Maxillary implant overdentures retained with bars or solitary attachments

Onclin, Pieter; Boven, G. Carina; Vissink, Arjan; Meijer, Henny J. A.; Raghoebar, Gerry M.

Published in:
Journal of Prosthodontic Research

DOI:
10.2186/jpr.JPR_D_22_00076

Publication date:
2023

J Prosthodont Res. 2023; 67(3): 400–409

OPEN ACCESS

Journal of Prosthodontic Research

Original article

Maxillary implant overdentures retained with bars or solitary attachments: A 5-year randomised controlled trial

Pieter Onclin [a,*], G Carina Boven [a], Arjan Vissink [a], Henny JA Meijer [a,b], Gerry M Raghoebar [a]

[a] Department of Oral and Maxillofacial Surgery, University of Groningen, University Medical Center Groningen, Groningen, The Netherlands, [b] Department of Implant Dentistry, Dental School, University of Groningen, University Medical Center, Groningen, The Netherlands

Abstract

Purpose: To compare the 5-year follow-up outcomes of maxillary overdentures retained by bars or solitary attachments.
Methods: Fifty consecutively selected fully edentulous patients experiencing problems with their conventional denture received four implants and were randomly allocated to receive a maxillary overdenture with either bar- or solitary attachment retention. Marginal bone level change (primary outcome), implant- and overdenture survival rate, clinical- and patient related outcome measures were recorded at baseline, and after 1 and 5 years. Biological and technical complications were recorded throughout the entire follow-up period.
Results: After 5 years, the mean marginal bone level change was higher in the solitary attachment group (-1.41±1.38mm, *P*=0.024) than in the bar group (-0.99±0.96mm). Also, fewer implants survived in the solitary attachment group (89.5%, *P*=0.027) than in the bar group (96.3%). The overdenture survival rate was 95.0% and 91.3% in the bar and solitary attachment group, respectively. Although the clinical and patient related outcomes were favourable and did not differ significantly between the groups, the peri-implantitis incidence was 25.8% in the solitary attachment group and 5.1% in the bar group. Any technical complications were minor.
Conclusions: In maxillary 4-implant overdenture therapy, the marginal bone level, implant survival rate and the number of complications are better with bar attachments than with solitary attachments. Both groups' clinical and patient related outcome measure scores were equal throughout the entire follow-up period.

Keywords: Dental implants, Maxilla, Overdenture, Bar, Solitary attachments

Received 9 March 2022, Accepted 1 September 2022, Available online 18 October 2022

1. Introduction

Patients experiencing problems with their conventional maxillary denture can benefit from implant-retained overdentures (IODs) [1-3]. Several retention systems are available which can be roughly divided into bar-retained IODs, in which multiple implants are splinted and the overdenture is attached through retentive clips, and into retention systems using non-splinted solitary attachments. Bar-retained IOD's on four implants provide good retention, require little maintenance, but are more expensive than solitary attachments. The medium term results of IOD's on four implants are promising, with high implant and overdenture survival rate and a low incidence of complications, and may be considered the gold standard [1-6]. Solitary attachments, an alternative to bars, are more economical and easy to clean by the patient [7], but wear more easily, which can cause lack of retention [8]. However, replacing these attachments can often be done chair side. A recent review reported that, when a maxillary IOD is supported by four implants, both types show equal implant survival rate, overdenture survival rate and patient satisfaction [9]. However, these conclusions are based on a limited number of randomised controlled trials. Moreover, most studies of solitary attachments were retrospective and of maxillary IOD attachment systems were mostly short term, non-comparing or retrospective, and therefore inconclusive. This underlines the need for studies comparing different attachment systems with a longer follow-up. We conducted a randomised controlled trial to compare the treatment outcomes of fully edentulous patients with maxillary IODs, supported by four implants, retained by either bars or solitary attachments. Marginal bone level change, implant and overdenture survival rate, technical and biological complications, clinical characteristics and patient related outcome measures were assessed during a 5-year follow-up.

2. Materials and Methods

2.1. Patients

Between January 2013 and January 2016, all eligible fully edentulous patients experiencing problems with their maxillary conventional denture and referred to the Department of Oral and Maxillofacial Surgery (University Medical Center Groningen, the Netherlands (UMCG)) were asked to participate in a randomised controlled trial. The patients were considered eligible to participate if they had been fully edentulous for at least one year and had sufficient bone vol-

DOI: https://doi.org/10.2186/jpr.JPR_D_22_00076
***Corresponding author:** Pieter Onclin, Department of Oral and Maxillofacial Surgery, University of Groningen, University Medical Center Groningen, PO Box 30.001, NL-9700 RB Groningen, The Netherlands.
E-mail address: p.onclin@umcg.nl

