Prospective Clinical Trial Evaluating a New Implant System for Implant Survival, Implant Stability and Radiographic Bone Changes

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ABSTRACT

Background: There are a few prospective studies reporting on new implant systems. When a new implant is brought to market, prospective trials should be carried out to determine the predictability of that system.

Purpose: This prospective study evaluates implant survival, Resonance Frequency Analysis (RFA), and crestal bone level changes for a new implant system (Neoss System, Bimodal surface, Neoss Ltd, Harrogate, UK).

Materials and Methods: Seventy-six patients, 38 females (age ranging from 23 to 57 years) and 38 males (ranging in age from 17 to 85 years) received 100 Neoss implants. Patients were consecutively enrolled in the study if they were missing one or more teeth in either arch, or a single tooth was scheduled for removal and immediate implant replacement. Evaluated implants were 4, 4.5, or 5 mm wide and were 7, 9, 11, 13, or 15 mm long. A one-stage approach was followed. At first stage and prior to healing abutment placement RFA measurements were taken. Measurements were retaken at second stage. Fifty-one implants were placed for restoration of single missing teeth and 49 were for short span implant bridges.

Results: The cumulative survival rate at 1- to 2-year interval was 93%. Average initial RFA measurement for all implants was 72.06, while the average final score was 72.58. These changes were not statistically significant. Changes in RFA scores for maxillary implants were insignificant. Forty-two paired mandibular RFA measurements were evaluated. Initial and final mean mandibular RAF measurements were 73.65 (SD 9.203) and 77.186 (SD 6.177), respectively. These changes were statistically significant ($p = .02$). Sixty-four paired radiographs were available for evaluation. Between examinations, there was an average –0.6 mm of bone loss, which was statistically significant ($p = .03$). On average, 4.0-mm-wide implants lost 0.1 mm of bone when compared with 5-mm-wide implants. These differences were insignificant ($p = .86$). Bone loss was adjusted for implant length, and tooth position and there were small, but clinically insignificant changes. Five-millimeter-wide implants lose 0.2 mm more than 4.0-mm-wide implants ($p = .7$). Maxillary incisors lose the least amount of bone 0.152 ($p = .33$).

Conclusions: The implants tested in this study had initially high RAF readings, indicating good primary stability. RFA readings for implants placed in the mandible improved from baseline and the changes were statistically significant. Marginal bone levels revealed clinically insignificant bone loss from implant installation to second stage. Loss of seven implants with initially high RFA readings is surprising.

KEY WORDS: implant survival, prospective, RFA, X-ray measurements

Replacement of missing teeth with dental implants for fully and partially edentulous patients has become an acceptable and, in many situations, preferred method for tooth replacement. Branemark and

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colleagues presented long-term data describing the predictability of dental implants.[1–6] Their data demonstrated implant survival in the high 90 percentage over 10–15 years follow-up. Since their original work, there have been numerous studies reporting on various implant systems with different designs, surfaces, sizes, and indications for implant placement. Implants are placed according to one or two stage protocols,[4,5,7] or immediately after tooth extraction.[8,9] Short implants have been reported to have excellent survival rates as have implants placed into maxillary sinuses.[10–14] Resonance frequency analysis (RFA) has become an acceptable, noninvasive method for measuring implant stability.[15–19] The method requires placement of an electronic transducer in the implant and passing a low-voltage current, undetectable by the patient, through a transducer. Resistance to vibration of the transducer to the surrounding bone is registered in a small computer device and measured in Hertz. Hertz measurements are converted to ISQ (International Stability Quotient) units in the computer. This method is known as RFA.

In 2004, a new implant system was introduced to the dental market (Neoss Ltd, Harrogate, UK). The implant is threaded and has an internal connection, slight taper, one size prosthetic table, and is available in multiple lengths and widths. The implants have a slightly roughened biomodal surface.[20] At this time, there are relatively few papers relating to the predictability and versatility of this system. Zumstein[21] reported a retrospective study with an overall survival rate of 95% at 5 years. Sennerby and colleagues[22] recently reported a prospective study of bimodal implants. Ninety patients received 218 implants for the replacement of single teeth, short bridges, and fixed detachable bridges. The cumulative survival was 98.6%. Resonance frequency measurements were taken at implant insertion, abutment connection, and 1-year follow-up. There was a significant increase in implant stability between implant insertion and 1-year follow-up. Moreover, there was a significant correlation between bone quality and implant stability at implant placement ($p < .0001$) and at abutment connection ($p < .001$) but not after 1 year.

