A 5-Year Multicenter Study on Implant-Supported Single Crown Restorations

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In this multicenter prospective study, the results achieved with the use of Brånemark implants for single tooth replacement were evaluated. The overall cumulative success rate was 95.9% for implants and 91.1% for crowns. Two of the 99 implants placed had to be removed before the prosthodontic stage of treatment; thus, 97 were restored with CeraOne crowns. Seventy-seven implants were evaluated radiographically at the 1-year follow-up, 57 at 3 years, and 47 at 5 years. Mean marginal bone resorption was well within the limits set by Albrektsson et al in 1986. The status of the soft tissue around crowns and adjacent teeth remained stable over the evaluation period. The gold abutment screw in the CeraOne system seems to have eliminated the problem of loosening abutment screws in single tooth replacements. The results suggest that the Brånemark system can be safely used for tissue-integrated replacement of single teeth.
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Key words: CeraOne, full ceramic crown, osseointegrated Brånemark implant, prospective follow-up study, single tooth replacement

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In edentulous jaws, a high level of success has been documented for osseointegrated screw-shaped implants ad modum Brånemark on a large number of implants in numerous publications.[1–5] In cases of single tooth loss, implant-supported single crowns are being used increasingly more often.[6] Today, single tooth replacement can be included among the classic indications for implant-supported tooth replacement[7,8] (Nentwig GH, personal communication, 1983). From an esthetic perspective, the early single tooth replacement was not without problems,[9,10] and the occurrence of abutment screw loosening was rather high.[8] Therefore, a new single tooth abutment for the Brånemark implant system, the CeraOne components, were developed. The components include (besides the single tooth abutment) prefabricated ceramic caps on which full ceramic crowns are fired, or metal cylinders on which porcelain can be fused to metal crowns. The fabricated single crowns are nonrotational and cemented on the abutments.[11]

The aim of this 5-year multicenter prospective study was to determine the short- and long-term suc-

Table 1 Patient Distribution by Center

Center†	Included patients	Included implants	Withdrawn* patients/implants	Failed implants	Fractured crowns
1	11	13	4/6	0	2**
2	3	3	0	0	1
3	8	11	3/4	2	2
4	10	13	1/2	0	1
5	4	4	0	0	0
6	10	10	0	0	0
7	5	6	4/5	0	1
8	10	13	1/1	0	0
9	3	4	0	0	0
12	3	4	1/1	0	0
14	6	8	2/3	2	1
15	9	10	0	0	0

†Centers 11 and 13 did not participate in the study because of administrative difficulties. Center 10 did not complete the study according to protocol (only two patients have been seen since 1992). No complications were reported from this center on study forms or by oral communication; however, the center chose not to participate in any further follow-up, which is why these patients are not included in the results.
*For reasons other than implant failure or crown fracture.
**One of these crowns did not fracture, but was recemented for other reasons with unsatisfactory results, and is therefore considered a failure.

cess rate for single tooth restorations involving CeraOne abutments with cemented crowns supported by Brånemark system implants. Furthermore, the effects on the soft tissue around the crowns and the adjacent teeth were evaluated.

Materials and Methods

In this multicenter prospective clinical study, with a follow-up period of 5 years following prosthetic treatment, 82 patients were provided with single crowns by March 1992. The patients were treated at 12 clinical centers worldwide, and treatment, as well as follow-up visits, was performed according to a strict study protocol. The personnel at all centers were experienced in the use of the Brånemark system (Nobel Biocare, Göteborg, Sweden). The aim of the study was to include 10 patients at each center, but difficulties in finding enough patients who met the inclusion and exclusion criteria at some centers resulted in a somewhat uneven distribution of patients (Table 1). Since the inclusion period had already been extended by 1 year, a decision was made not to prolong it any further.

All implants were placed following complete healing of the implant site. The surgical procedures were performed ad modum Brånemark.[12] After approximately 3 to 6 months of healing, the CeraOne abutment was attached, using an electric torque controller, to a torque of 32 Ncm, to resist unscrewing of the abutment when in function.

Besides the radiographic evaluation before implant placement, to determine bone quality and quantity[13] at the implant site, radiographs were taken at second-stage surgery of the implant and adjacent teeth. After cementation of the single crown, the first clinical examination (baseline) was performed at the 2-week follow-up visit. Additional annual clinical follow-ups were undertaken with radiographic evaluations of the implant and adjacent teeth every second year (at 1, 3, and 5 years after cementation of the crown).

