Immediate Occlusal Loading of Brånemark System® TiUnite™ Implants Placed Predominantly in Soft Bone: 4-Year Results of a Prospective Clinical Study

In memoriam Professor Peter Schärer, MS

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ABSTRACT

Background: Immediate occlusal implant loading has been documented as a viable treatment option for various indications. However, most of the available studies reported on the short-term outcome of this treatment modality.

Purpose: The purpose of this prospective clinical study was to document, on a long-term basis, the outcome of immediate occlusally loaded Brånemark System® Mk IV TiUnite™ (Nobel Biocare AB, Göteborg, Sweden) implants placed to support fixed reconstructions in various regions of the jaws.

Materials and Methods: Thirty-eight patients received a total of 51 fixed prosthetic reconstructions, all of which were connected on the day of implant insertion. Twenty restorations replaced single teeth, 30 were fixed partial dentures, and 1 was a full-arch fixed lower restoration. These prostheses were supported by 102 Brånemark System Mk IV TiUnite implants (38 maxillary and 64 mandibular), the majority of which were placed in posterior regions (88%) and mainly in soft bone (76%). Resonance frequency measurements and marginal periimplant soft tissue evaluations were conducted during the course of the study. Furthermore, radiographic examinations were performed at the time of prosthesis delivery and at the 1- and 6-month and 1-, 2-, 3-, and 4-year follow-up visits. This report summarizes the results after 4 years of loading.

Results: Three maxillary implants were removed, although stable, in one patient at the 8-week follow-up owing to postoperative infection in the adjacent guided bone regeneration area. No implants were lost further on. This resulted in a cumulative implant success rate of 97.1% after 4 years of prosthetic loading. The mean marginal bone remodeling after 4 years of function was 1.3 ± SD 0.9 mm. At 4 years, absence of marginal plaque and bleeding on probing was reported for 87% and 69% of the sites, respectively, thereby remaining unchanged since the 1-year follow-up. On average, the interproximal soft tissue fill increased for both mesial and distal papillae from scores of 1.4 ± 1.1 and 1.0 ± 1.1, respectively, at the preoperative assessment to 2.0 ± 0.8 and 1.7 ± 0.8, respectively, at the 4-year assessment.

Conclusion: The applied immediate loading protocol, in combination with a slightly tapered implant design and a modified implant surface texture, was shown to be a successful treatment alternative in regions exhibiting soft bone.

KEY WORDS: Brånemark dental implants, immediate loading, marginal bone level, oxidized surface, papilla index, resonance frequency analysis

Immediate occlusal loading of osseointegrating implants has been demonstrated to be a viable treatment option for replacing missing teeth in dense bone areas.[1–3] Although some reports indicate that immediate loading in soft bone may be precarious,[1,4] recent studies have demonstrated encouraging results for immediately loaded, nonsplinted[5] and splinted implants[6,7] predominantly placed in regions in which bone quality is nonoptimal. These results indicate that reduced bone quality per se does not have to be a contraindication to immediate loading provided an adequate surgical and prosthetic protocol is followed.

Clinical success for immediately loaded implants relies on the achievement of primary implant stability

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to accomplish secondary stability. Based on experimental studies it has been suggested that microtextured implant surfaces may contribute to the maintenance of primary stability and to reduce the time necessary to achieve secondary stability.[8–11] One such mictotextured surface (TiUnite™, Nobel Biocare AB, Göteborg, Sweden) is produced by anodic oxidation of the titanium, resulting in increased thickness of the native oxide layer and a porous surface topography. [12] Moreover, such implant surfaces may have a pronounced beneficial impact in areas of soft bone quality in which the viability of immediate loading protocols has been questioned. The feasibility of this hypothesis has been indicated in a prospective study evaluating immediately loaded implants in the posterior parts of the mandible in which Rocci and colleagues reported 10% higher success rate for implants with the TiUnite surface compared with machined-surfaced implants.[6]

Since the introduction of implants with microtextured surfaces, however, some authors have expressed their concerns in instances where part of the roughened surface becomes exposed to the soft tissue or to the oral cavity. Consequently, these surfaces may induce increased plaque accumulation,[13] resulting in inflammation of the surrounding soft tissues.[14] Thus, the possible clinical relevance of rough implant surfaces in contact with the soft tissue or exposed to the oral cavity needs to be further investigated.

