One-Year Results of a Clinical and Radiological Prospective Multicenter Study on NEOSS® Dental Implants

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ABSTRACT

Background: NEOSS® (Neoss Ltd., Harrogate, UK) dental implant system was introduced on the clinical arena in 2003. It is important that novel implant systems are systematically evaluated in a multicenter setting.

Purpose: The aim of this study was to follow a large number of consecutively treated patients, with NEOSS dental implant system, both clinically and radiographically. The current report constitutes the 1-year data of a planned 5-year study.

Materials and Methods: The study included a total of 177 patients treated with 590 NEOSS implants at 13 clinics in Sweden. The material was composed of 72 males and 105 females treated for single, partial, and total edentulism. Clinical, radiographic, and subjective evaluations were performed.

Results: Out of 590 implants, 13 early failures have been reported, corresponding to a 1-year cumulative survival rate (CSR) of 97.8%. Evaluation of function and esthetics at the 1-year visit resulted in 100% success for function and 98% success for the esthetic outcome. The mean marginal bone loss was 0.6 mm (SD 1.1) after 1 year in clinical function. No adverse effects of the NEOSS dental implants were reported, and complications were few and similar to those reported for implant treatment in general.

Conclusion: The CSR in the present study was 97.8%. No adverse effects of the NEOSS implants were reported, and complications during the study period were few and similar to those reported to for other well-documented implants system. Based on the present data, we conclude that NEOSS dental implant is a safe and predictable implant system. However, the high number of dropouts in the radiological evaluation must be considered when interpreting the data.

KEY WORDS: dental implants, osseointegration, prospective multicenter study

INTRODUCTION

Prospective clinical studies in a multicenter setting are useful tools when evaluating novel dental implant systems. History-wise, these types of studies have been useful when collecting information of the outcome of novel implant designs, surfaces, and treatment modalities. Examples of this are a series of prospective multicenter studies focusing on the 5- to 10-year behavior of various turned Brånemark System® implants in different indiciations.[1–5] These studies have shown encouraging results and served in many ways as a "gold standard" for clinical studies on oral implants. NEOSS® dental implants were clinically introduced in 2000. Experimental[6–10] and clinical studies[11–13] have shown promising results. Hence, it was of great interest to also

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TABLE 1 Age at Implant Placement

Year	
<20	7
21–40	9
41–60	23
61–80	122
>81	16

TABLE 2 Reason for Withdrawal

Passed away	2
Moved	2
*Due to adverse event	3

*Two single-tooth patients lost the implant, one full-jaw patient had a problematic clinical situation.

evaluate the NEOSS implants in a consecutive prospective multicenter study. The aim of the present report is to demonstrate clinical and radiographic 1-year data.

MATERIALS AND METHODS

In brief, the research protocol and inclusion criteria used in the present study have previously been used in similar studies.[14,15] The study protocol was examined and approved by the local ethical committee. The present report was composed of 13 clinics in Sweden. Patients treated in daily practice between April 2007 and April 2008 were included in the study. A total of 177 patients were included in the study (for distribution, see Table 1) with a total of 590 NEOSS implants. The reasons for withdrawal are listed in Table 2. No medical problems, which might interfere with dental implant placement, were found in this population. A total of 26% of the patients used tobacco. The majority of the patients were older than 50 years. The patient population was composed of 72 males and 105 females. Various jaw situations were treated: single-tooth restorations (38 patients), partially edentulous (77 patients), and totally edentulous (60 patients). Two additional patients had a single-tooth replacement and a partial reconstruction in the same jaw. The distribution of implants with regard to jaw, tooth position, implants lengths, and dimensions are presented in Table 3–5. The majority of the implants were installed in the maxilla (65%). Of the 177 included patients, 125 were treated in two-stage protocol and 46 with a one-stage protocol (six of these with immediate function). Furthermore, 91 implants were placed in extraction sites.

With regard to bone quality and quantity, the distributions are presented in Table 6. In brief, the absolute majority of implants were installed in quality type 2 and 3 (40% and 53%, respectively). Shape group B (51.5%) and C (35.4%) predominated. Logically, this was reflected by the relative high number of long implants placed (13–15 mm) (Table 4) as well as the corresponding diameters of the implants (Table 5).

