A Within-Subject Comparison of Mandibular Long-Bar and Hybrid Implant-Supported Prostheses

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A Within-Subject Comparison of Mandibular Long-Bar and Hybrid Implant-Supported Prostheses

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SUMMARY

The osseointegrated implant technique was originally designed to support a fixed prosthesis for edentulous patients. Subsequently, mandibular implant-supported removable overdentures were developed as an alternative way of treating patients with compromised bone or other special needs, and they are now used widely. Although it has been claimed that patients are more satisfied with mandibular implant-supported removable overdentures than with conventional dentures, no appropriate direct comparisons of overdentures with conventional dentures or between different designs of overdentures have been carried out.

The objective of this within-subject crossover clinical trial is to compare two types of removable prostheses that are frequently prescribed for the edentulous mandible: a long-bar overdenture supported mainly by four root-form implants and a two-implant hybrid overdenture, while subjects wore new conventional dentures in maxilla.

Sixteen completely edentulous patients were selected and given a new maxillary conventional denture. Ten of them received the mandibular long-bar overdentures first; six, the hybrid prostheses. After a two-month adaptation period, the subjects returned to the clinic three times in one-week intervals for collecting data. Visual analogue scale and category scale questionnaires were given before and after a masticatory efficiency test at each appointment to
measure patients' perceptions of the prostheses. Mandibular movements and masticatory muscle electromyographic activity were recorded while the subjects ate test foods for physiological evaluation of masticatory efficiency. In addition, speech recording was carried out at the third session of each type of prosthesis. The mandibular prostheses were then changed and the procedures repeated. At the end of the study, subjects were asked to choose the mandibular prosthesis that they wished to keep, and the final patient-based assessment of the prostheses was made.

*Psychometric Assessment and Patient Preference:* general satisfaction was used as the primary outcome and many secondary outcomes were measured, e.g., stability, retention, comfort, esthetics, ease of cleaning, speaking and chewing, and how well-chewed foods were before swallowing. Most of the factors except ease of cleaning and speaking were rated significantly better with long-bar overdenture than with hybrid [estimated mean of difference ($\Delta$) in general satisfaction: 10.7 mm; $\Delta$ stability: 9.8 mm; $\Delta$ retention: 9.6 mm; $\Delta$ comfort: 9.4 mm; $\Delta$ esthetics: 2.3 mm]. All foods evaluated except cheese were rated significantly easier to chew with long-bar overdentures than with hybrid prostheses ($\Delta$ lettuce: 11.4 mm; $\Delta$ nuts: 9.4 mm; $\Delta$ carrot: 6.9 mm, $\Delta$ apple: 6.3 mm; $\Delta$ sausage: 6.2 mm; $\Delta$ bread: 2.7 mm). These results are consistent with the fact that all subjects chose long-bar overdentures, reporting stability, ease of chewing and comfort as the most important factors influencing their choice.
Masticatory Efficiency Tests: masticatory time was used as the primary outcome to evaluate masticatory efficiency. In addition, cleaning time, duration and amplitude of masticatory cycles and phases were calculated. No significant differences in masticatory time were found between these two prostheses for any test food. However, cleaning time for carrot and bread was slightly but significantly longer when wearing long-bar overdentures (Δ carrot: 1.6 s; Δ bread: 1.0 s). No significant differences in cycle duration were detected between these two prostheses for any test food, except for carrot. When eating carrot, cycle duration was longer with the long-bar overdenture both early (cycles 3-13: Δ = 20.2 ms) and late in the chewing sequence (cycles 14-40: Δ = 13.5 ms). A shorter opening phase and a longer closing phase were detected with the long-bar overdenture for almost all test foods. Vertical amplitude was significantly less with the long-bar overdenture for cheese (Δ = -2.6 mm), apple (Δ = -2.6 mm) and sausage (Δ = -2.9 mm).

Speech: no difference was found between the two prostheses from patients' ratings of ease of speaking.

Correlation Analysis: no or weak correlations were found between masticatory time and patient-based ratings of ease of chewing for the five test foods or of how well-chewed the food was before swallowing.

In conclusion, the results of masticatory efficiency tests indicate that the masticatory function of a mandibular two-implant hybrid overdenture is as efficient
as that of a long-bar overdenture supported completely by four implants, when both are opposed to maxillary conventional prostheses. However, subjects prefer long-bar overdentures to hybrid overdentures because of significantly better stability, comfort and ease of chewing. The patients' ratings of ease of chewing are not well correlated with scores of the masticatory function derived from laboratory tests. In addition, patients' ratings of speaking ability show that there is no difference in speech between the two prostheses.
Les implants endo-osseux ont d'abord été conçus pour servir de support aux prothèses fixes destinées aux patients édentés. Nous avons, par la suite, conçu des prothèses amovibles montées sur implants pour les patients ayant conservé une masse minimale de tissus osseux ou ayant des besoins particuliers; l'usage de ces prothèses est désormais répandu. Beaucoup soutiennent que les prothèses amovibles procurent plus de satisfaction que les prothèses conventionnelles, même si personne n'a encore établi de comparaison directe entre ce type de prothèse et les prothèses conventionnelles ou entre différents types de prothèses amovibles de recouvrement.

Cet essai clinique à double insu avec permutation chez un même groupe de patients visait à comparer deux types de prothèses mandibulaires amovibles, la prothèse de recouvrement implanto-portée soutenue intégralement par quatre implants radiculaires et la nouvelle prothèse hybride à deux implants. L'expérience a aussi été menée avec des sujets qui portaient aussi une nouvelle prothèse maxillaire conventionnelle.

Seize patients entièrement édentés ont été sélectionnés et ont reçu une nouvelle prothèse maxillaire conventionnelle. Dix d'entre eux ont d'abord reçu une prothèse de recouvrement implanto-portée; les six autres, une prothèse
hybride. Après une période d’adaptation de deux mois, les sujets nous ont rencontré, à trois reprises à intervalles d’une semaine, pour la collecte de données. Des questionnaires (échelle analogue visuelle et échelle par catégories) leur ont été administrés avant et après chaque essai de mastication afin de mesurer leurs impressions quant à l’efficacité de ces prothèses. Nous leur avons fait manger différents aliments pour évaluer l’efficacité de la mastication sur le plan physiologique; à cette fin, on a enregistré les mouvements mandibulaires et l’activité électromyographique des muscles masticateurs. Pour chaque type de prothèse, on a également évalué l’élocution des sujets lors de la troisième séance. Les prothèses mandibulaires ont alors été remplacées et la procédure répétée. À la fin de l’étude, on a demandé aux sujets de choisir la prothèse mandibulaire qu’ils souhaitaient conserver et on a procédé à l’évaluation définitive des prothèses en tenant compte des indications des patients.

Évaluation psychométrique et préférence du patient: la satisfaction générale des patients a été choisi comme facteur primaire. De nombreux facteurs secondaires ont été mesurés avec les échelles psychométriques comme la stabilité, la rétention, le confort, l’aspect esthétique, la facilité de nettoyage, d’élocution et de mastication et enfin, le degré de mastication avant la déglutition. Pour la plupart des facteurs sauf la facilité de nettoyage et d’élocution, la prothèse de recouvrement implanto-portée a été mieux notée que les prothèses hybrides [écart moyen estimatif (Δ) pour les différents facteurs: satisfaction
générale : 10,7 mm; ∆ stabilité : 9,8 mm; ∆ rétention : 9,6 mm; ∆ confort : 9,4 mm; ∆ aspect esthétique : 2,3 mm]. Tous les aliments évalués ont semblé beaucoup plus faciles à mastiquer à l'aide de la prothèse de recouvrement implanto-portée qu'à l'aide des prothèses hybrides (∆ laitue : 11,4 mm; ∆ noix : 9,4 mm; ∆ carotte : 6,9 mm; ∆ pommes : 6,3 mm; ∆ saucisse : 6,2 mm; ∆ pain : 2,7 mm). Ces résultats concordent avec les préférences exprimées par les sujets, qui ont tous choisi la prothèse de recouvrement implanto-portée, en précisant que leur choix a été influencé avant tout par la stabilité, la facilité de mastication et le confort.

Valeur du test de mastication: le temps de mastication a servi de facteur primaire pour évaluer l'efficacité masticatoire. On a également tenu compte du temps de nettoyage, de la durée et de l'amplitude des cycles et phases masticatoires. Aucune différence notable n'a été observée entre ces deux prothèses pour ce qui est du temps de mastication des aliments étudiés. On a toutefois observé une augmentation légère mais significative du temps de nettoyage chez les patients portant une prothèse de recouvrement implanto-supportée pour deux aliments, la carotte et le pain (∆ carotte 1,6 s; ∆ pain: 1,0 s). Aucune différence quant à la durée du cycle n'a été observée entre les deux prothèses pour les aliments étudiés sauf la carotte. Dans ce dernier cas, la durée du cycle a légèrement augmenté chez les patients portant une prothèse de recouvrement implanto-portée tant au début (cycles 3-13 : ∆ = 20,2 ms) qu'à la fin de la séquence de mastication (cycles 14-40 : ∆ = 13,5 ms). Pour presque tous les aliments étudiés, on a observé un raccourcissement de la phase
d’ouverture de la bouche et un allongement de la phase de fermeture chez les patients portant une prothèse de recouvrement implanto-portée. On a en outre observé chez ceux-ci une réduction significative de l’amplitude verticale dans le cas du fromage (\( \Delta = -2,6 \) mm), de la pomme (\( \Delta = -2,6 \) mm) et de la saucisse (\( \Delta = -2,9 \) mm).

Élocution-Parole: aucune différence n’a été observée entre les deux types de prothèses en ce qui a trait à la facilité à parler.

Analyse corrélatives: pas ou de très faibles corrélations ont été trouvées entre le temps de mastication et les données des patients en ce qui concerne à la facilité de mastiquer lors des cinq tests d’aliments ou en se qui concerne la qualité avec laquelle les aliments étaient mâchés avant la déglutition.

En conclusion, les résultats des tests d’efficacité masticatoire révèlent que la prothèse hybride à deux implants possède une efficacité masticatoire aussi bonne que la prothèse de recouvrement implanto-portée par quatre implants lorsqu’elles sont toutes deux opposées à une prothèse maxillaire conventionnelle. Toutefois, les sujets préfèrent la prothèse de recouvrement implanto-portée, qu’ils trouvent plus stable, plus confortable et plus facile à nettoyer. L’évaluation faite par les patients de la facilité de nettoyage ne sont que faiblement associés aux résultats des essais masticatoires réalisés en
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ABBREVIATIONS

CAT: Category scale
CT: Cleaning time
EMG: Electromyograph
IRED: Infrared-emitting diode
HO: Hybrid overdenture
LBO: Long-bar overdenture
MT: Masticatory time
SE: Standard error
SED: Standard error of difference
VAS: Visual analogue scale
To my husband Xiaoping

And my son Kai
My heartiest gratitude to:

Dr. Jocelyne S. Feine
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Toute ma vie gratitude à
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1. Literature Review and the Question

When many edentulous patients are satisfied with their complete dentures, others just cannot bear this kind of treatment (1-4). Problems of adaptation to dentures are especially common in patients with severely resorbed mandibular ridges. How to provide an adequate prosthodontic treatment for these patients has been a real challenge to dentists for many years.

The problems encountered are either functional and / or psychosocial. Golds (5) stated that when a mandibular ridge is very resorbed, fabrication of an adequate prosthesis is difficult because of the decreased support and because of the encroachment of surrounding mobile tissue under the denture border. Together, these changes reduce the stability and the retention of the denture. It has been now accepted that reductions of load-bearing capacity of tissues, stability and retention of dentures are the major causes of the compromised oral functions in these patients. Psychosocially, patients suffer from a constant fear of loosing their dentures during jaw movements. Furthermore, tooth loss and progressive bone resorption can cause unattractive changes in the soft tissues of the face. All these physiological and psychosocial impairments may influence patients’ self-confidence and even their quality of life. However, these are often impossible to correct well with conventional dentures.
Lack of stability and compromised chewing ability of conventional dentures are claimed to be the main reasons that denture wearers seek implant treatments. Kiyak et al. (6) reported that the major motivation for seeking implant therapy is related to difficulties in eating and with the fit of dentures. In a survey of patient attitudes about implant prostheses, Grogono et al. (7) reported that the most common reason that patients sought implant treatment was to improve their eating ability. The least common reason among those that they investigated turned out to be the improvement of appearance. Akagawa et al. (8) showed that dissatisfaction with stability and comfort were especially associated with the desire for implant treatment.

