

# Immediate Functional Loading of Implants Placed with Flapless Surgery in the Edentulous Maxilla: 1-year Follow-up of a Single Cohort Study

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**Purpose:** To evaluate success rates and complications of implants placed with a flapless technique and immediately loaded in fully edentulous maxillae. **Materials and Methods:** Implants were placed in fully edentulous maxillae with a minimum insertion torque of 45 Ncm in underprepared sites to allow maximum stability at insertion using a flapless technique. Implants were immediately loaded. Outcome measures were prosthesis and implant success, biologic and prosthetic complications, pain, and edema evaluation. Stability of individual implants was assessed both manually and with Osstell at baseline and after 12 months of loading. A single sample t test was used with a significance level of .05. **Results:** Thirty-three consecutively treated edentulous patients received 202 implants in the maxilla. In 10 patients, 53 implants were immediately inserted in fresh extraction sockets. At implant insertion, a flap had to be elevated to control the direction of the drill in 5 patients. Three implants in 2 patients did not reach sufficient stability and were left to heal for 45 to 90 days. All restorations (21 fixed prostheses and 12 overdentures) were delivered the same day of the surgery. Twenty-six patients experienced no or slight postoperative pain; 7 experienced moderate to severe pain. No or slight edema was recorded for 19 patients and moderate to severe edema for 14 patients. Two implants failed in 2 patients but were successfully replaced the same day they were removed. No major complications occurred. Five patients experienced biologic complications, eg, peri-implantitis; 10 experienced prosthetic complications. No prosthesis failed; however, 1 patient was unsatisfied with his overdenture and requested a fixed alternative. There was a highly significant difference ( $P < .001$ ) between the stability at implant insertion and after 12 months. **Conclusion:** Implants placed in the edentulous maxilla with a flapless procedure can be successfully loaded the same day of surgery. INT J ORAL MAXILLOFAC IMPLANTS 2007;22:87–95

**Key words:** dental implants, edentulous maxilla, flapless procedures, immediate loading

Traditionally, to minimize the risk of failures for osseointegrated dental implants, it has been recommended that the implants be load-free for 3 to 4 months in mandibles and 6 to 8 months in maxillae.<sup>1</sup> This means that patients have to wait for significant time while wearing suboptimal provisional dentures.

It would therefore be beneficial if the healing period could be shortened without jeopardizing implant success. In 1990 the first longitudinal clinical trial was published suggesting that osseointegrated implants could be loaded immediately in the mandibles of selected patients.<sup>2</sup> Nowadays, immediate and early loaded implants are commonly used, particularly in mandibles of good bone quality.<sup>3</sup> The results of a Cochrane systematic review<sup>4</sup> evaluating timing for loading of dental implants suggested that immediately loaded mandibular dental implants can be as effective as implants loaded after a conventional healing period in selected patients; however, no randomized controlled clinical trial (RCT) evaluating immediately loaded implants in edentulous maxillae was identified. Recently, several uncontrolled investigations have reported on immediately loaded implants in edentulous maxillae.<sup>5–10</sup>

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Traditionally, when placing dental implants, a flap is elevated to better visualize the bone site that will receive the implants. Flap elevation also ensures that some anatomical landmarks, eg, foramina, lingual undercuts or maxillary sinuses, are clearly identified and protected. In cases where there is a limited amount of available bone, raising a flap can facilitate implant placement to maximize bony contact, minimizing the risk of bone fenestrations or perforations. However, flap elevation is associated with some degree of morbidity and discomfort, and requires suturing. There are situations where the elevation of a flap may be not necessary since the estimated amount of bone is more than adequate for receiving dental implants and the risk of complications is minimal. Under these circumstances, implant placement without flap elevation may be indicated. However, when deciding whether to place dental implants without raising a flap, several considerations have to be kept in mind. The operator is working "blind," and bone perforations may be more likely to occur. To minimize the risk of perforation and incorrect implant alignment, surgical templates with drilling guides can be used to help the surgeon to give the implant the proper axial direction. Retrospective<sup>11,12</sup> and prospective studies<sup>13,14</sup> suggest that in many instances it is possible to place dental implants successfully without raising a flap. More recently, an RCT<sup>15</sup> showed that patients treated with flapless implant placement experienced pain of lower intensity and less duration than patients in whom conventional flaps were elevated. From the patient's point of view, it would be attractive to receive a functional fixed prosthesis the same day as implant placement, with a minimally invasive surgical intervention that reduced discomfort, treatment time, and cost, if the risk of implant failure were not increased. To the authors' knowledge, only 2 studies<sup>12,14</sup> have evaluated immediately loaded implants placed with a flapless procedure in the maxilla; however, 1 retrospective investigation included only partially edentulous patients.<sup>12</sup>

