Randomized, prospective, clinical evaluation of prosthodontic modalities for mandibular implant overdenture treatment

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Statement of problem. Mandibular implant overdentures provide improved treatment outcome than conventional denture therapy, but there is controversy as to which overdenture treatment is the best choice.

Purpose. This study evaluated 3 different mandibular implant overdenture treatments with respect to prosthesis retention and stability, tissue response, patient satisfaction and preference, and complications to determine treatment outcomes.

Material and methods. In a prospective, randomized clinical trial, using a crossover design, 30 subjects (mean age, 58.9; 63% male) received 4 implants in the anterior mandible. For each subject, 3 different overdenture attachment types were fabricated and/or fitted to the implants. These included a 4-implant bar attachment fitted to all 4 implants, a 2-implant bar attachment, and 2 independent ball attachments. Subjects were randomly assigned to 1 of 6 possible treatment sequences and received all 3 attachment types each for approximately 1 year. Data were collected at baseline, and at 6 and 12 months for treatment types. Denture retention and stability and parameters of soft tissue response were recorded. Complications were documented and questionnaires were used to identify subject masticatory ability, denture complaints, and preferences. Data were analyzed to determine statistical equivalence among the 3 different treatments using the Schuirmann's two one-sided test (TOST) procedure, and the Wilcoxon-Mann-Whitney TOST procedure (α=.05).

Results. Force gauge prosthesis retention measurements showed that the 3 treatment types were not statistically equivalent, with the 4-implant bar demonstrating the greatest retention. Criterion-based retention scores were statistically equivalent for all treatments. Both the force gauge and criterion-based prosthesis stability measurements were statistically equivalent among all 3 treatment types. Analysis of all other multiple criterion-based scoring systems indicated the majority of these variables demonstrated equivalence. Where equivalence was not identified, the most favorable responses were typically found with the O-ring treatment, and the least favorable with the 4-implant bar treatment. From the small percentage of treatment visits demonstrating minor complications, no single treatment presented with greater complications than the others. For the treatment preference among subjects, 52% selected the independent ball attachment, 32% the 4-implant bar, and 16% the 2-implant bar (P=.10).

Conclusions. The 2-implant independent treatment used in this study provided equivalent or more favorable treatment outcomes for most measured parameters relative to the more complex and costly 2- and 4-implant bar attachments. The 4-implant bar treatment provided greater prosthesis retention than the other treatment types in this study, but after experience with all systems, subjects were more satisfied with and preferred the independent implant treatment. (J Prosthet Dent 2011;106:12-22)

Supported by grant #R01 DE12204 from The National Institute of Dental and Craniofacial Research.

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Clinical Implications

The 2-implant independent mandibular implant overdenture treatment is preferred by patients to the bar attachment treatments. This preference occurs despite greater prosthesis retention with the 4-implant bar.

The benefits of implant-retained/supported mandibular implant overdenture (IOD) treatment relative to conventional mandibular denture treatment have been well documented.[1-9] Half of all conventional mandibular dentures demonstrate problems with prosthesis stability and retention, with retention being the single most important deficiency reported.[10] Feine et al[11] and Thomason et al[12] stated that for the edentulous mandible, a 2-implant overdenture treatment should be the standard of care relative to conventional denture treatment.

Enhanced prosthesis retention and stability have been identified as perhaps the most important factors for producing more favorable mandibular IOD treatment outcome and improved patient satisfaction.[2,10,13] Mandibular IOD prosthesis retention, stability, and support are provided by both the mucosa and implants. As increasing numbers of implants are used, it is possible they will assume a greater role with treatment outcome, particularly involving prosthesis support.[14] However, more implants may not translate to improved prosthesis retention and/or stability, and subsequent treatment outcome may be relatively unaltered,[14] other than a slight increased risk from additional treatment and added expense. Zarb and Schmitt[15] and Visser et al[16] indicated that successful IOD treatment outcome can be achieved regardless of the number of implants used, but this concept remains controversial.[14]

Two implants have been considered the minimum necessary for mandibular IOD treatment[1,15] and can be used either with independent, unsplinted attachments or splinted together using a cast metal bar and a bar-clip attachment.[17] Four implants splinted with 3 interconnecting bar and bar-clip attachments is another treatment alternative. With a lack of consensus regarding the number of implants necessary for mandibular implant overdenture treatment, the best choice of an attachment mechanism between the implants and denture base also remains controversial.[14,18]

Wismeijer et al[19] studied 110 mandibular IOD patients, who received either 2 implants with a ball attachment, 2 implants with an interconnecting bar, or 4 implants splinted with 3 bars. Treatment outcome was measured using patient questionnaires. Nearly all subjects were satisfied with treatment after 16 months, and no statistical difference was found among the 3 treatment strategies. The authors concluded that the 2-implant ball attachment treatment was a good choice, but the need for additional clinical trials was emphasized. Mau et al[20] conducted a randomized study to evaluate 2-versus 4-implant bar attachments. The authors found a higher rate of complication for the 4-implant design, but in terms of treatment efficacy, both methodologies were the same after 5 years of service. Using 3-dimensional finite-element analysis, Meijer et al[21] studied bone stress in the anterior mandible surrounding implants when either 2 or 4 implants were used for IOD treatment. The authors concluded that when the occlusal load was distributed over increasing numbers of implants, there was no reduction in the principal bone stresses surrounding the individual implants.

