

A 10-year Randomized Clinical Trial on the Influence of Splinted and Unsplinted Oral Implants Retaining Mandibular Overdentures: Peri-implant Outcome

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Purpose: This randomized controlled clinical trial aimed to evaluate the efficacy of splinted implants versus unsplinted implants in overdenture therapy over a 10-year period. **Materials and Methods:** The study sample comprised 36 completely edentulous patients, 17 men and 19 women (mean age 63.7 years). In each patient, 2 implants (Brånemark System, Nobel Biocare, Göteborg, Sweden) were placed in the interforaminal area. Three to 5 months after placement, they were connected to standard abutments. The patients were then rehabilitated with ball-retained overdentures, magnet-retained overdentures, or bar-retained overdentures (the control group). Patients were followed for 4, 12, 60, and 120 months post-abutment connection. Group means as well as linear regression models were fitted with attachment type and time as classification variables and corrected for simultaneous testing (Tukey). **Results:** After 10 years, 9 patients had died and 1 was severely ill. Over 10 years, no implants failed. Mean Plaque Index, Bleeding Index, change in attachment level, Periotest values, and marginal bone level at the end of the follow-up period were not significantly different among the groups. **Discussion:** The annual marginal bone loss, excluding the first months of remodeling, was comparable with that found around healthy natural teeth. **Conclusion:** The fact that no implants failed and that overall marginal bone loss after the first year of bone remodeling was limited suggested that implants in a 2-implant mandibular overdenture concept have an excellent prognosis in this patient population, irrespective of the attachment system used. INT J ORAL MAXILLOFAC IMPLANTS 2004;19:695-702

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Social changes, evolution in dentistry, and changes in prosthetic techniques have led to higher patient expectations regarding esthetics, function, and oral comfort. This is also the case for completely edentulous patients.^{1,2} However, the main problem with the mandibular complete denture is lack of stability, since the resorption degree of jawbone is about 4 times that of the maxilla.³ Jemt and associates⁴ were among the first to report on the possibility of using overdentures supported by 2 implants to improve mandibular denture retention.

Studies have been carried out over the last 2 decades to evaluate the benefits of implant-supported overdenture therapy. It has already been established, through medium- to long-term studies, that the survival of root-form titanium implants is very high in mandibular overdenture therapy.⁵⁻¹³ Bar, magnet, and ball attachments and rigid and

Table 1 Variables Among the 3 Groups

	Bar	Magnet	Ball
Mean age (y)	65	61	64
Gender (male/female)	7/5	5/7	5/7
Mean period of edentulism (y)	14.8	15.0	11.5
Mean bone height in the canine region (mm)	23.8	24.9	25.9
Bone quality*			
Class 2	5	4	8
Class 3	7	8	4
Bone quality*			
Class A	1	0	0
Class B	2	3	3
Class C	7	6	7
Class D	2	3	2

*No. of patients in each class.

There were no significant differences for the variables tested between the 3 groups ($P > .05$).

nonrigid telescopic copings have been used to retain mandibular overdentures. The type of attachment influences the retention and stability of the denture.¹⁴ A few studies have compared the clinical outcomes of splinted and unsplinted attachment systems.^{9,15-18} None of these studies lasted more than 5 years, and none except that of Naert and colleagues⁹ reported on the efficacy of the treatment according to a randomized controlled design.

This study aimed to evaluate the effectiveness of splinted and unsplinted implants retaining a mandibular overdenture over a 10-year period.

MATERIALS AND METHODS

Patient Selection and Implants

Thirty-six completely edentulous patients (19 women and 17 men; mean age, 63.7 years; range, 36 to 85 years) were selected for this study. The population represented a consecutive group of patients treated at the University Hospitals, Catholic University of Leuven, Belgium. Exclusion criteria were insufficient bone volume to place 2 implants with a minimum length of 10 mm, sagittal mandibular retrusion, psychologic problems with the acceptance of a conventional removable denture, gagging reflexes, less than 1 year of edentulism in the mandible, the absence of a maxillary complete denture, and administrative or physical considerations that would seriously affect the surgical procedure or constitute a hindrance for longitudinal follow-up. Functional problems were the main reason that patients presented for treatment. The patients complained about lack of retention or stability of their existing mandibular dentures, which, from a technical point of view, were deemed to be well made.

