A 5-Year Retrospective Study on Replace Select Tapered Dental Implants

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ABSTRACT

Background: Long-term data regarding survival and crestal bone loss for Replace Select Tapered implants (Nobel Biocare AB, Gothenburg, Sweden) are lacking.

Purpose: The study aims to present the 5-year outcomes from a retrospective analysis of Replace Select Tapered implants placed and restored in consecutive patients.

Materials and Methods: A total of 88 consecutive patients (32 male, 56 female, mean age 65 ± 12 years) treated by one clinician (PP) were clinically and radiographically evaluated during at least 5 years of function. A total of 271 dental implants (Replace Select Tapered, Nobel Biocare AB) with an oxidized surface (TiUnite, Nobel Biocare AB) had been placed in both jaws (228 in the maxilla, 43 in the mandible). The majority of implants were placed in healed sites (n = 244), while 27 implants were immediately placed in extraction sockets. The majority of implants (n = 262) healed for 3 to 4 months prior to loading, and nine implants were immediately loaded. A total of 121 implant-supported restorations were delivered; 42 single tooth replacements, 61 fixed partial bridges, 14 fixed full bridges, and 4 fixed partial implant-tooth connected bridges. The marginal bone level was measured in intraoral radiographs taken after surgery (baseline), and after 1, 2, 3, 4, and 5 years.

Results: Fifty-one patients with 160 implants were followed throughout the study. One implant failed at healing abutment connection 4 months after insertion, resulting in a cumulative survival rate of 99.6%. The average crestal bone loss was 0.9 ± 1.6 mm after 1 year and $0.1 \text{ mm} \pm 2.4$ after 5 years. There were 14.8% of measured implants that showed more than 2 mm and 5.2% more than 3 mm bone loss after 5 years, with no progression since the 1-year examination. One patient (2.0%) treated with six implants presented with significant crestal bone loss and recurrent peri-implant purulent infections at all implants.

Conclusion: The present retrospective 5-year study showed high survival rate and steady crestal bone levels for Replace Select Tapered dental implants.

KEY WORDS: crestal bone loss, dental implants, radiography, retrospective clinical study

INTRODUCTION

The use of implants for replacement of missing teeth is a first-choice treatment modality offered in many dental practices as an integrated part of the overall dental caretaking. In the early days, most implant patients were

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referred to specialists in surgery/periodontology and prosthodontics for the different treatment steps. Today, clinicians make both the surgical and prosthetic treatment, in spite of not being specialist in one or none of the involved disciplines. Implant dentistry is part of the undergraduate curriculum at dental schools and universities,¹ which means that many newly examined dentists are performing implant treatments. It can be anticipated that the implants in published studies, which constitute the base of our knowledge of implant dentistry, have mainly been placed and restored by specialists. Moreover, previous studies have commonly been using specific inclusion criteria to select patients for a certain indication and/or treatment technique.^{2–5} Thus, it is important to report the clinical outcome of implants

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placed and restored by inexperienced dentists and nonspecialists in consecutive patients seen in daily practice. For instance, studies have indicated that less surgical experience may lead to less good outcomes with regard to implant angulation⁶ and survival rates,^{7,8} and particularly in immediate loading.⁹

The long-term marginal bone and soft tissue responses to surface-modified implants in general and to oxidized ones in particular are under debate.¹⁰ Some authors foresee more problems related to crestal bone loss with such implants as shown in ligature-provoked animal studies.¹¹ However, although clinical studies have shown crestal bone loss at oxidized one-piece implants,^{12,13} the long-term literature on oxidized twopiece implants of Brånemark design shows high survival rates in general, stable crestal bone levels, and low incidences of peri-implant infection.^{14–17} The Replace Select Tapered dental implant (Nobel Biocare AB, Gothenburg, Sweden) is one of the world's most used implant according to the manufacturer. Although documented in a number of short-18-22 and medium-term23 clinical and radiographic studies, only one study²⁴ has presented 5-year data to the knowledge of the present authors. In that study, 79 implants placed in fresh extraction sockets in 56 patients were evaluated after 5 years. The author reported no implant loss, no purulent peri-implant infections and, on average, 0.6 mm of crestal bone loss after 5 years of follow-up.²⁴ However, the study focused on a specific indication in selected patients and the longterm outcomes of this implant design when used in consecutive patients in daily practice are not known.

