

# Mandibular Overdentures Retained by Two Implants: 10-Year Results from a Crossover Clinical Trial Comparing Ball-Socket and Bar-Clip Attachments

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**Purpose:** The aim of this study was to evaluate patient satisfaction and clinical and prosthetic outcomes of two-implant mandibular overdenture treatment with different attachment types after 10 years of function. **Materials and Methods:** In a crossover clinical trial, 18 edentulous subjects with complaints regarding their mandibular dentures received two implants and a new denture with magnet, ball-socket, or bar-clip attachments that were applied in a random order. At the end of the experiment, the attachment type of their choosing was fitted in the overdenture. After 10 years, 7 subjects with a ball-socket and 7 subjects with a bar-clip attachment were available for evaluation. The same questionnaire from 10 years before was completed, and subjects were asked to express their overall appreciation of their dentures on a visual analog scale (VAS). Six scales of denture complaints were constructed. Mean scale and VAS scores between initial evaluation and after 10 years were compared. In addition, marginal probing depths, Bleeding Index, and radiographic marginal bone loss were assessed. **Results:** There was no marked difference in satisfaction between subjects with ball-socket- and bar-clip-retained two-implant mandibular overdentures at initial evaluation and after 10 years of function. **Conclusion:** Patients' appreciation of their implant-retained denture was and remained high over time. Clinical parameters revealed healthy mucosal conditions and stable marginal bone levels, determined radiographically. Probing depths around implants provided with ball-socket attachments were slightly shallower than those with bar-clip attachments after 10 years of function ( $P < .05$ ). *Int J Prosthodont* 2010;23:310–317.

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Lack of retention and stability of the mandibular denture is a common problem among edentulous denture wearers. Initially, treatment with endosseous implants consisted of the placement of four to six implants in combination with a fixed prosthesis. It proved quite successful.<sup>1</sup> Implant overdenture treatment was adopted later, and long-term clinical results were shown to be excellent as well.<sup>2</sup> Over the years, much experience has been gained regarding the benefits of two implant-retained mandibular overdentures. It was demonstrated convincingly in well-designed clinical trials that two-implant overdentures provide superior function and satisfaction when compared to conventional dentures and preprosthetic surgery in patients with persistent denture complaints.<sup>3–10</sup> By some, it is even considered to be the standard of care in cases of mandibular edentulism.<sup>11</sup> Others point out that the benefits in masticatory performance are limited to patients with an atrophic mandible who experience difficulties in adapting to complete conventional dentures and that initial treatment costs are higher.<sup>12,13</sup> Using more than

two implants generally has no obvious clinical, functional, and subjective advantages when they are used to support an overdenture, although specific indications for the use of more than two implants may apply.<sup>14-16</sup> Favorable 1-year clinical and subjective results on the application of a single implant in the symphysis region as compared to two implants have been reported,<sup>17</sup> but a lack of evidence to support this treatment option has also been recognized.<sup>18</sup> There appears to be little difference in oral function and patient satisfaction between mainly tissue-supported and implant-supported mandibular overdentures, and the same applies to removable versus nonremovable prosthetic appliances.<sup>8,19-24</sup> In addition, treatment with fixed dentures has been shown to generate significantly more costs with respect to prosthetic maintenance compared to implant overdenture treatment,<sup>25,26</sup> although others state that the initial costs of treatment need not be different.<sup>27</sup>

When providing a removable two implant-retained mandibular overdenture, various attachment types are available to the clinician: splinting the implants by means of a bar construction or loading them separately through ball-socket attachments, telescopic crown attachments, or magnets. In addition, several variations of conceptionally similar attachment systems (eg, bar-clip attachments with round bars versus egg- or U-shaped Dolder bars and different shapes of ball-socket attachments with gold matrices versus O-ring matrices) may be used.

The ultimate choice of attachment type should be based on scientific evidence related to the clinical performance of the implants and attachments, on objective oral function, and on the patients' appreciation of treatment. The initial and eventual costs of maintenance and repairs must also be taken into account. Such evidence should come from clinical trials comparing restorative options in a single study population, preferably with a long observation period. Unfortunately, studies that address all of these aspects are quite scarce. From a systematic review on patient- and dentist-mediated outcome measures of treatment modalities for the edentulous mandible, a lack of evidence for a single, universally superior treatment modality was noted. The author stipulates the need for better designed, long-term studies to further explore the benefits of each treatment intervention for the edentulous mandible.<sup>28</sup>