Many techniques were developed to deal with these problems before the advent of implants (9-12). The simplest approach is to extent the denture base so as to use all available supporting tissues. Preprosthetic surgery is also used to lower the vestibule and / or to augment the ridge. Each technique may have merit, but they do not resolve the predicament of most edentulous patients.

Failures to rehabilitate oral functions adequately for patients with compromised ridges have resulted in the rapid development of numerous forms of implants. Although subperiosteal and transosteal implants have been used to support prostheses, it appears that endosseous implants are the most popular treatment for compromised mandibular ridges (13).
The general application of endosseous implants in the dental clinic is credited to Brånemark's seminal research on osseointegration (14-15), which brought prosthodontic therapy into a new era. Osseointegration of pure titanium root-form implants offers an attachment that functions similarly to teeth ankylosed to bone. This finding has greatly encouraged dentists to use titanium root-form implants to bear prostheses, especially for the patient possessing a poor mandibular alveolar ridge (16-18).

Over more than two decades of development, the excellent long-term biologic results of osseointegrated dental implants have been well documented by a series of prospective studies (19-22). With careful case selection and surgical technique, successful osseointegration of a fixture can almost be guaranteed. Successful reconstruction, however, means more than implant integration. The design of functional, esthetic and hygienic implant-supported prostheses often poses challenges. With high patients' expectation, implant treatment does not necessarily result in a satisfied patient. Today's research goal has changed from whether implants should be considered as a treatment towards the search for the most beneficial design of implant-supported prosthesis for each edentulous individual.

Osseointegrated implants were originally designed to provide anchorage for fixed prostheses. The effectiveness of the implant-supported fixed prosthesis has been proved to substantially improve oral function and to have positive
psychosocial effects (17, 23-24). In a more than 11 year follow-up study of implant-supported fixed prostheses, Zarb and Schmitt (17) reported that the fixed prosthesis successfully resolved the edentulous predicament with only inconsequential associated problems or complications. They concluded that osseointegrated implants provided a predictable and long-lasting abutment, which retarded bone resorption themselves and which were not associated with significant adverse soft-tissue responses. Carlsson and Lindquist (23) reported that placement of a mandibular fixed complete denture on osseointegrated implants in dissatisfied complete denture wearers led to a rapid and dramatic improvement of masticatory function in their ten-year investigation of implant treatment. The study of de Grandmont et al. (24) also supported the claim that mandibular implant-supported prostheses are superior to conventional dentures in terms of chewing ability, self-confidence, general satisfaction, etc.

The expense of a treatment that requires a large number of implants and a costly framework, as well as the fact that some patients only have enough bone for 2-4 implants, prevents many edentulous patients from benefiting from this breakthrough in dentistry. Therefore, an alternative design, the implant-supported removable overdenture, has consequently drawn the attention of both clinicians and scientists (25).

A removable overdenture can usually be supported by fewer implants than a fixed prosthesis. Thus, the majority of edentulous patients with advanced
resorption of bone could benefit from this form of treatment. Furthermore, the relevant surgical procedure is less complicated and the treatment is more affordable. Other benefits, such as easier access for cleaning as well as the concerns of psychology, esthetics and phonetics, contributed to its development.

Feine et al. (26) reported that many patients who had the opportunity to compare removable mandibular long bar overdentures with fixed bridges did not consider the removable type to be a second choice. They also indicated that older edentulous patients in their studies preferred mandibular long bar overdentures because of the ease of cleaning and the fact that the prosthesis could be taken out at night.

The effectiveness and reliability of mandibular implant-supported removable overdentures are much better understood now than ten years ago. Many studies have shown that mandibular implant-supported removable overdentures provide significantly greater patient satisfaction and chewing ability than do conventional dentures (27-31). Some other studies have reported that mandibular implant-supported removable overdentures perform just as well as fixed implant prostheses (17, 32). Based on a long-term prospective investigation, Zarb and Schmitt (17) pointed out that implant-supported overdentures could provide improved retention, stability and comfort for patients with a chronic history of prosthetic maladaptation, and that this type of prosthesis is viable alternative to the fixed prescription. However, long-term well-controlled prospective studies are still necessary.
Although mandibular implant-supported overdentures have been shown to be an excellent choice for edentulous patients, no well-controlled clinical studies comparing different types of mandibular implant-supported removable overdentures that are commonly used in the clinic have been carried out previously. Furthermore, there are a variety of implant systems available in the clinic and different methods of attachment to connect implants and overdentures. It is evident that effectiveness of different designs is likely to vary.

Chan et al. (16) reported a retrospective analysis of different types of connection between the overdenture and implants, i.e., bar and clips, stud attachments and magnets. There was no statistical comparison done, since the sample size was too small, and they also recognized the unreliability of an uncontrolled retrospective study. In a between-group prospective study of different attachment systems (magnets, ball attachments and bars), Naert et al. (33) concluded that the state of connection did not influence the clinical success of implants in their short follow-up period. However, Burns et al. (30) indicated that O-ring attachments were significantly better than magnet attachments for retention and stability in a within-subject prospective study. In a review of previous studies, Kent (34) pointed out that prospective clinical trials incorporating appropriate comparison groups are necessary and that patients' self-assessment should be measured in the future studies of implant treatment.
Direct comparisons of the different types of overdentures are few. In a review of design considerations of implant-supported prostheses, Sadowsky (35) described the anatomy of jaw, and functional, esthetic, and economic concerns, while discussing the indications of choosing a complete implant-supported overdenture or an implant- and tissue-supported overdenture. But he or she could not provide any appropriate research dealing directly with the comparison of the prostheses. Geertman et al. (36-37) did carry out a clinical trial to compare patient satisfaction and chewing ability of two types of overdenture. However, one type of overdenture was supported by transmandibular implants, the other by root-form implants, which made it difficult to draw any conclusions about the prostheses alone.

To help clinicians provide an adequate mandibular implant prosthesis for each individual edentulous patient, we carried out this within-subject crossover clinical trial. It compared the two most commonly used implant-supported overdentures, a mandibular long bar overdenture supported mainly by four implants and a hybrid overdenture borne by two implants and the mucosa. Brånemark titanium root-form implants were used and connected by bars soldered to the abutments. The overdentures were retained with clip attachments.

2. Study Design and Sample Size
There are several reasons why we decided to use a within-subject crossover strategy instead of a between-group design in the present study. Firstly, it is very difficult to match edentulous patients since each has a unique history of dental disease, tooth loss and previous denture wearing experience.

Secondly, Jemt and Stalblad (38) reported that there was a great inter-subject variability in masticatory performance. Our previous studies showed that large inter-subject variability occurred not only in masticatory efficiency measures but also in patient's ratings of masticatory difficulty (24, 32). A within-subject design minimizes the effects of inter-subject variability and allowed us to use fewer subjects than would be required with a between-group design. This is especially significant for treatments like those used in the present study because they are very expensive.

Thirdly, the influence of patient preference has to be considered since subjects cannot be blinded to treatment as in a randomized clinical trial of drugs. Subjects may have a preference for one of the treatments being offered. It has been reported (39) that the denial of preferred treatment influences study outcomes because it can lead to drop-outs and non-compliance, and to assessments that are biased by feelings of disappointment. This is especially significant when outcomes are measured by questionnaires. In the present study, there are obvious differences between the treatments that are being compared, such as the number of implants, surgical procedures, prosthesis design and cost.
The treatment was provided free of change to all patients in this clinical trial, but the more expensive one may be considered as better. Many methods have been tried to overcome such problems in between-group designs (40), but the best way to deal with them is a within-subject trial.

The within-subject crossover design is a very powerful design. However, it can only be used if a series of requirements are met. Firstly, subjects must be in a chronic state that remains stable over a long period. Secondly, the treatment must be relatively short. Finally, a washout period must be allowed to prevent any effect of the first treatment when conducting the second treatment.

The present study fulfills these special requirements. Firstly, edentulism is a true chronic condition. Furthermore, the criteria of inclusion required that all subjects should be completely edentulous for at least five years to ensure a stable condition during the trial. Secondly, the two-month period of denture treatment is short in comparison with five or more years in edentulousness. Furthermore, there were no carry-over effects because the influence of a prosthesis disappears whenever it is removed from the mouth. The two-month period of wearing each prosthesis allows physiological and psychological adaptation to the new prosthesis.

Multilevel analyses were carried out on both psychometric and functional data collected during the trial. These were utilized not only to test the effects of
the two prostheses, but also to investigate the possible effects of other sources of variance, such as the period (first prosthesis vs. second prosthesis), sequence (order of presentation of prosthesis) and time (week 1, 2 and 3).

The same sample size was used as in the previous comparison of mandibular long bar overdentures and the fixed prostheses (24). With using the mean and variance of scores of general satisfaction of the prostheses on visual analogue scales (VAS), standard statistical criteria were $\alpha = 0.05$, $\beta = 0.20$, and the effect size was 10 mm (differences of less than 10 mm were thought to be of little clinical significance), Feine et al. (41) found that minimal 14 subjects were necessary for a within-subject crossover design in the study of implant treatment.

3. Measurements

The primary goal of denture treatment is to replace missing teeth and restore an acceptable function. As we stated at the beginning, the principle complaint of denture wearers was poor stability and retention, which might induce discomfort, inability to chew certain foods, low satisfaction and psychosocial problems. I will now address the problem of evaluating the effectiveness of an implant treatment using patient-based and functional measures.
In the past, a number of terms, such as masticatory ability, masticatory capacity, masticatory efficiency, or masticatory performance, have been used interchangeably for masticatory function. Boretti et al. (42), in a review of masticatory ability and efficiency, suggested that estimates of masticatory function include patients' subjective assessment of chewing (masticatory ability) as well as their capacity to chew as measured by a test of function (masticatory efficiency). This definition has been accepted in this within-subject comparison, and masticatory function was evaluated from both psychometric and functional measures.

3.1 Psychometric Measure

The major advantage of psychometric measures is that they can be used to measure much more than just masticatory ability. Kent (34) suggested that patients' satisfaction and psychosocial well-being are important issues in evaluating the effects of osseointegrated implants. In the present study, we measured patients' ratings of general satisfaction, stability, retention, comfort, ease of chewing, speaking and cleaning, and several other factors that affect quality of life.

In this study, two kinds of questionnaires were used, visual analogue scales (VAS) and category scales (CAT). The previous study (24) has shown that the 100 mm VAS is sensitive enough to detect differences of less than 5 mm in
some variables between mandibular implant-supported long bar overdentures and fixed bridges. The CATs were found to be not as sensitive to small differences between the two implant-supported prostheses as the VAS, but they did reveal large differences between implant-supported prostheses and conventional dentures.

There are two sources of psychometric data about treatment, patients and clinicians. In an investigation of the impact of patient preference on the design and interpretation of clinical trials, Feine et al. (40) reported that the ratings of denture effectiveness from patients and clinicians were different and that there was poor correlation between the two. Their results are consistent with the findings in many other studies in the fields of low back pain, peptic ulcer, depression, high blood pressure, hip prostheses and general health (43-48). Since the objective in rehabilitation is to provide a palliative treatment to help improve life for the patient, it is logical to consider patient-based assessments of treatment effectiveness to be more important than clinicians' ratings. Feine et al. (40) suggested that variables rated as important by patients be used as outcomes in clinical trials and that, in most cases, these needed to be measured from subjects’ self-reports. Clinicians’ assessments of the prostheses were collected as well during the trial and will be analyzed in the future.

