



A Single-Center Retrospective Analysis of 1001 Consecutively Placed NobelActive Implants

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Endosseous implants have been widely used in dental treatment to replace natural teeth in edentulous spaces.¹⁻⁵ The original protocol for placement of the 2-piece Brånemark dental implants suggested 3 months of soft and hard tissue healing after tooth removal and an additional submerged 3 to 6 month load-free osseointegration period.^{6,7} This submerged approach was considered a mandatory condition for achieving successful osseointegration.^{8,9}

The survival rate for osseointegration of endosseous dental implants depends on several variables such as (1) implant macrostructure (shape), (2) surgical technique, and (3) implant microstructure (surface).⁶

Implant macrostructure (shape) refers to parallel or tapered body dental implants. Some of the tapered body implants from Nobel Biocare AB, Gothenburg Sweden are Replace Select (RS); Replace tapered body groovy (RTG) and the NobelActive (NA) implants. The NA implant is a variable thread tapered implant that has some additional features such as an extensive self-drilling capacity, ax-

This single-center retrospective study evaluated the survival rates of the NobelActive implant (Nobel Biocare AB, Gothenburg, Sweden) with a tapered body design. One thousand and one implants demonstrated a

cumulative survival rate of 97.4% (97.1% in maxilla and 98% in the mandible) for up to 31 months of loading. (Implant Dent 2012;21:28-35)

Key Words: NobelActive implant, survival rates, tapered body implants

ial and radial bone compression and an inward tapered body collar designed for marginal bone maintenance and soft tissue stabilization. The design makes it possible to place the implant into narrower osteotomies requiring less drilling as compared with the standard implants (RS and RTG). The NA implant is designed to enhance primary stability and allows the surgeon to dictate and change the direction of the implant during insertion. Studies have been published on the initial torque stability of the NA implant¹⁰ and clinical evaluation of the same.¹¹

In another study, survival rates of the NA implant (96.6%) were comparable with a standard tapered body implant (96.6%).¹² Previously published, literature indicates that standard tapered body implants achieve better primary stability and have a higher likelihood of osseointegration when compared with parallel body designs. This is possibly due to the fact that tapered body implants distribute the forces into the surrounding bone in a much more uniform manner.¹³⁻¹⁷ Tapered body implants such as the RS are associated with greater early stability and higher long-term success rates.^{14-16,18} Several short-term studies with tapered body implants (RS and RTG) reported excellent survival rates

from 94% to 100% after a 1-year follow-up.¹⁹⁻²⁶ Long-term studies have reported survival rates of upto 99.3% for tapered body implants (RS).^{27,28}

With regard to surgical technique, dental implants were historically placed using a 2-stage procedure. A flap was raised during the first-stage procedure and an osteotomy site was prepared. The flap was then repositioned covering the implant and bone during healing. After a specified healing period, a second-stage surgery was performed to uncover the implant, and allow connection of transmucosal components and subsequent prosthesis fabrication and connection.⁸

Advancement of implant dentistry indicate that the submerged healing period used in the traditional 2-stage dental implant treatment may not be necessary and that implants can be placed in a nonsubmerged 1-stage manner. In this 1-stage procedure, transmucosal components are immediately connected to the implant and an immediate prosthetic loading protocol may be applied without compromising osseointegration, provided that primary stability of the implant when controlled occlusal loads have been established.²⁹⁻³¹ No significant differences were observed between survival rates of tapered body implants (RS and RTG) placed using the 1-stage or the

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2-stage surgical technique.^{20,23,25,27,32} Survival rates of the NA implant (96.6%) placed using a 1-stage surgical technique were comparable with those of standard tapered body implant design (96.6% RTG).¹²

