

Complications and Patient Centered Outcomes with a Monolithic Zirconia Implant Supported Fixed Prosthesis

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Abstract

BRYAN LIMMER: Complications and Patient Centered Outcomes with a Monolithic Zirconia Implant Supported Fixed Prosthesis
(Under the direction of Lyndon Cooper DDS, PhD)

Objectives: To quantify the number and type of complications that occur with a monolithic zirconia implant supported fixed prosthesis (MZISFP) and to examine change in oral health quality of life over the course of six months. **Methods:** Fifteen edentulous patients were enrolled. Each patient was provided conventional dentures, four mandibular implants, and a mandibular MZISFP. Complication data were recorded over 6 months. The 49-item Oral Health Impact Profile was administered on three occasions: at enrollment, at implant surgery, and at 6-month recall. **Results:** Seven complications occurred during the MZISFP observation period. Implant survival was 93% and 98% from the patient and implant perspectives respectively. Prosthesis survival was 93%. OHIP-49 severity and extent scores decreased significantly over the course of the study ($p < 0.001$). **Conclusions:** Complications were infrequent and patient centered outcomes were significantly improved with a MZISFP.

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Introduction

Prevalence of edentulism in the United States has declined approximately 10% per decade over the past 30 years; yet, continued population growth and an increased proportion of older individuals within the population ensures a rise in the total number of edentulous patients. The need for conventional dentures will continue to increase in the United States through the year 2020 to an estimated 38 million adults (Douglass 2002). Edentulism results in reduced oral and social function. It is associated with poorer health status across a wide range of measures, including physical health, nutrition, disability and self-esteem (Felton 2008). Conventional dentures address the problems associated with edentulism, but do so incompletely and introduce their own set of related problems (Cooper 2009). The rapid rate of bone resorption observed in the edentulous mandible is of particular concern, as the accompanying instability of the mandibular denture is often the most troublesome complaint of the denture patient (Tallgren 1972, Allen 2001).

Dental Implant therapy offers advantages over conventional denture therapy in the treatment of mandibular edentulism by providing significant improvements in prosthesis function and patient comfort, as well as by aiding alveolar bone preservation. (Fueki 2007, Carlsson 1994, Harris 2011, Lindquist 1988, Arvidson 1998). The current literature shows a high level of biologic success with the use of 2 to 4 implants with a removable prosthesis or 4 to 6 implants with a fixed prosthesis in the edentulous parasymphyseal mandible (Adell 1981, Branemark 1995, Eliasson 2000, Ekelund 2003, Attard 2004, Bryant 2007, Malo 2011). However, many different implant prosthesis designs exist for the treatment of mandibular edentulism and despite uniformly high biologic success at the implant level, the degree of prosthetic success and the magnitude of improvement in patient centered outcomes for many of the various implant prosthesis designs

are either debated or unknown (Feine 1998, Emami 2009, Strassburger 2006, Brozini 2011, Papaspyridakos 2012).

Considering its purported benefits, the implant supported fixed prosthesis (ISFP) is one of the more desirable options in the treatment of mandibular edentulism. The most commonly used and most commonly studied ISFP is the metal-acrylic hybrid, which comes with a particular set of implementation challenges and prosthetic risks (Bozini 2011, Papaspyridakos 2012). Patient selection, surgical and prosthetic planning, fabrication method, material selection, and provider skill all contribute to successful outcomes as well as to costs (Jensen 2011, Mericske-Stern 2000, Chee 2006, Attard 2005). Further, correction of certain errors, such as a malpositioned implant, pose difficulties with the conventional metal acrylic design and invites structural or esthetic compromise (Bidra 2010). Known prosthetic complications for the ISFP over time include fracture of the acrylic veneer, wear or debonding of the resin denture teeth, and screw/ abutment loosening or fracture (Bozini 2011, Papaspyridakos 2012). Different ISFP designs and materials may have entirely different outcomes, but little data are available.

Introduction of zirconia-based materials in the 1990's has generated considerable interest for restorative applications in the dental community (Manicone 2007). Zirconia is the metal oxide of zirconium (ZrO_2) and can exist in one of 3 crystalline phases: monoclinic, tetragonal, or cubic. Combining pure zirconia with yttria (Y_2O_3) enables the material to remain in the more stable tetragonal phase at room temperature and therefore control the stress-induced transformation from tetragonal to monoclinic states. This process, known as transformation toughening, is valuable in that it inhibits crack propagation within the material (Denry 2008). Zirconia has mechanical properties similar to stainless steel, is biocompatible, can be tooth colored, and can be manipulated using CAD/CAM technology. It has been used in endodontic dowels, dental implants, dental implant abutments, single crowns, and multi-unit fixed dental prostheses with varying degrees of success (Ozkurt 2008). Challenges remain regarding the opacity, veneering ceramics, and the phenomenon of low temperature degradation; yet recent studies suggest progress in the resolution of these issues (Al-Amleh 2010, Lughfi 2010). The use of zirconia, specifically monolithic zirconia, which side-steps many of the aforementioned constraints, has not been rigorously investigated in the fabrication of a full arch ISFP.

A monolithic zirconia implant supported fixed prosthesis has the potential to achieve improvement in patient centered outcomes and reduction in the complication rate found in conventional ISFPs. The monolithic nature creates fewer material interfaces, arguably minimizing fracture events, and also enables a more streamlined fabrication and care delivery protocol through CAD/CAM manufacturing. However, little information is available regarding prosthetic survival and maintenance of full arch zirconia implant supported fixed prostheses. Aside from case reports, no longitudinal clinical studies on full arch zirconia (layered or monolithic) are reported (Papaspolidakos 2008, Rojas 2011).

