One-Year Prosthetic Outcomes with Implant Overdentures: A Randomized Clinical Trial

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Purpose: *This randomized clinical trial examined implant overdenture (IOD) fabrication and maintenance time and costs, adjustment and repair incidence, and patient satisfaction after 1 year.* ***Materials and Methods:*** *Sixty-four patients received 2 mandibular implants and an IOD with either a bar with 2 clips or 2 ball attachments for denture retention.* ***Results:*** *Fabrication time, number of appointments, and chair time for adjustments were similar for the 2 denture designs. The most common adjustments for both types were to the IOD contours. Ball-attachment dentures required about 8 times longer for repairs than bar-clip prostheses. Approximately 84% of patients with ball-attachment dentures needed at least 1 repair, versus 20% of those with a bar-clip mechanism. The most common repairs were replacement of the cap spring or cap for the ball-attachment IOD and replacement of a lost or loose clip for bar-clip dentures.* ***Discussion:*** *Patients were equally and highly satisfied with the improvements in function, comfort, and appearance with both types of IOD compared to their original conventional dentures.* ***Conclusions:*** *Given equivalent levels of patient satisfaction with either method of retention and a much higher repair rate for the ball attachment, it is suggested that a bar-clip design be used rather than the particular ball attachment utilized in this study.* (INT J ORAL MAXILLOFAC IMPLANTS 2002;17:391–398)

Key words: *dental implants, denture attachment, implant overdenture, prosthodontics, randomized clinical trial*

There is clinical evidence that 2 endosseous implants can retain a removable denture successfully in the mandible. Although less secure than the original fixed prostheses supported by 5 or 6 implants, by comparison, removable implant prostheses require less jawbone for the implants,[1] are substantially less expensive to fabricate,[2–4] are easier to clean,[5,6] can accommodate esthetic and phonetic variables readily,[7] and provide better support for the facial muscles.[8] The level of satisfaction expressed by denture wearers can be equally high with either the fixed or the removable design.[4,9–11]

The most common method for retaining implant overdentures (IODs) is a combination of adjustable metal clips attached to a bar connecting 2 or more implants.[12–14] Alternatively, individual attachments can be used when the implants are not connected. The relative success of the 2 methods is controversial, with 1 report indicating that they were "not successful over time,"[15] another stating that only bar-clip retention should be used because it created "more effective bone stimulation,"[16] and others claiming that there was no difference in success between bar-clip and ball attachment–retained IODs.[17,18] The question as to whether or not implants must be splinted together for maximum implant or prosthetic success remains without a definitive answer, although in a short-term study comparing splinted and nonsplinted implants in a small group of patients,[19] there were no differences in implant or prosthesis clinical performance. In

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addition, there is some evidence that stresses and loads are distributed more uniformly if the implants are not connected by a bar.[20,21]

Similarly, the need to reinforce the acrylic resin denture base to improve the strength of IODs is not clear. One study[22] indicated that 60% of the prosthetic complications observed were related to problems with the acrylic resin matrix, although there was no mention of whether or not reinforcing frameworks had been used in any of the prostheses evaluated. While some investigators have indicated that a cast alloy framework (typically, chrome-cobalt) should be used to reinforce the denture,[16,23] the evidence may not be strong enough to justify the cost of the metal reinforcement.[24]

In general, the numbers of adjustments and repairs required to maintain IODs have been shown to be substantial[16,25–27] and are required usually within the first year of service.[4,28–32] Most often, prosthetic problems have been related to the materials used and have been considered technical in nature.[22] Reported difficulties with removable IODs include fractured metal retentive clips, acrylic resin, and denture teeth,[33,34] and the need for frequent reactivation of retentive elements.[35]

A more complete picture of the influence of retention and reinforcement mechanisms on removable implant prosthesis fabrication and maintenance costs, posttreatment adjustment/repair requirements, and patient satisfaction could lead to a reduction in the treatment time and costs, as well as ensuring more accurate informed consent to treatment. To that end, this clinical trial recruited subjects desiring mandibular implants to stabilize and retain their mandibular denture. Subjects were stratified by gender and by ridge status, and then blocks of subjects within each stratum were randomized as to whether their mandibular IODs would be retained by a ball-attachment mechanism or by a bar and clips, with or without a metal framework (randomization formed 2 attachment groups, each containing 2 subgroups). Primary comparisons were between the 2 attachment modes. This report presents descriptive statistics and tests of hypotheses that there are no differences in *(1)* time or costs to fabricate and maintain IODs, *(2)* time or costs to make adjustments or repairs to the IODs, or *(3)* patient satisfaction.

