# Rehabilitation of Edentulous Mandibles by Means of Four TiUnite<sup>™</sup> Implants after One-Stage Surgery: A 1-Year Retrospective Study of 75 Patients

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#### ABSTRACT

*Background:* Recently, the present team reported the 1-year data of a one-stage surgery and mainly early loading with five supporting implants in completely edentulous mandibles, indicating more bone loss at the central implant, placed in the midline of the jaw.

*Purpose:* The aim of the present retrospective investigation was to evaluate the 1-year results of the same treatment technique with four instead of five supporting implants in completely edentulous mandibles. The outcome was compared with that of a former study (control) on five implants per patient during first year of function.

*Materials and Methods:* The present study comprised 75 patients with a total of 300 TiUnite<sup>TM</sup> implants (Nobel Biocare AB, Göteborg, Sweden) of mainly the Brånemark System  $\geq$  Mark III design. The prosthetic procedure started and was completed on an average of 9.1 days (standard deviation [SD] 4.47) and 33.2 days (SD 16.09) after the surgical intervention, respectively. Intraoral radiographs were obtained at prosthesis insertion and at the 1-year follow-up visit. Failure rates of test and control groups were compared by means of the chi-squared test.

*Results:* All four implants in one patient were found to be mobile at the first annual check-up, resulting in an implant cumulative survival rate (CSR) of 98.5%. The corresponding CSR for the control group was 100% (p > 0.05). The mean marginal bone resorption during the first year of function was 0.3 mm (SD 0.74) as compared with 0.5 (SD 0.56) mm for the control group (p > 0.05).

*Conclusions:* The outcome of 300 TiUnite<sup>™</sup> implants placed in 75 patients with edentulous mandibles, of which 268 implants in 67 patients were followed for 1 year, showed an implant CSR of 98.5%. The implant survival was not significantly different from that of the control study result of 100%, in which five instead of four supporting implants were used. The levels of marginal bone were close to identical for the corresponding test and control implants at the 1-year check-up.

KEY WORDS: 1-year study, early loading, one-stage surgery, oxidized oral implants

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#### **INTRODUCTION**

Oral implant treatment of edentulous mandibles is a well-documented and predictable procedure with up to 20 years of documented follow-up. From a two-stage surgical protocol with mainly six implants to support a fixed prosthesis,<sup>1-4</sup> the modality has gradually changed to a one-stage surgical procedure with either early or immediate loading and with the reduction to 5, 4, or even to 3 supporting implants.<sup>5-8</sup>

Evaluations of the 1-year outcome of one- versus two-stage surgical procedures<sup>9</sup> and of turned versus

TABLE 1 Distribution of Patients with Regard to Gender and Mean Age(SD) at the Time of Implant Treatment. Distribution of Females and Maleswithin the Two Groups Are Given in Percentage as Well								
Group	Mean Age Females (%) Males (%) Total							
Test group	68.7 (10.12)	41 (55)	34 (45)	75				
Control group*	70.7 (11.1)	47 (52)	43 (48)	90				

\*Friberg & Jemt.10

oxidized (TiUnite<sup>™</sup>, Nobel Biocare AB, Göteborg, Sweden) Brånemark System® implants<sup>10</sup> in edentulous mandibles have formerly been reported by the present team. The first study<sup>9</sup> compared the outcome of 750 one-stage, early loaded turned implants with 338 contemporary placed, two-stage, conventionally loaded (~3 months) turned implants. The implant survival at 1 year was in favor of the two-stage procedure with implant survivals of 99.7% versus 97.5%. The marginal bone response was similar for the two groups; however, the second study<sup>10</sup> compared the outcome of 750 onestage, early loaded turned implants with 450 contemporary placed, one-stage, early loaded oxidized implants. The implant survival at 1 year was significantly in favor of the oxidized implant with survival rates of 100% versus 97.5%. The marginal bone response was similar for the two groups, although the central oxidized implant (out of the five placed) showed significantly more marginal bone loss, as compared with the central turned implant. Based on this finding, it was decided by our team to reduce the number of implants to four when treating edentulous mandibles, and thus eliminate the central one.

