# Immediate Loading of Fixed Complete Denture Prosthesis Supported by 4–8 Implants Placed Using Guided Surgery: A 5-Year Prospective Study on 66 Patients with 356 Implants

Silvio Mario Meloni, DDS, PhD, MS;* Marco Tallarico, DDS, MS;† Milena Pisano, DDS;‡ Erta Xhanari, DDS;§ Luigi Canullo, DDS, PhD#

## ABSTRACT

*Background:* High primary implant stability is considered one of the main factors necessary for achieving predictable treatment outcomes with immediately loaded implant-supported screw-retained fixed complete denture prosthesis (FCDP).

*Purpose:* To evaluate the 5-year clinical and radiographic outcomes of immediately loaded implants placed in edentulous patients using computer-assisted template-guided surgery to support a FCDP.

*Materials & Methods*: Patients in need to be restored with a FCDP in the mandible or maxilla were included in this prospective study/ and treated using computer-assisted template-guided surgery. Implant sites were prepared in order to achieve an insertion torque ranging between 35–45 Ncm in the mandible and 45–55 Ncm in the maxilla. A prefabricated screw-retained provisional prosthesis was delivered the day of the surgery. Outcomes were: implant and prosthesis cumulative survival rate (CSR), any complications, and peri-implant marginal bone loss (MBL).

*Results:* Sixty-six patients received 356 implants to support 68 FCDPs. Each patient received 4–8 implants. Seven implants failed in six patients, resulting in a CSR of 98.1%. Two definitive prostheses failed resulting in CSR of 97.1%. Mean MBL of $1.62 \pm 0.41$ mm was reported at the 5-year follow-up. Five implants (1.4%) showed a mean mesio-distal peri-implant bone loss greater than 3.0 mm and received nonsurgical therapy.

*Conclusions:* immediately loaded implants placed in edentulous patients using computer-assisted template-guided surgery to support a FCDP is a valid treatment concept in the medium term follow-up, for edentulous patients.

KEY WORDS: computer assisted surgery, guided surgery, immediate loading

## INTRODUCTION

Immediately loaded fixed complete denture prosthesis (FCDP), represents a scientifically and clinically validated treatment modality for the restoration of function and esthetics in the edentulous patient.[1–4] The major clinical implications of immediate provisionalization/loading protocols are related to the treatment time and morbidity, that can be both drastically reduced without jeopardizing the implant success.[5,6]

High primary implant stability and lack of micromovements are considered two of the main factors necessary for achieving a predictable high success rate.[7–9] Nevertheless, no consensus has been reached regarding the optimal and/or maximum recommended insertion torque values.[8–10]

Recently, new implant designs and surfaces have been introduced to decrease the risk of early failure of immediately loaded implants.[11–15] The osteotome effect of the tapered implant body design improves the likelihood of adequate primary stability needed to ensure immediate implant placement and loading.[16]

*Adjunct Professor, University of Sassari, Italy; †Lecturer, University of Sassari, Italy; ‡Private Practice, Arzachena, Italy; §Private Practice Tirana, Albania; #Independent Research, Rome, Italy

Corresponding Author: Dott. Silvio Mario Meloni, Viale San Pietro 43/B 07100 Sassari, Italy; e-mail: melonisilviomario@yahoo.it

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**TABLE 1 Exclusion Criteria**

| |
|---|
| The subject is not able to give her/his informed consent of participating; |
| Health conditions which do not permit the surgical or restorative procedure (including pregnant or nursing); |
| Psychiatric problems or unrealistic expectations to believe that the treatment might have a negative effect on the subject's overall situation; |
| Alcohol or drug abuse as noted in subject records or in subject history; |
| Smoking of >10 cigarettes/day; |
| Uncontrolled diabetes, that is, a subject with diagnosed diabetes that has a history of neglecting doctor's recommendations regarding treatment, food and alcohol intake; |
| Treated or under treatment with intravenous amino-bisphosphonates or long-term (more than 3 years) oral bisphosphonate therapy; |
| Pathologic occlusion, for example, severe bruxism or other destructive habits; |
| Lack of opposing dentition or unstable occlusion; |
| Any disorders in the planned implant area such as previous tumors, chronic bone disease or previous irradiation in the head/neck area (less than 1 year before implantation); |
| Active infection or severe inflammation in the area intended for implant placement; |
| Major bone augmentation (more than 3 mm vertical height) performed less than 3 months prior to planned implant placement; |
| Insertion torque at the time of implant placement lower than 35 Ncm in the mandible and 45 Ncm in the maxilla; |
| Residual bone of least 5 mm beyond the root apex in the maxilla and 4 mm in the mandible, in case of post-extractive implants. |
| Subject shows poor oral hygiene and motivation; |
| Subject has known allergic or adverse reactions to the restorative material; |
| The subject is not available for the follow-up period. |

Furthermore, the under-preparation of the implant site have been proposed to achieve high primary stability even in poorly dense bone.[13]

Computer-guided implant protocols may help clinicians to perform implant therapy avoiding elevation of large flaps or eliminating them at all, causing less pain and discomfort to patients.[17] However deviations in three-dimensional directions between virtual planning and actual final position of the implant in the patient's jaws,[18,19] and technique-related perioperative complications have to be taken into account.[20,21] Although, favorable clinical results of computer-assisted template-guided surgery have been shown in several studies,[22–24] Only one randomized clinical trials (RCTs) has been published comparing the use of computer-guided surgery with conventional treatment, reporting no statistically significant differences in term of implant and prosthetic survival and success rates between computer-guided and free-hand rehabilitations.[17]

