CLINICAL AND RADIOGRAPHIC EVALUATION OF EARLY LOADED NARROW DIAMETER IMPLANTS - 5-YEARS FOLLOW-UP OF A MULTICENTRE PROSPECTIVE CLINICAL STUDY

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CONFLICT OF INTEREST AND SOURCE OF FUNDING

None of the researchers have economic interests in the product related in this study or in the company.

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ABSTRACT

Objective: This study was initiated to evaluate the 5-year implant survival rate and marginal bone levels around a 3.0mm implant when replacing a single tooth in the anterior region.

Material and Methods: The study was designed as a prospective, single arm, multi-center clinical study. Patients missing 12, 22, 32, 31, 41 or 42 teeth were included and implants of 3.0 mm diameter and different lengths were placed by a one-stage surgery protocol. Definitive cemented crowns were placed 6 to 10 weeks later. Clinical and radiographic measurements were taken at implant installation, loading, and at the 6, 12, 24, 36, 48 and 60-months follow-up visits.

Results: 69 patients with 97 implants were included in this study. 4 implants were lost before loading (4.12% failure rate). Implant marginal bone levels did not differ statistically after the 1-year follow-up visit. After 5 years, no bone loss was observed for 50.60% of the implants and only 8.43% of them lost more than 1 mm. Similarly, pocket probing depths and gingival zenith scores did not change significantly.

Conclusions: The use of the two-pieces narrow 3.0mm titanium dental implant for the restoration of upper lateral or lower incisors is safe and results in stable marginal bone levels and pocket probing depths after 5 years of function.

CLINICAL RELEVANCE

Scientific rationale for study

Long-term results of narrow diameter implants are not conclusive, particularly in the case of two-piece implants with an internal Morse taper connection.

Principal findings

The peri-implant marginal bone levels did not significantly change over the 5 year period of the study with less than 10% of the implants losing more than 1 mm of bone support. Pocket probing depths and gingival zenith scores also remained stable.

Practical implications

Two-piece narrow diameter implants with an internal Morse taper connection can be safely and effectively used for the rehabilitation of narrow edentulous tooth spaces.

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INTRODUCTION

Implant Dentistry has become a routine treatment modality in daily dental practice. Deeper knowledge about implant development in the fields of Engineering and Biology, in conjunction with better resources and greater experience in surgical techniques, has provided better and more reliable options for clinicians and patients. As a consequence, some previously established frontiers have been trespassed, stressing the systems and the treatment outcomes. One of these barriers related to implant size, both in length and diameter. The established biomechanical concept supported the idea that bigger implants improve long-term survival due to promotion of a higher total bone to implant contact and increased resistance to fracture of the implant to occlusal loading, a new treatment philosophy advocates the use of smaller implants. This paradigm shift is based on the use of improved materials and the preservation of a better healing environment of bone surrounding the implant and by limiting the space occupied by the implant itself.

Certainly, there are some situations where narrower diameter implants are not just an option but the only option. In Caucasian population, the upper lateral and lower incisors are the smallest teeth in the mesio-distal aspect (Hanihara & Ishida 2005). Therefore, their restoration by utilizing dental implants is often challenged by the limited space available between adjacent teeth. In these cases, respecting the established rule of keeping a 1.5 mm space between the implant and adjacent teeth (Grunder et al. 2005) is not always possible without the risk of exposing the implant threads (Romeo et al. 2006) or damaging the periodontal ligament (Cardaropoli et al. 2006). A standard implant of 4.0 mm diameter would, therefore, need at least 7 mm in the mesio-distal dimension (Froum et al. 2007). Furthermore, in the buccal aspect, at least 2 mm of bone is recommended to support the implant (Cardaropoli et al. 2003). When these distances are not maintained esthetic problems related to the presence and height of the interdental papilla can arise, as well as an increased risk of losing crestal bone around the

implant and adjacent teeth (Choquet et al. 2001; Gastaldo et al. 2004; Grunder et al. 2005; Tarnow et al. 2000, 1992; Tarnow & Eskow 1995). Moreover, reports indicate that the long-term success of narrow diameter implants is lower than that of standard diameter implants (Albrektsson et al. 2007; Ortega-Oller et al. 2014; Renouard & Nisand 2006; Romeo et al. 2006; Winkler et al. 2000). In contrast, similar success rates have been reported in a number of long-term clinical studies (Andersen et al. 2001; Block & Kent 1993; Cordaro et al. 2006; Degidi et al. 2008; Hallman 2001; Lee et al. 2013; Saadoun & Le Gall 1996; Sohrabi et al. 2012; Zinsli et al. 2004; Zweers et al. 2015).

Over 5 years ago, a two-piece 3.0 mm diameter titanium dental implant was clinically introduced (Dentsply Sirona Implants, Sweden). The 1 year (Galindo-Moreno et al. 2012) and 3 year clinical results (Maiorana et al. 2015) demonstrated good success with the clinical performance of the narrow diameter implants. The current manuscript presents the 5 year long-term follow-up results from the continued clinical study.

