CLINICAL ORAL IMPLANTS RESEARCH

Christoph Vasak
Ralf J. Kohal
Stefan Lettner
Dennis Rohner
Werner Zechner

Clinical and radiological evaluation of a template-guided (NobelGuide™) treatment concept

Authors' affiliations:
Christoph Vasak, Werner Zechner, Department of Oral Surgery, Bernhard Gottlieb Dental School, Medical University of Vienna, Vienna, Austria
Ralf J. Kohal, Department of Prosthodontics, Dental School, University Hospital Freiburg, Freiburg, Germany
Stefan Lettner, Karl Donath Laboratory for Hard Tissue and Biomaterial Research, Medical University of Vienna, Vienna, Austria
Dennis Rohner, Department of Oral and Maxillofacial Surgery, cfc Hirslanden Medical Center, Aarau, Switzerland

Corresponding author:
Christoph Vasak, MD, DMD
Department of Oral Surgery
Bernhard Gottlieb School of Dentistry
Medical University of Vienna
Sensengasse 2A
A-1090 Vienna
Austria
Tel.: +43 1 40070 4101
Fax: +43 1 40070 4109
e-mail: christoph.vasak@meduniwien.ac.at

Key words: computer-aided implant dentistry, concept evaluation, dental implants, immediate loading, survival rate, template-guided surgery

Abstract

Objectives: The study was designed to evaluate the clinical use of the NobelGuide™ concept over a follow-up period of 12 months with respect to implant success and survival rates, development of soft tissue condition and recording of potential surgical and prosthetic complications. In addition, radiological assessment of peri-implant bone levels was performed at the 1-year follow-up post-implant placement.

Material and methods: Thirty patients (male/female = 15/15) with partially dentate and edentulous mandibles and maxillae were included. All patients were planned and operated on using the computer-aided, template-guided treatment concept NobelGuide™. Overall, 163 implants (NobelReplace® Tapered Groovy) were placed (mandible/maxilla = 107/56 implants). Recall appointments were performed after 1–2 weeks, 1, 3, 6 and 12 months after implant placement. Clinical parameters of the soft tissue conditions [e.g. bleeding on probing (BoP), pocket probing depth $\geq$3 mm (PPD), marginal plaque index (mPI)] and the dentist's esthetic and functional evaluation using a visual analogue scale (VAS) were documented. Marginal bone level was evaluated on radiographs made at implant insertion and at the 1-year follow-up.

Results: All 30 patients with 161 implants completed the 1-year follow-up resulting in a cumulative survival rate of 98.8% (two implant losses). Clinical parameters improved in a majority of the implants. The mean marginal bone level at implant insertion and at 1-year follow-up was reported with 0.17 mm (SD 1.24; n = 125) and −1.39 mm (SD 1.27; n = 110), respectively. The mean change in bone level from implant insertion to 1 year was −1.44 mm (SD 1.35; n = 98).

Conclusions: The 1-year follow-up showed a cumulative survival rate and success rate of 98.8% and 96.3%, respectively. Immediate or delayed loading of implants using a flapless, guided surgery approach (NobelGuide™) appears to be a viable concept demonstrating good clinical and radiographic outcomes at the 1-year time point.

Apart from predictable osseointegration (Albrektsson et al. 1988; Pjetursson et al. 2007; Jung et al. 2008), alignment of implants for a functional and esthetic result is critical for any implant-prosthetic restoration. Any surgical intervention will be associated with a growing risk of complications with increasing complexity (Ruppin et al. 2008). Computer-aided implant planning and implant placement has been developed to allow for more efficient preoperative planning of safe implant placement with adequate consideration of the future suprastructure. Using a customized stereolithographic implantation template, the NobelGuide™ concept permits appropriate implementation of preoperative planning. Treatment planning by virtual three-dimensional implant placement is based on the anatomical and prosthetic considerations and criteria.

Accurate preoperative diagnostic assessment and planning with subsequent template-guided implant placement is to provide for predictable surgical results (Puig 2010). However, template-guided implantology is not only accurate, and thus predictable, implant placement, but also a minimal invasive flapless surgical procedure (Hahn 2000). Similarly, precise implant placement in combination with a rapid surgical procedure will be associated with a reduced burden for the patient and decreased morbidity (Rocci et al. 2003). With adequate precision in the implementation of preoperative planning,

Date:
Accepted 6 August 2012

To cite this article:
Vasak C, Kohal RJ, Lettner S, Rohner D, Zechner W. Clinical and radiological evaluation of a template-guided (NobelGuide™) treatment concept.
Clin. Oral Impl. Res. **00**, 2012, 000–000
doi: 10.1111/clr.12038

© 2012 John Wiley & Sons A/S

preoperative fabrication of the prosthetic restoration may also allow for immediate restoration and loading (van Steenberghe et al. 2005; Sanna et al. 2007; Komiyama et al. 2008). Similarly, osseointegration may be ensured in spite of immediate loading of dental implants (van Steenberghe et al. 2002; Glauser et al. 2003; Olsson et al. 2003). Apart from being a minimally invasive, low-complication surgical method, template-guided implant placement may also provide for immediate esthetic and functional rehabilitation (Gillot et al. 2010).

While template-guided implantology appears to warrant safe, precise and less invasive implant placement, its clinical application should be critically evaluated, especially because navigated implantology has already assumed part of daily clinical routine. In addition, only few scientific and, in particular, clinical studies of the concept of computer-aided implantation in combination with preoperatively fabricated fixed restorations for implementation of immediate loading have been reported (van Steenberghe et al. 2002, 2005; Sanna et al. 2007; Komiyama et al. 2008).

Thus, it has been the primary objective of this study to evaluate the clinical use of the NobelGuide™ concept over a follow-up of 12 months with regard to implant success and survival rates as well as the development of soft tissue conditions and for collecting and recording any surgical and prosthetic complications. The secondary objective was to provide for a radiological evaluation of peri-implant bone level at the 1-year follow-up post-implant placement.

Material and methods

Patients

Three study centers (cfc Hirslanden Medical Center, Switzerland; Bernhard Gottlieb University School of Dentistry, Medical University Vienna, Austria and Dental School, University Hospital Freiburg, Germany) were involved in this prospective, multicenter study. The study protocol was submitted to and approved by the three local Ethics Committees (Study numbers in order of the above-mentioned centers: EK 2007/017; EK 320/2006; EK 68/07). In the time from 2008 to 2009, 30 consecutive patients were enrolled in the study after having signed the informed consent.

