4-Implant Supported Fixed Prosthesis (ISFP) In The Edentulous Maxilla: A Pilot Study on Strategic Use of Short Implants Implant, Prosthetic and Quality of Life Outcomes

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A thesis submitted to the faculty of the University of North Carolina at Chapel Hill in partial fulfillment of the requirements for the degree of Master of Science in the School of Dentistry (Prosthodontics).

Chapel Hill
2011

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Abstract

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4-Implant supported fixed prosthesis (ISFP) in the edentulous maxilla: A pilot study on strategic use of short implants - Implant, prosthetic and quality of life outcomes
Under the direction of Lyndon F. Cooper, DDS PhD

Complete edentulism is a tremendous global health care burden with expected need for treatment to rise in the next 20 years (1). Maxillary dentures may provide acceptable patient satisfaction, however patients may desire a maxillary implant Supported Fixed Prosthesis (ISFP). ISFP's in the edentulous maxilla is associated with perceived need for grafting to support 'large' implants (>10 mm long), large number of implants (6 or more) and complex prostheses. Improved access to care and success of therapy may involve simplification. This was a pilot study involving 10 patients treated with four Astra Tech Osseospeed™ implants for an ISFP using a CAD-CAM Co-Cr framework. This study aims at simplifying therapy by avoiding or minimizing bone grafting and the use of short implants. Treatment efficacy and quality of life was evaluated with the OHIP-49 questionnaire and by documenting prosthetic complications and implant survival. The overall objective was to assess the feasibility, safety and potential of this new treatment modality.

ACKNOWLEDGEMENTS

To the Staff of UNC Graduate Prosthodontics for their help during my residency

To the Faculty at UNC Prosthodontics, for their guidance

My special acknowledgement goes to Dr. Kent Healy for sharing with me his experience, knowledge and skill on the art of complete denture therapy.

To my fellow residents for their camaraderie and friendship

To my classmates Astrid, Sandra & Thomas, you made residency fun, motivating, and intellectually enriching.

To my committee members: Dr. Ingeborg De Kok, Dr. Glenn Reside, and Dr. Anne Sanders for all their help, patience and teachings during this clinical project.

To my mentor and program director, Dr. Lyndon Cooper, for accepting me at UNC & providing me with the opportunity to refine my knowledge and skill. And for your inspiration to always strive for excellence in our work.

To my sons, Terrence and Ryan, for all the fun and joy that they bring to our family

To my wife Pearl, thank you for all your love and support over the years. Without you, none of my endeavors would have any meaning. I love you.

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PART ONE: IMPLANT AND PROSTHETIC OUTCOMES

1 INTRODUCTION

Complete edentulism is recognized as a global healthcare burden and is associated with several co-morbid health factors (2). In the US, the number of adults in need of complete denture therapy is expected to reach nearly 38 million by the year 2020 (1). There are three treatment choices (in addition to no treatment) available to treat the edentulous maxilla: (a) conventional complete dentures (b) implant supported overdentures and (c) implant supported fixed prostheses (ISFP's). ISFP's may be fabricated using metal-acrylic, metal-ceramic or all-ceramic modalities. Treatment planning for ISFP's involve a perceived need for significant bone grafting, long implants (10mm or more), large number of implants (6 or more) and complex prostheses (3)(4). These therapies often result in increased treatment cost, time, morbidity and may impede access to care. This study focused on the fixed implant rehabilitation of the edentulous maxilla using four Astra Tech Osseospeed™ implants and a rigid Cobalt Chromium prosthetic framework (Metal-acrylic screw-retained ISFP) for rigid cross-arch stabilization and splinting. The aim was to present a rationale for simplification of therapy with strategic and judicious placement of only four implants, as short as 6 mm when necessary, to avoid bone grafting and maximizing the confines of the patient's native bone in the presence of atrophied ridges. The working hypothesis is: A maxillary implant supported fixed denture can be supported by 4 implants of minimal dimension (as short as 6mm) using a rigid one-piece Co-Cr prosthetic framework (fabricated by CAD-CAM).

1.1 Challenge of ISFP's in the edentulous maxilla

The edentulous maxilla presents a challenge to the clinician mainly due to available bone quantity and edentulous ridge topography. The challenges encountered are mainly anatomic in nature: protruding alveolar process of the premaxilla with thin labial and thick palatal cortical plates, tooth loss in the posterior region is usually associated with vertical and horizontal bone deficiencies, but also increased pneumatization of the maxillary sinuses and residual ridge resorption patterns, thus limiting the possibilities to place implants without involving peri-implant bone grafting (5). Anatomic limitations direct our choices for potential implant sites if grafting is not included. For these reasons, implant rehabilitation in the edentulous maxilla remains one of the most complex therapies in prosthodontics (6). In addition there are numerous variables affecting esthetic and functional aspects of the prosthesis that should be assessed. As a consequence, treatment modalities have often included bone augmentation prior to or in conjunction with implant placement. Prosthodontic management should involve a thorough evaluation of intraoral and extraoral patient factors (7). These factors include: facial support, esthetic plane, maxillo mandibular relationship (Angle Class), lip support, smile line, vestibular space, horizontal tooth display, length of the upper lip (subnasal to philtrum), mucosal quality and quantity, incisal papilla position, speech, bone quality and quantity. These assessments may limit the number of available implant sites and influence the choice between a fixed or a removable implant supported prosthesis.

1.2 Contemporary treatment modalities

In the review paper by Att et al.(5), contemporary management of fixed implant therapy in the edentulous maxilla is categorized in 2 groups: first, rehabilitations without bone augmentation and second, rehabilitations with bone augmentation.

The first group (without bone grafting) includes 3 subcategories involving:

(i) Regular implants defined as 10 mm in length or longer: this treatment modality shows a survival rate of 78% to 97.2% in the included studies and 88% to 100% survival rate of the prostheses over a period of 5 to 15 years.

(ii) Tilted implants such as the All-on-4 concept (8): Att et al. (5)included eight studies in this category. Implant survival rates ranged from 92.8% to 100% for immediate loading protocol over a period of 1 to 3 years. Conventional loading studies reported survival rates ranging from 97% to 99% over a period of 3 to 12 years. Four of the eight studies reported prosthesis survival at 100%. Although long-term outcomes are not available for tilted implants, the short term data reported appear promising. Recently, Jensen et al.(9) refined the tilted-implant approach without grafting describing the “All-on-4 Shelf” technique for the edentulous maxilla. The precept to this approach is to satisfy esthetic and prosthetic objectives by performing a prosthetically prescribed crestal bone leveling technique (“shelf”) to move the prosthetic/tissue junction apically to hide the junction behind the lip drape. This technique also offers other advantages such as increased restorative space, establishment of the alveolar plane, shelf width which

determines implant diameter and several surgical advantages including available bone stock source should autogenous grafting be required for exposed implant threads.

(iii) Zygomatic implants: 12 studies were included for review by Att et al. including conventionally and immediately loaded protocols. Implant survival rates ranged from 93% to 100% over observation periods of 0.5 to 12 years. Four of the studies reported prosthesis survival rates of 96% to 100%. Biologic complications with zygomatic implants reported include sinusitis (2.3% to 13.6% incidence), soft tissue hyperplasia, intraoral infections and fistula formations. Long-term clinical trials are needed to provide more information on this treatment modality.

The second category (with bone augmentation) includes 2 subcategories (5):

(i) Sinus floor elevation using lateral window technique

First presented by Tatum in 1977, this technique is based on access to the maxillary sinus through a lateral bone window. The sinus membrane is elevated and mobilized together with the bone window to allow placement of autogenous bone, bovine bone or bone substitute on the sinus floor. The window is then covered with a resorbable membrane followed by primary flap closure. Most often, a healing period of several months should precede implant placement. Implant survival for the delayed loading approach in the edentulous maxilla ranged from 82.4% to 96% over an observation period of 12 to 72 months. In a randomized control trial (10) comparing immediate versus delayed implant placement in edentulous maxillae, the 12-month survival rate

of immediately placed implants (1-stage: sinus grafting and implant placement) was significantly lower than delayed placement (implants placed after 6 months healing of sinus graft) (79% versus 89%). In healed sinus grafts, the survival rate of implants has been shown to be comparable to non-grafted sites (11,12).

(ii) Le Fort osteotomy and interpositional bone graft

A 11 to 16 year follow-up study was published by Nystrom et al. (13). This is a two stage surgical protocol to treat severely atrophied edentulous maxillae. It can be used with immediate or delayed implant placement. The surgical technique is performed with the patient under general anesthesia. Corticocancellous bone blocks are harvested, usually from the iliac crest. Following the Le Fort osteotomy, a manual downfracture is performed and interpositional bone blocks are rigidly fixated. The placement of implants is usually performed 6 months after reconstructive surgery. The miniplates and fixations screws are usually removed at the time of implant placement. Frequently a surgical guide is used to facilitate implant placement. The general complications associated with this procedure include unpredictable bone resorption during graft healing and exposure of the grafted bone in the initial healing period.

Nystrom's study comprised 26 patients. At the 10-year examination, 23 patients were examined, 3 patients were lost to follow-up. Of 167 inserted implants, 24 failed. There were 19 early failures (implants lost within the first year after placement) and 5 late failures. Two late failures occurred at the 2-year examination, two at the 3-year examination and one at the 5-year examination. No more failures were seen thereafter. The estimated implant survival rate was 85% after a mean follow-up time

of 13 years. All patients that were examined after 11 to 16 years (23 of 26) were still wearing their original fixed prostheses for a 100% prosthetic survival.

Hence, several treatment modalities are presently available for the fixed rehabilitation of the edentulous maxilla. The decision to utilize one technique over others mainly depends on the quantity of available bone (9). Immediate loading of the edentulous maxilla may be successful in select patients (14). Patient driven requests for immediate function however make this approach almost impossible with simultaneous sinus augmentation for example.

1.3 Rationale for simplification

It appears, from a review of the literature, that ISFP's in the edentulous maxilla have often been associated with bone grafting surgeries with simultaneous or delayed implant placement. It is obvious that treatment time and cost tend to increase with such approaches. Over the past few years, protocols with angulated implants without grafting have become more popular (8,9). Maxillary sinus augmentation procedures are often necessary in the posterior maxilla if long implants are planned in an upright position. Maxillary sinus grafting appears to be the most predictable hard tissue augmentation technique in implant dentistry(12) and long-term implant survival in the grafted maxillary sinus is comparable to non-grafted sites(11) but necessitates additional surgery, cost, and time. In addition, patients may decline the procedure due to added risk and morbidity.

The All-on-4 concept in the maxilla utilizes four tilted implants to improve anterior-posterior spread and avoids the maxillary sinuses. This concept has been gaining increased popularity due to the reduction in number of appointments and the possibility to immediately function. However, the majority of implants (116/128) utilized in a retrospective report (8) were 15 mm long or in severely atrophied cases zygomatic implants (as long as 52.5mm) have been prescribed(15) – risks associated to surgery may therefore be heightened. The rationale for using long implants seems related to the need for increased primary stability which allows an immediate function approach.

The strategic use of short implants (as short as 6mm) with or without tilting may offer the possibility to provide maximum anterior-posterior spread (A-P Spread) without bone grafting in select patients. In the first molar sites, sinus grafting may not be necessary. In the pre-maxillary sites, short implants may be placed upright or more lingual within the angled premaxilla ridge, facilitating prosthetic design and lingual access for bridge screws. In case of failure, minimal morbidity may be assumed with a shorter implant site which allows re-treatment immediately or within a short period of time. Simplification of treatment may be associated with reduced costs and improved access to care for patients who cannot be treated without bone augmentation procedures.

Prosthetic simplification may then be achieved with less prosthetic and implant parts involved when only four implants are utilized without adversely affecting implant and prosthetic survival. A ten-year follow-up study (16) involving 156 edentulous patients compared ISFP’s supported by 4 versus 6 implants (84 maxillae and 72 mandibles).

The survival rate for both individual implants and prostheses was the same in both groups at the end of the 10-year observation period. It was concluded from this study that the tendency of some clinicians to install as many implants as possible in full edentulism should be seriously questioned.

2 MATERIALS AND METHODS

This study was an open prospective clinical trial to document implant survival rates, prosthetic performance and impact of ISFP's on patient satisfaction and quality of life. All recruited patients had an edentulous maxilla for at least two months and sought some type of implant therapy in the upper jaw. All patients obtained the same protocol of treatment which involved the initial fabrication of a maxillary complete denture for esthetic and functional evaluation followed by surgical placement of four Astra Tech Osseospeed™ implants to support a definitive maxillary metal-acrylic ISFP. Implants as short as 6mm were strategically used when necessary. The prosthetic framework was made of Cobalt-Chrome alloy fabricated by CAD-CAM technology (ISUS – DENTSPLY Prosthetics). Quality of life and patient satisfaction was assessed with the use of the OHIP-49 instrument. This clinical research study was submitted to and approved by the Institutional Review Board (IRB) of the University of North Carolina, Chapel Hill.

2.1 Patient selection

Patients seeking implant therapy for the edentulous maxilla who had interest or were potentially in need of a maxillary ISFP were asked to contact the investigators regarding possible enrollment in the study protocol. Potential patients were offered a screening appointment in the Graduate Prosthodontic Clinic at the School of Dentistry of the University of North Carolina at Chapel Hill (UNC-CH).