The aim of this single cohort study was to describe some preliminary results using a flapless approach for placing dental implants that were immediately loaded in fully edentulous maxillae.

## MATERIALS AND METHODS

### Study Design

This trial was designed as a prospective single-cohort clinical trial. Consecutively treated patients were included and were followed for up to 1 year after implant loading. A written informed consent form was

signed by each patient, but ethical approval was not sought from an institutional review board. The surgical interventions were done in a private dental practice in Italy between January and June 2004. Surgical procedures and all clinical assessments were performed by a single experienced operator. To be included patients had to be 18 years or older and be totally edentulous in the maxilla or have hopeless dentition. Patients also had to have enough bone to allow the placement of at least four 10-mm-long implants with a 3.7-mm diameter without the need for bone augmentation procedures. Exclusion criteria were: oral lichen planus lesions, irradiation in the head and neck region or chemotherapy during the previous 6 months, severe skeletal jaw discrepancies, bruxism and clenching, dubious patient cooperation, unrealistic esthetic expectations, emotional instability, psychiatric problems, substance abuse, HIV-positive status, autoimmune diseases, metabolic diseases affecting bone, uncontrolled diabetes, serious coagulation problems, pregnancy or lactation, or acute infections at the implant sites.

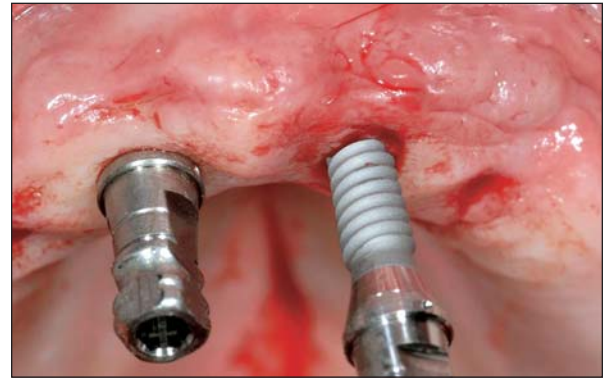
Preliminary screening was performed using panoramic orthopantomographs or computerized tomographic (CT) scans. When CT scans were not deemed necessary, a bone caliper was used to clinically determine the thickness of the available bone. Diagnostic tooth arrangements and surgical templates to guide implant insertion were made.

The following outcome measures were considered:

1. Prosthesis success. A failed prosthesis or a prosthesis that could not be placed was considered a failure.
2. Implant success. Mobile implants or stable implants that to be removed because of infection were considered as failures. Implants were individually assessed for stability by tightening the abutment screws after removal of the prosthesis.
3. Any biologic or prosthetic intraoperative and postoperative complication.
4. Implant stability. This was assessed via the resonance frequency analysis (RFA) using Osstell (Integration Diagnostics, Göteborg, Sweden) after prosthesis removal. Results were expressed as an implant stability quotient (ISQ) with values ranging from 1 (minimum stability) to 100 (maximum stability). Implants showing values  $\leq 40$  1 year after loading were considered failures. All Osstell measurements were made by the main investigator. Implant stability was measured just after implant placement and 1 year after loading.
5. Pain and edema. The level of postoperative pain and edema was assessed at the first control visit 3 to 4 days after implant placement. Pain was



**Fig 1a** An edentulous maxilla.



**Fig 1b** Placement of the implants with a flapless procedure.



**Fig 1c** Four implants were inserted.



**Fig 1d** A bar to support an overdenture was provided a few hours after implant placement.

scored by patient according to the following scale: 0 = no pain; 1 = slight pain; 2 = moderate pain; 3 = severe pain. Edema was scored by the surgeon according to the following scale: 0 = no visible edema; 1 = slight edema; 2 = moderate edema; 3 = severe edema and/or visible hematoma and ecchymosis.