METHODS AND MATERIALS

Study design

The study was designed according to the STROBE guidelines for observational clinical studies as a multicenter prospective, single arm study with specific inclusion and exclusion criteria. Subjects missing a single tooth in position 12, 22, 32, 31, 41 or 42 (FDI) were eligible to the study and recruited at six different study sites in Denmark, Germany, Italy, Spain, Sweden and the United Kingdom. Ethics committees at the University Hospital of Copenhagen, Denmark (H-D-2007-0122), the University of Ulm, Germany (137/08), the University of Milan, Italy (YA-NAR-001), the University of Granada, Spain (YA-NAR-001), The Institute for Postgraduate Education in Jönköping, Sweden (M20-08) and the National Research Ethics Service of the United Kingdom (08/H0206/24) approved the study before any procedures were

performed. The study was also registered on http://www.clinicaltrials.gov from the US National Institutes of Health, identified as NCT00646113, from March 25, 2008.

Participants

Before any study procedure was initiated all subjects were thoroughly informed about the study and signed a written consent form. To be recruited in the study, the patients had to fulfill the following specific inclusion criteria: good general health, tobacco consumption of less than 10 cigarettes per day, absence of dental and oral pathologies, single tooth loss with adjacent teeth in normal occlusion, recipient sites for implants healed at least 2 months after extraction. Only one study implant was placed in each patient. However, for patients missing the contra-lateral incisor, both positions could be treated with study implants. The implants used in the study were OsseoSpeed™ TX 3.0S (Dentsply Sirona Implants, Mölndal, Sweden).

Surgical procedure

All patients received antibiotic prophylaxis (2 g Amoxicillin or 600 mg Clindamycin) 1 hour before surgery. After local anesthesia, incisions were made at the neighboring teeth and connected by a crestal incision over the edentulous area. Flaps were elevated to expose the bone ridge. The implants were placed following the manufacturer instructions. Each surgeon determined the final drill diameter and implant length (drill diameter of 2.7 mm or 2.85 mm; implant length 11mm, 13mm and 15mm) to prepare the implant bed depending on the bone density and anatomy. The use of an osteotome technique was not permitted. If required only grafting with autogenous bone chips harvested during the surgery was allowed around the implant site. After implant installation the flaps were sutured around a trans-mucosal healing abutment. The patients were given full post-operative instructions. When requested by the patient, a temporary restoration, not connected to the implant, could be placed after surgery. Sutures at the surgical site were removed 7-13 days after surgery.

Prosthetic procedure

Impressions were taken from 5 to 7 weeks postoperatively. 6-10 weeks after implant placement metal-ceramic or all-ceramic permanent crowns were cemented over different height straight or 15° angulated abutments (TiDesign™, Dentsply Sirona Implants), according to the keratinized mucosa width and position of the implant.

Clinical and radiological examinations

The patients were followed as reflected in **Figure 1A**. The primary outcome in this study was implant survival after 5 years of loading. Secondary outcomes were marginal bone level change, soft tissue status, gingival zenith score, and clinical safety. Other recorded variable was height of the abutments. Clinical and radiological examinations were performed at implant and crown placement as well as at the follow-up visits after 6, 12, 24, 36, 48 and 60 months. An independent radiologist from the University of Gothenburg analyzed all the radiographs. Marginal bone levels (MBL) were determined as the distance from the mesial and distal interproximal bone to the junction between the micro threads and the machined bevel of the implant neck. These numbers were presented as a mean of the two values per implant at each designated time point. Finally, MBL change from implant placement and from restoration delivery to the designated time point was defined as gain if a positive value was obtained or loss if negative. The probing pocket depth (PPD) and bleeding on probing (BOP) on four sides of each restoration and time point were used to study the condition of the peri-implant mucosa. Similarly, changes in PPD were calculated from restoration delivery to each time point. Maintenance of the soft tissues in the frontal area was checked by measuring the gingival zenith score, defined as the distance from the most apical aspect of the buccal gingiva to the incisal edge of the crown.

Statistical analysis

Data is mainly presented by descriptive statistics. Number of observations and percent is given for categorical variables and mean and standard deviation for continuous variables unless otherwise noted. To test for statistically significance differences over time within the different parameters, the Wilcoxon signed rank test was used and not controlled for confounding factors. As this test is non-parametric no sensitivity analyses were performed. All tests were 2-tailed and p values <0.05 were considered to be significant. No adjustment for multiple comparisons were made. Sub-group analyses based on potential confounders of interest were conducted, including gender and smoking status. Patients lost to follow-up were not replaced and missing data for any reason were not imputed.

RESULTS

The recruitment, treatment and follow-up phases of the study have been completed (**Figure 1B**). A total of 72 patients were initially included in the study and signed the informed consent. Three patients were excluded from the study: 2 patients did not fulfill all eligibility criteria and 1 patient never showed up for the implant installation visit. Thus, a total of 69 patients, with a total of 97 implants, were treated in this study.

The study population represents a wide variety of patients with respect to age (mean 32.5 years, and ranging from 18 to 72 years), gender (52% male and 48% female), smoking history (16% smokers, 13% previous smokers, 71% non-smokers) and duration of edentulism (average of 73.6 months with a range of 2 to 487 months) (**Table 1**).

Four implants in four patients were lost during the healing period, before loading of the implant (95.9% and 94.2% survival rate at the implant and patient level, respectively). Three implants were lost due to insufficient osseointegration at the time of impression and 1 implant was lost

due to infection. No implants were lost after loading (100% survival rate after loading). Only five patients were lost to follow-up at the 5-year visit.