Development of valid and reliable measures for patient centered outcomes is challenging and many different instruments have been constructed in the attempt to quantify a patient's perceived benefit from dental care. Additionally, clinician assessment of prostheses has been shown to be a poor predictor of patient satisfaction (Awad 2000). Oral health quality of life is considered to a more complete valuation of oral disease and its treatment than general measures of "patient satisfaction" (Heydecke 2000). Further, the Oral Health Impact Profile has emerged as one of the most powerful and most widely accepted tools for the assessment of OHQoL (Strassburger 2006). The 49-item Oral Health Impact Profile (OHIP-49) (Slade 1994) was developed on the basis of the 1980 World Health Organization's International Classification of Impairments, Disabilities, and Handicaps (ICIDH). The purpose of the ICIDH was to serve as a unifying framework for classifying the impact of morbidity on functioning and disability. In accordance with the ICIDH, the OHIP-49 comprises seven subscales to evaluate impairment (functional limitation, physical pain, psychological discomfort) disability (physical, psychological and social disability) and handicap resulting from dental conditions (Appendix A). Despite the commonly held view that a fixed prosthesis is superior to a removable prosthesis for patient centered outcomes, the evidence is mixed (Feine 1998, Strassburger 2006, Brennan 2010).

In 2008, Purcell commented that "of the few studies investigating prosthetic complications, there exists an enormous variability in prosthesis design included in each study, recall period length, and the manner in which complications are reported" (Purcell 2008). Most authors agree on classifying complications as biologic or mechanical, yet further definition and classification is often disputed (Andreietelli 2010,

Papaspyridakos 2012). The current lack of consensus necessitates investigation into complication rate be as descriptive as possible, which is consequently the approach used in this study.

The purpose of this study was investigate the biologic and prosthetic complications over the course of 6 months, as well as the within subject change in OHIP-49 score, for the mandibular monolithic zirconia implant supported fixed prosthesis.

Methods

This is a prospective clinical study utilizing a single arm design to assess the biologic and prosthetic complications, as well as the within subject change in OHIP-49 score, for the mandibular monolithic zirconia implant supported fixed prosthesis. A consecutive sample of 15 patients from those presenting to the University of North Carolina Graduate Prosthodontic Clinic was screened and enrolled according to the inclusion and exclusion criteria.

Inclusion Criteria

Included patients were aged 18-80 at time of enrollment, in good physical health (ASA Class I or II), and gave informed consent. Patients who were completely edentulous or possessing a terminal dentition requiring extraction (up to 8 teeth per arch) were included.

Exclusion Criteria

Patients were excluded if they met any of the following criteria: history of radiotherapy in the head and neck region, uncontrolled diabetes, known alcohol and/or drug abuse, taking medication that might significantly interfere with coagulation and /or subjects with bleeding disorders, smoking greater than 10 cigarettes per day, vertical bone height less than 10 mm, severe Angle's class III jaw relationship, inadequate vertical space for the final prosthesis, unrealistic esthetic expectations, and/or psychological problems that prevent acceptance of a removable prosthesis (unwilling to wear dentures; severe gag reflex). Pregnant women and ASA Class III or IV patients were also excluded.

Assessment and Conventional Denture Fabrication

A panoramic radiograph and preliminary impressions were used for initial diagnosis and planning. New conventional dentures were fabricated in the traditional manner using custom trays, a semi-adjustable articulator, and a facebow transfer to establish functional and esthetic parameters. Ivolar Vivadent Phonares denture teeth were utilized in the denture tooth set up, and a clinical remount was performed at the time of delivery. A radiographic guide was created by duplicating the mandibular denture in radioopaque acrylic and a cone beam computed tomography (CBCT) scan was used to evaluate mandibular implant sites.

Surgical Procedures

Four AstraTech Osseospeed implants were surgically placed in the parasymphyseal mandible using a clear acrylic duplicate of the mandibular denture as a surgical guide. The posterior implants were tilted distally as described by the All-On-Four protocol (Malo 2011), such that screw access holes exit approximately through the mandibular laterals and second premolars, and the first molar is on a distal cantilever. The Osstell resonance frequency analysis device was used to assess primary stability for immediate loading. Twenty degree UniAbutments and the corresponding UniAbutment Pick-ups were inserted. An abutment level impression was made using the surgical guide as a custom tray and the UniAbutment Pickups were secured within the guide using bis-acryl methacrylate resin. A centric relation record was made with the surgical guide locked in place. The patient was provided with either an overdenture or a fixed interim prosthesis following surgery and a post-operative panoramic radiograph was taken.

Zirconia Prosthesis Fabrication

The clear acrylic duplicate denture that was originally used as the surgical guide was converted into what we now call the “prosthetic guide”. This contains the exact position of the implant abutments, the maxillo-mandibular relationship, the midline and occlusal plane, as well as the shape and position of mandibular teeth. A master cast was made from the prosthetic guide and mounted against a stone model of the upper denture using the intraoperative centric relation record. A polymethylmethacrylate mock-up of the future prosthesis was then fabricated on the master cast and after 2 months of healing, was evaluated intraorally to confirm fit, esthetics, phonetics, and occlusion. The mock-up was then scanned, milled out of monolithic zirconia, stained,

and sintered by ZirkonZahn GmbH. The final mandibular prosthesis was delivered approximately 12 weeks post implant surgery. Patients were seen 6 months after prosthesis delivery for radiographic and clinical evaluation, and were instructed to contact the clinic immediately if any biologic or prosthetic complications arose prior to the 6 month recall.

Prosthetic and Biologic Outcomes

Implant survival was defined as the implant being present and functional at the time of assessment. Prosthetic survival was defined as the prosthesis being present and functional at the time of assessment. Complications were broadly defined as any event that requires additional patient visits or any event that requires additional treatment. The exact nature, frequency, and timing of each complication was recorded from the time of enrollment until the end of the 6 month follow up period. Complications were reported as descriptively as possible to avoid issues with categorization and were only subsequently classified as either biologic or prosthetic, and as either prior to prosthesis delivery or after prosthesis delivery.

Oral Health Impact Profile

The OHIP-49 questionnaire was first administered at the time of enrollment to obtain baseline values. It was next administered immediately prior to implant surgery, and finally at 6-month post implant surgery. This serial administration was timed to assess patient outcomes at critical treatment phases. Responses to each of the 49 OHIP items are made on a five-point ordinal scale, labeled and coded: never=0; hardly ever=1; occasionally=2; fairly often=3 and very often=4.

