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A Pilot Study of Complete Edentulous Rehabilitation With Immediate Function Using a New Implant Design. Case Series.

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Abstract

Background: Current investigation focus on new implant designs for increased predictability in clinically demanding situations. Microtextured implant surfaces create favorable conditions for enhanced osseointegration of dental implants compared to implants with a smooth surface

Purpose: The aim of the present study was to retrospectively evaluate the clinical performance of a novel implant design in the rehabilitation of completely edentulous jaws and in combination with an immediate function protocol.

Materials and Methods: Forty-six (46) consecutive patients received 189 study implants (NobelSpeedy concept implant, Brånemark System[®], Nobel Biocare AB, Gothenburg, Sweden) supporting 53 full-arch all-acrylic prostheses (44 maxilla, 9 mandible). The majority (66%) of the reconstructions were supported by four implants, of which the two posterior implants were tilted. All patients were followed for a minimum of 1 year. Radiographic assessment of the marginal bone level was performed.

Results: Two implants were lost in two patients, rendering a 1-year cumulative clinical survival rate of 98.9 %. The marginal bone level was, on average, situated 1.2 ± 0.7 mm below the implant-abutment interface after 1 year of loading. Good soft tissue health and overall esthetic outcome was reported.

Conclusions: The results of the present pilot study indicate that fully edentulous jaws with various types of bone can be treated with high success and good esthetics using immediately loaded implants with the presented design, and that favorable marginal bone levels can be maintained.

Keywords: pilot study, case series, implant design, immediate function, implant tilting, all-acrylic prosthesis, All-on-4, NobelSpeedy

Introduction

Current implant research focuses on developing safe and cost-effective surgical and prosthetic protocols for the treatment of complete and partial edentulism. Immediate function is one treatment concept, which is receiving much attention. One such protocol for the rehabilitation of completely edentulous jaws was presented with its clinical documentation in two recent publications by Maló and colleagues.^{1,2}

Parallel to the development of improved treatment protocols, investigation continues to focus on new implant designs for increased predictability in clinically demanding situations. Modification of the implant micro design by means of different surface treatment techniques has received much attention in the literature, and the unanimous results of numerous studies suggest that microtextured implant surfaces create favorable conditions for enhanced osseointegration of dental implants compared to implants with a smooth surface.³⁻⁷

Current research also focuses on the macroscopic implant design, which is one of the factors that influence implant stability. Initial implant stability is a prerequisite for immediate function, but is often difficult to achieve in conditions with soft bone. Various authors have employed under-preparation of the implant site as a method of achieving improved anchorage of the implant in the surrounding bone.⁸⁻¹⁴

It may be hypothesized that implant insertion in under-prepared sites may benefit from an implant design featuring a conical implant apex. A narrow implant tip with aggressive threads extending to the apex may function as an osteotome, thus allowing

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variable—and if needed extensive—under-preparation of the site, resulting in enhanced mechanical anchorage of the implant at insertion, which clinically translates into extended indications for immediate function.

Bone resorption often accompanies tooth loss and results in deficient implant beds, thus rendering implant placement difficult. Implant tilting in posterior sites has been proposed by a number of authors as an alternative to bone grafting.^{15,16}

In cases such as posterior implant tilting in distal regions of the mandible makes it possible to use longer implants anchored in the interforaminal region, which allows for good bone anchorage and prevents conflict with the mandibular nerve. In the resorbed posterior maxilla, implant tilting makes it possible to avoid the sinus antrum. Various authors have reported encouraging clinical outcomes with tilted implants.^{1,2,15,17-19}

However, when tilting implants, it is sometimes difficult to achieve a favorable emergence profile, which is decisive for the esthetic outcome of a restoration. Since the implant platform emerges at an angle, the abutment often ends up protruding excessively through the mucosa. A deeper positioning of the implant to avoid such a situation results in the non-threaded implant neck being situated in the bone, which may undermine the retention of the marginal bone crest. The situation may be improved by using implants with a short collar, in combination with angulated abutments.