Timmerman et al[22] reported that after 8 years, subjects from their study were more satisfied with a 2-implant single bar treatment than either 2 independent implants with ball attachments or 4 implants with 3 bars. They suggested that patient satisfaction was linked to prosthesis retention and stability, and not the number of implants used. Cune et al[23] measured patient satisfaction using a crossover design, where 18 subjects received 2 implants, and then in a randomized order, received magnetic, bar-clip, or ball attachments, each for a 3-month period. Questionnaires were used to register complaints, satisfaction, and preference. The authors reported that after subjects experienced all treatments, 1 subject preferred the magnetic attachment, 7 preferred the ball attachment, and 10 preferred the bar-clip.

Walton et al[24] evaluated time and cost factors associated with IOD. Sixty-four subjects received 2 mandibular implants and either a bar with 2 clips or 2 ball attachments. The authors found that subjects were equally satisfied with their treatments, but 84% of subjects with the ball attachment required at least 1 repair versus 20% for the bar-clip attachment. They concluded that because of the lower rate of repair, the bar-clip design was a better choice. However, Watson et al[25] stated that all IOD attachments required significant post insertion maintenance, but there were advantages to using independent implant attachments relative to bar attachment designs. The free-standing attachments required less space within a denture base; they were easier for a patient to keep clean; the initial prosthodontic treatment was less involved and more economical to perform; and routine maintenance, such as denture relines, was easier to manage. Gotfredsen and Holm[26] studied maintenance requirements for both ball and bar attachments over a

5-year period. They found that during the first year, there were significantly more complications requiring repairs with the bar group relative to the ball group. After the first year, there was no significant difference between the 2 groups.

Naert et al[17] compared prosthodontic treatment and subject satisfaction with splinted versus unsplinted 2-implant mandibular IODs in 36 subjects over a 10-year period. The authors found that at year 10, the ball attachment provided better prosthesis retention and patient satisfaction, with fewer soft tissue complications relative to bar or magnetic attachment designs. The bar attachment negatively influenced the opposing maxillary denture in terms of comfort and stability. Stoker et al[27] provided a cost analysis of initial treatment and aftercare expenses associated with 3 mandibular IOD treatments over an 8-year period. The authors compared a 4-implant bar, a 2-implant bar, and a 2-implant ball attachment. They found that aftercare patient expenses were comparable for all treatments, but initial costs represented 75% of the total costs, and were significantly higher for the 4-implant treatment relative to the 2-implant varieties.

The hypothesis of this study was that clinical treatment outcomes using measured parameters to define prosthesis performance and patient satisfaction/preference for the various mandibular IOD treatment modalities were equivalent. If the hypothesis were supported, it would imply that a 2-independent implant treatment option might be preferred because the more costly and complex treatment involving additional implants and bar splinting would provide similar treatment outcomes to those using less costly and simpler solutions.

MATERIAL AND METHODS

This study was a prospective, randomized clinical trial, using a crossover design to prospectively test the statistical equivalence among the 3 different mandibular IOD treatments. In contrast to the typical clinical trial, in which the intent is to demonstrate the superiority of one treatment over another, the goal of this study was to demonstrate equivalence among the 3 treatment types. Preliminary data were gathered during a previous study and were used for the statistical power analysis.[1,2] Equivalence testing with dental clinical trials was described in a previous study.[28] It was determined that 30 subjects were required to provide appropriate statistical power, and additionally, allow for a potential 25% subject dropout over the course of the study. Prospective subjects were all patients of record at Virginia Commonwealth University School of Dentistry, and all had conventional complete denture experience for at least one year. Inclusion criteria included adult patient, male or female, at least 1 year of previous conventional complete denture treatment history, willingness to accept the conditions of the study and freely provide informed consent, ability to participate for at least 6 years, ability to understand and respond to self-reporting measurement scales used in the study, a minimum of 20-mm interarch distance at the estimated occlusal vertical dimension, bone quality of 1 or 2 according to the Lekholm and Zarb criteria,[29] and adequate bone quantity to minimally accommodate 4 (3.75mm diameter) implants (Brånemark; Nobel Biocare USA, Yorba Linda, Calif) anterior to the mental foramen bilaterally. Exclusion criteria included administrative or physical considerations that would seriously affect the surgical procedure or constitute a hindrance for a 6-year involvement, history of drug or alcohol abuse, excessive smoking (1+ pack/day), uncontrolled systemic disease, inability to undergo minor oral surgery because of health or personal reasons, irradiated surgical site, unrealistic expectations of the prosthodontic treatment outcome, psychological or psychiatric conditions that could influence the subject's reaction to treatment, acute or chronic temporomandibular disorder (TMD) problems, pregnancy, class II jaw relationship, and after informed consent, conventional dental treatment as the treatment of choice.

Selected subjects were required to provide written informed consent. The study was approved and continuously monitored by an internal Institutional Review Board and an external National Institutes of Health, Data and Safety Monitoring Board. Eighty-seven potential subjects were screened and of these, 51 were excluded due to failure to meet inclusion criteria or willingness to sign the informed consent. Thirty-six subjects were enrolled and provided informed consent. Six of these subjects dropped out for various reasons after enrollment, but before implant placement. Thirty subjects provided pretreatment demographic information. After implant placement and during the course of the investigation, 3 subjects were discontinued from the study and therefore provided no postintervention data. One was removed because of compliance concerns regarding prosthesis use. This subject was diagnosed with Alzheimer's disease and was unable to communicate effectively as to his treatment satisfaction, complications, and preferences. The second subject was unable to continue because of his wife's chronic illness and inability to return for data collection. A third subject died due to a ruptured coronary aneurysm. Demographic data for enrolled subjects with postintervention data are presented in Table I.

