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Maxillary implant overdentures retained by use of bars or locator attachments: 1-year findings from a randomized controlled trial

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ABSTRACT

Purpose: Comparison of outcomes of maxillary implant overdentures retained by use of either locator attachments or bars in a 1-year randomized controlled trial.

Methods: Fifty edentulous participants received four maxillary implants. They were allocated to two groups (n = 25) differing in type of prosthetic attachment used to retain the maxillary prosthesis: either locator attachments or bars were applied. After one year, implant and overdenture survival was assessed. Peri-implant hygiene (Plaque-index, presence of calculus), soft tissue conditions (Gingiva-index, Sulcus Bleeding-index and pocket probing depth) and patient satisfaction (oral health impact profile (OHIP-49), denture complaints questionnaire and general satisfaction score (GSS)) were compared. The peri-implant bone level was estimated using intra-oral radiographs (student T-test).

Results: Implant survival was 96.7% in the locator group and 97.9% in the bar group. No overdentures had to be remade. Patient satisfaction was significantly greater in the bar group when rated by OHIP-49 sum score and by GSS. When comparing the denture complaints questionnaire and the separate OHIP-49 item scores, no significant difference was found. There was not a significant difference in hygiene and soft tissue conditions. Marginal bone loss was estimated 0.58 ± 0.71 mm for locators and 0.31 ± 0.47 mm for bars.

Conclusions: Maxillary overdentures on four implants retained by bars or locators were compared. Bone loss was within an acceptable range for both groups after 1 year. However, less bone was lost in the bar group. Even though both treatment options improved patient satisfaction, bars seem to be particularly beneficial with regard to OHIP-49 sum score.

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1. Introduction

Implant treatment is the current choice to eliminate problems of conventional complete dentures wearers. Implants give support, improve retention and stability and reduce or eliminate pain during eating [1–3]. Implants clearly improve patient satisfaction, and after an adaption period, also improve masticatory performance [4,5].

Various systems for attachment have been successfully used for implant-supported overdentures. These systems can be classified as bars and solitary attachment systems. Dental practitioners and technicians make a choice based on their experience and clinical outcomes [6].

Overdentures on bars offer many advantages for patients with a severely resorbed edentulous ridge. Bars are seen as a very interesting option for mandibular overdentures due to their good retention capacity and low maintenance costs [7]. The relatively high costs for manufacturing are a disadvantage of the bar system. Whereas it is assumed that a solitary attachment system is less expensive than bar attachments [8,9]. Additionally, some evidence indicates that solitary attachments are easier for the patient to clean than bars with the consequence that peri-implant soft tissues and bone are healthier as a result [10–12].

Solitary attachments come with various matrix systems. Design and choice of material for the retentive part influence friction and wear and possible need for replacement [13]. Some authors have reported that ball attachment systems needed more aftercare than bar attachments [14,15]. However, it is said that solitary attachment systems have the advantage that replacement of the matrix system can be done more quickly compared with bars, the procedures are more straightforward and can mostly be done chair-side [16].

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CONSORT 2010 Flow Diagram

Fig. 1. Algorithm of participant selection procedure.

Looking at solitary systems, ball attachments have resulted in more prosthodontic complications than locator attachments [17], although no difference was seen in patient satisfaction and peri-implant hard and soft tissue outcomes between ball and locator attachments after one year of function [18]. In the mandible, the locator attachment is therefore often preferred due to its low costs, good oral hygiene and easy handling. However, few studies have made a direct comparison between bars and locator attachments for implant overdentures in the edentulous maxilla. If more was known about the treatment outcomes of both options, then evidence-based choices could be made about which attachment system is preferred. Therefore a 1-year, prospective randomized controlled trial was conducted to compare outcomes of maxillary implant overdentures retained by use of either locator attachments or bars. Implant survival, peri-implant soft tissue health, marginal bone changes, and patient satisfaction were measured before and at regular intervals during the one-year follow-up.

2. Materials and methods

Between January 2013 and January 2016, all eligible fully edentulous participants were invited to participate in a randomized controlled trial. These participants were referred to the Department of Oral and Maxillofacial Surgery (University Medical Center Groningen, The Netherlands (UMCG)) because they experienced lack of retention and stability of the maxillary conventional denture. Participants had to be edentulous in the maxilla for at least one year and having sufficient bone volume in the anterior region of the

maxilla to place four implants. Participants also had to be fully edentulous in the mandible for at least one year and either having a conventional mandibular denture or a two-implant mandibular overdenture. Cone beam computed tomography (CBCT) was used to assess volume of bone volume in the maxilla. Exclusion criteria were American Society of Anaesthesiologists score (ASA score) $\geq$ III [19] as well as smoking, former radiotherapy in the head and neck region, former pre-prosthetic surgery or loss of implants in the maxilla.

