Reconstruction of the resorbed maxilla with iliac crest or calvarial bone grafts

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CHAPTER 3

Morbidity of anterior iliac crest and calvarial bone donor graft sites:

A 1-year randomized controlled trial

This chapter is an edited version of the manuscript: T. F. Putters, D. E. Wortmann, J. Schortinghuis, B. van Minnen, C. Boven, A. Vissink, G. M. Raghoebar. Morbidity of anterior iliac crest and calvarial bone donor graft sites: a 1-year randomized controlled trial

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Background Autogenous bone graft harvesting is still commonly considered the gold standard for the reconstruction of a severely resorbed maxillary alveolar ridge; however, the preferred donor site remains a subject of debate.

Purpose This study compared the morbidity of calvarial and iliac crest donor sites after harvesting.

Methods Twenty edentulous patients with an insufficient volume of maxillary bone for reliable implant placement were assigned randomly to either calvarial (n = 10) or anterior iliac crest (n = 10) bone harvesting groups. All patients underwent a maxillary sinus floor elevation procedure combined with widening of the alveolar process using buccal bone blocks. Donor site morbidity was assessed before, during, and at 1 year after the surgery through patient questionnaires, physical examination, and medical records.

Results No perioperative complications occurred. The anterior iliac crest group reported minor postoperative pain after harvesting. The scars after calvaria harvesting were significantly longer (p = 0.003), but this was not bothersome for the group of patients. Long-term pain was negligible, and satisfaction was high in both groups.

Discussion Both the calvaria and anterior iliac crest are associated with low long-term donor site morbidity and high patient satisfaction. Thus, patient-centred decision-making is appropriate when selecting the preferred harvesting method for that patient.

Key words: bone augmentation, iliac crest, calvarial bone, morbidity, patient satisfaction

1 INTRODUCTION

Implant overdentures are widely recognized as the treatment of choice for edentulous patients experiencing problems wearing conventional dentures. Pre-implant augmentation surgery is needed in severe cases of resorption whereby insufficient bone volume is present for adequate implant placement and stability.

Several augmentation techniques have been described[1], either with human bone, animal bone, synthetic materials, or a combination of these. Grafting with autogenous bone is still considered the gold standard[2]. Bone can be grafted from numerous places in the human body, of which the anterior iliac crest is mostly used when a large volume is needed[2]. The anterior iliac crest is easily accessible and can provide considerable amounts of cortical and cancellous bone. Furthermore, when using a two-team surgical approach, the bone harvesting can be done simultaneously with the augmentation surgery, thereby reducing surgery time. However, the common limitation of this procedure is the inherent donor site morbidity including pain, sensory disturbances, and gait problems[3].

The calvaria offers an alternative to the iliac crest as a donor site when large bone grafts are needed. Grafts taken from the outer cortex of the posterior parietal skull bone provide a large volume of cortical bone, while the diploic space contains copious amounts of cancellous bone[4]. The associated donor site morbidity is suggested to be low compared to iliac crest bone grafting. However, the possibility of neurological sequelae represents the major argument against calvarial bone grafting[5]. The recently developed safe harvesting technique, introduced by Kellman[6] and modified by Schortinghuis et al.[4], decreases the risk of intracranial complications to a minimum.

Despite the existing extensive knowledge on donor site morbidity associated with various bone grafting sites[1,3,7–11], the best donor site remains undefined. Accordingly, a prospective comparative trial was designed to assess donor site morbidity and patient satisfaction following anterior iliac crest and calvarial bone harvesting when applied as a pre-implant augmentation procedure to reconstruct a severely resorbed maxilla.

