Clinical Outcome and Bone Preservation of Single TiUnite™ Implants Installed with Flapless or Flap Surgery

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ABSTRACT

Background: Flapless, free-handed implant surgery offers advantages for patient comfort, but studies on long-term clinical success based on marginal bone loss are scarce.

Aim: The aim of this study was to compare single implants installed with a flap (F) or flapless (FL) surgery with respect to survival and marginal bone preservation after at least 3 years.

Materials and Methods: Fifty-three TiUnite™ Brånemark implants, installed in 49 patients (27 females; 22 males; mean age 53 years) were examined. Then, 25 F and 28 FL were delayed loaded; bone level from the abutment-implant level was measured on intraoral radiographs. From 44 (21 F, 23 FL), 31 (18F, 13FL), and 36 (18 F, 18 FL) implants, radiographs were available at baseline and after 1 and 3 years of function.

Results: The overall survival rate was 100% and the overall mean bone loss after an average of 38 months was 1.35 mm (SD 0.91; range 0–3.7). Both F and FL showed increasing bone loss during the first year with a higher bone loss for FL than for F sites ($p < .01$). Afterward, no further bone loss occurred and both groups were statistically equal ($p > .7$). On individual implant level, nearly 80% in both F and FL were considered a success showing bone loss between 1.5 and 1.9 mm.

Conclusions: Single implants yield an excellent prognosis with stable bone levels irrespective of the surgical technique, and free-handed flapless surgery is a viable alternative to more extensively planned guided surgery. Proper case selection and clinical experience are considered prerequisites for a predictable treatment outcome.

KEY WORDS: bone remodeling, flapless surgery, one-stage surgery, single implant, TiUnite surface

Dental implants for single-tooth replacements have shown to be highly predictable and clinically successful. Above 5 years survival rates reported in systematic reviews[1] are in the range of 95.6%. The original Brånemark protocol using turned titanium surface implants advocated the use of two-stage procedures requiring a waiting time after implant surgery whereby the implant was completely buried into the alveolar bone prior to a second abutment surgery. This imposed a lengthy treatment time, two surgical interventions, and consequently more risk for patient complaints and discomfort. With the introduction of moderately rough or bioactive implant surfaces, early or immediate loading has been advocated and shown similar survival rates as the delayed loading protocol when certain clinical criteria are taken into account.[2] A recent 4-year study has shown comparable results for single TiUnite™ (Nobel Biocare AB, Zurich, Switzerland) surface implants in terms of implant survival and crestal bone remodeling following early and delayed loading.[3] Even immediate

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nonfunctional loading of single TiUnite implants inserted into extraction sockets seems predictable at least on a short-term basis in well-selected patients.[4] In line with the evolution toward more minimal invasive procedures in general medicine, this has also been introduced in implant dentistry. In a flapless procedure, a dental implant is installed through the mucosal tissues without reflecting a flap. This approach has advantages for soft tissue healing and patient comfort because it is less traumatic and less time consuming compared to an open-flap approach. With less postoperative bleeding and swelling, it offers the possibility to adjust the provisional appliance (often a one-tooth flipper or resin-bonded tooth) immediately. A disadvantage of flapless surgery is that the true topography of the underlying available bone cannot be observed because the mucogingival tissues are not raised. This may increase the risk for unwanted perforations which in its turn could lead to esthetical problems or implant losses. A thick epithelium and mucosa may hide a narrow ridge and, therefore, bone sounding should be performed. The risk for perforations has been discussed in a preclinical model study whereby specialists, dentists, and undergraduate students were asked to perform a flapless free-handed surgery on models. It was obvious that very often perforations were seen because of malpositioning of the drills.[5] These drawbacks may be overcome with the use of guided surgery based on computed tomography scan analysis. On the other hand, this increases the costs of the treatment significantly.

