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Two or four implants for maxillary overdentures in edentulous patients: 1-year results of a randomized controlled trial

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Abstract

Introduction: Maxillary implant overdenture therapy is a good treatment option for treating patients experiencing problems with their conventional maxillary denture. Retaining the overdenture with four implants and a bar attachment system serves as the current gold standard. However, there is a demand for less costly and less invasive treatment options. The aim of this randomized controlled trial was to compare marginal bone level change (MBLC), implant and overdenture survival, clinical, masticatory, and patient-related outcomes (PROMs) of maxillary implant overdentures with either two or four implants and a bar attachment system.

Materials and Methods: Forty edentulous participants were randomly allocated to two groups ($n = 20$), to receive either two or four implants in the maxilla. After healing, all the participants received an implant overdenture retained by a bar attachment system. All the participants were evaluated 1 and 12 months after overdenture placement. The primary outcome was MBLC. Secondary outcomes were implant and overdenture survival, clinical, masticatory, and PROMs. The outcomes were analyzed using parametric and non-parametric tests.

Results: MBLC was −0.03 mm in the 2-implant group and −0.16 mm in the 4-implant group ($p = 0.21$). Implant survival was 83.3% in the 2-implant group and 94.4% in the 4-implant group ($p = 0.03$). The median pocket depth change and clinical outcomes were low, and masticatory performance along with PROMs improved in both groups and did not differ significantly between them.

Conclusion: Maxillary 4-implant overdentures perform better than maxillary 2-implant overdentures with a bar attachment system in terms of implant and overdenture survival and therefore remains the gold standard. However, both overdentures perform similarly in terms of MBLC, clinical, masticatory, and PROMs.

KEYWORDS

atrophic, edentulous, implant, masticatory performance, maxilla, overdenture

Summary box

What is known

- The current gold standard for maxillary overdentures is four implants with a bar attachment system.
- There is a demand for less costly and less invasive treatment options.
- Current knowledge of these treatment options is based on non-comparative studies with varying results.

What this study adds

- This is the first registered randomized controlled trial comparing four implants with two implants using a bar attachment system.
- The study confirms the gold standard value of four implants for maxillary overdenture therapy, although both systems improve the patient's masticatory performance and quality of life.

1 | INTRODUCTION

Four implant maxillary IODs (IOD-4), combined with bar attachment systems, are seen as the gold standard treatment option due to their high implant survival rates, low marginal bone level changes (MBLC), high patient satisfaction, improved masticatory performance, and low complication rates for up to 10 years.[1–6] Treating patients with a maxillary IOD-4 can be an invasive and costly procedure, especially if reconstructive surgery is needed prior to implant surgery[7] and may therefore be inaccessible for many patients. Next to this, for the aged and/or medically compromised patient, there is a demand for less invasive treatment options.

The need for reconstructive surgery could possibly be reduced by retaining the maxillary IOD with less than four implants. Current knowledge comes from a small number of studies which show varying results regarding MBLC, implant survival, and patient-related outcomes (PROMs).[8–14] Three of these studies reported on 3-implant maxillary overdentures (IOD-3) retained by bars and ball/stud attachments,[8,10,11] of which two reported favorable clinical outcomes after at least 5 years[10,11] and one reported favorable outcomes regarding patient satisfaction.[8] Four studies reported on 2-implant maxillary overdentures (IOD-2) retained by bars or ball/stud attachments.[9,12–14] While two studies experienced high implant losses in the first 2 years of function,[9,13] the other two studies reported favorable results during a short and long follow-up period.[12,14] It must be mentioned, however, that the studies on IOD-2 were not conducted as randomized controlled trials (RCTs) and had relatively small groups of participants. To our knowledge there are no RCTs on maxillary implant overdentures comparing four with two implants, opposing mandibular implant overdentures.

Therefore, the aim of this RCT was to compare MBLC, implant and overdenture survival, clinical, masticatory, and PROMs of maxillary implant overdentures with either two or four implants and a bar attachment system.

2 | MATERIALS AND METHODS

2.1 | Patients

Between February 2018 and September 2020, all the eligible edentulous patients experiencing functional problems with their maxillary conventional denture, who were referred to the Department of Oral and Maxillofacial Surgery (University Medical Center Groningen, the Netherlands) were asked to participate in a RCT. The patients were deemed eligible for participation if they had been edentulous for more than 1 year and if they had sufficient bone volume for the placement of four implants in the maxilla. The patients were allowed to have mandibular IODs. Bone sufficiency was assessed by using cone beam computed tomography. Patients were excluded from the RCT if they had been formerly treated with pre-prosthetic or reconstructive surgery in the maxilla, had a medical contra-indication for a surgical intervention, were smoking or had undergone radiotherapy in the head- and neck region. Forty participants were included in the study (Figure 1). All the participants received oral and written information about the trial. Signed informed consent was obtained from each participant. This 1-year trial was independently reviewed and approved by the Medical Ethical Committee of the UMCG (METc 2017/551ABR NL63532.042.17) and the study was registered in the Dutch Trial Register (NTR6742/NL6561, available at https://trialsearch.who.int/Trial2.aspx?TrialID=NTR6742). This study was conducted in accordance with the 2013 revised requirements of the Helsinki Declaration of 1975 and the CONSORT Guidelines. Each participant was randomly assigned to be treated with an overdenture supported by either two (experimental group) or four (control group) implants via sealed envelope randomization.

