Marginal Bone Loss Around One-Piece **Implants: A 10-Year Radiological and Clinical Follow-up Evaluation**

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s an alternative to conventional removable dentures, implant treatment has become one of the most accepted modalities to treat selected edentulous or partially edentulous patients.1

In the traditional 2-stage surgical protocol, which was established by Brånemark,² the implant is inserted into the bone after raising a soft tissue flap and it is submerged for 3 to 6 months. After healing, a second surgery is required to expose the implants for abutment connection and subsequent loading.^{3–5} The main concept of submerged healing is based on the fact that closure of the gingival wound minimizes the risk of infection and prevents apical downgrowth of epithelium due to compromised host site conditions.^{6–8}

Clinical evidence supports the notion that implants may osseointegrate

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Purpose: This study was conducted to investigate one-piece narrow-diameter implants installed in maxillary lateral and mandibular incisor sites using immediate nonfunctional loading.

Materials and Methods: In this 10-year clinical trial study, 42 narrow-diameter (3.0-mm)onepiece implants for 35 patients were inserted. Clinical and radiographic measurements were recorded in 10 years and analyzed statistically using t test.

Results: A total of 26 patients (20 females and 6 males) with 30 implants were available for the 10year follow-up. The 10-year implant survival rate was 100%. A statistically significant mean marginal bone loss was observed between 12 months and 10 years (0.18 \pm 0.29 mm). The mean pocket depth increase was statistically significant $(0.68 \pm 0.83 \text{ mm})$. No bleeding on probing was observed around 90% of the implants. Full-mouth plaque index was registered at 20% of the implants.

Conclusion: The results obtained in this analysis suggest that modest marginal bone loss was observed around the implants. *One-piece narrow-diameter* implants (Maximus 3.0; BioHorizons) can predictably restore missing maxillary lateral incisors and mandibular incisors in cases of careful patient selection. (Implant Dent 2019;28:237-243) Key Words: dental implants, imme-

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in a single stage in which they extend above the bone and through the soft tissues and oral cavity in a nonsubmerged implant healing protocol,9 without jeopardizing the healing process,^{10–12} provided that the primary stabilization is achieved and occlusal loads are controlled.^{3–6,9} There are several advantages to immediate nonfunctional loading including fewer surgical interventions, reduced surgical healing time, and less trauma to the patient.¹³ Furthermore, it is a cost- and time-benefit treatment option, since the prosthetic phase can start earlier, because there is

no wound healing period required for the second surgical procedure.¹⁴ It also allows the implants to be accessible for clinical monitoring during the osseointegration period.¹⁵ Moreover, immediate implant placement after extraction may preserve alveolar bone height and width, and also provide optimal soft tissue esthetics.13

Crestal bone loss may be assessed around different dental implant designs. A possible cause of that is the implant abutment junction, which allows for microbial colonization, increased inflammatory cell accumulation and

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related bone loss, and eventually implant loss.^{16–21}

One-piece implants were introduced as an anchorage unit and contiguous transmucosal prosthetic part manufactured as one unit and thus eliminate the structural weakness built in 2-piece implants.^{22,23} The seamless transition of implant to abutment is the advantage offered by one-piece implants, which also concludes many advantages such as strong unibody design, no split parts, single-stage surgery with either flap or flapless approach, and simple restorative techniques in conjunction with patient satisfaction.^{22,24–26} This design eliminates the need for placing abutments as a secondary procedure and avoids manipulation of the soft tissue interface after initial healing. The preparable abutment portion of the implant permits occlusal reduction and the creation of individualized contours to meet functional and esthetic needs without violating the soft tissue seal.²⁷ In addition, narrow-diameter one-piece implants provide satisfactory results in anterior parts of the jaw where the width of the edentulous crest might be insufficient and it may be considered to obviate the need for invasive reconstructive techniques such as grafting procedures.^{28–32}

The long-term reports on one-piece implants are rare.^{15,33} The aim of this study was to assess the marginal bone loss around one-piece dental implants after a 10-year period.

MATERIALS AND METHODS

This study evaluated 10-year clinical and radiographic outcomes of onepiece implants. The study protocol had been submitted to and approved by the local Ethical Committee of Mashhad University of Medical Sciences in 2006, and the procedures were performed at Department of Periodontology, Mashhad University, Iran (ethical clearance approval number: IR.MUMS.-REC.1384.111). Thirty-five healthy patients (20 women and 15 men; mean age 51 years) referred for rehabilitation with implant-supported prostheses in the mandible and/or the maxilla met the inclusion criteria and participated in the study. The presurgical evaluation included clinical and radiographic examinations with standardized periapical radiographs, orthopantograph, and tomography when needed. General health, ongoing medication, and smoking habits were registered. Patients who met the inclusion criteria were invited to participate in the study. Informed consent was provided by each subject after a thorough explanation of the risks, benefits, and nature of the study.