The aim of the present investigation was to retrospectively analyze the 1-year result of a group of mainly consecutive patients, where four oxidized surface implants (TiUnite<sup>™</sup>) were placed with the one-stage surgical protocol and early loading. Current data were compared with the outcome of the aforementioned study, in which instead five oxidized surface implants (TiUnite<sup>™</sup>) were placed and handled in basically the same way in another group of consecutively rehabilitated edentulous mandibles in the same clinic.

#### MATERIALS AND METHODS

#### Patients and Implants

Altogether, 83 patients were treated with four implants according to a one-stage surgical protocol between January 2001 and May 2007. Eight of these patients were excluded because they were provided with the fixed prosthesis at referral clinics (n-6) or were patients from abroad, not scheduled for any follow-up examinations after delivery. Accordingly, the present study comprised of 75 patients (41 females and 35 males) with a mean age of 68.7 years (standard deviation [SD] 10.12 years, range: 41–91 years) at the time of implant placement (Table 1). The first nine patients were provided with only four implants because of space problems during the period when five implants were to be placed, using a one-stage procedure (January 2001 to September 2005). Thereafter, 66 patients were consecutively treated with four implants and a fixed prosthesis at the clinic between October 2005 and May 2007.

Patients' general health disorders at the time of surgery and dentition in the opposite upper jaw are presented in Tables 2 and 3, respectively.

#### TABLE 2 Distribution of Number of Patients (%) Recorded with General Health Disorders. Total Numbers of Patients (*n*) Are Given within Parentheses

Diagnosis	Test Group (%) ( <i>n</i> = 75)	Control Group (%)* ( <i>n</i> = 90)
Cancer	9 (12)	2 (2)
Cardiac and vascular diseases	42 (56)	34 (38)
Deep depression	4 (5)	5 (6)
Diabetes	10 (13)	6 (7)
Rheumatoid arthritis	3 (4)	5 (6)
Tuberculosis/lung disease	8 (11)	7 (8)
Warfarin medication	2 (3)	3 (3)
Irradiation head and neck	0	1 (1.1)
Cytotoxic drugs	0	1 (1.1)
Smokers	40	34
Healthy patients, no diagnoses	20	39
No drugs or medications	27	37

\*Friberg & Jemt.10

### TABLE 3 Distribution of Dentitions in the Opposing Maxilla

Dentition in Upper Jaw	Test Group (%) (n = 75)	Control (%)* (n = 90)
Full natural dentition incl. second premolar	t	20 (22.2)
Natural teeth with/without removable partial denture	17 <sup>†</sup> (22.6)	5 (5.6)
Natural teeth and implants	1 (1.3)	1(1.1)
Fixed implant-supported prosthesis	28 (37.3)	24 (26.7)
Removable implant-supported denture	1 (1.3)	1 (1.1)
Complete removable denture	28 (37.3)	39 (43.3)

\*Friberg & Jemt.10

<sup>†</sup>Data not available on numbers of remaining teeth.

The procedures of collecting preoperative clinical and radiographic data, the use of antibiotic prophylaxis, the decision-making on how to use one- or two-stage surgical procedures, the placement of implants and connection of abutments, have all been presented in the earlier publications.<sup>9,10</sup>

Altogether, 47 patients (63%) were provided with implants within 1 year after final tooth extraction (mean 108.6 days; SD 87.49 days). Six of these patients (8%) were provided with implants in connection with tooth extraction. The remaining 28 patients had implants after more than 1 year after removal of the remaining teeth. A total of 300 implants were inserted (Table 4) according to the surgical protocol described earlier,<sup>9,10</sup> of which

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

implants in the	1050 0			Caps			
		Bone Quality					
Bone Quantity	1	2	3	4	Total		
Test group							
А							
В		22	16	3 (4)	41 (4)		
С	2	10	18	1	31		
D	1	1			2		
E	1				1		
Total	4	33	34	4 (4)	75 (4)		
Control group*							
А		1	1		2		
В		35	26	3	64		
С	3	4	8		15		
D	2	3	3		8		
E							
Total	5	43	38	3	89†		
E				3			

\*Friberg & Jemt.10

<sup>†</sup>Missing data for one patient.

Numbers of failed implants are given within parentheses.

