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# Implants and Sinus-Inlay Bone Grafts in a 1-Stage Procedure on Severely Atrophied Maxillae: Surgical Aspects of a 3-Year Follow-up Study

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This 3-year follow-up study compares implant treatment in 39 1-stage sinus-inlay block-grafted patients (study group) with 37 patients treated without bone grafting (reference group), all of whom were edentulous in the maxilla and were treated over the same time period. The cumulative success rate (CSR) of implant stability after 3 years in the study group was 75.3% in grafted areas and 82.2% in non-grafted areas. The CSR after 3 years in the reference group was 93.1%. The mean marginal bone resorption after 3 years of loading was 1.4 mm in grafted areas and 1.6 mm in non-grafted areas in the study group and 1.1 mm in the reference group. Complications noted during the postoperative healing periods correlated significantly with implant failures later on ( $P < .05$ ). Since prosthesis stability (CSR) after 3 years was 94.9% in the study group and 97.3% in the reference group, it can be concluded that 1-stage sinus-inlay block grafts can be regarded as a safe method with a predictable outcome for use on patients with severely atrophied edentulous maxillae, although increased failure rates are to be expected for implants placed in bone-grafted regions. (INT J ORAL MAXILLOFAC IMPLANTS 1999;14:811-818)

**Key words:** bone graft, dental implants, implant prosthesis success, marginal bone resorption, maxilla, sinus-inlay

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**T**he rehabilitation of edentulous patients with titanium implants is a well-established treatment.<sup>1</sup> However, in patients with advanced resorption of the alveolar process, especially in the maxilla, implant treatment may be impossible or less predictable.<sup>2,3</sup> In such situations with severe alveolar resorption, autogenous bone grafting in combi-

nation with implants might be the only alternative to removable dentures, and is now increasingly used in clinical practice. A review of data on Brånemark System implants on bone-grafted patients has recently been published.<sup>4</sup> Various bone-grafting techniques have been used, eg, grafts in combination with immediate placement of implants (1-stage), grafts with implants placed after healing (2-stage), block grafts or particulate grafts from different donor sites, and various bone substitutes.<sup>5-10</sup> When results are presented and discussed, objective standards are set originally, but are often difficult to achieve. Since treatment methods change rapidly, long-term follow-up studies with well-defined inclusive criteria are difficult to carry out.<sup>11</sup> The aim of this prospective study of autogenous bone grafts in maxillary edentulous patients (study group) was to describe the 3-year results and complications and compare them with a group of patients treated following the standard protocol described by Adell et al<sup>1</sup> without bone grafts (reference group). Preoperative conditions,

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**Table 1** Distribution of Preoperative Factors in the Study Group and the Reference Group

	Study group (n = 39)	Reference group (n = 37)
Median age (range)	56 (40 to 77)	68 (38 to 86)
Gender (M/F)	8/31	10/27
ASA index		
1	34	24
2	5	13
No. of patients who smoked	15	14
Reason for edentulism		
Caries	24	25
Periodontitis	14	12
Trauma	1	0
Edentulous for >10 y	28	19
Opposing arch		
Natural teeth	32	26
Implant	7	9
Denture	0	2
Origin of graft		
Iliac crest	28	—
Mandible	11	—

such as general health, smoking habits, bone quantity, and duration of and reason for edentulism, received special attention.

### Materials and Methods

This study comprised 2 groups of patients, the study group (39 patients) and the reference group (37 patients), who were all consecutive admissions treated by 1 of 2 surgeons over the same period of time (1990 to 1992). The reference group is a group of patients with normal, adequate residual bone volume, representing the normal standard of most edentulous patients, to whom the results of the study group can be compared. All patients were edentulous in the maxillary arch. The criteria for inclusion in the study group was a bone height of less than 5 mm inferior to the sinus cavities and an alveolar width exceeding 5 mm (thus without the possibility to place a sufficient number of implants for rehabilitation), and a tolerance to treatment under general anesthesia. Only patients without any clinically or radiographically diagnosed pathology in their maxillary sinuses were accepted. The 2 groups differed as to remaining bone quantity according to Cawood and Howell<sup>12</sup>; the study group was classified in the posterior maxillary regions as Class 5 or 6 and the reference group was, in general, Class 3 or 4. Their general health was classified according to standards set by the American Society of Anesthetists (ASA) on a 5-

grade scale.<sup>13</sup> The patients in this study were classified as grade 1 or 2. Grade 1 represents patients without any serious illness and not on medication. Grade 2 represents patients with a fully compensated illness, eg, hypertension or diabetes mellitus. The question of whether a patient smoked was recorded. Age, gender, general health, reason for and duration of edentulism, and occlusion from the opposing arch were recorded and are all presented in Table 1.

