Choosing or Refusing Oral Implants: A Prospective Study of Edentulous Volunteers for a Clinical Trial

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Purpose: Little is known about why people accept or refuse oral implant treatment. The purpose of this study was to assess edentulous subjects' acceptance or refusal of free implants to retain mandibular dentures, and to evaluate factors that might predict those who are more likely to choose implants. ***Materials and Methods:*** One hundred one volunteers completed questionnaires about their background, satisfaction with conventional dentures, oral health-related quality of life, and preference for implants. Results were analyzed using Pearson chi-square tests and logistic regression. ***Results:*** While 79% of volunteers accepted and 21% refused an initial offer of free implants, a number of them changed their minds, leaving 64% who wanted implants and 36% who did not want them. The most common reason for choosing implants was anticipation of improved mandibular denture stability or security (73%), while the most common reason for refusal was concern about surgical risks (43%). A logistic regression model identifying those who complained of poor chewing function, poor speech, pain, and dissatisfaction with appearance improved the prediction of those who wanted implants from 64% to 80%. ***Conclusion:*** When cost was removed as a factor, more than one third (36%) of the older, edentulous participants in this study ultimately refused an offer of free implants to retain their mandibular dentures. Poor chewing function, poor speech, pain, and dissatisfaction with appearance were the most important factors in predicting who would choose implants. *Int J Prosthodont 2005;18:483–488.*

Implant-assisted dental prostheses for edentulous patients improve physical function, comfort, and satisfaction.[1–6] However, the financial cost of this treatment remains a substantial barrier to many people,[7] probably because implant dentures are more expensive to fabricate and maintain than conventional dentures.[8–10] It is reasonable to assume, therefore, that more patients would seek implant dentures if the treatment were less expensive; however, little is known about the factors that motivate patients to choose or refuse implant treatment. There is evidence from subjects in clinical trials that edentulous subjects with and without implants compared to people with natural teeth have more psychosocial problems,[11] and that subjects seeking implant dentures rather than conventional complete dentures give significantly more negative responses to the Oral Health Impact Profile (OHIP).[12]

The objectives of this study were to assess edentulous subjects' acceptance or refusal of an offer of free implants to retain their mandibular dentures, and to identify factors that might help predict those more likely to choose implants.

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Inclusion Criteria

1. Functional in English or accompanied by a responsible adult who can provide translation services
2. Able to consent to and participate in the treatment provided
3. Available for the duration of the study
4. Edentulous and with at least 6 months' experience with conventional complete dentures
5. Currently wearing conventional complete dentures that are esthetically satisfactory to the patient and technically acceptable in the judgment of the study prosthodontist(s)
6. Medically/psychologically suitable for implant surgery in the judgment of the study clinicians

Exclusion Criteria

1. Insufficient alveolar bone height for implant(s) (less than 6 mm)
2. History of head and neck radiation
3. Presence of 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 bacteremia, due to either surgery or implants, that may compromise general health, eg, immunocompromise, steroids, in-dwelling catheters, stents, and prosthetic heart valves
   - Type 1 diabetes, pituitary and/or adrenal insufficiency, and untreated hypothyroidism
   - Chronic granulomatous disease, eg, tuberculosis and sarcoidosis
   - Bone disease, eg, histiocytosis X, Paget disease, and fibrous dysplasia
   - History of congenital or acquired uncontrolled bleeding, eg, coumadin treatment
4. Previous oral implant treatment
5. Need for additional preprosthetic surgery
6. Need for new complete dentures
7. Medically/psychologically unsuitable for surgery in the opinion of the study clinicians

Fig 1 Inclusion and exclusion criteria for the Vancouver Implant Prosthesis clinical trial.

Materials and Methods

This study was approved by the Clinical Research Ethics Board of the University of British Columbia (UBC), and volunteers were recruited using letters of invitation to patients who had received new dentures at the UBC Faculty of Dentistry undergraduate clinic as well as by advertising to local dentists, denturists, organizations for senior citizens, and libraries in the greater Vancouver area. Volunteers were invited to the university for a clinical oral examination and to answer questions about their social background, health, and satisfaction with complete dentures. They were informed about the possibility of being selected for a study in which, if they chose to participate, they would be assigned randomly to receive either 1 or 2 implants in the mandible, and have their mandibular denture relined, "all at no financial cost."

Recruits who responded with interest were offered general information about the trial and an appointment for a clinical oral examination. Everyone who accepted the offer came to the clinic to meet the prosthodontist, who explained the commitment expected from participants, answered questions, and reviewed with each patient the consent form they were given, which described in detail the treatment offered, along with its risks and benefits. The prosthodontist performed a clinical examination of the mouth and dentures, and if necessary, consulted with an oral and maxillofacial surgeon to identify those who met the criteria for inclusion in the clinical trial (Fig 1).

