A Randomized Clinical Trial Comparing Patient Satisfaction and Prosthetic Outcomes with Mandibular Overdentures Retained by One or Two Implants

Joanne N. Walton, DDS, Cert Pros, FRCD(C)[a]/Ned Glick, PhD[b]/
Michael I. MacEntee, LDS (I), Dip Pros, PhD, FRCD(C)[a]

Purpose: This randomized clinical trial tested hypotheses that there are no differences in patient satisfaction, component costs, or treatment and maintenance times when mandibular overdentures are retained by one or two implants. ***Materials and Methods:*** Subjects wearing conventional complete dentures were randomized to receive either one midline or two bilateral mandibular implants followed by a mandibular denture reline to incorporate implant retention. They indicated on a visual analog scale satisfaction with their dentures before implants and at 2 months and 1 year after implant retention. Satisfaction outcomes between the two groups were compared using the Wilcoxon/Mann-Whitney nonparametric rank test, while changes within each group were analyzed using signed-rank tests. Component costs and times for surgery, prosthodontic treatment, and maintenance were compared using nonparametric and *t* tests. ***Results:*** Eighty-six subjects enrolled in this study and 85 completed the 1-year follow-up, at which median satisfaction was 93 (maximum 100) in the single-implant group and 94 in the two-implant group ($P > .5$). Within each group, median improvement in satisfaction was similarly dramatic (~44) and significant ($P < .001$). Prosthodontic maintenance time was similar for both groups ($P > .37$), but the single-implant group had significantly lower component costs ($P < .001$) and lower times for surgery ($P = .002$), postsurgical denture maintenance ($P = .021$), and denture reline ($P < .001$). Five implants failed in four subjects, all in the two-implant group and all before denture reline. ***Conclusion:*** Lower component costs and treatment times, with comparable satisfaction and maintenance time over the first year, indicate that a mandibular overdenture retained by a single midline implant may be an alternative to the customary two-implant overdenture for maladaptive denture patients. *Int J Prosthodont 2009;22:331–339.*

Around 37 million people in North America are without natural teeth. Because the elderly population is increasing, this number is unlikely to decline over the next 30 years,[1,2] despite improved methods for caries control and tooth preservation. Moreover, tooth loss is especially likely among individuals with low incomes.[3]

Although many denture-wearers tolerate conventional dentures, others are unhappy or handicapped by them.[4,5] Research with oral implants has focused on the mandible and mandibular dentures, where problems are greatest. Studies show that mandibular dentures retained by two or more implants are more satisfactory and functional than conventional dentures.[6–10] Patient satisfaction, as measured with a visual analog scale (VAS),[11] has been shown to be equally high with either a fixed or removable implant prosthesis (IP) design.[12–14]

Evidence of biologic success and psychosocial satisfaction has led to an emerging consensus that a two-implant overdenture should be recommended for everyone with an edentulous mandible.[15,16] However, this view of two implants as the standard of care has been challenged by clinicians who contend that the evidence does not support the assertion that implants are

[a]*Professor, Department of Oral Health Sciences, University of British Columbia, Vancouver, British Columbia, Canada.*
[b]*Professor Emeritus, School of Population and Public Health, Department of Statistics, University of British Columbia, Vancouver, British Columbia, Canada.*

Correspondence to: *Dr Joanne N. Walton, 2199 Wesbrook Mall, Vancouver, British Columbia, Canada V6T 1Z3. Fax: (604) 822-3562. Email: jnwalton@interchange.ubc.ca*

This study served as part of the Vancouver Implant Prosthesis (VIP) clinical trial.

necessary or advisable for all edentulous denture-wearers.[17,18] For example, Fitzpatrick,[19] in a systematic review on the standard of care for the edentulous mandible, stated that there is no evidence supporting one particular treatment modality as superior to all others for the edentulous mandible.

Unfortunately, even for cases where most clinicians might agree that mandibular implants would be appropriate, high costs may be an obstacle,[20] with estimates indicating that only about one in 1,000 partially or totally edentulous individuals worldwide have benefited from implant-assisted treatment.[21]

Single implants, which ought to be less expensive than multiple implants, have been used to retain dentures temporarily before placing additional implants.[22] At least one prospective study of 21 patients[23] and a clinical report on nine patients[24] suggest that a single implant can successfully retain a mandibular complete denture. However, these studies were small and the outcome measures were limited. A study by Liddelow and Henry,[25] published after this trial began, showed good results with 25 patients who had complete mandibular dentures retained by an immediately loaded single midline implant. Another recent in vitro study[26] demonstrated similar lateral forces on the abutments with mandibular dentures retained by one or two implants. Nevertheless, more evidence is needed to show that a single implant could satisfactorily retain a mandibular denture and that clinicians could reliably offer this treatment, which is less expense than two implants, as an alternative to a conventional mandibular denture.

