Rehabilitation of Edentulous Mandibles by Means of Five TiUnite[™] Implants After One-Stage Surgery: A 1-Year Retrospective Study of 90 Patients

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ABSTRACT

Background: Recently, the present team reported the 1-year data of one-stage surgery and mainly early loading performed in edentulous mandibles using 750 turned Brånemark System[®] implants in 152 patients.

Purpose: The aim of the present investigation was to retrospectively evaluate the 1-year results of the same treatment technique, using Brånemark System implants with an oxidized surface (TiUniteTM, Nobel Biocare AB, Göteborg, Sweden). The outcome was compared with that of the former study (control) on turned implants.

Materials and Methods: The present study involved 90 individuals with 450 TiUnite implants of mainly the Brånemark System Mark III design, placed in edentulous mandibles and using one-stage surgery. The prosthetic procedure was commenced as a mean 8 days after the surgical intervention. Intraoral radiographs were obtained at prosthesis insertion and at the 1-year annual checkup. Failure rates of test and control groups were compared by means of the chi-square test.

Results: No implants were found to be mobile up to and including the first annual checkup, resulting in an implant cumulative survival rate (CSR) of 100%. The corresponding CSR for the control group was 97.5%, and this difference in implant survival was statistically significant when analyzed with the chi-square test (p < .001). A statistically significant difference was also demonstrated (p < .01) when conducting the same statistical analysis on the patient level. The mean marginal bone resorption during the first year of function was 0.49 mm (SD 0.56), and the corresponding figures for the control study were 0.39 mm (SD 0.46). The central TiUnite implant, that is, the one placed in or in close relation to the symphyseal region showed significantly more bone loss (p < .05) than the corresponding central turned implant of the control study. Distally positioned test implants demonstrated less marginal bone loss than the corresponding central one.

Conclusions: The outcome of 450 TiUnite implants placed in 90 patients with edentulous mandibles, of which 380 implants in 76 patients were followed for 1 year, showed an implant CSR of 100%. The figure was significantly different from the control study result of 97.5% on turned surface implants. The levels of marginal bone were close to identical for test and control implants at the 1-year checkup.

KEY WORDS: early loading, edentulous mandibles, implant failure, one-stage surgery, oxidized implants

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The use of Brånemark System[®] implants and a onestage surgical technique with early or immediate loading has become a standard treatment modality in the rehabilitation of edentulous mandibles. Many reports show excellent results over study periods of 1 to 5 years.¹⁻⁴ Recently, the present authors published the 1-year data of 750 early loaded one-stage turned Brånemark System implants inserted in edentulous mandibles.⁵ The implant survival rate was high (97.5%), but when comparing the outcome with that of a

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contemporary study on two-stage surgery, the latter showed a significantly higher survival figure (99.5%).⁵

With the introduction of an oxidized surface (TiUnite[™], Nobel Biocare AB, Göteborg, Sweden), various studies were executed to compare the behavior of TiUnite and turned Brånemark System implants of the same design in laboratory as well as in clinical situations. Thus, TiUnite implants inserted in dogs showed significantly higher stability figures during early healing, as evaluated with resonance frequency analysis.⁶ Also, removal torque measurements revealed significantly higher values for the TiUnite implants after 6 and 10 weeks of healing in rabbits and dogs, respectively.^{7,8} In the same rabbit study, a histomorphometrical analysis demonstrated at 6 weeks significantly greater percentage bone-to-implant contact for the TiUnite implants compared to turned implants.7 Further, the expected loss of implant stability in the early healing period was shown to be significantly lower for immediately loaded TiUnite implants than for the corresponding turned implants in posterior maxillae of patients.9 So, laboratory and clinical studies have shown that the TiUnite surface produces supportive jawbone and secondary implant stability much quicker than the turned one, which is important when performing one-stage surgery with early or immediate loading.

