A Prospective Randomized Study of 1- and 2-Stage Sinus Inlay Bone Grafts: 1-Year Follow-up

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The purpose of the present study was to compare the success of and surgical differences between 1- and 2-stage sinus inlay bone grafts and implants after 1 year in function. The individual risk for implant failure in grafted areas among 1-stage patients was about twice the risk in 2-stage patients (odds ratio 2.3, CI 0.6; 8.5). The risk for implant failure in non-grafted areas was significantly lower ($P < .05$) than in grafted areas, regardless of the technique used. Forty edentulous patients, selected according to strict inclusion criteria from consecutive referrals, were allocated to one or other of the 2 sinus-inlay procedures. Twenty patients received bone blocks fixed by implants to the residual alveolar crest in a 1-stage procedure (group 1). In another 20 patients, particulated bone was condensed against the antral floor and left to heal for 6 months before implants were placed (group 2). An almost equal number of implants was placed in the patients of each group, 76 in the 1-stage procedure and 74 in the 2-stage procedure. Additionally, 72 and 66 implants were placed in the anterior non-grafted regions of group 1 and group 2 patients, respectively. After 1 year in function, a total of 20 implants failed in 1-stage patients, versus 11 in 2-stage patients. Sixteen and 8 implants, respectively, of these were placed in grafted bone. All but one 1-stage patient received the planned fixed prosthetic restorations, but 1 restoration was redesigned after the first year in function because of a functionally unacceptable prosthetic design. At the 1-year follow-up, one 2-stage patient lost her prosthesis as the result of multiple implant failures. Bruxism and postoperative infections were the only parameters that could be related to implant failure, however, depending on the statistical method used.
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Rehabilitation of completely or partially edentulous arches with implants and prosthetic treatment following the Brånemark concept has become routine treatment worldwide.[1] However, lack of sufficient bone volume for adequate implant placement made earlier rehabilitation with a fixed prosthesis impossible. To enhance bone volume, various augmentation procedures have recently been introduced. The first method to gain clinical use was the full-arch iliac crest onlay graft.[2–4] Since problems occurred with wound dehiscence, uncertain prognosis, and prosthetic difficulties, efforts were made to place the grafted bone in more sheltered positions.

Le Fort I osteotomy with sandwich corticocancellous bone grafts was introduced and could be recommended, especially for situations of reversed jaw relationship.[5–7] Augmentation of the maxillary sinuses with autogenous bone became an alternative for patients with moderate anterior alveolar ridge resorption and enlarged maxillary sinuses. For treatment of these patients, 2 surgical techniques were developed. In one procedure, corticocancellous bone grafts, harvested in blocks, were fixed by implants to the residual maxillary bone in a 1-stage procedure.[8,9] In the other, the harvested bone was particulated and condensed onto the floors of the maxillary sinuses for delayed implant placement in a 2-stage procedure.[10,11]

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Table 1 Distribution of Preoperative Factors in Patients

Factor	1-stage patients (n = 20)	2-stage patients (n = 20)
Median age (range)	54 (31 to 72)	57 (39 to 78)
Gender (F/M)	14/6	14/6
Smokers	8	8
ASA index 1	15	15
ASA index 2	5	5
Bruxism habit	7	3
Edentulous for > 10 years	5	7
Reason for edentulism		
Periodontitis	10	11
Caries	7	6
Other	3	3
Opposing arch		
Natural teeth	18	16
Implants	2	4

Recently, the 2-stage technique has gained increased popularity, although no convincing evidence for its superiority has been shown.[12,13] Results are difficult to compare because of the lack of standardized inclusion criteria and specific criteria for success.[14] Technical variations and varying augmentation materials further complicate evaluation.[15–19]

The present study was prospective and randomized into 1- or 2-stage maxillary sinus augmentation with corticocancellous iliac bone grafts and implants. The aim was to study the prognosis and outcome of the methods with respect to surgical and prosthetic factors.