MATERIALS AND METHODS

Subjects were recruited by advertising and sending information about the clinical trial to numerous organizations, including dentists throughout the province of British Columbia, local denturists, part-time faculty at the University of British Columbia (UBC), and various senior citizens' groups around the greater Vancouver area. Potential subjects who indicated an interest in participating were interviewed over the telephone by one of the dental assistants associated with the study and then sent written information about the study. Respondents were then screened jointly by a surgeon and a prosthodontist according to pre-established inclusion and exclusion criteria as follows. Patients had to be edentulous with at least 1 year experience wearing conventional complete dentures, medically and psychologically suited for implant surgery in the opinion of the study surgeon, able to complete study forms and communicate verbally in English, and available for the duration of the study. Patients were excluded if they had insufficient bone height for at least an 8.5-mm mandibular implant, a history of head and neck radiation, systemic or neurologic diseases, previous oral implant treatment, or a need for additional preprosthetic surgery (as determined by the study surgeon).

One hundred subjects were enrolled after signifying their informed consent, stratified according to gender and amount of mandibular residual ridge resorption, and randomly allocated to 1 of 4 treatment groups. Each subject received 2 Brånemark System implants (Nobel Biocare Canada, North York, Ontario) in the anterior mandible, a new complete maxillary denture, and a mandibular IOD that was fabricated either with or without a metal framework and retained with either 2 individual ball attachments (2.25-mm ball abutment with titanium alloy cap; Nobel Biocare Canada) (Fig 1) or a bar-clip mechanism (round gold bar system, Nobel Biocare) (Fig 2). Prior to implant surgery, and at 1-month and 1-year intervals after prosthesis placement, subjects completed visual analog scales (VAS) to measure satisfaction with their dentures in each of 8 categories: pain, comfort, appearance, function, stability, speech, cleaning difficulty, and overall satisfaction. The VAS had been used in previous studies[25] and patients were shown how to use the instrument prior to the first survey.

Implants were placed in the mandibular lateral incisor or canine areas and uncovered after a healing period of approximately 4 months. Five surgeons (1 oral and maxillofacial surgeon and 4 periodontists) and 1 prosthodontist, each aided by 1 of 3 certified dental assistants, provided the clinical care to patients in the study.

All implants and prosthetic components were supplied by 1 manufacturer (Nobel Biocare Canada) and all laboratory procedures were completed by 1 commercial dental laboratory (Fine Arts Dental

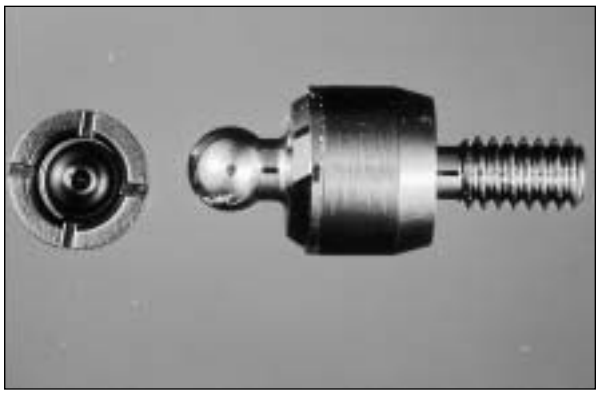

Fig 1 The 2.25-mm ball abutment and titanium alloy cap with retentive "c" spring.

Fig 2 Standard abutments with round gold bar, spacer, and clip attachment.

Laboratories, Vancouver, British Columbia, Canada) under the supervision of the study prosthodontist. Specifics of the prosthesis design, including maximum and minimum flange thicknesses, were recorded by a dental assistant, and the type of denture teeth (Bioform acrylic resin, Dentsply USA, York, PA), denture base acrylic resin (Lucitone 199, Dentsply USA), and occlusal scheme (lingualized occlusion) were standardized.