2.2 | Surgical procedure

The surgical procedures for all the participants were planned with a computer 3D virtual surgical planning software (Proplan CMF

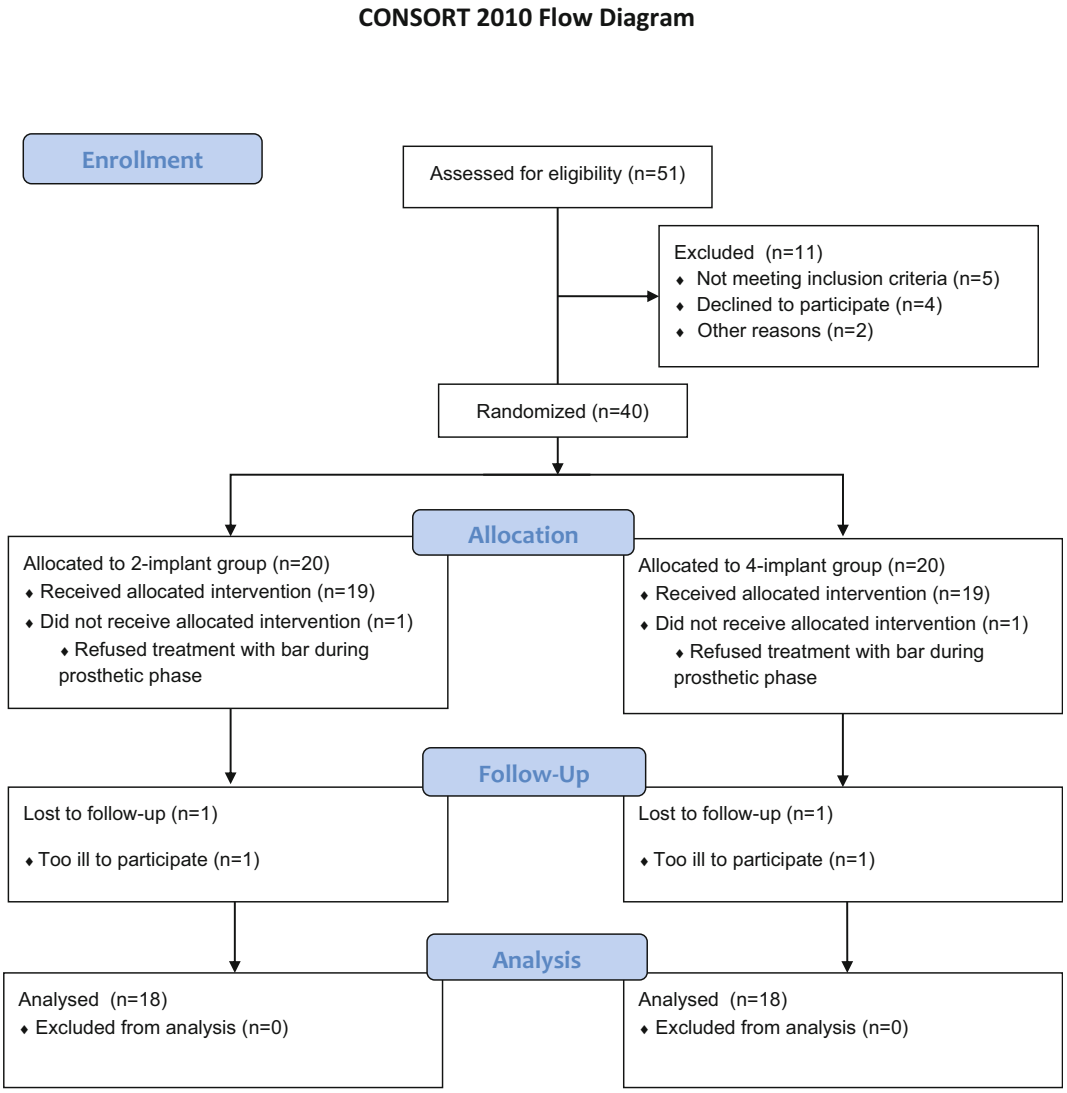

FIGURE 1 Consort 2010 flow diagram.

software; Materialise, Leuven, Belgium) to ensure optimized implant location from both a surgical and prosthodontic perspective. In case a participant did not already have a mandibular implant overdenture, the participant was simultaneously treated with two implants in the mandible for an opposing bar overdenture. Regarding the experimental group, the implants were planned in the canine to lateral incisor region, enabling the connection of both implants by using a bar attachment system. The implants for the control group were planned in the first premolar to lateral incisor region. The implant positions were transferred to a surgical template using computer software (3-Matic Medical 11.0; Materialise, Leuven, Belgium). To ensure optimal stability, the template was bone supported and extended into the nasal aperture.[15] All the participants were treated by the same oral and maxillofacial surgeon (GMR). All the implants (NobelActive NP 3.5 mm, Nobel Biocare Services AG, Kloten, Switzerland) were placed at crestal bone level using a surgical template and consecutive diameter drill sleeves, following the manufacturer's instructions. Small bone dehiscences were covered with intra-orally harvested bone and a resorbable membrane (Bio-Gide®, Geistlich Pharma North America Inc., Princeton, NJ, USA). After placement, the flap was primarily closed using non-resorbable sutures, following a two-stage submerged procedure and a conventional loading protocol. All the participants received antibiotics (500 mg Clamoxyl, GlaxoSmithKline, Utrecht, the Netherlands) for 7 days, three times daily, and a mouth