MATERIALS AND METHODS

The study comprised 40 patients with edentulous maxillae. The patients were selected according to specified inclusion criteria: more than 2 mm but less than 7 mm of residual bone under the maxillary sinuses, age less than 80 years, no clinically or radiographically diagnosed pathology in the maxillary sinuses, and no diagnosed bone disease or medication known to affect bone metabolism, ie, corticosteroids and biphosphonates. Maxillary sinusitis was diagnosed when clinical (ie, pain, tenderness, nasal airway obstruction) and radiographic signs of inflammation were found. All patients were accepted for treatment under general anesthesia, and no obstacles for harvesting bone from their iliac crests were found. The patients were classified as Class V-VI in the posterior regions of the maxilla and as Class III-IV in the anterior parts, all according to Cawood and Howell.[20]

The patients were randomized to either of 2 grafting procedures: 1- or 2-stage sinus inlay bone graft, with 20 patients in each group. All patients gave their informed consent and the study was approved by the ethical committee at Karolinska Hospital, Stockholm, Sweden. Age, gender, health, smoking habits, reason for and duration of edentulism, and any previous history of bruxism were recorded and are presented in Table 1. The general health of the patients in this study was classified on a 5-grade scale according to the American Society of Anesthetists (ASA).[21] Grade 1 represents patients without any serious illness and not on medication. Grade 2 represents a standard of medically fully compensated illness, eg, hypertension or diabetes. The patients were registered as smokers when daily consumption exceeded 5 cigarettes per day. Bruxism was noted when the patient exhibited a history of grinding or clenching teeth with or without symptoms from the temporomandibular joint or the jaw muscles.

One-Stage Surgery

Monocortical iliac bone blocks were harvested and shaped to fit the maxillary sinuses,[22] explored by the sinus lift technique.[9] The bone blocks were oriented with the cortical layer superiorly and were bilaterally stabilized to the alveolar ridge, usually with 2 self-tapping implants (Nobel Biocare AB, Göteborg, Sweden). To simplify prosthetic handling, efforts were made to place the implants as vertically as possible. Three to 4 implants were placed in the anterior non-grafted bone. Altogether, 76 implants were placed in grafted bone and 72 implants were placed in non-grafted areas. The length of the implants ranged from 10 to 18 mm, all with a diameter of 3.75 mm. The mean time of active surgery was 135 minutes (range, 90 to 150 minutes). The bone grafts and implants were left to heal for 6 months before abutment connection.

Two-Stage Surgery

Bone was harvested from the iliac crest, as in the 1-stage surgery patients. Before placement into the maxillary sinuses, explored with the sinus lift technique,[9] the harvested corticocancellous bone was particulated in a bone mill (Tessier Osseous Microtome, Leibinger, Germany) and mixed with blood, sampled from the crest or drawn from a vein. The milled bone was condensed onto the floors of the maxillary sinuses, beneath the elevated sinus membrane. The technique used was slightly modified from the technique described by Jenssen et al[11]; the present authors used bone from the hip rather than mandibular bone. After wound closure, the bone was left to heal for 6 months. Then, where possible, 2 self-tapping implants (Nobel Biocare AB) were placed in each grafted region as vertically as possible. Three to 4 implants were placed in the anterior non-grafted bone following the standard procedure.[1] Altogether, 74 implants were placed in grafted areas, while 66 implants were placed in anterior non-grafted bone. The length of the implants ranged from 10 to 15 mm, all with a diameter of 3.75 mm. Reduced initial stability was noted in 6 implants placed in the most posterior parts of the grafted maxillary sinuses. The mean time of active surgery, bone grafting, and implant placement was 105 minutes (range 100 to 120 minutes). The healing time allowed after implant placement was 6 months.

Postsurgical Care

Either benzyl-penicillin (3 g × 3) or clindamycin (600 mg × 3) was given parenterally immediately preoperatively and for the following 24 hours postoperatively. Either phenoxymethyl-penicillin (2 g × 2) and tinidazole (500 mg × 2) or clindamycin (300 mg × 3) was prescribed thereafter for the following 10 days. For implant placement in the 2-stage patients, either phenoxymethyl-penicillin or clindamycin was given for 7 days, starting 1 hour before surgery. Analgesics containing non-steroidal anti-inflammatory drugs or paracetamol were, in general, prescribed for 7 to 14 days postoperatively. No dentures were worn during the first 10 days after surgery, and they were always adjusted and relined before use. Any surgical or prosthetic complication during the healing period, such as severe pain, dehiscence, fistulae, or local infections (eg, maxillary sinusitis), was registered in the individual protocols.

