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

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DOI:
10.33612/diss.196167204

CHAPTER 4

Patients' appreciation of pre-implant augmentation of the severely resorbed maxilla with calvarial or anterior iliac crest bone: a randomized controlled trial

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This chapter is an edited version of the manuscript: D.E. Wortmann, C.G. Boven, J. Schortinghuis, A. Vissink & G.M. Raghoebar. Patients' appreciation of pre-implant augmentation of the severely resorbed maxilla with calvarial or anterior iliac crest bone: a randomized controlled trial

Int J Implant Dent 2019 Sep 30;5(1):36

Background: Little is known about the impact of bone graft harvesting for pre-implant augmentation of the maxilla from a patient's perspective. To assess patient reported outcome measures (PROMs) related to augmentation of the extremely resorbed edentulous maxilla with calvarial or anterior iliac crest bone.

Materials and methods: For this randomized controlled trial, twenty consecutive edentulous patients needing extensive pre-implant surgery of the maxilla were randomly assigned to either anterior iliac crest (n=10) or calvarial (n=10) bone harvesting. Patient reports on procedure related satisfaction, questionnaires on oral functionality (Denture Satisfaction, Chewing Ability) and oral health related quality of life (OHIP-49NL) and subjective donor site related outcomes (eg, of post operative pain, scar formation, physical mobility) were assessed.

Results: Irrespective of the harvesting site, patients were generally satisfied (median VAS-score 93(86-99) mm, p=0.400) with the procedure and its final results. Post-operative pain was mild (median 40(20-40) mm) and deceased within 14 days. Early post-operative pain was significantly higher following anterior iliac crest harvesting (p<0.00). Impact on physical mobility, daily functioning and satisfaction with the scar formation were similar in both groups.

Conclusions: The assessed PROMs confirmed that bone graft harvesting from the calvarium or anterior iliac crest are appropriate procedures, reflected by high levels of satisfaction, minor long-term sequela and improvement of perceived oral health. For clinical decision-making, decisions can be based on individual features and preferences.

Key words: patient satisfaction; PROM; autogenous bone graft; edentoulous atrophic maxilla; RCT; iliac crest; calvarium

1 INTRODUCTION

Pre-implant augmentation of the maxilla using extra orally grafted bone has been studied objectively on medical indicators, such as surgical complication rate, donor site morbidity and physical characteristics[1–4]. Little is known about the patients' perceptions of the applied bone harvesting techniques for reconstruction of the maxilla[5]. Moreover, the studies performed thus far assessing patients' perspectives have been mainly retrospective[6–10].

The use of objective outcome measures strikes to the modern view on clinical research that appropriate judgments on the outcome of therapeutic procedures come from those who experience them from beginning to end i.e., the patients themselves[11]. Hence, the use of patients' reported measures (PROMs) to assess patients' opinion on healthcare has been set as a standard in treatment evaluation. As a result, patient satisfaction ratings have become important indicators for therapeutic efficacy[12].

PROMs have shown that an edentate state is associated with a significant decrease in oral health related quality of life (OHRQoL)[13,14], and that adequate prosthetic treatment results in improvement in OHRQoL and patients' satisfaction[5,13,14]. The introduction of implant supported overdentures has been a great asset in resolving problems related to a maxillary denture[13–15]. Implant placement in the extremely resorbed maxilla usually requires, however, augmentation with extra orally grafted bone. While there is ample evidence that the PROMs are favorable regarding replacement of a conventional maxillary denture with a maxillary overdenture on implants, scarce information is available in terms of how patients experience the bone harvesting procedure enabling maxillary augmentation surgery. Therefore, the aim of this prospective study was to assess patient satisfaction and patient reported morbidity of patients needing calvarial or anterior iliac crest bone harvesting to reconstruct an extremely resorbed edentulous maxilla before being treated with an implant-retained maxillary overdenture.

