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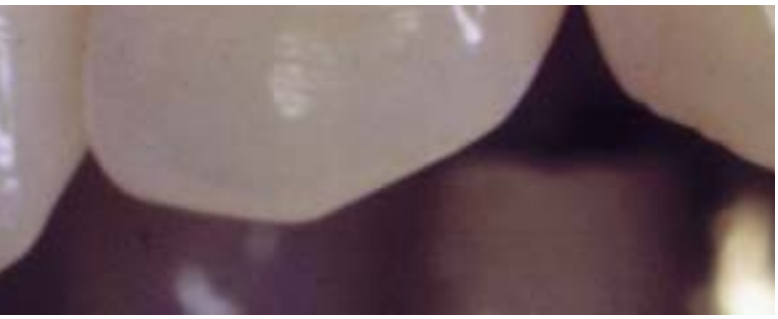
Radiographic and Clinical Evaluation

NobelDirect® and NobelPerfect®






Nobel Biocare

Multiple Center Clinical and Radiographic Evaluation of One-piece Implants. A Retrospective 6-year Evaluation · Clinical Evaluation of One-piece Implants Used for Immediate Function. A Preliminary Report of Bone Level up to 2-year · Worldwide Radiographic Evaluation of Nobel Biocare One-piece Implants · General Radiographic Evaluation of NobelPerfect® Implants

Why This Special Report?

"Primum non nocere" , "Do not harm" has remained since Hippocrates throughout the centuries one of the key principles of medical ethics. Professor Per-Ingvar Brånemark repeated this sentence at all his lectures. It means that, above all, the medical profession should never cause harm, but rather, when possible, provide proper care. Therefore if anyone has any knowledge about a pharmaceutical component or medical instrument would lead to unknown side-effects, he or she is morally, and eventually legally, obliged to report this to the appropriate controlling health authorities.

Each new endosseous implant design, intended for whatever part or function of the human body, is a challenge. The literature is full of trial and errors. Indeed, implantable devices are not subject to the stringent pre-launch legislations, pharmaceutical components are. Nevertheless both national and supranational (EC, FDA ..) controlling bodies do monitor possible problems.

The NobelDirect® implant is a one-piece screw-shaped implant with a well-documented TiUnite® surface. Several other manufacturers have been using and promoting one-piece implants since even decades. The particularity of the NobelDirect® implant is that its Ti Unite surface is intended to reach coronally of the bone crest. The idea is to improve the soft tissue integration.

Personally I have not used this implant, since I prefer the versatility of two-piece implants where angulations can be modified and implants can be put "to sleep" again if needed. When I heard of rumors that this implant may lead to clinically relevant marginal bone loss, my interest as a scientist was aroused.

After a meeting organized by the Swedish control board for medical devices with the Nobel Biocare company and the clinicians who had claimed there was a problem; it was concluded that, on the basis of the available data, there was no reason to take any action, except of course to continue to monitor the outcome (as for any other new device). Both parties were also encouraged to meet and to exchange to share each other's data. It is regrettable this could not be achieved so far.

Thus it should be appreciated that on the other hand, the company involved, has invested great efforts to collect as many more data as possible available concerning the clinical outcomes of this one-piece implant. These data will allow us to understand better why most people did not but others did report a higher incidence of marginal bone loss. Anyone who has data should step forward because of the ethical principles indicated above. It will be more beneficial to the patients and the community that discussions go on within such scientific environment rather than in financial platforms, which should not be the playground of health care workers.

Professor Daniel van Steenberghe
MD, PhD
Holder of the Professor P-I Brånemark Chair in Osseointegration

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Responsible for the content
of this supplement:

Nobel Biocare

A retrospective 6-year evaluation

Multiple Center Clinical and Radiographic Evaluation of One-piece Implants

Siepenkothen T.[1], Clauder A.[2], Mehlau R.[3]

The aim of the present study was to retrospectively evaluate the clinical performance of one-piece implants (NobelDirect®, Nobel Biocare AB, Gothenburg, Sweden) over several years. Clinical data was obtained from 25 clinics in Germany. Before placing the first one-piece implant, all surgeons received the same implant installation training from the International Institute of Dental Seminar clinicians. Data was obtained for all consecutively placed one-piece implants in each clinic. Five hundred forty-four consecutive patients received 1009 NobelDirect implants supporting both multiple and single tooth reconstructions. Six hundred thirty-four implants (62.8%) were placed in the maxilla and 375 implants (37.2%) were placed in the mandible. One hundred fifty-one implants (15.0%) were immediately placed in extraction sites, and 858 implants (85.0%) were placed in healed sites. Surgical techniques for implant installation included flapless surgery (77.0%) or modified flap technique (23.0%). Sixty five percent of the implants were subjected to immediate loading. Periodontal probing and radiographic assessment of the marginal bone level was performed. All patients were followed for a minimum of 6 months up to 6 years. Eighteen implants were lost, rendering a clinical survival rate of 98.2 %. The marginal bone level, registered as 1) coronal to or at the first thread, or 2) below the first thread, remained stable.

KEYWORDS: one-piece implants, NobelDirect, immediate function, marginal bone level

Introduction

Implants are presently placed in either one or two-stage procedures[1]. Implant placement at the time of tooth extraction has been established as a safe and predictable procedure. The advantages of an immediate placement protocol includes reduction in the number of surgical interventions and in the total treatment time. Moreover, it has been suggested that immediate placement may preserve alveolar bone height and width, and allow for optimal soft tissue esthetics [2-4]. Furthermore, there is substantial evidence that implants can be loaded at, or shortly after the time of placement without jeopardizing the survival rates, provided high initial stability of the implant and controlled loads [5-7].

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The one-piece implant design eliminates the need for placing esthetic abutments and makes it possible to avoid manipulation of the soft tissue portion after initial healing. The implant can be provided with a provisional restoration immediately after insertion, allowing for the mucosal epithelium and the connective tissue adhesion to form coronal to the alveolar crest [8]. The restorative process resembles that of a natural tooth, and the preparable abutment part enables an individualized borderline of the preparation to exactly follow the contour of the gingival margin without violating the soft tissue seal, potentially leading to better preserved interproximal bone and papillae.

The aim of the present study was to retrospectively evaluate the clinical performance of NobelDirect one-piece implants placed in all areas of the dental arches, in both healed and extraction sites, and to evaluate the soft tissue development and marginal bone levels .

Materials and Methods

This retrospective study included data collected from 25 individual implant clinics in Germany. The study included 544 patients (246 males and 298 females) consecutively treated with immediately or delayed loaded one-piece implants, placed both in healed sites (delayed implants) and in fresh extraction sockets (immediate implants) in all areas and indications of the upper and lower jaw, including sinus lift procedures. Before placing the first one-piece implant, all surgeons received the same implant installation training from the International Institute of Dental Seminars clinicians. All surgeons used the same protocol for placement, which was consistent to the manufacture's manuals. When multiple implants were placed in a patient, the NobelDirect Guided Surgery concept was used.

