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Direct loading of Nobel Direct® and Nobel Perfect® one-piece implants: a 1-year prospective clinical and radiographic study

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Abstract

Objectives: The aim of this prospective study was to evaluate the Nobel Direct® and Nobel Perfect® one-piece implants (OPIs) when used for immediate function.

Material and methods: Forty-eight patients were provided with 115 OPIs for loading with a provisional crown or a bridge within 24 h and followed for at least 12 months with clinical and radiographic examinations. A group of 97 patients previously treated under identical conditions by the same team with 380 two-piece implants (TPIs) for immediate loading in the mandible and maxilla served as the reference group.

Results: Six (5.2%) OPIs failed during the follow-up due to extensive bone loss. Five (1.3%) implants failed in the reference group. After 1 year, the mean marginal bone loss was 2.1 mm (SD 1.3) for OPIs and 0.8 mm (SD 1) for TPIs. 20% of OPIs showed more than 3 mm of bone loss compared with 0.6% for TPIs. When compensating for vertical placement depth, OPIs still showed a lower marginal bone level and thus more exposed threads than TPIs. Depending on the criteria used, the success rate for OPIs was 46.1% or 72.2% compared with 85% or 91.6% for TPIs.

Conclusions: The Nobel Direct® and Nobel Perfect® OPIs show lower success rates and more bone resorption than TPIs after 1 year in function. Factors such as implant design, insertion depth, rough surface towards the mucosa, *in situ* preparation and immediate loading may have an influence on the clinical outcome.

The Nobel Direct® and Nobel Perfect® one-piece implants (OPIs) represent a novel immediate-loading concept including flapless surgery and placement of a one-piece titanium implant (Dragoo 2005; Hahn 2005; Parel & Schow 2005). The technique offers a simple solution to the problem of missing teeth as surgery is minimally invasive and conventional prosthetic methods are used. The implants are also intended to be used for immediate replacement of extracted teeth. This OPI system is allegedly designed to minimize marginal bone resorption as there is no submucosal microgap, which is believed to cause the initial bone loss usually seen at TPIs (Dragoo 2005). Moreover, the implant has a moderately rough surface (TiUnite™) all the way up through the mucosa, which is suggested to result in 'soft tissue integration' and to lead to improved attachment of the mucosa to the implant surface, thereby giving better long-term aesthetics. One recent histological study in patients demonstrated the presence of a shorter contact epithelium at oxidized and acid-etched surfaces than at machined surfaces (Glauser et al. 2005). According to the manufacturer,
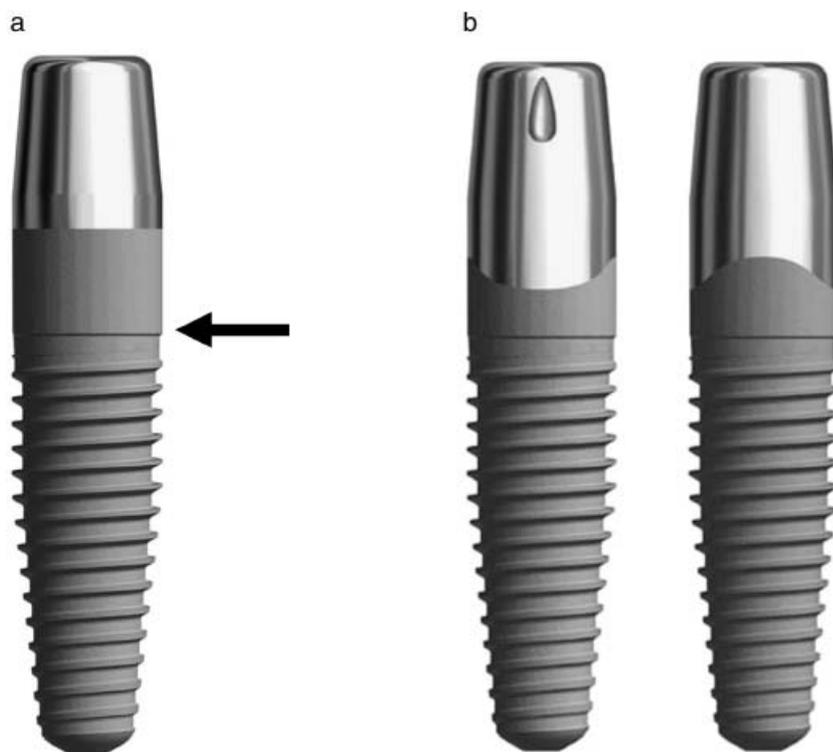
Fig. 1. Schematics of the (a) Nobel Direct® and (b) Nobel Perfect® one-piece implants tested in the study. Both implant types have a threaded part and an integrated abutment cylinder. For (a) the margin between the turned and oxidized part is horizontal and for (b) the margin is scalloped, where the highest parts are intended to be placed approximally. The implant has an oxidized surface at the threaded and cylindrical parts facing bone and soft tissues. Depending on the thickness of the mucosa, the cylinder will be partly submerged in bone. Arrow indicates the reference point used for radiographic measurements.

the vertical placement of the implant in bone can be varied as the rough surface will allow for osseointegration of the coronal abutment cylinder. A recent publication presented the clinical outcome of 51 prototype OPIs with an acid-etched surface placed in 38 patients (Dragoo 2005). No implants were lost and marginal bone loss was found to be 0 mm after 1 year based on measurements of 20 of the 51 implants after 1 year. Thirty-one implants had technically poor radiographs and were, according to the author, impossible to evaluate radiographically. To the knowledge of the present authors, no clinical follow-up studies including marginal bone height measurements of commercially available Nobel Direct® or Nobel Perfect® OPIs with the present design have been presented in the scientific literature.