2 MATERIALS AND METHODS

2.1 Patients

Between November 2014 and March 2016, 20 patients fulfilled the inclusion criteria for this study. All patients had been referred to the Department of Oral and Maxillofacial Surgery of the University Medical Centre Groningen (UMCG) because of problems while wearing

an upper denture (pain, mobility, loss of retention, chewing) due to severe resorption of the edentulous maxilla. The patients were eligible to be included in this study when the available bone volume was insufficient for reliable implant placement, i.e., <3 mm bone height in the maxillary sinus area and <2 mm bone width in the anterior maxillary area, as assessed on a cone beam computed tomography (CBCT) scan. Furthermore, the thickness of the parietal bone (>5 mm) in the area between the articular tubercle and the end of the mastoid bone had to be suitable, as assessed on a CBCT scan of the calvaria with frontal reconstructions. Exclusion criteria were the following: presence of contraindications to surgery due to severe health problems, former or current use of intravenous bisphosphonates, currently pregnant or lactating, and a previous operation at the donor site. Informed consent was obtained from all patients. The study was approved by the Medical Ethics Committee of UMCG. The eligible participants were divided randomly into two equal groups. One group was treated using calvarial bone for the augmentation procedure (n = 10) and the other group with bone from the anterior iliac crest (n = 10).

2.2 Surgery

Calvarial bone was harvested after raising a full-thickness flap. Next, the outline of the outer table graft was marked with a burr until the diploë was encountered. A bone scraper (SafeScraper Twist; META, Reggio Emilia, Italy) was used to create a bevelled trough around the calvarial outer table graft to facilitate its removal with a reciprocating saw. Using the scraper, copious amounts (>10 ml) of 'cancellous'-like bone could be collected. Parallel saw-cuts were made in situ so that the graft could be removed piece by piece thus preventing graft breakage[4,12]. The defect in the skull was reconstructed with bone cement (Palacos; Zimmer Biomet, Warsaw, Indiana, USa).

Anterior iliac crest bone was harvested according to the technique of Kalk et al.[13]. The incision was started 1 cm behind the anterior superior iliac spine and continued posteriorly, following the iliac crest. It was carried down sharply to the midcrest, dividing the musculotendinous aponeurosis of the tensor muscle of the fascia lata and the oblique abdominal muscles, without transecting muscle fibres. The bony ilium was exposed directly by reflecting the iliac muscle sub-periosteally and the donor site was exposed with a retractor. The corticocancellous bone blocks were harvested by making two horizontal and five vertical cuts. The superior horizontal cut was made midcrestal with a reciprocating saw. The inferior horizontal cut was made 4 cm inferior in the inner table with a curved osteotome. The horizontal cuts were connected by verticals cuts using a reciprocating saw. After removal of the corticocancellous bone block piece by piece from the inner table, additional cancellous bone was harvested with gouges and curettes. Care was taken not to perforate the lateral cortex.

All the operations were performed at UMCG by an experienced oral and maxillofacial surgeon. After harvesting the calvarial or iliac crest bone, sinus elevation surgery was performed according to the procedure described by Raghoebar et al.[14].

Broad-spectrum antibiotics (amoxicillin–clavulanic acid) and non-steroidal anti-inflammatory drugs (NSAIDS) (ibuprofen) were prescribed for 1 week post-surgery. Patient instructions included a soft diet and not wearing the maxillary denture for 2 weeks.

After 4 months, the dental implants were placed in the augmented maxilla. All of the patients were enrolled for a dental hygiene protocol.

2.4 Outcome measures

The primary outcome measure was donor site morbidity (perioperative, early, and late postoperative). The secondary outcome measures were patient satisfaction, self-reported postoperative pain, and implant survival.

For the assessment of perioperative donor site morbidity, the presence (reported as yes/no) of each of the following items was recorded during the grafting procedure: dura exposure, dural tear, accidental falling of the graft, graft fracture during removal and/or bicortical perforation of the iliac crest, and size of the graft. The duration of the harvesting procedure was measured (min). The hospitalization period was also recorded in days. During implant placement, bone loss or signs of bone resorption (yes/no) were recorded.