Analytic methods

Two OHIP-49 summary scores were computed as dependent variables. The *extent* score is a count of the items that a patient reports having experienced “very often”. It has a potential range of zero to 49. The *severity* score is the cumulative sum of ordinal responses across all items with a possible range of zero to 196. Unlike the extent score, the severity score takes into account items that were experienced “never”, “hardly ever”, “occasionally” and “fairly often”. For both scores, higher values denote worse oral health quality of life. In addition to these two summary scores, the seven OHIP-49 subscales (Appendix A) were individually

examined to identify factors associated with change in OHIP-49 scores. To account for multiple tests (7 subscales x 2 points in time), Bonferroni correction reduced the critical significance threshold to $P < 0.0035$ ($P = \frac{0.05}{14}$). These baseline associations were tested for statistical significance using one-way analysis of variance. Analyzing data with serial measurements on the same patient requires a different methodology from ordinary least squares regression. This is because hierarchically structured data—where repeated measures are obtained at multiple time points—violate standard linear regression assumptions of independence and lead to incorrect inferences. To correctly account for this hierarchical structure, the statistical approach estimated covariance parameters using two-level fixed slope, random intercept variance components models. These were fitted using the *xtmixed* command in STATA version 12.0 SE statistical software (Stata Corporation, Texas). The OHIP extent and severity scores were the dependent variables and time of OHIP-49 administration was the exposure of interest. Beta coefficients from the model are directly interpretable as within-patient change in mean OHIP-49 extent and severity scores, i.e. the treatment effect. Coefficients prefixed with a minus symbol indicate a reduction in OHIP-49 scores relative to the referent category.

Results

Results are presented for 15 patients, 11 male and 4 female, who ranged in age from 30 to 78 years (mean 55.8 years) at enrollment. Six patients were edentulous and 9 had a terminal on enrollment.

Prosthetic and Biologic Outcomes

Sixty implants were placed in 15 patients. One implant failed to integrate during the first 6 months following placement, resulting in patient-related and implant-related survival rates of 93% and 98% respectively over 6 months. Fourteen of the 15 prostheses were present and in function at the 6 month recall, resulting in a 93% prosthesis survival rate. A total of 13 complication events occurred in 9 patients throughout the course of the entire protocol, from time of enrollment until the 6 month recall. Six complications occurred prior to the delivery of the MZISFP, and 7 occurred in the period from delivery to 6 month recall. Eight of the complications were patient initiated and 5 were observed by clinician.

The seven complications recorded during the MZISFP observation period occurred in 6 patients, while 9 patients were complication free over the same period. Five of the 7 reported complications required 1 additional visit. The remaining 2 events occurred in the same patient, were related in etiology, and required more than 1 additional visit. The most common problem found was chipping of the maxillary denture teeth, which accounted for 2 of the 6 events prior to MZISFP delivery and 4 of the 7 after delivery. The exact nature of each complication can be found in (Table 1).

Oral Health Impact Profile Scores

The mean OHIP-49 severity score at enrollment was 91.8 [95% confidence interval (CI): 68.8, 114.8] and the lowest and highest severity scores were 45 and 168 respectively. All but one patient (93.3%) reported

having experienced one or more impact “very often” at enrollment. Lowest and highest extent scores were zero and 37 and the mean value was 10.5 [95% CI: 3.8, 17.3].

Differences in mean OHIP-49 severity and extent scores failed to reach statistical significance on the basis of patient characteristics at baseline, possibly due to type-2 error arising from the small sample size. OHIP-49 extent scores were markedly higher in females than males, were higher in patients with no prosthesis or a denture compared to those with a partial denture or fixed appliance, and were inversely related to age (Table 2).

A greater than five-fold reduction in mean OHIP-49 severity scores was observed over the treatment period. Scores reduced 74.8 units per patient on average; from 91.8 at enrollment to 17.0 at Visit 3 (Table 3, Fig 1). The magnitude of reduction in severity scores following surgery (32.1 units on average) was smaller than the reduction from baseline highs, but still substantial and clinically important. Mean OHIP-49 extent scores also declined markedly from a high of 10.5 to 1.2 immediately prior to surgery (Table 4, Fig 2). Further improvements were observed six months post-surgery, but at this negligible level, the difference was statistically non-significant.

Six of the seven OHIP-49 subscale scores decreased significantly ($P < 0.0035$) from baseline levels, with only “physical disability” ($P = 0.026$) failing to reach the Bonferroni-corrected threshold of statistical significance (Fig 3). OHIP-49 scores reduced significantly on four of the seven subscales in the time following implant surgery. Greatest absolute reduction across the study (15.0 units) was observed for items on the *functional limitation* subscale. These items deal with problems with chewing, pronunciation of words, sense of taste, appearance and breath.

Tables and Figures

Table 1. Number and exact description of biologic and prosthetic complications observed.

	Prior to prosthesis delivery	After prosthesis delivery	Total
Biologic	1 wound dehiscence 1 candida infection	1 failed implant	3
Prosthetic	2 chipped maxillary denture teeth 2 fracture interim fixed (conversion) prostheses	4 chipped maxillary denture teeth 1 debonded prosthesis tooth 1 removed prosthesis	10
Total	6	7	13

Table 2: Selected patient characteristics and baseline mean (s.d.) OHIP-49 severity score and mean (s.d.) OHIP-49 extent score (n=15)

	N (%)	Baseline mean (sd) OHIP severity score ^(a)	P-value	Baseline mean (sd) OHIP extent score ^(b)	P-value
All patients	15 (100.0)	91.8 (41.5)		10.5 (12.1)	
Sex					
Male	11 (73.3)	84.5 (33.1)	0.271	6.9 (7.7)	0.051
Female	4 (26.7)	112.0 (60.4)		20.5 (17.6)	
Age (years)					
<50	3 (20.0)	119.7 (34.9)	0.237	19.0 (13.1)	0.200
50–64	6 (40.0)	98.5 (53.2)		12.7 (15.6)	
≥65	6 (40.0)	71.2 (21.8)		4.2 (1.8)	
Mandible status					
Edentulous	6 (40.0)	112.0 (44.3)	0.128	15.0 (13.8)	0.260
Terminal dentition	9 (60.0)	78.3 (35.8)		7.6 (10.7)	
Mandible prosthesis					
No prosthesis	4 (26.7)	55.4 (47.8)	0.578	15.3 (13.0)	0.256
Denture	5 (33.3)	62.9 (53.9)		16.0 (15.2)	
Partial denture	3 (20.0)	39.9 (26.8)		1.0 (1.0)	
Fixed prosthesis	3 (20.0)	44.6 (24.1)		4.7 (2.3)	
Opposing arch					
Conventional denture	13 (86.7)	96.2 (43.1)	0.147	11.7 (12.6)	0.331
Four-implant over denture	2 (13.3)	63.5 (6.4)		3.0 (4.2)	

