Immediately Loaded Platform-Switched Implants in the Anterior Mandible with Fixed Prostheses: A Randomized, Split-Mouth, Masked Prospective Trial

Georgios E. Romanos, DDS, PhD, Prof. Dr. med. dent.;* Hans Malmstrom, DDS;† Changyong Feng, PhD;‡ Carlo Ercoli, DDS;§ Jack Caton, DDS, MS¶

ABSTRACT

Background: Platform-switched implants have been demonstrated to maintain marginal bone-level stability after immediate loading. The present study evaluated crestal bone loss and soft tissue stability around ANKYLOS plus® implants (A-implants) and Certain® PREVAIL™ (B-implants).

Materials and Methods: Patients were identified to receive three A- or three B-implants on each side of their mandibles, with randomization. All implants were loaded immediately after their insertion and splinted with a cemented provisional prosthesis. Final prostheses were delivered 3 months after implantation. Peri-implant crestal bone loss, gingival recession, and other soft tissue changes were evaluated throughout a 2-year follow-up.

Results: A total of one hundred seven implants were placed in 18 patients. Two of the group A-implants and one group B-implant failed. At the final 24-month assessment, bone loss of at least 2 mm (mesially or distally) was recorded at 5 of the 44 surviving A-implants (11%) and 33 of the 47 B-implants (70%), a success rate of 88.63% for the A- and 29.78% for the B-implants.

Conclusions: Significant changes in the level of the crestal bone loss around immediately loaded platform-switched dental implants seem to be related to the platform shape and size, as well as the implant-abutment connection, when abutments are not removed.

KEY WORDS: immediate loading, platform switching

INTRODUCTION

Traditionally, implants have been placed in a two-step surgical procedure that involves soft tissue incisions to the alveolar bone, reflection of a mucoperiosteal flap, drilling of an osteotomy with drills of successively larger diameters, placement of the implants, and suturing of the soft tissue flap. Three to six months following this first surgery, a second flap reflection has been performed, and the transmucosal abutment[1] has been inserted, followed by loading of the implant after fabrication of the prosthetic restoration.

Alternatively, today, when good primary stability[2–5] (implant stability during abutment connection[6]) can be achieved, implants may be loaded immediately after their insertion. Various clinicians have suggested immobilizing the implants (via splinting) and dealing with biomechanical considerations (e.g. prescribing a soft/liquid diet in the initial stages of the healing) in order to achieve long-term success for immediately loaded implants.[2–6]

In most clinical studies, the implant survival rate has been equated with clinical success, with little attention paid to peri-implant marginal bone levels.

*Professor, Division of Periodontology, Eastman Institute for Oral Health, University of Rochester, Rochester, NY, USA, and Division of General Dentistry, Eastman Institute for Oral Health, University of Rochester, Rochester, NY, USA; †professor, Division of General Dentistry, Eastman Institute for Oral Health, University of Rochester, Rochester, NY, USA; ‡associate professor, Department of Biostatistics and Computational Biology, University of Rochester, Rochester, NY, USA; §associate professor, Division of Prosthodontics, Eastman Institute for Oral Health, University of Rochester, Rochester, NY, USA; ¶professor, Division of Periodontology, Eastman Institute for Oral Health, University of Rochester, Rochester, NY, USA

Reprint requests: Professor, Dr. George E. Romanos, Department of Dental Medicine, School of Dental Medicine, Stony Brook University, 184C Sullivan Hall, Stony Brook, NY 11794-8700, USA; e-mail: georgios.romanos@stonybrook.edu

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However, Albrektsson and colleagues[7] and Smith and Zarb[8] pointed out that clinical success in implant dentistry is determined by different measurements of the soft and hard peri-implant tissues.

In order to preserve peri-implant crestal bone, Lazzara and Porter[9] suggested using a wider diameter implant with a smaller diameter prosthetic component. They called this strategy "platform-switching" and introduced it as a new concept in implant dentistry. The PREVAIL® Implant (Biomet 3i) was designed with a 4.8 mm implant platform that was restored with a 4.0 mm prosthetic component.