Bone quality and quantity at the moment of implant placement, implant position, final drill diameter, implant length and use of temporary restorations have been presented previously (Galindo-Moreno et al. 2012; Maiorana et al. 2015).

At loading and after 6 months, average MBL change compared to surgery was -0.34(0.91) mm and -0.30(0.94) mm, respectively (**Table 2**; **Figure 2**) ($p<0.001$, Wilcoxon Signed Ranks Test). After that and up to 5 years, the differences were not statistically significant. The mean MBL change from surgery to the 12, 36 and 60 months follow-up visits was -0.11(1.02), -0.11(0.96) and -0.15(0.95) mm, respectively ($p=0.285$, $p=0.163$, $p=0.053$, Wilcoxon Signed Ranks Test). In fact, after 5 years, no bone loss compared to the surgery was observed for 50.60% of the implants while 8.43% of them lost more than 1 mm (**Figure 3**). No differences were found at any visit comparing by gender and smoking status (**Supplementary Tables 1-2**).

There was a high prevalence of sites with positive BOP with a tendency to increase over time (34 to 60% at the follow-up visits) (**Table 3**; **Figure 4**), but PPD did not show any significant changes from crown placement to 60 months (**Table 3**; **Figure 5**). No significant changes in mean gingival zenith score from crown placement to 5 years follow-up were observed (**Table 3**; **Figure 6**).

In terms of reported adverse events (RAE) (**Table 4**), after loading and over the 5 years period, 7 (7.22%) implants in 7 (10.15%) patients experienced abutment fracture. Six (6.19%) crowns were lost in 6 (8.70%) patients. In some cases, the crowns were lost more than once per implant/patient and were associated with abutment fractures. All of these technical complications (17 times in 10 implants/patients, 10.31 and 14.49%, respectively) were solved with no damage at the implant level. The soft tissue around implants was healthy after 5 years, with no signs of recessions and exposure of the implant abutments, although minor soft tissue

complications were seen over the follow-up period. No implant was reported to suffer peri-implantitis, according to the measurements taken at the different time points, including BOP, PPD and MBL change.

DISCUSSION

Narrow diameter implants have become a successful option for the rehabilitation of small spaces both in the mesio-distal as well as the bucco-lingual dimensions (Davarpanah et al. 2000). In particular, the implant type used in the current report has demonstrated successful performance and high survival rate at 1-, 3- (Galindo-Moreno et al. 2012; Maiorana et al. 2015) and 5-years after loading. Specifically, no implants have failed after occlusal loading. No implant was reported to suffer peri-implantitis either, according to the measurements taken at the different time points, including BOP, PPD and MBL change. Although some implants might have some level of marginal bone loss, following published recommendations (Heitz-Mayfield 2008; Lang et al. 2011; Padial-Molina et al. 2014; Ramanauskaite & Juodzbalys 2016; Tözüm et al. 2016), the level of change over time was used to indicate that disease activity was not present. In terms of survival rates, the scientific literature has been so far contradictory. Clinical reports indicate that the long-term success of narrow diameter implants is lower than that of standard diameter implants (Albrektsson et al. 2007; Romeo et al. 2006; Winkler et al. 2000) although similar rates have also been reported (Andersen et al. 2001; Cordaro et al. 2006; Degidi et al. 2008; Hallman 2001; Lee et al. 2013; Zinsli et al. 2004; Zweers et al. 2015). If the literature is carefully and comprehensively reviewed, the reason for these discrepancies can be determined. First, a standardised definition of narrow, regular and wide diameter implants is needed if multiple studies in the literature are to be compared using different measurements. One initial attempt by Quek et al (2006) suggested sizes of mini (<2.9 mm), small or narrow (3 to 3.4 mm), regular (3.75 to 4 mm) and wide (5 to 6 mm) (Quek et al. 2006). More recently Al-Johany et al (2016) has proposed a classification based on descriptive terms more frequently

used in the literature such as Extra-narrow <3.0 mm; Narrow ≥3.0 mm to <3.75 mm; Standard ≥3.75 mm <5 mm; Wide ≥5 mm (Al-Johany et al. 2016). However, this classification system needs consensus agreement and further use to normalize it. According to this global definition, the more recent meta-analysis systematic reviews conclude differing results: 3.92 times greater failure rates for narrow implants than for regular implants (Ortega-Oller et al. 2014) vs. no statistically significant differences (odds ratio: 1.16 [0.7 to 1.69]) (Klein et al. 2014). Particularly related to the use of two-piece narrow implants, a survival rate between 93.8% and 100% for implants with a diameter of 3.0 to 3.25 mm and between 88.9% and 100% for implants with a diameter of 3.3 to 3.5 mm. Other reviews report similarly (Sierra-Sánchez et al. 2014). Thus, not only the diameter should be taken into consideration, but also the specific configuration of the implant and prosthetic abutments that may influence several key factors that determine implant performance and marginal bone loss. These include, among others, the dimensions of the edentulous space (Galindo-Moreno et al. 2016b), the type of connection (Galindo-Moreno et al. 2015a) and the platform switching concept, the gap between the implant and the abutment (Galindo-Moreno et al. 2016a) or the specific height of the abutment (Galindo-Moreno et al. 2014).

