Guided Surgery and Presurgical Prosthesis: Preliminary Results of 33 Fully Edentulous Maxillae Treated in Accordance with the NobelGuide® Protocol

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ABSTRACT

Objective: The aim of this study was to present the preliminary results of 33 edentulous maxillary patients treated using the Nobelguide® (Nobel Biocare AB, Göteborg, Sweden) technique.

Materials and Methods: Thirty-three patients were treated according to the conventional protocol of the Nobelguide® technique in two clinical centers. This group of patients received 211 implants. Monitoring was carried out for over 12–51 months, depending on the patient. The Nobelguide® protocol was used for all patients.

Results: Of the 211 implants loaded, four were lost (1.9%). The implant survival rate was therefore 98.1%. The prosthetic survival rate was 100%. There were some per-operative complications (four) and some postoperative complications (10 fractures of resin).

Conclusion: These preliminary results seemed rather promising. These were the first cases of experienced surgeons who needed to learn a new implant placement protocol. It was clear that analysis and understanding of the system were essential in order to obtain such a success. Only one implant was replaced without there being any impact on the prosthesis survival rate which is 100%.

KEY WORDS: full edentulous, guided abutments, guided surgery, immediate loading, Nobelguide®

INTRODUCTION

Oral implantology was first described by Professor Branemark. The initial protocol required the use of a two-stage surgical protocol in order to obtain a high reproducible osteointegration result in the short and long-term.[1–4] This protocol, however, presents some major constraints limiting the extension of the indications of implant treatment. In fact, the overall duration of treatment is relatively long in order to allow time for osseous cicatrization (around 6 months). Moreover, during this time, the wearing of a removable full-arch prosthesis is advised against in order to avoid the creation of micro-movements which may have harmful effects on the osseous cicatrization (Notion of threshold:[5,6]). Another disadvantage lies in the postoperative pain following the second operation to place the cicatrization abutments.[7]

All these elements have led to the drawing up of new protocols. Henry and Rosenberg,[8] Ericsson and colleagues,[9,10] and Becker and colleagues [11] developed treatment protocols in one surgical stage in order to reduce the overall treatment time as well as the number of procedures while increasing patient comfort. However, relining every 3 weeks was still necessary in order to reduce the stress on the implants and thereby the micro-movements which could compromise osseous cicatrization[5,6] by creating lateral pressure.

With the same aim in mind (shorter treatment time and increased patient comfort), Branemark proposed as early as 1999 the immediate loading of a definitive standard prosthesis. This immediate loading removes the

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need to use a temporary removable prosthesis, a source of implant failure because of the transmission of harmful pressure on the implants during cicatrization. By connecting the implants to each other early, the pressure transmitted can be controlled and the most harmful biomechanical stresses can be avoided (Engquist). This rigid connection of the implants proposed in the Novum protocol (through the use of a standard armature) has enabled a success rate similar to conventional loading (98% at 2 years) to be obtained.[12,13] This system presented a major disadvantage: the use of a premanufactured standard armature on wide diameter implants which meant the patient had to be adapted to the prosthesis. This proved to be complicated both in terms of the adaptation to the osseous volume as well as the functional aspect of the prosthesis.[14] The technique assessed here enables an individualized prosthesis to be used for an immediate loading.[15] However, this initial treatment protocol (Novum) enabled immediate loading to be developed and today, this therapy is scientifically validated with regard to the treatment of the completely edentulous mandible.[16]

The development of mandibular immediate loading was fast. It is not the case for the maxilla for several reasons (bone density, osseous volume, operative difficulties). The introduction of guided surgery[15,17] together with a premanufactured, but individual, prosthesis enabled completely edentulous maxillae to be treated using immediate loading. The accuracy of this treatment appears advantageous in terms of patient comfort[18,19] as it enables a flapless procedure to be carried out reducing the risk of complications during the operation as well as offering immediate esthetic and functional rehabilitation.

