Four-Year Treatment and Radiographic Outcomes of 1-Piece Implants Used in Immediate Function: A Prospective Study in a Single Private Practice

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The aim of this study was to prospectively evaluate treatment outcomes of 1-piece implants (NobelDirect and NobelPerfect, Nobel Biocare AB, Gothenberg, Sweden) in routine private clinical practice. Forty-seven implants placed in 30 subjects demonstrated a cumulative survival rate of 97.9% with stable marginal bone levels after 4 years of loading.

Key Words: NobelDirect implants, 1-piece implants

INTRODUCTION

Originally, the Branemark dental implant was designed as a 2-piece implant, to be submerged in the bone to allow for healing. Following a 3- to 6-month healing period, a second surgery was done by raising a flap to allow connection of the transmucosal component with a subsequent prosthetic connection.[1,2] This submerged approach, ad modum Branemark, was considered a mandatory condition for achieving successful osseointegration.[3,4]

It has since been demonstrated that a 2-stage procedure with a submerged healing period may not be required, and dental implants can be successfully placed in a 1-stage procedure without the need for a submerged healing period to achieve osseointegration.[5–7] Furthermore, implants may be placed in a single stage and loaded immediately with a provisional prosthesis, provided the occlusal loads are controlled and implants achieved primary stability at insertion.[8–10] A single-stage surgery with controlled immediate loading of the non-submerged implants compares favorably with the traditional 2-stage submerged implant method.[11] Excellent success rates have been documented with this approach.[8–10,12,13] The 1-stage procedure, which generally incorporates immediate function, includes fewer surgical interventions, shorter treatment time, and less trauma for the patient.[14]

One-piece implants (NobelDirect, NobelPerfect Nobel Biocare AB, Gothenburg, Sweden) have been indicated for immediate function as well as immediate placement in

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Table 1
Implant size report: 1-piece NobelDirect NobelPerfect TiUnite implants

Platform		Maxillae		Mandibles	
		Placed	Failed	Placed	Failed
3	15 mm	1	0	0	0
NP	10 mm	0	0	0	0
	13 mm	1	0	0	0
	16 mm	4	1	2	0
RP	10 mm	1	0	3	0
	13 mm	7	0	3	0
	16 mm	5	0	2	0
WP	10 mm	1	0	1	0
	13 mm	6	0	5	0
	16 mm	4	0	1	0
Total	47	30	1	17	0

fresh extraction sockets. They may be used in combination with flapless surgery. The 1-piece implant eliminates the implant-abutment interface and the requirement to place abutments as an additional procedure, therefore avoiding manipulation of the soft-tissue interface after initial healing. The implants used in this study had a body for the bone anchorage, and part of the soft-tissue–penetrating collar was a TiUnite surface (TiUnite, Nobel Biocare, AB). The TiUnite surface has been reported to promote faster osseointegration and increased bone-to-implant contact.[15–19]

The aim of the study was to evaluate the radiographic outcome of a 1-piece implant when used for immediate function in an ordinary patient pool. The study had been initially planned as a 3-year study, which was extended to 4 years. Preliminary results have been reported elsewhere.[20,21] This is a final report on outcomes after 4 years of loading.

Materials and Methods

The present study was conducted in accordance with the principles of the Declaration of Helsinki (1975) and the Belmont report. Informed consent was obtained from all subjects prior to clinical examination. The Independent Review Consulting Inc (Calif) approved the study protocol (approval no. 03098-04).

This is a 1-center, open, prospective 4-year clinical investigation. Subjects missing at least 1 tooth in the maxilla or the mandible were consecutively enrolled and followed for a period of up to 4 years after functional loading.