### Surgical Technique

Tapered SwissPlus implants (Zimmer Dental, Carlsbad, CA) with diameters of 3.7 and 4.8 mm and length of 10, 12, and 14 mm were used.

Three days prior to the intervention, patients were instructed to use 0.2% chlorhexidine mouthwash (Corsodyl; GlaxoSmithKline, London, UK) for 1 minute 4 times a day and to continue for 10 days after the intervention. One day before the intervention, all dentate patients received professional oral hygiene. Prior to the surgical intervention, 2 g of amoxicillin with clavulanic acid (Augmentin; GlaxoSmithKline) was administered to each patient. Patients continued to receive 2 g 2 times a day for 3 days. The maxilla was locally anesthetized by injecting approximately 8 mL of articaine with 1:100,000 adrenaline. Intravenous sedation was administered to 4 patients and consisted of 5 mg Midazolam (Mayne Pharma Italia, Naples, Italy). Two milliliters of Midazolam were diluted in 8 mL of physiologic solution. Three milliliters were injected just before the intervention. An

additional dose of 2 to 3 mL was administered during the intervention only if the patient reported some pain.

The operations were planned to be flapless (Figs 1 to 3). If a flap had to be raised due to technical difficulties or complications, the event was recorded. Fresh postextractive alveoli were included (Figs 3a to 3c). Surgical templates were used to facilitate proper implant positioning for ideal prosthetic rehabilitation. For fully edentulous patients, templates were held firm with the help of the assistant while the surgeon made holes through the mucosa with a 2.3-mm-diameter drill. If the thickness of the residual bone was judged to be sufficient, the bone was perforated up to 4 mm. Otherwise the template was removed, and the drilling of the bone was done by freehand. When residual teeth were present, the template was affixed to them with clasps. The direction of the extracted roots was followed for immediate postextractive implants.

An implant stability of at least 45 Ncm was to be obtained for an implant to be immediately loaded. To achieve this goal, bone quality was evaluated during surgery and implant sites were underprepared to achieve maximum primary stability. The degree of underpreparation to use was decided in relation to bone quality and implant diameter. The surgical sequence was as follows: a 2.3-mm-diameter pilot drill was used (maximum speed 600 rpm) to prepare



**Fig 2a** Another edentulous maxilla.



**Fig 2b** Placement of the implants with a flapless procedure.



**Fig 2c** Six implants were inserted.



**Fig 2d** A screw-retained Toronto-type restoration was provided a few hours after implant placement.



**Fig 3a** Edentulous maxilla with 4 remaining roots.



**Fig 3b** Placement of the implants with a flapless procedure immediately after extraction of the residual roots.



**Fig 3c** Six implants were placed.



**Fig 3d** Cast with the metallic superstructure to be used for replacement of the provisional acrylic resin fixed denture delivered a few hours after implant placement.



**Fig 3e** A definitive fixed prosthesis supported by 6 implants was delivered a few weeks after implant placement.

the implant site directly in the alveolar mucosa and to determine bone quality. Bone quality was subjectively classified as "dense," "normal," or "soft."<sup>16</sup> In dense bone, the standard drilling sequence suggested by the manufacturer was followed. To place a 3.7-mm-diameter implant, a 2.8-mm-diameter twist drill was used, followed by a 2.8-/3.4-mm-diameter drill. To place a 4.8-mm-diameter implant, 2.8-/3.4 mm- and 3.8-/4.4-mm-diameter drills were used. In normal bone, the 2.8-mm-diameter twist drill was followed by a custom-made tapered drill (3.2- or 3.9-mm-diameter for 3.7- or 4.8-mm-wide implants, respectively) to prepare the crestal 2 to 3 mm of the osteotomy site. In soft bone, a 2.8-mm-diameter twist drill was used to enlarge the first 2 to 3 mm of the implant site for 3.7-mm-diameter implants. If a 4.8-mm-diameter implant was to be placed, the first 2 to 3 mm of the implant site was enlarged with a surgical drill 3.5 mm in diameter.