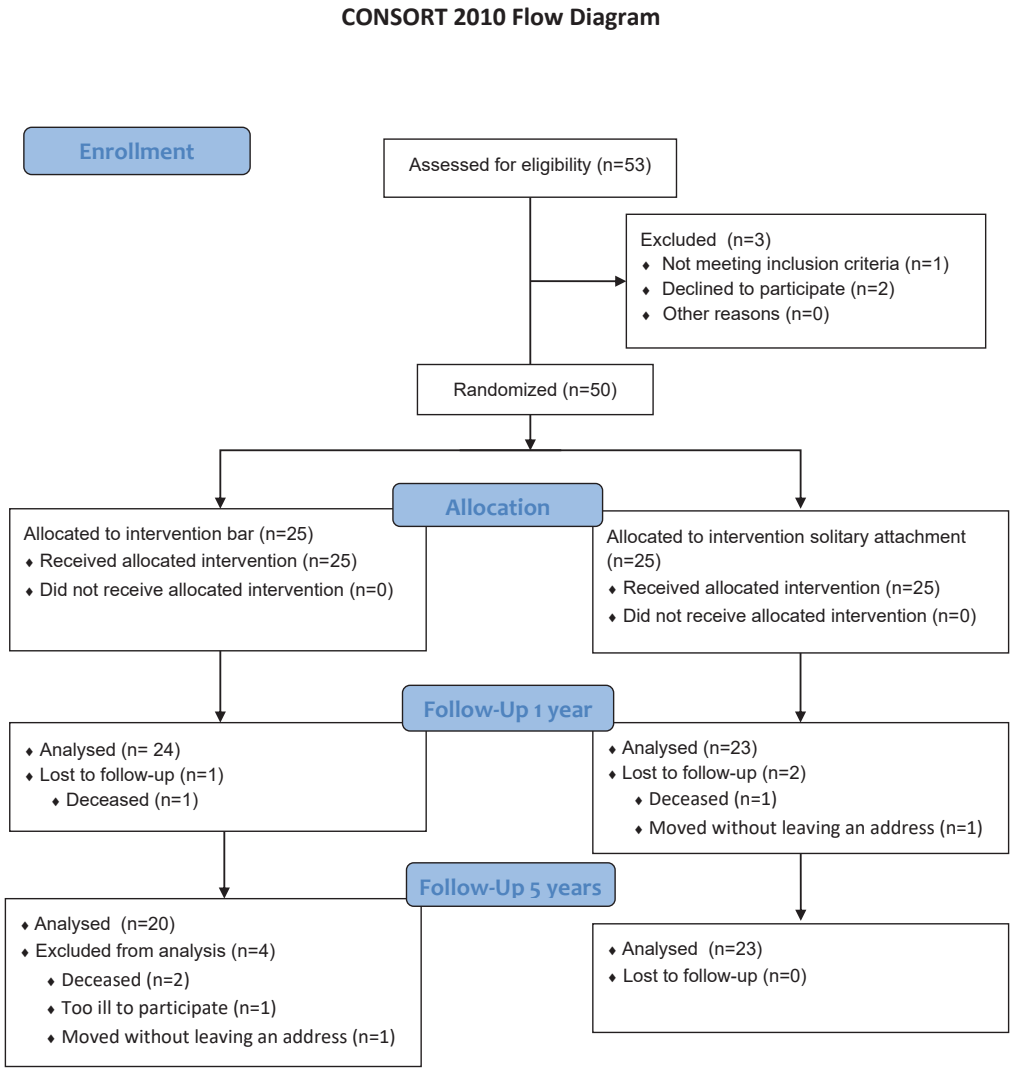

Fig. 1. CONSORT flow diagram

ume to place four implants in the anterior maxilla. The patients were allowed to have mandibular IOD's. The bone volume was assessed using cone beam computed tomography (CBCT). The exclusion criteria were an American Society of Anaesthesiologists score (ASA score [10]) of ≥III, smoking, former radiotherapy in the head and neck region, pre-prosthetic surgery or previous loss of implants in the maxilla. All the participants received oral and written information about the trial. Signed informed consent was obtained from each participant.

The initial 1-year trial was approved by the Medical Ethical Committee of the UMCG and the study was registered in the Dutch Trial Register (NL3813). In the present 5-year follow-up study, no new interventions were carried out and was therefore not considered research performed on test-subjects as meant in the Medical Research Involving Human Subjects Act (WMO) (MEC-reference M20.259187). The study was registered in the trial register as NL9031. This study was conducted in accordance with the 2008 revised requirements of the Helsinki Declaration of 1975 and the CONSORT Guidelines.

Using sealed envelope randomisation, the participants were randomly assigned to receive either the maxillary overdenture with solitary attachments (n = 25), or the maxillary overdenture with bar attachments (n = 25) (**Fig. 1**). The treatment procedures will be described in brief; a full description of all the procedures can be found in the previously reported 1-year results [8].

2.2. Surgical procedure

All the participants received four maxillary implants (Nobel Active Narrow Platform ⌀ 3.5 mm, Nobel Biocare AB, Gothenburg, Sweden), guided by a surgical stent at crestal bone level in predefined positions (anterior implants in the central/lateral incisor region, posterior implants in the cuspid/first bicuspid region) via a two-stage surgical protocol. Incidental bone dehiscence was covered with a mixture of maxillary tuberosity bone and organic bovine bone (Bio-Oss, Geistlich Pharma AG, Wolhusen, Switzerland), and covered with a resorbable membrane (Bio-Gide, Geistlich Pharma AG). In case of partial extension into the anterior region of the sinus, sinus floor elevation surgery was performed using the lateral window technique [11] with bone harvested from the tuberosity and mixed with organic bovine bone. The lateral window was covered by a resorbable col-

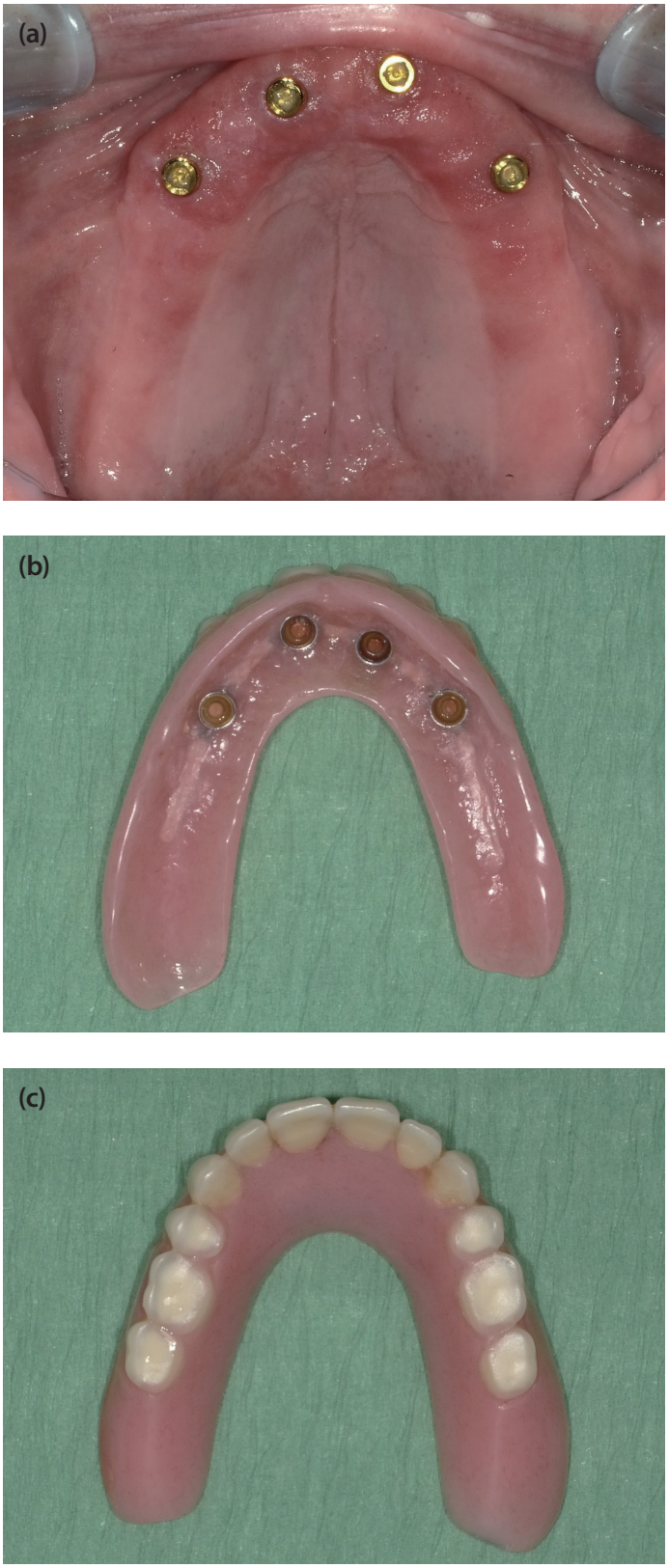

Fig. 2. Intra-oral view (a) and corresponding overdenture (b/c) of a participant with solitary retention after five years

lagen membrane. If not already present, the participants simultaneously received two mandibular implants (Nobel Replace Select TC, Nobel Biocare AB). All the participants received antibiotic prophylaxis before the surgery (Amoxicillin, 3000mg, one hour preoperatively), and then continued afterwards with antibiotics (amoxicillin, 500mg, three times daily, seven days) and an additional 0.2% chlorhexidine mouth rinse (Corsodyl, GlaxoSmithKline). The participants were instructed not to wear their conventional prosthesis for two weeks. Thereafter, 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 a standard prosthetic procedure was initiated.