The overall aim of this prospective clinical study was to evaluate clinically and radiographically Nobel Direct® and Nobel Perfect® OPIs when used for immediate loading. The Specific aims were to analyse whether this implant minimizes marginal bone loss, whether vertical placement can be varied and whether the aesthetical result is optimized as claimed by the manufacturer.

Materials and methods

Patients and inclusion criteria

A total of 48 patients (28 females, 20 males, mean age 67.8 years) from consecutive referrals for rehabilitation with implant-supported prostheses in the mandible and/or the maxilla participated in the study. The treatments were performed by one surgeon and one restorative dentist in one centre. The pre-surgical evaluation included clinical and radiographic examinations with periapical radiographs, OPG and tomography when needed. General health, ongoing medication and smoking habits were registered. Infected extraction sites healed within 3 months in the maxillae and 6 months for mandible, respec-

tively. Patients who met the inclusion criteria were invited to participate in the study and thoroughly informed about the procedure.

Inclusion criteria

The inclusion criteria were as follows:

- Need for implant treatment in the maxilla or mandible due to loss of one or several teeth.
- Residual bone with sufficient bone volume to house at least 10 mm long implant(s) with a diameter of 3 mm.
- The implant site(s) free from infection.

Exclusion critera

The exclusion criteria were general contraindications for oral surgery and age < 18 years.

All patients agreed to participate. All patients were healthy, and only one was a smoker.

Implants

A total of 115 OPIs were used. Seventy-seven were Nobel Direct® implants and 38 Nobel Perfect® were OPIs with diameters from 3 to 5 mm and lengths from 10 to 16 mm (Fig. 1a and b; Table 1). Nobel Perfect® implants have a scalloped contour between the smooth and rough-surfaced part of the integrated abutment cylinder and the supra-mucosal part while Nobel Direct® implants have a horizontal contour. They otherwise have identical designs.

Surgery

The patients were given 2 g of V-penicillin (Kåvepenin; AstraZeneca, Södertälje, Sweden) and diazepam (0.3 mg/kg body weight, Stesolid®, Alpharma, Stockholm, Sweden) orally 1 h before surgery. Infiltration anaesthesia (Xylocaine®–Adrenaline; AstraZeneca) was used. Implant placement was made using a flapless procedure (n = 23) or by raising mucoperiosteal flaps (n = 92). One-hundred and one implants were placed in healed sites and 14 in extraction sockets. For flap-less placement in healed sites (n = 10), a 2 mm twist drill and a slide-over guide sleeve were used to evaluate and determine the position of the osteotomy. A tissue punch guide was placed and a motor-driven circular tissue punch was used to remove the soft tissue. In

Table 1. **One-piece implants used in the test group**

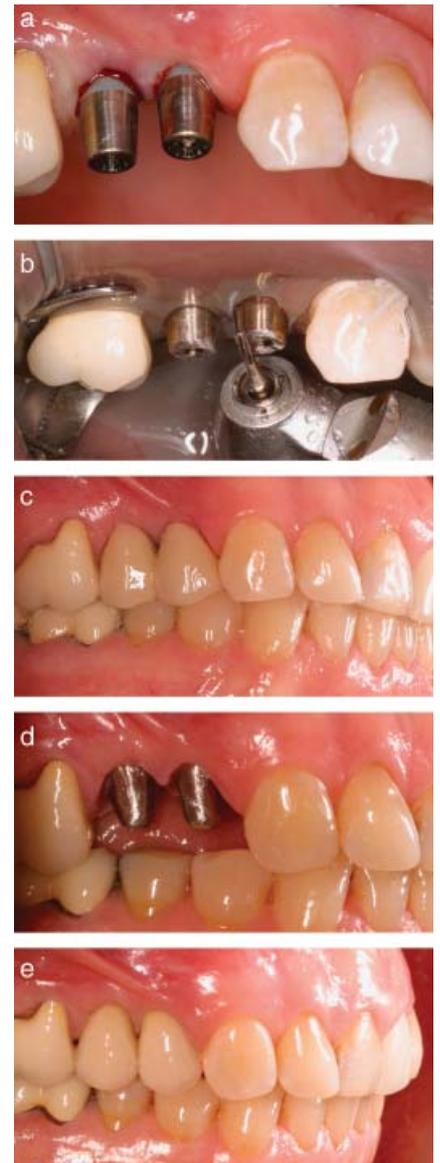| Implant	Length (mm)	Maxilla	Mandible
Nobel Direct®, NP	10	0	2
	13	0	6 (1)
	16	3	3 (1)
Nobel Direct®, RP	10	0	16
	13	2	6
	16	12	11
Nobel Direct®, WP	10	0	4
	13	0	2
	16	1	2
Nobel Direct® 3	15	3	4
Total Nobel Direct® (*n* = 77)		21	56
Nobel Perfect® One-piece, NP	10	0	2
	13	0	0
	16	0	5
Nobel Perfect® One-piece , RP	10	0	9
	13	1	4
	16	4	2
Nobel Perfect® One-piece, WP	10	0	6 (4)
	13	0	1
	16	4	0
Total Nobel Perfect® one-piece (*n* = 38)		9	29
Total, test group		30	85 (6)
Failures within brackets.			