This retrospective investigation was initiated to study the clinical and radiographic outcomes of a tapered implant design placed and restored by a specialist in prosthodontics and evaluated after at least 5 years of follow-up with regard to survival and crestal bone loss.

MATERIALS AND METHODS

Patients

The present retrospective study was initiated to retrospectively evaluate the clinical and radiographic outcomes of Replace Select Tapered dental implants (Nobel Biocare AB) after at least 5 years of function, which were the two inclusion criteria for the study. A total of 88 consecutive patients (32 male, 56 female, mean age 65 ± 12 years) were identified. The patients had been surgically and prosthetically treated by a specialist in prosthodontics (PP) from August 2003 to November 2006 and examined at annual check-up appointments for 5 years or longer. The notes and radiographs from follow-up appointments constituted the source of information for the study.

The reasons for implant treatment were problem with removable denture (n = 42), periodontitis and/or decay (n = 34), root fracture (n = 6), and other reasons (n = 16). A total of 121 areas were subjected to implant treatment due to total edentulism (n = 14), partial edentulism (n = 65), and single tooth gaps (n = 42).

Surgery and Implants

The implant placement surgery was made according to the manufacturers guidelines. In brief, the patients were given 2 g of amoxicillin (Amimox®, Tika Läkemedel AB, Lund, Sweden) prior to surgery. Infiltration anesthesia was induced with Septocain Forte (Bigman AB, Sundbyberg, Sweden) and a crestal incision was used to expose the bone. Implant sites were marked with a 1.8 mm round burr. The final preparation was made with designated tapered drills, which are available for each length and diameter. Mandibular sites were threaded with a screw tap. All implants were inserted with hand using a ratchet.

A total of 271 dental implants (Replace Select Tapered, Nobel Biocare AB) with an oxidized surface (TiUnite, Nobel Biocare AB) had been placed (Table 1). Most implants (n = 228) were placed in the maxilla and 43 implants were placed in the mandible (Table 2). The majority of implants were placed in healed sites (n = 244), while 27 implants were immediately placed in extraction sockets (Table 3). A two-stage procedure with cover screws was used for 235 implants and healing abutments for one-stage healing were applied to 36 implants (Table 3). Flaps were closed with resorbable sutures.

TABLE 1 Impl	ant Diame	ter and Le	ngths	
		Diam	neter	
Length (mm)	3.5 mm	4.3 mm	5.0 mm	Total
8		4	2	6
10	12	26	17(1)	55 (1)
13	23	89	19	131
16	9	52	18	79
Total	44	171	56 (1)	271 (1)

TABL	E 2 Im	plant	Distril	bution	accor	ding t	o FDI	Syste	m								
Maxil	la																
Site	18	17	16	15	14	13	12	11	21	22	23	24	25	26	27	28	Total
п	—		4	31	22	20	8	17	15	17	24	19	47 (1)	4	—	—	228 (1)
Mand	ible																
Site	48	47	46	45	44	43	42	41	31	32	33	34	35	36	37	38	Total
п			1	10	5	1	1	1	2	1	2	6	8	5			43

Failure in brackets.

The majority of implants (n = 260) healed for 3 to 4 months prior to abutment connection or impression (Table 3). The abutment connection surgery was made in local anesthesia, and in case of thin attached mucosa a minimal flap was used to make sure that the abutment was not piercing movable mucosa. In case of wide attached mucosa, a 5 mm punch was used to exposing the cover screw and applying a healing abutment. Resorbable sutures were used when needed.

Nine implants, five placed in extraction sockets and four in healed sites, were immediately loaded with a chair-side-made temporary crown retained to a temporary abutment (Immediate Provisional Abutment, Procera Esthetic Abutment, Nobel Biocare AB) with chloxhexidine gel and bonded with composite to the neighbouring teeth (Table 3).