2 METHODS

2.1. Patient population

A total of 20 consecutive eligible patients was asked to join the study. These patients were referred to the Department of Oral and Maxillofacial Surgery of the University Medical Centre Groningen (UMCG), Groningen, the Netherlands, having problems with wearing an upper denture (pain, mobility, loss of retention). These problems were a result of severe resorption of the edentulous maxilla. Patients were included when insufficient bone volume was available for reliable implant placement, that is, <3 mm bone height in the maxillary sinus area and <2 mm bone width in the anterior maxillary area. The bone height and width were assessed using

cone beam computed tomography (CBCT) scanning. For temporal bone, the thickness in the area between the articular tubercle and the end of the mastoid bone had to be >5mm to allow for harvesting calvarial bone. None of the participants had undergone an operation at the donor site before.

2.2 Design of the study

20 patients gave written consent to participate in the study. Randomization software was applied to divide them into two groups based on the location for harvesting the bone grafts: the anterior iliac crest (n=10) or the calvarium (n=10). All patients were subjected to a bilateral maxillary sinus floor augmentation and reconstruction of the width of the maxilla. The surgeries took place between November 2014 and September 2016. Each patient was followed -up until at least 12 months.

PROMs were assessed at several moments in time (Figure 1). To control for equality between groups and determine improvement in perceived oral health, OHRQoL, denture satisfaction and chewing ability were assessed at baseline and 12 months post-treatment. Furthermore, postoperative pain was assessed during the first 30 postoperative days. At the 12-month follow-up meeting, patient reported satisfaction and donor site related outcomes were assessed too.

The study protocol was reviewed and approved by the medical ethical committee of the UMCG, reference NL48614.042.14. Written consent was obtained from all participants.

2.3 Surgical procedures

For harvesting anterior iliac crest bone, an incision was made from 1 cm behind the anterior superior iliac spine toward posteriorly, following the iliac crest. It was continued sharply to the midcrest, separating the aponeurosis of the fascia lata and the oblique abdominal muscles. By reflecting the iliac muscle sub-periosteally, the bony ilium was exposed. A retractor was used to expose the donor site. Two horizontal and five vertical cuts were made to harvest corticocancellous bone. The upper horizontal cut was placed midcrestal using a reciprocating saw. 4 cm inferior, in the inner table, the other cut was made with a curved osteotome. These were connected by the vertical cuts using a reciprocating saw. After piece-by-piece removal of the corticocancellous bone blocks, additional cancellous bone was harvested with gouges and curettes[2]. To harvest calvarial bone, a full-thickness flap was raised, followed by marking the outer table graft with a burr until the diploe was encountered. With a bone scraper (SafeScraper Twist; META, Reggio Meilia, Italy) a bevel was created through around the calvarial outer table graft to facilitate its removal with a reciprocating saw. The scraper was used to collect copious amounts of cancellous like bone. To remove the graft without breaking,

parallel saw cuts were made in situ[16]. Next, the graft was removed piece by piece. The ensuing defect in the skull was reconstructed with bone cement (Palacos®, Zimmer Biomet, Warsay, Iniana, USA).

All the operations were performed by the same experienced oral and maxillofacial surgeon at the UMCG. After harvesting the calvarial or iliac crest bone, maxillary augmentation surgery was performed according to the procedure according to Raghoebar et al. (2001)[17].

Broad-spectrum antibiotics (amoxicillin/clavulanic acid, 625 mg t.i.d) and non-steroidal anti-inflammatory drugs (ibuprofen, max. 600 mg t.i.d.) were provided for one week post-surgery. Patient instructions included a soft diet and chlorhexidine mouth rinse (1 min, two times daily) for 2 weeks. Two weeks after surgery, the dental prostheses were corrected and the patients were allowed to wear them again.

The implants were placed in the augmented maxilla after a period of 4 months. All the patients were enrolled in a dental hygiene protocol. The final maxillary overdenture was made after a 3 month osseointegration phase.

2.4 Patient reported outcomes

2.4.1 OHRQoL assessment: OHIP-49

OHRQoL was assessed using the validated Dutch version of the Oral Health Impact Profile-questionnaire (OHIP-49) (Slade and Spencer, 1994; Slade, 1998; Van Der Meulen et al., 2008). This 49-item questionnaire assesses improvement or regression in a patient's OHRQoL, enabling an analysis of any changes in OHRQoL over time. The questions are divided into seven domains describing different oral health impact problems: functional limitations, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap. Patients must complete five categories per question (graded 0-4) indicating how frequently a certain situation occurs (never, hardly ever, sometimes, fairly often or very often). A high OHIP-49 score corresponds to a low OHRQoL. In this study, the OHIP scores were analysed according to an ordinal scale. The internal reliability, test/retest reliability and OHIP-49 validity have been previously established[19,21]. The Dutch version of the questionnaire, that has been evaluated for reliability and validity[18], was used for the current study.