A similar approach was embodied much earlier in the ANKYLOS® Implant System (Degussa, Hanau, Germany). This implant design was initially introduced in the market with the name NM-dental implant.[10] This system incorporated a conical implant-abutment connection that creates an inherent shift between the diameter of the implant collar and the abutment. Researchers have been demonstrating crestal bone stability around this platform-shifted implant system for more than 20 years.[11,12] Immediately loaded ANKYLOS implants have exhibited marginal bone-level stability without any initial bone loss.[13] More recently, the ANKYLOS plus implant system was introduced, featuring a progressive thread design; a sandblasted, acid-etched surface; a 2 mm acid-etched (only) implant collar surface; and a conical (Morse-tapered) platform-switched implant-abutment connection.

Up to now, no clinical and radiological data have been gathered to compare these two implant systems (Certain® PREVAIL and ANKYLOS plus) when used in a conventional or an immediate loading treatment protocol placed at the same patients. The present study was designed to evaluate crestal bone loss and soft tissue stability around both types of implants throughout 2 years of follow-up. This is of clinical significance in order to control the crestal bone loss and prevent peri-implant inflammatory reactions and esthetic complications.

MATERIAL AND METHODS

The study was conducted in accordance with the Declaration of Helsinki, and the protocol was approved by the institutional review board at the University of Rochester, Rochester, NY (#RSRB00026544). A total of 19 subjects with edentulous mandibles were sought from patients presenting at the University of Rochester, Eastman Institute for Oral Health. In order to participate, patients needed to be in general medical and dental health (no patients with uncontrolled diseases were included), have width and height of bone to enable placement of implants with diameters of 4.8 mm and lengths of 11 mm, and be willing and able to return for visits over a 2-year follow-up period.

Exclusion criteria included pregnancy, nicotine abuse (more than 20 cigarettes per day), consumption of medications that would compromise postoperative healing and/or osseointegration (e.g., corticosteroids, calcium channel blockers, phenytoin, and bisphosphonates), allergies to dental materials, and restorative angulation requirements exceeding approximately 15 degrees.

One hour prior to implant placement, antibiotic medication was administered to all subjects according to the Policy of the Department of Periodontology in the institution where the study performed. After a mucoperiosteal flap elevation with a mid-crestal incision, the bone was prepared with a denture bur to create a flat surface (a minimum 8 mm ridge width) to achieve the same bone levels for precise measurements. Immediately after bone plateau preparation, all participants were randomized (using a computer-generated randomization schedule and anonymous, numerical-base system to ensure confidentiality) to receive three ANKYLOS plus implants (A-implants, 11 mm length and 3.5 mm diameter; Dentsply Implants, Waltham, MA, USA) or three Certain PREVAIL Implants (B-implants, 10 mm length and 4.0 mm (body)/4.8 mm (top) diameter; Biomet 3i, Palm Beach Gardens, FL, USA) on one side of the mandible in the areas of the lateral incisor, canine, and first premolar. Three of the other type of implants was to be placed on the contralateral side (Figure 1, A and B).

All implants were then placed at the bone level (crestal placement) using custom surgical guides designed to achieve the prosthetic goals for each individual patient. Immediately after placement, implant stability was measured using the Periotest method.[14] The Periotest® (Medizintechnik Gulden, Modautal, Germany) device was calibrated prior to each measurement session. All measurements of implant stability (Periotest values) were performed by the same examiner at the middle facial area of the abutment after placement of the Periotest device-handpiece, parallel to the floor and parallel to the occlusal plane in order to provide possible standardization. All surgical procedures were

