

# One-Year Outcomes of Neoss Bimodal Implants. A Prospective Clinical, Radiographic, and RFA Study

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## ABSTRACT

*Background:* The Neoss implant system has been available since 2004. Few studies documenting the clinical performance of this implant are available.

*Purpose:* To study the stability and clinical/radiographic outcomes of Neoss implants 1 year of loading when using a two-stage protocol.

*Materials and Methods:* Ninety (90) consecutive patients scheduled for implant treatment using a two-stage procedure were enrolled in a prospective follow-up study. A total of 218 implants (Neoss System, Bimodal surface, Neoss Ltd, Harrogate, UK) in diameters of 3.5, 4.0, and 4.5 mm and in lengths from 7 to 15 mm were placed to support 29 single tooth replacements, 53 partial bridges, 5 full bridges, and 10 overdentures in both jaws. Abutment connection was made after a healing period of 3–4 months. The patients were followed during 1 year of loading with clinical, radiographic, and resonance frequency analysis (Osstell Mentor™, Osstell AB, Gothenburg, Sweden) examinations. Prostheses were removed at the annual check-up for individual testing of implant stability.

*Results:* Three implant failures were experienced, giving a survival rate of 98.6% after 1 year. A mean bone loss of 0.6 mm (SD 0.8) was observed after 1 year. There was a significant inverse correlation between implant diameter and marginal bone loss ( $p < .003$ ). The mean implant stability quotient levels were 73.7 (SD 7.6), 74.4 (SD 6.4), and 76.7 (SD 5.2) at placement, abutment connection, and first annual check-up, respectively. The stability had increased significantly from placement to 1 year ( $p < .001$ ) and from abutment to 1 year ( $p < .0001$ ). Implant stability was higher in the mandible than in the maxilla at all time points. There was a significant correlation between bone quality and stability at placement ( $p < .0001$ ) and abutment connection ( $p < .001$ ) but not after 1 year.

*Conclusions:* The use of Neoss implants for prosthetic rehabilitation of consecutive edentate patients with different needs resulted in predictable clinical and radiographic outcomes after 1 year of loading. Implant stability measurements revealed a favorable bone tissue reaction to the implants.

**KEY WORDS:** clinical follow-up, ental implants, radiography, resonance frequency analysis, two-stage technique

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## INTRODUCTION

The use of dental implants is today a self-clear and in many cases the first choice of treatment for replacement

of missing teeth.<sup>1</sup> Long- and short-term clinical follow-up studies have, in general, shown predictable outcomes, and risk factors for implant failure have been identified.<sup>2–4</sup> For instance, short implants and implants placed in soft bone densities have historically been regarded as prone to failure.<sup>5</sup> Thus, firm primary stability has been pointed out as one important determinant for successful integration.<sup>6</sup>

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Initially, the osseointegration technique followed strict and often ceremonious two-stage protocols to ensure good outcomes.<sup>7</sup> Today, the vast majority of published clinical studies are on simplified protocols such as immediate/early loading, which is a likely consequence of the good experiences from the original and lengthy

treatment protocols. Although immediate/early loading may be successfully used in selected cases,<sup>8</sup> a two-stage protocol is still regarded as the standard procedure in daily clinical practice by the present authors. Moreover, the contemporary dentist has to select a simple, versatile, and safe implant system when considering that consecutive patients with different needs and demands have to be successfully treated. However, this is not an easy task because new dental implant systems are continuously introduced to the market. According to Jokstad<sup>9</sup>, close to 600 different implant systems from some 146 different manufacturers are commercially available, although only few products can be scientifically supported by clinical follow-up studies. Although most of the new implants are made from the same biocompatible materials, based on recognized principles and that studies are not required from a regulatory point of view, it is important to document the clinical performance of each and every implant system. The Neoss implant has been commercially available since 2004. This implant is characterized by a slightly tapered geometry and a micro-rough surface created by a double blasting technique.<sup>10</sup> Tapering has previously been shown to result in firm primary implant stability, especially in soft bone densities, in vitro<sup>11</sup> and in vivo.<sup>12</sup> Moreover, numerous experimental studies using roughened titanium surfaces have demonstrated a stronger bone response to such surfaces as compared with smoother ones<sup>13–16</sup> which suggest improved integration of such implants. Also, the clinical literature indicates better outcomes for surface-modified implants, at least in conjunction with bone augmentation<sup>17,18</sup> and when using immediate/early loading.<sup>8,19,20</sup>

The aim of the present prospective study is to evaluate the clinical and radiographic outcomes of two-stage Neoss implants in 90 consecutive patients during 1 year of loading.