Implant microstructure (surface) is another factor affecting osseointegration and subsequent survival rates.⁶ The RS, RTG, and NA implants possess a specialized anodized surface called TiUnite. This textured surface extends all the way to the top in the RTG and the NA implants. It has been noted that textured implant surfaces, including appropriately placed surface grooves on the threads of implants, can increase stability when compared with implants without textured surfaces.³³⁻³⁶ Studies have also reported that bone preferentially bonds with grooves in the body of an implant and grooves that have been extended to the collar of the implants increase the surface area and the bone-to-implant contact.^{37,38} The RTG and NA implants have grooves on both the threads and the collar whereas the RS has a machined collar with no grooves on the surface. Overall, published studies with a follow-up of up to 1 year with tapered body implants and grooves on the surface (RTG, NA) reported excellent survival rates between 96.2% and 100%.^{12,32,39}

Survival rates of tapered body implants from Nobel Biocare have been reported in the literature predominantly with the RS and RTG implants as previously mentioned. To the author's knowledge, only 1 study has been published with NA implants reporting a high survival rate of 96.6%. This study showed survival rates of the NA implant to be comparable with the standard tapered body implant (RTG).¹² This retrospective article presents the survival rates of the NA for up to 31 months of loading.

MATERIALS AND METHODS

Patients in need of endosseous dental implants were treated with NA implants in a single clinic. Consecutive patients included in this retrospective analysis met the following criteria:

1. They were medically able to withstand the procedure and had acceptable oral hygiene.
2. They possessed a bone profile for the placement of implants of at least 10 mm in length.
3. Implants were placed in healed or extraction sites.
4. Smoking was not an exclusion criterion, although patients were advised to quit smoking because it may increase the implant failure rate.

In general, patients were not treated with endosseous dental implants for the following reasons:

1. Alcohol or drug abuse was noted.
2. Severe bruxism or clenching habits were noted.
3. Insufficient bone quality and quantity for placement of endosseous implants.
4. Compromised medical history that would affect implant placement (eg, bisphosphonates, chemotherapy).
5. The need for bone augmentation to obtain an ideal positioning of the implant (minor augmentation to cover the exposed threads was not an exclusion criterion).
6. Psychiatric disease.

Patients with partially or fully edentulous arches and/or in need of extraction of the remaining compromised teeth were rehabilitated with the NA implants. The first implant was placed on February 18, 2008, and the last implant was placed on September 12, 2009, for the purpose of this analysis. The definitive prostheses were delivered within 6 to 8 months after implant insertion. An actuarial life table method was used to determine implant cumulative survival rate (CSR).⁴⁰

Following discussion of the planned treatment strategy with patients, a comprehensive clinical and radiographic examination was performed by 2 experienced clinicians (G.K., C.B.) using a cone beam computed tomographic scan (I-CAT cone beam CT-scan; Imaging Science Corp, Hatfield, PA) the bone profile, which included the bone quality and bone volume was assessed.⁴¹ In the vast majority of cases, the patient was administered intrave-

nous (conscious) sedation using Fentanyl citrate 0.5 mg/mL (Fentanyl; Hospira, Lake Forest, IL), Diazepam 5 mg/mL injection (Valium; Hospira), and nitrous oxide oxygen inhalation. This was in addition to Articaine hydrochloride 4% with epinephrine bitartrate 1:100,000 (Septodont, Paris, France) local anesthesia which was administered in both block and infiltration technique. When required, a few patients were administered general anesthesia based on their preexisting medical profile.

In cases where teeth had to be extracted, patients were advised to begin a course of antibiotic (Penicillin VK 250 mg, Dispensing solutions, Santa Ana, CA), 4 times a day, starting 2 days before the surgical procedure. Postoperatively, all patients were given the same antibiotic 4 times per day over a period of 10 days. If patients were allergic to Penicillin, Clindamycin tablets (Clindamycin HCL 150 mg; Dispensing solutions) were given with a similar dosage regimen. In addition, Hydrocodone bitartrate and acetaminophen 7.5 mg/750 mg (Hydrocodone; Dispensing solutions) were used as an analgesic and Methylprednisolone; 4 mg dose pack (Medrol; Dispensing solutions) was used as an anti-inflammatory medication. At the end of the procedure Bupivacaine 0.5% with 1:200,000, Epinephrine (Bupivacaine-Cook-Waite, Greensboro, NC) was also administered for its analgesic sparing effect.

