Immediate Occlusal Loading of Single Lower Molars Using Brånemark System® Wide Platform TiUnite™ Implants: A 5-Year Follow-Up Report of a Prospective Clinical Multicenter Study

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ABSTRACT

Introduction: Although not essential, molars hold their importance in terms of functional jaw stability, antagonist opposition, and support of facial height. Therefore, implant therapy is an attractive concept in molar areas. However, especially in the posterior mandible, the conventional two-stage surgical approach to implant therapy was reported to cause higher bone loss and/or higher implant failures with machined implants because of the peculiar anatomic and physiologic conditions of this area. As the TiUnite™ (Nobel Biocare AB, Göteborg, Sweden) surface results in faster bone healing than with machined-surface implants, it was hypothesized that this surface would also improve the performance of wide implants in posterior mandibles. Based on these assumptions, a protocol for immediately loaded implants for single molar replacement was developed.

Purpose: This paper aimed to report on the clinical and radiological performance of Brånemark System® TiUnite Wide Platform implants supporting single molars in the lower jaw, loaded immediately and followed for up to 5 years, and to assess if the benefit delivered by oxidized surfaces in the short run is also present after 5 years.

Materials and Methods: The study includes 33 consecutive patients treated between March 2001 and September 2003 and monitored until September 2008 in two private dental offices. A total of 40 Brånemark System TiUnite Wide Platform MK III implants were placed. All implants were provided with provisional crowns in full centric occlusion at the time of surgery. Patients were clinically and radiologically followed up for up to 5 years.

Results: Two implant failed so that the cumulative success rate at 5 years was 95.0%. The mean marginal bone remodeling ($n = 38$) expressed as mesial plus distal value averages was −1.17 mm (SD ± 0.90) at the 5-year time point.

Conclusion: Although limited by the number of patients treated in accordance with the protocol described, 5-year results encourage the use of immediately loaded single lower molars supported by Brånemark System Wide Platform TiUnite implants and further document the clinical advantages of titanium oxidized surfaces.

KEY WORDS: immediate load, occlusal load, single molar, smokers, TiUnite™, un-splinted, wide platform

INTRODUCTION

The two-stage surgical approach for implant placement was first documented by P.I Brånemark[1] in 1977 and today represents the most documented protocol for placing implants. Comparable results have been reported with the one-stage surgical procedure and transmucosal healing of implants.[2] From the early 1990s, when Schnitman and colleagues[3] first documented the reliability of the immediate loading of implants in the fully edentulous mandible, this one-stage surgical concept has been further documented and reported to be also feasible and predictable in cases of partial edentulism.[4] Predictable results are believed to depend on good initial implant stability, controlled loading conditions, and an osteoconductive implant surface.[5]

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When this clinical study started in 2001, few articles had reported on immediate loading of implants, and none had focused on immediate loading of wide implants-supporting single molar crowns in the lower jaw. The implants used and immediately loaded in this study were Brånemark System® TiUnite™ Wide Platform MK III implants (Nobel Biocare AB, Göteborg, Sweden), and the novelties, as well as by the one-stage surgery with immediate functional loading and full centric occlusal contacts, were represented by the wide diameter of the implants used and the anoxidized surface. The surface called TiUnite was demonstrated to be osseoconductive in previous histological reports.[6] At that start of the study, a number of unanswered issues were addressed. First, the clinical performance of wide-diameter implants with the macrodesign used had been reported to produce conflicting findings in the two-stage surgical approach.[7–9] In this respect, the anatomic and physiologic peculiarity of the posterior mandible was taken into account. In fact, despite the fact that a high initial stability is commonly reachable, factors like higher functional load, lower vascularity of dense bone combined with the wider surgical trauma associated with wide implants (especially in two-stage approach) play an important role in accounting for the lower success rate and/or higher bone loss described by several authors.[7,8] Second is the feasibility of the immediate loading protocol, which implied the theoretical advantage of reduced surgical trauma because of the one-stage surgical approach. The last is the contribution to bone healing and secondary stability given by the new surface.

The preliminary 1-year follow-up results previously published[10] were encouraging. None of the 50 implants inserted in 44 patients failed, and the overall mean marginal bone loss was 1.0 mm (SD ± 0.5) at 6 months and 1.3 mm (SD ± 0.6) at 1 year. Resonance frequency analysis showed high and consistent implant stability during follow-up, and no biomechanical or other problems associated with the wide platform TiUnite implants were found. Overall, the above results, although limited by being a short-term study, favored the immediate loading of Brånemark System TiUnite Wide Platform implants placed in the molar region of the lower jaw.