## MATERIALS AND METHODS

### Patients

The study comprised 90 patients (51 females and 39 males, mean age 50.6 years, range 22–82) which had been consecutively included according to inclusion criteria: (1) need of implant treatment, replacing one or several teeth using a two-stage procedure; (2) sufficient amount of bone to place at least 7 mm long and 3.5 mm wide implants. Exclusion criteria were: (1) less than 18 years of age; (2) any condition that precluded oral surgery in local anesthesia; (3) need of bone augmentation prior to implant placement; and (4) planned immediate/early loading. The pre-operative assessments included clinical and radiographic examinations using intraoral radiographs and sometimes OPGs and/or CT-scans. Smoking, bruxism, and periodontal disease were considered only as risk factors and not as contraindications for treatment. All patients were carefully informed about the procedure and gave their written consent to participate. They could at any time point withdraw from the study.

### Implants

A total of 218 dental implants of different lengths and diameters were used in the study (Neoss Implant System, Bimodal surface, Neoss Ltd, Harrogate, UK) (Table 1) (Figure 1). The implants were placed in both the mandible ( $n = 143$ ) and maxilla ( $n = 75$ ) sites to replace single ( $n = 29$ ) teeth, and to support partial bridges ( $n = 53$ ), full bridges ( $n = 5$ ), and overdentures ( $n = 10$ ) (Table 2).

### Surgical and Prosthetic Procedures

Patients were given 2 g amoxicillin (Augmentin™, GlaxoSmithCline, Verona, Italy) prior to implant surgery. If required, the patients were also given

**TABLE 1** Number of Implant Diameters and Lengths

Diameter	Implant Length					Total
	7 mm	9 mm	11 mm	13 mm	15 mm	
3.5 mm	2	14	19	19	9	66
4.0 mm	9	23	26	28	20	106
4.5 mm	4	22	16	4	3	49
Total	15	59	61	51	32	218



**Figure 1** The Neoss implant used in the present study.

diazepam (0.15 mg/kgBw). Surgery was made under sterile conditions in local anesthesia with articain (4%) with epinephrine (1/100,000) (Septanest™, Septodont, Saint-Maur-des-fossés, France). The bone was exposed via a mid-crest incision. Implant site preparation was made using a 2.2-mm spiral drill for the possibility of making screw-retained crowns and bridges. A 3.0-mm drill was then used which was the final diameter for 3.5-mm wide implants. When using 4-mm wide implants, a 3.4-mm drill was used and a 3.9-mm drill for 4.5-mm wide implants. In case of soft bone, the final drill diameter was reduced one step to improve primary stability. A countersink drill was used and the implants placed flush with the bone crest. The implants were inserted with a pre-set insertion torque of 40 Ncm. The final insertion was made using a manual wrench. Implant stability was measured with resonance frequency analysis (RFA, Osstell Mentor™, Osstell AB, Gothenburg, Sweden) in implant stability quotient values (ISQ). Cover screws were applied and the wound closed. Bone quality and quantity was assessed during surgery using the Lekholm & Zarb index<sup>21</sup> (Table 3).

Abutment connection was made 3–4 months after implant placement using a punching technique or a flap

**TABLE 2** Number of Implants and Prostheses

	All	Mandible	Maxilla
Implants	218	143	75
Prostheses	97	65	32
Full bridge	5	1	4
Overdenture	10	9	1
Partial bridge	53	38	15
Single tooth	29	17	12