In a short-term crossover clinical trial (within-subject comparison) by the present group of authors, the hypothesis that the greater retention and stability of a two implant-retained mandibular overdenture yields higher patient satisfaction and will improve various parameters of masticatory function was tested in 18 subjects. The variation in retention and stability was modeled by applying bar-clip, ball-socket, and magnet

attachments in a random order. The subjects exhibited a higher maximum occlusal force and chewed more efficiently after implant treatment, irrespective of the attachment type used.<sup>7,29,30</sup> No difference in oral functions between the three attachment types was observed, although the degree of retention varied considerably.<sup>31</sup> Subjects strongly preferred bar-clip and ball-socket attachments over magnet attachments, but their preference could not be predicted on the basis of baseline observations.<sup>32</sup> The initial experiment took 1 year to complete for each subject.

The aim of the present study was to compare these initial measures of patient satisfaction and clinical performance of two implant-retained mandibular overdentures with data obtained after 10 years under the null hypothesis that they would be similar. Different attachment types were compared.

## Materials and Methods

### *Patient Population and Treatment Protocol*

Eighteen edentulous subjects from the Royal Dutch Army and Air Force participated in this randomized crossover clinical trial. They were referred to the Centre for Special Dental Care of the Central Military Hospital in Utrecht, The Netherlands, because of functional complaints regarding their mandibular denture. The group consisted of 1 woman and 17 men ranging in age from 33 to 56 years. All subjects were healthy and fit for military service. The bone height in the interforaminal region exceeded 15 mm. Two oral implants (Frialit-2, Friadent) were placed according to a standardized surgical protocol published elsewhere.<sup>30</sup>

Prosthetic procedures started 1 week after stage-one surgery. New, conventional maxillary and mandibular dentures were made. The dentures were made in centric occlusion with balanced articulation and with anatomically shaped acrylic teeth (Bonartic, Ivoclar). In each quadrant, one premolar and two molars were used. One week following stage-two surgery, the healing collars were removed and pickup impression posts were placed at the implant level. A master cast was poured and one of three different attachment types was incorporated in the existing, newly fabricated denture: magnet (Dyna magnet ES, type extra strong, Dyna Dental Engineering), bar-clip (round bar in conjunction with a metal omega-shaped IMZ clip, Friadent), and ball-socket (Ball-socket attachment, Frialit-2, Friadent). The mean resistances to vertical dislodgement were approximately 8, 31, and 30 N, respectively.<sup>31</sup>

The attachment type was changed after 3 and 6 months, respectively, in a random order. Because the same denture base was used, similar occlusion and articulation, vertical height, and denture base extension



**Figs 1a and 1b** Examples of (a) ball-socket attachment and (b) bar-clip attachment.



**Figs 1c and 1d** Clip used for the (c) ball-socket attachment and (d) bar-clip attachment.

was maintained throughout the course of the trial.<sup>31</sup> At the end of the initial study, approximately after 1 year, the dentures were fitted with the attachment type of the subjects' choosing. The subjects were referred back to their own dentist for regular maintenance and aftercare. These subjects were recalled and reexamined after 10 years.

Data were gathered prior to implant treatment (old denture), just prior to stage-two surgery (new denture without attachments, after 3 months of function), after 3 months of function with each of the attachment types (overdenture), and after 10 years.

After 10 years, 4 of the initial 18 subjects were lost to follow-up. They left military service and their current whereabouts could not be retrieved. One of these subjects was the only subject who, after the initial experiment, had chosen a magnet-retained mandibular overdenture. It is important to note that in the present report, results are reported on the 14 subjects with a complete data set only. Ball-socket and bar-clip attachments were evenly distributed among the current population. Consequently, two subgroups existed: 7 subjects with ball-socket and 7 subjects with bar-clip attachments, all males (Fig 1).

### ***Patient Satisfaction***

A questionnaire consisting of 54 questions with a four-point scale was developed to gauge patient satisfaction (0 = no complaints, 1 = minor complaints, 2 = moderate problems, and 3 = severe complaints). Subsequently, six scales were constructed (Table 1). The reliability of the constructed scales, measured by calculating their internal consistency and expressed as Cronbach alpha, was satisfactory, showed little variation, and varied between 0.76 and 0.89, depending on the study and the scale.<sup>33</sup>

In addition, the subjects were asked to grade their dentures (overall satisfaction) on a visual analog scale (VAS) ranging from 0 to 100. The subjects were requested to place a dot on a line 100-mm long (0 on one end, 100 on the other). The distance from 0 represented the degree of overall satisfaction. The higher the score, the more satisfied the subject was.

The initial mean scale scores obtained for the final attachment chosen were compared with those after 10 years of function.