At the inception, all patients underwent an initial examination, including recording of their medical and dental histories and evaluation of their existing dentures. Each patient was provided with 2 turned, screw-type implants made of commercially pure titanium (Brånemark System, Nobel Biocare, Göteborg, Sweden) in the mandibular left and right canine areas.¹⁹ The periodontist used a drill template to assist placement in prosthetically optimal locations. Surgical treatment was performed according to a standard technique.²⁰ Jawbone quality and degree of jawbone resorption were evaluated by the surgeon at the time of implant placement. Bone height in the canine regions was assessed on panoramic radiographs. The alveolar crest was also evaluated tactilely during drilling. Assessment of the alveolar crest both radiographically and clinically facilitated classification according to the Lekholm and Zarb index.²¹

Abutment Connection and Loading

Three to five months after implant placement, transmucosal standard abutments (Brånemark System; Nobel Biocare) were connected. The final length of the abutment was selected at the time of impression making. The tops of the abutments were 1 to 2 mm above the mucosal margin.

Before prosthesis fabrication, a randomized procedure allocated the 36 patients into 3 groups of equal size, each with a different attachment system. The characteristics of the 3 patient groups are shown in Table 1.

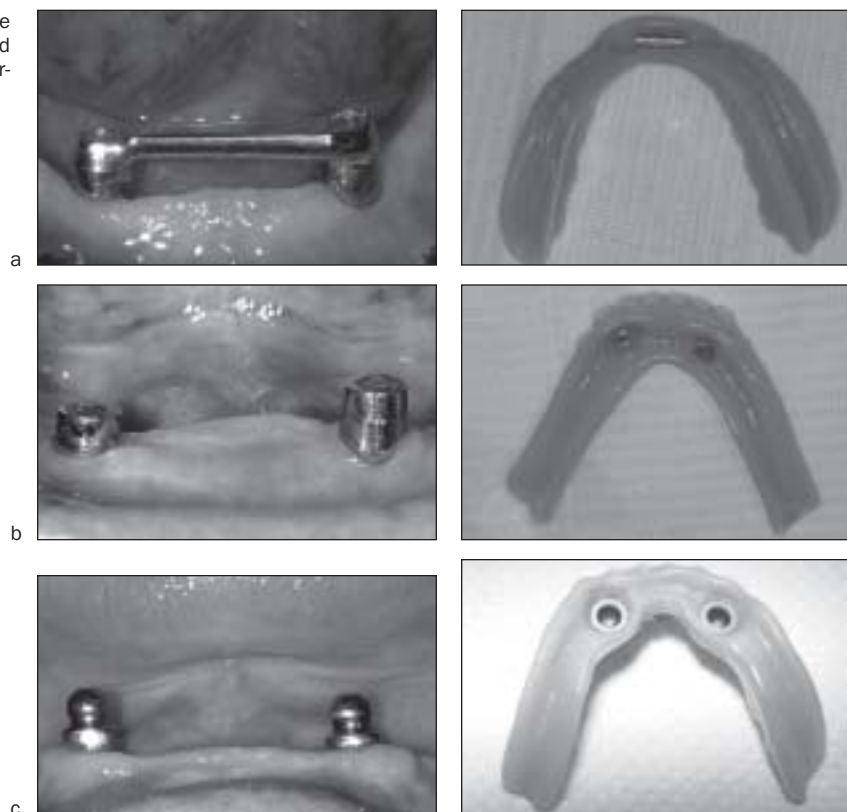
The bar group (Fig 1a) was considered the reference or control group. Patients in this group were provided with an egg-shaped Dolder bar (Cendres et Métaux, Biel, Switzerland) splinting the 2 implants. In the magnet group (Fig 1b), 2 open-field magnets (art. no 1102; Dyna Engineering BV, Bergen op Zoom, The Netherlands) were used as the attachment system. In the ball group (Fig 1c), 2 ball attachments (art. no. SDCB 115 - 17; Nobel Biocare) retained the overdenture.