With regard to early postoperative donor site morbidity, the morbidity data of both groups were recorded by the surgeon at 1, 2, 6, 16, 20, and 28 weeks postoperative. The following items were each assessed with regard to the donor site (reported as yes/no): scar aspects (dehiscence, erythema, swelling, and pain), hair loss, localized pain, and contour deficit. If contour deficits were present, the patient was asked whether or not this was bothersome (yes/no). With regard to the receptor site, the presence of dehiscence, fistula, erythema, loss of implant, and gingivitis were also recorded (reported as yes/no).

Late postoperative donor site morbidity was assessed at 1 year after prosthetic loading. All patients were invited for a physical examination by an independent investigator at UMCG. The following variables were investigated: contour deficits, sensitivity, tenderness, and length of the scar. In addition, alopecia around the donor site, defined as evident hair loss next to the scar, was assessed for the calvaria group.

The assessments of the donor site contour changes were standardized for both groups. The operated parietal surface of the head was palpated, or the contour of the operated anterior

superior iliac crest was dorsally palpated after localizing the iliac spine. Subtle or evident deficits were reported. The patients were asked to report tenderness or pain accompanying the examination.

Tactile sensitivity of the donor site was determined by touching the skin lightly with a piece of cotton wool. Patients were asked to identify the number of contacts. Sensitivity was established by touching with a dull cotton bud and a sharp needle, and the participants had to discriminate between them. The patients were blinded for both tests.

For the assessment of postoperative pain, the participants graded the donor site pain experienced (skull or iliac crest region) following augmentation and implantation surgery for 30 days at 12:00 a.m. each day. Twelve months after prosthetic construction, the participants were asked to score their current pain. This was measured using a 10-cm visual analogue scale (VAS), ranging from 'no pain' (0) to 'the worst pain imaginable' (10).

Patient satisfaction was assessed at 12 months post-augmentation. This was measured with a VAS, with 0 representing 'a bad outcome' and 10 'a good outcome'.

Implant survival was investigated by assessing loose and lost implants, which were recorded at any time after placement.

2.5 Statistical analysis

The data management and analysis were performed using IBM SPSS Statistics version 23.0 (IBM Corp., Armonk, NY, USA). The Student *t*-test, Mann–Whitney *U*-test, and Pearson c^2 test were used to compare the outcomes of the parametric variables, non-parametric variables, and categorical sex variable, respectively, between the groups. Concerning the outcome data, the Pearson c^2 test (or, if necessary, Fisher's exact test) was used to compare any dichotomous variables. Categorical variables with an outcome scale greater than 2 were compared with the Fisher–Freeman–Halton exact test. The means of continuous variables, pain experience, scar length, and satisfaction rate were compared with the Mann–Whitney *U*-test. With regard to pain experience, a Pearson's *r* test was used to assess the correlations with age, body mass index (BMI), and duration of follow-up. Significance was set at an α level of 0.05.

3 RESULTS

3.1 Clinical characteristics

Table 1 describes the baseline characteristics of the study patients. One patient in each group had minor intraoral wound dehiscence. Both were closed with a pedicle mucosal flap and they healed without further complaints.

3.2 Implant survival

In all cases, the augmentation procedure resulted in sufficient bone volume for implant placement at the prosthodontically preferred sites. A total 44 implants were placed in each group. One patient in each group lost an implant because of mobility during the osseointegration phase, resulting in a 1-year implant survival rate of 97.7%.

3.3 Perioperative morbidity

The harvesting of calvarial bone took an average of 53 ± 13 min. One monocortical bone strip fractured during harvesting, but without hampering the augmentation procedure (Tables 2 and 3). The mean graft surface was 13.5 ± 1.8 cm^2.

The harvesting of anterior iliac crest bone took an average 42 ± 8 min. The mean graft surface was 18.3 ± 3.6 cm^2.

Table 1. Characteristics of the calvaria and anterior iliac crest groups[1].