A majority of the patients underwent a 1-stage protocol with a fixed, partial provisional prosthesis, immediately loaded on the day of implant placement. In each completely edentulous arch, 4 implants were placed according to the "All-on-Four" concept. This concept is based on an optimal number of 4 implants supporting an edentulous jaw with a complete arch prosthesis. Two implants were placed vertically in the anterior region and 2 implants were tilted in the posterior region (All-on-Four).⁴²⁻⁴⁹ In the completely edentulous jaw and the postextraction patient, problems such as minimum bone volume, poor bone quality, and the need for bone grafting procedures before implant placement create some challenging conditions. For these situa-

tions, it has been demonstrated that distal tilting of implants may be advantageous. Tilting preserves relevant anatomical structures and allows for placement of longer implants with good cortical anchorage in optimal positions for prosthetic support.⁴⁶ All "All-on-Four" patients underwent immediate implant placement with immediate provisionalization. In cases of immediate implant placement, the soft tissues were readapted to obtain a primary closure around the abutments, and sutured into position with interrupted resorbable 4.0 chromic sutures (Salvin dental specialties, Charlotte, NC). When implants did not achieve primary stability, a 2-stage surgical protocol was used. In these cases, implants were placed with healing screws, and flaps were closed with interrupted resorbable 4.0 sutures. The bone was left to heal for a period of 3 months.

All implants were inserted according to the manufacturer's guidelines (Manual No: 21279-GB085, Nobel Biocare Services 2008). The drilling protocol followed the manufacturer's guidelines. For soft bone type IV, medium type III, type II, and dense type I bone, the recommended drill sequences were followed. Implants were routinely placed in undersized receptor sites to the level of the crestal bone only, thus avoiding countersinking. This technique maximized the cortical support and subsequently increased primary stability. Insertion torque was measured for all implants using a special torque wrench capable of measuring torques up to 70 N · cm (surgical manual torque wrench; Nobel Biocare, AB).

Straight, 17 and 30-degree angulated multiunit abutments, internal (Nobel Biocare) were used for the "All-on-Four" patients. Immediate temporary abutments, internal, and Quick temporary abutment conical were used for single and partial restorations. Healing screws were used when implants were placed using the 2-stage surgical procedure.

Open tray multiunit impression copings (Nobel Biocare) were placed on the abutments and an impression was made with a custom open tray using precision impression material

Table 1. Implant Placement

Maxilla			Mandible		
Position (FDI)	Position (US)	Total = 597	Position (FDI)	Position (US)	Total = 404
18	1	1	48	32	0
17	2	2	47	31	1
16	3	24	46	30	32
15	4	95	45	29	58
14	5	26	44	28	31
13	6	45	43	27	32
12	7	71	42	26	39
11	8	20	41	25	4
21	9	16	31	24	12
22	10	76	32	23	34
23	11	47	33	22	34
24	12	41	34	21	14
25	13	98	35	20	69
26	14	33	36	19	38
27	15	2	37	18	6
28	16	0	38	17	0

US, Universal tooth numbering system used in the United States; FDI, Fédération Dentaire Internationale (tooth numbering used internationally).

(Flexitime; Heraeus Kulzer, Hanau, Germany). Patients were asked not to clean or brush the implant area and to use warm water rinses for 1 week after implant placement. A cold, or room temperature, soft diet was recommended for the first 24 hours after surgery, followed by a semisolid diet for the next 3 months. Patients were given antibiotics and analgesics as listed previously. A cone beam computed tomographic scan was taken immediately postoperatively to verify the implant positions and the prosthetic components in the case of total arch reconstructions; whereas digital periapical radiographs were taken for single or partial restorations, using the paralleling technique.