Four implants (Brånemark Nobel Biocare USA) were placed anterior to the mental foramen bilaterally in the mandible of each subject using conventional 2-stage surgical techniques.[30] All subjects received 3.75 mm diameter implants, but implant length varied for each subject to provide the most favorable treatment prognosis. A presurgical trial denture was fabricated and used to produce a surgical implant guide for each sub-

Table 1. Demographic summary (n=27)

Enrolled with Postintervention Data	
	Frequency (%)
Male	17 (63%)
Female	10 (37%)
	Mean (SE)
Subject age	58.9 (1.87)
	Mean (SE) Years Edentulous
Maxillary	9.8 (2.08)
Mandibular	6.8 (1.85)
	Mean (SE) Years with Current Denture
Maxillary	2.1 (0.77)
Mandibular	1.1 (0.18)

ject. Implants were allowed to integrate for 4 to 6 months. After healing, all implants were required to show no evidence of implant mobility, radiographic periimplant radiolucency, or pain.[31] Two implants failed during the course of the investigation by becoming mobile during the integration phase. These implants were retreated and were successful thereafter.

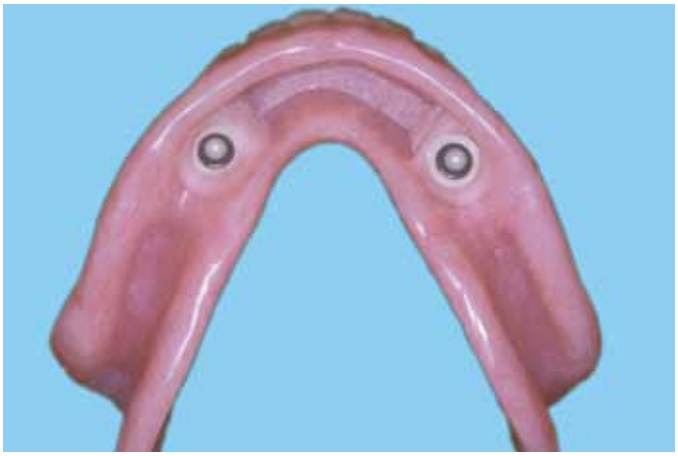
Upon successful integration of 4 implants, soft tissue height measurements were made and standard abutments (Nobel Biocare USA) were selected for each implant. Mandibular bar attachment kits (Overdenture Kit, with gold bar; Nobel Biocare USA) were used to fabricate the 2-implant and 4-implant bar attachments. The 2-implant O-ring attachment (Ball Attachment; Nobel Biocare USA) was selected for each subject. The mandibular IOD definitive cast impression was made with the completed 4-implant bar positioned intraorally. Subsequently, the completed mandibular IOD had space allocated in the denture base to accommodate the 4-implant bar, the largest of the treatment types to be tested. Definitive denture treatment was completed in both arches using a flat occlusal plane and 0-degree teeth.

A crossover design was used in this investigation; each subject received all 3 attachment systems over the course of the trial. Specifically, a 4-period (12 month duration/period), a 6-sequence (A-B-C-C; A-C-B-B; B-A-C-C; B-C-A-A; C-A-B-B; C-B-A-A), and a 3-treatment crossover experimental design was used. Each of the subjects was randomly assigned to 1 of 6 treatment sequence groups according to a randomization schedule generated by the biostatistician investigator. The 3 implant overdenture treatments consisted of (2I), an independent O-ring attachment using 2 implants, (2B), a bar attachment using 2 implants, or (4B), a bar attachment using 4 implants. The purpose of the fourth period was to allow for testing of an equal carryover effect on the crossover design by repeating the third period data collection for an additional 12 months. During this fourth period, the direct effects of the treatments were estimated more efficiently because they were not confounded with carryover influence.

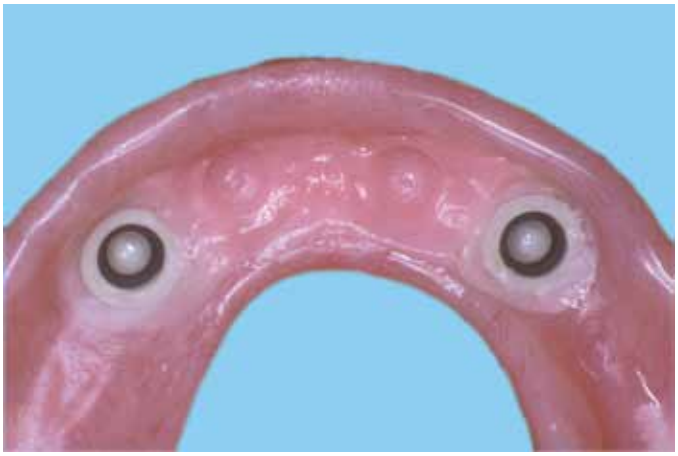
The respective denture bases were fitted and adjusted to the alveolar tissues. Space previously created in the tissue surface of the mandibular denture to correspond with the 4B attachment permitted easy access and orientation for placement of all bar clips or O-ring housings within the denture base, regardless of the treatment type being used. These retentive elements were positioned on their corresponding implant components and secured within the denture base using autopolymerizing acrylic resin (Perm Reline and Repair Resin; The Hygienic Corp, Akron, Ohio), while the prosthesis was accurately and simultaneously positioned on the supporting alveolar tissues (Fig. 1). Resilient lining material (TruSoft; HJ Bosworth, Skokie, Il) was used to provisionally fill the open denture base space not being used when the 4B treatment was not being tested (Fig. 2). Final prosthesis occlusal adjustment was completed after the addition of the attachment mechanism.