In addition to possible cost savings with a single implant overdenture, there are potential surgical advantages as well. For example, midline implant placement allows for simplified imaging and flap design, without concerns for the position of the mental foramen or possible postoperative paresthesia related to direct or indirect damage to branches of the inferior alveolar nerve.

This randomized clinical trial was designed to test the null hypothesis that there would be no difference in patient satisfaction, component costs, or treatment and maintenance times through 1 year after placement of either a single central implant or two bilateral implants to retain a mandibular overdenture. The study also monitored implant failures.

The authors previously reported on reasons given by respondents for choosing or refusing no-cost implants,[27] and on the screening of all 220 volunteers[28] to account for those who enrolled and those who either did not qualify or chose not to participate. This paper reports outcomes regarding patient satisfaction, component costs, and treatment times for the 86 subjects who consented and enrolled in the clinical trial. Results are reported following the revised CONSORT statement for reporting randomized trials,[29] recognizing that the parametric confidence interval methods envisaged by CONSORT are not suited to VAS measurements, and that this research has some aspects of a non-inferiority trial.[30]

Materials and Methods

The primary outcome measure in this trial was patient satisfaction, as indicated by scores on VASs. The study also compared component costs, as well as treatment and maintenance times, for single- and double-implant–retained mandibular dentures.

For the VAS satisfaction data, nonparametric statistical methods are appropriate, and in anticipation of treatment group comparisons, adequate subject recruitment was calculated using the Wilcoxon/Mann-Whitney nonparametric rank tests.[31] Hypotheses about relative efficacy of the treatments can be framed in terms of probability (Q) that a random subject would be more satisfied with two implants than with a single implant. The null hypothesis (no difference between the two treatments) can be expressed as: $Q = 1/2$. For the alternative, $Q = 2/3$ or greater (equivalently, odds ratio $= 2$ or greater), a rank test (with significance level $\alpha = 0.05$) has about 80% power ($\beta = 0.2$) if 76 subjects are divided equally and at random between the treatment groups. Enrollment was increased to a total of 86 subjects as a precaution to retain statistical power in the event of dropouts and/or unequal treatment group numbers, because subjects were stratified according to sex and mandibular ridge resorption and randomized into blocks, with four subjects per block.

This study was approved by the Clinical Research Ethics Board of the University of British Columbia (UBC), Vancouver, British Columbia, Canada. Volunteers were recruited via letters of invitation to patients who had received dentures at the UBC Faculty of Dentistry undergraduate clinic, as well as by advertising to local clinicians, UBC dental students, denturists, elders' organizations, and libraries in the greater Vancouver area. All volunteers were screened and all subjects treated at the UBC Faculty of Dentistry clinic.

Two hundred twenty volunteers were screened by a prosthodontist and when indicated, by an oral and maxillofacial surgeon in order to enroll 86 subjects who met the inclusion criteria for the trial, as described in a previous paper.[28] Inclusion and exclusion criteria are listed in Table 1. Volunteers who otherwise met the inclusion criteria but whose complete dentures were not judged to be technically acceptable (Table 2) were referred for denture revisions or new dentures and offered the opportunity to be examined again after denture improvements for possible inclusion in the trial. To

Table 1 Inclusion and Exclusion Criteria for Subjects in the VIP Clinical Trial

Inclusion criteria
• Functional in English or accompanied by a responsible adult who can provide translation services
• Able to consent to and participate in the treatment provided
• Available for the duration of the study
• Edentulous and with at least 6 month's experience with conventional complete dentures
• Currently wearing conventional complete dentures that are esthetically satisfactory to the patient and technically acceptable in the judgment of the study prosthodontist(s)
• Medically/psychologically suitable for implant surgery in the judgment of the study clinicians
Exclusion criteria
• Insufficient alveolar bone height for implant(s) (< 6 mm)
• History of head and neck radiation
• Systemic or neurologic disease, including:
- ASA class 3 with recently diagnosed severe systemic disease, eg, recent (within 6 months) myocardial infarction or stroke
- Risks associated with bacteraemia, (eg, immune compromise, steroids, in-dwelling catheters, stents, prosthetic heart valves)
- Type 1 diabetes, pituitary and adrenal insufficiency, and untreated hypothyroidism
- Chronic granulomatous disease, (eg, tuberculosis and sarcoidosis)
- Bone disease (eg, histiocytosis X, Paget's disease, fibrous dysplasia)
- History of congenital or acquired uncontrolled bleeding
• Previous oral implant treatment
• Need for additional preprosthetic surgery
• Need for new complete dentures
• Medically/psychologically unsuitable for surgery in the opinion of the study clinicians

Table 2 Denture Criteria for Inclusion in the VIP Clinical Trial

Technically acceptable dentures[32]
• Hard densely processed acrylic resin bases without missing parts, fractures, visible porosity, or other structural defects
• Periphery of denture bases within usual anatomical parameters
• Maxillary denture retentive when denture-wearer opens the mouth to 15 mm between incisors
• Mandibular incisors within the anatomical boundaries of the ridge crest and the labial vestibule
• Posterior teeth on mandibular denture no higher than 3 mm above the retromolar pad and within the triangular zone outlined by the width of the retromolar pad and the tip of the canine
• Comfortable interocclusal rest space for the denture-wearer
• Centric occlusal contacts within 2 mm of centric relation
• No cheek biting

participate in the clinical trial, each subject signed an informed consent form and then received an ID number, which was used for subsequent data entry and analysis.