The patient population enrolled included patients (male/female = 15/15) with partially dentate and edentulous mandibles and maxillae. Subjects were consecutively included according to the inclusion criteria and excluded according to the exclusion criteria. For study inclusion, subjects needed to be in such a physical and mental condition to carry out a 1-year follow-up period. Furthermore, sufficient amount of bone should guarantee implant placement without general or local bone augmentation procedures. Five to six implants and 2–4 implants need to be placed in fully edentulous and partially edentulous cases, respectively. Subjects were excluded if the treatment could affect the patient's health or if clinical signs of severe functional disorders or any disorders, such as previous tumors, chronic bone disease or previous irradiation in the planned implant area were existent. In addition, patients where excluded if teeth adjacent to the planned implant site showed ongoing infections, endodontic or periodontal problems and if extraction sockets, healed <3 months, in the area for implant placement were present.

All patients were planned and operated on by experienced prosthodontists and surgeons (R.K., D.R., C.V., W.Z.) using the computer-aided, template-guided implantation system NobelGuide™ (NobelBiocare, Gothenburg, Sweden) and were followed for 12 months after receiving the individually designed framework as their prosthetic restoration. Possible drop-outs and withdrawals, as well as adverse events, were recorded during the entire study and follow-up period.

Pre-treatment examination

Subject history and oral status were recorded, and a preoperative radiographic orthopantomogram was performed. On the basis of the clinical and radiological diagnosis, a prosthetically idealized CT template with appropriate fiducial markers was fabricated. Preoperative high-resolution CT scans (SOMATOM Sensation 10; Siemens Medical, Forchheim, Germany; Tomoscan SR-6000; Philips Medical Systems, Einhoven, the Netherlands; NewTom 3G; ImageWorks, Elmsford, NY, USA) of patients and templates applying the double-scan technique (Verstreken et al. 1998) were performed according to the NobelGuide™ protocol at all participating study sites.

Planning phase

The two DICOM data sets collected were converted and merged within the Procera™ planning software (Nobel Biocare, Gothenburg, Sweden) allowing for three-dimensional preoperative implant positioning based on the anatomical and prosthetic environment and conditions. The finalized preoperative planning was sent to a certified manufacturing facility (Nobel Biocare) for having a stereolithographic surgical template manufactured.

Surgical procedure

Guided implant site preparation and insertion was carried out according to the clinical procedure for the NobelGuide™ concept. The implants (NobelReplace® Tapered Groovy; Nobel Biocare) were inserted according to the pre-treatment planning using a flapless surgical procedure. Depending on the dental status, a mucosa-supported, tooth-supported or tooth- and mucosa-supported surgical template was applied. When preparing the implant sites, the surgeons evaluated bone quality clinically and bone quantity from the radiographs, according to the scale suggested by Lekholm & Zarb (1985).

Prosthetic treatment

The prosthetic reconstructions were carried out according to the NobelGuide™ concept. At two study sites, each patient received a fixed prosthetic reconstruction on the same day as surgery. At one study site, healing abutments were placed postoperatively. After a healing period of 2–3 months and depending on bone quality, the implant-supported prosthesis was seated. The provisional prosthesis consisted of a stable, individually designed mostly fiber-reinforced acrylic device with light centric contacts. The final prosthetic solution consisted of an individually designed framework of titanium in fully edentulous cases and a titanium or zirconia framework in partially dentate cases provided with acrylic or porcelain teeth depending on individual conditions. The final prosthesis was screw-retained or cemented onto the implants. If immediate loading was performed, all patients were advised to eat soft food during 2 months after surgery and to irrigate with chlorhexidine solution for 2–4 weeks after surgery.

Recall

The subjects were followed on a regular basis throughout the entire study period as required by the study protocol. Recall appointments were performed after 1–2 weeks, 1, 3, 6 and 12 months after implant placement. At each study center, all appointments were performed by one experienced oral surgeon or prosthodontist.

For the assessment of the success rates on patient, prosthesis and implant levels, success criteria suggested by van Steenberghe

© 2012 John Wiley & Sons A/S

(1997) were used during the follow-up period. Further follow-up visits included documentation of the soft tissue conditions (e.g. bleeding on probing (BoP), pocket probing depth ≥3 mm (PPD), marginal plaque index (mPI), signs of inflammation and pain), signs of bruxism and the dentist's esthetic and functional evaluation using a visual analogue scale (VAS; defining four scales: excellent, good, acceptable, poor). The prosthetic evaluation of the delayed loading cases was accordingly performed 2–3 months after implant placement. In addition, potential serious and non-serious adverse events were reported.

Orthopantomograms (OPGs) taken after surgery and 12 months postoperative had been used for the radiographic evaluation. Although standardized intra-oral radiographs are the most precise method to visualize peri-implant bone changes, OPGs were chosen to postoperatively control adjacent anatomical structures as the mandibular canal, mental foramen, maxillary sinus and teeth to the placed implants. However, no significant differences of marginal bone level measurements between standardized intraoral and panoramic radiographs had been demonstrated (De Smet et al. 2002; Zechner et al. 2003). Marginal bone levels on both the mesial and distal aspects of the implant were measured by two independent radiologists (Gothenburg University, Sweden). The lower edge of the implant collar was used as a reference point for the marginal bone level measurements. Marginal bone level was reported at implant insertion and at the 1-year follow-up. Film radiographs were measured to the nearest 0.1 mm using a ×7 magnifying lens. Digital radiographs were displayed in software (Illustrator CS; Adobe Systems Inc, San Jose, CA, USA) on a 24-inch LCD screen (iMac; Apple Inc, Cupertino, CA, USA). The screen resolution was 1920 × 1200 pixels. The measuring tool of the software was used to make the measurements with adequate consideration of the magnification. The radiologist adjusted brightness, contrast and zoom of the images to achieve optimal measuring conditions. Displayed implants with an undetermined peri-implant bone level were excluded from measurements.