The effect of implant diameter on marginal bone loss has been classically reported to be higher than the effect of length and shape (Petrie & Williams 2005) so that a standard implant would distribute the forces in a better way and, therefore, reduce the bone loss (Qian et al. 2009). However, these studies are based on finite element models that, although useful, do not exactly represent the reality of the bone. A number of clinical studies reflect good outcomes in terms of MBL. Although some studies refer up to 1.6 mm (Zembić et al. 2012) and 1.2 mm (Zarone et al. 2006) marginal bone loss after different follow-up times, most studies reflect better results, below 0.7-0.8 mm (Degidi et al. 2009; Galindo-Moreno et al. 2012; King et al. 2016; Maiorana et al. 2015; Reddy et al. 2008). Compared to standard diameter implants, two-piece narrow

diameter implants lose an average of 0.78 ± 0.48 mm after 12 months vs. 0.31 ± 0.03 mm (Klein et al. 2014). More interestingly, the population described in the current study has evolved positively during the 1-, 3- (Galindo-Moreno et al. 2012; Maiorana et al. 2015) and 5-year follow-ups. In all cases, the MBL change has improved when using the prosthesis delivery as reference. This reflects a remodeling process that occurs before loading and recovers thereafter, considering the protocol was one-stage. This process is explained by the establishment of the biologic width, as extensively described in the literature (Berglundh & Lindhe 1996; Cardaropoli et al. 2006; Tarnow et al. 2000). Interestingly, in the current study, these biological changes were not statistically significant after 1 year. At this point, it is important to remember that MBL rates at early stages (before 6 months post-loading) higher than 0.44 mm have been associated with significantly higher MBL progression that may compromise the final outcome (Galindo-Moreno et al. 2015b). The implants in the current study do not follow this pattern which may reflect them being smaller in diameter and used only for the rehabilitation of single-unit edentulism. We have also recently reported on the possible cause for the maintenance of the peri-implant bone, even when the space is compromised. The marginal bone associated to the adjacent teeth is maintain over time (Galindo-Moreno et al. 2016b), which consequently could be responsible for the maintenance of the peri-implant bone in these cases. Therefore, using small-diameter implants is desirable even more if the bucco-lingual dimensions are also limited.

Abutment fracture occurred in seven patients in the current series. To our knowledge, this is a non-studied adverse event that might be more related to prosthetic reasons than to the implant itself. At first, narrow implants can be suspected to be mechanically weaker. However, recent reports conclude the opposite. Hirata et al (2015) found no differences between a number of implant systems, including the system used in this study, in terms of mechanical reliability following the application of a 130-N load for 100.000 cycles (Hirata et al. 2015). It should be

highlighted, however, the importance of the connection between the abutment and the implant, in all types of implants (Galindo-Moreno et al. 2015a) and particularly in those with reduced dimensions. The use of narrow implants with external hexagon presents a lower bending elastic limit than those of regular implants with external hexagon or implants with internal conical connection.

In the case of other type of technical complications, it should be mentioned that in the current study, no major complications were found since the implants were not irremediably affected by any of the prosthesis-related complications. Six crowns lost cementation over the course of 5-years, in some cases more than once. Seven abutments fractured. Other minor complications included soft tissue inflammation, mobility of the temporary crown and 1 patient unhappy with the aesthetic outcome. Overall, these complications can be considered to be within reported ranges, according to the literature (Jung et al. 2008, 2012; Sailer et al. 2012). In the particular case of narrow implants, technical complications have been reported for 10.21% of implants (Lee et al. 2013), which is within the findings of the current study (10.31%).

CONCLUSIONS

Two-piece narrow, 3 mm diameter, titanium dental implants can be considered a valuable solution for the replacement of upper lateral and lower incisors with early loading. Moreover, the data collected from all centers participating in this study demonstrates stable marginal bone levels and soft tissues around the implants.

COMPLIANCE WITH ETHICAL STANDARDS

All procedures performed in studies involving data from human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

The study was registered on http://www.clinicaltrials.gov from the US National Institutes of Health, identified as NCT00646113, from March 25, 2008

Ethics committees at the University of Granada (YA-NAR-001), the University of Ulm (137/08), the University Hospital (Copenhagen, Denmark) (H-D-2007-0122), The Institute for Postgraduate Education (Jönköping, Sweden) (M20-08), the National Research Ethics Service (08/H0206/24) and the University of Milan (YA-NAR-001) approved the study before it began. All patients received detailed oral and written information on the study and signed a written consent.

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TABLES

Table 1. Subject population and disposition.

Population			
N^P		69	
N^I		97	
Demographic characteristics			
N^P Sex (% of subjects)			
	Male	36	(52.2%)
	Female	33	(47.8%)
Age			
	Mean years	32.5	
	Range	18 - 72	
N^P Smoking (% of subjects)			
	Non-smoker	49	(71%)
	Ex-smoker	9	(13%)
	Occasional smoker	2	(3%)
	Habitual smoker	9	(13%)
Baseline characteristics			
Oral examination (N^P)			
	Abnormal jaw	3	
	Hyperkeratosis	3	
	Periodontitis	10	
	Bruxism	7	
	Other oral condition	3	
Edentulous period			
	Mean months	73.6	
	Range months	0* to 487	
Primary stability (N^I, Visit-2)			
	Yes	96	
	No	1	

N^P = Number of patients
N^I = Number of implants
* Since Edentulism was registered at Visit 1 the actual number of months at surgery might differ. In this case with 0 months 2 teeth were extracted at Visit 1; then a 2 months healing period was waited before surgery at Visit 2.