The rationale for the patient selection was to include all patients who had received one or more one-piece implant as support for multiple and/or single tooth reconstructions during a specific time interval. The time interval was chosen so as to include the very first patient who received the treatment, and all the consecutive patients treated in the same way up to a date which allowed for the collection of at least 6 months follow-up data postoperative.

Radiographic examination was performed immediately after implant placement, and then every 6-months for evaluation of bone levels and signs of periimplant pathology. Several of the clinics changed radiographic techniques during the study period; i.e. panograph, parallel technique and digital systems, resulting in difficulties to obtain reproducible measurements. Consequently, bone level changes were evaluated from the first thread of the one-piece implant. The bone level was recorded as at or coronal to the first thread, or below the first thread. Periodontal sulcus probing was performed 6-month postoperatively to evaluate the clinical soft tissue integration of the gingival tissues.

The majority of the one-piece implants in this study were NobelDirect implants produced by Nobel Biocare AB, Gothenburg, Sweden.The NobelDirect implant is a one-piece implant, machined from a single piece of titanium, comprising a threaded, tapered implant body and an integral preparable abutment in a single component. The implant body as well as the transmucosal cylindrical collar of the NobelDirect implant has the anodized TiUnite® surface.[9,10]

Results and Discussion

In the current retrospective study a total of 1009 implants, placed in 544 patients were evaluated. Six hundred thirty-four implants were placed in the maxillae and 375 were placed in the mandible. The number of implants in relation to position and type of site (healed or extraction site) is presented in Table 1. It is interesting to note that most of the delayed implants were placed in posterior areas (83.6%), but only 16.4% of the delayed implants were placed in the esthetic zone. However, the number of implants placed in the esthetic zone increased to 51% when immediate implants were used (Table 1).

	Delayed Placement		Immediate Placement	
Implant Position	Maxillae	Mandibular	Maxillae	Mandibular
Incisor	73	23	52	4
Cuspid	28	17	21	0
Bicuspid	262	107	57	9
Molar	138	210	3	5

Table 1. Implant position

All patients included in this retrospective analysis were followed for a minimum of 6 months postoperative. Most implants (870) were followed between 6 and 12 months. Sixty-one implants were followed for 2 years, and 31 implants were followed for 5 years. The longest evaluations were 6 years postoperative, however, information was only available for 23 implants.

	Delayed Placement	Immediate Placement
Failed endodontic treatment	315	76
Periodontal disease	412	35
Fracture	26	32
Congenital missing tooth	5	2

Table 2. Pre-implant pathology of the edentulous area

The reason for replacing missing teeth with one-piece implants was evaluated and presented in Table 2. In 38.8% of the cases, failing endodontic treatment was the stated reason. In 44.3% of the cases periodontal disease was the cause, and fractures and congenially missing teeth was the stated reason in 5.8% and 1% of the cases, respectively.

	Delayed Placement	Immediate Placement
Cyst site and poor stability	2	0
Acute endodontic abscesses and poor stability	9	4
Heavy smoking and poor stability	3	0

Table 3. Implant failures

Eighteen implant failures occurred, rendering an implant survival rate of 98.2 %. Table 3 lists the implant failures and the conditions at the time of implant placement. It is interesting to note that the failed implants were placed in “high risk” situations and exhibited poor initial stability.

	Delayed Placement	Immediate Placement
Modified flap	202	29
Flapless	656	122

Table 4. Surgical technique used

Several of the clinics used antibiotics as a routine, and (33.9%) of the one-piece implants were placed with antibiotic coverage. However, the success rate of implants placed in patients receiving antibiotics (342) did not differ compared to implants placed in patients who did not receive antibiotics as a routine (667).

Surgical techniques for implant installation included flapless surgery and modified flap technique. Flapless surgery was used when placing 77.1% of the implants, and 22.9% of the implants were placed with modified flaps, depending on the anatomy of the alveolar crest and the amount of gingiva available. The number of delayed and immediate implants placed with either modified flap or flapless surgery is presented in Table 4.

Internal sinus lifts were used with 151 one-piece implants. One hundred thirty-five of the implants placed with sinus lift were placed in healed sites, and 16 implants were immediately placed in extraction sites. No failures or adverse postoperative sequella were reported for the implants placed with sinus lift.

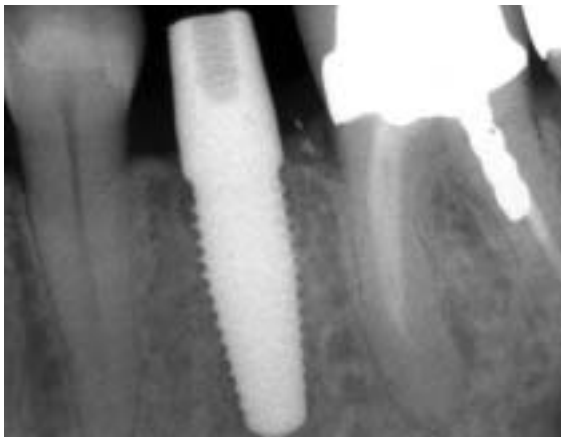

Fig 1a. Immediate postoperative radiograph of a NobelDirect one-piece delayed implant placed in the mandible.

Fig 1b. 6-year postoperative radiograph of the same implant. Note the stability of the alveolar crest when compared to the immediate postoperative radiograph.

Fig 1c. 6-year postoperative clinical image of the implant.

Marginal bone levels were recorded for each implant at the most recent evaluation period from 6 months to 6 years postoperative (Figure 1a, b, c). Due to different radiographic techniques used among the 25 clinics it was difficult to obtain reproducible measurements. The bone level was therefore recorded from the first thread, and was registered to be either at or coronal to the first thread, or below the first thread of the implants.

Visit	Bone level in relation to first thread	Delayed Placement	Immediate Placement
6 months	At or above	322	95
	Below	18	4
1 year	At or above	377	36
	Below	17	1
2 year	At or above	50	9
	Below	2	0
5 year	At or above	30	0
	Below	1	0
6 year	At or above	19	3
	Below	1	0

Table 5. Radiographic bone level

Delayed placed implants had post operative bone levels at or coronal to the first thread in 94.7% of the cases at the 6-month evaluation, in 95.7 % at the 1-year evaluation, in 96.2% at the 2-year evaluation, in 96.8% at 5-year evaluation and in 95.0% of the cases at the 6-year evaluation (Table 5).