Statistical methods

Cumulative survival rate (CSR) was calculated by an Altman's actuarial life table method. Descriptive statistics including mean values, median values, standard deviations and percentages were used for presentation of the results. To investigate the effect of immediate and delayed loading on bone levels over time (from implant placement to 12 months), a linear mixed model (Bates et al. 2012) including patient and implant as nested random effect was computed. Missing data were handled using multiple imputation (m = 25) (Little & Rubin 1987; van Buuren & Groothuis-Oudshoorn 2011). Further analysis was performed to demonstrate an effect of several potential confounders (e.g. age, sex, implant position, number of implants, periodontitis, smoking habits). P-values below a level of 0.05 were considered as statistically significant. All computations were carried out using (R Development Core Team 2012).

Results

The 30 patients enrolled in the time from 2008 to 2009 showed an age distribution from 31–80 years, most of the patients (n = 15) were between 61 and 70 years. A history of periodontitis was reported in 37% (11 patients) of the enrolled patients; at study enrollment, 21 patients showed good and nine patients acceptable oral hygiene. Patients with poor oral hygiene were not enrolled. Twenty-six of the 30 patients enrolled (87%) were non-smokers. The duration of edentulism at the implant site was in <1 year in 13 patients (43%), between 1 and 5 years in 11 (37%) and more than 5 years prior to implant placement in six patients (20%).

All patients underwent an uneventful one-stage implant surgery. An overall 163 Nobel-Replace® Tapered Groovy implants (maxilla/mandible = 56/107) were placed in the study. All implants were placed according to the manufacturer's instructions and achieved primary stability (≥35 Ncm) except for four implants (2%) exhibiting rotational mobility. Implant distribution, implant size and implants in relation to the bone quality and bone quantity are reported in Fig. 1 and Tables 1 and 2.

At two study centers, an overall 17 patients (98 implants) received a fixed prosthetic reconstruction. At one study site, all 13 patients (65 implants) were provided with healing abutments for a period of 2–3 months. During the healing period, all patients used a provisional prosthesis. After the healing period, the prosthetic restoration was seated.

For the delayed loading group, two implants (anterior/posterior = 1/1) failed, one each at the 1 and 3-month follow-up visits in two separate patients, resulting in a cumulative survival rate of 98.8% at 1 year after implant placement (Fig. 2). For both implants, no primary stability could be achieved (Tables 1 and 2). One implant (1-month follow-up) was removed during the healing period because of postoperative infection. Concerning the second failed implant (3-month follow-up), non-osseointegration occurred on account of inappropriate pressure of the provisional prosthesis on the implant's healing abutment.

For the evaluation of the concept, the time for planning, fit of the surgical template, time for the surgical procedure and for placing the prosthetic restoration were documented. Dependent on the number of implants, the virtual planning as well as the surgical procedure was mostly performed within 40 min. In most of the cases, the surgical template and the prosthetic restoration were placed in <5 and 20 min, respectively.

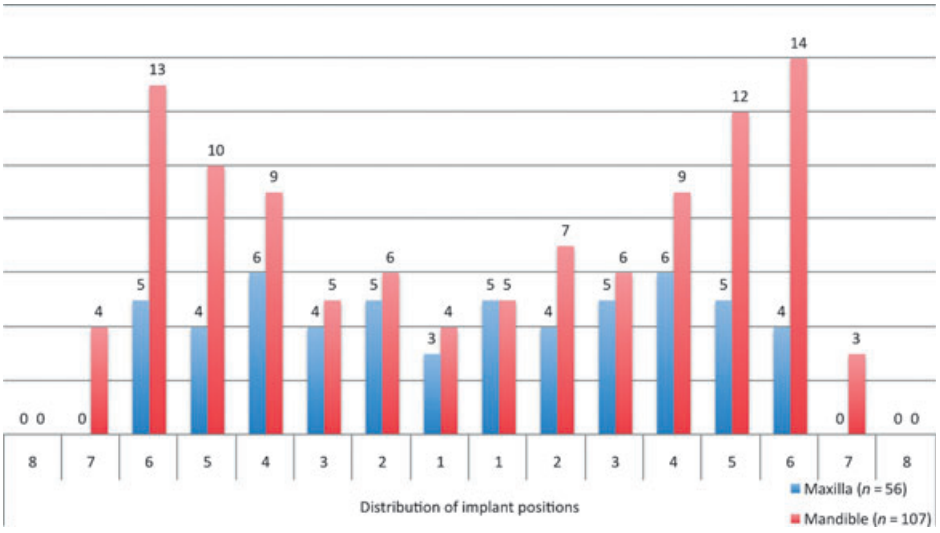

Fig. 1. Distribution of all implants according to implant position.

© 2012 John Wiley & Sons A/S

Table 1. **Distribution of all implants according to implant parameters and jaw (failed implants in parenthesis)**

NobelReplace tapered groovy implants	Lengths in mm	Maxilla	Mandible
3.5 mm diameter	8	0	0
	10	1	9
	13	5	23 (1)
	16	3	3
4.3 mm diameter	8	3 (1)	1
	10	14	23
	13	22	26
	16	2	5
5.0 mm diameter	8	1	5
	10	1	12
	13	4	0
	16	0	0
Total		56	107

Table 2. **Distribution of all implants according to bone quality and quantity (failed implants in parenthesis)**

Bone quality & quantity	1	2	3	4	Total
A	0	24	0	0	24
B	7	48	32	0	87
C	0	7	23	0	30
D	0	5	11 (1)	6 (1)	22 (2)
E	0	0	0	0	0
Total	7	84	66 (1)	6 (1)	163 (2)

Eighty per cent of the surgical templates showed an ideal fit. The others were preoperatively modified for precise fit according to the manufacture's protocol.

All patients completed the 1-year follow-up. No subjects were withdrawn from the study. The type of indications and restorations are shown in Fig. 3. At the 1-year follow-up, 24 patients were provided with their final prosthetic restoration. In most of the cases, a titanium framework with acrylic occlusal surface was used. Generally, the final prostheses were screw-retained on the implants, only one patient received a cemented final prosthetic reconstruction. Six patients had a temporary reinforced prosthetic reconstruction at the 1-year follow-up because of their personal decision. Therefore, it could be stated that all treated patients met the success criteria as the patient's treatment had been improved upon the patient's request.