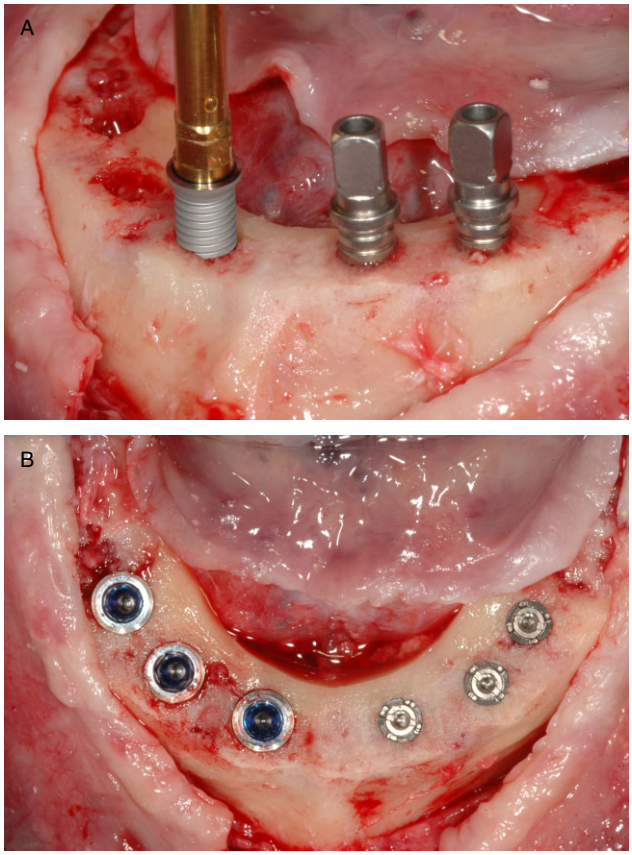

Figure 1 *A*, Implant placement in the anterior mandible with platform switching. *B*, Implant placement with platform switching at the left (A-design) and at the right side (B-design) for immediate loading.

performed under local anesthesia, and all implants were placed according to the ANKYLOS plus and Certain PREVAIL system surgical manuals. Intraoral measurements determining the exact interimplant distances were performed during surgery.

Independent on the recorded Periotest value of the placed implants, all implants were loaded immediately after their insertion using standard abutments (for the A-implant system) and Provide® (Biomet 3i, Palm Beach Gardens, FL, USA) abutments (for the B-implant system) that were torqued according to the manufacturers' recommendations (Figure 2A). Interruptive permanent silk sutures with 4-0 suturing material were used to close the flaps. The six implants were then splinted with a cemented provisional prosthesis extending from one premolar to the other, with a mesial cantilever in the region of the central incisors (Figure 2B). Standardized periapical radiographs with specified reference points (i.e., implant platform and bone crest) were taken immediately after abutment connection using customized jigs.

All patients were instructed to consume a soft/liquid diet until delivery of the final restoration (approximately 3 months after implant placement). Chlorhexidine gluconate oral rinse (0.12%) was prescribed to all patients for the first 10–14 days after surgery as standard chemical antiseptic and antibacterial solution. Suture removal occurred 7 to 10 days after implant surgery. Two months after implant placement, impressions of the mandibular implants were taken for the final restoration, and the soft-tissue status was evaluated using a plaque index (PI),[15] a Sulcus Bleeding Index (SBI),[16] and a 1 mm-scaled periodontal probe to measure pocket depth depths and keratinized mucosal width.[17,18] Aquasil® (Dentsply, Milford, DE, USA) impressions were made with customized trays to evaluate the soft tissue recessions from the abutment margin to the middle facial margin of the soft tissue after removal of the restorations. These impressions were taken at 6 weeks (final impression), 3 month-, 6-month-, 1-year, and 2-year intervals (Figure 3).

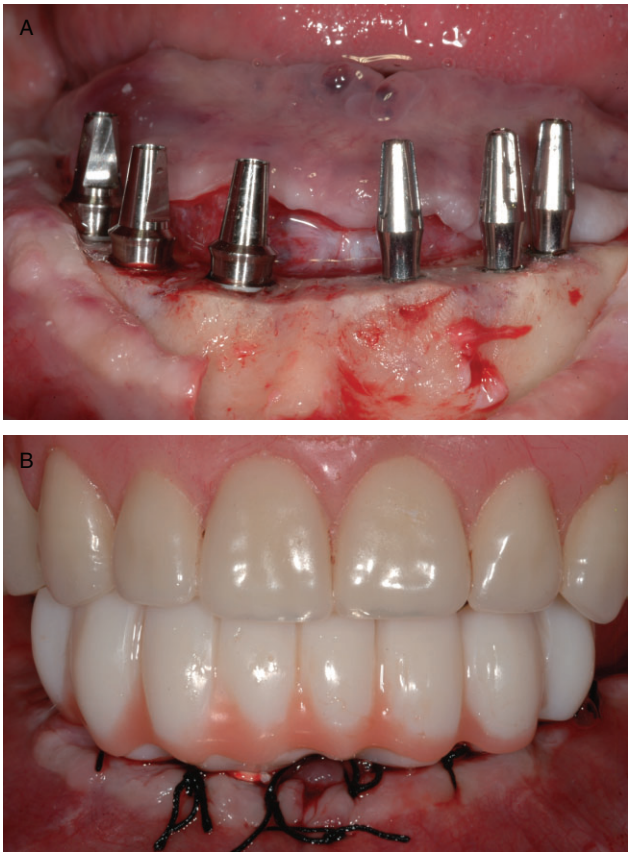

Figure 2 *A*, Abutment connection in the anterior mandible for immediate loading. *B*, Provisional restoration immediately after surgery for immediate loading.