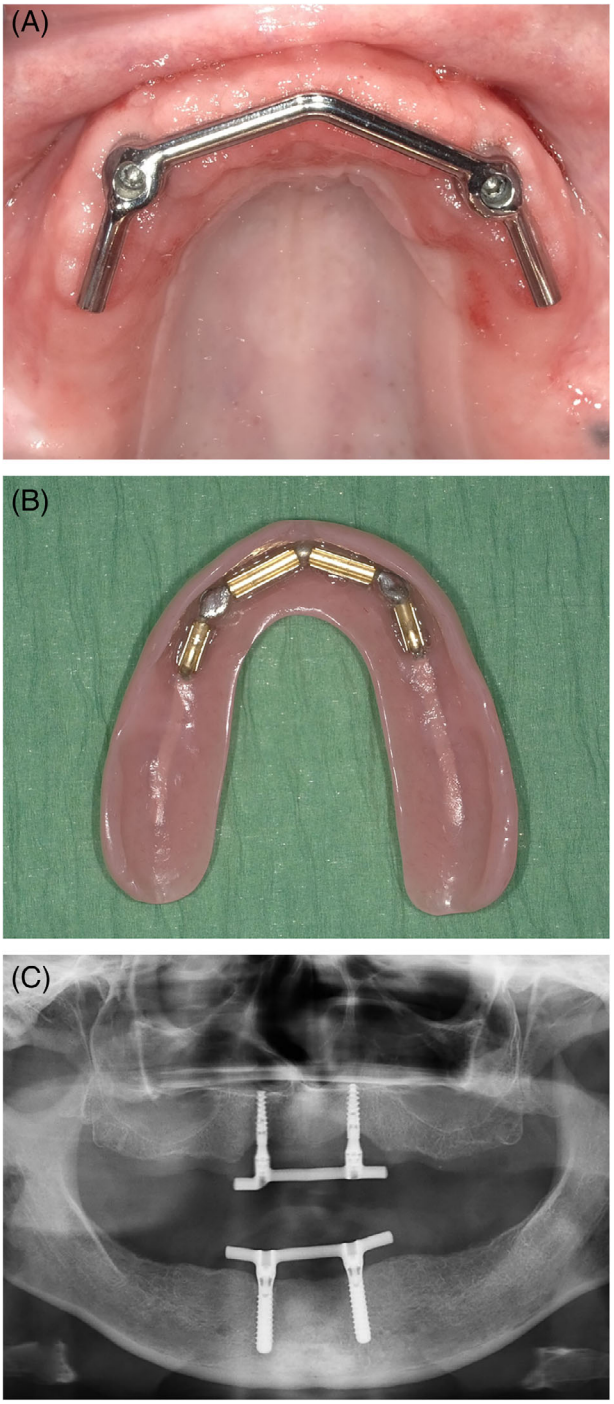

FIGURE 2 A participant of the 2-implant group 1 year after overdenture placement. (A) Intra-oral view. (B) Overdenture base. (C) Panoramic x-ray 1 year after placement.

wash containing 0.2% chlorhexidine (Corsodyl, GlaxoSmithKline, Utrecht, The Netherlands). All the participants were instructed not to wear their conventional denture until suture removal. After 2 weeks, the sutures were removed and the conventional denture was relined (Soft-Liner, GC, Leuven, Belgium). After 3 months of osseointegration the implants were provided with healing abutments during second-stage surgery, enabling the prosthodontic procedure.

2.3 | Prosthodontic procedure

Preliminary impressions were made using stock metal trays (Schreinemakers; Clan Dental Products, Maarheeze, the Netherlands) and alginate (Cavex CA 37; Cavex Holland BV, Haarlem, the Netherlands), enabling the dental technician to produce individual impression trays (Lightplast base plates; Dreve Dentamid GmbH, Unna, Germany). The rims of the individual trays were relined using wax-based material (Iso Functional; GC Europe A.G., Leuven, Belgium). After placing screw-retained impression copings the final impressions were made with a polyether impression material (Impregum F; 3M ESPE, St. Paul, MN, USA). Vertical and intermaxillary relations were verified using wax rims and a pin registration device mounted on an individual record base (Lightplast base plates; Dreve Dentamid GmbH, Unna, Germany). Next, the wax rims were replaced by acrylic resin teeth (Ivoclar SR Orthotyp DCL and Ivoclar VivodentPE, Ivoclar Vivadent AG, Schaan, Liechtenstein), providing a trial arrangement following a bilateral balanced occlusion concept. Finally, the overdenture was provided with a virtually designed, 3D printed cobalt chromium reinforcement (Proscan, Zonhoven, Belgium) with point-lasered gold retentive clips (Cendres+Metaux, Biel/Bienne, Switzerland). Both groups' participants received milled ovoid titanium bars or "Dolder bars" with distal extensions. In the experimental group, the overdenture was attached to a single bar using 3 to 5 clips, dependent on the shape of the bar (Figure 2). In the control group, the overdenture was attached to one or two bars using 4 to 6 clips dependent on the shape of the bar(s) (Figure 3). All the participants received oral hygiene instructions and routine maintenance appointments. All the prosthodontic procedures were accomplished by one prosthodontist (HJAM).