2.3. Prosthetic procedure

The solitary attachment group's final superstructure consisted of an overdenture with a built-in cobalt chromium reinforcement structure with Locator® denture caps and nylon Locator® males which were connected to four Locator® attachments (DIT-USA, Scottsdale, Arizona, USA; **Fig. 2**). The study's participants were initially provided with pink inserts (13.4 N; medium force), providing possibilities to strengthen or loosen the retentive force. Regarding the bar group, the final superstructure consisted of an overdenture with gold retentive clips (Cendres+Metaux, Biel/Bienne, Switzerland) that were point-lasered to a virtually designed, 3D-printed cobalt chromium reinforcement (Proscan, Zonhoven, Belgium), attached to a virtually designed, milled ovoid titanium bar with distal extensions (Proscan, Zonhoven, Belgium) which were screw-retained to multi-unit abutments (Nobel Biocare AB) (**Fig. 3**). The overdenture was attached to the two bars with three retentive clips per bar. Both groups' overdentures were designed without palatal coverage of the maxilla. Most participants simultaneously received a mandibular IOD. In case the participant's current IOD was adequate, no new IOD was made. The participants were instructed in hygiene procedures associated with the overdentures and superstructures, and routine maintenance appointments were scheduled.

2.4. Outcome measures

The primary outcome measure was marginal bone level change (MBLC). Implant survival rate, overdenture survival rate, clinical characteristics, biological complications, technical complications and patient related outcome measures (PROMs) were the secondary outcome measures. Clinical and radiographic evaluations took place at one month (T1), 12 months (T12) and 60 months (T60) after the prosthetic loading. The PROMs were evaluated before treatment (T0), at T12 and T60.

2.4.1. Marginal bone level change

The radiographs were taken with an Extension Cone Paralleling Photostimulable Phosphor holder (RINN, Dentsply, Elgin, IL, USA). Linear measurements were performed by one blinded experienced observer (HJAM) with measurement software (Biomedical Engineering, University Medical Center Groningen, the Netherlands). Prior to analysis, the superstructures were cropped from the digital radiographs to facilitate blinded measurements. The neck of the implant was used as a reference line for all the measurements. The images were calibrated using the implant's dimensions. Measurements were done at the mesial and distal side of each implant. MBLC was defined as the difference in bone height between the radiograph taken at T1 (baseline) and T12 or T60. The side having the largest MBLC (mesial or

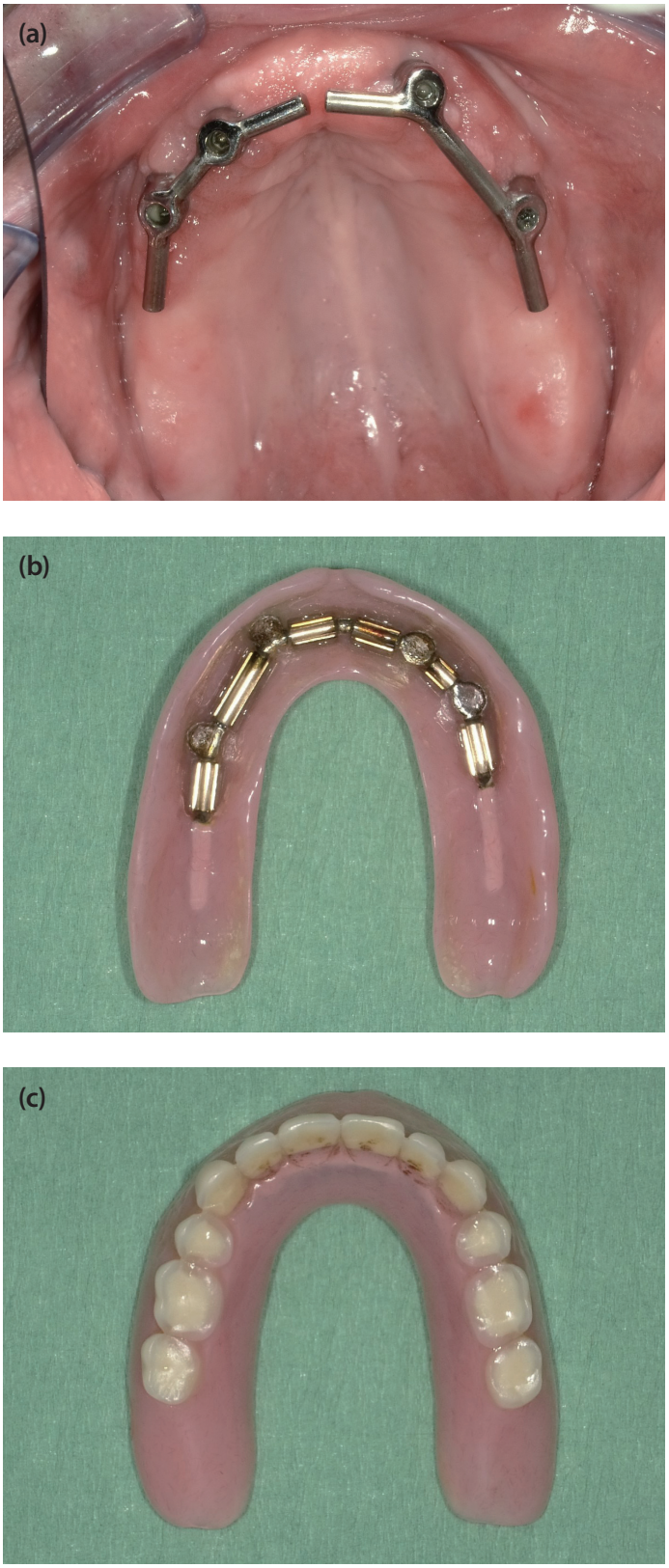

Fig. 3. Intra-oral view (a) and corresponding overdenture (b/c) of a participant with bar retention after five years

distal) of each individual implant was used for analysis.

2.4.2. Implant and overdenture survival rate

Implant survival rate was defined as the percentage of implants still present and not mobile at the follow-up evaluation. Percussion testing was done to assess implant mobility. The bar group's assessment occurred after the bar was removed. Maxillary overdenture survival rate was defined as the percentage of the initially placed overdentures still present at the follow-up.

2.4.3. Clinical parameters

For each implant, the following clinical characteristics were assessed:

- The presence of plaque using the index described by Loë and Silness [12] (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: an abundance of plaque). For each participant, the implant with the highest score was used for analysis.
- The presence of calculus with a score of 0 or 1 (the absence or presence of calculus, respectively). For each participant, the implant with the highest score was used for analysis.
- Peri-implant mucosa health using the modified Löe and Silness index [12] (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 each participant, the implant with the highest score was used for analysis.
- Bleeding on probing using the Mombelli *et al*. index [13] (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). For each participant, the implant with the highest score was used for analysis.
- The peri-implant probing depth was measured at four sites of each implant (mesial, vestibular, distal and oral) with a manual periodontal probe; the distance between the marginal border of the mucosa and the tip of the periodontal probe was noted as probing depth. Probing depth change (PDC) was defined as the difference in probing depth between the T1 (baseline) and T12 or T60. The largest PDC of each participant was used for analysis.