The purpose of this prospective study is to report clinical outcomes for the Neoss implant system (Neoss Ltd.). Study outcomes are implant survival, radiographic changes in crestal bone levels, and implant stability using RFA. RFA scores and periapical radiographs were taken at implant placement and at second-stage evaluation.

MATERIALS AND METHODS

This study consists of 76 patients, 38 females (age ranging from 23 to 57 years) and 38 males (ranging in age from 17 to 85 years) who received 100 implants. Patients were consecutively enrolled in the study if they were missing one or more teeth in either arch or if a single tooth that was scheduled for removal and immediate implant replacement. Patients were excluded if they had untreated or poorly controlled diabetes, a history of radiation to the head and neck, a cerebral vascular accident within the past 2 years, a myocardial infarction within the past year, or the need to augment the proposed site with either bone grafting, barrier membranes, or both. Patients were given comprehensive periodontal examinations, photographs, and study casts. Bone width and height were determined from long cone periapical radiographs and panograms. Linear tomograms or computerized tomography was taken when the mandibular nerve or maxillary sinuses were not clearly delineated from the preceding radiographs. Study inclusion required a minimum of 4 mm of bone width at the alveolar crest, 10 mm of bone height coronal to the mandibular nerve, and 7 mm coronal to the floor of the maxillary sinus. These measurements were estimated from either linear tomograms, measurements taken from study casts, or directly in the area of proposed implant placement. The study purpose was explained to patients, and they signed surgical consent forms. Treatment was performed according to the Helsinki Accords.[23]

Surgery

One hour prior to surgery, patients took 2 g of oral amoxicillin or if allergic, 600 mg of clindamycin. Patients were sedated with intravenous conscious sedation. An appropriate local anesthetic was then administered. Vital signs were continuously monitored and patients were maintained with nasal oxygen. A sterile surgical technique was followed. Initial osteotomies were made with a 2 mm diameter precision drill (Nobel Biocare, Yorba Linda, CA, USA). As an example, for placement of a 3.5 mm diameter implant, a series of twist drills were used to prepare the osteotomy (2.2 mm, 3.0 mm). For 4.0 mm implants, 2.2 mm, 3.0 mm, and 3.4 mm twist drills were used. For 4.5 mm implants, 2.2, 3.0, 3.6 and 3.9 mm twist drills were used; for 5-mm-wide implants, a 4.4 mm final twist drill was used to prepare the final osteotomy.

A one-stage approach was followed for all placed implants. Starting at 20 N/Cm on the drilling console, implants were placed to a final machined torque of 40 N/Cm. Resonance frequency measurements was determined immediately after implant placement and prior to implant restoration (RFA, Osstell Mentor™, Osstell AB, Gothenburg, Sweden). Four measurements were taken for each implant (buccal, lingual/palatal, distal, mesial). For statistical evaluation, these measures were averaged. Healing abutments were attached to the implant(s) and a baseline parallel cone periapical radiograph was taken. Clinical photographic documentation was also made. Bone quality and quantity were assessed according to the classification described by Lekholm and Zarb.[24] Bone quality, quantity, RFA scores, implant length and width was recorded on study computer forms and data were entered into a data base designed to monitor various aspects of patient and implant demographics (Triton Dental Implant Management System, Tucson, AZ, USA).

Data Evaluation

Implant survival was evaluated using the method described by Kaplan Meir.[25] Comparison of mean RFA measurements between implant placement and second stage was determined. (SAS 2002–08 by SAS Institute Inc., Cary, NC, USA. NOTE: SAS [r] Proprietary Software 9.2 [TS2M2]).

