically significant relationship between the depth of submergence of the fixture and bone loss at 2<sup>nd</sup> stage (mean of differences = 0.351 and the 95% confidence interval (CI) for the mean difference was between 0.042 and 0.660) and a highly significant relationship between initial submergence of the fixture and bone loss at 3 to 6 months after final restoration (mean difference = 0.427, 95% CI between 0.112 and 0.741). However there was no significant relationship between bone loss at 2<sup>nd</sup> stage and bone loss at 3 to 6 months following final restoration. This indicates that as the depth of submergence of the implant increases the likelihood of bone loss at 2<sup>nd</sup> stage and, to a greater extent, at 3 to 6 months post restoration decreases.

## **4.7 Plaque and Gingival Health**

### **4.7.1 Plaque Score.**

25 patients were available for a plaque assessment between 3 and 6 months following final restoration. The average full mouth plaque score excluding porcelain surfaces using the O'Leary plaque index was 24.5% with a range from 2% to 62%. The average number of surfaces on an integrated abutment crown with plaque amounted to 36.1% (Range: 0% to 83%). On average 11% (range: 0% to 48%) of the full mouth plaque score was located on the integrated abutment crowns. 2 patients had no plaque on integrated abutment crown surfaces. Any porcelain surfaces in the mouth were excluded. In those patients who had porcelain restorations (n=12) a plaque recording of those surfaces was taken. 5.6% of all porcelain surfaces had plaque. 8 patients had no plaque on the porcelain surfaces. 4 patients had 33%, 17%, 10% and 7% of porcelain surfaces with plaque respectively

4.7.2 Gingival Inflammation

The Lobene index (Lobene et al. 1986) was used to assess gingival health. 4 sites per tooth were assessed by two clinicians not otherwise involved in the study. The highest score per tooth was recorded.

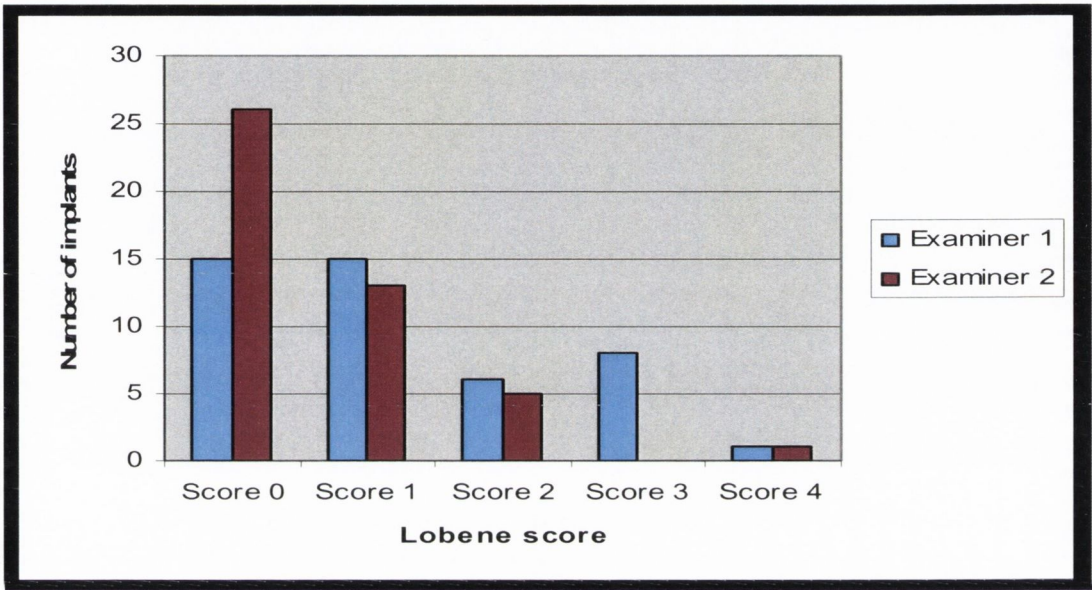


Fig 4.3: Health of periimplant gingival tissue. (Lobene index)

67% (Examiner 1) and 86% (Examiner 2) of the implants had no inflammation or very slight inflammation. 2% (n=1) (Examiner 1 and Examiner 2) had severe inflammation according to the Lobene index. This 2% (n=1) of the sample group amounted to one tooth. Both examiners gave this tooth a score of 4. These results indicate good gingival health in general.

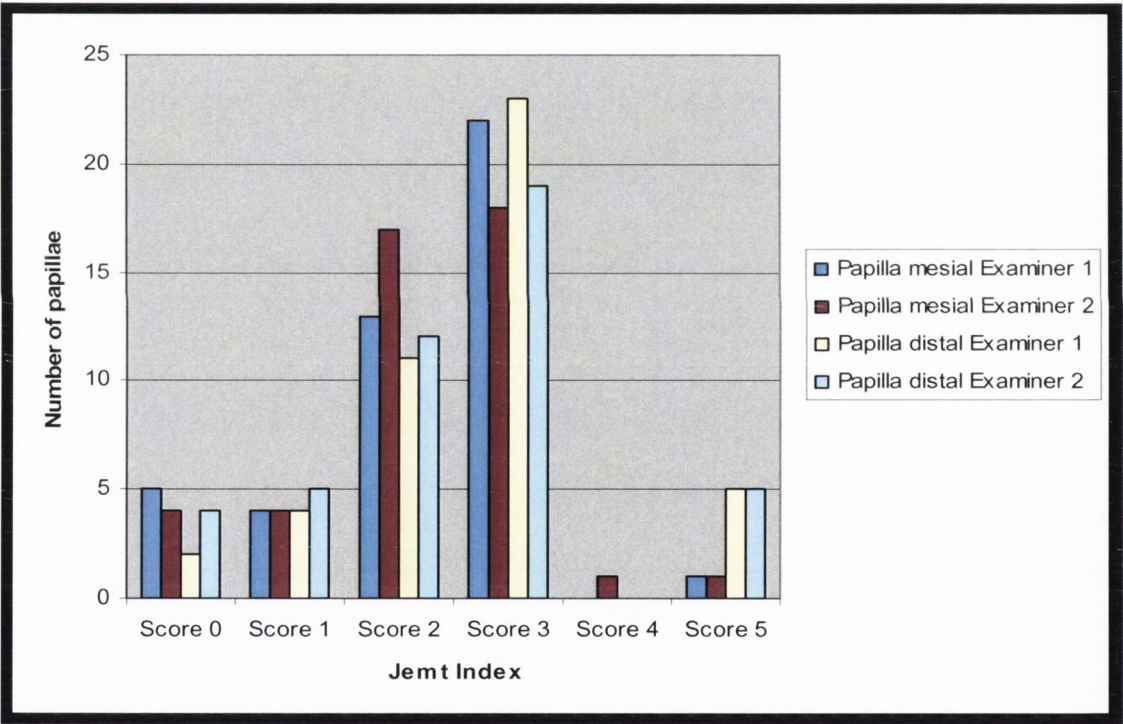


### 4.8 Papilla Presence

11% of distal sites (n=5) had no adjacent tooth and therefore were considered not applicable to analysis. Similarly 2% of the mesial sites (n = 1) were not suitable for analysis. Excluding these sites 50% of mesial papillae and 58% of distal papillae according to examiner 1 completely filled the area to the contact point and were in harmony with the adjacent papillae. Examiner 2 reported that 41% of mesial papillae and 48% of distal papillae were complete.

Both examiners found less than 12% of both mesial and distal papillae respectively filled less than half the area to the contact point.

Examiner 2 found 1 mesial papilla to be hyperplastic.



**Fig 4.4: Description of papilla mesial and distal to each implant when viewed from buccal surface only. Score 5 is not part of the Jemt index but was used in this study to categorize those sites without an adjacent tooth/contact point and hence, a lack of papilla.**

Examiner 1 and examiner 2 found 22 and 18 of the mesial sites respectively to have complete papilla fill to the contact point and 23 and 19 of the distal sites respectively. The majority of the remaining sites had at least half the papilla present (score 2).

## 4.9 Patient Experience

20 out of the 25 patients taking part in the study correctly completed and returned the anxiety analysis forms, pain, interference, analgesic requirement and sequelae of surgery diaries.