The purpose of this prospective observational study was to to evaluate the 5-year clinical and radiographic outcomes of immediately loaded implants placed in the edentulous jaws using computer-assisted template based surgery, to support a FCDP. This study followed the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) guidelines.[25]

## MATERIALS AND METHODS

This prospective observational study was designed to evaluate maxillary and mandible edentulous patients, or with failing dentition requiring extraction of the remaining teeth, confirmed by clinical and radiographic examination, with a preference for a FCDP, to be treated using computed-assisted template-based implant surgery and immediate loading. The patients were selected and treated in private practices between January 2007 and December 2009. The investigation was conducted according to the principles embodied in the Helsinki Declaration of 1964 for biomedical research involving human subjects. All patients were duly informed about the nature of the study and gave their written consent.

Any healthy patient aged 18 years or older, at the time of implant placement and a sufficient amount of

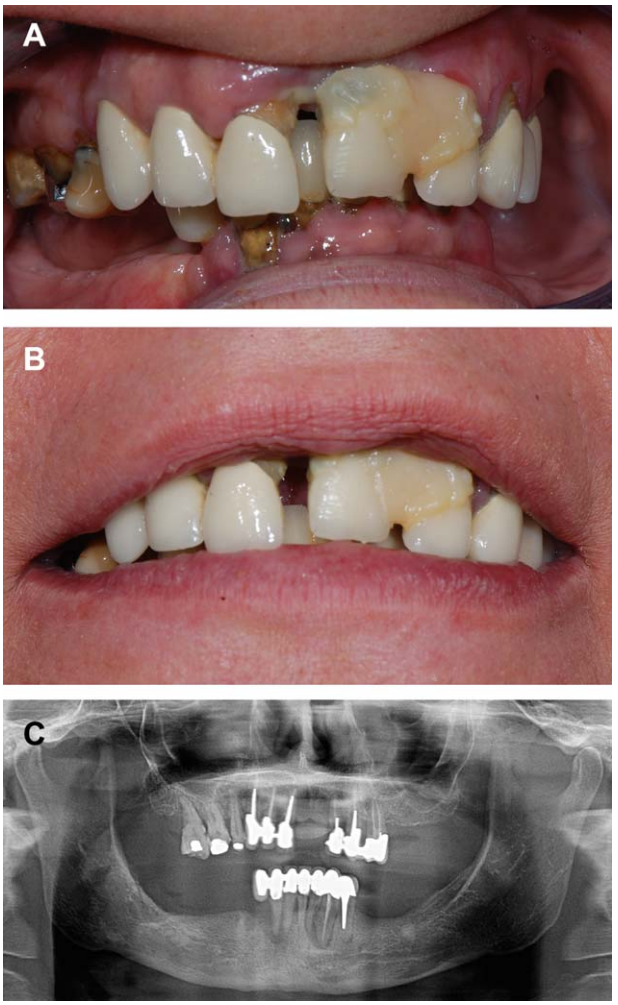


**Figure 1** (A) Compromised upper and lower jaw dentition. Frontal view. (B) Pre-operative smile view. (C) Pre-operative panoramic x-ray.

bone for placing in healed or extraction sites four to eight implants with a length of at least 8 mm, were asked to participate in the investigation in a consecutive order. Exclusion criteria were shown in Table 1.

Medical history of the patients was collected and study models were made. Preoperative photographs and radiographs including panoramic X-rays were obtained for initial screening and evaluation, and careful functional and aesthetic planning was performed (Figure 1, A–C). Before implant placement, all the patients underwent a computed tomography (CT) or cone beam CT scans according to a previously published double-scan protocol,[17,26–29] to assess the possibility of placing implants in healed bone or at the same stage as tooth extraction, if required.[28] (Figure 2A and B, Figure 3A and B). In case of immediately post-extractive implants, a previously reported, two pieces, radiographic guide was used for the diagnostic study and the virtual implant planning.[30,31] The Digital Imaging and Communication in Medicine (DICOM) data of the two sets of scans were transferred to a 3D soft-ware planning program (NobelGuide, Nobel Biocare) and matched to each other. The calibration of the software was performed every six months according to the guidelines of the manufacturer. The software was used to place the virtual implants with positions and angulations allowing an optimal prosthetic emergence profile. Four to eight implants were placed for the rehabilitation of each participant in healed sites or in post-extraction sockets, and whenever possible with an axial fashion. In all the recipients sites with less than 8 mm height, in patients that refuse to undergo a major bone augmentation procedures, implants were tilted according to the All-on-4 surgical protocol.[29,32]

After careful inspection and final verification, the virtual plan was approved and immediately sent to a