Participants with complete dentures that were not technically acceptable were referred for denture revisions or new dentures and examined again for inclusion in the trial. Technically acceptable dentures include the following[13]: (*1*) dentures consist of hard, densely processed acrylic resin bases without missing parts, fractures, visible porosity, or other structural defects; (*2*) periphery of denture bases is within usual anatomic parameters; (*3*) maxillary denture is retentive when denture wearer opens the mouth to 15 mm between incisors; (*4*) mandibular incisors are within the anatomic boundaries of the ridge crest and the labial vestibule; (*5*) posterior teeth on mandibular denture are 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; (*6*) there is comfortable interocclusal rest space for the denture wearer; (*7*) centric occlusal contacts are within 2 mm of centric relation; and (*8*) no cheek biting is present.

All volunteers were asked to complete 4 questionnaires addressing: (*1*) background information; (*2*) negative impacts of specific oral conditions; (*3*) satisfaction with dentures; and (*4*) their interest in accepting or refusing implant(s) at no financial cost to retain their mandibular denture and the reasons for their choice. The background information included marital status, income, dental history, use of tobacco, use of dentures, self-awareness of bruxism, and self-assessed general health. Negative impacts of oral conditions were solicited by the OHIP in the form of 49 questions addressing seven conceptual domains relating to functional limitation, pain, psychologic discomfort, physical disability, psychologic disability, social disability, and handicaps.[14] Satisfaction with dentures was determined using 8 questions relating to pain, comfort, appearance, function, stability, speech, hygiene, and over-

Table 1 Recruitment Sources of the First 101 Volunteers Screened for the VIP Clinical Trial

	Recruitment source						
		Referral			Advertisement		
Subject status	University dental clinic	Dentists	Denturists	Friends	Senior centers	Newspapers	Total
Screened	69	7	2	2	1	20	101
Accepted in trial	55	4	2	2	1	15	79
Refused implants	27	0	0	0	0	8	35

all satisfaction, each associated with a measurable response on a visual analogue scale (VAS).[15]

The implant preference questionnaire began with the statement: "If you wish to become a participant in the study, you will be offered 1 or 2 permanent surgical implant(s) in your lower jaw and your lower denture will be adjusted to accommodate the implant(s), all at no cost to you. Right now, please select only ONE of the following by placing an X on the line corresponding to your response: (a) I want implant(s) (at no extra cost); (b) I do not want implant(s)." The questionnaire continued with a series of questions listing possible reasons for accepting or declining implant treatment, along with an "other" option for both, and asking participants to rank the factors influencing their opinion, with a rating of 1 indicating that the reason listed was the least important, and a rating of 10 indicating that the reason listed was the most important factor influencing their opinion. Those who presented for the screening appointment received $50.00 when the examination and questionnaires were complete, and they were given a copy of the consent form to take home if they wished to participate in the trial. Participants who initially wanted implants but later refused them were asked by a research assistant either in person or on the telephone to explain why they had changed their minds. All explanations were recorded immediately in writing.

Responses to the questionnaires assessing the volunteers' satisfaction with existing dentures, along with their demographic background and treatment preference, were analyzed using Pearson chi-square tests to identify bivariate associations and logistic regression analysis to test the predictive power of a multivariate model relating to implant preference. Responses to the satisfaction questionnaire were made dichotomous ("less satisfied" versus "more satisfied") using a median split for the responses in each of the categories. Also, each OHIP response was collapsed into 2 categories by adding "hardly ever" or "occasionally" into 1 category, and "fairly often" or "very often" into the other, and the responses were analyzed from the 45 questions applicable to edentulous respondents. (The following 4 questions in the full OHIP-49 version were removed: (3) Have you noticed a tooth which doesn't look right?; (12) Have you had a sensitive tooth, for example, due to hot or cold foods or drinks?; (13) Have you had a toothache?; (27) Have you been unable to brush your teeth properly because of problems with your teeth, mouth or dentures?)

Results

Volunteers were recruited from several sources, including patients attending a university dental clinic; referrals from dentists, denturists, or other participants in the trial; and advertisements in local newspapers and senior centers (Table 1). In all, 101 potential participants were screened for inclusion in the study (61 women and 40 men; median age, 70.2 years; age range, 42 to 89 years) and completed the questionnaires. Although 22 volunteers did not meet the inclusion criteria for the clinical trial, all 101 were invited to complete the questionnaires. When first asked about their preference, 79% of the subjects accepted and 21% refused implants. A further 17 subjects who had initially agreed to accept implants later refused them, while 2 who originally refused later accepted, leaving 64% who wanted implants and 36% who did not want them, with most refusals coming from those who had attended the university clinic or responded to a newspaper advertisement. Of the 17 subjects who changed their minds from "Yes" to "No," 41% gave no reason for the change, while others cited reconsideration of surgical risks, health issues, and time constraints equally commonly. The 2 who changed their minds from "No" to "Yes" explained simply that they had reconsidered their options.