Subjects were asked to return as needed for follow-up and any required adjustments or repairs of their dentures for at least 2 years following placement. The time and associated costs of all treatment provided during the screening, treatment, and maintenance phases of care over this period were recorded. On completion of the study, patients were offered the opportunity to be assigned to students in the undergraduate dental clinic at the UBC Faculty of Dentistry for regular follow-up examinations and maintenance.

Subjects were stratified on the basis of gender (female/male) and ridge status (normal/resorbed) and, within the 4 strata, they were allocated to treatment groups via balanced randomization. The purpose of stratification was to assure comparability of the 4 treatment groups, and also to ensure that the effects of treatment factors would not be confounded by the effects of gender or ridge status. Previous studies[16,24,36] indicated a preponderance of female patients seeking implant treatment. The reasons for this imbalance are not clear, but it could be related to the suspected impact of osteoporosis on the severity of alveolar ridge resorption and its prevalence in women.[37–39] Because of the possibility that men may apply more stress to a denture, subjects were stratified by gender. Similarly, because the bulk of a denture may affect its strength and therefore the risk of fracture, patients were also stratified based on the amount of mandibular alveolar ridge resorption. Although a classification based on 5 groups of jaw shape[40] has been proposed, absolute quantification of ridge resorption was deemed unnecessary for the purposes of this study, since relative resorption could give an indication of whether the definitive denture would be bulky (severe resorption) or thin (normal resorption). Thus, height of the ridge relative to the mental foramina as seen on a presurgical panoramic radiograph was used to distinguish between those subjects with severe and normal resorption. Those ridges in which the mental foramina were below the ridge crest bilaterally were classified as normal, while those where the mental foramina were at the ridge crest unilaterally or bilaterally were labeled as severe in terms of resorption.

Surgeons placing the implants in this study were blinded to the planned prosthodontic treatment, but blinding was not possible for either the patients or the prosthodontist. Randomization for prosthetic treatment was done after second-stage surgery, so as to reduce bias caused by potential early loss of patients. All care providers were cautioned to avoid making evaluative statements to subjects about any of the treatment possibilities, and none of them were present when subjects were completing the VAS. Because assessments of the types of adjustments and repairs were objective, and because their occurrence was recorded not by the prosthodontist but by the assistant, these outcomes should not have been subjectively influenced. The research assistant entering the data and the statisticians analyzing it were blinded to the identity of the subjects, who were identified by numeric codes and not by name.

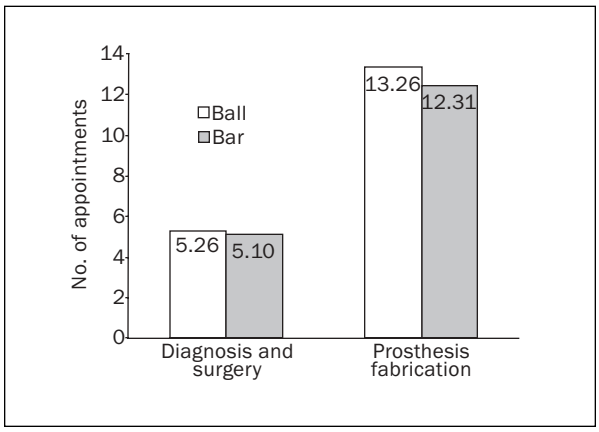

Fig 3 Mean numbers of treatment appointments for diagnosis, implant surgery, and prosthesis fabrication, by attachment type.

RESULTS

Of the 100 subjects enrolled, 67 had their IOD for a minimum of 1 year prior to the present analysis. Three of these 67 were lost to follow-up (1 died, 1 delayed treatment because of financial problems, and 1 was lost to follow-up after implant placement surgery), leaving 64 continuing subjects who had a mandibular IOD for at least 1 year.

A comparison of treatment groups with respect to baseline variables (ie, gender, ridge resorption, and age) and demographic variables (eg, socioeconomic data), using chi-squared tests for categorical variable values, and a 2-sample *t* test for the continuous variable of age, showed no significant differences, except that subjects receiving a bar-clip attachment mechanism reported better overall health ($P = .008$) at baseline than those who received a ball-attachment denture. Overall, it appeared that the block randomization was successful and the treatment groups were comparable at baseline.

As expected, female subjects (n = 41) outnumbered male subjects (n = 23) by a ratio of almost 2 to 1. Similarly, there were almost twice as many subjects with severe residual ridge resorption (n = 42) as normal ridge resorption (n = 22). Subjects ranged in age from 41.4 to 88.9 years, with a mean age of 64.4 years.