Prosthetics

Impressions were taken on fixture level using Impregum[™] (3M, Sollentuna, Sweden). Eighty-seven prosthetic constructions were screw retained and 34 were cemented (Rely X Luting Cement, 3M ESPE, St. Paul, MN, USA) on individual titanium or zirconium abutments due to angulation problems (Table 4). Angulated abutments had been used in a few screw-retained partial and total cases to correct angulation. The screw-retained

TABLE 3 Type of Site Protocol	e, Surgery, and Loading	
	n	%
Healed site	244 (1)	90
Extraction socket	27	10
One-stage surgery	36	13
Two-stage surgery	235 (1)	87
Immediate loading	9	3
Delayed loading	262	97

single tooth replacements were porcelain-titanium or porcelain-zirconium crowns (Procera, Nobel Biocare AB). The partially edentulous cases were restored with porcelain on milled titanium frameworks (Procera Implant Bridge, Nobel Biocare AB). Full fixed bridges were made with acrylic teeth on milled titanium frameworks. Angulated abutments had been used in a few cases to correct angulation.

A total of 121 implant-supported restorations were delivered to the patients; 42 single tooth replacements, 61 fixed partial bridges, 14 fixed full bridges, and 4 fixed partial implant-tooth connected bridges (Table 4).

Radiography

The marginal bone level was measured in intraoral radiographs taken after surgery (baseline), and after 1, 2, 3, 4, and 5 years. The distance from the top of the collar to the first bone contact was measured at mesial and distal aspects of each implant by an independent radiologist. Measurement of the width of the implant collar was used for calibration. A mean value from each implant, based on calibrated mesial and distal measurements, was used for the further analyses.

The average distance from the top of the collar to the first bone contact (bone level) was calculated for each time-point based on all available radiographs.

TABLE 4 Type of Restorat	tions and Retention	
	n	%
Single tooth replacement	42 (1)	35
Fixed partial bridge	61	50
Fixed full bridge	14	12
Connected to tooth	4	3
Total	121 (1)	
Screw retained	87 (1)	72
Cemented	34	28
Total	121 (1)	

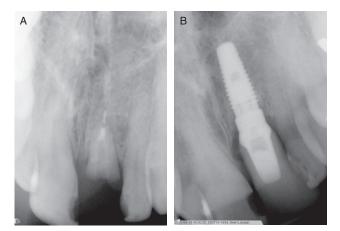


Figure 1 *A*, Radiograph showing root remnant before extraction and immediate placement of an implant for immediate loading. *B*, Radiograph showing same site after 7 years of loading.

The average crestal bone loss was calculated for each time-point based on available pairs of follow-up and baseline radiographs.

In addition, crestal bone levels and changes were evaluated for implants placed above, at, and below the bone level for all implants and after exclusion of implants placed in extraction sockets.

Frequency distributions based on bone level and bone loss measurements were calculated in millimeter intervals for each time-point.

RESULTS

Clinical Results

Thirty-seven patients with 111 implants were withdrawn during the 5 years of follow-up. The reasons were: moving away from the area (14), death (6), serious illness (5), poor compliance (10), family problems (1) and implant failure (1). Thus, 51 patients with 160 implants were followed for 5 years (Figures 1 and 2). One implant failed at healing abutment connection 4 months after insertion, resulting in a cumulative survival rate of 99.6% (Table 5). The failed implant was a 5×10 mm implant placed in the maxilla to replace a single second premolar using a two-stage technique. The patient was a smoker (+40 cigarettes/day) and had implant surgery another two times at the same site but lost the implants.

One patient (2.0%) treated with six implants for full fixed bridge in the maxilla presented with significant crestal bone loss and recurrent peri-implant purulent infections at all implants (3.8%). The sites were surgically explored and cleaned. The patient sees a dental hygienist every 3 months for professional cleaning. In spite of this, the infections are still recurrent. This patient is a smoker (+20 cigarettes/day) and suffers from Mb Crohn.

Radiographic Findings

Crestal Bone Levels. The crestal bone was located on average 1.6 ± 2.1 mm from the implant collar after implant surgery. This corresponds to 0.1 mm below the 1.5 mm high collar. The corresponding figures after follow-up were 2.5 ± 1.1 mm after 1 year (n = 206), 2.2 ± 1.2 mm after 2 years (n = 210), 2.0 ± 1.2 mm after 3 years (n = 175), 1.4 ± 1.0 mm after 4 years (n = 137), and 1.7 ± 1.5 mm after 5 years (n = 158) (Table 6, Figure 3).