Fig. 2. Clinical photographs illustrating the surgical and prosthetic techniques. (a) The implants were placed with some rough surface visible above the highest point of the mucosa, usually at approximal aspects. (b) A rubberdam was used to protect the wound during height reduction of the implants. (c) Showing the temporary crowns in place. (d) The fixtures were prepared with a chamfer using purpose-made drills after 3 months of healing. (e) Clinical appearance after cementation of the final construction.

flapped cases, an incision was made on the top of the crest. In mandibular cases of sufficient bone width, a muco-periosteal flap was raised only at the lingual aspect to enable visibility and avoid perforation into the floor of the mouth. Relieving incisions were made in the mandible to enable identification of the mental foramen. The continuing preparation for both flapless and flapped sites followed the drill steps (preparation protocol) for Replace Select Tapered implants (Nobel Biocare AB, Gothenburg, Sweden). The vertical position was determined by the goal of placing each implant with some rough surface just visible above the highest point of the mucosa, usually at approximal aspects (Fig. 2a). However, in flapped cases where it was possible to control implant threads in relation to marginal bone, the first priority was to place all implant threads in bone, which, in some cases, resulted in a deeper final positioning of the implant. The implants were inserted by motor and exceeded an insertion torque of 30 Ncm. If the final insertion torque was above 50 Ncm, as determined by the manual torque wrench, the implant was backed out and inserted again with a torque of 30–50 Ncm in order to avoid overtightening. Bone quality and quantity were determined according to the criteria proposed by Lekholm & Zarb (1985) (Table 2). Flapped sites were closed with resorbable sutures.

No bone augmentation was performed when implants were placed in a fresh extraction socket or in healed sites.

Post-operative measures

During the 10 days after implant installation, the patients were given 3 g of V-penicillin (Kåvepenin, AstraZeneca), advised mouth rinsing with chlorhexidine 0.1% two times a day and recommended to eat soft food.

Prosthetics

The prosthetic treatment was carried out immediately after surgery. No preparation of the implants was made at this point, except in situations when the implant height interfered with occlusion. In such cases, preparation was made using purpose-made drills (Nobel Biocare AB) with protection of the wound by a rubber dam (Fig. 2b). Care was taken not to overheat the fixture by using generous irrigation with a lower temperature fluid than normally used on vital teeth.

In single-tooth cases (23 implants), a prefabricated translucent strip crown (Frasaco, Tettnang, Germany) was filled with a composite (Ceram-x, Dentsply, York, PA, USA). Care was taken to present the material from entering the pocket by using a rubber dam and not overfilling the strip crown. No bonding was used to prevent contamination of the TiUnite™ surface. After light curing,

the composite crown was adjusted outside the mouth and then cemented with temporary cement using a rubber dam (except in one case). Single crowns were not in occlusion and were free from approximal contacts.

In partially dentate cases (82 implants), a quick-setting high-viscosity polyvinyl siloxane impression (Dimension™ Penta™ H Quick, 3M ESPE, St. Paul, MN, USA)

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Table 2. **Bone quality and quantity of the one-piece implant sites according to Lekholm & Zarb (1985)**

Bone quantity	Bone quality				Total no. of implants
	1	2	3	4	
A		1	5		6
B		9(1)	20	2	31
C		30(3)	24	2	56
D		10(2)	10	2	22
E					
Total		50	59	6	115
Failures within brackets.					

Table 3. **Two-piece implants used in the reference group**

Implant	Length (mm)	Maxilla	Mandible
MkII, turned	11.5		2
	13		2
	15		2
MkIII, turned	7		4
	8.5		4 (2)
	10		11
	11.5		7
	13		12
	15		6
	18		11 (1)
MkIV, turned	10		4
	11.5		2
	13		6
	18		1
Standard, turned	10		3
Total, control turned ($n = 77$)			77 (3)
MkIV, TiUnite	11.5		3
	13	1	5
	15	25	2
	18	22	13
MKIII, TiUnite	7		6
	8.5		19
	10	2	42
	11.5	3	13 (1)
	13	4	37
	15	21	15
	18	12	25
Replace select tapered	13	6	
	16	27 (1)	
Total, control TiUnite ($n = 303$)		123 (1)	180 (1)
Total, control ($n = 380$)		123 (1)	257 (4)
Failures within brackets.			

was taken after application of a rubber dam (except in one case with two implants). Bite registration was performed and an impression of the opposing jaw was taken. The provisional bridges were fabricated in a dental laboratory using a Triad composite (Raintree Essix Inc., Los Angeles, CA, USA) without cantilevers. The constructions were cemented with temporary cement using a rubber dam (except in the one case with two implants) and ground into light centric occlusion (Fig. 2c). Careful adjustment of occlusion and articulation were performed to minimize lateral forces.

All 48 patients received a provisional construction within 6 h.

One to three months after fixture installation, depending on soft tissue healing, the fixtures were prepared with a chamfer using purpose-made drills as described above (Fig. 2d). Impression cores were placed superficially in the pocket to ensure proper impression of the preparation border according to the manual. An impression was then taken with the same technique as that described for the temporary solution. The final prosthetic crowns and bridged were fabricated from All-zirconium™ with

Rondo™ porcelain (Nobel Biocare). The constructions were cemented with Ketac-cem (3M ESPE) (Fig. 2e). Minimal amounts of cement were used for temporary and final constructions in all cases and applied to the crowns with a brush. Radiographs were used to ensure that no excess cement remained beneath the crown margins (Fig. 3a and b).

Clinical follow-up

All patients participating in the study agreed to be enrolled in a strict and individually designed maintenance care programme focusing on the following: (1) oral hygiene, (2) stability of provisional/permanent bridge, (3) soft tissue condition and (4) function of the therapy (patient satisfaction, aesthetic outcome, occlusion/articulation). Clinical follow-up was carried out at 3, 6, 12 months and thereafter yearly. Besides planned check-ups, hygiene controls were carried out individually.

Reference patient group

A group of 97 patients (48 men, 49 female, mean age 62.3 years) treated by the same team under identical conditions with 380 TPIs (MKIII, MKIV and Replace Select Tapered; Nobel Biocare AB) with either turned ($n = 77$) or oxidized ($n = 303$) surfaces were used as a control (Table 3 and Table 4). Twenty patients had been treated with 123 implants for immediate loading in the totally edentulous maxilla (Östman et al. 2005), and 77 patients had been treated with 257 implants for immediate loading in the partially edentulous mandible and followed for at least 1 year (Östman et al. 2006).