Radiographic Analysis

Radiographs were obtained at abutment connection, at the connection of fixed prostheses, and at the 1-year follow-up examination. One independent radiologist performed the radiographic readings. The upper border of the implant head was used as reference point. The numbers of implants available for evaluation were 314 (Figures 1 and 2).

Statistics

The implant cumulative survival rate (CSR), based on all NEOSS implants inserted, are presented using a life table analysis (Table 7).

RESULTS

Two patients passed away during the study period. Two moved to other locations and three patients withdrew for other reasons, accounting for a total number of seven implants.

Thirteen implants in 10 patients were found to be mobile up to and including the 1 year follow-up (see Table 1). All failures occurred during the time period from implant installation to completion of the prosthetic construction. No further losses were recorded

TABLE 3 Implant Positions

Maxilla	**28**	**27**	**26**	**25**	**24**	**23**	**22**	**21**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**Total**
	0	1	7	45	36	42	23	43	39	18	37	39	50	4	0	0	384
	0	0	5	38	25	21	8	5	11	8	19	24	35	5	1	0	205
Mandible	**38**	**37**	**36**	**35**	**34**	**33**	**32**	**31**	**41**	**42**	**43**	**44**	**45**	**46**	**47**	**48**	**Total**

TABLE 4 Distribution of Implant Lengths

Implant Length (mm)	Placed Implants
7	2
9	44
11	140
13	240
15	163
17	0
Missing	1

TABLE 5 Distribution of Implant Diameter

Implant Diameter (mm)	Number of Implants
3.5	255
4.0	321
4.5	14
5.5	0

during the 1-year clinical function period. This revealed a total CSR of 97.8% (see Table 7). Ten out of the 13 losses were found in the maxilla. The majority of failures

TABLE 6 Distribution of Implants with Regard to Assessed Bone Quality and Quantity Values

	Number of Implants
Jaw shapes	
A	53
B	304
C	209
D	24
E	0
Bone quality	
1	12
2	237
3	312
4	29

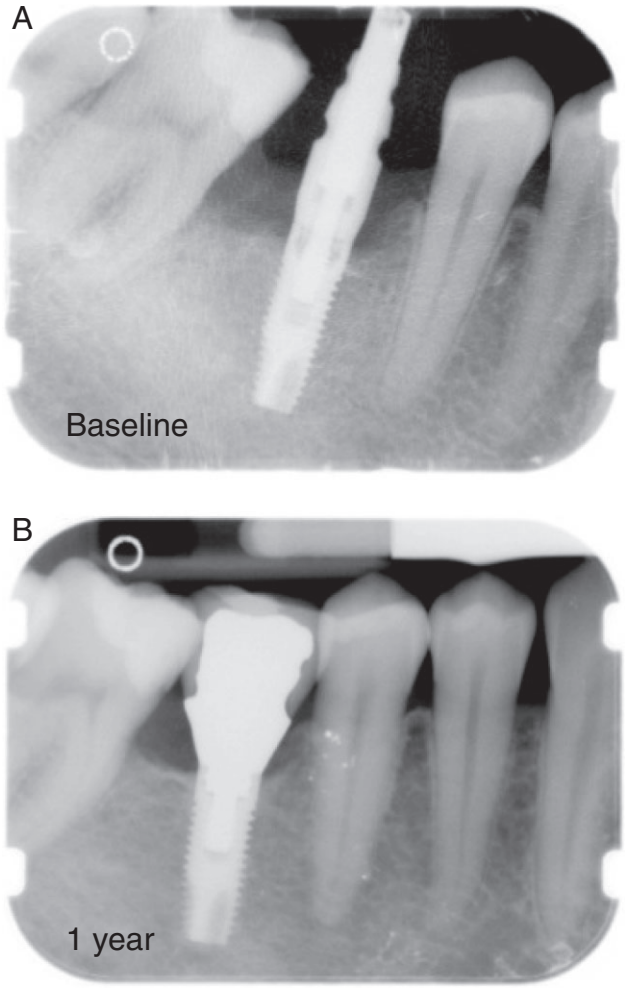

Figure 1 *A*, Radiograph demonstrating single NEOSS implant installed in the mandible at the time of impression (*baseline*). *B*, Single tooth restoration after 1 year in clinical function. Note stable marginal bone levels.

were found in quality 3 and 4 type of bone. The majority of losses were found in totally edentulous cases (10 out of 13). Two implants were lost in patients with partial edentulism, and one of the single-tooth implants failed during the duration of the study (see Table 8). No implant losses in the extraction sites were seen.

