Five-Year Evaluation of Lifecore Restore® Implants: A Retrospective Comparison with Nobel Biocare MK II® Implants

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ABSTRACT

Purpose: The purpose of this study was to compare survival rates and marginal bone resorption of the Lifecore (LC) Restore® Implant System with the benchmark Nobel Biocare (NB) MK II® Implant System.

Materials and Methods: All implants were inserted by the same surgeon and all radiological analyses were performed by the same radiologist. Two hundred ninety LC implants were analyzed radiologically after 1 year and compared with the same number of NB implants serving as a historical reference group. After 5 years, 200 LC implants could be compared with 224 NB implants. Each implant was monitored for exposed threads, as compared with the baseline registrations.

Results: No significant differences were found between the two implant systems regarding survival rates (LC 100% and NB 99.2%). Considering the findings of this study, the two implant systems compared might be regarded as clones. Nevertheless, because of dissimilar onset of threads, about 1 mm more implant-retaining bone anchorage is gained with the Lifecore Restore Implants as compared with NB MK II Implants.

Conclusions: Based on the assumption that >3 exposed NB threads correspond to >4 exposed LC threads, significantly more bone loss ($p < .01$) could be demonstrated for the NB implants after 5 years. Thus, it may be justified to consider the differences in implant design to have a decisive clinical relevance.

KEY WORDS: bone resorption, clinical comparison, implant design, radiologic evaluation

INTRODUCTION

Among different types of dental implants, the screw-shaped titanium implant has by far the best scientific documentation.[1–11] This is mainly due to the extensive documentation of the original turned-surface screw-shaped implants, that is, the Brånemark System® (Nobel Biocare [NB] AB, Göteborg, Sweden), which are renowned worldwide and has, for a long time, served as a "gold standard".[5] Based on studies in the 1960s, Brånemark and colleagues [12] advocated a submerged two-stage technique in order to achieve osseointegration. Following the success of the Brånemark System, similar types of screw-shaped dental implants have been introduced on the market. The abundance of implants similar to the Brånemark System (MK II) indicates a great confidence not only in the submerged technique, but also in factors as implant material, surface characteristics, and implant design.

Because of the increasing competition between manufacturers, commercial products are introduced on the dental market at a continuously accelerated speed.[13] It is in the greatest interest of the patient and financing health-care systems that dental implant treatment can develop towards increased cost-effectiveness. Still, a cost reduction in hardware must not jeopardize established success rates. Implants are often claimed to have similar clinical performance as the previously documented benchmark. However, truly scientific documentation supporting similarity between the presumed clone and

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DOI 10.1111/j.1708-8208.2008.00115.x

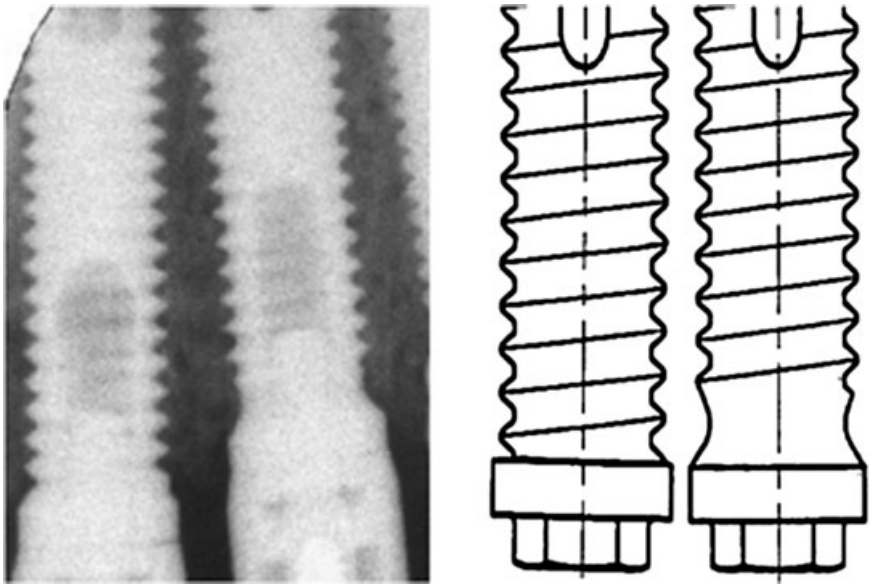

Figure 1 Radiograph and drawing illustrating the designs of Lifecore Restore® Titanium Threaded Implants (LC) and Nobel Biocare MK II® Implants (NB) shown next to each other. In both radiograph and drawing, the LC implant is at the left. The threaded portion of the LC implant starts at 0.2 mm below the implant head, whereas there is a 0.8–1.2-mm smooth titanium before the threaded portion below the NB implant head. Dimensions according to the manufacturers.