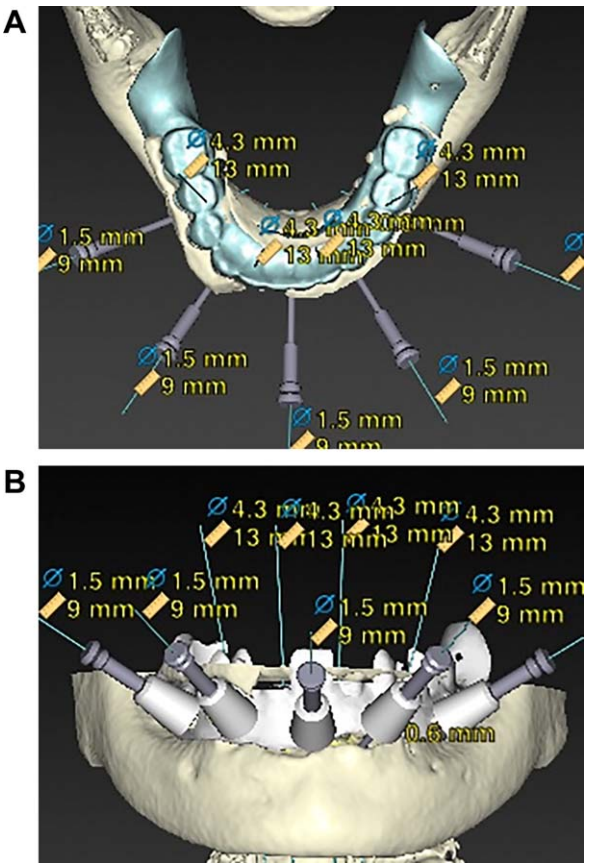


**Figure 2** (A) Three-dimensional implant planning lower jaw: two parallel and two tilted implants. Occlusal view. (B) Three-dimensional implant planning lower jaw: two parallel and two tilted implants. Frontal view.

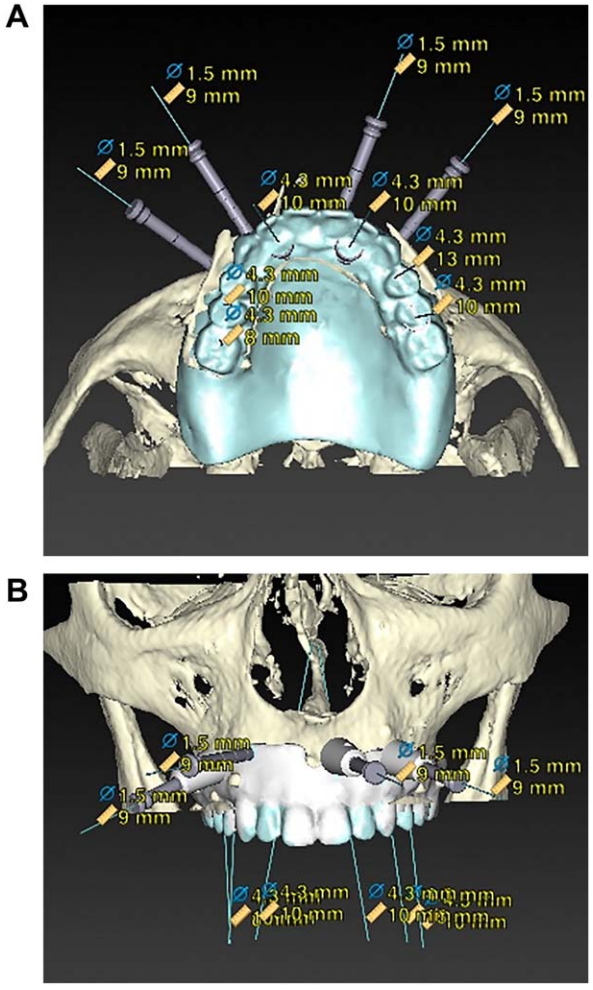


**Figure 3** (A) Three-dimensional implant planning upper jaw 6 parallel implants. Occlusal view. (B) Three-dimensional implant planning upper jaw 6 parallel implants. Frontal view.

milling center (NobelProcera, Nobel Biocare), where stereolithographic surgical templates with hollow metallic cylinders to guide were fabricated.

## Surgical Protocol

Patients received professional oral hygiene prior to the surgery and were instructed to rinse with a chlorhexidine mouthwash 0.2% for 1 minute, twice a day, starting 2 days prior to the intervention and thereafter for 2 weeks. The day of surgery, a single dose of antibiotic (2 g of amoxicillin and clavulanic acid or clindamycin 600 mg if allergic to penicillin) was administered prophylactically 1 hour prior to surgery and continued for 6 days (1 g amoxicillin and clavulanic acid or 300 mg clindamycin twice a day) after surgery. Local anesthesia was induced by using a 4% articaine solution with epinephrine 1:100.000 (Ubistein; 3M Italy SpA, Milan, Italy). The surgical templates were placed using the silicon surgical index derived from the mounted casts, and stabilized with three to four pre-planned anchor pins. The precise fit of the surgical templates was visually and manually checked before surgery. Implants were placed through the sleeves of the surgical template, in the planned anatomic sites using computer-guided template-assisted (NobelGuide, Nobel Biocare) surgery. Flapless or a miniflap approach, with or without tissue grafting was performed as needed (Figure 4A and B, Figure 5A–C). Two different types of implants were used. The NobelSpeedy Groovy implants (Nobel Biocare) features a flat-to-flat matched implant-abutment interface with a 0.7 mm-tall external hexagonal prosthetic connection, and the NobelReplace Tapered Groovy implants (Nobel Biocare) features a flat-to-flat matched implant-abutment interface with an internal tri-channel prosthetic connection. All the implants featured the same moderately rough, highly crystalline and phosphate-enriched titanium oxide surface (TiUnite, Nobel Biocare).