2.4.2 Denture satisfaction questionnaire

Patient reported denture satisfaction, including functional problem complaints in general, specific features related to facial and denture aesthetics and accidental lip, cheek, and tongue biting, were assessed using a validated questionnaire[22]. The patients were asked to report the

applicability of 40 denture-related complaints to their situation using a four-point scale (0 = no complaints, 1 = few complaints, 2 = moderate complaints, 3 = severe complaints), with a lower score indicating a higher satisfaction.

2.4.3 Chewing ability questionnaire

Patients' eating ability was assessed by a validated chewing ability questionnaire[23]. This questionnaire focuses on how patients experience eating soft, tough, and hard foods and has three answer options: 0 = good, 1= moderate and 2 = bad. A lower score equals a better outcome as it indicates better chewing ability.

2.4.4 Direct post-operative pain

Each patient was asked to score the postoperative pain felt at the donor site during each of the first 30 days after harvesting surgery was performed. A 10 cm vertical visual analogous scale (VAS-)score was used, with the bottom anchor representing 'No pain' and the top anchor as 'Worst pain imaginable'. Assessments took place at 12 o'clock each day. By measuring the distance (mm) on the 10-cm line between the "no pain" anchor and the patient's mark, the score is determined on a range from 0–100. For interpretation of the scores, the following cut points on the pain VAS were used: no pain (0-4mm), mild pain (5-44mm), moderate pain (45-74 mm) and severe pain (75-100mm).

2.4.5 Patient satisfaction with the procedure and outcomes

A three-item list questioned several aspects of the patient's experience with the procedure. The patient's satisfaction with the end result was assessed using a 10 cm VAS-scale with the bottom anchor representing "very unsatisfied" and the upper anchor "very satisfied". The other two items questioned (yes/no) whether the patient would recommend the procedure to other patients with the same problem and whether the patient would be willing to undergo the same operation if needed. Furthermore, satisfaction with the outcomes was assessed regarding the scar aesthetics at the donor site (yes/no) and whether the altered donor site contour was bothersome (yes/no).

2.4.6 Long-term sequela

Twelve months after the implant-based prostheses' were placed, the patients were seen for the final follow up. They were asked to rate the current pain at the donor site (VAS-score). In addition, the patients were questioned regarding difficulties with wearing clothes (wearing a hat/cap, a belt or a pair of trousers) and difficulties with functional mobility (complaints during walking, climbing stairs or cycling). Patients were asked whether they had perceived such

difficulties during the seven days prior to the follow-up meeting and whether these problems had been present before surgery. If the latter was positive, the results were excluded from the evaluation. The items were formulated as two-choice questions (yes/no).

2.5 Statistical analysis

The data were collected by one observer (ABE). Data management and analysis were performed using SPSS 23.0. Data were tested for normal distribution with a Shiparo-Wilk test and checked visually using a histogram with a distribution curve. If required, the outcomes of a non-normally distributed variable were transformed into a normal distribution using a Log10-transformation. The Student-*t* test, the Mann-Whitney-U test and the Pearson-c^2 test compared the outcomes of the parametric variables, nonparametric variables and the categorical gender variable between groups, respectively. Concerning the outcome data, the Pearson-c^2 test compared dichotomous variables. For the post-operative pain dairy, a mixed ANCOVA was performed. Medians instead of means were calculated for non-normally distributed continuous variables such as the general satisfaction (VAS-score) and questionnaire-scores. A significance level of 0.05 was chosen for all tests.