Table 2. MBL change from Surgery. Negative sign = bone loss, AND positive sign = bone gain.

MBL Average (mm)	Loading	6 months	12 months	36 months	60 months
Mean	-0.34	-0.30	-0.11	-0.11	-0.15
SD	0.91	0.94	1.02	0.96	0.95
Min	-6.20	-6.30	-6.75	-5.65	-5.55
Median	-0.20	-0.20	0.00	0.00	0.00
Max	1.40	2.45	2.85	2.85	2.60
P-value*	<0.001	<0.001	0.285	0.163	0.053

* MBL at each visit compared to surgery. Wilcoxon Signed Ranks Test. 2-sided p-value (exact).

Table 3. PPD change from Loading (mean(SD); Negative sign = pocket depth reduction, AND positive sign = pocket depth increase), BOP (% of positive sites), and Gingival Zenith (mean(SD)) at the different time points.

	Loading	**6 months**	**12 months**	**24 months**	**36 months**	**48 months**	**60 months**
PPD Change (mm)	-	0.20(0.70)	0.20(1.02)	0.10(1.06)	-0.20(1.17)	-0.30(1.07)	-0.20(0.98)
BOP (%)	34.83	46.51	34.44	46.59	46.59	50.69	57.50
Gingival Zenith (mm)	8.85(1.67)	8.72(1.86)	8.67(1.64)	8.68(1.69)	8.78(1.87)	8.56(1.33)	8.55(1.36)

Table 4. Reported Adverse Events related to the implant and/or prosthesis over the 5 years follow-up. No serious adverse events were reported in the study. None of the patients suffered complications in more than one implant so the absolute numbers are the same for implants and patients.

Event	Number of events	% of implants	% of patients
Loss of crown cementation *	10	6.19	8.70
Abutment fracture **	7	7.22	10.15
Technical complications (loss of crown cementation + abutment fracture) *, **	17	10.31	14.49
Mobility of provisional crown	1	1.03	1.45
Lack of osseointegration ***	1	1.03	1.45
Implant loss	4	4.12	5.80
Soft tissue complications	2	2.06	2.90
Aesthetic complication	1	1.03	1.45

* 1 implant/patient suffered the event 3 times and 2 implants/patients suffered it 2 times.

** Three implants/patients also suffered loss of crown cementation.

*** Osseointegration was achieved after prolonged healing.

FIGURE LEGENDS

Figure 1. A) Study time line and B) flow chart of the included patients.

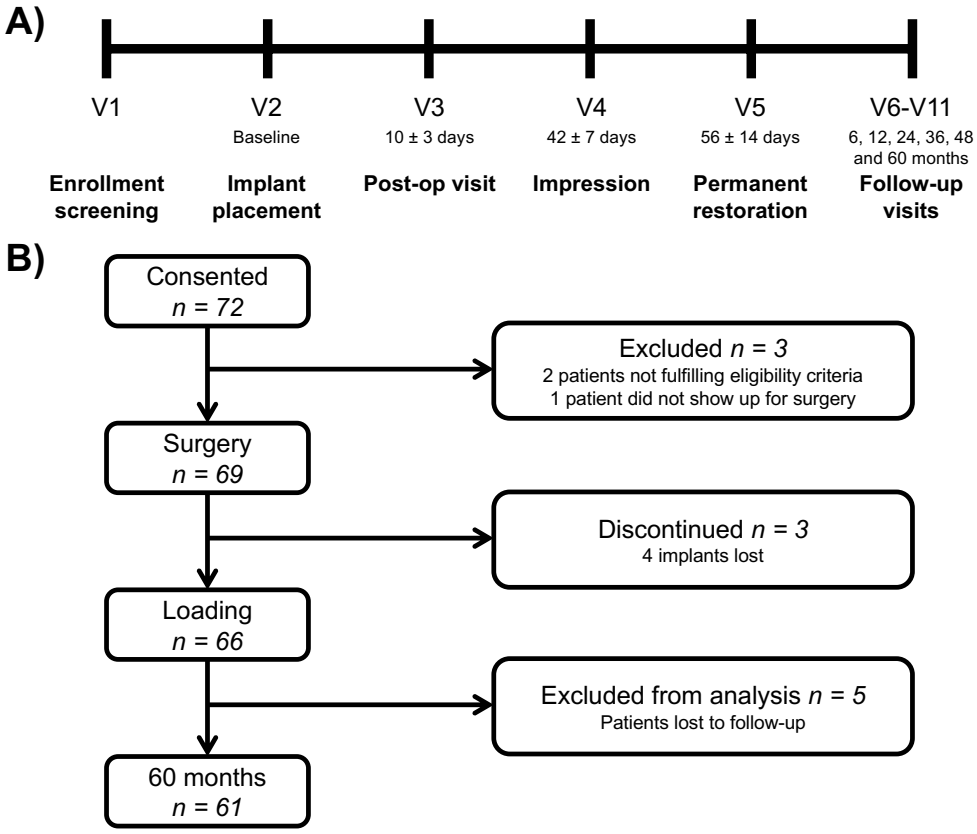

Figure 2. Average MBL change from Surgery to each time from the reference point on the implant to the most coronal bone to implant contact. Negative sign = bone loss, AND positive sign = bone gain; Error bars = Standard Deviation.