For standardization, the clips used with all bar attachments were arbitrarily adjusted before installation to 10±0.1 N of retentive quality. This was done by placing each clip on a section of the gold bar material used in this investigation and removing it using a push/pull force gauge (Chatillon 5 kg push/pull force measurement gauge; Hunter Products, Bridgewater, NJ). Crimping adjustments to each clip were accomplished as necessary until the proper retentive force measurement was achieved.

In addition to screening demographic and implant integration information, the clinical conditions associated with each subject's preexisting dentures were evaluated and recorded after both preimplant and postimplant placement surgery using each investigative parameter. Thereafter, subjects received the appropriate treatment at approximately 12-month intervals in response to their specific randomized treatment sequence schedule. During this time, denture adjustments were accom-



1 Space allocated in denture base to accommodate all 3 treatment modalities. 2I attachment were positioned into denture base with autopolymerizing acrylic resin.



2 Provisional denture reline material used to fill open denture base space when not all implants were used. Note imprint of healing abutments in provisional reline material for implants not used for treatment.

plished as needed. O-ring replacement (2I), bar clip replacement (2B), or adjustment (4B) was completed on an as-needed basis, and the clips were recalibrated when this was done.

Data were independently and concurrently recorded by 3 prosthodontic coinvestigators. To address measurement reliability,[2] the observations from the 3 raters were averaged to create a single observation. Data were collected at 6 and 12 months after placement of each attachment system. After 12 months of monitoring and data collection for the first overdenture attachment treatment, all subjects was recalled and their particular attachment system was replaced with the next, as defined by the subject's randomized treatment sequence group. After monitoring and data collection for another 12 months, the third and final attachment system was placed, and the same monitoring and data collection protocol was followed. This final treatment was sustained for an identical fourth 12-month period of data collection. Subjects were included in the data analysis regardless of outcome during the clinical trial, following the intent to treat principle. All post-implant data were included in the data analysis.

Throughout the investigation, the following data collection standardized procedures were uniformly followed: The push/pull force gauge (Chatillon 5 kg) was used to quantitatively measure denture retention and stability. With prostheses in place, subjects sat upright in a dental chair. To measure retention, the "pull" end of the force gauge was connected to a 15-cm long, 18 gauge orthodontic wire (Great Lakes Orthodontics, Tonawanda, NY) with the ends of the wire bent into a hook. The hook was positioned under the mid-labial flange of the IOD, and the force gauge was pulled vertically upward until denture retention was lost and the prosthesis moved vertically. This force was measured in newtons (N) and recorded. For stability, the "push" end of the gauge was positioned in the gingival embrasure area of the canine denture tooth on the right side of the prosthesis. The gauge was pushed horizontally against the denture. The force (up to a maximum of 20 N) necessary to destabilize and dislodge a denture was measured and recorded. In addition to this objective analysis, each subject's mandibular denture was evaluated for denture retention and stability with the criteria scoring system previously reported.[1] Examiners independently observed a subject's IOD and recorded the numbered criteria that best described the denture retention and stability. The retention criterion was defined as a score from 0 to 3 with 0 = no retention, 1 = minimal retention, 2 = moderate retention, and 3 = good retention. Similarly, the stability criterion was defined as a score from 0 to 2 with 0 = no stability, 1 = some stability, and 2 = sufficient stability.

The condition of the prosthesis-supporting oral mucosa and perimplant health were assessed using multiple criterion-based scoring systems. Where multiple readings were required around individual and multiple implants, a mean score was calculated and recorded. Prosthesis supporting tissues for each arch were evaluated with a scoring system previously reported by Burns et al.[1] Periimplant parameters were evaluated in the following locations: the Gingival Index as adapted from Loe and Silness[32] and the Plaque Index, as adapted from Silness and Loe,[33] were measured in 4 locations around each implant; measurements of the amount of keratinized mucosa were measured according to Apse et al [34] in 2 locations around each implant; the attachment level was measured in millimeters from the top of the implant to the level of implant-tissue attachment in 4 locations for each implant. The probing depth as adapted from Geertman et al[35] was measured in 4 locations in millimeters around each implant, and radiographic evaluation

of each implant, as adapted from Geertman et al[35] was recorded from a panoramic radiograph made for each treatment at the 12-month data collection appointment. Additionally, the radiographic bone-crest to inferior border-of-mandible measurement in millimeters was recorded for each implant, and the radiographic mandibular symphyseal bone height was recorded. Implant mobility was assessed by tapping the abutments alternatively back and forth with 2 instrument handles. Observable movement was identified as evidence of individual implant mobility using the criteria suggested by Smith and Zarb.[36]

At each data collection appointment, subjects were asked to complete a 40-item denture complaint questionnaire.[37] Each item was rated on a 4-point scale: 0 = not at all; 1 = a little; 2 = quite a lot; 3 = extremely. The maximum score was 120 and the minimum score was 0, where lower scores corresponded to greater denture satisfaction.