The aim of the present pilot study was to retrospectively evaluate the performance of a novel implant design in combination with an immediate function protocol employing two axial and two tilted implants as support for a full-arch reconstruction. The study implants featured a narrow implant apex and a short implant collar intended to provide

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good initial stability in soft bone and to increase the flexibility in the vertical positioning of the implant.

Material & Methods

This retrospective pilot study was performed in a private clinic, Clínica Malo, in Lisbon, Portugal. The study included 46 patients (17 males and 29 females, mean age 55.2 years) consecutively treated with immediately loaded study implants between March 2003 and May 2004 (table 1).

The study implant (NobelSpeedy concept implant, Brånemark System[®], Nobel Biocare AB, Gothenburg, Sweden) featured a straight implant body with an anodically oxidized surface (TiUnite[™]), and a narrow implant tip with engaging threads extending to the apex of the implant (Fig. 1). The implant collar had the same diameter as the threaded portion of the implant and was shorter (0.3 mm collar height) compared to the collars of Brånemark System MkIII (0.8 mm) and MkIV (0.4 mm) implants (Nobel Biocare AB, Gothenburg, Sweden).

Inclusion/exclusion criteria

The rationale for the patient selection was to include all patients who had received one or more study implants as support for a full-arch reconstruction during a specific time interval at the clinic; the time interval was chosen so as to include the very first patient who received this treatment, and all the consecutive patients treated in the same way up to a date which allowed for the collection of at least 1-year follow-up data. The patients who received the treatment were in need of complete-arch rehabilitation, and presented

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a bone situation allowing for the placement of at least four implants. Exclusion criteria were chemotherapy and radiotherapy.

Sixteen of the included patients (35%) were smokers. No systemic conditions judged to influence the treatment outcome were present in the study population.

Surgical protocol

The surgical procedures were performed under local anesthesia with mepivacaine chlorhydrate with epinephrine 1:100,000 (Scandinibsa[®] 2%, Inibsa Laboratory, Barcelona, Spain). All patients were sedated with diazepam (Valium[®] 10 mg, Roche, Amadora, Portugal) prior to surgery. Antibiotics (amoxicillin 875 mg + clavulanic acid 125 mg, Labesfal, Campo de Besteiros, Portugal) were given 1 hour prior to surgery and daily for 6 days thereafter. Cortisone medication (prednisone [Meticorten[®] Schering-Plough Farma, Lda, Agualva-Cacém, Portugal], 5 mg) was given daily in a regression mode (15 mg to 5 mg) from the day of surgery until 4 days postoperatively. Antiinflammatory medication (ibuprofen, 600 mg, Ratiopharm, Lda, Carnaxide, Portugal) was administered for 4 days postoperatively starting on day 4. Analgesics (clonixine [Clonix[®], Janssen-Cilag Farmaceutica, Lda, Barcarena, Portugal] 300 mg) were given on the day of surgery and postoperatively for the first 3 days if needed. Antiacid medication (omeprazole, 20 mg, Lisbon, Portugal) was given on the day of surgery and daily for 6 days postoperatively.

Grafting with autogenous bone from the iliac crest was performed in four patients 6 months prior to implant placement.

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The implants and abutments were placed in one position at a time, starting with the two posterior locations. Implant placement was assisted by a specially designed surgical guide (All-on-4 Guide, Nobel Biocare AB, Gothenburg, Sweden) to facilitate correct implant tilting and precise positioning of the implants in relation to the opposing jaw.

The guide was placed into to a 2 mm hole made at the midline of the jaw and the titanium band was bent so that the occlusal centerline of the opposing jaw was followed.