Fifty consecutive participants were included in this randomized controlled trial (Fig. 1). All subjects received an oral and written study explanation. Signed informed consent was obtained from each participant. The Medical Ethical Committee of the UMCG gave approval for the study (ABR NL43293.042.13) and the study was registered in the Netherlands National Trial Register (NTR3813). The participants were randomly assigned to one of the two groups by opening sealed envelopes: the locator group (participants receiving maxillary overdentures on locator attachments, (n = 25)) or the bar group (participants receiving maxillary overdentures on a bar attachment system, (n = 25)).

2.1. Surgical procedure

All participants received four dental implants, diameter of 3.5 mm (NobelActive Narrow Platform (Nobel Biocare AB, Gothenburg, Sweden), in the maxilla. Participants, not already having implants in the mandible received two implants (Nobel-Replae Select TC (Nobel Biocare AB)) placed in the same session as the ones in the maxilla (17 participants in the locator group and 3

participants in the bar group). Implants in the maxilla were placed, guided by a surgical stent, at crestal bone level in predefined positions (positions 13, 11, 21, 23) in a two-stage surgical protocol. Dehiscences or fenestrations of the implants were covered with bone from the maxillary tuberosity and subsequently with organic bovine bone (Bio-Oss, Geistlich Pharma AG, Wolhusen, Switzerland), and covered with a resorbable membrane (Bio-Gideivoc, Geistlich Pharma AG). In case the most distally placed implants partially extended in the anterior region of the sinus, sinus floor elevation surgery was performed using the lateral window technique [20], with bone harvested from the tuberosity and mixed with organic bovine. The lateral window was covered by a resorbable collagen membrane. All participants, irrespective whether an augmentation was performed or not, had amoxicillin, to start one hour preoperatively (3 g Clamoxyl, GlaxoSmithKline, Utrecht, the Netherlands) orally and continuing (500 mg Clamoxyl; GlaxoSmithKline) for seven days, three times daily. Next to this, patients had to rinse with 0.2% chlorhexidine (Corsodyl; GlaxoSmithKline).

The patient was not allowed to wear the old prosthesis for two weeks after implant placement. After this time period, the prosthesis was adjusted with a resilient lining material (Soft liner; GC Corp., Tokyo, Japan). After a 3-month osseointegration period, second stage surgery was performed by placing healing abutments and the prosthetic procedure was initiated. Healing time between augmented and non-augmented participants did not differ.

2.2. Prosthetic procedure

After the second stage surgery, a preliminary impression was made by using a stock metal tray (Schreinemakers; Clan Dental Products, Maarheeze, the Netherlands) and irreversible hydrocolloid (Cavex CA 37; Cavex Holland BV, Haarlem, the Netherlands). Individual impression trays of acrylic resin (Lightplast base plates; Dreve Dentamid GmbH, Unna, Germany) were made. Screw-retained impression copings were attached to the implants and a complete arch impression was made with polyether material (Impregum F; 3M ESPE, St. Paul, MN, USA).

The occlusal vertical dimension and maxillo-mandibular relationship was recorded with composite resin record bases (Lightplast base plates; Dreve Dentamid GmbH) with wax rims. Acrylic resin teeth (Ivoclar SR Orthotyp DCL and Ivoclar Vivodent PE, Ivoclar Vivadent AG, Schaan, Liechtenstein) were placed on the record base for a trial arrangement, following a bilateral balanced occlusion concept.

The final superstructure for the bar group consisted of a milled titanium egg-shaped bar with distal extensions, screw-retained to multi-unit abutments (Nobel Biocare AB) (Fig. 2) and an overdenture with built-in cobalt chromium reinforcement structure and gold retentive clips. The final superstructure for the locator group consisted of four locator attachments (Fig. 3) and an overdenture with built-in cobalt chromium reinforcement structure with locator denture caps and nylon locator males. The nylon male elements are available in different color-coded designs with different retention forces (blue 6.7 N [light], pink 13.4 N [medium], and clear 22.3 N [strong]). In the present study, all participants were initially provided with pink inserts (13.4 N; medium force), providing possibilities for strengthening or loosening the retention force. Overdentures in both groups were designed without palatal coverage of the maxilla. Participants were instructed in hygiene procedures associated with the dentures and superstructures and scheduled for routine maintenance recalls.