Immediately placed implants in fresh extraction sockets had postoperative bone levels at or coronal to the first thread in 96.0% of the cases at the 6-month evaluation, in 97.3% at the 1-year evaluation, and in 100% of the cases at both the 2-year and 6-year evaluation, respectively (Table 5).

Five hundred forty-seven implants (63.8%) were subjected to immediate loading after delayed placement in healed sites. One hundred-seven of the implants (70.9%) that were immediately placed in extraction sockets were subjected to immediate loading. Immediate loading of the implants did not seem to adversely affect neither the survival rates nor postoperative bone levels.

It was noted that marginal bone levels of immediately loaded implants placed in healed sites seemed to be particularly stable when NobelDirect Guided Surgical Procedures were used to place multiple implants. This may, in part, be due to the immediate fixed provisional reconstruction and splinting of the implants, reducing the influence of micro-movements on the surrounding bone and soft tissue.

Fig 2a. Immediate postoperative radiograph of a NobelDirect one-piece immediate implant placed in a fresh extraction socket in the maxilla. Note that the width of the implant fills the entire mesial-distal distance of the socket.

Fig 2b. 6-year postoperative radiograph of the same implant. Note the stability of the alveolar crest height when compared to the immediate postoperative radiograph.

Fig 2c. 6-year postoperative clinical image of the implant.

Fig 3a. Immediate postoperative radiograph of a NobelDirect one-piece immediate implant placed in a fresh extraction socket in the maxilla. Note that the implant is too narrow to fill the mesial-distal width of the socket.

Fig 3b. 3-month postoperative radiograph of the same implant. Note only a partial apposition of bone between the implant and the socket wall at this time period.

Fig 3c. 6-month postoperative radiograph of the same implant. Note that a complete fill of the gap has occurred.

Interproximal bone levels and papillae height were preserved at immediately placed implants when the implant diameter matched the width of the extracted tooth. This was observed up to 6 years postoperative (Figure 2a, b, c).

However, when the implant diameter was smaller than the width of the extraction socket at the coronal margin of the alveolar bone, remodeling of the alveolar bone down to the first thread occurred, with subsequent recession of the papillae (Figure 3a, b, c). The distance between the alveolar bony wall and the implant body was not grafted in any of the immediately placed implants evaluated in the study.

It has been suggested that the three-dimensional positioning of the implants in the extraction sockets can affect esthetics and function. Of the implants retrospectively evaluated in the current study,14.6%

Fig 4a. 6-months post-operativeradiograph of a loaded NobelDirect one-piece implant in the maxilla. Note the mesial bone resorption.

Fig 4b. Same implant as in Fig. 4a taken 12 months post operatively.

were placed in the center of the alveoli whereas 85.4% of the implants were placed more facially. None of the investigated implants had a lingual positioning. The placement position did not seem to affect the survival rate or the bone levels. However, final restorations and esthetics were positively influenced when the facial position was used. The center position yielded best results when placed in the posterior areas.

Another interesting clinical observation was that some implants that had radiographic bone loss at 6 months postoperative but where the soft tissue was intact to the implant often seemed to recover 1-2 years postoperative (Figure 4a, b). This appeared to be a consistent finding when the probing depth was 3 mm or less (Figure 5a, b, c).

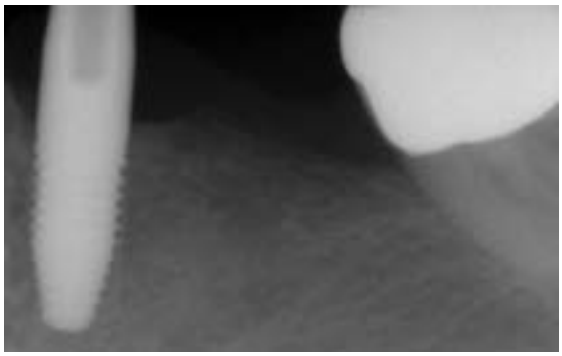

Fig 5a. 6-month postoperative radiograph of an unloaded NobelDirect one-piece implant placed in the mandible. Note the mesial bone level.

Fig 5b. 6-month clinical image of the same implant. The probing depth was 2 mm and the gingiva was clinically healthy.

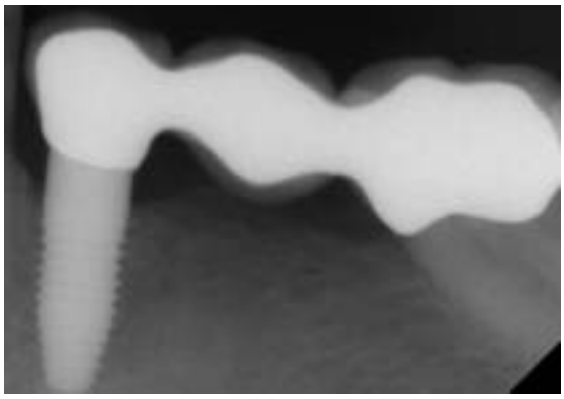

Fig 5c. 24-months postoperative radiograph of the same implant. Note the improved mesial bone level.

Fig 6a. Clinical image of a maxillary first bicuspid in need of extraction due to endodontic failure. Note the excessive length of the clinical crown, which could create an esthetic problem with restoration of an immediate implant.

Fig 6b. Clinical image of an immediate NobelDirect one-piece implant placed in the facial position of the extraction socket. Note that the provisional restoration was left short of the marginal gingiva to allow creeping attachment of the gingiva to move coronal toward the margin of the provisional restoration.

Fig 6c. Clinical image 2 months after implant placement. Note that the gingiva has migrated coronally near to the margin of the provisional restoration.

Fig 6d. Clinical image of the same implant 12 months after implant placement. Note the improved esthetics.

Moreover, it was observed that when provisional reconstructions were left short of the marginal gingiva, 1-2 mm creeping attachment frequently occurred. This was especially seen for the implants immediately placed in fresh extraction sockets (Figure 6a, b, c, d).

To evaluate the clinical soft tissue integration of the gingival tissues, periodontal sulcus probing was performed 6-month postoperative. Most of the delayed placed implants (769 implants, 89,6%) had probing depth of 2 mm or less. Only 89 implants (10.4%) had probing depth of 3-4 mm at 6 months postoperative. The 133 immediately placed implants(88.1%) had a probing depth of 2 mm or less, but only 18 implants (11,9%) had a probing depth of 2-4 mm at 6 months postoperative. No implants in either group exhibited probing depths greater than 4 mm at 6 months postoperative.

All involved surgeons agreed on the benefits of complete soft tissue closure to prevent apical proliferation of the epithelium around immediately placed implants. Complete soft tissue closure was reported in 96.6% of the cases.