Whenever possible, bicortical engagement of the implants was sought. When the 2.3- and/or 2.8-mm-diameter drills were used, they were pushed until they were about 1 mm from the cortical bone of the floor of the nose or the sinus. A 2.8-mm-diameter osteotome was then used to elevate the residual bone and the membrane about 2 mm. This allowed the placement of implants 2 mm longer than the actual vertical bone height.

Implants were inserted with a speed of 15 rpm using a torque of 45 Ncm. Once the motor stopped, they were rotated manually with a ratchet until seated in the proper position. Whenever possible the transition between the machined collar and the textured surface was placed level with the alveolar bone crest. In cases an implant was seated with a torque inferior to 45 Ncm, it was left to heal unloaded for some time.

### Prosthetic and Follow-up Procedures

Impression copings were attached to the implants, interrupted sutures provided where needed, and impressions were made with individual trays using Impregum F (Espe Dental, Seefeld, Germany). Definitive casts were mounted in articulators using interocclusal records and casts of the opposing arch. Acrylic resin provisional prostheses, screw-retained metal/resin Toronto-type restorations (Fig 2d) or bars for supporting overdentures (Fig 1d) were fabricated and inserted 4 to 8 hours after implant insertion according to the therapy plan and to number of implants placed. Implants were rigidly connected and immediately loaded. All prosthetic components were screwed using a standard torque of 30 Ncm. Cantilevers were avoided for all fixed provisional restorations. Provisional fixed prostheses were designed in

such a way that they were hardly in contact posterior to the canines. The occlusal surfaces of the posterior teeth had a reduced occlusal area compared to natural dentition, and it was attempted to place the occlusal contacts inside the implant diameter.

After surgery patients were instructed to avoid brushing and trauma to the surgical site. Ice packs were provided. A cold, soft diet was recommended for 7 days. Smokers were asked to avoid smoking for 3 days postoperatively. Pain killers (Nimesulide 100 mg; Doc Generici, Milan, Italy) were prescribed to be taken as needed. When placed, sutures were removed after about 1 week.

Patients were seen about every 3 to 4 days for the first 2 weeks; once a week for the following 2 weeks, and thereafter once a month for the entire duration of the study. Patients received oral hygiene maintenance according to their individual needs. Chlorhexidine mouthwash (0.2%, 3 to 4 times a day) was also prescribed for 1 week each month for 6 months.

When needed, definitive prostheses were inserted approximately 45 days after initial loading (range, 2 weeks to 4 months; Figs 3d and 3e). Cantilevers the size of a premolar were added to the majority of the fixed prostheses, and the nonoccluding posterior teeth were put in full occlusion.

### Statistical Analysis

Differences between the initial and 12-month Osstell measurements (ISQ values) were calculated for each implant and averaged to obtain a mean change for each patient. A single sample *t* test was then applied comparing the mean difference with zero. Significance was established when alpha was less than .05.

## RESULTS

### Patient Characteristics

Thirty-three patients were enrolled in the study (18 men and 15 women). Age at implant insertion ranged from 39 to 70 years (mean, 56.6 years). Eighteen patients provided no relevant anamnestic information. Three male patients had suffered from myocardial infarction 2 to 3 years earlier and were taking related medications. Two patients were affected by hypertension, which was being controlled by drugs. Four women suffered of various forms of depression (2 were on regular medication). Two patients were affected by hepatitis C and were treated with interferon; 1 patient was affected by hepatitis B and chronic bronchitis. One patient had had a breast carcinoma treated with surgery and chemotherapy about 3 years earlier and suffered from obesity and diabetes controlled with oral hypo-

**Table 1 Summary of Failures and Complications**

Complication type	No. of patients affected
Prosthesis failure	1*
Implant failure	2
Peri-implantitis	2
Peri-implant mucositis	1
Hyperplastic tissues	1
Intermittent pain	1
Loosened provisional prosthesis	4 <sup>†</sup>
Overdenture adjustment	2
Abutment loosening	1
Detachment of a prosthetic tooth	1
Prosthesis coating fracture	1
Overdenture palatal fracture	1

\*One patient was psychologically unsatisfied with an overdenture. He requested and obtained a fixed prosthesis after undergoing a bilateral sinus lift procedure 2 months after the end of this study. However, the overdenture was successful from a prosthetic viewpoint.