The study was designed so the single- and double-implant treatment groups not only had similar sizes, but were also comparable with regard to patient characteristics that might be confounded with treatment effects, specifically patient sex (female or male) and the amount of mandibular ridge resorption (normal or severe). The height of the ridge relative to the mental foramina when viewed on a presurgical panoramic radiograph was used to differentiate normal and severe resorption. When the mental foramina were below the ridge crest bilaterally, resorption was classified as normal; when the mental foramina were at the ridge crest unilaterally or bilaterally, resorption was labeled as severe.

In combination, the sex and ridge categories stratified subjects into four subsets. Within each subset or stratum, blocks of four subjects were randomly divided to receive either one or two implants. Randomized block allocations were generated by a statistician. After determining a subject's stratum (the prosthodontist confirmed the amount of ridge resorption), an assistant drew the subject's treatment assignment from an envelope in the current randomization block.

Obviously, neither the subjects nor care providers could be blinded as to the number of implants placed, but care providers were counseled to avoid commenting about treatment possibilities to subjects and were not present when subjects completed the questionnaires.

Each subject completed two questionnaires prior to randomization. A background questionnaire provided information about the subject's income, marital status, use of tobacco, dental history and use of dentures, self-awareness of bruxism, and self-assessed general health. The other baseline questionnaire focused on eight denture-related issues: pain, comfort, appearance, function, stability, speech, hygiene, and overall satisfaction with maxillary and mandibular dentures. For each of these items, a subjective response was indicated on a VAS that had no markings between its endpoints (interpreted as 0 and 100). Using a customized interface on a computer screen, each subject positioned a pointer and the study's database (Access,

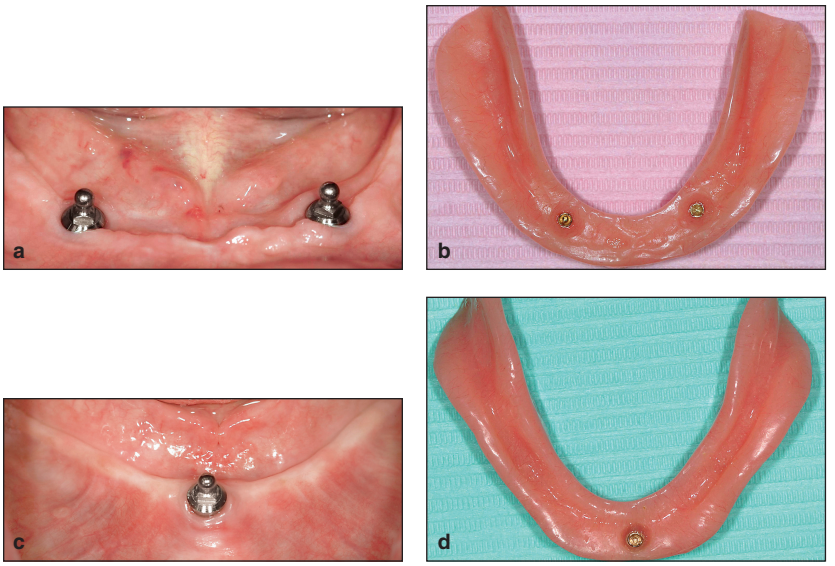

Fig 1 Clinical photographs showing the two implant retention systems used in the mandible. Two implants: **(a)** patrices (intraoral) and **(b)** matrices (in denture); one implant: **(c)** patrix (intraoral) and **(d)** matrix (in denture).

Microsoft) recorded the position automatically to eliminate measurement and data entry errors. The VAS score for overall satisfaction is the only questionnaire item considered here, but it was correlated with more specific denture issues. Subjects were asked to complete satisfaction questionnaires again at 2 months and then 1 year after the mandibular denture had been modified for implant retention.

After baseline questionnaires were completed, subjects were scheduled for implant surgery. Single implants (Solid Screw, SLA surface, Straumann Canada) were placed in the mandibular midline, while two implants of the same design, when assigned, were placed in the mandibular canine areas bilaterally. The implants were allowed to heal for approximately 6 weeks, with a healing abutment and a temporary reline in the mandibular denture. The prosthodontist then placed the ball abutment(s) and completed a processed denture reline incorporating implant retention (Straumann ITI spherical stud, Retentive Anchor, and gold matrix) (Fig 1).