The most common and most highly rated reason given for accepting implants was anticipation of improved stability or security of the mandibular denture (73%) (Fig 2), while the most common and most highly rated reason for refusal was concern about surgical risks (43%) (Fig 3).

Subjects who reported dissatisfaction in 1 or more of the areas measured on the VAS of the satisfaction questionnaire—ie, pain ($P = .045$), comfort ($P = .001$),

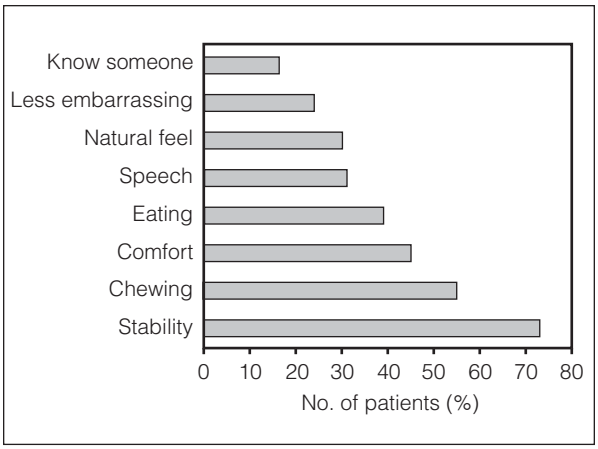

Fig 2 Reasons for accepting free implants.

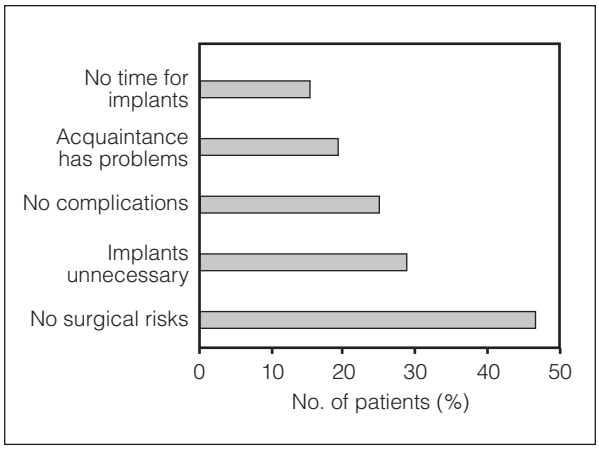

Fig 3 Reasons for refusing free implants.

appearance ($P = .016$), chewing function ($P = .000$), stability ($P = .001$), speech ($P = .002$), cleaning difficulty ($P = .011$), and overall satisfaction ($P = .000$)—were all significantly more likely to opt for implants. Likewise, those who reported on the background questionnaire that they were under 71 years of age ($P = .016$) or that they wore their dentures at night ($P = .026$) were also significantly more likely to accept an offer of free implant treatment. Subjects who reported 1 or more negative OHIP responses out of a maximum of 45 responses were also significantly more likely to accept implants ($P < .001$).

A logistic regression model that used a cutoff value of .500 and was based on those who complained of poor chewing function, poor speech, pain, and dissatisfaction with the appearance of their dentures improved the prediction of those who wanted implants from 64% to 80%, with a sensitivity of 83% and a specificity of 75%. The addition of the other variables with a significant ($P < .05$) bivariate association with acceptance of implants, such as one or more negative OHIP responses or age, did not enhance the predictive ability of the model. This same model can also be used to better predict those who are less likely to opt for implant treatment, ie, those who do not complain about poor chewing function, poor speech, pain, or dissatisfaction with the appearance of their dentures.

Discussion

We expected that patients who were dissatisfied with their conventional dentures would be more likely to accept an offer of implants. The anticipation of improved satisfaction is consistent with previous studies that showed a significant improvement in patient satisfaction with implant overdentures compared to conventional dentures.[16] Indeed, mandibular implant overdentures have recently been recommended as the standard of care for edentulous patients.[17]

The 21 subjects who initially refused implants, and the additional 17 who changed their minds from initial acceptance to refusal of implant treatment, indicate strongly that choices involving surgery may cause anxiety and uncertainty. Anxiety related to implant treatment has also been noted in other studies.[18] This rejection of implant treatment is especially noteworthy considering the fact that financial barriers to implant treatment were eliminated; this finding may limit the potential application of the mandibular 2-implant overdenture as the first-choice standard of care for edentulous patients. Most consent forms used for clinical research place more emphasis on risks than on potential benefits of treatment so that recruits are not unduly influenced to participate. It is possible that the study consent form, in which all possible complications and adverse effects of treatment are disclosed, caused some of the volunteers to reconsider their original inclination toward implants. However, current practice in most countries requires that potential complications of treatment be disclosed to patients in advance, preferably in writing.