The inclusion criteria were as follows:

- 1. Need for implant treatment in the anterior region of maxilla or mandible due to loss of one tooth.
- 2. Residual bone with sufficient bone volume to house at least 12-mm long implant(s) with a diameter of 3 mm.

The patients were excluded if they were smokers; were subject to uncontrolled periodontal diseases; had parafunctional habits such as bruxism; had medically compromised conditions (uncontrolled diabetes, radiotherapy, and chemotherapy), and were unwilling to participate in this study or refused to provide informed consent.

The residual ridge width was measured by a digital caliber, and then the soft tissue width was determined by using an endodontic file after administrating anesthesia. The patients with 5- to 5.5-mm ridge width were included in the study. All patients were required to receive oral hygiene instructions before implant surgery. For all the cases, local anesthesia was used. After a midcrestal incision, a full-thickness mucoperiosteal flap was reflected. No releasing incisions were performed. Preparation and installation of implants was performed following the criteria according to the standard surgical procedures defined by the manufacturer. Forty-two one-piece Maximus implants (BioHorizons, Birmingham, AL) were placed. Implants were 3 mm in diameter and 12 mm in length and had resorbable blast-surface texture and square threads. They had flat apex and cylindrical body shape (Figs. 1 and 2). In the cases included in the current study, no implant sites required soft or hard tissue augmentation procedures. No thread exposure was seen after insertion and they were all placed nonsubmerged.

Suturing was accomplished with Silk 4-0 (Supa, Iran). The abutments were evaluated to be completely out of occlusion. The temporary crown made of immediate acryl was delivered to provide immediate nonfunctional loading. After surgery, anti-inflammatory amoxicillin 500 mg three times a day and metronidazole 250 mg three times a day were prescribed. In addition, chlorhexidine oral rinse (0.2%) was prescribed for 60 seconds for 3 times a day for 14 days. The sutures were removed 7 to 10 days after surgery.

After a healing time of 4 months for the lower jaw and 6 months for the upper jaw, permanent single crowns were fabricated and cemented. Professional tooth cleaning was performed at weeks 1, 2, 6, and 12 postoperatively. Parallel periapical radiographies were obtained after cementing temporary crowns and the distance of crest to upper level of fixture (implant shoulder) was measured in mesial and distal aspects. Further radiographies were taken at 3, 6, and 12 months and at 10 years. The distance between implant shoulder and first visible bone-toimplant contact was measured on the mesial and distal aspects. The values were calculated as the average of the obtained mesial and distal values. The known distance between 2 implant threads was used for calibration and the determination of the exact magnification of the images (Figs. 3 and 4).³⁴ The radiographic readings were performed by one experienced examiner who was neither involved in the surgical nor prosthetic treatment of the patients.

Moreover, periodontal indices were recorded at each session. Full-Mouth Plaque Score³⁵ and Full-Mouth Bleeding Score³⁶ were recorded. All the measurements were taken by the same periodontist using a periodontal probe (15 UNC/CP-11.5B Screening Color-Coded Probe; Hu Friedy, Chicago, IL). Implant success index (ISI) was used to measure success rate.³⁸ The implant survival criteria were determined by the following: no clinically detectable implant mobility, no pain or any subjective sensation, no recurrent periimplant infection, and no continuous radiolucency around the implant.³⁷



Fig. 1. BioHorizons one-piece 3.0 implant. The implant features resorbable blast texturing (RBT) surface and square threads. It is available in body lengths of 12, 15, and 18 mm. The abutment height is 8 mm.

Statistical Analysis

Implant success, marginal bone loss, and probing depth were selected as variables. Descriptive statistics (mean values and SDs) were used. Data were analyzed with SPSS software (version 22.0; IBM, SPSS Inc., Chicago, IL). Paired *t* test analysis was conducted to determine the overall significance between the day of surgery and each follow-up after surgery (at 1 and 10 years), and P < 0.05 was assumed to be statistically significant.

RESULTS

Twenty-six patients with 30 narrowdiameter one-piece implants were reassessed after 10 years in 2016. Patients



Fig. 2. The stated length is measured from the apex to the top of the small flare at the base of the abutment portion of the implant. Titanium alloy (Ti-6AI-4V) with resorbable blast texturing (RBT) surface.

were 32 to 63 years old with a mean age of 47 years. Nine implants were located in the lateral maxillary incisor area, 20 in the mandibular incisor area, and 1 in the maxillary canine region.