**Surgery.** The study group was treated with implants in a 1-stage sinus-inlay block procedure, as described previously.<sup>10,14</sup> All patients were operated under general anesthetic, and bone was harvested from the iliac crest (n = 28) or from the chin (n = 11). The iliac grafts, consisting of both cortical and trabecular bone, were each approximately 2 × 1.5 × 1.5 cm in size and were harvested from the superior and lateral part of the iliac crest.<sup>15</sup> The mandibular grafts were smaller in size, approximately 1.5 × 1 × 1 cm, and consisted mainly of cortical bone from the subapical symphysis.<sup>16</sup> Both grafts were harvested as monocortical block grafts.

After exposure of the lateral sinus wall, the sinus membrane was carefully elevated and if possible preserved. Because of technical problems related to this procedure, it was not possible to observe and evaluate lacerations. Great care was taken to fit the bone graft to the floor of the maxillary sinus, with the cortical layer oriented superi-

orly, and to achieve stable fixation of the graft to the alveolar process with self-tapping implants (Nobel Biocare AB, Göteborg, Sweden). In general, 2 implants were placed bilaterally in each block in either of the sinus cavities; thus they were placed in both alveolar and grafted bone. In the frontal regions (anterior of the maxillary sinuses), implants were placed without bone grafts. The reference group was treated following a standard procedure with self-tapping implants (Nobel Biocare AB) without bone grafting.<sup>1</sup>

In the study group, 254 implants were placed; 131 implants were placed in grafted areas and 123 implants were placed in non-grafted areas. In the reference group, 206 implants were placed. The implants used in the 2 groups were 10, 13, 15, or 18 mm in length and 3.75 mm in diameter.

Benzyl-penicillin was routinely administered intravenously preoperatively and phenoxymethylpenicillin was prescribed for 10 days postoperatively. Analgesics containing paracetamol or NSAIDs were prescribed for the immediate postoperative period. Usually pain from the donor site was more intense. However, in all patients the postoperative pain was well managed and subsided within 2 to 3 weeks postoperatively. Patients with iliac crest grafts were normally partially disabled for 1 to 2 months. All patients were totally recovered after 3 months. No dentures were allowed during the first 10 days after surgery, and before further use, the dentures were adjusted and relined. During the healing periods, the patients were seen for surgical and prosthodontic check-ups. After 6 months of healing, abutments were connected according to the standard protocol. In general, standard abutments were used.

**Prosthodontics.** In the study group, 36 patients were treated using a standard gold/acrylic resin prosthesis. In 3 patients, the number of implants was regarded as insufficient or load factors were regarded as unfavorable and the patients were provided with overdentures. In the reference group, 33 patients received gold/acrylic resin prostheses and 4 patients received overdentures. The overdentures were of a fixed/removable design. The implants were splinted with a gold bar, to which the denture was attached.<sup>17</sup>

**Follow-up.** All complications during the 6-month healing period after bone grafting and implant placement, such as unexpected severe pain, dehiscence, fistulae, or local infections (eg, maxillary sinusitis), were recorded. Maxillary sinusitis was diagnosed when clinical (ie, pain, tenderness, nasal airway obstruction) and radiographic signs of inflammation were found. Clinical

data were recorded when the patients received their prostheses (baseline) and after 1 and 3 years. At the 3-year follow-up, all prostheses were removed and implant stability was tested manually. Clinically mobile implants were considered to be failures and were removed. The presence of any peri-implant disease with corresponding bone loss (peri-implantitis) was recorded.<sup>18</sup>

Radiographic examinations were performed after 1 year and after 3 years in both groups and were compared to the baseline marginal bone level of the collar of the implant with respect to the residual marginal bone. The examinations were done using parallel intraoral techniques in the Department of Dental Radiology, Eastman Institute, Stockholm, Sweden.<sup>19</sup> Measurements were performed by 1 of the authors using a scale loup. The marginal bone loss during the first year and between the first and third years was calculated as the mean of the mesial and the distal values for each implant.

**Statistics.** To calculate the 3-year cumulative success rate (CSR) of implant and prosthesis stability, a life table analysis was performed.<sup>11</sup> The impact on implant failures of various factors, such as gender, health, smoking habits, reason for and duration of edentulousness, complications during the 6-month healing period, occlusion from the opposing arch, and the origin of bone graft taken individually or in combination, were analyzed using logistic regression.<sup>20</sup> The probability of future implant failure was projected with this test by giving odds ratio values. The level of statistical significance was set at  $P < .05$ .