One serious adverse event was reported 3 h after prosthesis connection when a patient experienced a hypoglycemic episode of unconsciousness due to diabetes. The surgically related non-serious adverse events included a postoperative inflammation of an anchor pin ruptured mucosal site and reduced mouth opening for 1 week because of posterior implant placement. The reported prosthetic-related non-serious adverse events were screw loosening (five cases), lip biting (two cases), chipping (one case) and restoration-related sigmatism (one case). As a result of repeated screw loosening, one immediately restored full-arch reconstruction had to be refabricated. In the group of immediate loading 94.1% of the prostheses (one out of 17 cases) met the success criteria for successful prosthesis as only one prosthesis had to be removed during the follow-up period. Regardless of loading group and type of implant-supported reconstruction, no further removals were reported resulting in an overall success rate of 96.7%.

The documented key parameters for the follow-up visits at 1–2 weeks, 1, 3, 6 and 12 months post-implant placement and prosthetic treatment were summarized as follows. In 90% of the cases, no signs of inflammation and/or pain were reported at 1–2 weeks follow-up. At 1-year follow-up visit, an increase to even 98% was documented. The gingival mucosa showed healthy conditions at an average of 29% at the 1-month follow-up, which increased considerably to up to 63% at the 1-year follow-up. Bleeding on probing (BoP) was found on 70.2% of implant sites at the 1-month follow-up and decreased to 49.1% at the 1-year follow-up. Plaque (mPI) was located on 24% of the evaluated implant sites at the 1-month follow-up and slightly decreased to 20% at 1-year follow-up (Table 3). Concerning the reported pocket probing depths (PPD) of $\geq$3 mm, an improvement [45 cases (1-month) to 32 cases (1-year)] was documented over the recall period. However, pocket depths of $\geq$ 5 mm (maximum 6 mm) had slightly increased over time [0 cases (1-month) to 7 cases (1-year)] (Fig. 4). Moreover, the dentist's esthetic and functional evaluation of the prosthetic restoration increased between the 3-month (esthetic: 57%; functional: 57%; summarized percentage for excellent/good) and the 1-year follow-up (esthetic: 97%; functional: 93%; summarized percentage for excellent/good). Signs of bruxism were reported with 1% of the implants at the 3-month, 6-month and 1-year follow-up.

In addition, marginal bone level and marginal bone remodeling were evaluated using the orthopantomograms (OPGs) taken at implant insertion and at 12 months. As reference point, the top of the implant shoulder was used. Negative numbers indicate bone levels apical to the reference point. The mean marginal bone level at implant insertion was 0.17 mm (± 1.24 mm; n = 125) and at 1 year −1.39 mm (± 1.27 mm; n = 110) (Table 4). As the collar height of the used implants is 1.5 mm, it can be stated that the mean marginal bone level was maintained well above the level of the first thread (Fig. 5). The mean marginal bone remodeling between the time of implant insertion and 1 year was −1.44 mm (± 1.53 mm; n = 98) (Table 4).

As the study represented two types of loading protocols (immediate loading vs. delayed loading), the radiological evaluation of the marginal bone was also accomplished separately for the two groups. The mean marginal bone levels for the immediate loading protocol were 0.02 mm (± 0.95 mm; n = 70) at implant placement and −0.92 mm (± 0.81 mm; n = 63) at the 1-year follow-up. For the delayed loading protocol, the mean marginal bone levels were 0.37 mm (± 1.52 mm; n = 55) at implant placement and −2.01 mm (± 1.49 mm; n = 47) at the 1-year follow-up (Table 5). According to the linear mixed model, lower marginal bone levels were seen for implants subject to delayed loading during the first year of loading when

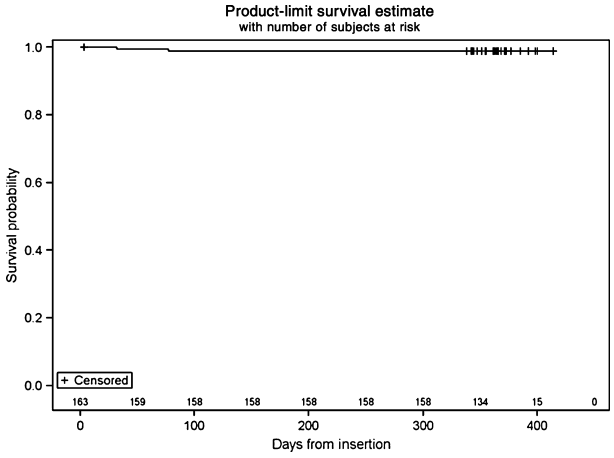

Fig. 2. Kaplan–Meier curve: 1-year cumulative survival rate resulted in 98.8%.

© 2012 John Wiley & Sons A/S

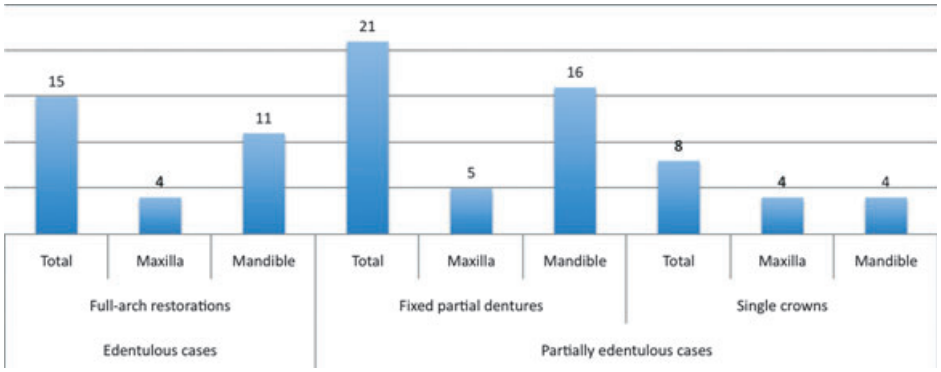

Fig. 3. Type of indications and restorations.

Table 3. **Development and changes of clinical parameters (BoP, mPI) within the 12-month follow-up period**

n = 163	1 month (%)	3 month (%)	6 month (%)	1 year (%)
Bop				
0	29.8	59.4	61.9	50.9
1	70.2	40.6	38.1	49.1
mPI				
0	76	83.6	83	80
1–3	24	16.4	17	20

Bop, Bleeding on probing; mPI, marginal plaque index.

compared to implants subject to immediate loading ($P = 0.005$). Also the mean marginal bone remodeling (Table 6) showed significantly ($P = 0.005$) less bone loss for the immediate loading protocol (mean −0.78 mm ± 0.99 mm; $n = 51$) compared to the delayed loading protocol (mean −2.15 mm ± 1.34 mm; $n = 47$).