294 were of the Mark III design (diameter 3.75 mm), and six implants were of the Mark IV design (diameter 4.0 mm). Implants of wider diameters (>3.75 mm) were placed in sites of poor bone texture in order to establish an improved primary implant stability. The distribution of jaw bone quality and quantity, as described by Lekholm and Zarb<sup>11</sup> for the total jaw, was registered for each patient at the time of implant surgery (Table 5).

TABLE 4 Life Table Analysis Showing the CSR for Implants and Prostheses								
Test Group; 4 TiUnite™ (implants)								
Implants Patients								
	Number of Implants			CSR	Number of Patients			CSR
Time Period	Followed-up	Failure	Withdrawn	(%)	Followed-up	Failure	Withdrawn	(%)
Implant placement	300			100	75			100
Prosth. placement	300		32	100	75		8	100
1-year	268	4		98.5	67	1		98.5
Control group; 5 TiUnite <sup>™</sup> (implants) (Friberg & Jemt 2008) <sup>10</sup>								
Implant placement	450		5	100	90		1	100
Prosth. placement	445		65	100	89		13	100
1-year	380			100	76			100

#### CSR, cumulative survival rate.

TABLE 6 Mean Marginal Bone Level in Relation to FAJ during the Follow-Up Period								
		Bone Levels in Relation to FAJ						
	Test Group;	4 TiUnite <sup>®</sup> Implants	Control Group	; 5 TiUnite <sup>®</sup> Implants*				
	Prosthesis	1-Year Follow-Up	Prosthesis	1-Year Follow-Up				
Patients	74	66	82	76				
Implants	296	264	410	380				
Bone level to FAJ (mm)								
Mean	1.2	1.5	1.08	1.56				
SD	0.77	0.58	0.37	0.55				
Bone level to FAJ (mm)		Number of implants (%)						
0.0–0.8	183 (62)	108 (41)	307 (75)	150 (40)				
0.9–1.9	104 (35)	116 (44)	83 (20)	156 (41)				
2.0–2.5	1 (0)	28 (11)	13 (3)	51 (13)				
2.6–3.1	2 (1)	5 (2)	6 (2)	19 (5)				
3.2–3.7	1 (0)	3 (1)	1 (0)	2 (1)				
>3.8	5 (2)	4 (2)	0	2 (1)				

\*Friberg & Jemt.10

Percentage of implants is given within parentheses. Bone levels are presented in relation to FAJ where the radiographic reference point<sup>11</sup> is placed 0.8 mm below FAJ and the first thread of the implant is placed, on an average, 1.9 mm below FAJ. The second, third, and fourth threads of the implants are placed on an average 2.5, 3.1, and 3.7 mm below FAJ, respectively.

FAJ, fixture-abutment junction; SD, standard deviation.

Prosthetic procedures started with final impressions at a mean of 9.1 days (SD 4.47 days; range: 0–24 days) after implant placement. Patients, who were using removable dentures, had these relined with soft tissue conditioners after about 1 week postoperatively to be used up to final placement of the fixed prosthesis. The final prostheses, fabricated by using Procera® titanium frameworks with resin veneers,<sup>12,13</sup> were placed on an average 33.2 days (SD 16.1 days; range 10–123 days) after implant surgery.

Intraoral radiographs were obtained at the time of connection of prostheses and at the 1-year check-up. Examinations and evaluations were performed at The Department of Oral and Maxillofacial Radiology, The Sahlgrenska Academy at Göteborg University, Göteborg, Sweden. Based on these radiographs, assessments of mean marginal bone levels (mesial and distal) in relation to the fixture–abutment junction (FAJ) were performed (Table 6). In general, the first thread of the Mark III and Mark IV implants is situated 1.9 mm below FAJ and thereafter, the distance between each thread is 0.6 mm. The marginal bone loss during the first year of function was calculated from the two radiographic examinations (Table 7).

Various complications that occurred during the study period were registered in the patients' files.

#### Statistical Analyses

In the present report, descriptive statistics and life table analysis expressing implant cumulative survival rates (CSRs) were used. Comparison of distribution of, for example, failures between the test and control groups was performed with the chi-squared test. When comparing differences of patient mean values between the groups, the *t*-test was used. Statistical significant difference was set to 5% and was only conducted on patient level.