All overdentures were carefully evaluated for occlusion and articulation on an articulator and intraorally. The aim was to achieve a balanced occlusion without anterior tooth contact in centric relation. The interabutment distance ranged from 12 to 29 mm (mean 19.5 mm), depending on the jaw size and anatomy.

Follow-up

Patients were examined at the time of abutment connection and at follow-up visits 4, 12, 60, and 120 months after abutment connection. At each follow-up visit several peri-implant parameters were recorded:

Figs 1a to 1c Clinical views of (a) the ovoid bar, (b) the open-field magnets, and (c) the ball attachments used with their corresponding overdentures.



- Using the Plaque Index (PI), the presence or absence of plaque at the abutment was scored at 4 sites (mesiobuccal, mesiolingual, distobuccal, and distolingual) by visual inspection (0 = no plaque, 4 = plaque on all surfaces of one implant, and 8 = plaque on all surfaces of both implants). The 8 subscores for each patient were used to calculate the patient's final mean score. The final scores varied from 0 (no plaque on both implants) to 1 (plaque on all surfaces of both implants).
- The bleeding tendency of the soft tissue surrounding the abutments was assessed at the same 4 sites by gently running a Merritt-B periodontal probe (Hu-Friedy; B. Oftrictin, Heidelberg, Germany) 1 mm into the gingival sulcus strictly parallel with the axial wall of the abutment. The Bleeding Index (BI) was used to assess bleeding (0 = no bleeding, 1 = bleeding on all surfaces of both implants). If bleeding became visible within 20 seconds, a BI score was given.
- Probing pocket depth was measured with a Merritt-B periodontal probe (Fig 2). Six measurements were made for each implant. For the bar group, the bar was removed each time.²²
- Recession, defined as the distance between the top of the abutment and the margin of the soft tissue (Fig 2), was simultaneously measured at the same 6 sites assessed for PPD.²²

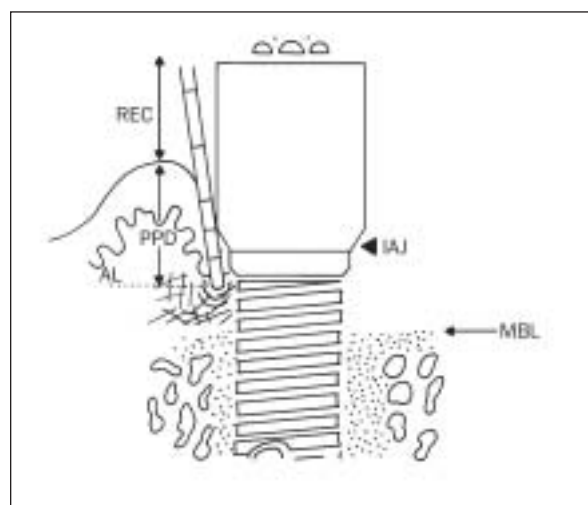


Fig 2 Diagram of the peri-implant parameters. IAJ = implant-abutment junction; REC = recession (ie, the distance between the top of the abutment and the margin of the soft tissue); PPD = probing pocket depth; AL = attachment level (ie, the distance between the IAJ and the tip of the periodontal probe inserted into the pocket, calculated by the formula $AL = [PPD + REC] - \text{abutment length}$); MBL = marginal bone level (ie, the distance between the marginal bone level and the IAJs measured on long-cone radiographs). Adapted from Quirynen and associates²² by permission of the author.