2.4 | Outcome measures

The primary outcome measure was MBLC. The secondary outcome measures were implant survival, overdenture survival, clinical outcomes (presence of plaque and calculus, mucosal health, bleeding on probing, and pocket depth change [PDC]), masticatory performance, PROMs and complications. Clinical and radiographic evaluations took place 1 month (T1) and 12 months (T12) after the prosthetic loading. Masticatory performance and PROMs were evaluated prior to treatment (T0) and at T12.

2.4.1 | Marginal bone level change

Standardized intra-oral radiographs were made at T1 and T12 using a paralleling extension-cone system (RINN, Dentsply, Elgin, IL, USA). The radiographs were assessed with a computer software (Biomedical Engineering, UMCG, the Netherlands), which utilizes the implant diameter (3.5 mm) for calibration purposes. To enable blinded assessment, the superstructures were cropped from

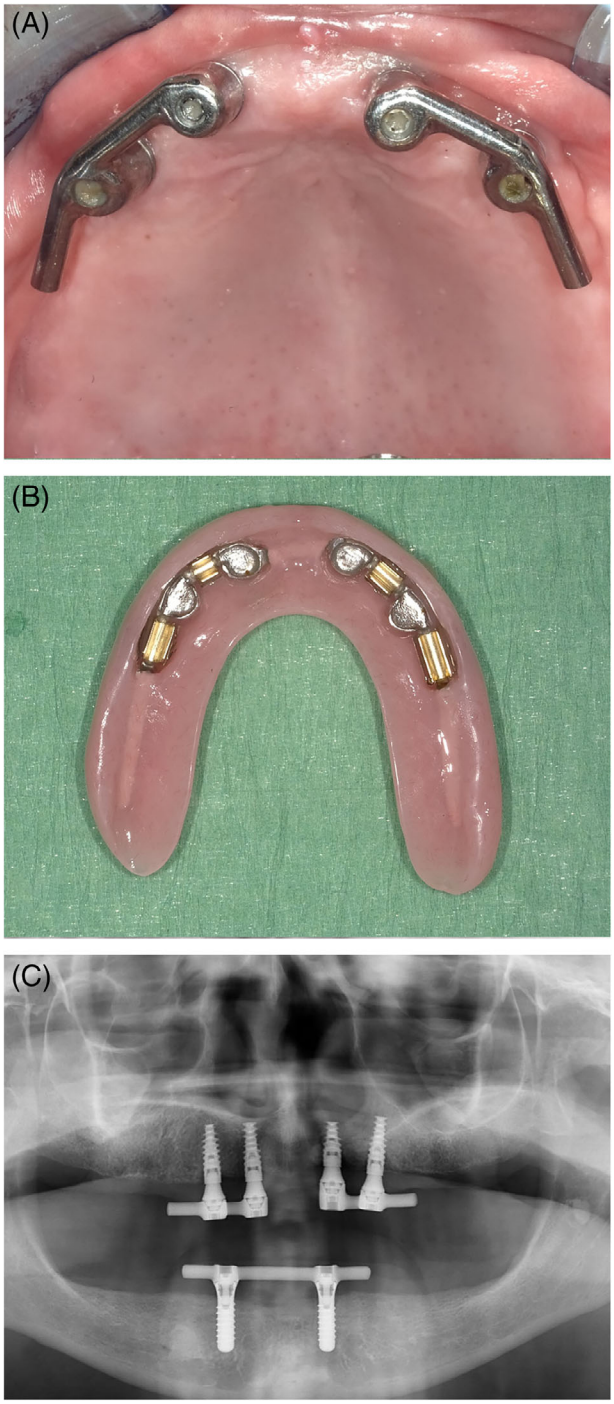

FIGURE 3 A participant of the 4-implant group 1 year after overdenture placement. (A) Intra-oral view. (B) Overdenture base. (C) Panoramic x-ray 1 year after placement.

the digital radiographs. The assessments were performed by one experienced examiner (HJAM). Measurements were taken at the mesial and distal side of each implant. MBLC was defined as the difference in bone height between the radiographs taken at T1 and T12. The side of each implant that had experienced the largest amount of bone loss (mesial or distal) was used for the analysis.

2.4.2 | Implant and overdenture survival

Implant survival was defined as the percentage of implants still present and not mobile at the follow-up evaluation. Implant mobility was assessed using a percussion test, which was tested after removing the bar. Maxillary overdenture survival was defined as the percentage of the initially placed overdentures still present at the T12 follow-up.

2.4.3 | Clinical outcomes

The clinical outcomes were measured by one experienced examiner (PO). Probing depth (PD) was measured at the distal, vestibular, mesial, and oral site of each implant using a manual periodontal probe. PD was defined as the distance between the marginal border of the mucosa and the tip of the periodontal probe. Subtracting the measurements of T1 from T12 resulted in the PDC value.

The presence of plaque was assessed by using the index described by Loë and Silness[16] (range 0–3: no plaque detection (0); plaque accumulation after probing (1); visible plaque detection (2); and an abundance of visible plaque (3)).

The presence of calculus was scored with a 0 or 1 (absence (0) or presence of calculus (1)).