Frequency distribution showed some changes of crestal bone levels over time with the majority of measurements found within the intervals from 1.1 to 3 mm from the top of the collar after 5 years (Table 6). There was a decrease or no changes in the number of implants in the intervals 3.1 to 4.0 mm and >4.0 mm from 1 to 5 years of follow-up.

Crestal Bone Loss. The mean crestal bone loss based on pairs of baseline and follow-up radiographs was

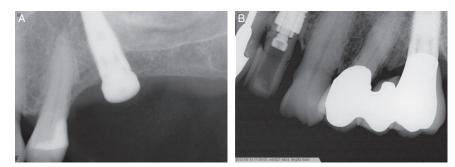


Figure 2 *A*, Radiograph taken after placement of an implant in upper second premolar region. *B*, Radiograph showing same site after 8 years of loading with an implant-tooth connected bridge.

TABLE 5 Life-Table Ana	lysis			
Interval	Implants	Failures	Withdrawn	Cumulative Survival Rate (%)
Placement – 1 year	271	1	23	99.6
1-2 years	247	0	12	99.6
2–3 years	235	0	13	99.6
3–4 years	222	0	36	99.6
4–5 years	186	0	26	99.6
>5 years	160			

 $0.9 \pm 1.6 \text{ mm}$ after 1 year (n = 130), 0.5 mm ± 2.4 after 2 years (n = 136), 0.4 mm ± 2.5 after 3 years (n = 128), 0.0 mm ± 1.9 after 4 years (n = 89), and 0.1 mm ± 2.4 after 5 years (n = 155) (Table 7).

Frequency distribution of crestal bone loss revealed that more than 30% of implants showed bone gain from baseline to 1 and 5 years (Table 7). Apart from the positive values, crestal bone loss was otherwise evenly distributed around the 1.1 mm to 2.0 mm bone loss interval. There was a decrease of implants in the intervals from 2.1 to 3.0 mm, 3.1 mm to 4.0 mm, and >4.0 mm intervals from the 1st to the 5th year.

Influence of Placement Depth. In general, analyses indicated less bone loss for implants with the collar placed above the crestal bone level compared with implants placed at or below the bone level (Figure 4). The mean crestal bone levels strived toward a similar value after 4 to 5 years, which could explain the different resorption patterns for the placement techniques. However, the majority of implants had been placed above bone level and too few implants had been placed at or below the bone level to allow for statistical analysis.

DISCUSSION

The present retrospective study was undertaken as a quality assurance measure to ensure that acceptable results can be achieved when a specialist in prosthodontics is surgically placing and restoring dental implants in consecutive patients in daily practice. The aim of the present study was also to evaluate the crestal bone levels and loss around the implant design used, that is, the Replace Select Tapered implant. A total of 37 of the original 88 patients were withdrawn during the study,

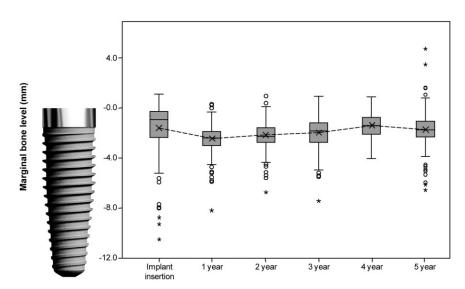


Figure 3 Box plot of crestal bone level over time based on all readable radiographs. X-values represent mean of group. Boxes show median, quartiles, and extreme values. Circles show outliers (cases with values between 1.5 and 3 box lengths from the upper or lower edge of the box). Stars represent values >3 box lengths.