However, there are still few scientific data on the use of 3D imaging for the planning and creation of a presurgical prosthesis in the framework of the treatment of a fully edentulous patient using immediate loading.[15,17,18,20]

The aim of this study is to assess the treatment of fully edentulous maxillae by this flapless surgical protocol with the use of 3D imaging.

MATERIALS AND METHODS

Materials

Thirty-three patients (Table 1) were treated using guided surgery using the Nobelguide® protocol first described by Van Steenberghe and colleagues[15] (LITORIM protocol). Of these 33 patients, 23 were fully edentulous and 10 were initially partially dentulous. The latter group had fewer than five residual teeth which were extracted on the day of the surgery. No alveolus was used as an implant site. Of these 33 patients, 21 were women and 12 were men. The average age was 61.2 years (60.6 for men, 61.4 for women) (Table 2). This group of patients received 211 implants. None of the patients smoke. Monitoring is carried out for over 12–51 months, depending on the patient (Table 3).

Methods

The Nobelguide® (Nobel Biocare AB, Göteborg, Sweden) protocol was used.[15] The main stages of this protocol are:

1. Creation of a removable full-arch prosthesis (or its wax model) respecting the fundamental principles for its creation in order to obtain a stable base with good sustentation and which is accurately positioned. It therefore seems essential to create two impressions, a primary and a secondary, in order to obtain a precise recording of the soft tissues.
2. Transformation of this prosthesis or model into a radiologic guide. The main condition for this guide apart from its mucous stability is the creation of gutta-percha radiopaque markers (diameter 1.5 mm and depth 1 mm) in a three-dimensional positioning enabling the computer data obtained from the double scan to be superimposed (bone-markers-guide) (Figure 1).
3. After educating the patient on the correct positioning of this guide using an occlusion check-bite, the double scan is carried out: firstly, a scan of the patient with the guide in the mouth and then a second scan of the guide by itself (two scans).
4. Recovery of the Digital Imaging and Communications in Medicine (DICOM) data (definition native files of the medical scan) and transfer using the Procera® Software (NobelBiocare AB, Göteborg, Sweden). Planning of the implant (positioning of the implant according to the osseous volumes and the prosthesis simulated by the radiologic guide). At the end of this stage, the guide is ordered (Figure 2).
5. Once the guide is received, the prosthetist can prepare the working cast which will be used to create the definitive or temporary prosthesis. The surgical guide is stabilized by an occlusal index at the

TABLE 1 Overview of the Subjects, Age, Follow-Up, and Type and Characteristics of Treatment

Patient Rank	Age (years)	Gender	Follow-Up (months)	Number of Implants	Type of Prosthesis	Number of Anchor Pins	Failure	Fractures of Resin
1	67	F	51	8	D	3	0	–
2	55	F	44	7	D	3	0	–
3	71	M	43	8	D	3	0	–
4	54	F	42	6	D	3	0	–
5	73	M	42	6	D	3	0	1
6	64	M	42	6	D	3	1	2
7	66	M	41	8	D	3	0	–
8	76	F	41	6	T	4	1	–
9	60	M	40	6	D	3	0	–
10	68	M	40	6	D	3	0	1
11	56	M	39	6	T	4	0	–
12	46	M	38	6	D	3	0	1
13	65	F	36	6	D	4	1	2
14	47	M	35	6	D	6	0	–
15	73	F	34	6	T	3	1	2
16	62	M	34	6	D	3	0	–
17	53	F	33	7	T	4	0	–
18	53	F	31	6	T	0	0	–
19	56	F	30	8	D	5	0	1
20	53	F	29	6	D	5	0	–
21	56	M	26	7	T	5	0	–
22	56	F	25	6	D	5	0	–
23	60	F	24	6	D	5	0	–
24	52	F	21	6	D	5	0	–
25	80	F	21	8	T	5	0	–
26	64	F	20	6	T	6	0	–
27	59	M	17	8	T	1	0	–
28	50	F	16	6	D	5	0	–
29	70	F	16	6	T	5	0	–
30	53	F	14	6	T	5	0	–
31	65	F	14	4	T	5	0	–
32	65	F	13	6	D	5	0	–
33	70	F	12	6	T	5	0	–

M, male; F, female; D, definitive; T, temporary.

beginning of the procedure. A clinical session is therefore required prior to the surgery in order to validate the guide and the occlusal index in the mouth.