Peri-implant gingival health was assessed by using the modified Löe and Silness index[16] (range 0–3: normal mucosa (0); mild inflammation with slight oedema and redness (1), moderate inflammation with oedema, redness and glazing (2); and severe inflammation with marked redness, oedema and ulceration (3)).

Bleeding on probing was assessed by using the Mombelli et al. index[17] (range 0–3: no bleeding (0); isolated bleeding (1); confluent bleeding along the mucosal margin (2); and heavy or profuse bleeding (3)).

2.4.4 | Masticatory performance

The mixing ability test (MAT) was used to objectively measure the participants' mastication. This test entailed each participant chewing on a prefabricated paraffine wax tablet with a red and blue layer for 20 strokes, which gradually decreased the spread of the blue and red color intensities. After this, the tablet was heated to 28°C and compressed using a hydraulic hand press at 50 bar resulting in a wax plate with a spread of blue and red colors and a thickness of 2.0 mm. Both sides of the plate were then optically scanned using a high quality scanner (Epson V750, Long Beach, CA, USA).[18] The image was then analyzed using a computer software (Adobe Photoshop CS3; Adobe, San Jose, CA, USA) by obtaining the intensity distributions of the red and blue colors in the combined images, which correspond with the mixing ability index (MAI).[19] The MAI ranges from 30 (badly mixed) to 5 (a theoretically perfect mix).

2.4.5 | PROM measures

The PROMs were assessed using three validated questionnaires on subjective chewing ability (Chewing Ability Questionnaire [CAQ]), denture complaints (Denture Complaints Questionnaire [DCQ]), and oral health quality of life (Oral Health Impact Profile questionnaire [OHIP-NL49]). The CAQ consists of questions rating the chewing ability of nine different foods on a three-point scale, for example, good, moderate, or bad.[20] The foods were divided into three categories, for example, soft foods (boiled vegetables, crustless bread, minced meat), tough foods (crusty bread, steak, Gouda cheese), and hard foods (apple, carrot, peanuts), each scored within a maximum score of 6. The DCQ uses a four-point scale, ranging from 0 (no complaints) to 3 (severe complaints) and a 10-point scale rating overall denture satisfaction, ranging from 1 (very bad) to 10 (excellent).[21] The DCQ rates the participants denture complaints by means of 54 questions, divided into six categories, for example, functional problems of the upper denture (max. score: 27), general functional complaints (max. score 54), denture aesthetics (max. score: 36), facial aesthetics (max. score: 9), and accidental lip, cheek, and tongue biting ("neutral space"; max. score: 9). The OHIP-49NL uses a five-point scale, ranging from 0 (never) to 4 (very often). The OHIP-49NL questionnaire consists of 49 questions, divided into seven categories, for example, functional limitation (max. score: 36), physical pain (max. score: 36), psychological discomfort (max. score: 20), physical disability (max. score: 36), psychological disability (max. score: 24), social disability (max. score: 20), and handicap (max. score: 24).[22]

2.4.6 | Complications

Surgical and prosthodontic complications were scored throughout the entire follow-up period (i.e., post-operative complications, denture fractures, relining, attachment repairs, and denture adaptation because of pressure ulcers).

2.5 | Sample size estimation

The sample size was calculated using a computer software.[23] An inter-group difference of 0.5 mm ± 0.6 mm was estimated as clinically relevant for the mean MBLC. Using alpha = 0.05 and power = 0.85, the sample size for between group comparison was calculated as 36. To vouch for possible loss to follow-up, a sample size of 40 was determined as suitable (2-implant experimental group, $n = 20$ and; 4-implant control group, $n = 20$).

2.6 | Statistical analysis

The continuous data (MBLC, PDC, MAI, and PROMs) were tested for normality using the Shapiro Wilk test and by analyzing Q-Q-plots. If normality could be assumed, differences within and between groups were tested using the paired samples *t*-test (for within group analyses) and the independent samples *t*-test (for between group analyses) and, if not, the differences were analyzed with the Wilcoxon signed rank test (for within-group differences) and the Mann–Whitney *U*-test (for between-group differences) as a non-parametric alternative. The remaining clinical variables (ordinal data) were analyzed using the Wilcoxon signed rank test (for within-group differences) and the Mann–Whitney *U* test (for between-group differences). Implant and prosthesis overdenture survival rates were analyzed using the Log Rank test. A *p*-value of <0.05 was considered statistically significant. All the analyses were performed with a computer software (SPSS 23.0, Inc, Chicago, IL, USA).

3 | RESULTS

3.1 | Patients

Forty consecutive participants (2-implant group: mean age 64.4 ± 9.3 years, 12 female; 4-implant group: mean age 58.3 ± 11 years, 10 female) were included in this RCT. Of the 40 participants, two participants (one in each group) became too ill during the follow-up period to participate, and two participants (one in each group) requested to be treated with solitary attachments for personal reasons (Figure 1).

3.2 | Marginal bone level change

The median MBLC was −0.03 mm for the 2-implant group and −0.16 mm for the 4-implant group. The MBLC was not statistically different between both groups ($p = 0.21$). A frequency distribution of the MBLC is depicted in Table 1.

3.3 | Implant and overdenture survival

At the end of the osseointegration period, four implants in one of the 4-implant group participants and six implants in four of the 2-implant group participants were lost. This resulted in a 1-year implant survival rate of 83.3% in the 2-implant group and 94.4% in the 4-implant group ($p = 0.03$; Table 2). Consequently, four IODs in the 2-implant group and one IOD in the 4-implant group were lost because the number of remaining implants was too low to retain the IOD, resulting in an IOD survival rate of 77.8% in the 2-implant group and a 94.4% in the 4-implant group ($p = 0.32$; Table 2).