**Table 1** Constructed Scales<sup>32</sup>

- Maxillary denture (n = 9 items): eg, “the maxillary denture loosens while eating,” “the maxillary denture loosens while speaking,” “the maxillary denture hurts while eating hard food types,” “burning sensation underneath the maxillary denture”
- Mandibular denture (n = 9 items): eg, “the mandibular denture loosens while eating,” “the mandibular denture loosens while speaking,” “the mandibular denture hurts while eating hard food types,” “burning sensation underneath the mandibular denture”
- General (n = 18 items): eg, “dry mouth,” “chewing is hard,” “teeth and molars from maxillary and mandibular denture make contact while speaking,” “nervousness because of the dentures”
- Physiognomy (n = 3 items): “the lip has fallen in,” “the cheeks have fallen in,” “the mouth has fallen in”
- Neutral space (n = 4 items): “the tongue has too little space,” “I bite my tongue,” “I bite my cheeks,” “I bite my lip”
- Esthetics (n = 11 items): eg, “the teeth are too large,” “the teeth are too white,” “you don’t see enough teeth,” “the teeth are not positioned the way I would like them to be”

### Clinical Parameters

The health of the peri-implant mucosa was assessed after marginal probing with a periodontal probe (Hu-Friedy) at four locations, as expressed by a Bleeding Index in which 0 = healthy with no signs of inflammation or inflammation-related symptoms; 1 = slight inflammation, no bleeding on marginal probing, no swelling; 2 = bleeding on marginal probing, redness or swelling; and 3 = spontaneous bleeding, swelling, redness, or necrosis.<sup>34</sup>

Fifteen seconds were allowed for bleeding to occur after probing. Probing depths were measured at four locations using gentle probing to measure the distance from the marginal peri-implant mucosa to the deepest point of the peri-implant sulcus. The measurements for the Bleeding Index and probing depth after 10 years of function were compared with those obtained at initial evaluation when a similar attachment type was in situ. Intraoral radiographs made after implant placement and after 10 years of function were compared. The mesial and distal marginal bone levels were assessed using the edge of the implant as a reference point, as previously described in detail.<sup>35,36</sup> Clinical and radiographic measurements for all sites and for both implants were grouped and subsequently averaged for all parameters.

### Prosthetic Outcome

Subjects were interviewed with respect to the occurrence of complications, major repairs, or renewal of their dentures over the past 10 years.

### Statistical Analysis

Mean scale scores (patient satisfaction), probing depths, and marginal bone levels (clinical parameters) were compared by means of paired *t* tests. For comparison of Bleeding Index scores, the Wilcoxon signed ranks test was used. All analyses were performed using a standard statistical program (SPSS version 15.0 for Windows, SPSS).

**Table 2** Mean Scale and VAS Scores (SD) at Initial Evaluation and After 10 Years (n = 14 Subjects)

Scale	Initial evaluation	10-year evaluation	<i>P</i> *
Maxillary denture	0.4 (0.4)	0.2 (0.2)	NS
Mandibular denture	0.2 (0.2)	0.3 (0.4)	NS
General	0.2 (0.3)	0.2 (0.3)	NS
Physiognomy	0.1 (0.3)	0.3 (0.5)	NS
Neutral space	0.2 (0.3)	0.1 (0.2)	NS
Esthetics	0.1 (0.1)	0.2 (0.3)	NS
VAS score	88.7 (11.4)	86.6 (17.5)	NS

SD = standard deviation; NS = not significant.

\*Paired *t* test.

Scale scores (range 0 to 3): 0 = no complaints, 1 = little complaints, 2 = moderate complaints, 3 = severe complaints. VAS scores (range 0 to 100): 0 = very dissatisfied, 100 = very satisfied.

## Results

A comparison of the initial scale and VAS scores, as well as clinical and radiographic measures of the dropouts with those who could be reevaluated after 10 years, revealed no significant differences.

### Patient Satisfaction

The differences in mean scale and VAS scores for subjects with ball-socket (n = 7) and bar-clip attachments (n = 7) did not reach a statistically significant level at the initial nor at the 10-year evaluation. The scores were grouped and are presented in Table 2. Therefore, the null hypothesis that there would be no statistical difference in scale and VAS scores between initial evaluation and observations after 10 years could not be rejected.