6. Finally, after all these preparatory stages, the surgical and prosthetic phase can begin (Figure 3).

A part of this original protocol was modified.

For the first 21 patients, the initial procedure was scrupulously respected (Teeth-in-an-hour® protocol) enabling, with the help of NobelGuide® guided

TABLE 2 Distribution of Patients with Regard to Age and Gender

Age (year)	Male	Female
40–49	2	0
50–59	3	11
60–69	5	6
70–79	2	3
80–89	0	1
Total	12	21

TABLE 3 Life Table Showing the Cumulative Survival Rate for Implants

Follow-Up Period (months)	Number of Patients	Fixtures at the Beginning of the Period	Failures	Internal Survival Rate (%)	Cumulative Survival Rate (%)
0–6	33	211	1	99.53	99.53
6–12	33	210	1	99.52	99.05
12–24	32	204	1	99.51	98.58
24–36	21	143	1	99.30	98.10
36–48	12	79	0	100.00	98.10
>48	1	8	0	100.00	98.10

surgery an immediate definitive bridge with Procera® titanium armature (Nobel Biocare AB, Göteborg, Sweden) to be loaded, directly connected to the implants using a new type of adjustable guided abutments (guided abutments®) (Nobel Biocare AB, Göteborg, Sweden).

Figure 1 Radiologic guide. 1,236 × 824 mm (72 × 72 DPI).

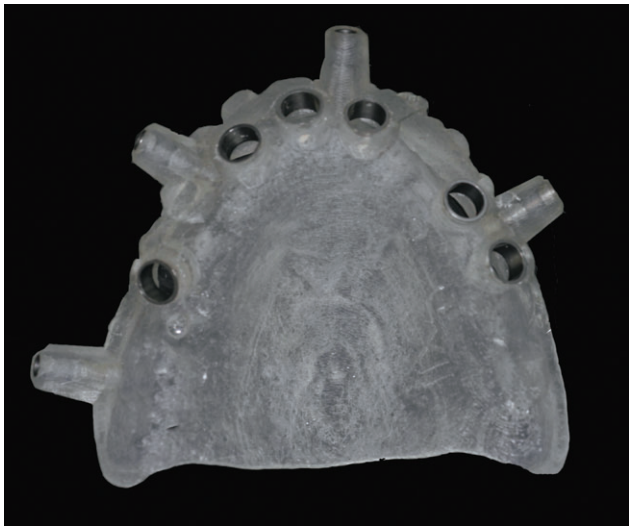

Figure 2 Surgical guide. 987 × 824 mm (72 × 72 DPI).

These abutments proved to be very effective in compensating for deviations in the positioning of the implants with regard to the previously planned location. However, as several cases required the prosthesis to be removed some months following the surgery (to repair cosmetic fractures), the placing and removal of these adjustable guided abutments proved to be particularly unpleasant for the patients (see discussion below). In fact, the use of MUA® abutments (Nobel Biocare AB, Göteborg, Sweden) was preferred. This is only possible if the initial protocol is adapted. On the presurgical model from Nobelguide®, MUA® abutments are placed on the implants and the temporary prosthesis is placed on temporary titanium cylinders. Only two abutments are connected to the prosthesis beforehand. The other cylinders are connected at a second stage (postsurgical) either in the mouth or in the laboratory. This second prosthetic stage is essential when using MUA® abutments in order to compensate for slight implant deviations during the surgery (a role initially successfully fulfilled by the guided abutments).