Becker and colleagues[6] reported that flapless implant surgery in extraction sockets resulted in 98.7% cumulative implant success after 2 years. The same group compared both surgical techniques in a dog study with split mouth design to examine whether introduction of soft tissue in the recipient sites hampered osseointegration.[7] Implant survival stability changes in time; marginal bone level and histomorphometric composition of the tissues were not different. Implants placed after punching the mucosal tissues with a drill, without reflection of mucoperiosteal flaps and with less effective irrigation during implant placement, showed the same degree of osseointegration without unwanted reactions. In a retrospective study reporting on flapless surgery, the up to 10 years survival of 770 implants installed in 359 patients was 93.6%. Implants were installed in mandibles and maxillae, and the success rate was influenced by the surgeons learning curve.[8] Rocci and colleagues[9] installed 97 implants with turned surfaces in 46 maxillae for single or partial rehabilitations. After 3 years of prosthetic loading, the cumulative survival rate was 91% with a mean bone loss of 1.5 mm. The failure rate was higher in sites implanted immediately after tooth extraction. Recently, 97.3% survival was reported for immediately loaded implants in the posterior maxilla with a flapless approach, but using a stereolithographic surgical guide.[10] The flapped contralateral sites were delayed loaded and had no failures. Patient-centered variables such as satisfaction, self-reported pain, or discomfort were similar between both groups. Others reported 25% failures of immediately loaded single implants installed with flapless surgery compared to no failures for a delayed loading group.[11] Despite higher failure rate, they reported similar esthetic results with both techniques. Currently, very few prospective studies comparing flapless with flap surgery and using the same loading protocol are available. Based on the limited available literature, flapless surgery merits to be scrutinized as a proper alternative for implant treatment in selected and appropriately planned cases. In order to determine the long-term prognosis, bone levels should be reported besides the clinical survival rates.

The aim of the present retrospective study was to describe the outcome of single-tooth replacements installed in a daily clinic, and secondly, to compare the clinical survival and success of implants installed with a flapless versus open flap surgery based on internationally accepted criteria.[12]

MATERIALS AND METHODS

Inclusion and Exclusion Criteria

All patients consecutively operated with single Brånemark® system TiUnite implants (Nobel Biocare AB) from 2003 to 2005 were included in the study provided they had: (1) adequate bone volume to allow placements of implants of at least 7 mm length and 3.3–5 mm width; (2) healed bone or tooth extraction that had been performed at least 3 months prior to implant insertion; (3) antagonistic teeth, either being natural teeth or as part of crown and bridgework; (4) at least one neighboring tooth present; and (5) no medical contraindications for implant surgery. Smokers and bruxists were not excluded from the study. Immediate implantation in extraction sites and immediate loading sites were excluded.

Implant Surgery and Follow-Up

Because only single cases were treated, it was easy to control proper implant placement using neighboring teeth for guiding. It was considered that clinical inspection and a peri-apical or orthopantomographic image was sufficient for case planning prior to surgery. However, flapless surgery was only considered when thick biotype with adequately attached gingiva was present and when additional soft tissue augmentation or flap management was not required. Bone mapping was performed by means of probing the bone after anesthesia.[13] In the flapped sites, a conventional mucoperiosteal flap was raised after crestal incision. After implant placement, the flap was sutured around the healing abutment. In the flapless sites, the drill of diameter 2 mm was used to perforate the soft tissues initially. After carefully probing the initial drill hole with a blunt probe, in order to detect possible perforations, the site was enlarged and prepared at final depth. A countersink drill was used to remove soft tissue remnants at the recipient site and to enlarge the entrance of the bone prior to implant placement. This was considered important to create sufficient space for the proper seating of the healing abutment that has a wider diameter than the implant. The clinical flapless procedure is summarized in Figure 1. After implant surgery, the patients were prescribed antibiotics