### 4.9.1 Anxiety

Results from the Spielberger State Trait Anxiety Inventory

| Patient       | Pre-op state | Pre-op trait | Surgical state | Surgical trait | Post-op state | Post-op trait |
|---------------|--------------|--------------|----------------|----------------|---------------|---------------|
| 1             | 23           | 29           | 33             | 31             | 21            | 26            |
| 2             | 25           | 33           | 41             | 35             | 22            | 30            |
| 3             | 52           | 58           | 42             | 56             | 31            | 60            |
| 4             | 22           | 47           | 41             | 41             | 23            | 46            |
| 5             | 37           | 44           | 48             | 44             | 38            | 45            |
| 6             | 33           | 41           | 40             | 40             | 38            | 41            |
| 7             | 22           | 26           | 28             | 27             | 24            | 26            |
| 8             | 24           | 30           | 35             | 35             | 36            | 34            |
| 9             | 40           | 37           | 45             | 39             | 34            | 36            |
| 10            | 25           | 30           | 42             | 27             | 24            | 26            |
| 11            | 42           | 38           | 59             | 42             | 38            | 39            |
| 12            | 23           | 32           | 27             | 33             | 23            | 32            |
| 13            | 23           | 36           | 26             | 29             | 23            | 27            |
| 14            | 61           | 56           | 58             | 57             | 30            | 28            |
| 15            | 36           | 37           | 29             | 39             | 33            | 37            |
| 16            | 27           | 43           | 59             | 43             | 56            | 43            |
| 17            | 26           | 38           | 47             | 38             | 21            | 32            |
| 18            | 28           | 46           | 41             | 49             | 20            | 42            |
| 19            | 31           | 32           | 42             | 34             | 24            | 34            |
| 20            | 34           | 41           | 45             | 40             | 34            | 43            |
| Average score | 31.7         | 38.7         | 41.4           | 38.95          | 29.65         | 36.35         |

**Table 4.1: Results of Spielberger State Trait Anxiety Inventory**

Pre-op = 1 week prior to surgery, Surgical = immediately prior to surgery, post-op = 1 week after surgery

The average trait anxiety score remained similar from 1 week pre-op (38.7) to 1 week post-op (36.35) including data taken immediately pre-op (38.95). The scores ranged from 26 to 50 which demonstrates the variation among anxiety levels in a group of individuals. (Table 4.1)

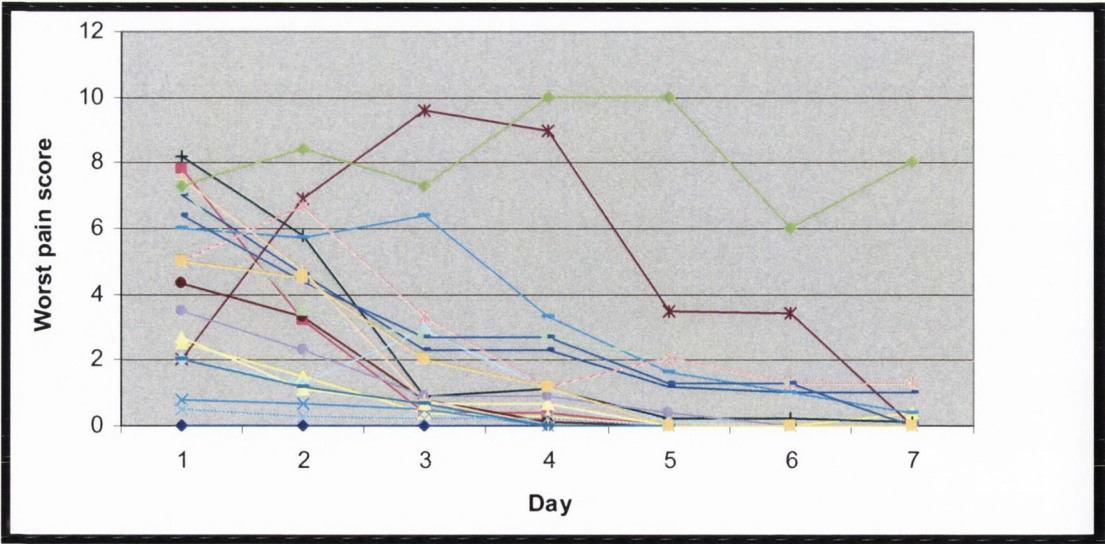


The average state anxiety scores rose from 31.7 1 week preoperatively to 41.4 immediately prior to surgery and then reduced to 29.65 one week postoperatively. (Table 4.1)

Hardly surprisingly significant positive correlations were found using the Spearman Rank non parametric test for preoperative trait (spielberger test taken 1 week before surgery) and preoperative state anxiety ( $\rho = 0.5713, p = 0.0106$ ); surgical state (spielberger anxiety test immediately prior to surgery) and preoperative state ( $\rho = 0.6167, p = 0.0049$ ); surgical state and preoptrait ( $\rho = 0.5329, p = 0.0188$ ); surgicaltrait and preoperative state ( $\rho = 0.6868, p = 0.0012$ ); surgical trait and preoperative trait ( $\rho = 0.9467, p < 0.0001$ ); surgical trait and surgical state ( $\rho = 0.5816, p = 0.009$ ); postoperative state (anxiety Spielberger scores on 7th day post op) and preoperative state ( $\rho = 0.5044, p = 0.0276$ ); postoperative trait and preoperative trait ( $\rho = 0.7482, p = 0.0002$ ); postoperative trait and surgical trait ( $\rho = 0.7228, p = 0.0005$ ); postoperative trait and postoperative state ( $\rho = 0.4443, p = 0.0567$ ).

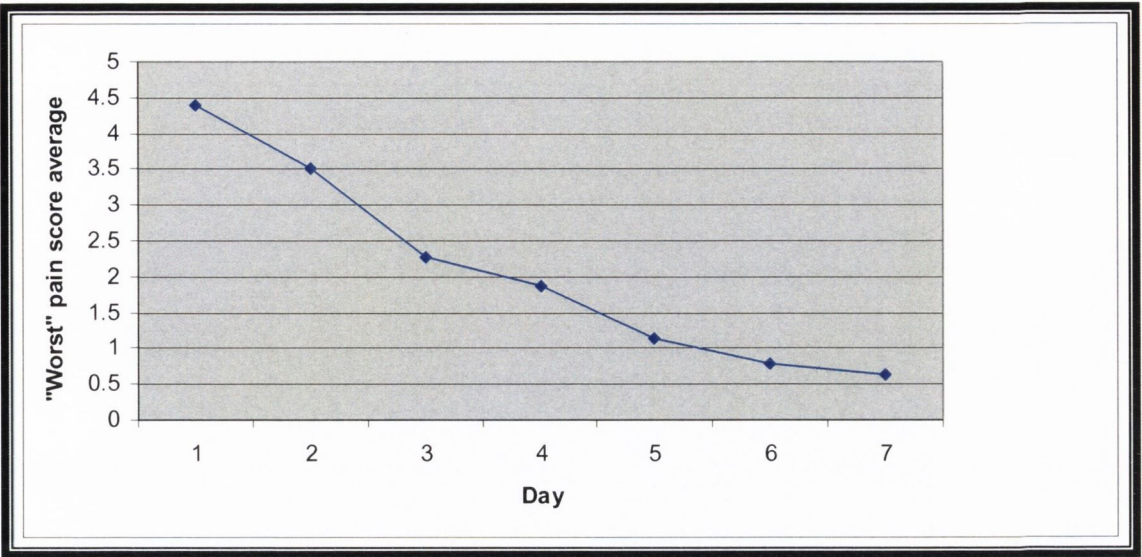
#### 4.9.2 Pain

Each patient was asked to record the worst pain they experienced in each 24 hour period using a 10cm line as a VAS. Figure 4.5 and 4.6 depict the data recorded.



**Fig 4.5: Each patient’s worst pain score using VAS (max score of 10) for each of the 7 post operative days. Each coloured line corresponds to one patient**

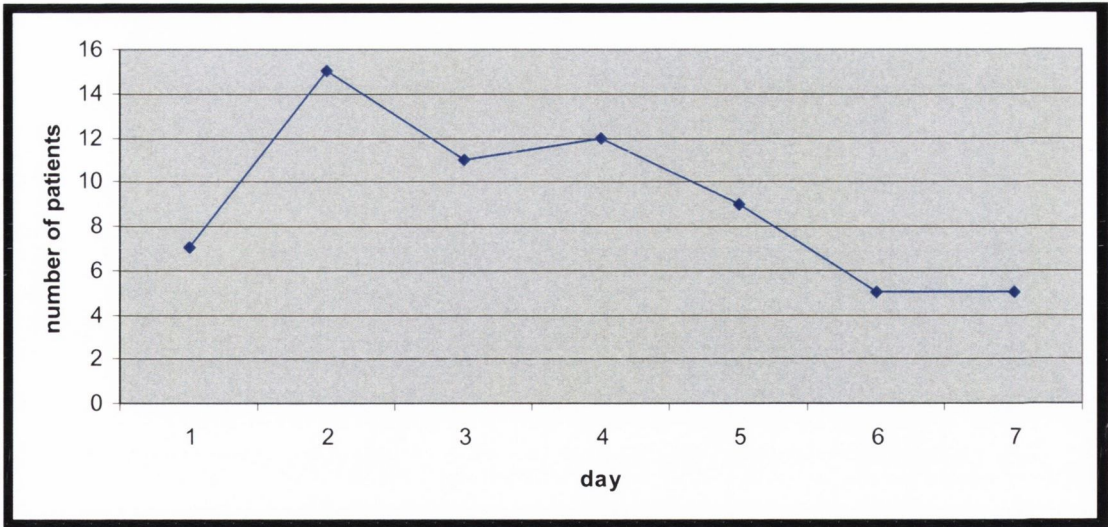




**Fig 4.6: Average recording for worst pain each day when considering all patients on each day**

For the majority of patients the pain was at its worst on day 1( the day of surgery but after the surgery) and decreased gradually over the following 6 days to minimal pain levels or no pain by day 7. 3 patients experienced a higher level of pain between day 3 and 4. One patient continued to experience significant pain on day 7.