Sixty-four of the 100 implants was evaluated for bone-level changes for 4- and 5-mm-wide implants according to tooth type and implant length. There were too few 3.3 mm and 3.5 mm and 4.5 mm implants ($n = -x$) from which to make statistical comparisons. Radiographs were scanned at 300 dpi and saved in a personal computer. An outside examiner measured crestal bone changes using ImageJ, a computer program designed to make measurements from images (NIH Image, National Institute for Health, Bethesda, MD, USA). Measurements were made from the top of the prosthetic table to the first point of bone to implant contact. For each implant, mesial–distal bone level measurements were taken and averaged. Generalized Estimating equations were used to estimate mean patient changes adjusting for within-patient correlation. The models had an identity link, a Gaussian error distribution, and an independent correlation structure. Changes were considered significant when the p value was equal to or less than 0.05.

TABLE 1 Number of Implants Placed According to Bone Shape and Quality.[24]

Quality	A	B	C	D	Total
1	4	0	0	0	4
2	59	29	4	0	92
3	1	2	1	0	4
4	0	0	1	0	0
Total	64	31	5	0	100

RESULTS

One hundred implants were placed in 76 patients (Neoss Implant System, Neoss Ltd.). Table 1 shows the number of implants placed according to bone quality and quantity. The majority of implants were placed in bone shape A (64) or B (31) and bone quantity 2 (92). The average time between implant placement and second stage was 4.0 months. The implants were of varying lengths and widths (Table 2) and were installed for replacement of single teeth or for short-span implant supported bridges. Fifty-one implants were placed for restoration of single missing teeth, and 49 were for short-span implant supported bridges.

Implant Survival

Of 100 placed implants, 93 survived (Table 3). The cumulative survival rate at the 1- to 2-year interval was 93%. Of the lost implants, two were placed with a flapless approach, two received an open flap approach, and three were placed immediately after tooth removal.

Prior to implant restoration, a periapical radiograph was taken, healing abutments were removed, and RFA measurements were taken. Seven patients experienced discomfort or implant mobility during these procedures. If the implant was mobile and radiolucency was present between the implant and adjacent bone, it was determined to have failed. A local anesthetic was administered and the implant was removed. A total of seven implants were removed (two single units, and five implants placed for short span bridges). All remaining implants were considered to have survived and were referred back to their restorative dentists for restoration.

The remaining 93 implants were considered to be successful. Twenty patients with 25 implants have been followed between 1 and 2 years. The survival rate during this interval was 100%, while the cumulative survival rate remained at 93%.

TABLE 2 Number of Implants Placed by Diameter and Length

Diameter	7 mm	9 mm	11 mm	13 mm	15 mm	Total
3.25*	0	0	0	1	0	1
3.5*	1	0	1	3	0	5
4.0	1	10	17	14	8	50
4.5	0	3	1	2	0	6
5.0	3	12	20	3	0	38
Total	5	25	39	23	8	100

*The number of placed 3.3 mm and 3.5 mm implants is too small for statistical testing but are included in the overall data.

RFA

Paired RFA scores were available for 96 patients. Changes between examinations for all implants as well as maxillary and mandibular comparisons can be seen in Table 4. The average initial RFA measurement for all implants was 72.1, while the average final score was 72.6. These changes were not statistically significant. Changes in RFA scores for maxillary implants were also insignificant ($p = .52$) Forty-two paired mandibular RFA measurements were evaluated. The initial and final mean mandibular RAF measurements were 73.7 (SD 9.2) and 77.2 (SD 9.2), respectively. These changes were statistically significant ($p = .02$). At implant insertion, the average RFA score for the seven lost implants is 66.6 (Table 5).

Marginal Bone Levels

Sixty-four paired radiographs were available for marginal bone level evaluation. Between examinations, there was an average of –0.6 mm of bone loss, which was statistically significant ($p = .03$). When stratified by tooth type, differences were not apparent (Table 6). Bone level changes for implants according to implant width (4 mm and 5 mm) were compared for differences in bone loss or gain. On average, the 4.0-mm-wide implants lost 0.1 mm more bone when compared with 5-mm-wide implants. These differences were insignificant ($p = .86$). Implant length did impact on bone loss (roughly 0.1 mm of additional bone loss for each additional mm implant length). Anatomic area of implant placement appeared to be the greatest determinant of bone loss (upper incisors lose the least bone approached significance, $p = .06$), while lower incisors had the greatest bone loss. When data were adjusted for anatomical location, 5.0-mm-wide implants lose 0.1 mm more than 4.0 mm wide implants ($p = .8$). This difference was not significant. When adjusted for anatomical position and implant length, 5.0-mm-wide implants lost 0.2 mm more than 4.0-mm-wide implants ($p = .7$). The changes were statistically and clinically insignificant. Although not statistically significant, 7-mm-long implants had the least average crestal bone loss (–0.32 mm), while 13-mm-long implants had the greatest crestal bone loss (–1.28 mm) (Table 7).