## Results

In the study group (39 patients), 2 patients, 1 at the 1-year check-up and 1 at the 3-year check-up, were regarded as total treatment failures because of multiple implant failure and subsequent prosthesis instability. Within the reference group (37 patients), 1 patient had lost all implants at the 1-year check-up. Three patients died during the period between the 1- and 3-year check-ups and were thus lost to follow-up. Accordingly, a total of 70 patients (37 study group, 33 reference group) remained in the study after 3 years, which represents a 9% overall loss to follow-up after 3 years. The implant stability recorded during the different time periods in grafted and non-grafted regions studied is shown in Tables 2 and 3 as success rates within the period (SR) and for the accumulated periods (CSR).

The 3-year result (CSR) for implant stability in the study group was 75.3% in the grafted areas

**Table 2 Life Table of Implant Stability, Success Rate (SR), and Cumulative Success Rate (CSR)**

	Total no. of implants	No. of failed implants	No. of withdrawn implants	SR (%)	CSR (%)
Study group					
Placement to loading					
Non-grafted areas	123	11	—	91	91
Grafted areas	131	21	—	83.9	83.9
Loading to 1 y					
Non-grafted areas	112	4	—	96.4	87.2
Grafted areas	110	5	—	95.5	80.1
1 y to 3 y					
Non-grafted areas	108	—	3	100	87.2
Grafted areas	105	—	2	100	80.1
3 y					
Non-grafted areas	105	6	—	94.3	82.2
Grafted areas	103	6	—	94.1	75.3
Reference group					
Placement to loading	206	6	—	97.1	97.1
Loading to 1 y	200	7	2	96.5	93.7
1 y to 3 y	191	—	10	100	93.7
3 y	181	1	—	99.4	93.1

**Table 3 Life Table of Prosthesis Stability, Success Rate (SR), and Cumulative Success Rate (CSR)**

	Total no. of prostheses	No. of failed prostheses	No. of patients withdrawn	SR (%)	CSR (%)
Study group					
Loading to 1 y	39	—	—	100	100
1 y to 3 y	39	2	—	94.8	94.8
3 y	37	—	—	100	94.8
Reference group					
Loading to 1 y	37	1	—	97.3	97.3
1 y to 3 y	36	—	3	100	97.3
3 y	33	—	—	100	97.3

and 82.2% in the non-grafted areas, a relationship that is not statistically significant. In the reference group, implant stability after 3 years was 93.1%. The CSR regarding prosthesis stability after 3 years was 94.8% and 97.2%, respectively. The total marginal bone loss, measured after 1 and 3 years, is shown in Table 4.

Patients are presented as having implant failure or non-failure with regard to the evaluated factors, as seen in Table 5. The only factor evaluated that was found to be significantly associated with implant failures in the study group was postoperative complication during the healing period (Tables 5 and 6). Alveolar fistulae (4 patients), postoperative maxillary sinusitis (2 patients), and a period of

uncontrolled load on the operated alveolar process were significantly related to the presence of implant failures (odds ratio 11.4,  $P < .05$ , Table 6). Peri-implantitis was not found within the study group or the reference group.

### Discussion

Over the last 10 years, several studies on bone grafting of edentulous maxillae have been published.<sup>8-10,21-23</sup> However, results are difficult to compare, as surgical techniques are often modified during the studies and drop-outs are sometimes numerous or not even stated. To achieve reliable results, all the patients in this study were followed

**Table 4 Marginal Bone Resorption (in mm)**

	0 to 1 y*	1 to 3 y*
Study group		
Implants in grafted bone	1.1 ± 0.1 (-4.8 to 0)	0.3 ± 0.1 (-4.5 to 0)
Implants in non-grafted bone	1.3 ± 0.1 (-3.8 to 0)	0.3 ± 0.1 (-2.4 to 1.2)
Reference group	0.8 ± 0.1 (-7.2 to 0)	0.3 ± 0.1 (-2.4 to 1.8)

\*Mean ± SEM and range shown.