3 RESULTS

All consecutive eligible patients that were referred to our department between November 2014 and March 2016, and met the inclusion criteria, were willing to join the study. The augmentation surgery resulted in sufficient bone volume for implant placement at the prosthodontically preferred sites in all cases. No peri-operative complications occurred. A total of 44 implants was placed in each group. In each group, one patient lost an implant because of mobility during the osseointegration phase, resulting in a 1-year implant survival rate of 97.7%. The clinical characteristics of both groups are listed in Table 1.

3.1 OHIP-49NL, Denture satisfaction and chewing ability

3.1.1 OHIP-49NL

For both groups, the OHIP-49NL sum scores and scores on all seven domains improved between baseline and 12-months post denture placement (Wilcoxon signed-rank test, p=0.001-0.003, Table 2). The functional limitation and physical disability domains showed the largest improvements whereas psychological discomfort, social disability and handicap improved the least. The OHIP-49-scores showed no significant differences in improvement scores between the groups (Mann-Whitney U-test, u=34.00-49.50, p=0.23–0.98, Table 3).

3.1.2 Denture satisfaction

The scores improved significantly after treatment (median score 61.00 (IQR 56.38,74.30) (Wilcoxon signed-rank test, *p*=0.001, Table 2) and were similar in both groups (Mann-Whitney U-test, u=27.00, *p*=0.09, Table 3).

3.1.3 Chewing ability

Chewing ability improved from 16.00 (IQR 13.00, 18.00) at baseline to 11.00 (IQR 9.00, 13.00) 12 months after overdenture placement (Wilcoxon signed rank-test, *p*<0.0001, Table 2), and the group-outcomes were also similar (Mann-Whitney U-test, respectively u=27.00, *p*=0.09 and u=43.00 *p*=0.61, Table 3).

Table 1. Characteristics of the study group

	Total n = 20	**Anterior iliac crest group n = 10**	**Calvarium group n = 10**	**Comparing groups**	
				Test statistic	***p*-value[1]**
Sex				Pearson-c^2-test	
Male	9	4	5	0.202	1.000
Female	11	6	5		
Number of implants placed					
Participants with 4 implants	10	8	8		
Participants with 6 implants	10	2	2		
Number of implants lost	2	1	1		
	Median (IQR)	**Median (IQR)**	**Median (IQR)**	**Mann-Whitney U**	
Age at implant placement (years)	65.4 (56.4;71.1)	63.5 (56.5;69.3)	68.4 (54.6;72.7)	41.000	0.529
Time between augmentation and implant placement (days)	133 (126;145)	126 (119;133)	140 (131;152)	17.500	0.011

Results are presented as the number or the median (interquartile ranges: IQR).
[1]Exact sig. (2-sided)

Table 2. OHIP-49NL, Denture satisfaction and chewing ability scores before and after treatment

		Anterior iliac crest group n=10		Calvarium group n=10	
Questionnaire	**Max.[1]**	**Pre-treatment Median (IQR)**	**Post-treatment**	**Pre-treatment Median (IQR)**	**Post-treatment**
OHIP-49					
Functional limitations	36	17.4 (15.0;25.3)	3.2(1.1;7.0)	18.0(14.8;24.3)	4.0(1.8;14.5)
Physical pain	36	15.5(11.5;25.5)	2.5(0.8;11.3)	14.5(9.0;20.5)	4.0(1.5;14.5)
Psychological discomfort	20	11.0(6.0;16.5)	0.0(0.0;1.8)	11.5(10.0;16.3)	4.5(0.0;8.3)
Physical disability	36	15.0(9.8;21.0)	0.0(0.0;4.8)	16.5(9.8;25.8)	4.5(0.0;9.5)
Psychological disability	24	7.0(1.0;12.5)	0.0(0.0;1.5)	10.0(6.8;18.3)	2.5(0.0;7.3)
social disability	20	3.5(0.0;8.5)	0.0(0.0;0.0)	3.5(1.5;11.3)	3.0(0.0;5.3)
Handicap	24	4.0(1.0;9.8)	0.0(0.0;0.0)	3.2(0.8;12.3)	0.5(0.0;3.5)
Summary scores OHIP	196	78.8(48.0;125.7)	10.5(2.5;27.7)	77.4(55.5;128.1)	24.3(5.1;57.5)
Denture satisfaction	216	111.1(85.4;126.4)	58.0(55.1;69.9)	90.3(72.3;113.5)	65.8(58.1;78.3)
Chewing ability	27	15.5(12.8;126.5)	9.0(9.0;12.0)	16.0(12.3;20.3)	12.5(9.0;16.2)