Radiographic follow-up

The marginal bone was evaluated in digital periapical radiographs taken after surgery and after 1 year in function. Measurements were made in a personal computer using Image J 1.34S software (National Institutes of Health, USA) at mesial and distal aspects. Each radiograph was calibrated using the known width of the coronal cylinders of the implants. The lower corner of the coronal cylinder was used as a reference point for measurements. For TPIs, the marginal bone level was measured from the implant–abutment junction.

Measurements were used to calculate (i) the true bone resorption, i.e. the distance

from the initial bone level to the bone level at follow-up examinations, and (ii) the marginal bone level in relation to the lower corner of the coronal cylinder of OPIs and in relation to the lower corner of the head of the TPIs at placement and after 1 year.

Success rating

Implant success was evaluated using a four-field table according to Albrektsson & Zarb (1993) using the following categories:

Success

An implant meeting with success criteria. The criteria for success according to Albrektsson et al (1986) and Albrektsson & Zarb (1993) include absence of implant mobility and absence of pain and neuropathy. Originally, 1 mm of bone loss was

acceptable during the first year and <0.2 mm annually thereafter. Slightly less strict criteria were used in the present study as implants cemented into multi-unit constructions could not be tested individually for mobility. Moreover, more bone loss was accepted; success grade 1 was defined as an implant with no clinical and radiographic signs of pathology showing <2 mm of bone resorption at 1 year of follow-up. Success grade 2 was defined as an implant with no clinical and radiographic signs of pathology showing <3 mm of bone resorption at 1 year of follow-up.

Survival

An implant still in the mandible or maxilla that does not meet with or has not been tested for success criteria.

Unaccounted for

An implant in a patient who dropped out of the study for any reason.

Failure

An implant removed for any reason.

Statistics

Descriptive statistics were used and the data were presented as mean values with standard deviations. A frequency distribution was made of marginal bone measurements and divided into quartiles. The 'best' 25% and 'worst' 25% of implants from the OPI and TPI groups were compared. A Life-table was used to calculate implant survival rates. The Spearman's correlation test was used to evaluate the possible relation between implant insertion depth and marginal bone resorption.

Results

Clinical observations

The initial soft tissue healing around the OPIs was uneventful in most cases. Grey colouring of the marginal mucosa was frequently seen (Fig. 4a–c). With time, many sites showed retraction of soft tissue and papillae and exposure of the TiUnite™ surface, often in conjunction with radiographic bone loss (Fig. 5a and b). Excess cement could not be identified in patients with exposed crown margins.

Few complications were observed for the TPIs and were generally related to fracture of the provisional prostheses, which could be repaired.

Implant failure

Six OPIs (5.2%) were removed during the follow-up period because of extensive bone resorption and subsequent soft tissue problems (Table 5) (Fig. 6a–d,7). All failures occurred in the mandible (7.1%) (Table 1). Two implants were lost within 3 months, one after 6 months and three implants were removed during the second year in function (after 14 months). Two Nobel Direct® and four Nobel Perfect® OPIs failed (Table 1).

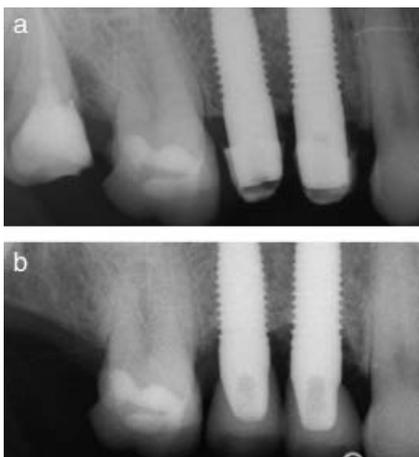Five (1.3%) TPIs failed in the reference group: one in the maxilla and four in the

Fig. 3. Radiographs of the case shown in Fig. 2. (a) Baseline radiograph after cementation of the provisionals to ensure that no excess cement remained beneath the crown margins. (b) 12 months later. Note the ongoing marginal bone loss, which is more extensive at the implant in the first pre-molar region.

Fig. 4. Clinical examples of grey colouring of the marginal mucosa at one-piece implant sites. (a) Anterior mandible. (b) Left posterior mandible. (c) Right posterior mandible.

Table 4. Bone quality and quantity of the two-piece implant sites according to Lekholm & Zarb (1985)

Bone Quantity	Bone quality				Total no. of implants*
	1	2	3	4	
A	–	1	–	–	1
B	–	25	92 (1)	26	143 (1)
C	–	79 (3)	81 (1)	42	202 (4)
D	–	21	3	10	34
E	–	–	–	–	–
Total	–	126	176	78	380
*Failures within brackets.					

Table 5. Life-table of one-piece implants

Interval	Implants in interval	Failures	CSR
Placement-6 months	115	3	97.4
6 to 12 months	112	0	97.4
12 to 24 months	111	3	94.8
>24 months	11	–	–

Fig. 5. Clinical examples of soft tissue retraction and exposure of the oxidized surface at one-piece implant sites (a) Right posterior mandible. (b) Right posterior mandible.