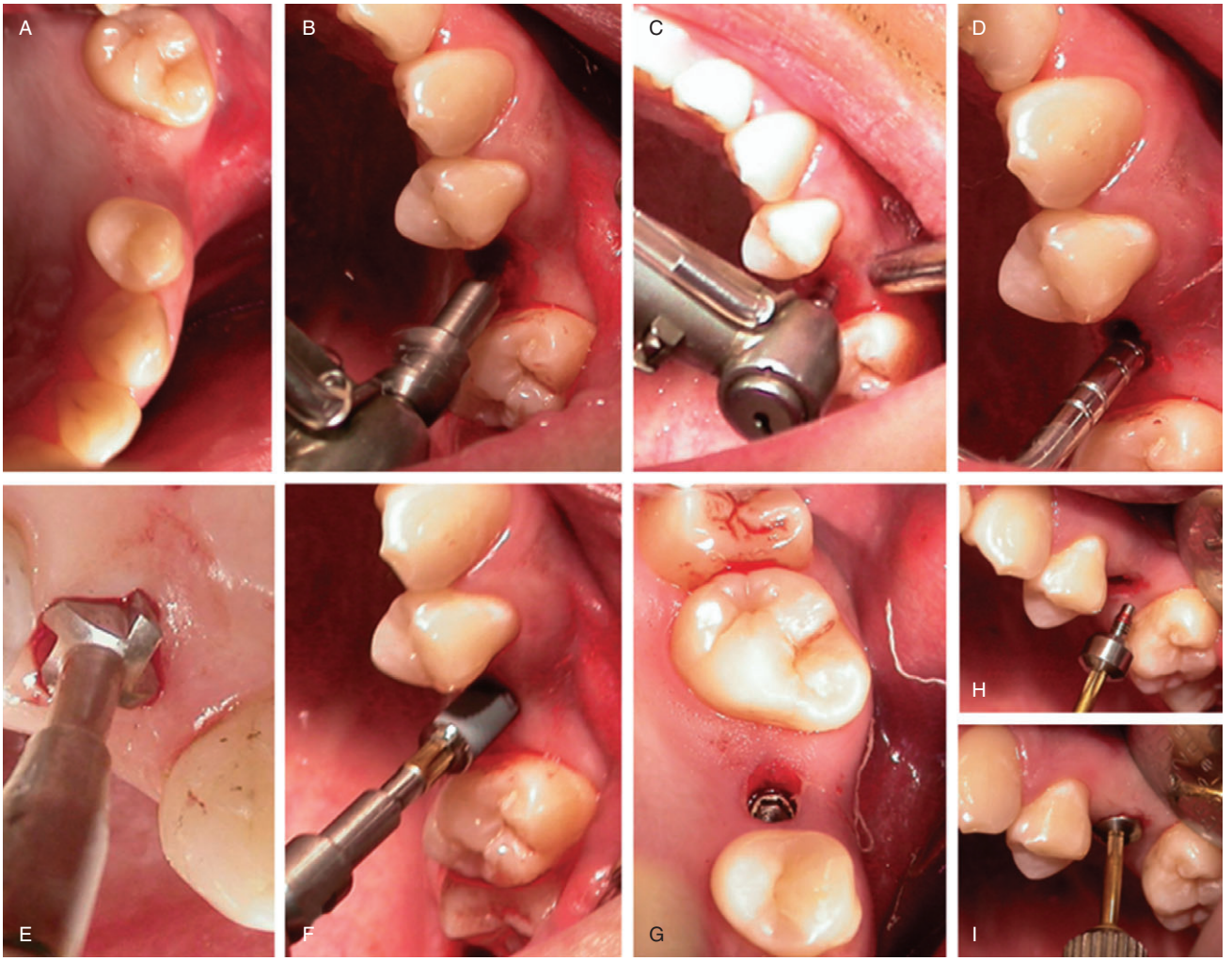

Figure 1 Case report demonstrating the flapless procedure. A second premolar region representing a wide alveolar crest with a good anatomical as well as soft tissue condition (A). The implant bed is prepared through the mucosal tissues (B) and widened with appropriate drills according to the manufacturer's protocol (C). After carefully checking for possible bone fenestrations as well as checking the sinus membrane (D), the mucosal entrance as well as the coronal bone crest is enlarged with the counter sink drill (E). The implant is then installed (F) until primary stability is obtained with a minimal torque value of 30 Ncm. Whenever necessary for the emergency profile, the depth position is adapted by manual torqueing until the implant is seated 2–3 mm submucosally (G). A healing abutment is installed (H–I) flush with the mucosal crest.