Prosthodontics

Abutments were connected to the implants after 6 months. Implant stability was manually tested at this time. The type of abutment was noted in the protocol. According to protocol, all patients were to receive fixed prosthetic restorations. Gold or titanium frameworks were used, veneered with either acrylic resin or porcelain. The need for angulated abutments to obtain a satisfactory functional and esthetic result was noted to assess the degree of technical difficulty.

Follow-up Protocol

When the prosthetic treatment was completed and again after 1 year in function, the patients' protocols, including clinical and radiographic data, were completed. The protocol included:

- Lengths and positions of implants
- Technical data on prosthetic restorations
- Surgical and prosthetic complications
- Immediate and late implant instability
- Marginal bone level on the mesial and distal surfaces of each implant
- Level of grafted bone in relation to the apical ends of the implants
- Radiolucent areas between implants and bone, visible on radiographs

The radiographic examinations were done with parallel intraoral techniques[23] at the Department of Dental Radiology, Eastman Institute, Stockholm, Sweden, and the Radiographic Department of Gävle County Hospital, Gävle, Sweden. The mean marginal bone loss in grafted and in non-grafted areas was calculated, along with the frequency of implants with a marginal bone resorption greater than 2 mm. At the 1-year check-up, all prosthetic restorations were removed and individual implant stability was tested manually. Implants that were clinically mobile were considered to be failures and were removed.

Statistics

To calculate the 1-year cumulative success rate (CSR) for implant stability, a life table analysis was performed.[14] The Wilcoxon rank sum test, taking the relative frequency of implant loss in each patient as a computational unit, was used to test differences in implant success rates between groups of patients (1-stage versus 2-stage). The probability of future implant failure was analyzed on an individual level with attention to the number of implant losses (statistical method 1) and was also analyzed considering the loss of 1 or several implants in each individual with logistic regression by giving odds values (statistical method 2). To estimate the dependence between implants in each patient, the intraclass correlation coefficient was calculated.[24,25] Student's *t* test was used to analyze any differences between groups with respect to

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

Group	No. of implants placed	No. of implants failed	SR (%)	CSR (%)
Placement to loading				
1-stage non-grafted	72	3	95.2	
1-stage grafted	76	11	85.5	
2-stage non-grafted	66	1	98.4	
2-stage grafted	74	7	90.5	
Loading to 1 y				
1-stage non-grafted	69	1	98.6	94.4
1-stage grafted	65	5	92.3	79.0
2-stage non-grafted	65	1	98.5	97.0
2-stage grafted	67	1	98.5	89.2

marginal bone loss. The level of statistical significance was set at $P < .05$.

RESULTS

No patients dropped out during the study period. Since multiple implant failures were noted in a few patients, this was regarded as a dependent factor, and the intraclass correlation coefficient was calculated to 0.58. As a result, failures were studied on an individual patient level. The number of implants was too few to obtain reliable, significant results on the implant site level.

Implants in Non-Grafted Regions

In total, 138 implants were placed in anterior non-grafted areas. Four of these (3%) were removed during abutment connection. Two further implant losses were registered at the 1-year check-up. The CSR for respective groups of patients is shown in Table 2. The mean marginal bone resorption was 0.31 mm (SD 0.54). The frequency of implants with bone resorption greater than 2 mm during the first year in function was 5.1%.

Implants in Grafted Regions (1-Stage)

In 9 patients, 11 perforations of the sinus membrane were noted during surgery (27.5%). Eleven implants were found to be unstable at the time of abutment connection (14.5%). Eight patients lost 1 or more implants. At the 1-year examination, 5 of the 65 remaining implants were removed. The CSR after 1 year was 79.0% (Table 2).