the already documented product in long-term clinical use is scarce.[14–19]

Lifecore (LC) Biomedical Inc. (Chaska, Minnesota, USA) offers implant systems that are ISO 9001 certified, have the Food and Drug Administration approval and are CE marked. LC Restore® implant components thus fulfill the requirements for clinical and mechanical equivalency with the Brånemark System according to regulatory demands in the United States and Europe, respectively. Although the Restore implant components are very similar in shape and dimensions, deviations in titanium grade and minor surface characteristics exist. The designs of Restore and NB MK II implants differ regarding the portion immediately below the implant shoulder and also in the apical cutting part. Otherwise, the two implants can be regarded as clones (Figure 1). The intercomponent fit of Restore parts has been shown to be more precise than the Brånemark System and also several other implant systems.[20,21] However, physical, chemical, or mechanical comparisons alone are insufficient to confirm assertions on equivalency. Only clinical studies fulfill the requirements of doing so.

Until now, no long-term scientific documentation regarding the clinical outcome of the Restore Implant System from LC has been published in peer-reviewed papers, although the company has a substantial worldwide sale. Therefore, the aim of the present study was to perform a 5-year evaluation of LC Restore implants using the benchmark MK II implants[22] from NB as a historical reference group.

MATERIALS AND METHODS

All patients in this study were treated at the Specialist Centre for Dental Implants, Nacka (Stockholm), Sweden. The LC group comprised of 60 consecutive patients with 61 totally edentulous full arches in 39 upper and 22 lower jaws. In order to eliminate operator variability, only patients treated by one and the same oral surgeon were considered for the study. The oral surgeon's experience for a 12-year period comprised of nearly 8,000 inserted implants, the majority of them in full-arch cases representing nearly 1,200 jaws.

In total, 359 LC Restore Titanium Threaded Implants were inserted, 129 in the mandibles and 230 in the maxillas. The LC implants were inserted following the standard surgical protocol.[2,12] If required, pretapping was performed in order to fully seat the implants. In the upper jaw, second stage surgery was performed after 6 months, and in the lower jaw after 3 to 5 months. Following the abutment connection, each patient received a full-arch fixed prosthesis within 3 weeks. The restorations were produced by licensed specialists in prosthetic dentistry, following generally accepted prosthodontic

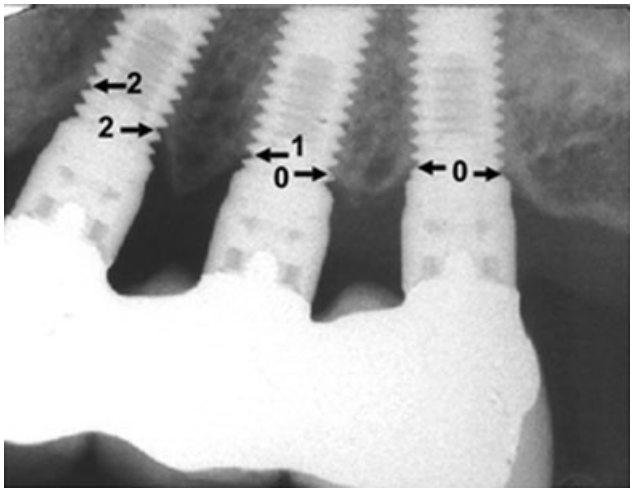

Figure 2 Radiograph illustrating radiologic rating criteria. The number of exposed threads at both sides of each implant was registered. Arrows indicate the rated number of exposed threads. The distance between two threads is 0.6 mm. All implants in this radiograph are Lifecore Restore® Implants.

protocols. Prior to insertion, each restoration was clinically controlled to have a precise fit and was checked to have simultaneous occlusal contacts in centric occlusion. Altogether 359 implants were loaded by 61 full-arch fixed prostheses in 60 patients.

Baseline intraoral radiographs were taken at each implant within 2 weeks after insertion of the fixed prosthesis.[23,24] Efforts were made to assure that the radiographic film was placed parallel to the implant with the aid of a specially designed film holder with an aiming device. The X-ray beam was directed perpendicular to the long axis of the implant in order to provide an as undistorted image of the threads of the implant as possible. The radiographs were developed immediately after exposure and then mounted in dark frames. The evaluation was made using an X-ray viewer (×2 magnification) and a light box. When necessary, extra strong light (Philips Densoscope, Philips, Stockholm, Sweden) was used. The status of each implant was analyzed considering the number of exposed threads and peri-implant radiolucencies. In order to minimize evaluation errors, each implant was analyzed repeatedly until the bone level was consistently established. Exposed threads at both the left and the right side of each implant were registered. If there was a difference between the two sides, the highest number of exposed threads determined the radiological rating of the implant (Figure 2). All radiographs were analyzed by one and the same licensed specialist in oral radiology.