- Attachment level was calculated using the formula: (probing pocket depth + recession) – abutment length. Negative values indicated that the tip of the probe did not reach the implant-abutment junction, which indicated the clinical attachment level of the abutment.²²
- The rigidity of the implant-bone continuum was systematically assessed at each follow-up visit by means of a Periotest device (Siemens, Bensheim, Germany). This device measures the damping capacity of the implant-bone continuum. It consists of a handpiece connected to a unit that analyses the bracing time of a rod applied to a surface.²³ The values were only accepted when 2 consecutive measurements did not deviate more than 1 unit from each other. Periotest values can range from –8 (very stable) to +50 (very mobile).
- The marginal bone level was measured mesially and distally for each implant on intraoral radiographs. The radiographs were made with a parallel long-cone technique, which allowed standardization of consecutive radiographs.²⁴ The reference was set at the implant-abutment junction (Fig 2). A digital-sliding caliper with an accuracy of 0.01 mm (Mitutoyo, Tokyo, Japan) was used for the measurements at a 4× magnification. Radiographic follow-up of marginal bone level changes between baseline and 1, 5, and 10 years postloading, was performed for both implants in each patient. As the patient was considered a statistical unit, the mean marginal bone level of 2 implants was calculated. The intra-examiner variability of radiographically determined bone height scores was 0.2 mm [SE = 0.07 and SD = 0.42].⁹

Baseline for PI, BI, and attachment level was defined at 4 months post-abutment connection, while the baseline for marginal bone level and the Periotest values was set at the time of abutment connection. To investigate the correlation between BI and marginal bone loss, the baseline marginal bone level was considered 4 months post-abutment connection, not at abutment connection. To explore the correlation between attachment level and marginal bone level, only proximal measurements were used (ie, buccal and lingual site measurements were excluded). Again, 4 months post-abutment connection was used as the baseline for both marginal bone level and attachment level in this instance.

Implant Failure

An implant was considered a failure if

- A peri-implant radiolucency could be detected on the intraoral radiographs.
- An individual implant showed the slightest signs of mobility, corresponding to a Periotest value of > +5.
- The patient showed subjective signs of pain or infection that prompted implant removal.

Attachment and marginal bone levels were not used as success criteria but rather to determine prognosis.

Statistical Analysis

Attachment types and elapsed time were inserted into a linear mixed model (PROC MIXED) as classification variables. The model incorporated a compound symmetric error structure model for observations of the same patient over time and to correct for confounding variables. Compound symmetry means that correlations between the observations of same patient are considered the same; the difference in time is disregarded. *P* values for comparisons between group means were adjusted for simultaneous hypothesis testing according to the Tukey method for multiple comparisons.

Correlation coefficients and linear regression models (PROC REG) were fitted to the data as well. *P* values indicated whether the null hypothesis of no linear relation between the 2 variables under consideration had been refuted. The overall threshold for significance (α) was set at .05 to detect the level of significance.

The box-and-whisker plot design was bounded by the following values: the full horizontal line in the box represented the mean; the dashed line, the median; the rectangle stretches, from the 25th to the 75th percentile (the 25th percentile is the value that is at which 25% of the observations are smaller than that value, the 75th percentile is that value of which 75% of the observations are smaller). The lines extending the rectangle are called the whiskers. They are considered to represent all values that are not outliers. An outlier is defined as a value larger than the 75th percentile + $1.5 \times (75\text{th percentile} - 25\text{th percentile})$ or smaller than the 25th percentile – $1.5 \times (75\text{th percentile} - 25\text{th percentile})$. Hence, the whiskers extend to the farthest data point that still lies in the interval bounded by these 2 formulas.

SAS Version 8 for Windows was used (SAS Institute, Cary, NC). Graphing was done using R version 1.7.