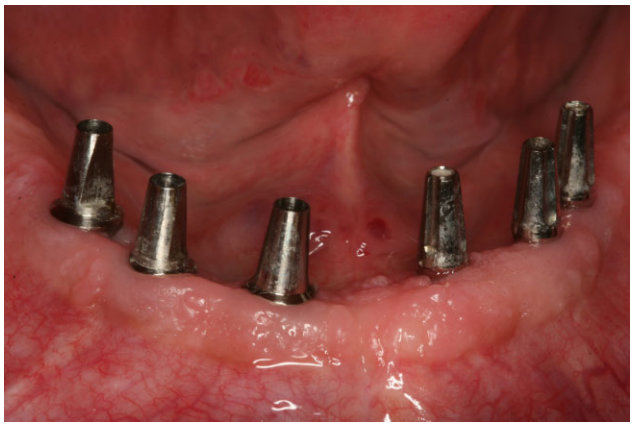

Figure 3 Soft tissue healing 2 years after immediate loading.

The same assessments were also conducted on each patient 3 months after implantation, when the final prosthesis (a hybrid prosthesis) was delivered and cemented and at follow-up visits 6, 12, and 24 months after implant placement. At the 6-, 12-, and 24-month visits, the implant stability was evaluated using the Periotest device (after removal of the prosthesis), and intraoral radiographs of the implants were taken, using the same reference points and angulations (according to a jig and a Rinn holder with standardized marking for each patient) used at the initial time of loading.

At the conclusion of the data collection for each patient, the peri-implant crestal bone loss was evaluated by a dentist familiar with radiographic bone assessment but not belonging to the investigational group and blinded to the exact implant-surgical protocol in terms of implant positioning. The distance from the implant/abutment junction reference point to the most coronal bone-to-implant contact on the mesial and distal side of each implant was recorded to the nearest 0.1 mm using a 7× magnifying device.

Changes in the patients' mucosal height over time (gingival recessions) also were evaluated, based on the Aquasil impressions made at the 2-, 3-, 6-, 12-, and 24-month follow-up visits to evaluate soft tissue changes in the height of the gingiva at the middle facial areas.

Statistical Analysis

Analysis of all outcome data was performed with SAS version 9.13 (Cary, NC, USA), according to the intent-to-treat principle. Hypothesis-driven comparisons were made to control the family-wise type I error rate at 0.05.f.

The use of both types of implants for each patient created nested paired data (due to the within-subject correlation). The power calculation was thus based on a two-sided paired *t*-test testing the null hypothesis that there would be no difference (on average) in within-subject changes of marginal bone level between the two implant types. Thirteen patients were required to detect an effect size of 0.85 with 80% power at a 5% significance level, where the effect size was defined as the expected mean difference between the two implant types of average within-subject changes of crestal bone level divided by the standard deviation of itself. Recruitment of 15 subjects allowed for a 13.3% attrition rate.

For the primary outcome variable, treatment difference in mean change in crestal bone level (change from postoperative status to 6, 12, and 24 months later) was assessed using a linear mixed model to accommodate the longitudinal feature of the data. Random subject effect and random linear time-trend effect were added into the regression model to account for the correlations created by the multiple implants per subject within the split-mouth protocol. Independent, exchangeable, and unstructured covariance matrix was assessed and compared using deviance and log likelihood. The treatment effect was estimated after adjusting subject characteristics like age, sex, and baseline bone level. Clinical success of an implant in this protocol was defined as <0.1 mm crestal bone level change. A binary outcome of success or nonsuccess (0 or 1) was created for each observation at each assessment point. A mixed-effects logistic regression model with random intercepts, random subject effect, and linear trend of time was used to evaluate the difference in success rate between the two treatments, after adjusting for age and sex. Standard diagnostic measures such as residual plots were used to check the goodness-of-fit of the regression model assumptions and identify any outliers.