	Calvaria group ***n*** **= 10**	**Anterior iliac crest group** ***n*** **= 10**
Sex		
Male	5	4
Female	5	6
Age at implant placement (years)	65.9 ± 8.7	63.5 ± 7.0
BMI (kg/m^2)	30.6 ± 7.9	28.5 ± 6.13
Time between augmentation and implant placement (years)	0.5 ± 0.2	0.4 ± 0.1

BMI, body mass index.

[1]*Results are presented as the number, or the mean ± standard deviation.*

Table 2. Complications in the calvaria and anterior iliac crest groups.

	Calvaria group *n* **= 10**	**Anterior iliac crest group** *n* **= 10**	***P*-value[1]**
Perioperative complications			
Dura mater exposure without dura tear	0	-	
Dura mater tear with leakage of CSF	0	-	
Accidental bicortical perforation of the iliac crest	-	0	
Breakage of graft	1	0	0.317
Early postoperative complications			
Donor site haematoma	0	0	
Need for extra surgical interventions	0	0	
Need for extra non-surgical interventions	0	0	
Referral to physiotherapy because of persistent pain during movement	0	0	
CT scan because of prolonged tenderness of the scalp	0	0	
Antibiotics because of oedema and prolonged tenderness of the scalp	0	0	
Late postoperative complications[2]			
Difficulties in daily functioning at 12 months postoperative			
Walking	0	1	0.317
Climbing stairs	0	1	0.317
Cycling	0	0	
Persistent headache episodes	0	0	
Difficulties with wearing			
Headgear	0	0	
Pair of trousers	0	1	0.317
Belt	0	1	0.317
Tenderness during palpation	1	0	0.317
Sensory disturbances	1	1	
Hyperalgesia in combination with hypoalgesia	0	1	0.317
Solitary hypoalgesia along the scar	1	0	0.317
Solitary hyperalgesia along the scar	0	0	
Localized alopecia	0	0	
Contour examination			
Evident deficit	2	0	0.146
Subtle deficit	5	3	0.170
Normal contour	3	7	0.089
Contour alteration (subjective)	1	1	
Implants			
Participants with 4 implants	8	8	
Participants with 6 implants	2	2	

CSF, cerebrospinal fluid; CT, computed tomography.
[1]*Mann–Whitney U-test.*
[2]*Assessed at the 12-month follow-up meeting.*

3.4 Early morbidity

In the calvaria group, no dura mater exposure or dura tear occurred during the bone harvesting procedures (Table 2). There was no case of donor site haematoma. No extra (non)surgical interventions were needed at the donor site.

In the anterior iliac crest group, no bicortical perforation of the iliac crest occurred. No donor site haematoma was observed. There was no requirement for extra (non)surgical interventions or for referral to a physiotherapist because of persistent pain during movement.

3.5 Late morbidity

None of the patients in the calvaria group reported difficulties in daily functioning (walking, climbing the stairs, or cycling) at 12 months postoperative (Tables 2 and 3). Persistent episodes of headache did not occur. One patient reported a subjective contour alteration. Physical examination revealed five subtle and two explicit contour deficits (including the patient who reported the contour alteration). The mean scar length was 9.6 ± 2.5 cm. Solitary hypoalgesia along the scar was observed in one patient.

With regard to the anterior iliac crest group, difficulties in daily functioning were reported by two patients at 12 months postoperative. Difficulties with wearing a pair of trousers or a belt were each reported once. Persistent headache episodes did not occur. One patient reported a subjective contour alteration, whereupon a physical examination revealed that a subtle contour deficit was indeed present. No contour defects were observed in the other patients. The mean scar length was 5.7 ± 2.2 cm. Sensory disturbances at the donor site were noted by one patient (hyperalgesia in combination with hypoalgesia).

3.6 Postoperative pain

In the assessment of the calvaria group patients, direct postoperative pain scores in relation to sex, age, and BMI were not significantly correlated, as determined by a Pearson product-moment correlation test ($P > 0.05$, Pearson's r). At the 1-year follow-up, the mean VAS score for current pain of the skull was 0.1 ± 0.1. The participants were highly satisfied with the result of the procedure after 12 months (mean score of 8.0 ± 2.9 on a 0-10 VAS, Table 3).