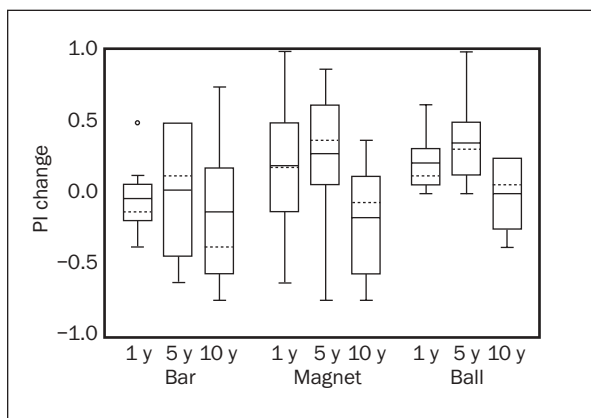


Fig 3 Box-and-whisker plot for PI changes from the baseline at years 1, 5, and 10 for the 3 different groups.

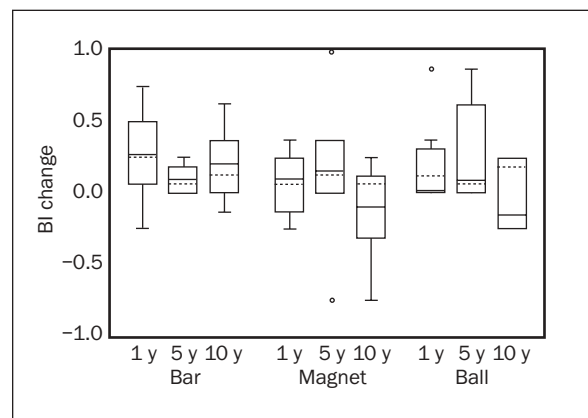


Fig 4 Box-and-whisker plot for BI changes from the baseline at years 1, 5, and 10 for the 3 different groups.

RESULTS

Patient Dropout

Because of the randomization procedure, patient characteristics between the 3 different groups did not significantly differ from one another. The reasons for patient dropout at year 10 are presented in the Discussion section. The remaining 26 patients respected the follow-up schedule over the entire 10-year period.

Implant Outcome

Overall, 73 implants were placed; 54 were standard 3.75-mm-wide implants, 2 were standard 5-mm-wide implants, and the remaining 17 were self-tapping implants 3.75 mm wide. Implants of various lengths (10, 13, 15, 18, and 20 mm) were used (for details see Naert and associates^{9,25}).

None of the implants failed during the observation period. One failed at the time of abutment surgery and was replaced by a new one, which healed uneventfully.

Peri-implant Outcome

The mean PI scores at year 10 were 0.39 for the bar group, 0.31 for the magnet group, and 0.18 for the ball group. There was no significant difference between the 3 groups over time. However, a significant decrease in PI appeared at year 10 compared to year 5 when the 3 groups were taken together ($P = .02$). The mean PI changes between baseline and year 10 were -0.13 for the bar group, -0.17 for the magnet group, and 0 for the ball group (Fig 3). These values were not significantly different from each other.

The mean BI scores at year 10 were 0.41 for the bar group, 0.21 for the magnet group, and 0.11 for

ball group. The BI changes from baseline to 1 year, 5 years, and 10 years for the 3 groups are shown in Fig 4. The mean BI changes between year 10 and baseline were $+0.21$ for the bar group, -0.09 for the magnet group, and -0.15 for the ball group. Neither the BI over time nor the changes from baseline was significantly different between the 3 groups.

The mean attachment level changes between baseline and years 1, 5, and 10, for the 3 groups are shown in Fig 5. No significant differences in mean attachment level changes between the 3 groups over time were found ($P > .05$). The mean attachment level changes between baseline and year 10 were 1.07 mm for the bar group, 0.1 mm for the magnet group, and 1.13 mm for the ball group.

Figure 6 reveals the Periotest score changes between baseline and years 1, 5, and 10 for the 3 different groups. No significant differences were found between the 3 groups over time. However, mean Periotest values at year 10 were significantly lower than those measured at the baseline in all 3 groups ($P < .001$). The mean Periotest value at year 10 for the 3 groups together was -5.2 , and the mean difference between baseline and year 10 was -1.7 .