To date, most of the information that we have about the effectiveness of implant-supported prostheses was obtained by psychometric methods. Blomberg
and Lindquist (49) reported that the majority of patients indicated that their lives were improved, that the self-confidence was regained and that they accepted the prosthesis as a part of themselves after the replacement of complete dentures with fixed implant-retained prostheses. Many later studies (7, 50-51) support the claim that osseointegrated implants can have positive effects on oral and psychosocial well-being. Hoogstraten and Lamers (50), in a comparison of the physiological and social satisfaction of implant patients and conventional denture users, reported that implant patients were much more satisfied. Geogono et al. (7) conducted a survey of patient attitudes about implants, and they found that satisfaction with implant prostheses was significantly greater than with the previous removable prostheses. Harle and Anderson (51), in a survey of patient satisfaction with implant-supported overdentures, demonstrated pervasive advantages of implant therapy, in terms of improved physiological, psychological and social functions. Although many later studies did not show such strong effects on psychosocial well-being as those originally published by Blomberg and Linquist, it has been a consistent finding that implant treatment significantly improves patients' satisfaction and chewing ability.

The instruments that were used in this study to measure patient attitudes to their prostheses were developed from the previous studies. Dao et al. (54) in their study of patient's satisfaction with dental prosthesis identified the factors that edentulous patients consider to be the most important when they evaluate their own prostheses. A version of French language questionnaires that used
both VAS and CAT methods was developed and used in a comparison of mandibular long bar overdentures and fixed prostheses (24). The same instrument, with some minor changes, was used in the present trial.

Patients have a tendency to show gratitude for the time and effort expended by the people who treat them and this could affect ratings. For this reason, the questionnaire was administered by a research technician who was not part of the treatment team. In addition, the measurements were made without knowing the treatment assignment.

3.2 Masticatory Efficiency Tests

Direct measurement of masticatory efficiency is difficult. Efficiency is defined as the ratio of work done to energy used. Nobody has tried to measure directly the energy used by the body during mastication, nor the work that is required to reduce food for swallowing, but several methods have been developed over the years to estimate masticatory efficiency indirectly. These include the measurement of the size of masticated food particles, bite force, the time or the number of chewing strokes needed to prepare food for swallowing (55-59).

As early as 1924, Christiansen (60) used fractional sieving as a technique of measuring the size of the food particles after chewing for a given time. Later
developments were made with the goals of simplifying the procedure and reducing the time involved (61-62). Mahmoon et al. (61) reported on a method of computer-assisted image analysis to measure the size of masticated test particles. They claimed that it had the advantages of simplicity, speed, accuracy, reproducibility and hygiene comparing with the traditional sieving. Mowlana et al. (62) introduced an optical method to determine particle size distributions and they claimed that it was simpler and faster than the sieving technique. Others used artificial materials test such as formalin-hardened gelatin (63), and round tablets of silicone impression materials (64), in an attempt to standardize the physical properties of test foods. Helkimo et al. (57) developed an index of chewing efficiency from 1 to 5 where 1 meant very good and 5 represented very poor ability to reduce the particle size of a test food. Using this index, they reported that there was a clear relationship between masticatory efficiency when chewing almonds and an individual’s dental state. A group of 94 persons who had natural teeth was compared with another group of 45 denture wearers (partial and / or complete). They found that the denture wearers had a significantly lower masticatory efficiency than the group with natural teeth, and that number of occluding pairs of teeth was closely correlated with masticatory efficiency. Individuals with less than 20 teeth had a poorer ability to reduce the test particles. Later studies confirmed their findings (61, 65).

However, we decided not to use the measurement of masticated test particle size in the present study. First, the procedure is complicated and is time
consuming, although some have tried to simplicity the method (61-62). The another reason is particle size measurement can only be used to test brittle substances and most natural foods cannot been evaluated by this method. Finally and most important, subjects have to count their chewing cycles, stop, and spit out. This transforms unconscious natural mastication into a voluntary act (66).

Based on the assumption that masticatory function correlates with bite force, measurement of bite force has been used to estimate masticatory function and studies have shown that bite force of denture wearers is lower than that of dentate subjects (56). Bite force is usually recorded with strain gauge transducers mounted in a bite fork. The bite fork is placed in the region of the premolars and canines bilaterally or between the upper and lower central incisors. Subjects are usually asked to perform two tasks: to bite at equivalent to that which they use when chewing and at maximal biting force. It is a doubtful that subjects can really translate dynamic chewing forces into an isometric bite. Furthermore, the significance of maximal bite forces in estimating masticatory function is not very clear, since they are never used during mastication.

Comparing the advantages and disadvantages of the several methods that are presently used in evaluating masticatory efficiency, we chose to measure the time spent on chewing standard-sized test foods (masticatory time) for the following reasons.
Firstly, masticatory time has been shown to be as clearly related to the state of the dentition as masticated particle size. Helkimo et al. (57) reported that persons with poor masticatory efficiency estimated from particle size in general tended to chew for a longer time. This original claim has been confirmed by many later studies. Lindquist and Carlsson (67) reported that both particle size and masticatory time were consistently reduced when a conventional denture was replaced by a mandibular implant-supported fixed prosthesis, and that there was significant relationship between these two variables. Gunne and Wall (68) observed that chewing time and the area of masticated gelatin particles changed in concert after the insertion of new dentures. In another investigation of masticatory efficiency and dental state, Gunne (65) reported that complete and removable partial denture wearers tried to compensate for their impaired efficiency by chewing for a longer time. Similarly, the study of Renaud et al. (12) revealed a correlation between masticatory time and a masticatory efficiency index based on the size of chewed almond particles before and after surgical reconstruction of the mandibular residual ridge.

Secondly, unlike the measurement of particle size, subjects chew each test food under fewer constraints when the masticatory time is recorded. This ensures that the test is carried out in as natural a situation as possible.
Thirdly, it is possible to test all of the different foods that people eat when measuring masticatory time, instead of just brittle substances. Our previous studies have shown that masticatory time is sensitive to the change in the texture and hardness of food and to the size of food load as well (32). The foods tested in the present study were selected from a list of foods ranked by complete denture wearers in the order of increasing chewing difficulty (69), which are white bread, hard cheese, raw apple, dry sausage and raw carrot. Furthermore, subjects were also asked to estimate their chewing ability of these five test foods before and after each laboratory test.

Finally, the measurement of masticatory time is simple, and it is easy to standardize the method for repeated measurements. The same foods were used in the previous trial (32).

We have added an additional measurement to the present study and to other ongoing between-group comparison of conventional dentures and hybrid overdentures because we have seen that denture wearers usually take a period of time to clear their mouths with the tongue, cheeks and lips after chewing each piece of test food. Their mandibular movements and electromyographic activity (EMG) recorded during this period were quite different from those seen during the masticatory period. Therefore, we decided to divide the whole period of ingestion into a masticatory period and a cleaning period, and to analyze them independently.
Masticatory time and cleaning time are obtained from mandibular movements and EMGs that were recorded with an Optotrak motion analysis system when subjects were eating a piece of test food. Data from individual cycles were also analyzed. A pilot study of young dentate adults had been carried out with the same recording method and same-sized test foods to see whether there was any difference between the mandibular movement recorded from an infrared-emitting diode (IRED) attached in the skin of the chin and that from an IRED on a clutch attached to the lower anterior teeth of dentate subjects (70). The results showed that the difference in the mean duration of cycles and of the opening and closing phases measured from the two IREDs were very small, but the division of jaw closure into fast- and slow-closing phases was found to be inaccurate when the chin IRED was used. Thus, the analysis of mandibular movement was limited to the duration of cycles, opening and closing phase, and vertical amplitude.

3.3 Speech

Denture patients often have speech difficulties with even the best conventional prostheses, and when prostheses become unstable, speech can get worse (52, 53).
Osseointegrated implants restore stability and improve chewing ability. However, the goal of implant treatment should not be limited to the restoration of masticatory function. Improvement of compromised speech function also should be a goal. It is particularly important that the design of the new prosthesis should not make speech worse.

There are significant differences between implant-supported prostheses and conventional dentures. These differences could influence the time that it takes to adapt speech to the new prosthesis, and perhaps the ability to adapt totally to the appliance. Sones (71) claimed that the elimination of the palatal coverage, the increase in the bulk of the denture to accommodate the thickness of gold cylinders and the metal framework, excessive air flow beneath the metal framework, excessive saliva, and alteration of tongue function were the possible reasons that speech is altered after changing from a complete denture to a maxillary fixed bridge. Other anecdotal reports (27, 31) on the improvement of speech with implant-supported overdentures are mainly based on patients' assessment of speaking ability. Clearly, in addition to the patients' perception, it is important to assess the intelligibility of the speech produced with the prosthesis to the average listener. Until now, no study has systematically assessed the speech produced with implant-supported prostheses. Therefore, we recorded examples of speech from each subject with each type of prosthesis to investigate the possible differences of speech between the two prostheses. These data will
not be presented in this thesis because the analysis have not completed for the time being.

4. Objectives

General goal: To compare two types of removable implant-supported prostheses that are commonly prescribed for severe resorbed edentulous mandibles: a long bar overdenture supported mainly by four root-form implants and a hybrid overdenture partially supported by two root-form implants and partially by the mucosa under it. The general aim of this study is to provide information to help clinicians and patients in choosing the prosthesis that would provide the greatest benefit for the latter.

Objectives in paper 1: 1) to identify differences between the two prostheses in regard to patients' self-assessment of general satisfaction, stability, retention, comfort, esthetics, ease of chewing, speaking and cleaning, how well-chewed the foods are before swallowing, and the quality of life.
2) to ask the patients which prosthesis they would prefer to keep and to identify the factors that influence their choice.

Objective in paper 2: 1) to measure the masticatory efficiency of these two implant-supported overdentures to see whether there is a difference in their functional performance.

2) to compare laboratory measures of masticatory efficiency with patients' assessments of their ability to prepare food for swallowing.
A Within-subject Comparison of Mandibular Long-bar and Hybrid Implant-supported Prostheses: Psychometric Evaluation and Patient Preference

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Abstract. Although it has been shown that patients are more satisfied with prostheses supported by implants than with conventional dentures, there have been few direct comparisons of the various designs of implant-supported prostheses. This within-subject crossover clinical trial was designed to compare two forms of removable prostheses which are frequently prescribed for the edentulous mandible: a long-bar overdenture supported by 4 implants and a two-implant hybrid overdenture. Sixteen completely edentulous subjects were given a new maxillary conventional denture. Ten of them received the mandibular long-bar prosthesis first and six the hybrid. After a two-month adaptation period, psychometric measures of various aspects of the prostheses and physiological tests of masticatory efficiency were carried out over three weeks. The mandibular prostheses were then changed and the procedures repeated. At the end of the study, subjects were asked to choose the mandibular prosthesis that they wished to keep, and final psychometric measures were taken. In this paper, the results of the psychometric assessment and patient preference are presented. Subjects assessed factors such as general satisfaction, quality of life, stability, retention, comfort, esthetics, ease of cleaning, speaking, and chewing, and how well-chewed foods were before being swallowed. Most of the factors except ease of cleaning and speaking were rated significantly better with long-bar overdentures than with hybrid ones. These results are consistent with the fact that all subjects chose long-bar overdentures, reporting stability, ease of chewing, and comfort as the most important factors influencing their choice. These results suggest that, although subjects assign high ratings for most factors to hybrid overdentures, they find long-bar overdentures to be significantly more stable, comfortable, and easier for chewing.

Key words: endosseous implants, oral prostheses, clinical trial, patient-based outcomes.

Introduction

Many studies have shown that implant-supported prostheses improve oral function and satisfaction in edentulous patients who were wearing conventional dentures (Grogono et al., 1989; Tavares et al., 1990; Harle and Anderson, 1993, MERICZE-Stern and Zarb, 1993). However, there was little information to aid clinicians in prescribing the best type of implant prosthesis for edentulous individuals at that time. In a review of previous studies, Kent (1992) pointed out that prospective designs incorporating appropriate comparison groups were necessary, and that patients' views should be taken into account in the future studies. To provide such data, we have been carrying out a series of within-subject clinical trials. The first to be completed (de Grandmont et al., 1994; Feine et al., 1994a,b) showed that there were no significant differences in general satisfaction between mandibular fixed implant-supported prostheses and long-bar overdentures. This paper describes a within-subject crossover comparison of two types of mandibular removable prostheses: long-bar and hybrid overdentures opposed by maxillary conventional dentures.