<sup>†</sup>Two provisional acrylic resin prostheses had to be remade and replaced with metal-reinforced provisional restorations.

glycemics. One patient had an episode of multiple sclerosis treated with steroids 4 years earlier. One patient suffered from vasomotor (cluster) headache. Twenty-one patients were nonsmokers, 5 were light smokers (< 10 cigarettes per day), and 7 were heavy smokers (> 10 cigarettes per day). One patient wore a denture in the mandible, whereas other patients had natural dentition or fixed or implant-supported prostheses in the mandible.

### Implants and Prostheses

In total, 202 implants were inserted in 33 patients. Of these, 53 implants were placed in the fresh alveolar sockets of 10 patients. Eighteen implants were placed in soft bone, 148 in normal bone, and 36 in dense bone. In 5 patients it was necessary to elevate 5 localized flaps because the surgeon wished to check the direction of the drills. All implants reached the planned stability of 45 Ncm, with 3 exceptions. In 1 patient 2 implants that did not reach the planned stability were allowed to heal for additional 45 days. In the other patient, the implant was immediately replaced by a Zimmer Spline self-tapping implant coated with crystalline MP-1 hydroxyapatite (Zimmer Dental, Carlsbad, CA) and left to heal for 3 months.

All patients received the planned prostheses the same day as implantation. Twelve overdentures were delivered; of these, 10 were in their definitive form. Ten Toronto-type fixed restorations were delivered, 4 the same day of the intervention. The remaining 6 replaced provisional prostheses after 2 to 7 weeks.

Eleven provisional resin-reinforced prostheses were delivered. They were replaced by gold-alloy/ceramic fixed complete prostheses after 1 to 4 months.

No patient dropped out during the course of the study.

### Prosthesis and Implant Failure

No prosthesis failed; however, 1 patient who received an overdenture requested a fixed prosthesis and underwent a bilateral sinus augmentation procedure 3 months after the end of the study.

Two implants failed. One patient wearing an overdenture felt some pain in the right canine region 2 months after implantation. The implant was found to be mobile. It was removed and immediately replaced with a larger-diameter implant (4.8 mm). The next day a new bar was fabricated, and the overdenture was adapted to it. The other failure was implant in the right first premolar region. The patient reported similar symptoms 4 weeks after implantation. The implant was removed and immediately replaced with a larger-diameter one. Since patient was still wearing a provisional prosthesis, it was relined the same day.

### Biologic Complications

Five biologic complications<sup>17</sup> occurred in 5 patients (Table 1). One patient reported intermittent pain around an implant in the left first molar region. The implant was stable and displayed no radiolucency. It was left in situ untreated. After about 3 months, the pain disappeared. Hyperplastic tissues were observed under the overdenture bar of 1 patient 10 months after loading. The hyperplastic tissues were surgically removed. In 1 patient affected by depression, peri-implant mucositis was observed 1 month after implant placement. The patient's oral hygiene was very poor; the patient was not motivated. After repeated professionally delivered oral hygiene treatments, use of local and systemic antibiotics, and involvement of the husband in the oral hygiene control, the situation improved. Two patients had 1 implant each affected by peri-implantitis. One implant in the second premolar region displayed pus drainage from the sulcus 4 months after insertion. The other implant, which was in the right canine region, displayed redness and bleeding of the peri-implant tissues without purulent exudate 5 months after placement. Both implants were surrounded by crateriform bony defects about 3 mm deep, which were successfully treated by elevating a flap, manually cleaning the implant surface, and reducing the infrabony component with osteoplasty. Systemic antibiotics were administered to 1 patient.

### Prosthetic Complications

Ten prosthetic complications occurred (Table 1). The provisional acrylic resin prostheses became loose in 4 patients: in 2 cases it was sufficient to carefully recement them. In the other 2 cases, the restorations had to be replaced with metal-reinforced provisional dentures. Two overdentures had to be adjusted because they were pressing excessively on the patient's mucosa. In 1 patient, 2 abutments became loose after 2 weeks and had to be retightened. A tooth fractured off of 1 overdenture. In another case, an overdenture fractured on the midline of the palate after 8 months. One patient with a Toronto-type restoration had a fracture of the resin coating at the midline after 1 year. With 1 exception, all prosthetic complications were solved the same day the patient came to the practice.