[1]*Maximum score possible on test/domain*

Table 3. Score changes following treatment for OHIP-49, denture satisfaction and chewing ability

	Anterior iliac crest group n = 10 Median (IQR)	**Calvarium group n = 10 Median (IQR)**	**Comparing groups Mann-Whitney U**	***p*-value[1]**
OHIP-49				
Functional limitation	13.44(9.66; 20.41)	9.69 (5.50; 15.75)	34.00	0.24
Physical pain	12.00(1.50; 22.75)	5.19 (-2.00; 15.85)	39.00	0.42
Psychological discomfort	11.00(5.50; 13.25)	9.00 (1.75; 12.00)	36.00	0.30
Physical disability	10.50(9.00;19.50)	12.50(0.75;17.50)	43.50	0.64
Psychological disability	5.00(1.00;12.25)	5.00(1.50;11.25)	49.50	0.98
Social disability	2.00(0.00;8.50)	1.50(-0.25;4.00)	39.50	0.44
Handicap	4.00(1.00;9.75)	1.50(0.00;5.25)	34.00	0.23
Summary scores	61.80(26.08;92.14)	51.39(14.67;85.79)	39.00	0.44
Denture satisfaction	39.02(27.95; 70.40)	12.34(4.37; 54.80)	27.00	0.09
Chewing ability	4.50(2.75; 7.50)	5.00(-0.75;7.28)	43.00	0.61

[1]*Exact sig. (2-sided)*

3.4 Direct post-operative pain

For the anterior iliac crest group, the mean VAS-scores for pain ranged from 34.0±14.3 mm (day 2) to 1.0±3.2mm (day 30). For the calvarium group, the highest mean pain score was 32.0±22 (day 3) and this deceased to 0.0±0.0 on day 14 (figure 2). After a Log10-transformation of the data to correct for skewness, a Linear Mixed Model was run to determine to compare the course of pain scores between the treatment groups. There was a significant difference between treatment groups with an estimated effect of 0.09 (standard error=0.015) for the anterior iliac crest group (G=31.3, p=0.00), meaning the pain scores of anterior iliac crest group are higher than the calvarium group scores (F=31.30, p<0.00).

To determine the effect of time and covariates such as age, gender and BMI on the VAS-scores, a repeated measures ANCOVA was run. Mauchly's test of sphericity indicated that the assumption of sphericity had been violated (X^2=0.000, p<0.0005) and therefore, a Greenhouse-Geisser correction (ε=0.11) was used. There was a significant effect of time on VAS-scores, F(3.1;55.3)=32.6, p<0.0005. (Figure 2). Furthermore, an interaction was found between BMI and VAS-scores of the anterior iliac crest group (Greenhouse-Geisser, ε=0.14, F(3.3;26.4)=2.9, p=0.04), but not for the calvarium group (Greenhouse-Geisser, ε=0.084, F(2.4;19.5)=0.1, p=0.93)

3.5 Patients' satisfaction

The results on general patient satisfaction are listed in Table 4. All the participants (n=20) confirmed that they would undergo the same procedure again if needed and that they would recommend the procedure to others. The overall level of satisfaction with the end result was high with a median of 93 (IQR 86, 99) on a 100 mm VAS-scale (n=20).

On separating the results according to treatment group, the median VAS-score of the calvarium group was 87mm (IQR 74, 100) and of the anterior iliac crest group, 95mm (IQR 90, 100) (Mann Whitney U-test, U=34.5, p=0.247). The VAS-scores on satisfaction with the end result contained one outlier (VAS-score: 4mm) in the calvarium group. The final appearance of the prosthetic device did not match this patient's expectations. The complaint was directed at the prosthetic technique and not at the surgical procedure. On excluding this case from the analysis, the remaining scores provided a median score of 93mm (IQR 86, 99) for the entire study group (n=19) and 89mm (IQR 81, 100) for the calvarium group (n=9). There was no significant difference either when the median VAS-scores were compared without the outlier (Mann-Whitney U-test, U=34.00, p=0.400).