Conclusions

Retrospective data from 1009 one-piece NobelDirect implants in 544 patients suggests an overall survival rate of 98.2% for evaluation intervals between 6 months and 6 years postoperatively. The marginal bone level remained stable over time, and the implants were not adversely affected by internal sinus lifts, immediate loading and facial flap reflections. The majority of the 1009 one-piece implants placed (89.4%) had probing depths of 2 mm or less at 6 months postoperative. Facial placement of immediately placed one-piece implants yielded positive effects on esthetics and center placement yielded the best results in the posterior areas.

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A preliminary report of bone level up to 2-year

Clinical Evaluation of One-piece Implants Used for Immediate Function

Jack A Hahn DDS

Background

One-piece implants are not a new invention. Already back in 1986, Babbush et al reported on the use of titanium plasma-sprayed screw shaped one-piece implants in the mandible. The protocol used in that study employed 4 implants placed between the mental foramina and connected to a bar for retention of an overdenture.

Since then, new concepts have constantly been developed to optimize osseointegration, and to simplify dental implant treatment. Brånemark (Brånemark et al 1985, Albrektson et al 1981) asserted that osseointegration was best achieved by placing the implants in a submerged manner, letting them heal unloaded for a certain period. For a long period of time, the success documented for submerged healing of implants convinced clinicians that this was the only acceptable protocol. In parallel with the technical development of implant components and a better understanding of biology, this concept has been challenged. As a consequence, today implants are to a great extent placed in a 1-stage procedure and are provided with a prosthetic restoration immediately after implant placement, with high success rates (Schnitman et al 1997, Tarnow et al 1997). Most clinicians use two-piece implant systems despite placing the implants in a 1-stage manner, even though the design of such implants never were intended for doing so. The implant-abutment junction in a two-piece implant design constitutes a structural weakness. The need to remove a healing abutment and replace it with a final abutment adds complexity to the procedure and interference with healed or healing peri-implant mucosa.

My short-term experience with this implant design (Hahn 2005) was the ease of obtaining primary stability and excellent esthetic results. Due to the minimally invasive surgery, patients reported little or no discomfort.

The aim of the present report is to evaluate the radiographic outcome of a one-piece implant when used for immediate function in an ordinary patient pool. This is a preliminary report on an up to 2-year outcome.

Material and Methods

The investigation was approved by the Institutional Review Board (San Anselmo, CA, USA). This was a single center investigation, where 22 subjects (14 females and 8 males) were consecutively included based on set inclusion and exclusion criteria. Thirty-seven NobelDirect and NobelPerfect One-piece implants (Nobel Biocare AB, Gothenburg, Sweden) were placed for tooth replacement in upper and lower jaws. The implants are machined from a piece of titanium and incorporate the screw-shaped implant body and the integral fixed abutment in one single component. The screw-shaped implant body and part of the circular soft tissue penetrating part of the implant have a TiUnite® surface. The implants are available in 3 different diameters (3.5, 4.3, and 5 mm) and in 3 lengths (10, 13, and 16 mm).

Of the 37 implants, 22 were placed in maxillae and 15 in mandibles. The implants were evenly distributed in the posterior upper (27%), lower (35%) and the

anterior upper (32%) jaw, while only 5% of the implants were placed in the anterior lower jaw. The inclusion criteria included healthy subjects with acceptable oral hygiene planned for implant treatment using a 1-stage procedure with immediate placement of a provisional restoration. No cantilevered restorations were applied. Immediate placement in extraction sockets was not an exclusion criterion.

The implants were placed according to the instructions from the manufacturer. The surgical technique included both flapless placement and placement after flap elevation. The provisional restorations were made according to general praxis, and placed out of occlusion or in light central occlusion. Replacement of provisional restorations with permanent prosthetic restorations was carried out on an individual base.

Intra-oral radiographs from the 1- and 2-year follow-ups have been examined by an independent radiologist.

Results

Fifteen (68%) patients have attended the 1-year follow-up visit and 2 (9%) patients have attended the 2-year follow-up visit. Permanent prosthetic restorations have been delivered to 20 patients. Status of follow-up of patients and the life table analysis of implants are presented in (Table 1 and 2). One implant (16 mm long NobelDirect NP) placed in the maxilla was lost prior to the 3-month visit, resulting in a survival rate of 97.3% after up to 2 years of loading. Intra-oral preparation at implant placement to achieve interarch clearance was reported for 43% of the implants. The duration of the preparation lasted 1 to 5 minutes per implant. Forty-nine percent of the implants were reported placed in extraction sockets immediately after tooth extraction, without raising a flap. The remaining implants were placed in healed sites after raising a flap or making an incision by a punch. Local bone grafting was performed around 26% im-plants. All implants were immediately provided with a provisional restoration. Forty-six percent of the implants were reported out of occlusion and 22% put in light central occlusion.

Table 1 Status of Follow-up Patients

Number of:	Implant Insertion & Provisional Prosthesis	3 months	6 months	1 year	2 years	Permanent Prosthesis
Followed patient	22	15	17	15	2	20
Withdrawn	0	1	1	1	1	1
Missing forms	0	6	4	6	9	0
Time not passed	0	0	0	0	10	1

Table 2 Life Table Analyses Implants

	Placed/ followed implants	Failed	Withdrawn	Missing form or time not passed	CSR* %
Implant insertion »» 6 months	37	1	0	4	97.3
6 months »» 1 year	32	0	0	3	97.3
1 year »» 2 years	29	0	0	13	97.3
2 years »» 3 years	16				

*Cumulative survival rate

1 YEAR		
Number	25	
Mean value	-0.23	
S.D.	1.02	
	n	%
>0	9	36
0	2	8
-0.1 - -1.0	7	28
-1.1 - -2.0	7	28
-2.1 - -3.0	0	0
<-3.0	0	0
2 YEARS		
Number	12	
Mean value	-0.62	
S.D.	0.79	
	n	%
>0	1	8
0	2	17
-0.1 - -1.0	5	42
-1.1 - -2.0	4	33
-2.1 - -3.0	0	0
<-3.0	0	0

Table 3 Marginal Bone Level (in relation to reference point)

The lower corner of the cylindrical part of the implant was used as reference point for the radiological evaluation. The mean marginal bone level at the 1-year follow-up was –0.23 mm (SD 1.02), and at 2 years –0.62 mm (SD 0.79) relative to the reference point (Table 3).

Discussion

In this study 1 out of the 37 implants had to be removed resulting in a cumulative implant survival rate of 97.3 % after up to 2 years of loading.

The mean marginal bone level relative to the reference point after 1 year of loading, –0.23 mm (SD 1.02), as well as after 2 years of loading is located above the first implant thread. This is in accordance with or better than previously reported results from studies using two-piece implant designs. In the present study, no individual implants had, at any of the follow-up visits, a marginal bone level exceeding 2 mm below the reference point.