Altogether, 36 patients (16 men and 20 women) were screened. Consecutive enrollment of 10 patients fulfilling all inclusion criteria was completed over a period of five months from May to September 2009. A screening questionnaire (Appendix B) was used to assist in recruitment.

The reasons for exclusion of the remaining 26 patients are listed in Table 2-1-1.

Table 2-1-1: Reason for Exclusion from research study

Reason for Exclusion	Number of Patients
Age > 80	1
Smoker	1
Severe Class III Skeletal	1
Fear of Treatment	1
Medication	1
Financial	5
Insufficient Vertical Bone Dimension	1
Insufficient Facial/Lingual Bone Dimension	6
Insufficient V & F/L Bone Dimension	9
Total excluded	**26**

All enrolled subjects were provided with an IRB approved information package concerning the details of the study. The overall treatment protocol and objective of the study was thoroughly discussed with each subject and informed consent was obtained prior to any treatment.

Demographic data of the 10 subjects upon enrollment are presented in table 2-1-2.

Table 2-1-2: Demographic Characteristics for enrolled subjects.

Characteristic	Statistic	Subjects (N=10)
Age	Mean	62.1
	Min, Max	39.3, 78.3
Gender		
Males	N (%)	3 (30%)
Females	N (%)	7 (70%)
Race		
Caucasian	N (%)	8 (80%)
African-American	N (%)	2 (20%)

2.2 Inclusion and exclusion criteria

Inclusion criteria

Patients that could be included in the study should be aged between 18-80 at time of enrollment, have good physical health (ASA Class I or II), have been edentulous in the maxilla for at least 2 months, possess maxillary vertical bone height of at least 5mm and 4 mm in width in the selected implant sites, no history of radiotherapy in head and neck region, non-smokers, and willing to give informed consent.

Exclusion criteria

Patients were excluded from the study for the following: history of radiotherapy in head and neck region; smokers; vertical bone height less than 5 mm and less than 4 mm in Facial – Lingual width in any of the implant sites; severe Angle's class III jaw relationships; psychological problems for accepting a removable prosthesis (fear, unwilling to wear dentures; severe gag reflex); pregnancy; steroid use; ASA Class III

or IV patients; uncontrolled diabetes; known alcohol and/or drug abuse; patients taking medication that might interfere with coagulation (e.g. Aspirin dose of more than 81mg/day, Coumadin) and/or subjects with bleeding disorders (e.g. liver disease); patient with unrealistic esthetic expectations; lack of cooperation and patient with conditions that contraindicate dental implant therapy.

2.3 Prosthodontic and implant treatments

The study was planned to span over approximately 18 to 20 months from the first enrollment visit to the 12-month follow up visit. Approximately 12 appointments were completed during the first 6 to 8 months of active treatment. Follow-up appointments were made 6 months and 12 months after delivery of the final prosthesis.

Five patients (50%) required prosthodontic treatment of their mandibular arch as part of their comprehensive therapy. These treatments were rendered either prior to or in parallel with the research protocol.

The total treatment time within protocol including examinations and follow-ups totaled an average of 15 hours and consisted of 15 appointments which are described below. All patients were asked to contact the investigator if they had any questions or concerns during the protocol.

Visit 1:

Screening, examination, consent & initial records

During this visit, screening was conducted and the questionnaire (figure 2-1-1) was completed by the potential subject. Following the screening process, suitable subjects were asked if they were interested in participating in the study. After thoroughly explaining details of the protocol, the patient was given the opportunity to read the consent form, have any questions answered, and provide consent if they decided to enroll in the study. All patients appointed for screening were asked to have a recent panoramic radiograph, the standard screening x-ray for all edentulous patients in the Department of Prosthodontics at UNC-CH. Medical and dental history, a standardized set of photographs, and preliminary impressions were obtained followed by extra-oral and intra-oral examinations.

The patient was given an OHIP-49 form (Oral Health Impact Profile – 49) to fill out.

Visit 2:

Final Impressions for Complete Denture and Maxillo-mandibular relations

Study casts were fabricated from the preliminary impressions obtained at visit 1and a custom tray was fabricated to obtain the final impression (Poly-vinyl siloxane) for the maxillary complete denture. The impression technique followed the selective pressure method described by Chafee et al.(17).

Final master casts were fabricated and used for immediate fabrication of a record base and wax-rims to provide registration of centric relation and occlusal vertical dimension. The wax rims were tried intra-orally, modified in shape and contour to

refine the occlusal plane and provide an indication for the midline, vertical dimension, and position of future denture teeth. A face-bow transfer record was also obtained to orient the maxillary cast to the articulator. Occlusal records registered and confirmed the maxillo-mandibular relationship in centric relation (CR). Appropriate acrylic denture teeth and shade were chosen with the patient's participation.

Visit 3:

Teeth try-in on wax for Maxillary Complete Denture

Between visits 2 and 3, the maxillary master cast was mounted on a semi-adjustable articulator using the face-bow record. The selected denture teeth (Ivoclar Blue line) were set on the wax-rims / record base and finished for clinical try-in during this visit. The teeth set-up on wax was tried clinically and teeth positions were modified and refined to meet esthetic, phonetic and occlusal objectives. Esthetic approval was confirmed with the patient in order to proceed to completion of the maxillary complete denture.

Visit 4:

Delivery of maxillary complete denture and fabrication of surgical/radiologic guide

A thin layer of pressure indicator paste was applied onto intaglio surfaces of the maxillary denture before insertion in the patient's mouth to locate pressure spots. Any pressure spots, overextensions and sharp edges were trimmed and relieved.

The patient was guided to close into CR position and any prematurity or deflective contacts in CR were identified. Occlusal corrections, if any, were accomplished after remounting the denture on the articulator. Patients were asked to contact the Graduate Prosthodontic Clinic if they experienced any discomfort with their new prosthesis. None of the patients requested a visit for denture adjustments.

A surgical/radiologic guide was fabricated by duplicating the maxillary denture with clear cold-cure radio opaque acrylic resin (Biocryl-X). The guide was also tried in the patient's mouth to confirm adequate fit and acceptable occlusion.

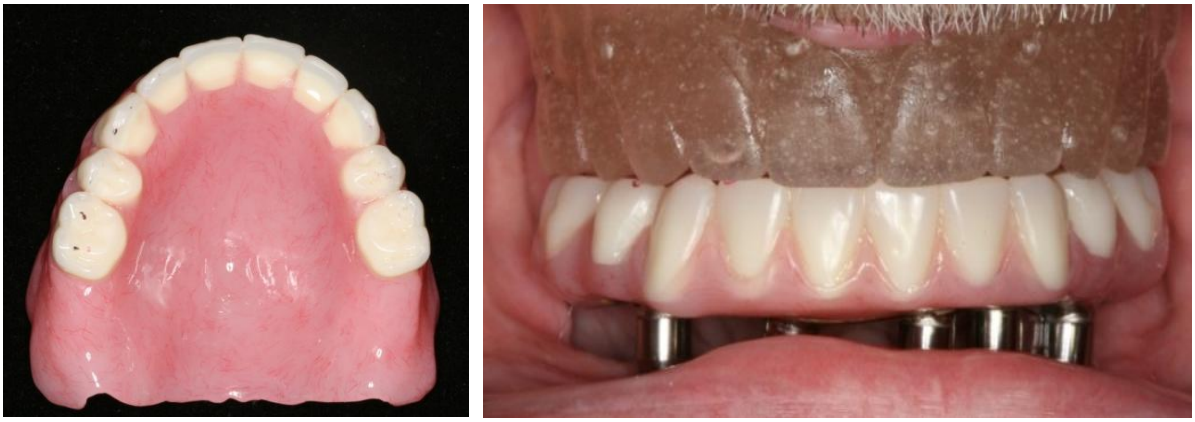


Figure 1.1: Complete denture duplicated in radio-opaque surgical/radiologic guide (Biocryl X™)

Visit 5:

Cone Beam Computed Tomography to evaluate implant sites and surgical approach

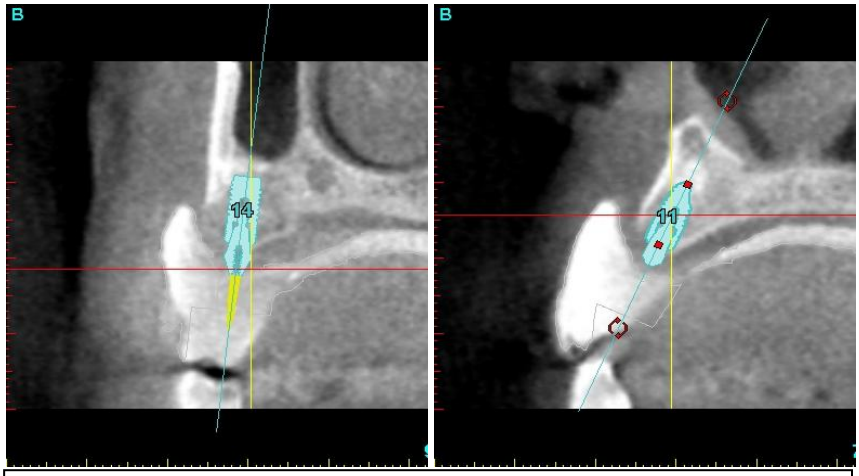


Figure 1.2: Individual implant site analysis with Facilitate™ software

This visit was completed with the co-operation of the Oral Maxillofacial Radiology clinic at UNC-CH. Patients were evaluated three-dimensionally by Cone Beam Computerized Tomography (CBCT) to identify contours of the maxillary sinus in relation to anticipated implant sites as well as potential implant sites (canines and first molars) . The guide was placed in the patient's mouth and a CBCT was obtained. This is a standard procedure for three dimensional evaluations of anatomic structures in proximity to the implant sites and the volume of bone available prior to surgical placement of implants. The chosen implant sites were then marked and located on the guide. For nine of the ten patients (90%), visits 4 and 5 were completed on the same day.

Visit 6:

Implant placement surgery

Patients were pre-medicated with 2 g of Amoxicillin (600 mg of Clindamycin if penicillin allergy). The antibiotic prescription was extended for a period of 7 days postoperatively. Immediately before surgery, patients were given perioral lavage with 0.12% Chlorexidine Digluconate solution. A sterile surgical set-up was utilized throughout this appointment. Topical anesthetics was applied to the oral mucosa of the maxillary vestibule and maintained for one minute. Infiltration anesthesia using 2% lidocaine with epinephrine 1/100,000 was provided to the maxilla. On average, 7.2 ml (4 carpules) of anesthetic was required.

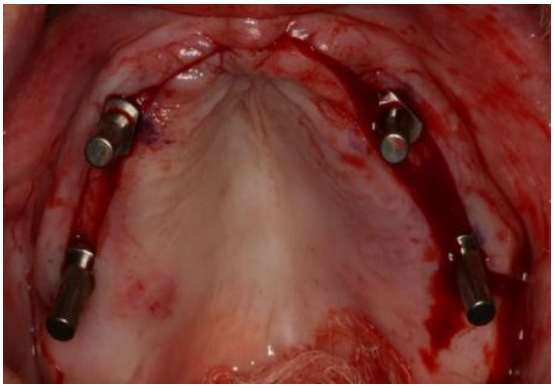


Figure 1.3: Direction indicators placed in osteotomy sites demonstrating angulation and A-P spread of four maxillary implants

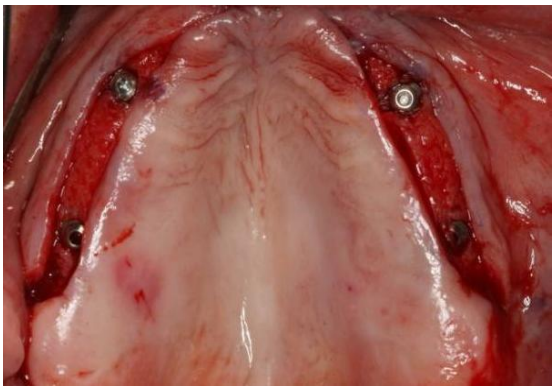


Figure1.4: Cover screws placed prior to suturing

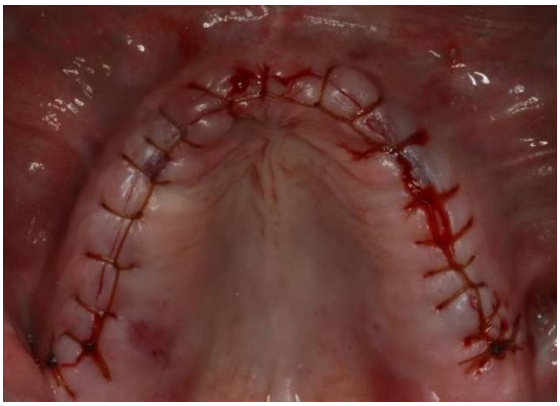


Figure 1.5: Primary wound closure with continuous 4.0 chromic gut suture.