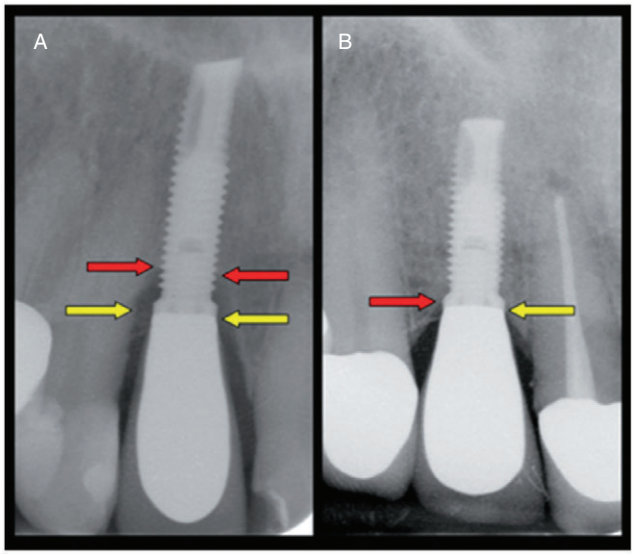

Figure 2 Periapical radiograph of an implant in function for 52 (A) and 54 (B) months, respectively, representing the worst and the best radiographical image of bone loss. The yellow arrow indicates the reference point from where bone level was determined. Bone level indicated by the red arrow.

(amoxicillin 500 mg, 3 times a day for 1 week, or erythromycin 200 mg, 1 × 4 per day for 1 week) and analgesic, and anti-inflammatory medication (ibuprofen 600 mg 3 times a day for 3 days). In addition, the patients were advised to rinse with a 0.2% chlorhexidine mouthwash (Corsodyl®, GlaxoSmithkline, Brentford, UK) and asked to brush the treated site with a very soft brush (Tepe, surgical, Malmö, Sweden). The patients were checked 1 day after surgery when the temporary spoon denture was relieved to avoid overloading. In the esthetic zone, often a resin-bonded tooth was attached to the neighboring teeth whenever possible. The patients were advised not to use the provisional dentures overnight. Sutures were removed 8–10 days later, and oral hygiene was reinforced. The patients were checked at regular time intervals. The final metallo-ceramic crowns were made 3–6 months after surgery and either screw retained on fixture level using the manufacturer's components or cemented on customized abutments (Procera®, Nobel Biocare AB). In preparation for the report, the patients were asked to attend a clinical checkup to scrutinize implant survival and bone level by means of a peri-apical radiograph. All patients signed an informed consent of the treatment and research procedure.

Radiographic Examination

Baseline peri-apical radiographs were taken on average 3.1 months after surgery (range 0–9 months) in most cases to examine proper seating of the healing abutment or impression coping. All radiographs taken after crown placement and during regular maintenance were evaluated. The abutment-implant interface was arbitrarily used as the baseline reference point (0 mm) from where the nearest level of bone-to-implant contact was determined (Figure 2). Measurements were analyzed by an experienced clinician (T.V.D.V.) not involved in the surgery and not knowing which group the radiographs were allocated in. DBSWIN software (precision 0.1 mm) was used using the known distance between implant threads for calibration. Because there was no given interval for examination, the available radiographs were grouped into intervals 0 to 6 months, 7 to 12 months, 12 to 24 months, 25 to 36 months, and 37 to 54 months.

Statistical Analysis and Success Criteria

For simplification and because only three patients had multiple implants, the number of implants ($n = 53$) was used as the unit for statistical analysis. Wilcoxon signed ranks test was used to test the difference in mesial and distal bone level measurements. Because this was not significant ($p > .05$), it was decided to calculate the mean of both and use this as the single implant bone value. An individual fixture was considered successful if it caused no pain, was clinically immobile under loading conditions and radiographic bone loss compared to baseline did not exceed 1.5 mm during the first year, and was

below 1.9 mm after 3 years as suggested in the internationally accepted criteria.[12] Besides descriptive statistics on fixture level, changes with respect to the previous interval were tested with Wilcoxon signed ranks test, and differences between flap or flapless sites were tested with Mann-Whitney *U*-tests. $p < .05$ was considered as statistically significant. Statistics and graphs were performed in SPSS version 16 (Chicago, IL, USA).