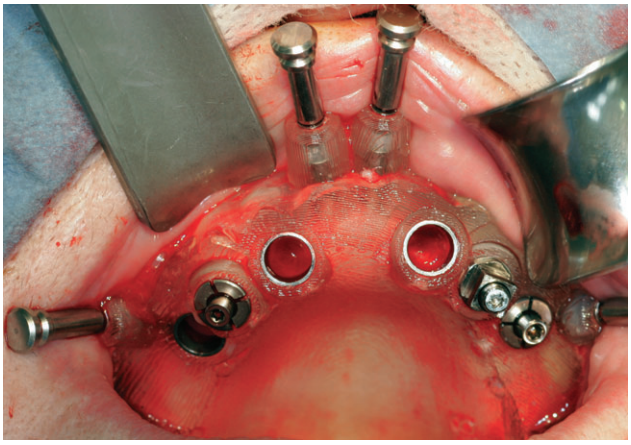

Figure 3 Final prosthesis. 921 × 594 mm (72 × 72 DPI).

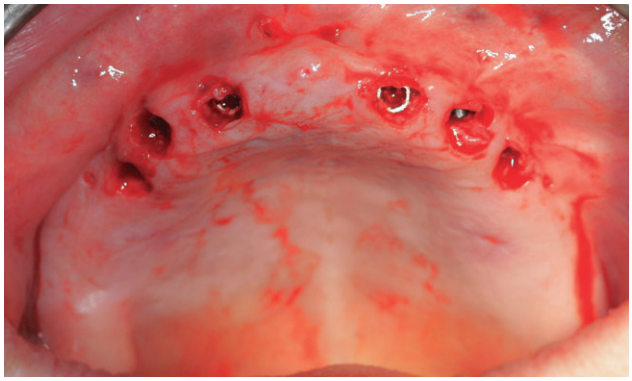

Figure 4 985 × 687 mm (72 × 72 DPI).

RESULTS

The 33 patients were monitored for a period ranging from 12 to 51 months. The male/female ratio is 12/21. The average age of the patients in our study is 61.2 (61.4 for the women and 60.6 for the men). The age range is from 46 to 80 years.

The implants were loaded between February 2005 and April 2008. A total of 211 rough surface implants – Speedy® ($n = 102$ or 48.3%), MkIII® ($n = 107$ or 50.7%) and MkIV® ($n = 2$ or 1%) Branemark System® Implants (Nobel Biocare AB, Göteborg, Sweden) – were placed on the level of the maxilla (Figure 4).

All the implants were of standard diameter (i.e., 4 mm). In cases of reduced osseous volume, some implants were inclined. On all the patients, immediate loading was carried out. The temporary or definitive presurgical prosthesis was placed straight after the surgical procedure to load the implants (Figure 5).

The number of implants per patient is recorded in Table 4.

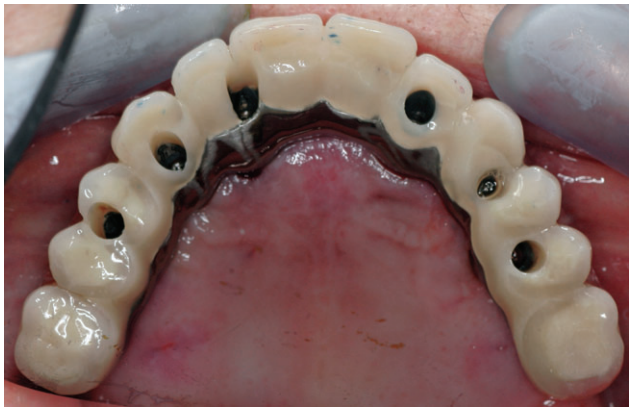

Figure 5 810 × 482 mm (72 × 72 DPI).