With the surgical guide in place, the planned implant positions were marked with an indelible marker (Thompson Marker). A mid-crestal incision extending 5 mm past the posterior implant sites was made with a #15 blade and full thickness muco-periosteal flap elevated. Implant site preparation is accomplished using an electric implant motor with a maximum speed of 1500 rpm and external irrigation of sterile saline water according to the Astra Tech surgical manual. The drill sequence was adjusted according to the surgical manual to accommodate different implant width and length. Round end osteotomes were used to prepare implant sites in areas of low bone density or minimal facial-lingual dimension. In the implant sites where an osteotome sinus elevation was indicated prior to implant placement, a concave osteotome corresponding to the implant being placed was used to elevate the sinus floor following the technique described by Fermergard et al. (18)

All implants were placed using an electric handpiece and good primary stability was obtained. One patient (1 of 10) was treated using a flapless guided surgery protocol (Astra tech Facilitate – Figure 1.6) followed by placement of healing abutments. The remainder of the subjects (9 of 10) received a two –stage surgical approach. Cover screws were placed and primary flap closure obtained with 4.0 chromic gut sutures.

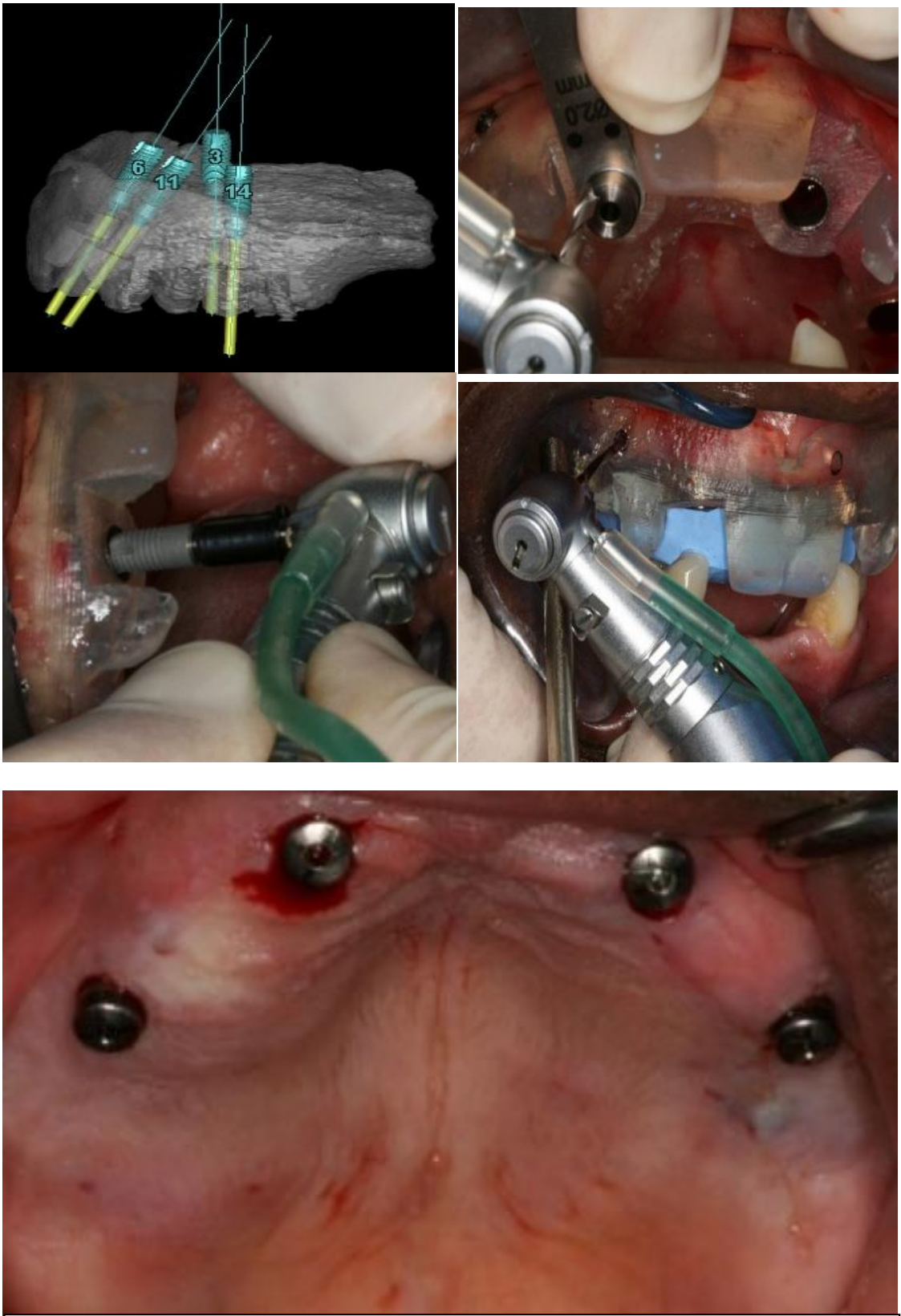


Figure 1.6: Implant placement using flapless guided surgical approach (Astra Facilitate™)

Some implants displayed exposed threads on the facial aspect and autogenous bone collected from the osteotomy of the implant sites or alveolectomy sites were placed on the exposed threads. All implants with exposed threads were in the pre-maxillary sites.

Of the 40 initially placed implants in the 10 patients, only 17 sites were straightforward. The standard drill sequence was followed, implants were placed with the surgical handpiece and good primary stability was achieved.

The remaining 23 implants required some site manipulation: osteotome sinus lift, osteotome lateral site expansion and/or bone graft collected from osteotomies.

For 1 posterior site and 1 anterior site on the same patient (#1), a barrier membrane (Biogide) was used in conjunction with the bone grafts.

For most pre-maxillary sites, with limited facial-lingual dimension, the drill sequence was used up to the 3.2 mm twist drill and osteotomes (3.2mm to 3.7 mm) were used to expand the osteotomy prior to implant placement.

For 1 posterior site, an osteotome sinus elevation was performed.

For 3 posterior sites on 2 patients, the sinus floor and membrane were inadvertently perforated during the osteotomy.

Table 2-3-1 summarizes site specific manipulation performed for each subject.

Table 2-3-1 Site specific summary during fixture placement.

Patient I.D #	Posterior Right	Anterior Right	Anterior Left	Posterior Left
1	Straight-forward	Bone graft from osteotomy sites Osteotome 3.2-3.7	Bone graft from osteotomy sites Osteotome 3.2-3.7	Straight-forward
2	Straight-forward	Osteotome 3.2-3.7	Osteotome 3.2-3.7	Straight-forward
3	Straight-forward Flapless Guided	Straight-forward Flapless Guided	Straight-forward Flapless Guided	Straight-forward Flapless Guided
4	Sinus floor perforation	Straight-forward	Straight-forward	Straight-forward
5	Straight-forward	Bone graft from osteotomy sites Osteotome 3.2-3.7	Bone graft from osteotomy sites Osteotome 3.2-3.7	Straight-forward
6	Sinus floor perforation	Bone graft from osteotomy sites	Bone graft from osteotomy sites	Sinus floor perforation
7	Osteotome sinus lift	Bone graft from osteotomy sites Osteotome 3.2-3.7	Bone graft from osteotomy sites Osteotome 3.2-3.7	Bone graft from osteotomy sites Osteotome 3.2-3.7
8	Bone graft from osteotomy sites Osteotome 3.2-3.7	Bone graft from osteotomy sites Osteotome 3.2-3.7	Bone graft from osteotomy sites Osteotome 3.2-3.7	Bone graft from osteotomy sites Osteotome 3.2-3.7
9	Straight-forward	Bone graft from osteotomy sites Osteotome 3.2-3.7	Bone graft from osteotomy sites Osteotome 3.2-3.7	Straight-forward
10	Osteotome 3.2-3.7	Bone graft from osteotomy sites	Bone graft from osteotomy sites	Osteotome 3.2-3.7

Peri-apical radiographs of each implant placed were obtained as baseline for future comparison of crestal bone levels. The patient's dentures were relieved and relined where necessary with a temporary soft liner. Standard written post-operative instructions were provided to all patients.

All implants were 4.0 mm diameter and the length and distribution are summarized in table 2-3-2

Table 2-3-2 Implant length (mm) and distribution

Patient ID #	Posterior Right	Anterior Right	Anterior Left	Posterior Left
1	8	8	8	8
2	9	9	9	9
3	9	9	9	9
4	9	11	9	9
5	6	8	8	6
6	9	11	11	11
8	8	11	6	8
9	8	8	8	8
10	9	6	6	9

Mean implant length for total of 36 implants = 8.5 mm

Visit 7:

Post-operative 1 week to 2 weeks after implant placement

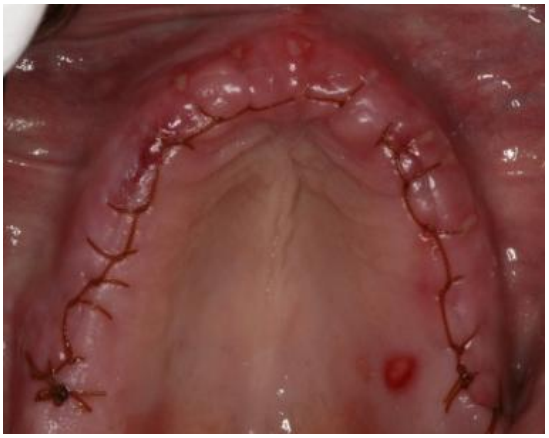


Figure 1.7: One week after implant placement

During this visit, soft tissue healing was assessed. Any excessive pressure areas from the maxillary denture were verified and relieved as deemed necessary. All patients reported using pain medications for 3 days or less and reported that discomfort improved and became acceptable within 1 week following surgery.

Visit 8:

Post-operative 4 weeks after implant placement.

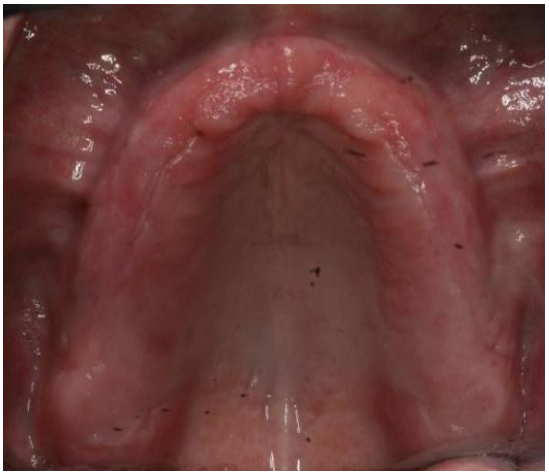


Figure 1.8: Four weeks after implant placement

This visit was for the assessment of soft tissue healing and to check for any pressure areas from the wear of the maxillary denture. These areas were relieved

and adjusted extra orally as deemed necessary. All patients reported good comfort and three required additional interim soft reline to improve retention of their maxillary dentures.

Visit 9:

Final Abutment level impressions 8-20 weeks after implant placement.

Framework design / wax-up & set-up in the laboratory

During this visit, the implants were exposed (stage 2 surgery) under local anesthesia and appropriate abutments (Uni-abutment 20 degrees, angled or uni-abutment 45 degrees) were connected to the implants. The exposure of the implants was facilitated with the use of the surgical guide used during fixture installation (visit 6). This allowed a short crestal incision of 5 to 6 mm or less – this minimally invasive approach allowed for straight-forward abutment impressions during the same appointment.

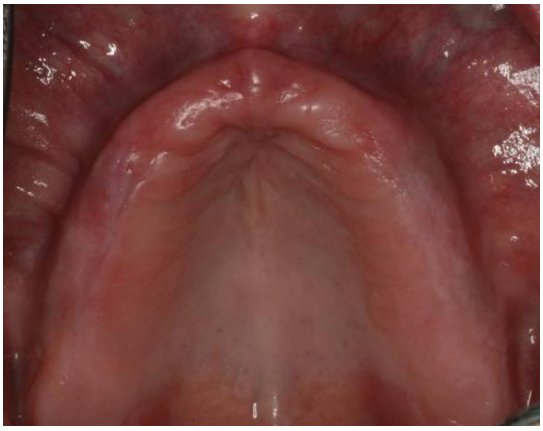


Figure 1.9: Twelve weeks after implant placement

Patient to receive stage-2 surgery and abutment installation

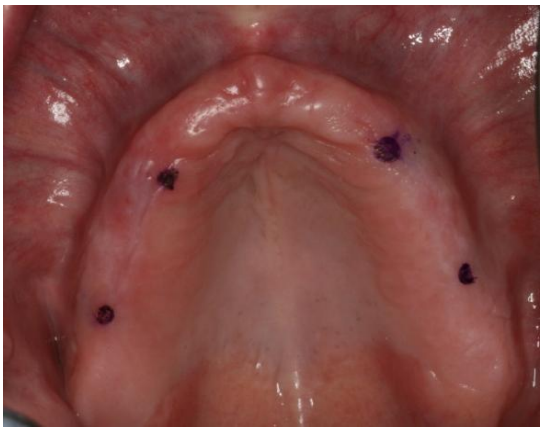


Figure 1.10: implant sites marked prior to incision

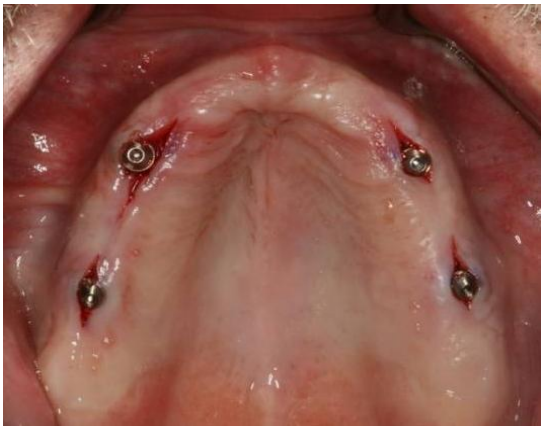


Figure 1.11: installed prosthetic abutments

Each abutment was torqued according to manufacturer's specification (Astratech manual). Impression copings were connected to the abutment and a full-arch PVS impression was made. Closed tray abutment transfers were primarily used except for angled abutments that necessitated an open tray transfer.