It is evident that a prosthesis completely supported by a large number of implants will be inherently more stable than a hybrid overdenture; however, there are some obvious advantages to treatment with a hybrid overdenture. The most fundamental is that only two implants in the anterior mandible are required. This means that the majority of patients have adequate bone for the procedure, that surgery is uncomplicated, and that a hybrid overdenture is more affordable than an implant-supported fixed bridge or a long-bar overdenture. Despite worries that mandibular root-form implants would be overloaded if only two were used to support a hybrid overdenture, the survival rate of loaded osseointegrated root-form implants under mandibular hybrid overdentures in 12 studies that included follow-ups of up to five years varied from 97 to 100% (Chao et al., 1995).
Table 1. Selection process

- 1823 responded to advertisements.
- 819 were interviewed by telephone.
- 446 did not meet telephone criteria.
- 371 were screened in clinic.
- 189 did not meet screening criteria.
- 122 were sent for panoramic and lateral cephalometric radiographs.
- 106 did not meet radiographic criteria.
- 76 were sent for maxillary CT scans.
- 44 did not meet CT criteria.
- 32 patients were accepted, and 16 were recruited for this study.

Table 2. Selection criteria

Inclusion Criteria
(1) By telephone
- Male or female
- Ages 30 to 85 years
- Completely edentulous for at least five years and having significant problems with the existing mandibular prosthesis
- Possessing an adequate understanding of written and spoken French

(2) At screening
- Able to understand and respond to scales used in the study
- Willing to accept the conditions of the study and to give informed consent

(3) By radiograph and CT
- Sufficient bone to place a minimum of 4 implants in mandible and 6 implants in maxilla

Exclusion Criteria
(1) By telephone
- Habitual use of tobacco

(2) At screening
- Acute or chronic symptoms of temporomandibular disorders
- History of radiation therapy to the orofacial region
- Systemic or neurologic disease
- Other health conditions that jeopardize surgical treatment (e.g., obesity, cardiovascular disease, etc.)
- Psychological or psychiatric conditions that could influence the subject's reaction to treatment

Materials and methods

Selection process and study population
Sixteen completely edentulous French-speaking subjects participated in this study. We calculated the sample size for standard statistical criteria ($\alpha = 0.05$, $\beta = 0.20$) and an effect size of 10 mm, using the mean and variance of scores of general satisfaction of mandibular long-bar overdentures on a 100-mm Visual Analogue Scale (VAS) taken from de Grandmont et al. (1994).

The subjects were selected from a population that responded to three local newspaper advertisements and two radio announcements. Due to the large number of responses (1323 callers), only the first 819 callers were contacted (Table 1). The remaining 509 responders were put on a waiting list for future studies. The inclusion and exclusion criteria are listed in Table 2. Responders who qualified after being interviewed by telephone attended an information session in which the details of the study and the procedures involved in implant treatment were explained. Those interested in participating were then examined, and panoramic and lateral cephalometric radiographs were taken. If it appeared as though the patient had adequate alveolar bone in both jaws for multiple implants, he/she was sent for a maxillary CT scan. Sixteen subjects who had enough bone in the maxilla to receive six implants were recruited into this study and will be included in a second trial for comparison of maxillary fixed prostheses and long-bar overdentures (Table 1). Another group of 10 subjects with less maxillary bone were included in another trial of two types of maxillary long-bar overdentures.

All subjects received a written description of the study and gave informed consent. The treatments were provided at no cost to all subjects. The protocol was approved by the Human Ethics Committee of the participating institutions.

Study design
Subjects rated their perceptions of their original conventional dentures in two sessions during one month prior to treatment. By a quasi-random method designed to ensure similar sex and age distributions in the two groups, half of the subjects were assigned to the group that first received long-bar overdentures, and half to the hybrid-first group. After a two-month period of adaptation, the subjects returned to the clinic three times at one-week intervals for patient-based measures and functional tests (manuscript in preparation). The prostheses were then changed and the procedures repeated. At the end of the study, subjects returned to the clinic for a final assessment of the two prostheses, and were asked to choose the one that they wished to keep.

Surgical and prosthetic protocol
From 6 to 8 titanium implants (Bränemark System, the registered trademark of Nobel Biocare AB) were inserted into the maxilla of each subject, following the surgical procedures established by Bränemark et al. (1977). After a minimum of two months for healing, another 4 titanium implants were inserted into the mandible. Four months later, the mandibular implants were exposed. A new maxillary complete denture and two mandibular removable implant-supported prostheses, long-bar and hybrid
Table 3. List of questions used in VAS

<table>
<thead>
<tr>
<th>General Satisfaction</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>In general, are you satisfied with your lower prosthesis?</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Physical Function</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Ease of Chewing: Is it difficult to chew fresh white bread?</td>
<td></td>
</tr>
<tr>
<td>(2) Quality of Bolus: Are the pieces of fresh white bread well-chewed before swallowing?</td>
<td></td>
</tr>
<tr>
<td>(3) Ease of Speaking: Is it difficult to speak with your prostheses?</td>
<td></td>
</tr>
<tr>
<td>(4) Ease of Cleaning: Is it difficult to clean your lower prosthesis?</td>
<td></td>
</tr>
<tr>
<td>(5) Stability: Are you satisfied with the stability of your lower prosthesis?</td>
<td></td>
</tr>
<tr>
<td>(6) Retention: Are you satisfied with the retention of your lower prosthesis?</td>
<td></td>
</tr>
<tr>
<td>(7) Comfort: Is your lower prosthesis comfortable?</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Psychosocial Function</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Esthetics: Are you satisfied with the appearance of your lower prosthesis?</td>
<td></td>
</tr>
</tbody>
</table>

* For questions 1-2, six other questions were asked, with hard cheese, raw carrot, dry sausage, raw apple, nuts, and lettuce substituted for bread.

* For questions 4-7, and esthetics, similar questions were asked about the upper prosthesis.

overdentures, were fabricated for each subject according to standard procedures (Zarb and Janson, 1995). The long-bar and hybrid overdentures had a design similar to that of a conventional denture except for the cavity over the anterior ridge to accommodate a parallel-sided gold bar (Cendre et Metaux SA) that linked 2 (hybrid overdenture) or 4 implants (long-bar overdenture). Two 7 to 10-mm distal cantilever extensions were incorporated for a long-bar overdenture, so that this prosthesis was completely supported by implants and the bar. Healing caps were used to cover the abutments of the two unused implants when the subject wore a hybrid overdenture. The prosthesis was relieved around the healing caps to prevent contact between the prosthesis and the caps at rest and during function. Thus, the hybrid overdenture was supported partly by the bar, and partly by the mucosa under the posterior saddles. Each type of prosthesis was secured to the bar by 2 (hybrid overdenture) or 4 (long-bar overdenture) clips embedded in the acrylic. The prosthesis were fabricated for each patient at the same time by the same prosthodontist. The same denture teeth (Ivoclar®) were used, and the prosthesis were replicated as closely as possible to ensure the same angulation, tooth contour, vertical dimension, and occlusion. This was done by means of a cast of the new conventional maxillary prosthesis with a polysilicone occlusal key to guide placement and angulation of the mandibular teeth.

Outcome variables

Ratings of prostheses. The patient-based outcomes that were used in this comparison included the variables measured on the 100-mm VAS and on Category Scales (CAT) that had been previously validated (de Grandmont et al., 1994). The individual variables assessed by VAS included: general satisfaction, stability, retention, comfort, esthetics, ease of cleaning, speaking, and chewing, and how well-chewed the foods were before being swallowed (Table 3). Subjects were asked to draw a vertical line anywhere across the horizontal on the spot that best represented their perception. The data from each session were collected before and after the subjects chewed the standard-sized pieces (3 x 1 x 1 cm) of fresh white bread, raw apple, raw carrot, hard cheese, and dry sausage. Details of the functional tests were described in Feine et al. (1994b). The CAT scales were used to measure patients' physical function, psychosocial function, and general health. Patients were asked to choose a word or a group of words that best described their responses to the questions (Table 4).

Choice of prosthesis. The VAS scales used during the final appointment were similar to those used in a previous study (Feine et al., 1994a). Subjects were asked to compare the 2 prostheses directly for: general satisfaction, stability, retention, comfort, esthetics, and ease of cleaning, speaking, and chewing. They then chose the prosthesis that they wanted to keep and rated, on another VAS, the relative influence that each of the above factors had on their choice.

Statistical analyses

The VAS data collected from the 6 recording sessions (3 per prosthesis) were analyzed by the use of multilevel models described by Steno et al. (1983) and Goldstein (1986, 1987). Several possible sources of variation (explanatory variables) were investigated: treatment effects (long-bar or hybrid overdentures), sequence effects (order of presentation of prosthesis), period effects (first prosthesis vs. second prosthesis), and trial effects (measurement before each functional test vs. measurement after). Residual variance was partitioned among subject, session, and trial levels.

The CAT data of the 6 recording sessions were analyzed by the chi-square test (SYSTAT). The categories of response were combined when the frequency in more than one cell was < 5. For example, the category "Worse or no change" in Fig. 1A is the combination of the categories of "Worse" and "No change". The VAS data taken at the final appointment were analyzed by
Table 1. Estimated means (mm) ± 1 standard error (SE) associated with each explanatory variable

<table>
<thead>
<tr>
<th>Explanatory Variable</th>
<th>General Satisfaction</th>
<th>Stability</th>
<th>Reenon</th>
<th>Comfort</th>
<th>Esthetics</th>
<th>Ease of Cleaning</th>
<th>Ability to Speak</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fixed Part</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Constant (LBO)^1</td>
<td>92.3 (1.3)^1</td>
<td>95.7 (3.3)</td>
<td>95.1 (3.3)</td>
<td>92.8 (3.4)</td>
<td>91.7 (2.7)</td>
<td>89.9 (2.7)</td>
<td>54.0 (3.1)</td>
</tr>
<tr>
<td>Treatment (HO-LBO)</td>
<td>-10.7 (2.2)</td>
<td>-9.9 (3.9)</td>
<td>-9.6 (2.3)</td>
<td>-2.1 (2.0)</td>
<td>-2.2 (1.1)</td>
<td>-2.2 (1.1)</td>
<td>&lt; 0.1 (1.1)</td>
</tr>
<tr>
<td>Period (2-1)</td>
<td>-1.7 (2.2)</td>
<td>-2.9 (1.9)</td>
<td>-1.7 (2.3)</td>
<td>0.3 (2.0)</td>
<td>0.7 (1.1)</td>
<td>-2.9 (1.9)</td>
<td>3.9 (1.1)</td>
</tr>
<tr>
<td>Trial (End-Begin)</td>
<td>1.5 (0.7)</td>
<td>0.3 (0.6)</td>
<td>0.3 (0.6)</td>
<td>-1.2 (0.5)</td>
<td>0.7 (0.6)</td>
<td>-1.2 (0.3)</td>
<td>0.3 (0.6)</td>
</tr>
<tr>
<td>Overall</td>
<td>81.6 (1.3)^1</td>
<td>85.6 (3.3)</td>
<td>85.8 (3.3)</td>
<td>86.6 (3.4)</td>
<td>85.5 (3.7)</td>
<td>83.7 (2.7)</td>
<td>51.7 (3.1)</td>
</tr>
</tbody>
</table>

Random Part

| Subject              | 126.1 (50.9)         | 136.7 (53.2)| 144.5 (58.3)| 140.2 (53.1) | 102.5 (37.9) | 78.7 (32.9) | 137.5 (50.2) |
| Session              | 94.0 (16.8)          | 74.0 (13.1)| 111.1 (18.9)| 86.1 (14.9)  | 16.3 (4.3)   | 66.3 (13.7) | 18.1 (4.6)  |
| Trial                | 21.6 (3.1)           | 15.5 (2.2) | 15.2 (2.2)  | 14.4 (2.1)   | 19.4 (2.5)   | 32.8 (4.8) | 19.3 (2.8)  |

Test

| x^2 p                | 4.416 < 0.01 | 26.34 < 0.01 | 17.36 < 0.01 | 20.99 < 0.01 | 4.32 < 0.04 | 1.28 < 0.25 | 0.00 < 1.00 |
| Treatment            | 24.37 < 0.01 | 26.34 < 0.01 | 17.36 < 0.01 | 20.99 < 0.01 | 4.32 < 0.04 | 1.28 < 0.25 | 0.00 < 1.00 |
| Period               | 0.60 (0.44)   | 2.24 (0.13)  | 0.33 (0.47)  | 0.06 (0.81)  | 0.37 (0.34) | 2.19 (0.14) | 12.11 (0.01) |
| Trial                | 6.74 (0.01)   | 0.19 (0.66)  | 0.89 (0.35)  | 4.67 (0.03)  | 1.21 (0.27) | 2.09 (0.15) | 1.46 (0.23)  |

<sup>1</sup> Data come from 16 subjects, 96 sessions, and 192 trials.
<sup>2</sup> LBO: long-bar overdenture.
<sup>3</sup> HO: Hybrid overdenture.