The mean baseline value of the marginal bone loss was 1.7 mm (SD 1.0) as measured from the upper level

TABLE 7 Life Table Total

	Surviving Implants	Failed Implants	Withdrawn Implants	CSR (%)
Implant – prosthesis	590	13	6	97.8
Prosthesis – 1 year	516	0	0	97.8
1 year	304	—	—	—

TABLE 8 Implant Failure Summary

Indication	Maxilla or Mandible	Diameter	Length	Quality and Jaw Shape	Initial Stability	Placement Depth
Full	Maxilla	3.5	13	2D	Excellent	Submerged
Single	Maxilla	3.5	13	3A	Excellent	Submerged
Full*	Maxilla	4.0	11	4D	Acceptable	Submerged
Full*	Maxilla	4.0	11	4C	Good	Submerged
Full*	Maxilla	4.0	11	4C	Acceptable	Submerged
Full	Mandible	3.5	13	3C	Excellent	Submerged
Full	Maxilla	3.5	11	2D	Acceptable	Half-submerged
Partial	Mandible	3.5	9	3B	Good	Non-submerged
Full	Maxilla	3.5	9	2D	Good	Half-submerged
Full	Maxilla	3.5	11	2B	Good	Half-submerged
Partial	Mandible	4.0	11	2B	Excellent	Submerged
Full**	Maxilla	3.5	11	3C	Excellent	Submerged
Full**	Maxilla	4.0	13	4B	Excellent	Submerged

of the implant head. The total marginal bone loss during the first year of clinical loading was 0.6 mm (SD 1.1) as measured from prosthesis delivery to the 1-year examination (Table 9). The frequency distributions with regard to marginal bone loss are presented in Table 10. A tendency toward a slightly higher bone loss around the 3.5 mm implant group could be noted, 0.8 mm (SD 1.3) in comparison with 0.5 mm (SD 0.8) for the 4.0 mm implant and 0.1 mm (SD 0.9) for the 4.5 mm implant, respectively.

Adverse events reported were few and are reported in Table 11. Five implants showed marginal bone resorption clinically during the first year. Minor soft tissue reactions were seen at three implants.

DISCUSSION

The present prospective multicenter study demonstrates a material of consecutively treated patients in an everyday practice situation. Multicenter trials with many participating clinics are difficult to conduct. Difficulties in reporting and the availability of postoperative radiographs may bring up criticism and hence must be taken into account when studying the data. Similar difficulties have been reported in similar study setups.[14,15] In the present study, 13 clinics participated. Despite the high number of participating clinics, the numbers of withdrawn patients were few. The final body of 177 patients with a total of 590 implants subjected for analysis was hereby in our opinion sufficient for interpreting the data. A total of 13 implants were lost up to and including prosthetic loading for one year, corresponding to an implant survival rate of 97.8%. It is notable that all losses were recorded prior to clinical loading and no further losses were recorded during the follow-up period. No correlation with regard to implant losses could be seen for implants placed in extraction sites. The implant survival rate was well in accordance with previous studies formerly reported for the Brånemark System implants using a similar multicenter design for various

TABLE 9 Radiographic Analysis (Marginal Bone Level)

Time Point	Bone Level (mm ± SD)
Baseline ($n = 303$)	1.7 ± 1.0
One year ($n = 213$)	2.3 ± 1.0
Change, paired radiographs ($n = 182$)	0.6 ± 1.1

TABLE 10 Frequency Distribution of Bone Loss during One Year from Measurements in Paired Radiographs ($n = 182$)

Interval (mm)	Proportion of Implants ($n = 182$) (%)
<0	28.2
0–1	39.6
1–2	24.7
2–3	3.8
>3	3.3

TABLE 11 Demonstrates Adverse Events (Number of Implants)