^(a) The severity score is the sum of OHIP-49 ordinal responses (potential range 0 to 196); higher scores denote worse oral health quality of life

^(b) The extent score is the number of OHIP-49 items reported “very often” (potential range is 0 to 49); higher scores denote worse oral health quality of life

Table 3: Mean OHIP-49 severity^(a) scores at enrollment and changes in mean OHIP-49 severity scores during treatment (n=15)

	Beta coefficient	95% CI	P value
Enrollment (mean severity score)	91.8	77.2, 106.4	--
Prior to implant surgery (change since enrollment)	-42.7	-59.8, -25.7	<0.001
Six months post implant surgery (change since enrollment)	-74.8	-91.9, -57.7	<0.001
Six months post implant surgery (change since implant surgery)	-32.1	-49.1, -15.0	<0.001

^(a) The severity score is the sum of OHIP-49 ordinal responses (potential range 0 to 196); higher scores denote worse oral health quality of life

Table 4: Mean OHIP-49 extent scores at enrollment and changes in mean OHIP-46 during treatment (n=15)

	Beta coefficient	95% CI	P value
Enrollment (mean extent score)	10.5	7.0, 14.0	--
Prior to implant surgery (change since enrollment)	-9.3	-14.2, -4.5	<0.001
Six months post implant surgery (change since enrollment)	-10.3	-15.2, -5.5	<0.001
Six months post implant surgery (change since implant surgery)	-1.0	-5.8, 3.8	0.685

^(a) The extent score is a count of OHIP-49 items reported "very often" (potential range is 0 to 49); higher scores denote worse oral health quality of life

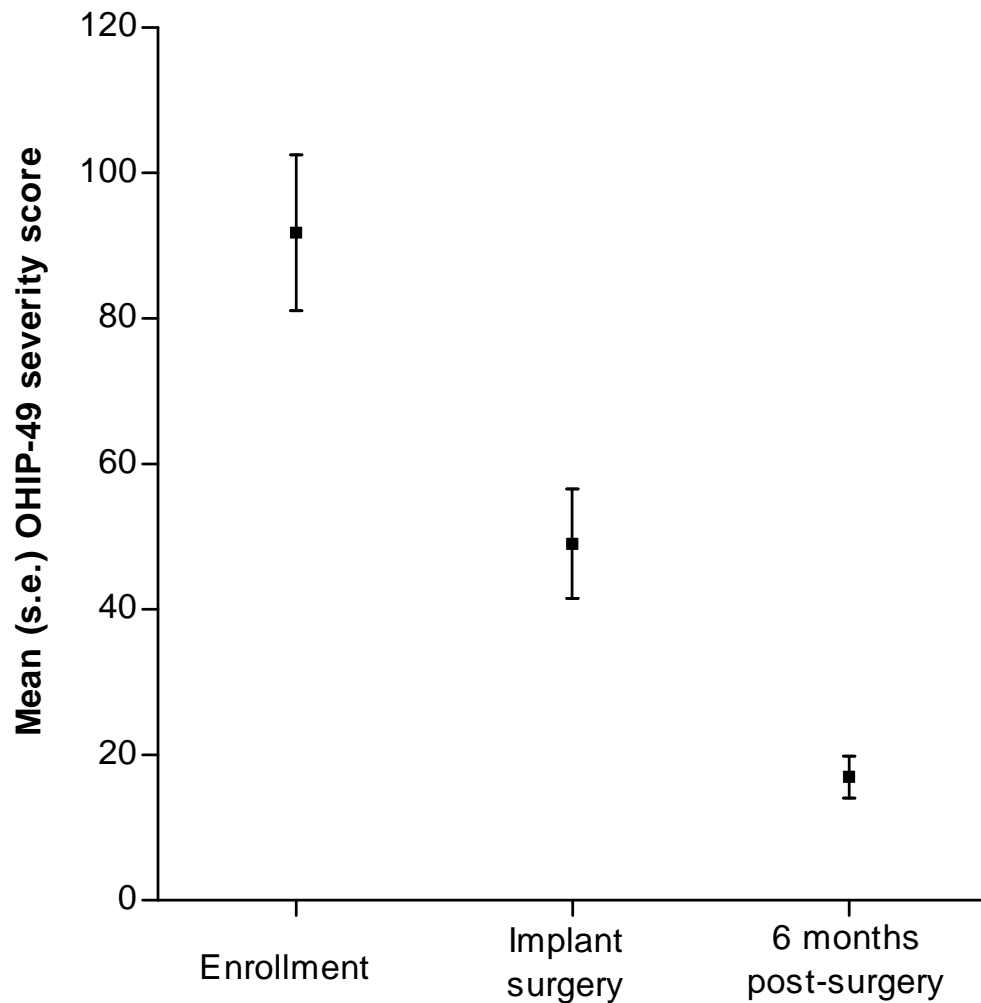


Figure 1: Mean (s.e.) OHIP-49 severity scores at enrollment, immediately prior to surgery and six months after surgery. Compared with the score at enrollment, scores prior to surgery were significantly lower ($P < 0.001$). The 6-month post-surgery score was significantly lower than that immediately prior to surgery ($P < 0.001$).