Patient eligibility was confirmed and subjects were enrolled in the study provided they met the following inclusion criteria: (1) healthy subjects with acceptable oral hygiene and planned implant treatment, (2) a surgical approach using a 1-stage procedure with immediate placement of a provisional

Table 2
Life table analysis implants

	Placed/Followed Implants	Failed	Withdrawn	Missed/Lost to Follow-Up	CSR
Implant insertion–6 mo	47	1	0	0	97.9
6 mo–1 yr	46	0	1	0	97.9
1 yr–2 yr	45	0	2	0	97.9
2 yr–3 yr	43	0	2	1	97.9
3 yr–4 yr	40	0	0	9	97.9
4 yr	31				

Table 3
Status of patient follow-up

	Fixture Insertion and Provisional Prosthesis	3 mo	6 mo	1 y	2 y	3 y	4 y	Permanent Prosthetic Delivery
Followed patients	30	20	23	24	21	24	17	27
Withdrawn/failed	0	1	1	1	4	5	5	0
Missed/lost to follow-up	0	9	6	5	5	1	8	3
Total	30	30	30	30	30	30	30	30

restoration, (3) no cantilevered restorations, (4) older than 18 years, (5) sufficient bone volume for placing implant(s) with a length of at least 10 mm, (6) final tightening torque at installation of 35 to 45 Ncm without further rotation, (7) stable occlusal relationship with no pronounced bruxism, and (8) an implant site free from infection and/or extraction remnants. Subjects were excluded from the study if they met any of the following criteria: (1) patient circumstances in which the treatment could affect the patient's health or the patient's cooperation; (2) any disorders in the planned implant area such as previous tumors, chronic bone disease, or previous irradiation; (3) angulation requirements of the restoration exceeding 10° (NP) to 15° (RP, WP); (4) subject unable to give her or his informed consent for participation.

The implants placed in the study were 1-piece implants (NobelDirect, NobelPerfect Nobel Biocare AB, Gothenburg, Sweden). The implants are machined from a single piece of titanium and incorporate a screw-shaped implant body with a fixed abutment in a single component. The screw-shaped implant body for bone anchorage and part of the circular soft tissue penetrating part of the implant have a TiUnite surface. The implants are available in 4 diameters (3.0, 3.5, 4.3, and 5.0 mm) and 4 lengths (10, 13, 15, and 16 mm). The abutment portion of the implant could be prepared in situ to create an individualized profile. The implants were placed according to the manufacturer's instructions with an immediate provisional restoration. The provisional restorations were made chairside, according to the routine clinical procedures either out of occlusion or in light central occlusion. The definitive restorations were carried out by the clinician on an individual basis.

Implant length and diameters are accounted for in Table 1.

Table 4
Implant placement

Position	Jaw Type	
	Maxilla	Mandible
Central incisor		
Right	2	
Left	1	
Lateral incisor		
Right	9	1
Left	3	1
Canine		
Right	1	
Left		
First premolar		
Right	5	3
Left	1	2
Second premolar		
Right	3	2
Left	2	3
First molar		
Right	3	
Left		2
Second molar		
Right		2
Left		1
Third molar		
Right		
Left		
Total	30	17

TABLE 5
Marginal bone levels*

				>0		0		−0.1 to −1.0	
	Number	Mean	SD	n	%	n	%	n	%
1 y	25	−0.81	1.78	8	32	1	4	5	20
2 y	38	−0.42	1.33	13	34	2	5	9	24
3 y	39	−0.62	1.39	11	29	4	10	12	31
4 y	26	−0.4	1.57	9	34	1	4	10	39

*Bone levels presented as averages (mesial + distal)/2. Negative numbers indicate bone levels apical to the reference point.

Intraoral radiographs were obtained at the 1-, 2-, 3-, and 4-year follow-ups. Marginal bone levels on both the mesial and distal aspects of the implant were measured by 2 independent radiologists (Göteborg University, Sweden). The lower edge of the implant collar was used as a reference point (Figure 1) for the marginal bone level measurements. A bone level apical or coronal to the reference point was given a negative or positive value, respectively. An implant was classified as surviving when it remained in the jaw and was functionally loaded. Descriptive statistics, including mean values and standard deviations, were used for presentation of the results. The implant cumulative survival rate was calculated by an actuarial life table method.