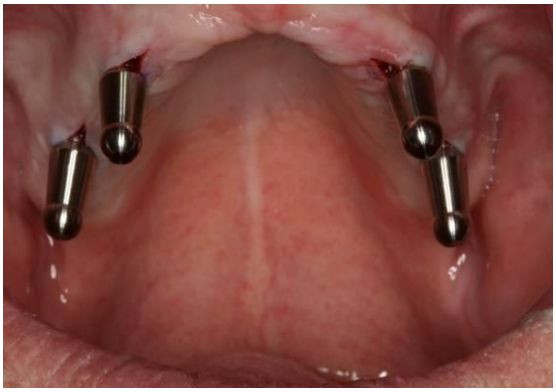


Figure 1.12: Abutment transfer copings in place

The master cast accuracy was verified with a resin jig fabricated with light-cured trial tray material and temporary titanium cylinders.

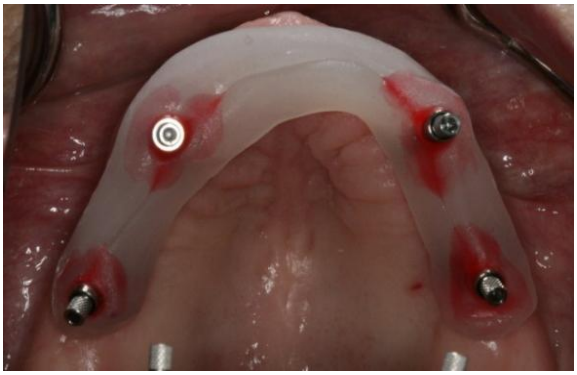


Figure 1.13: Verification Jig

The cured resin was left on the master cast for at least 1 hour before trial clinically. All master casts (8 patients who received their definitive ISFP) had acceptable accuracy.

Table 2-3-4 Type and distribution of prosthetic abutments

Patient ID #	Posterior Right	Anterior Right	Anterior Left	Posterior Left
1	20/3	A/6	A/11	20/14
2	20/3	20/6	20/11	20/14
3	20 /4	20/7	20/10	20/13
4	45/4	20/6	A/11	45/13
6	20/3	A/7	A/9	45/14
8	20/3	A/7	A/11	20/14
9	20/5	20/7	20/10	20/13
10	20/3	A/7	A/11	20/14

Abutment Type / Implant Position
20 = Astra Straight 20-degree uni-abutment
45 = Astra Straight 45-degree uni-abutment
A = Astra angled abutment

The initial goal during planning and fixture placement was to exclusively use 20-degree uni-abutments, however, ridge morphology and available bone dictated implant angulations beyond what would be tolerated by straight 20-degree uni-abutments without having screw accesses through the facial of prosthetic teeth. This was particularly challenging in the anterior region in spite of the use of short implants. Hence angled and straight 45-degree uni-abutments were indicated in some cases. Tables 2-3-4 and 2-3-5 summarize the type and distribution of abutments used for the 8 patients that completed treatment. Angled abutments were required for 9 implants all in the pre-maxilla for 5 of the 8 patients that received their definitive ISFP.

Three 45-degree uni-abutments were required for severely angulated implants in the posterior maxilla for 2 of 8 patients that received their definitive ISFP.

Altogether, only 3 of 8 patients were restored exclusively with straight 20-degree uni-abutments. These 3 patients presented with the most favorable ridge volume and morphology – 1 of these 3 patients had all 4 implants placed using a flapless guided surgical technique.

Table 2-3-5 Percentage of abutments by type

Abutment	**n**	**%**	**Note**
Angled	9	28	All in premaxilla 5 of 8 patients
20-Degree Straight Uni-abutment	20	63	Used exclusively on 3 of 8 patients
45-Degree Straight Uni-abutment	3	9	All in posterior maxilla 2 of 8 patients
TOTAL	**32**	**100**	

Visit 10:

Framework try-in, verification of fit and Maxillo-Mandibular relationship

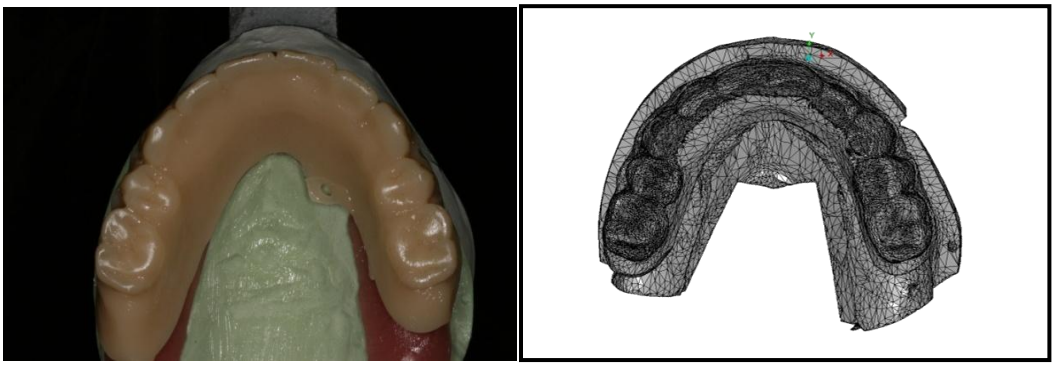


Figure 1.14: Duplicated denture in Bis-Acryl for framework design

Between visits 9 and 10, a Cobalt-Chrome framework was fabricated using CAD-Cam technology (DENTSPLY – ISUS Prosthetics). The maxillary master cast was provided with a duplicated denture made of Bis-acryl. This duplicate provides the outer outline of the definitive prosthesis and hence, permits adequate design of the prosthetic bar, tooth supports, and maximizes the use of available restorative dimension.

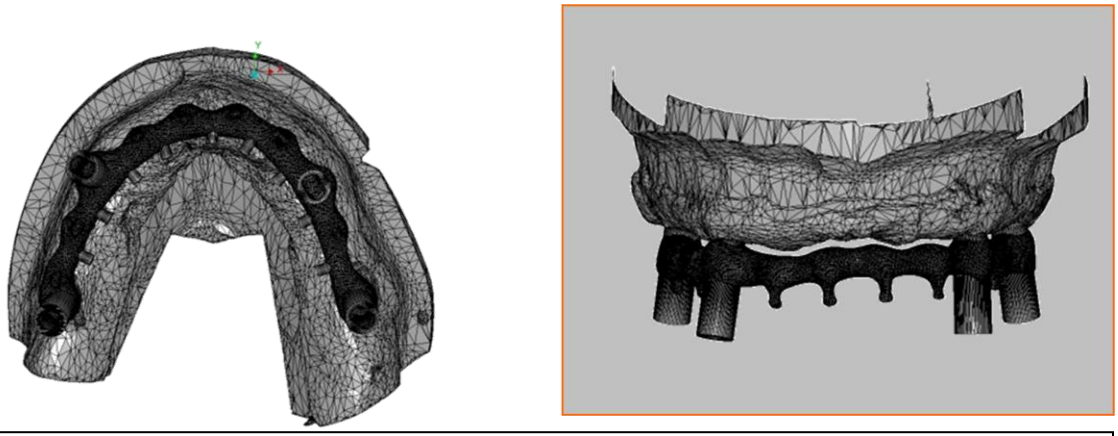


Figure 1.15: Digital conception and design of prosthetic framework (DENTSPLY ISUS)

At this visit, Pro-Heal Caps were removed from all 4 abutments. The Cobalt-Chrome milled framework was tried on the abutments to determine acceptable fit.

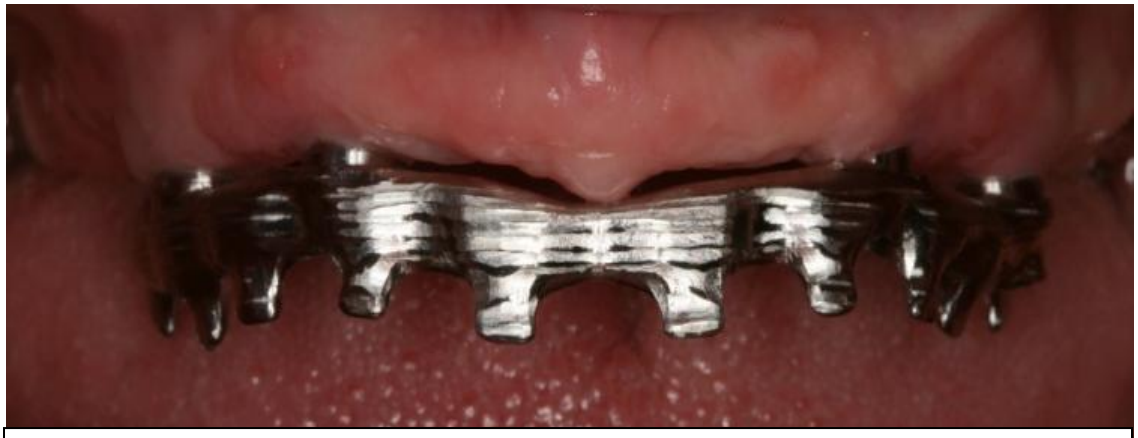


Figure 1.16: CAD-CAM Cobalt-Chromium Framework – Verification of passive fit

Four methods described in the results section were used to assess passive framework fit. Once passive fit was confirmed, a CR bite registration was obtained with the framework in place, using a PVS (Regisil), at the same vertical dimension of occlusion as the complete removable denture. The Pro-Heal caps were secured back on the abutments. The patients left with their complete dentures.

Visit 11:

Teeth and wax try-in

Between visits 10 and 11, the mandibular cast was mounted to the maxillary frame / occlusal registration assembly. Ivoclar Blue line (6 of 8 ISFP's) or Phonares (2 of 8 ISFP's) Denture Teeth were set on the framework using base plate wax.

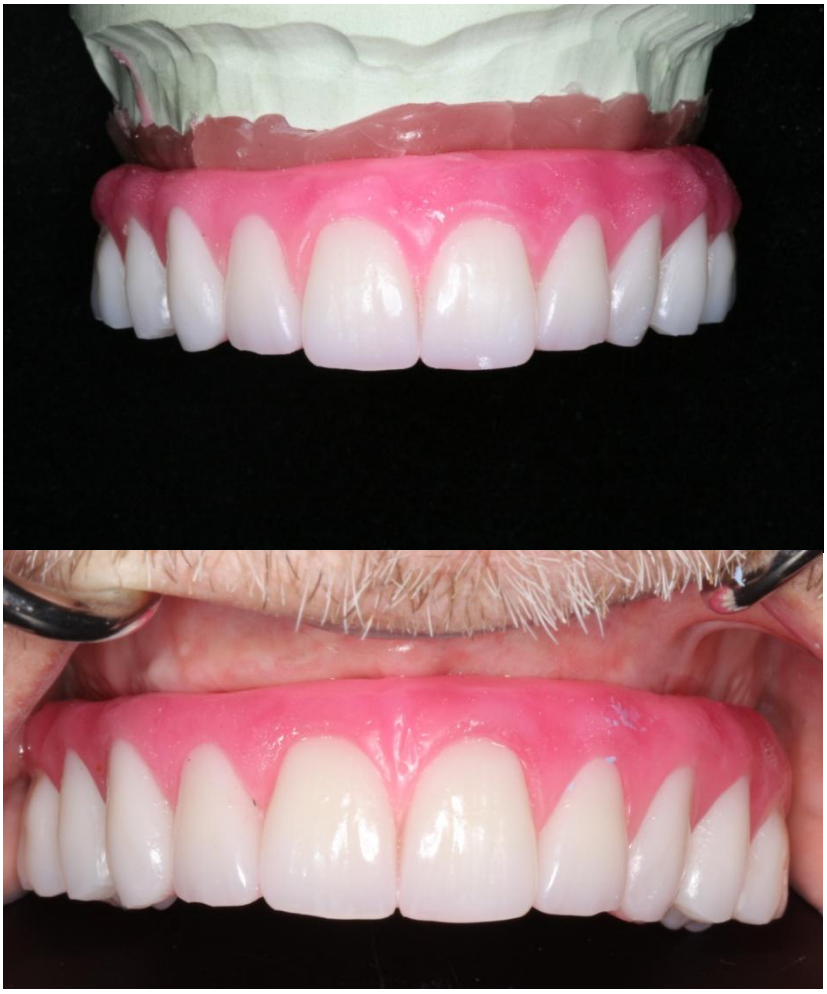
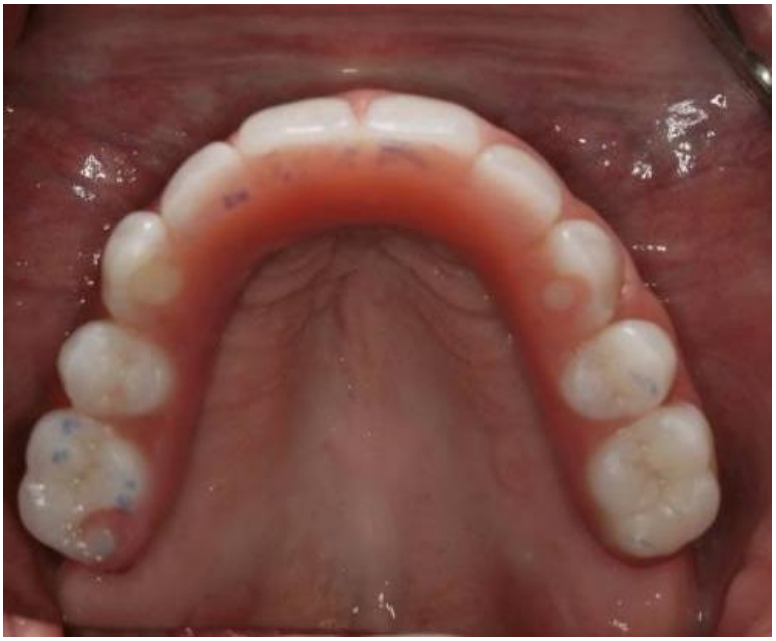


Figure 1.17: Wax-up on master cast and clinical try-in

Tooth position as determined on the complete denture was used as reference for the set-up. During this visit, the teeth wax-up was tried on the patient for esthetics and to confirm CR. Teeth were repositioned on the wax as deemed necessary based on esthetics and phonetics. Patient approval was obtained prior to proceeding. The patients left with their complete dentures.