The analysis concerning several potential confounders (e.g. age, sex, implant position, number of implants, periodontitis, smoking habits) did not reveal an effect on the results.

On the basis of the applied success criteria for implants, a total of 157 implants (96.3%) were successful. Among two implant failures, four implants in one patient exhibited an increased marginal bone loss, notable at the same patient, where an inappropriate pressure of the provisional prosthesis caused an implant loss.

Discussion

The advantages of state-of-the-art flapless surgery include reduced postoperative pain and swelling, reduced intraoperative bleeding, preservation of soft and hard tissue and maintenance of periosteal blood supply (Brodala 2009; Komiyama et al. 2008; Nkenke et al. 2007; Fortin et al. 2006). However, the flapless procedure is associated with a reduced surgical overview, thus requiring appropriate implementation accuracy of template-guided implantation systems (Vercruyssen et al. 2008; Vasak et al. 2011). Upon accurate and precise implementation of preoperative planning, immediate restoration/loading by preoperative fabrication of the implant-prosthetic restoration can be achieved (van Steenberghe et al. 2002). The objective of this study was to evaluate the clinical use of the Nobel-Guide™ concept over a follow-up period of 12 months with respect to implant success and survival rates as well as development of soft tissue conditions and to record and collect surgical and prosthetic complications. Moreover, peri-implant bone level was radiographically evaluated at 1 year after implant placement and implant-prosthetic restoration.

In the present study a cumulative implant survival rate of 98.8% could be documented over a follow-up period of 12 months. A review article on the topic of "flapless implant surgery" published by Brodala in 2009 comprised 14 articles with an average observation period of 19 months. The prospective cohort studies reviewed showed similar results regarding the implant survival rate (98.6%). Similarly, the retrospective studies of minimally invasive implant placement provided for implant survival rates of 95.9% and thus are comparable with the conventional surgical procedure.

A total of four implants showed lacking primary stability (≥35 Ncm). Implant losses ($n = 2$) were exclusively seen in the group with delayed loading. The two implant losses encountered in separate patients presumably were the result of inadequate primary stability because of reduced bone quality. This is consistent with the observation of Meredith (1998), who described implant stability, type of implant loading and thus implant success and/or osseointegration as critical factors.

In the immediate loading group, no implant losses were seen during the observation period. As a result of the immediate loading,

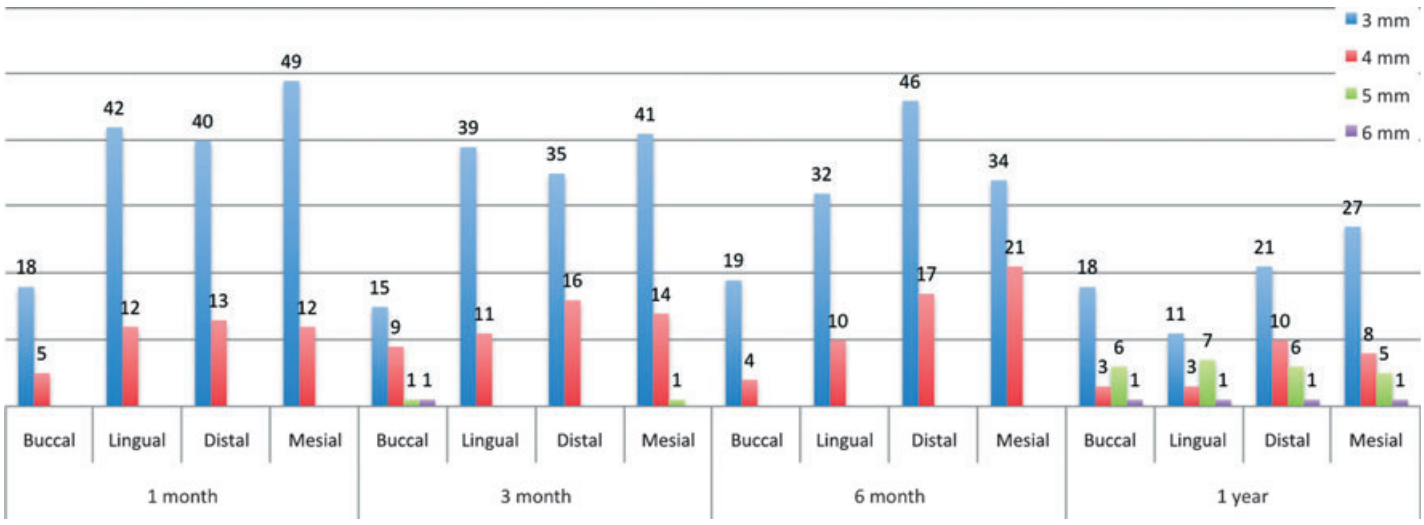

Fig. 4. Development and changes of pocket probing depths over 3 mm within the 12-month follow-up period.

© 2012 John Wiley & Sons A/S

Table 4. **Mean and median marginal bone levels (mesial + distal/2) at implant insertion and 1 year as well as mean and median marginal bone remodeling from implant insertion to 1 year. Negative numbers indicate bone levels apical to the reference point (top of implant shoulder)**

	Implant insertion	1 year	Implant insertion to 1 year
Mean	0.17	−1.39	−1.44
Median	0.00	−1.00	−1.25
SD	1.24	1.27	1.35
Number	125	110	98
in mm	*n* (%)	*n* (%)	*n* (%)
>3.0	2 (1)	0 (0)	0 (0)
2.1–3.0	7 (4)	0 (0)	0 (0)
1.1–2.0	17 (11)	0 (0)	0 (0)
0.1–1.0	30 (19)	5 (3)	7 (4)
0	27 (17)	8 (5)	6 (4)
−1.0 to −0.1	25 (16)	43 (27)	32 (20)
−2.0 to −1.1	12 (8)	28 (17)	25 (16)
−3.0 to −2.1	3 (2)	15 (9)	16 (10)
−4.0 to −3.0	2 (1)	7 (4)	8 (5)
<−4.0	0 (0)	4 (3)	4 (3)
Readable implants	125 (79)	110 (68)	98 (62)
Missing/not readable	36 (21)	51 (32)	63 (38)
Total	161 (100)	161 (100)	161 (100)