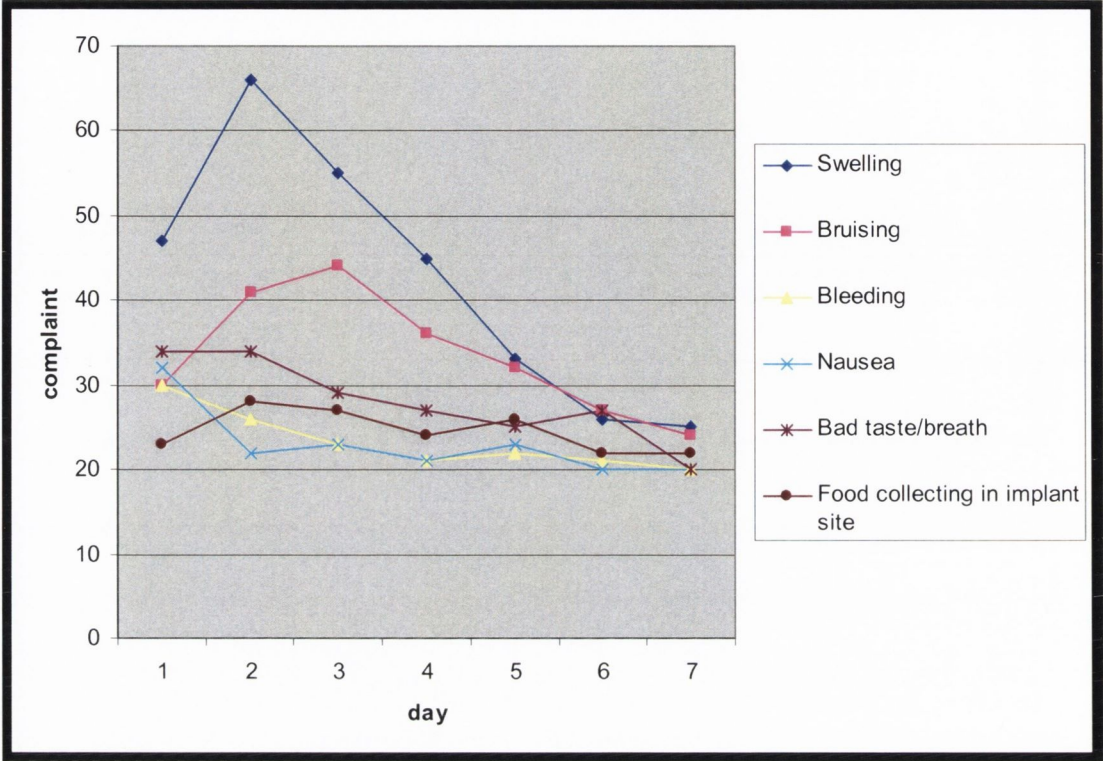
**4.9.3 Requirements for analgesics.**



**Fig 4.7: Number of patients requiring analgesics on each of the 7 post operative days**

The requirement for analgesics was highest on day 2. On each day some patients did not require analgesics i.e. 20 patients were included in this analysis but the greatest number of patients to need analgesics amounted to 15 on day 2.

4.9.4 Postoperative sequelae

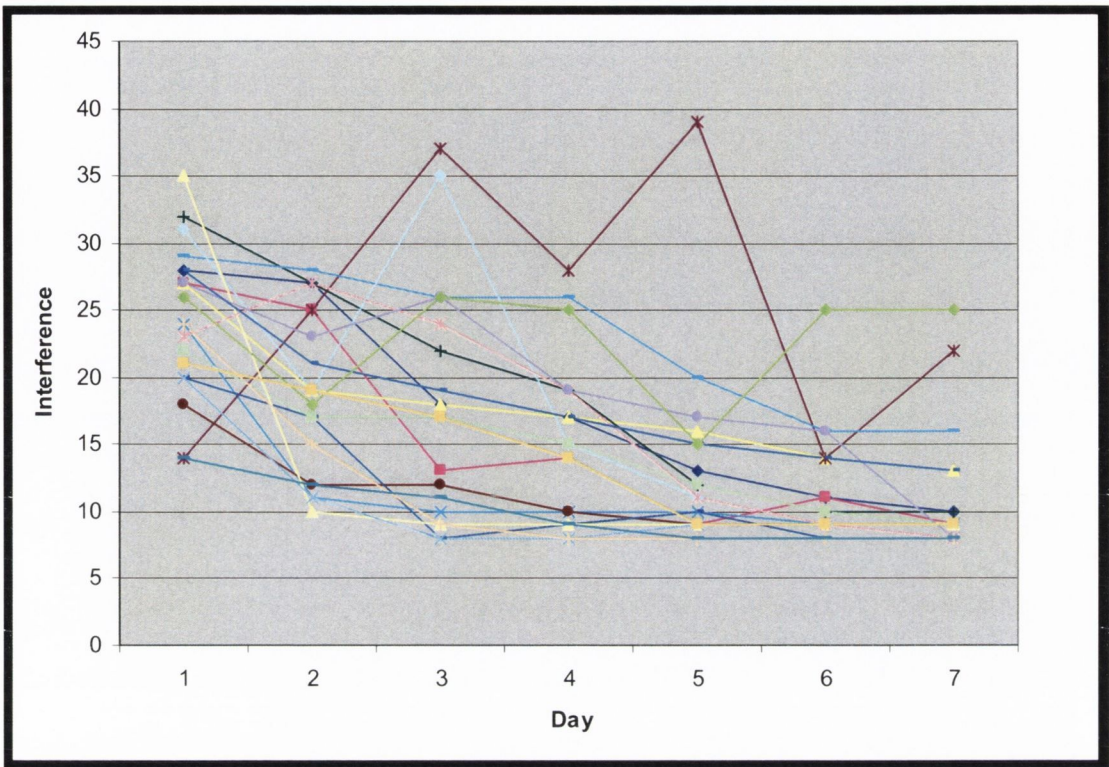


**Fig 4.8:Severity of each symptom when considering all patients together on each of the seven days post operatively (Max score 100, Min score 20)**

Patients were asked to document various symptoms each day for seven days following surgery. Each symptom received a score from 1 to 5. 1 indicated an absence of that symptom and a score of 5 was the maximum score demonstrating the extreme extent of a symptom's presence. 20 patients correctly completed the questionnaire and were included in this analysis. The scores for each symptom were added for each day. Therefore, the minimum score possible was 20 indicating an absence of that symptom in every patient for that day. A maximum score of 100 for each symptom was possible. Symptoms in general decreased in severity over 7 days, especially after day 3. Swelling and bruising were the most common symptoms reported and these tended to be worse on day 2 than day 1. Some patients experienced nausea on day one but on subsequent days it was mostly absent. By day seven, no patients suffered from nausea, bleeding or bad taste and halitosis. (Fig 4.8)



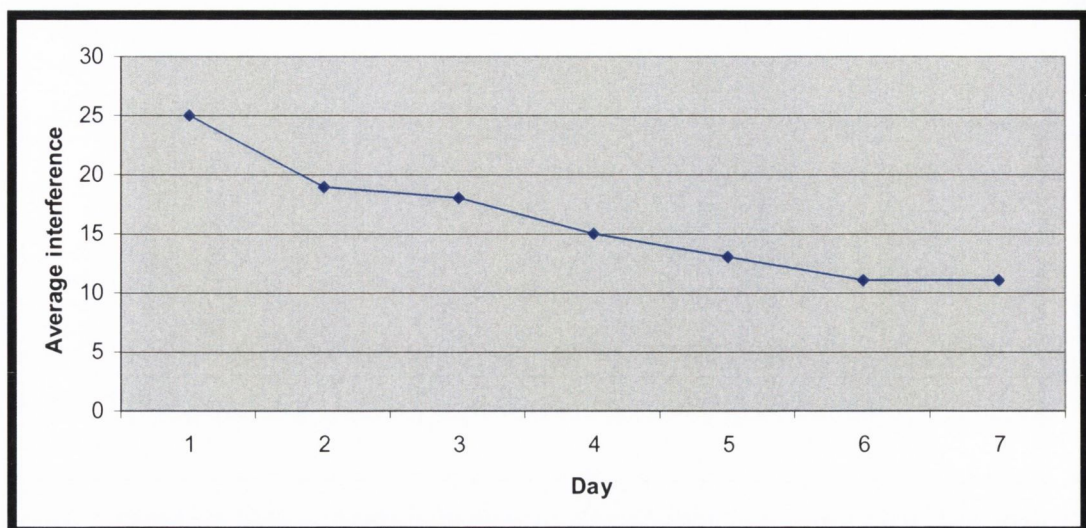
4.9.5 Interference with daily activities



**Fig 4.9: Score for interference with daily activities for each patient on each of the 7 post operative days. Each coloured line corresponds to each different patient.**

The interference score for each patient on each day was calculated by adding the scores indicating the extent of interference endured by the patient in relation to 8 individual daily activities. A score of 1 indicated no interference and 5 indicated maximal interference. Therefore a minimum score of 8 indicated that the patient experienced no interference with any daily activities on a particular day after surgery. A maximum interference score of 40 was possible on each of the post operative days.