**TABLE 3** Bone Quality and Quantity According to the Lekholm & Zarb Index

Bone Quality	Bone Quantity					Total
	A	B	C	D	E	
1	—	3	7	2	—	12
2	3	63	69	7	—	142
3	6	25	11	2	—	44
4	—	11	8	1	—	20
Total	9	102	95	12	—	218

procedure. RFA measurements were performed and healing abutments connected. Impressions were made at fixture level after another 2 weeks of healing, using Impregum (ESPE, Seefeld, Germany) and an open tray. The prostheses were made on Neolink™ abutments (Neoss Ltd, Harrogate, UK) made of titanium or gold depending on the material of the framework. Both porcelain and acrylic teeth were used in the study. All but 11 prostheses were screw-retained and the access holes covered with composite fillings. Individual titanium abutments for cementation were used on nine single-tooth implants and in two full maxillary bridges because of angulation of one or several implants. Overdentures were retained to two implants using a straight bar and clips in the mandible ( $n = 9$ ). One overdenture in the maxilla used four implants, two straight bars, and clips for retention. Occlusion was controlled aiming for group function and avoiding loading of cantilever teeth. Function and occlusion was further checked 2–4 weeks after delivery of the prosthetic appliance.

#### Follow-Up Measurements

All patients were followed for 1 year of loading. At the first annual check-up, all constructions except the cemented ones were removed for checking of the stability of each individual implant using RFA measurements. Thus, RFA measurements were made at implant placement, abutment connection and after 1 year of loading. Intraoral radiographs were taken at impression and after 1 year for measurements of marginal bone loss. The upper corner of the coronal shoulder of the implant was used as reference point and measurements from the reference point to the first bone contact at the mesial and distal aspects of the implant were performed using a PC and specially designed software (National Institutes of Health, Bethesda, MD, USA). A mean value was calculated for each implant and time point.

Interval	Implants	Failures	Drop-Outs	CSR (%)
Placement to abutment	218	2	—	99.1
Abutment to 1 year	216	1	—	98.6
1 to 2 years	215			

CSR = cumulative survival rate.

An implant was considered a survival if clinically stable and complying with the function of supporting the prosthesis and causing no discomfort to the patient. Failure was defined as removal of an implant because of any reason.

### Statistics

Student's *t*-test and Spearman's correlation tests were used for statistical analyses of marginal bone and RFA data. A significant difference or correlation was considered when  $p < .05$ .

## RESULTS

### Clinical Observations

All patients attended the 1-year check-up appointment. Three implant failures were experienced during the year of follow-up giving a total survival rate of 98.6% after 1 year (Table 4). Two mobile implants were found at abutment connection: one in the mandible and one in the maxilla. The maxillary implant was partly exposed into the maxillary sinus after placement. The mandibular implant was placed in a post-extraction defect. The third failure was observed in the posterior maxilla at the first annual check-up (Table 5). This implant was a short implant placed in quality 4 bone (Table 5). Moreover, the bridge showed misfit to the first implant. No other severe complications were encountered during the study.

In spite of the failures, all patients received and maintained a crown or bridge during the study giving a

prosthesis survival rate of 100%. The patients with early failures were fitted with a temporary fixed bridge, a new implant was placed and a final fixed bridge was delivered after another 3 months of healing. In the late failure case, the tooth supported by the failed implant was cut from the bridge and re-inserted to the two remaining implants. A new implant was inserted after 3 months of healing using a sinus membrane elevation procedure. Four months later, the bridge was adjusted by adding a new third tooth and delivered to the patient.

### Marginal Bone Loss

All surviving implants ( $n = 215$ ) were radiographically evaluated with intraoral radiographs after 1 year. Twenty-eight implants lacked intraoral radiographs at baseline. For these implants, the marginal bone level was assumed to be 0, ie, at the most superior part of the implant collar.

The average marginal bone level was 0.4 mm (SD 0.6) at baseline and 1.0 mm (SD 0.9) after 1 year. The average bone loss was 0.6 mm (SD 0.8). There was a significant correlation between implant diameter and marginal bone loss ( $p < .003$ ). The average bone loss was 0.8 mm (SD 0.7) for 3.5 mm implants ( $n = 56$ ), 0.6 mm (SD 0.9) for 4.0 mm implants ( $n = 109$ ), and 0.2 mm (SD 0.5) for 4.5 mm implants (Table 6) (Figure 2, A and B).