Each patient was recalled for clinical and radiographic examination 1, 3, and 5 years after delivery of the fixed prosthesis. In order to study cumulative survival rates, data were compiled in life table analyses (Tables 1 and 2). In this context individual marginal bone loss was not part of the evaluation.[25] Instead, individual marginal bone loss was used as a success criterion,[26] when evaluating the two implant systems. The assumption that >3 exposed NB threads correspond to >4 exposed LC threads was based on the difference in design, regarding the onset of implant threads. The examinations and the evaluations were performed using the same radiographic technique as at baseline. No bridges were removed for evaluating individual implant immobility, unless clinical symptoms were present.

One-Year Examination

Out of 61 treated jaws, 49 jaws (30 maxillae and 19 mandibles) in 48 patients with 290 LC implants were examined at 1 year. The reasons for not having been

TABLE 1 Numbers of Followed, Failed, and Dropout Implants in the Mandibles Together with CSRs (%) at 1, 3, and 5 Years of Follow-Up

	Followed		Failed		Dropout		CSR (%)	
Mandibles	LC	NB	LC	NB	LC	NB	LC	NB
Placement–baseline*	129	111	0	1†	0	0	100	99,2
Baseline–1 year	129	110	0	0	18	0	100	99,2
1–3 years	111	110	0	0	23	0	100	99,2
3–5 years	88	110	0	0	18	18	100	99,2
5 years	70	92	—	—	—	—	—	—

*Baseline is when the implants were connected to the prosthesis and thus loaded.
†One implant had a peri-implant radiolucency, all threads exposed.
CSR = cumulative survival rate; LC = Lifecore Restore®; NB = Nobel Biocare MK II®.

TABLE 2 Numbers of Followed, Failed, and Dropout Implants in the Maxillae Together with CSRs (%) at 1, 3, and 5 Years of Follow-Up

	Followed		Failed		Dropout		CSR (%)	
Maxillae	LC	NB	LC	NB	LC	NB	LC	NB
Placement–baseline*	230	179	0	0	0	0	100	100
Baseline–1 year	230	179	0	0	51	0	100	100
1–3 years	179	179	0	0	36	12	100	100
3–5 years	143	167	1	0	12	36	99.3	100
5-years	130	131	—	—	—	—	—	—

*Baseline is when the implants were connected to the prosthesis and thus loaded.
CSR = cumulative survival rate; LC = Lifecore Restore®; NB = Nobel Biocare MK II®.

examined at 1 year were (number of jaws/implants within brackets): deceased (1/6); illness (4/24); declined to come (2/12); and did not respond (5/27). These 12 "unaccounted for" patients, who failed to turn up for 1-year examinations, had 51 implants in 9 maxillae and 18 implants in 3 mandibles.

All 49 jaws examined had been supplied with full-arch fixed prostheses. The mean functioning time of the prostheses was 398 days; median 399 days; range 308–530 days. In 29 maxillae six implants each were used, and in one maxilla, five implants. In 16 mandibles six implants each were used, and in three mandibles five implants each. Thus, the LC group of 290 LC implants comprised 179 implants in the maxillae and 111 implants in the mandible at the 1-year radiological and clinical evaluation.

For the purpose of having a historical reference group, 290 NB MK II implants were selected and the NB group was formed. The NB implants were inserted immediately prior to the insertion period for the LC implants. The NB group of 290 NB implants was compiled from patient records of consecutive jaws/treatments, until an identical distribution was achieved of implants and prosthesis as for the LC implants in the experimental group at the 1-year follow-up. All NB implants were inserted by one and the same oral surgeon who also had inserted the LC implants mentioned above. In general, no pretapping of the surgical site was performed. Also the NB implants were clinically and radiologically analyzed at baseline and at year 1, using the same method as described earlier for LC implants.

Three-Year Examination

At the 3-year examination, in the experimental group, six patients with six LC implants each in their maxillae, one patient with five LC implants in her mandible, and four patients with six LC implants each in their mandibles could not be examined. The reasons were (number of jaws/implants): was deceased (5/29); had illness (2/12); was abroad (2/12); and did not respond (2/12). Thus, 37 patients/38 jaws (24 maxillae and 14 mandibles) with 221 implants were examined after 3 years.

In the NB group, two patients with six NB implants each in their maxillae had died and could not be examined. Thus, 278 NB implants, whereof one classified as a failure, in 28 maxillae and 19 mandibles were examined and evaluated after 3 years.