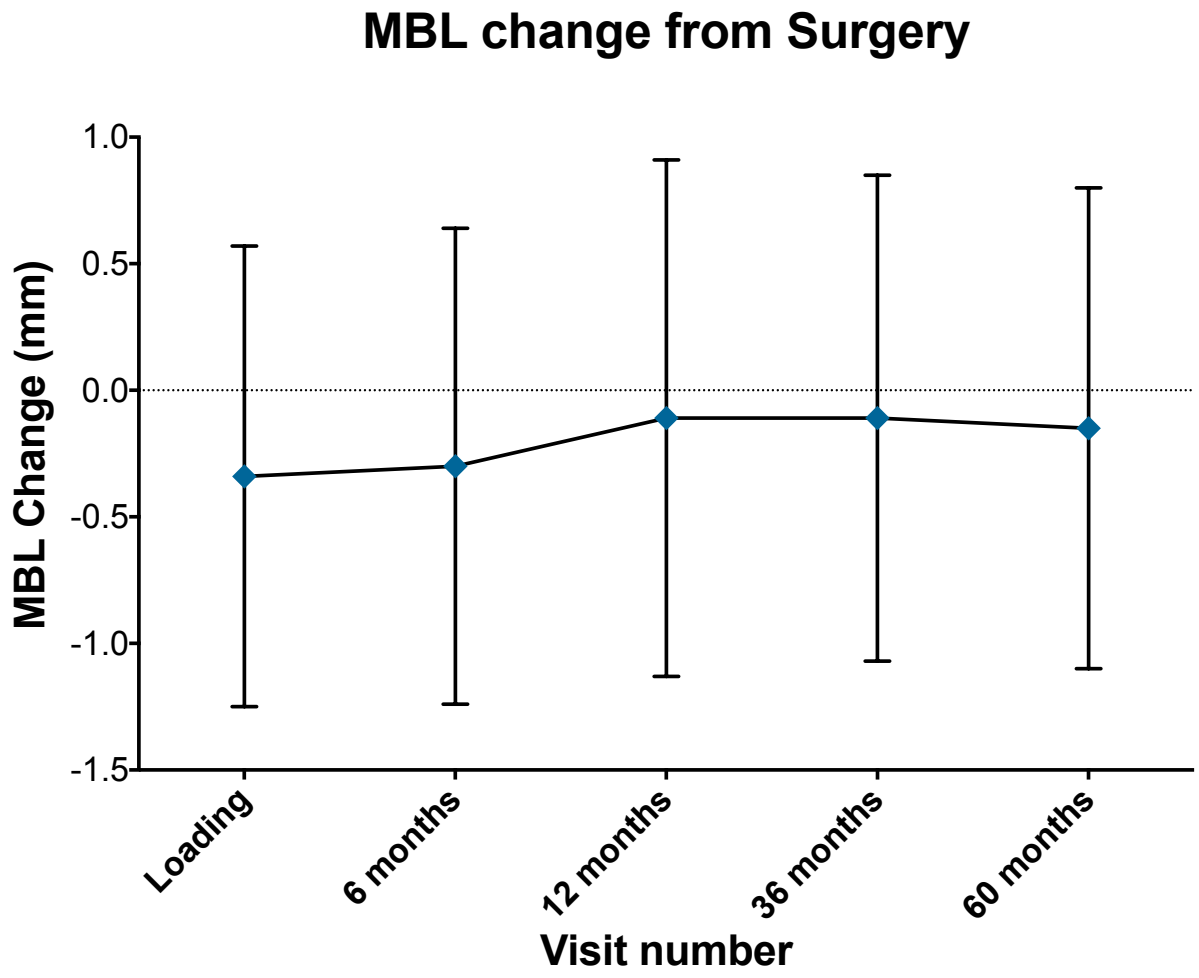

Figure 3. Cummulative bone level change per implant from Surgery to 60 months.