Clinical Parameters. For the implants and their adjacent teeth, the gingival status was determined using a modified Löe and Silness[14] bleeding index with ratings between 0 = no inflammation/healthy and 2 = moderate inflammation with bleeding on probing.

Further, the crown margin with respect to the gingival level was evaluated. The position of the crown margin was rated as 1 = subgingival; 2 = at gingival level; and 3 = supragingival.

Both the gingival status and the level of the crown margin were evaluated on the mesial, distal, buccal, and lingual sides of each crown. For the adjacent teeth, pocket depth was measured at the four sites as well; pockets shallower than 4 mm were rated 0, and those 4 mm or deeper were rated to the closest millimeter.

The mobility of the implants and teeth was measured and evaluated as follows: 0 = no mobility of the implant, less than 0.2 mm horizontally for teeth; 1 = mobility of the implant (failure), mobility 0.2 to 1.0 mm horizontally for teeth; 2 = greater mobility than 1.0 mm horizontally for teeth; and 3 = mobility also axially for teeth.

All complications during the treatment and follow-up period were carefully reported at each follow-up visit.

Radiographic Evaluation. The radiographic follow-ups were performed at scheduled intervals, as described above. During these follow-up visits, marginal bone resorption around the endosseous implants was evaluated. All radiographs were taken according to a standardized method[15] with a parallel long-cone technique. A film holder was used to secure the position of the film. The threads of the implant, with a thread distance of 0.6 mm, indicated that the x-ray beam hit the implant perpendicularly and therefore was useful in determination of the bone level. On the mesial and distal sides of the implant, the bone level was determined within 0.1 mm accuracy using the implant-abutment interface as the reference point. All radiographs were evaluated by the same radiologist.

Statistics. The results of this report are mainly presented in a descriptive statistical manner. Life table analysis was performed to present cumulative success rates of implants and crowns.

To be regarded as successful, an implant should be immobile and show no persistent pathology. Mean marginal bone resorption for the implants should be less than 1 mm the first year of loading, and less than 0.2 mm annually thereafter. A successful crown should be in function during the whole study period. A fractured crown is regarded as a failure, and not replaced by a new one within this study. For this reason, these implants were withdrawn from the study even though they could be replaced successfully.

Results

Eighty-two patients (47 men, 35 women) with a mean age of 35 years (range 14 to 73 years), who received a total of 99 implants, were included in the study. Eighty-seven implants were placed in the maxilla and 12 were placed in the mandible. The exact distribution of implant locations is shown in Fig 1. Seventy-three standard implants (71 with a diameter of 3.75 mm, and 2 with a diameter of 4.0 mm) were seated after pretapping. In the remaining 26 sites, self-tapping implants were used. The bone quality, according to the criteria established by Lekholm and Zarb,[13] was assessed as 2 or 3 at 94 of the implant sites. In one instance in the mandible, the bone quality was assessed as 1, and in two maxillary cases it was assessed as 4. For two implant sites, the bone quality was not registered. Forty-six of the implants were placed after loss of tooth by trauma or fracture of the root, and in 20 cases aplasia of a single tooth was the reason for treatment. For 14 teeth, tooth extraction was necessary because of periapical or advanced marginal inflammation. For the remaining 19 teeth, the reason for tooth loss was unknown or involved a combination of the reasons described above.

Of the 99 implants placed, 2 were lost before commencement of the prosthetic treatment. One additional implant failed 2 weeks after cementation of the crown. Two of the failed implants were seated in the maxillary anterior region, and the third failed implant was seated in the mandibular posterior region. The bone quality in the first two sites was 3 and in the third site was 2. One other implant was regarded as a failure during the second year of follow-up. Since retention of the crown (porcelain fused to metal) was impossible to maintain, the crown was removed together with the abutment, and the implant was buried.

Of the 97 cemented single crowns, 16 were porcelain fused to metal crowns and 81 were full ceramic crowns. Sixty-nine crowns were cemented with zinc phosphate cement, 5 with glass-ionomer cement, and 22 with provisional cement. For one crown, the cement used was not recorded.