The one-piece implant design enables an undisturbed healing of the soft tissue portion and the possibility to avoid any disruption of the soft tissue seal when placing the permanent prosthetic restoration. This benefit by design of the implant may be one reason for the high mean marginal bone level demonstrated after 1 year of functional loading.

The majority of the implants were placed using a flapless surgical technique, which may also have contributed to the beneficial marginal bone level outcome. In addition to a reduced post-operative swelling, minimized bleeding and eliminated need for stitches, flapless surgery also admits a maintained better blood supply to the marginal bone, thus reducing the likelihood of bone resorption.

Conclusion

Thirty-seven implants placed in 22 patients were followed for up to 2 years. Only one implant failed before the 3-month follow-up visit. Thirty-five implants have passed the 1-year follow-up, whereof 16 implants have passed the 2-year follow-up. Radiographic evaluation of bone level has been performed for 25 of the 29 implants after 1 year and 12 of 16 implants after 2 years. The mean marginal bone level was at the 1-year follow up 0.23 mm below the reference point. Corresponding figure for the 2-year follow-up was 0.62 mm. (Fig 1-5)

The one-piece implant design resulted in a high cumulative implant survival rate and beneficial marginal bone levels.

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Fig 1. Implant placement in extraction sites, for molar replacement in the mandible.

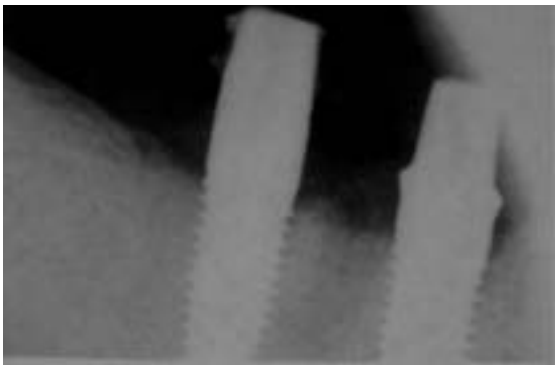

Fig 2. Radiograph from implant placement.

Fig 3. Provisional restoration in place.

Fig 4. Healed soft tissue with restoration in place.

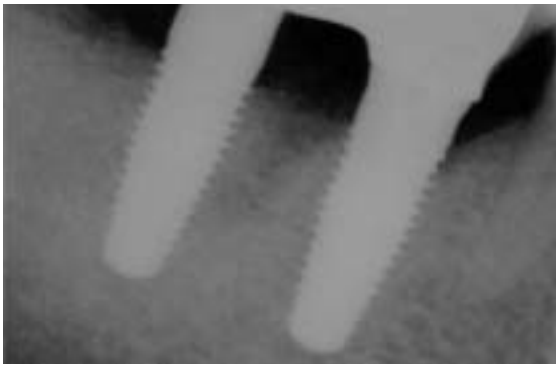

Fig 5. Radiograph, 2 year following implant placement.

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Base of radiographic data

Worldwide Radiographic Evaluation of Nobel Biocare One-piece Implants

A general call for radiographs from NobelDirect® and NobelPerfect® one-piece implants (Nobel Biocare AB, Gothenburg, Sweden) was made to collect radiographic information of bone level at different time points around the implants. The aim was to collect radiographic information from as many clinicians and one-piece implants as possible to get the broadest possible base of radiographic data for this type of implant when used in daily practice. The call was made in the Italian, Japanese, American, Swedish, and German speaking markets. The criterion was to collect all x-rays available from NobelDirect or NobelPerfect one-piece implants. Information of implant type, implant diameter, implant position and time of follow-up was requested. No patient specific data was collected. All clinicians were informed that the radiographs were to be included in a general evaluation to be presented in public. Independent radiologists at the University of Göteborg, Sweden, examined all radiographs.

Material and Methods

In this general call for radiographs on Nobel Biocare implants, radiographs of 1722 one-piece implants were received by Nobel Biocare AB, Sweden. The majority of the radiographs (1475) could be evaluated. However, for some cases essential information required is presently not available. (Note: The collection and evaluation is continuing with additional information and radiographs currently). Separate reports are published on 1009 (Siepenkothen et al) and 37 (Hahn) implants.

The present report includes radiographs from 247 patients, corresponding to 739 radiographic readings of 429 implants provided by 49 clinics. For specification of type and diameter of implants, see Table 1A.

	Placed
NobelDirect 3.0	22
NobelDirect, NP	53
NobelDirect, RP	198
NobelDirect, WP	112
Missing information	44
Total	429

Table 1A Number of implant per design

Maxilla																
Position	18	17	16	15	14	13	12	11	21	22	23	24	25	26	27	28
No of implants	1	5	5	19	19	2	16	11	10	13	6	25	19	12	1	0
Mandible																
Position	48	47	46	45	44	43	42	41	31	32	33	34	35	36	37	38
No of implants	1	20	49	23	6	8	11	11	9	12	3	14	22	48	28	0

Table 1B Distribution of Implants per position

Follow-up	Mesial	Distal	Per position*
Baseline			
Mean	-0.08	-0.21	-0.18
SD	1.78	1.79	1.73
n	246	245	251
3 m			
Mean	-0.98	-1.05	-1.00
SD	1.79	1.88	1.75
n	179	181	182
6 m			
Mean	-0.77	-0.97	-0.88
SD	1.74	1.83	1.69
n	194	192	196
12 m			
Mean	-0.47	-0.68	-0.57
SD	1.20	1.21	1.14
n	82	82	83
18 m			
Mean	-0.48	0.40	-0.44
SD	0.91	1.02	0.91
n	27	27	27

*Distal + mesial value /2

Table 2 Marginal bone levels at different time points

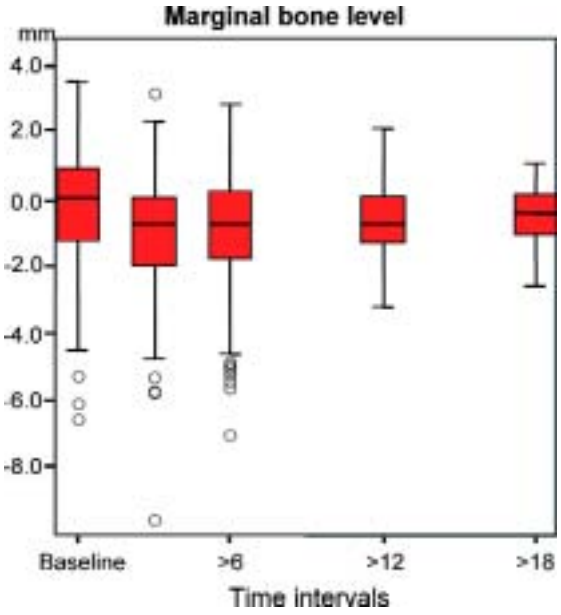


Fig. 1 Boxplot on all available values on marginal bone level in the different time intervals

Radiographs from NobelDirect, NobelPerfect One-piece as well as from NobelDirect 3.0 mm, and NobelDirect Oval were received. The majority of the radiographs were from NobelDirect implants, regular platform (46%).