Table 2 shows that there was a slight marginal bone loss over time. The changes in marginal bone level between baseline (abutment connection) and years 1, 5, and 10 for the 3 different groups are shown in Fig 7. No significant differences between the 3 groups were found over time ($P = .1$). The mean marginal bone level was located significantly more apically at years 1, 5, and 10 than at baseline ($P < .001$). The mean marginal bone loss between baseline and year 10 was 1.15 mm for the bar group, 0.53 mm for the magnet group, and 0.9 mm for the ball groups. No significant differences were found

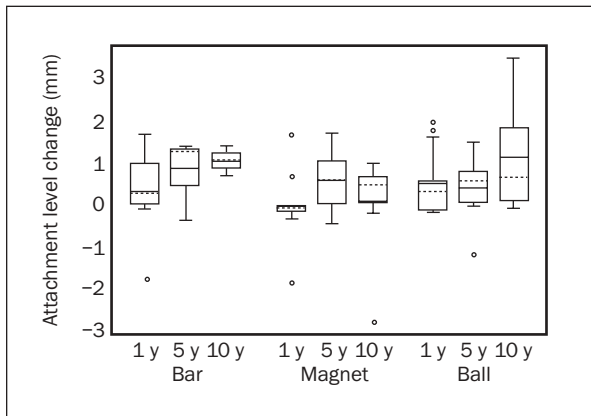


Fig 5 Box-and-whisker plot for attachment level changes from the baseline at years 1, 5, and 10 for the 3 different groups. Six sites per patient were measured.

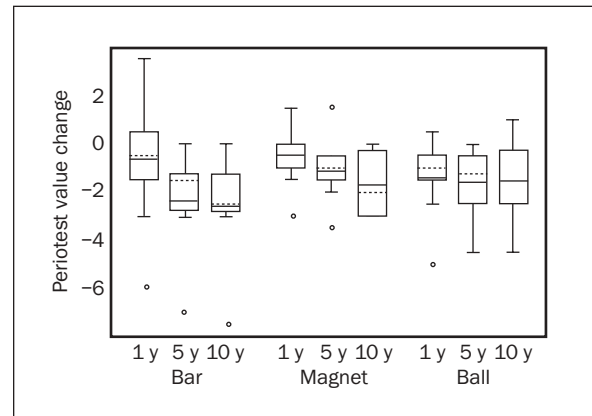


Fig 6 Box-and-whisker plot for Periotest value changes from the baseline at years 1, 5, and 10 for the 3 different groups.

Table 2 Frequency Distribution of Bone Loss Categories at Year 5 and 10*

Bone loss (mm?)	No. of implants	
	Year 5	Year 10
≤ 0	9	2
0.1 to 0.5	24	19
0.6 to 1.0	13	12
1.1 to 2.0	5	15
2.1 to 3.0	1	4
> 3.1	0	0

*Data per individual implant.

between the 3 groups. Excluding the first year of bone remodeling, marginal bone loss was 0.53 mm for the bar group, 0.32 mm for the magnet group, and 0.29 mm for the ball group.

A linear regression did not show correlation between the BI and the marginal bone loss over the 10-year period when the 3 groups were taken together ($P = .77$).

A linear regression for attachment level for distal and mesial sites (4 sites) and marginal bone level over time is presented in Fig 8. A significant correlation ($P = .004$) was found between both parameters (correlation coefficient = 0.36).

DISCUSSION

A total of 10 patients (27.7%) dropped out. Nine patients died, and 1 was unable to complete 10 years of follow-up because of severe illness. This might be predictable for a prospective study in which the mean age at the time of patient inception was quite high (63.7 years).

No implant failures occurred after loading; this corroborates the preliminary and the 5-year data of the same study population.^{9,25} The mean PI and BI scores and the attachment level data were not significantly different between groups. Karabuda and associates²⁶ found no significant difference between the bar and ball attachment types used for implant-supported overdentures with respect to soft tissue health.²⁷ They reported a 100% survival rate for 2 implants supporting a mandibular overdenture with ball or bar attachment for 5 years. No differences in marginal bone loss were observed either bar and ball attachments. In the current study, a remarkable significant decrease in mean PI scores was seen at year 10 compared to year 5. The reason for this outcome remains speculative.