2.3. Outcome measures

Primary outcome measure in the study was change of radiographic peri-implant bone level. Implant survival, overdenture

Fig. 2. Intra-oral view of a patient with bars.

Fig. 3. Intra-oral view of a patient with locators.

survival, peri-implant hygiene (Plaque-index, presence of calculus), soft tissue conditions (Gingiva-index, Sulcus bleeding-index and pocket probing depth), patient satisfaction (Dutch oral health impact profile with 49 questions (OHIP-49), denture complaints questionnaire and general satisfaction score (GSS) were secondary outcome measures. Evaluation was one month after placement of the overdenture (T1) and after 12 months of loading (T12). Patient satisfaction was evaluated before treatment (T0) and at T12.

2.3.1. Change of radiographic peri-implant bone level

Standardized intra-oral radiographs were made at T1 and T12 (Figs. 4 and 5). The radiographs were taken with an Extension Cone Paralleling Photostimulable Phosphor holder (RINN, Dentsply, Elgin, IL, USA). Linear measurements using computer software (Biomedical Engineering, University Medical Center Groningen, the Netherlands) were performed on the images with a reference line for bone level evaluation at the neck of the implant. Images were calibrated using the implant diameter (3.5 mm). Measurements were done at mesial and distal side of the implant and bone height change was defined as the difference in bone height between the radiograph taken at T1 and the radiograph taken at T12.

2.3.2. Implant and overdenture survival

Implant survival was defined as the percentage of implants initially placed, being still present and not mobile at the follow-up

Fig. 4. Panoramic radiograph of a patient with bars.

Fig. 5. Panoramic radiograph of a patient with locators.

evaluation. A percussion test was done to assess implant mobility. For the bar group, this was assessed after removal of the bar. Survival of maxillary overdentures was defined as the percentage of overdentures initially placed and still present at the follow-up evaluation.

Technical complications were scored at any time after placement of the overdenture. Technical complications included: loosening of denture teeth, replacement/tightening of nylon caps/gold clips due to retention loss on request of the patient and adaption of denture edges because of pressure ulcers.

2.3.3. Oral hygiene and soft tissue condition

The index of Loe and Silness [21] was used to score the presence of plaque (score 0: no detection of plaque, score 1: plaque can be detected by running a probe across the smooth marginal surface of the abutment and implant, score 2: plaque can be seen by the naked eye, score 3: abundance amount of plaque).

The presence of calculus was scored with score 0, being absence of calculus and score 1, being presence of calculus.

For health of peri-implant mucosa, the modified Loe and Silness index [21] was used (score 0: normal peri-implant mucosa, score 1: mild inflammation; slight change in colour, slight oedema, score 2: moderate inflammation; redness, oedema and glazing, score 3: severe inflammation; marked redness and oedema, ulceration).

The index of Mombelli et al. [22] was used to score bleeding tendency (score 0: no bleeding when using a periodontal probe, score 1: isolated bleeding spots visible, score 2: a confluent red line of blood along the mucosa margin, score 3: heavy or profuse bleeding).

At four sites of each implant (mesial, labial, distal, and lingual) probing depth was measured by using a manual periodontal probe (Williams Colour-Coded Probe; Hu-Friedy, Chicago, IL, USA); the distance between the marginal border of the mucosa and the tip of the periodontal probe was noted as probing depth.

2.3.4. Patient satisfaction

Patient satisfaction was assessed using a validated questionnaire [23]. This questionnaire, focussing on denture complaints, consisted of 54 questions. Each question could be addressed to one of six scales.

The six scales are:

- A Nine items addressing functional problems of the lower denture
- B Nine items addressing functional problems of the upper denture
- C Eighteen items addressing functional problems complaints in general
- D Three items addressing facial aesthetics
- E Three items addressing accidental lip, cheek, and tongue biting ("neutral space")
- F Twelve items addressing aesthetics of the denture

The severity of a complaint could be expressed on a four-point rating (0: no complaints, 1: little, 2: moderate, 3: severe complaints).