When using the "All-on-Four" procedure, a full denture was prefabricated with heat-cured acrylic resin (Ivoclar high impact acrylic; Ivoclar Vivadent, Schaan, Liechtenstein) before the surgical procedure. Immediately after surgery, the provisional was modified to the master model in the laboratory. Fabrication was completed using cold curing material (Probace; Ivoclar Vivadent). This provisional, all acrylic resin prosthesis was seated within 3 to 4 hours of completion of surgery. For single or partial cases placed in the aesthetic areas of the oral cavity, temporaries were made chairside. When implants were

placed with a 2-stage procedure, a stage 2 uncovering of the implant was performed approximately 3 months after implant placement. The cover screws were removed and healing abutments were placed.

In immediate placement cases, acrylic provisional restorations were placed within 3 to 4 hours of surgery. Occlusal contact was limited to the anterior area only in cases of total maxillary or mandibular reconstructions. In cases of partial dentures or single crowns, provisional restorations were placed out of occlusal contact.

Patients were scheduled for routine follow-up visits after surgery at 1, 2, 4 weeks and at 3 months postoperatively and on a yearly basis. At the 3-month appointment, fabrication of the definitive prosthesis was initiated. Periapical digital radiographs using a parallel technique were obtained at the 3-month appointment and thereafter, on a yearly basis from the date of the surgery. Implants were checked by visual observation for plaque and bleeding on probing at the follow-up intervals. Periapical radiographs, plaque and bleeding indices at various follow-up intervals are part of routine care for patients at the clinic and not a part of the analysis in this article.

The "All-on-Four" definitive prostheses consisted of a milled titanium

frame with a wrap around heat-cured acrylic resin (Ivocap high impact acrylic). Single or partial definitive prostheses were either All-ceramic or Porcelain fused to metal crowns or bridges, no attempt was made to obtain a numerical count of these restorations in this analysis. All prosthetic procedures were conducted by the same prosthodontist (G.K.).

A modified implant survival criteria used in this investigation are the following: implants should be functional and stable (the stability of individual implants was tested using a long laboratory screw or torque wrench applied to the abutment), no periimplant radiolucency on radiographs, no suppuration, or pain at the implant site and no signs of periimplantitis.⁵⁰ A "failed implant" is an implant that has to be removed because it can no longer be maintained due to periimplantitis, is mobile and/or has not undergone osseointegration. A "successful prosthesis" is a stable prosthetic restoration in functional load.⁴

Table 2. Implant Size Report

Implant Type	Diameter	Length	Maxillae	Mandibles	
NobelActive, 3.5	8.5 mm	—	—	—	
	10 mm	—	5	13	
	11.5 mm	—	16 (1)	11 (4)	
	13 mm	—	58 (2)	13	
	15 mm	—	30 (1)	53	
	18 mm	—	—	—	
NobelActive TiUnite, 4.3	8.5 mm	—	1	—	
	10 mm	—	6	8	
	11.5 mm	—	20 (2)	23	
	13 mm	—	116	38 (2)	
	15 mm	—	123 (5)	102	
	18 mm	—	5 (1)	1	
NobelActive TiUnite, 5.0	8.5 mm	—	—	—	
	15 mm	—	5	4 (1)	
	11.5 mm	—	14	12	
	13 mm	—	36	37 (1)	
	10 mm	—	150 (4)	85	
	18 mm	—	12	4	
Total			1001 (24)	597 (16)	404 (8)

Values in parentheses represent failed implants.

A single reviewer (C.B.) abstracted the relevant data from medical records of the patients that were treated consecutively and rehabilitated with the NA implants. Data were entered into a spreadsheet (Excel 2007; Microsoft, Redmond, WA). An actuarial life table⁴⁰ was used to calculate the CSR. Statistical analysis was done in SPSS version 17.0 (SSPS, Chicago, IL) using the Fisher exact test to determine the level of significance ($P < 0.05$) comparing the survival rates of the arches and the various implant sizes.