TABLE 6 Marginal Bone Level Measurements Based on All Readable Radiographs	nal Bone Le	vel Measurer	nents Based	d on All Read	dable Radiog	graphs						
	Implant Insertion	nsertion	1-Year Follow-Up	llow-Up	2-Year Follow-Up	llow-Up	3-Year Follow-Up	dU-wolld	4-Year Fo	4-Year Follow-Up	5-Year F	5-Year Follow-Up
Number	162		206		210		175		137		158	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
Mean value	-1.62	.62	-2.46	46	-2.16	.16		-1.98	-1.4	.41	Ĩ	-1.74
SD	2	2.01	1.	.10	1.	1.15	1	1.24	0	0.98		1.49
	u	%	и	%	ч	%	ч	%	ч	%	u	%
>3.0	0	0	0	0	0	0	0	0	0	0	2	1.3
1.1-2.0	1	0.6	0	0	0	0	0	0	0	0	3	1.9
0.1 - 1.0	6	5.6	2	1.0	3	1.4	4	2.3	8	5.8	5	3.2
0	21	13.0	6	1.5	7	3.3	9	3.4	5	3.6	2	1.3
-1.0 to -0.1	57	35.2	15	7.3	28	13.3	28	16.0	31	22.6	28	17.7
-2.0 to -1.1	24	14.8	50	24.3	50	23.8	57	32.6	58	42.3	57	36.1
-3.0 to -2.1	25	15.4	90	43.7	87	41.4	53	30.3	29	21.2	42	26.6
-4.0 to -3.1	6	5.6	33	16.0	23	11.0	19	10.9	9	4.4	6	5.7
<4.0	16	6.6	13	6.3	12	5.7	8	4.6	0	0	10	6.3

All readable radiographs are included.

	Implant Insertion to 1-Year Follow-Up	sertion to llow-Up	Implant Insertion to 2-Year Follow-Up	sertion to llow-Up	Implant Insertion to 3-Year Follow-Up	sertion to Ilow-Up	Implant In 4-Year Fe	Implant Insertion to 4-Year Follow-Up	Implant Ir 5-Year F	Implant Insertion to 5-Year Follow-Up
Number	130		136		128		89		115	5
Mean value	-0.88	88	-0.46	46	-0.37	37	0.	0.00	Ĭ	-0.07
SD	1.	1.61	2.	2.36	2.	2.48	1.	1.91		2.41
	и	%	и	%	и	%	u	%	и	%
>0	39	30.0	49	36.0	46	35.9	42	47.2	42	36.5
0	Ŋ	3.8	Ŋ	3.7	7	5.5	2	2.2	Ŋ	4.3
-1.0 to -0.1	29	22.3	24	17.6	17	13.3	18	20.2	20	17.4
-2.0 to -1.1	25	19.2	23	16.9	26	20.3	13	14.6	31	27.0
-3.0 to -2.1	22	16.9	22	16.2	20	15.6	8	9.0	11	9.6
-4.0 to -3.1	8	6.2	11	8.1	6	7.0	9	6.7	5	4.3
<-4.0	2	1.5	2	1.5	ŝ	2.3	0	0	1	0.0

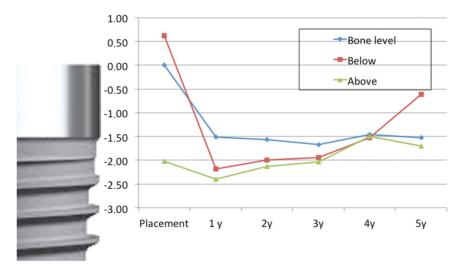


Figure 4 Plots of crestal bone levels for implants placed above (n = 76-133), at (n = 8-19), and below (n = 5-10) the crestal bone level.

which means that only 58% of included patients could be followed for the full 5 years. This is an obvious drawback with the study, as further failures and other problems may have occurred in this group, particularly in the 10 patients with poor compliance. However, more than 85% of all implants were followed for at least 3 years and most failures are expected during the first year in function.²⁵ Furthermore, because the number and reasons for dropouts are reported, full transparency is given to the readers. The study showed that only one implant was lost (0.4%) after 5 years, which is encouraging considering that the majority of implants were placed in the maxilla and that implants were placed in extraction socket and immediately loaded. Apart from the patient with an implant failure, one more patient presented with complications in form of recurrent peri-implant infection around all six maxillary implants. Hence, the prognosis for these implants is questionable and if lost the survival rate will drop to 97.4%. Otherwise, the radiographic analyses showed minor bone loss and steady bone levels over time, which will be discussed next.