RESULTS

Thirty subjects, 13 men and 17 women, participated in the study. Forty-seven implants were placed, 30 in the maxillae and 17 in mandibles. In 1 subject, 1 maxillary implant was lost prior to the 3-month visit, rendering a survival rate of 97.9% after 4 years of loading. The life table analysis is presented in Table 2.

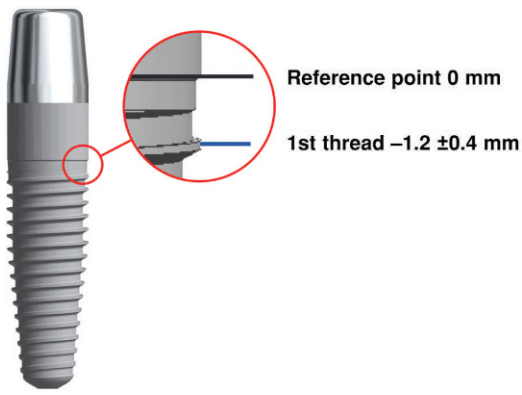


FIGURE 1. One-piece implant.

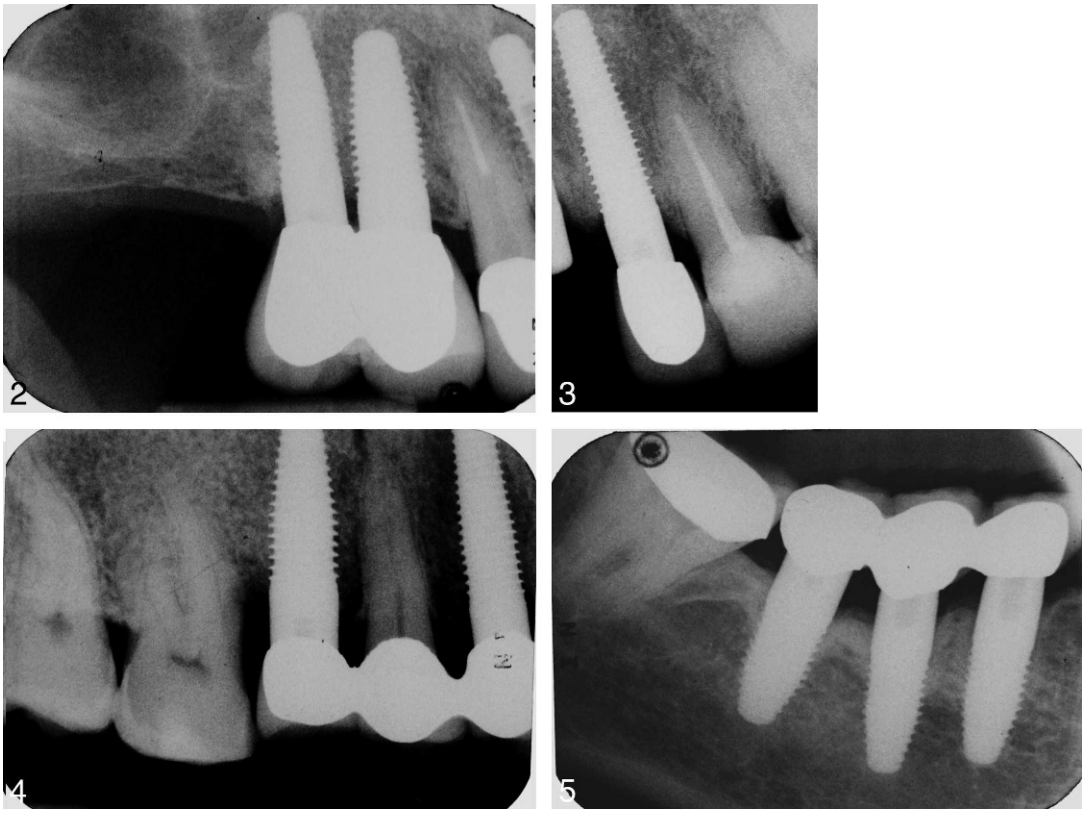
Seventeen patients with 31 implants have completed the 4-year follow-up. During the course of the study, 4 subjects withdrew from the study for the following reasons. One subject was withdrawn at the 1-year follow-up visit as she wished to withdraw from the study. Two subjects were withdrawn at the 2-year follow-up visit: one moved away as she was attending college, and another wished to withdraw from the study. One subject aged 92 years was withdrawn from the study at the 3-year follow-up visit. This subject passed away due to natural causes. Another 8 subjects have been lost to follow-up. The status of patient follow up is presented in Table 3. The implants were placed after raising a flap or making an incision with a tissue punch. Eighteen implants were placed in extraction sites immediately after tooth extraction without raising a flap. Local bone grafting was performed on 35 implants. Implants were evenly distributed in the posterior maxilla (30%), posterior mandible (32%), and anterior maxilla (34%); only 4% of the implants were placed in the anterior mandible (Table 4). All implants were placed according to the manufacturer's instructions and achieved primary stability. All implants were immediately provisionalized