### Resonance Frequency Analysis

Data from 3 implants were excluded from this analysis: the 2 failed implants and the hydroxyapatite (HA)-coated implant. The mean ISQ for the 33 patients at implant placement was 68.9 (SD = 2.05). One year after placement, the mean ISQ was 71.4 (SD = 1.6). The mean difference was 2.5 (SD = 1.7), which was highly statistically significant from baseline ( $P < .001$ ). Increased stability was observed after 1 year.

### Pain and Edema Assessment

Eight patients experienced no postoperative pain; 18 had slight pain; 6 had moderate pain; and 1 experienced severe pain. The surgeon scored 11 patients as having no visible edema; 8 as having slight edema; 10 as having moderate edema; and 4 as having severe edema and/or visible hematoma and ecchymosis. The 5 patients where a flap had to be elevated were too few to allow any statistical comparison with patients where the surgery was conducted flapless as planned; however, 1 patient experienced no pain; 2 patients, slight pain; and the remaining 2 patients, moderate pain. The surgeon recorded moderate edema for all 5 patients.

## DISCUSSION

Although uncontrolled trials are not the ideal study design to evaluate efficacy of an intervention,<sup>18</sup> they can still provide useful information on the prognosis of a specific technique. However, direct comparisons with alternative techniques should be avoided, since they may provide biased information. RCTs remain the gold standard for evaluation of the efficacy of medical interventions.

The results of the present investigation are indeed very positive and are in agreement with another recent prospective study<sup>14</sup> in which 100% success rates for 27 consecutively patients treated with a flapless procedure and immediate loading of fully edentulous maxillae were reported. In the other investigation<sup>14</sup> customized surgical templates derived from CT scans were used; in the present study, CT scans, and sometimes orthopantomograms, were used to evaluate whether there was sufficient bone to insert four 10-mm-long implants, and conventional templates were used. Therefore, the procedure used in the present investigation was simpler and cheaper but required a great deal of experience. The use of custom-made templates with metallic sleeve guiding implant insertion could be easier and more appealing to less-experienced surgeons. Flapless implant placement can be a difficult procedure, as exemplified by the fact that in 5 patients small, localized flaps had to be raised to place some implants.

It is difficult to evaluate the significance of postoperative pain or edema assessment in the absence of a control group. However, in a recent RCT,<sup>15</sup> it was shown that patients treated with flapless implant placement experienced pain at a lower intensity and for a shorter duration than patients treated with conventional flap procedures. In the present study, 25 patients reported some postoperative pain: slight pain in 18 cases, moderate pain in 6 patients, and severe and prolonged postoperative pain in 1 patient. In another similar trial it was reported that only 4 patients of 27 treated experienced moderate pain, whereas the remaining patients reported no pain at all.<sup>14</sup> The reasons for these differences are unknown; they could be related to different postoperative pain control regimens, to the use of different methods to record pain, or to both.

Several other recent studies on immediately loaded implants in edentulous maxillae also achieved similarly high success rates.<sup>6-10</sup> Table 2 summarizes the findings of 6 uncontrolled studies, including the present one. It is somewhat surprising to observe that none of the 183 planned maxillary prostheses failed or could not be placed, and that only 1% of the 1,143 placed implants failed. How can this impressive success rate of 99% for immediately loaded maxillary implants be explained in relation to the higher failure rates of conventionally loaded implants in edentulous maxillae observed until a few years ago, at least for machined Brånemark implants?<sup>19</sup> Of course over the years, additional experience on dental implant treatment has accumulated; this could partially explain the favorable