RESULTS

In total, 53 single-tooth replacements were provided in 49 patients. The study involved 27 women and 22 men with a mean age of 53 years (SD 13.5; range 20–79). One patient had three and two patients each two implants. Twenty-seven implants were installed in women (51%) and 26 (49%) in men. Twelve implants were installed in 10 smokers.

All 53 installed implants were survivals until 2 years of loading. From seven implants, no information was available at the 3-year follow-up. These patients were lost from recall because of illness or leaving the practice. Hence, the dropout was 15% after 3 years. From an additional four implants, the radiographs could not be evaluated properly, leaving in total 42 implants (83%) for long-term scrutiny after an average loading period of 38 months.

Forty-three of fifty-three implants (81%) were regular platform of diameter 3.75 to 4.0 mm, eight (15%) were narrow diameter 3.3 mm, and two (4%) were wide platform diameter 5 mm implants (Table 1). Forty-two cases were treated in the maxilla (79%) and 11 (21%) in the mandible. Implant location and implant length are given in Tables 2 and 3. There are no differences between the F and the FL group.

Wilcoxon signed ranks tests revealed that for the complete study material, there was a statistically significant increase in bone loss during the 0–6 months interval and the 7–12 months interval ($p = .004$), indicative of a bone remodeling proces. After the first year, however, no further bone loss was observed at all intervals with $p > .05$ (Figure 3). For the whole study, the mean loading time was 39 months (range 23–58). The corresponding mean bone loss was 1.36 mm (SD 0.91, range 0–3.7) based on 42 radiographs taken at the last examination visit. Taking into consideration the individual implant site, it is obvious that nearly 80% had less than the 1.9 mm bone loss at the last examination, which can be considered a success according to the criteria (Figure 4). The mean bone loss for F is 1.27 mm (SD 1.1, range 0–3.7) and for FL 1.40 (SD 0.8, range 0.4–3.1) with no statistically significant difference ($p < .7$ Mann-Whitney *U*-test). When only the implants ($n = 22$) with a loading period above 3 years were considered, the mean bone loss was 1.28 (SD 1.04 – range 0–3.7). A boxplot (Figure 5) shows the maximal bone loss at the last recall interval for the F ($n = 20$) and FL sites ($n = 22$). Mann-Whitney *U*-test revealed that only during the initial year of function, there was a higher bone loss in the FL sites versus the F sites ($p < .009$) (Figure 6). After 1–4 years, no statistically significant difference was found between the two treatment modalities (Figure 7).

TABLE 1 Implant Width (mm)

	Surgical Procedure		
Implant Width (mm)	Flap	Flapless	Total
RP (3.75–4.0)	21	22	43
NP (3.3)	3	5	8
WP (5.0)	1	1	2
Total	25	28	53

TABLE 2 Implants per Location

Implant Location	Maxilla	Mandible	Total	%
Incisors	23	2	45	47.1
Canines	3	0	3	5.6
Premolars	13	4	17	32
Molars	3	5	8	15.1
Total	42	11	53	100

TABLE 3 Implant Length (mm)

	Surgical Procedure		
Implant Length (mm)	Flap	Flapless	Total
7.0	1	0	1
10.0	1	2	3
11.5	1	4	5
13.0	3	9	12
15.0	19	12	31
18.0	0	1	1
Total	25	28	53

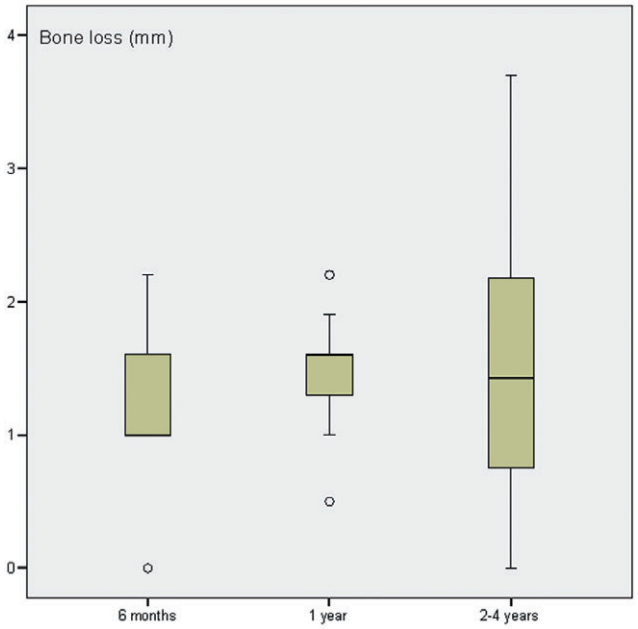

Figure 3 Box plot expressing maximal bone loss in mm, measured with respect to the reference point for all implants included in the study. During the first year, bone remodelling occurred to a distance of 1.5 mm. However, no additional further bone loss occurred ($p = .7$).