Although subjects were not billed, costs were recorded in Canadian dollars (at the time of writing, 1 CAD = 1.00 USD) for all surgical and prosthodontic implant components used in the study. Times for implant surgery, postsurgical denture maintenance (about 6 weeks after implant placement and before activation of implant retention), denture modification for implant retention (impression and delivery of relined denture with implant matrix), and implant prosthesis (IP) maintenance were also recorded for 1 year after implant retention. Chair time was recorded with a minute timer that was started when the patient was seated for each appointment and stopped when the patient was dismissed.

The types of adjustments and repairs required during maintenance of the implant dentures were also noted. "Adjustments" did not require the addition of any new material to the denture or the replacement of broken or missing components or materials, while "repairs" required such additions or replacements. Prosthetic outcomes were also categorized according to a six-field protocol[33] designed to allow comparisons of results from one study to another.

For satisfaction scores, component costs, and treatment times in this study, a group's median rather than mean value characterizes a "typical" outcome, because the data sets for all of these outcome measurements had skewed distributions, while baseline satisfaction scores had U-shaped distributions. Such characteristics are obvious when data are summarized graphically using histograms or boxplots. Figure 2 gives boxplots for both groups' satisfaction data at baseline (preimplant) and after wearing implant-retained mandibular dentures for 2 months and 1 year (boxplot graphics were generated using Microsoft Excel spreadsheets with an add-in from Peltier Technical Services). Statistical testing of medians relied primarily on nonparametric rank procedures (SPSS). Wilcoxon/Mann-Whitney tests of "no difference" between groups and signed-rank tests of "no change" over time were computed for individuals within each group. Student *t* tests comparing groups were also completed and they led to similar conclusions.

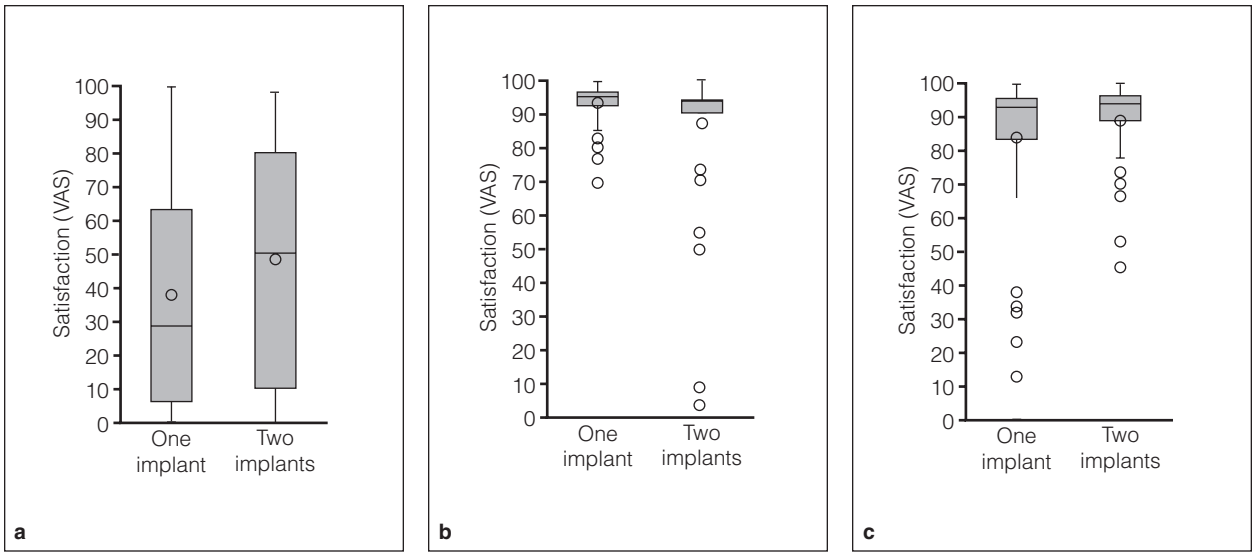

Fig 2 Boxplots comparing satisfaction with a mandibular denture at **(a)** baseline (preimplant) and then **(b)** 2 months and **(c)** 1 year after implant retention. Subjects in the treatment groups received one central implant or two bilateral implants. The two-implant group includes only 43 VAS scores at 1 year after implant retention since one subject did not complete this satisfaction questionnaire.

Results

From 2002 through 2006, 86 subjects were enrolled in this study, of whom 42 were randomized to the single-implant group (22 women and 20 men, mean age: 68 years) and 44 were randomized to the double-implant group (21 women and 23 men, mean age: 66 years). After stratification based on mandibular ridge resorption, there were 38 subjects with normal resorption in the one-implant group and 37 with normal resorption in the two-implant group.

With one exception, all subjects were followed for at least 1 year after denture modification for the implant(s). The subject who withdrew was a woman in the two-implant group who left the study complaining about her maxillary denture approximately 3 months after receiving her modified mandibular denture. The study's 1-year data and related analyses omit this subject.