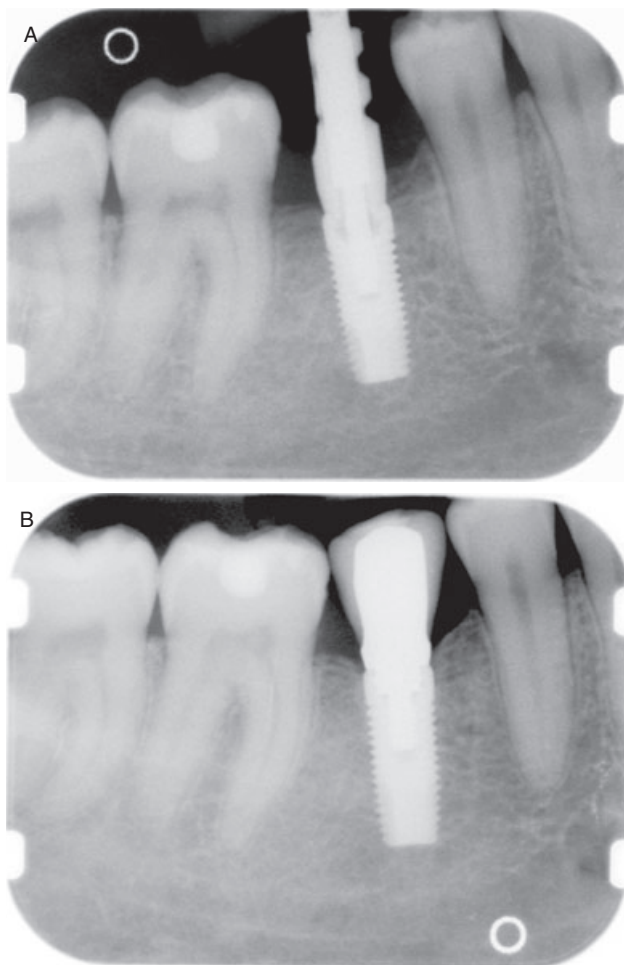
Frequency distribution showed that 13 implants showed more than 2 mm (6.1%) and four implants (1.9%) showed more than 3 mm of bone loss after 1 year

Patient	Case	Time	Position	Diameter	Length	Bone	ISQ1	ISQ2	ISQ3
1	Partial	Abutment	25	3.5	15	B2	72	X	—
2	Full	Abutment	34	4.0	13	B2	77	X	—
3	Partial	1 year	26	4.5	7	C4	63	61	X

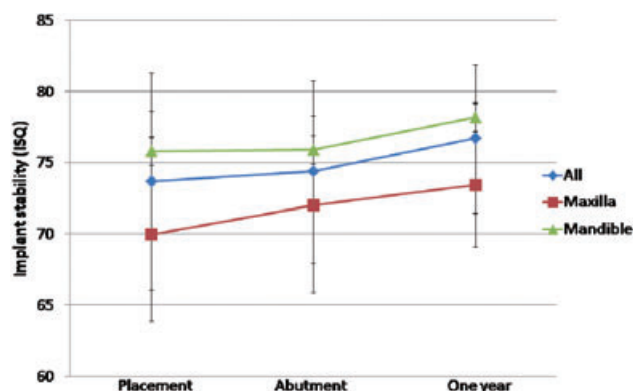
ISQ = implant stability quotient values; X = removed.

TABLE 6 Marginal Bone Levels and Bone Loss	
	mm (SD)
Marginal bone level	
Baseline	0.4 (0.6)
One-year	1.0 (0.9)
Marginal bone loss, average	0.6 (0.8)
Distribution of bone loss (mm)	n (%)
<0	54 (25)
0 to 1	114 (52.7)
1 to 2	35 (16.2)
2 to 3	9 (4.2)
>3	4 (1.9)

SD = standard deviation.



**Figure 2** Radiographs from a single tooth replacement with a 4.5-mm wide and 15-mm long implant at (A) baseline and (B) after 1 year of loading.



**Figure 3** Showing the development of stability with time for all and for maxillary and mandibular implants (see text).

(Table 6). Two of the latter implants were in the same patient that lost one implant in the posterior maxilla after 1 year in function.