The original Replace Implant was introduced by the Steri-Oss company (Yorbalinda, CA, USA) in 1998 and was available with a rough titanium-plasma sprayed or hydroxyapatite coating. In 1999, Nobel Biocare AB (Gothenburg, Sweden) acquired Steri-Oss, after which the implant was modified and became available with an oxidized surface (TiUnite). In spite of the long use, relatively few studies, including radiographic analyses, have been published.^{18–24} All studies. but one, report outcomes from immediate/early loading. In a study

by Bahat,23 290 maxillary two-stage implants in 126 patients were prospectively followed for at least 3 years. The survival rate was 99.3% and the marginal bone loss amounted to 2.2 mm where 1.5 mm was lost from placement to loading. Thus, 0.7 mm was lost during the 3 years of loading. These numbers corroborate with the results from other studies using the same implant for immediate loading as 1-year survival rates from 96.7% to 100% and crestal bone loss from 0.3 to 1.2 mm were reported.^{18–22} Less average bone level changes were seen over the 5 years of follow-up in the present study, which may relate to how the implants were placed. In general, crestal bone levels seem to stabilize at the first thread of many implant designs.²⁵ In the present study, the majority of implants were placed with the machined collar above the marginal bone. Analyses of implants with different placement depths in this study indicated less bone loss for implants with the collar placed above the crestal bone level compared with implants placed at or below the bone level. However, there were too few implants in each group to confirm possible effects of placement depth with statistical tests. Nevertheless, the results support the findings from other experimental²⁶ and clinical studies^{12,16} and the idea that implant geometry is the major drive behind marginal bone remodeling rather than infection. Extensive marginal bone loss and relative high failure rates have been described for onepiece implants with the same body configuration as the Replace Select Tapered implant.^{13,27,28} However, this implant was marketed to inexperienced implant users for flapless placement and immediate loading, which

required high-speed grinding of the collar in order to fit a crown or bridge. It is likely that the trauma due to the crude handling during placement, preparation of the collar, and immediate loading was to blame rather than the implant design itself. The same and other studies have shown better results when using a conservative approach with the one-piece implant.^{13,29}

Our outcomes are comparable with the 5-year results from studies on other oxidized implants.^{14,30-33} Friberg and Jemt reported survival rates of 97.1% and 98.4% and mean marginal bone loss of 0.7 and 0.8 mm for two patient groups treated with implants ad modum Brånemark.¹⁴ A survival rate of 97.3% and an average bone loss of 0.7 mm were observed for a group of totally edentulous patients followed for 5 years.³⁰ In a randomized study comparing early and delayed loading of two implants in the mandible with an overdenture, Turkyilmaz and colleagues³¹ reported no implant losses and a mean marginal bone loss of 1.3 mm after 7 years of loading. Glauser³² reported a survival rate of 97.1% and a mean marginal bone loss of 1.5 mm after 7 years for tapered implants (MkIV, Nobel Biocare AB) used in immediate loading. Calandriello and Tomatis³³ evaluated the use of a wide-platform oxidized implant used for immediate loading of single molar reconstructions, and showed a survival rate of 95% and an average marginal bone loss of 1.2 mm after 5 years of follow-up. In a review of 40 five-year investigations on three different implant designs and surfaces, Laurell and Lundgren reported that the average crestal bone loss was 0.24 mm, 0.48 mm, and 0.75 mm for Astra Tech, Strauman, and Brånemark implants, respectively.³⁴

About 14.8% of the present implants showed more than 2 mm bone loss after 5 years, which is similar to the 18% found by Mura.²⁴ In both studies, similar or higher proportions were seen after 1 to 3 years than after 5 years, which indicates that most bone loss occurred during the early healing and loading periods. This is in line with Glauser³² who found small further changes for oxidized implants showing more than 2 mm bone loss during the first year over another 6 years in loading. In their review on crestal bone loss at three different implant systems, also Laurell and Lundgren concluded that the major bone loss occurred during the first year in function followed by no or minor further changes.³⁴

Only one patient with six maxillary implants showed peri-implant bone loss and purulent infection. This corresponded to 3.8% of examined implants and 2.0% of patients after 5 years, which seems to be in line with the findings of other authors. A recent review of 10 ten-year studies on different surface-modified implants showed that on average, 2.7% of implants presented with purulent infection over 10 years.¹⁰ In a survey among private practitioners in Switzerland, the prevalence of peri-implantitis was found to be 5% after 5 years.³⁵

With the limitations of the present retrospective study, it is concluded that good clinical outcomes with high survival rates and minimal bone loss can be obtained when Replace Select Tapered implants are placed and restored by a specialist in prosthodontics.

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