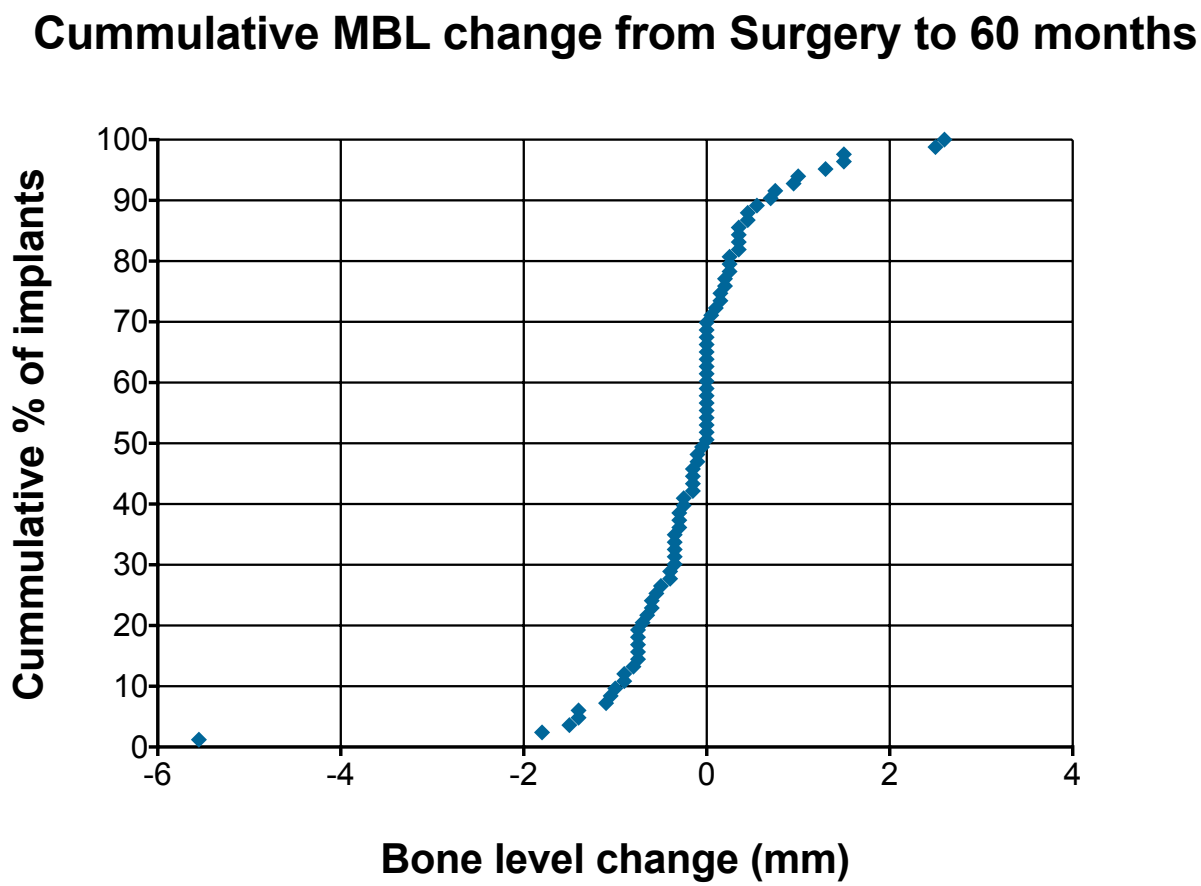

Figure 4. Bleeding on probing. Percentage of sites with any bleeding at the implant level.