TABLE 4 Distribution of Implants Regarding Length

Length (mm)	Number of Implants	%
7	3	1.42
8.5	6	2.84
10	45	21.33
11.5	46	21.80
13	71	33.65
15	39	18.48
18	1	0.47
	211	100.00

The most commonly used implant lengths were between 10 and 13 mm; these lengths represent 75% of the overall pool of implants (10 mm: $n = 45$ or 21.3%; 11.5 mm: $n = 46$ or 21.8%; 13 mm: $n = 71$ or 33.6%).

The other lengths were used only occasionally (18 mm: $n = 1$ or 0.5%; 15 mm: $n = 39$ or 18.5%; 8.5 mm: $n = 6$ or 2.8%; 7 mm: $n = 3$ or 1.4%). Their distribution is recorded in Table 4.

On 21 patients, the implant abutments used were adjustable guided abutments (Nobel Biocare, Gothenburg, Sweden). On the other 12 patients, Multi Unit abutments® were used.

Twenty patients were equipped with screw-retained, osteoanchored bridges with a machined titanium definitive armature (Teeth-in-an-Hour® protocol); 13 were temporarily rehabilitated with a temporary bridge consisting of a smaller armature (single reinforcement) (Table 5). Whatever the type of prosthesis, all the patients received a prosthesis screwed onto all the loaded implants (Table 6). For one patient, only four out of six implants were connected – see the first per-operative complication described below. This procedure was carried out within 8 hours.

Implant Survival

Of the 211 implants, four were lost (1.9%). The implant survival rate is therefore 98.1%. The prosthetic survival rate is 100% (Table 3).

TABLE 5 Distribution of Patients with Regard to Prosthesis Type

Type of Prosthesis	Number
Definitive	21
Temporary	12

TABLE 6 Distribution of Patients in Relation to Number of Implants

Number of Implants per Maxilla	Number of Patients
4	1
5	0
6	23
7	3
8	6

Per-Operative Complications

1. Guide difficult to insert on one maxilla. The distal implants could not be connected to the prosthesis. They were connected when the definitive prosthesis was made at 6 months.
2. Absence of primary stability of an implant in a type IV bone. The implant was in fact removed at the end of the surgical operation. The presurgical temporary prosthesis was placed on five implants instead of six without the prosthetic prognosis being comprised.
3. One implant situated in position 15 showed no primary stability (type IV bone). Its removal was therefore envisaged and it was replaced by a type MkIV implant in a per-operative freehand procedure.
4. Major occlusal adjustments for one patient.

Mechanical Complications

The prosthetic complications all concern fractures of the prosthesis resin cosmetic element. In fact, 10 fractures of resin element were recorded on seven different patients. A loose prosthetic screw on the level of a distal implant of an armature was recorded at 10 months.

When prostheses were removed to be repaired or rebuilt, the patients wearing adjustable guided abutments showed signs of soreness and gum sensitivity in the days following the replacement of the prosthesis causing daily discomfort. These stages require local analgesia and antalgic treatment for a few days. The difficult management of these repairs on guided abutments is the reason for the modification of the protocol to favor the use of MUA® abutments.

Biological Complications

All the patients are satisfied with their implant-supported prostheses both from an aesthetic as well as a functional point of view. In the context of this study, few patients reported complications resulting from the operation: the pain was minimal; a patient presented a jugal hematoma and a slight genial tumefaction for 3 days. A fistulus was found after a few weeks on a patient without there being any clinical consequences for the implants (spontaneous resorption after a loose abutment screw was tightened).

DISCUSSION

This study focuses only on completely edentulous maxillae.