Up to now, most reports on immediately loaded implants were based on short-term results. Furthermore, the majority of the available literature is limited to implant survival or implant success. Therefore, the present study intends to focus on the long-term clinical outcome with regard to implant stability, marginal bone and soft tissue reaction. Because the marginal bone is the base for the supracrestal soft tissue (ie, the periimplant biologic width), one prerequisite to maintaining soft tissue stability and thereby ensuring long-term aesthetics is that marginal bone resorption is kept to a minimum. Also, the maintenance of adequate oral hygiene to preserve periimplant mucosal tissues from inflammation is decisive for long-term success.

The aim of this report is to present the 4-year follow-up results of immediate occlusally loaded TiUnite Mk IV implants with regard to implant success and marginal hard and soft tissue reactions.

MATERIALS AND METHODS

Study Protocol

The inclusion criteria for patients, the surgical and prosthetic protocol, and the follow-up regimen during the first year of implant function for this prospective study have been described.[15]

The study population of this open prospective study consisted of 38 patients (21 males and 17 females) with a mean age of 51 years (range 19–77 years). Twelve of the patients were smokers (32%).

All implants were prosthetically loaded the day of implant placement with a provisional reconstruction. A metal- or fiber-reinforced framework and acrylic veneering were used for fixed partial provisional prosthetic reconstructions, whereas single-tooth reconstructions consisted of a provisional acrylic crown. Full contact in centric occlusion was ensured for all prosthetic reconstructions, and excursive contacts were avoided whenever possible. Moreover, cantilevers and pontics were avoided in all reconstructions.

Clinical and Radiographic Follow-Up

The clinical performance of treatment was reviewed during follow-up examinations conducted on a weekly basis during the first month. Thereafter, the patients were recalled 2, 3, and 6 months and 1, 2, 3, and 4 years after implant installation. The individual implant stability was assessed by means of resonance frequency analysis (RFA) (Osstell™, Integration Diagnostics AB, Sävedalen, Sweden) at implant insertion, prosthesis delivery, and all but the 2-week follow-up visit. In particular, the RFA technique allows for chair side measurements where the individual implant stability is expressed in Implant Stability Quotient (ISQ) units. A value between 1 and 100 is obtained where 1 is the lowest and 100 the highest degree of stability.

Intraoral radiographic examinations were performed at the time of prosthesis delivery (baseline), at 1 and 6 months, and at 1, 2, 3, and 4 years postoperatively. The radiographs were taken perpendicular to the long axis of the implants with a long-cone parallel technique. An evaluation of the marginal bone height and its change over time was performed at the mesial and distal surfaces of the implants. The reference point for the reading was the implant-abutment interface.

To evaluate the status of the periimplant mucosa, plaque accumulation and occurrence of bleeding on

probing were assessed buccally and lingually 4 weeks postoperatively and at all of the subsequent follow-up visits. Furthermore, an assessment of the interproximal soft tissue contours adjacent to the planned implant site was made preoperatively and annually following implant insertion using the papilla index presented by Jemt.[16] Briefly, this index consists of five scores, where 0 denotes the absence of a papilla, 1 denotes the presence of less than half of a papilla, 2 denotes the presence of at least half of a papilla but that does not fill out to the contact point between the crowns, 3 denotes a papilla that fills the entire proximal space and is in good harmony with the adjacent papillae, and 4 denotes a hyperplastic papilla that covers too much of the implant restoration and/or the adjacent tooth. Moreover, all biologic and technical adverse events related to the treatment that occurred during the course of the study were recorded.

Implant Success and Failure Criteria

Implants had to meet the following criteria, which are a modification of the proposal by Albrektsson and colleagues,[17] to be regarded as successful: (1) no radiolucent zone around the implant; (2) the implant is acting as an anchor for the functional prosthesis; (3) confirmed individual implant stability; and (4) no suppuration, pain, or ongoing pathologic processes. All implants that failed to fulfill these success criteria were regarded as failures.

Statistical Methods

A conventional life table analysis was used to calculate the cumulative implant success rate. Test for trend in contingency tables (Mantel-Haenszel chi-square), based on the patient as a unit, was used to analyze the change in papillae index during follow-up.