The insertion of the implants (Brånemark System®, Nobel Biocare AB; Göteborg, Sweden) followed standard procedures, except that under-preparation was used when needed to get a final torque of at least 30 Ncm before the final seating of the implant. Countersinking was used only when needed to create space for the head of the tilted implants and/or to secure both buccal and lingual cortical bone contact at the implant head in thin bone crests. The preparation was typically done by full drill depth with a 2mm or a 2.5mm twist drill (depending on bone density), followed by a widening of the entrance in the cortical bone with a 3mm twist drill and an adjustment with the countersink, if needed. The implant neck was aimed positioned at bone level, and bicortical anchorage was established whenever possible. After closing and suturing the flap with 3-0 non-resorbable suture, the access to the abutments were opened by a punch and impression copings were placed.

Implant stability, as assessed manually, was achieved in all cases.

Implant placement in the mandible: In the mandible, a mucoperiosteal flap was raised along the top of the ridge in the intermentonian area. The two most anterior implants followed the jaw anatomy in direction, which in severe resorption cases meant a posterior tilting. Two additional implants were inserted just anterior to the foramina and tilted distally about 30 degrees relative to the occlusal plane. The posterior implants typically emerged at the second premolar position. Angulated abutments (Brånemark System®, Nobel Biocare AB, Göteborg, Sweden) were used. The angle was either 17° or 30° at the anterior implants (in cases with severe bone resorption) and always 30° at

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the posterior implants. These abutment angulations were chosen such that the prosthetic set screw access holes were in an occlusal or lingual location.

Implant placement in the maxilla: In the maxilla, a mucoperiosteal flap was raised along the top of the ridge with relieving incisions on the buccal aspect in the molar area. A small window was opened to the sinus using a round bur for identification of the exact position of the anterior sinus wall. The posterior implant tilting followed the anterior sinus wall with about 45° of inclination. 30° angulated abutments were placed on the implant correcting the inclination to a maximum of 15°.

Care has to be taken in the selection of the anterior positions not to come in conflict with the apex of the tilted posterior implants, which normally reach the canine area. The anterior implants were placed in lateral or central incisor positions, while the posterior implants typically emerging at the second premolar / first molar position.

Additional implants were placed in some patients with soft bone and/or in combination with extensive grafting (1 to 4 extra implants, totaling 5-8 implants per patient).

Prosthetic Protocol

Provisional complete-arch all-acrylic prostheses were delivered on the day of surgery. A pre-made impression tray was used. Small volumes of silicon were placed around the copings, followed by complete filling with soft putty. After removal of the copings, protection caps were placed to support the peri-implant mucosa during the manufacturing of the prosthesis. Based on the impression, high-density baked all-acrylic prosthesis with titanium cylinders was manufactured at the laboratory and most often delivered to the patient within 2-3 hours.

Final all-acrylic bridges of the same type, or metal-ceramic bridges with a titanium framework, Procera copings (Nobel Biocare AB, Gothenburg, Sweden) and ceramic crowns, were delivered, at the earliest, 12 months post-surgery.

Hygiene maintenance

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The patients were enrolled in the implant maintenance program (Table 2). The patients were instructed to have a soft food diet for 2 months. Ten days after surgery, the sutures are removed, and hygiene and implant stability were checked. The procedure was repeated 2 and 4 months after surgery was performed until a stable situation was envisioned.

Follow-up

The patients were frequently recalled during the early healing period for detection of mechanical complications or clinical signs of inflammation/infection in the treated sites.

At the 10-day and 1-year follow-up examinations intraoral and/or panoramic radiographs were taken for evaluation of bone levels and signs of periimplant pathology. Radiographic readings were performed by a dental surgeon, not involved in the patient treatment. The implant-abutment interface was used as reference point for the bone level measurements, which were performed with an accuracy of 0.5 mm.

Implant survival and failure criteria

An implant was classified as surviving if: 1) it fulfilled its purported function as support for a full-arch reconstruction, 2) it was stable when tested manually, 3) no signs of infection were detected during clinical examination, and if 4) no signs of periimplant pathology were seen on the radiograph. Implants that did not meet the survival criteria were classified as failures.

Statistics

The implant cumulative survival rate, based on all the inserted study implants, was evaluated using life table analysis.