Fig. 7. Clinical photographs showing the implants in Fig. 6c and d at surgical removal. Note crater-shaped defect and granulation tissue.
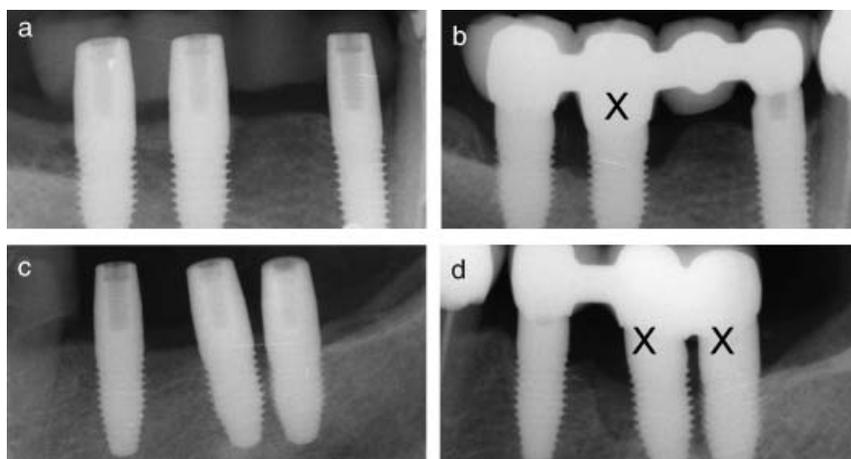

Fig. 6. Radiographs showing crater-like marginal bone resorption at one-piece implants leading to soft tissue problems and implant removal. (a) Baseline radiograph of three implants in the posterior mandible (b) 6 months later. The two posterior implants show bone loss and the middle one was removed. (c) Baseline radiograph of three implants in the left posterior mandible. (d) 12 months later. The two posterior implants were removed.

Table 6. Life-table of the two-piece implants in the reference group

Interval	Implants in interval	Failures	CSR
Placement-6 months	380	3	99.2
6 to 12 months	377	2	98.7
12 to 24 months	260	–	98.7
>24 months	211	–	98.7

mandible (Table 3). All failures occurred during the first year of loading (after 2, 3, 4 and 11 months) (Table 6). Two of the implants were found to be rotationally mobile when taking an impression for the definitive prosthesis with no radiographic signs of failure. Three implants showed peri-implant radiolucency and were found to be mobile. None of the failures showed crater-like defects. Two oxidized (MKIII and Replace Select Tapered) and three turned implants (MKIII) failed (Table 3).

Marginal bone measurements

Marginal bone resorption

Marginal bone resorption at OPIs was seen as thin vertical defects (Fig. 8a and b) crater-like lesions (Fig. 8c–f) or as horizontal bone loss (Fig. 8g and h). The average marginal bone loss was 2.1 mm (SD 1.3) for OPIs based on 104 radiographs of the 115 implants followed (Table 7). The bone loss was identical for mandibular and maxillary implants, i.e., 2.1 mm (SD 1.3). Single-tooth implants showed 2.2 mm (SD 1.3) and implants in multi-unit constructions with 2.1 mm (SD 1.3) of bone loss.

For TPIs, the bone loss was 0.8 mm (SD 1) based on measurements in 350 radiographs of the 380 implants (Table 7).

For OPIs, 49% showed more than 2 mm and 20% more than 3 mm of bone loss after 1 year. For TPIs, 7.7% showed more than 2 mm and 0.6% more than 3 mm of bone loss after 1 year (Table 7) (Fig. 9a and b).

The marginal bone loss data were divided into quartiles for comparison of the 25% best (Q1) and the 25% worst (Q4) implants. The mean Q1 value was −0.6 mm (SD 0.3) (bone loss) for OPIs and 0.4 mm (SD 0.8) (bone gain) for TPIs. The mean Q4 values were −3.9 mm (SD 0.8) and −1.9 mm (SD 0.6) for OPIs and TPIs, respectively (Table 7).

There was a significant correlation between vertical placement depth of OPIs and marginal bone loss ($P<0.001$, $r=-0.32$), indicating that the cylindrical part of the implant did not integrate with the bone (Fig. 10).

Marginal bone level in relation to the reference point

After 1 year, the marginal bone was on average 1.2 mm (SD 1.3) below the reference point at OPIs and 0.2 mm (SD 0.8) for TPIs (Table 8).

For OPIs, 25% showed a marginal bone level more than 2 mm and 7.7% more than 3 mm below the reference point after 1 year. For TPIs, 4.6% showed a marginal bone level more than 2 mm and 1.1% more than 3 mm below the reference point after 1 year.
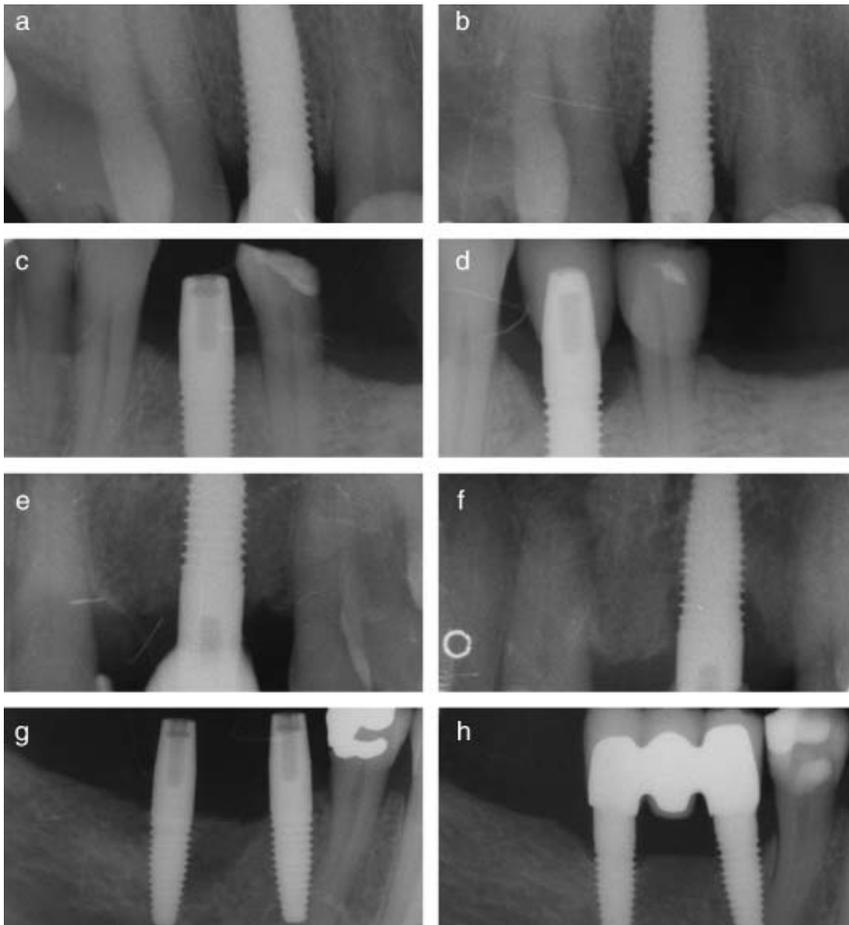
Fig. 8. Series of radiographs demonstrating marginal bone loss. (a) Baseline radiograph of a maxillary single-tooth replacement. (b) 12 months later. Note thin vertical defect. (c) Baseline radiograph of a mandibular single tooth replacement. (d) 12 months later. Note crater-like defect. (e) Baseline radiograph of a maxillary single tooth replacement. (f) 12 months later. Note crater-like defect. (g) Baseline radiograph of two posterior mandibular implants. (h) 12 months later. Note horizontal bone loss.