RESULTS

In this study, 102 implants (38 maxillary and 64 mandibular) were placed and immediately loaded. Seventy-one implants were placed in healed sites (more than 6 months postextraction), 23 were placed immediately after extraction, and 8 were placed 1 to 6 months postextraction. Implant distribution by bone quality and quantity is illustrated in Table 1. All planned implants could be adequately positioned according to the prosthetic needs, and no implants were excluded from the study owing to a lack of primary stability. At 64 implant sites, guided bone regeneration (GBR) was performed owing to buccal dehiscences (32 sites), infrabony defects (15 sites), fenestrations (5 sites), or a combination of these bone defect configurations (12 sites). Owing to these bone defects, the initially uncovered implant surface area was intraoperatively estimated to 5 to 30% of the total implant surface area in 54 sites, to 30 to 50% in 7 sites, and to more than 50% of uncovered implant surface in 3 sites.

TABLE 1 Implant Distribution According to Bone Quality and Quantity

Bone Quantity	Bone Quality*				Total Number of Implants
	1	2	3	4	
A	0	0	5	0	5
B	0	16	36	22	74
C	0	7	10 (3)	5	22 (3)
D	0	1	0	0	1
E	0	0	0	0	0
Total	0	24	51 (3)	27	102 (3)

*Number of failed implants is presented within parentheses.

Altogether, 51 prosthetic reconstructions were connected to the 102 implants on the day of implant insertion. Twenty-three of the reconstructions exhibited group function, and 28 reconstructions displayed canine guidance. Table 2 shows the distribution of implants and reconstructions placed in the maxilla and the mandible according to the type of indication.

The mean follow-up time for all implants was 49 months (range 42–58 months), including 34 patients who passed the 4-year follow-up. Two patients were withdrawn from the study. One patient (including four implants) moved abroad after the first year of follow-up, and one patient (including five implants) died and could not be followed after the 2-year examination.

Three implants were recorded as failures during the observation period, rendering an implant survival rate of 97.1% after the 4-year follow-up, as indicated by the life table analysis shown in Table 3. These three failed implants (all in one patient) were lost 8 weeks postoperatively following flap dehiscence with suppuration in a GBR area around a three-unit reconstruction supported by three implants; despite a strict regimen of systemic antibiotics and local measurement, the three implants had to be removed together with the grafting material.

The results from the radiographic evaluation of the marginal bone level and its change over time are presented in Figure 1 and Table 4. Four years after implant

TABLE 2 Number of Reconstructions and Implants per Indication

Indication	Maxilla			Mandible		
	Single Anterior*	Single Posterior†	Partial Posterior†	Single Posterior†	Partial Posterior†	Complete
Reconstructions	5	7	10	8	20	1
Implants	5	7	26	8	51	5
Failures	0	0	3	0	0	0

*Corresponds to tooth positions 13 to 23 and 33 to 43.
†Corresponds to tooth positions 14 to 18, 24 to 28, 34 to 38, and 44 to 48.

TABLE 3 Overall Cumulative Success Rate

Placement	Number of Implants				Clinical Success Rate, %
	Implants	Failed	Withdrawn	Not Due Yet	
–4 wk	102	0	0	0	100.0
4 wk–2 mo	102	3	0	0	97.1
2–6 mo	99	0	0	0	97.1
6 mo–1 yr	99	0	0	0	97.1
1–2 yr	99	0	4	0	97.1
2–3 yr	95	0	5	0	97.1
3–4 yr	90	0	0	10	97.1
4 yr	80	0	0	0	0

insertion (loading), the mean change in marginal bone level per implant position was 1.3 ± 0.9 mm; no significant difference in the marginal bone resorption between the mesial and distal aspects of the implants could be observed (1.3 ± 0.9 and 1.3 ± 10, respectively). Furthermore, no individual implant had more than 4.3 mm bone remodeling during the 4-year