2.4.4. Biological and technical complications

Biological complications, i.e. peri-implantitis and peri-implant mucositis, were calculated at the end of the follow-up period. A case of peri-implantitis was defined as a site showing bleeding and/or suppuration on probing and a MBLC ≥-2 mm, whereas peri-implant mucositis was defined as a site showing bleeding and/or suppuration on probing with a radiographic MBLC <-2mm, following the consensus reached at the 2017 World Workshop on the Classification of Periodontal and Peri-Implant Diseases and Conditions [14]. Implants that failed due to severe bone loss (e.g. were untreatable for peri-implantitis) were removed and were scored as lost implants. Any implants that were treated or lost because of peri-implant diseases were added to the 5-year follow-up data. Technical complications

Table 1. Mean values and standard deviations (SD) of the marginal bone level change in mm for the solitary attachment and bar groups, and the frequency distribution of the marginal bone level change 1 and 5 years after overdenture placement

	1 year after prosthesis placement			5 years after prosthesis placement		
	Solitary attachment (n = 23)	Bar (n = 24)		Solitary attachment (n = 23)	Bar (n = 20)	
Mean mm (SD)	-0.58 (0.71)	-0.31 (0.47)	$P = 0.002$[a]	-1.41 (1.38)	-0.99 (0.96)	$P = 0.024$[a]
0 to -0.5 mm	55.9%	71.4%		29.5%	42.7%	
>0.5 to -1.0 mm	17.2%	18.4%		18.2%	15.9%	
>-1.0 to -1.5 mm	17.2%	6.1%		18.2%	17.1%	
>-1.5 to -2.0 mm	6.5%	3.1%		11.4%	6.1%	
> -2.0 to -2.5 mm	1.1%	1.0%		1.1%	8.5%	
> -2.5 to -3.0 mm	1.1%	0.0%		5.7%	4.9%	
> -3 mm	1.1%	0.0%		15.9%	4.9%	

[a] Differences between the study groups were tested with the independent Student's t-test

were scored at any time after overdenture placement and included loosening of denture teeth, replacement or tightening of nylon caps or gold clips due to retention loss, and adaptation of the denture edges because of pressure ulcers.

2.4.5. Patient related outcome measures

The PROMs were assessed from three validated questionnaires focusing on chewing ability [15], denture satisfaction [16] and oral health quality of life [17]. PROMs were compared within and between groups.

2.5. Sample-size estimation

A sample size estimation was carried out with a statistical power analysis software [18]. A 0.4±0.5 mm marginal bone level change was estimated as a clinically relevant difference between groups, partly based on a previous systematic review on implant overdentures [19]. An alpha of 0.05 and a power of 0.85 meant the calculated sample size for between group comparison had to be n = 46. A sample size of 50 took into account any possible loss to follow-up.

2.6. Data analysis

Continuous data (MBLC, PDC, PROMs) were tested for normality with the Shapiro-Wilk test and additional histogram observation. If normality was assumed, these data were analysed using a student T-test. If normality was not assumed, these data were analysed with the Wilcoxon signed rank test (for within-group differences) and Mann-Whitney U-test (for between-group differences).

All the other clinical variables (ordinal data) were analysed via Wilcoxon signed rank tests (for within-group differences) and a Mann-Whitney U test (for between-group differences). Implant and overdenture survival rate differences between the groups were calculated using a Log Rank test.

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

3. Results

3.1. Patient Characteristics

The solitary attachment group's mean age was 60.1 years (+- 8.6, range 37.5-75.0) and the bar group's was 63.8 years (+- 5.4, range 53.0-72.6). Gender distribution was equal in both groups (13 male, 12 female). During the follow-up period, four participants deceased (one in the solitary attachment group, three in the bar group), two participants moved without leaving an address (one in each group) and one participant (bar group) was too ill to attend the 5-year follow-up. Consequently, 23 solitary attachment group participants and 20 bar group participants were available for the 5-year evaluation (**Fig. 1**).

3.2. Normality testing

Regarding MBLC and PDC, normality of data was assumed since the Shapiro-Wilk test did not result in a significant difference between the groups and the histograms had a bell-shaped curve. The PROMs showed there was a significant difference between the groups, thus normality of data was not assumed.

3.3. Marginal bone level change

The mean MBLC after 5 years was -1.41±1.38mm for the solitary attachment group and -0.99±0.96mm for the bar group, which was statistically significant (*P*=0.024, **Table 1**).

3.4. Implant survival rate

Five implants in five participants were lost during osseointegration (three in the solitary attachment group, two in the bar group); they were not replaced since an overdenture could still be fabricated using the remaining three implants. No additional implants were lost in the first year but, after five years, four other participants had lost seven implants, all in the solitary attachment group. This resulted in a 5-year survival rate of 89.5% in the solitary attachment group and 96.3% in the bar group. The difference in implant survival between the groups was statistically significant ($P = 0.027$, Log Rank test, **Fig. 4**).

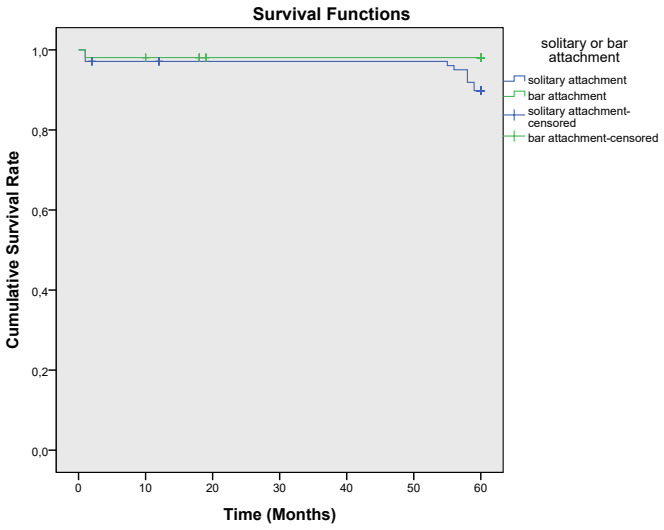

Fig. 4. Kaplan Meier curve of implant survival

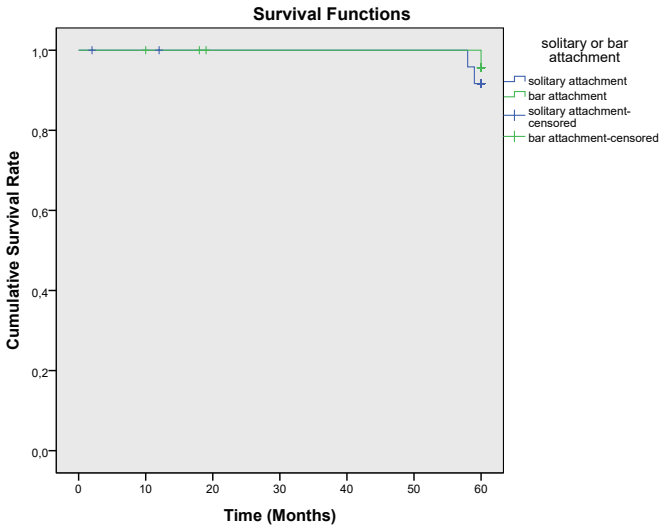

Fig. 5. Kaplan Meier curve of overdenture survival

Table 2. Median change and interquartile range of the highest score per participant, from baseline to the 1 and 5 year follow-ups, for plaque-index, bleeding-index, gingival-index and presence of calculus. Mean change and standard deviations of the largest probing depth change per participant from baseline to the 1 and 5 year follow-ups.