RESULTS

One center consecutively treated 293 patients (172 men and 121 women). Patient age at the time of

surgery was reported to be a mean of 59 years (SD ±12). A total of 1001 implants were placed (Table 1). Five hundred ninety-seven implants were placed in the maxilla and 404 in the mandible. The implants were available in 3 diameters (3.5, 4.3, and 5.0) in 6 different lengths (8.5, 10, 11.5, 13, 15, and 18 mm) (Table 2). Of the 1001 implants, 42 were re-stored by 26 other clinics, data collected from these clinics reported no adverse events or failures.

Fifty-nine implants underwent single-tooth replacements, 234 partially edentulous replacements and 708 were placed in fully edentulous patients in healed and/or immediate extraction sites. A total of 44 implants in 27 patients failed and/or were lost to

Table 3. Life Table Analysis (All Implants)

	Placed/Followed Implants	Failed/ Replaced	Time Not Passed	Lost to Follow-Up	CSR
II to 3 mo	1001	8	0	15	99.2
3-6 mo	978	8	0	0	98.4
6-12 mo	970	6	0	4	97.8
12-18 mo	960	0	373	1	97.8
18-24 mo	586	2	368	0	97.4
24 mo	216				

II indicates implant insertion.

Table 4. Life Table Analysis

	Placed/Followed Implants	Failed/ Replaced	Time Not Passed	Lost to Follow-Up	CSR
3.5 Diameter implants					
II to 3 mo	199	1	0	5	99.5
3-6 mo	193	3	0	0	98.0
6-12 mo	190	1	0	0	97.4
12-18 mo	189	0	77	0	97.4
18-24 mo	112	1	69	0	96.6
24 mo	42				
4.3 Diameter implants					
II to 3 mo	443	3	0	3	99.3
3-6 mo	437	4	0	0	98.4
6-12 mo	433	4	0	2	97.5
12-18 mo	427	0	154	1	97.5
18-24 mo	272	1	174	0	97.1
24 mo	97				
5.0 Diameter implants					
II to 3 mo	359	4	0	7	98.9
3-6 mo	348	1	0	0	98.6
6-12 mo	347	1	0	2	98.3
12-18 mo	344	0	142	0	98.3
18-24 mo	202	0	125	0	98.3
24 mo	77				

II indicates implant insertion.

follow-up (24 implants failed in 20 patients and 20 implants were lost to follow-up in 7 patients). Twenty of the failed implants were replaced whereas 4 were not replaced for various reasons being insufficient crestal bone in 1 implant and 3 failed implants (1 patient) were not replaced because patient opted out of further treatment.

Seven hundred eight implants restoring fully edentulous jaws (109 maxillae and 68 mandibles) have been placed. Twelve patients were treated in both jaws. Each prosthesis was supported by 4 implants ("All-on-Four"). The definitive prosthesis has been delivered in 174 jaws of 177 jaws (4 implants in each jaw); 3 of these implants failed during the provisional phase and were replaced. Sixteen implants with 4 jaws were lost to follow-up (3 jaws before definitive prosthetic delivery and 1 jaw lost to follow-up after definitive prosthetic delivery) This group demonstrated a 100% prosthetic survival rate to date.

The most common reasons for implant failure were periimplant radiolucency, pain, infection, and implant mobility. All failed implants reached primary stability at implant placement. None of the implant failures compromised prosthesis function, and no relationship was found between implant failure, and the opposing dentition. All patients in the analysis have completed the 1-year follow-up.