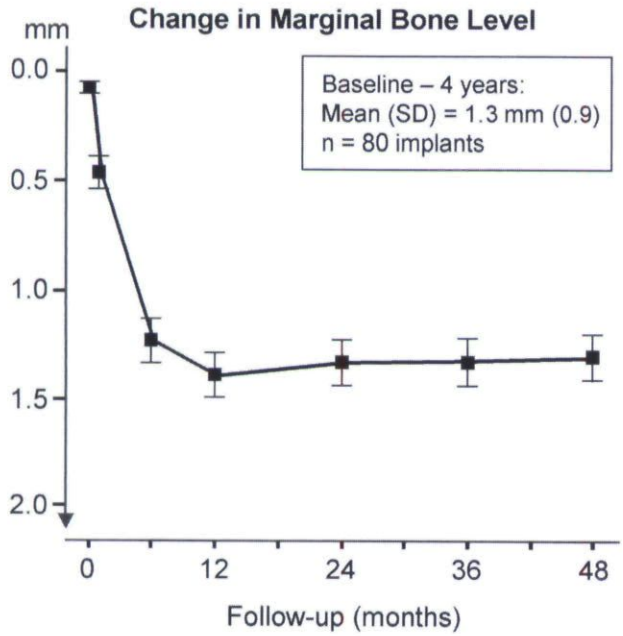

Figure 1 Change in marginal bone level (mean value) plotted over time for implants that have passed the 4-year follow-up. Error bars = ± 1 standard error.

TABLE 4 Marginal Bone Remodeling between Placement (Loading) and 1-Year Follow-Up and between 1- and 4-Year Follow-Up

Change in Marginal Bone Level, mm	Number of Implants		
	Distal	Mesial	Per Position
Between placement and 1-yr follow-up			
< 0	1	0	0
0	15	18	12
0.1–1.0	28	33	37
1.1–2.0	35	33	33
2.1–3.0	14	11	15
> 3.0	3	3	1
Mean value, mm	1.2	1.1	1.2
SD, mm	0.9	0.9	0.9
Between 1-yr and 4-yr follow-up			
< 0	40	38	44
0	10	12	8
0.1–1.0	24	21	21
1.1–2.0	3	5	4
2.1–3.0	0	2	1
> 3.0	1	1	1
Mean value, mm	–0.1	0.01	–0.04
SD, mm	0.9	0.9	0.8

follow-up period. As indicated in Figure 1 and Table 4, most of the marginal bone resorption took place during the first year of loading, whereas there was no change in marginal bone level between the 1- and 4-year follow-up visits (–0.04 ± 0.8 mm).

The RFA revealed an initial decrease in implant stability in terms of the mean value of the implant stability quotient (ISQ) during the first 4 weeks after insertion (from mean ISQ 68 ± 7 to mean ISQ 61 ± 8), followed by an increase by 7 units up to the 1-year follow-up visit (mean ISQ 67 ± 7). Subsequent RFA measurements at the 2-, 3-, and 4-year follow-up examinations indicated a stable mean ISQ value of 66 ± 7, which is comparable to the mean value recorded at implant insertion (Figure 2).

Plaque and bleeding data collected throughout the study are compiled in Tables 5 and 6. The absence of visible plaque was slightly more frequent at the buccal aspect of the implant surface than at the lingual aspect but remained fairly constant throughout the observation period. On average, 77% of the individuals were negative for plaque buccally and 66% lingually during the 4-year follow-up period. A similar pattern was observed in terms of bleeding on probing; only small fluctuations were recorded around the average values of 76% (buccally) and 64% (lingually) reporting absence of bleeding on probing.

The interproximal soft tissue evaluation according to Jemt's papilla index[16] did not, at any follow-up time, show an index score of 4. The average of the interproximal soft tissue fill increased for both mesial and distal papillae from 1.4 ± 1.1 and 1.0 ± 1.1, respectively, at the preoperative assessment (n = 92 and 91) to 2.0 ± 0.8 and 1.7 ± 0.8, respectively, at the 4-year assessment (n = 89). This increase was statistically significantly different for both the mesial (p = .009) and the distal papillae (p = .001). The major increase in papilla volume occurred during the first 2 years, after which the volume remained stable. The development of the papilla index during the follow-up period was similar for the distal and mesial papillae; however, the distal papilla started and ended at a lower score. Figure 3 illustrates the development of the mesial papillae during the course of the study and of all implants, as well as of different subgroups (implants in extraction sockets, implants in healed sites, implants next to teeth, implants next to an implant).