Change from baseline	After 1 year			After 5 years		
	Solitary attachment (n=23)	Bar group (n=24)	*P*-value	Solitary attachment (n=23)	Bar group (n=20)	*P*-value
Plaque-index [IQR] (range 0-3)	0 [-1;1]	0 [-1;1]	0.870[a]	0 [-1;0]	0 [-1.5;0]	0.541[a]
Bleeding-index [IQR] (range 0-3)	0 [-1;0]	0 [0;0.75]	0.135[a]	0 [0;1]	0 [0;0.5]	0.719[a]
Gingival-index [IQR] (range 0-3)	0 [-1;0]	0 [-0.75;0]	0.239[a]	0 [-1;0]	0 [0;0.5]	0.490[a]
Calculus-presence [IQR] (range 0-1)	0 [0;0]	0 [0;0]	1.000[a]	0 [0;0]	0 [0;0]	0.114[a]
Probing depth change in mm (SD)	0.4 (1.0)	0.3 (0.9)	0.541[b]	0.6 (1.1)	0.7 (0.9)	0.697[b]

Differences between the study groups were tested with the [a]Mann–Whitney U test or [b]the independent Student's t-test.
IQR: interquartile range; SD: standard deviation

3.5. Overdenture survival rate

A decision was made not to replace two of the participants' implants because they did not experience any loss of retention. The two and three implants that were lost by two other participants were replaced, as were their overdentures. One additional participant's (bar group) overdenture was replaced due to wear, resulting in an overdenture survival rate of 95.0% for the bar group and 91.3% for the solitary attachment group. The difference between the groups was not statistically significant ($P = 0.591$, Log-Rank test, **Fig. 5**).

3.6. Probing depth change and clinical indices

The mean PDC at the 5-year follow-up was +0.6±1.1mm for the solitary attachment group and +0.7±0.9mm for the bar group. The median plaque, calculus, gingival condition and bleeding indices scores are depicted in **Table 2**; there were no significant differences between the groups.

3.7. Biological and technical complications

Peri-implant mucositis occurred in 47.8% and 15.0% of the solitary attachment and bar groups' participants, respectively. Peri-implantitis occurred in 25.8% and 5.1% of the solitary attachment and bar groups' participants, respectively (**Table 5**). The calculated incidence rates include the treated and lost implants. Technical complications consisted of the replacement of attachment matrices (n=4), retightening of an abutment screw (n=1, solitary attachment group), tooth fracture repair (n=2, solitary attachment group) and prosthesis base fracture repair (n=1, bar group).

3.8. Patient related outcome measures: within group comparison

The within group PROMS comparison is listed in **Table 3**. All the OHIP-NL and subscale items had improved significantly at the 5 year follow-up. The functional complaints questionnaire items regarding 'functional complaints upper denture', 'general functional complaints', 'facial aesthetics' and 'general satisfaction score upper

Table 3. Within-group comparison of the patient related outcome measures, specifically the OHIP-49NL, denture complaints questionnaire and chewing ability before treatment and 1 and 5 years after treatment

	Solitary attachment group					Bar group				
	Pre-treatment	After 1 year	Comparison Pre-treatment –After 1 year	After 5 years	Comparison Pre-treatment –After 5 years	Pre-treatment	After 1-year	Comparison Pre-treatment –After 1 year	After 5-year	Comparison Pre-treatment –After 5 years
Functional limitation [IQR] (max. 36)	17 [12.5-23]	9 [3-17]	$P = 0.002$**	7.5 [5-12.75]	$P < 0.001$***	19 [11.5- 23.25]	6 [2-8.5]	$P < 0.001$***	4 [0.75-11.25]	$P < 0.001$***
Physical pain [IQR] (max. 36)	17 [10-23]	3.5 [0.25-10.5]	$P < 0.001$***	4 [1-11]	$P < 0.001$***	19 [10.75-23]	2 [0-6.75]	$P < 0.001$***	1 [0-10]	$P < 0.001$***
Psychological discomfort [IQR] (max. 20)	10 [8-16]	4 [0-9]	$P = 0.001$**	1 [0-8]	$P < 0.001$***	8.5 [2-14]	1 [0-6.5]	$P = 0.002$**	0 [0.3.25]	$P < 0.001$***
Physical disability [IQR] (max. 36)	17 [9-26.5]	4.5 [1-10]	$P < 0.001$***	3.5 [0.25-8.5]	$P = 0.001$**	16 [9-21.5]	1 [0-6]	$P < 0.001$***	1.5 [0-6.75]	$P < 0.001$***
Psychological disability [IQR] (max. 24)	6 [3-15]	1.5 [0-4]	$P = 0.002$**	1 [0-5.5]	$P = 0.016$*	7 [0.75-13]	0 [0-2]	$P < 0.001$***	0 [0-2.5]	$P = 0.001$**
Social disability [IQR] (max. 20)	6 [1.5-13.5]	0 [0-2.75]	$P = 0.006$**	0 [0-1.75]	$P = 0.002$**	4 [0.75-8.25]	0 [0-0.5]	$P = 0.001$**	0 [0-0.25]	$P = 0.004$**
Handicap [IQR] (max. 24)	8 [3-11]	1 [0-3.75]	$P = 0.001$**	0 [0-2.75]	$P < 0.001$***	3.5 [1.75-9]	0 [0-0]	$P < 0.001$***	0 [0-2]	$P = 0.002$**
Total OHIP-NL49 score [IQR] (max. 196)	77 [59.5-120.5]	26.0 [9.0-61.0]	$P < 0.001$***	21.0 [8.0-46.0]	$P < 0.001$***	84 [52-105.5]	12.5 [3-36.5]	$P < 0.001$***	8 [2-43.5]	$P < 0.001$***
Functional complaints upper denture [IQR] (max. 27)	13 [8.75-23]	2 [0-4]	$P < 0.001$***	2 [1-4]	$P < 0.001$***	15.5 [8.75-19.25]	1.06 [1-2]	$P < 0.001$***	1 [0-4]	$P < 0.001$***
Functional complaints in general [IQR] (max. 54)	23 [16.25-31.25]	3 [1-6.25]	$P < 0.001$***	2.5 [0-5.75]	$P < 0.001$***	15 [7.25-27.50]	1 [0-4.75]	$P < 0.001$***	2 [0-7.25]	$P < 0.001$***
Facial aesthetics [IQR] (max. 9)	4.5 [1-6.5]	0 [0-3]	$P = 0.006$**	1 [0-2.75]	$P < 0.001$***	2 [0-5.25]	0 [0-0]	$P = 0.003$**	0 [0-3]	$P = 0.045$*
"Neutral Space" [IQR] (max. 9)	1 [0-3]	0.5 [0-2.25]	ns	0 [0-2]	ns	0.5 [0-2]	0 [0-1]	ns	0 [0-2]	ns
Aesthetics [IQR] (max. 36)	1[0-5.5]	0 [0-1.25]	ns	1 [0-3]	ns	0 [0-1.25]	0 [0-1]	ns	0 [0-2.25]	ns
General satisfaction score upper denture [IQR]	4 [1-6]	8 [7-9]	$P < 0.001$***	8 [8-9]	$P < 0.001$***	4 [2-6]	9 [8-10]	$P < 0.001$***	8 [8-9]	$P < 0.001$***
Total food chewing score [IQR] (max. 18)	11 [6-15]	4 [2-7]	$P < 0.001$***	3 [1-6]	$P < 0.001$***	11 [9-12]	0 [0-3]	$P < 0.001$***	2 [2-5]	$P < 0.001$***
Soft foods score [IQR] (max. 6)	1 [1-3]	0 [0-0]	$P = 0.007$**	0 [0-0]	$P = 0.007$ **	2 [1-3]	0 [0-0]	$P < 0.001$***	0 [0-0]	$P < 0.001$***
Tough foods score [IQR] (max. 6)	3 [2-5]	0 [0-2]	$P < 0.001$***	1 [0-2]	$P < 0.001$***	4 [3-4]	0 [0-0]	$P < 0.001$***	0 [0-0]	$P < 0.001$***
Hard foods score [IQR] (max. 6)	6 [4-6]	3 [2-6]	$P = 0.007$**	2 [1-4]	$P < 0.001$***	6 [5-6]	0 [0-2]	$P < 0.001$***	2 [0-4]	$P < 0.001$***

