Four-implant maxillary overdentures on bars or locators: a 1-year randomized controlled trial

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Four-implant maxillary overdentures on bars result in less marginal bone loss and higher patient satisfaction than comparable overdentures on locators: a randomized controlled trial
Submitted
Abstract

Objective The aim of this 1-year, prospective randomized controlled trial was to assess the treatment outcomes of completely edentulous patients with removable four-implant overdentures supported by either locators® (Zest Anchors, Inc. homepage, Escondido, CA, USA) or bars.

Material and methods Fifty edentulous patients were enrolled in a two-arm randomized controlled trial. One group (n=25) received maxillary four-implant overdentures on locators and the other group (n=25) on bars. Outcome measures were change in radiographic bone level, implant survival, overdenture survival, soft tissue conditions (plaque index, presence of calculus, gingiva index, sulcus bleeding index and pocket probing depth) and patient satisfaction (denture complaints questionnaire, OHIP-49NL and general satisfaction score (GSS)). Follow-up was one year.

Results Marginal bone loss was 0.58±0.71 mm for the locator group and 0.31±0.47 mm for the bar group. Implant survival was 96.7% and 97.9% in the locator and bar group, respectively. Overdenture survival was 100% in both groups. After 1 year, the bar group scored better on total OHIP-49NL and GSS for the upper denture. Clinical indices and all separate item scores (denture complaints questionnaire and OHIP-49NL) were not different between the groups.

Conclusions Maxillary overdentures retained by bars on four implants opposed by a mandibular overdenture are associated with significantly less peri-implant marginal bone loss and patients are more satisfied with maxillary overdentures retained by bars than by locators.
Introduction
Placement of implants is the current treatment of choice to eliminate common problems reported by wearers of conventional complete dentures. Implants provide support, improve the retention and stability of overdentures and reduce or eliminate pain during mastication (1–3). Implants not only eliminate problems, they also clearly improve patient satisfaction and improve masticatory performance (4).
Various attachment systems have been successfully used for implant-supported overdentures in recent years. These systems can be classified as bars and solitary attachment systems (ball and Locator® (Zest Anchors, Inc. homepage, Escondido, CA, USA)). Dental practitioners and technicians select attachment systems based on their experience and clinical outcomes (5).

Overdentures on bars are a therapeutic option that offers many advantages for patients with a severely resorbed edentulous ridge. Bars are seen as the gold standard for mandibular overdentures due to their good retention capacity and low maintenance costs, and because they enable simple insertion and removal of the denture (6). The relatively high initial costs are a disadvantage of the bar system, it is assumed that a solitary attachment system is less expensive than bar attachments (7,8). Additionally, some evidence indicates that solitary attachments are easier for the patient to clean than bars and that the peri-implant soft tissues and bone are healthier as a result (9–11).

Solitary attachments can be used with various matrices. Attachment design and the choice of material used for the retentive part of the matrix influence the friction grip and thus the need for aftercare (12). It has been reported that, for mandibular overdentures, ball attachments need more aftercare than bar attachments (13,14). However, an advantage of a solitary attachment system in comparison to the bar attachment system is that when maintenance, repair or replacement is needed, this can be done more quickly, the procedures are more straightforward and can mostly be done chair-side (15). Repair and replacement of a bar superstructure takes more time and is more complicated.

In contrast, ball attachments have resulted in more prosthodontic complications than locator attachments (16), although no differences have
been shown between ball and locator attachments with regard to patient satisfaction and peri-implant parameters after one year (17). The locator attachment system therefore seems promising and is often preferred over the bar attachment system due to its lower cost, improved oral hygiene and easier handling and maintenance. However, few studies have made a direct comparison between bars and locators for maxillary implant overdentures. If more was known about the treatment outcomes of both options, then evidence-based choices could be made about which attachment system is preferred. We therefore conducted a 1-year, prospective randomized controlled trial to compare the treatment outcomes of completely edentulous patients with removable four-implant overdentures supported by bars or locators. Implant survival, peri-implant tissue health, marginal bone resorption, and patient satisfaction were measured before and at regular intervals during the one-year follow-up.