Because follow-up of these patients has continued and new patients were recruited, the aims of this paper were to report on the clinical and radiological performance of the implants over 5 years and to assess if the highly favorable risk/benefit ratio showed by oxidized surfaces in the short term might be confirmed after a period of 5 years.

MATERIALS AND METHODS

A total of 40 Brånemark System TiUnite Wide Platform MK III implants with lengths between 8.5 and 18 mm were placed in the first molar ($n = 32$) and second molar ($n = 8$) (Table 1). Twelve (30%) were distal abutments of the arch.

The 40 implants were placed in the mandibular molar areas of 33 patients, 16 (48%) male and 17 (52%) female who were enrolled and treated in consecutive order provided that they fulfilled the inclusion criteria and accepted the treatment. The patients had an average age of 52 years (range: 27–72 years) and were treated between March 2001 and September 2003. Monitoring continued until September 2008. Twenty-six were nonsmokers, while just three of the remaining seven patients smoked more than 10 cigarettes per day. The treatment was performed at two private dental offices in Bologna, Italy.

Nontreatment or traditional therapies (including fixed partial dentures on natural teeth or implants with two-stage protocol) were given as options, and the subjects that chose immediate implant loading gave their consent for this procedure. All periodontally involved teeth were treated before the implant treatment, and all patients were enrolled in a maintenance program.

Inclusion Criteria

The inclusion criteria included (1) surgical sites healed at least 4 months, (2) vertical bone height allowing for placement of implants at least 8.5 mm long, (3) implant to crown length ratio minimum of 1:1, and

TABLE 1 Implant Size in Relation to Location

	LR6	LR7	LL6	LL7	Total
WP					
8.5 mm	1 (1)	0	0	0	1 (1)
10 mm	6	2 (1)	6	2	16 (1)
11.5 mm	6	1	4	3	14
13 mm	2	0	6	0	8
18 mm	0	0	1	0	1
Total	15 (1)	3 (1)	17	5	40 (2)

Number of failures within parentheses.
LR = lower right; LL = lower left; WP = wide platform.

TABLE 2 Implants in Relation to Bone Quality and Quantity

	1	2	3	4	Total
A	1	16	8	0	25
B	2 (1)	5	5 (1)	1	13 (2)
C	0	0	2	0	2
D	0	0	0	0	0
E	0	0	0	0	0
Total	3 (1)	21	15 (1)	1	40 (2)

Number of failures within parentheses.

(4) minimum insertion torque of 35 Ncm before final seating of the implant neck in the bone.

Exclusion Criteria

Patients with uncontrolled diabetes, immune diseases, or severe bruxism were excluded.

Surgical Protocol

Antibiotic prophylaxis (Zimox®, 1 g, Pharmacia & Upjohn, Milan, Italy) was administered 1 hour before surgery and for 3 days after. The patients were given anti-inflammatory and analgesic medication (Synflex® Forte, 550 mg, Recordati, Milan, Italy). A sedative premedication (Valium®, Roche, Milan, Italy) was administered to patients who exhibited anxiety. Chlorhexidine digluconate 0.12% (Corsodyl®, SmithKline Beecham, Milan, Italy) mouth rinses and ice applications were made postoperatively.

Local anesthesia, articaine with 2% epinephrine (Ultracain®, Espe, Seefeld, Germany), was administered.

A midcrestal scalloped incision was performed. After reflection of the flap, a bone ridge evaluation was made, and the bone quality and quantity were recorded.[11] The distribution of implants in relation to bone quality and quantity is reported in Table 2. Countersinking was avoided for the implant to engage as much of the crestal bone as possible. The sites were slightly underprepared in full length to ensure high implant stability. A 3.85-mm drill diameter was used in type III bone quality, and a 4.3-mm drill diameter was used in type II. Table 3 shows the last drill used in drilling sequence with relation to the bone type.

A torque controller (Osseocare®, Nobel Biocare) was used for implant insertion. Its torque limit was 50 Ncm, and a manual wrench had to be employed in cases of incomplete seating of the implant.