Differences were tested with the Wilcoxon Matched Pairs Signed Ranks test. IQR: interquartile range; ns: no significant differences. *: $P < 0.05$, ** $P < 0.01$, ***$P < 0.001$

denture' had also improved significantly in both groups. The same applied to chewing of all types of foods according to the 5 year follow-up questionnaire.

3.9. Patient related outcome measures: between group comparison

A comparison of the between group PROMs, as listed in **Table 4**, did not result in significant differences between the groups for any individual questionnaire items or the Total OHIP-NL49 score. Considering the functional complaints questionnaire, both groups were equally satisfied with their maxillary overdenture. Despite chewing in general, as well as chewing tough and hard foods favouring the bar group at the 1 year follow-up, these differences had balanced out by the 5-year follow-up.

4. Discussion

Based on the results of the present study's 5-year follow-up period, a maxillary four-implant overdenture and a bar attachment system is the more favourable therapy for fully edentulous patients compared to a solitary attachment system, considering the significantly lower amount of marginal bone level change and significantly higher implant survival rate.

4.1. Other studies

Current maxillary overdenture research is mainly focused on retention with bars. Several prospective studies with a 5-year follow-up period reported high survival rates, ranging from 97.7% - 100%, combined with a low MBLC ranging from -0.2mm to -1.2mm after five years [1-5], which are in line with the present study's findings. The studies focusing on solitary attachments were mostly retrospective. Compared to bars, these studies showed a predominantly higher MBLC ranging from -0.4 to -1.7 mm, lower survival rates ranging from 92% to 98.9%, but with a shorter mean follow-up period ranging from 32.9-58 months [20-23]. The only prospective study on IODs retained by solitary attachments, performed by Bouhy *et al.* [24] reported a mean MBLC of -1.01 mm after one year, with a relatively low survival rate of 86.2%. There are two comparative prospective studies available with a follow-up longer than 5 years. The first

Table 4. Between-group comparisons of patient related outcome measures, specifically the OHIP-49NL, Denture Complaints questionnaire and chewing ability before treatment and 1 and 5 years after treatment

	Pre-treatment			After 1 year			After 5 years		
	Solitary attachment group (n=25)	Bar group (n=25)		Solitary attachment group (n=23)	Bar group (n=24)		Locator® group (n=23)	Bar group (n=20)	
Functional limitation [IQR] (max. 36)	17 [12.5-23]	19 [11.5-23.25]	ns	9 [3-17]	6 [2-8.5]	ns	7.5 [5-12.75]	4 [0.75-11.25]	ns
Physical pain [IQR] (max. 36)	17 [10-23]	19 [10.75-23]	ns	3.5 [0.25-10.5]	2 [0-6.75]	ns	4 [1-11]	1 [0-10]	ns
Psychological discomfort [IQR] (max. 20)	10 [8-16]	8.5 [2-14]	ns	4 [0-9]	1 [0-6.5]	ns	1 [0-8]	0 [0.3.25]	ns
Physical disability [IQR] (max. 36)	17 [9-26.5]	16 [9-21.5]	ns	4.5 [1-10]	1 [0-6]	ns	3.5 [0.25-8.5]	1.5 [0-6.75]	ns
Psychological disability [IQR] (max. 24)	6 [3-15]	7 [0.75-13]	ns	1.5 [0-4]	0 [0-2]	ns	1 [0-5.5]	0 [0-2.5]	ns
Social disability [IQR] (max. 20)	6 [1.5-13.5]	4 [0.75-8.25]	ns	0 [0-2.75]	0 [0-0.5]	ns	0 [0-1.75]	0 [0-0.25]	ns
Handicap [IQR] (max. 24)	8 [3-11]	3.5 [1.75-9]	ns	1 [0-3.75]	0 [0-0]	ns	0 [0-2.75]	0 [0-2]	ns
Total OHIP-NL49 score [IQR] (max. 196)	77 [59.5-120.5]	84 [52-105.5]	ns	26.0 [9.0-61.0]	12.5 [3-36.5]	ns	21.0 [8.0-46.0]	8 [2-43.5]	ns
Functional complaints upper denture [IQR] (max. 27)	13 [8.75-23]	15.5 [8.75-19.25]	ns	2 [0-4]	1.06 [1-2]	ns	2 [1-4]	1 [0-4]	ns
Functional complaints in general [IQR] (max. 54)	23 [16.25-31.25]	15 [7.25-27.50]	$P = 0.033$*	3 [1-6.25]	1 [0-4.75]	ns	2.5 [0-5.75]	2 [0-7.25]	ns
Facial aesthetics [IQR] (max. 9)	4.5 [1-6.5]	2 [0-5.25]	ns	0 [0-3]	0 [0-0]	ns	1 [0-2.75]	0 [0-3]	ns
"Neutral Space" [IQR] (max. 9)	1 [0-3]	0.5 [0-2]	ns	0.5 [0-2.25]	0 [0-1]	ns	0 [0-2]	0 [0-2]	ns
Aesthetics [IQR] (max. 36)	1 [0-5.5]	0 [0-1.25]	$P = 0.046$*	0 [0-1.25]	0 [0-1]	ns	1 [0-3]	0 [0-2.25]	ns
General satisfaction score upper denture [IQR]	4 [1-6]	4 [2-6]	ns	8 [7-9]	9 [8-10]	$P = 0.041$*	8 [8-9]	8 [8-9]	ns
Total food chewing score [IQR] (max. 18)	11 [6-15]	11 [9-12]	ns	4 [2-7]	0 [0-3]	0.001	3 [1-6]	2 [2-5]	ns
Soft foods score [IQR] (max. 6)	1 [1-3]	2 [1-3]	ns	0 [0-0]	0 [0-0]	ns	0 [0-0]	0 [0-0]	ns
Tough foods score [IQR] (max. 6)	3 [2-5]	4 [3-4]	ns	0 [0-2]	0 [0-0]	0.034	1 [0-2]	0 [0-0]	ns
Hard foods score [IQR] (max. 6)	6 [4-6]	6 [5-6]	ns	3 [2-6]	0 [0-2]	<0.001	2 [1-4]	2 [0-4]	ns

Differences between the study groups were tested with the Mann–Whitney U test. IQR: interquartile range; ns: no significant differences. *: $P < 0.05$, ** $P<0.01$.