All participants were also requested to fill out the OHIP-49. This questionnaire consists of 49 items covering seven domains: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap. The severity of a complaint could be expressed on a five-point rating (0: never, 1: rarely, 2: sometimes, 3: often, 4: very often). The total OHIP-49 score ranges between 0 and 196 points. The separate domain scores give an impression of the level at which the effects of the oral problem manifest itself. A lower score indicates a better oral health related quality of life (OHRQoL). Next to these questionnaires, the participants stated their overall denture satisfaction (GSS) with the upper or lower denture a ten-point rating scale (1: very bad to 10: excellent). The participants evaluated their satisfaction at T0 and T12.

2.4. Sample-size estimation

A statistical power analysis was carried out for sample size estimation, based on an estimation of a difference between the groups of 0.4 mm in marginal bone loss as a relevant difference. For the standard deviation (SD) data from the systematic review about overdentures done by Slot et al. [24] was used (the used SD for the power analysis was 0.5 mm). With an $\alpha = 0.05$ and power = 0.85, the calculated sample size was for between group comparison is $n = 46$ (GPower 3.1 [25]). A sample size of 50 was determined, taking into account possible loss to follow-up.

2.5. Data analysis

The normality of the data was assessed using the Shapiro–Wilk test. Except for general satisfaction scores and clinical indices, all data was normally distributed. Inter-group differences with regard to the marginal bone loss and probing depth (continuous data) were analysed using the student T-test. Also, inter-group differences with regard to the OHIP-49 and denture questionnaire scores were analysed using the student T-test. Even though these questionnaires with Likert scales produce ordinal data, when a Likert scale is symmetric and equidistant, it may nevertheless approximate an interval-level measurement. And if interval nature is assumed for a comparison of two groups, the paired samples t-test is not inappropriate [26]. This also facilitates comparison with other studies, since most authors present their data this way.

Intra-group differences for the scores of the marginal bone loss, probing depth, OHIP-49 and denture questionnaire scores between T0 and T12 were analysed with paired samples t-tests.

The results of each group's general satisfaction scores and clinical indices (ordinal data, not normally distributed) were

Table 1. Baseline characteristics of the locator and bar group.

	Locator (n = 25)	Bar (n = 25)
Mean age in years (SD, min. – max.)	60.1 (8.6, 37.5–75.0)	63.8(5.4, 53.0–72.6)
Gender (male/female)	13/12	13/12
Sinus lift (patients/sinuses)	9/18	7/14
Lateral augmentation		
Fenestration coverage (impl. with/without)	6/94	7/93
Coverage of implant margin (impl. with/without)	8/92	13/87
Median plaque-index (Q1–Q3)	0 (0–2)	1 (0–2) ^a
Median calculus-index (Q1–Q3)	0 (0–0)	0 (0–0) ^a
Median gingival-index (Q1–Q3)	0 (0–1)	0 (0–1) ^a
Median bleeding-index (Q1–Q3)	1 (0–1)	0 (0–1) ^a
Mean probing depth in mm (SD)	3.7 (1.0)	4.1 (0.9) ^{a,b}

Differences between study groups were tested with the ^a: Mann–Whitney U test or the ^b: independent Student's t-test.

^{**} $p < 0.01$.

Table 2. Mean values and standard deviations (SD) of radiographic bone loss in mm for the locator and bar groups, and frequency distribution of bone loss 1 year after placement of the overdenture.

	Locator	Bar	
Mean (SD)	0.58 (0.71)	0.31 (0.47)	$p = 0.004^{**}$
0–0.5 mm	55.9%	71.4%	
>0.5–1.0 mm	17.2%	18.4%	
>1.0–1.5 mm	17.2%	6.1%	
>1.5–2.0 mm	6.5%	3.1%	
>2.0 mm	3.2%	1.0%	

Differences between study groups were tested with the independent Student's t-test.

^{**} $p < 0.01$.

analysed with a Wilcoxon Matched Pairs Signed Ranks test. Inter-group differences were analysed by using the independent samples Mann–Whitney U test.

A p -value of less than 0.05 was considered statistically significant. Pairwise deletion was used for missing data and inter-group comparisons. List-wise deletion was used for missing data and intra-group comparisons. All analyses were performed with SPSS 23.0 software (SPSS, Inc., Chicago, IL, USA).