Prosthetic Protocol

Titanium abutments (CeraOne or Titanium Temporary Cylinder, Nobel Biocare) were used. The prosthetic procedures were performed with open flaps. The aim of this technique was to utilize a surgical stent to provide restoration-driven implant placement[12] and a temporary composite crown with high performance. The following step-by-step procedure was executed to develop a fast and reliable solution:

A stone cast model of the arch was made. The edentulous space of the cast was filled with a commercial acrylic tooth and covered by a thermo-forming disk (Erkopress-Erkodent, Pfalzgrafenweiler, Germany). The disk was pressed over the area, resulting in a transparent stent, which included the acrylic temporary tooth. The acrylic tooth was removed, and the stent was coated along the inner surface with composite, forming a composite crown.

A hole was created in the direction of the long axis of the implant to fit the abutment and the prosthetic screw. After the abutment was fastened, the stent was repositioned and anchored to the adjacent teeth. The stent and the temporary crown were removed from the mouth, and the crown was separated from the stent. The crown was completed and relined. The flap was adapted to the emergence profile and sutured.

The temporary crowns were placed in full centric occlusal contact with a simplified occlusal design.[13] The occlusion was checked with articulating paper. Patients were asked to exercise normal mastication function and to avoid very hard food.

Six months post surgery, all implants received Procera® (Nobel Biocare) abutments with cemented or screw-retained Procera crowns. All crowns were coated

TABLE 3 Last Drill Used in Relation to Bone Type

		Bone type			
		1	2	3	4
WP	4.3 mm	2	13	2	—
5.0 mm	3.85 mm	—	6	12	1
	tapping	1	1	—	—
	$^1/_2$ length	—	1	—	—
	$^3/_4$ length	—	1	—	—

with low-fusing ceramic (Triceram, Dentaurum, Ispringen, Germany).

Follow-Up

Periapical radiographs were taken at surgery and 3, 6, 12, 24, 36, 48, and 60 months thereafter. Implant stability was recorded by resonance frequency analysis and reported as implant stability quotient (ISQ) values (Osstell®, Integration Diagnostics, Göteborg, Sweden) at surgery and at each month the first half-year. The prostheses were unscrewed, and the transducer was attached to the implant for each measurement.

Marginal Bone Level Determination

Marginal bone level was evaluated on the basis of the periapical radiographs taken perpendicular to the long axis of the implants where the implant platform and threads were clearly visible. Conventional film holders or manual forceps were used to place the films. The radiographs were repeated when quality was poor. An independent radiologist made the bone-height measurements. An image analysis program (NIH Scion Image Corporation 4.0.2, Frederick, MD, USA) was used to measure the distance between the implant platform and the most coronal level of the bone deemed to be in contact with the fixture surface. The first bone-to-implant contact at surgery is defined as the baseline. The marginal bone remodeling was calculated as the difference between the reading at the examination and the baseline value. Mesial and distal bone height measurements were averaged for each implant.

Success and Failure Criteria

In the 1-year report of the study, we adopted survival criteria. A surviving implant was defined as an implant that was in function, was stable (ISQ min 65), and did not exhibit any signs of pain or infection to the patient. In light of the lack of frequency analysis determinations after the 1-year follow-up, the success and survival criteria used in this 5-year report are a modification of the success criteria suggested by Van Steenberghe.[14]

According to the criteria given, a "successful implant" is an implant that

1. does not cause allergic, toxic, or gross infectious reactions either locally or systematically;
2. offers anchorage to a functional prosthesis;
3. does not show any signs of fracture or bending;
4. does not show any mobility when individually tested by tapping or rocking with a hand instrument; and
5. does not show any signs of radiolucency on an intraoral radiograph using a paralleling technique strictly perpendicular to the implant-bone interface.

A "surviving implant" is an implant that remains in the jaw and is stable, and occurs when the subject's treatment is functionally successful even though all the individual success criteria are not fulfilled.

A "successful prosthesis" is a prosthetic reconstruction that is stable and in good function.

A "failed implant" is an implant that has been removed, fractured beyond repair, or cannot be classified as a successful or surviving implant.

Withdrawals

No patients withdrew from the study.