	Prosthesis Delivery	1-Year Follow-Up	2-Year Follow-Up	3-Year Follow-Up
No adverse event	495	272		
Loss of osseointegration	13	0		
Marginal bone resorption (clinical)	5	2		
Infection	0	1		
Soft tissue reaction	3	0		
Other	2	0		

jaw indications.[14–19] The outcome of the study was also very close to the 1-year results reported by both Widmark and colleagues[14] and by Friberg and colleagues[15] who studied the turned Mk III implants and Brånemark TiUnite surface, respectively, in a similar study setup. Despite the fact that close to 60% (341/590) of the implants in the present study were placed in quality type 3 and 4 bone did not affect the successful outcome. Only eight out of the 341 implants (2.3%) failed in these type of bone. This was almost identical to data reported by Friberg and colleagues[20] in a similar setting analyzing the Brånemark System implants with TiUnite surface. It could be assumed that this relatively high success rates also in the present study were related to the use of modified surfaces. This type of surface with its documented stronger early bone response could have an impact on the present outcome. This has also been proposed in a recent study by Sennerby and colleagues.[13] The surface of the presently used NEOSS® oral implant has a micro-rough surface due to double blasting with ZrO_2 spheres and irregularly shaped Ti-based particles.[6] Furthermore, it has been shown in previous animal studies an affinity of bone formation to this surface in a similar pattern as described for both oxidized and TiO_2-blasted implants in the clinical setting.[1] No clear pattern could be detected in the present study with regard to implant losses and location and or indication. A majority of the losses were single implant losses in complete edentulous cases in the maxilla, which is in accordance with other studies.[1,20] This meant that the majority of these cases could actually be completed prosthetically without additional implant placement. An independent radiologist performed the radiographic analysis. The marginal bone loss was estimated to be 0.6 mm (SD 1.0), which is well within the range of marginal bone loss reported for other implant systems.[1–5] It is generally anticipated that the marginal bone level should be at the level of the first thread after 1 year in clinical function and loading.[21] Interestingly, approximately 75% of the implants demonstrated a marginal bone level still

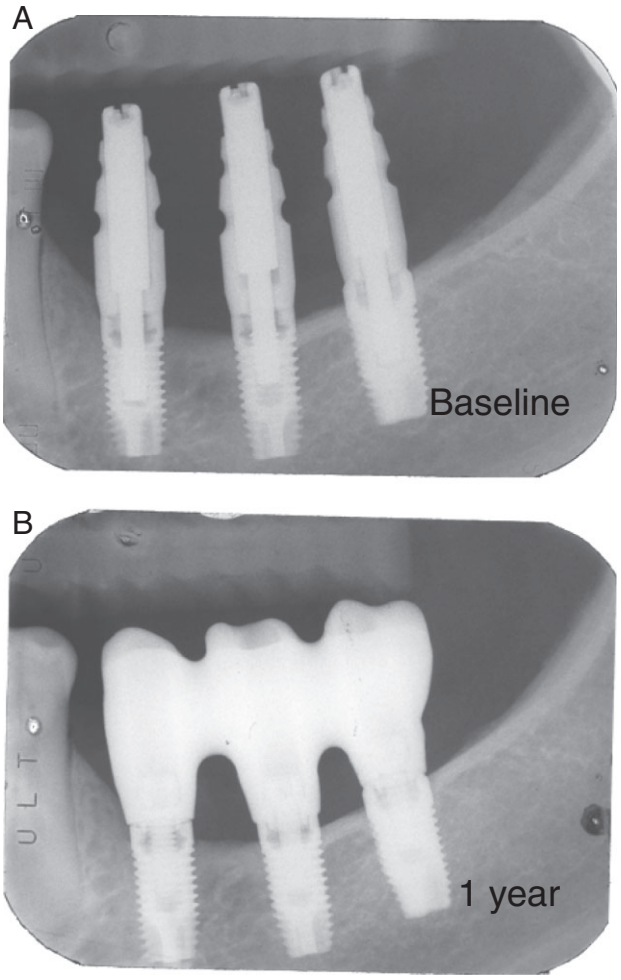

Figure 2 *A*, Clinical radiographs of three NEOSS implants placed in the posterior mandible after completed healing. *B*, Clinical follow-up radiograph after 1 year in clinical function of three-unit bridge construction. Note stable bone levels and corticalization of the marginal bone adjacent to the implants.

present on the collar of implant head after 1 year of clinical function. Another retrospective study on the same implant system has demonstrated a similar outcome.[12]

CONCLUSION

Within the limitations of the present study, the use of NEOSS Implant system for surgical and prosthetic rehabilitation of patients treated in an everyday multicenter setting resulted in predictable clinical and radiological outcome. The CSR reported after 1 year of clinical loading was 97.8%. The level of patient satisfactory was high, and few adverse effects were reported.

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