**Table 2 Summary of Findings from Recent Investigations on Immediately Loaded Implants in Edentulous Maxillae**

Study	No. of patients (failed)*	No. of implants (failed)	No. of failed prostheses	Follow-up	Implant system
Present	33 (2)	202 (2)	0	1 y	Zimmer Spline
Bergkvist et al <sup>7</sup>	28 (2)	168 (3)	0	8 mo	Straumann sand-blasted, large-grit, acid-etched
Degidi et al <sup>8</sup>	44 (5)	338 (3) <sup>†</sup>	0	5 y	Various
Maló et al <sup>9</sup>	32 (2)	128 (3) <sup>†</sup>	0	1 y	Nobel Biocare TiUnite
Östman et al <sup>10</sup>	20 (1)	123 (1)	0	1 y	Nobel Biocare TiUnite
van Steenberghe et al <sup>14</sup>	27 (1)	184 (0)	0	1 y	Nobel Biocare TiUnite
Total	184 (13)	1143 (15)	0		

\*The number of patients who had at least 1 implant failure is shown in parentheses.

<sup>†</sup>Implants were not individually tested for stability; therefore, the number of implant failures may be underestimated.

comparison with historical controls. Any attempted explanation is obviously speculative; however, the following factors are worth mentioning: the use of (1) rougher implant surfaces; (2) excellent primary implant stability; and (3) splinting of the implants.

The great majority, if not all, of the implants immediately loaded in Table 2 had roughened surfaces. Even though absolute scientific evidence of the superiority of implants with rougher surfaces over machined surfaces has not been established,<sup>20</sup> the lack of evidence should not be erroneously interpreted as lack of efficacy.

Most of the authors stressed the importance of achieving excellent primary implant stability, which can be achieved in various ways, eg, by placing implants in underprepared sites,<sup>9,10,12,14</sup> placing implants 1 to 2 mm below the level of the alveolar crest,<sup>7</sup> using a minimum insertion torque entrance criteria such as 30 Ncm<sup>10</sup> or 40 Ncm,<sup>9</sup> or systematically looking for bicortical implant engagement.<sup>9</sup> In the present study all these precautions were adhered to, and the sinus membrane was lifted about 2 mm with the help of osteotomes to allow the placement of 10-mm-long implants.

The mean ISQ of 68.9 recorded at implant placement in the present study was higher than the value (ISQ = 62.9) recorded in another similar trial.<sup>10</sup> This is indicative of a high primary implant stability. The mean ISQ significantly increased after 1 year up to 71.4. Although this is not a staggering increase in absolute terms, it suggests that bone may have remodeled around implants and, possibly, that higher degrees of implant stability are difficult to achieve. It is curious to observe that the lowest ISQ

value (53) was recorded in the site where optimal implant stability could not be achieved and an HA-coated implant was placed instead. The HA-coated implant was left to heal unloaded for 3 months. After 1 year, the highest ISQ value (78) was recorded for the same implant, which was not included in the mean calculations. These values could be simply coincidental, but they might also be indicative of a different bone response toward HA-coated implants. Reliable clinical trials confirming or rejecting this hypothesis are, surprisingly, still lacking.<sup>20</sup>

All implants were immediately splinted. It is possible that splinting at least 4 implants together allows sufficient stability for the implants to properly integrate. In several trials, presented in Table 2, full acrylic resin provisional dentures were used. Although full acrylic resin prostheses may retain some degree of flexibility, this did not seem to have jeopardized the final outcome.

## CONCLUSION

Implants placed in the edentulous maxilla with a flapless procedure can be successfully loaded the same day of surgery, eliminating the need of a healing period for the patients' benefit, if optimal primary implant stability is achieved. However, the technique may require a certain degree of clinical experience, and anatomic requirements (eg, sufficient bone quantity) must be fulfilled. Additional properly designed randomized controlled clinical trials are needed to confirm these preliminary results.