Time and Costs to Fabricate Prostheses

The number of appointments and the amount of time needed to treat patients with IODs can be used as measures of treatment costs. When considering both the number of appointments and the amount of time required to fabricate and maintain the prostheses, comparisons were made based on whether the IOD was attached to the implants with a ball or bar-clip mechanism.

Diagnostic and surgical procedures required, on average, approximately 5 appointments for both attachment groups (*t* test, 2-sided $P = .6$) (Fig 3). Likewise, prosthesis fabrication for both the IOD and the opposing maxillary denture averaged between 12 and 13 appointments, irrespective of attachment mechanism ($P = .3$).

Considering the overall amount of time, rather than the number of appointments, to fabricate each prosthesis type, again the difference was minor and statistically insignificant, with the ball-attachment group needing an average of 5.37 hours and the bar-clip group needing an average of 5.01 hours to complete prosthetic treatment (*t* test, 2-sided $P = .4$). Chair time was measured in 15-minute increments, starting when the patient was seated and ending when the patient was dismissed.

Overdenture Adjustments

All patients in the study required at least 1 postinsertion adjustment to their IOD. An adjustment was defined as any treatment to the denture that did not involve the addition of new material or the replacement of broken or missing components or material. If such addition or replacement was required, it was recorded as a repair. None of the subjects with ball-attachment dentures needed more than 9 adjustments, with 68% of them requiring between 4 and 9 adjustments. This contrasts with the bar-clip group, where, although 50% of subjects required fewer than 4 adjustments, 17% required more than 9. For both types of prosthesis, the most common adjustment was to the contour of the denture, while the second most common adjustment was to the retentive mechanism (Fig 4). Other types of postinsertion adjustments included occlusal adjustment and abutment tightening.

The number of appointments required for adjustments averaged 4.50 (median = 3, maximum = 9) for the ball-attachment design and 5.20 (median = 4, maximum = 15) for the bar-clip IOD, a difference that was not significant (*t* test, 2-sided $P = .5$; Mann-Whitney-Wilcoxon ranks test, 2-sided $P = .7$). The bar-clip group had greater variability both in the number of appointments and the total time required for adjustments.

The total amount of chair time needed for adjustments averaged 69.85 minutes (SD = 47.60) for the ball-attachment dentures and 94.10 minutes (SD = 87.88) for the bar-clip IOD. Because of the large variability in the length of appointment to adjust the bar-clip IOD, the mean difference was not statistically significant (*t* test, 2-sided $P = .2$).

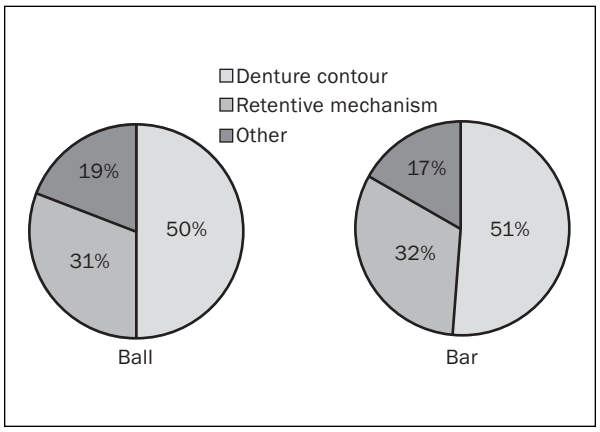

Fig 4 Types of adjustments made to the implant prostheses, by attachment type.

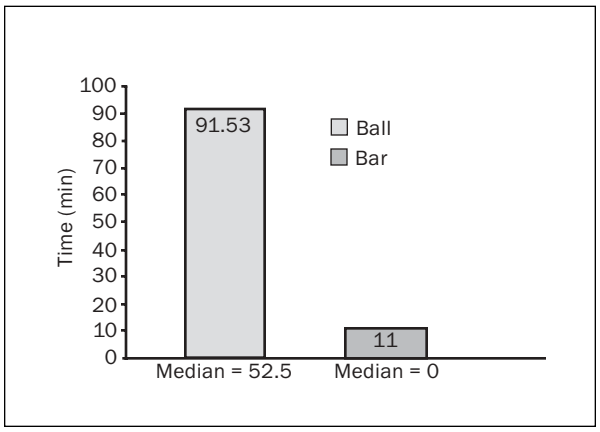

Fig 5 Mean and median lengths of time for implant prosthesis repair, by attachment type.