Additionally, an 8-item masticatory ability questionnaire was used that asked how well 8 different foods could be masticated.[38,39] The 8 items were answered according to a 3-point scale: 0 = good; 1 = moderate; 2 = bad. The maximum score was 16 and the minimum score 0, where lower scores corresponded to better masticatory ability. The score from each questionnaire and for each subject was determined and recorded.

The clinical implant performance scale (CIP scale) as adapted from Geertman et al[35] was used to assess complications and failures. The CIP scale documents complications and categorizes them according to severity. Itemized complications were documented for each subject relative to type, date, and the treatment conditions in use at the time of the complicating outcome. Specific attention was given to ongoing changes in physical or mental health that could influence complications, failures, and adverse events.

At the completion of all data collection, when subjects had experienced all IOD attachment systems, they were given an IOD treatment preference questionnaire, modified from Burns et al.[2] It consisted of questions designed to determine subject preference among the 3 implant overdenture treatment modalities tested. Additional assessment of subject preference relative to treatment was established by allowing subjects to choose and receive their "favorite" treatment type at the end of the data gathering period.

To minimize carryover influence, at the completion of a 12-month data collection period for each treatment type, selected tissue criteria scores were required to ensure standardized optimal healthy conditions before the next 12-month time period could begin. This provided an adequate amount of time to washout the effect of previous treatment influence before data collection for the next treatment in the sequence. As a result, it was necessary that the alveolar mucosa tissues were free of pathology with a maxillary and mandibular supporting tissue score of no less than 3, a Gingival Index score of 1 or 2, and no mobility around any independent, unattached implant. Any mobility excluded a subject from further study participation. If minimum scores were not met, at the discretion of the investigators, subjects could be temporarily returned to conventional denture treatment by replacing implant healing abutments and temporarily relining the mandibular denture base with resilient denture base lining material. The next 12-month investigative sequence was only initiated upon successful completion of this interim treatment period.

This study used multiple variables as endpoint measurements. Because variation of endpoint outcomes could result in conflicting conclusions, equivalence in this investigation was defined as using prosthesis retention and stability (force gauge and criterion-based measurements) as primary indicators of equivalence. Also, to establish equivalence among treatment modalities, similar results from retention and stability measurements were required, with the largest difference being no greater than 20% as documented in Imrey et al.[40] As a result, an adjustment for multiplicity was not required, and an alpha of .05 was used for all comparisons, except for an alpha of .1 for tests of carryover effect. Secondary measures were prosthesis supporting and periimplant tissue response, subject satisfaction and preference, and complications.

All endpoints except for the criterion-based retention and stability scores and the IOD treatment preference questionnaire were analyzed to determine statistical equivalence using the Schuirmann's two one-sided tests (TOST) procedure[41-43] from the 3-treatment, 6-sequence, 4-period, crossover model. The least square means presented in the figures and tables arose from a mixed effects model that included fixed effects for treatment types, sequence, period and carryover, and a random effect for subject. The Schuirmann's TOST was operationalized by calculating the 90% confidence interval about the paired difference between the least square means, and then if this 90% confidence interval fell within the interval ± 20% of the reference mean (for the 4B group), the treatments were declared equivalent. Criterion-based retention and stability were tested for equivalence using the Wilcoxon rank sum TOST procedure.[43] Similar to the Schuirmann's TOST, the non-parametric Wilcoxon tested the equivalence of the medians by first calculating a 90% confidence interval about the median of the Walsh average difference, and then if this 90% confidence interval fell within the interval ± 20% of the reference median (for the 4B group), the treatments were declared equivalent. For the Wilcoxon test, it was not possible to use the fourth period data, thus the testing used the 3-treatment, 6-sequence, 3-period, crossover model. Finally, the IOD treatment preference questionnaire responses were compared

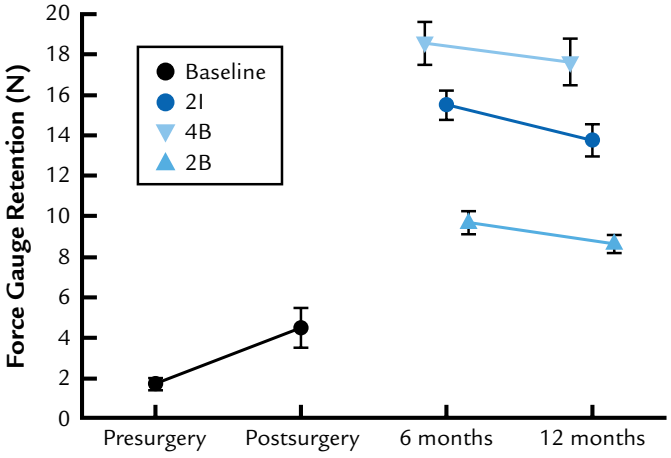
among the 3 treatment modalities using a Chi-square test for superiority.