Fifty-seven patients with 65 implants and crowns participated in the 5-year follow-up after crown cementation, and thus completed the study. Twenty-five patients have not been followed for the entire 5-year period, representing 34 implants and 32 crowns (8 implants resulting from crown fracture, 4 resulting from implant failure, and 22 because of other reasons [poor compliance, death, and so forth]). None of the examined implants was mobile at any time. During the 5 years, 7 crown fractures occurred, and 1 crown was regarded as a failure since it could not be recemented with a successful esthetic result after the patient had been seen by his local dentist. The failed crowns were all full ceramic crowns. Seven of the crown failures occurred in the maxilla, five in the anterior and two in the premolar region, and one crown failure occurred in the mandibular molar region. Table 2 shows cumulative success rates for implants and crowns.

No conclusion could be drawn as to whether the failed implants or fractured crowns were center related (Table 1). The uneven number of patients/implants at the various centers and the high number of withdrawals (mainly drop-outs and patients who were lost track of) at some centers made a thorough statistical analysis unfeasible.

On only four occasions, in four different patients, was the gold screw found to be loose. These all occurred in the maxilla: two in the incisor region, one in the canine, and one in the premolar region. After tightening of the gold screws and recementing of the crowns, all but one crown remained stable. In one patient treated in the premolar region, the crown fractured (during the second year in function) 6 months after the gold screw was retightened. This patient was reported to be a bruxer.

Fig 1 Implant distribution according to site.

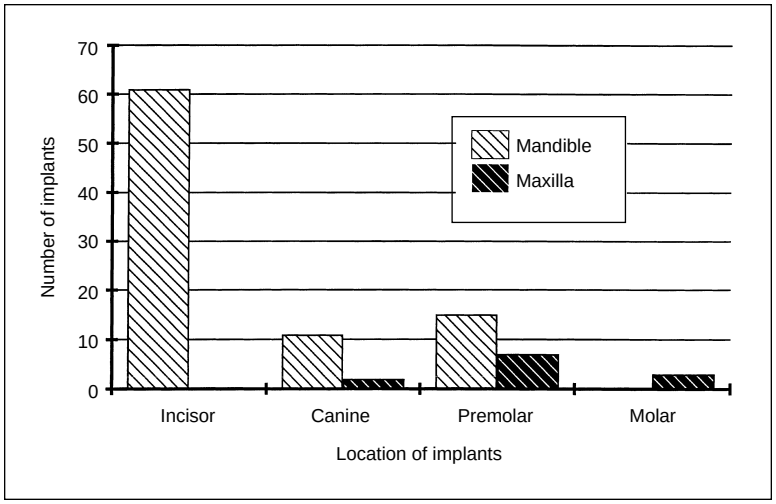

Table 2 Cumulative Implant and Crown Success Rates 5 Years After Crown Cementation

Time period	Implant	Implant failures	Crown fractures	Withdrawn*	Implant CSR (%)	Crown CSR (%)
Maxillae						
Placement to loading	87	1	—	0	98.9	—
Loading to 1 year	86	1	2	3	97.7	97.7
1–2 years	80	0	3	0	97.7	94.0
2–3 years	77	0	1	6	97.7	92.8
3–4 years	70	0	0	4	97.7	92.8
4–5 years	66	0	1**	6	97.7	91.4
5 years	59	—	—	—	—	—
Mandibles						
Placement to loading	12	1	—	0	91.7	—
Loading to 1 year	11	0	0	0	91.7	100
1–2 years	11	1	0	0	83.3	100
2–3 years	10	0	0	2	83.3	100
3–4 years	8	0	0	0	83.3	100
4–5 years	8	0	1	1	83.3	87.5
5 years	6	—	—	—	—	—

*For reasons other than implant failure or crown fracture.
**Crown did not fracture, but needed to be recemented for other reasons, with unsatisfactory results; considered a failure.
CSR = cumulative success rate.

Other reported complications were loose crowns where the abutment was secure (three crowns), which were solved by recementing the crowns, and soft tissue problems (five crowns), which were treated and thereafter remained symptom-free.