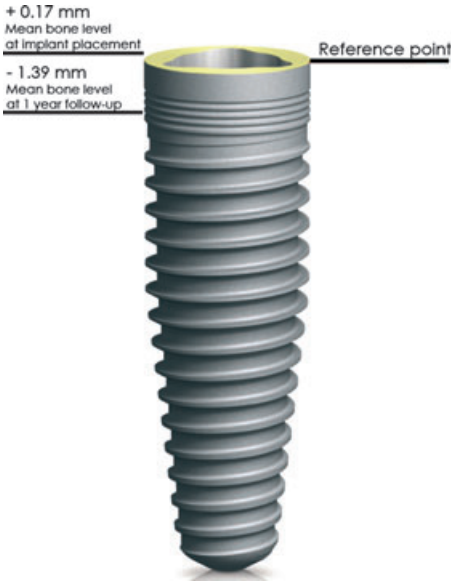

Fig. 5. Illustration of the reference point (top of implant shoulder) and the mean bone levels at implant placement (+0.17 mm) and at 1-year follow-up (−1.39 mm). The mean marginal bone level at 1-year maintained well above the level of the first thread.

Table 5. **Mean and median marginal bone levels of the immediate vs. delayed loading protocol from implant insertion and 1 year. The delayed loading protocol showed significant lower marginal bone levels at 1 year (*P* = 0.005)**

	Immediate loading		Delayed loading	
	Implant insertion	1 year	Implant insertion	1 year
Mean	0.02	−0.92	0.37	−2.01
Median	0.00	−1.00	0.50	−1.70
SD	0.95	0.81	1.52	1.49
Number	70	63	55	47
in mm	*n* (%)	*n* (%)	*n* (%)	*n* (%)
>3.0	0 (0)	0 (0)	2 (4)	0 (0)
2.1–3.0	3 (4)	0 (0)	4 (7)	0 (0)
1.1–2.0	5 (7)	0 (0)	12 (22)	0 (0)
0.1–1.0	16 (23)	4 (6)	14 (26)	1 (2)
0	21 (30)	8 (12)	6 (11)	0 (0)
−1.0 to −0.1	17 (24)	28 (44)	8 (15)	15 (24)
−2.0 to −1.1	8 (11)	17 (27)	4 (7)	11 (18)
−3.0 to −2.1	0 (0)	6 (10)	3 (6)	9 (14)
−4.0 to −3.0	0 (0)	0 (0)	2 (4)	7 (11)
<−4.0	0 (0)	0 (0)	0 (0)	4 (6)
Readable implants	70 (71)	63 (64)	55 (87)	47 (75)
Missing/not readable	28 (29)	35 (36)	8 (13)	16 (25)
Total	98 (100)	98 (100)	63 (100)	63 (100)

Table 6. **Mean and median marginal bone remodeling of the immediate and delayed loading group from implant insertion to 1 year. The immediate loading protocol demonstrated significant less bone remodeling (*P* = 0.005)**

	Implant insertion to 1 year	Implant insertion to 1 year
	Immediate loading	Delayed loading
Mean	−0.78	−2.15
Median	−0.75	−2.15
SD	0.99	1.34
Number	51	47
in mm	*n* (%)	*n* (%)
>0	6 (12)	1 (2)
0	6 (12)	0 (0)
−1.0 to −0.1	24 (47)	8 (17)
−2.0 to −1.1	8 (16)	17 (36)
−3.0 to −2.1	6 (12)	10 (21)
−4.0 to −3.1	1 (2)	7 (15)
<−4.0	0 (0)	4 (9)
Readable implants	51 (52)	47 (75)
Missing/not readable	47 (48)	16 (25)
Total	98 (100)	63 (100)

there is no need for a provisional removable prosthesis, which may be a contributing cause to implant loss during the healing phase as a result of a potential misloading of the implant (Gillot et al. 2010). Splinting of the implants with a fixed restoration will help to avoid biomechanical stress, in particular, on implants with lack of primary stability. Other studies besides the present one also reported promising results for the treatment concept of immediate loading (Brånemark et al. 1999; Becker et al. 2003; Glauser et al. 2005). Moreover, success rates comparable to those with conventional loading (98% at 2 years) were also reported with the minimally invasive surgical procedure and with respect to the concept of immediate loading (Brånemark et al. 1999; Henry et al. 2003).

As an additional advantage, the template-guided implant placement and prosthetic restoration was substantially less time-consuming compared to a conventional surgical procedure. For the predominant majority of the study cases, the complete procedure could be performed within the time period of 30–45 min as proposed by van Steenberghe et al. (2002) and Komiyama et al. (2008).

Surgical, non-serious adverse events included a postoperative inflammation in the region of an anchor pin as also described by Komiyama et al. (2008) as well as reduced mouth opening for 1 week following implant placement in the posterior maxilla presumably because of increased mouth opening required during the procedure. Otherwise, the reduced postoperative complaints (pain, swelling, bleeding) reported as a result of the minimally invasive surgical procedure could be confirmed (Komiyama et al. 2008; Johansson et al. 2009;). As a non-concept-related serious adverse event, a hypoglycemic crisis with fainting due to diabetes was documented. The patient underwent appropriate general support and treatment.

In the group with immediate loading, one single prosthesis had to be refabricated as a result of repeated screw loosening (94% success rate). Another prosthesis had to be readapted by the dental technician because of subjectively narrowed tongue space. All other documented prosthetic, non-serious adverse events were not specific concept-related complications (screw loosening, lip biting, chipping etc.). In contrast to the

© 2012 John Wiley & Sons A/S

increased surgical and prosthetic complication rates with template-guided implantation and immediate loading in the study of Komiyama et al. (2008), the present study did not reveal any increased implant-prosthetic complications vs. conventional implant restorations. Thus, immediate postoperative and delayed complications appear to be similar to those encountered with a conventional surgical approach (Brodala 2009).

In general, oral hygiene and dentist satisfaction with respect to the esthetic and overall performance of the treatment were comparable to similar studies (Arvidson et al. 2008; Arnhart et al. 2012).