3. Results

Characteristics at baseline of the study groups are shown in Table 1. Two participants died before T12 and one patient moved without leaving an address. Consequently, 47 participants were present at the 1-year follow-up evaluation: 23 participants in the locator group and 24 participants in the bar group (Fig. 1).

3.1. Change of radiographic bone level

The mean loss of peri-implant marginal bone between T1 and T12 was 0.58 ± 0.71 mm for the locator group and 0.31 ± 0.47 mm for the bar group. The mean bone loss (Table 2) differed significantly between the groups ($p = 0.004$, mean difference 0.26 ± 0.09 mm, 95% CI [0.09–0.43]). An additional sub analysis was done for implants that were augmented at the margin of the implant during implant placement and those that were not. No statistical significant differences were found between augmented and non-augmented implants. For the locator group the mean loss of peri-implant marginal bone between T1 and T12 was 0.55 ± 0.71 mm and 0.86 ± 0.65 mm for the

Table 3. Median change from baseline to the 1 year follow-up for plaque-index, calculus-index, gingival-index, bleeding-index, and mean change for probing depth.

Median change from baseline	Locator group (n = 23)	Bar group (n = 24)
Plaque-index (Q1–Q3) Score 0–3	0 (–1–1)	0 (–1–1) ^a
Calculus-index (Q1–Q3) Score 0–1	0 (0–0)	0 (0–0) ^a
Gingival-index (Q1–Q3) Score 0–3	0 (0–1)	0 (–1–0) ^a
Bleeding-index (Q1–Q3) Score 0–3	0 (0–1)	0 (–1–0) ^a
Mean change in probing depth in mm (SD)	0.4 (1.3)	0.3 (1.2) ^b

Differences between study groups were tested with the ^a: Mann–Whitney U test or the ^b: the independent Student's t-test.

No time-dependent significant changes in these indices were found. The probing depth increased significantly for both groups.

non-augmented and augmented implants, respectively ($p = 0.232$). And for the bar group the mean loss of peri-implant marginal bone between T1 and T12 was 0.29 ± 0.46 mm and 0.64 ± 0.57 mm for the non-augmented and augmented implants, respectively ($p = 0.083$).

3.2. Implant and overdenture survival

During the osseointegration period three implants were lost in three participants of the locator group. Because an overdenture could still be placed on the remaining implants, it was decided not to replace the implants. One patient asked for a replacement of the lost implant after three months of functioning with the three-implant overdenture. In the bar group, two implants in two participants were lost during the osseointegration period. Again, there was no need to replace the lost implants. Thus, one-year post loading survival rate of implants was 96.7% in the locator group and 97.9% in the bar group. There was no significant difference between the survival distributions (log rank test).

One year after implant placement, no overdentures had failed. This results in an overdenture survival rate of 100% for both groups. After overdenture placement no abutments disconnected. In the bar group one denture tooth got loose after 1.5 month. Two patients requested tightening of the gold retention clips after 6 and 6.5 month. Three patients requested replacement of the nylon caps after 4, 5.5 and 7 months. After adaptations done in the first after care sessions right after placement of the overdenture, no adaption of denture edges because of pressure ulcers were done. There were no statistically significant differences between the groups with regard to complications.

3.3. Oral hygiene and soft tissue parameters

Median scores of the indices for plaque, calculus, gingiva, and bleeding at the T1 were low and did not differ significantly between both groups (Table 1). Also there was no difference between the groups at T12. The median change from baseline for the indices is shown in Table 3. There were no statistically significant differences between the groups with regard to the amount of change for the clinical indices.

Mean probing depth was 3.7 ± 1.0 mm for the locator group and 4.1 ± 0.9 mm for the bar group at T1 (Table 3), which was significantly different between the groups ($p = 0.006$, independent Student's T-test, mean difference 0.4 ± 0.1 mm 95% CI [0.1–0.7 mm]). At T12 the probing depth increased significantly for both groups ($p = 0.002$ for the locator group and $p = 0.009$ for the bar group (paired samples-T test)). There was no significant difference between the groups with regard to the probing depth at T12.

Table 4. Mean and standard deviation (SD) of the outcomes of the OHIP-NL and subscales, mean score of scales concerning denture complaints (possible range 0–3) and median and inter-quartile range (Q1–Q3) of the general satisfaction scores (GSS) before and after treatment. A comparative inter-group analysis.