**Results**

Subjects

Eight males and eight females, aged from 35 to 58 yrs with a mean age of 44.3 yrs (SD = 6.9), were selected as subjects for this study. Due to an error, two subjects who should have received hybrid overdentures first were given long-bar ones first. Nevertheless, each group contained equal numbers of men and women, and the two groups were similar in mean age [long-bar first, 45.3 ± 6.0 (SD); hybrid first, 43.5 ± 8.8 (SD)].

Outcomes

In general, both prostheses were very highly rated by the subjects. However, ratings for most of the variables were significantly higher for long-bar overdentures during the course of the trial. These differences were consistent with the direct comparisons made at the final appointment, and with the fact that all subjects chose long-bar overdentures. Stability, ease of chewing, and comfort were given as the most important factors influencing choice.

VAS data gathered during the crossover period. In the final calculations of the multilevel models, sequence was not included as an explanatory variable, because no significant sequence effects were detected when it was included. Summaries of the results are given in Tables 5-7.

**General satisfaction.** General satisfaction was rated higher with long-bar overdentures than with hybrids (mean, 92.3 vs. 81.3 mm), and the difference (∑) of 10.7 mm was highly significant (p < 0.01). A small trial effect was also detected (∑ = 1.3 mm, p = 0.01; see Table 5).
Table 6. Estimated means (mm) ± 1 standard error (SE) associated with each explanatory variable (ease of chewing).

<table>
<thead>
<tr>
<th>Explanatory Variable</th>
<th>Lettuce</th>
<th>Nuts</th>
<th>Carrot</th>
<th>Apple</th>
<th>Sausage</th>
<th>Bread</th>
<th>Cheese</th>
</tr>
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<tbody>
<tr>
<td><strong>Fixed Part</strong></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Constant (LBO)</td>
<td>92.9 ± 4.5</td>
<td>99.0 ± 4.1</td>
<td>84.6 ± 3.0</td>
<td>90.0 ± 3.9</td>
<td>89.7 ± 3.0</td>
<td>94.2 ± 1.0</td>
<td>95.0 ± 2.2</td>
</tr>
<tr>
<td>• Treatment (HO-LBO)</td>
<td>-11.4 ± 2.7</td>
<td>-9.4 ± 2.1</td>
<td>-6.9 ± 2.0</td>
<td>-6.3 ± 1.4</td>
<td>-6.2 ± 1.7</td>
<td>-7.2 ± 1.2</td>
<td>-7.0 ± 1.0</td>
</tr>
<tr>
<td>• Period (C-1)</td>
<td>0.7 ± 0.2</td>
<td>-0.8 ± 0.1</td>
<td>-0.9 ± 0.2</td>
<td>1.3 ± 1.4</td>
<td>-1.4 ± 1.7</td>
<td>-6.0 ± 1.2</td>
<td>-0.3 ± 1.0</td>
</tr>
<tr>
<td>• Trial (End-Begin)</td>
<td>-0.4 ± 0.6</td>
<td>-0.4 ± 0.3</td>
<td>-1.0 ± 1.0</td>
<td>1.5 ± 0.0</td>
<td>-0.2 ± 0.0</td>
<td>1.6 ± 0.0</td>
<td>&lt;0.1 ± 0.0</td>
</tr>
<tr>
<td><strong>Random Part</strong></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>• Subject</td>
<td>248.2 ± 97.2</td>
<td>225.9 ± 85.3</td>
<td>297.6 ± 114.4</td>
<td>123.3 ± 46.5</td>
<td>230.9 ± 85.5</td>
<td>57.1 ± 22.2</td>
<td>72.9 ± 25.9</td>
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<td>• Session</td>
<td>148.4 ± 25.2</td>
<td>85.3 ± 16.2</td>
<td>128.2 ± 24.0</td>
<td>32.1 ± 7.6</td>
<td>45.7 ± 11.0</td>
<td>27.0 ± 5.4</td>
<td>14.9 ± 3.4</td>
</tr>
<tr>
<td>• Trial</td>
<td>19.1 ± 2.8</td>
<td>30.4 ± 4.3</td>
<td>49.0 ± 7.1</td>
<td>26.6 ± 3.9</td>
<td>40.9 ± 6.0</td>
<td>13.2 ± 6.9</td>
<td>11.3 ± 1.6</td>
</tr>
<tr>
<td>• Treatment</td>
<td>18.48 &lt; 0.01</td>
<td>19.39 &lt; 0.01</td>
<td>6.92 &lt; 0.01</td>
<td>19.21 &lt; 0.01</td>
<td>12.92 &lt; 0.01</td>
<td>4.03 &lt; 0.03</td>
<td>1.06 &lt; 0.08</td>
</tr>
<tr>
<td>• Period</td>
<td>0.08 0.78</td>
<td>0.13 0.72</td>
<td>0.12 0.73</td>
<td>1.59 0.21</td>
<td>0.62 0.43</td>
<td>0.28 0.60</td>
<td>0.11 0.74</td>
</tr>
<tr>
<td>• Trial</td>
<td>0.30 0.58</td>
<td>0.22 0.64</td>
<td>0.88 0.35</td>
<td>3.90 0.05</td>
<td>0.04 0.54</td>
<td>0.33 &lt; 0.01</td>
<td>0.01 &lt; 0.02</td>
</tr>
</tbody>
</table>

* Footnotes as in Table 5.

Stability and retention. The stability and retention of long-bar overdentures were very highly rated (means, 95.7 and 95.1 mm, respectively), while scores for hybrid overdentures were significantly lower ( stability, 9.3 mm (p < 0.01); retention, 9.6 mm (p < 0.01); see Table 5).

Comfort. The estimated mean of the ratings of comfort for long-bar overdentures was 92.5 mm, which was 9.4 mm higher than that of hybrid overdentures (p < 0.01). Again, a small trial effect was found ( stability = 1.2 mm, p = 0.03; see Table 5).

Esthetics. Although the mean rating of long-bar overdentures was significantly better than that of hybrids (p = 0.04; see Table 5), the difference between the mean ratings of the esthetics of the two prostheses was very small (2.3 mm).

Ease of cleaning and speaking. There were no significant differences between long-bar and hybrid overdentures for these variables. However, a period effect for the ease of speaking was detected. It was easier to speak with the second prosthesis than with the first ( p = 3.9 mm, p > 0.01; see Table 5).

Ease of chewing. Subjects rated all foods as relatively easy to chew with both prostheses, and all except cheese were significantly easier to chew with long-bar overdentures than with hybrids (see Table 6). However, the differences between the two prostheses for each food varied. Differences for lettuce (11.4 mm) and nuts (9.4 mm) were large, followed by carrot (6.9 mm), apple (6.3 mm), and sausage (6.2 mm). The smallest significant difference was found with bread (2.7 mm; see Table 6). Small trial effects were detected in apple ( stability = 1.5 mm, p = 0.05) and bread ( stability = 1.6 mm, p < 0.01).

Quality of bolus. When subjects were asked how well-chewed the different foods were before being swallowed, they replied that long-bar overdentures were significantly better than hybrids, except for apple. However, the estimated means of the ratings for both of the prostheses were all greater than 86 mm, and the differences between the two prostheses were very small, except for lettuce (see Table 7). A trial effect was detected only for apple ( stability = 1.6 mm, p = 0.01).

Random variation. The random variations associated with the subject, session, and trial levels were estimated. It can be seen from Tables 5-7 that the between-subject variance was much larger than that at the session level, with the variance between trials being low.

CAT data gathered during the crossover period. There were no significant treatment differences in response to any of the questions about the maxillary prosthesis. However, some significant differences between long-bar and hybrid overdentures were found in response to the questions on physical function, psychosocial function, and general health focusing on the lower prosthesis or on both jaws.

Physical function. Most subjects believed that the quality of their meals was better when they were wearing long-bar overdentures (p = 0.012, Fig. 1A), and their choices of foods were less limited with long-bar overdentures than with hybrids (p = 0.025, Fig 1B).

Psychosocial function. When asked if they considered their prostheses to be "a foreign body", "a part of yourself", or "both", most subjects chose "a foreign body" for the maxillary conventional denture and "both" for long-bar and hybrid overdentures. No differences were found between the two lower prostheses (p = 0.076). In addition, there were no differences between long-bar and hybrid overdentures when subjects were asked: "Do you refuse social invitations because of your prostheses?" or "Do you avoid speaking with someone else because of your prostheses?" Most subjects chose "Never". However, the subjects rated long-bar overdentures better than hybrids when asked: "How do you..."
you rate your confidence after wearing this lower
prosthesis?" (p = 0.004, Fig. 2A).

General health. Again, long-bar overdentures were rated as
better than hybrids when subjects answered the question:
"How has the lower prosthesis changed your life?" (p =
0.025, Fig. 2B).

VAS data gathered at final appointment. When subjects were
asked to compare the two prostheses directly at the end of
the trial, the results were consistent with the VAS data
gathered throughout the course of the study. The VAS
scores of long-bar overdentures were significantly higher
than those of hybrids for all of the variables (p < 0.05;
Wilcoxon), except for ease of cleaning (Fig. 3). The data also
revealed that the ratings were more variable for hybrid
overdentures (SDs = 13.3 - 18.2 mm) than for long-bar ones
(SD = 3.9 - 10.5 mm).

Subjects were also asked to rate, on a VAS, the relative
influence that each of the above factors had on their choice.
Most subjects gave the highest scores to stability, ease of
chewing, and comfort, while the scores for esthetics and ease
of cleaning and speaking were low and more variable (Fig. 4).

Discussion

In this crossover clinical trial, we asked edentulous subjects to
wear both long-bar and hybrid mandibular overdentures and
to rate their perceptions of each. Although both prostheses
performed very well, significantly higher ratings were
assigned to long-bar overdentures for most factors.
Furthermore, all subjects chose to keep long-bar overdentures.
These results suggest that, although subjects rate hybrid
overdentures very highly, they prefer long-bar ones.

These findings are in marked contrast to those of
Geertman et al. (1996b), who found no significant differences
in satisfaction, complaints, or subjective chewing ability
between patients wearing long-bar overdentures and those
with hybrids. We suggest that several differences in

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<th>Fixed Part</th>
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<tr>
<td>Explanatory Variable</td>
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</tr>
<tr>
<td>Constant (LBO)</td>
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<tr>
<td>Treatment (HO-LBO)</td>
</tr>
<tr>
<td>Period (2-1)</td>
</tr>
<tr>
<td>Trial (End-Begin)</td>
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</table>

Random Part

<table>
<thead>
<tr>
<th>Explanatory Variable</th>
<th>Lettuce</th>
<th>Nuts</th>
<th>Carrot</th>
<th>Apple</th>
<th>Sausage</th>
<th>Bread</th>
<th>Cheese</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject</td>
<td>156.4 (62.6)</td>
<td>101.8 (39.6)</td>
<td>78.0 (30.1)</td>
<td>60.8 (22.4)</td>
<td>102.4 (37.9)</td>
<td>38.6 (14.9)</td>
<td>46.4 (17.3)</td>
</tr>
<tr>
<td>Session</td>
<td>83.3 (20.2)</td>
<td>27.7 (10.6)</td>
<td>20.9 (6.5)</td>
<td>7.5 (2.7)</td>
<td>20.6 (4.6)</td>
<td>11.4 (3.4)</td>
<td>12.1 (2.6)</td>
</tr>
<tr>
<td>Trial</td>
<td>77.0 (11.2)</td>
<td>63.7 (9.3)</td>
<td>21.8 (3.1)</td>
<td>15.6 (2.3)</td>
<td>15.3 (2.2)</td>
<td>16.9 (2.5)</td>
<td>7.3 (1.1)</td>
</tr>
</tbody>
</table>

VAS data

The high ratings for long-bar overdentures are consistent
with the result of a previous study of long-bar overdentures
and fixed bridges (de Grandmont et al., 1994). The means
associated with long-bar overdentures for the factors that
were rated on VAS in both of the studies (general
satisfaction, esthetics, ease of speaking, and ease of chewing
five test foods) were similar, with the exception of esthetics,
which was rated lower in the first study (80.0 vs. 91.7 mm).
Furthermore, the orders in which foods were rated for ease
of chewing in the two studies were the same (bread > cheese
> apple > sausage > carrot), and the mean ratings of general
satisfaction differed by less than 8 mm.