No correlation was found between bleeding tendency and marginal bone loss. This is in agreement with previous observations made at the University of Leuven.^{28,29} However, a significant correlation was observed between the attachment level and the marginal bone level. This follows previous observations reporting correlation coefficients of 0.6 and 0.7, respectively.^{5,28,30} The overall annual bone loss up to year 10, excluding the first months of remodeling, was nearly 0.04 mm; this corroborates previous results as well.^{5,28,31} This value is comparable with the annual bone loss around healthy natural teeth³² and falls within the criteria for implant success suggested by Albrektsson and colleagues.³³

The mean Periotest values were not significantly different between the 3 different groups, but a decrease in Periotest values over time was observed, which is in agreement with previous observations.^{9,34-36} This might be explained by an increase in bone contact and mineralization with time at loaded implant-bone interfaces, as has been demonstrated radiographically.²⁴

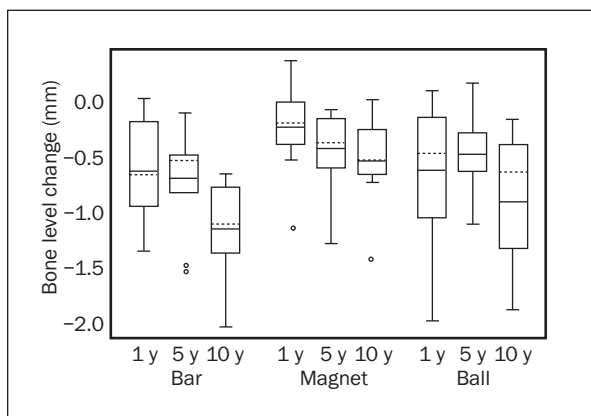


Fig 7 Box-and-whisker plot for marginal bone level changes from the baseline at years 1, 5, and 10 for the 3 different groups.

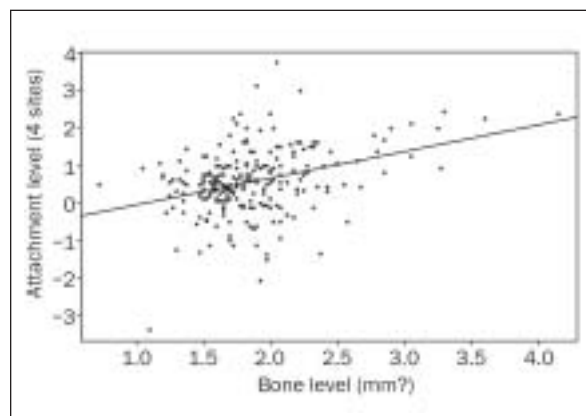


Fig 8 Linear regression for attachment level and marginal bone level over time at mesial and distal sites only ($P = .004$).

In an *in vitro* study, Tokuhsa and coworkers³⁷ compared the load transfer between the 3 attachment systems (bar, magnet, and ball) retaining a mandibular overdenture. They reported that the bar attachment induced the greatest axial force and bending moment on both the loading- and non-loading-side implants, and the ball attachment the least. This contradicts the present clinical *in vivo* findings.

CONCLUSIONS

From this 10-year randomized controlled clinical trial involving 36 edentulous patients, several conclusions can be formulated. The implant-retained overdenture supported by 2 implants in the mandible had a success rate of 100% for loaded implants. The peri-implant clinical parameters differed only slightly between splinted and unsplinted implants retaining mandibular overdentures. Excluding the first year of bone remodeling, the overall annual marginal bone loss was less than 0.04 mm. No correlation was found between bleeding on probing and marginal bone loss during the 10-year period. Although the Periotest value was not significantly different between the 3 groups, the bone-implant rigidity increased over time.

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