A similar approach was employed to analyze changes in the implant and soft tissue stability, PI, SBI, pocket depths, and keratinized mucosal width. For continuous normal outcomes, a linear mixed model was used. For non-normal outcome variables, generalized linear mixed models including a random time-trend and subject effects was carried out. Appropriate link functions were specified according to the type of the outcome variables, and age and sex were included in the models as control variables.

RESULTS

Nineteen patients were recruited to participate. One of the patients died (due to heart attack) before the 6-month follow-up appointment and was consequently excluded from the study results. One patient was lost to follow-up after 6 months. Two others had to relocate and were lost to follow-up after 1 year.

Seventeen of the 18 patients who were followed for 6 or more months received a total of six implants (three of each type). One patient received three A-implants and two B-implants due to lack of intrafo-raminal space for placement of six implants. The decision to place three A- and two B-implants (and not vice versa) was done intra operatively in a randomized way. A total of one hundred seven implants was thus placed (54 A and 53 B). Two of the A-implants failed and were removed. One implant removed by another dentist (within the first 6 weeks after surgery), when the patient was on vacation. This implant presented slight mobility due to overloading. The patient reported use of hard food in the early healing stages. The other implant was removed due to acute peri-implant disease (5 months after surgery) resulting from retained cement very deep into the subgingival area. One of the 53 B-implants was removed (7 months after surgery) because of excessive mobility (Periotest score = 18).

Crestal Bone Loss

Six months after implant placement, crestal bone loss of at least 2 mm was recorded on either the mesial or the distal of 7 of the 52 surviving A-implants (13%) and 29 of the 53 B-implants (55%). At the 12-month visit, it was recorded at 10 of the 49 surviving A-implants (20%) and 28 of the 50 B-implants (56%). At the final 24-month assessment, bone loss of at least 2 mm (either mesially or distally) was recorded at five of the 44 surviving A-implants (11%) and 33 of the 47 B-implants (70%) (Figure 4, A and B).

Implants were considered to be successful in terms of crestal bone loss if the 2 mm or less of crestal bone loss, as measured both mesially and distally, occurred at the beginning of loading. By this measure, 88.63% of the A-implants were successful 24 months after implant placement, as compared with 29.78% of the B-implants. Table 1 presents these results. Figure 5 displays them as a box plot.

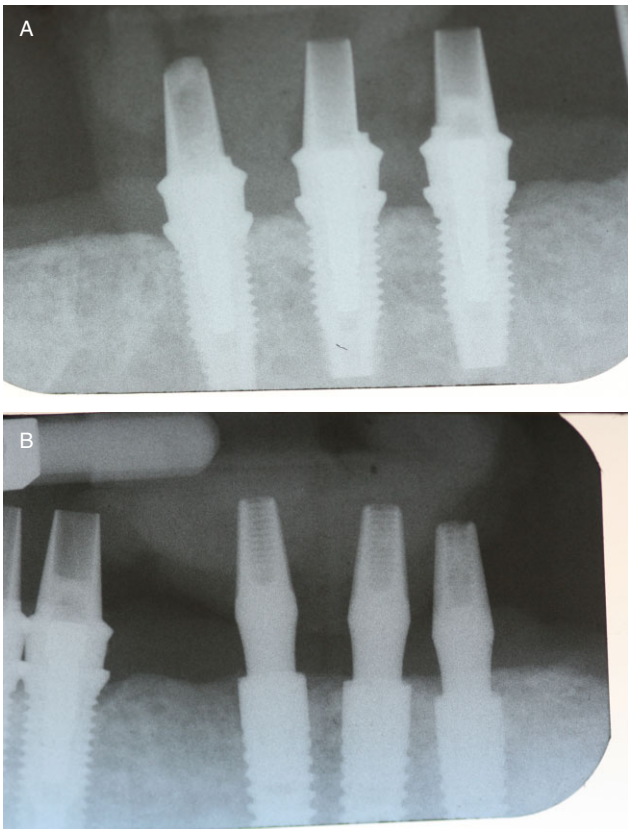

Figure 4 *A*, Crestal bone loss around implants with platform switching and wide platform after 2 years of immediate loading. *B*, No crestal bone loss around implants with narrow platform and platform shifting 2 year after immediate loading.