### Clinical Parameters

None of the 14 subjects reported any major complications such as implant loss. No additional surgical interventions were reported. Healthy soft tissues were encountered, with no statistically significant differences between initial and 10-year evaluations or among the two attachment types at either moment in time. Mean probing depths were  $2.3 \pm 0.8$  mm and  $2.6 \pm 0.7$  mm

**Table 3** Mean Scores (SD) for Probing Depth and Marginal Bone Level and Distribution of Bleeding Index Values at Initial Evaluation and After 10 Years (n = 14 Subjects)

Measure	Initial evaluation			10-year evaluation		P
<b>Probing depth</b>						
Ball-socket	2.0 (0.7)		NS	2.2 (0.6)		P = .04
Bar-clip	2.5 (0.7)			2.9 (0.5)		
<b>Marginal bone level</b>						
Ball-socket	1.5 (0.5)		NS	1.6 (0.4)		NS
Bar-clip	2.1 (0.6)			2.1 (0.6)		
<b>Bleeding Index</b>						
Ball-socket	0.03 (0.1)		NS	0.04 (0.1)		NS
Bar-clip	0.07 (0.2)			0.08 (0.2)		

SD = standard deviation; NS = not significant.

**Table 4** Major Prosthetic Events as Reported by the Patient

Patient	Attachment type	New maxillary denture	New mandibular denture	Relining maxillary denture	Relining mandibular denture	Clip replacement	Complications
1	ball	1	1	1			
2	ball				1		Broken mandibular and maxillary denture (n = 1)
3	bar	1	1			1	Broken mandibular denture (n = 3, now metal reinforced)
4	ball			3	2		
5	bar	1	1				
6	ball	1	1				
7	bar	1	1	1			
8	bar						
9	ball	1	1				Loosening of ball-attachment matrix (several times)
10	bar						
11	bar	1	1				
12	ball						
13	bar	1	1	1			
14	ball					1	

at the initial and 10-year evaluation, respectively (not significant). The mean probing depth at 10 years around implants with a ball-socket attachment was shallower than around implants provided with a bar-clip attachment ( $P < .05$ ).

The marginal bone levels remained quite stable between implant placement and after 10 years of function ( $1.8 \pm 0.6$  mm versus  $1.9 \pm 0.6$  mm, respectively). The difference between ball-socket and bar-clip attachments was not statistically significant (Table 3).

**Prosthetic Outcome**

No change of attachment type occurred. The major prosthetic events are presented in Table 4. A new set of dentures had been made in 8 of 14 subjects during the 10-year evaluation period. The data set does not allow detailed and statistical comparison between ball-clip and bar-socket attachments with respect to prosthetic maintenance, but only a slight difference in the occurrence of major prosthetic events seemed apparent between the two attachment types (Table 4).

**Discussion**

In The Netherlands, a two implant-retained mandibular overdenture is generally the treatment of choice in the case of mandibular edentulism and denture complaints. It has been included in the national health insurance scheme for over 20 years, whereas a fixed implant-supported prosthesis is not. The out-of-pocket expenses for initial surgical and prosthetic treatment, as well as for long-term maintenance, are low.<sup>37,38</sup>

There is ample information available from various research groups to indicate the effectiveness of implant-retained mandibular overdentures when compared to conventional dentures, both with respect to patients' appreciation of treatment and improvement in oral function, although the impact on general health-related quality of life has not been shown convincingly to date.<sup>3-10,12,32,39,40</sup> Also, detailed studies comparing different treatment choices in mandibular implant overdenture treatment are relatively scarce.<sup>28</sup> Long evaluation periods are important to establish whether the initial enthusiasm frequently associated with new

treatment strategies proves justified in the long run. In the present study, subjects who underwent two-implant mandibular overdenture treatment with ball-socket and bar-clip attachments were reevaluated after 10 years and compared. The results from clinical and subjective outcome measures are reported.

Subjects were and remained satisfied with different aspects of their two implant-retained mandibular overdenture fit with the attachment type of their choice, even after 10 years (Table 2). This is in agreement with the results from other long-term prospective clinical trials in a comparable edentulous Dutch population<sup>5,6,8</sup>; they used bar-clip attachments only. As in the present study, Naert et al<sup>41</sup> could not demonstrate a difference in patients' appreciation between mandibular implants provided with a bar-clip or with a ball-socket attachment (O-ring) in a Belgian population after 10 years. However, Timmerman et al<sup>19</sup> reported a statistically significant drop in appreciation with ball-socket attachments, whereas the opinion of patients with bar-clip attachments remained stable after 8 years. The latter is in contrast to the observations in the present study. One can only guess as to an explanation for the different findings in these two studies. Patients treated in the study population of Timmerman et al<sup>19</sup> were enrolled in a more strict protocol of aftercare than the subjects in the present study, and a fair amount of maintenance was required and provided by them. It is interesting to note that the total number of visits and total treatment time required for maintenance does not seem markedly different between patients from their ball-socket and bar-clip groups.<sup>42</sup>