In 10 years, there was no implant failure, which represents a cumulative survival rate of 100%. ISI³⁸ was measured I, II, III, IV, and V in 8, 5, 2, 13, and 2 implants, respectively (Table 1). No serious adverse complications such as pain or swelling and abscess occurred. Mandibular incisor region needed connective tissue graft in 3 implants in 2 patients due to metallic shadow of implants and esthetic issues.

Distance of marginal bone level to the reference point (SD \pm mean) in radiographic analysis was measured as 0.90 ± 1.06 mm in 1-year follow-up and 0.75 ± 1.24 mm in 10 years; thus, the marginal bone loss was $0.29 \pm$



Fig. 3. Intraoral radiograph demonstrating the mesial and distal marginal bone level at the 10-year follow-up examination of onepiece implants. The values were calculated as the average of the obtained mesial and distal values. The known distance between the 2 implant threads was used for calibration and determination of the exact magnification of the images.

0.18 mm in 10 years after implant placement and the difference was statistically significant (P = 0.003).

The average pocket depth was 2.3 \pm 0.96 mm, which indicated an increase of 0.83 \pm 0.68 mm in 10 years and this difference was statistically significant (P = 0.0) (Table 2).

The full-mouth plaque index was below 20% in all patients because all patients attended regular follow-up courses, and patients with more than 20% of plaque index had been excluded.

Bleeding on probing was recorded in 10% of patients. Based on *t* test, the effect of aging, bone loss, and probing depth in different regions was not significant.

DISCUSSION

The current study measures 10year treatment outcomes of immediate nonfunctional loading of one-piece implants with a diameter of 3 mm. Implant



Fig. 4. By using a digital caliber, the space between the bone crest and the fixture was determined in the mesial and distal parts of the BioHorizons one-piece 3.0 implants in periapical radiographs. The known distance between the 2 implant threads was used for calibration and determination of the exact magnification of the images.

Table 1. One-Piece Implant Distribution Based on ISI								
No. of Patients	Clinical Findings	HL	SL	Score				
8	Clinically healthy	HL+	SL+, PPD ≤4 mm, BOP-	L				
5	Soft tissue inflammation	HL+	SL+, PPD ≤4 mm, BOP+	Ц				
2	Deep soft tissue pocket	HL+	SL+, PPD >4 mm, BOP+	LII				
13	Initiation of hard tissue breakdown	HL–, RBL ≤2 mm (≤20%)	SL+	IV				
2	Hard tissue breakdown plus	HL–, RBL ≤2 mm (≤20%)	SL-	V				
0	Notable hard tissue breakdown	HL–, RBL: 2–4 mm (<40%)	SL+	VI				
0	Notable hard tissue breakdown	HL–, RBL: 2–4 mm (<40%)	SL-	VII				
0 0	Severe bone loss Clinical failure	RBL ≥40% Clinical mobility	_	VIII IX				

If the periapical area of implants has a bone loss/radiolucent view (retrograde periimplantitis), it is identified by placing the letter R (eg ISI IR, ISI IIR, ISI IIR, etc).

 - indicates level apical to the reference line; +, tissue level located at or coronal to the reference line; BOP, bleeding on probing; HL, hard tissue level; PPD, probing pocket depth; RBL, radiographic bone loss detected using long cone parallel periapical technique; SL, soft tissue level.

survival rate of 100% was observed, and mean marginal bone loss was 0.29 \pm 0.18 mm.

The 10-year implant survival rate was comparable with conventional 2-

piece implants $(97\%)^{39-41}$ and it was also comparable with 97% for 5-year survival rate in the single-tooth implants.⁴²

The clinical outcomes of dental implants with reduced diameter have

been determined. In a study by Zarone et al,⁴³ survival rate of 93% was obtained in a follow-up period of 63 months. Conventional 2-part implants with reduced diameter were evaluated by Romeo et al and Cordaro et al in an average 23-month follow-up period,⁴⁴ and similar results were attained.^{41,45} However, further studies to achieve firm conclusions for the use of implants with small diameter in comparison with conventional implants are required.

Treatment outcomes of immediate loading have been previously investigated. Implant survival rates of 94% after 10.2 months, 89.1% after 1 year, 100% after 17 months, 75% after 2 years, and 98% after more than 2 years of loading have been reported. 13,41,46-48 In addition, only 53% of patients in the study by Hahn attended the final followup.¹³ The study by Siepenkothen⁴¹ had both retrospective basis and prospective basis. Finally, a variety of suprastructure and loading protocols were used. To conclude, the results of this study and those of the studies listed above are difficult to compare.