Table 5. Incidence rates of peri-implant mucositis and peri-implantitis (including the lost implants data)

	5 years after prosthesis placement		
	Solitary attachment	Bar	Total
Implants at risk (n)	89	79	168
Peri-implant mucositis	69.6%	45.0%	58.1%
Peri-implantitis	44.9%	22.8%	34.5%
Patients at risk (n)	23	20	43
Peri-implant mucositis	47.8%	15.0%	32.6%
Peri-implantitis	25.8%	5.1%	16.1%

study compared 3-implant retained overdentures with ball- or bar-attachments over a follow-up period of 10 years and reported a mean MBLC of -0.84 mm and a 87% survival rate, with no differences between the groups [6]. The low survival rate was mostly due to failed osseointegration (12 out of 16 implants). The second study compared 4-implant overdentures with bars and solitary in a prospective cohort study with a mean follow-up of 11.4 years [25]. They reported a cumulative failure rate of 23.8%. Though more implants were lost by the solitary attachment group, the difference was not significant. Interestingly, most of the bar group's implants failed in the first year after loading, while the solitary attachment group's implant failure was more wide-spread, with 5 failures in the first year, 4 in the fourth year and 2 in the eleventh year. We also observed such a failure pattern in both groups.

4.2. The effect of clinical parameters

In the present study, the median plaque-, bleeding, gingival- and calculus scores and mean probing pocket depth remained low throughout the entire follow-up period, which is in line with the findings of other studies [1-3], and so we do not think it contributed to the differences in MBLC and implant loss found between the groups. Therefore, the idea that solitary attachments aid in easier oral hygiene could not be supported either. In fact, while the peri-implantitis incidence in the bar group was in line with comparable studies [1,2], the solitary attachment group suffered from higher incidences of infection, suggesting that solitary attachments are more prone to infection.

4.3. Possible cause for group differences

A possible explanation for the group differences may be associated with the higher load that the solitary attachment group's system has to bear, which was demonstrated *in vitro* [26-28], combined with the poor bone quality that is often present in edentulous maxillae, leading to a higher incidence of implant failure [29,30]. Unfortunately, a correlation between occlusal (over)load and implant and/or peri implant bone loss could not be made here and should therefore be included in future research.

4.4. The patient's experience

Though the complication rate with solitary attachments seems to be higher than with bars, most repairs are minor and can often be performed chair side, which was also recognized by other studies [20-23]. This, however, does not seem to influence the patient's experience. Both our groups scored equally high in terms of patient related outcome measures, which is in line with other studies [1-3,20,21]. While the bar group's score on patient satisfaction was significantly better than the solitary attachment group's at the 1-year follow-up, this did not remain significant after five years. The equalization may be attributed to a longer adaptation period in the solitary attachment group compared to the bar group. On the other hand, the bar group's median satisfaction score decreased, which means both groups' scores became more similar. Also the ability to chew hard and tough foods did not remain significantly different between the groups, which may have contributed to the equal satisfaction scores. Nonetheless, both groups' PROMs scores were significantly higher compared to baseline, underlining the participants' sustained satisfaction with their overdentures in spite of higher implant loss and more minor complications in the solitary attachment group.

4.5. Future research

Given the differences and similarities between the present study's groups, it would be interesting to know how both PROMs, as well as radiographic- and clinical parameters, will develop over the coming years. Additionally, to be able to provide more predictable results, future research should focus more on the possible factors influencing peri-implant health and disease, especially in patients with poor baseline bone conditions, as in the present study.

4.6. Limitations

A limitation of studies with a relatively long evaluation period is the loss to follow-up, especially patients with a relatively higher age, which is often the case with fully edentulous patients. In the present study, the conclusions on MBLC change may have lost some power since three participants from the bar group had deceased and one was too ill to participate. On the other hand, the MBLC was strongly significant, which may have compensated for the loss to follow-up. It is also important to realize that, since the study was university-based, the results may deviate from those achieved by a daily dental practice.

5. Conclusions

In maxillary 4-implant overdenture therapy, the marginal bone level, implant survival rate and the number of complications are better with bar attachments than with solitary attachments. Both groups' clinical and patient related outcome measure scores were equal throughout the entire follow-up period.

Conflicts of interest

The authors declare no conflict of interest.

References

[1] Slot W, Raghoebar GM, Cune MS, Vissink A, Meijer HJ. Maxillary overdentures supported by four or six implants in the anterior region: 5-year results from a randomized controlled trial. J Clin Periodontol. 2016;43:1180-7. https://doi.org/10.1111/jcpe.12625, PMID:27630092

[2] Slot W, Raghoebar GM, Cune MS, Vissink A, Meijer HJA. Four or six implants in the maxillary posterior region to support an overdenture: 5-year results from a randomized controlled trial. Clin Oral Implants Res. 2019;30:169-77. https://doi.org/10.1111/clr.13403, PMID:30636064

[3] Boven GC, Slot JWA, Raghoebar GM, Vissink A, Meijer HJA. Maxillary implant-supported overdentures opposed by (partial) natural dentitions: a 5-year prospective case series study. J Oral Rehabil. 2017;44:988-95. https://doi.org/10.1111/joor.12557, PMID:28856707

[4] Akca K, Cehreli MC, Uysal S. Marginal bone loss and prosthetic maintenance of bar-retained implant-supported overdentures: a prospective study. Int J Oral Maxillofac Implants. 2010;25:137-45. PMID:20209196

[5] Mangano C, Mangano F, Shibli JA, Ricci M, Sammons RL, Figliuzzi M. Morse taper connection implants supporting "planned" maxillary and mandibular bar-retained overdentures: a 5-year prospective multicenter study. Clin Oral Implants Res. 2011;22:1117-24. https://doi.org/10.1111/j.1600-0501.2010.02079.x, PMID:21251077

[6] Ma S, Waddell JN, Atieh MA, Alsabeeha NH, Payne AG. Maxillary three-implant overdentures opposing mandibular two-implant overdentures: 10-Year Prosthodontic Outcomes. Int J Prosthodont. 2016;29:327-36. https://doi.org/10.11607/ijp.4631, PMID:27479337