The gingival status around the implants showed, in most cases, no inflammatory reaction. Between the third and fifth year, a slight increase in bleeding on probing was observed, but no complications related to this were reported. For the adjacent teeth, similarly good gingival conditions were found. Around most teeth, healthy gingiva was recorded. All values of the gingival status for implants and adjacent teeth are presented in Table 3. Similar to the gingival status, pocket depth for the adjacent teeth showed good results. Only minor increases in pocket depth were found. The exact figures are provided in Table 4. In Tables 3 and 4, only registrations of mesial and distal surfaces are presented; however, these are comparable to the registrations performed on the buccal and mesial surfaces.

Levels of the crown margin at the mesial, distal, buccal, and lingual measuring points at 2 weeks, at 3 years, and at 5 years after cementation are presented in Table 5. The corresponding changes of the gingival level compared to the crown margin during this time are presented in Table 6.

Table 7 shows the marginal bone resorption mesial and distal to the implants after 1 and 3 years of function. The mean marginal bone resorption after 1 year was 0.5 mm mesially (SD 1.0 mm) and

0.4 mm distally (SD 0.9 mm). During the following 4 years, only minor marginal bone resorption changes could be seen.

Discussion

In dentistry, prosthetic treatment decisions are based on long-term considerations. Statements of the potential time of function must rely on results from long term studies. Thus, retrospective and prospective studies are, at this point, the most important sources of information for verification of the success or failure of tooth replacement.[16] At the same time, reaction of the marginal periodontium and, in the case of endosseous implants, marginal bone resorption after prosthetic reconstruction, is well described in the literature.

Although this study is a 5-year follow-up study, primary success or failure may be seen at an earlier stage.[18] Following the placement of the suprastructure, a so-called remodeling of the adjacent bone presumably occurs because of functional forces. After approximately 1.5 years, a steady state is accomplished, ie, a balance between the involved forces and the reconstruction capacity of the bone is established.[19] Such was the case in this study, as virtually no changes were seen in the mean bone height after 1 year of function.

Table 3 Gingival Status of Implants and Corresponding Adjacent Teeth at 2 Weeks (Baseline), 3 Years, and 5 Years

	Adjacent teeth		CeraOne	
Time/location	Healthy	Bleeding	Healthy	Bleeding
2 Weeks				
Number*	173		94	
Facing crown/mesial	157 (90%)	18 (10%)	87 (93%)	7 (7%)
Opposing crown/distal	159 (93%)	12 (7%)	87 (93%)	7 (7%)
3 Years				
Number**	126		68	
Facing crown/mesial	117 (91%)	11 (9%)	59 (87%)	9 (13%)
Opposing crown/distal	107 (86%)	17 (14%)	60 (88%)	8 (12%)
5 Years				
Number†	124		59	
Facing crown/mesial	114 (90%)	12 (10%)	48 (81%)	11 (19%)
Opposing crown/distal	101 (83%)	21 (17%)	45 (76%)	14 (24%)

*Ten crowns have another crown on one side; 3 crowns have a space on one side; 2 teeth have crowns on both sides (1 crown missed 2 weeks).
**Seven crowns have another crown on one side; 3 crowns have a space on one side; 2 teeth have crowns on both sides (8 crowns missed 3 years).
†Three crowns have another crown on one side; one crown has a space on one side; 2 teeth have crowns on both sides; for 6 crowns, information only for the adjacent teeth was available.

Table 4 Pocket Depth Around Adjacent Teeth at 2 Weeks (Baseline), 3 Years, and 5 Years

	Adjacent teeth			
Time/location	< 4 mm	4 mm	5 mm	6 mm
2 Weeks				
Number*		173		
Facing crown	170 (97%)	2 (1%)	2 (1%)	1 (1%)
Opposing crown	166 (97%)	2 (1%)	2 (1%)	1 (1%)
3 Years				
Number **		126		
Facing crown	121 (95%)	2 (2%)	4 (3%)	1 (1%)
Opposing crown	115 (93%)	2 (2%)	6 (5%)	1 (1%)
5 Years				
Number†		120		
Facing crown	109 (89%)	8 (7%)	4 (3%)	1 (1%)
Opposing crown	102 (86%)	8 (7%)	7 (6%)	1 (1%)

*Ten crowns have another crown on one side; 3 crowns have a space on one side; 2 teeth have crowns on both sides (1 crown missed 2 weeks).
**Seven crowns have another crown on one side; 3 crowns have a space on one side; 2 teeth have crowns on both sides (8 crowns missed 3 years).
†Three crowns have another crown on one side; 1 crown has a space on one side; 2 teeth have crowns on both sides; 4 teeth were not measured.