**Fig 4.10: Average interference with daily activities when considering all patients on each of the 7 post operative days**

20 patients correctly completed a diary of interference over the 7 days post implant placement. On average the level of interference with daily procedures decreased over the seven days post implant placement. A minimal level of interference, on average, was found by day 6. Most patients at this stage were able to carry out daily activities as they normally would. However 2 patients continued to have interference scores greater than 20 on day 7. (Fig 4.9 & 4.10)

#### **4.10 Patient satisfaction**

The patient satisfaction score had a maximum score of 30. 13 patients were 100% satisfied with their restoration. This was based on 3 combined visual analogue scale scores which were used to answer the following 3 questions.

1. How do you rate the appearance of your implant/implants?
2. How do you feel about your speech since receiving the implant/implants?
3. How do you feel about your chewing ability since receiving the implant/implants?

Each VAS had a maximum score of 10. 16.4 was the lowest satisfaction score recorded. The average score for satisfaction was 26.4.

One patient out of the 25 patients said the implant did not feel like a natural tooth when chewing but otherwise it was no different to a natural tooth.

14 patients gave the maximum score of 10 using a VAS when asked to rate how worthwhile the overall experience was. The average score for this question was 9.5.

2 patients said they would not be 100% willing to undergo the procedure again using the knowledge of what is involved having experienced the treatment.

All patients said they would recommend the treatment to others.

#### **4.11 Relationship between anxiety, pain, interference, worthwhile experience and satisfaction scores**

A regression model was used for the relationship between patient satisfaction with the treatment outcome, patients' opinion as to whether the treatment had been a worthwhile experience, anxiety levels, pain perception and interference with daily activities. Patient scores of worthwhile experience (whether the patient felt it was a worthwhile experience when asked at 3 to 6 months after final restoration) did not correlate to either state or trait anxiety or pain experience. Furthermore, pain experience did not correlate to anxiety levels. There was a significant tendency for pain levels to negatively correlate with satisfaction, although this tendency was not marked for the majority of patients. ( $p \leq 0.04$ , *spearman rho* -0.3867) There was a tendency for patient experience scores to correlate negatively with interference scores, although this was only slight. A strong correlation was found between satisfaction levels and worthwhile experience scores.

A regression model controlling for the number of implants placed in patients was used to study the relationship between satisfaction and patient experience as dependant variables and pain experience as the independant variable. Again satisfaction levels were found to be significantly associated with patient experience ( $p=0.0024$ ). No other significant relationships unfolded.

#### **4.12 Clinician satisfaction**

Due to the design of the Integrated Abutment crown, no marginal gaps on any restoration were found by either examiner. Examiner1 found 33 of the restorations to

have correct anatomical form, 9 to have acceptable but slightly defective anatomic form and 3 to have unacceptable anatomic form. Examiner 2 found 34 implants to have excellent anatomic form, 4 to be acceptable but slightly defective and 7 to be unacceptable. Examiner 1 found 32 implants to have excellent surface texture, 13 were slightly dull and none were rough or pitted. Examiner 2 found only 11 implants to have the ideal texture, 33 were slightly dull and 1 was rough and pitted. Examiner 1 reported that 24 restorations were an excellent colour match when compared to adjacent teeth and 21 were acceptable. There were no restorations with a severe colour mismatch. Examiner 2 reported that 12 restorations were an excellent colour match to adjacent teeth, 32 were acceptable and 1 had a severe colour mismatch. Overall, when considering marginal gap, anatomic form, surface texture and colour match, examiner 1 found 17 restorations to be excellent and the remainder were acceptable and examiner 2 found 5 restorations to be excellent. Examiner 1 found 3 restorations to be unacceptable. Examiner 2 found 8 restorations to be unacceptable. The overall grade of “unacceptable” was due to either colour mismatch, rough or pitted surface or incorrect anatomic form or a combination of these. Incorrect anatomic form was given, however, to some restorations due to a distal space between the restoration and the next tooth. However, in most circumstances this was due to a space which was too small for two fixtures but too large for one and the decision had been made to place only one implant and to accept a distal space. One IAC fractured at placement along the distal proximal surface and was repaired at chairside. On the day of the independent clinician examination this repair had once again fractured resulting in the lack of a distal contact point. The IAC which examiner 2 found to have a severe colour mismatch was considered to be satisfactory by the patient and she did not request a replacement.



4.13 Correlation between patient satisfaction scores and clinician satisfaction scores.

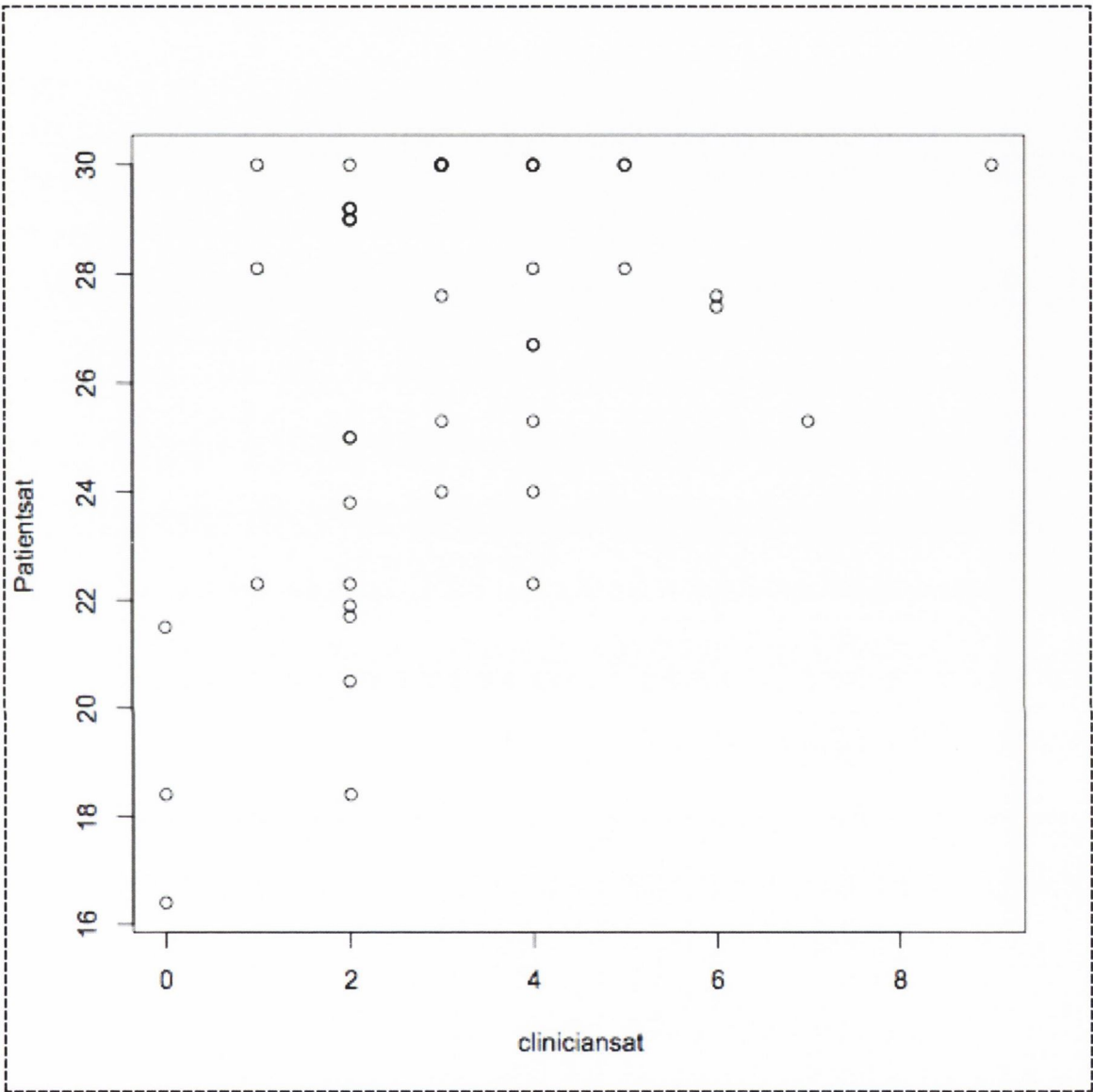


Fig 4.11 : Patient satisfaction scores vs. Clinician satisfaction scores

A plot of the patient satisfaction scores vs clinician satisfaction scores was created. The scores were not strongly correlated. The correlation coefficient (Spearman rank)  $\rho$  was equal to 0.382 ( $p\text{-value} = 0.009$ ) This result, although statistically significant, is modest in terms of the relationship between clinician satisfaction and patient satisfaction.