RESULTS

Clinical Examination

The 5-year follow-up period was uneventful in all but two patients. All the other patients felt comfortable and were without pain and without any other complication. One implant failed 10 months after placement. It was an 8.5-mm implant placed in bone quantity/quality B1. As for the second failed implant (Figure 1–3), breakdown of ISQ value and crestal bone loss were detected at the 3-month visit. The crown was left in place, and the patient was advised to limit function. After some weeks

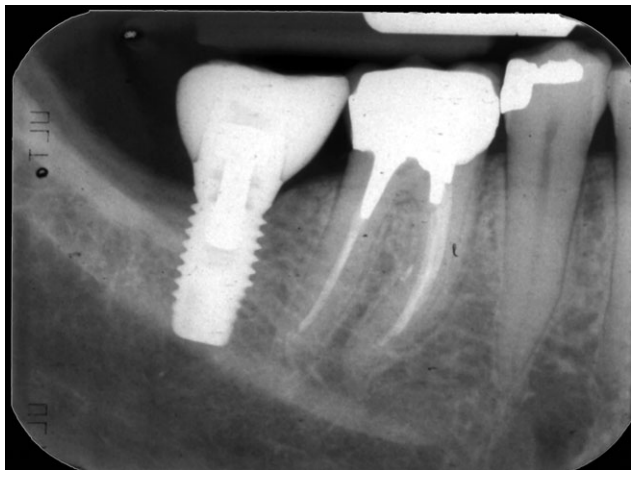

Figure 1 Baseline radiograph: bone crest up to platform level.

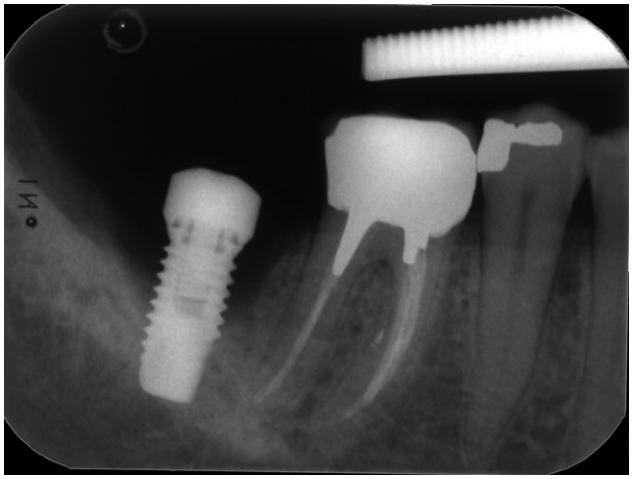

Figure 2 Six-month radiograph with apparent bone loss reaching the half implant length.

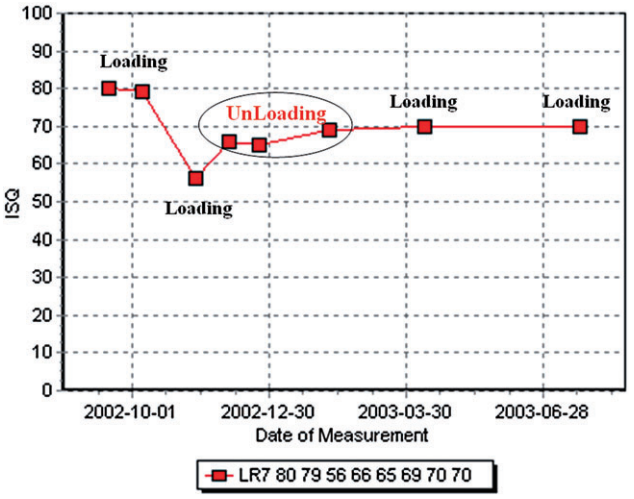

Figure 4 Implant stability quotient value evolution in the second failed implant.

of the recommended limited function, the ISQ value showed a slight increase, without any sign of bone gain. The crown was removed, and a healing abutment was screwed in. Three weeks later, neither the ISQ value nor the bone level was improved. It was determined at the final control visit that the patient was chewing with the implant. When asked, the patient admitted to chewing a gum habitually. She was told that her habit was causing a potential overloading condition, and stopped. After 1 year, the ISQ values were up to 70, and the bone level started to improve. Bone level improvement continued until there was a full recovery of the baseline bone level and remained stable for all the follow-up period, as witnessed by the radiograph control at 5 years (Figure 4).