DISCUSSION

The present study reports the 3 to 4 years outcome of over 50 single-tooth cases operated either with a classical flap surgery or by means of a flapless procedure. The results obtained in the study are better than generally accepted and this despite the absence of strict exclusion criteria. On the other hand, 90% of the used implants were 11.5 mm or longer, and perfect initial stability was obtained by using diameter 4 mm implants as the standard whenever possible. This reflects a proper patient

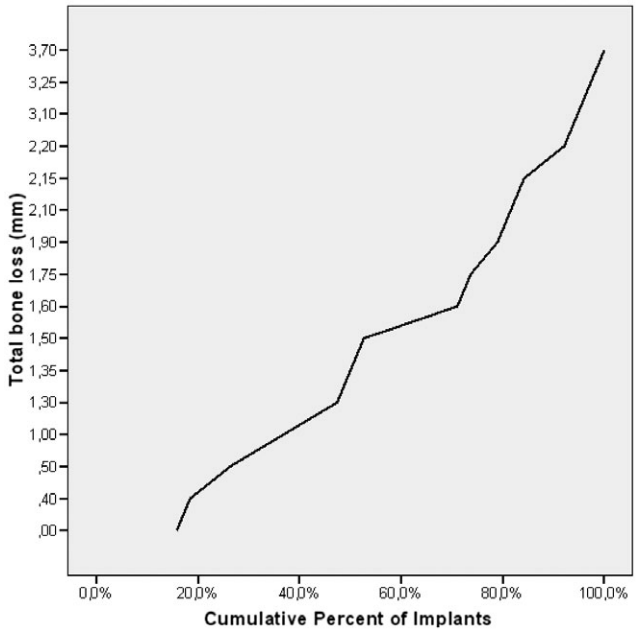

Figure 4 Cumulative percentage of all available implants ($n = 42$) expressed versus the maximal encountered bone value as measured from the reference point on the last available time point, which is on average 38 months after loading. With 1.90 mm as threshold, nearly 80% of the implants can be considered a success.

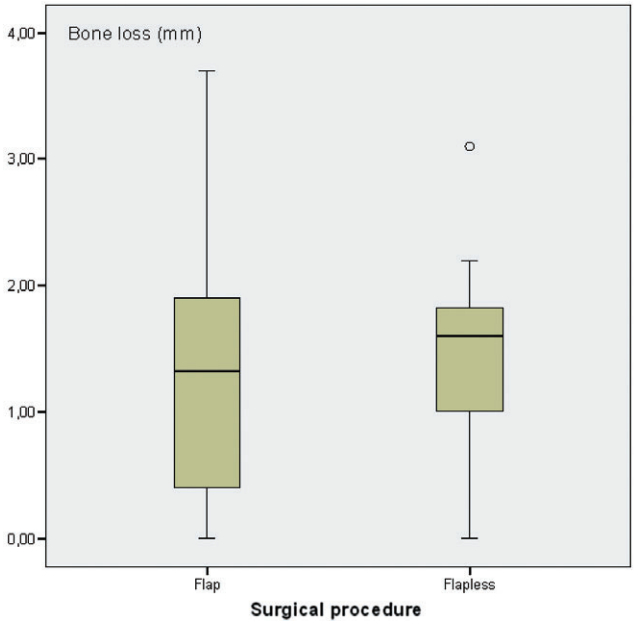

Figure 5 Box plot expressing maximal bone loss at the last radiographical control with respect to the reference point for all implants included in the study and divided in surgical treatment modality flap ($n = 20$) or flapless ($n = 22$). There is no significant difference between both groups after 2–4 years.