For the anterior iliac crest group, the Pearson product-moment correlation test revealed a relationship between BMI and the direct postoperative pain scores. After excluding one outlier, the BMI and post-augmentation pain scores for the hip region were significantly correlated ($r = 0.830$, $n = 9$, $P = 0.006$). Direct postoperative pain scores were not correlated with sex or

age ($P > 0.05$, Pearson's r). At the 1-year follow-up, the mean VAS score for current pain of the skull was 0.4 ± 0.9. The participants in this group were very satisfied with the results after 12 months (mean VAS score 9.4 ± 0.5, Table 3).

3.7 Calvarial versus anterior iliac crest bone

The operating time was significantly shorter for the anterior iliac crest group than for the calvaria group ($P = 0.03$, independent samples t-test). Grafts taken from the skull were significantly smaller in surface area than the grafts from the iliac crest ($P = 0.001$, independent samples t-test), but the harvested bone volume from both procedures was sufficient for all the augmentation procedures applied. There were no significant differences in early and late complications between the two groups.

The physical examination at the 1-year follow-up revealed more contour alterations in the calvaria group ($P = 0.089$, Mann–Whitney U-test), and the scars after calvarial bone grafting were significantly longer than the scars after anterior iliac crest grafting ($P = 0.003$, independent sample t-test). Although these results seem unfavourable for the calvaria group, the subjective outcomes of the contour alterations and scar formation were similar in the two groups.

On comparing the pain diaries of the two groups, it was evident that there was a difference in postoperative pain development. Fig. 1 shows that post-augmentation pain was similar until day 5, following which the anterior iliac crest group experienced more pain at the donor site and intraorally than the calvaria group. The pain reported for both procedures was minor, which may explain the observation of no significant differences between the groups over the 30-day postoperative period in this patient cohort (Independent sample t-test, p-values ranging from $p = 0.047$ to $p = 1.00$). Also, the pain curves of the two groups were similar after implantation (Fig. 2).

Table 3. Grafting aspects, scar length, postoperative pain, and patient satisfaction in the calvaria and anterior iliac crest groups.

	Calvaria group Mean ± SD	Anterior iliac crest group Mean ± SD	P-value[1]
Grafting			
Graft surface (cm^2)	13.5 ± 1.8	18.3 ± 3.6	0.001*
Graft operation time (min)	53 ± 13	42 ± 8	0.033*
Visible scar length (cm)	9.6 ± 2.5	5.7 ± 2.2	0.003*
Postoperative pain score (0–10) at long-term follow-up	0.1 ± 0.1	0.4 ± 0.9	0.270
Patient satisfaction (0–10)	8.0 ± 2.9	9.4 ± 0.5	0.142

SD, standard deviation.
[1]*Independent samples t-test*
**significant difference.*