For distribution of implant/position see Table 1B. Implants placed in all positions of the jaws were represented in the radiographs; 38% of the implants were placed in the maxilla and 62% in the mandible. The majority of the implants were placed in posterior positions in the lower jaw (49%). The radiographs were divided into different time intervals depending on the follow-up time at which the radiographs were taken. Radiographs taken from placement and up to 1 month post placement were referred to the baseline group, radiographs taken between 2 and 5 months post placement were referred to the 3 months group, radiographs taken between 6 and 11 months post placement were referred to the 6 months group, radiographs taken between 12 and 17 months post placement were referred to the 12 months group, and all radiographs taken 18 months or more post placement were referred to the 18 months group. Independent radiologists at the University of Göteborg, Sweden, examined all radiographs. The lower corner of the straight cylinder portion of the implant was used as reference point. This is located approximately 1.2 mm above the first thread. The first bone to implant contact was recorded, above or below the reference point.

Descriptive statistics were used to present the received radiographic data. The Mann-Whitney U test was used to compare marginal bone levels between implants placed in anterior or posterior regions and between implants placed in the upper or lower jaw.

RESULTS

Mean marginal bone level and standard deviations are presented for the different time intervals (Table 2). The implants were on average placed with the threaded part in the bone and the cylindrical part above the bone crest (-0.18 ± 1.78 mm). A box plot illustrating the marginal bone level for the different follow-up times is presented in Figure 1. The results indicate a stabilization of the marginal bone level slightly above the first thread after 1 year of loading. The major part of the decrease in marginal bone level occurred during the first 3 months, followed by only minor changes of the bone level. The marginal bone level of all implants with a follow-up of at least 12

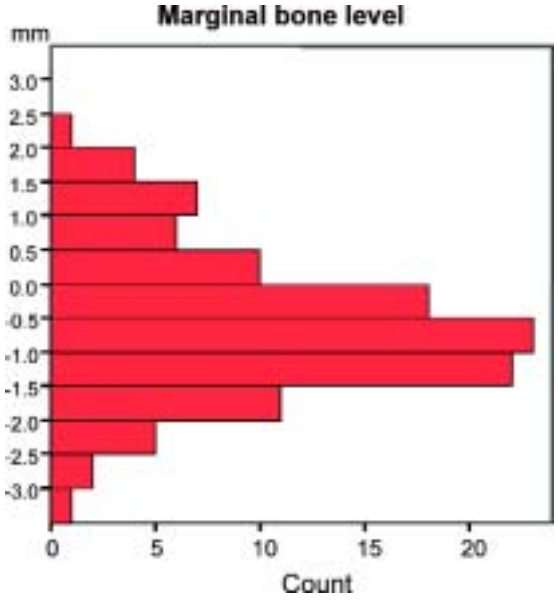
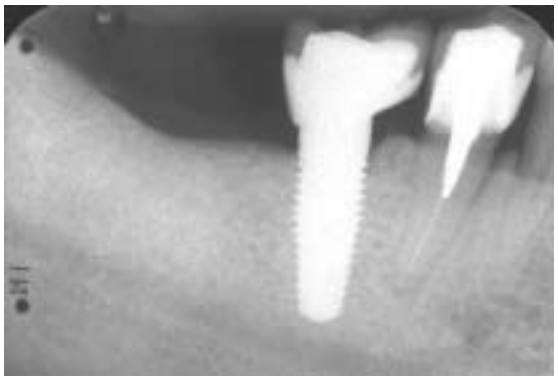


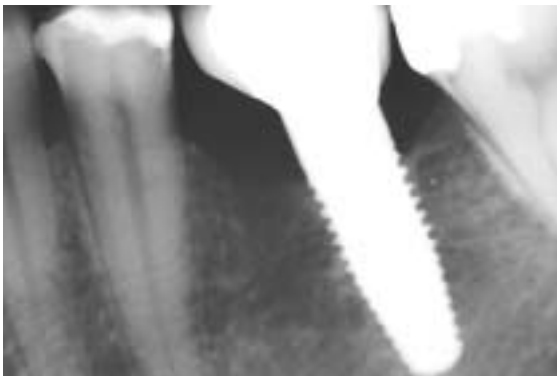
Fig. 2 Frequency distribution of the bone level values for the implants with a follow-up more than 12 months

	Per position*
Mean	-0.54
SD	1.08
Min	-3.20
Max	2.11
n	110
Frequencies	
> 0	28 (26%)
0	8 (7%)
-0.1 – -1.0	34 (31%)
-1.1 – -2.0	32 (29%)
-2.1 – -3.0	7 (6%)
< -3.0	1 (1%)

*Distal + mesial value/2

Table 3 Mean marginal bone level and frequency distribution for all implants with a follow-up of more than 12 months.





Figs. 3a and b Radiographs showing NobelDirect® implants, placed in position 45 and 36 respectively, one year after placement. Figure 3a by courtesy of Dr Calandriello, Bologna, Italy and figure 3b by courtesy of Dr Zugni, Brescia, Italy.

months is shown in Table 3 together with the frequency distribution (Table 3 and Fig.2). The majority of the implants show a bone level slightly above the first thread as illustrated in Figure 3a and b. Seven percent of the implants show a bone level exceeding 2 mm below the reference point. No significant difference was found between marginal bone levels of implants placed in anterior or posterior regions (mean value –0.64 ± 0.97 and –0.50 ± 1.13 respectively, p>0.30), or between implants placed in the upper or lower jaw (maxilla: -0.50 ± 1.22, mandible: -0.55 ± 1.04, p>0.30).

Discussion

In this analysis, radiographs from 429 implants from different time points from 49 different clinics were evaluated. This extensive bulk of radiographic data is considered valuable due to the great number of implants and clinicians represented, although the data collection was not performed under a strict prospective study protocol, which would have been preferable from a scientific standpoint.

The data shows that the marginal bone level decreases slightly during the first 3 months after placement, whereafter it stabilizes at a level slightly above the first thread. This is in correspondence with

bone levels reported for two-piece implants after 1-year of loading (e.g. Jemt et al 1994, Widmark et al 2003, Vanden Bogaerde 2003).

In the present data collection, 7% of the implants showed a bone level more than 2 mm below the reference point after at least 1 year in function. Glauser et al (2005) reported on immediate function of a 2-piece implant, where 16% of the implants had a bone level >2 mm below the reference point after 1 year of loading. A multi-centre study reported by Friberg et al (2005) showed that 19-20% of the implants had >2 mm bone loss. Thus, the data obtained in the present data collection shows fewer implants with a low marginal bone level as compared to pre-viously reported data.