The aim of the present investigation was to retrospectively evaluate the 1-year treatment outcome of a consecutive group of edentulous mandibles provided with five oxidized surface implants (TiUnite) in a onestage surgical technique. The retrieved data were compared with the results of the aforementioned study on turned implants,⁵ placed and loaded in a similar way in another group of consecutively treated edentulous mandibles.⁵

MATERIALS AND METHODS

Patients and Implants

This is the step 2 presentation of a series of investigations evaluating the outcome of Brånemark System implants in a large number of patients in various treatment situations of edentulous mandibles. The step 1 report compared the 1-year outcomes of turned implants placed according to the classical two-stage procedure and one-stage surgery with early loading.⁵

The present study group comprised 90 consecutively treated patients (47 females and 43 males) with a mean

TABLE 1 Distribution of Treated Patients with Regard to Gender and Mean Age (SD) at the Time of Implant Treatment							
Group	Mean Age	Females	Males	Total			
Test	70.7 (11.1)	47	43	90			
Control⁵	66.0 (10.4)	90	62	152			

age of 71 years (range: 36 to 98 years) at the time of implant surgery (Table 1). All surgical procedures were performed at The Brånemark Clinic, Göteborg, Sweden, between January 2001 and September 2005. Two patients received prosthetic constructions at the referral clinics.

Patients' medical histories and general health problems are presented in Table 2. Smoking habits were reported for 89 patients, revealing 30 smokers (34%) and 59 nonsmokers.

In all, 450 implants with an oxidized surface (TiUnite) were placed (Table 3), of which 443 implants were of the Mark III design (Nobel Biocare AB) with a diameter of 3.75 mm, and six implants were of the Mark IV design (Nobel Biocare AB). The reason for choosing the somewhat tapered and wider (\emptyset 4 mm) Mark IV implant was to promote the primary stability in bone with sparse trabeculation. One implant, of the wide Mk III platform design (\emptyset 5 mm), was used as a rescue implant, that is, it was not possible to obtain primary stability with a less wide diameter. All patients received five implants each.

TABLE 2 Distribution of Number of PatientsRecorded with General Health Disorders

Diagnosis	Test Group (<i>n</i> = 90)	Control Group $(n = 152)^5$
Cancer	2	3
Cardiac and vascular diseases	34	53
Deep depression	5	1
Diabetes	6	5
Down syndrome	0	1
Hepatitis C	0	2
Rheumatoid arthritis	5	4
Tuberculosis/Lung disease	7	1
Warfarin medication	3	6
Irradiation head and neck	1	1
Cytotoxic drugs	1	0
Smokers	34%	39%

Total numbers of patients (n) are given within brackets.

TABLE 3 Life Table Analysis Showing the Cumulative Survival Rate (CSR) for Implants and Prostheses									
	Implants			Patients					
	Number of Implants				Number of Patients				
Time Period	Followed	Failure	Withdrawn	CSR (%)	Followed	Failure	Withdrawn	CSR (%)	
Test Group (TiUnite Implants)									
Implant placement	450		5	100	90		1	100	
Prosthesis placement	445		65	100	89		13	100	
1 Year	380				76				
Control Group ⁵									
Implant placement	750	5		99.3	152			100	
Prosthesis Placement	745	13	48	97.5	152	1	10	99.3	
1 Year	684				141				

Implant failures: Test group – control group; p < .001%.

Patients with implant failures: Test group – control group; p < .01%.

Data on dentition (natural or artificial) in opposite jaws were recorded and are presented in Table 4.

Treatment Protocol

Clinical and radiographic preoperative data were gathered according to a standard protocol,^{10,11} and the available jawbone quantity and bone quality were registered as proposed in the classification by Lekholm and Zarb¹² (Table 5).

The final decision with regard to choosing one- or two-stage surgery was made during the procedure and, thus, based on the insertion torque¹³ to be >30 Ncm and/or an implant stability quotient¹⁴ to be >60. Extractions of residual lower teeth were executed during implant surgery in nine of the treated patients.

TABLE 4 Distribution of Dentitions in the Opposing Maxilla							
Dentition in Upper Jaw	Test Group (<i>n</i> = 90)	Control ⁵ (<i>n</i> = 152)					
Full natural dentition including	20	35					
Natural teeth and removable partial denture	5	3					
Natural teeth and implants	1	3					
Fixed implant-supported prosthesis	24	30					
Removable implant-supported 1 1 denture							
Complete removable denture	39	78					
Missing data	0	2					

Prophylactic antibiotics were used as one single dose of 2 g amoxicillin or, in case of penicillin allergy, 600 mg of clindamycin 1 hour preoperatively. Implants were inserted according to the guidelines described by Widmark and colleagues.¹⁵ Abutments were placed during the same session.