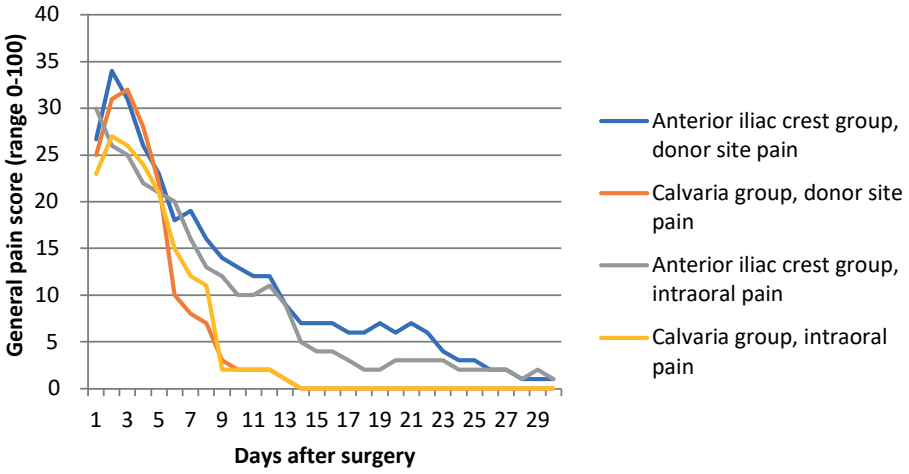

Figure 1. Pain scores following augmentation surgery. The figure shows the mean pain scores (VAS) after augmentation surgery for anterior iliac crest (blue) and calvarial (red) bone graft harvesting. To compare, the mean intra-oral pain is shown as well (gray for anterior iliac crest group and orange for the calvarial group). The figure demonstrates that the pain levels take a similar course for both donor locations, however the pain following calvarial harvesting deceases after two weeks whereas some patients from the anterior iliac crest group perceive pain for almost 30 days post-surgery.

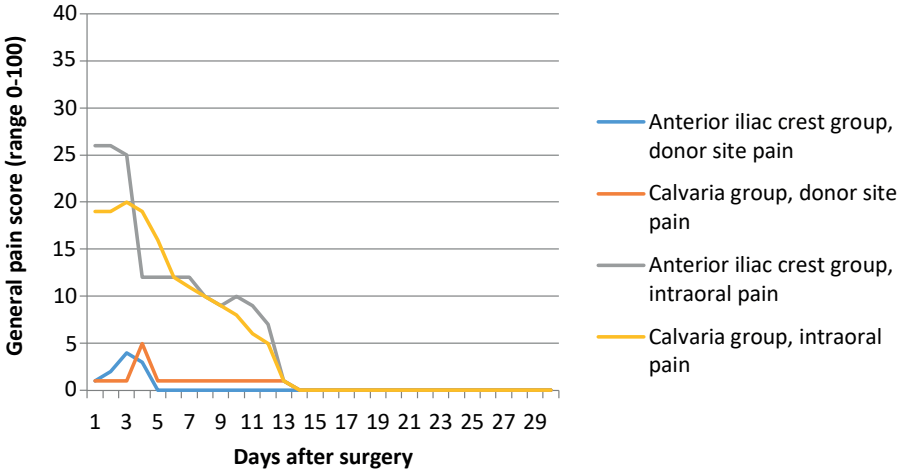

Figure 2. Pain scores following implantation surgery. After 4 months healing, the implants were places. Again, patients were asked to score the pain perceived at donor site and intra-orally. The figures shows that the pain at donor site was very low for both groups.

4 DISCUSSION

No apparent difference in short- or long-term donor site morbidity between calvaria and anterior iliac crest harvesting was evident. This study revealed that few complications occurred and that the pain experienced was very minor, hence patient satisfaction was high.

As mentioned, the complication rate was negligible for both calvaria and iliac crest harvesting. This result is somewhat different from the morbidity reported in the literature, as iliac crest harvesting is commonly associated with a higher rate of minor complications than calvaria harvesting[7,8]. Furthermore, any complications occurring following calvaria harvesting are generally more severe, especially dura exposure [2,5,8,9,11]. The fact that no complications were observed after calvaria harvesting may be due to the technique applied, which prevents dura exposure[4].

Regarding late morbidity, the postoperative mobility assessment showed that two patients in the iliac crest bone harvesting group had minor gait problems, but this did not interfere with their daily activities. This observation is in line with the reported postoperative impaired mobility following iliac crest and calvaria harvesting[9,15–19].

Furthermore, any pain experienced by patients is commonly reported to be higher following iliac crest bone harvesting[8,9]. A similar pattern was observed in the present study, as shown in Fig.1, but the postoperative pain experienced was rather low, hence the lack of a significant difference between the two groups with regard to postoperative pain up to 30 days after treatment. However, postoperative pain levels in the iliac crest region and BMI were strongly correlated. This may be due to accessibility of the donor site and forces on the operated area during rehabilitation.