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## REFERENCES

1. Brånemark P-I, Hansson BO, Adell R, et al. Osseointegrated implants in the treatment of the edentulous jaw. Experience from a 10-year period. *Scand J Plast Reconstr Surg* 1977;16(suppl):1–132.
2. Schnitman PA, Wöhrle PS, Rubenstein JE. Immediate fixed interim prostheses supported by two-stage threaded implants: Methodology and results. *J Oral Implantol* 1990;16:96–105.
3. Brånemark P-I, Engstrand P, Öhrnell L-O, et al. Brånemark Novum: A new treatment concept for rehabilitation of the edentulous mandible. Preliminary results from a prospective clinical follow-up study. *Clin Implant Dent Relat Res* 1999;1:2–16.
4. Esposito M, Worthington HV, Thomsen P, Coulthard P. Interventions for replacing missing teeth: Different times for loading dental implants. *The Cochrane Library* 2004. Chichester, UK: John Wiley & Sons, 2004.
5. Tarnow DP, Emtiaz S, Classi A. Immediate loading of threaded implants at stage 1 surgery in edentulous arches: Ten consecutive case reports with 1- to 5-year data. *Int J Oral Maxillofac Implants* 1997;12:319–324.
6. Balshi SF, Wolfinger GJ, Balshi TJ. A prospective study of immediate functional loading, following the Teeth in a Day protocol: A case series of 55 consecutive edentulous maxillas. *Clin Oral Implants Res* 2005;7:24–31.
7. Bergkvist G, Sahlholm S, Karlsson U, Nilner K, Lindh C. Immediately loaded implants supporting fixed prostheses in the edentulous maxilla: A preliminary clinical and radiologic report. *Int J Oral Maxillofac Implants* 2005;20:399–405.
8. Degidi M, Piattelli A, Felice P, Carinci F. Immediate functional loading of edentulous maxilla: A 5-year retrospective study of 388 titanium implants. *J Periodontol* 2005;76:1016–1024.
9. Maló P, Rangert B, Nobre M. All-on-4 immediate-function concept with Branemark System implants for completely edentulous maxillae: A 1-year retrospective clinical study. *Clin Implant Dent Rel Res* 2005;7(suppl 1):S88–S94.
10. Östman PO, Hellman M, Sennerby L. Direct implant loading in the edentulous maxilla using a bone density-adapted surgical protocol and primary implant stability criteria for inclusion. *Clin Implant Dent Relat Res* 2005;7(suppl 1):S60–S69.
11. Dominguez Campelo L, Dominguez Camara JR. Flapless implant surgery: A 10-year clinical retrospective analysis. *Int J Oral Maxillofac Implants* 2002;17:271–276.
12. Rocci A, Martignoni M, Gottlow A. Immediate loading in the maxilla using flapless surgery, implants placed in predetermined positions, and prefabricated provisional restorations: A retrospective 3-year clinical study. *Clin Implant Dent Relat Res* 2003;5(suppl 1):29–36.
13. Becker W, Goldstein M, Becker BE, Sennerby L. Minimally invasive flapless implant surgery: A prospective multicenter study. *Clin Implant Dent Relat Res* 2005;7(suppl 1):S21–S27.
14. van Steenberghe D, Glauser R, Blomback U, et al. A computed tomographic scan-derived customized surgical template and fixed prosthesis for flapless surgery and immediate loading of implants in fully edentulous maxillae: A prospective multicenter study. *Clin Implant Dent Relat Res* 2005;7(suppl 1):S111–S120.
15. Fortin T, Bosson JL, Isidori M, Blanchet E. Effect of flapless surgery on pain experienced in implant placement using an image-guided system. *Int J Oral Maxillofac Implants* 2006;21:298–304.
16. Trisi P, Rao W. Bone classification: Clinical-histomorphometric comparison. *Clin Oral Implants Res* 1999;10:1–7.
17. Esposito M, Hirsch J-M, Lekholm U, Thomsen P. Differential diagnosis and treatment strategies for biologic complications and failing oral implants. A review of the literature. *Int J Oral Maxillofac Implants* 1999;14:473–490.
18. Esposito M, Worthington HV, Coulthard P. In search of truth: The role of systematic reviews and meta-analyses for assessing the effectiveness of rehabilitation with oral implants. *Clin Implant Dent Rel Res* 2001;3:62–78.
19. Esposito M, Hirsch J-M, Lekholm U, Thomsen P. Biological factors contributing to failures of osseointegrated oral implants. (I) Success criteria and epidemiology. *Eur J Oral Sci* 1998;106:527–551.
20. Esposito M, Coulthard P, Thomsen P, Worthington HV. Interventions for replacing missing teeth: Different types of dental implants. *Cochrane Database Syst Rev* 2005. Chichester, UK: John Wiley & Sons, 2005.