All implants achieved primary stability at placement. Ninety-four percent of the implants were placed using a 1-stage, immediate loading protocol, whereas 6% percent of implants did not achieve primary stability (torque = <35 N·cm at implant insertion) and were placed using a 2-stage surgical technique. The majority of the implants were seated with a minimum of 35 N·cm torque. Two percent ($n = 17$) of the implants were seated with a torque of <35 N·cm and 64% of the implants were seated at torque values ranging from 66 to 70 N·cm. For 50 implants, exact torque values have not been documented in the medical records of the patient. Five hundred forty-one implants were placed in extraction sites immediately after tooth extraction and 460 were

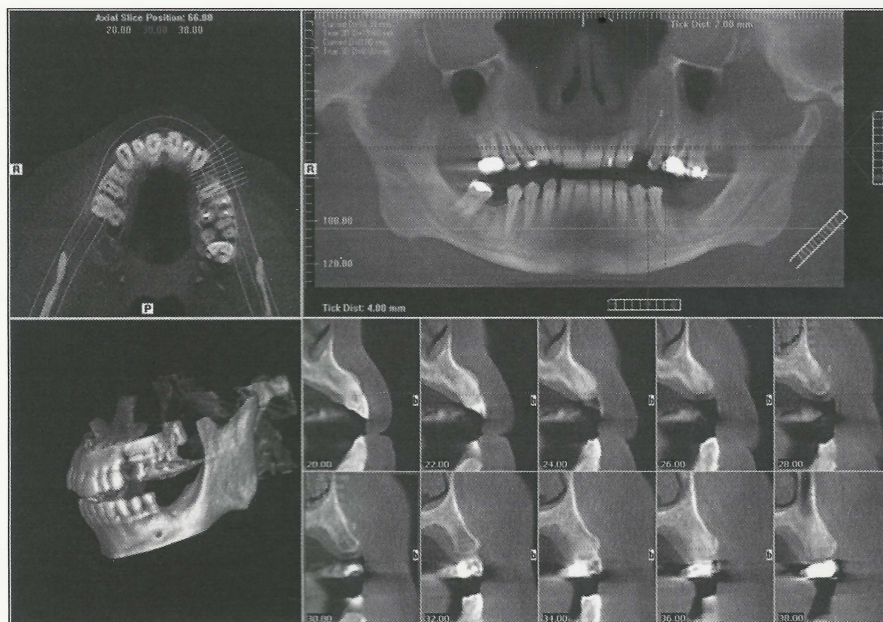


Fig. 1. Preoperative CT scan.

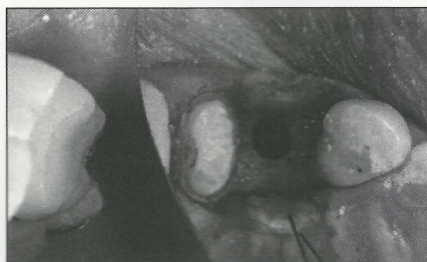


Fig. 2. Completed implant receptor site.

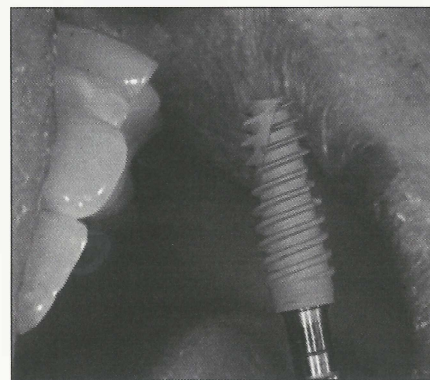


Fig. 3. The NobelActive implant.

placed in healed sites. Local bone grafting was performed at 63% of the implant sites (62% with Demineralized bone matrix gel (Dyna graft-D; Keystone Dental, Boston, MA) and 1% of implant sites were grafted with autogenous bone from the local surgical area); no bone grafting was reported in 37% of the sites. Implant follow-up occurred up to 31 months.