Results from other clinical trials with a shorter observation period in which ball-socket and bar-clip attachments were compared with respect to the required amount of maintenance appear contradictory. The design of the ball attachment and matrix and materials used in mandibular overdenture treatment seem to be an important determinant.<sup>42</sup> The use of a two-piece ball-abutment,<sup>43</sup> O-ring matrices,<sup>41</sup> and matrices with a so-called "c-spring"<sup>44,45</sup> have been associated with relatively high maintenance when compared to bar-clip attachments and some have even been taken off the market. On the other hand, Gotfredsen and Holm<sup>46</sup> reported favorably on one-piece ball-socket Dalbo attachments with a golden matrix compared to bar-clip attachments after 5 years. In another study, the amount of maintenance between ball-socket and bar-clip attachments was not statistically different, although a slight superiority of the rigid bar was suggested by the authors.<sup>47</sup> On a more general note, it can be stated that new types of attachment systems are introduced to the market on a regular basis. Some appear to function reasonably well (eg, Locator abutments) but lack long-term evaluation.<sup>48</sup>

It was felt that registration of the occurrence of minor prosthetic revisions over a 10-year period (eg, relieving of pressure points, activation of matrices) could not be done in a reliable manner by means of an interview. As a consequence, the subjective documentation of repairs and revisions may have led to unintentional underreporting by the subjects. Because they were referred to their general dentist after the conclusion of the initial experiment and a strict maintenance program with yearly recall visits was not always offered, the extent of the actual provided prosthodontic maintenance may have been relatively low as well. The former issues should be taken into consideration when interpreting the observations on prosthodontic maintenance reported in this study.

A general impression of the major prosthodontic events is presented in Table 4. Eight of 14 subjects received a new denture during the 10-year time span, but the type of attachment remained unchanged. The number of remakes seems rather high when compared to a study by Visser et al<sup>49</sup> covering a similar evaluation period. Well-defined criteria that determine when a denture should be remade are not available. Replacement dentures are not only provided when they no longer fit well or provide adequate function and when repairs and revisions are not indicated or possible. External circumstances such as the prospect of changing health insurance may also play a role. The latter was the case during the observation period of this study on several instances. It is important to note that in the present study, a new denture was provided for several patients just before the subject left the military as a service to the patient and not necessarily because the denture needed replacement at that particular time, but possibly in the near future. In a more general context, standardized criteria to document prosthodontic success or failure and terms and criteria for maintenance have not been available or uniformly applied in the literature, although suggestions have been made.<sup>50,51</sup> As such, reports and data from different centers on the amount of maintenance, particularly long-term ones, are hard to compare with one another, although attempts again have been made.<sup>52</sup> Comparisons with the findings from the present study should be made prudently and with care.

The health of the peri-implant mucosa in this study was monitored by means of probing and the assessment of a Bleeding Index. The reliability of such parameters in measuring peri-implant health around implants in the edentulous mandible has been questioned.<sup>53</sup> However, from the results of a systematic review on clinical, radiologic, and biochemical parameters used to monitor peri-implant health, their ongoing use for the early diagnosis of peri-implant disease was recommended and is generally accepted.<sup>54-56</sup> Clinical and radiographic data in

the present study revealed healthy, stable intraoral conditions, and the absence of major comparative changes in marginal bone level forms an important and favorable outcome measure reflecting the peri-implant condition.<sup>53</sup> In light of the fact that no major changes in marginal bone levels were observed between baseline and after 10 years of function, measurements at intervening time points would have been interesting but are not missed critically.

The favorable clinical and radiographic findings are in agreement with other long-term observational studies and clinical trials.<sup>5,40,57</sup> A difference in peri-implant health between implants supporting bar-clip- and ball-socket-retained two-implant mandibular overdentures was not noted in several clinical trials lasting 5 to 10 years.<sup>46,57,58</sup> In the present study, however, somewhat shallower probing depths were observed around ball-socket attachments when compared to the bar-clip attachments after 10 years.

### Conclusion

There was no marked difference in patient satisfaction between subjects with ball-socket- and bar-clip-retained two-implant mandibular overdentures at initial evaluation and after 10 years of function. Furthermore, patients' appreciation for their two implant-retained mandibular overdenture was and remained high at initial observation and after a decade. Healthy and stable clinical and radiographic conditions were seen after 10 years of function, with slightly shallower probing depths around implants that were provided with ball-socket attachments.

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