TABLE 3 Lifetable Analysis for Placed Implants

Time Period	Patients	Implants	Number Lost	% Survival	% Cumulative Survival Rate
0 Years	76	100	3	97	97
0–1	74	96	4	95.8	93
1–2	20	25	0	100	93

TABLE 4 Measurements and Statistical Comparisons for RFA Readings at Implant Placement and Second Stage

RFA Measurement	Number	Statistic *p* Value†	Mean	SD	SE Mean
All*	100	0.74	72.1	8.3	0.8
Second stage	96	(ns)‡	72.6	14.3	1.4
Maxilla					
Placement	54	0.52	70.9	70.5	1.0
Second stage		(ns)‡	71.6	69.5	0.9
Mandible					
Placement	42	0.02	73.7	9.2	1.4
Secondstage			77.2	6.2	0.9

*Means, standard errors, and *p*-values for resonance frequency analysis (RFA) measurements taken at implant placement and second stage for ISQ Measurements for mandibular and maxillary implants.
†First versus second measurement.
‡ns = not significant.

DISCUSSION

This single center clinical study is among the first to evaluate a relatively new implant system. Seventy-six patients received 100 bimodal implants of varying lengths and widths. At 2 years, the survival rate is 93%, reflecting a loss of seven implants. Sennerby[22] reported a 98% survival at the 1–2-year follow-up examination. Implants were placed using a two-stage approach, while in this study the implants were placed using a minimally invasive one-stage approach. Healing times were similar

TABLE 5 Lost Implants According to Location, Implant Size, Resonance Frequency Analysis (RFA) Readings, and Method of Placement

Patients	Site	Implant Size	Mean Initial RFA	Mean Final RFA	Method of Placement
BR	4*	5.0 × 9	73	55	Flapless
ML	7	4.0 × 15	60	76	Immediate
DM	19	5.0 × 11	75	69	Flap
RP	4	4.0 × 9	55	Na	Immediate
RR	21	4.0 × 11	60	Na	Flapless
DS	5	5.0 × 13	75	Na	Immediate
KT	4	4.5 × 9	68	Na	Immediate
Mean		66.57			

*Number 4 is the maxillary second bicuspid.

in both studies (Sennerby, 3–4 months; this study, 4.0 months). Zumstein reported a retrospective study using bimodal, tapered implants, and reported an overall survival rate of 95%.[21]

RFA is a good indicator of initial- and second-stage implant stability, but does not account for when torque is applied. The overall initial mean RFA was 72.1, while at second stage the average was 72.6. These differences were not statistically significant. Changes in RFA scores between initial and final mandibular measurements were statistically significant, while those for the maxillary arch were not. Others reported similar findings.[20] The mean initial RFA scores for the seven lost implants was 66.64. The number of lost implants is too small for statistical comparison, but is less than the initial mean of the entire group of 76 implants.

To our knowledge, this is one of the first studies evaluating radiographic bone loss according to implant width and length, tooth type, and position (lower incisors, maxillary incisor, bicuspids, molars). Overall bone changes between initial and second stage were statistically and clinically insignificant (0.59 mm). In this study, crestal bone changes were from implant placement to second stage, and were recorded for unrestored implants. Bone loss in this study is the same as reported by Sennerby and coworkers (0.6 mm at 1 year).[22] and less than that reported by others (1.9 mm at 1 year).[21] Differences in bone loss between our study and those reported by others may be related to bone quality, differences in measurement and statistical methods, surgical technique, and random variability. Astrand and colleagues[26] reported results from a comparison study of two implant systems. The greatest measurable bone loss occurred from implant insertion to implant restoration. From restoration and up to 5 years, crestal bone changes for both implant systems stabilized. It appears from our study and other reports that crestal bone loss with a slightly tapered biomodal implant is minimal. Sennerby reported a