The overall implant survival rate was 97.8% (1 year) (Table 3), with no significant difference between the maxillae and mandibles (97.7% vs 98.0% at 1 year; $P = 0.83$ Fisher exact test). The 4.3-mm diameter implants were most frequently used with a survival rate of 97.5% (97.4% for 3.5 mm and 98.3% for 5.0 mm) at 1 year (Table 4). The overall definitive prosthesis survival rate was 99.8%, no total arch failures have occurred to date.

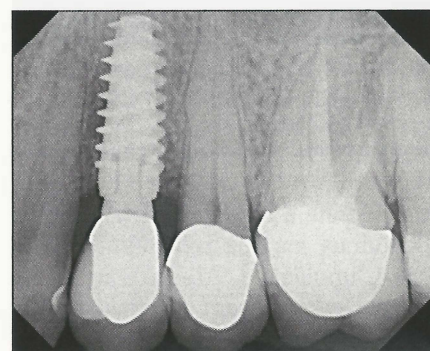


Fig. 4. Postoperative radiograph at 1 year with final crown.

The life table analysis demonstrating the CSR is reported in Table 3.

Figures 1 to 4 demonstrate a case in a healed site, and Figures 5 to 9

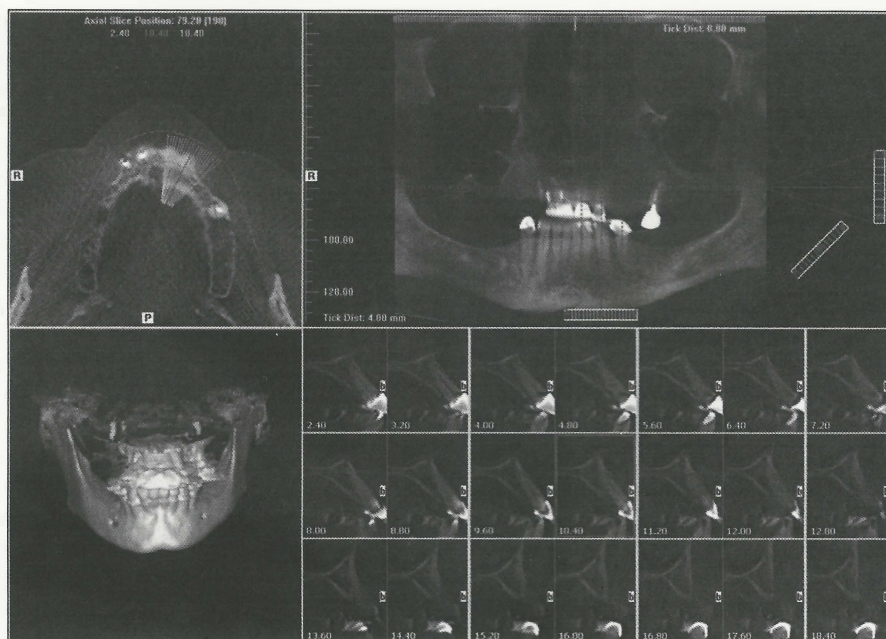


Fig. 5. The preoperative CT scan.

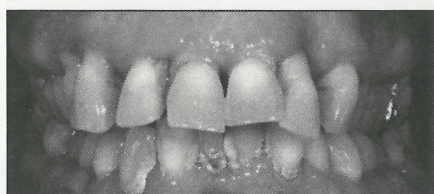


Fig. 6. The preoperative clinical view of the patient.



Fig. 7. Panoramic radiograph demonstrating the immediate postoperative position of the NobelActive Implant.

demonstrate a case in a patient with an edentulous maxilla rehabilitated with 4 NA implants ("All-on-Four"). No adverse events were reported during surgery or immediately after surgery.

DISCUSSION

These results of this retrospective analysis demonstrated that NA tapered body implants placed in various regions of the jaws, supporting single crowns/partial or full mouth recon-



Fig. 8. Final maxillary "All-on-Four" implant bridge and the mandibular removable partial denture.