## **Chapter 5**

### **Discussion**

This prospective cohort study aimed to evaluate the success of the Bicon implant system in the short term when using short implants, analyse patient experience in relation to implant placement and evaluate patient satisfaction with the ultimate outcome of treatment. In addition, the study examined the interplay between patient anxiety, the experience as perceived by the patient of the treatment and their satisfaction with the outcome of treatment. The patient's satisfaction with the outcome of treatment was then compared to two independent clinician's opinions regarding the aesthetic outcome of the implant therapy.

An implant survival rate of 98% was found in this study over a follow up period of 3 to 6 months after placement of the final restoration using 45 short and wide hydroxyapatite (HA) coated Bicon implants restored with Integrated Abutment Crowns (IAC) in 25 patients. In general single unit implant survival rates over 5 years have been shown to be 95% and greater (Jemt & Lekholm, 1993, Bahat, 1993, Gentile et al. 2005). Longer term studies over 20 years have reported implant cumulative success rates of 98.9% (Ekelund et al. 2003).

The implants in this study were short and wide. The three implant sizes used were 4.5 x 8mm, 5 x 6mm and 6 x 5.7mm implants. Despite some previous research, which indicated short implants to be associated with higher failure rates (Jemt & Lekholm, 1993, Bahat, 1993, Lekholm et al. 1994), quite an extensive body of research exists to the contrary (Teixeira et al. 1997, ten Bruggenkate, 1998, Tawil et al. 2003, Griffen et al. 2004, Gentile et al 2005, Arlin, 2006, Misch, 2006, Romeo, 2006, Anitua et al. 2008). The majority of these studies had a follow up time ranging from 1 to 5 years. However Romeo (2006) demonstrated a 14 year cumulative survival rate of 97.9% for 8mm titanium plasma sprayed (TPS) or sandblasted Strauman implants and a 97.1% survival rate for 10mm implants when used both as single and multi unit restorations.

The survival rates of wider implants have been documented to be poorer than regular implants by Ivanoff et al. (1999) and Eckert et al. (2001), however these authors suggested that a learning curve, poor bone quality and changed implant design were contributing factors. In addition, the possibility of placement of wider fixtures as "rescue" implants in compromised situations cannot be overlooked in retrospective studies. Recent studies indicate wide implants to be a viable option when planned from



the outset (Degidi et al. 2007, Krennmair 2004) and can in fact improve functional and aesthetic aspects such as increasing the seating surface of the implant and facilitating a better emergence profile (Davarpanah et al. 2001).

Despite the short follow up time of 3 to 6 months following final restoration the survival rate of 98% in this study clearly demonstrates short, wide implants as a viable treatment option. Such implants are of particular benefit to the clinician when faced with a situation of limited vertical height under the maxillary sinus or above the inferior dental nerve canal. The greater surface area afforded by the wider implant more than compensates for the shorter vertical height (Griffen et al. 2004).

One implant failed at 4 months following final restoration. This implant was in the maxillary canine region of a patient with a previous history of aggressive periodontitis. Although the evidence from previous publications is inconclusive (Al-Zahrani et al, 2008), some research indicates patients with previous histories of aggressive periodontitis to be at a greater risk of implant failure (Anitua et al. 2008) Regarding the patient in this study, the crown:implant ratio was greatly increased due to a loss in vertical bone height due to previous periodontal destruction. However, in a study carried out by Schulte et al. (2007) a survival rate of 98.2% at 2.3 years using single unit Bicon implants was found with crown to implant ratios ranging from 0.5:1 to 3:1. In addition, the patient in this study was a smoker. Local bone was classified as type III. Initial osseointegration was achieved. No clear reason for the failure of this implant was identified however any one or a combination of the above factors may have been causative. McDermott et al. (2003) found smoking, one stage implant placement procedures and reconstructive procedures to be associated with an increased risk for overall complications. Woo et al. (2004) found smoking, implant length, implant staging and type of prosthesis to be associated with implant failure. Gentile et al. (2005) in a study using Bicon implants found only implant staging to be statistically associated with implant failure. Other studies demonstrate the impact of poor bone quality on implant failure rates. (ten Bruggenkate et al. 1998, Tawil et al, 2003). Due to the limited number of patients in the present study, it was not possible to statistically investigate potential risk factors for implant failure.

Müftü & Chapman (1998) found a cumulative implant survival rate of 90% for the maxilla and 96.8% for the mandible in a prospective four year study of 432 posterior

single unit Bicon implants with cemented restorations. The results of the present study over the shorter term are superior to this, although, comparable to a retrospective cohort study of 889 single tooth Bicon implants placed in 294 patients and followed over a mean time of 2.3 years with a survival rate of 98.2% (Schulte et al. 2007) Gentile et al. (2005) found a one year survival rate between 92% and 95% in a retrospective study of Bicon implants.

Many studies incorrectly use the term “implant success” to denote the presence of an implant which is more accurately described as “implant survival”. Criteria for implant success should be clearly stated and should include aspects of function, aesthetics and patient satisfaction. Using the criteria for success as outlined by Albrektsson et al. (1986), two implants in the present study could be regarded as unsuccessful. One implant, as discussed above, was no longer integrated at 4 months post restoration and was mobile. This implant was removed. The second implant demonstrated 3.2mm marginal bone loss at second stage. This is substantially greater than the 1 to 1.2mm peri-implant marginal bone loss in the first year following restoration which has been commonly expected in the past (Adell et al. 1981, Albrektsson et al. 1986, Quirynen et al. 1992). However this implant remained in function with no mobility or related pathology. There was no bleeding on probing and no suppuration. Furthermore, the patient was satisfied with the outcome (satisfaction score of 29.2/30) and the clinician satisfaction score indicated an acceptable restoration. Shortly after implant placement this patient was hospitalised due to an exacerbation of ulcerative colitis and was placed on steroid medication for several months. Although according to Albrektsson’s criteria and previous research indicating the bone loss on this implant to be indicative of implant failure, all other aspects of success are present. Therefore, it could be stated that there was only one true implant failure in this study in terms of implant success. All other implants were immobile and integrated at 2<sup>nd</sup> stage and remained integrated and in function at 3 to 6 months after final restoration. There were no related pathologies, no peri-implant radiolucencies, no infection, pain neuropathies, paraesthesias or violations of the mandibular canals. Care should be taken when comparing the marginal bone loss results of the present studies to previously accepted bone loss of 1 to 1.2mm in the first year following implant placement in other studies due to the use of different implant designs. Such studies were investigating implants which were not submerged to a depth



of 3 mm below the crestal bone. In addition, such studies often involved implants with smooth collars.

71% (n=32) of implants demonstrated no bone loss from the time of implant placement to 3 to 6 months after final restoration when marginal bone heights from the level of the first plateau to the head of the fixture were measured radiographically. 28.8% (n=13) of implants had an average bone loss of 0.44mm over the study period. One implant, as discussed above, had 3.2mm of bone loss. The Bicon implant system protocol requires the implants to be submerged at least 3 mm below the bone crest. Although it was felt in most cases that this had been achieved clinically (unfortunately clinical measurements of depth of placement were not carried out at implant placement), radiographic measurements of periapical x-rays taken immediately post-operatively indicated that the average depth of submergence of the implants was in fact only 1.8mm. Four implants were actually placed slightly supracrestally. A record of this was documented and related to a difficulty at the time of surgical placement. Difficulty preparing the osteotomy site in type I bone in one case was recorded and difficulty when attempting to fully seat two other implants in type II bone was documented. Three of these implants demonstrated bone gain over the study period.