selection with good anatomical conditions of the implant recipient bone. Furthermore, the surgical technique of bone compression by underpreparing the implant recipient bed enhanced initial stability.[14]

With 100% implant survival, a mean bone loss below 1.9 mm after 3 to 4 years and nearly 80% of the individual implants showing acceptable bone loss (see Figure 4), the two-piece implants with the TiUnite

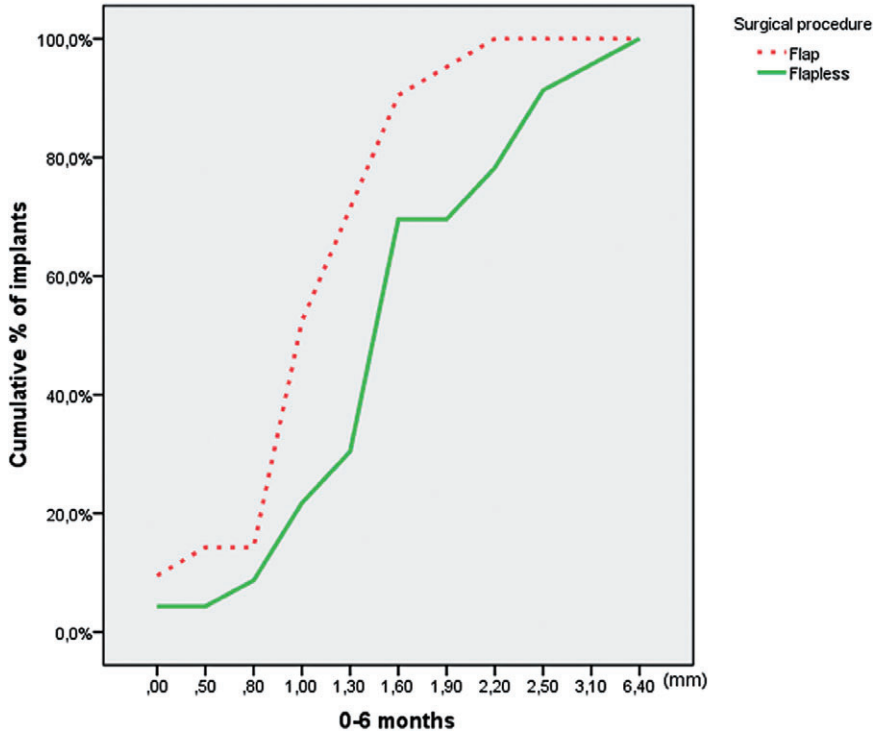

Figure 6 Cumulative percent of implants ($n = 44$) expressed versus the bone-implant level (in mm) during the interval 0–6 months (mean time 4.3 months). The mean bone value is 1.5 mm (SD 1.0, range 0–6.4). Mann Whitney test revealed a lower bone level with respect to the reference point at the flapless sites ($p = .009$).