#### RESULTS

#### Controls

The current study group was compared with a control group,<sup>10</sup> in which five TiUnite<sup>™</sup> Brånemark System<sup>®</sup> implants were placed. The control group comprised 90 subjects with edentulous mandibles, and 450 implants were inserted using a one-stage surgical protocol.<sup>10</sup> The control group was treated at the same clinic (The Brånemark Clinic) between January 2001 and September 2005, mainly by the same surgeons and prosthodontists under more or less identical treatment conditions. Test and control groups matched well with regard to patient age and gender (Table 1). General health complaints (Table 2) were more frequently reported in the test

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

		Mean Marginal Bone Loss after 1 Year in Function						
	Test Gro	Test Group; 4 TiUnite <sup>®</sup> Implants			Control Group; 5 TiUnite <sup>®</sup> Implants*			
	Terminal	Intermed	Overall	Terminal	Intermed	Central	Overall	
Patients			66				73	
Implants	132	132	264	146	146	73	365	
Bone loss (mm)								
Mean	0.3	0.3	0.3	0.5	0.4	0.6	0.5	
SD	1.04	0.84	0.74	0.67	0.66	0.74	0.56	
Bone loss (mm)		Distribut	tion of number of	of implants with	regard to bone lo	oss (%)		
0	89 (67)	86 (65)	175 (66)	82 (56)	86 (59)	36 (49)	204 (56)	
0.1-0.6	15 (11)	16 (12)	31 (12)	16 (11)	21 (14)	9 (12)	46 (13)	
0.7-1.2	15 (11)	23 (17)	38 (14)	33 (23)	28 (19)	17 (23)	78 (21)	
1.3-1.8	10 (8)	4 (3)	14 (5)	13 (9)	9 (6)	5 (7)	27 (7)	
1.9–2.4	1 (1)	1 (1)	2 (1)	1 (1)	1 (1)	6 (8)	8 (2)	
>2.4	2 (2)	2 (1)	4 (2)	1 (1)	1 (1)	0 (0)	2 (1)	

\*Friberg & Jemt.10

"Terminal" implants include the two distal implants (right and left #2), "intermediate" implants include the implants placed in between the terminal ones (right and left #1), and the "central" implant is the one placed close to the midline in the control group only. Percentage of patients is given within parentheses. Distance between threads is 0.6 mm.

SD, standard deviation.

group (80% vs 61%) and smoking habits (Table 2) were also more common in the test group (40% vs 34%), but differences were not significant (p > 0.05). Altogether, 57 patients (63%) were provided with implants within the first year after final tooth extraction (mean 119.4 days; SD 100.17 days). Nine of these patients (10%) were provided with implants in connection with tooth extraction. The remaining 33 patients (37%) had implants after more than 1 year after removal of the remaining teeth. The implants in the control group were mainly of the Mark III design (443/450). Impressions procedures commenced at a mean of 8.7 days (SD, 4.1 days; range: 0-24 days) after implant placement and a mean interval of 31.8 days (SD, 12.75 days; range: 13-90 days) was recorded between implant placement and connection of final prostheses. All control patients received also fixed prostheses with Procera® titanium frameworks and resin teeth. Retrieved available data of the control group are presented in Tables 1-7, and are more detailed than given in the previous publication.<sup>10</sup>

Altogether eight out of the original 75 patients in the test group were lost to follow-up during the first year (10.7%). The reasons for withdrawal were the following: five patients were not compliant (n - 5), two were seriously ill (n - 2) and one patient was deceased (n - 1).

Another patient was lost because of implant failures, as accounted for below.

The distribution of jaw bone quantity according to the Lekholm and Zarb classification<sup>11</sup> revealed a preponderance of shape B (41/75) and C (31/75), while the jaw bone quality was dominated by textures 2 (33/75) and 3 (34/75), respectively (Table 5). The same Table 5 shows similar favorable conditions also for the control group. Four jaws were assessed as quality 4 (sparse central trabecular bone content with thin external cortical bone layers), as compared with the three jaws of the control group.