The drilling protocol recommended by the manufacturer was customized by under-pre-paring the width of the implant site according to the

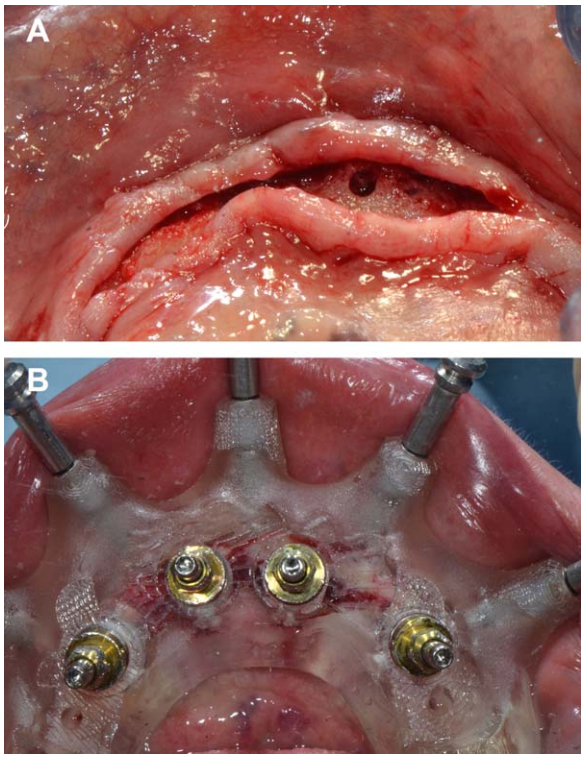


**Figure 4** (A) Miniflap elevation lower jaw. Occlusal view. (B) Guided implant installation lower jaw, 4 implants. Occlusal view.

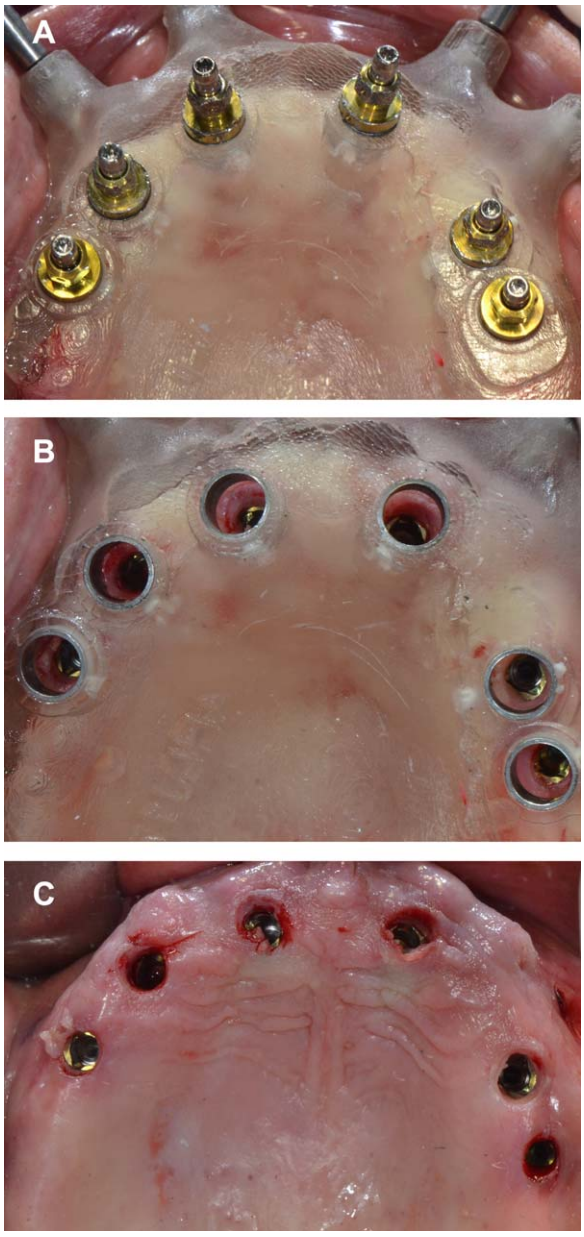


**Figure 5** (A) Guided implant installation upper jaw six implants. Occlusal view. (B) Flapless implant installation upper jaw. Occlusal view. (C) Flapless implant installation upper jaw after template removal. Occlusal view.

manufacturer's instructions in relation to the bone density,[33] achieving an insertion torque of 35–45 Ncm in the mandible and 45–55 Ncm in the maxilla, evaluated using the surgical unit (OsseoCare Pro Drill Motor Set, Nobel Biocare) during the implant insertion, after removal of the surgical template, in order to avoid any bias related to the friction of the guided implant mounter with the metallic sleeve of the template. The implant platform was positioned at the alveolar crest level or slightly below in the aesthetic areas, in order to enhance a prosthetically driven transmucosal emergence.

In the post-extracted sites, atraumatic tooth extractions were performed. Crowns of multi-rooted teeth were sectioned and then the roots were individually removed if needed using a periotome. The residual extraction sockets were debrided thoroughly of granulation tissue and residual periodontal ligament fibers with curettes. An examination of the residual alveolar socket was performed with the aid of a periodontal probe in order to evaluate minor residual bony defects, such as a slightly resorbed crestal bone or a small bony fenestration. The implant placement was planned through the software in order to engage as much as possible native bone and dense cortical bone structures, apically and laterally the alveolar walls, and the implant platform was positioned 1.5 mm below the buccal wall margin. In case of multi-rooted teeth, the implant placement was aimed to maintain the alveolar septum to increase primary stability and bone preservation.