Five-Year Examination

In the experimental group, eight patients with six LC implants each in their maxillae, and seven patients with 41 LC implants in their mandible did not have their 5-year examinations as planned. The reasons given were (number of jaws/implants): deceased (6/35), illness (2/12; declined to come back 7/42. Consequently, 34 patients/35 jaws (22 maxillae and 13 mandibles) with 200 implants were examined clinically and radiologically 5 years after baseline.

In the NB group (11 patients with 66 NB implants) 3/18 had died and 8/48 did not cooperate and could consequently not be examined. After 5 years, 131 maxillary and 92 mandibular NB implants were examined in 37 patients.

The dropouts at 5 years, as well of the experimental group (LC) as those of the historical reference group (NB), were analyzed with regard to exposed threads, as well as *additional* exposed threads. Comparisons were made with the evaluations at baseline and at year 1.

Considering the 1-year registrations, the additional number of exposed threads as compared with baseline

TABLE 3 Numbers and Percentages (within brackets) of LC and NB Implants with 0, 1, 2, and ≥3 Exposed Threads at Baseline

	0		1		2		≥3		Total	
Baseline	LC	NB	LC	NB	LC	NB	LC	NB	LC	NB
Maxillae	137	143	30	23	8	9	4	4	179	179
	(76.5)	(79.9)	(16.8)	(12.8)	(4.5)	(5.0)	(2.2)	(2.2)	(100)	(100)
Mandible	88	84	17	15	5	11	1	1*	111	111
	(79.3)	(75.7)	(15.3)	(13.5)	(4.5)	(9.9)	(0.9)	(0.9)	(100)	(100)
Total	225	227	47	38	13	20	5	5	290	290
	(77.6)	(78.3)	(16.2)	(13.1)	(4.5)	(6.9)	(1.7)	(1.7)	(100)	(100)

*This implant had a peri-implant radiolucency and its exposed threads were classified as ≥3.
LC = Lifecore Restore®; NB = Nobel Biocare MK II®.

would indicate the degree of marginal bone loss at each implant during the first year of loading. Accordingly, when comparing the 5-year registrations with baseline, the additional number of exposed threads would indicate the degree of marginal bone loss at each implant during the 5 years of functional load. According to the implant manufacturers, the distance between two adjacent threads is 0.6 mm for both LC and NB implants. In compliance with generally accepted guidelines,[26–28] the average radiographic marginal bone loss should not exceed 1.2–1.5 mm during the first year of functional load and 0.2 mm each of the following years, resulting in a maximal acceptable bone loss of 2.3 mm after 5 years of functional loading.

When comparing the two implants as regards bone loss, the differences in design must be considered (Figure 1). In LC implants, the threads begin immediately below the implant screw head. In NB implants, there is an unthreaded portion of 0.8–1.2 mm before the onset of threads. Consequently, two to three exposed LC threads correspond to one exposed NB thread regarding implant-retained bone distance. In order to focus on the implant's bone-retained distance, bone resorption should be measured between the implant screw head and the marginal bone level. Thus, when transforming millimeters to visible threads, 2.3 mm of acceptable bone loss after 5 years would correspond to ≥4 visible LC threads and ≥2 or three NB threads.

STATISTICAL PREREQUISITES AND METHODS

Life Table Analyses

Cumulative success rates for different time periods were calculated for the two implant systems, and also the maxilla and the mandible separately, using life table analysis according to Kaplan and Meier.[29] Four preset time periods were evaluated, starting at insertion of the implants to the 5-year clinical and radiographic follow-up (Tables 1 and 2).

In order to perform the statistical calculations, approximated normality was used for the significance and life table evaluations. Descriptive statistics were used to present percentages of evaluated patients and also groups of exposed threads, respectively (Tables 3–10).

Chi-Squared Tests

Fisher's exact test was used when only two groups were compared with identify possible differences. The Pearson chi-squared test was used to test if any group, when more than two groups were compared, significantly differed from the others. A significant difference was acknowledged when $p < .05$.

Statistical Package for the Social Sciences® (SPSS Inc., Chicago, IL USA) were used for the statistical evaluations.

RESULTS

Neither LC nor NB implants failed prior to or at abutment connection. All inserted implants, but one, of each brand passed as successful according to the survival criteria[25] ($p > .05$). One NB implant placed in a mandible showed radiolucency around the implant at baseline and was consequently regarded as not "osseointegrated," although it was found to be functioning clinically (Table 1). One LC implant in the maxilla lost osseointegration after 4.5 years of clinical function and was therefore removed (Table 2).