Twenty-eight nonserious events have been reported during the 4-year observation period, including a partial flap necrosis or prolonged pain during the first weeks of healing, recementation of loosened provisional crowns, chipping or fracture of acrylic veneering at provisional crowns, abutment screw mobility, and pronounced probing depth. In detail, the flap necrosis

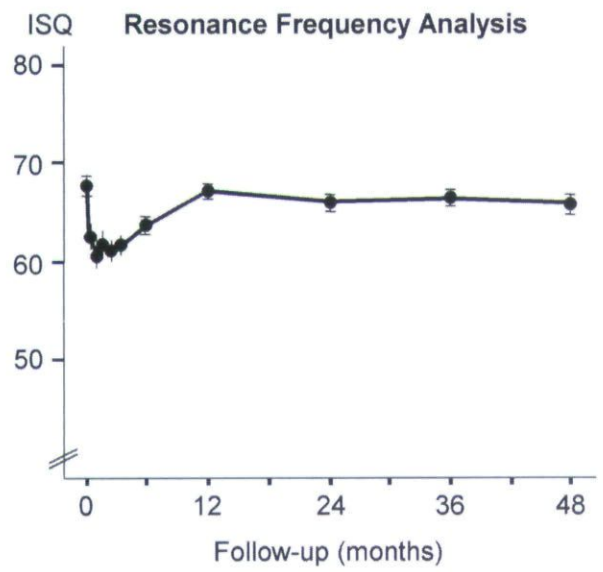

Figure 2 Resonance frequency analysis (mean value) plotted over time. Error bars = ± 1 standard error. ISQ = implant stability quotient.

TABLE 5 Absence of Visible Plaque, %

	Buccal	Lingual
4 wk (n = 92)	75	77
6 wk (n = 92)	65	70
2 mo (n = 96)	73	70
3 mo (n = 95)	69	60
6 mo (n = 97)	74	65
1 yr (n = 99)	73	43
2 yr (n = 92)	86	61
3 yr (n = 90)	91	71
4 yr (n = 80)	90	84

TABLE 6 Absence of Bleeding on Probing, %

	Buccal	Lingual
4 wks (n = 67)	79	67
6 wk (n = 66)	71	76
2 mo (n = 79)	73	73
3 mo (n = 76)	66	63
6 mo (n = 82)	78	71
1 yr (n = 92)	70	42
2 yr (n = 92)	83	57
3 yr (n = 90)	87	68
4 yr (n = 80)	74	64

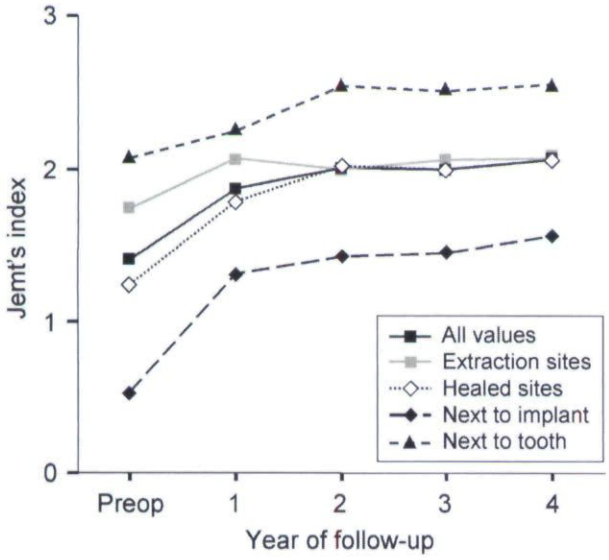

Figure 3 Illustration of the development of the Jemt index[16] at the mesial papillae during the course of the study.

resulted in rather extensive marginal bone resorption around the three implants concerned, thereby exposing coronal parts of the microtextured surface to the oral cavity. However, after the treatment of the necrosis, the bone level stabilized and soft tissue healing was combined with a slight coronal creeping.

DISCUSSION

In the present study, 102 implants (38 maxillary and 64 mandibular) were placed to immediately support 51 prosthetic reconstructions. Owing to a postoperative infection, three implants were recorded as early failures. Thereafter, no further implant was lost during the course of the study, rendering an implant success rate of 97.1% after a 4-year follow-up. Even though the majority of all implants were placed in posterior regions and in soft bone conditions, the present study demonstrates that implants used as an immediate anchorage for prosthetic reconstructions may integrate with the same high predictability as documented for the traditional staged loading protocol.[18,19]

With regard to implant stability as evaluated using RFA, the results indicate that an initial decrease in stability is followed by a re-increase in ISQ on average between the 4- and 6-week follow-up (see Figure 2). In an earlier study on immediate occlusal loading using machined-surfaced Brånemark System Mk IV implants, it has been reported that a re-increase in stability, as measured with the RFA technique, was, on average, not detectable before the 6-month follow-up.[20] Furthermore, a drop in ISQ values (ie, loss of implant stability) during the early healing period was more pronounced for the group of machined implants compared with the present evaluation on oxidized implants. Moreover, when immediately loading the machined implants, the authors were confronted with a high failure rate of 17.3% during the first year of function.[1] Based on the current results, it can be concluded that the roughened-surface implants, as selected for this immediate occlusal implant loading protocol, reduced the risk of implant failure.