The so-called outliers, i.e. significantly lower bone level values recorded at implant placement, can be explained by implant positioning into extraction sockets, where the bone walls were initially not in contact with the coronal part of the implant. The same explanation may apply to outliers observed after 3 and 6 months of follow-up, but it may also be an indication of loss of osseointegration of a failing implant.

To conclude, 739 radiographic readings were made on radiographs from Nobel Biocare one-piece implants, which were received from 49 clinics, corresponding to 247 patients and 429 implants. The data shows a stabilization of the marginal bone level slightly above the first thread after 1 year of loading.

Acknowledgement

We would like to thank following clinicians for providing data on Nobel Biocare one-piece implants:

AUSTRIA:	Drs. Luftensteiner, Monov, Steinwandtner;
GERMANY:	Drs. Aghazadeh, Bochdalofski, Böhrnsen, Eger, Engelke, Gressmann, Peter, Hassel, Hugo, Neubauer, Nölken, Offner, Otto, Pytlik, Ropers, Scherg, Schwertfeger;
ITALY:	Drs. Barlattani, Benzi, Calandriello, Campione, Carrazza, Euwe, Mariorana, Mura, Polenghi, Polizzi, Rao, Seeberger, Zugni, Gargari, Ottria;
JAPAN:	Drs. Horiuchi, Iwatsuki, Nakasato, Tokutomi, Tokuyama, Yoshinaga;
SWITZERLAND:	Drs. Holzscheitel, Kalla, Kempf, Mattiola, Meier, Mericske-Stern, Meyer, Rieder;
SWEDEN:	Dr Jonsson
USA:	Drs. Baker, Clark, Dudhat, Grimes, Hakimi, Karst, Krause, LeBlanc, Lockwood, Malouf, Mesimeris, Nguyen, Skopp, Sorrera, Spengler

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Glauser R, Ruhstaller P, Windisch S, Zembic A, Lundgren AK, Gottlow J, Hämmerler CHF. Immediate occlusal loading of Brånemark System® TiUnite™ implants placed pre-dominantly in soft bone: 4-year results of a prospective, clinical study. Clin Implant Dent Relat Res 2005;7 (suppl 1):52-59

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Widmark G, Friberg B, Johansson B, Sindet-Pedersen S, Taylor Å. MkIII: A third genera-tion of the self-tapping Brånemark system imlpant, including the new Stargrip design. A 1-year prospective four-center study. Clin Implant Dent Relat Res 2003;5:273-279

Base of radiographic data

General Radiographic Evaluation of NobelPerfect Implants

A general call for radiographs from NobelPerfect® implants (Nobel Biocare AB, Gothenburg, Sweden) was made to collect radiographic information of bone level at different time points around the implants. The aim was to collect radiographic information from as many clinicians and NobelPerfect implants as possible to get the broadest possible base of radiographic data for this type of implant when used in daily practice. The call was made in the German speaking markets as well as in the Italian market. The criterion was to collect all x-rays available from NobelPerfect implants. Information of implant diameter, implant position and time of follow-up was requested. No patient specific data was collected. All clinicians were informed that the radiographs were to be included in a general evaluation to be presented in public. Independent radiologists at the University of Göteborg, Sweden, examined all radiographs.

Material and Methods

Five clinics provided radiographs from 80 patients, corresponding to 197 radiographic readings of 106 implants. Radiographs from NobelPerfect implants with all diameters were received. There was an even distribution between the 3 different platforms (NobelPerfect NP 31%, NobelPerfect RP 40%, NobelPerfect WP 29%). For distribution of implant/position see Table 1. The vast majority was placed in the maxilla (88%), in the anterior region (81%). The radiographs were divided into different time intervals depending on the follow-up time at which the radiographs were taken. Radiographs taken from placement and up to 1 month post placement were referred to the baseline group, radiographs taken between 2 and 5 months post placement were referred to the 3 months group, radiographs taken between 6 and 11 months post placement were referred to the 6 months group, radiographs taken between 12 and 17 months post placement were referred to the 12 months group, and all radiographs taken 18 months or more post placement were referred to the 18 months group. Independent radiologists at the University of Göteborg, Sweden, examined all radiographs. The lower corner of the straight cylinder portion of the implant was used as reference point. The first bone to implant contact was recorded, above or below the reference point. Descriptive statistics were used to present the received radiographic data.

Maxilla																
Position	18	17	16	15	14	13	12	11	21	22	23	24	25	26	27	28
No of implants	0	0	0	1	3	4	18	25	21	15	3	3	0	0	0	0
Mandible																
Position	48	47	46	45	44	43	42	41	31	32	33	34	35	36	37	38
No of implants	0	0	1	1	1	1	0	4	2	1	1	0	1	0	0	0

Table 1 Distribution of Implants per position

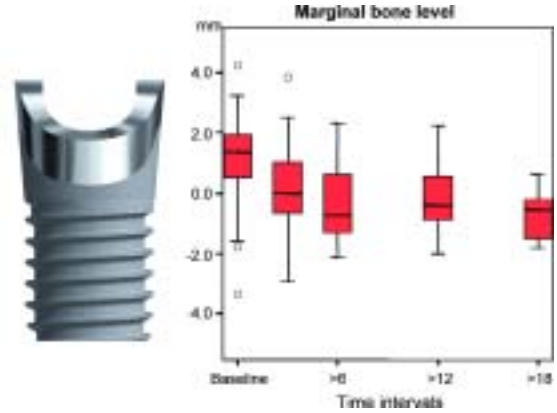

Fig. 1 Boxplot on all available values on marginal bone level in the different time intervals.

Follow-up	Mesial	Distal	Per position*
Baseline			
Mean	0.97	1.19	1.08
SD	1.76	1.50	1.35
n	71	67	72
3 m			
Mean	0.30	0.02	0.17
SD	1.54	1.38	1.38
n	43	39	45
6 m			
Mean	-0.31	-0.32	-0.35
SD	1.31	1.33	1.25
n	45	42	46
12 m			
Mean	-0.50	-0.04	-0.26
SD	0.94	1.53	1.07
n	22	21	22
18 m			
Mean	-0.77	-0.62	-0.78
SD	0.97	0.74	0.80
n	12	10	12

*Distal + mesial value/2

Table 2 Marginal bone levels at different time points

	Per position*
Mean	-0.44
SD	1.00
Min	-2.00
Max	2.25
n	34
Frequencies	
> 0	9 (27%)
0	1 (3%)
-0.1 – -1.0	14 (41%)
-1.1 – -2.0	10 (29%)
-2.1 – -3.0	0
< -3.0	0

*Distal + mesial value/2

Table 3 Mean marginal bone level and frequency distribution for all implants with a follow-up of more than 12 months.