The method of measurement of marginal bone height in this study included strictly the bone level immediately adjacent to the sloping shoulder of the implant. Changes in bone height in the interproximal areas were not considered in this measurement. This fact must not be overlooked. By virtue of the implant system design with an inwardly sloping fixture shoulder, narrow abutment post extending from the fixture head to the crest of the bone and a hemispherical shape to the abutment base, bone loss may have been apparent along the fixture shoulder but may have remained stable or even increased in the interproximal areas. In addition, the location of a locking tapered 1.5 degree implant abutment connection with an absence of bacterial leakage along a microgap (Dibart et al. 2005) and minimal micromotion away from the crest of the alveolar ridge and the use of a platform switching design (Lazarra et al, 2006) may have resulted in less crestal bone resorption as suggested by previous researchers such as Jansen et al. (1997), Hermann et al. (2001) and King et al. (2002). However other researchers (Heijdenrijk et al. 2006) suggested that functional stress may be of greater importance. Quirynen et al (2002), in a review of the literature, suggested that crestal



bone loss may be the result of an interplay between various factors such as the host defence mechanism, duration of infection and implant system design. Omitting measurement of this aspect of marginal bone levels is a shortcoming of this study. This feature of the Bicon implant system is suggested by the manufacturer to be of importance in facilitating good papilla support in the interproximal areas which has been shown to be important for papilla preservation and maintenance (Choquet et al. 2001). Two independent clinicians individually found less than 12% of both mesial and distal papillae respectively to fill less than half the area to the contact point. Papilla preservation or creation in previously edentulous areas can be difficult to achieve. The design of the Bicon implant and IAC restoration appears to be advantageous in this respect.

A significant relationship between the depth of submergence of the fixture and bone loss at 2<sup>nd</sup> stage and at 3 to 6 months after final restoration emerged as a coincidental finding in this study. This relationship was highly significant at the final 3 to 6 month post restoration recording. This finding highlights the importance of a 3mm submergence of the Bicon fixture at implant placement in order to limit the potential for ongoing marginal bone loss.

From the point of view of the patient's satisfaction with the treatment outcome, the implants placed in this study were successful with the exception of the implant which was removed at four months due to mobility and lack of integration. However, this patient completed the satisfaction questionnaire prior to failure of the implant and was therefore included in the results. Overall, patient satisfaction was high with 13 patients being 100% satisfied with their restoration. The average score for satisfaction was 26.4 out of a maximum score of 30. This patient satisfaction score took into consideration the patients' satisfaction with aesthetics and function in terms of both speech and chewing. The patients were also asked if they felt that the entire experience had been worthwhile. The results indicated a positive attitude towards the entire experience with an average score of 9.5 out of a maximum score of 10. Only 2 patients said they would not be 100% willing to undergo the procedure again using the knowledge of what is involved. All patients said they would recommend the treatment to others. There are few studies available in the published literature investigating patient's satisfaction with dental implant placement and restoration. However, the results of available studies reflect

similar patient satisfaction levels to those found in the present study (Chang et al. 1999, Pjetursson et al. 2004, Palmer et al. 2007). Patient satisfaction with implant therapy based on these studies is high with 93.9% of patients in one study (Pjetursson et al. 2004) willing to undergo the treatment again if necessary. Palmer et al. (2007) found that all patients were maximally satisfied with their implant restorations from an aesthetic point of view. Of note, Pjetursson et al, (2004) found both VAS and questionnaires to be effective methods of determining patient satisfaction. In the present study a mixture of both were used.

Pain and anxiety during implant therapy may influence the patient's opinion of ultimate satisfaction with the treatment outcome, perhaps more notably in terms of whether they consider the outcome to have been worthwhile. Assessment tools of pain measurement alone can lead to false conclusions due to the fact that an element of pain is due to the individual's perception of pain. Pain perception is related to behavioural and psychosocial aspects of the individual character (Gracely et al. 1978, Eli et al. 2003). For this reason the Spielberger State Trait Anxiety Inventory (Spielberger 1970) was used in the study in addition to visual analogue scales demonstrating the patient's pain experience and daily accounts of interference with routine activities. Physical side effects of surgery were also recorded by the patient on a daily basis, as was their requirement for analgesics.

Average trait anxiety levels remained constant throughout the study and demonstrated a range of scores representing individual variability in anxiety levels similar to findings in other studies (Scott et al, 1982). However, state anxiety levels increased from the 1 week pre operative average STAI score of 31.7 to an immediately pre-operative score of 41.4. The state anxiety score then decreased to a one week post-operative score of 29.65. Similar results were found in a study carried out by Hashem et al. (2006) which investigated pain and anxiety related to dental implant placement. Likewise, similar results were reported in a study by Eli et al. (2003).

In the present study Spearman rank tests indicated significant positive correlations between state and trait anxiety tests indicating that a patients' anxiety levels before and after surgery are closely related to their general levels of anxiety. This is of potential benefit to the clinician in terms of predicting the patient who will be more likely to



experience high levels of anxiety in the peri-operative period. By identifying these patients, the clinician could then decide whether there is a need for sedative medication prior to the surgical procedure. The sample size in the present study was small and predominantly female and therefore prevented an analysis of differences between male and female anxiety levels.

Similar to other studies (Al-Khabbaz et al. 2007, Hashem et al. 2006) pain associated with implant placement was mild to moderate, peaking in the first 24 hours and reducing to a minimal level by day 7. However, the number of patients requiring analgesics was substantially greater on day 2 after surgery. A decrease in the number of patients requiring analgesics after day 4 occurred. Unfortunately due to the fact that patients could not be prevented from taking analgesics for ethical reasons, a clear pattern of postoperative pain levels cannot be determined. It is interesting to note that there was no significant correlation between pain and anxiety levels indicating, contrary to common belief (Eli et al. 2003, Sokol et al, 1985), that anxiety levels did not result in greater pain perception.

Patients completed a questionnaire indicating the extent of various common post-operative sequelae, the most common of which were swelling and bruising. A maximum score was calculated for each sequelae on each consecutive day by adding each individual's score for that particular sequelae. Most sequelae peaked on day two post operatively with the exception of nausea which was worse on day one and bruising which was worse on day 3. By day seven minimal post-operative sequelae were remaining. The pattern of these results is in agreement with those found by Hashem et al. (2006) and Al-Khabbaz et al. (2007). Post operative sequelae following implant placement are in general mild to moderate over the first three postoperative days and then reduce to a minimal level over the remaining week.

Due to post-operative pain, possible anxiety and uncomfortable sequelae, the patient may experience an inability to carry out certain daily routines. This interference can vary in its extent. This was found in this study. The maximum average interference score occurred on day one. This score was 25 out of a possible 40 which indicates a moderate level of interference. After day four the extent of interference with daily activities was, on average, minimal. Once again, these results compare favourably to the



study carried out by Hashem et al. (2006). Interestingly, no correlation was found statistically between interference with daily activities and pain experience.

A clinician has a responsibility to inform the patient of what to expect following implant placement to allow the patient to come to an informed decision regarding their desire for treatment. The absence of an informed decision may lead to dissatisfaction.

Statistical analysis demonstrated that neither state/trait anxiety nor pain experienced on day 1 following implant placement had any bearing on the patient's opinion as to whether the outcome of treatment was worthwhile or not. There was a significant tendency for higher pain levels to correlate with lower levels of satisfaction with the treatment outcome. However, this was not marked for the majority of patients with the average score for satisfaction being 26.4 out of a maximum score of 30. In addition, there was a significant, although slight, tendency for patients to feel that the outcome of treatment was less worthwhile as the level of interference with daily activities increased. When controlling for the number of implants placed, a positive relationship between satisfaction levels and patient's opinion of how worthwhile the treatment had been was the only significant relationship found. These results indicate that despite a slight effect of an unpleasant experience on patient satisfaction with the treatment outcome, patients in general were contented with their treatment and the number of implants placed was irrelevant with regard to their overall satisfaction and experience.

The unique design of the Bicon Integrated Abutment Crown (IAC) consisting of a chemomechanical bond between a light cured highly filled composite resin and the coronal portion of a titanium alloy abutment, has various potentially advantageous design features over the commonly used porcelain restoration. Surface roughness, marginal fit and contour of crown margins were three factors identified by Sorensen et al. (1989) to have an important influence on plaque accumulation and gingival health at the tissue-restoration interface.

The IAC "all in one" design eliminates the need for cement or screw retention of the coronal restoration and associated complications such as excess cement subgingivally potentially causing inflammation and periimplant bone loss (Wannfors & Smedberg, 1999, Weber et al., 2006) screw fracture (Ekfeldt et al. 1994), limited access for screw

placement, interference with occlusion and compromised aesthetics. One of the components of the modified United States Public Health Service Criteria which were used in this study by two independent clinicians to assess the IACs comprises evaluation of the presence of a marginal gap. Not surprisingly neither examiner found any marginal gap to be present on any of the IACs.

Plaque accumulation on composite resin fillings has been shown to be higher than that on natural teeth within the same subject. (Larato, 1972) This was clearly suggested in the present study. The average full mouth plaque score excluding porcelain surfaces was 24.5% with a range from 2% to 62%. The average plaque score for integrated abutment crown composite surfaces was 36.1% with a range from 0% to 83%. An average of 11% of the full mouth plaque score was located on the integrated abutment crowns. In patients who had porcelain restorations elsewhere in the mouth only 5.6% of those surfaces had plaque. 8 out of a total of 12 patients with porcelain restorations had no plaque on the porcelain surfaces. This highlights the benefit of porcelain restorations in terms of minimal plaque accumulation and corresponds to results of previous studies indicating porcelain surfaces to be even less plaque retentive than natural teeth (Chan & Weber, 1986). Despite the potential for plaque accumulation on the IAC surfaces, 2 independent clinicians found 67% and 86% of the implants to have no inflammation or very slight inflammation respectively, indicating an overall healthy gingival condition adjacent to IAC restorations.