Impressions were made at a mean of 8.7 days (SD, 4.1 days; range: 0 to 24 days) postoperatively. Patients

TABLE 5 Distribution of Jaws with Regard to Bone
Quality and Bone Quantity for Placed and Failed
Implants in the Test and Control Groups

	Bone Quality						
Bone Quantity	1	2	3	4	Total		
Test Group							
А		1	1		2		
В		35	26	3	64		
С	3	4	8		15		
D	2	3	3		8		
Е							
Total	5	43	38	3	89*		
Control Group⁵							
А	0	7 (5)	0	0	7 (5)		
В	1	80 (4)	23 (2)	3	107 (6)		
С	1(1)	17 (1)	9 (5)	2	29 (7)		
D	2	3	2	0	7		
Е	0	1	0	0	1		
Total	4(1)	108 (10)	34 (7)	5	151 (18)*		

*Missing data for one patient.

Numbers of failed implants are given within parentheses.

TABLE 6 Mean Marginal Bone Level in Relation to Fixture/Abutment Junction (FAJ) During the Follow-Up Period

	Bone Levels in Relation to FAJ							
	TiU	nite Surface		Turned Surface				
	Prosthesis	1-Year Follow-Up	Prosthesis	1-Year Follow-Up				
Patients	82	76	151	149				
Implants	410	380	738	690				
Bone Level to FAJ (mm)								
Mean	1.08	1.56	1.16	1.53				
SD	0.37	0.55	0.40	0.56				
Bone Level to FAJ (mm)	Number of Implants (%)							
0.0–0.8	307 (75)	150 (40)	466 (63)	284 (41)				
0.9–1.9	83 (20)	156 (41)	226 (31)	269 (39)				
2.0–2.5	13 (3)	51 (13)	34 (5)	87 (13)				
2.6–3.1	6 (2)	19 (5)	5(1)	33 (5)				
3.2–3.7	1 (0)	2 (1)	4(1)	13 (2)				
>3.8	0	2 (1)	3 (0)	4 (1)				

Percentage of implants is given within parentheses. Bone levels are presented in relation to FAJ where the radiographic reference point¹¹ is placed 0.8 mm below the FAJ, and the first thread of the implant is placed on an average 1.9 mm below the FAJ. The second, third, and fourth threads of the implants are placed on an average 2.5, 3.1, and 3.7 mm below the FAJ, respectively.

with removable prostheses had these relined with a soft tissue conditioner 7 days postsurgery to be used until the fixed prostheses were finalized. The latter were all fabricated with machined titanium frameworks¹⁶ and resin veneers.¹⁷ A mean interval of 31.8 days (SD, 12.75 days; range: 13 to 90 days) was recorded between implant surgery and connection of final prostheses.

Implants/abutments were examined with intraoral radiographs at the time of prosthesis delivery and at the 1-year follow-up visit. Radiographs were obtained and analyzed at the Department of Oral and Maxillofacial Radiology, The Sahlgrenska Academy at Göteborg University, Göteborg, Sweden. Mean levels of marginal bone (mesial, distal) in relation to the fixture/ abutment junctions (FAJs) were assessed (Table 6). Bone levels are presented in relation to the design of the implant where the implant radiographic reference point¹¹ is placed 0.8 mm below the FAJ. The first thread is placed on an average 1.9 mm below the FAJ, and the following thread is placed 0.6 mm further apical in relation to the FAJ (ie, 2.5 mm). Based on two examinations, calculations were performed of the mean marginal bone loss during the first year of function (Table 7). The bone loss intervals used in Table 7 refer to the implant threads, placed on a distance of 0.6 mm between each other, where bone loss of, for example, 1.8 mm corresponds to bone loss of three threads.

All complications that occurred during the study period were documented.