	Pre-treatment		Comparative analysis	1 year		Comparative analysis
	Locator (n = 25)	Bar (n = 25)		Locator (n = 23)	Bar (n = 24)	
Functional limitation (SD)	19.0 (7.4)	18.2 (8.5)	ns ^a	8.7 (7.6)	6.1 (1.1)	ns ^a
Physical pain (SD)	17.8 (8.7)	17.5 (8.1)	ns ^a	5.4 (6.1)	4.7 (5.8)	ns ^a
Psychological discomfort (SD)	11.1 (5.1)	8.4 (6.7)	ns ^a	4.9 (5.6)	3.3 (4.4)	ns ^a
Physical disability (SD)	17.7 (10.1)	15.2 (7.6)	ns ^a	6.5 (7.6)	4.3 (8.1)	ns ^a
Psychological disability (SD)	8.4 (7.5)	7.4 (6.2)	ns ^a	3.1 (5.4)	1.6 (2.9)	ns ^a
Social disability (SD)	6.9 (6.2)	5.0 (4.5)	ns ^a	2.4 (4.6)	1.0 (2.6)	ns ^a
Handicap (SD)	8.3 (6.6)	5.5 (5.2)	ns ^a	2.9 (5.4)	1.6 (4.0)	ns ^a
Total OHIP-NL49 score (SD)	88.9 (43.7)	75.8 (38.0)	ns ^a	36.6 (36.7)	18.4 (17.5)	p = 0.036 ^a
Functional complaints about upper denture (SD)	1.7 (0.9)	1.6 (0.7)	ns ^a	0.3 (0.5)	0.2 (0.2)	ns ^a
Functional complaints in general (SD)	1.4 (0.7)	1.0 (0.6)	p = 0.025 ^a	0.3 (0.5)	0.1 (0.2)	ns ^a
Facial aesthetics (SD)	1.4 (1.0)	1.0 (1.1)	ns ^a	0.5 (0.7)	0.3 (0.6)	ns ^a
"Neutral Space" (SD)	0.7 (0.9)	0.5 (0.6)	ns ^a	0.3 (0.5)	0.4 (0.6)	ns ^a
Aesthetics (SD)	0.4 (0.6)	0.1 (0.2)	p = 0.048 ^a	0.1 (0.3)	0.1 (0.1)	ns ^a
General satisfaction score upper denture (SD)	4 (1–6)	4 (2–6)	ns ^b	8 (7–9)	9 (8–10)	p = 0.041 ^{a,b}
General satisfaction score lower denture (SD)	4 (2–7)	8 (6–9)	p = 0.001 ^{a,b}	8 (7–8)	8 (7–10)	ns ^b

Differences between study groups were tested with the ^a: independent t-test or ^b: Mann-Whitney U test.

^{*} p < 0.05. ^{**} p < 0.01.

Table 5. Mean and standard deviation (SD) of the total score of the OHIP-NL and subscales, mean score of scales concerning denture complaints (possible range 0–3) and median and inter-quartile range (Q1–Q3) of the general satisfaction scores (GSS) before and after treatment. A comparative intra-group analysis.