### Resonance Frequency Analysis

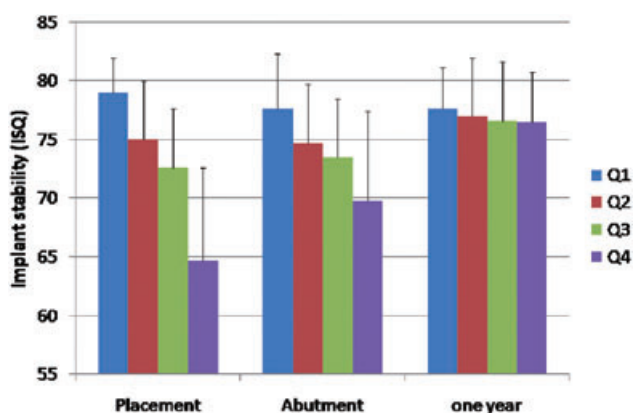
At the first annual examination, 201 implants were individually checked for stability after the prosthetic constructions had been removed. A total of 188 1-year RFA measurements could be used; measurements from eight implants were missing or faulty, one patient with two implants refused removal of the bridge, 17 implants in cemented constructions and the three failures were not measured.

The mean ISQ levels were 73.7 (SD 7.6), 74.4 (SD 6.4), and 76.7 (SD 5.2) at placement, abutment connection, and first annual check-up, respectively (Figure 3). The stability had increased significantly from placement to 1 year ( $p < .001$ ) and from abutment to 1 year ( $p < .0001$ ). Implant stability was higher in the mandible than in the maxilla at all time points. There was a significant correlation between bone quality and stability at placement ( $p < .0001$ ) and abutment connection ( $p < .0001$ ) but not after 1 year (Figure 4).

The two early failures showed ISQ values of 72 and 77, respectively (Table 5). The late failure in the posterior maxilla showed a primary stability of 63 ISQ which decreased to 61 at abutment connection (Table 5).

### DISCUSSION

The present prospective study showed that the Neoss implant system resulted in predictable clinical and radiographic outcomes. The overall survival rate of 98.6% and the average marginal bone loss of 0.6 mm after 1 year of loading are in line with the results from



**Figure 4** Showing implant stability for the different bone densities with time. There was a significant correlation between bone density and implant stability quotient value at placement and abutment connection, but not after 1 year (see text).

previous clinical follow-up studies of this<sup>10</sup> and other modern implant systems.<sup>22</sup> The patients in the present study represented consecutive everyday cases treated with a two-stage procedure in two private offices by one surgeon and three different restorative dentists. The implants were used to treat single, partial, and total tooth loss in the mandible and maxilla. A large number of implants were short (9 and 7 mm) and were placed in the posterior mandible, an area subjected to high functional loads.<sup>23</sup> In spite of this, no failures were encountered in this region. Based on the experiences from machined Brånemark implants, short implants (<10 mm) have historically been regarded as more prone to failure than longer ones (10 mm and longer).<sup>24</sup> However, recent studies have demonstrated high survival rates with shorts implants also in biomechanically demanding situations.<sup>25</sup> One plausible reason is the present use of surface-modified implants. Numerous experimental studies have shown a stronger bone tissue response to implants subjected to different surface modifications, ie, blasting, etching, oxidation, etc. and combination of techniques when compared with non-modified implants.<sup>26</sup> It seems that modified implants are more rapidly integrated because of bone formation directly to the surfaces and that these are more resistant to reverse torque than non-modified control implants.<sup>13–16</sup> The presently used implant has a micro-rough surface because of double blasting with ZrO<sub>2</sub> spheres and irregularly shaped Ti-based particles.<sup>10</sup> Previous animal studies have shown affinity of bone formation to this surface and no difference when compared with oxidized and TiO<sub>2</sub> blasted implants.<sup>27,28</sup>