Regarding time periods from implant surgery to start of the prosthetic treatment, that is, mean 9.1 days (SD 4.47) as well as time to prosthesis placement, that is, mean 33.2 days (SD 16.9) were comparable and not significantly different (p > 0.05) from the corresponding periods of the control group.

One patient lost all four implants, which was evident at the 1-year check-up, and thus the CSR of implants and patients was 98.5% (Table 4). Because no implants were lost in the control group,<sup>10</sup> the corresponding CSR was 100% (Table 4). The difference in implant failure rates of the two studies were not statistically significant (p > 0.05).

Besides the above described total failure, pus and obvious bone loss was reported from one patient in the test group, and another four test group patients also had comments on bone loss at one or several implants in their files during the first year of function. No other clinical problems or adjustments were reported in the test group, that is, altogether, 61 patients had "no events" reported during the first year in function (91%). In the control group, out of the 76 patients followed-up for 1 year, 73 patients had "no events" reported during the first years (96%). In the control group, two prostheses were remade because of adaptation problems, and another patient had mucositis and hyperplasia problems underneath the prosthesis that had to be temporarily removed for adjustments.

Mean marginal bone levels as well as mean marginal bone loss during the follow-up period are presented for test and control groups in Tables 6 and 7, respectively. Data indicate a similar pattern of average bone response at the implants in both groups, not reaching any significant levels (p > 0.05).

#### DISCUSSION

In accordance with the present control group, no implants were lost before prosthesis placement in the test group (CSR 100%), while four implants were found mobile in one test patient at the 1-year check-up. When pooling these two groups together, one-stage surgery using four to five implants with oxidized surfaces presented an overall 1-year CSR of 99.5%. The earlier report for comparable one-stage surgery using turned surfaces showed after prosthesis placement and after 1 year in function a CSR of 99.3% and 97.5%, respectively.9 This difference showed significantly more failures for turned as compared for oxidized surfaces (p < 0.05). Accordingly, the "higher bioactivity" reported for medium-rough implant surfaces<sup>14</sup> could be assessed to clinically improve early osseointegration with about 1-3% in the edentulous lower jaw.

Thus, the outcome of the present investigation resulted in a 1-year implant CSR of 98.5% at 1 year, which was in line with the outcome of previous studies,<sup>1–7</sup> and also comparable with the result of the control group.<sup>10</sup>

The trend of somewhat higher frequencies of general health disorders and tobacco use in the test group, as compared with the control group, did not, in general, reflect unfavorably upon increased incidences of soft or hard tissue complications. The patient with lost implants was a smoker, though, and another patient of the test group presented "peri-implantitis symptoms" with pus and bone loss during the first year.

Distributions of patients' jaw bone quantity and quality were favorable and equal for test and controls. Further, the number of days from implant insertion to start of the prosthetic procedure was basically identical for the two groups. This was also seen for the number of days from implant insertion to prosthesis placement. Thus, the two groups were treated under more or less identical conditions, handled by the same dentists and with the same clinical setup.

In the control group, the implant positioned close to the mid-line of the five placed (central implant) showed more bone loss at 1 year than the others, which was one of the reasons for refraining from it in the present investigation. Comparing the mean marginal bone loss at 1 year of the remaining four implants (two terminal and two intermediate), the figures for test and controls were similar. The frequency distribution of implants with various degrees of marginal bone loss showed, as well, a similar outcome for the two groups, and the number of implants with bone loss >2 mm at 1 year was 1–2%.

A 1-year follow-up period of implants is short and will perhaps not reveal any major or drastic complications with minor alterations of a well-known technique. Reducing the number of supporting implants from five to four of complete fixed prostheses in the rehabilitation of edentulous mandibles may, however, show negative consequences after years of function because of reduction of load bearing area from the implants, and thus, 5-year data of the previously investigated patients<sup>9,10</sup> and of the present test group are currently being gathered.

#### CONCLUSION

This study shows that in the fully edentulous mandible, a complete jaw anchored bridge on four TiUnite<sup>™</sup> implants yields the same short-term clinical outcome as a bridge on five implants.

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### CONFLICT OF INTEREST STATEMENT

The authors have no conflicts of interest to declare. [Correction added after online publication 24 May 2010: Conflict of Interest Statement added.]

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