Edentulous people generally do not visit a dental practitioner or denturist regularly, probably because they do not feel the need to seek care[19] or they have not had particularly successful treatment with complete dentures[20]; in addition, patterns of attendance for preventive health care established in youth seem to continue into old age.[21] In general, people seek medical and dental attention because they feel something is wrong, rather than because there is an "objective"

clinical sign or symptom, and "wrongness" is highly subjective and subject to social stigmas.[22,23] Many complete denture wearers live in social and cultural surroundings where the discomfort and difficulties associated with dentures are accepted with resignation and without complaint, and where the ability to cope and adapt is promoted. A recent study in the United Kingdom,[24] for example, found that complete denture wearers with uncomfortable and well-worn dentures could not eat all foods easily, yet two-thirds of the subjects interviewed and examined managed to eat most of the food available to them without complaint. We are not suggesting that denture wearers consider their denture-related problems trivial or easily managed: tooth loss can cause severe and chronic psychologic disturbances.[25,26] Nor are we implying that access to oral implants should be restricted. Clearly, many volunteers were attracted to our trial because of distressing discomfort, mostly from their mandibular dentures, and they expressed optimistic expectations of implants. However, it is significant that about one third of those attracted and initially accepting of the offer of free implant treatment decided that the surgical risks or potential disturbance to general health were unacceptable, even when the financial cost was nothing. It is worth noting that most of the volunteers who refused implants had received their dentures from the university dental clinic; while they may have been curious or felt a commitment to the dental school to attend the initial appointment for this study, many were satisfied with their dentures and saw no reason to seek additional treatment (Table 1). It is unclear why more than half of the respondents to the newspaper advertisement also refused implants, other than the possibility that they too were simply curious about implants but did not want them after they understood what was involved in implant treatment. We assume that the volunteers from the other sources, who were more likely to accept the offer of implant treatment, were referred by clinicians in the community or friends because they had clearly identified difficulties coping with their dentures. Apparently, a surprising number of denture wearers in this trial had a good sense of coherence, which allowed them to adapt and cope with unstable, unsightly, and painful dentures, presumably by using well developed and resilient physical and psychosocial buffers.[27,28]

A shortened 19-item OHIP instrument applicable to edentulous respondents (OHIP-EDENT) is available to measure the psychosocial and functional impact of prosthodontic treatment.[29] However, we used the longer version (OHIP-49) because we wanted to explore the potential of the full psychosocial instrument as a predictor of volunteers who are disposed to implants. Various logistic regression models were analyzed to identify the combination of characteristics identified by the VAS and OHIP responses that predicted most effectively the volunteers who would accept implant treatment. The VAS responses identifying those who felt disturbed by a combination of chewing and speech difficulties, oral pain, and dissatisfaction with the appearance of their dentures provided the best prediction (80%) of those who would say "Yes" to implants. We were surprised that the range of responses on the OHIP did not enhance the predication of volunteers disposed to implants. The domains of impact or concerns addressed by the VAS and the OHIP were similar: pain, functional limitation, physical disability, psychologic disability, social disability, psychologic discomfort, and handicap by OHIP responses; and pain, comfort, appearance, function, stability, speech, hygiene, and overall satisfaction by VAS scores. However, the presentation and structure of the VAS may have a more personal or direct impact than the structured presentation of 45 questions for the OHIP. This observation supports a previous suggestion that structured questionnaires or psychometric instruments are less sensitive than more direct, global, and open-ended questions to the subtleties of human beliefs, behaviors, and feelings.[30] Further analyses of the relationship between the VAS and OHIP scores are underway to identify the source of the differences in sensitivity.

The fact that just over a third of the volunteers in this study chose not to receive free implant treatment may give pause to the argument that the cost of implant treatment is the main roadblock in the way of implant overdentures becoming the standard of care for edentulous patients. Although the significant costs of implant treatment cannot be discounted, it seems that we need to know more about how patients manage with their conventional dentures to successfully predict those who may be interested in considering an implant option.

Conclusions

1. When cost was removed as a factor, almost two thirds of the participants in this study ultimately accepted an offer of free implants to retain their mandibular dentures.
2. Stated another way, just over one third of the study participants refused an offer of implant treatment, even though it was free.
3. The most common reason given for choosing implants was a desire for increased denture stability or security.
4. Using this model, 80% of those who complain of poor chewing function, poor speech, pain, and dissatisfaction with the appearance of their conventional dentures could be predicted to choose implants.

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