Visit 12:

Delivery of final prosthesis



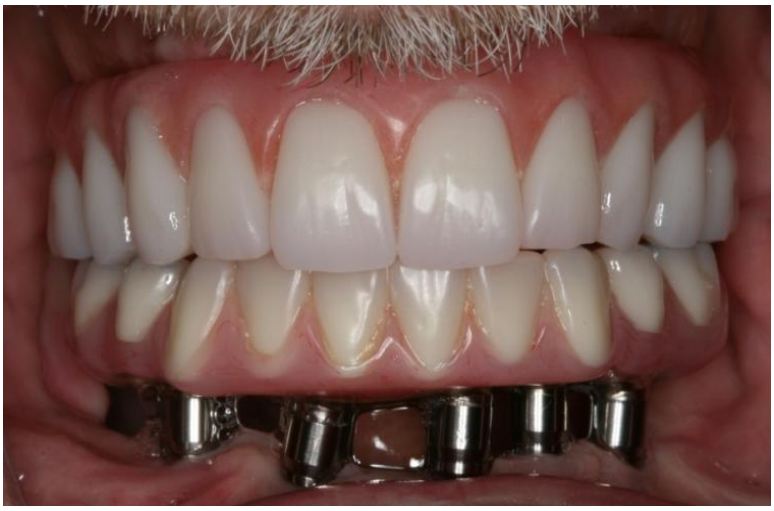


Figure 1.18: Definitive ISFP Occlusal and Frontal view

Following removal of Pro-Heal Caps, the final ISFP was placed on the implants and the screws hand tightened. The occlusion was then verified and adjusted accordingly. After all necessary adjustments are made the prosthesis was polished; bridge screws were tightened to 15 Ncm using the AstraTech calibrated hand

wrench. All screw access holes were closed with a cotton pellet on each screw and using a light cured composite material.

Visit 13:

Post op 1-2 weeks after delivery of final prosthesis.

The occlusion, function and phonetics of the fixed prosthesis were evaluated. Adjustment to the occlusion if necessary was completed intra-orally with a hand piece and acrylic bur and polished accordingly. OHIP-49 form (19) was administered to the patients.

Visit 14 and 15:

Post-Delivery ISFP - 6 months & 12 months

At both visits, the patients were given an OHIP-49 form (19)(Oral Health Impact Profile – 49) to complete. The prosthesis was thoroughly evaluated at this appointment. The occlusion, function and prosthesis integrity was verified.

All four implants were examined and evaluated and one periapical radiograph was taken for each implant.

3 RESULTS

Implant and Prosthetic data are reported for the 10 patients enrolled in this study. At time of reporting (3/23/2011), the status of the subjects were as follows:

- 8 of the 10 patients received their definitive ISFP. (8 had a 2 week follow-up, 7 had a 6-month follow-up and none had a 1-year follow-up)
- 1 patient is at the stage of definitive ISFP fabrication
- 1 patient (#7) will not able to obtain the definitive ISFP because of cluster failure of all four of her initially placed implants.

Table 3-1 summarized the status of each patient in the study protocol.

Table 3-1: Summary status of each patient in protocol

Patient ID	ISFP installed	2-week FU	6-month FU	12-month FU
1	Completed	Completed	Completed	In progress
2	Completed	Completed	Completed	In progress
3	Completed	Completed	Completed	In progress
4	Completed	Completed	Completed	In progress
5	In progress	In progress	In progress	In progress
6	Completed	Completed	Completed	In progress
7	Implant Failures	N/A	N/A	N/A
8	Completed	Completed	In progress	In progress
9	Completed	Completed	Completed	In progress
10	Completed	Completed	Completed	In progress

3.1 Implant outcomes

3.1.1 Implant Survival

Patient #7 was excluded from the implant survival data based on medical reasons that were not evident at the time of enrollment (see implant complications). A total number of 39 implants were installed on 9 patients (36 fixtures placed initially and 3 failed fixtures replaced after removal). Implant survival was defined (20)as the implant still in place and functioning in the mouth.

If preloading failures of the 3 fixtures are included in the survival analysis, this accounts for a 92.3 % survival rate.

Implant survival rate after abutment and prosthesis delivery was 100 %.

No patients were lost to follow-ups at time of reporting.

3.1.2 Implant Complications

Preloading failures were predominantly in the premaxilla. A total of 3 patients (Patients #'s 5, 7 and 8) lost one or more implants between placement and prosthesis loading.

Patient #5: at stage 2 surgery about 3 mm bone loss was found on both 6 mm anterior implants – this was confirmed with periapical radiographs. One of the anterior implants was loose. Both implants were removed and the sites were grafted with Bio-oss & Bio-gide and allowed to heal. Two 8 mm implants were placed 4 months after healing. These implants have integrated and the patient is awaiting delivery of her final prosthesis at time of writing.

Patient #8: contacted the investigator and presented with a loose implant in the right anterior at stage 2 surgery. The implant was removed and a new 11 mm implant was placed a few weeks after its removal. Bio-oss and Bio-gide were used to graft the site with simultaneous implant placement. This implant integrated and the patient has already received her definitive ISFP.

Patient #7: this was a cluster failure situation. The patient lost all her 4 initial implants over a period of 20 weeks following placement. The first implant (#11 – 8 mm long) came loose and was replaced with a 9 mm implant in conjunction with a Bio-Oss™ and Bio-Gide™ graft. A few weeks later, the three other implants were either removed due to infection or severe bone loss (#'s 14 and 6) or came loose (#3) over a period of 5 weeks. The replaced #11 implant is the only one surviving at time of reporting. The last three implants lost (#3, 6, 14) were not replaced after loss or removal.

3.2 Prosthetic outcomes

3.2.1 Fit and accuracy of CAD-CAM Co-Cr prosthetic framework

Brånemark (21) stated that achieving passive fit between implant frameworks and underlying structures is critical for successful long-term osseointegration. Ill-fitting framework may also be associated with mechanical and technical failures of ISFP's. Common mechanical complications include loosening or fracture of prosthetic abutment screws (22). Acceptable levels of fit vary greatly in the literature, ranging from 10 microns (21) to 150 microns. The later value was reported by Jemt (23) who defined passive fit as a level that did not cause any long-term clinical complication.

This corresponds to less than half-a-turn to completely tighten the gold screw after its initial seating resistance was encountered.

Several methods have been described to evaluate implant framework fit and passivity (24).

Four methods were utilized to assess framework fit in the present study:

(i) Alternate finger pressure: this is a simple method for initial macroscopic assessment of framework fit by manually seating the framework with finger pressure applied alternatively over 1 terminal abutment and then the other. Any rocking or fulcruming would denote an unacceptable fit.

(ii) Direct vision and tactile sensation: this method can be enhanced with excellent lighting and magnification, however may be limited by margin location and size of explorer tip.

(iii) One-screw test: for this method, 1 screw is tightened at one terminal abutment and discrepancies observed at the other abutments. This technique is particularly effective in long span frameworks. The one-screw test is often combined with direct vision and tactile sensation.

(iv) Screw-resistance test: introduced by Jemt in 1991 based on his experience that a clinically acceptable level of misfit was 150 microns, which corresponds to half the distance between the Nobel Biocare prosthetic gold screw threads. Gold screws are tightened one by one starting with the implant closest to the midline until initial resistance between the head of the screw and the framework is encountered. A

maximum of a half turn (150 microns) was then allowed to completely seat the screw.

Altogether, 8 frameworks were tried, installed, and successfully demonstrated clinically acceptable fit using all four testing modalities at first attempt.

Table 3.2.1.1 summarizes the results of the different tests.

Table 3.2.1.1 Summary of tests – Framework Fit

Patient I.D #	**1**	**2**	**3**	**4**	**6**	**8**	**9**	**10**
Alternate finger pressure	ok	ok	ok	ok	ok	ok	ok	ok
Visual and Tactile	ok	ok	ok	ok	ok	ok	ok	ok
One-screw test	ok	ok	ok	ok	ok	ok	ok	ok
Screw resistance test (turns)	<0.5	<0.5	<0.5	<0.5	<0.5	<0.5	<0.5	<0.5

3.2.2 A-P Spread and Cantilever Values

Using a theoretical mathematical model, Skalak (25) concluded that cantilevered ends of an ISFP increases the loading on the first screw nearest to the cantilevered end and that moderate cantilevers may be tolerated provided the fixtures are sufficiently strong. Based on theoretical geometric consideration and clinical experiences with the Brånemark System, Rangert (26) provides simple guidelines for controlling occlusal loads on implants and prosthetic reconstructions – an A-P spread (distribution distance between the most anterior and most posterior implants) of 10mm was proposed for a cantilever of 20 mm (2 x A-P spread) for mandibular ISFP's. English (27) proposed anecdotally that a very reasonable rule of thumb for

determining posterior cantilever in mandibular ISFP's should be 1.5 times A-P spread. According to English, this would allow a 10-12 mm posterior cantilever for the mandible whereas maxillary ISFP posterior cantilevers should be reduced to 6-8mm due to lower bone density. Taylor (28) suggests that cantilevers greater than 10-12 mm may be overloading factors for ISFP's in the edentulous maxilla. A systematic review, Salvi et al.(29) appraised the literature relating the impact of mechanical/technical risk factors on implant-supported reconstructions. The authors conclude that presence of cantilever extension(s) greater than 15 mm and the length of the reconstructions were associated with increased mechanical and technical complications. In one of the included studies, Shackleton et al. (30)retrospectively analyzed the effect of cantilever extensions in ISFP's for 25 patients (28 ISFP's: 24 mandibles and 4 maxillae) and concluded that ISFP's with cantilevers of 15mm or less had survived significantly better than ISFP's with greater than 15 mm of cantilever.

Reported guidelines for cantilever extensions appear to be referenced to (i) a maximum acceptable value which tends to be greater in the mandible compared to the maxilla and (ii) a multiplying factor of the A-P spread providing individualized patient dependent values.

In a 15-year follow-up study of 76 patients treated with ISFP's in the edentulous maxilla, posterior cantilever values ranging from 7 to 12 mm were reported. A review of published maxillary ISFP's studies revealed that anterior cantilever values have not been previously reported.

The authors of the present study speculate two possible explanations: (i) forces of occlusion are higher in the posterior areas and, by extension, cantilevers in the anterior regions may not contribute to stress on ISFP's, hence reducing its significance (ii) ISFP's in the edentulous maxilla are traditionally supported by more than 4 implants with more implants distributed in the premaxilla.

With the use of 4 implants in the present study (canine and first molar position), we have found that anterior cantilevers may have significant values sometimes exceeding posterior cantilever values in the same patient.

For each ISFP, one anterior cantilever value (A) was measured using the most anterior tooth on a perpendicular from the line joining the two anterior implant abutments and two bilateral posterior cantilever values (P(Rt) & P(Lt)) were measured. The mean anterior cantilever value was 10.1 mm (range of 7 to 15mm) and the mean posterior cantilever value was 10 mm (range of 2 to 16mm).

Table 3-2-2-1 lists the cantilever values for 8 subjects who received their ISFP.