	Locator group		Comparative analysis	Bar group		Comparative analysis
	Pre-treatment (n = 25)	1 year (n = 23)		Pre-treatment (n = 25)	1 year (n = 24)	
Functional limitation (SD)	19.0 (7.4)	8.7 (7.6)	p < 0.001 ^{***a}	18.2 (8.5)	6.1 (1.1)	p < 0.001 ^{***a}
Physical pain (SD)	17.8 (8.7)	5.4 (6.1)	p < 0.001 ^{***a}	17.5 (8.1)	4.7 (5.8)	p < 0.001 ^{***a}
Psychological discomfort (SD)	11.1 (5.1)	4.9 (5.6)	p < 0.001 ^{***a}	8.4 (6.7)	3.3 (4.4)	p < 0.001 ^{***a}
Physical disability (SD)	17.7 (10.1)	6.5 (7.6)	p < 0.001 ^{***a}	15.2 (7.6)	4.3 (8.1)	p < 0.001 ^{***a}
Psychological disability (SD)	8.4 (7.5)	3.1 (5.4)	p = 0.002 ^{***a}	7.4 (6.2)	1.6 (2.9)	p < 0.001 ^{***a}
Social disability (SD)	6.9 (6.2)	2.4 (4.6)	p = 0.001 ^{***a}	5.0 (4.5)	1.0 (2.6)	p < 0.001 ^{***a}
Handicap (SD)	8.3 (6.6)	2.9 (5.4)	p < 0.001 ^{***a}	5.5 (5.2)	1.6 (4.0)	p < 0.001 ^{***a}
Total OHIP-NL49 score (SD)	88.9 (43.7)	36.6 (36.7)	p < 0.001 ^{***a}	75.8 (38.0)	18.4 (17.5)	p < 0.001 ^{***a}
Functional complaints about upper denture (SD)	1.7 (0.9)	0.3 (0.5)	p < 0.001 ^{***a}	1.6 (0.7)	0.2 (0.2)	p < 0.001 ^{***a}
Functional complaints in general (SD)	1.4 (0.7)	0.3 (0.5)	p < 0.001 ^{***a}	1.0 (0.6)	0.1 (0.2)	p < 0.001 ^{***a}
Facial aesthetics (SD)	1.4 (1.0)	0.5 (0.7)	p = 0.001 ^{***a}	1.0 (1.1)	0.3 (0.6)	p = 0.001 ^{***a}
"Neutral Space" (SD)	0.7 (0.9)	0.3 (0.5)	ns ^a	0.5 (0.6)	0.4 (0.6)	ns ^a
Aesthetics (SD)	0.4 (0.6)	0.1 (0.3)	ns ^a	0.1 (0.2)	0.1 (0.1)	ns ^a
General satisfaction score upper denture (SD)	4 (1–6)	8 (7–9)	p < 0.001 ^{***a}	4 (2–6)	9 (8–10)	p < 0.001 ^{***a}
General satisfaction score lower denture (SD)	4 (2–7)	8 (7–8)	p = 0.002 ^{***b}	8 (6–9)	8 (7–10)	ns ^b

Differences between study groups were tested with the a: paired samples t-test or b: Wilcoxon Matched Pairs Signed Ranks test.

^{**} p < 0.01. ^{***} p < 0.001.

3.4. Patient satisfaction

Differences in mean scores on the patient satisfaction questionnaires and median scores of the GSS between the locator and bar group at T0 and at T12 are listed in Table 4. Differences between T0 and T12 for both groups are listed in Table 5.

For the denture complaints questionnaire, all item scores improved significantly between T0 and T12 for both groups, except for "neutral space" and "aesthetics". At T12 there were no significant differences between the groups.

For the OHIP-49 questionnaire, all scores improved significantly between T0 and T12 for both groups. Although all scores in the locator group were slightly higher than those for the bar group, at T12 the item scores did not differ significantly between the groups. However, the total OHIP-49 score at T12 differed significantly in favour of the bar group.

The GSS for the upper denture improved significantly between T0 and T12 for both groups. At T0 the score did not differ significantly between the groups, but at T12 the score did differ in favour of the bar group.

Between T0 and T12, the GSS for the lower denture improved significantly for the locator group. At T0 there was a significant difference between the groups, but at T12 this difference was no longer present.

4. Discussion

Based on the results of this trial with a one-year follow-up period, a maxillary four-implant overdenture with a bar attachment system has a more favourable peri-implant radiographic outcome than the overdenture with a locator attachments, although the difference is small. Additionally, patient satisfaction with a bar attachment is higher. However, clinical outcomes and scores on all separate items of the questionnaires do not differ significantly.

Bone loss was higher around implants provided with a locator attachments supporting an overdenture. Although there is not much literature about maxillary four-implant overdentures on locator attachments, the observed amount of peri-implant bone is in line with the few other studies [27,28]. Also the amount of bone

loss for the bar overdentures found in this study is comparable to earlier reports about maxillary bar overdentures [3]. Recently, in vitro studies revealed that stress levels in surrounding bone tissues are significantly higher for four-implant maxillary overdentures with a solitary attachment system compared to a bar system [29,30]. The same applies for the mandibular two-implant overdenture. In the study of Jofre et al. the relationship between stress levels and marginal bone loss was measured, and the effects of bone stress levels reported in that study may explain why unsplinted implants supporting a mandibular overdenture show more marginal bone loss compared to splinted implants [31].

In a previous study it was suggested that bone loss of 2 mm or more, in combination with bleeding on probing, should be interpreted as a 'red flag' to critically evaluate if any peri-implantitis treatment is indicated [32]. Although the marginal bone loss for the locator group in the present study was higher than the marginal bone loss for the bar group, the amount of bone loss for this group was still well within a healthy range. Also, marginal bone loss should always be assessed in combination with bleeding and/or suppuration on probing and pocket depth, because a deep pocket without any bleeding and/or suppuration is classified as a healthy pocket [33,34].