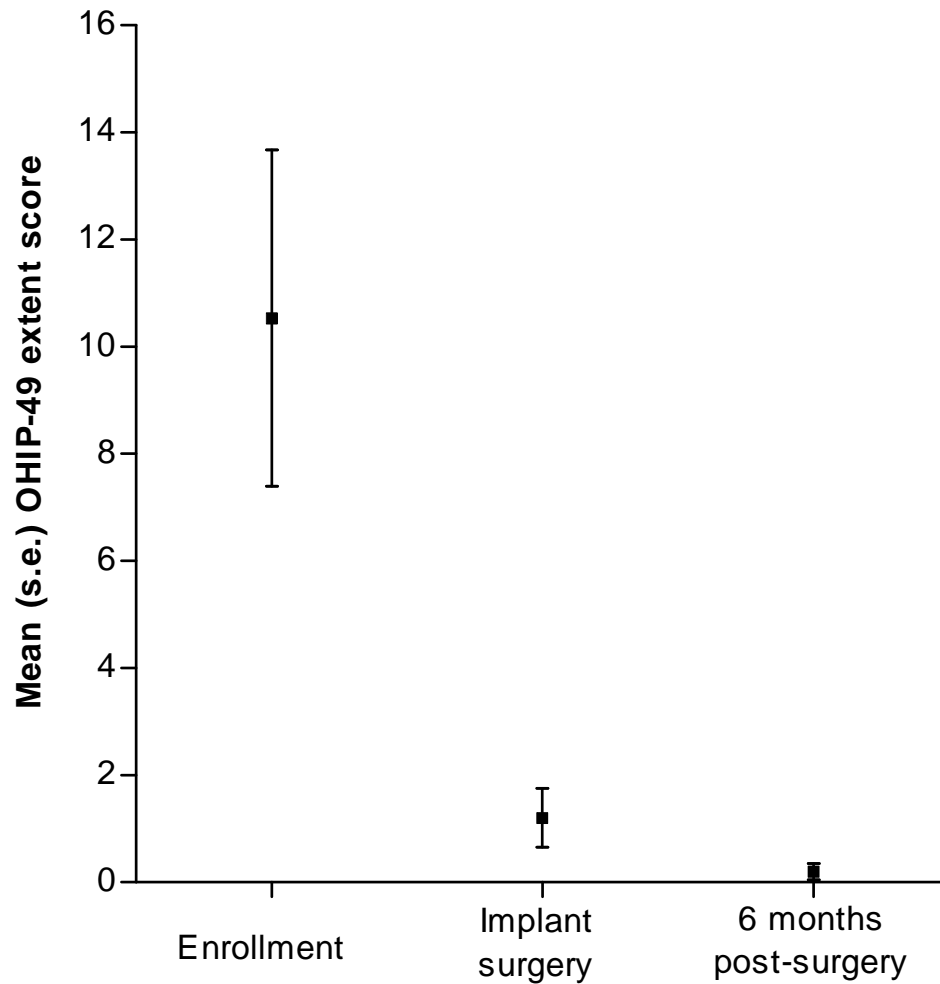


Figure 2: Mean (s.e.) OHIP-49 extent scores at enrollment, immediately prior to surgery and six months after surgery. Scores prior to surgery and post-surgery were significantly lower than at enrollment. The post-surgery score did not reduce significantly ($P=0.685$) in the six months following surgery.

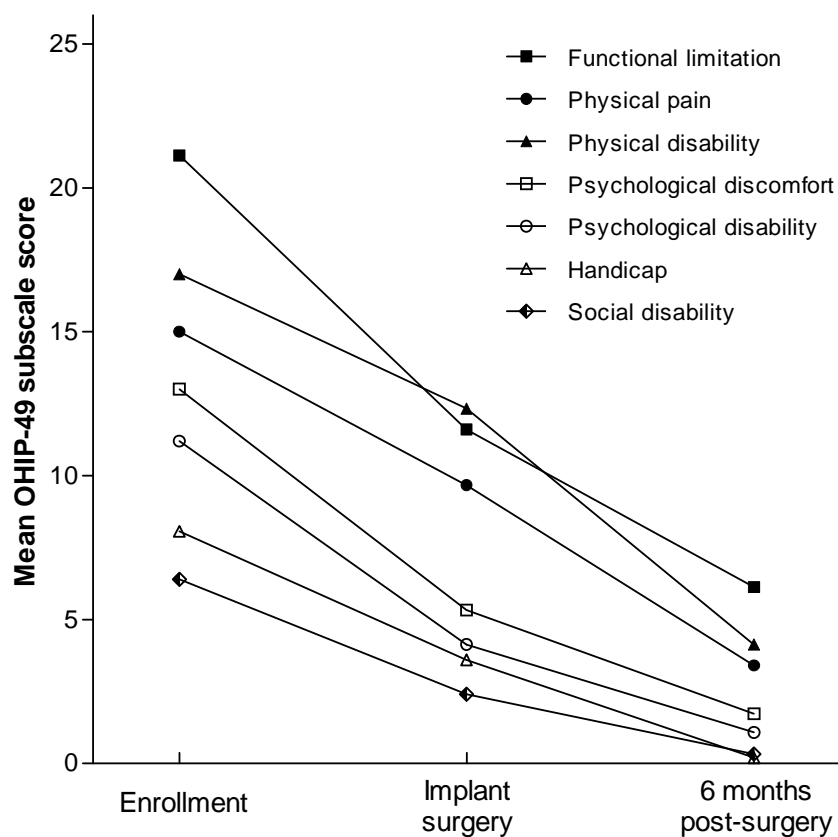


Figure 3: Reduction in mean OHIP-49 subscales scores from enrollment, to immediately prior to implant surgery and at six months post-surgery follow-up.

Function: enrollment to surgery ($P < 0.001$); surgery to 6 month follow-up ($P = 0.001$)

Physical pain: enrollment to surgery ($P < 0.001$); surgery to 6 month follow-up ($P < 0.001$)

Physical disability: enrollment to implant surgery ($P = 0.026$); surgery to 6 month follow-up ($P = 0.003$)

Psychological discomfort: enrollment to implant surgery ($P < 0.001$); surgery to 6 month follow-up ($P < 0.001$)

Psychological disability: enrollment to implant surgery ($P < 0.001$); surgery to 6 month follow-up ($P = 0.032$)

Social disability: enrollment to surgery ($P < 0.001$); surgery to 6 month follow-up ($P = 0.061$)

Handicap: enrollment to implant surgery ($P = 0.002$); surgery to 6 month follow-up ($P = 0.016$)

Figure 4: Clinical photo of mandibular monolithic zirconia implant supported fixed prosthesis with no cementable units



Figure 5: Clinical photo of mandibular monolithic zirconia implant supported fixed prosthesis with a cementable unit at tooth #23 site.