RESULTS

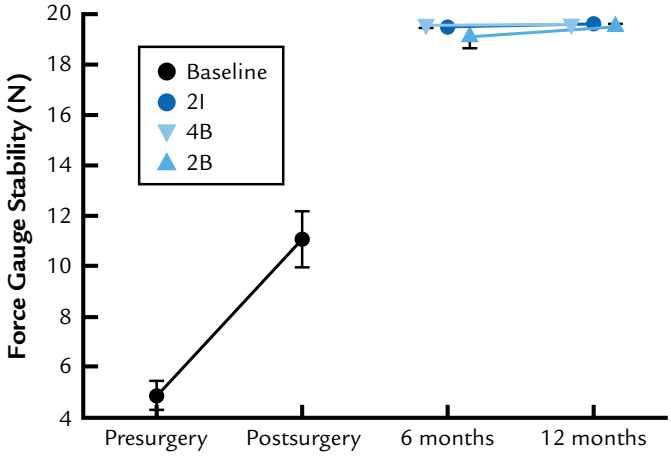
The potential influence of any carryover effect was monitored throughout the investigation using the clinical evaluation process previously described. No subjects were delayed from progressing to the next study period due to the influence of previous treatment on the health of the tissues or implants. No independent implant mobility was found for any implant during the investigative phase. Additionally, at the end of the investigation, potential carryover influence was tested for each study variable and no statistically significant carryover effect was found.

Figures 3 and 4 demonstrate the least mean square force gauge retention and stability values and standard errors. The force gauge retention was not equivalent for any of the 3 treatment types; however, the force gauge stability was equivalent across all 3 treatments. Figures 5 and 6 show the retention and stability criterion-based medians and interquartile range. Both the retention and stability criterion-based medians demonstrated equivalence among the 3 treatments.

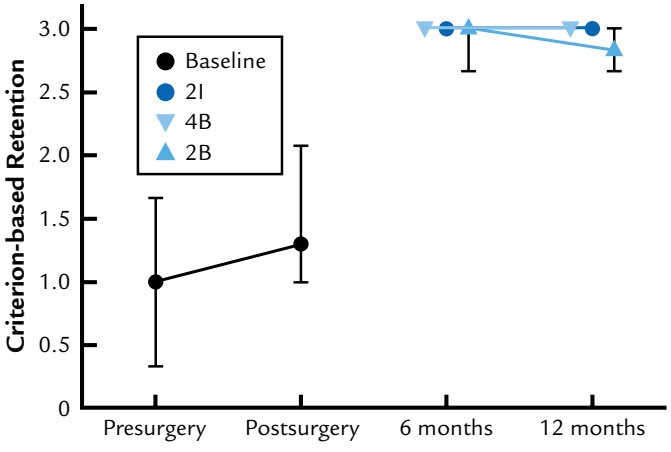
Table II shows the multiple criterion-based scoring systems used to assess the prosthesis-supporting oral mucosa and periimplant health. Maxillary and mandibular supporting tissue health was found to be equivalent among all treatment groups. Gingival and Plaque Index scores were not equivalent and showed more favorable tissue responses and less plaque associated with the 2I attachment. The 4B had the highest plaque scores and the least desirable Gingival Index scores of the 3 treatments. Other parameters were equivalent for all treatments. Masticatory ability and denture complaint data from subject questionnaires are shown in Figures 7 and 8, respectively. Even though there was no demonstration of equivalence in either questionnaire, the 2I and 4B treatments provided the most favorable, and the 2B treatment, the least



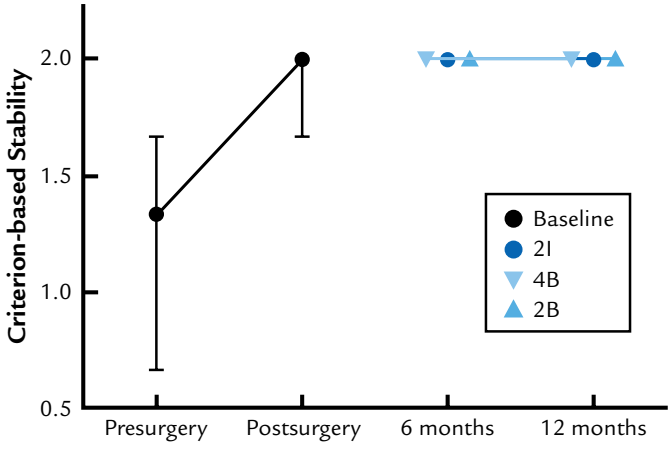
3 Force gauge retention. Presented as least square means (± standard errors). Three treatment modalities were not statistically equivalent.



4 Force gauge stability. Presented as least square means (± standard errors). Three treatment modalities were statistically equivalent.



5 Criterion-based retention. Presented as medians (± interquartile range). Three treatment modalities were statistically equivalent.



6 Criterion-based stability. Presented as medians (± interquartile range). Three treatment modalities were statistically equivalent.