Implant Stability

At the time of implant placement, the mean Periotest value of the A-implants was –0.84 (SD = 1.4), as compared with –2.04 (SD = 2.13) for the B-implants. At the

TABLE 1 Incidence of Crestal Bone Loss (>2 mm Mesial or Distal) as Measured on Radiographs Taken on the Day or Surgery and at 6, 12, and 24 Months Later

Time	A-Implants # of Implants with 2 mm or More of Bone Loss (mesial or distal)	B-Implants # of Implants with 2 mm or More of Bone Loss (mesial or distal)
6 months	7/52	29/53
	13%	55%
12 months	10/49	28/50
	20%	56%
24 months	5/44	33/47
	11%	70%

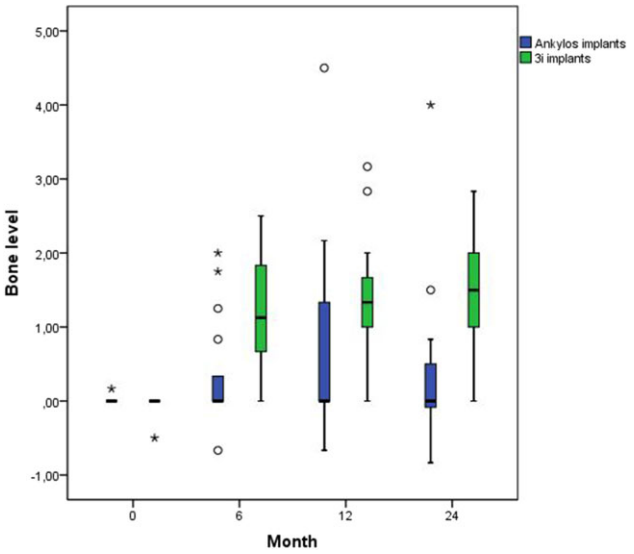

Figure 5 Bone levels between the two implant designs over the 2-year follow-up period.

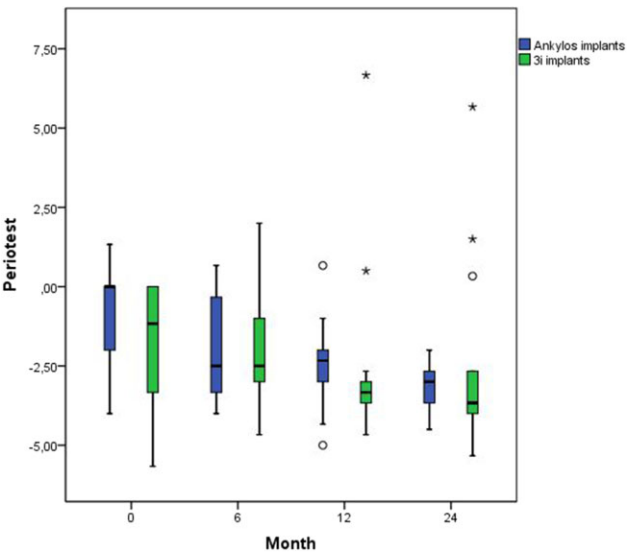

Figure 6 Periotest values for the two implant designs after 2 years of immediate loading representing no differences in implant stability.

6-month visit, the respective mean Periotest values were −1.95 (SD = 1.57) for the A-implants and −2.02 (SD = 1.91) for the B-implants. At the 12-month visit, the respective mean Periotest values were −2.53 (SD = 1.41) for the A-implants and −2.75 (SD = 2.68) for the B-implants. After 24 months, the respective mean Periotest values were −3.09 (SD = 0.68) for the A-implants and −2.75 (SD = 2.79) for the B-implants. Only the difference at the time of surgery was statistically significant. Table 2 presents these results, and Figure 6 displays them as a box plot.