Similarly, a study of Ostman et al. (2008) revealed no significant difference between immediate loading and a two-step procedure with appropriate delayed loading with respect to implant stability and mean marginal bone resorption. Moreover, a study of Sennerby et al. (2008) described no significant difference between a flapless vs. a flapped surgical procedure with respect to marginal bone loss. A review (Brodala 2009) of flapless surgery revealed a mean radiographic alveolar bone loss ranging from 0.7 to 2.6 mm after 1 year of implant placement. Studies (Malo et al. 2007; Rao et Benzi 2008; Sanna et al. 2007; van Steenberghe et al. 2005) evaluating the flapless surgical approach utilizing guided surgery demonstrated a mean marginal bone loss of 1.3 mm after 1 year. The mean marginal bone resorption in the present study was 1.39 mm (SD 1.27) after 1 year and is consistent with the results of Johansson et al. (2009) (mean 1.3 mm; SD 1.28). The percentage of mean marginal bone remodeling of more than 2 mm (16% vs. 19%) was also comparable. Within the limitations of this study, the results of Ostman et al. (2008) with respect to mean marginal bone remodeling in the immediate loading group (mean 0.78 mm; SD 0.9) were comparable with those in the present study (mean 0.78 mm; SD 0.99), but also with the higher levels seen with the conventional, delayed loading group. However, the study of Elsyad et al. (2012) also did not show any differences between the two groups.

Conclusion

The 1-year follow-up reported a cumulative survival rate and success rate of 98.8% and 96.3%, respectively. Immediate or delayed loading of implants using a flapless, guided surgery approach (NobelGuide™) appears to be a viable concept demonstrating good clinical and radiographic outcomes at the 1-year time point.

Acknowledgements: This study has been supported by Nobel Biocare Services AG, study code: T119.

References

Albrektsson, T., Dahl, E., Enbom, L., Engevall, S., Engquist, B., Eriksson, A.R., Feldmann, G., Freiberg, N., Glantz, P.O., Kjellman, O., Kristersson, L., Kvint, S., Köndell, P., Werndahl, L. & Astrand, P. (1988) Osseointegrated oral implants. A Swedish multicenter study of 8139 consecutively inserted Nobelpharma implants. *Journal of Periodontology* **59**: 287–296.

Arnhart, C., Dvorak, G., Trefil, C., Huber, C., Watzek, G. & Zechner, W. (2012) Impact of implant surface topography: a clinical study with a mean functional loading time of 85 months. *Clinical Oral Implants Research* doi: 10.1111/j.1600-0501.2012.02498.x.

Arvidson, K., Esselin, O., Felle-Persson, E., Jonsson, G., Smedberg, J.I. & Soderstrom, U. (2008) Early loading of mandibular full-arch bridges screw retained after 1 week to four to five Monotype implants: 3-year results from a prospective multicentre study. *Clinical Oral Implants Research* **19**: 693–703.

Bates, D., Maechler, M. & Bolker, B. (2012) lme4: linear mixed-effects models using S4 classes. R package version 0.999999-0

Becker, W., Becker, B.E. & Huffstetlert, S. (2003) Early functional loading at 5 days for Brånemark implants placed into edentulous mandibles: a prospective, open-ended, longitudinal study. *Journal of Periodontology* **74**: 695–702.

Brånemark, P.I., Engstrand, P., Ohrnell, L.O., Grondahl, K., Nilsson, P., Hagberg, K., Darle, C. & Lekholm, U. (1999) Branemark Novum: a new treatment concept for rehabilitation of the edentulous mandible. Preliminary results from a prospective clinical follow-up study. *Clinical Implant Dentistry and Related Research* **1**: 2–16.

Brodala, N. (2009) Flapless surgery and its effect on dental implant outcomes. *International Journal of Oral and Maxillofacial Implants* **24**(Suppl): 118–125.

van Buuren, S. & Groothuis-Oudshoorn, K. (2011) mice: multivariate imputation by chained equations in R. *Journal of Statistical Software* **45**: 1–67.

De Smet, E., Jacobs, R., Gijbels, F. & Naert, I. (2002) The accuracy and reliability of radiographic methods for the assessment of marginal bone level around oral implants. *Dentomaxillofacial Radiology* **31**: 176–181.

Elsyad, M.A., Al-Mahdy, Y.F. & Fouad, M.M. (2012) Marginal bone loss adjacent to conventional and immediate loaded two implants supporting a ball-retained mandibular overdenture: a 3-year randomized clinical trial. *Clinical Oral Implants Research* **23**: 496–503.

Fortin, T., Bosson, J.L., Isidori, M. & Blanchet, E. (2006) Effect of flapless surgery on pain experienced in implant placement using an image-guided system. *International Journal of Oral and Maxillofacial Implants* **21**: 298–304.

Gillot, L., Noharet, R. & Cannas, B. (2010) Guided surgery and presurgical prosthesis: preliminary results of 33 fully edentulous maxillae treated in accordance with the NobelGuide protocol. *Clinical Implant Dentistry and Related Research* **12** (Suppl 1): e104–e113.

Glauser, R., Lundgren, A.K., Gottlow, J., Sennerby, L., Portmann, M., Ruhstaller, P. & Hämmerle, C. H.F. (2003) Immediate occlusal loading of Brånemark TiUnite™ implants placed predominantly in soft bone: 1-year results of a prospective clinical study. *Clinical Implant Dentistry and Related Research* **5**(Suppl 1): 47–56.

Glauser, R., Ruhstaller, P., Windisch, S., Zembic, A., Lundgren, A., Gottlow, J. & Hämmerle, C.H. (2005) Immediate occlusal loading of Brånemark System TiUnite implants placed predominantly in soft bone: 4-year results of a prospective clinical study. *Clinical Implant Dentistry and Related Research* **7**(Suppl 1): S52–S59.

Hahn, J. (2000) Single-stage, immediate loading, and flapless surgery. *Journal of Oral Implantology* **26**: 193–198.

Henry, P.J., van Steenberghe, D., Blombäck, U., Polizzi, G., Rosenberg, R., Urgell, J.P. & Wendelhag, I. (2003) Prospective multicenter study on immediate rehabilitation of edentulous lower jaws according to the Brånemark Novum protocol. *Clinical Implant Dentistry and Related Research* **5**: 137–142.