Seventeen degrees or 30° angled multi-unit abutments were immediately connected only in cases were needed otherwise regular temporary abutment were connected to implants, and a full acrylic resin or metal-reinforced, screw-retained, provisional restoration was delivered (Figure 6). All patients received oral and written recommendations regarding medication, oral hygiene maintenance and diet.

*Prosthetic Protocol.* Definitive impressions were taken 2–6 months after healing at implant or abutment level with either plaster (Snow White Plaster no. 2, Kerr, Orange, CA, USA) and vinyl polysiloxane material (Flexitime dynamic Putty and Flexitime Light Flow [Heraeus Kulzer GmbH, Hanau, Germany]), according to a previously reported protocol.[23] The definitive implant-supported screw-retained FCDPs could be

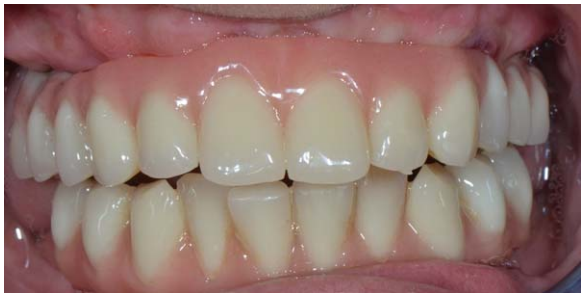

**Figure 6** Screw retained metal-resin immediate loaded prosthesis. Frontal view.

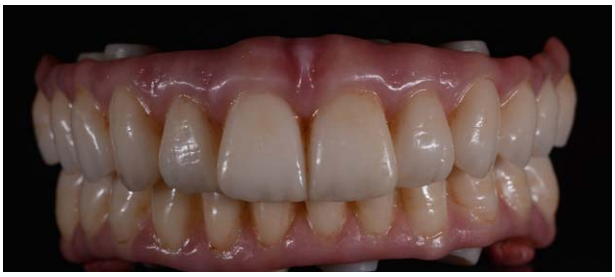

**Figure 7** Screw retained zirconia-ceramic final prosthesis. Lab frontal view.

designed with (hybrid design) or without pink material in the cervical region (crown design), and the veneering material could be of ceramic, acrylic or composite, according to the patient demands (Figure 7). Precision of the delivered restoration was clinically and radiographically tested in the patient's mouth by evaluating periapical radiographs taken according to the paralleling technique with a radiograph holder, tightening individual fixation screws at 15 Ncm with the others remaining unscrewed (Sheffield one-screw test).[34–36]

The occlusion was adjusted avoiding any premature contacts. Mutually protected occlusion with anterior guidance or balanced occlusion was used in cases of opposing natural dentition or a fixed dental prosthesis and complete removable denture, respectively. Follow- up visits were scheduled 1, 6 months and then annually up to 5 years of function (Figure 8, Figure 9A–C, Figure 10, Figure 11).

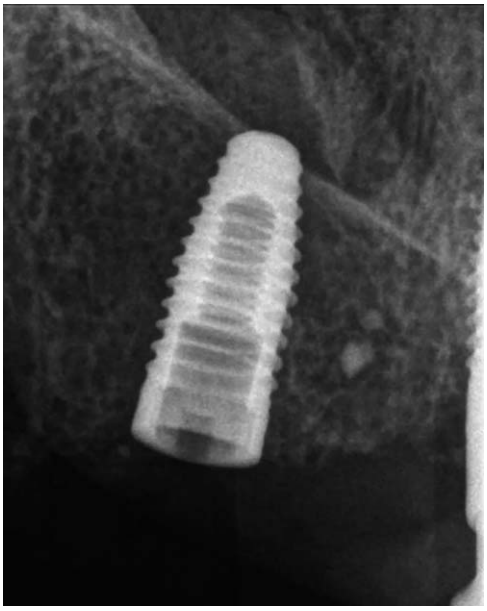

**Figure 8** Failed implant 6 month after loading.

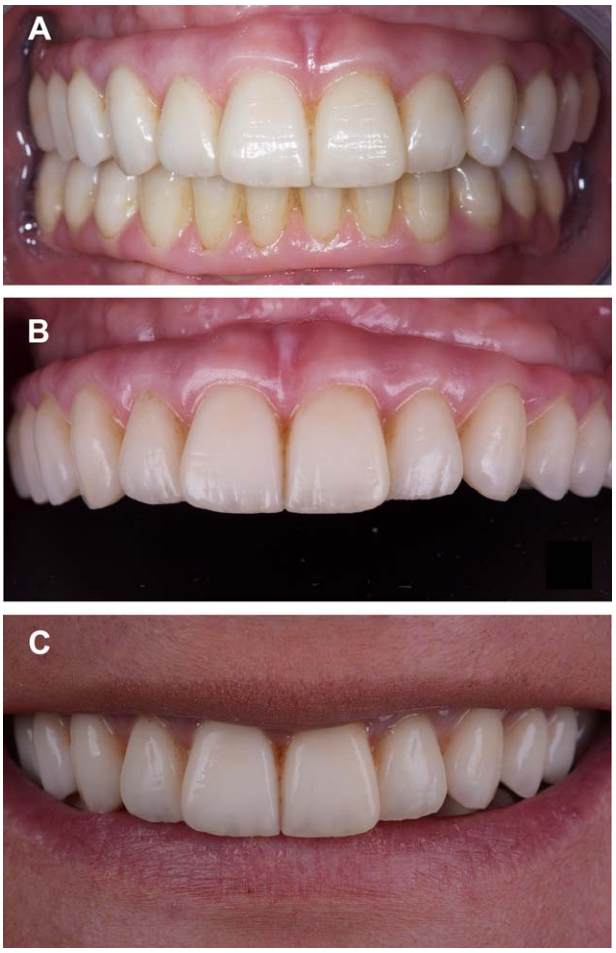


**Figure 9** (A) Final prosthesis 5 years after loading. Frontal view, (B) Final prosthesis 5 years after loading. Upper jaw frontal view, (C) Final prosthesis 5 years after loading. Smile view.