Results

A total of 234 implants were placed and immediately loaded by 53 full-arch reconstructions (44 maxilla, 9 mandible) in 46 patients. One-hundred eighty-nine (189) of the implants had the novel implant design described in previous sections, and are referred to as study implants. All study implants had a diameter of 4 mm and were represented in two different lengths: 13 mm (n=28) and 15 mm (n=161). The remaining 45 implants were Brånemark System MkIII (n=19) or MkIV (n=26) implants (Nobel Biocare AB, Gothenburg, Sweden). This report focuses exclusively on the study implants.

Of the study implants, 166 were placed in the maxilla and 23 in the mandible, and 105 implants were placed in posterior sites. Ninety-six (96) of the implants were tilted and 93 were placed in axial positions. The tilted implants were provided with angulated abutments; 86 of the angulated abutments had a 30° angulation and the remaining 10 had a 17° angulation.

The number of implants in relation to position is presented in table 3.

The opposing dentitions were implant-supported prostheses (27 patients), natural teeth (13 patients), a combination of both (5 patients), or removable prostheses (1 patient).

The bone quality and quantity of the implant sites varied (table 4).

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Thirty patients received four implants as support for the complete-arch reconstructions (35 reconstructions, 27 maxilla, 8 mandible). The remaining reconstructions were supported by 5 to 8 implants. Figure 2 shows the clinical case of a 49-year-old female receiving the treatment.

All patients were followed for a minimum of 1 year after loading, with a mean follow-up time of 12.9 months. Two implant failures occurred, rendering an implant survival rate for the study implants of 98.9 % after 1 year of loading (table 5).

The two failures were two maxillary tilted posterior implants (position 26), which were lost due to loss of osseointegration in two bruxing patients. The failures occurred after 1 month in a female patient with bone quality 4, and after 6 months in a male patient with bone quality 2. The sites were left to heal for a period of approximately six months, during which the prostheses functioned on the three remaining implants, before new implants were placed and included in the prostheses.

Marginal bone level

Readable radiographs were obtained for 75% of the patients. At the end of the observation period, the bone level was situated, on average, 1.2 ± 0.7 mm below the implant-abutment interface. The marginal bone levels were 1.2 ± 0.8 mm and 1.1 ± 0.9 mm at the mesial and distal sides, respectively.

Mechanical complications

The only mechanical complication recorded was prosthetic screw loosening in six patients. All these patients were identified as bruxers, which probably was the main

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cause of the screw loosening. After retightening and employment of night guards, no

further loosening occurred during the observation period. No implant fractures and no

fracture or loosening of abutment screws was observed during the observation period.

Soft tissue health

The overall soft tissue health was good. Persistent biological problems stemming from an infected mucosa were observed at the 1-year follow-up in two patients, who had not attended all the postoperative follow-up visits. Radiographic examinations revealed local bone defects around two adjacent implants in one of the patients, and around one implant in the other patient. After detection of the periimplant problems, both patients received a rigorous hygiene maintenance treatment, whereby further bone resorption was avoided. Implant stability was maintained throughout the treatment.

Esthetic outcome

Overall good esthetic outcomes were achieved. The reduced collar height of the implants made it possible to avoid implant and abutment protrusion through the mucosa, resulting in esthetically favorable emergence profiles. On the request of 33 of the patients, their provisional prostheses were not replaced.

Discussion

The present pilot study evaluated the performance of implants with a novel design, placed in edentulous jaws as support for immediately loaded complete-arch restorations.

The clinical survival rate of 98.9% after 1 year of loading shows that this implant design

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can be used with predictable results in combination with immediate function in various types of bone.

The narrow tip of the study implant facilitated insertion in under-prepared sites by acting as an osteotome. This design feature resulted in good mechanical anchorage of the implant, which makes it especially suitable for soft bone situations and immediate function protocols. In the present study, the use of the study implants was initially restricted to sites presenting soft bone; it was believed that the implant design might cause bone necrosis by excessive compression of the surrounding bone if applied in under-prepared sites in high-density bone. However, during the course of the study, it was concluded that the implants performed equally well in all types of bone.