Soft Tissue Changes

Tables 3–6 show the results of the keratinized mucosa, Probing Pocket Depth (PPD), bleeding index, and PI assessments conducted between 2 and 24 months. The only significant differences found between the two kinds of implants were as follows: At the 6-month visit, the mean PPD score for the A-implants was 1.89 mm, as compared with 2.24 mm for the B-implants. At the 2-, 3-, and 6-month visits, the mean bleeding index for the A-implants was 0.22, 0.24, and 0.37, respectively,

TABLE 2 Periotest Data Presenting No Significant Difference Except at the Time of Surgery

	Ankylos			3i			
Time	*n*	Mean	SD	*n*	Mean	SD	*p* Value
Surgery	17	−0.84	1.40	17	−2.04	2.13	0.01
6	18	−1.95	1.57	18	−2.02	1.91	0.90
12	17	−2.53	1.41	17	−2.75	2.68	0.76
24	16	−3.09	0.68	17	−2.75	2.79	0.84

TABLE 3 Keratinized Mucosa Data (in mm). No Significant Differences between the Two Kinds of Implants Were Found

	Ankylos			3i			
Time	*n*	Mean	SD	*n*	Mean	SD	*p* Value
2	18	3.81	0.87	18	4.15	1.17	0.16
3	17	3.55	0.88	17	3.55	1.16	0.99
6	18	3.37	0.69	18	3.34	1.09	0.92
12	17	3.39	0.68	17	3.41	0.92	0.92
24	15	3.11	0.80	15	3.17	1.08	0.70

TABLE 4 PPD Findings (in mm). No Significant Differences Were Found between the Two Kinds of Implants Except at 6 Months

	Ankylos			3i			
Time	*n*	Mean	SD	*n*	Mean	SD	*p* Value
2	18	2.11	0.67	18	2.10	0.60	0.95
3	17	1.86	0.55	17	1.91	0.54	0.50
6	18	1.89	0.43	18	2.24	0.54	0.008
12	17	1.99	0.44	17	2.02	0.50	0.72
24	15	1.76	0.47	15	2.11	0.73	0.80

TABLE 5 Bleeding Index Findings. Significant Differences Were Found between the Two Kinds of Implants at 2, 3, and 6 Months

	Ankylos			3i			
Time	*n*	Mean	SD	*n*	Mean	SD	*p*-value
2	18	0.22	0.22	18	0.62	0.60	0.004
3	17	0.24	0.26	17	0.49	0.45	0.02
6	18	0.37	0.25	18	0.68	0.50	0.02
12	17	0.52	0.54	17	0.64	0.46	0.34
24	15	0.53	0.32	15	0.60	0.44	0.50

compared with 0.62, 0.49, and 0.68 for the B-implants, respectively. The middle facial recessions were recorded according to the soft tissue measurements in the master casts during the entire observation period. No statistically significant difference between the two implant designs was observed at the different time intervals (Table 7, Figure 7).

DISCUSSION

The present study examined peri-implant changes around two types of platform-switched implants simultaneously placed in patients' anterior mandibles, using an immediate loading protocol and cross-arch stabilization. This protocol is an established and successful protocol, in implant dentistry.[4,6] The implants were placed without compromising their primary stability and were connected to abutments using the final torque-moment immediately after surgery. The abutments were never removed, and final (abutment-level) impressions were made using prefabricated caps for the final prostheses. Due to the issue that the abutments were never removed, it was not possible to evaluate the implant stability using another method, such as resonance frequency analysis.

TABLE 6 Plaque Index. No Significant Differences between the Two Kinds of Implants Were Found

	Ankylos			3i			
Time	*n*	Mean	SD	*n*	Mean	SD	*p* Value
2	18	0.62	0.83	18	0.72	0.91	0.50
3	17	0.32	0.28	17	0.51	0.61	0.08
6	18	0.17	0.28	18	0.35	0.64	0.07
12	17	0.17	0.20	17	0.51	0.75	0.08
24	15	0.37	0.45	15	0.48	0.53	0.20

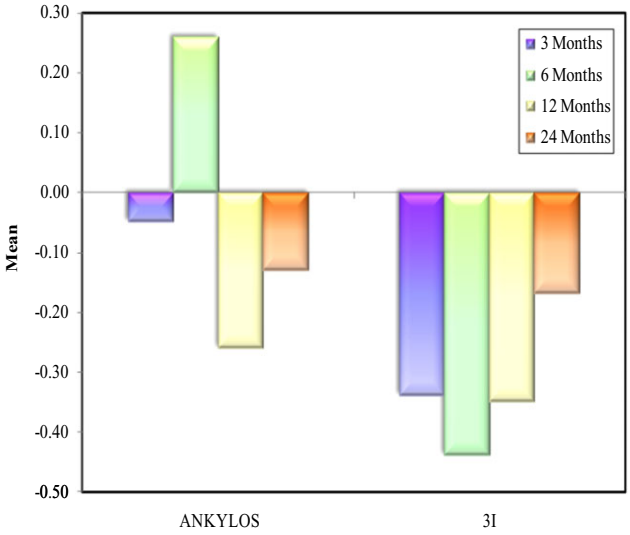

Figure 7 Soft tissue changes (recessions) around implants with platform switching after 2 years of immediate loading showing similar tissue levels for both systems after 2 years (abutments were never removed).