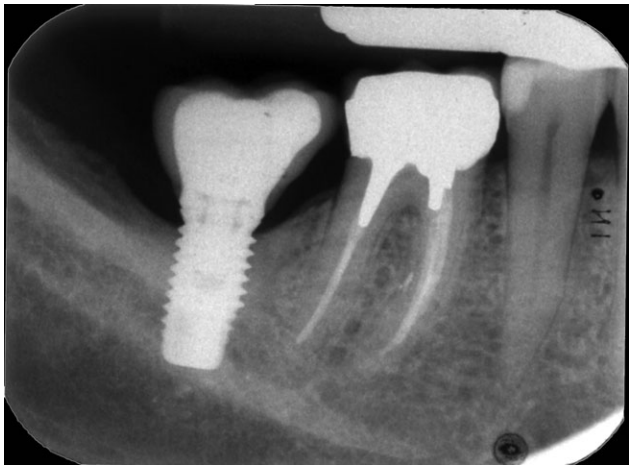

Figure 3 Five-year radiograph reveal reosseointegration at the first implant thread.

All the remaining implants were successful, resulting in a cumulative success rate at 5 years of 95.0% (Table 4).

Radiographic Analysis

Marginal bone levels presented as averages (mesial + distal/2) at different time points are shown in Table 5. Marginal bone remodeling results always expressed as averages (mesial + distal/2) are reported in Table 6, where it can be seen that the mean marginal bone loss after 5 years ($n = 38$) was 1.17 mm (SD ± 0.90).

Figure 5 depicts evolution of mean marginal bone remodeling at different time points.

Implant Stability Analysis

Except for two failed implants, resonance frequency analysis showed high initial stability, which was

TABLE 4 Life Table Analysis

Time period	Implants	Failed	WD	CSR%
Insertion to:				
3 months	40	0	0	100
3–6 months	40	1	0	97.4
6–12 months	39	1	0	95.0
12–24 months	38	0	0	95.0
24–36 months	38	0	0	95.0
36–48 months	38	0	0	95.0
48–60 months	38	0	0	95.0
60 months	38			

CSR = cumulative success rate; WD = withdrawals.

TABLE 5 Marginal Bone Levels

	Insert		3 mo		6 mo		12 mo		24 mo		36 mo		48 mo		60 mo	
Mean	0.26		0.91		0.91		0.98		0.99		1.30		1.28		1.43	
SD	0.33		0.43		0.38		0.42		0.41		0.60		1.02		0.86	
N	40		37		36		36		26		27		22		38	
	n	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%
>2.0	0	0	1	3	1	3	0	0	0	0	4	15	4	18	5	13
1.01–2.0	2	5	14	38	10	28	14	39	11	42	13	48	9	41	22	58
0.01–1.0	24	60	21	57	24	67	21	58	14	54	10	37	9	41	11	29
–0.9–0.0	14	35	1	3	1	3	1	3	1	4	0	0	0	0	0	0

Bone levels presented as averages (mesial + distal/2). Positive numbers indicate bone levels apical to the reference point.

maintained over time. The mean ISQ values were above 70 at baseline and kept stable for the entire observation period.

Complications

Aside from previously stated implant failures, no other biologic nor biomechanical complications occurred.

DISCUSSION

The 5-year follow-up results support the hypothesis that immediate loading of single unsplinted implants in the lower molar areas can be a successful and predictable procedure over a long term.

The findings from the current study confirm, in a longer-term perspective, the favorable results that were previously mentioned[10] and those subsequently published by other authors. In 2004, Cornelini and colleagues[15] reported on the immediate restoration of 30 unsplinted transmucosal International Team Implantology (ITI) solid implants with a sand-blasted, acid-etched surface (Straumann Institute, Waldenburg, Switzerland) in mandibular molar sites. In that study, only one implant was lost during the 1-year follow-up period, resulting in a 96.7% survival rate after 12 months. They concluded that, in the molar mandibular area with good implant primary stability, this protocol of immediate restoration can be safe and successful.

In 2007, Rao and Benzi[16] published a report on single, mandibular first-molar implants (Replace Select Tapered TiUnite) placed with flapless guided surgery and immediately loaded with premanufactured individualized abutments and crowns. All 51 tapered implants placed were stable and successful in function after 1 year, providing a 100% survival rate.

TABLE 6 Marginal Bone Remodeling

	Insert to 3 mo		Insert to 6 mo		Insert to 12 mo		Insert to 24 mo		Insert to 36 mo		Insert to 48 mo		Insert to 60 mo	
Mean	0.64		0.64		0.73		0.77		1.04		1.05		1.17	
SD	0.39		0.34		0.43		0.36		0.58		1.02		0.90	
N	37		36		36		26		27		22		38	
	n	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%
>2.0	0	0	0	0	0	0	0	0	1	4	3	14	3	8
1.01–2.0	7	19	5	14	10	28	6	23	13	48	8	36	19	50
0.01–1.0	30	81	29	81	24	67	19	73	12	44	9	41	14	37
–0.9 to 0.0	0	0	2	6	2	6	1	4	1	4	2	9	2	5

Bone remodeling data from all available radiographs. Bone remodeling presented as averages, (mesial + distal)/2. Reference points as above. Positive numbers indicate bone loss.