Four subjects experienced implant failures, all in the two-implant group and all before the implants were placed in function. One subject had both implants fail; they were both replaced and subsequently integrated. The other three subjects each had one implant fail; two subjects had the failed implant replaced, and the third chose to stay with a single implant. Following the "intent to treat" principle, results reported here include all four of these subjects in the two-implant group, but results did not change noticeably when we excluded or reclassified these subjects.

Stratification assured that the one-implant and two-implant treatment groups were similar with respect to proportions of men to women and proportions of subjects with normal to severe ridge resorption. There were no notable group disparities found with respect to age, income, marital status, use of tobacco, dental history, use of dentures, self-awareness of bruxism, or self-assessed general health.

On the other hand, although any satisfaction differences between the groups at baseline were random, some differences were observed. Subjects randomly assigned to receive one implant had baseline satisfaction VAS scores with a median of 28.5 (mean: 38.1), while those randomly assigned to receive two implants had scores with a median of 50.5 (mean: 48.8). No causal factor(s) were found. Rather, such differences occurred by chance because baseline distributions of VAS scores varied widely, and with distributions that were quite distinct from normal "bell" concentrations (Fig 2). That is, baseline satisfaction differences between the groups were not statistically significant ($P = .27$, Wilcoxon/Mann-Whitney test; $P = .17$, t test).

Figure 2 also graphically summarizes satisfaction results. After wearing a modified mandibular denture retained by the implant(s) for 2 months, the median VAS score was 95 in both groups. After 1 year, median satisfaction was 93 in the single-implant group and 94 in the two-implant group. Satisfaction differences at 1 year were not statistically significant ($P > .5$, Wilcoxon/Mann-Whitney test; $P = .36$, t test). Also, the median improvement in overall satisfaction from baseline to 1 year was similar within each group (around 44), and was statistically very significant ($P < .001$, Wilcoxon signed-rank test).

Table 3 Comparisons of Component Cost, Surgical Time, and Prosthodontic Time for the One- and Two-Implant Groups

	Group medians		Statistical tests	
	One implant (22 F:20 M)	Two implants (21 F:23 M)	W/M-W *P* value	*t* test *P* value
Component costs (CAD)	$957.14†	$1678.64†	< .001	< .001
Surgical time* (min)	69.0†	89.0†	.002	.011
Prosthodontic time (min)				
Postsurgery	167.5†	220.0†	.021	.022
IP modification	50.0†	60.0†	< .001	< .001
IP maintenance	198.5	200.5	.37	.21
Total prosthodontic time	431.5†	485.0†	.042	.047

M = male; F = female; W/M-W = Wilcoxon/Mann-Whitney test; IP = implant prosthesis.
*Surgical times were not recorded for six subjects in the one-implant group and four in the two-implant group.
†Observed difference between treatment groups is both statistically significant and regarded as clinically important.

Table 4 Frequency of Adjustments for One- and Two-Implant Overdentures Over the First Year of Wear

Type of adjustment	One implant	Two implant
Contour	60	44
Adjust matrix	37	34
Tighten patrix	5	1
Occlusal	4	2

Table 5 Frequency of Repairs for One- and Two-Implant Overdentures Over the First Year of Wear

Type of adjustment	One implant	Two implant
Broken denture	5	2
Cracked denture	2	2
Loose matrix	4	4
Otherwise defective matrix	0	2

While satisfaction outcomes showed no difference between groups treated with one or two implants, the component costs and most of the treatment times associated with the study over 1 year were notably reduced for the single-implant group (Table 3). The maximum component cost ($1,123) in the single-implant group was below the minimum cost ($1,419) in the two-implant group. The respective cost medians were $957 and $1,679. This cost difference between treatment groups was statistically very significant ($P <$ .001,Wilcoxon/Mann-Whitney test and *t* test) (Table 3).

Median prosthodontic maintenance time over the first year after implant denture delivery was almost identical for both groups, approximately 3.3 hours ($P = .37$) (Table 3).

On the other hand, the single-implant group had significant reductions for surgical time to place implants ($P = .002$, two-sided Wilcoxon/Mann-Whitney test), for postsurgical maintenance time ($P = .021$), and for time to modify the mandibular denture ($P < .001$). The median surgical appointment to place a single implant was just under 1.2 hours in length versus almost 1.5 hours to place two implants. Similarly, median postsurgical maintenance time (before activating the implant for retention) was 2.8 hours for one implant versus 3.7 hours for two implants. Median IP modification time during the year was 0.8 hours in the group with one implant and 1.0 hour in the group with two implants (Table 3).

There were no differences in satisfaction or in treatment and maintenance times based on age, between men and women, or between those with normal and severe ridge resorption. Component costs and surgical time results did differ somewhat for women and men, but not with any clear pattern.

The most common adjustments to the implant dentures were to the denture contour for both groups (Table 4), while the most common repairs involved a broken denture for the single-implant group and replacing a loose matrix for the two-implant group (Table 5).

Using the six-field protocol to categorize prosthetic outcomes, 88% of the single-implant dentures and 93% of the two-implant dentures were considered successful over the study period (Table 6).