The odds ratio for implant failure in the 1-stage grafted group was 8.9 (CI 2.9; 28) compared to the implants in non-grafted areas in 1-stage patients.

Angulated abutments were used in 8 patients (40%). In 1 patient, the palatal angulation of the implants placed in grafted bone blocks was extreme. The prosthesis was redesigned at the implant level without the use of abutments, since the patient had insufficient space for her tongue. One patient lost 4 implants and received complementary surgery after healing. Thus, 18 of the 20 patients were wearing their originally planned prosthetic restorations at the 1 year check-up. Two patients refused the baseline radiographic examination, and 1 patient refused the 1-year radiographic check; these patients were registered as drop-outs from the radiographic evaluation.

After 1 year in function, the mean marginal bone loss for implants in grafted areas was 0.2 mm (SD 1.0). The frequency of marginal bone loss greater than 2 mm was 5.0%. There were no radiographic signs of non-integration, although 5 implants were found to be clinically mobile at the 1-year check-up. Uncovered apical ends of the implants caused by bone graft resorption were not seen at the 1-year radiographic check, nor were any pathologic reactions seen in the adjacent sinus membranes.

Implants in Grafted Regions (2-Stage)

Eleven perforations of the sinus membrane were noted in 10 patients (27.5%). Seven implants were mobile and were removed at the time of abutment connection. Six patients lost 1 or more implants. One additional implant was removed at the 1-year clinical check-up. The CSR at this point was 89% (Table 2). The odds ratio for implant failure in 2-stage grafted patients was 4.1 (CI 1.2; 14) compared to implants in non-grafted areas. All patients received fixed prostheses according to the original plan. Angulated abutments were used in 3 patients (15%). At the 1-year check-up, 1 patient lost 1 strategically positioned implant in grafted bone and had her fixed prosthesis replaced by an overdenture.[26]

Table 3 No. of Patients with Implant Failures in Grafted Regions with Respect to Local and General Factors

Patients with implant failures (n = 17)	*P* value (method 1)	*P* value (method 2)	Odds ratio (method 2)
Gender, female (n = 14)	NS	NS	5.0
Smoking (n = 9)	NS	NS	3.1
Health index, ASA = 2 (n = 6)	NS	NS	1.7
Bruxism (n = 6)	< .05	NS	3.0
Loss of teeth due to periodontitis (n = 6)	NS	< .01	0.1
Initial stability (n = 2)	NS	NS	1.0
Complications during healing period (n = 10)	.07	< .05	13.8

P values and odds ratio are given without respect to grafting technique. NS = not significant.

All patients appeared for radiographic appointments. The mean marginal bone loss during the first year in function was 0.2 mm (SD 0.61). The frequency of implants with marginal bone resorption greater than 2 mm was 1.6%. No pathologic conditions were seen in the grafted regions or the maxillary sinuses. In 1 patient, peri-implant radiolucencies were seen along 2 implants placed close together, 1 in grafted and 1 in non-grafted bone. These implants were found to be unstable at the clinical check-up.

The risk of implant failure (1 or more implants lost in each patient) in 2-stage sinus inlay patients was half of the risk calculated for the patients treated according to the 1-stage sinus inlay technique (odds ratio 2.3, CI 0.6; 8.5).

Reasons for Implant Failure

Patients with implant failures are shown in Table 3 with respect to factors that possibly influenced the stability of implants, regardless of operative technique. With statistical method 1, a positive correlation ($P < .05$) was found between bruxism and implant failure. A weak correlation was seen between postoperative infection and implant failure ($P = .07$). When odds ratios were calculated with method 2, significant positive correlations were found between implant failure and complications during the healing period. However, a negative correlation was also found between implant failure and periodontitis as the reason for the loss of teeth.

DISCUSSION

This study was planned and conducted in the light of the authors' documented clinical experience with implants and 1-stage sinus inlay bone grafts.[27] The planned prosthetic rehabilitation was accomplished in most patients. However, some surgical and prosthetic complications occurred that could perhaps have been avoided by the use of a 2-stage surgical technique. However, since several reports on different grafting techniques have recently been presented, often with sparse scientific evidence of priority, the authors' general intention was to conduct a randomized, prospective study in accordance with the theories of evidence-based medicine.[28,29]

The present study raises some questions.