Materials and methods
Between January 2013 and January 2016, all eligible fully edentulous patients, who were referred to the Department of Oral and Maxillofacial Surgery (University Medical Centre Groningen, the Netherlands) because they suffered from a lack of retention and stability of the upper denture, were invited to participate in this randomized controlled trial. The patients in the trial had to have been edentulous in the maxilla for at least one year and they had to have sufficient bone volume in the anterior region of the maxilla to place the implants. To assess the bone volume of the maxillary processus, cone beam computed tomography (CBCT) was used. Exclusion criteria were patients with American Society of Anaesthesiologists score (ASA score) ≥III (18) as well as patients who were smoking, those with a history of radiotherapy in the head and neck region, a history of pre-prosthetic surgery or previous implant placement in the maxilla.

A total of 50 consecutive patients were included in this randomized controlled trial. All the subjects received a written explanation of the study. Written informed consent was obtained from each patient after an additional in-person explanation of the clinical trial. 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 patients were randomly assigned to one of the two groups by means of sealed envelopes, i.e. to the locator group (patients
receiving maxillary overdentures on a locator attachment system, (n=25)) or the bar group (patients receiving maxillary overdentures on a bar attachment system, (n=25)).

**Surgical procedure**

All patients received four dental implants with a diameter of 3.5 mm (NobelActive™ Narrow Platform (Nobel Biocare AB, Gothenburg, Sweden) in the maxilla. The implants were placed, guided by a surgical stent, at crestal bone level in predefined positions (positions 13, 11, 21, 23) according to a two-stage surgical protocol. When needed, an augmentation procedure (19) was done using bone harvested from the maxillary tuberosity and organic bovine bone (Bio-Oss®, Geistlich Pharma AG, Wolhusen, Switzerland), after which the bone was covered with a resorbable membrane (Bio-Gide®, Geistlich Pharma AG, Wolhusen, Switzerland).

Patients received amoxicillin, starting one hour preoperatively (3 g Clamoxyl®, GlaxoSmithKline, Utrecht, the Netherlands) orally and continuing (500 mg Clamoxyl®; GlaxoSmithKline, Utrecht, the Netherlands) for seven days, three times daily, after surgery. Postoperatively, the patient received a 0.2% chlorhexidine mouth rinse (Corsodyl®; GlaxoSmithKline, Utrecht, the Netherlands) with which the patient had to rinse for 1 minute, 2 times daily for 2 weeks.

Two weeks after implant placement, the patient was allowed to wear his or her prosthesis again after adjustment of the prostheses with a resilient lining material (Soft liner; GC Corporation, Tokyo, Japan). After a 3-month osseointegration period, second stage surgery was performed, healing abutments were placed and the prosthetic procedure was initiated.

**Prosthetic procedure**

Custom acrylic resin impression trays (Lightplast base plates; Dreve Dentamid GmbH, Unna, Germany) were fabricated with openings for screw-retained impression copings. Impression copings were attached to the implants. The final complete arch impression was made with polyether material (Impregum F; 3M ESPE, St. Paul, Minn).

A composite resin record base (Lightplast base plates; Dreve Dentamid
GmbH, Unna, Germany) with a wax occlusion rim was used to determine the occlusal vertical dimension and to record the maxillo-mandibular relationship. Acrylic resin artificial teeth (Ivoclar SR Orthotyp DCL and Ivoclar Vivodent PE, Ivoclar Vivadent AG, Schaan, Liechtenstein) were selected and arranged on the record base for a trial arrangement. A bilateral balanced occlusion concept was followed.

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, Gothenburg, Sweden) (Figure 1) 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 (Figure 2) and an overdenture with built-in cobalt chromium reinforcement structure with locator denture caps and nylon locator males. The locator abutment comprises a self-aligning double retention cylinder with retention surfaces on the inner and outer areas.

A metal denture cap is incorporated in the base of the denture and, in this cap, nylon elements in the negative form of the abutment connect the prostheses with the implant. 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 patients were initially provided with pink inserts (13.4 N; medium force), providing possibilities for strengthening or loosening the retention force.

The overdentures were designed with full coverage of the alveolar process, but without palatal coverage in the maxilla. The patient was instructed in hygiene procedures associated with the dentures and superstructures and scheduled for routine maintenance recalls.