Given the small number of implant failures (five implants in four subjects, all in the two-implant group), no statistical analysis of implant failure is possible in this study.

Discussion

The findings presented in this study support mounting evidence that implant overdentures are much more satisfying to wear than conventional dentures. Moreover, using one implant to retain and stabilize the mandibular denture is as satisfactory as using two.

In comparing subjects with dentures retained by one or two implants, the null hypothesis was not rejected

Table 6 Six-Field Outcomes for the First Year of the VIP Clinical Trial

Field	Definition	One Implant	Two Implants
Successful	No evidence of retreatment except for accepted maintenance, which includes patrix activation/repair/replacement; matrix activation/repair/replacement and asymptomatic, peri-implant/interabutment mucosal enlargement, not requiring excision. No more than two patrix or matrix replacements; no more than one reline (not including modification for implant retention) in first year.	37	41
Surviving	Patient cannot be examined directly, but the patient or another clinician confirm no evidence of retreatment, except that described for a successful outcome. Number of implants, support differentiation, and status of the opposing arch are identified.	–	–
Unknown (lost to follow-up)	Patient cannot be traced; surviving or successful implant overdenture removed to allow provision of a new overdenture (eg, conversion to another overdenture design with additional implants or a fixed implant prosthesis using the same or additional implants).	–	1
Dead	Patient died during the study period, regardless of whether successful or surviving criteria were experienced before death.	–	–
Retreatment (repair)	Treatment of the implant overdenture and/or mucosa where the marginal integrity and associated patrices/matrices are maintained irrespective of modifications as long as it continues as an implant overdenture. More than two replacements of either patrix or matrix in the first year. Includes replacement of worn or fractured overdenture teeth/fractured overdentures, relining of the overdenture more than once, or excision of patrix-associated mucosal enlargement as a result of infringement on the shoulder/undersurface of the patrix.	5	2
Retreatment (replace)	Part or all of the implant overdenture is no longer serviceable because of either loss of implants or irreparable mechanical breakdown. A replacement prosthesis is indicated.	–	–
Total		42	44

for patient satisfaction or IP maintenance time. However, it was rejected with respect to component costs and time related to surgery, postsurgical maintenance, and implant denture modification.

If the two-implant group had shown superior satisfaction after implant surgery and denture modification, then one might question whether such a result should be attributed to an inadvertent "head start" bias (superior satisfaction at baseline in the two-implant group), rather than to superiority of the two-implant treatment. But, in fact, data at the latter times (see Fig 2) indicate no differences between the one-implant and two-implant groups with respect to satisfaction, contrary to any notion of such a bias.

Intuitively, the putative superiority of the standard two-implant overdenture might be evident if certain subjects were excluded from analysis, namely the male subject who had been randomized to the two-implant group but who ended up with only one implant, and seven apparently "easy-to-please" subjects (five in the one-implant group and two in the two-implant group) who had baseline satisfaction scores higher than 95 with their preimplant mandibular conventional dentures. However, reanalyzing the data with such exclusions did not alter statistical test results substantially, and median satisfaction scores remained essentially unchanged from results without the exclusions. At 2 months and 1 year after implant placement, median satisfaction scores with the exclusions noted were 95 and 92 in the one-implant group and 95 and 94 in the two-implant group, respectively.

Given that the authors did not seek to only recruit subjects who were dissatisfied with their existing dentures, it was not a surprise to see that there were some subjects, 14 in total (including the seven noted above), who reported a high level of satisfaction with their dentures at baseline (score of 90 or higher). Six were in the single-implant group while eight were in the two-implant group. There did not seem to be any pattern to the sex or age of these subjects, and all but three of the 14 maintained satisfaction scores over 90 at study completion. Even those three subjects rated their satisfaction with implant overdentures highly, at 84 or better.

In contrast to the widely dispersed preimplant satisfaction scores, the scores for both groups with implant-retained dentures were predominantly homogeneous and dramatically high. There were, however, a number of low satisfaction outliers at both 2 months and 1 year, ie, individuals who indicated satisfaction below the lower "whiskers" in the box-and-whisker plots shown in Fig 2. While the five outliers in the single-implant group appear to be more dissatisfied at the end of the study than the four outliers in the other group, it should be noted that VAS scores are not ratio scale measurements, meaning that, for example, a difference between satisfaction scores of 20 and 40 cannot be assumed to have the same meaning as a difference between scores of 70 and 90. It seems that the nine outliers at the end of the study were also a very dissatisfied group at the start, with baseline median satisfaction scores of 9 for the outliers in the one-implant group and 45 for those

in the two-implant group (compared with overall baseline satisfaction medians of 28.5 and 50.5 for the one- and two-implant groups, respectively). Although eight of the nine outliers showed improved satisfaction at 2 months postimplant retention, the same eight reported decreased satisfaction at 1 year (albeit higher than baseline for six of the eight), indicating that they may be a particularly hard-to-please group despite their initial perception of improvement. The ninth outlier, a subject in the two-implant group, reported lower satisfaction at 2 months, with a return to near baseline (1 point lower) at completion. Overall, despite lower than average satisfaction scores at study completion, six of the nine outliers still reported greater satisfaction with their implant dentures than with their conventional dentures. To further put these results into perspective, only three of the 85 subjects who completed the study, one in the single-implant group and two in the two-implant group, indicated less satisfaction with their implant dentures than with their conventional dentures.