*Outcome Measures.* Primary outcomes were: implant and prosthetic success and survival rates.

"Successful" was defined an implant offering anchorage to a functional prosthesis, with not cause allergic, toxic, or gross infectious reactions either locally or systematically, without signs of fracture, radiolucency, suppuration or mobility. "Surviving" was defined an implant remaining in the jaw stable

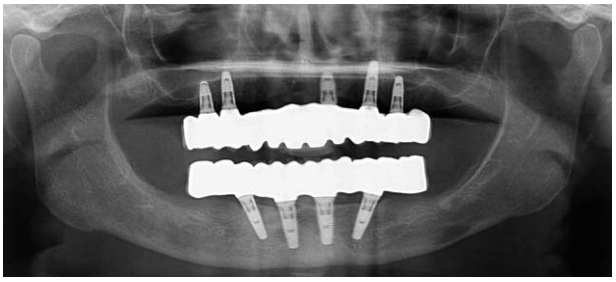

**Figure 10** Panoramic x-ray 5 years after loading.

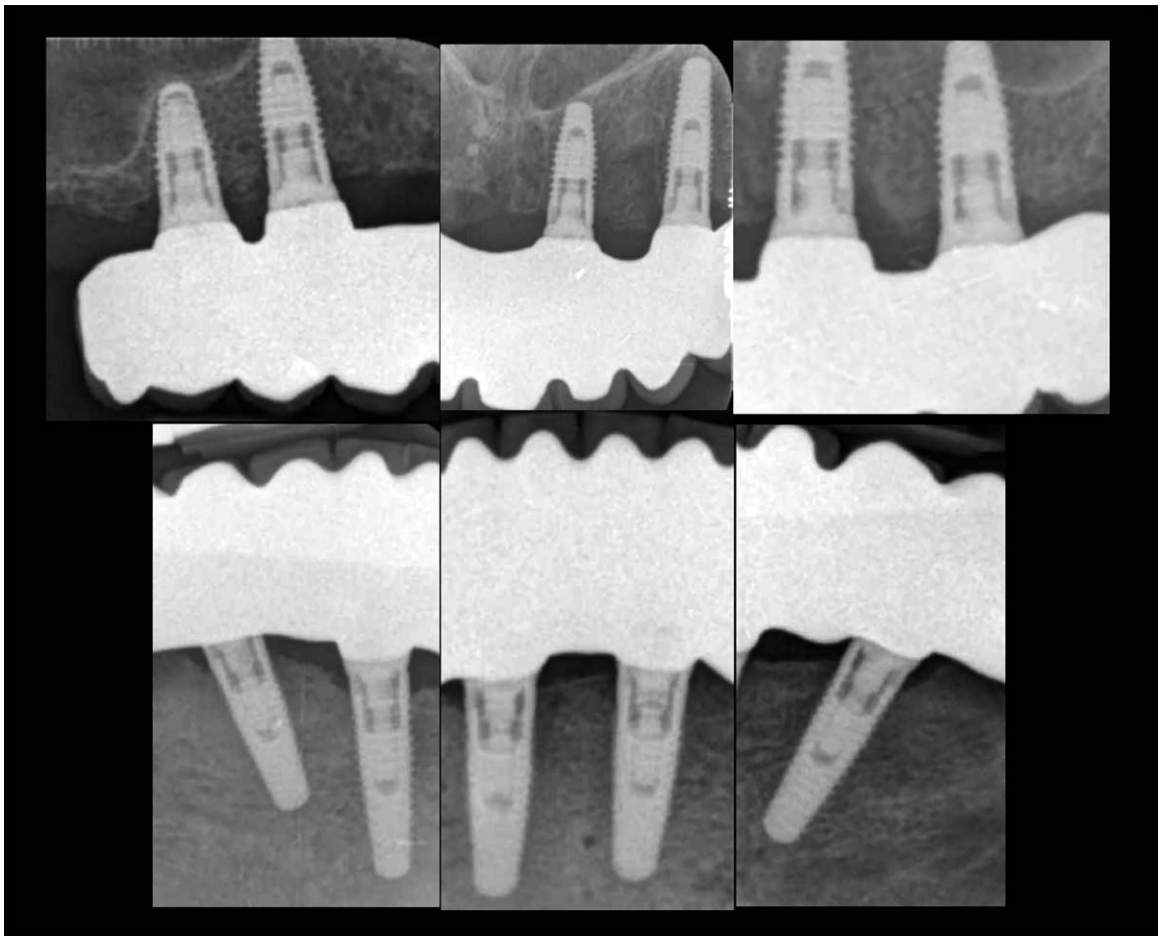

**Figure 11** Peri-apical x-ray 5 years after loading.

after the bar was removed, and when the patient's treatment is functionally successful even though all the individual success criteria are not fulfilled.

A "successful" implant-supported FCDP was defined the dental prosthesis remaining in function. The esthetic evaluation was assessed from dentist and subjects to be satisfactory at delivery and remains so during the study period.