Outcome measures
The primary outcome measure was change of radiographic peri-implant bone level. Secondary outcome measures were implant survival, overdenture survival, soft tissue conditions (plaque index, presence of calculus, gingiva index, sulcus bleeding index and pocket probing depth), patient satisfaction (OHIP-49NL, denture complaints questionnaire and general satisfaction score (GSS)). These parameters were scored one month
after placement of the overdenture (T1) and after 12 months of loading (T12). Patient satisfaction was scored before treatment (T0) and 12 months after placement of the overdenture (T12).

![Figure 1. Intra-oral view of a patient with bars.](image1)

![Figure 2. Intra-oral view of patient with locators.](image2)

**Change of radiographic peri-implant bone level**

Standardized panoramic radiographs were taken at T1 and T12 (Figures
3 and 4). The digital images were analysed using computer software (Biomedical Engineering, University Medical Centre Groningen, the Netherlands) to perform linear measurements on digital radiographs. The reference line for bone level evaluation was the outer border of the neck of the implant. Mesial and distal bone changes in this region were considered as radiographic bone height change and were defined as the difference in bone height between the radiograph taken at T1 and the radiograph taken at T12.

Figure 3. Panoramic radiograph of a patient with bars.

Figure 4. Panoramic radiograph of a patient with locators.
Implant survival
Implant survival was defined as the percentage of implants initially placed that was still present and not mobile at follow-up. Lost implants were scored any time after placement. Mobile implants were scored by percussion. For the bar group, this was assessed after removal of the bar.

Overdenture survival
Survival of maxillary overdentures was defined as the percentage of overdentures initially placed that were still present at follow-up. Remake of the maxillary overdenture was scored any time after placement.

Clinical parameters
For presence of plaque, the index according to Mombelli et al. (20) was used (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 (score 1) or the absence of calculus (score 0) was scored.

To qualify the degree of peri-implant inflammation, the modified Löe 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).

For bleeding, the bleeding index according to Mombelli et al. (20) was used (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).

Probing depth was measured at four sites of each implant (mesial, labial, distal, and lingual) 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 scored as the probing depth.
Patients’ satisfaction
Patient satisfaction with their overdenture was assessed using a validated questionnaire (22). This questionnaire focused on complaints and consisted of 54 questions. Each question could be addressed to one out of six specific scales.

The six scales are:
A. Nine items concerning functional problems of the lower denture
B. Nine items concerning functional problems of the upper denture
C. Eighteen items concerning functional problems complaints in general
D. Three items concerning facial aesthetics
E. Three items concerning accidental lip, cheek, and tongue biting (“neutral space”)
F. Twelve items concerning aesthetics of the denture

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

All patients were also requested to fill out the Dutch oral health impact profile with 49 questions (OHIP-49NL). The OHIP-49NL consists of 49 items covering seven domains: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap. The extent of each specific complaint could be expressed on a five-point rating (0: never, 1: rarely, 2: sometimes, 3: often, 4: very often). The total OHIP-49NL 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 patients stated their overall denture satisfaction (general satisfaction score (GSS)) with the upper or lower denture on a 10-point rating scale (1: very bad to 10: excellent). The patients scored their satisfaction at T0 and T12.

Sample-size estimation
A statistical power analysis was performed 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. (23) was used (the used SD for the power analysis was 0.5 mm). With alpha = .05 and power = 0.85, the sample size needed for this between group
comparison is n = 46 (GPower 3.1 (24)). Our proposed sample size of 50 was determined to be more than adequate for the main objective of this study and should also allow for expected attrition.

Data analysis
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-49NL 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. If interval nature is assumed for a comparison of two groups, the paired samples t-test is not inappropriate (25). 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-49NL 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) were analysed with a Wilcoxon Matched Pairs Signed Ranks test. Inter-group differences were analysed by applying 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. Listwise deletion was used for missing data and intra-group comparisons. All analyses were performed with SPSS 23.0 software (SPSS, Inc., Chicago, IL, USA).

Results
Baseline characteristics of the study groups are shown in Table 1. Two patients died before T12 and one patient was lost to follow-up (moved without leaving an address). Consequently, 47 patients were available for the 1-year evaluation: 23 patients in the locator group and 24 patients in the bar group.
Table 1. Baseline characteristics of the locator and bar group.