When it came to surgical and prosthetic treatment times, the hypothesis was that there would be no difference between the treatment groups. This hypothesis was defeated for both implant placement and prosthesis modification. The authors had expected that the number of implants placed or restored would be less influential than all of the steps required, such as anesthesia, flap preparation, suturing, or impressions and other reline-related prosthetic steps that are common to all patients, irrespective of the number of implants involved. Instead, the single-implant time advantages in both the surgical and prosthetic phases of treatment were both statistically and clinically significant, with median time savings differing by about 22% at implant placement and 16% at reline impression to add implant retention. There were further savings in time because the single-implant group required about 24% less time to deal with postsurgical complications and conventional denture adjustments during the 6-week implant integration phase. This time is often particularly unproductive for both surgeons and prosthodontists, so any reduction in postsurgical care requirement can be clinically significant.

The hypothesis that IP maintenance time would be similar between the one- and two-implant groups was supported. Here, it appears that the adjustments and repairs are similar in type and number, irrespective of the number of implants present. This may relate to the fact that the same attachment mechanism was used for both groups. Likewise, because an implant overdenture is supported by the residual ridge and should only be retained and stabilized by the implant(s), many of the adjustments are similar to those required for conventional dentures. The fact that subjects were already wearing technically satisfactory dentures that were merely relined for implant retention may also have reduced the amount of time needed for IP maintenance.

The tendency of stresses to concentrate within the denture bases over the implants may explain why relatively more dentures fractured in the one-implant group. Although fracture numbers were small, it was noticed that in the single-implant group of 42 subjects, there were five mandibular dentures that fractured during the first year, compared to only two in the two-implant group. Greater propensity to fracture may be related to a tendency for the denture to fulcrum over a single implant as either the mucosa overlying the residual ridge compresses with denture wear or the ridge resorbs, and warrants continued scrutiny over time. Overall, however, the numbers of adjustments and repairs were much less than we have seen previously,[34] and similar high proportions of implant prostheses were classified as successful, according to the criteria used in the six-field protocol.

It stands to reason that implant component costs would be less for a single-implant retained overdenture, and indeed, the component cost median for a single implant was just over half of that for a two-implant overdenture. Reduced component costs, along with the time savings in treating patients with a single-implant–retained overdenture, should make this treatment a more affordable option for patients who struggle with a conventional mandibular denture but who are deterred by the expense of a denture retained by two implants. Indeed, the overall savings to healthcare could be substantial.

Conclusions

One-year results in this randomized clinical trial indicate comparable satisfaction and maintenance times, with lower component costs and treatment times, when mandibular implant prostheses were retained by a single implant as compared to two implants. Although longer observation periods with similar results will increase practitioner comfort with this option, a mandibular overdenture retained by a single midline implant appears to warrant consideration as an alternative to the standard two-implant overdenture for maladaptive denture patients.

Acknowledgments

This study was supported by the Canadian Institutes of Health Research (grant no. 58954), the ITI Foundation (grant no. 222), and Straumann Canada.