A disadvantage of porcelain restorations is the excessive wear of the opposing dentition. The composite material of the IAC system claims to have a similar wear rate to tooth enamel. In addition the composite manufacturers (Shofu Dental Corporation) claim that the material has good flexural and compressive strength, a refractive index similar to natural teeth, good colour stability, good viscosity and modelling properties and good polishability minimising plaque accumulation. Long term clinical studies however are lacking.

Over the short period of follow up time of the present study, the two independent examiners found 13 and 32 implant surfaces respectively to be slightly dull. It appeared that the commonly found glossy appearance of the porcelain surfaces was not as apparent on the composite surfaces.



Using the modified United States Public Health Service criteria two independent clinicians assessed the IAC restorations in terms of marginal gap, anatomic form, surface texture and colour match. Clinician 1 found 17 restorations to be excellent and 25 to be acceptable. Clinician 2 found 5 restorations to be excellent and 32 to be acceptable. The remainder were deemed unacceptable due to defective anatomic form such as the absence of a contact point, a severe colour mismatch or a rough or pitted surface. However, regarding the absence of a contact point, in the majority of cases this was due to the absence of an adjacent tooth or an edentulous space which was too large for a single restoration but too small for two restorations. In these cases it was decided preoperatively to accept the absence of a distal contact point. When placing one of the 45 IACs a fracture occurred along the distal aspect of the tooth. A chairside repair was carried out at the time of placement, however, on the day of examination this had once again fractured. Although this repair had failed, one of the benefits of the Bicon IACs is the ability to restore what would otherwise have been considered an unacceptable restoration at the chairside both intraorally and extraorally but this may be quite technique sensitive. Another restoration was deemed to have a severe colour mismatch. However, this patient was more than satisfied with the implant restoration and in the absence of any other defects it was decided to accept the restoration.

Interestingly, Spearman non-parametric tests showed that patient satisfaction with the outcome of treatment was not strongly correlated to the opinion of the clinician with regards to the aesthetic quality of the IACs. Similarly, when Chang et al. (1999) compared a clinicians opinion regarding the aesthetics of a restored implant to its contralateral tooth and patient satisfaction with the implant restoration, it was concluded that what a clinician may perceive as a pertinent difference or inadequacy may be insignificant in the eyes of the patient. Palmer et al. (2007) and Jemt et al. (1997) suggested that soft tissue contour can improve over time. Unfortunately the follow up time of the present study is short.

The patient sample group in this study is limited to a total of 25 patients. The implant sample group consisting of 45 implants however is substantial but due to the fact that some patients received multiple implants the power of this implant number was reduced. The follow up time after final restoration is short which perhaps has less of an



effect on the “patient experience and satisfaction” aspect of the study than on the survival and success rate analysis and IAC success evaluation. Marginal bone levels were assessed using non-standardized radiographs and measurement analysis was limited to the area of the shoulder of the implant. Peri-implant probing depths are commonly reported in other research and considered a diagnostic sign when combined with other signs such as bleeding or suppuration of periimplantitis. Due to the design of the Bicon implant system, incorporating a submerged implant with platform switching consisting of a narrow abutment post connecting the fixture head to a hemispherical abutment base, accurate probing pocket depths were difficult to determine and had limited reproducibility. For this reason their validity in this study was questioned and a decision was made to omit them. Finally, the inclusion of a control would have greatly increased the value of this study. Ideally each patient should have received two different implant designs to demonstrate a true advantage or disadvantage of the Bicon implant system.

Despite these limitations, this study demonstrates the success of the Bicon implant system short and wide implants restored with Integrated Abutment Crown restorations in the short term, extensively describes the implant placement experience and highlights the interplay between experience, anxiety and satisfaction from the patient’s perspective. This knowledge enables the clinician to satisfactorily carry out clinical decision making when devising a treatment plan and to deliver accurate information to the patient of what to expect following treatment in terms of both experience and satisfaction as evidenced by clinical research. It must be remembered, however, that this study has a limited follow up time and further research is needed to evaluate this system over the longer term.

# **Chapter 6**

## **Conclusions**

- The Bicon Implant System which features a hydroxyapatite coated plateau root form press fit implant with sloping shoulders and utilises the platform switching concept at its screwless 1.5 degree Morse taper implant abutment connection is a truly successful system, at least in the short term. Further longer term studies are needed.
- Short Bicon implants with widths ranging from 4.5mm to 6mm are a viable treatment option. Such implants provide the clinician with an alternative to more extensive surgical procedures such as sinus lifts or inferior dental nerve repositioning in situations with limited vertical bone height.
- The Bicon implant system protocol involves placement of the fixture 3mm below the crest of the alveolar bone. This study demonstrated that as the depth of submergence of the implant decreases from 3mm the greater the likelihood is of marginal bone loss at 3 to 6 months following placement of the final restoration.
- The Bicon system appears to facilitate good interproximal papilla support which has a dramatic effect on the aesthetics of an implant restoration.
- The screwless, cementless Integrated Abutment Crown is a satisfactory restoration in the short term, proving to be aesthetically pleasing and facilitating maintenance of healthy gingival tissue.
- Plaque accumulation may be a disadvantage of the composite Integrated Abutment Crown. This accumulation is more extensive than on a natural tooth surface and greatly increased when compared to a porcelain surface.
- Patients do not experience similar levels of dental anxiety and the extent to which an individual's anxiety levels increase before surgery is closely related to their trait anxiety levels. This fact provides the clinician with a tool to identify those patients who may benefit from treatment under sedation or who may not be suitable for surgical therapy.



- Anxiety levels are higher immediately prior to implant surgery than one week previous to surgery and one week following surgery. However, in general anxiety levels prior to dental implant placement are at most moderate.
- On average moderate levels of pain are experienced following implant placement which decrease to mild levels by day 3 and are minimal by day 7. The worst pain is experienced on day 1 (the day of surgery but after the surgery).
- Pain levels in this study did not relate to anxiety.
- The majority of patients require analgesics at some stage over the 7 days following surgery. The greatest number of patients requiring analgesics occurs on day 2. One quarter of patients continue to take analgesics on day 7 following surgery despite apparently minimal levels of pain experience at this stage. It must not be forgotten that pain level recordings may not have been completely accurate due to the fact that the patients could not have been prevented from taking the analgesics.
- Swelling and bruising are the most common post operative sequelae and these tend to be worse on day 2. Minimal postoperative sequelae are present by day 4.
- Interference with daily activities is greatest on day one after surgery (i.e. day of surgery but after the surgery). After day one there is a substantial decrease in interference which reaches a minimal level after day 4.
- This study demonstrates that patient satisfaction with implant therapy is high with a substantial portion of patients being 100% satisfied with their treatment. Few patients refuse to undergo the treatment a second time and all patients would recommend the treatment to others.
- Overall, patients felt the procedure to have been worthwhile irrespective of pain and anxiety endured.
- Satisfaction with treatment outcome was slightly negatively affected by pain and interference with daily activities but overall this effect was not marked.

- Patient overall satisfaction with the treatment outcome when considering both aesthetics and function did not strongly correlate with clinician opinion of anatomic form, colour match, marginal gap and surface texture standards. Clinician dissatisfaction with the final restoration does not necessarily imply patient dissatisfaction. A clinician has a duty to inform the unaware patient of any potential harm a particular deficiency may cause however every deficiency may not warrant replacement and patient satisfaction with the treatment outcome should be considered.

## **Chapter 7**

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## **Appendices**



## Consent Form

I \_\_\_\_\_  
of \_\_\_\_\_  
\_\_\_\_\_ consent to participate in the study evaluating the success of the Bicon implant system in the short term and patient experience during treatment. I understand that the information I provide will be treated in the strictest confidence, and I also understand that my name will not be mentioned in any reports of the study when the data I provided is published. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction.

I also understand that the study will not imply the use of new medications, nor involve any alteration of the routine surgical procedures.

Signature: \_\_\_\_\_

I have explained the nature, purpose, procedures and benefits of this study. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

Dentist's name:

Dentist's signature:

Date



# Patient Information Leaflet

Title of the study: An evaluation of the Bicon Implant System: Patient experience and short term success.

The purpose of this study is to evaluate patient experience in terms of pain experience and stress and anxiety following dental implant placement. Also the success of the system in the short term will be evaluated both clinically and radiographically by the clinician.