<table>
<thead>
<tr>
<th>Group</th>
<th>Locator (n=25)</th>
<th>Bar (n=25)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age in years (SD, min. – max.)</td>
<td>60.1 (8.6, 37.5 – 75.0)</td>
<td>63.8 (5.4, 53.0 – 72.6)</td>
</tr>
<tr>
<td>Gender (male/female)</td>
<td>13/12</td>
<td>13/12</td>
</tr>
<tr>
<td>Augmentation during implant surgery</td>
<td>9/18</td>
<td>7/14</td>
</tr>
<tr>
<td>Median plaque-index (Q1-Q3)</td>
<td>0 (0-2)</td>
<td>1 (0-2)</td>
</tr>
<tr>
<td>Median calculus-index (Q1-Q3)</td>
<td>0 (0-0)</td>
<td>0 (0-0)</td>
</tr>
<tr>
<td>Median gingival-index (Q1-Q3)</td>
<td>0 (0-1)</td>
<td>0 (0-1)</td>
</tr>
<tr>
<td>Median bleeding-index (Q1-Q3)</td>
<td>1 (0-1)</td>
<td>0 (0-1)</td>
</tr>
<tr>
<td>Mean probing depth in mm (SD)</td>
<td>3.7 (1.0)</td>
<td>4.1 (0.9)</td>
</tr>
</tbody>
</table>

* p<0.05, ** p<0.01, *** p<0.001 Differences between study groups were tested with the a: Mann-Whitney U test or the b: independent Student’s t-test.

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 = 0.002, mean difference 0.3±0.1 mm, 95% CI [0.1 - 0.4]).

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.

<table>
<thead>
<tr>
<th>Group</th>
<th>Locator (n = 25)</th>
<th>Bar (n = 25)</th>
<th>p = 0.002**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (SD)</td>
<td>0.58 (0.71)</td>
<td>0.31 (0.47)</td>
<td></td>
</tr>
<tr>
<td>0-0.5 mm</td>
<td>57%</td>
<td>74.5%</td>
<td></td>
</tr>
<tr>
<td>&gt;0.5-1.0 mm</td>
<td>17.2%</td>
<td>15.3%</td>
<td></td>
</tr>
<tr>
<td>&gt;1.0-1.5 mm</td>
<td>16.1%</td>
<td>6.1%</td>
<td></td>
</tr>
<tr>
<td>&gt;1.5-2.0 mm</td>
<td>6.5%</td>
<td>3.1%</td>
<td></td>
</tr>
<tr>
<td>&gt;2.0mm</td>
<td>3.2%</td>
<td>1.0%</td>
<td></td>
</tr>
</tbody>
</table>

* p<0.05, ** p<0.01, *** p<0.001 Differences between study groups were tested with the independent Student’s t-test.

Implant survival

During the osseointegration period three implants were lost in three patients 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 patients 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).

**Overdenture survival**
One year after implant placement, no overdentures had failed. This results in an overdenture survival rate of 100% for both groups.

**Clinical 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.

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

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

\(^a\) p<0.05, \(^b\) p<0.01, \(^*\) p<0.001 Differences between study groups were tested with the \(a\): Mann-Whitney U test or \(b\): the independent Student’s t-test.

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 Students’ T-test, mean difference
0.4±0.1 mm 95% CI [0.1-0.7mm]) 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.

**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. Table 4 and 5 can be found at the end of this chapter. 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-49NL 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-49NL 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.

**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 attachment system, 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 attachment
system supporting an overdenture. Although there is not much literature about maxillary four-implant overdentures on locator abutments, the observed amount of peri-implant bone is in line with the few other studies on locators (26,27). 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 (28,29). This also 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 (30).

In a previous study it was suggested that bone loss ≥2 mm, compared to initial radiographs at delivery of the overdenture, in combination with bleeding on probing, should be interpreted as a ‘red flag’ for the clinician to critically evaluate if any peri-implantitis treatment is indicated in the individual case (31). 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 (32,33).

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 0.1-0.4 mm. So there is only a chance of 5% that the true population difference is higher than 0.4 mm. This puts our findings in perspective regarding clinical relevance.

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 by the patient than bars and that the soft tissues and bone are healthier because of this (9–11).

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 (23,34). 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 (26,35). A limitation of this study is that, to assess the implant survival, 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 (3,36). Also the mean probing depths are comparable to other studies (3,37). 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 (3,38).