The occurrence of sensory disturbances did not differ significantly between the groups. Such sensory alterations, probably due to the transection of local nerve endings, are well known consequences of both procedures: Kalk et al.[13] described sensory loss after iliac crest harvesting, and Kuik et al. [7], Scheerlinck et al.[9], and Touzet et al.[11] have described several presentations of altered sensitivity after calvaria harvesting. The changes after calvaria harvesting are thought to be more prominent when a coronal incision is used, as nerves supplying the scalp follow a parasagittal course. Hence, a parasagittal incision of the scalp was used to minimize the chance of cutting through the sensory nerves[10,11]. Some sensitivity could have been due to the described correlation between the extensive use of electrocautery and postoperative hyperalgesia[20] and/or the strong correlation between electrocautery and alopecia[11].

Several studies have described contour alterations after calvarial bone harvesting. To prevent an aesthetically undesirable outcome, reconstruction using biomaterials directly after obtaining the graft is generally advised. In the current study, the bone alterations in the calvaria group patients were reconstructed with bone cement. Despite this, contour deficits were seen on physical examination in more than half of the participants at the 12-month follow-up. However, this was reported as bothersome by only one patient. Kuik et al. described similar results[7]. Hence, this raises the question of whether objectively reported contour changes are relevant in the context of calvarial bone harvesting. Furthermore, the anatomical differences between the two donor sites might explain the different results on examination: irregularities in the skull are easier to identify than alternations to the inner table of the anterior iliac crest.

Furthermore, the restoration of the skull defect caused by the harvesting of calvarial bone was performed with the bone cement Palacos. Although the reconstruction is aesthetically favourable, the cement itself may cause complications such as allergic reactions and infection. However, no such complications were observed. Furthermore, as pointed out by Zanotti et al.[21], all currently available materials for cranial reconstruction have their inherent advantages and disadvantages, and none of these materials lacks an infection risk or potential biological toxicity.

The aim of this study was to make a fair comparison between bone grafting techniques. Some limitations can be pointed out. Although postoperative pain and mobility were primary parameters, the presurgical level of daily physical functioning and usage of pain medication were not assessed at inclusion. It is possible that the frequent use of NSAIDs was a confounding factor. Furthermore, the participants were only followed-up for 1 year postoperatively. Long-term effects could have been analysed better by extending this follow-up period. Moreover, the differences in functionality of the grafts in the long term were not assessed. Specific assessments of bone metabolism at a microscopic level could provide further information about the sustainability and stability of the grafts. The patient-reported outcomes in the present study consisted of pain levels and general satisfaction with the procedure. Following the current trend towards patient-centred decision-making in medical science, the assessment of patient experiences deserves a more prominent role when considering treatment options for pre-implantation surgery. Future studies should pay special attention to this point.

To conclude, both the calvaria and anterior iliac crest are appropriate options for pre-implantation maxillary augmentation with regards to donor site morbidity. The complication rate is low for both procedures and the level of patient satisfaction is high. Therefore, when deciding between these two options, it is recommended that patient-specific factors be taken into account. Pain following calvaria harvesting is apparently lower than that after anterior iliac crest harvesting, especially in those with a higher BMI. Furthermore, the findings of this

and previous studies advocate taking the patient's daily mobility into account when choosing a procedure: calvaria harvesting might be more favourable for highly active patients. However, in the case where large bone volumes are required or limited surgical time is available, the iliac crest (two-team approach) might be the donor site of choice. Furthermore, due to the frequently described contour changes after harvesting, the use of the calvaria as a donor site requires a direct reconstruction with biomaterial. Finally, to reduce the risk of alterations in sensitivity and alopecia, it is recommended that the use of electrocautery is minimized.

5 DECLARATIONS

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Competing interests

There is no conflict of interest in this study.

Ethical approval

The study protocol was approved by the Medical Ethics Committee of the University Medical Centre of Groningen (reference number NL48614.042.14).

Patient consent

Written consent was obtained from all participants.

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