**Table 5 No. of Patients with Implant Failures and Non-Failures with Respect to Local and General Factors**

	Study group (n = 39)		Reference group (n = 37)	
	Failure (n = 24)	Non-failure (n = 15)	Failure (n = 10)	Non-failure (n = 2)
Gender (M/F)	8/16	0/15	1/9	9/18
Health index (1/2)	19/5	15/0	7/3	17/10
Smoking	11	4	2	12
Loss of teeth due to periodontitis	10	4	3	9
Edentulous for >10 y	14	14	7	12
Complications during healing period	7	1	2	0
Dehiscence	0	1	0	0
Fistulae	4	0	2	0
Sinusitis	2	0	0	0
Adverse loads	1	0	0	0
Opposing occlusion, own teeth	18	14	6	20
Origin of graft				
Iliac crest	18	10	N/A	N/A
Mandible	6	5	N/A	N/A

for 3 years and drop-outs were few and specified. Prostheses were removed for individual checks of implant stability and results were given in cumulative rates (CSR). Marginal bone level changes were evaluated radiographically. The removal of the prosthesis to check implant stability, not often noted in other studies, is necessary to fulfill the criteria for implant success.<sup>11</sup> In the present study, 23% of the total implant failures found within the study group were detected after removal of the prosthesis, at the 3-year examination (Table 2). Although not specifically correlated to the radiographic findings, as in the work by Nyström et al,<sup>19</sup> several of the failing implants at the 3-year follow-up were completely unexpected, as no peri-implant radiolucency had been seen.

Overall, implant stability in the study group treated by a 1-stage sinus inlay block technique was lower compared to other studies using this or other techniques with grafted bone in severely resorbed maxillae<sup>9,21,23</sup> (for review see Esposito et al<sup>4</sup>). Implant stability in grafted bone within the study group after 3 years was 75.3%. However, as this is

a report of the initial experiences with a non-selected group of patients and the follow-up regime was very strict, the results are within expectations.

Although the study and reference groups in this investigation were in most aspects comparable (eg, number of patients, gender, and smoking habits), they did differ with regard to median age. None of these factors could be related to the risk of increased implant failures.

In this study the ASA index,<sup>13</sup> which is an anesthetic risk index, was used to evaluate the possible influence of impaired health. Although not ideal, this index does allow a medical classification of patients. When specifically analyzing all medically compromised patients (ASA index of 2) within the study and the reference groups, it was found that they all exhibited 1 or several implant failures within the study group. One patient who lost all implants suffered from diabetes mellitus, which became more serious during the follow-up period. However, the number of medically compromised patients was insufficient to verify statistically any relation between implant failures and impaired

**Table 6** Implant Failures in Relation to Local and General Factors Studied in a Multivariate Model

Evaluated factors	Odds/ratio	P value
Gender, male	1.5	n.s.
Health index of 2	1.69	n.s.
Smoking	0.99	n.s.
Loss of teeth due to periodontitis	1.45	n.s.
Duration of edentulism	0.99	n.s.
Complications during healing period	11.4	< .05
Opposing occlusion, own teeth	2.14	n.s.
Origin of graft, iliac crest	1.5	n.s.

health using the ASA index. No correlation in this matter has been shown, and the influence of other systemic factors on implant stability has not as yet been shown.<sup>24</sup>

General factors influencing bone metabolism, such as osteoporosis, reduced urinary function, and hormonal disturbances, are said to have influence on bone quality and thus also implant stability.<sup>25</sup> In a recent retrospective study, single-photon gamma absorptiometry was used to detect any possible influence of reduced bone mineral density on implant failure in a similar group of bone-grafted patients.<sup>26</sup> Even if the method used cannot be considered as state-of-the-art and the number of patients was limited, the results indicate that bone mineral content might play a role in osseointegration. Further prospective studies on the influence of bone quality in general on long-term implant stability is needed to further analyze the pathogenesis of implant failures. The question related to the origin of grafted bone, iliac crest versus chin bone or endochondral versus membranous bone, is controversial. Indices favor chin bone as being more resistant to resorption, but no study has yet shown if this is the result of its more cortical morphology rather than its membranous origin. From the present study no reliable conclusions can be drawn.

Unexpected events or complications during the healing period, such as dehiscence, fistulae to the posteriorly oriented implants, or inflammatory reactions in the maxillary sinuses were found to significantly increase the risk of implant failures (odds ratio 11.4). This indicates that the use of 1-stage intra-sinus block grafts is surgically demanding and that the follow-up should be careful. When using this technique, perforations of the sinus membrane are probably frequent but difficult to detect and were not recorded. It has therefore not been possible to evaluate the influence of this factor on graft healing.