It was observed that the narrow tip of the study implant prevented the implant from starting to spin, with subsequent loss of stability, when higher density areas were reached during insertion, thus facilitating a smooth insertion without wobbling of the implant. It can be speculated that the good insertion characteristics of the implant in variable bone qualities makes it suitable for grafted bone, which often consists of layers of varying densities. It was also noticed that the osteotome effect allowed for placement of the implant in narrow ridges.

The majority of the restorations (83%) in this study were maxillary complete-arch prostheses. Immediate/early function of complete-arch reconstructions in the mandible is well documented^{1, 21-31} while the available clinical data on immediate/early function in the fully edentulous maxilla is limited.^{2,11,32-35} The good clinical outcome of the

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present study adds to the relatively scarce literature that supports immediate loading of implant-supported maxillary full-arch restorations.

Rehabilitation of the region posterior to the first premolar in the maxillary arch is particularly demanding, because of the often compromised bone situation in this region of the jaw. Implant tilting has proven to be a way of circumventing the problem of reduced bone volume in distal sites, thus avoiding the use of bone grafts.¹⁵⁻¹⁹ Encouraging results from recent publications suggest that implant tilting in combination with immediate/early function may be a viable concept.^{1,2,17} In the present study, out of the ninety-two (92) implants placed in the posterior maxilla, 75 were tilted. Despite the failure of two of these implants, posterior implant tilting in combination with immediate loading may be considered a reliable treatment modality, provided high mechanical stability of the implant is granted at insertion. The two implant failures occurred in two bruxing patients.

The overall marginal bone remodeling of 1.2 ± 0.9 mm after 1 year of loading is in accordance with previous publications on immediately loaded anodized implants.^{12,14,36} For example, in a recent long-term clinical study³⁷ a marginal bone resorption of 1.2 mm was recorded during the first year of loading, after which the bone level remained stable throughout the four-year observation period.

Regarding the mechanical problems, the prosthetic screw loosening occurred in six bruxing patients was solved by manufacturing a night guard. The fact that these problems were detected and solved in an early stage, accounted for a good prosthetic outcome, as no further mechanical problems were encountered.

The overall esthetic outcome of the treatment was judged good by the clinician and excellent by the patients. The reduced collar height of the study implant allowed for deeper placement of the implant platform as compared to Brånemark System MkIII and MkIV implants, which resulted in esthetically favorable positioning of the transmucosal abutment. In edentulous cases, which are often characterized by a very thin mucosa, abutment protrusion through the mucosa may be difficult to avoid, especially when implant tilting is employed. In the present study, angulated abutments with minimum heights of 2 and 4 mm (17° and 30° abutments, respectively) were used to correct the emergence profile of the tilted implants, and supragingival abutment exposure was avoided thanks to the reduced implant collar height. The fact that seventy-two percent (72%) of the patients declined having their provisional prostheses replaced by final prosthesis as suggested by the protocol indicates a very high patient satisfaction in terms of esthetics and function.

The short collar in combination with the narrow implant tip rendered the study implant more flexible in terms of vertical positioning, as compared to implants lacking these features. This important characteristic is valuable whenever it is desirable to adjust the axial position of the implant without having to repeat the drilling procedure.

The strict patient observation protocol including frequent follow-up examinations during the initial period following implant placement was performed to allow for early detection of signs of adverse biological conditions. At the 1-year follow-up, bone healing was uneventful and good soft tissue health was maintained in all cases but two. In these two patients, persistent biological problems, stemming from an infected mucosa

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and affecting the periimplant bone, were detected. These conditions would probably

have been avoided, had the patient not neglected the important early follow-up visits

postsurgery.

Conclusions

The results of the present pilot study indicate that fully edentulous jaws with various types of bone quality can be treated with high success and good esthetics using immediately loaded implants featuring a narrow implant apex, reduced collar height and an anodically oxidized implant surface, and that favorable marginal bone levels can be maintained.