Table II. Mean values (standard errors) from crossover analysis with results of equivalence testing

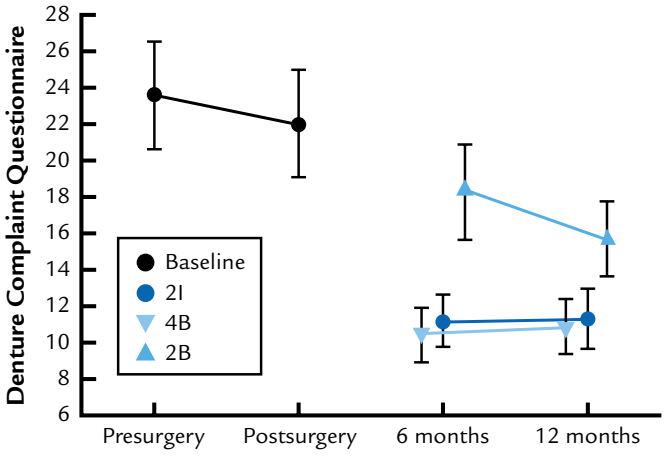
Variable	Treatment *			Equivalence Comparison†		
	4B	2I	2B	4B vs. 2I	2I vs. 2B	4B vs. 2B
Maxillary supporting tissue score	3.73 (0.08)	3.80 (0.09)	3.78 (0.09)	yes	yes	yes
Mandible supporting tissue score	3.73 (0.06)	3.73 (0.06)	3.71 (0.06)	yes	yes	yes
Gingival Index score	0.455 (0.048)	0.417 (0.048)	0.424 (0.050)	no	no	no
Plaque Index score	1.228 (0.134)	0.848 (0.136)	0.923 (0.146)	no	no	no
Probing depth (mm)	0.285 (0.041)	0.142 (0.041)	0.141 (0.041)	no	yes	yes
Keratinized tissue score	1.801 (0.102)	1.767 (0.103)	1.786 (0.104)	yes	yes	yes
Attachment level (mm)	0.786 (0.059)	0.795 (0.059)	0.787 (0.059)	yes	yes	yes
Radiographic implant bone height (mm)	29.56 (1.18)	29.07 (1.18)	29.36 (1.18)	yes	yes	yes
Radiographic mid-symphyseal bone height (mm)	29.85 (1.16)	29.23 (1.16)	29.85 (1.16)	yes	yes	yes

* Least square means (± standard errors) from crossover mixed effects model are presented except where noted otherwise.

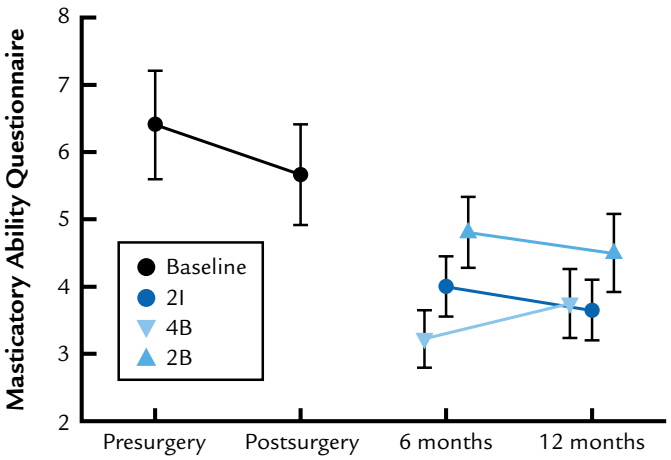
† Equivalence assessed by Shuirman's TOST procedure using 3-treatment, 6-sequence, 4-period, crossover model except where noted

** Medians and interquartile range

‡ Equivalence assessed by non-parametric Wilcoxon-Mann-Whitney TOST procedure from 3-treatment, 6-sequence, 3-period, crossover model



7 Denture complaint questionnaire. Presented as least square means (± standard errors).



8 Masticatory ability questionnaire. Presented as least square means (± standard errors).

TABLE III. Frequency (%) of implant overdenture treatment preference (n=25)

Question	2I	4B	2B	All Same	No Opinion	P‡
Overall best satisfied	12 (48%)	8 (32%)	4 (16%)	1 (4%)	0 (0%)	0.15
Selected treatment	13 (52%)	8 (32%)	4 (16%)	0 (0%)	0 (0%)	0.09
Easiest to get used to	11 (44%)	5 (20%)	3 (12%)	6 (24%)	0 (0%)	0.12
Best denture retention	9 (36%)	8 (32%)	4 (16%)	4 (16%)	0 (0%)	0.43
Best able to chew	11 (44%)	6 (24%)	3 (12%)	5 (20%)	0 (0%)	0.14
Best able to speak	7 (28%)	5 (20%)	3 (12%)	10 (40%)	0 (0%)	0.62
Greatest movement	4 (16%)	2 (8%)	12 (48%)	5 (20%)	2 (8%)	0.026*
Easiest to keep clean	12 (48%)	1 (4%)	2 (8%)	8 (32%)	2 (8%)	0.01**

‡ Chi-square test of "no preference" or "equal preference"

* 2B provides statistically significantly greater movement

** 2I statistically significantly easier to keep clean

favorable results.

For the CIP data, there were no complications noted for the vast majority of treatment visits across all 3 treatments. Of the 212 recorded subject visits, in which a subject received CIP ratings from 3 investigators, 93% (n=197) of the subject visits had all 3 ratings scored at 0 (success with no complications) and were trouble free. Only 7% (n=15) of the visits included 1 or more of the ratings with a score of 1 (minor complications). None of the subject visits received CIP scores of 2, 3, or, 4. The 12-month CIP mean (SD) scores for the 3 treatment groups were 0.07 (0.28) for the 4B, 0.09 (0.27) for the 2I, and 0.10 (0.27) for the 2B. From the small percentage of treatment visits that demonstrated minor complications, no single treatment presented with greater complications. Radiographic bone height levels remained stable over time and equivalent among treatments.