TABLE 4 Numbers and Percentages (within brackets) of LC and NB Implants with 0, 1, 2, and ≥3 Exposed Threads at the End of the First Year

	0		1		2		≥3		Total	
	LC	NB	LC	NB	LC	NB	LC	NB	LC	NB
Maxillae	78	104	61	49	32	17	8	9	179	179
	(43.6)	(58.1)	(34.1)	(27.4)	(17.9)	(9.5)	(4.5)	(5.0)	(100)	(100)
Mandible	55	51	36	35	15	13	5	12*	111	111
	(49.5)	(45.9)	(32.4)	(31.5)	(13.5)	(11.7)	(4.5)	(10.8)	(100)	(100)
Total	133	155	97	84	47	30	13	21	290	290
	(45.9)	(53.4)	(33.4)	(29.0)	(16.2)	(10.3)	(4.5)	(7.2)	(100)	(100)

*One of these implants had a peri-implant radiolucency and its exposed threads were classified as ≥3.
LC = Lifecore Restore®; NB = Nobel Biocare MK II®.

Baseline Results

At baseline registration no LC implants, but one NB implant showed a peri-implant radiolucency. However, this implant was not removed during the entire follow-up period because of the refusal of the patient. Of the LC and NB implants, 77.6 and 78.3%, respectively, showed 0 exposed threads. A small difference was seen between jaws: a higher percentage (79.3%) of LC implants had 0 exposed threads in the mandibles as compared with NB implants (75.7%). In the maxillae the difference was reversed: 76.5% LC implants and 79.9% NB implants had 0 exposed threads (Table 3).

One-Year Results

At the 1-year examination, the LC implants seemed to perform equally well in both jaws, that is, 4.5% of the implants had ≥3 exposed threads, which means that 95.5% of them had ≤2 exposed threads as well in the maxillae as in the mandibles. The corresponding figures of ≤2 exposed threads for NB implants were 95.0% in maxillae and 89.2% in the mandibles ($p > .05$). Thus, when comparing with baseline examination, the percentages of both LC and NB implants with ≥3 exposed threads had increased. However, a more pronounced increase was seen in the NB mandibular implants (Table 4).

Considering the number of additional exposed threads at the 1-year examination, ≤2 additional exposed threads (equal to ≤1.2 mm) were observed in 174/179 (97.2%) of the LC maxillary implants, and in 178/179 (99.4%) of the NB maxillary implants. In mandibles, the corresponding figures were 108/111 (97.3%) of the LC and 105/111 (94.6%) of the NB implants.

TABLE 5 Numbers and Percentages (within brackets) of LC and NB Implants with 0, 1, 2, 3, and ≥4 Additional Exposed Threads at 1 Year as Compared with Baseline

	0		1		2		3		≥4		Total	
	LC	NB	LC	NB	LC	NB	LC	NB	LC	NB	LC	NB
Maxillae	104*	121‡	49	41	21	16	4	0	1	1	179	179
	(58.1)	(67.6)	(27.4)	(22.9)	(11.7)	(8.9)	(2.2)	(0.0)	(0.6)	(0.6)	(100)	(100)
Mandible	69†	65§	32	32	7	8	3	6	0	0	111	111
	(62.2)	(58.6)	(28.8)	(28.8)	(6.3)	(7.2)	(2.7)	(5.4)	(0.0)	(0.0)	(100)	(100)
Total	173	186	81	73	28	24	7	6	1	1	290	290
	(59.7)	(64.1)	(27.9)	(25.2)	(9.7)	(8.3)	(2.4)	(2.1)	(0.3)	(0.3)	(100)	(100)

*Five of these implants had a bone apposition of one thread.
†Three of these implants had a bone apposition of one thread.
‡Eight of these implants had a bone apposition of one thread; one of these implants had a bone apposition of two threads.
§Two of these implants had a bone apposition of one thread; one of these implants had a bone apposition of two threads; one of these implants had a peri-implant radiolucency with all threads exposed, already at baseline.
LC = Lifecore Restore®; NB = Nobel Biocare MK II®.

TABLE 6 Numbers and Percentages (within brackets) of LC and NB Implants with 1, 2, 3, and ≥4 Exposed Threads at the End of Year 5

	0		1		2		3		≥4		Total	
	LC	NB	LC	NB	LC	NB	LC	NB	LC	NB	LC	NB
Maxillae	34	43	39	50	35	22	14	9	8*	7	130*	131
	(26.2)	(32.8)	(30.0)	(38.2)	(26.9)	(16.8)	(10.8)	(6.9)	(6.2)	(5.3)	(100)	(100)
Mandible	21	34	28	23	11	18	7	15	3	3†	70	93
	(30.0)	(36.6)	(40.0)	(24.7)	(15.7)	(19.4)	(10.0)	(16.1)	(4.3)	(3.2)	(100)	(100)
Total	55	77	67	73	46	40	21	24	11	10	200	224
	(27.5)	(34.4)	(33.5)	(32.6)	(23.0)	(17.9)	(10.5)	(10.7)	(5.5)	(4.5)	(100)	(100)

*One additional implant lost osseointegration and was removed after 4.5 years.
†One of these implants had a peri-implant radiolucency and its exposed threads were classified as ≥4.
LC = Lifecore Restore®; NB = Nobel Biocare MK II®.