Table 5 Extended					
−1.1 to −2.0		−2.1 to −3.0		<3.0	
n	%	n	%	n	%
9	36	0	0	2	8
12	32	1	3	1	3
8	21	2	6	2	6
4	15	2	8	0	0

according to general practice procedure and made chairside. In 16 implants, intraoral preparation was performed to achieve interarch clearance; the preparation time lasted up to 5 minutes per implant, with the exception of 2 implants, whose preparation lasted 1 minute each. Preparation was done with carbide burs and diamond rotary cutting instruments. Provisional restorations were placed out of occlusion or in light central occlusion. Definitive restorations were delivered on an individual basis to 27 subjects.

Intraoral radiographs were taken using a standardized method in which a long-cone paralleling technique was applied. Radiographs were taken at 1, 2, 3, and 4 years after implant placement. The apical corner of the cylindrical transmucosal part of the implant was used as a reference point for the radiologic evaluation. The mean marginal bone levels were as follows: −0.81 mm (SD, 1.78; n = 25) at 1 year, −0.42 mm (SD, 1.33; n = 38) at 2 years, −0.62 mm (SD, 1.39; n = 39) at 3 years, and −0.40 mm (SD, 1.57; n = 26) at 4 years relative to the reference point (Table 5).

Besides the reported failure, no serious device-related adverse events have been reported. One subject reported swelling in the area around pos #14 at the 3-month



Figures 2–5. Figure 2. X ray 4 years after placement; 2 implants replaced 2 maxillary premolars. **Figure 3.** X ray 4 years after placement; an implant replaced a maxillary lateral incisor. **Figure 4.** X ray 4 years after placement; 2 implants replaced a maxillary premolar and a molar. **Figure 5.** X ray 4 years after placement; 3 implants replaced 2 mandibular molars and a premolar.

follow-up visit. At the subsequent 6- and 12-month follow-up visits, no swelling was reported.

Discussion

In this current prospective, single-center study, only 1 implant out of 47 failed prior to the 3-month visit, resulting in a cumulative survival rate of 97.9%, which remained unchanged over a 4-year period. Radiographic outcomes in function at the end of 4 years of some cases are illustrated in Figures 2 through 5.

The mean marginal bone level relative to the reference point after 4 years of loading was −0.40 mm (SD, 1.57). The mean marginal bone levels reported at 1, 2, 3, and 4 years of loading was reported to be well above the first implant thread.

The study demonstrates that 1-piece oxidized surfaced implants used in immediate function are comparable with other clinical studies applying immediate function on dental implants.[20–23]

The undisturbed healing of the peri-implant soft tissue and the possibility to avoid disruption of the soft-tissue seal when placing the definitive prosthetic restorations may have contributed to the favorable mean marginal bone levels over time.

Conclusion

After 4 years of functional loading, 1-piece implants demonstrated a good cumulative survival rate and beneficial marginal bone levels when placing a provisional restoration in immediate function.

Note

The author has a clinical consulting agreement with Nobel Biocare for ongoing clinical studies and continuing education courses.

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