The fact that general satisfaction was significantly higher
with long-bar overdentures than with hybrids was consistent with the ratings of most of the other factors. The patients judged a long-bar overdenture to be more stable, retentive, comfortable, esthetically pleasing, and easier for chewing than a hybrid one. Furthermore, subjects rated stability, ease of chewing, and comfort as the most important factors influencing their decision to choose long-bar overdentures. In the earlier comparison of mandibular long-bar overdentures and fixed prostheses, there was no significant difference in general satisfaction, and approximately equal numbers (eight vs. seven) chose to keep each type (de Grandmont et al., 1994; Feine et al., 1994a). All these findings support the use of general satisfaction as the primary outcome variable in this type of trial.

In a previous paper, we speculated that the method of support (implant only vs. implant and mucosa) would have more influence on patient satisfaction than the mechanism of attachment to implants (de Grandmont et al., 1994), and the results of the present study lend credence to this hypothesis. The fact that a hybrid overdenture was partially supported by the mucosa could be the main reason for the lower ratings for stability, retention, comfort, and ease of chewing. It has already been suggested that the much lower levels of satisfaction that characterize conventional mandibular dentures are probably due almost entirely to the poor bearing properties of the soft tissues (Boerrigter et al., 1993; Burns et al., 1995a).

It has also been proposed that the level of comfort is related to the degree of bone resorption under the denture (Humphries et al., 1995). Although the rate of bone loss below long-bar and hybrid overdentures could be different, this could not be a factor in our crossover experiment, because both groups had equal exposure to both forms of treatment.

Overall, ease of chewing was rated significantly better with long-bar overdentures than with hybrids. However, the differences between the prostheses were strongly dependent on the type of food. Bread and cheese were the easiest to chew, and the differences between long-bar and hybrid overdentures were small. They were greater for sausage, carrot, and nuts, which are consistent with our previous study and other studies which showed that difficulties with chewing become most evident when tough or hard foods are being chewed (de Grandmont et al., 1994; Geerman et al., 1996a). However, the biggest difference between the prostheses was found with lettuce, which we are unable to explain at the moment.

Although significant, the differences in ratings of esthetics between long-bar and hybrid overdentures are very small (2.3 mm). We have previously discussed the probability that differences of this size are probably of little biological or clinical significance. This seems particularly true since the arrangement of the teeth was as similar as possible.

There were no differences between these two removable prostheses in ratings of ease of cleaning. The results of the previous study—which showed that a mandibular long-bar overdenture was much easier to clean than a fixed bridge (de Grandmont et al., 1994), and that subjects who chose long-bar overdentures identified ease of cleaning as one of the most important factors influencing choice (Feine et al., 1994a)—all confirm the clinical impression that patients find that oral hygiene is easier to manage with removable appliances (Beumer et al., 1993; DeBoer, 1993; Zarb and Schmitt, 1996).

No significant differences were found in ratings of speaking ability between long-bar and hybrid overdentures during the course of this crossover trial. However, speaking ability was found to be slightly better in subjects wearing the second prosthesis than those wearing the first. Although this could mean that it takes five months or longer for the subjects to adapt their speech to implant-supported prostheses, they had also received a new maxillary conventional denture. Speech problems are probably more strongly associated with maxillary prostheses, since speech is influenced by factors such as maxillary anterior tooth form, position, and palatal coverage (Petrovic, 1985; Sones, 1989). The importance of palatal coverage and adaptation of implant prostheses to the maxillary ridge for speech is being tested in two other trials that we are conducting.

Subjects rated their perceptions before and after each
functional test, in which they chewed standard pieces of the test foods. Small but significant differences (trial effects) were found 5 times out of the 21 tests. General satisfaction was rated slightly higher after subjects chewed food than before, and there was a slight improvement in ratings of masticatory efficiency, perhaps because they were pleased with the way their prostheses had just performed. On the other hand, comfort went down, perhaps because of pressure on the mucosa, or food lodging under the prostheses.

CAT data

No significant treatment-related differences were found in response to the CAT questionnaires about the conventional maxillary prosthesis, which was not changed during the study. This suggests that the subjects were responding appropriately to the questions and reinforces the conclusion drawn from our previous study (de Grandmont et al., 1994), that these CAT instruments are valid tools for the measurement of patients' attitudes to different prostheses.

The maxillary conventional denture was considered by the subjects to be a foreign body and long-bar and hybrid overdentures to be a combination of a foreign body and a part of themselves. This result is consistent with data from the earlier study, in which most subjects rated fixed bridges as a part of themselves, conventional dentures as a foreign body, and long-bar overdentures as a combination of the two (de Grandmont et al., 1994).

Results of the CAT questionnaires in physical function reinforced the conclusion drawn from the VAS data, that a long-bar overdenture was significant better than a hybrid one in the ratings of ease of chewing. The fact that a large number of patients reported that the quality of their meals was better and that their choice of food was greater with long-bar overdentures may be related to the fact that differences between prostheses in ease of chewing were greater for hard and brittle foods. Subjects' self-confidence was greater with long-bar overdentures, and changes in life were rated as significantly more positive.

Patient preference

All patients chose to keep the long-bar overdentures. If a patient had decided to choose a hybrid overdenture, then two abutments would have had to be taken off and the implants recovered with mucosa. This probably influenced the subjects' choice in favor of
long-bar overdentures over hybrids. However, the decision of all subjects to choose long-bar overdentures was strongly consistent with the ratings of almost all of the patient-based outcomes during the trial, which clearly favored long-bar overdentures. In addition, when the two prostheses were directly compared during the final appointment, the ratings of hybrid overdentures were significantly lower than those of long-bar ones for almost all variables.

In conclusion, our data show that when patients are given the opportunity to compare, they tend to prefer a removable mandibular prosthesis fully supported by four implants over an overdenture that is retained by two implants.

Acknowledgments
The authors gratefully acknowledge the help given by our research assistants, Mr. Benoit Boulanger and Mr. Mario Fournier, and by our statistician, Mr. Richard Tanguay. This study was funded by a University-Industry Grant from the Canadian Medical Research Council. We thank Nobel Biocare Canada Inc., Laboratoire Dentachrome Inc., and W.L. Gore and Associates Inc. for their generous support.

References
A Within-subject Comparison of Mandibular Long-bar and Hybrid Implant-supported Prostheses: Evaluation of Masticatory Function

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Short title: Implant-Supported Prostheses: Masticatory Function

Key words: mastication, patient satisfaction, dental implants, oral prostheses, clinical trial

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**Abstract.** Sixteen edentulous subjects participated in a within-subject crossover clinical trial to test the hypotheses that a long bar overdenture attached to four implants gives greater patient satisfaction and masticatory efficiency than a two-implant hybrid overdenture. All subjects were given a new maxillary conventional denture. Ten received mandibular long bar overdentures first and six the hybrid overdentures. Two months later, psychometric assessments and functional tests were repeated three times at one-week intervals. The mandibular prosthesis was then changed and recordings were repeated after another two months. Mandibular movements and electromyographic activity of jaw muscles were recorded while subjects chewed standard-sized pieces of five foods: bread, cheese, apple, sausage and carrot. Measurements included masticatory time, cleaning time (the time between the end of mastication and the last swallow), and duration and amplitude of masticatory cycles and phases. Multilevel analyses were performed. No significant differences in masticatory time were found between prostheses for any test food. However, cleaning time for carrot [estimated mean of difference (Δ) ± SE: 1.6 s ± 0.7] and bread (Δ = 1.0 s ± 0.4) was slightly but significantly longer when wearing long bar overdentures. Cycle duration was longer with the long bar overdenture only when chewing carrot. The opening phase was shorter and the closing phase longer with the long bar overdenture for almost all test foods. Vertical amplitude was significantly less with the long bar overdenture for cheese (Δ = -2.6 mm ± 1.1), apple (Δ = -2.6 mm ± 1.0) and sausage (Δ = -2.9 mm ± 1.3). These results suggest that mastication with the two prostheses is equally efficient, although clearance of some foods from the mouth is longer with the long...
bar overdentures. They also indicate that patients adapt their masticatory movements to the characteristics of different prostheses.

**Key words:** dental prosthesis, dental implants, patient satisfaction, edentulism, mastication

**Introduction**

Mandibular implant-supported removable overdentures are widely used in clinical practice, and studies have shown that they provide significantly greater patient satisfaction and perceived chewing ability or chewing comfort than conventional dentures (de Grandmont *et al*., 1994; Burns *et al*., 1995a & b; Boerrigter *et al*., 1995; Chan *et al*., 1995; Kapur *et al*., 1998).

In other studies, functional measures of masticatory efficiency (e.g. masticatory time, particle size estimates) were compared. Jemt and Stalblad (1986) showed that the chewing time decreased significantly when a hybrid overdenture replaced a conventional lower denture. The chewing movements also changed. However, in a second report on the same patients, Haraldson *et al*. (1988) reported that differences between the groups were not significant.

Geertman *et al.* later (1994) compared masticatory efficiency in groups of subjects wearing mandibular conventional dentures, long bar overdentures and hybrid overdentures. They
found that subjects with overdentures were able to comminute an artificial test material with significantly fewer chewing strokes than did subjects wearing conventional dentures. In contrast, Garret et al. (1998) found no significant differences in particle size distribution after chewing peanuts and carrots in groups of elderly diabetic patients given either new conventional dentures or mandibular overdentures supported by two root-form implants.

The aim of the present within-subject crossover clinical trial was to compare patient satisfaction and masticatory efficiency of mandibular overdentures supported by four implants and of two-implant hybrid overdentures in edentulous subjects wearing maxillary conventional dentures. Although Geertman et al. (1994, 1996) found no significant differences between groups wearing long bar overdentures supported by transmandibular implants and hybrid overdentures supported by root form implants in either patient satisfaction or in masticatory efficiency, we have already shown that patients are significantly more satisfied with a long bar overdentures supported by four endosseous root-form implants than with a hybrid overdenture partially supported by two root-form implants (Tang et al., 1997). In this paper, we present the results of the comparison of masticatory efficiency carried out to test the hypothesis that there are also differences between the prostheses in functional performance.

**Materials and methods**

**Study design and surgical & prosthetic protocol**
Eight male and eight female edentulous French Canadians 35 to 58 years old [44.8 yrs ± 6.9 (mean ± SD)] were selected as subjects. The selection process, inclusion and exclusion criteria and justification of the size of the sample can be found in Tang et al. (1997). Subjects had been completely edentulous for a minimum of five years, had significant problems with their existing mandibular prostheses and had sufficient bone for four implants in the mandible. They received written descriptions of the study, which had been approved by the Human Ethics Committees of the participating institutions, and gave informed consent. Four endosseous root-form implants (Brånemark System®) were inserted in the anterior mandible between the mental foramina. Subjects wore their relined conventional prostheses during the healing period of four months or more.

All subjects received a new conventional maxillary denture. They were randomly allocated to two groups in blocks of four, stratified for age (> 50 years, ≤ 50 years) and gender. Eight subjects were assigned to receive mandibular long bar overdentures first and eight the hybrids. Because of an error, two subjects who should first have received hybrid overdentures were given long bar overdentures. However, each group contained equal numbers of men and women and the two groups were similar in age [long bar first: 45.5 yrs ± 6.0 (SD); hybrid first: 43.5 yrs ± 8.8 (SD)].