The length of healing periods after implant placement has been discussed.<sup>4,27</sup> It has been experimentally shown that after 6 months of healing, approximately 50% of an autogenous block graft is lost because of resorption.<sup>28</sup> On the other hand, after the same interval, the biologic properties of this bone, and its micromorphology and the angiographic image, are shown to be practically back to normal. However, clinical experiences involving the mechanical properties and the osseointegration of implants of grafted bone are sparse. Differences between grafted and non-grafted bones probably exist, and a delayed bone response might be expected in grafted bone.<sup>25</sup> This has also been shown in a case report by Nyström et al.<sup>29</sup> No controlled clinical study has yet shown any difference regarding implant stability in the long-term perspective, using 1- or 2-stage procedures. However, recently published data have shown far better bone-implant contact at the time of loading by using 2-stage surgery, with delayed implant placement.<sup>30</sup>

Several authors have tried to identify factors associated with the loss of implants and the long-term prognosis of implant-supported prostheses.<sup>24,26,31</sup> Few statistical analyses have been presented, but bone quantity and bone quality stand out as being of great importance.<sup>3,25</sup> A 7% difference in failure rates of loaded implants without grafts in the study and reference groups is likely to be the result of difference in preoperative bone volume.

An interesting classification of implant failures has recently been suggested, dividing failures into biologic, mechanical (technical), iatrogenic, and inadequate patient adaptation.<sup>4</sup> By far the most common reasons for failed implants were biologic. These failures were further categorized as early (before loading) and late (after loading). A meta-analysis of 16 publications concerning grafted patients reported on 1,833 placed implants, of

which early failures accounted for 62% and late failures for 38%.<sup>4</sup> In the present study group, 60% of the failures were considered early and 40% were considered late. In the reference group these figures were 43% and 57%, respectively. The slightly increased number of early failures after 1-stage sinus block bone grafting, also found by others,<sup>4</sup> has been suggested to be the result of reduced initial implant stability.

In this study, the early failures, which took place before completion of prosthetic treatment, were higher in the grafted areas, 16.1% in comparison to 9% in the non-grafted areas. The failures in the reference group during this period were 2.9%. The vulnerability of implants in non-resistant 1-stage grafted bone seems obvious, and excessive loads should therefore be avoided until complete healing of the graft has occurred.

When failures were analyzed during the 3-year follow-up, as shown in Table 2, the rates in the study group were found to be 5.9% in grafted areas and 5.7% in non-grafted areas. The failure rates in the reference group during this period were 0.6%. Thus, this study suggests that after the first year of healing, implants in grafted bone will have the same prognosis as implants in non-grafted bone in patients with severely atrophied maxillae, while in the long run patients with moderate maxillary alveolar resorption have a better prognosis for implant success.

In agreement with others, the baseline marginal bone level was estimated as a reference point for standardized radiologic evaluations.<sup>19,21</sup> In the first year, marginal bone resorption in the study group, grafted and non-grafted, was 1.1 mm and 1.3 mm, respectively, and in the reference group marginal bone resorption was 0.8 mm. The figures in this material are fairly equal in all groups both during this period and for the following 2 years of load-bearing, and are also well in accordance with the results of others.<sup>21</sup> As the range in each interval (0 to 1 year, 1 to 3 years) is quite wide, the clinical variation of marginal bone resorption in this material is obvious. However, usually only mean values are presented. The results differ from Nyström et al,<sup>19</sup> who found 3.52 mm marginal bone loss during the first year and a further 1.39 mm for the following 2 years. One can only speculate that this difference might be the result of the different implant design and of the use of onlay grafts in their study instead of inlay grafts in this study.

As the range in each interval was wide, the clinical variation of the marginal resorption is obvious, and clinical conclusions are difficult to draw.

The mean and median values of resorption correspond with other published investigations, as previously commented on. These results indicate, however, that when the grafts are presumed to have been revascularized and remodeled after 1 year, marginal bone resorption stabilizes.

The total failures in the study group were probably caused by late medical complications (1 patient) and an initially unstable graft and adverse load factors (1 patient). In the reference group, total failure occurred in a patient who smoked and suffered from muscular hyperactivity. In this 3-year follow-up study, complications during the 6-month healing period were found to be of statistical significance for implant success. However, the findings do not allow any further conclusions because the patient population is too small. Smoking habits have been shown by others as contributing to implant failures, but no such relationship was documented in this study.<sup>32</sup> The reliability of data in this and other studies regarding smoking habits can be questioned, as the results have not been related to objective measurements in saliva, blood, or urine.

## Conclusions

Based on the present results in a limited patient population it is concluded that:

1. Treatment with implants and 1-stage intra-sinus block bone grafts of severely atrophied edentulous maxillae suggest that a predictable prognosis may be realized and clinically acceptable success rates achieved.
2. In patients with reduced bone volume, the removal of restorations is recommended to detect unstable implants.
3. Postoperative complications during the healing periods are a factor influencing the loss of implants.
4. After the initial 23-month healing period, a level of equilibrium is reached for implant stability and marginal bone resorption.

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