TABLE 6 Bone Loss According to All Measured Implants and According to Tooth Type

Obs	Area	_Type_	_FREQ_	*p* Value	Mean
1		0	64	0.0325	−0.59
2	LI	1	2	na	−1.55
3	LM	1	16	0.8394	−0.13
4	LP	1	15	0.1842	−0.89
5	UI	1	8	0.7330	−0.15
6	UM	1	4	0.8907	−0.17
7	UP	1	19	0.0199	−1.02

LI = lower incisors. Insuffient numbers to calculate *p*-values. LM = lower molars; LP = premolars; UI = upper incisors; UM = upper molars; UP = upper premolar.

TABLE 7 Changes in Crestal Bone Loss According to Implant Length

Implant Length (mm)	Number of Implants Placed	Mean Crestal Loss (mm)
7	3	−0.32
9	19	−0.52
11	23	−0.39
13	11	−1.28
15	8	−0.51
Average	64	−0.60

significant correlation of bone loss between 3.5-, 4-, and 4.5-mm-wide implants. In this study, when the data was adjusted for anatomical location, 5.0-mm-wide implants lost 0.1 mm more than 4.0-mm-wide implants, but this difference was not significant ($p = .8$). Differences between studies may be related to the number of evaluated implant widths. In the present study, 5.0-mm-wide implants were frequently placed. Although the bone loss was greater than with 4.0-mm-wide implants, the loss is not considered to be clinically significant. Differences in implant loss between this study and others are difficult to explain. We previously presented data relating to implants placed immediately after tooth extraction.[27] At 2–3 years, the survival rate was 97.2%, while in the present study it was 93%.[27] Differences in implant survival might be due to random variability or might be due to implant design, surface differences, or other undetermined factors. In the immediate implant study, implants had parallel walls, a Tiunite (Nobel Biocare) surface, and were loaded for an average of 5.8 months after implant insertion. RFA measurements reported in the immediate implant study were recorded with an earlier Osstell version (Osstell AB) than the one used in the present study. The digital unit used in this study may be more accurate than the one used in the earlier version. Further, implants in this study were evaluated after a shorter healing interval than the previously noted study. The initial and final ISQ measurements were less than in the current study (mean ISQ at implant placement 60.9, 63.9 at second stage). In the present study, the implants had a tapered design, a bimodal surface, and were loaded after 4 months. These implants had higher ISQ values than the previously mentioned study, indicating greater initial implant stability (mean initial ISQ 72, final 72). It is interesting to note that the average ISQ for the seven lost implants was 66.6. One immediate implant had an initial RFA of 60 and a final RFA of 76 and was lost. Explanation for this loss is perplexing. Review of this patient's records did not indicate any specific problems during healing. Sennerby and colleagues[20] reported relatively high ISQ values for the two implants that failed (ISQ 72 and 77). Balleri and colleagues[28] reported that successfully integrated implants have ISQ levels from 57 to 69 ISQ readings. The initial implant ISQs in this study were higher than those reported in the previously mentioned study. Use of RFA testing provides clinicians and patients a degree of assurance that installed implants are clinically stable; however, the relationship between RFA readings to crestal bone, implant stability, and bone to implant contacts in the canine model has been questioned.[29] It must be pointed out that ISQ measurements do not assure implant stability when torque is applied. Use of RFA measures after implant placement and prior to implant restoration has value, but does not assure clinicians that the evaluated implants have successfully integrated. Use of RFA measurements alone may provide false positives relating to implant stability and should be used with other clinical evaluation measures. RFA is another tool for evaluation of implant integration and should be used with radiographic evaluation and patients clinical signs and symptoms. Sullivan and colleagues[30] suggested using a reverse torque test prior to implant restoration. Upon completion of healing, a reverse torque of 20 N/Cm is applied to the implants. If discomfort was elicited, the implant is either removed or allowed to heal for two additional months. We feel that prior to implant restoration, in addition to RFA measurements, a torque of 15 N/Cm should be applied to implants.

CONCLUSION

The implants tested in this study had initially high RAF readings, indicating good primary stability. RFA readings for implants placed in the mandible improved from baseline and the changes were statistically significant. Marginal bone levels revealed clinically insignificant bone loss from implant installation to second stage.

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