Table 7. **Marginal bone loss at one-piece implants and two-piece reference implants**

	One-piece implants (n = 104)	Two-piece implants (n = 350)
Change, [mm (SD)]	− 2.1 (1.3)	− 0.8 (1)
Change Q1 [25% best, mm (SD)]	− 0.6 (0.3)	0.4 (0.8)
Change Q4 [25% worst, mm (SD)]	− 3.9 (0.8)	− 1.9 (0.6)
>2mm (%)	49	7.7
>3mm (%)	20	0.6

Quartile analysis of bone-level data showed that for Q1 OPIs, the bone level was −0.3 mm (SD 0.5 mm) (below the reference point) and 0.6 mm for TPIs (SD 0.2) (above the reference point). The Q4 values were −3 (SD 1) for OPIs and − 1.5 mm (SD 0.7) for TPIs.

Implant success
When applying the stricter criteria, implant success grade 1 was 46.1% for OPIs and 85.5% for TPIs (Table 9). When applying the more moderate success grade 2 criteria,

the corresponding success grades were 72.2% and 91.6% for OPIs and TPIs, respectively (Table 10).

Discussion

The present prospective clinical study evaluated the use of 115 OPIs (Nobel Direct® and Nobel Perfect®) for immediate function in 48 patients. Six of the implants were removed due to extensive bone resorption and subsequent soft tissue pro-

blems. Many of the remaining OPIs showed signs of unacceptable marginal bone loss as 49% showed a loss of more than 2 mm and 20% more than 3 mm after the first year of function. This was in contrast to the reference group of the TPIs used for immediate loading, where only 7.7% and 0.6% of the implants showed more than 2 and 3 mm of bone loss, respectively. Other studies, also using oxidized TPIs for early/immediate-loading protocols, have shown figures similar to our reference group, where 0–4.4% of the implants were reported to have more than 3 mm bone resorption during the first 12–18 months (Glauser et al. 2003; Rocci et al. 2003; Vanden Bogaerde et al. 2005). A multicentre study evaluating 121 oxidized implants used for two-stage procedures showed that about 4% of the implants had more than 3 mm of bone loss after 1 year in function (Friberg et al. 2005). Keeping in mind that the tested OPI concept was designed to minimize marginal bone resorption (Dragoo 2005), the results from the present study are alarming.

The reasons for the initial bone loss seen at TPIs during the first year have been discussed in the literature and may be related to overload, surgical trauma, peri-implantitis, biological width, etc. (Oh et al. 2002). The Nobel Direct® implant was allegedly designed to minimize marginal bone loss based on the theory that contamination of the implant–abutment junction, the microgap and violation of the biological width are the causes for the initial bone loss (Dragoo 2005). Although results from experimental studies in part support such a theory (Hermann et al. 2001), clinical follow-up studies have reported a similar degree of initial bone loss for non-submerged OPIs as for submerged TPIs during the first year of function (Oh et al. 2002). The results from the present study clearly showed that the OPI design did not preserve the marginal bone but resulted in more bone resorption than observed for the two-piece reference implants.

One feature of this novel implant design is the use of a moderately rough, oxidized, surface also at the part of the implant facing the soft tissues, which, according to the manufacturer, is believed to result in 'soft tissue integration' and better long-term aesthetics. A pilot histological study on
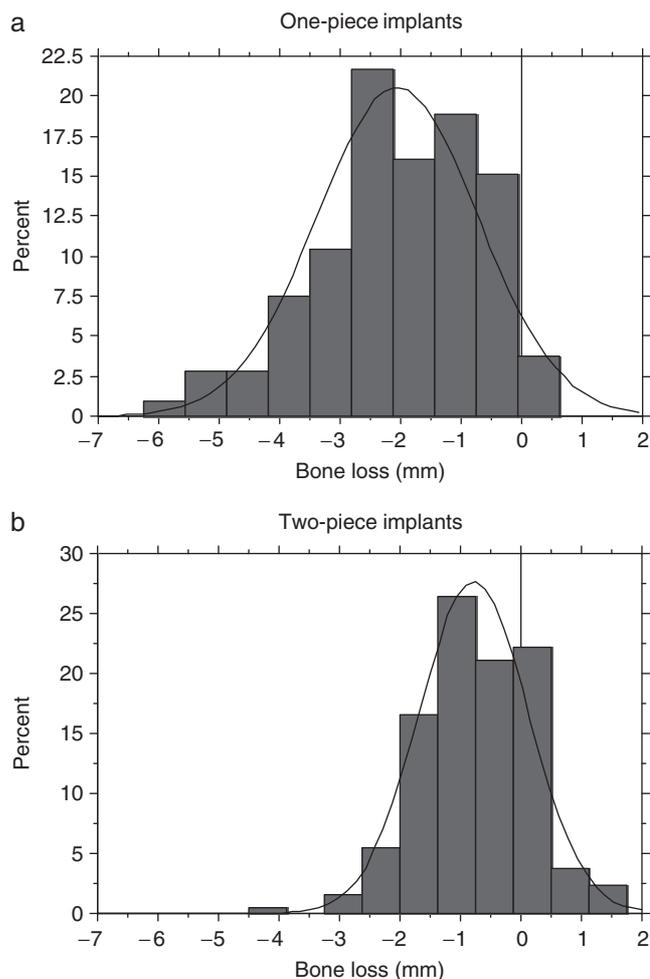
a