The OHIP-49NL 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 (39,40). The similarity in scores between these studies and the present study can be explained because the OHIP-49NL 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-49NL score did differ significantly between the groups in favour of the bar group. We found no other studies comparing bars and locators 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 (41).

If all three satisfaction measures (denture complaints questionnaire, OHIP-49NL, GSS) are combined it can be concluded that both treatment options improve patient satisfaction. However, based on the total OHIP-49NL score and GSS, the added value of the maxillary overdenture on bars is higher than that of the overdenture on locators.

**Conclusion**

At 12 months after overdenture placement, patients who receive a maxillary overdenture on four implants retained by bars opposed by a mandibular overdenture have significantly less peri-implant marginal bone loss and are more satisfied than those who are given maxillary overdentures retained by locators. However, clinical indices and scores on separate items of the denture complaints questionnaire and OHIP-49NL do not appear to differ.
Table 4. Mean and standard deviation (SD) of the outcomes of the OHIP-NL49 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.

<table>
<thead>
<tr>
<th></th>
<th>Pre-treatment</th>
<th>1 year</th>
<th></th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Locator (n=25)</td>
<td>Bar (n=25)</td>
<td>Comparative</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>analysis</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Locator (n=23)</td>
</tr>
<tr>
<td>Functional limitation (SD)</td>
<td>19.0 (7.4)</td>
<td>18.2 (8.5)</td>
<td>ns</td>
</tr>
<tr>
<td>Physical pain (SD)</td>
<td>17.8 (8.7)</td>
<td>17.5 (8.1)</td>
<td>ns</td>
</tr>
<tr>
<td>Psychological discomfort (SD)</td>
<td>11.1 (5.1)</td>
<td>8.4 (6.7)</td>
<td>ns</td>
</tr>
<tr>
<td>Physical disability (SD)</td>
<td>17.7 (10.1)</td>
<td>15.2 (7.6)</td>
<td>ns</td>
</tr>
<tr>
<td>Psychological disability (SD)</td>
<td>8.4 (7.5)</td>
<td>7.4 (6.2)</td>
<td>ns</td>
</tr>
<tr>
<td>Social disability (SD)</td>
<td>6.9 (6.2)</td>
<td>5.0 (4.5)</td>
<td>ns</td>
</tr>
<tr>
<td>Handicap (SD)</td>
<td>8.3 (6.6)</td>
<td>5.5 (5.2)</td>
<td>ns</td>
</tr>
<tr>
<td>TOTAL OHIP-NL49 SCORE (SD)</td>
<td>88.9 (43.7)</td>
<td>75.8 (38.0)</td>
<td>ns</td>
</tr>
<tr>
<td>Functional complaints about upper denture (SD)</td>
<td>1.7 (0.9)</td>
<td>1.6 (0.7)</td>
<td>ns</td>
</tr>
<tr>
<td>Functional complaints in general (SD)</td>
<td>1.4 (0.7)</td>
<td>1.0 (0.6)</td>
<td>p = 0.025*</td>
</tr>
<tr>
<td>Facial aesthetics (SD)</td>
<td>1.4 (1.0)</td>
<td>1.0 (1.1)</td>
<td>ns</td>
</tr>
<tr>
<td>“Neutral Space” (SD)</td>
<td>0.7 (0.9)</td>
<td>0.5 (0.6)</td>
<td>ns</td>
</tr>
<tr>
<td>Aesthetics (SD)</td>
<td>0.4 (0.6)</td>
<td>0.1 (0.2)</td>
<td>p = 0.048*</td>
</tr>
<tr>
<td>Overall satisfaction score upper denture (SD)</td>
<td>4 (1-6)</td>
<td>4 (2-6)</td>
<td>ns</td>
</tr>
<tr>
<td>Overall satisfaction score lower denture (SD)</td>
<td>4 (2-7)</td>
<td>8 (6-9)</td>
<td>p = 0.001*</td>
</tr>
</tbody>
</table>

*: p<0.05; **: p<0.01; ***: p<0.001; differences between study groups were tested with the a: independent t-test or b: Mann-Whitney U test
Table 5. Mean and standard deviation (SD) of the total score of the OHIP-NL49 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.