Bone apposition was seen at a number of implants after the first year of functional load (Table 5).

Five-Year Results

Regarding a marginal bone loss of ≥4 threads after 5 years, the differences between LC (5.5%) and NB (4.4%) implants were minor (Table 6), and no statistical differences could be detected between the compared implant systems ($p > .05$). However, when considering an unacceptable distance of ≥2.3 mm – that is, 1.5 mm + (4 × 0.2 mm)[26] between the implant screw head and the marginal bone after 5 years – this would correspond to ≥4 LC or ≥3 NB exposed threads. Accordingly, after 5 years ≥4 exposed threads were registered in 6.2 (maxillae) and 4.3% (mandibles) of the LC implants, and ≥3 exposed threads were observed in 12.2 (6.9 + 5.3; maxillae) and 19.3% (16.1 + 3.2; mandibles) of the NB implants (Table 6). Taking the dissimilarity in design into consideration, these differences between the two implant systems were found to be statistically significant ($p < .01$). One NB and two LC implants showed a marginal bone loss of five or seven exposed threads in the maxillae, respectively. The one mandibular NB implant with the peri-implant radiolucency was still retained without any clinical symptoms. Having all threads exposed, it was classified as having ≥4 threads of marginal bone loss (Table 7).

Regarding additional exposed threads at the 5-year registration, 96.0% of the LC implants showed ≤3 additional threads between baseline and year 5 as compared

TABLE 7 Numbers and Percentages (within brackets) of LC and NB Implants with 0, 1, 2, 3, and ≥4 Additional Exposed Threads at 5 Years as Compared with Baseline

	0		1		2		3		≥4		Total	
	LC	NB	LC	NB	LC	NB	LC	NB	LC	NB	LC	NB
Maxillae	42*	59‡	40	42	29	17	13	8	6¶	5	130¶	131
	(32.1)	(45)	(30.5)	(32.1)	(22.1)	(13)	(9.9)	(6.1)	(4.6)	(3.8)	(100)	(100)
Mandible	29†	46§	24	22	8	16	7	7	2	2**	70	93
	(41.4)	(49.5)	(34.3)	(23.7)	(11.4)	(17.2)	(10)	(7.5)	(2.9)	(2.1)	(100)	(100)
Total	71	105	64	64	37	33	20	15	8	6	200	224
	(35.3)	(46.9)	(31.8)	(28.6)	(18.4)	(14.7)	(10)	(6.7)	(4.0)	(2.7)	(100)	(100)

*Six of these implants show a one-thread apposition of bone.
†One of these implants shows a one-thread apposition of bone.
‡Nine of these implants show a one-thread apposition of bone.
§Three of these implants show a one-thread apposition of bone.
¶One additional implant lost osseointegration and was removed after 4.5 years.
**One of these implants had a peri-implant radiolucency with all threads exposed, already at baseline.
LC = Lifecore Restore®; NB = Nobel Biocare MK II®.

TABLE 8 Dropout Patients at 5 Years: Numbers and Percentages (within brackets) of LC and NB Implants with 1, 2, and ≥3 Exposed Threads when Evaluated at Baseline

	0		1		2		≥3		Total	
	LC	NB	LC	NB	LC	NB	LC	NB	LC	NB
Maxillae	30	43	14	3	2	1	2	1	48	48
	(62.5)	(89.6)	(29.2)	(6.3)	(4.2)	(2.1)	(4.2)	(2.1)	(100)	(100)
Mandible	33	13	3	3	4	2	1	0	41	18
	(80.5)	(72.2)	(7.3)	(16.7)	(9.8)	(11.1)	(2.4)	(0.0)	(100)	(100)
Total	63	56	17	6	6	3	3	1	89	66
	(70.8)	(84.8)	(19.1)	(9.1)	(6.7)	(4.5)	(3.4)	(1.5)	(100)	(100)

LC = Lifecore Restore®; NB = Nobel Biocare MK II®.

with 97.3% of the NB implants. Notably, 3.5% of LC and 5.4% of NB implants showed bone apposition (Table 7).