Osseous resorption because of edentulousness reduces the alveolar crest in both height and length. The supporting area of the mandible is smaller than with the maxilla on which the hard palate remains an excellent surface area on which to rest a guide. The stabilization of the radiologic guide as well as the surgical guide in a strictly reproducible position is more difficult on the lower arch. The positioning of the anchor pins is also a complex element in the treatment of a resorbed mandible as they must find room between the implants and the anatomical elements. It appears difficult in certain situations to place all these elements in a reduced osseous volume. As the stabilization of the various guides is an essential element in ensuring the accuracy of this technique, a poor position would therefore compromise the success of the treatment. Komoyama and colleagues[18] reports operative difficulties during the treatment of a completely edentulous mandible (fracture of guides) thereby complicating the treatment. Fractures can occur because of problems of stabilization and the reduced thickness of the guide's resin (linked to the positioning of the anchor pins, implants, and an insufficient volume of resin). The stability of the imaging and surgical guide is more difficult to obtain on the mandible and requires greater stringency in the different stages of the protocol (Cannas).

Albrektsson and Wennerberg,[21,22] Goransson and Wennerberg[23] show that certain surface characteristics play a fundamental role in accelerating the anchoring of the implant in the bone. Some studies[15,17,24] effectively present a varying success rate between the different types of implant surface, in favor of rough surface implants (99%) compared with machined surface implants (83%). In fact, all the implants used have a modified surface (rough) in order to optimize the implant result.

The duration of the procedure complied with that reported by various authors[15,18] was 30–45 minutes. Some prostheses were however, more difficult to insert therefore requiring more time. It seems that the further the implants are from a strict parallelism between themselves, the more difficult it is to insert the prosthesis. This difficulty is probably because of the optimization of the reduced osseous volumes by the planning of inclined implants. However, the precision of the device[25,26] nevertheless enables the prosthesis to be inserted thanks mainly to the use of adjustable guided abutments. The problem no longer arises with the MUA abutments as they are compatible with a more marked angulation of the implants.

In the context of this study, few patients reported problems resulting from the operation. Pain was minimal; one patient presented a jugal hematoma and a slight genial tumefaction for 3 days. These results corroborate the different studies relating to the flapless techniques with regard to the postoperative complications.[27–29] Eli and colleagues[28] shows a direct correlation between pain and the emotions felt by the patient (stress, anxiety). In fact, dental implants constitute one of the most stressful procedures for our patients. Oral implant treatment is not a health necessity and the treatment is much more associated with quality of life.[19] The fact that this technique reduces postoperative complications seems in fact to be an advantage with regard to the acceptance of the treatment.

Implant Failure

The surgical failures are analyzed in terms of difficulties or incidents during the surgical procedure.

Failure 1: It occurred following the per-operative complication described above and concerns the implant which was modified (model) during the procedure. During the operation, the NobelSpeedy® type implant was blocked at 50 N/cm before its final position was obtained, despite the presence of a large initial cystic lesion on a level of the sector concerned (23–24). This implant was therefore removed after the removal of the surgical guide. A new hands-free implant was placed, the osseous site being more favorable compared with the guided area.

Failure 2: It concerns a female patient with a low overall maxillary osseous volume. Two embedded canines extracted 20 years earlier had left a small residual volume. The loaded implant had a low primary stability which was lost during the placing of the angulated abutment. It was therefore not retained. The prosthesis was placed on five implants. It is difficult to consider this as a true implant failure. In fact, it is a modification of the initial planning.

Failure 3: The lost implant is a short implant: 4×7 mm type Speedy Shorty. The loss was only noticed during a removal which was necessary following a fracture of resin elements of the procera implant bridge on adjustable guided abutments. Because of painful complications during its removal and replacing, Multi-Unit abutments were placed and a conventional osteoanchored bridge was used to replace the procera bridge on adjustable guided abutments.

Failure 4: No incident occurred during its surgical insertion. The removal of the implant took place when the osteointegration was checked with the temporary prosthesis. It was not reloaded: The definitive prosthesis was loaded on five implants.