3.4 | Clinical parameters

The median PDC at the 1-year follow-up was 0 mm for both the 2-implant and 4-implant group and plaque, calculus, gingiva, and bleeding scores were 0 at the 1-year follow-up for both groups (Table 3).

TABLE 1 Median changes, interquartile ranges, and the frequency distribution of the marginal bone level change 1 year after overdenture placement.

	1 year after prosthesis placement		
	2-implant group ($n = 15$)	4-implant group ($n = 17$)	p-Value
Median MBLC in mm [Q1–Q3]	−0.03 [−0.52 to 0.18]	−0.16 [−0.74 to 0.0]	0.21[a]
0 to −0.5 mm	76.7%	69.1%	NA
>−0.5 to −1.0 mm	13.3%	11.8%	NA
>−1.0 to −1.5 mm	10.0%	10.3%	NA
>−1.5 to −2.0 mm	0.0%	7.4%	NA
>−2.0 to −2.5 mm	0.0%	1.5%	NA

Abbreviations: [Q1–Q3], interquartile range; NA, not applicable.
[a]Differences between the study groups were tested with the Mann–Whitney *U* test.

TABLE 2 Implant and overdenture survival 1 year after overdenture placement.

	2-implant group	4-implant group	p-Value
Implants	36	72	
Implants lost	6	4	
Implant survival in %	83.3%	94.4%	0.03[a]
Overdentures	18	18	
Overdentures lost	3	1	
Overdenture survival in %	77.8%	94.4%	0.32[a]

[a]Differences between the study groups were tested with the Log-rank test.

TABLE 3 Median changes and interquartile ranges at baseline and 1 year after overdenture placement for plaque-index, bleeding-index, gingival-index, presence of calculus, and probing depth change.

	Baseline			After 1 years		
	2-implant IOD ($n = 18$)	4-implant IOD ($n = 18$)	p-Value	2-implant IOD ($n = 15$)	4-implant IOD ($n = 17$)	p-Value
Plaque-index [Q1–Q3]	0 [0–1]	0 [0–0]	0.15	0 [0–0]	0 [0–0]	0.63[a]
Bleeding-index [Q1–Q3]	0 [0–0]	0 [0–0]	0.66	0 [0–1]	0 [0–0]	0.90[a]
Gingival-index [Q1–Q3]	0 [0–1]	0 [0–1]	0.42	0 [0–0.25]	0 [0–1]	0.37[a]
Calculus-presence [Q1–Q3]	0 [0–0]	0 [0–0]	0.16	0 [0–0]	0 [0–0]	1.00[a]
Median probing depth change in mm [Q1–Q3]	NA	NA	NA	0 [0–1.25]	0 [0–1]	0.53[a]

Abbreviations: [Q1–Q3], interquartile range; NA, not applicable.
[a]Differences between the study groups were tested with the Mann–Whitney *U* test.

3.5 | Masticatory performance

In both groups, the MAI improved significantly between baseline and the 1-year evaluation (Table 4). The between group analysis showed that the MAI did not differ significantly at both baseline and after 1 year (Table 4).

3.6 | PROMs measures

The PROMs outcomes are depicted in Table 4. In both groups, almost all the OHIP-NL, DCQ, and CAQ items had improved significantly by the end of the follow-up period, the exception being neutral space (DCQ) in the 2-implant group. There were no significant differences between the groups in the OHIP-NL and the DCQ questionnaires both prior to treatment and after 1 year. Regarding the CAQ, the total chewing score ($p = 0.041$, Mann–Whitney *U*-test) and soft food chewing score ($p = 0.004$, Mann–Whitney *U*-test) showed significant better results for the 2-implant group compared to the 4-implant group at T0. However, after 1 year, the total food score was better in the 4-implant group compared to the 2-implant group ($p = 0.016$, Mann–Whitney *U*-test).

3.7 | Complications

All implants were placed without any surgical complications (Table 5). During the entire follow-up period prosthodontic complications were

TABLE 4 Within and between group comparisons of masticatory performance, the Chewing Ability Questionnaire, the Denture Complaints Questionnaire and the Oral Health Impact Profile-49NL, before treatment and 12 months after treatment.