1. Was the Design of This Study Accurate and Were the Results Concerning Implant Failures Reliable? Although prospective, randomized studies are recommended to obtain comparable and reliable results,[29] adequate test/control investigations of free autogenous bone grafts and implants have not yet been presented.[12] To minimize the risk of exogenous influence on the results, inclusion criteria were set strictly. However, the intraclass correlation coefficient for failure was found to be 0.58, so all data were analyzed at the individual level, not the site level. To present the individual risk for implant failure using the different surgical techniques, the odds ratio was also calculated.[25]

To demonstrate a statistically significant difference ($P < .05$) in implant failure between the 2 methods, about 50 patients in each group would be required for the estimated odds ratio. However, implant failure rates are often analyzed with the implant site as the basis for evaluation. On this basis, the 288 implants in this study would have been a sufficient number. Yet not to take the dependency among implants in the same patient into account might lead to false conclusions.[25] By using a prospective and randomized design for the study, and by using observations from the patient as the statistical unit, the risk of design-related errors would be minimized, although factors that can be related to implant failure also depend on the statistical method.

2. Was the Pattern of Failures Similar to That Seen in Earlier Reports? The success rate for implants placed in grafted bone was significantly lower than in non-grafted anterior bone, irrespective of the grafting technique used ($P < .05$). The calculated risk of implant failure was found to be about twice as high for the 1-stage procedure as for the 2-stage procedure, although it was not significant ($P > .10$). In grafted bone, 79% of the failures were recognized at the time of abutment connection. The pattern of failures during the first year of loading was in accordance with other studies.[3,4,18,24] In an analysis of 14 published articles on Brånemark implants with a follow-up period up to 5 years, Esposito et al discovered 50% of the failures at abutment connection and 50% during function.[12] Probably the majority of the early failures were the result of technical and host-related factors, while overload relative to bone quality and initial bone volumes caused late failures. Peri-implantitis as the cause for implant failure has been reported to be infrequent for Brånemark System implants.[12] No case of peri-implantitis was found in this 1-year study, and only 4.3% of the implants showed marginal bone resorption exceeding 2 mm after the first year of loading.

3. What Was the Main Cause of Failure? When this material was analyzed on an individual level and the number of lost implants was examined (statistical method 1), it was found that patients with bruxism lost significantly more implants than patients without hyperactivity in the masticatory muscular system ($P < .05$), regardless of whether the 1- or 2-stage grafting technique was used. Postoperative infection showed a weak correlation with implant loss ($P = .07$). No other host-related factor seemed to be of prognostic relevance. There are few clinical reports that cite excessive load caused by muscular hyperactivity as a risk factor for late implant loss. However, it has been shown under experimental conditions that implants can fail because of excessive occlusal load.[30] At the 1996 World Workshop in Periodontics,[31] consensus was achieved that marginal loss around implants can sometimes be associated with implant overload.

If, on the other hand, the results are examined using logistic regression, which gives odds ratio values (statistical method 2), as in an earlier article,[27] the outcome of prognostic influencing factors will be different. Bruxism is no longer significant, but complications during the healing period, ie, dehiscence, sinusitis, and unexpected severe pain still significantly imply an increased risk of implant failures during the first year of follow-up.

Postoperative infections have been connected by others with an increased risk of implant failures.[11,27,32] There is always a need for meticulous surgical technique and observant care during healing to avoid infection. Implants placed in non-vital block bone grafts might be more susceptible to infection than implants placed in already reorganized bone. The remodeling potential of bone grafts, and therefore of their ability to integrate implants at different times after the grafting procedure, was recently studied by Lundgren et al.[33] In this study, 2-stage surgery was found to be superior to the 1-stage technique and was advocated for this reason.