3.5.1 Donor site appearance

Regarding changes at the donor site, one patient from each treatment group noticed an alteration in the contour. Two patients from the anterior iliac crest regarded the scar aesthetics as being acceptable instead of satisfactory (Pearson c^2-test, 2.222, *p*-value = 0.474).

3.6 Long-term sequelae

3.6.1 Pain

The median VAS-scores for current donor site pain at the calvarium and anterior iliac crest site were 1mm (IQR 0, 1mm) and 2mm (IQR 1, 3), respectively. (Mann Whitney U-test, U=30.500, *p*=1.000 for the current pain at donor site) (Table 5).

3.6.2 Difficulties in daily functioning

None of the participants in the calvarium group reported difficulties with wearing clothes or functional mobility (Table 5). One participant in the anterior iliac crest group reported difficulties with wearing clothes. Furthermore, two participants from the anterior iliac crest group noted they had problems with functional mobility. One of these two patients reported pre-surgical problems with walking as well. It was unclear whether the complaints were stable or had worsened or improved. The differences between the groups were not statistically significant (Pearson *c*2-test, *p*-values 0.31-1.00, Table 2).

Table 4. Patient reported outcomes on general satisfaction regarding the treatment procedure

	Iliac crest group *n* = 10 Median (IQR)		**Calvarium group *n* = 9[1] Median (IQR)**		**Comparing groups**	
					Mann-Whitney U	***p*-value[2]**
How satisfied are you concerning the end result? (VAS-score in mm)	95(90;95)		87(74;100)		34.500	0.247[2]
	Yes	*No*	*Yes*	*No*		
Would you recommend the procedure to other patients with the same problem?	10	0	10	0		
Would you be willing to undergo the same operation when needed?	10	0	10	0		

Results are presented as the number or the median (interquartile ranges: IQR).
[1]*After excluding one outlier from the calvarium group who reported a VAS-score of 4mm*
[2]*Exact sig. (2-sided)*

Table 5. Patient reported outcomes on donor site pain (VAS-score), difficulties in daily functioning and satisfaction with the procedure; assessed after bone graft harvesting surgery

	Iliac crest group *n* = 10		**Calvarium group *n* = 10**		**Comparing groups**	
	Median (IQR)		**Median (IQR)**		**Mann-Whitney U**	***p*-value[1]**
Donor site pain (VAS-scores)						
How would you rank the current pain felt at the donor site?	2(1;3)	1(0;1)			30.500	1.000
Donor site related complaints in daily functioning	Yes	Yes	No	No	Pearson-c[2] test	
During the past week, did you perceive any of the following						
Headache	2	2	8	8	.000	1.000
Difficulties with wearing cloths[2]	1	0	10	9	1.053	0.305
Difficulties with functional mobility [3,4]	1	0	10	9	1.053	0.305
Are you satisfied with the scar aesthetics at the donor site?	8	10	0	2	2.222	0.474
Do you consider the altered contour of the donor site bothersome?	1	1	9	9	0.000	1.000

Results are presented as the number or the median (interquartile ranges: IQR).

[1]*Exact sig. (2-sided)*

[2]*Difficulties with wearing daily cloths such as a hat, cap, belt or pair of trousers*

[3]*Difficulties with getting around in daily living, such as with walking, climbing the stairs or cycling*

[4]*Statistical test performed exclusive of one case with pre-surgical difficulties on functional mobility*