Fig. 2 Radiograph showing a NobelPerfect® implant, placed in position 21, 8 months after placement. By courtesy of Dr Schober, Vienna, Austria.

Results

Mean marginal bone level and standard deviations are presented for the different time intervals (Table 2). The implants were on average placed with the reference point 1.08 ± 1.35 mm below the bone crest. A box plot illustrating the marginal bone level for the different follow-up times is presented in Figure 1. The results indicate an initial decrease in bone level with a stabilization after 6-months of follow-up. The marginal bone level of all implants with a follow-up of at least 12 months is shown in Table 3 together with the frequency distribution . Twenty-seven percent of the implants show a bone level above the reference point (Fig 2) and 70% in the range between 0.1 and 2.0 mm below the reference point. None of the implants show a bone level exceeding 2 mm below the reference point.

Discussion

The data shows that the preferential use of this implant was in the upper, anterior region (81%), i.e. in the esthetic zone. In this analysis, radiographs from 106 implants from different time points from 5 different clinicians were evaluated. This is considered an extensive bulk of radiographic data, due to the limited indication area of the NobelPerfect implant. The material is considered valuable, although the data collection was not performed under a strict prospective study protocol, which would have been preferable from a scientific standpoint.

The data shows that the marginal bone level decreases slightly during the first 6 months after placement, whereafter it stabilizes at a level slightly below the bottom corner of the implant collar.

In the present data collection, none of the implants showed a bone level more than 2 mm below the reference point after at least 1 year in function. Glauser et al (2005) reported on immediate function of a 2 -piece implant, where 16% of the implants had a bone level >2 mm below the reference point after 1 year of loading. A multi-centre study reported by Friberg et al (2005) showed that 19-20% of the implants had >2 mm bone loss. Thus, the data obtained in the present data collection shows fewer implants with a low marginal bone level as compared to previously reported data.

The so-called outliers, i.e. significantly lower or higher bone levels recorded at implant placement, can be explained by implant positioning into extraction sockets, where the bone walls were initially not in contact with the coronal part of the implant, or the use of local bone graft material. The same explanation may apply to outlier with a high value observed after 3 months of follow-up.

To conclude, 197 radiographic readings were made on radiographs from NobelPerfect implants, which were received from 5 clinics, corresponding to 80 patients and 106 implants. The data shows a stabilization of the marginal bone level slightly below the bottom corner of the implant collar after 1 year of loading.

Acknowledgement

We would like to thank following clinicians for providing data on NobelPerfect implants:

AUSTRIA:	Dr. Schober;
GERMANY:	Drs. Nölken, Offner and Schwertfeger;
ITALY:	Dr. Mura;
SWITZLAND:	Drs. Grunder and Kalla

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Friberg B, Dahlin C, Widmark G, Östman PO, Billström C. One-year results of a prospec-tive multicenter study on Brånemark system implants with a TiUnite surface. Clin Implant Dent Relat Res 2005 ;7(suppl 1):70-75

Glauser R, Ruhstaller P, Windisch S, Zembic A, Lundgren AK, Gottlow J, Hämmerler CHF. Immediate occlusal loading of Brånemark System® TiUnite™ implants placed pre-dominantly in soft bone: 4-year results of a prospective, clinical study. Clin Implant Dent Relat Res 2005;7 (suppl 1):52-59

Statement

I am part of two clinical studies on the one-piece implant system NobelDirect and NobelPerfect One-Piece, the T-106B and T-106A studies, respectively.

I have reviewed a compilation of the data from the clinical studies T-106A, T-106B and T-108 dated January 2006. The T-108 study is evaluating the NobelDirect Ø 3.0 mm implant. The compilation was provided by Nobel Biocare.

All three studies are prospective, multi-centre, clinical studies. The data consists of clinical and radiographical data. The evaluation of the radiographs was performed by independent radiological experts.

As control, a historical reference is used. This reference is the study T-091, which evaluates the two-piece implant, Brånemark System, where an immediate loading had also been performed.

The chosen reference is relevant for comparison of implant survival rates, mean marginal bone values and frequency distribution, in absence of a control within the respective studies.

The comparison shows that the bone remodels, on average, to the first thread of the implant for both the one-piece and the two-piece system. The frequency distribution of bone level values below the first thread is similar for the compared systems.

These results also fit with an internal study performed in our university and comparing the bone level at three implant systems (Brånemark, Straumann TE, Replace Straight) where the average bone remodelling reaches the first thread on all three systems.

As to my own experience, I have not observed any unusual implant losses, and the bone-remodelling around the one-piece implant is normal and does not differ from what is typically seen around other traditional two-piece implant systems.

There are no indications in the reviewed data that would support any allegation made to withdraw the one-piece implants from the market.

Eric Rompen, DDS, PhD
Professor of Periodontology Dental surgery
Medical Faculty, University of Liège

Statement
One-Piece Implant Users

I am a user of dental implants and I have placed both traditional two-piece implants and one-piece implants (NorbelDirect and/or NobelDirect 3.0 mm).
My experience with the one-piece implant system is that this implant, as all other implants, requires adequate training to secure safety and efficacy of the treatment.
I have not observed any unusual implant losses with the one-piece implant. My clinical observation is that this implant provides good and predictable results with respect to implant stability and hard and soft tissue reactions.

I will continue to place both two-piece and one-piece implant systems, depending on the clinical indication.

Signed by:

Japan

Dr. Shigeki Nakasato, Nakasato Dental Clinic,
Dr. Tetsuo Nagumo, Nagumo Dental Office
Dr. Yuichiro Iwatsuki, Iwatsuki Dental Clinic
Dr. Takashi Yamaguchi,Yamaguchi Dental Office
Dr. Takuma Shimizu, Ishihama Dental Office
Dr. Takashi Tokuyama, Tokuyama Dental Urawa Clinic
Dr. Junichi Sato / Mariko Kobayashi, Tsurumi University School of Dental Medicine, Implant
Dr. Wataru Tokutomi, Tokutomi Dental Office

Italy

Dr. Carlo Maiorana, Studio Stomatologico Associato
Dr. Rodolfo Blasone, Studio Fabbro
Dr. Mario Zugni, Medical Chirurgo Odontoiatra
Dr. Sandro Fabbro, Studio Fabbro
Dr. Guiseppe, Carrazza

Germany

Dr. Torsten Siepenkothen, Kelkheim
Dr. Martin Spukti, Trier
Dr. Oliver Otto, Schwetzingen
Dr. Michael Knapp, Fulda
Dr. Michael Tessmer, Frankfurt am Main
Dr. Klaus Manske, Fulda
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