The success rate of this study is in accordance with the various authors already having proposed treatments for fully edentulous maxillae with immediate loading. In fact the success rates range from 83 to 100%.[15–18,24] Increasing numbers of studies are focusing on immediate loading for fully edentulous maxillae and should give rise to scientific elements which are as convincing as those relating to the treatment of the fully edentulous mandible. This protocol, thanks to its rigor, provides excellent results and can be easily implemented as the impressions are made and the intermaxillary relation recorded before the day of the surgery. The success rate is also favored by the rigid inter-implant connection[29] by a prosthetic armature. For the patient, one of the most obvious benefits is the sizeable reduction of operative complications linked to the flapless technique.

It is important to point out that tactile sensation during drilling enabling the bone density to be assessed and therefore a drilling sequence adapted to the site to be planned is reduced because of the positioning of the surgical guide between the operator (via the drill) and the bone.

With regard to the anchor pins used to stabilize the surgical guide, the number has increased with experience. In fact, the increase in their number appears to favor the stabilization of the guide and therefore the accuracy of the system. However, in two cases of marked maxillary atresia, fewer pins were used (0 and 1) (Table 7). Following Komiyama and colleagues'[18] article

TABLE 7 Distribution of Patients in Relation to Number of Anchor Pins

Number of Anchor Pins	Number of Patients
0	1
1	1
2	0
3	12
4	4
5	13
6	2
	33

reporting on osseous defects linked to the presence of the wedges, all the radiographic elements of each patient were looked at again. No osseous defects were found. However, it is advisable to follow the advice of the author in order to reduce the risks of osseous defects by controlling the speed of drilling and drilling intermittently in order to reduce the risk of overheating.

Mechanical Complications

The occlusal design chosen was a balanced occlusion scheme in order to distribute the occlusal load over the whole of the implant-supported complex. Jaffin and colleagues[30] shows that an unbalanced scheme gives rise to prosthetic complications (unscrewing and loss of prosthesis and abutment screws) causing the implant to be lost. A single case required sizeable occlusal adjustments. The other prostheses only underwent minor modifications, if any. The occlusal aspect must be taken into account in order to obtain a favorable success rate as well as the durability of this osteointegration. In fact, the main causes of implant loss after the osteointegration phase are of traumatic origin[1,31,32] while the presence and persistence of occlusal overloading is one of the main causes of mechanical failures.[33]

Mechanical complications such as resin fracture were recorded (Table 1). They can either be explained by particular biomechanical contexts[30] or remain unexplained, or they may be due to errors during the prosthesis laboratory stage (in particular, by an insufficiently profiled titanium armature design providing inadequate support to the resin cosmetic element of the bridges). In fact, three patients suffered two fractures each. Meticulous attention was paid to the occlusal context of each patient.

The treatment consisted in removing the implant-supported prosthesis. This removal obviously requires the maxilla to be anesthetized in order to avoid extremely uncomfortable pain. This pain is specific to the use of adjustable guided abutments. The peri-implant mucous and this device being interdependent. This is the one reason behind the modification of the protocol with the use of MUA® abutments (Nobel Biocare AB, Göteborg, Sweden). The repair was carried out at the laboratory. A completely new resin structure (false gum and teeth) was produced.

Despite these elements relating to postoperative events, a relatively low level of implant failures and complications is recorded. As with any new technique, and however experienced the surgeon, a learning curve is to be expected. All the cases studied here are severely resorbed and treated by experienced practitioners.

CONCLUSION

These preliminary results seem very promising. The implant success rate is above 98% despite these being the early stages of the learning curve. In fact, these are the first cases for surgeons who are experienced practitioners of implant surgery. Only one implant was replaced without there being any impact on the prosthesis survival rate which is 100% These first cases have enabled an accurate retrospective analysis of the drawbacks and difficulties of the per-operative technique to be carried out and to conclude that the protocol must be followed very closely.[33,34] It is clear that an analysis and full understanding of the system are essential in order to obtain such a success. This technique is a valuable and rigorous tool for the development of immediate loading with fully edentulous maxillae.[17]

CONFLICT OF INTEREST STATEMENT

The authors have no conflicts of interest to declare. [Correction added after online publication 24 May 2010: Conflict of Interest Statement added.]

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