Subject treatment preference data are presented in Table III. Most often, subjects preferred 2I treatment as the one to keep after experiencing all treatment options. Overall, subjects were best satisfied with the 2I treatment, which had the highest frequency for all questions except for "greatest movement." The 4B showed the most favorable results, with the least favorable results found with the 2B treatment; this was with the exception of the "Easiest to keep clean" question, where the 4B treatment demonstrated the lowest frequency.

DISCUSSION

The standardization of methods was an important aspect of this investigation; therefore, all clips used for the bar-clip attachments were standardized to an arbitrary 10 N of retentive quality prior to use. This value was selected because it represented an appropriate retentive quality that subjects had preferred in a previous investigation.[1] The standardization assisted with comparisons among bar-clip attachments, but the 10 N provided an arbitrary retentive quality for the 4B IOD that exceeded that of both the 2B and 2I IOD. This resulted in a greater retentive mean value for the 4B IOD that was not equivalent to that of either the 2I or 2B IOD. Consequently, the study hypothesis was not supported, and the greater retentive mean could be considered an indicator of more favorable treatment. After completion of the study, however, the authors believe that this is directly associated with the arbitrary standardization of the bar clip retentive value and is not a valid conclusion. This is a significant limitation of the study. Currently, many IOD attachment systems allow for the adjustment of retentive quality. Patients may prefer a higher retentive quality, but because retention can be commonly adjusted within a range, the measured retentive quality at any given time may not provide an appropriate measure of treatment outcome.

What is interesting about this study result is, that if indeed greater retention were a valid indicator of better treatment outcome, it would be expected that other data from the study would corroborate this finding. Instead, the 2I IOD, with less retention than the 4B IOD, showed equivalent or more favorable results according to other data collected in this study. These other combined data presented a clearer understanding of treatment outcome and provided compelling evidence that the 2I treatment was a more favorable choice than the other treatment types. For instance, with both the masticatory ability and denture complaint questionnaires, the 2I treatment showed more favorable

responses than the 4B treatment. According to the preference data, nearly half of all subjects were most satisfied with the 2I IOD and more than half preferred and selected the 2I as the treatment they kept after completion of the investigation. In fact, for the preference questionnaire that was completed after subjects experienced all treatments and could make valid judgments, the 2I IOD demonstrated the most favorable responses for most questions. Other factors such as subject treatment preference and satisfaction with prosthesis functional aspects, ease of subject accommodation to a treatment type, tissue health, hygiene and maintenance issues, and complications outweighed the superior retentive features of the 4-implant bar. When these factors were weighed together, prosthesis retention was only one aspect of the entire process.

It is not surprising that subjects responded most favorably to the 2 independent-implant treatment, since it provides a satisfactory treatment outcome without the added treatment of 2 additional implants and interconnecting bar attachments. The 2 independent abutments require less space in the denture base, and data from this study demonstrate that they are easier to clean than those with a bar. Since the weak link in conventional mandibular denture treatment is inadequate prosthesis retention and stability,[10] subjects appear to prefer the ability to overcome these issues with only 2 implants that provide a near equivalent outcome to more costly and complex treatments using more implants or bar interconnection between implants. This finding is in agreement with the Feine et al[11] and Thomason et al[12] consensus reports that indicate that for the edentulous mandible, a 2-implant overdenture is the treatment of choice.

There were few complications due to attachment-related or other problems. From the complications encountered, no single treatment stood out as having more complications than any other. Other studies have found that attachment mechanism complications can be problematic, but there is no clear evidence that one treatment is more problematic than another.[20, 24-26] Of course the nature of this study involved frequent recall with new treatment on a yearly basis, and therefore, many complications were avoided.

The benefits of the crossover design for this implant-related investigation were numerous.[28] The ability to accommodate a variety of treatment types by switching back and forth among implants and abutments worked well. Additionally, because all subjects were able to experience all treatments, fewer subjects required statistical testing, and the completed subject preference information gathered after the routine data collection provided a strong indicator of treatment outcome. Equivalence testing is new to dental research. In essence, if this investigation could prove equivalence among the treatment types, then the less expensive, simpler treatment would be the treatment of choice and the hypothesis would be proven.

In a broader sense, results from this study for the 2I IOD can probably be generalized to represent other similar 2-independent-implant treatment types, and this study might provide a greater understanding of the treatment outcomes for more contemporary 2-independent-implant attachment systems. Nonetheless, the O-ring attachment that was used is no longer commercially available, a limitation of the study. In this regard, the findings from this study are in agreement with 2 consensus conferences[11,12] that both concluded that the 2-implant, independent IOD treatment was the best choice.

CONCLUSIONS

The results of this investigation showed that IOD retentive quality was less important than other clinical parameters in determining treatment outcome. Even though prosthesis retention for the 2I IOD was less than the 4B attachment, most other measured parameters showed equivalent or more favorable results for the 2I system when compared with the 2B or 4B attachments. Subjects preferred the 2I attachment to the other choices, and more than half the subjects selected the 2I IOD as their prosthesis after the conclusion of the investigation.

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