One-piece implants

b

Two-piece implants

Fig. 9. Frequency distribution diagrams of marginal bone loss from baseline to the 1-year follow-up examination for (a) one-piece and (b) two-piece implants.
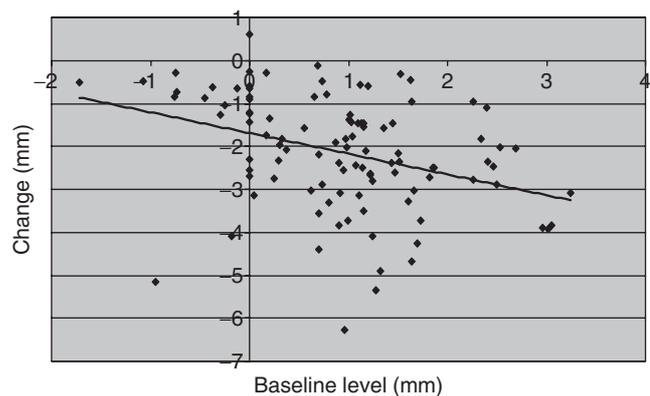

Fig. 10. A plot showing a statistically significant correlation ($P < 001$, $r = -0.32$) between one-piece implant insertion depth (baseline level) and change of marginal bone loss from placement to the 12 month follow-up.

12 biopsies of OPIs with either turned, acid-etched or oxidized surfaces against the mucosa reported less epithelial downgrowth and a longer connective tissue seal for the rough surfaces after 8 weeks of healing. Their preliminary observations seem to support soft tissue integration in the short-term perspective, although meaningful statistics could not be extracted from the small number of specimens (Glauser et al. 2005). The results are in contrast to the findings from previous *in vitro* work and

the general perception that endothelial cells and fibroblasts are rugophobic and hence prefer smooth surfaces (Brunette 2001). Although surface roughness may have a positive effect on the submucosal tissue response, any soft tissue retraction and exposure of the rough surface to the oral cavity, as seen in the present study, will facilitate plaque accumulation, which in turn may lead to soft and bony tissue pathology (Quirynen & Bollen 1995). We are unaware of any published clinical studies on the long-term effects of using rough surfaces in soft tissue.

It is possible that contamination of the oxidized surface when making the temporary crown in single cases, during impression taking for provisional bridges and when cementing the constructions, can explain the observed marginal bone loss. However, great care was taken to protect the wound with a rubber dam during these procedures, except for three implants. There was no difference in bone loss when comparing single tooth implants and implants in multi-unit constructions, indicating that the intraoral manufacture of provisionals using strip crowns and composite did not influence the outcome. Minimal amounts of cement were applied to the crowns using a brush, and radiographs were used to ensure that no excess cement could be seen below the crown–implant margin. Moreover, no cement could be seen clinically or in high-magnification photographs of cases with retraction and exposure of the oxidized surface.

Using a vital microscopic titanium implant chamber model, Eriksson & Albrektsson (1984) demonstrated bone tissue damage after heating the chamber to 47°C for 1 min. *In situ* high-speed preparation of the implant and overheating is another plausible explanation to the problems encountered. However, the majority of implants were not drilled on after placement and many implants showed bone loss already at the time of preparation for the final construction.

As no control group with implants allowed to heal before loading was used, the effect of immediate function itself on the clinical outcome could not be evaluated. All provisional single crowns were out of occlusion, while multi-unit constructions were in light centric occlusion. However, a comparison between the two groups did

Table 8. **Marginal bone level in relation to the reference point at one-piece implants and two-piece reference implants**

	One-piece implants (n = 104)	Two-piece implants (n = 350)
Marginal bone level, [mm (SD)]	− 1.2 (1.3)	− 0.2 (0.8)
Bone level Q1 [25% best, mm (SD))	− 0.3 (0.5)	0.6 (0.2)
Bone level Q4 (25% worst, mm (SD)]	− 3 (1)	− 1.5 (0.7)
>2mm from reference point (%)	25	4.6
>3mm from reference point (%)	7.7	1.1

Table 9. **Four-field distribution of one-piece and two-piece implants according to success grade 1 criteria**

One-piece implants	
Success grade 1 = 46.1%	Unaccounted for = 0%
Survival = 48.7%	Failure = 5.2%
Two-piece implants	
Success grade 1 = 85.5%	Unaccounted for = 0%
Survival = 13.2%	Failure = 1.3%

Table 10. **Four-field distribution of one-piece and two-piece implants according to success grade 2 criteria**

One-piece implants	
Success grade 2 = 72.2%	Unaccounted for = 0%
Survival = 22.6%	Failure = 5.2%
Two-piece implants	
Success grade 2 = 91.6%	Unaccounted for = 0%
Survival = 7.1%	Failure = 1.3%

not reveal any differences in marginal bone loss. However, it could be argued whether the single crowns can be regarded as unloaded as they will be loaded as soon as the patient chews food.