	2-implant group			4-implant group			2 versus 4 implants	
	Pre-treatment	After 1 year	*p*-Value	Pre-treatment	After 1 year	*p*-Value	Pre-treatment *p*-Value	After 1 year *p*-Value
Masticatory performance	20.2 (2.9)	18.3 (2.7)	0.023*,a	21.4 (3.4)	17.5 (2.3)	0.002**,a	0.302[b]	0.370[b]
Chewing Ability Questionnaire								
Total [Q1–Q3]	10 [8–12]	3 [1–5]	0.006**,c	13 [9.5–14]	0 [0–2]	<0.001**,c	0.041*,d	0.016*,d
Soft foods [Q1–Q3]	0 [0–1]	0 [0–0]	0.014*,c	2 [0.75–3]	0 [0–0]	0.001**,c	0.004**,d	1.0[d]
Tough foods [Q1–Q3]	4 [3–5]	0 [0–2]	0.007**,c	5 [2.75–5]	0 [0–0.5]	<0.001**,c	0.388[d]	0.25[d]
Hard foods [Q1–Q3]	6 [5–6]	2 [1–4]	0.013*,c	6 [5.75–6]	0 [0–2]	<0.001**,c	0.217[d]	0.08[d]
Denture Complaints Questionnaire								
Functional complaints upper denture [Q1–Q3]	13 [6.75–17]	2 [1–2]	<0.001**,c	18 [12.75–22.25]	1 [1–3]	<0.001**,c	0.068[d]	1.000[d]
Functional complaints in general [Q1–Q3]	15 [9.75–15]	2 [1–3]	<0.001**,c	22.5 [12.75–35.25]	2 [0–6]	<0.001**,c	0.103[d]	0.985[d]
Facial aesthetics [Q1–Q3]	2.5 [0–6]	0 [0–2]	0.007**,c	3 [0–5]	0 [0–1.5]	0.004**,c	0.584[d]	0.970[d]
"Neutral Space" [Q1–Q3]	0.5 [0–2]	1 [0–3]	1.000	0 [0–3.5]	0 [0–1.5]	0.084*,c	0.875[d]	0.155[d]
Aesthetics [Q1–Q3]	3 [0–6]	0 [0–1]	0.008**,c	2 [0–5.5]	1 [0–1]	0.005**,c	0.821[d]	0.207[d]
General satisfaction score upper denture [Q1–Q3]	5 [2.75–6]	9 [8–9]	<0.001**,c	4 [1–4]	9 [8–10]	<0.001**,c	0.085[d]	0.682[d]
Oral Health Impact Profile-NL49								
Functional limitation [Q1–Q3]	16.5 [13.5–20.25]	4 [3–7]	<0.001**,c	18 [12–23]	5 [2–9]	<0.001**,c	0.690[d]	0.740[d]
Physical pain [Q1–Q3]	13 [8.25–19]	6 [5–9]	0.001**,c	12.5 [7.75–21.75]	4 [3–9]	<0.001**,c	0.849[d]	0.393[d]
Psychological discomfort [Q1–Q3]	10.5 [2–15]	1 [0–5]	0.005**,c	10.5 [3.25–17.25]	3 [0.5–4.5]	0.001**,c	0.899[d]	0.773[d]
Physical disability [Q1–Q3]	13.5 [8.75–22]	4 [2–7]	0.001**,c	20 [9.75–27.25]	2 [1.5–7.5]	<0.001**,c	0.199[d]	0.730[d]
Psychological disability [Q1–Q3]	10 [2.25–13]	1 [0–3]	0.002**,c	8 [1.5–11.25]	0 [0–4]	0.001**,c	0.577[d]	0.677[d]
Social disability [Q1–Q3]	5 [0.75–12]	1 [0–4]	0.001**,c	5 [0.75–8.5]	2 [0–4]	0.004**,c	0.762[d]	0.598[d]
Handicap [Q1–Q3]	6 [0.75–10.25]	2 [0–3]	0.002**,c	4.5 [0–4.5]	1 [0–3]	0.001**,c	0.949[d]	0.507[d]
Total OHIP-NL49 score [Q1–Q3]	63.5 [31.75–92.75]	16 [12–20]	<0.001**,c	69.5 [31.25–83]	17 [8–27]	<0.001**,c	0.740[d]	1.000[d]

Abbreviations: [Q1–Q3], interquartile range; NA, not applicable; SD, standard deviation.
[a]Differences between the study groups were tested with the paired-samples *T*-test.
[b]Differences between the study groups were tested with the independent samples *T*-test.
[c]Differences between the study groups were tested with the Wilcoxon Signed Rank test.
[d]Differences between the study groups were tested with the Mann–Whitney *U* test.
*$p < 0.05$; **$p < 0.01$.

TABLE 5 Complications during the 1 year evaluation period.

	2-implant group	4-implant group
Surgical complications		
Pre-operative complications	0	0
Direct post-operative complications	0	0
Prosthodontic complications		
Pressure ulcers	0	0
Loose abutment screw	1	0
Bar attachment repair (patrix)	0	0
Bar attachment repair (matrix)	0	0
Fractured abutment screw	1	2
Fractured prosthetic tooth	3	1
Fractured overdenture base	1	2
Occlusion adjustment	0	0
Overdenture relining	0	0
New overdenture	0	0

considerable (Table 5). Fractured or loosened abutment screws were replaced or retightened chairside. Prosthetic fracture problems could be solved within 1 day by the dental laboratory.

4 | DISCUSSION

Based on the results of this RCT with a 1-year follow-up period a maxillary 4-implant overdenture is the more favorable treatment in terms of implant survival rate compared to a 2-implant overdenture and therefore remains the gold standard. However, 2 and 4-implant maxillary overdentures perform similarly in terms of MBLC, clinical outcomes, masticatory performance, and PROMs.