FIGURES

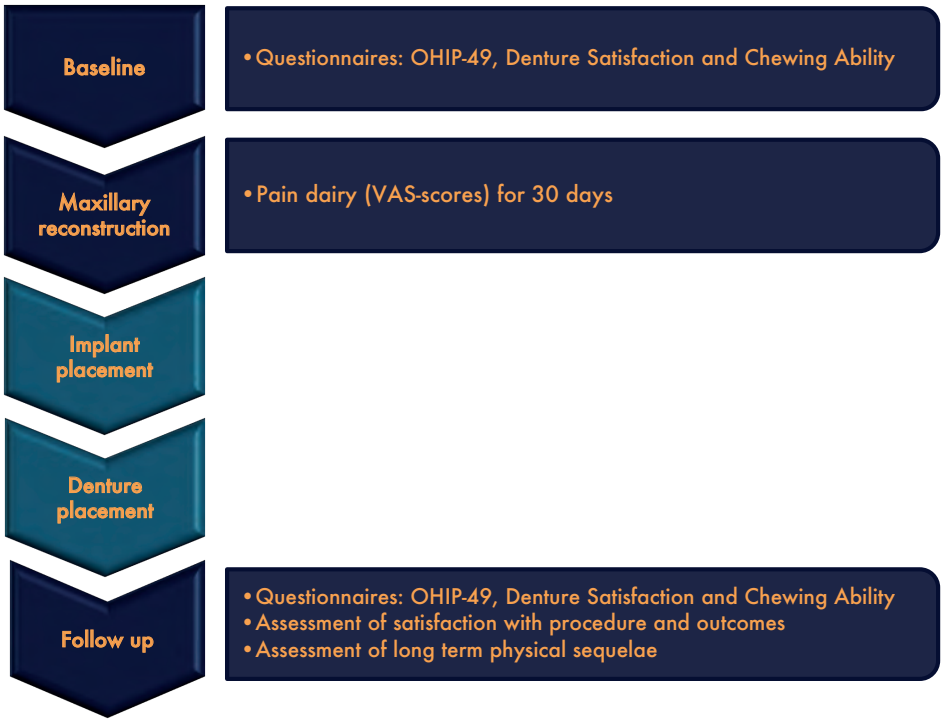

Figure 1. The PROMS were assessed at pre-defined steps in the treatment program of an individual participant. First, when a participant was included for the study but before an intervention had taken place, the OHIP-49, Denture Satisfaction and Chewing Ability questionnaires were administered to determine the baseline level of oral health related quality of life, satisfaction with the current denture and perceived ability to chew food, respectively. Next, directly following the reconstruction surgery that included the bone graft harvesting from either calvarium or anterior iliac crest, the post-operative pain was assessed by asking participants to report the perceived pain at donor site on a 100 mm VAS-score for 30 days. Following a four months osseointegration phase, the implants were placed in the reconstructed maxilla. Another four months later, the patients received their implant retained denture. No PROMs were assessed during these two steps as they were not related to the bone graft harvesting surgery. Finally, at a 12-months follow up meeting, again the OHIP-49, Denture Satisfaction and Chewing Ability questionnaires were administered again to measure improvement or decrease in scores. Moreover, patient satisfaction with the procedure and the outcomes were assessed as well as presence of long-term physical sequelae resulting from the bone graft harvesting procedure.

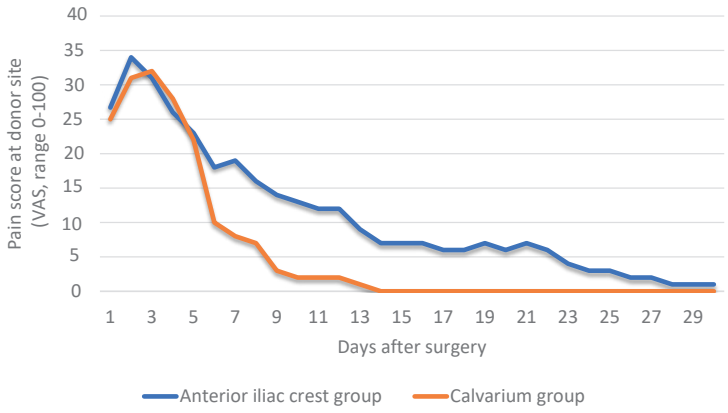

Figure 2. During the first 30 days following maxillary reconstruction with either calvarial (n=10) or anterior iliac crest (n=10) bone grafts, participants scored the pain felt at donor site using a 100 mm VAS-scale ('0' represents 'no pain' and '100' represents 'worst pain ever'). For the anterior iliac crest group, the mean VAS-scores for pain ranged from 34.0±14.3 mm (day 2) to 1.0±3.2mm (day 30). For the calvarium group, the highest mean pain score was 32.0±22 (day 3) and this deceased to 0.0±0.0 on day 14. A Linear Mixed Model determined a significant difference between treatment groups with an estimated effect of 0.09 (standard error=0.015) for the anterior iliac crest group (G=31.3, *p*=0.00), meaning the pain scores of anterior iliac crest group are higher than the calvarium group scores (F=31.30, *p*<0.00).