Sinus mucosa tearing was recognized in 27% of the exposed maxillary sinuses, compared with 36% reported by Raghoebar et al[16] and 14% by Krekmanov,[34] thereby confirming Timmenga et al's results.[35] Tearing of the sinus mucosa during surgery could not be connected with the development of postoperative sinusitis or later implant failures. The incidence of maxillary sinusitis as a complication of the sinus lift procedure and bone grafting to the antral floor has been reported to be significantly higher in patients with predisposing factors for sinusitis than in patients without these factors.[35] Although the present patients were free from sinus pathology preoperatively, 2 patients developed acute sinusitis during the healing period. In 1 patient, this was the result of an upper airway infection, and in the other patient, it was caused by an infected, probably unstable, graft. In the first patient, the infection subsided with antibiotic treatment, but the other patient lost 2 implants, and the graft sequestered.

Also with statistical method 2, a negative correlation of implant loss was seen regarding periodontitis as the reason for tooth loss. No such information is given in the literature. Some authors have speculated a positive correlation, but no specific advice has been given.[36]

4. Did the Radiographic Examinations Give Information Regarding the Prognosis of the Respective Treatment Modalities? The baseline for radiographic evaluation was set at the time of functional loading, thereby excluding the marginal changes resulting from remodeling during the healing period and the postoperative reaction to abutment connection. Mean marginal bone resorption (residual crest bone) during the first year of loading did not differ with respect to implant placement in grafted bone according to the 1- or the 2-stage technique or in non-grafted bone. No resorption of apical bone exposing the apical ends of the implants was seen on the radiographs.

According to the radiographic protocols, only 2 of the 8 implants that were found to be mobile at the 1-year clinical check-up were thought to be failures.

The radiographic technique is limited, and the projection of anatomic structures might hide the thin soft tissue layer surrounding an unstable implant.[37] Indeed, these peri-implant radiolucencies, a "math band effect," can occasionally be noted even in cases of successful implants.[37,38] In this study, this was confirmed by peri-implant radiolucencies around 3 implants in the radiographic protocol, although manual clinical testing could not demonstrate the mobility of these implants.

Radiographic examinations appear to be of questionable value in assessing the stability of dental implants. The use of mean values to estimate marginal bone resorption in longitudinal studies has also recently been questioned. This is because increased marginal bone loss observed around the few implants that are affected by peri-implantitis is averaged in with figures recording minimal or no change in bone levels for the other implants.[36] The use of figures recording the frequency of increased marginal bone resorption in implants has therefore been advocated recently.[36] However, there is no doubt of the value of radiographic measurements in longitudinal studies of marginal bone levels in introducing new rationales and new hardware.

5. The Patient's Subjective Appreciation of Successful Treatment Can Be Assessed by the Achievement of a Stable Prosthetic Restoration. Did the 1-Stage or 2-Stage Treatments Fulfill This Criterion for Success? In the present study, the planned prosthetic treatment was carried out in all patients treated with the 2-stage technique and in all but 1 patient treated with the 1-stage technique. Ninety percent and 95% of the original prosthetic restorations, respectively, were functioning after 1 year. In previous reports, 71%, 85%, and 92% of patients received the initially planned prosthesis after a 1-stage grafting procedure[15,18,23] and 76% received fixed prostheses after a 2-stage procedure.[32] This 1-year follow-up study showed no prognostic difference for oral rehabilitation with fixed prostheses supported by implants, regardless of whether the 1- or 2-stage technique was used.

6. Are There Surgical or Technical Reasons for a First Choice of Either of the 2 Methods? One-stage surgery was more demanding, as shown by the extended surgical time. The simultaneous placement of bone grafts and implants makes greater demands on the healing process and postoperative care. One-stage surgery necessitates a more frequent use of angulated abutments to straighten less favorably positioned implants, confirming the results of Blomqvist et al.[18] The use of 2-stage surgery, although it extended the treatment period by 6 months, reduced the risk of implant failures by half, compared to 1-stage surgery. The decision as to which bone grafting method to use is complicated and includes the evaluation of host factors, surgical experiences, and clinical traditions. However, 2-stage sinus inlay surgical techniques are favored at the authors' clinics today.

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