[7] Cordaro L, di Torresanto VM, Petricevic N, Jornet PR, Torsello F. Single unit attachments improve peri-implant soft tissue conditions in mandibular overdentures supported by four implants. Clin Oral Implants Res. 2013;24:536-42. https://doi.org/10.1111/j.1600-0501.2012.02426.x, PMID:22320359

[8] Boven GC, Meijer HJA, Vissink A, Raghoebar GM. Maxillary implant overdentures retained by use of bars or locator attachments: 1-year findings from a randomized controlled trial. J Prosthodont Res. 2020;64:26-33. https://doi.org/10.1016/j.jpor.2019.04.013, PMID:31201036

[9] Di Francesco F, De Marco G, Sommella A, Lanza A. Splinting vs not splinting four implants supporting a maxillary overdenture: a systematic review. Int J Prosthodont. 2019;32:509-18. https://doi.org/10.11607/ijp.6333, PMID:31664267

[10] Smeets EC, de Jong K J, Abraham-Inpijn L. Detecting the medically compromised patient in dentistry by means of the medical risk-related history. A survey of 29,424 dental patients in The Netherlands. Prev Med. 1998;27,530–5. https://doi.org/10.1006/pmed.1998.0285, PMID:9672946

[11] Raghoebar GM, Meijer HJ, Telleman G, Vissink A. Maxillary sinus floor augmentation surgery with autogenous bone grafts as ceiling: a pilot study and test of principle. Clin Implant Dent Relat Res 2013;15:550–7. https://doi.org/10.1111/j.1708-8208.2011.00409.x, PMID:22171568

[12] Loë H, Silness J. Periodontal disease in pregnancy. I. Prevalence and severity. Acta Odontol Scand 1963;21:533–51. https://doi.org/10.3109/00016356309011240, PMID:14121956

[13] Mombelli A, van Oosten MA, Schurch Jr E, Land NP. The microbiota associated with successful or failing osseointegrated titanium implants. Oral Microbiol Immunol 1987;2:145–51. https://doi.org/10.1111/j.1399-302x.1987.tb00298.x, PMID:3507627

[14] Berglundh T, Armitage G, Araujo MG, et al. Peri-implant diseases and conditions: Consensus report of workgroup 4 of the 2017 World Workshop on the Classification of Periodontal and Peri-Implant Diseases and Conditions. J Clin Periodontol. 2018;45 Suppl 20:S286-91. https://doi.org/10.1111/jcpe.12957, PMID:29926491

[15] Raghoebar GM, Meijer HJ, van 't Hof M, Stegenga B, Vissink A. A randomized prospective clinical trial on the effectiveness of three treatment modalities for patients with lower denture problems. A 10 year follow-up study on patient satisfaction. Int J Oral Maxillofac Surg. 2003;32:498-503. PMID:14759108

[16] Vervoorn JM, Duinkerke AS, Luteijn F, van de Poel AC. Assessment of denture satisfaction. Community Dent Oral Epidemiol 1988;16:364–7. https://doi.org/10.1111/j.1600-0528.1988.tb00583.x, PMID:3060310

[17] Slade GD, Spencer AJ. Development and evaluation of the Oral Health Impact Profile. Community Dent Health. 1994;11:3-11. PMID:8193981

[18] Faul F, Erdfelder E, Lang A-G, Buchner A. G*Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. Behav Res Methods 2007;39,175-91. https://doi.org/10.3758/bf03193146, PMID:17695343

[19] Slot W, Raghoebar GM, Vissink A, Huddleston Slater JJ, Meijer HJ. A systematic review of implant-supported maxillary overdentures after a mean observation period of at least 1 year. J Clin Periodontol. 2010;37:98-110. https://doi.org/10.1111/j.1600-051x.2009.01493.x, PMID:19995402

[20] Troeltzsch M, Troeltzsch V, Brodine AH, Frankenberger R, Messlinger K, Troeltzsch M. Clinical performance and peri-implant parameters of 132 implants supporting locator-retained overdentures: a case series of 33 patients. Int J Oral Maxillofac Implants. 2013;28:1132-9. https://doi.org/10.11607/jomi.3009, PMID:23869372

[21] Wang F, Monje A, Huang W, Zhang Z, Wang G, Wu Y. Maxillary Four implant-retained overdentures via Locator® attachment: intermediate-term results from a retrospective study. Clin Implant Dent Relat Res. 2016;18:571-9. https://doi.org/10.1111/cid.12335, PMID:25810348

[22] Mo A, Hjortsjö C, Olsen-Bergem H, Jokstad A. Maxillary 3-implant removable prostheses without palatal coverage on Locator abutments - a case series. Clin Oral Implants Res. 2016;27:1193-9. https://doi.org/10.1111/clr.12724, PMID:26566604

[23] Guédat C, Nagy U, Schimmel M, Müller F, Srinivasan M. Clinical performance of LOCATOR® attachments: A retrospective study with 1-8 years of follow-up. Clin Exp Dent Res. 2018;4:132-45. https://doi.org/10.1002/cre2.122, PMID:30181910

[24] Bouhy A, Rompen E, Lamy M, Legros C, Lecloux G, Lambert F. Maxillary implant overdenture retained by four unsplinted attachments and opposed by a natural or fixed dentition: One-year clinical outcomes. Clin Oral Implants Res. 2020;31:747-67. https://doi.org/10.1111/clr.13623, PMID:32497274

[25] Mañes Ferrer JF, Fernández-Estevan L, Selva-Otaolaurruchi E, Labaig-Rueda C, Solá-Ruíz MF, Agustín-Panadero R. Maxillary implant-supported overdentures: mechanical behavior comparing individual axial and bar retention systems. A Cohort Study of Edentulous Patients. Medicina (Kaunas). 2020;56:139. https://doi.org/10.3390/medicina56030139, PMID:32204564

[26] Takahashi T, Gonda T, Maeda Y. Effect of attachment type on denture strain in maxillary implant overdentures: Part 2. Palateless Overdentures. Int J Oral Maxillofac Implants. 2018;33:80-6. https://doi.org/10.11607/jomi.5936, PMID:29340347

[27] Takahashi T, Gonda T, Tomita A, Maeda Y. Effect of attachment type on implant strain in maxillary implant overdentures: comparison of ball, locator, and magnet attachments. Part 2: Palateless Dentures. Int J Oral Maxillofac Implants. 2018;33:357-64. https://doi.org/10.11607/jomi.6157, PMID:29534124

[28] Nishimura Y, Takahashi T, Gonda T, Ikebe K. Influence of Implant Distribution and Palatal Coverage on the Strain of Splinted Implant and Overdenture in Maxillary Implant Overdentures. Int J Oral Maxillofac Implants. 202;36:281-8. https://doi.org/10.11607/jomi.8558, PMID:33909717

[29] Herrmann I, Lekholm U, Holm S, Kultje C. Evaluation of patient and implant characteristics as potential prognostic factors for oral implant failures. Int J Oral Maxillofac Implants. 2005;20:220-30. PMID:15839115

[30] Chrcanovic BR, Albrektsson T, Wennerberg A. Bone quality and quantity and dental implant failure: a systematic review and meta-analysis. Int J Prosthodont. 2017;30:219–37. https://doi.org/10.11607/ijp.5142, PMID:28319206