The A-P spreads were measured bilaterally for the 8 subjects that have received their definitive ISFP. The right and left A-P spread values were obtained by measuring the distance between the implant abutments on the definite master casts and reported in table 3-2-2-2

Table 3-2-2-1 Anterior and posterior cantilever values in (mm)

Patient ID #	Anterior	Posterior(Rt)	Posterior(Lt)
1	14	13	13
2	15	2	2
3	9	16	12
4	12	12	11
5	Treatment	in progress	
6	7	5	5
7	Excluded	from study	
8	7	9	9
9	8	13	10
10	9	14	14
Mean (mm)	**10.1**	**10.5**	**9.5**

Table 3-2-2-2 Anterior-Posterior (A-P) values in (mm)

Patient ID #	A-P Spread Right	A-P Spread Left
1	18	15
2	16.5	16
3	18	16
4	13.5	14.5
6	26	26
8	22	17
9	11	11
10	20.5	14
Mean A-P Value (mm)	**18.2**	**16.2**

3.2.3 Anterior horizontal and vertical overlap

Anterior horizontal and vertical overlap has not been reported in clinical studies on ISFP's. The authors hypothesize that minimal anterior vertical overlap should be a clinical goal to minimize fracture of acrylic veneer or denture teeth. During chewing function, the mandibular anterior teeth may impart eccentric horizontal forces causing technical failure/fractures of the maxillary anterior acrylic teeth. Minimal vertical overlap may offer a significant advantage to minimize horizontal forces on the maxillary anterior teeth. In a review article, Kim et al.(31) propose group function occlusion or mutually protected occlusion with shallow anterior guidance when opposing natural dentition.

The distribution of occlusal function during protrusive movement may also have some merit in maximizing occlusal load on several teeth. In the present study, mean values of vertical and horizontal overlap are presented (Table 3-2-3-1).

Table 3-2-3-1 Vertical and Horizontal Overlap

Patient ID #	Vertical Anterior Overlap	Horizontal Anterior Overlap
1	3	3
2	1	1
3	4	2
4	2	3
6	1	1
8	2	3
9	3	4
10	2	3.5
Mean Value (mm)	**2.3**	**2.6**

The authors have also made every effort to minimize vertical overlap (shallow anterior guidance) and to provide anterior group function on protrusion. It should be noted that the only resin tooth fractures encountered in the study population was observed on the subject presenting the highest vertical overlap (Patient #3 = 4 mm) and opposed natural dentition.

3.2.4 Prosthetic Complications

Prosthetic complications were minimal and could easily be managed during the same visit. In the present study, two technical complications were observed: (1) an acrylic tooth came loose and was repositioned with repair acrylic and (2) a small incisal chip was noted on another acrylic tooth, the chip was not noticed by the patient – the chip was too small to justify replacement and was therefore smoothed with patient's consent. Both technical complications were observed on the same patient (#3). It may be worthy to note that the opposing dentition was fixed/natural dentition.

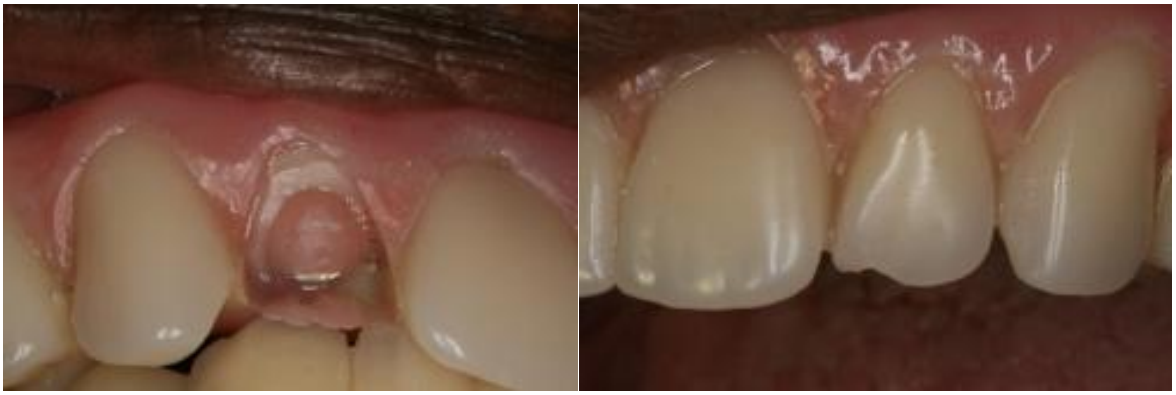


Figure 1.19: Patient #3 – Prosthetic Complications

No prosthetic/abutment screw loosening/fractures or other prosthetic/technical complications were observed over the observation period of up to one year.

The most prevalent prosthetic complication associated with metal-acrylic ISFP's is acrylic veneer/tooth fracture (22). Less frequent complications include loose/fractured prosthetic and abutment screws and framework fractures. One study (23) identified a significantly higher ratio of problems in maxillary ISFP's than in mandibular ISFP's. Fractures of resin teeth were more common problems in the maxillary ISFP's.

4 DISCUSSION

This new treatment approach with 4 implants showed successful short-term outcomes in select cases and implant failures in a three of the 10 subjects. Implant failures occurred predominantly in the premaxilla between implant placement and abutment installment. Complications were minimal after prosthesis loading and were technical in nature (acrylic teeth fracture).

Other studies compared tilted and axial placement of implants. Number and length of implants, implant failures encountered, the evolution of ISFP's, prosthodontic planning as it related to A-P spread and cantilevers, and finally strengths/limitations of the present study will be discussed.

Tilted versus axial implants

Aparicio et al. (32)studied the use of a combination of tilted and axial implants with severely resorbed maxillae as an alternative to sinus grafting. 25 patients were restored with 29 fixed partial dentures supported by 101 implants (59 axial and 42 tilted). They reported 100 % cumulative implant survival rate for the tilted implants and 96.5% for the axial implants. All prostheses except two were stable at the fifth year follow-up. 18 abutment screws, 5 gold screws in a total of 14 prostheses needed retightening. 2 abutment screws and 2 occlusal surfaces fractured. This suggests that the use of tilted implants to avoid sinus grafting in the posterior maxilla is an effective approach with some technical complications related to fracture or loosening of gold screws and abutments.

Malo et al. (8) applied the “All-on-4” immediate function concept with long angled implants within the anatomic limitation of the edentulous maxilla and reported a 1-year cumulative survival rate of 97.6%.

Rosen et al. (33) in a long-term follow-up study placing 4 to 6 tilted implants in severely resorbed edentulous maxillas on 19 patients (total of 103 implants) reported a survival rate of 97%. The mean follow-up time was 10 years, demonstrating that in patients with severely resorbed maxillas may be treated successfully with tilted implants as an alternative to more resource-demanding techniques with bone grafting.

Astrand at al. (34) in a 20-year follow-up study recalled 21 patients with a total of 23 ISFP’s – all patients were treated ad modum Branemark. Most prostheses in the upper jaw were supported by 4 implants while 6 implants were used in the mandible. The choice of 4 maxillary implants was because of restricted bone volume. In the reported patient group, the implant survival rate was 99.2%. This group, however, is part of a larger group of 48 patients treated over 20 years ago. Technical complications were few and easy to take care of since the prostheses were screw retained. Jemt et al, (35) reported in a 15-year follow-up study on 28 patients examined (168 implants) with ISFP’s in the edentulous maxilla. The ad modum Branemark protocol was used for this study also. They reported a 90.9 % cumulative survival rate and prosthetic complications were related to fractures (14 resin veneers, 1 framework and 1 gold screw).

From these studies, it may be concluded that survival rates of tilted implants remain comparable to axially placed implants. Abutment/screw loosening and fractures are

related to implant supported prostheses, however the rate of these complications seem to increase on tilted implants.

Number and length of implants (short)

Implant size and number in the present study may be controversial. The concept of using implants of small dimension (short) and in small numbers (four) to support a full arch fixed prosthesis in the edentulous maxilla defies conventional treatment planning whereby at least 6 implants(4) or even 8 to 10 implants(7) have been advocated.

When Brånemark (21) introduced osseointegration to North America, he suggested that a minimum of four fixtures appears to be adequate for support of a full arch prosthesis in the edentulous jaw. However, if morphologically feasible, six fixtures are installed to provide a certain reserve should a fixture not become integrated or lose its integration over the years.

Short implants (6 - 8.5 mm) in posterior segments of severely atrophied maxillae have demonstrated cumulative survival rates of 94.6% for an average follow-up of 37.6 months for the 85 patients with 96 implants supporting single-tooth and partial reconstructions(36).

High Crown/implant ratios may also be a subject of discussion. The use of short implants inevitably increase crown/implant rations which may be perceived as unfavorable for both implants and restorations. Blanes et al. (37) in a long-term prospective study on 192 implants showed that implant restorations with high Crown/implant (C/I) ratios greater than 2 showed a cumulative survival rate of

94.1%. Within the limitations of the study, they concluded that implant restorations with high clinical C/I ratios do not demonstrate lower survival or success rates as compared with implant restorations with low C/I ratios. As a result, the use of implant restorations with C/I ratios of 2–3 may be successful in the posterior region of the mouth.

In the present study, four implants, no longer than 11mm and as short as 6 mm, were utilized for a mean implant length of 8.5 mm. This approach allowed placement of fixtures in patients with limited ridge dimension and so-called unfavorable sites. Implant angulations were kept within prosthetically manageable limits and axial placement was achieved in most posterior sites. Another noticeable advantage of this modality was the ability to provide excellent A-P spread and acceptable cantilever values even when second molar replacement was provided. This will be further discussed later.

Implant failures

In the present study, several implant losses were experienced. All failures occurred between initial implant placement appointment and stage-2/abutment installation appointment and were predominantly in the premaxilla (5/7). One patient (#7) lost all 4 initial implants accounting for the 2 posterior implants lost in the study.

In a descriptive analysis (38) of implant and prosthodontic survival rates with fixed implant-supported rehabilitations in the edentulous maxilla. The 1 to 15-year survival rates of fixed implant rehabilitations in the edentulous maxilla was reviewed**.** Thirty-three studies, including 1,320 patients and 8,376 implants, were selected for

analysis. The overall calculated implant survival rates ranged from 94% (1 year) to 87.7% (15 years). Two conclusions from this study: (i) Implants placed in augmented bone had a statistically lower survival rate, except for rough-surface implants, for which no statistical difference between augmented and non-augmented bone survival rates was found and (ii) Implant number and distribution along the edentulous maxilla seemed to influence the prosthodontic survival rate. When comparing the number of implants per edentulous maxilla, protocols with 6 or more implants showed higher prosthetic survival than protocols with less than 6 implants. there was a trend at each time point without statistical significance. Implant-prosthetic protocols with an anterior-posterior implant distribution resulted in statistically significant higher prosthodontic survival rates compared to those with an anterior implant allocation design. From this review, it appears that increased A-P spread seems to improve prosthesis survival.

For the present study, 3 patients lost 5 pre-maxillary implants. 3 of 5 implants were replaced after grafting the sites with Bio-oss/Biogide. One patient (#8) presented with a loose anterior implant: the implant was removed and replaced in conjunction with grafting. For the second patient (#5), the two premaxillary implants were removed the sites were grafted. The implants were replaced after 4 months of healing. The third patient (#7) lost all 4 of her initially placed implants and was unable to complete the protocol. All 3 patients (#'s 5, 7, 8) initially presented with less than 5mm of Facial-lingual bone dimension at the implant sites, requiring the use of osteotomes for site expansion and placement of bone collected from the osteotomy sites.

These observations could suggest that: (i) a minimal facial-lingual dimension of 6 mm may be required for placement of 4mm diameter implants and (ii) deficient premaxillary sites (< 6mm facial-lingual dimension) may benefit from bone grafting at the time of implant placement or delayed placement of implants in the healed grafted sites. Although none of the 10 enrolled subjects in the present study had unfavorable maxillomandibular relationships, the patients that experienced implant losses prior to implant loading, had limited facial-lingual bone dimensions in the premaxilla. However, other patients in the protocol (#'s 1, 2, 9, 10), also with limited bone dimensions did not experience implant failures prior to implant loading.

Zitzmann and Marinello (7) discussed that if a treatment planning protocol considering anatomic patient factors (among other considerations) is followed, implants can be placed to comply with the selected prosthetic solution (fixed or removable) and compromised solutions may be averted. They conclude that the fixed design for implant prosthesis is only appropriate for patients with minimal resorption of the alveolar bone and an optimal maxillomandibular relationship. A removable overdenture may be indicated from the outset and is no longer restricted to patients with a compromised situation in which fixed implant prostheses are not feasible.

Evolution of ISFP's

ISFP's have evolved and changed over the years. Maxillary and mandibular ISFP concepts and design were originally dependent on available bone and placement of axial implants anterior to the maxillary sinus and between the mental foramen in the

mandible. Cantilevers as much as 15 mm were not unusual. The cantilever problem was resolved with the evolution of distributed implant placement. To achieve better A-P spread and distribution, implants were tilted. This concept still enabled placement of longer implants that avoided anatomic structures and provided sufficient primary stability for immediate function. The effects of angulated implants include reduced cantilever values, required use of angulated abutments in most cases and possible increased occurrence of loose and fractures abutments/screws.

Prosthetic frameworks in ISFP's have also undergone noticeable evolution. The original ad modum Branemark prostheses utilized cast gold alloy frameworks. Long-term studies have reported framework fractures although rare. Ortorp et al., in a 10-year comparative clinical study showed that milled titanium framework were comparable to cast gold frameworks and offered an alternative for full arch ISFP's. there were a total of 3 framework fractures (1 Titanium and 2 Gold) reported at follow-up from a total of 72 ISFP's (37 mandibles, 35 Maxillae) examined at 10 years.