Controls

For comparisons with the test group, provided with TiUnite surfaced implants, a control group was used with patients provided with turned surfaced implants. The control group⁵ comprised 152 consecutive patients with edentulous mandibles, in which 750 turned Brånemark System implants were placed using a one-stage surgical procedure. This treatment was executed at the same clinic (The Brånemark Clinic) between November 1996 and November 2002, to a high extent by the same surgeons and prosthodontists, and the same surgical setup was used. Test and control studies matched well with regard to patient age, gender, smoking habits, and general health disorders. The implants were predominantly of the same Mark III design (441/750), albeit with the turned surface. Impressions were made at a mean of 12.6 days (SD, 3.3 days; range: 7 to 20 days) postoperatively. A mean interval of 42.1 days (SD, 28.5 days; range: 10 to 133 days) was recorded between surgical insertion

TABLE 7 Intra-Individual Measurements of Mean Marginal Bone Loss and Distribution of Implants and Patients with Regard to Bone Resorption During the First Year in Function

		Mean Marginal Bone Loss After 1 Year in Function							
		TiUnite Surface				Turned Surface			
	Terminal	Intermediate	Central	Overall	Terminal	Intermediate	Central	Overall	
Patients				73				141	
Implants	146	146	73	365	269	281	140	690	
Bone Loss (mm)									
Mean	0.48	0.40	0.62	0.49	0.41	0.36	0.42	0.38	
SD	0.67	0.66	0.74	0.56	0.65	0.64	0.68	0.46	
Bone Loss (mm)		Distribut	tion of Num	ber of Impla	ints with Rega	rd to Bone Loss (%	6)		
0	82 (56)	86 (59)	36 (49)	204	155 (58)	170 (60)	74 (53)	399	
0.1-0.6	16 (11)	21 (14)	9 (12)	46	41 (15)	38 (14)	28 (20)	107	
0.7-1.2	33 (23)	28 (19)	17 (23)	78	52 (19)	55 (20)	25 (18)	132	
1.3–1.8	13 (9)	9 (6)	5(7)	27	14 (5)	14 (5)	9 (6)	31	
1.9–2.4	1 (1)	1 (1)	6 (8)	8	4(1)	3 (1)	2(1)	15	
>2.4	1 (1)	1 (1)	0 (0)	2	3 (1)	1 (0)	2 (1)	6	

"Terminal" implants include the two distal implants (right and left #2). "Central" implants include the implant placed in the symphysis region in the midline, and the "intermediate" implants include the two implants between the terminal and the central implants (right and left #1). Percentage of patients is given within parentheses. Distance between threads is 0.6 mm.

of implants and connection of final prostheses. All control patients received fixed prostheses with titanium (n = 147) or cast gold (n = 5) frameworks with resin teeth. The retrieved available data are presented in Tables 1–7.

Statistical Analyses

Descriptive statistics and life table analysis presenting implant cumulative survival rates (CSRs) were utilized. Failure rates between test and control groups were compared by means of the chi-square test. The difference in time periods elapsing from implant surgery to the impression procedure and from implant surgery to delivery of the fixed prosthesis for test and control groups was analyzed with *t*-test. This statistical method was also used when analyzing the difference in marginal bone loss between the central test and control implants. Statistical significance was set to 5%.

RESULTS

In all, 76 patients were followed up for 1 year with clinical and radiographic examinations in the test group. Out of the 14 patients not accomplishing study completion, three patients were deceased, five were seriously ill, and six patients did not show up for the 1-year visit (see Table 3). One of the seriously ill patients was not able to attend all the prosthetic visits and did not receive the fixed prosthesis.

Thus far, that is, up to and including the first annual checkup, no implants were found mobile, resulting in an implant CSR of 100% (see Table 3). The corresponding figures for the control study⁵ are shown in the same table. Here, 18 implants in 12 patients were lost during the study period. Outcome differences between the studies on TiUnite and turned implants were statistically significant both on implant (p < .001) and patient (p < .01) levels.

Jaw bone classification¹² revealed an overall majority of shape B (64/90) and a rather equal distribution between qualities 2 and 3, that is, favorable conditions with regard to bone volume and texture were at hand (see Table 5). Only three jaws were judged as the soft quality 4. As shown in Table 5, similar favorable jawbone conditions were reported also for the control group.

In the present study, there was a significantly shorter mean time period between implant surgery and the impression procedure (8.7 vs 12.6 days; p < .001) and also between implant surgery and delivery of the finalized fixed prosthesis (31.8 vs 42.1 days; p < .01), as compared to the control study.

Two of the fixed prostheses were remade during the study period because of adaptation problems. Mucositis with hyperplastic tissue was reported in one patient, and this fixed prosthesis was removed and polished at the 1-year checkup.