<table>
<thead>
<tr>
<th></th>
<th><strong>Locator group</strong></th>
<th><strong>Comparative analysis</strong></th>
<th><strong>Bar group</strong></th>
<th><strong>Comparative analysis</strong></th>
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<tr>
<td></td>
<td>Pre-treatment</td>
<td>1 year</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>(n=25)</em></td>
<td><em>(n=23)</em></td>
<td></td>
<td><em>(n=25)</em></td>
</tr>
<tr>
<td>Functional limitation (SD)</td>
<td>19.0 (7.4)</td>
<td>8.7 (7.6)</td>
<td>p &lt;0.001***,a</td>
<td>18.2 (8.5)</td>
</tr>
<tr>
<td>Physical pain (SD)</td>
<td>17.8 (8.7)</td>
<td>5.4 (6.1)</td>
<td>p &lt;0.001***,a</td>
<td>17.5 (8.1)</td>
</tr>
<tr>
<td>Psychological discomfort (SD)</td>
<td>11.1 (5.1)</td>
<td>4.9 (5.6)</td>
<td>p &lt;0.001***,a</td>
<td>8.4 (6.7)</td>
</tr>
<tr>
<td>Physical disability (SD)</td>
<td>17.7 (10.1)</td>
<td>6.5 (7.6)</td>
<td>p &lt;0.001***,a</td>
<td>15.2 (7.6)</td>
</tr>
<tr>
<td>Psychological disability (SD)</td>
<td>8.4 (7.5)</td>
<td>3.1 (5.4)</td>
<td>p = 0.002**,a</td>
<td>7.4 (6.2)</td>
</tr>
<tr>
<td>Social disability (SD)</td>
<td>6.9 (6.2)</td>
<td>2.4 (4.6)</td>
<td>p = 0.001**,a</td>
<td>5.0 (4.5)</td>
</tr>
<tr>
<td>Handicap (SD)</td>
<td>8.3 (6.6)</td>
<td>2.9 (5.4)</td>
<td>p &lt;0.001***,a</td>
<td>5.5 (5.2)</td>
</tr>
<tr>
<td>TOTAL OHIP-NL49 SCORE (SD)</td>
<td>88.9 (43.7)</td>
<td>36.6 (36.7)</td>
<td>p &lt;0.001***,a</td>
<td>75.8 (38.0)</td>
</tr>
<tr>
<td>Functional complaints about upper denture (SD)</td>
<td>1.7 (0.9)</td>
<td>0.3 (0.5)</td>
<td>p &lt;0.001***,a</td>
<td>1.6 (0.7)</td>
</tr>
<tr>
<td>Functional complaints in general (SD)</td>
<td>1.4 (0.7)</td>
<td>0.3 (0.5)</td>
<td>p &lt;0.001***,a</td>
<td>1.0 (0.6)</td>
</tr>
<tr>
<td>Facial aesthetics (SD)</td>
<td>1.4 (1.0)</td>
<td>0.5 (0.7)</td>
<td>p = 0.001**,a</td>
<td>1.0 (1.1)</td>
</tr>
<tr>
<td>“Neutral Space” (SD)</td>
<td>0.7 (0.9)</td>
<td>0.3 (0.5)</td>
<td>ns(^a)</td>
<td>0.5 (0.6)</td>
</tr>
<tr>
<td>Aesthetics (SD)</td>
<td>0.4 (0.6)</td>
<td>0.1 (0.3)</td>
<td>ns(^a)</td>
<td>0.1 (0.2)</td>
</tr>
<tr>
<td>Overall satisfaction score upper denture (SD)</td>
<td>4 (1-6)</td>
<td>8 (7-9)</td>
<td>p &lt;0.001***,a</td>
<td>4 (2-6)</td>
</tr>
<tr>
<td>Overall satisfaction score lower denture (SD)</td>
<td>4 (2-7)</td>
<td>8 (7-8)</td>
<td>p = 0.002**,b</td>
<td>8 (6-9)</td>
</tr>
</tbody>
</table>

\(^a\): p<0.05; \(^b\): p<0.01; \(^*\): p<0.001; Differences between study groups were tested with the a: paired samples t-test or b: Wilcoxon Matched Pairs Signed Ranks test
References


29. Ahmadzadeh A, Teimouri A. Four