The present study utilized a CAD-CAM Cobalt-Chromium which is a stronger metal than titanium. The framework design incorporated individual extensions (tooth–supports) that may minimize acrylic fractures and provide enhanced support to the acrylic prosthetic teeth and pink veneering acrylic. Adequate cross-sectional framework dimensions and contour were well controlled prior to fabrication by using a three-dimensional viewer software. The digital rendering of the framework was evaluated in relation to the planned tooth-positions and arch shape defined by the

patients duplicated maxillary denture. This provided improved utilization and distribution of available restorative space between the prosthetic framework and the acrylic veneer/prosthetic teeth. The authors hypothesize that this methodology helped the design and fabrication of a robust prosthesis.

Prosthodontic Planning: Cantilevers and A-P Spread

The prosthodontic treatment planning goals included maximization of A-P spread, minimizing cantilever and providing minimal vertical anterior overlap / shallow anterior guidance. Individual measurements and mean values of A-P spread, cantilever values, anterior vertical and horizontal overlaps that were achievable for 8 patients that received their definitive ISFP were provided. The authors hypothesize that these factors may reduce fatigue and stress on the abutment/screw/prosthesis assembly and reduce the frequency of fractures/chipping of the anterior acrylic teeth which is one of the common complications reported.(22,23,35). In the present study, the ratio of posterior cantilever length to A-P spread was 0.6 bilaterally (Table 4.1), significantly less than what has been proposed (26,27). By extension, this may enable increased cantilever values while maintaining an acceptable Cantilever/A-P Spread ratio if required.

Table 4.1: Ratios of Posterior Cantilever to A-P spread

	Ratios Posterior Cantilever to A-P Spread	
Patient ID #	RIGHT	LEFT
1	0.7	0.9
2	0.1	0.1
3	0.9	0.8
4	0.9	0.8
5		
6	0.2	0.2
7		
8	0.4	0.5
9	1.2	0.9
10	0.7	1.0
Mean Ratio	**0.6**	**0.6**

Strengths and limitations

Limitations

This study investigated the safety, potential and feasibility of a new treatment modality incorporating the use of a perceived small number (4) of implants as well as the strategic use of implant as short as 6 mm. It was a pilot study on a small sample of patients (n=10). As such, the implant and prosthetic data are descriptive and explanatory with no statistical significance. During the clinical trial, problems of early implant loss were experienced with some patients prior to prosthesis loading. This may suggest that perhaps bone grafting to augment the implant sites prior to placement were needed on these patients. The study was short term and more long-term data is required before any conclusive recommendations may be presented on this treatment modality.

Strengths

This was a prospective study that sought to expand the application of fixed implant rehabilitations in the edentulous maxilla. If non-anatomic (financial limitations, medical, age, fear) exclusion criteria were not applied, altogether 19 of the 36 patients (52.8%) initially screened could have been included in this study. This may suggest that a high percentage of edentulous maxillas could be treated with a simplified protocol. Minimal prosthetic complications were experienced and were easily manageable at the same appointment. No patients were lost to follow-ups during the study and no implant losses were experienced after prosthesis delivery.

5 CONCLUSION

i. Short implant placement and support of maxillary ISFD using four short implants is possible in select patients, but with caution, due to lack of long-term follow up at 1 and 5 years to determine implant survival and prosthetic complications.

ii. Short implant in the posterior maxilla may allow a reduction of posterior cantilever by engaging more posterior sites without grafting.

iii. Short implants in the premaxilla allows lingual and quasi-axial placement within the protruding ridge compared to longer implants of equal diameter. This may facilitate prosthetic design and conception.

iv. All Implant failures occurred prior to prosthesis delivery (preloading) and were predominantly in pre-maxillary sites.

v. No implant loss was reported after prosthesis delivery in 8 patients.

vi. CAD/CAM Cobalt-Chrome Framework technology offers several advantages including fidelity of design, goodness of fit and high modulus of elasticity.

vii. Prosthetic complications were minimal and easily managed.

PART TWO: ORAL HEALTH & QUALITY OF LIFE

1 INTRODUCTION

1.1 Prevalence and scope of edentulism

Edentulism is unfortunately still a prevalent disability among the older-age group. The percentage of complete edentulism has been estimated to be 26% for people more than 65 years of age in the USA (39). In 2002, Douglass et al. stated that the prevalence of edentulism dropped by approximately 10% for each decade of the past 30 years in the United States(1), yet, because of population growth, especially in older age group, an increase in the number of edentulous patients can be expected. The total need for treatment of edentulism will rise in the next 10 years. Therefore, the need for complete dentures will continue to increase through the year 2020.

More recently, complete edentulism has been described as the terminal outcome of a multi-factorial process involving biological factors and patient-related factors. It continues to represent a tremendous global health care burden, and will for the foreseeable future. Furthermore, systemic and oro-facial comorbid factors associated with complete edentulism have also been discussed (2).

1.2 Quality of life and complete dentures

A recent review article(40) found that despite the best efforts of dentists, there seems to be a small but ever existent group of complete denture wearers who remain dissatisfied despite the provision of technically correct dentures. Several authors who have attempted to quantify the proportion of the edentulous population that may be non-adaptive were included in the review paper.

The results are summarized in table 1-2-1.

Table 1-2-1: Residual dissatisfied patients with complete dentures

Author		Residual Dissatisfied Patients
Al Quran et al.	2001 (41)	16 %
Berg et al.	1984(42)	10 – 15 %, Mandible > Maxilla
Bergman & Carlsson	1972(43)	10 – 15%
Celebic et al.	2003(44)	7.2 %
Magnusson	1986(45)	10 %
Van Waas	1990(46)	Maxilla: 10 %, Mandible: 21 %

1.3 Rationale for ISFP's in the edentulous maxilla

A prospective clinical study (47) comparing the treatment outcomes of fixed and removable implant-supported prostheses in the edentulous maxilla emphasized the patient's point of view. 20 patients were included and 10 patients received a fixed prosthesis and 10 patients a removable overdenture. A visual analogue scale was administered to the patients to evaluate patients' assessments of their treatment. Patients in both groups were similarly satisfied with regard to their well-being and cost-utility irrespective of whether their implant-supported prosthesis was fixed or removable.

A retrospective study of 62 patients to assess patient satisfaction and oral health related quality of life (OHQOL) outcomes of implant overdentures and fixed complete dentures, Brennan et al.(48) has shown high satisfaction for both groups. Of the 62 patients 9 had maxillary ISFP's and 22 maxillary implant-supported overdentures. Using the OHIP-14(49) instrument, the authors concluded that overall OHQOL was high, however, the ISFP group demonstrated significantly lower psychological discomfort and disability compared to the removable overdenture group. Also, among the patients receiving similar number of implants, those who received an implant overdenture were less satisfied and had a lower OHQOL that those with an ISFP.

When provided with a choice between removable and fixed restorations in the edentulous maxilla, some patients have elected to have a fixed prosthesis. Heydecke et al.(50) studied 13 subjects edentulous in the maxilla in a within-subject comparison of fixed versus removable implant-supported maxillary prostheses. The aim was to assess patients' satisfaction and choice of prosthesis. 8 and 5 subjects were initially provided with a fixed and removable implant-supported maxillary prosthesis respectively. The prostheses were then switched for removable and fixed respectively after 2 months of wear. The patients were then asked to choose which prosthesis they wanted to keep. 4 of 13 decided to keep the fixed prosthesis. It appears that some patients would prefer to have an ISFP in the maxilla when given the choice.

These three studies present some evidence that both removable and fixed implant supported prostheses in the edentulous maxilla may provide satisfaction and

OHQOL to patients. Some patients when given the choice, prefer a fixed prosthesis. It is possible in some patients that an ISFP may provide superior OHQOL and lower psychological disability when compared to a removable implant-supported prosthesis.

Therefore, there seems to be a good rationale to provide ISFP's to some patients that may desire and benefit from such therapy. It is important that, when possible, treatment plans for implant therapy in the edentulous maxilla should include both modalities – fixed and removable.

2 MATERIALS AND METHODS

2.1 Patient selection

Patient seeking implant therapy for the edentulous maxilla who had interest or were potentially in need of a maxillary ISFP were asked to contact the investigators regarding possible enrollment in the study protocol. Potential patients were offered a screening appointment in the Graduate Prosthodontic Clinic at the School of Dentistry of the University of North Carolina at Chapel Hill (UNC-CH).

Table 2-1-1: Demographic Characteristics for enrolled subjects.

Characteristic	Statistic	Subjects (N=10)
Age	Mean	62.1
	Min, Max	39.3, 78.3
Gender		
Male	N (%)	3 (30%)
Female	N (%)	7 (70%)
Race		
Caucasian	N (%)	8 (80%)
African-American	N (%)	2 (20%)

Altogether, 36 patients (16 men and 20 women) were screened. Consecutive enrollment of 10 patients fulfilling all inclusion criteria was completed over a period of five months from May to September 2009. A screening questionnaire (Appendix B) was used to assist in recruitment. Reasons for exclusion were mostly due to anatomic limitations, financial, medical or patient's choice. The details of inclusion and exclusion was presented in part one. The aim of this study was to assess the impact of an ISFP in the edentulous maxilla on the OHQOL and satisfaction

compared to baseline values. The OHIP-49 instrument (19) was utilized for this assessment. The patients' demographic information is summarized in table 2-1-1.

2.2 From complete dentures to ISFP's

The study was a prospective clinical trial involving treatment of patients edentulous in the maxilla with a definitive maxillary metal-acrylic implant supported fixed prosthesis (ISFP). Through a series of 15 appointments described in part one, the 10 enrolled subjects underwent the same protocol for treatment over a period of 15 to 18 months. One patient did not complete the protocol because of early failure of all initial implants and therefore could not receive her final ISFP.

The treatment protocol is chronologically outlined below:

- Screening, enrollment, examination, initial records and consent
- Baseline administration of OHIP-49
- Fabrication of ideal maxillary complete denture
- Treatment planning of Implant therapy and ISFP
- Implant placement (surgery)
- Following implant integration, abutment connections and impressions for ISFP fabrication
- Delivery of ISFP
- 1 to 2 weeks post-delivery of ISFP and administration of OHIP-49
- 6 months post-delivery of ISFP and administration of OHIP-49
- 12 months post-delivery of ISFP and administration of OHIP-49

2.3 The Oral Health Impact Profile (OHIP-49) instrument

Guckes et al. presented a conceptual framework for understanding outcomes of oral implant therapy. This framework addressed four major required concepts: safety, efficacy, effectiveness and outcomes. In the treatment outcomes, the authors suggest that one should understand longevity/survival, physiologic impact, psychologic impact, and finally economic impact. The main aim of the present study was to assess the physiologic and psychologic impact of the maxillary ISFP treatment modality on a group of 10 patients. Physiologic and psychologic impact include masticatory efficiency, bite force, maintenance of bone, effect of treatment on diet/nutrition, oro-facial body image, perceived satisfaction with prosthesis, self-esteem and interpersonal relations.

The ultimate goal of implant therapy is the improved OHQOL of the patient receiving care. An instrument for evaluating OHQOL is the Oral Health Impact Profile – 49. This is a self-administered 49 item questionnaire that assesses theoretical subscales or dimension of the adverse oral health adapted by Locker from the1980 World Health Organization International Classification of Impairments, Disabilities and Handicaps (ICIDH). The subscale categories are functional limitation, physical pain, psychological discomfort, physical disability, psychological disability and handicap.(19,51)

2.4 Data collection

The OHIP-49 questionnaire was administered to the patients at 4 time points:

- 1. Baseline: prior to any treatment upon enrollment

- 2. One to two weeks after final delivery of ISFP
- 3. Six months after final delivery of ISFP
- 4. Twelve months after final delivery of ISFP (not available at time of reporting).

At the time of reporting, 10 patients provided completed questionnaires at baseline. 7 patients provided completed questionnaires at one to two weeks after final delivery of ISFP and 7 patients provided completed questionnaires for six months after final delivery of ISFP. The OHIP-49 data was input on an excel file by the investigator and verified by another person prior to statistical analysis.

2.5 Methods

The OHIP-49 questionnaire measures the adverse consequences of oral disorders on different aspects of quality of life.(19) Each of 49 items asks respondents how often they have experienced an adverse impact within a specified time interval. Responses are made on an ordinal scale ranging from “never” (coded 0), “hardly ever” (coded 1), “occasionally” (coded 2), “fairly often” (coded 3) to “very often” (coded 4). The summary variable used in this analysis was the severity score computed as the sum of ordinal responses across all items.(52) This yields a potential range of zero to 192, with higher scores indicating poorer oral health quality of life. The OHIP-49 typically yields low severity scores since the questionnaire intentionally captures only severe adverse impacts. In the few instances where responses were missing or the response was marked “don’t know”, the sample mean for that item was substituted.

2.6 Analytic Methods

The small number of observations violated the assumption of normally distributed OHIP-49 scores and precluded use of parametric methods. Instead, the Wilcoxon signed-ranks test performed a non-parametric analog of the paired Student's t test. Consistent with this test, median OHIP-49 severity scores were reported as the measure of central tendency with the interquartile range (IQR) acting as the measure of dispersion. Analysis compared a patient's OHIP-49 severity score at baseline against their OHIP-49 score reported 1−2 weeks post prosthetic delivery. Also compared were paired scores at 1−2 weeks and six months post delivery.