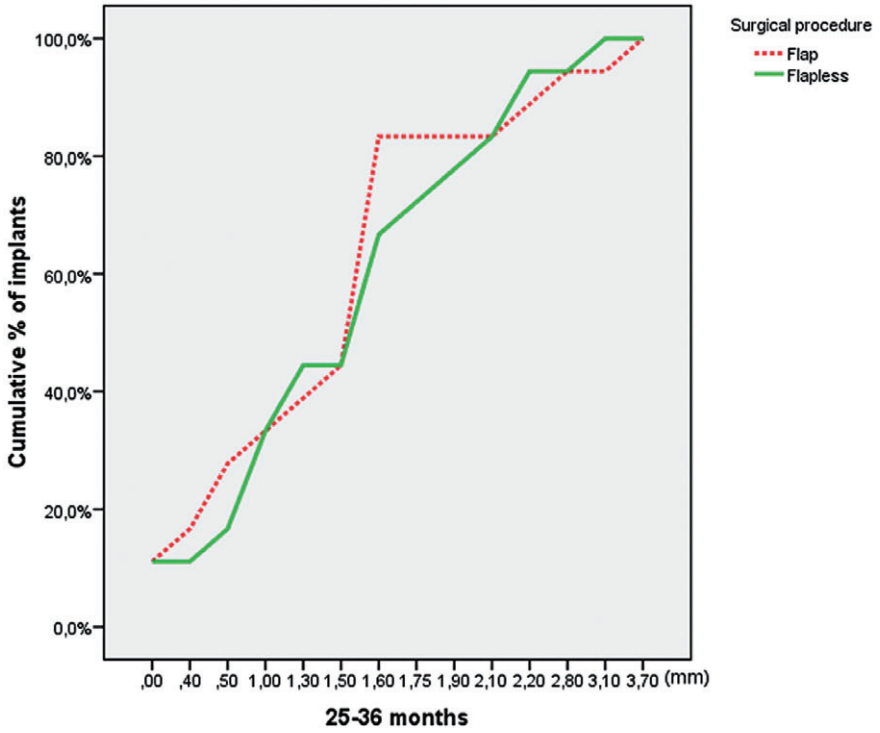

Figure 7 Cumulative percent of implants ($n = 36$) expressed versus the bone-implant level (in mm) during the interval 25–36 months (mean time 29 months). The mean bone value is 1.4 mm (SD 0.8, range 0–3.7). Mann Witney test revealed no difference between flap or flapless sites ($p = .70$). Taking 1.9 mm as the threshold for individual implant success, above 80% and 70% of the implants in the flap or flapless group can be considered a success.

surface stand the international criteria for success. This is in agreement with other clinical studies[4,9] but in contradiction with one-piece implants with the same surface texture known to yield high failure rates.[15,16]

As can be seen from Figure 6, there was a difference in bone loss between F and FL during the first year. In other words, the bone-to-implant contact level was further apical from the reference point in the FL group. This is probably caused by overdoing the countersinking procedure. More extensive widening of the crestal bone was necessary to remove enough bone as to allow proper placement of the healing abutment. By countersinking wider and deeper, the coronal portion of the implant is not always in intimate contact with the bone. As is expected, bone healing does occur in the following months and biological width is established. In the flapped sites, the countersinking procedure was more controlled according to the guidelines of the manufacturer because visual inspection in situ was possible. Mann-Whitney *U*-test revealed that only during the initial year of function there was a lower bone level in the flapless surgery versus the flapped surgery ($p < .009$) (see Figures 6 and 7), but after 1 to 4 years no statistically significant difference was found between the two treatment modalities.

The study was not set up as a randomized controlled trial because flapless surgery was considered a treatment option based on clinical examination and largely depending on the anatomical condition of the bone after clinical and radiographic inspection. The surgeon had the opportunity to make a choice during the procedure and, hence, chose the best option according to his personal feeling and experience. Sometimes, the surgery was intended to be flapless, but in case of doubt during the preparation of the implant recipient site, it was decided to raise the flap for inspection. These implants were confound to the flapped group. Because flapless surgery was only considered in favorable clinical conditions, the allocation to the surgical approach may have been biased. This phenomenon called "selection bias" where only the ideal cases were treated flapless, and borderline cases and challenging cases by means of flap surgery, could have masked substantial intergroup disparity. Evidently those should be taken into account when interpreting the results of the present study. On the other hand,

our approach reflects somehow the decision-making process in reference to the used surgical technique as it actually occurs in real-life clinical practice. Alternatively, a randomized controlled study comparing both surgical techniques in only ideal cases may not reflect the real clinical situation and is probably also unethical. We wish to emphasize, however, that comparable frequency distributions in implant length, implant diameter among the groups are indicative of relatively similar cases in the flap or flapless group.

CONCLUSIONS

In this clinical study performed in daily clinical practice, single implants installed in a one-stage flapless surgery without the use of computer-assisted guides showed equal clinical success, as those installed with conventional one-stage flap surgery. Overall, implant survival was 100% and implant success 80% with stable bone conditions indicative of a good long-term prognosis. Within the limitations of single-tooth restorations and within the 3 to 4 years of loading time, it seems that flapless surgery in healed bone with delayed loading offers a good alternative to conventional surgery. We wish to emphasize that cases planned for a flapless approach had been strictly selected and that all procedures had been performed by an experienced clinician.

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