Discussion

In this prospective clinical study, 15 patients were treated first with new conventional dentures, and then with a monolithic zirconia implant supported fixed prosthesis supported by 4 implants in the edentulous mandible. Each mandibular prosthesis possessed bilateral distal cantilevers designed to reach first molar occlusion. Thirteen of the patients had a conventional denture in the maxilla and 2 had an implant retained overdenture. Biologic and prosthetic complications, as well as the within subject change in OHIP-49 scores are reported from initial presentation to 6 month recall.

Six complications occurred prior to delivery of the MZISFP. This is important when generalizing the viability of this treatment protocol to the dental community, but is not related to the monolithic prosthesis per se. Two issues were biologic in nature and 4 prosthetic (Table 1). All 6 events were resolved in 1 or less patient visits and none of the 6 prevented delivery of the MZISFP. Two events involved chipping of the maxillary denture teeth and occurred in the same patient, who incidentally had a third chip after delivery of the MZISFP.

Within the actual MZISFP observation period, 7 complications were recorded in 6 different patients. Four of the 7 were the result of a continued problem with the maxillary denture tooth chipping. Interestingly 2 of the 4 patients with chipped incisors actually preferred to leave the defect unrepaired, as they felt it added uniqueness or character. The causes of maxillary denture tooth chipping in the present study may include the particular chemical formulation of this brand of denture tooth and the occlusal scheme utilized. The manufacturer reports higher inorganic filler content in the Phonares line as compared to other available varieties, which adds wear resistance and superb esthetics, but also appears to increase the risk of chipping (Scientific Documentation SR Phonares 2010, Ivoclar Vivadent). Further, many of the patients presented with

a skeletal class II appearance, and it is believed that these individuals possess a wider envelop of function, and are thus more prone to prosthetic complications (Dawson 2007). Only one biologic complication was encountered during this period, in the form of a single implant failure. The same patient subsequently lost his MZISFP because the failed implant was the distal prosthesis support, which accounted for 2 related complications. The final complication recorded was a tooth that debonded from the MZISFP. Thirteen patients had their mandibular prostheses made from a single block of zirconia, where access holes could be easily hidden with composite fillings (Figure 4). However, two patients required a design variation to account for an error in implant angulation, where the prosthesis was designed with one or more single teeth that could be cemented onto the main prosthesis (Figure 5). The limitation of this modification is that it significantly decreases retrievability or increases the risk of debonding, depending on which type of cement is selected. Our study is in agreement with others, that prosthetic complications are more frequent than biologic ones (Bozini 2011, Papaspyridakos 2012)

Many authors have commented on the lack of uniformity in reporting complications found in the literature, as well as the problem of how to properly define a complication (Papaspyridakos 2012, Bozini 2011, Purcell 2008, Gallucci 2009). One finding of this study, that half of the patients experiencing chipped maxillary incisor teeth actually preferred keeping the chip, underscores this debate. Further, is a lost prosthesis due to implant failure one event or two? And how does one count the number of appointments needed to remedy the problem? However, certain metrics do give insight into the maintenance profile of prosthetic devices. A recently published systematic review and meta-analysis of complications with a fixed rehabilitation of the edentulous patient used complication rate per 100 prosthesis-years and “prosthesis free of complications” rate at 5 and 10 years. Of the 7 studies reviewed, the estimated complication rate per 100 prosthesis years varied from 14 to 39 events and the “complication free prosthesis” rates varied between 14 and 49 percent at 5 years and between 2 and 24 percent over 10 years. This study is not directly comparable by the same measures, but several interesting observations can be noted. The MZISFP is a novel prosthesis design that has not received the same extent of technique development, and still had 9 of 15 patients classified as “complication free” with a total of 7 complications despite the issue with denture tooth chipping. If we

consider the chipping problem a separate issue, which would hypothetically be eliminated by using a different type of tooth, then 13 of the 15 patients would be classified as “complication free”, with a total of 3 complications over the 6 month observation period. At the very least, and as will be discussed later, the degree of prosthetic and biologic complications did not prevent a significant improvement in OHIP-49 scores. A final point is that the MZISFP is a CAD/CAM restoration made from a digital file, so if more frequent or severe complications were to arise, remaking the full prosthesis is an entirely different proposition than remaking a conventional metal acrylic prosthesis from a time and cost perspective. Through 6 months of follow up, the MZISFP is within the same range of maintenance events as found in conventional metal-acrylic designs, but longer follow up is absolutely necessary to realistically assess the maintenance profile of this prosthesis.

The other primary aim of this study was to assess the within subject change in OHIP-49 score as the patient transitions from baseline to conventional dentures and from conventional dentures to a mandibular MZISFP. Each patient averaged a drop of 74.8 OHIP-49 units over the course of the study, dropping 42.7 points from baseline to new conventional dentures and another 32.1 points from conventional dentures to the mandibular fixed prosthesis (Table 3). Both increments are statistically significant (<0.001). Several observations can be made from the severity data. First, the elimination of disease in those with a terminal dentition, or the fabrication of new conventional dentures for those with an ill-fitting prosthesis, as well as some degree of placebo effect all contribute to a significant change in a patient’s OHQoL. Second, a mandibular MZISFP imparts a further improvement and enables patients to believe they have not lost their teeth. The subscale analysis further supports this but showing great reduction in functional outcomes after the fixed prosthesis has been provided (Figure 3). The results for disease extent show a similar reduction from baseline to conventional dentures, but fail to show a significant drop from conventional dentures to MZISFP (Figure 2). This may be caused by the particular spectrum of complaints within the patient population, where many of the “very often” responses may have been for social or esthetic variables that were well addressed by a new set of conventional dentures, and their functional complaints were slightly milder by comparison. The placebo effect may also be of clinical importance here by altering the “very often” responses just enough.