The null hypothesis stated that the paired scores, when ranked, were the same at each time point. The P-value describes the difference in the distribution of ranked paired-scores, as opposed to a difference in the median values themselves. A two-tailed P-value of less than 0.05 was considered adequate to reject the null hypothesis; and hence indicate a statistically significant difference in the paired observations. To identify in which dimensions were associated with changes in OHIP-49 after treatment, each of the seven OHIP dimensions was separately examined. Analysis was conducted using Stata software, release 11.1 (StataCorp. 2009. Stata Statistical Software: Release 11. College Station, TX: StataCorp LP).

3 RESULTS

All 10 patients completed the OHIP-49 questionnaire at baseline. Because two patients did not complete the questionnaire at the 1−2 week visit, statistical analysis

was confined to those with paired data (n=8). Baseline OHIP-49 severity scores ranged from a low of 12 to a high of 137 with a median value of 72 (IQR 44, 103). At 1-2 weeks post prosthetic delivery, these scores had fallen substantially, now ranging from 8 to 24 with a median value of 13 (IQR 9, 11) (P-value =0.0173), permitting rejection of the null hypothesis (results not tabulated).

Table 3-1: Absolute OHIP-49 severity score recorded at baseline and at two points post prosthetic delivery

Patient #	Baseline OHIP-49 severity score	1-2 week OHIP-49 severity score	6 month OHIP-49 severity score
1	89	8	11
2	12	13	4
3	117	9	6
4	36	10	3
6	57	20	11
8	137	24	…
9	52	12	10
10	86	19	8

Among the 7 patients with data at all three time-points, OHIP-49 severity scores decreased for all but patient #1 who reported a small increase at the six-month visit. The magnitude of effect was immense. It ranged from a three-fold decrease in adverse impacts for patient #2 to a 20-fold reduction in impacts for patient #3 (Table 3-1).

OHIP-49 data from the 6-month visit were obtained for seven patients. Further small reductions in OHIP-49 scores were observed at this time. The range of distribution was 3-11 with a median of 8 (IQR 4, 11). In comparison with scores obtained at the 1-2 week visit, these 6 months scores were lower, but the difference failed to reach statistical significance (P= 0.0630)(Figure 3-3).

To identify the subscale on which greatest gains in oral health quality of life were achieved, scores on each of the seven subscales were examined at the three time points. OHIP scores fell significantly on all seven dimensions for every patient between baseline and the 1-2 week post delivery visit (Table 3-2). In absolute terms, greatest reduction occurred on the functional limitation subscale. These items (#1-#9) deal with factors such as chewing ability, speech, food catching and denture fit.

Table 3-2: Median OHIP severity scores (interquartile range) for the overall OHIP-49 questionnaire and its seven subscales at baseline, 1-2 weeks post prosthetic delivery, six-month post prosthetic delivery

	Baseline		1-2 week post delivery		
	Median	(IQR)	Median	(IQR)	P-value [(a)]
OHIP-49 severity score (items #1-49)	72	(44, 103)	13	(9, 20)	0.0173
Functional limitation (items #1−9)	18	(12, 28)	5	(5, 7)	0.0173
Physical pain (items #10−18)	14	(8, 20)	3	(2, 3)	0.0117
Psychological discomfort (items #19−23)	12	(6, 14)	1	(0, 3)	0.0170
Physical disability (items #24−32)	13	(10, 20)	4	(2, 5)	0.0173
Psychological disability (items #33−38)	7	(4, 12)	0	(0, 1)	0.0140
Social disability (items #39−43)	4	(1, 8)	0	(0, 1)	0.0193
Handicap (items #44−49)	2	(1, 9)	0	(0, 1)	0.0193

Table 3-2 (continued)

6 months post delivery		
Median	**(IQR)**	**P-value [(b)]**
8	(4, 11)	0.0630
3	(3, 6)	0.1255
1	(0, 2)	0.1669
0	(0, 0)	0.0496
2	(0, 0)	0.2008
0	(0, 0)	0.1585
0	(0, 0)	0.3173
0	(0, 0)	0.1585

(a) P-value denotes whether the distribution of ranked paired-scores differs at 1-2 weeks from baseline

(b) P-value denotes whether the distribution of ranked paired-scores differs at 6 months from 1-2 weeks

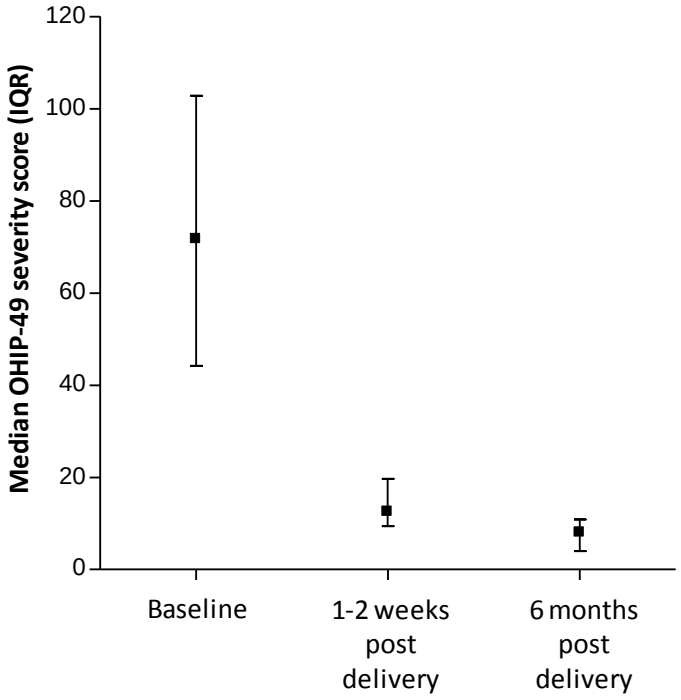


Fig 3-3: Median OHIP-49 severity score and interquartile range at baseline (n=8), and at 1−2 weeks (n=8) and 6 months (n=7) post prosthesis delivery. Reductions in OHIP severity scores from their baseline levels were statistically significant at 1−2 weeks post prosthetic delivery (P= 0.0173). The difference in OHIP-49 scores between the 1−2 weeks and 6 month visits failed to reach significance (P= 0.0630)

4 DISCUSSION

It was shown that 96 % of patients experience an improvement in OHQoL following treatment with fixed, removable and complete dentures. However, after treatment, patients receiving removable or complete removable prosthodontics had poorer OHQoL that did patients receiving fixed prosthodontic treatment. (53)

An ISFP is considered a fixed prosthodontic treatment. An alternative to ISFP's is the Implant-supported Removable Overdenture. Patients receiving treatment with an ISFP or ISRO may experience similar satisfaction provided similar specific indication criteria are carefully assessed by the clinician.(7,47)

Although, a majority of patients (9 of 13) in previously described study(50) preferred to keep their ISRO when given the choice between an ISFP and an ISRO after having used and experienced both prostheses for a period of 2 months each.

In the present study, within two weeks of ISFD delivery, clinically meaningful and statistically significant reductions in median OHIP-49 scores were observed, signifying a dramatic improvement in OHQoL. These post treatments OHIP scores were similar to those of healthy dentate adults in the US population. At six months post-treatment, these gains were maintained in all patients.

5 CONCLUSION

i. This was a prospective clinical study with a small sample size of 10 patients to investigate the impact of 4-Implant supported fixed prostheses (ISFP's) on oral health quality of life (OHQoL) of patients with edentulous maxillae.

ii. Greatest reduction in OHIP-49 severity scores occurred on the functional limitation subscale which deals with factors such as chewing ability, speech, food catching and denture fit.

iii. Maxillary ISFP's significantly improved the OHQoL of participants. Post-treatments OHIP scores were similar to those of healthy dentate adults in the US population.

APPENDIX A

Because of problems with your teeth, denture, or mouth have you….
(Oral Health Impact Profile-49)

	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know
1. Have you had difficulty chewing any foods because of problems with your teeth, mouth, or dentures?						
2. Have you had trouble pronouncing any words because of problems with your teeth, mouth, or dentures						
3. Have you noticed a tooth which doesn't look right?						
4. Have you felt that your appearance has been affected because of problems with your teeth, mouth, or dentures?						
5. Have you felt that your breath has been stale because of problems with your teeth, mouth, or dentures?						
6. Have you felt that your sense of taste has worsened because of problems with your teeth, mouth, or dentures?						
7. Have you had food catching in your teeth or dentures?						
8. Have you felt that your digestion has worsened because of problems with your teeth, mouth, or dentures?						
9. Have you felt that your dentures have not been fitting properly?						
10. Have you had painful aching in your mouth?						
11. Have you had a sore jaw?						
12. Have you had headaches because of problems with your teeth, mouth, or dentures?						
13. Have you had sensitive teeth, for example, due to hot or cold foods or drinks?						
14. Have you had tooth ache?						

15. Have you had painful gums?	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know
16. Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth, or dentures?	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know
17. Have you had sore spots in your mouth?	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know
18. Have you had uncomfortable dentures?	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know
19. Have you been worried by dental problems?	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know
20. Have you been self conscious because of your teeth, mouth, or dentures?	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know
21. Have dental problems made you miserable?	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know
22. Have you felt uncomfortable about the appearance of your teeth, mouth, or dentures?	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know
23. Have you felt tense because of problems with your teeth, mouth, or dentures?	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know
24. Has your speech been unclear because of problems with your teeth, mouth, or dentures?	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know
25. Have people misunderstood some of your words because of problems with your teeth, mouth, or dentures?	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know
26. Have you felt that there has been less flavour in your food because of problems with your teeth, mouth, or dentures?	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know
27. Have you been unable to brush your teeth properly because of problems with your teeth, mouth, or dentures?	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know
28. Have you had to avoid eating some foods because of problems with your teeth, mouth, or dentures?	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know

29. Has your diet been unsatisfactory because of problems with your teeth, mouth, or dentures?	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know
30. Have you been unable to eat with your dentures because of problems with them?	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know
31. Have you avoided smiling because of problems with your teeth, mouth, or dentures?	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know
32. Have you had to interrupt meals because of problems with your teeth, mouth, or dentures?	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know
33. Has your sleep been interrupted because of problems with your teeth, mouth, or dentures?	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know
34. Have you been upset because of problems with your teeth, mouth, or dentures?	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know
35. Have you found it difficult to relax because of problems with your teeth, mouth, or dentures?	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know
36. Have you felt depressed because of problems with your teeth, mouth, or dentures?	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know
37. Has your concentration been affected because of problems with your teeth, mouth, or dentures?	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know
38. Have you been a bit embarrassed because of problems with your teeth, mouth, or dentures?	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know
39. Have you avoided going out because of problems with your teeth, mouth, or dentures?	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know
40. Have you been less tolerant of your spouse or family because of problems with your teeth, mouth, or dentures?	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know
41. Have you had trouble getting on with other people because of problems with your teeth, mouth, or dentures?	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know
42. Have you been a bit irritable with other people because of problems with your teeth, mouth, or dentures?	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know

43. Have you had difficulty doing your usual jobs because of problems with your teeth, mouth, or dentures?	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know
44. Have you felt that your general health has worsened because of problems with your teeth, mouth, or dentures?	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know
45. Have you suffered any financial loss because of problems with your teeth, mouth, or dentures?	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know
46. Have you been unable to enjoy other people's company as much because of problems with your teeth, mouth, or dentures?	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know
47. Have you felt that life in general was less satisfying because of problems with your teeth, mouth, or dentures?	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know
48. Have you been totally unable to(eat) foods because of problems with your teeth, mouth, or dentures?	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know
49. Have you been totally unable to work to your full capacity because of problems with your teeth, mouth, or dentures?	☐0 Never or not applicable	☐1 Hardly ever	☐2 Occasionally	☐3 Fairly often	☐4 Very often	☐5 Don't know

Appendix B

QUESTIONS TO BE USED AT SCREENING APPOINTMENT

EXCLUSION CRITERIA QUESTIONS (Patients should answer "NO" to all before examination)

- Are you younger than 18 or older than 80?
- Are you unwilling to wear dentures or have a severe gag reflex?
- Are you pregnant or planning to become pregnant in the next 6 months?
- Do you have a history of radiotherapy in the head and neck region?
- Do you have any blood disorders or take medications that may interfere with coagulation? (For example: Aspirin, Coumadin)
- Do you have any systemic or local disease or condition (such as uncontrolled diabetes) that would compromise post-operative healing and specifically the healing of the implant with the bone, or systemic diseases or conditions that would make scheduled treatment or recall visits difficult or impossible?
- Are you taking systemic corticosteroids and IV bis-phosphonates and chemotherapy drugs that would compromise post-operative healing and specifically the healing of the implant with the bone?
- Do you presently have a problem with alcohol or drug abuse, or tobacco smoking or chewing during the last 6 months?
- Are you unable or unwilling to return for follow-up visits for a period of 1 year after final delivery of prosthesis?
- Do you have unrealistic esthetic expectations?
- Are you unwilling to allow access to your dental records by required personnel involved in the study?

Version 02/02/2009

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