After two-months of adaptation, patient-based measures and functional tests were carried out three times at one-week intervals. The prostheses were then changed. After two

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months more, recordings were repeated. At the end of the study, subjects chose the prosthesis that they preferred. All treatments were provided at no cost.

The long bar overdenture was supported by a parallel-sided gold bar (Cendre et Métaux SA) which linked the four implants and extended 7-10 mm bilaterally behind the posterior abutment. The prosthesis was mainly supported by the implants during function. The hybrid prosthesis was retained by a similar bar connecting two implants, and partially supported by the posterior mucosal ridge, and healing caps were used to cover the two unused implants. The prosthesis was relieved above them to prevent contact during function. Because of variations in the anterior mandibular ridge, the position of the two implants used to support the bar varied between patients. The same denture teeth (Ivoclar®) were chosen for each pair of prostheses, which were fabricated at the same time to ensure similar tooth angulation, contour, vertical dimension and occlusion. In addition, the distal extensions were designed to be equal and the shapes of the polished surfaces were made as similar as possible.

**Functional tests**

An Optotrak 3D Motion Analysis System was used to record masticatory movements while subjects chewed test foods. Subjects sat comfortably with their Frankfurt plane (porion to orbitale) approximately horizontal to the ground. A probe that carried six infrared-emitting diodes was used to locate right and left poria and orbitales within the frame of reference of the cameras. A rigid body with six diodes was fixed on the
forehead with a band around the head. A single diode was attached to the middle of the chin.

Electromyographic (EMG) activity was recorded at standard sites over the temporalis, masseter and digastric muscles on the both sides of the face, as described in Feine et al. (1994b). EMG signals were amplified and filtered (10-300 Hz) by a Model 12 Neurodata Acquisition System (Grass®). A mercury-elastic transducer placed around the neck detected the movements of swallowing. EMG and swallowing signals were then digitized (1 KHz) on an Optotrak Data Acquisition Unit and stored on optical disks along with the movement data digitized at 50 Hz.

Masticatory time was the primary outcome variable, but other masticatory variables were evaluated as previously described (Feine et al., 1994b). In addition, the time between the end of mastication and the final swallow was measured. We call this “cleaning time”, because subjects reported that they used this time to clear pieces of food from the mouth. Masticatory time and cleaning time appear to represent two aspects of the ability of patients to ingest efficiently with a prosthesis.

Five kinds of test food (white bread, hard cheese, raw apple, dry sausage and raw carrot) of standard size (3 x 1 x 1 cm) were chosen to represent a range of food types of differing textures (de Grandmont et al., 1994). Subjects ate each type of food five times (trials) in each session, and the order of presentation of foods was randomized.
To begin a trial, subjects placed food on the tongue, then closed their mouths. When told to begin, subjects began to chew while an operator behind a one-way mirror observed them. If a cough or excessive movements occurred, the trial was repeated. Subjects were instructed to chew normally, as they would do at home. No other instructions were given. Data were collected during three recording sessions per prosthesis and analysed off-line.

In addition, speech data were gathered at the third recording session per prosthesis. These data will be published later.

**Psychometric data and patient preference**

Patient-based data collected before and after each masticatory functional test has already been reported (Tang et al, 1997).

**Analyses of masticatory function**

Movements of the chin in reference to the Frankfurt plane were calculated with software supplied by the manufacturer of the Optotrak. Vertical chin movements, EMG and elastic transducer data were displayed on a computer screen (Figure 1). Each masticatory sequence was manually divided into a masticatory and cleaning periods (Figure 1), following set criteria (Table 1). The start and end of each masticatory cycle, opening and closing phases were marked automatically by a custom-made program (Figure 2), using published criteria (Feine et al., 1994b).
Before analyzing the characteristics of the masticatory cycles (cycle duration, opening and closing duration and vertical amplitude), the first two cycles of each sequence were excluded because they were usually irregular (Feine et al., 1994b).

Multilevel analyses were performed on all variables for each kind of food. Several possible sources of variation (explanatory variables) were investigated: treatment effects (long bar or hybrid overdentures), sequence effects (order of presentation of prosthesis), period effects (first prosthesis vs. second prosthesis) and time effects (weeks 1, 2 and 3). In addition, cycle number was included in analyses of masticatory cycles because a previous study demonstrated that these changed systematically from the beginning to the end of the sequence (Feine et al., 1994b). The sequences for carrot were divided into two parts for analysis (cycles 3-13 and 14-40), because earlier work showed that the effect of cycle number on the variables was significantly different for these two periods (Feine et al., 1994b). Random variation was apportioned among subject, session and cycle levels.

A Pearson correlation was carried out to assess the relationship between masticatory time and patient-based ratings of ease of chewing or of how well chewed the food was before swallowing, using the psychometric data that have already been published (Tang et al., 1997).

For all tests, $p \leq 0.05$ was accepted as an indicator of statistical significance.
Results

There were no significant differences in masticatory time (MT) between mandibular long bar and hybrid overdentures for any test foods. However, cleaning time (CT) for carrot and bread were slightly but significantly longer for long bar overdentures. Moreover, some significant differences between these two prostheses were detected in cycle duration, phase duration and vertical amplitude. The results of the multilevel analyses are summarized in Tables 2-7.

Masticatory time (MT)

Estimated means of MT drawn from the multilevel model varied with food type (Table 2) from approximately 11 s (bread) to 48 s (carrot). Bread was most quickly chewed, followed by cheese, apple and sausage and carrot. Although MT was slightly shorter with all foods with long bar overdentures, these differences were not significant. There were also no significant effects of sequence, time and period for any food except sausage, for which MT was significant longer during period two.

Much more random variation in MT was associated with the subject level than with session and trial levels. There were very large differences in random variation between foods with the greatest variation associated with carrot.
Cleaning time (CT)

It took between 7 and 13 s to clear food from the mouth after mastication. Estimated means of CT varied with food type, but between foods differences were much less than for MT (Table 3). Cheese took the longest time and apple took the least. CTs for carrot, sausage and bread were very similar.

Although CT was longer with long bar overdentures than with hybrid overdentures for all foods, effects of treatment was only significant for carrot and bread. No significant effects of sequence, period and time were found.

Random variation for CT was much lower than for MT, and differences between foods were much less. It was mainly associated with subject and trial levels. The greatest subject variation was associated with cheese and the least with apple.

Masticatory movements

Cycle duration (CyD). CyD for carrot was significantly longer with long bar overdentures (Table 4), both early (cycles 3-13) and later in the sequence (cycles 14-40). Treatment had no significant effect with other foods. Period effects were found for all foods, with shorter CyDs exhibited during period two. Moreover, time effects were detected for CyD of carrot and of sausage. CyD increased significantly during the sequence for bread, apple and
cheese, but for carrot it decreased rapidly from cycles 3-13 and thereafter increased gradually.

**Opening duration (OD).** OD was significantly shorter with long bar overdentures than with hybrids for cheese, bread, apple and sausage (Table 5). Period differences were also found for these four foods. As with CyD, OD decreased over time for carrot. Significant cycle effects were detected for carrot, cheese and sausage.

**Closing duration (CID).** CID was significantly longer with long bar overdentures than hybrids for all test foods except apple (Table 6). Period effects were found for carrot and apple, and time effects were found for carrot and sausage. Again, a significant cycle effect was detected for all foods.

**Vertical amplitude.** Amplitude was less for all test foods except bread with long bar overdentures (Table 7). However, this effect was significant only with cheese, apple and sausage. No sequence, period or time effects were found. On the other hand, amplitude decreased significantly as the sequence progressed for all test foods.

**Correlation analysis**

Only weak associations were found between MT and patient-based ratings of ease of chewing or of how well chewed the food was before swallowing. In Table 8 and 9, it can be
seen that correlation coefficients were never greater than 0.37. Five of these relationships were significant, but in two cases the slope was negative and in three it was positive.

Discussion

Measurements of masticatory efficiency

In this study, two measurements were used in comparing the masticatory efficiency of long bar and hybrid overdentures. MT was used as an indirect measure of efficiency when preparing a piece of test food for swallowing, while CT measured the time needed to clear food from the mouth. CT was expected to be longer if food particles became lodged beneath the prosthesis.

Masticatory time

Prostheses to replace parts of the body are made for two main reasons: to restore appearance and function. A major contribution to function is mechanic of efficiency, but mechanical efficiency is not easy to measure in humans. Efficiency is the ratio of work done to energy used, but nobody has tried to measure energy used by the body during mastication, or the work that is required to chew food, but several methods have been developed to estimate masticatory efficiency indirectly. The two most frequently used are the measurement of the size of particles of real or artificial test foods after comminution (Yurkstas et al, 1951; Slagter et al, 1992), and the duration of the process
of mastication when eating standard-sized pieces of food (masticatory time - Manly and Braley, 1950). The former gives an estimate of the work done, while the latter (MT) is proportional to the energy used. We discussed the advantages and disadvantages of these methods in our previous publication, and the reasons why MT was chosen as the primary outcome variable for our studies (Feine et al, 1994b).

Mean MT for all five test foods eaten with the mandibular long bar overdenture in this study was greater than in our previous trial, in which the same overdenture was compared to a fixed implant-supported prosthesis (Feine et al., 1994b). However, the order of MT among test foods was almost the same, i.e., carrot and sausage took longest to chew, and apple, cheese and bread needed less time. Moreover, differences in random variation between foods were also similar in the two studies: it was greatest for carrot, followed by sausage, and much smaller for the other foods. The large random variation at the subject level in both studies suggests that this may be the source of difference between the two small samples.

The period effect for sausage on MT is probably due to the fact that the type of sausage was changed in the middle of the trial because the manufacturer discontinued the first brand.

Geertman et al. (1994) have reported that groups of patients wearing mandibular long bar overdentures and hybrid overdentures have a similar capacity to comminute an artificial test food. Although this is in agreement with our findings, the two studies cannot be directly
compared because of differences in design. In our study, both types of prosthesis were supported by root-form implants; while Geertman et al. used two endosseous root-form implants for the hybrid overdentures and a transmandibular implant system for the long bar overdenture. In addition, only the hybrid overdenture group underwent vestibuloplasty. They also wore a mandibular prosthesis during most of the healing period, while the long bar overdenture group wore no lower dentures for about three months. Finally, there was a significantly higher rate of clinical complications associated with the transmandibular implant system than with endosseous implants (Kwakman et al., 1996). For all these reasons, the effects of the prosthesis and of the implant system on outcome cannot be separated, because each could act as an effect modifier on the other (Rothman, 1986). This may explain why we were able to show significant differences in patient-based measures between the prostheses (Tang et al., 1997) while they were not (Geertman et al., 1996).

Cleaning time

The data from this study reveal that denture wearers usually need considerable a period of time to clear their mouths of food. The mandibular movements and EMG activity recorded during this period were quite different from those seen during the masticatory period. Compared with MT, mean CT varied less between foods, and random variation was lower.
Subjects took slightly but significantly longer time to clear their mouth with the long bar overdenture while chewing carrot and bread than with the hybrid overdenture, perhaps because pressure on the posterior extensions of the hybrid during mastication prevents food from passing under the saddle or into the dead space around the metal bars.

Although no other studies have included cleaning time as a variable, the complete process of ingestion does include both rhythmic chewing and non-rhythmic cleaning movements. This has been recognised by Kapur et al. (1998), who have developed methods to measure the ability of denture patients to remove a load of food particle from the buccal sulcus.

**Masticatory movements**

In agreement with the previous study (Feine, et al., 1994b), mandibular movements changed as the sequence progressed; amplitude decreased, and the duration of cycles and phases increased during the sequence for four of the test foods. The rapid decline in cycle and phase duration in the first part of the masticatory sequence (cycles 3-13) for carrot, and subsequent increase (cycles 14-40) was also seen again. This reinforces our belief that the cycle effect must be taken into account in analyses of masticatory movements.