Dropout Group at 5 years

When evaluated at baseline, the LC implants of the dropout group at 5 years showed a higher percentage (3.4%) of ≥3 exposed threads than the NB group (1.5%) (Table 8). When evaluated at 1 year, 27.8% NB implants of the dropout group at 5 years showed ≥3 exposed threads in mandibles, as compared with 4.9% of the LC implants However, all five implants were in one and the same patient (Table 9). Of the LC and NB implants,

TABLE 9 Dropout Patients at 5 Years: Numbers and Percentages (within brackets) of LC and NB Implants with 1, 2, and ≥3 Exposed Threads When Evaluated at Year 1

	0		1		2		≥3		Total	
	LC	NB	LC	NB	LC	NB	LC	NB	LC	NB
Maxillae	24	34	19	10	3	3	2	1	48	48
	(50.0)	(70.8)	(39.6)	(20.8)	(6.3)	(6.3)	(4.2)	(2.1)	(100)	(100)
Mandible	24	6	10	5	5	2	2	5*	41	18
	(58.5)	(33.3)	(24.4)	(27.8)	(12.2)	(11.1)	(4.9)	(27.8)	(100)	(100)
Total	48	40	29	15	8	5	4	6	89	66
	(53.9)	(60.6)	(32.6)	(22.7)	(9.0)	(7.6)	(4.5)	(9.1)	(100)	(100)

*All these five implants were diagnosed in the same patient.
LC = Lifecore Restore®; NB = Nobel Biocare MK II®.

TABLE 10 Dropout Patients at 5 Years: Numbers and Percentages (within brackets) of LC and NB Implants with 0, 1, 2, 3, and ≥4 Additional Exposed Threads When Evaluated at Year 1

	0		1		2		3		≥4		Total	
	LC	NB	LC	NB	LC	NB	LC	NB	LC	NB	LC	NB
Maxillae	38*	39	9	7	0	2	0	0	1	0	48	48
	(79.2)	(81.3)	(18.7)	(14.6)	(0)	(4.1)	(0)	(0)	(2.1)	(0)	(100)	(100)
Mandible	30†	7	9	7	1	2	1	1	0	1	41	18
	(73.2)	(38.9)	(22.0)	(38.9)	(2.4)	(11.0)	(2.4)	(5.6)	(0)	(5.6)	(100)	(100)
Total	68	46	18	14	1	4	1	1	1	1	89	66
	(76.5)	(69.7)	(20.2)	(21.2)	(1.1)	(6.1)	(1.1)	(1.5)	(1.1)	(1.5)	(100)	(100)

*One of these implants had a bone apposition of one thread.
†One of these implants had a bone apposition of two threads.
LC = Lifecore Restore®; NB = Nobel Biocare MK II®.

2.2 and 3.0%, respectively, had ≥3 additional exposed threads between baseline and year 1. Bone apposition was seen in 2.2 and 0.0% for the LC and NB groups, respectively (Table 10).

DISCUSSION

Operator variability is known to play an important role in every clinical trial. Multicenter studies, by their nature, involve placement of implants by a number of different surgeons of varying experience.[15,17,30,31] Moreover, follow-up examinations on the same implants are usually carried out by a number of different assessors. Thus, inconsistencies and errors in data may easily be introduced. In order to minimize interoperator variability, only implants inserted by one and the same experienced oral surgeon were included in this study. Regarding intraoperator variability, the relatively large number of implants (290 implants in each group at 1-year) was thought to reduce the inherent risk for such errors.

The survival criteria chosen have been used before by Lekholm and colleagues[25] and others[13], and was also supplemented by a separate presentation of marginal bone resorption at each individual implant.

As operator variability is likely to be decisive for a consistent outcome, the radiographic examinations were performed by one and the same specialist in oral radiology in order to reduce interexaminer errors. Intraexaminer inconsistencies cannot be neglected and might influence the observations.[32] The errors in radiographic examinations may be in a magnitude that could severely impair the results of a radiographic follow-up study of screw-shaped dental implants.[33] The greatest risk of errors in radiographic analysis of marginal bone height comes from even small deviations from strict parallelism between the implant axis and the film plane. In an experimental model (using 3.75 mm Brånemark implants) with a simulated alveolar crest width of 5 mm, Sewerin (1990) demonstrated that a small (6°) angular deviation of the X-ray beam produced clearly definable threads, but resulted in nearly 0.6 mm displacement of the thread.[32] Obviously, the shown errors also give rise to questions whether recommended guidelines[26–28] of average radiographic bone loss are scientifically well-founded.