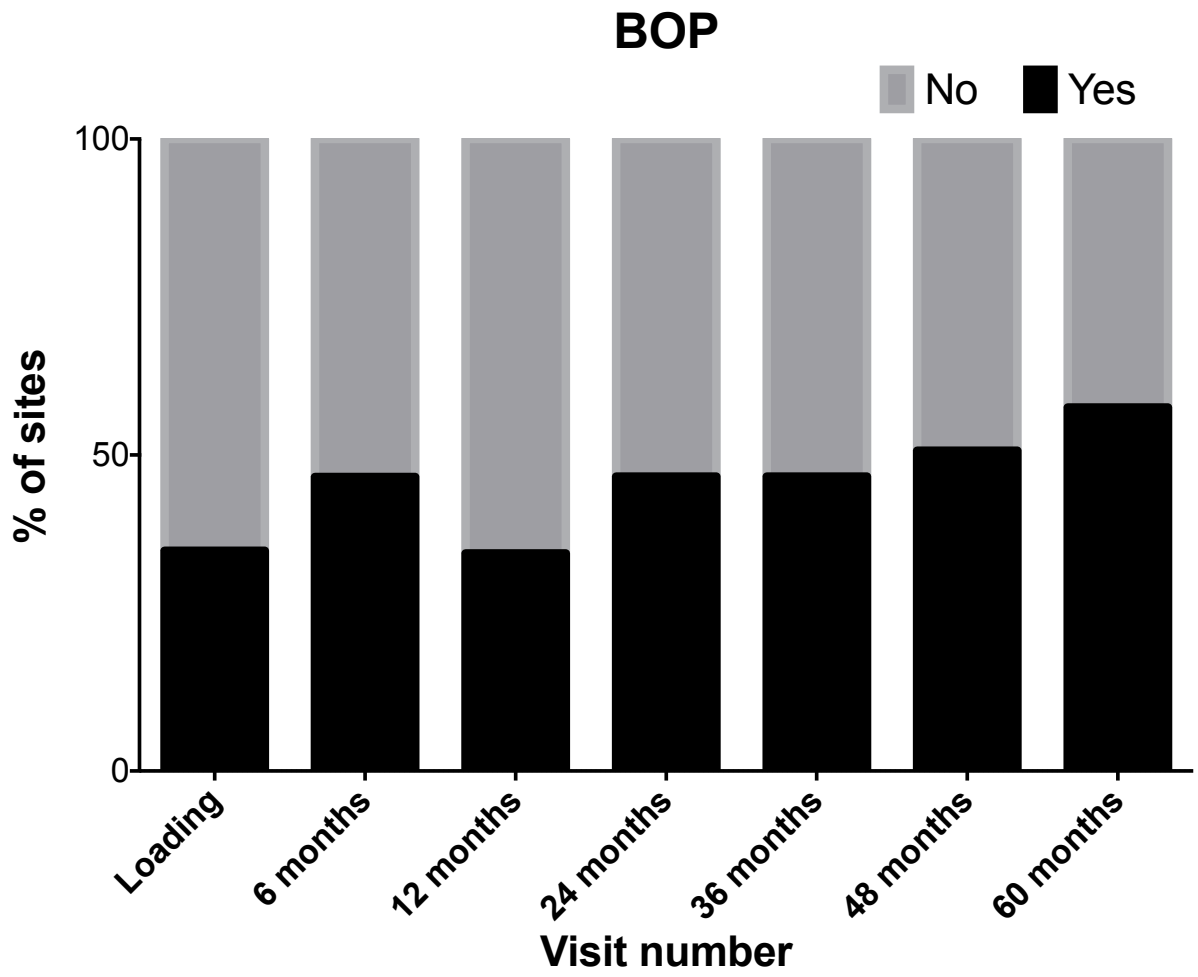

Figure 5. Pocket Probing Depth (PPD) change from Loading to each time. Negative sign = pocket depth reduction, AND positive sign = pocket depth increase; Error bars = Standard Deviation.

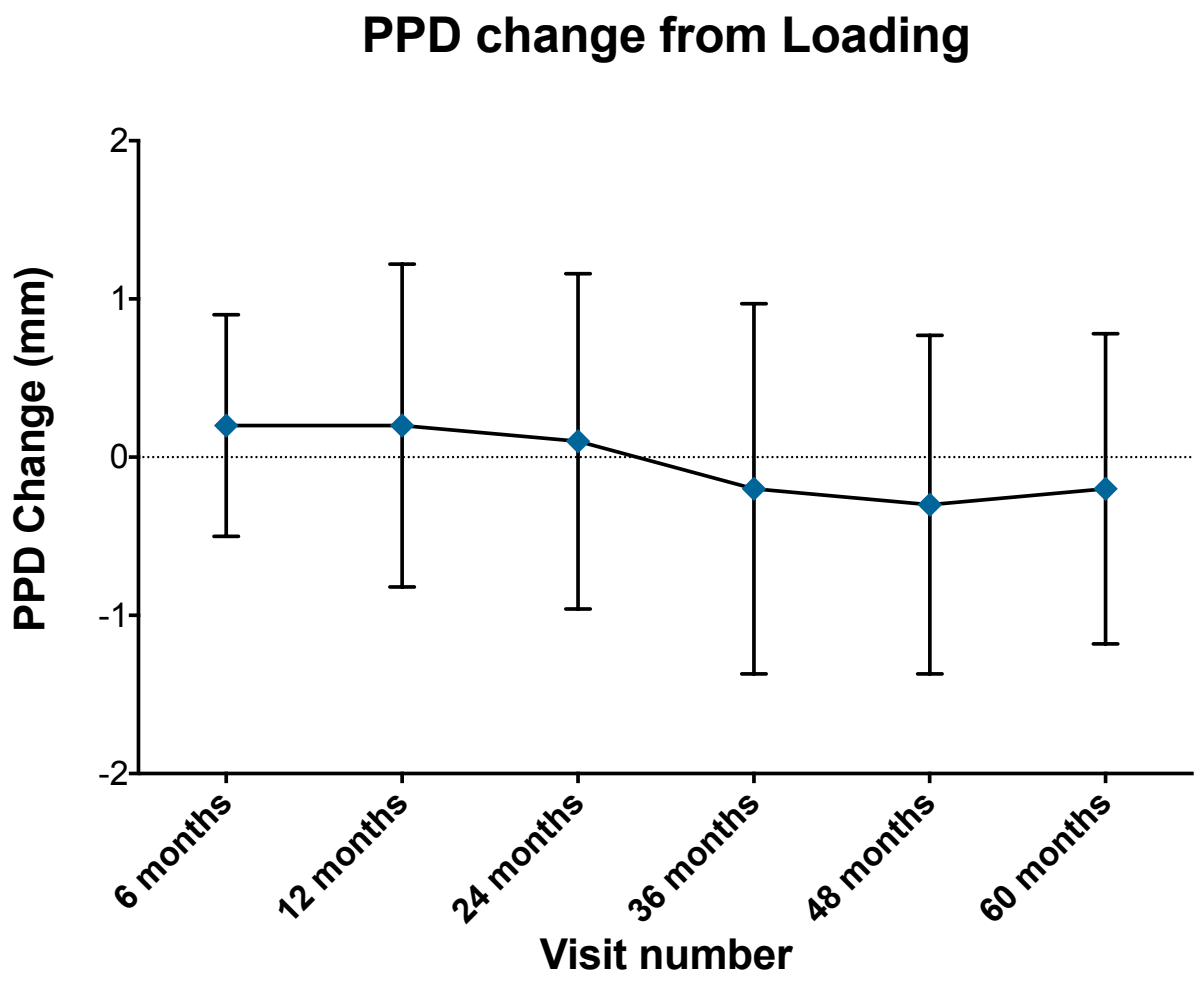

Figure 6. Gingival Zenith scores from Loading to 60 months. Error bars = Standard Deviation.