Overdenture Repairs

Ball-attachment dentures needed significantly more repairs, with concomitantly more appointments and chair time than the bar-clip group, making the latter generally much less costly from the perspective of either patient or dentist. Substantially more repairs were required for the ball-attachment IOD (172 in total) than for the bar-clip design (19 in total). With ball-attachment dentures, 31 of 34 subjects required at least 1 repair to their IOD. Moreover, almost half (47%) of this group required at least 4 appointments for repairs, and 6 of those subjects required at least 10 repair appointments (maximum = 18 appointments for 1 subject). In summary, while the majority of the 30 bar-clip dentures needed no repairs (only 6 needed 1 or more repairs), almost all of the ball-attachment dentures needed at least 1 repair.

As a group, subjects with ball-attachment dentures needed an average of 5.06 appointments for repairs. However, for the bar-clip attachment, only 6 of 30 subjects required any repair; and they averaged only 3.17 appointments (maximum = 5 appointments). Ball versus bar-clip differences with respect to numbers of visits for repairs were strongly significant according to several criteria (eg, cross-tabulating subjects by their attachment type and frequency of repair visits, a chi-square test gave $P < .01$ for the null hypothesis).

Repairs to ball-attachment dentures averaged around an hour and a half of dental chair time (SD = 95.12 minutes). In contrast, bar-clip dentures averaged just over 10 minutes for repairs (SD = 29.00 minutes), with a median of zero because only 6 of these subjects required any repair appointments (Fig 5). This repair time difference between the 2 attachment groups was strongly significant (either a t test or Mann Whitney-Wilcoxon ranks test gives 2-sided $P < .001$). Moreover, 10 of 34 ball attachment subjects each required at least 2 hours of chair time (maximum = 340 minutes), while only 1 of the 30 bar-clip subjects required as much as 2 hours in total (maximum = 130 minutes).

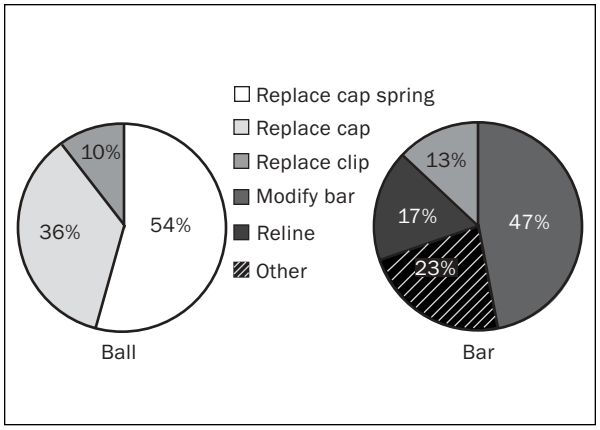

Fig 6 Types of repairs made to the implant prostheses, by attachment type.

Replacement of the matrix cap spring accounted for more than half of the repairs to the ball-attachment design, followed by replacement of the titanium matrix itself (Fig 6). Almost half of the repairs needed by the bar-clip group were related to the replacement of a lost or loose clip. Repairs classified as "other" included those needed as a result of cracked or fractured dentures and loose or lost denture teeth.

Whether implant prostheses were fabricated with or without a metal framework had no significant effect on either frequency of repairs or related chair

time; nor was there any interaction between this factor and the effect of ball versus bar-clip attachment. Furthermore, neither gender nor ridge resorption had any effect on the incidence of IOD repair.

Although the median cost of repairs for ball-attachment IODs was almost twice that for the bar-clip group ($168.00 vs. $88.00 [in Canadian dollars]), the difference was not significant ($P = .6$; Mann-Whitney-Wilcoxon test), again because of the small number of repairs incurred by the bar-clip group.

Patient Satisfaction

The satisfaction data consisted of 8 self-reported VAS that were administered at baseline (ie, with pre-existing conventional dentures still being worn prior to implant surgery) and at 1-month and 1-year intervals after the new prostheses were placed. Despite pronounced differences in the numbers of repairs required, there were no significant differences in overall patient satisfaction with the treatment provided (Mann-Whitney-Wilcoxon 2-sample rank tests). However, there were very significant improvements in all 8 domains of satisfaction with the new mandibular IOD as compared to the preoperative condition at both 1-month and 1-year intervals ($P < .001$), irrespective of retentive mechanism.