Two of the implant failures occurred before prosthetic reconstruction, and one failure occurred 2 weeks after cementation of the crown. These failures are possibly related to trauma at surgery or overload from the provisional prosthesis during the healing period.[1]

Since the limits for the breaking load of CeraOne crowns are well below those for the metal ceramic system, the risk for fracture was higher for the CeraOne crowns. The seven crown fractures were all among full ceramic crowns. No statistical analysis of the differences regarding crown fractures between the different crown types was performed, since the uneven number of the two crown types (fewer porcelain-metal crowns were placed) made it difficult to draw any conclusions. Also, the purpose of this study was not to evaluate the differences between the two types of crowns. It should be noted that all failed crowns could be replaced by new crowns, even if these were not part of this study.

By replacing the titanium abutment screw with a gold screw in the CeraOne system, the occurrence of abutment screw loosening virtually disappeared.[8] This is an important feature of a single-tooth system.

Marginal bone resorption around the implants, which averaged 0.5 mm during the first year and less than 0.1 mm annually thereafter, remained at the same level as in other studies[5,7,8,19] and well within the limits set by Albrektsson et al.[17] Together with the healthy gingival status around the implants and adja-

Table 5 Location of Crown Margin at 2 Weeks (Baseline), 3 Years, and 5 Years

	Mesial	Buccal	Distal	Lingual
2 Weeks				
Subgingival	73	63	72	63
At gingiva level	8	13	9	17
Supragingival	3	8	3	4
Not registered	10	10	10	10
3 Years				
Subgingival	46	40	46	34
At gingiva level	6	9	7	14
Supragingival	3	6	2	7
Not registered	13	13	13	13
5 Years				
Subgingival	45	38	44	34
At gingiva level	3	6	4	10
Supragingival	3	7	3	7
Not registered	14	14	14	14

Table 6 Changes in Location of the Crown Margin During the 5-Year Study Period

	Mesial	Buccal	Distal	Lingual
Subgingival to gingiva level	0	2	1	7
Subgingival to supragingival	1	3	1	4
Supragingival to gingiva level	1	2	1	1
Supragingival to subgingival	0	2	0	0
Gingiva level to subgingival	0	4	1	7
Gingiva level to supragingival	0	0	0	0
Location of the crown edge unchanged:	51	40	49	34

Table 7 Marginal Bone Resorption Around the Implant During 5 Years After Cementation of the Crown

Marginal bone resorption (mm)	0 to 1 Years (n)		1 to 3 Years (n)		3 to 5 Years (n)	
	Mesial	Distal	Mesial	Distal	Mesial	Distal
Less than 0	9	8	16	20	21	17
0	25	28	13	10	10	12
0.1–0.5	14	14	12	10	6	9
0.6–1.0	12	10	5	5	4	2
1.1–2.0	8	10	1	4	1	2
Greater than 2	3	2	2	1	0	0
Unreadable	1	0	1	0	0	0
Total	71	72	49	50	42	42
Mean	0.5	0.4	0.1	0.1	–0.2	–0.2
SD	1	0.9	1	1	0.8	0.7

cent teeth, the pocket depth around the adjacent teeth, and the minor changes of the gingival level in relation to the crown margins during the study period, this indicates that a positive prognosis can be expected for long-term function of the crowns. Pocket depth around the implants was not measured. When this study was started, unpublished information indicated that measurements of pocket depth around implants do not provide the same type of information for implants as for natural teeth, but rather could harm the osseointegration of the implants. This finding was later published by Ericsson and Lindhe.[20]

Conclusion

This study has demonstrated that stable long-term results can be achieved when replacing single teeth with Brånemark implants and cemented crowns on CeraOne abutments, with an overall cumulative success rate of 95.9% for implants and 91.1% for crowns. The fractured or failed crowns could all be replaced successfully. Bone resorption around these restorations was minimal following the first-year remodeling phase, and the status of soft tissues remained stable. Changing the abutment screw from titanium to gold seemed to resolve the problem with loosening of abutment screws.

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