A "surviving" implant-supported FCDP was defined the dental prosthesis remaining in function even though all success criteria are not fulfilled.

Secondary outcomes were: any surgical and prosthetic complications occurred during the entire follow-up and marginal bone loss (MBL). Any technical (fracture of the framework and/or the veneering material, screw loosening, etc.) and/or biologic (pain, swelling, suppuration, etc.) complications was considered;

The distance from the most coronal margin of the implant collar and the most coronal point of bone-to-implant contact was taken as MBL. MBL around the implants was evaluated on intraoral digital radiographs taken with the paralleling technique using a film-holder (Rinn XCP, Dentsply, Elgin, IL, USA) at implant placement (baseline) and after 1-year on function. The radiographs were accepted or rejected for evaluation based on the clarity of the implant threads. All readable radiographs were displayed in an image analysis program (DFW2.8 for windows, Soredex, Tuusula, Finland) calibrated for every single image using the known distance of the implant diameter or length. Measurements of the mesial and distal bone crest level adjacent to each implant were made to the nearest 0.1 mm and averaged at patient level.

An independent and fully blinded dentist evaluated the implant and prosthetic survival and success rate. Complications were assessed and treated by the treating clinicians who were non-blinded. The MBL was evaluated by an independent radiologist.

**TABLE 2 Patients' and Interventions' Characteristics**

| | Total |
|---|---|
| Males | 23 (34.8%) |
| Females | 43 (65.2%) |
| Mean age at implant insertion | 66,2 years |
| Smokers (<10 cigarettes/day) | 10 (15.2%) |
| Patients treated in the maxilla | 48 (72.7%) |
| Implants placed in the maxilla | 264 (74.2%) |
| Patients treated in the mandible | 18 (27.3%) |
| Implants placed in the mandible | 92 (25.8%) |
| Post-extractive implants | 59 (16.6%) |
| Implants placed axially | 288 (80.9%) |
| Implants placed tilted | 68 (19.1%) |
| Failed implants | 7 (2%) |
| Restorations delivered on 4 implants | 34 (50%) |
| Restorations delivered on 6 implants | 26 (38.2%) |
| Restorations delivered on 8 implants | 8 (11.8%) |

*Statistical Analysis.* All data analysis were carried out according to a pre-established analysis plan. A biostatistician with expertise in dentistry analyzed the data using SPSS for Windows release 18.0 (SPSS, Chicago, IL, USA). Descriptive analysis was performed for numeric parameters using means ± standard deviations (95% CI). Cumulative implants survival and success rates were reported with the implant as the statistical unit. Prosthetic success and survival rates, as well as complications and MBL were reported with the patient as the statistical unit of the analyses. Implant survival and success rate were also calculated using actuarial life table analysis. All statistical comparisons were conducted at the 0.05 level of significance.

## RESULTS

Four patients dropped out. Two patients moved out to another city and one patient got pregnancy before completion of the 1-year follow-up. The second patients died due to a pancreatic cancer between the 1- and 2-year follow-up. All of these patients were excluded from the statistical analysis. The final sample size resulted in 66 consecutive edentulous patients with a total of 356 implants (188 NobelSpeedy Groovy [52.8%], and 168 NobelReplace Tapered Groovy implants [47.2%], Nobel Biocare) and 68 screw-retained FCDPs. Minimum follow-up period was five year (mean 71.2 months, range 60–92). The main patient and implant characteristics are summarized in Table 2.

At the 5-year follow-up, seven implants (2%) on six patients (9.1%) failed resulting in a cumulative implant survival rate of 98% and 90.9% at implants and patient level, respectively. Most part of the failed implants ($n = 5$) were lost before definitive prosthesis deliver. In these patients, the provisional prosthesis was shortened and a new implant was placed in three cases, while in two maxillary cases the lost implant was not replaced (Figures 8, 10, 11). The final prosthesis was delivered after 3 months according to the original plan. One implant was lost after 40 months and one after 50 months after placement. In these cases a new implant was placed and a new final prosthesis was delivered. At the 5-year follow-up examination, two definitive prostheses failed resulting in a cumulative prosthetic survival rate of 97.1%. Life table analysis was reported in Table 3.

Thirteen patients (19.7%) experienced minor technical or biologic complication each resulting in 8 technical (12.1%) and 5 biologic (7.6%) complications reported during the entire follow-up period (Table 4). All the technical complications were resolved by adjusting the definitive prosthesis chairside, stabilizing the occlusion and a delivering a nightguard. Patients with biologic complications received a nonsurgical therapy consisting of

**TABLE 3 Life Table Analysis: Implant Survival Rate**

| Interval in Years ($t_i$) | Implants at Start of Interval ($a_i$) | Failures During Interval ($n_i$) | Survival Rate Within Period (%) ($S_i$) | Cumulative Survival Rate (%) ($CS_i$) |
|---|---|---|---|---|
| 0–1 | 356 | 5 | 98.6% | 98.6% |
| 1–2 | 351 | 0 | 100% | 98.6% |
| 2–3 | 351 | 0 | 100% | 98.6% |
| 3–4 | 351 | 1 | 99.7% | 98.3% |
| 4–5 | 350 | 1 | 99.7% | 98% |

**TABLE 4 Technical and Biologic Complications**

| | Total |
|---|---|
| Prosthetic screw loosening | 2 (3.0%) |
| Fracture of the provisional acrylic prosthesis | 1 (1.5%) |
| Chipping of the veneerer material (definitive restoration) | 5 (7.6%) |
| Mean mesio-distal peri-implant bone loss greater than 3.0 mm at the 5-year follow-up | 5 (7.6%) |

mechanical debridement with a glycine-based air-powder abrasive device and local application of antimicrobial agents followed by oral hygiene instructions and motivation.