All implants were placed after ridge reduction to create space for the framework and acrylic resin of the prosthesis. This protocol is important in case of not extreme bone resorption.

After leveling of the alveolar ridge, the side of the mandible on which each type of implant was to be placed was determined randomly (split-mouth design in terms of implant design selection independent on the cross-arch splinting). The data showed that under immediate loading conditions, when the implants were splinted together with a provisional or final cross-arch prosthesis, micro-movement at the bone-implant interface leading to subsequent implant failure did not occur. For that reason, the immobilization with cross-arch prostheses was used in the present study to avoid potential failures of implants. However, significant crestal bone loss around the B-implants did occur, due to the wide diameter of the implant top (the shape and size of the extended platform design) and the surgical trauma (bone grinding). All implants were placed at the bone level (crestal placement). Bone leveling (grinding) may be associated with bone resorption. Had the placement been subcrestal, resorption of the marginal bone would have been less likely to expose the implant threads, better controlling the risk peri-implant inflammatory diseases and compromising esthetics.

When implants are placed after extensive bone reduction that is necessary for prosthetic reasons, the surgical trauma may cause crestal bone loss around

TABLE 7 Comparison of the Mid-Facial Soft-Tissue Recession (in mm) at Different Loading Periods (*p* value for the Mann-Whitney test)

Implant System	3 Months	6 Months	12 Months	24 Months
ANKYLOS plus®				
Range	−1.75–1.0	−1.75–0.75	−1.75–0.75	−1.75–0.75
Mean ± SD	−0.23 ± 0.99	−0.38 ± 0.74	−0.39 ± 0.73	−0.25 ± 0.66
Median	0.0	−0.50	−0.25	−0.13
Certain Prevail				
Range	−2.0–1.50	−2.0–1.25	−1.50–0.75	−1.50–0.50
Mean ± SD	−0.52 ± 0.98	−0.55 ± 0.94	−0.55 ± 0.67	−0.38 ± 0.57
Median	−0.50	−0.75	−0.63	−0.25
p Value	0.321	0.501	0.518	0.498

platform-switched implants. Such resorption is not associated with an inflammatory process, but if the implant surface is roughened, this may foster plaque accumulation and bacterial invasion. Therefore, implants with a machined surface or implants with hybrid surfaces should be used in such cases.

When rough-surfaced implants are used, placement 2 mm subcrestally may help to avoid exposure of the implant to the oral cavity. When platform-switched implants are placed subcrestally, they can be connected to their abutments without causing crestal bone damage, as the abutment diameter is narrower than the implant diameter. Previous studies have demonstrated crestal bone stability when abutments were not removed from implants with the A-group design.[13,19,20] Beyond a doubt, more crestal bone resorption occurs if abutments are removed in order to take implant-level impressions.[6,21] However, the bone loss in the present study is not associated with the implant-abutment connection microgap,[22,23] as the final torque was used for both implant systems, and all implants were immobilized (splinted) together. More studies are needed to evaluate the best possible platform design for controlling crestal bone loss in order to extrapolate the results obtained from this study to the real life clinical scenarios.

Previous studies by Small and Tarnow[24] showed an association between the use of wide-body implants and complications such as crestal bone resorption and gingival recession. In the present study, however, peri-implant soft tissue around the two implant designs appeared to respond similarly in terms of gingival recession, and the soft-tissue changes did not appear to be associated with the crestal bone loss throughout the 2-year follow-up period. Further studies are needed to evaluate long-term soft and hard tissue stability around platform-switched implants with immediate loading and without abutment removal using implants with the same length and diameter.

CONCLUSION

Within the limitations of this study, platform switching was not always associated with control of crestal bone loss. In contrast, the implant platform diameter and shape, the implant-abutment connection, and the site preparation do appear to be significant parameters for controlling bone loss and possibly preventing peri-implant diseases.

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