When designing this study a power analysis was done, which showed that difference of 0.4 mm between the groups was relevant. In our study we found a difference of 0.3 ± 0.1 mm, with a 95% confidence interval from 0.1 to 0.4 mm. So there is only a chance of 5% that the true population difference is higher than 0.4 mm.

In our study the outcomes of the clinical indices were low and comparable between the two treatment groups, and for this reason could not contribute to the difference in bone loss between the groups. Additionally we found no evidence to support the assumption that solitary attachments are easier to clean than bars and that hard and soft tissues are healthier because of this [10–12]. Also, no evidence was found to support the hypothesis that solitary attachments need more aftercare than bar attachments. No differences were found between the groups till the one year follow-up. It must be noted that a follow-up of one year is relatively short and differences between groups might not yet show up.

Two systematic reviews have shown that implant survival for a four implant overdenture and a bar is higher than that of an overdenture with solitary attachments [24,35]. We found no difference between the groups in the present study. The implant survival rate for the bar group is slightly higher than the reported survival rates in these systematic reviews, but lower than an earlier study done by the same team using a similar treatment protocol with wider implants [3]. The implant survival for the locator group is similar to that reported in other studies [27,36]. A limitation of this study is that, to assess the implant survival, again, a follow-up of one year is relatively short and differences between groups might not yet show up.

Very low indices for plaque, calculus, gingiva, and bleeding were found at T1 and T12. The clinical outcomes are comparable to the other studies [3,37]. Also the mean probing depths are comparable to other studies [3,38]. The difference in probing depth at T1 could not be explained by the plaque, calculus, gingiva, and bleeding index. In a study done to evaluate inter- and intra-examiner variability of probing depth measurements, the standard error for tooth means was 0.38 ± 0.07 mm. Consequently the variation between the measured mean and the actual mean is around 0.38 mm, which is comparable to the difference in probing depth between the groups found in the present study. Additionally the upper bound of the confidence interval is 0.7 mm. Therefore, the difference found in the present study can be considered as very small and not clinically relevant.

In general patient satisfaction improved post-treatment. The scores of the denture complaints questionnaire are comparable to the scores reported in other studies [3,39].

The OHIP-49 item scores were not different between the groups. We found no other studies using the OHIP-49 for evaluating maxillary overdenture treatment. However, the scores in the present study are comparable to those reported in other studies on mandibular overdentures [40,41]. The similarity in scores between these studies and the present study can be explained because the OHIP-49 does not distinguish between maxillary and mandibular dentures, but asks about complaints in general and thus values overdenture treatment in general.

Post-treatment, the total OHIP-49 score did differ significantly between the groups in favour of the bar group. We found no other studies comparing bar and locator attachments using the OHIP-49. One study on ball and bar mandibular overdentures reported no significant differences between the groups, although the OHIP-14 scores for the ball overdenture group were higher, which is comparable to the present study [42].

If all three satisfaction measures (denture complaints questionnaire, OHIP-49, GSS) are combined it can be concluded that both treatment options improve patient satisfaction. However, based on the total OHIP-49 score and GSS, the added value of the maxillary overdenture on bars is higher than that of the overdenture on locator attachments. It must be noted that the amount of patients receiving both new maxillary and mandibular overdentures was bigger in the locator group. One should keep in mind that there is an adaptation period for a new (over)denture. The adaptation period might have influenced the results after one year in favour of the bar group. However, the adaptation period for conventional mandibular dentures is shorter than 12 months [43]. The same might also apply for overdentures.

5. Conclusion

Maxillary overdentures on four implants retained by bars or locators were compared. Bone loss was within an acceptable range for both groups after 1 year. However, less bone was lost in the bar group. Even though both treatment options improved patient satisfaction, bars seem to be particularly beneficial with regard to OHIP-49 sum score. However, clinical indices and scores on separate items of the denture complaints questionnaire and OHIP-49 do not appear to differ.

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Ethical approval

The study was approved by the Medical Ethical Committee of the UMCG (ABR NL43293.042.13) and was registered in the Netherlands National Trial Register (NTR3813). The principles outlined in the Declaration of Helsinki were followed in the study.

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