The presence of oxidized surfaces also at the integrated abutment cylinder of the OP implants allows for variation of vertical placement – according to the manufacturer. According to the instructions for use (Nobel Biocare AB), about 1.5 mm of the 3 mm high cylinder should face the soft tissues, meaning that about 1.5 mm should be placed in bone. In the present study, the initial marginal bone level was on average 1.1 mm above the lower corner of the cylinder. Our data showed a correlation between insertion depth and bone loss, indicating that the cylindrical part did not integrate with bone. This is in line with the experiences with the conical Brånemark fixture, which was originally used for single-tooth replacements and in bone-grafting situations. This implant had a 3.5 mm high conical collar that was submerged in bone, and follow-up studies have demonstrated more bone loss for the conical than for the standard Brånemark fixture design (Quirynen et al. 1992; Jemt & Lekholm 1995; Malevez et al. 1996). A recent follow-up study of 17 Nobel Perfect® implants demonstrated a similar loss of about 4 mm of marginal bone, down to the first thread, in spite of an oxidized surface on the collar (Nowzari et al. 2006). However, other implant systems, for instance with a titanium dioxide-blasted cylindrical collar in marginal bone, have shown stable bone levels (Rasmusson et al. 2005) and it is possible that other factors such as implant design, preparation technique and the degree of press fit of the coronal cylinder may have an impact on the marginal bone tissue response. Although, there was a correlation between insertion depth and bone loss for the OPIs of the present study, this alone cannot explain bone loss. Even when compensating for insertion depth, i.e. by calculating the marginal bone level in relation to the lower corner of the collar, the marginal bone level was situated more apical than for TPIs. The Nobel Direct® and Nobel Perfect® implants have the same geometry as the Replace Select Tapered implant, but no follow-up studies including radiography have been published that could have been used for comparison. Thus, the marginal bone response to this implant design is unknown.

The criteria for success previously presented in the literature are often based on the experiences from the standard Brånemark fixture and two-stage procedures (Albrektsson et al. 1986; Albrektsson & Zarb 1993; Roos et al. 1997). This implant design usually shows marginal bone resorption to the first thread during the first year in function while the bone loss is minimal in the subsequent years (Oh et al. 2002). Published criteria have stipulated that 1–1.5 mm of bone loss is acceptable when measured from the lower corner of the implant head (Albrektsson & Zarb 1993, Oh et al. 2002). Today, the implant–abutment junction is commonly used as a reference point, which, for the Brånemark implant is situated some 0.8 mm above the previous reference point. In the present study, we have therefore used up to 2 mm (success grade 1) and 3 mm (success grade 2) of bone loss as acceptable when evaluating the implants. When applying the criteria, both success grades 1 and 2 were much lower for the OPIs than for the TPIs as presented in four-field tables. The differences would have been even greater had life-table statistics been appealed to compensate for implants not evaluated as proportionally more radiographs of TPI implants could not be evaluated.

Based on the experiences from conventional two-piece Brånemark implants, the bone reactions towards the OPIs were different in many ways. The OPIs often presented with crater-like defects, which are rarely seen around conventional TPIs. Some of the implants also showed atypical juxtaradicular defects. Six implants were removed because of extensive resorption and soft tissue problems, in spite of being clinically stable. The crater-formed defect is generally looked upon as a radiographic sign of peri-implantitis, a condition that is usually seen after many years of loading (Tonetti & Schmid 2000). Although the present implants were not systematically evaluated with regard to peri-implant infection, deep probing depths, bleeding and pus were experienced around implants with extensive bone loss. The five implants lost in the reference group showed a different pattern as no implant showed crater-like bone resorption. Two implants were found to be rotationally mobile when taking impressions for the permanent bridge after 2 and 3 months without any radiographic signs of failure. Three implants that showed peri-implant

radiolucency were found to be mobile and removed.

It is concluded that in our hands, the Nobel Direct® and Nobel Perfect® OPIs show lower success rates and more bone resorption than TPIs after 1 year in function. No single determinant could be identified as an explanation to the findings, but it is suggested that factors such as implant design, insertion depth, rough surface towards the mucosa, *in situ* preparation and immediate loading may have an influence on the outcome. The further use of this implant design is seriously questionable, at least for immediate loading.

要旨

目的：本前向き試験の目的は Nobel Direct® と Nobel Perfect®のワンピース・インプラント（OPI）（Nobel Biocare AB、イエテボリ、スウエーデン）を即時機能させた場合の評価をすることであった。

材料と方法：患者４８名に、合計１１５本の OPI を埋入し、２４時間以内に暫間クラウンまたはブリッジを装着、荷重し、臨床的診査とレントゲンによって少なくも１２ヶ月間の経過観察を行った。同じチームが、同一条件において以前に治療を行い、上下顎に合計３８０本の２ピース・インプラント（TPI）を埋入し、即時荷重した患者９７名を対照群とした。

結果：経過観察中に重度の骨吸収のために６本（5.2%）の OPI が失われ、対照群では５本（1.3%）のインプラントが失われた。

１年後の平均辺縁骨の喪失量は OPI が 2.1mm（SD1.3）、TPI は 0.8mm（SD1.0）であった。3mm 以上の骨喪失を示した OPI は 20%であったが、TPI は 0.6%であった。垂直的な挿入深度について補正しても、TPI よりも OPI の辺縁骨レベルは低く、より多くのねじ山が露出していた。成功率は用いた基準によって、OPI が 46.1%または 72.2%、他方 TPI は 85.0%または 91.6%であった。

結論：Nobel Direct ® および Nobel Perfect ®のワンピース・インプラントは２ピース・インプラントよりも、機能１年後の成功率は低く、骨吸収が多かった。インプラント・デザイン、挿入深度、粘膜に接している粗面、口腔内での形成や即時荷重などの因子が臨床的結果に影響を及ぼすものと考えられる。

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