Three implant failures were experienced in the present study: two after abutment connection and one after 1 year of loading. The two early failures were most likely because of inadequate healing conditions. One 15-mm long and 3.5-mm wide implant placed in the second premolar region in the maxilla was mobile at abutment connection. Radiography revealed that this implant had its distal surface exposed to the maxillary sinus. Another 15-mm implant was placed in a defect in the mandible and was lost shortly after abutment connection. The third failure involved a 7-mm long implant placed in a 4–5-mm bone in the first molar region the maxilla as the most distal abutment of a three-implant and a three-unit bridge. Radiography revealed marginal bone resorption at the two mesial implants, which indicated an overload situation. A misfit of the framework was evident at the mesial implant. Moreover, the patient was diagnosed with bruxism and an unfavorable loading situation was considered as the cause of the failure. At removal of the failed implant, the two remaining implants showed bone resorption to the bottom of the collar. However, no implant threads were visible as indicated by the radiographs. It can be speculated that the bone at the innermost interface had demineralized as a response to overload without creating a vertical defect. In this case, the bridge was adjusted and connected to the two remaining implants out of occlusion. A new implant was inserted together with a sinus membrane elevation procedure and eventually included in the construction. Further follow-up of this patient (not reported here) has shown recovery of RFA values and marginal bone loss of the two mesial implants and good function of the new implant. This case demonstrates that marginal bone loss because of overload may be reversible.

All implants were subjected to RFA assessments which measure the implant stability as a function of bone-implant interface stiffness when applying a small bending force.<sup>6</sup> RFA is also sensitive to changes of the marginal bone level and previous work has shown a decrease of 2–3 ISQ units per mm of marginal bone resorption.<sup>6</sup> In the present study, an increase of the mean ISQ value was observed with time, indicating a favorable tissue response. A correlation was seen between bone density and ISQ value at implant placement and abutment connection. However, after 1 year in function, there were no significant differences between the different bone density groups, which is in line with previous

work.<sup>29</sup> This most likely reflects the healing process in cancellous bone around the implants, which results in an increased density and stiffness with time. In this study, the ISQ value at placement could not be used to predict implant failure. The two early failing implants were stable at placement with ISQ values of 72 and 77. The cause for failure was probably related to inadequate healing as discussed above. The late failing implants showed an initial stability of 63 which was the 25th lowest value in the group and significantly lower than the mean primary stability value of ISQ 73.8. This means that the 24 implants with lower primary stability were successful after 1 year of loading. However, all these showed an increase in stability from placement to abutment connection, while the failing implant showed a decrease. At abutment connection, the late failing implant showed the sixth lowest value of the group. This is in line with the findings of Glauser et al.,<sup>30</sup> who demonstrated a correlation between implant failure and stability after 1 and 2 months of immediate loading. It seems like monitoring of development of stability with RFA over time may be more sensitive as a predictor of implant failure than a single primary stability value.

The marginal bone loss was estimated to 0.6 mm after 1 year in function, which is within the range of bone loss reported for other implant systems.<sup>22</sup> Vanden Bogaerde et al.<sup>10</sup> observed a mean marginal bone loss of 0.7 mm after 18 months of immediate loading of Neoss implants. It is generally anticipated that the marginal bone level should end up at the first thread after 1 year in service.<sup>31</sup> However, in the present study, about 86% of all implants had the marginal bone level on the collar after 1 year in service. It is possible that the micro-topography of the collar has a retentative effect on the marginal bone. A recent retrospective study on the same implant system reported a bone loss of 0.4 mm after 1 and 5 years of functional loading, which indicated less bone loss as observed in the present study.<sup>32</sup> These implants had been placed with no or only minor submerging of the collars which may have influenced the marginal bone remodeling positively.

Interestingly, an inverse correlation between bone loss and implant diameter was seen in the present study. This may be explained by a platform switch effect because of the design of the present implant system because all three diameters utilize the same size of abutments.<sup>33</sup> Moreover, the 3.5- and 4.0-mm implants have the same diameter of the collar and showed similar

degree of bone loss, i.e., 0.8 vs 0.6 mm, while the 4.5 mm implants showed only 0.2 mm bone loss. However, the 4.5 mm implants had been placed in sites of good bone volume and were in many cases used for single tooth replacements, while the 3.5 mm implants were mainly used in narrow ridges.

## CONCLUSION

The use of Neoss implants for prosthetic rehabilitation of consecutive edentate patients with different needs resulted in predictable clinical and radiographic outcomes after 1 year of loading. Implant stability measurements revealed a favorable bone tissue reaction to the implants.

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