To evaluate patient experience there will be two questionnaires:

- 1) Visual analogue scale (VAS): is used to evaluate the intensity of pain following the operation, the questionnaire is to be filled on the day of the operation and six days following the operation.
- 2) Spielberger-self evaluation questionnaire: is used to measure the level of anxiety before and after the operation, the questionnaire is to be filled six days prior to the operation, on the day of operation, and six days following the operation.

You can fill both questionnaires at home.

For you to be able to participate in this study you have to be over 18 and healthy (i.e. No history of a serious systemic disease or regular use of medications).

**For women of child bearing age, should you become pregnant during this study you will be excluded from the study due to the need for further radiographic examination at specific time points. However your treatment will not be affected in any way and will be fully completed in due course avoiding radiographic examination or any unnecessary procedures during pregnancy.**

There will be a reduced cost for implants if you take part in this study.

**Alternative treatment options will be discussed with each patient at the time of initial assessment as these vary from patient to patient.**

There will be no risks to you from this procedure.

You will be excluded from the study if you are under 18 or if you are on medication for a chronic illness or if you are a chronic user of pain killers.

Your identity will remain confidential: your name will not be published and will not be disclosed to anyone outside the hospital.

**If you volunteer to participate in this study you may quit anytime.**

To get more information or answers to your questions about the study, your participation in the study and your rights, you can contact Dr. Emily Clarke at 01 6127200.

# Spielberger State Trait Anxiety Inventory

## SELF-EVALUATION QUESTIONNAIRE

Developed by C. D. Spielberger, R. L. Gorsuch and R. Lushene

STAI FORM X-1

NAME \_\_\_\_\_ DATE \_\_\_\_\_

**DIRECTIONS:** A number of statements which people have used to describe themselves are given below. Read each statement and then blacken in the appropriate circle to the right of the statement to indicate how you *feel* right now, that is, *at this moment*. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

|                                                            | NOT AT ALL | SOMEWHAT | MODERATELY SO |
|------------------------------------------------------------|------------|----------|---------------|
| 1. I feel calm .....                                       | ①          | ②        | ③             |
| 2. I feel secure .....                                     | ①          | ②        | ③             |
| 3. I am tense .....                                        | ①          | ②        | ③             |
| 4. I am regretful .....                                    | ①          | ②        | ③             |
| 5. I feel at ease .....                                    | ①          | ②        | ③             |
| 6. I feel upset .....                                      | ①          | ②        | ③             |
| 7. I am presently worrying over possible misfortunes ..... | ①          | ②        | ③             |
| 8. I feel rested .....                                     | ①          | ②        | ③             |
| 9. I feel anxious .....                                    | ①          | ②        | ③             |
| 10. I feel comfortable .....                               | ①          | ②        | ③             |
| 11. I feel self-confident .....                            | ①          | ②        | ③             |
| 12. I feel nervous .....                                   | ①          | ②        | ③             |
| 13. I am jittery .....                                     | ①          | ②        | ③             |
| 14. I feel "high strung" .....                             | ①          | ②        | ③             |
| 15. I am relaxed .....                                     | ①          | ②        | ③             |
| 16. I feel content .....                                   | ①          | ②        | ③             |
| 17. I am worried .....                                     | ①          | ②        | ③             |
| 18. I feel over-excited and "rattled" .....                | ①          | ②        | ③             |
| 19. I feel joyful .....                                    | ①          | ②        | ③             |
| 20. I feel pleasant .....                                  | ①          | ②        | ③             |



# **SELF-EVALUATION QUESTIONNAIRE** **STAI FORM X-2**

NAME \_\_\_\_\_ DATE \_\_\_\_\_

**DIRECTIONS:** A number of statements which people have used to describe themselves are given below. Read each statement and then blacken in the appropriate circle to the right of the statement to indicate how you *generally* feel. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe how you generally feel.

|                                                                                                      | ALMOST NEVER | SOMETIMES | OFTEN | ALMOST ALWAYS |
|------------------------------------------------------------------------------------------------------|--------------|-----------|-------|---------------|
| 21. I feel pleasant .....                                                                            | ①            | ②         | ③     | ④             |
| 22. I tire quickly .....                                                                             | ①            | ②         | ③     | ④             |
| 23. I feel like crying .....                                                                         | ①            | ②         | ③     | ④             |
| 24. I wish I could be as happy as others seem to be .....                                            | ①            | ②         | ③     | ④             |
| 25. I am losing out on things because I can't make up my mind soon enough ....                       | ①            | ②         | ③     | ④             |
| 26. I feel rested .....                                                                              | ①            | ②         | ③     | ④             |
| 27. I am "calm, cool, and collected" .....                                                           | ①            | ②         | ③     | ④             |
| 28. I feel that difficulties are piling up so that I cannot overcome them .....                      | ①            | ②         | ③     | ④             |
| 29. I worry too much over something that really doesn't matter .....                                 | ①            | ②         | ③     | ④             |
| 30. I am happy .....                                                                                 | ①            | ②         | ③     | ④             |
| 31. I am inclined to take things hard .....                                                          | ①            | ②         | ③     | ④             |
| 32. I lack self-confidence .....                                                                     | ①            | ②         | ③     | ④             |
| 33. I feel secure .....                                                                              | ①            | ②         | ③     | ④             |
| 34. I try to avoid facing a crisis or difficulty .....                                               | ①            | ②         | ③     | ④             |
| 35. I feel blue .....                                                                                | ①            | ②         | ③     | ④             |
| 36. I am content .....                                                                               | ①            | ②         | ③     | ④             |
| 37. Some unimportant thought runs through my mind and bothers me .....                               | ①            | ②         | ③     | ④             |
| 38. I take disappointments so keenly that I can't put them out of my mind ....                       | ①            | ②         | ③     | ④             |
| 39. I am a steady person .....                                                                       | ①            | ②         | ③     | ④             |
| 40. I get in a state of tension or turmoil as I think over my recent concerns and<br>interests ..... | ①            | ②         | ③     | ④             |

**Health Related Quality of Life Instrument**

**Function and VAS Questionnaires**

**Directions:** Answer the following questions in terms of how you felt in the *past 24 hours*.

1)How much did your implants placed interfere with your ability to do the following in the past 24 hours? (Circle one number for each statement that applies to you).

| Functions                                         | None | A little | Some | Quite a bit | Lots |
|---------------------------------------------------|------|----------|------|-------------|------|
| Chew the food you want                            |      |          |      |             |      |
| Open your mouth wide                              |      |          |      |             |      |
| Talk and carry on conversation                    |      |          |      |             |      |
| Sleep                                             |      |          |      |             |      |
| Go to work or school                              |      |          |      |             |      |
| Perform your regular daily routine                |      |          |      |             |      |
| Carry on your regular social life                 |      |          |      |             |      |
| Participate in your favourite recreation activity |      |          |      |             |      |

2) At it's worst, how would you rate your pain during the past 24 hours? Place an X on the line to indicate the severity of the pain at its worst.

NoPain

Mostintense pain

3) How much did you experience any of the following in the past 24 hours (circle one number for each condition that applies to you).

| Symptom                                         | None | A little | Some | Quite a bit | Lots |
|-------------------------------------------------|------|----------|------|-------------|------|
| Swelling                                        | 1    | 2        | 3    | 4           | 5    |
| Bruising                                        | 1    | 2        | 3    | 4           | 5    |
| Bleeding                                        | 1    | 2        | 3    | 4           | 5    |
| Nausea                                          | 1    | 2        | 3    | 4           | 5    |
| Bad Taste/ Bad Breath                           | 1    | 2        | 3    | 4           | 5    |
| Food collecting at implant site after placement | 1    | 2        | 3    | 4           | 5    |

4) If you took any medication to relieve pain or swelling write in the type of medication, the strength and number of pills you took today.

Name of medication: \_\_\_\_\_

Strength (such as mgs): \_\_\_\_\_

Number of pills in last 24 hrs: \_\_\_\_\_



## Patient Satisfaction Survey

Name: \_\_\_\_\_ Age: \_\_\_\_\_

*Please place a mark on the line at the point you feel most correctly indicates your opinion.*

1. How do you rate the appearance of your implant/implants?

Worse than \_\_\_\_\_ Better than  
expected \_\_\_\_\_ expected

2. How do you feel about your speech since receiving the implant/implants?

Worse than \_\_\_\_\_ Better than  
expected \_\_\_\_\_ expected

3. How do you feel about your chewing ability since receiving the implant/implants?

Worse than \_\_\_\_\_ Better than  
expected \_\_\_\_\_ expected

4. Do you consider your implant feels and functions as a natural tooth? Yes ☐ No ☐

5. Would you be 100% willing to undergo this procedure again using the knowledge you have of what is involved? Yes ☐ No ☐

6. Would you rate your overall implant experience as being worthwhile?

Absolutely not \_\_\_\_\_ Definately

7. Would you recommend the treatment to others? Yes ☐ No ☐