With regard to marginal bone reaction, it has been documented in previous studies that immediate implant loading is also related to marginal bone remodeling, which is equal to or slightly reduced than bone level changes documented around delayed loaded implants.[21–23] In addition, following the first year of function, marginal bone levels at implants placed within immediate loading protocols have been documented to be as stable over time as at delayed loaded implants.[24–28] In the present study, initial marginal bone remodeling leveled off during the first year of function, resulting in a mean change of 1.2 ± 0.8 mm (n = 96) at the 12-month evaluation, after which basically no further change occurred. In an earlier evaluation using the same immediate loading protocol but machined-surfaced implants, the mean marginal bone level assessed at the 1-year follow-up was 1.5 ± 1 mm (n = 82).[1] This difference in marginal bone remodeling indicates that an oxidized surface, as used in the present study, reduces the marginal bone remodeling compared with a smooth, machined surface. Furthermore, the mean marginal bone level within the current study remained stable up to 4 years, thereby matching the criteria for long-term marginal tissue stability as proposed by Albrektsson and colleagues.[29] Furthermore, the mean marginal bone remodeling of 1.2 mm, which occurred during the first year of loading, resulted in an average exposure of 0.8 mm of the coronal TiUnite surface to the supracrestal connective tissue compartment. Because there was no further change in marginal bone level between the 1- and the 4-year measurement, it can be concluded that the microtextured surface per se did not negatively affect the marginal tissue response.

The recorded presence of visible plaque was stable during the course of this study. The average was slightly higher lingually than buccally. In addition, these values correspond well to the figures for bleeding on probing. Besides stable marginal bone levels, these findings further

indicate that despite minor exposure of the rough implant surface to the supracrestal connective tissue compartment, the clinical measurements were not influenced.

Available reports on immediate loading of dental implants have mainly focused on implant success, whereas the aesthetic outcome has, in general, not been mentioned. The aesthetic outcome is a complex issue to evaluate because it depends on several parameters, such as the color and shape of the prosthetic restoration and the color and shape of the surrounding soft tissue, including the papillae, which, in turn, depend on the periimplant bone situation. One of a few articles on immediate implant loading and aesthetic outcome reported on the periimplant tissue response after 1 year of immediate loading using the plaque index, papilla level changes, patient satisfaction, and changes in the midfacial gingival level.[30] The authors reported an average of 0.5 mm of midfacial soft tissue recession and patient satisfaction of 9.9 of 10. In the present study, the Jemt index[16] was used in addition to the plaque and bleeding indices, thereby also evaluating a combination of volume and height of papillae. The general finding was that the papillae reestablished continuously during the first 2 years, after which they remained stable. This shows that the maturation and formation of the soft tissue occurred during a rather long period of time and that a papilla actually was formed even though it did not reach the optimal shape in all cases. This development of the papilla over time corresponds to the findings reported earlier.[31,32] In these studies, single-tooth restorations were placed following a two-stage technique and evaluated during a 2-year period after loading. A slightly higher mean papilla index score was reported in these studies, both preoperatively and at the 2-year follow-up, compared with the present evaluation. This is probably due to the circumstance that only single-tooth restorations were evaluated, whereas, in the present study, the majority were partial restorations. It is obvious from Figure 3 that papillae facing an implant on both sides start and end at a lower score compared with those facing a tooth on one side. The fact that an immediate implant restoration was applied in the present study did not seem to influence the development of the papillae. In particular, the mean index score values reported by Jemt (2.6 ± 0.6 mesially, 2.1 ± 0.6 distally) when using the two-stage technique correspond well to the mean index score values found in the present study for papillae facing a tooth (2.5 ± 0.6 mesially, 2.1 ± 0.8 distally).[31]

CONCLUSION

It was concluded that the applied immediate loading protocol, in combination with a slightly tapered implant design and a modified implant surface texture, was shown to be a successful treatment alternative in regions exhibiting soft bone.

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