Regardless, the magnitude of drop observed in the extent score is equally profound. A study by John *et al* reported on the minimally important difference in OHIP-49 scores (John 2009). They found that a change of approximately 6 OHIP-49 units is required for a patient to state that they feel at least “a little better”, and that a change of about 10 units is required for a patient to state they feel “a lot better”. The finding of our study, with changes of 30, 40, and 70 units, may indicate a profound change in a patient’s quality of life, vastly exceeding mere sense of improvement.

The present study serves as proof of concept, where future study should focus on longer follow up, as the data could provide valuable insight to cost-benefit analysis and resource allocation at the patient and population level. Further, the long-term stability of this result should be assessed by repeating the OHIP-49 administration at subsequent follow up visits.

Conclusions

A novel protocol utilizing CAD/CAM manufacturing technique for zirconia prostheses was presented. Prosthetic complications were found to be more frequent than biologic complications. Prosthetic and biologic complications rates with a monolithic zirconia ISFP appear, at this early point, to be sufficiently low to support proof of concept for the MZISFP. Well made, properly fitting conventional dentures provide significant improvement in oral health quality of life among patients with a terminal dentition or an ill-fitting prosthesis. The monolithic zirconia ISFP achieved significant improvement in oral health quality of life for patients with well made, properly fitting conventional dentures. The use of denture teeth with high inorganic filler content in patients with fixed implant prostheses requires very careful attention to occlusion and may lead to a higher risk of tooth chipping.

Appendix A

Oral Health Impact Profile questions and subscales

Functional limitation questions

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?

Physical pain questions

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?
16. Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth, or dentures?
17. Have you had sore spots in your mouth?
18. Have you had uncomfortable dentures?

Psychological discomfort questions

- 19. Have you been worried by dental problems?
- 20. Have you been self conscious because of your teeth, mouth, or dentures?
- 21. Have dental problems made you miserable?
- 22. Have you felt uncomfortable about the appearance of your teeth, mouth, or dentures?
- 23. Have you felt tense because of problems with your teeth, mouth, or dentures?

Physical disability questions

- 24. Has your speech been unclear because of problems with your teeth, mouth, or dentures?
- 25. Have people misunderstood some of your words because of problems with your teeth, mouth, or dentures?
- 26. Have you felt that there has been less flavour in your food because of problems with your teeth, mouth, or dentures?
- 27. Have you been unable to brush your teeth properly because of problems with your teeth, mouth, or dentures?
- 28. Have you had to avoid eating some foods because of problems with your teeth, mouth, or dentures?
- 29. Has your diet been unsatisfactory because of problems with your teeth, mouth, or dentures?
- 30. Have you been unable to eat with your dentures because of problems with them?
- 31. Have you avoided smiling because of problems with your teeth, mouth, or dentures?
- 32. Have you had to interrupt meals because of problems with your teeth, mouth, or dentures?

Psychological disability questions

- 33. Has your sleep been interrupted because of problems with your teeth, mouth, or dentures?
- 34. Have you been upset because of problems with your teeth, mouth, or dentures?
- 35. Have you found it difficult to relax because of problems with your teeth, mouth, or dentures?
- 36. Have you felt depressed because of problems with your teeth, mouth, or dentures?
- 37. Has your concentration been affected because of problems with your teeth, mouth, or dentures?
- 38. Have you been a bit embarrassed because of problems with your teeth, mouth, or dentures?

Social disability questions

- 39. Have you avoided going out because of problems with your teeth, mouth, or dentures?
- 40. Have you been less tolerant of your spouse or family because of problems with your teeth, mouth, or dentures?
- 41. Have you had trouble getting on with other people because of problems with your teeth, mouth, or dentures?
- 42. Have you been a bit irritable with other people because of problems with your teeth, mouth, or dentures?
- 43. Have you had difficulty doing your usual jobs because of problems with your teeth, mouth, or dentures?

Handicap questions

- 44. Have you felt that your general health has worsened because of problems with your teeth, mouth, or dentures?
- 45. Have you suffered any financial loss because of problems with your teeth, mouth, or dentures?
- 46. Have you been unable to enjoy other people's company as much because of problems with your teeth, mouth, or dentures?
- 47. Have you felt that life in general was less satisfying because of problems with your teeth, mouth, or dentures?
- 48. Have you been totally unable to function because of problems with your teeth, mouth, or dentures?
- 49. Have you been unable to work to your full capacity because of problems with your teeth, mouth, or dentures?

References

Adell R, Eriksson B, Lekholm U, Brånemark PI, Jemt T: Long-term follow-up study of osseointegrated implants in the treatment of totally edentulous jaws. *Int J Oral Maxillofac Implants* 1990;5(4):347-59

Allen PF, McMillian A, Walshaw D: A patient-based assessment of implant-stabilized and conventional complete dentures. *J Prosthet Dent* 2001;85:141-7

Al-Amleh B, Lyons K, Swain M: Clinical trials in zirconia: a systematic review. *J Oral Rehab* 2010; 37: 641-652

Arvidson K, Bystedt H, Frykholm A, von Konow L, Lothigius E: Five year prospective follow up report of the AstraTech Dental Implant System in the treatment of edentulous mandibles. *Clin Oral Impl Res* 1998; 9: 225-234

Attard N, Zarb G, Laporte A: Long-term treatment costs associated with implant supported mandibular prostheses in edentulous patients. *Int J Prosthodont*; 18: 117-123

Attard NJ, Zarb GA: Long term treatment outcomes in edentulous patients with implant overdentures: the toronto study. *Int J Prosthodont* 2004; 17:417-424

Awad M, Locker D, Korner-Bitensky N, Feine J: Measuring the effect of intra-oral implant rehabilitation on health-related quality of life in a randomized controlled clinical trial. *J Dent Res* 2000; 79(9):1 659-1 663

Bidra A: Surgical and prosthodontics consequences of inadequate treatment planning for fixed implant supported prosthesis in the edentulous mandible. *J Oral Maxillofac Surg* 2010; 68: 2528-2536

Brånemark PI, Svensson B, van Steenberghe D: Ten-year survival rates of fixed prostheses on four or six implants ad modum Brånemark in full edentulism. *Clin Oral Impl Res* 1995; 6(4):227-31