5 DISCUSSION

PROMs are a core aspect in treatment program evaluations[24]. Therefore, patients' appreciation of extra oral bone graft harvesting, used for pre-implant augmentation of the edentulous maxilla, was assessed. The bone graft harvesting surgery itself and the complete procedure enabled by the bone grafting showed a high patient reported satisfaction with the course and its results. The PROMs imply a successful treatment, and apart for the higher post-operative pain scores following harvesting anterior iliac crest bone the outcomes are similar for calvarial and iliac crest bone harvesting.

This study's results are in accordance with previous findings in literature on OHRQoL, denture satisfaction and chewing ability, procedure related satisfaction and long-term donor site related outcomes[9]. The prospective, controlled design of this study enables confirmation of the suggested similarites between the procedures from a patients point of view. For clinical decision making, the interaction between direct post-operative pain and BMI can be taken into account. Futhermore, the minor differences in satisfaction with the outcomes at donor site and problems with physical mobility should be considered as well.

Another previously described phenomenon was found: the surgery comes a long with moderate direct post operative pain and with high levels of satisfaction[14]. High pain levels following extra oral bone harvesting[8], especially when it comes the the anterior iliac crest[3,25], is frequently mentioned as a major disadvantage from a patients perspective and the coexistence with high satisfaction with the procedure is a frequent subject of debate[26]. This discussion might result from the way the patient satisfaction construct is interpreted. A complete model of this construct can explain this coexistence. Patient satisfaction covers all aspects of care quality, that is appropriate access to health services, provision of health information, relationship between patient and health care staff, participation in making choices regarding health treatment, satisfaction with the treatment provided, effectiveness of treatment including the extent to which the treatment meets the patient's expectations of care, and general satisfaction[27]. Thus, a patient's satisfaction with treatment is not dictated exclusively by physical parameters[27] and therefore, it can be high despite moderate post-operative pain.

This study assessed satisfaction at the final follow up to assure the patients' appreciation would entail each step in the treatment program. However, the course that patients' satisfaction makes was not registered. Furthermore, not all dimensions of patients' satisfaction were assessed as this study focused on the patients' appreciation of the technical procedure. Future research on these two points can help improving the treatment program.

To conclude, prosthetic rehabilitation programs, encompassing maxillary augmentation with extra-oral bone grafts from either the calvarium or anterior iliac crest, are reliable pre-implant surgery procedures for extremely resorbed maxilla cases, as they are associated with high patient satisfaction in terms of both treatment procedure and end results. As patient satisfaction is determined by the patient's expectations and provision of information, an explanation of the procedure and the course of postoperative complaints deserves special attention in clinical practice.

LIST OF ABBREVIATIONS

PROM:	Patient Reported Outcome Measures
OHRQoL:	Oral Health Related Quality of Life
OHIP-49NL:	Oral Health Impact Profile, 49 item version in Dutch
UMCG:	University Medical Centre Groningen
CBCT:	Cone Beam Computed Tomography
VAS:	Visual Analogues Scale
IQR:	Inter quartile range

6 DECLARATIONS

Ethical approval and patient consent

The study protocol was approved by the Medical Ethics Committee of the University Medical Centre of Groningen (reference number NL48614.042.14). Written consent was obtained from all participants.

Availability of data

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Authors' contribution

JS and GMR conceived and planned the work. DEW, CG and AV contributed to analysis and interpretation of the data for the work. DEW wrote the manuscript with consultation of CG, JS, AJ and GMR. DEW, CG, JS, AJ and GMR provided critical feedback and helped shape the research, analysis and manuscript. DEW, CG, JS, AJ and GMR approved the current version to be published and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any parts of the work are appropriately investigated and resolved.

Acknowledgements

The assistance of Mrs A. Bezema in the collection of all questionnaires and data is greatly appreciated.

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