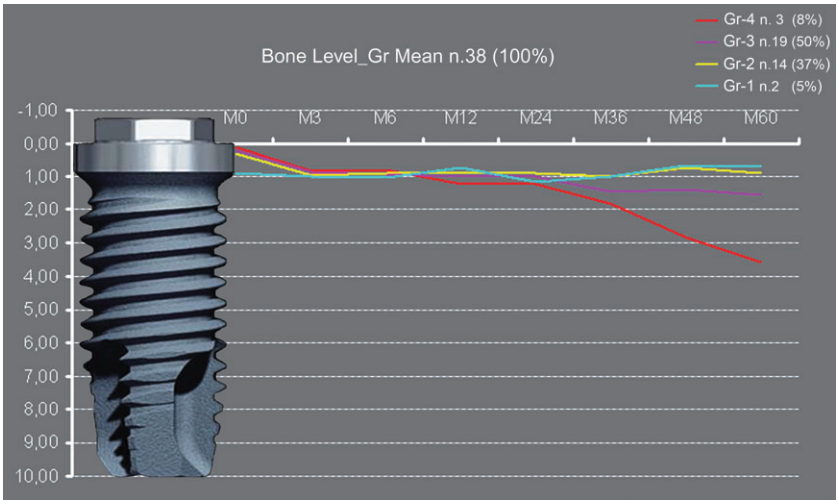

Figure 5 Mean marginal bone remodeling at different time points.

More recently, Schincaglia and colleagues.[17] published the findings from a randomized controlled study comparing immediate versus delayed loading of wide body implants (TiUnite Wide Platform MK III) supporting single-unit restorations in the molar area. No implants were lost in the delayed group (0/15), whereas one implant failed (1/15) in the immediate loading group after 1-year follow-up. In this study, the radiographic bone level change observed after 12 months of loading was statistically significantly less for immediately loaded implants than for implants with delayed loading.

Despite their differences for variables like patient selection criteria, type of one-stage surgical approach (flap elevation or flapless), type of immediate restorations delivered (screw-retained or cemented, standardized or individualized restorative components), all the above studies confirmed that immediate restorations of single implants in mandibular molar sites can be a suitable clinical option over a 1-year period.

As previously mentioned, the current 5-year follow-up results reinforce the predictability of the immediate loading procedure. All but two implants (2/40) were successful after the 5-year follow-up. Consistent with the success rate, the mean marginal bone change at 5 years ($n = 38$) was significantly stable (SD 1.17 ± 0.90), with just three implants showing a marginal bone change >2.0 mm. Nineteen implants had bone loss between 1.0 and 2.0 mm, 14 implants have bone loss between 0.01 and 1.0 mm, and the remaining 2 implants showed either a bone gain or no change. These findings are comparable to results from another clinical studies with immediately loaded TiUnite implants.[18]

In trying to interpret such long-term favorable results, various other factors need to be considered. For instance, the lesser surgical trauma associated with one-stage protocol may have contributed to preserve marginal bone; most implants were placed in both quantitatively and qualitatively favorable bone conditions, with subsequent use of implants of at least 10-mm length (only one implant was 8.5 mm long); the amount of keratinized mucosa that, although not included in the selection criteria, was generally good in the treated patients; avoidance of countersinking so that the implant would engage as much of the cortical bone as possible; slight underpreparation of the implant beds aimed at ensuring high initial stability; the high insertion torque reached by most implants: 34 out of 40 implants were placed with an insertion torque of ≥50 Ncm, 22 implants reached a torque of ≥70 Ncm; immediate temporization with screw-retained solutions to avoid cement penetration in the soft tissues; and, finally, the favorable role of the implant surface during the healing phase and the 5-year observation period.

CONCLUSION

Within the limitations of the present study, the findings document the safety and predictability of the immediate loading of single lower-molar implants over a 5-year period. Moreover, these results reinforce the conclusions from several other studies on the immediate-loading

approach. As long as the initial mechanical stability of the implant is high and the implant surface is optimal from a healing perspective, immediate loading per se does not appear to create a challenge to either short- or long-term implant survival.

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