Brennan M, Houston F, O'Sullivan M, O'Connell B: Patient satisfaction and oral health related quality of life outcomes of implant overdentures and fixed complete dentures. *Int J Oral Maxillofac Implants* 2010; 25: 791-800

Bryant SR, MacDonald-Jankowski D, Kim K: Does the type of implant prosthesis affect outcomes for the completely edentulous arch? *Int J Oral Maxillofac Implants* 2007; 22(suppl): 117-139

Brozini T, Petridis H, Tzanis K, Garefis P: A meta-analysis of prosthodontic complication rates of implant supported fixed dental prostheses in edentulous patients after an observation period of at least 5 years. *Int J Oral Maxillofac Implant* 2011; 26: 304-31

Carlsson GE, Lindquist L: Ten-Year longitudinal study of masticatory function in edentulous patients treated with fixed complete dentures on osseointegrated implants. *Int J Prosthodont* 1994; 7:448-453

Chee W, Jivraj S: Treatment planning of the edentulous mandible. *British Dental Journal* 2006; 201(6): 337-347

Cooper LF: The current and future treatment of edentulism. *J Prosthodont*. 2009; 18(2):116-22

Dawson PE. *Functional Occlusion: From TMJ to smile design*. St. Louis: Mosby Elsevier, 2007. Print

- Denry I, Kelly JR: State of the art of zirconia for dental applications. *Dent Mater* 2008; 24: 299-307
- Douglass CW, Shih A, Ostry L: Will there be a need for complete dentures in the United States in 2020? *J Prosthet Dent* 2002;87:5-8
- Ekelund JA, Lindquist LW, Carlsson GE, Jemt, T: Implant treatment in the edentulous mandible: A prospective study on Brånemark System implants over more than 20 years. *Int J Prosthodont* 2003;16:602–608
- Eliasson A, Palmqvist S, Svenson B, Sondell K: Five-year results with fixed complete-arch mandibular prostheses supported by 4 implants. *Int J Oral Maxillofac Implants*. 2000; 15(4):505-10
- Emami E, Heydecke G, Rompré PH, de Grandmont P, Feine JS: Impact of implant support for mandibular dentures on satisfaction, oral and general health-related quality of life: a meta-analysis of randomized-controlled trials. *Clin Oral Implants Res* 2009;20(6):533-44.
- Feine JS, Dufresne E, Boudrias P, Lund J: Outcome assessment of implant supported prostheses. *J Prosthet Dent* 1998; 79: 575-579
- Felton DA: Edentulism and comorbid factors. *J Prosthodont* 2009;18: 88-96
- Fueki K, Kimoto K, Ogawa T, Garrett NR. Effect of implant-supported or retained dentures on masticatory performance: a systematic review. *J Prosthet Dent*. 2007 Dec;98(6):470-7.
- Harris D, Hofer S, O’Boyle C, Sheridan S, Marley J, Benington I, Clifford T, Houston F, O’Connell B: A comparison of implant-retained mandibular overdentures and conventional dentures on quality of life in edentulous patients: a randomized, prospective, within-subject controlled clinical trial. *Clin. Oral Impl. Res.* 00, 2011, 1–8
- Heydecke G: Implantologie: Wohlbefinden für Senioren. *Zahnärztl Mitt* 2000; 90:52-57
- Jensen O, Adams M, Cottam J, Parel S, Phillips W: The All-on-4 shelf: mandible. *J Oral Maxillofac Surg* 2011; 69: 175-181
- John M, Reißmann D, Szentpetery A, Steele J: An approach to define clinical significance in prosthodontics. *J Prosthodont* 2009; 18: 445-460
- Lindquist L, Rockler B, Carlsson G: Bone resorption around fixtures in edentulous patients treated with mandibular fixed tissue-integrated prostheses. *J Prosthet Dent* 1988; 59: 59-63
- Lughi V, Sergo V: Low temperature degradation –aging – of zirconia: a critical review of the relevant aspects in dentistry. *Dental Materials* 2010; 26:807-820
- Malo P, Nombre M, Lopes A, Moss S, Molina G: A longitudinal study of the survival of All-on-4 implants in the mandible with up to 10 years follow up. *J Am Dent Assoc* 2011; 142(3): 310-320
- Manicone P, Iommetti PR, Raffaelli L: An overview of zirconia ceramics: basic properties and clinical applications. *J Dentistry* 2007; 35: 819-826
- Mericske-Stern R, Taylor T, Belser U: Management of the edentulous patient. *Clin Oral Impl Res* 2000; 11(suppl): 108-125
- Ozkurt Z, Kazazoglu E: Clinical success of zirconia in dental applications. *J Prosthodont* 2010; 19: 64-68

Papaspyridakos P, Chen C, Chuang S, Weber HP, Gallucci G: A systematic review of biologic and technical complications with fixed implant rehabilitations for edentulous patients. *Int J Oral Maxillofac Implants* 2012; 27: 102-110

Papaspyridakos P, Lal K: Complete arch implant rehabilitation using subtractive rapid prototyping and porcelain fused to zirconia prosthesis: A clinical report. *J Prosthet Dent* 2008;100:165-172

Rojas-Viscaya F: Full zirconia fixed detachable implant-retained restorations manufactured from monolithic zirconia: clinical report after two years in service. *Journal of Prosthodont* 2011; 20: 570–576

Scientific Documentation SR Phonares. 2010. Ivoclar Vivadent. 2 Feb. 2012.
<<http://www.ivoclarvivadent.us/en-us/download-center/scientific-documentation/#S>>

Slade GD, Spencer AJ: Development and evaluation of the oral health impact profile. *Community Dental Health* 1994; 11:3-11

Strassburger C, Kerschbaum T, Heydecke G: Influence of implant and conventional prostheses on satisfaction and quality of life: A literature review. Part II: Qualitative analysis and evaluation of the studies. *Int J Prosthodont* 2006; 19: 339-348

Tallgren A: The continuing reduction of the residual alveolar ridges in complete denture wearers: A mixed-longitudinal study covering 25 years. *J Prosthet Dent* 1972;27: 120-132