DISCUSSION

The numbers of adjustments for both IOD designs and of repairs for the ball-attachment design were substantial. While adjustments are to be expected with any complex treatment, repairs are not generally anticipated in the short-term postinsertion period and could affect not only patient confidence in their restorative dentist but also the financial viability of the procedure itself. The rapid growth of implant-assisted treatment and the use of standard prosthodontic materials and techniques in a new application may have combined to hinder successful prediction of potential complications and costs of implant prosthodontic treatment.

In light of the results of the current study, the cost-effectiveness of the titanium alloy cap on the 2.25-mm ball attachment must be brought into question. Although the ball-attachment IOD may be less expensive initially because of lower component costs and laboratory expenses, the need for repairs would no doubt increase the costs of treatment—costs that in many cases may be absorbed by the dentist because they were not predicted at the outset.[41]

It is important to note that the high level of repairs incurred by the ball-attachment prosthesis in this clinical trial should not be generalized to all other types of ball attachments. The titanium matrix and its retentive spring used in this study appear to be the "weak links" with the 2.25-mm ball abutment, together accounting for 90% of the 172 repairs needed by the 34 ball-attachment IODs. A high repair rate with the titanium alloy matrix has also been experienced by other researchers (personal communication, Dr Alan G.T. Payne, University of Otago, 2000). This particular attachment purports to offer the advantage of replacing the "c" spring inside the titanium cap when retention decreases over time, rather than having to replace the entire matrix, which is the case with an adjustable gold alloy matrix, also made by Nobel Biocare to fit the 2.25-mm abutment. However, in this study, the spring had, in many cases, an unacceptably short life span. The titanium alloy cap itself also required frequent replacement, usually because the 2 components that make up the cap unscrewed themselves from each other, with the portion that fits over the ball abutment being lost from the denture. The manufacturer recommends no more than 15 degrees of convergence or divergence between the ball abutments for the cap to seat. Although a paralleling device was used to place implants in the study[42] and all the caps seemed to seat fully, the angle between the implants was not measured over the course of the study, and it is possible that a lack of parallelism contributed to the untimely wear and loosening of the "c" spring and cap respectively. This possibility is being investigated in a follow-up study.

The high level of patient satisfaction that was recorded, despite the repair problems observed with the ball-attachment design, may reflect both limited patient expectations regarding the perceived experimental nature of implants and the probable severe functional deficit many of these patients experienced prior to their implant treatment. Patients may have been so pleasantly surprised at the functional improvements in their new prostheses that they were willing to overlook the inconvenience of multiple adjustments and repairs. Furthermore, the patients in this study were not financially liable for the repairs made to their prostheses, except for the time to attend additional appointments. Had charges been levied, rather than absorbed by the study, patient satisfaction may well have been affected. Patients should be fully informed regarding not only the risks and benefits of implant restorations, but also about the need for ongoing maintenance of the prosthesis itself, including the higher risk of repairs to a titanium alloy cap 2.25-mm ball-attachment IOD.

CONCLUSIONS

The 1-year results of this randomized clinical trial suggest that:

1. There were no significant differences between mandibular IODs retained by either titanium caps on two 2.25-mm ball abutments or 2 metal clips on a round gold bar in the number of appointments or overall time required to fabricate the dentures, the number of adjustments needed after prosthesis placement, or overall patient satisfaction with their new dentures.
2. There were no effects related to denture reinforcement with a cast framework, ridge resorption, or gender on the incidence of adjustments or repairs with either the ball attachment or bar-clip denture.
3. There was a significant difference in the number of repairs required by each type of prosthesis, with the titanium cap, 2.25-mm ball-attachment IOD needing approximately 9 times as many repairs as the dentures retained by 2 metal clips on a round gold bar. The vast majority of repairs (90%) to the ball-attachment denture involved the titanium matrix mechanism.
4. In light of these findings, clinicians may be advised that reinforcement of the denture base (with its attendant increased costs) is not warranted and that the titanium cap, 2.25-mm ball attachment should be used with caution.

ACKNOWLEDGMENTS

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