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Uncorrected version

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Table index

Table 1. Age distribution at surgery

Patient age	Number of patients
31-40 years	4
41-50 years	12
51-60 years	18
61-70	8
> 70 years	4
Total	46
Max	78 years
Min	32 years
Average	55.2 years

Table 2. Maintenance protocol

1st day (Day of the surgery)	Oral hygiene; explanation of treatment phases and maintenance procedures to the patient; Application of a chlorhexidine gel and hyaluronic acid gel after the surgery; Control of occlusion; Information that should not overload the structure.
10th day post surgically	Panoramic x-ray; Periapical X-ray; Removal of the prosthesis for disinfection and cleaning; Removal of suture (if used); Application of a chlorhexidine gel; Control of suppuration by finger pressure; Control of occlusion; Application of a hyaluronic acid gel. Information that should not overload the structure. Check for any fracture or loosening of prosthetic components
2 months post -surgically	Oral Hygiene; Jet-clean; Application of a chlorhexidine gel; Control of suppuration by finger pressure; Control of occlusion. Check for any fracture or loosening of prosthetic components
4 months post- surgically	Oral Hygiene; Periapical X-ray; Removal of prosthesis for cleaning and disinfecting; Application of a chlorhexidine gel; control of occlusion. Check for inflammation/infection. Check for any fracture or loosening of prosthetic components
6 months post-surgically or at placement of the final prosthesis	Oral Hygiene every 4 months without removal of the prosthesis; Control of occlusion; Check for inflammation/infection.
1 year post-surgically, ant from then onwards	Oral Hygiene every 6 months without removal of the prosthesis; Control of occlusion; Check for inflammation/infection; Annual X-ray.
In case of problem detection	Removal of prostheses for disinfection and cleaning, and for testing the implants in terms of infection and stability.

Table 3. Implant distribution

Number of implants per position																	
	Position	18	17	16	15	14	13	12	11	21	22	23	24	25	26	27	28
Maxilla	Axial (n=84)	-	-	2	-	7	4	29	2	2	27	3	6	1	1	-	-
	Tilted (n=82)	-	-	15	20	2	1	-	2	1	1	2	1	20	16*	1	-
	Total (n=166)	-	-	17	20	9	5	29	4	3	28	5	7	21	17	1	-
Mandible	Position	48	47	46	45	44	43	42	41	31	32	33	34	35	36	37	38
	Axial (n=9)	-	-	-	-	-	-	4	-	-	5	-	-	-	-	-	-
	Tilted (n=14)	-	-	1	4	1	-	1	-	-	-	-	1	6	-	-	-
	Total (n=23)	-	-	1	4	1	-	5	-	-	5	-	1	6	-	-	-

*Two of these implants failed

Uncorrected

Table 4. Bone quality and quantity per patient

		Bone quality *				Total
		1	2	3	4	
Bone quantity*	A	-	-	-	-	-
	B	1	19	3	1	24
	C	-	1	5	6	12
	D	-	-	2	8	10
	E	-	-	-	-	-
	Total	1	20	10	15	46

* According to Lekholm & Zarb (1985)²⁰.

Table 5. Life table analysis

Time Period	Implants	Failed	Withdrawn	Cumulative survival rate (%)
Placement = Loading	189	0	0	100.0
Loading - 1 month	189	1	0	99.5
1 - 6 months	188	1	0	98.9
6 months - 1 year	187	0	0	98.9
1 Year	187	-	-	98.9

Uncorrected version

Figure Legends



Fig. 1 The study implant features a short collar, a straight body and a narrow implant apex. The implant has a microtextured surface produced by anodic oxidation.

Fig. 2 Clinical images showing the case of a 49-year-old female patient receiving a full-arch mandibular reconstruction.



(a) Preoperative panoramic radiograph showing the need for prosthetic rehabilitation of the mandible.



(b) A surgical guide was used during drilling and implant insertion to facilitate precise implant positioning.



(c) Clinical view after abutment connection.

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(d) Provisional prosthesis in place.



(e) Postoperative panoramic radiograph.

Uncorrected version