Eighty-two patients with 410 implants underwent radiographic examinations at prosthesis placement, and 76 patients with 380 implants were examined at the 1-year checkup. Mean values and frequency distributions on bone levels for both test and control groups are shown in Table 6. As can be seen in Table 6, the marginal bone is located at identical levels after the first year of function for test and control implants. The central test implant, that is, the one located in or in close relation to the symphysis of the mandible, showed significantly more bone loss than the corresponding control implant site (p < .05), however (see Table 7). Furthermore, the central test implant tended to lose more bone than distally located test implants (see Table 7).

DISCUSSION

The current 1-year investigation on 450 TiUnite implants revealed a CSR of 100%, which is most encouraging. Although there exist studies with such optimal results on both turned and TiUnite implants in various treatment situations of mandibles and maxillae,^{1,4,10,18–20} these outcomes refer to smaller implant samples.

The statistically significant improved result, as compared to the control study on turned surface implants (CSR 97.5%), may partly be explained by the gathered knowledge acquired during a long time period by the present team of using an altered treatment technique, that is, the result of a clinical learning curve. One must keep in mind though that the inclusion periods for test and control groups partly coincided. The difference may as well be a result of the altered surface texture of TiUnite implants with its positive early bone tissue response. Such implants, as compared to the turned ones, may be more "forgiving" and less sensitive in the hands of surgeons performing the one-stage technique. In a recent study by Fröberg and colleagues,²¹ using both turned and TiUnite Brånemark System implants in anterior mandibles with a split-mouth design, it was not possible to verify any outcome differences between the two implant surfaces. Here, the implants were immediately loaded with fixed supra-constructions and such immediate splinting must be regarded favorable, because the exposure to preload/overload of individual

implants is more or less eliminated. Perhaps turned implants with the slower initial bone tissue response⁶⁻⁹ benefit more than TiUnite implants from this immediate load sharing. When comparing test and control groups in the current study, the time period from implant placement to prosthesis connection was significantly longer (p < .01) for the controls (42.1 vs 31.8 days). This may have exposed individual control implants to unfavorable loading to a higher extent.

The marginal bone loss during the period from prosthesis insertion to the 1-year follow-up examination was on an average 0.1 mm more for the TiUnite implants as compared to the control implants (see Table 7). The former implants presented, however, a bone level that was a mean 0.1 mm closer to the reference point at prosthesis insertion (see Table 6), a difference that may be explained by the fact stated earlier that significantly fewer days (p < .01) passed between implant and prosthesis insertion for the TiUnite implants. Thus, the marginal bone level was identical for test and control implants at the 1-year checkup. Frequency distributions of marginal bone level and marginal bone loss revealed, as well, more or less identical figures at the 1-year examination for the two groups of implants and few of them (1 to 2%) exhibited bone loss of more than three threads (1.8 mm). A review of the literature does not show any consistency with regard to bone loss and the type of implant surface used. While some studies,^{21,22} as the present one, claim no difference between the surfaces, another²³ has shown a significant difference in favor of the oxidized TiUnite implant.

The central test implant demonstrated significantly more bone loss during the first year of function than the corresponding control implant (p < .05). Whether this was an expression for the various surface textures is not possible to state. When comparing bone loss of test implants in various jaw regions, a clear trend toward more bone resorption was seen for the central one. This is in accordance with the study by Zechner and colleagues,²⁴ who found significantly more marginal peri-implant bone loss around mesially placed interforaminal implants than distally positioned ones, independent of surface roughness. Such tendencies have also been observed for longer follow-up periods.^{25,26} Reasons for this may be multifactorial loading conditions; calculus formation with development of mucositis and peri-implantitis; anatomical, that is, the implant has been inserted in the symphyseal region; less attached mucosa; pull from buccal/lingual frenulum; interference with prominent mental spine, etc. In part, as a consequence of this phenomenon, the present team has excluded the central implant, and full-arch prostheses in mandibles are now supported by four TiUnite implants only. Collection of data for a step 3 report using the four implant approach is in progress.

CONCLUSIONS

The present study comprised 90 patients (450 TiUnite Brånemark System implants) treated with a one-stage surgical procedure with mainly early loading and fixed prostheses in edentulous mandibles. Of these, 380 implants in 76 patients were followed for 1 year, exhibiting a 1-year CSR of 100%. The outcome differed significantly from the CSR (97.5%) of the control study on turned Brånemark System implants. The marginal periimplant bone loss was low and equal for the two groups of surface textures.

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