After an initial mean MBL of $1.09 \pm 0.38$ mm, all implants lost a slightly amount of bone during function. At the 5-year follow-up, the mean MBL was $1.61 \pm 0.41$ mm. The radiographic data are summarized in Table 5.

## DISCUSSION

The present prospective observational study was designed to evaluate the 5-year clinical and radiographic outcomes computer-guided template-assisted implant placement and immediate loading of screw-retained FCDP. Because it was designed as a single cohort prospective study, the limitation of the current study was the lack of a control group. However, 68 FCDPs, delivered on 356 implants in 66 participants, were followed for at least five years after loading, allowing some preliminary and generalizable conclusions to be drawn.

The results of the present study are in agreement with previously published works on immediate loading of edentulous maxilla and mandible with fixed complete denture prostheses.[29] According to a recent systematic review and meta-analysis, in the maxilla, the implant survival rate ranged from 90.43% to 100% (27 studies, follow-up ranged between 1 and 10 years), while, in the mandible, the implant survival rate ranged from 90% to 100%, (28 studies, follow-up ranged between 1 and 10 years).[37] The prosthesis survival rate ranged from 90% to 100%, and 93.75% to 100%, on the maxilla and mandible respectively.[37] A prerequisite for immediate loading protocol is an insertion torque of at least 30 Ncm (range from 10 to 80 Ncm).[37]

Overall, 13 (19.1%) technical and biologic complications were experienced during the entire follow-up period. These results are in accordance with previously published studies.[1,17,20,21,29,32] Three (4.5%) complications were reported before the definitive prosthesis delivery (2 prosthetic screw loosening and 1 fracture of the provisional prosthesis, Table 4). According to a previously published retrospective study,[32] delivery of a metal-reinforced temporary restoration during healing might be advisable. After delivery of the final restorations, 5 technical (7.6%) and 5 biologic (7.6%) complications were experienced. All the technical complications were chipping of the veneerer material and they were resolved chairside. The 5 biologic complications (mean mesio-distal peri-implant bone loss greater than 3.0 mm at the 5-year follow-up) seem to be ascribable purely to plaque accumulation in patients with "host susceptibility." All the patients were treated with nonsurgical therapy. The neck of the implants as never exposed. Hygiene instructions and motivations were reinforced, and patients were placed in a well-structured hygiene and occlusal maintenance program with more frequent follow-ups. In the subsequent follow-up visits the bone stopped receding and the soft tissue remained stable.

In the present study the overall 5-year mean MBL was $1.61 \pm 0.41$ mm, demonstrating well maintained marginal bone level in the medium-term perspective. Nevertheless, no comparisons between maxilla and mandible, and different number of implants to support FCDP were made. Little evidence from RCT or systematic reviews is present on the preferred or best number of implants to be used for the support of a fixed complete dental prosthesis in the

**TABLE 5 Marginal Bone Loss During Follow-Ups**

| 0–12 ($n$=356) | 12–24 ($n$=351) | 24–36 ($n$=351) | 36–48 ($n$=351) | 48–60 ($n$=350) | 0–60 |
|---|---|---|---|---|---|
| $1.09 \pm 0.38$ mm | $0.16 \pm 0.08$ mm | $0.10 \pm 0.07$ mm | $0.15 \pm 0.09$ mm | $0.10 \pm 0.08$ mm | $1.61 \pm 0.41$ mm |

edentulous maxilla or mandible, and no consensus has been reached.[38–41] Nowadays, clinical research is focusing on shorter and less invasive procedures. Tallarico and colleagues, in a randomized controlled trial concluded that four to six implants may represent a predictable treatment option for the rehabilitation of complete edentulous patients in the medium term.[29] However, a slight risk of complications during the entire follow-up period and a statistically higher mean MBL between 48 and 60 months after implant loading were experienced reducing the number of the implants.[29]

Computer-guided template-assisted surgery allows the clinician to place implants with less pain and swelling surgery.[17] In addition, implant-supported fixed acrylic resin prosthesis can be fabricated in advance and immediately delivered to the patient. These aspects of minimally invasive and simplified surgery, along with reducing the treatment time and post-surgical discomfort, are beneficial to the patient.[17] Despite that the current literature is growing, the long-term predictability of immediate implant placed in the atrophic mandible and maxilla by using computer-assisted template-based surgery is still pending, and limited scientific evidence comparing the position of the post-operative implants to the preoperative planning on patients with the voxel-based matching technique is available. Moreover, substantial deviations in three-dimensional directions have been reported in the literature between virtual planning and the final intraoral implant position.[16–20] Although, in the present study, such deviations did not produce any clinically relevant drawback, clinicians should take into consideration the differences reported in the literature between virtually planned implant position and actual position of implants in the patient's mouth, in order to plan implant placement procedures with adequate safety.

## CONCLUSION

Computer-guided template-assisted implant placement and immediate loading of screw-retained FCDP might be a valid treatment concept for the edentulous patients, with a 5-year implant survival rate of 98%. The substantial deviations in three-dimensional directions reported in the literature between virtual planning and the final intraoral implant position did not produce any clinically relevant drawbacks in the present study. Further, long-term studies are needed to confirm these results.

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