It is prescribed that implant treatments are checked up on a regular basis.[2] In order to assess individual treatment success as well as evaluation of treatment quality of larger patient groups, radiographic evaluation is indispensable. Threaded implants exhibit obvious measuring points with a known distance between two adjacent threads, to which marginal bone loss could be related. Therefore, in clinical practice, the most natural quality assessment of implant treatment with threaded implants would be to relate marginal bone loss to implant threads. Thus, to possibly avoid inherent errors connected with radiographic assessments of marginal bone loss in millimeters, it was decided to use the implant thread as a measuring gauge. This method is in accordance with some other recent clinical evaluations.[14,17,34,35]

The limits for acceptance would be well within the internationally recommended guidelines for 1.5 mm radiographic bone loss during the first year of functional load. Thereafter, 0.2 mm bone loss each of the years following the first year has generally been accepted. It is our opinion that because of the errors connected with radiographic bone level assessment around threaded implants, a millimeter-measuring scale may be less relevant than the method advocated here. In this context it should also be pointed out that reference points are differently and unclearly defined in several publications.[14,17,26,30]

The accepted marginal bone loss, or rather the implant-retaining bone distance, deserves more thorough scrutiny. Moreover, the length of the implant is also an important factor in the clinical situation. A recommendation of implant-retaining bone anchorage to at least two-thirds of the implant's length after 5 years has been suggested.[13,25] After 5 years, a 7-mm implant having lost the today accepted amount of 2.3 mm marginal bone [1.5 mm + (0.2 mm × 4)], will demonstrate an implant-retaining bone anchorage reduced with one-third of the implant's total length. A further increased risk of bone loss, depending on implant design, is indicated by findings in the present study. Thus, the length of the remaining implant-retaining bone anchorage is of meaningful clinical relevance when taking clinical decisions. Accordingly, to enhance clinical prognosis, the guidelines for implant treatment success might be revised and the recommendations for average marginal bone loss adjusted accordingly.

The compilation of a historical reference group based on NB MK II as reference group resulted in a complete match of number of patients, number of implants, and distribution between jaws. The insertion

of NB implants was performed by the same oral surgeon in a time period immediately preceding the insertion of LC implants. Thus, the treatment conditions for the two implant systems were very similar. Of course, a prospective randomized study with matched pairs would be an optimal study design to evaluate bone loss around implants of different systems. However, retrospective data compiled under systematic and realistic clinical conditions give important indications weather a new implant system will have a similar success as a previous one.

Although the same surgeon placed all the LC and NB implants, it may be of clinical significance that pretapping of the surgical site was performed for many of the LC implants but virtually none of the NB implants. Pretapping is only required in mandibles of denser bone quality, so the better performance of LC implants in mandibles may be related to the fact that more LC implant sites were pretapped. Conversely, without pretapping, the more effective threads of NB might introduce stress forces into the dense bone of mandibles and consequently possible bone damage, which may explain the less favorable NB results in the mandible.

In the maxilla, there was little pretapping of either system. In the softer maxillary bone the cutting threads of the NB implant may likely prepare a more physiologically acceptable site for healing to occur. Thus, a valid conclusion may be that LC and NB implants perform somewhat differently in maxillae and in mandibles.

With regard to countersinking, this procedure was used at the surgeon's discretion and did not appear to influence the pattern of results. However, as can be seen in the figures and radiographs comparing the designs of the two implants, the threaded portion of the LC implant starts almost immediately below the implant head, whereas there is approximately 1 mm of smooth titanium below the NB implant head before the threaded portion starts. As the performance of each implant with regards to bone loss to and beyond the first thread is comparable, it may preserve alveolar bone to use an implant with the LC design as this was shown to produce more bone to implant area than the NB implant design. Åstrand and colleagues[15] have also demonstrated similar consequences of the different designs in the marginal portion of Astra and NB implants.

The 25 patients with 89 LC implants and 66 NB implants who did not return for the 5 year examination represent 27% of the implants. The analysis of the dropout group at 5 years (when evaluated at year 1) revealed that LC implants showed a higher percentage of ≥3 exposed threads in the maxillae (4.2%) than the NB group (2.1%), not considering the possible, additional loss adjacent to the smooth neck of NB implants. In the mandibles, an undisputable difference between the two implant systems was seen: 27.8% NB and 4.9% LC implants had ≥3 exposed threads. These observations in the dropout group deviate from those of the examined implants, but it should be mentioned that all five (27.8%) NB implants in question were diagnosed in one and the same patient (Table 9). However, unaccounted for implants are known to have more failures/problems than implants remaining in a study and therefore the observed differences might have influenced the comparison of LC and NB implants.

Considering the findings of this study, together with the resemblance in design and the interchangeability of components, the two implant systems compared can be regarded as clones. Furthermore, because of the onset of threads, about 1 mm more implant-retaining bone anchorage is gained with the use of LC Restore Implants as compared with NB MK II Implants. Until further investigations would contradict the here presented results, it may be justified to consider the differences in implant design to have a decisive clinical relevance.

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