References

1. Mojon P, Thomason JM, Walls AWG. The impact of falling rates of edentulism. Int J Prosthodont 2004;17:434–440.
2. Douglass CW, Shih A, Ostry L. Will there be a need for complete dentures in the United States in 2020? J Prosthet Dent 2002;87:5–8.
3. Marcus SE, Kaste LM, Brown LJ. Prevalence and demographic correlates of tooth loss among the elderly in the United States. Spec Care Dentist 1994;14:123–127.
4. MacEntee MI, Hole R, Stolar E. The significance of the mouth in old age. Soc Sci Med 1997;45:1449–1458.
5. Fiske J, Davis DM, Frances C, Gelbier S. The emotional effects of tooth loss in edentulous people. Br Dent J 1998;184:90–93.
6. Dudic A, Merickse-Stern R. Retention mechanisms and prosthetic complications of implant-supported mandibular overdentures: Long-term results. Clin Implant Dent Relat Res 2002;4:212–219.
7. Timmerman R, Stoker GT, Wismeijer D, Ooosterveld P, Vermeeren JL, van Waas MA. An eight-year follow-up to a randomized clinical trial of participant satisfaction with three types of mandibular implant-retained overdentures. J Dent Res 2004;83:630–633.
8. Visser A, Raghoebar GM, Meijer HJ, Batenburg RH, Vissink A. Mandibular overdentures supported by two or four endosseous implants. A 5-year prospective study. Clin Oral Implants Res 2005;16:19–25.
9. Stoker GT, Wismeijer D, van Waas MAJ. An eight-year follow-up to a randomized clinical trial of aftercare and cost-analysis with three types of mandibular implant-retained overdentures. J Dent Res 2007;86:276–280.
10. MacEntee MI, Walton JN, Glick N. A clinical trial of patient satisfaction and prosthodontic needs with ball and bar attachments for implant-retained complete overdentures: Three-year results. J Prosthet Dent 2005;93:28–37.
11. McDowell I, Newell C. Measuring Health: A Guide to Rating Scales and Questionnaires, ed 2. New York: Oxford University Press, 1996:341–345.
12. Feine JS, de Grandmont P, Boudrias P, et al. Within-subject comparisons of implant-supported mandibular prostheses: Choice of prosthesis. J Dent Res 1994;73:1105–1111.
13. Tache R, Lamarche C, Brien N, et al. The assessment of treatment success by prosthodontists and their patients. J Dent Res 1991;70 (special issue):2348.
14. de Grandmont P, Feine JS, Taché R, et al. Within-subject comparisons of implant-supported mandibular prostheses: Psychometric evaluation. J Dent Res 1994;73:1096–1104.
15. Feine JS, Carlsson GE, Awad MA, et al. The McGill consensus statement on overdentures. Mandibular two-implant overdentures as first choice standard of care for edentulous patients. Gerodontology 2002;19:3–4.
16. Klemetti E. Is there a certain number of implants needed to retain an overdenture? J Oral Rehabil 2008;35(suppl 1):80–84.
17. MacEntee MI, Walton JN. The economics of complete dentures and implant-related services: A framework for analysis and preliminary outcomes. J Prosthet Dent 1998;79:24–30.
18. MacEntee MI. The impact of edentulism on function and quality of life. In: Feine J, Carlsson G (eds). Implant Overdentures as the Standard of Care for Edentulous Patients. Chicago: Quintessence International, 2003:1–7.
19. Fitzpatrick B. Standard of care for the edentulous mandible: A systematic review. J Prosthet Dent 2006;95:71–78.
20. Walton JN, MacEntee MI, Hanvelt R. Cost analysis of fabricating implant prostheses. Int J Prosthodont 1996;9:271–276.
21. Carlsson GE, Kayser AF, Owall B. Current and future trends in prosthodontics. In: Owall B, Kayser AF, Carlsson GE (eds). Prosthodontics: Principles and Management Strategies. London: Mosby-Wolfe, 1996:237–249.
22. Naert I, Quirynen M, Theuniers G, van Steenberghe D. Prosthetic aspects of osseointegrated fixtures supporting overdentures. A 4-year report. J Prosthet Dent 1991;65:671–680.
23. Cordioli G, Majzoub Z, Castagna S. Mandibular overdentures anchored to single implants: A five-year prospective study. J Prosthet Dent 1997;78:159–165.
24. Krennmair G, Ulm C. The symphyseal single-tooth implant for anchorage of a mandibular complete denture in geriatric patients: A clinical report. Int J Oral Maxillofac Implants 2001;16:98–104.
25. Liddelow GJ, Henry PJ. A prospective study of immediately loaded single implant-retained mandibular overdentures: Preliminary one-year results. J Prosthet Dent 2007; 97(6 suppl):S126–S137.
26. Maeda Y, Horisaka M, Yagi K. Biomechanical rationale for a single implant-retained mandibular overdenture: An in vitro study. Clin Oral Implants Res 2008;19:271–275.
27. Walton JN, MacEntee MI. Choosing or refusing oral implants: A prospective study of edentulous volunteers for a clinical trial. Int J Prosthodont 2005;18:483–488.
28. Walton JN, MacEntee MI. Screening and enrolling subjects in a randomized clinical trial involving implant dentures. Int J Prosthodont 2008;21:210–214.
29. Altman DG, Schulz KF, Moher D, et al. The revised CONSORT statement for reporting randomized trials: Explanation and Elaboration. Ann Intern Med 2001;134:663–694.
30. Piaggio G, Elbourne DR, Altman DG, et al. Reporting of noninferiority and equivalence randomized trials: An extension of the CONSORT statement. JAMA 2006;295:1152–1160 [erratum 2006;296:1842].
31. Noether GE. Sample size determination for some common nonparametric tests. J Amer Statistical Assoc 1987;82:645–647.
32. MacEntee MI, Wyatt CCL. An index of clinical oral disorder in elders (CODE). Gerodontology 1999;16:85–96.
33. Payne AGT, Walton TR, Walton JN, Solomons YF. The outcome of implant overdentures from a prosthodontic perspective: Proposal for a classification protocol. Int J Prosthodont 2001;14:27–32.
34. Walton JN. A randomized clinical trial comparing two mandibular implant overdenture designs: 3-year prosthetic outcomes using a six-field protocol. Int J Prosthodont 2003;16:255–260.