Johansson, B., Friberg, B. & Nilson, H. (2009) Digitally planned, immediately loaded dental implants with prefabricated prostheses in the reconstruction of edentulous maxillae: a 1-year prospective, multicenter study. *Clinical Implant Dentistry and Related Research* **11**: 194–200.

Jung, R.E., Pjetursson, B.E., Glauser, R., Zembic, A., Zwahlen, M. & Lang, N.P. (2008) A systematic review of the 5-year survival and complication rates of implant-supported single crowns. *Clinical Oral Implants Research* **19**: 119–130.

Komiyama, A., Klinge, B. & Hultin, M. (2008) Treatment outcome of immediately loaded implants installed in edentulous jaws following computer-assisted virtual treatment planning and flapless surgery. *Clinical Oral Implants Research* **19**: 677–685.

Lekholm, U. & Zarb, G.A. (1985) Patient selection and preparation. In: Brånemark, P.-I., Zarb, G.-A.

© 2012 John Wiley & Sons A/S

& Albrektsson, T., eds. Tissue integrated Prostheses: Osseointegration in Clinical Dentistry, 199–209. Chicago, IL: Quintessence.

Little, R.J.A. & Rubin, D.B. (1987) Statistical Analysis with Missing Data. New York: Wiley.

Malo, P., de Araujo Nobre, M. & Lopes, A. (2007) The use of computer-guided flapless implant surgery and four implants placed in immediate function to support a fixed denture: preliminary results after a mean follow-up period of thirteen months. *Journal of Prosthetic Dentistry* **97**(Suppl 6): S26–S34.

Meredith, N. (1998) Assessment of implant stability as a prognostic determinant. *International Journal of Prosthdontics* **11**: 491–501.

Nkenke, E., Eitner, S., Radespiel-Tröger, M., Vairaktaris, E., Neukam, F.W. & Fenner, M. (2007) Patient-centred outcomes comparing transmucosal implant placement with an open approach in the maxilla: a prospective, non-randomized pilot study. *Clinical Oral Implants Research* **18**: 197–203.

Olsson, M., Urde, G., Andersen, J.B. & Sennerby, L. (2003) Early loading of maxillary fixed cross-arch dental prostheses supported by six or eight oxidized titanium implants: results after 1 year of loading, case series. *Clinical Implant Dentistry and Related Research* **5**(Suppl 1): 81–87.

Ostman, P.O., Hellman, M. & Sennerby, L. (2008) Immediate occlusal loading of implants in the partially edentate mandible: a prospective 1-year radiographic and 4-year clinical study. *International Journal of Oral and Maxillofacial Implants* **23**: 315–322.

Pjetursson, B.E., Brägger, U., Lang, N.P. & Zwahlen, M. (2007) Comparison of survival and complication rates of tooth-supported fixed dental prostheses (FDPs) and implant-supported FDPs and single crowns (SCs). *Clinical Oral Implants Research* **18**(Suppl 3): 97–113.

Puig, C.P. (2010) A retrospective study of edentulous patients rehabilitated according to the 'all-on-four' or the 'all-on-six' immediate function concept using flapless computer-guided implant surgery. *European Journal of Oral Implantology* **3**: 155–163.

R Development Core Team (2012) R: A Language and Environment for Statistical Computing, Vienna, Austria: R Foundation for Statistical Computing, ISBN 3-900051-07-0.

Rocci, A., Martignoni, M. & Gottlow, J. (2003) Immediate loading of Brånemark System TiUnite and machined-surface implants in the posterior mandible: a randomized open-ended clinical trial. *Clinical Implant Dentistry and Related Research* **5**(Suppl 1): 57–63.

Ruppin, J., Popovic, A., Strauss, M., Spüntrup, E., Steiner, A. & Stoll, C. (2008) Evaluation of the accuracy of three different computer-aided surgery systems in dental implantology: optical tracking vs. stereolithographic splint systems. *Clinical Oral Implants Research* **19**: 709–716.

Sanna, A.M., Molly, L. & van Steenberghe, D. (2007) Immediately loaded CAD-CAM manufactured fixed complete dentures using flapless implant placement procedures: a cohort study of consecutive patients. *Journal of Prosthetic Dentistry* **97**: 331–339.

Sennerby, L., Rocci, A., Becker, W., Jonsson, L., Johansson, L.A. & Albrektsson, T. (2008) Short-term clinical results of Nobel Direct implants: a retrospective multicentre analysis. *Clinical Oral Implants Research* **19**: 219–226.

van Steenberghe, D. (1997) Outcomes and their measurement in clinical trials of endosseous oral implants. *Annals of Periodontology* **2**: 291–298.

van Steenberghe, D., Glauser, R., Blombäck, U., Andersson, M., Schutyser, F., Pettersson, A. & Wendelhag, I. (2005) 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. *Clinical Implant Dentistry and Related Research* **7**(Suppl 1): S111–S120.

van Steenberghe, D., Naert, I., Andersson, M., Brajnovic, I., Van Cleynenbreugel, J. & Suetens, P. (2002) A custom template and definite prosthesis allowing immediate implant loading in the maxilla: a clinical report. *International Journal of Oral and Maxillofacial Implants* **17**: 663–670.

Vasak, C., Watzak, G., Gahleitner, A., Strbac, G., Schemper, M. & Zechner, W. (2011) Computed tomography-based evaluation of template (NobelGuide™)-guided implant positions: a prospective radiological study. *Clinical Oral Implants Research* **22**: 1157–1163.

Vercruyssen, M., Jacobs, R., Van Assche, N. & van Steenberghe, D. (2008) The use of CT scan based planning for oral rehabilitation by means of implants and its transfer to the surgical field: a critical review on accuracy. *Journal of Oral Rehabilitation* **35**: 454–474.

Verstreken, K., Van Cleynenbreugel, J., Martens, K., Marchal, G., van Steenberghe, D. & Suetens, P. (1998) An image-guided planning system for endosseous oral implants. *International IEEE Transactions on Medical Imaging* **17**: 842–852.

Zechner, W., Watzak, G., Gahleitner, A., Busenlechner, D., Tepper, G. & Watzek, G. (2003) Rotational panoramic vs. intraoral rectangular radiographs for evaluation of peri-implant bone loss in the anterior atrophic mandible. *International Journal of Oral and Maxillofacial Implants* **18**: 873–878.

© 2012 John Wiley & Sons A/S