The MBLC was low in both groups and comparable to other studies describing maxillary overdenture treatment retained by bars.[1,5,6] On studying 2-implant IODs, Zembic et al. reported a high MBLC, with 70% of the implants showing 2 mm bone loss or more during the first year of follow-up.[14] They attributed the higher MBLC to the compromised bone conditions of the maxilla, combined with the higher biomechanical stress when treating patients with an overdenture without palatal coverage. The study of Sanna et al. assessed 44 participants with maxillary IODs during a mean follow-up period of 7 years.[12] Twelve of their participants' IODs were retained by two implants (bars or solitary attachments) and similar MBLC patterns were reported. However, both studies showed favorable implant survival rates for 2-implant IODs and thus contradicting the present study in both aspects. In contrast, Bergendal et al. observed high implant loss among the 2-implant maxillary overdentures retained by bars or balls, after a mean follow-up period of 5.1 years.[9] In that study, the highest implant loss was among participants with low bone quantities and quality and short implants with a relatively small osseointegration area. The authors attributed the early implant losses due to implant overloads and insufficient or nonexistent osseointegration. Although the implants used in the present study also had a relatively small osseointegration area (implant diameter: 3.5 mm), the bone properties were not assessed and so the assumptions made by Bergendal could not be either confirmed or refuted. Yet, the implants that survived in the present study gave successful outcomes, which means the maxillary 2-implant IOD treatment cannot be entirely discarded.

The higher implant load suggested by Bergendal et al. was confirmed by Takahashi et al. and Nishimura et al. who reported higher biomechanical stress in the 2-implant IODs compared to the 4 and 6-implant IODs.[24,25] They used an edentulous maxilla model containing six implants connected to strain gauges to test several IOD setups for implant strain. The lower strains were attributed to the distribution of forces, especially when using splinted implants. Though not tested in vivo, higher strains may be expected in 2-implant compared to 4-implant ODs since in the implants can only be splinted in a mediolateral orientation, which could actually be an additional factor that can explain the low implant survival in our 2-implant group. The length of the distal bar extensions may also have contributed to a higher implant strain, which has been reported in a mandibular in vitro study.[26] Unfortunately, the length of distal extensions was not taken into account in the present RCT and therefore could not be analyzed.

The present study's clinical outcomes were favorable in both groups, as was the median PD change. This is in line with other studies reporting on maxillary overdentures retained by bars.[1,27] Therefore, it is not likely that the difference in implant survival rates between the groups can be attributed to clinical outcomes.

Both groups' masticatory performance had significantly improved. The MAI values are comparable to other studies that performed the MAT after maxillary overdenture treatment.[2] Therefore, the improved circumstances that are created by retaining a maxillary IOD, regardless of the number of implants, enable the patient to chew their food more effectively. Interestingly, masticatory ability, which is tested subjectively with the chewing ability questionnaire, did differ significantly between groups, favoring the 4-implant group at T12. This could possibly be explained by the number of clips used, which was higher in the 4-implant group, therefore have a higher load bearing area, thereby enhancing the chewing experience, especially when eating hard foods.

The PROMs showed improved circumstances compared to the baseline in both groups. However, we could not test the intra-participant preference. This was tested by Kappel et al., who provided 24 participants with four implants during their cross-over study.[27] The overdentures were first retained with two solitary attachments in the anterior or posterior region, then inverted after 3 months and subsequently converted to 4-implant overdentures after another 3 months.[28] The preferable 2-implant retention (anterior/posterior) was equally distributed among all the participants but, interestingly, 23 out of 24 participants preferred the 4-implant overdenture over the 2-implant overdenture. This indicates that even though both groups' PROMs had improved compared to a conventional denture, as reported in the present study, 4-implant overdentures may also be the preferred choice in terms of PROMs.

The study was designed to assess MBLC non-inferiority in the two described groups. Unfortunately, the unexpected low implant survival rate in the 2-implant group combined with the loss-to-follow up may have resulted in an underpowered MBLC result. Simultaneously, the present study clearly demonstrates a higher risk of implant loss in the experimental group, which indicates that 4-implant overdentures should still remain the gold standard in maxillary overdenture therapy. It must be recognized that the present study included the use of narrow diameter implants (3.5 mm), which may limit the generalizability to the use of regular diameter implants, though some other studies also exclusively used implants with a narrow diameter.[8,10,13,14] Compromised bone conditions are often present in patients experiencing complaints of their conventional maxillary denture, which may require more pre-prosthetic reconstructive surgery to be able to place regular diameter implants. Though not specified by the authors of some studies, this may have also been the reason to use implants with a narrow diameter. Since the demand for less invasive treatments (i.e., treatment without reconstructive surgery) remains, this should be recognized by future research. Since bone properties are of interest in these treatments and can currently only be validly analyzed during surgery,[29] a new assessment method may also be needed to enable predictable implant placement in compromised bone conditions.

5 | CONCLUSION

Maxillary 4-implant overdentures perform better than maxillary 2-implant overdentures with bar attachment systems in terms of implant and overdenture survival. Therefore maxillary 4-implant overdentures still remain the gold standard, even though both designs in this RCT performed similarly in terms of MBLC, clinical, masticatory, and PROMs.

AUTHOR CONTRIBUTIONS

Pieter Onclin: Included the participants, first observer, data analyses and interpretation, drafted the article. **Caroline M. Speksnijder**: Interpreted the data, reviewed, and edited the main text of the article. **Henny J. A. Meijer**: Assessed the implant locations, prosthodontic treatment, reviewed, and edited main text of the article. **Arjan Vissink**: Substantial revisions of the main text of the article. **Gerry M. Raghoebar**: All the surgical treatment, reviewed and edited the main text of the article. All the authors read and approved the final manuscript.

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The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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