Periimplant marginal bone level is an important parameter to assess the long-term results of implant treatment modality and it is supposed to be much less around one-piece implants due to lack of microgap between the fixture and the abutment in these implants.¹¹ Numerous radiographic studies evaluating 2-piece implants have reported mean marginal bone of 0.9 to 1.6 mm in 1 year.^{6,49} The average annual bone loss of 0.1 mm is a common feature after first year of loading.^{6,49}

In a study by Van de Velde et al⁴⁸ on one-piece implants with immediate loading, only 3 of 12 implants were considered successful and bone loss was approximately 1.7 mm after 2 years of function. They ascribed it to the rough implant surface, which was not covered by bone and reserved as a niche to bacteria. In another study with 115 one-piece implants, a failure rate of 5.2% due to extensive marginal bone loss was reported by Östman et al.⁵⁰ The mean marginal bone loss around implants after 1 year was 2.1 mm.

Sennerby et al⁴⁷ conducted a retrospective study in which an average of 2.4 mm bone loss after a loading period **Table 2.** Mean, Range, and SD of Bone Loss and Probing Depth in 1 and 10 Years

 After Implant Insertion

	Minimum	Maximum	Mean	SD
1-year bone loss	0	3	1.06	0.9
10-year bone loss	0	3	1.24	0.75
1-year probing depth	1	2.5	1.6	0.33
10-year probing depth	0.5	4	2.3	0.96

of 10.2 months was reported, although 37.6% implants showed bone loss of more than 3 mm.

In a 3-year prospective study by Sato et al,⁵¹ immediate function resulted in a cumulative survival rate of 100% and mean bone level changes of 0.40 ± 1.46 , all in support of successful immediate function treatment of these implants. Some of the limitations of their study was unknown implant insertion techniques (flap or flapless surgery) and 2 different occlusal preparations.

Lauritano et al⁵² performed a 1-year retrospective study on one-piece implants placed in partially edentulous mandible. The implant survival rate was 80.5%. They did not mention implant insertion type and occlusal adjustment.

In a study by Ghaleh Golab et al,²⁴ 533 one-piece implants were evaluated and 98% survival rate was gained in a 12-month follow-up. The average bone loss was 0.59 ± 0.41 mm. Other recordings included 18% visible plaque and 17% bleeding in probing. The authors mentioned short follow-ups and using of panoramic radiographs as weakness of the study design.

In a cohort study,²² immediately loaded one-piece implants were compared to delayed loaded 2-piece implants in a 3-year period in radiographic aspect. Two-piece implants demonstrated less bone loss compared with one-piece implants in both jaws.

In the current study, the average loss of bone in a 10-year follow-up was elevated to 0.18 mm, which is in support of other studies reporting good bone stability.^{48,53–55} There is no consensus on comparison between results, which is probably as a result of using different baseline references among the studies.

In previous studies of conventional implants similar to ours, baseline was evaluated at the time of abutment placement, whereas in another study about one-piece implants, the baseline was assessed at the time of implant placement. As a result, primary bone remodeling was also included in the latter study.^{26,48,50}

There is a variety about marginal bone loss around dental implants, which is possibly due to various implant designs. Finne et al²³ explained a strong correlation between bone level at baseline and its level in 12 months. However, they expressed negative correlation between bone level at the time of implant placement and after 1 year in another study.²⁷

Along with contradictory results of these studies, the variation in depth of implant placement in different studies could explain the differences in bone loss. In addition, by positioning the crown margins more apically, there would be risks of cement remnants and further tissue inflammation and bone loss.⁵⁶ Finally, abutment preparation during prosthetic stages can lead to an increase in temperature in the periimplant bone, and implant micromovements can impair osseointegration⁵⁷; thus, properly designed prospective studies are needed to assess the factors mentioned above.

The results of this study could be affected by unknown factors such as operator skills, patient factors, and others that cause bias in the findings.

CONCLUSION

The results obtained in this 10-year analysis suggest that high 10-year implant survival rate and modest marginal bone loss were observed around one-piece narrow-diameter implants (Maximus 3.0; BioHorizons). These implants may predictably restore areas of limited space combined with immediate nonfunctional loading in case of careful patient selection.

DISCLOSURE

The authors claim to have no financial interest, either directly or indirectly, in the products or information listed in the article.

APPROVAL

The study protocol had been submitted to and approved by the local Ethical Committee of Mashhad University of Medical Sciences in 2006 and the procedures were performed at Department of Periodontology, Mashhad University, Iran (Ethical clearance approval number: IR.MUMS.REC.1384.111).

ROLES/CONTRIBUTIONS BY AUTHORS

M. Kadkhodazadeh: design of the work and interpretation of data. Y. Safi: revising the work and final approval. A. Moeintaghavi: acquisition of data. R. Amid: revising the work. M. T. Baghani: analysis of data and drafting the work. S. Shidfar: design of the work, interpretation of data, and drafting the work.

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