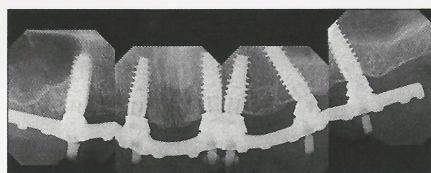


Fig. 9. Two-year postoperative series of periapical digital radiographs.

structions, exhibited an excellent overall survival rate of 97.4% CSR up to 31 months after loading. There was no significant difference between the survival rates within the maxillae and mandibles.

The results are comparable with other short-term studies using tapered body implants (RS). A high survival rate of 100% was reported in a 1-year, multicenter, prospective study where

120 tapered body implants (RS) were evaluated (32 were placed in the maxilla). The implants were loaded with fixed partial bridges (2–4 units) within 24 hours or 6 weeks.²⁰ In another 1-year prospective clinical study, Ostman et al²⁵ reported a survival rate of 97% for 33 tapered body implants (RS) which were placed in the edentulous maxilla using a 1-stage surgical technique when compared with a 2-stage historical control. De Rouck et al^{22,23} reported survival rates of 97% and 92% to 96% (1-stage vs 2-stage) in 2 different 1-year studies where 30 and 49 tapered body implants (RS) were used for single-tooth replacements.

Fischer et al²⁴ reported a high survival rate of 98.1% in a 1-year prospective clinical study with 53 tapered body implants (RS) where 16 single-tooth replacements were loaded the same day, whereas 37 partial bridges were delivered within 16 days. A 96.7% overall survival rate was reported in another 1-year, prospective study with 21 tapered body implants (RS) placed in partial or fully edentulous sites of the maxilla.²¹

The results of this study are in accordance with other long-term studies using tapered body implants (RS and RTG). Rao and Benzi²⁶ reported a high 100% survival rate in a 1 to 3 year prospective study with 51 implants (RS) where single-tooth implants were immediately loaded in the molar regions of the jaws. Bahat²⁷ also reported a high survival rate of 99.3%, 3 years after loading where the 290 RS implants were inserted using a 2-stage surgical procedure.

Previously published literature reports on survival rates of the RTG implants showed good survival rates, which are similar to the results of this analysis. A high survival rate of 100% was reported in 1 prospective randomized controlled, 1.9 to 2.1 year study with a split mouth design where 70 (RTG) and 63 (RS) tapered body implants were inserted in the mandible using a 2-stage delayed loading procedure,³² another 1-year prospective study reported a high survival rate of 100%, where 45 tapered body implants (RTG) were used to replace sin-

gle teeth.³⁹ Similarly good survival rates of 96.3% to 96.6% for NA implants and 97.6% survival rate for RTG implants was reported in a multicenter prospective, 1-year study where 199 NA and 126 RTG implants were inserted using a 1-stage surgical technique. Kielbassa et al¹² reported no significant differences between the survival rates of the NA and the conventional RTG implants. Other authors reported survival rates from 89.3% to 100% while using a similar tapered body implant design to the RS but with a hydroxyapatite-coated surface for single-tooth replacements.^{19,51-54}

CONCLUSION

Compared with the survival rates (92%–100%) of the RS and RTG tapered body implants as cited earlier, the overall CSR of 96.8% for the NA implant in this analysis can be considered as highly successful. Notably, only 1 published study reports the survival rates of the NA implant.¹² The authors conclude that the implant system (NA) used in this study demonstrates that this tapered body implant is an attractive addition to the armamentarium of tapered body implants offering clinicians an excellent solution for treatment of partially or fully edentulous and/or immediate extraction patients.

In essence, the overall survival rate using the NA implant with a tapered body and a variable thread design can be considered a viable treatment option for patients presenting with partially or completely edentulous arches.

DISCLOSURE

Dr. Babbush has a consulting agreement with Nobel Biocare AB, Gothenburg, Sweden, for ongoing clinical studies and continuing education courses.

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