The estimated mean CyD for the long bar overdenture is close to that found in the previous study for all foods (Feine et al., 1994b). Moreover, the order of the means
among the five test foods is the same, CyD of bread was the longest, followed by cheese, sausage, carrot (cycles 3-13), apple and carrot (cycles 14-40). However, the amplitude of movement with the long bar overdenture was somewhat less for all foods in this study than in Feine et al. (1994b) by from 3.1 mm (3.4%) for cheese to 13.4 mm (15.3%) for apple. The smallest amplitude was associated with bread in both studies, but the order of the mean amplitudes was different for the other foods. As with masticatory time, the difference between the two studies are likely to be due to the small number of subjects involved.

As in Feine et al. (1994b), significant differences in chewing pattern between prostheses were found. Although CyD was the same for both prostheses except when chewing carrot, the relative length of the closing phase was longer with the long bar overdenture. Vertical amplitude was also significantly less with the long bar overdenture for some foods and mean velocity during jaw closure was lower. The jaw first closes quickly but, when the teeth contact food, velocity drops even though the jaw closing muscles become more active in this slow closing phase (Schwartz et al, 1989). The longer the relative length of slow closure, the lower the mean closing velocity. It has been shown that pressure on periosteum shortens the slow phase (Schwartz and Lund, 1995), and this probably explains why velocity increases when masticatory forces are redirected from mucoperiosteum to bone by the replacement of the short bar by the long bar.

Comparison of functional tests and patient-based outcomes
The tentative conclusions drawn from the functional tests (no difference in masticatory efficiency, slightly easier cleaning of the mouth with the hybrid) are very different from the clear message that comes from patient-based ratings of ease of chewing (Tang et al., 1997). These subjects reported that all test foods were all significantly easier to chew with long bar overdentures than with hybrids, and all subjects preferred to keep the former.

This discrepancy between patient-based and functional measures is also emphasized by the correlation analysis, which showed weak associations between MT and ease of chewing and of how well food was chewed before swallowing. Even though some correlations were significant, the r values were very low and the slope was as likely to be negative as positive. Others have also reported low correlations between perceived chewing ability and masticatory performance. Lindquist and Carlsson (1985) reported that ratings of chewing ability and the results of chewing efficiency tests were not significantly related. Garret et al. (1996a) found that subjects reported improved chewing ability when full dentures were modified or replaced, but found no corresponding improvement in laboratory measures of masticatory performance (Garret et al., 1996b). Slagter et al. (1992) also reported that patients' ratings of their chewing experience were only weakly related to particle size, and they concluded that dentists cannot rely on the patients' perceptions of masticatory ability. However, it is becoming increasingly accepted that the most important and valid measures of treatments for chronic conditions like edentulism are based on patients' perceptions (Boretti et al., 1995). Subjects in this study found chewing easier with the long bar overdenture (Tang
et al., 1997), despite the fact that the functional tests suggest that the hybrid functions as efficiently as the long bar overdenture. Our previous study (de Grandmont et al., 1994; Feine et al., 1994a & b), together with other work (e.g. Garnett et al., 1996 a & b) confirms that patient-based measures are more sensitive than functional measures for detecting differences between prosthetic treatments.

The discrepancy between patients' perceptions and functional tests suggests that patients' and scientists' concepts of masticatory function are different. Masticatory time or particle size measures are used by scientists as indications of mechanical efficiency, but patients' ratings of ease of chewing reflect the experience of eating, which may be influenced by such things as stability and comfort (Garnett et al., 1996a). This is supported by the fact that self-assessments of ease of chewing were consistent with those of general satisfaction, comfort and stability, and all four were rated significantly higher for the long bar overdenture than for the hybrid (Tang et al., 1997).

In conclusion, no difference was found between long bar and hybrid overdentures for the primary outcome, masticatory time. This indicates that mastication is carried out as efficiently with a hybrid overdenture supported by two root-form implants as with a long bar overdenture supported by four implants. Masticatory time is only weakly related to the patient's own ratings of chewing ability.

Acknowledgements
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References


Table 1. Criteria for identifying masticatory and cleaning periods

- The beginning of the masticatory period was defined as the start of digastric activity during the first cycle.
- The end of the masticatory period (beginning of the cleaning period) was defined as the end of the last rhythmical burst in the jaw closing muscles.
- The end of the cleaning period was defined as the end of digastric activity after the terminal swallow.
Table 2. Masticatory time: estimated means (s) associated with each explanatory variable (SE in parentheses)

<table>
<thead>
<tr>
<th>Explanatory Variables</th>
<th>Carrot</th>
<th>Cheese</th>
<th>Bread</th>
<th>Apple</th>
<th>Sausage</th>
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\* Data from 16 subjects, 96 sessions.
\[ N^b = \text{total number of trials analyzed} \]
Table 3: Cleaning time: estimated means (s) associated with each explanatory variable (SE in parentheses)
Table 4. Cycle duration: estimated means (ms) associated with each explanatory variable (SE in parentheses)

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<tr>
<th>Explanatory Variables</th>
<th>Carrot (cycles 3-13)</th>
<th>Carrot (cycles 14-40)</th>
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* Data from 16 subjects, 96 sessions.

N = total number of cycles analyzed.
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<td>37'62</td>
<td>1'40&gt;</td>
</tr>
<tr>
<td>12'29 &gt;</td>
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<td>7'37</td>
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<td>1'40&gt;</td>
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<td>10'0&gt;</td>
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<td>10'0&gt;</td>
<td>10'0&gt;</td>
<td>37'62</td>
<td>1'40&gt;</td>
</tr>
</tbody>
</table>

Data from 16 subjects, 96 sessions.

- N = total number of cycles analyzed
- Cycle
- Time
- Period
- Sequence
- Treatment
- Test

Random Variation

- Cycle
- Time
- Period
- Sequence
- Treatment
- Covariant (Lpf grid)
- Fixed Par

Explanatory Variables

<table>
<thead>
<tr>
<th>Sample</th>
<th>Apple</th>
<th>Bread</th>
<th>Cheese</th>
<th>Carrot</th>
<th>Carrot (cycyles 3-13)</th>
</tr>
</thead>
</table>

Table 5. Opening duration: estimated means (us) associated with each explanatory variable (SE in parentheses)
Table 6. Closing duration: estimated means (ms) associated with each explanatory variable (SE in parentheses)

<table>
<thead>
<tr>
<th>Explanatory Variables</th>
<th>Carrot (cycles 3-13)</th>
<th>Carrot (cycles 14-40)</th>
<th>Cheese</th>
<th>Bread</th>
<th>Apple</th>
<th>Sausage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fixed part</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>· Constant (Hybrid)</td>
<td>389.2 (34.0)*</td>
<td>345.4 (33.1)</td>
<td>373.3 (36.8)</td>
<td>373.0 (36.5)</td>
<td>343.0 (30.9)</td>
<td>378.5 (36.3)</td>
</tr>
<tr>
<td>· Treatment</td>
<td>20.3 (8.5)</td>
<td>7.3 (6.3)</td>
<td>16.2 (7.0)</td>
<td>38.3 (7.8)</td>
<td>6.1 (6.3)</td>
<td>16.5 (6.1)</td>
</tr>
<tr>
<td>· Sequence</td>
<td>54.9 (41.0)</td>
<td>21.0 (41.2)</td>
<td>20.8 (45.5)</td>
<td>22.2 (44.9)</td>
<td>30.1 (38.1)</td>
<td>40.9 (45.3)</td>
</tr>
<tr>
<td>· Period</td>
<td>-16.8 (8.5)</td>
<td>-13.0 (6.3)</td>
<td>-9.7 (7.0)</td>
<td>-10.1 (7.7)</td>
<td>-19.7 (6.3)</td>
<td>-5.2 (6.1)</td>
</tr>
<tr>
<td>· Time</td>
<td>-12.5 (5.0)</td>
<td>-3.2 (3.7)</td>
<td>-2.4 (4.3)</td>
<td>-1.6 (4.8)</td>
<td>-7.3 (3.8)</td>
<td>-8.4 (3.6)</td>
</tr>
<tr>
<td>· Cycle</td>
<td>-7.8 (0.1)</td>
<td>0.5 (0.2)</td>
<td>3.2 (0.6)</td>
<td>2.6 (1.0)</td>
<td>1.7 (0.4)</td>
<td>-0.5 (0.1)</td>
</tr>
<tr>
<td><strong>Random Variation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>· Subject</td>
<td>6023.0 (2219.0)</td>
<td>6119.0 (2247.0)</td>
<td>7571.0 (2742.0)</td>
<td>7338.0 (2681.0)</td>
<td>5279.0 (1924.0)</td>
<td>7540.0 (2718.0)</td>
</tr>
<tr>
<td>· Session</td>
<td>942.9 (237.2)</td>
<td>602.5 (130.4)</td>
<td>589.1 (179.7)</td>
<td>583.8 (217.0)</td>
<td>501.2 (142.0)</td>
<td>628.7 (133.5)</td>
</tr>
<tr>
<td>· Cycle</td>
<td>5413.0 (256.7)</td>
<td>3985.0 (125.9)</td>
<td>6909.0 (284.8)</td>
<td>5842.0 (317.4)</td>
<td>5917.0 (221.3)</td>
<td>5800.0 (152.9)</td>
</tr>
<tr>
<td><strong>Test</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>· Treatment</td>
<td>5.64 0.02</td>
<td>1.34 0.25</td>
<td>5.30 0.02</td>
<td>24.37 &lt;0.01</td>
<td>0.93 0.34</td>
<td>7.26 0.01</td>
</tr>
<tr>
<td>· Sequence</td>
<td>1.79 0.18</td>
<td>0.26 0.61</td>
<td>0.21 0.65</td>
<td>0.24 0.62</td>
<td>0.62 0.43</td>
<td>0.82 0.37</td>
</tr>
<tr>
<td>· Period</td>
<td>3.85 0.05</td>
<td>4.20 0.04</td>
<td>1.89 0.17</td>
<td>1.70 0.19</td>
<td>9.75 &lt;0.01</td>
<td>0.73 0.39</td>
</tr>
<tr>
<td>· Time</td>
<td>6.30 0.01</td>
<td>0.74 0.39</td>
<td>0.31 0.58</td>
<td>0.11 0.74</td>
<td>3.67 0.06</td>
<td>5.27 0.02</td>
</tr>
<tr>
<td>· Cycle</td>
<td>109.66 &lt;0.01</td>
<td>5.95 0.02</td>
<td>32.19 &lt;0.01</td>
<td>6.31 0.01</td>
<td>20.14 &lt;0.01</td>
<td>14.36 &lt;0.01</td>
</tr>
</tbody>
</table>

| N<sup>a</sup>         | 980                    | 2090                  | 1269    | 767   | 1520   | 2971    |

<sup>a</sup> Data from 16 subjects, 96 sessions.

<sup>b</sup> N = total number of cycles analyzed.
Table 7. Vertical amplitude: estimated means (mm) associated with each explanatory variable (SI: in parentheses)

<table>
<thead>
<tr>
<th>Explanatory Variables</th>
<th>Carrot (cycles 3-13)</th>
<th>Carrot (cycles 14-40)</th>
<th>Cheese</th>
<th>Bread</th>
<th>Apple</th>
<th>Sausage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fixed Part</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Constant (Hybrid)</td>
<td>88.03 (6.7)*</td>
<td>76.67 (7.3)</td>
<td>88.88 (8.5)</td>
<td>68.32 (8.0)</td>
<td>76.65 (7.8)</td>
<td>85.58 (7.6)</td>
</tr>
<tr>
<td>- Treatment</td>
<td>-1.96 (1.3)</td>
<td>-1.43 (1.2)</td>
<td>-2.57 (1.1)</td>
<td>0.25 (1.1)</td>
<td>-2.63 (1.0)</td>
<td>-2.88 (1.3)</td>
</tr>
<tr>
<td>- Sequence</td>
<td>4.65 (8.2)</td>
<td>11.19 (9.1)</td>
<td>2.65 (10.7)</td>
<td>5.35 (10.0)</td>
<td>10.44 (9.8)</td>
<td>6.44 (9.5)</td>
</tr>
<tr>
<td>- Period</td>
<td>-0.18 (1.3)</td>
<td>0.65 (1.2)</td>
<td>2.10 (1.1)</td>
<td>0.29 (1.1)</td>
<td>1.22 (1.0)</td>
<td>1.53 (1.3)</td>
</tr>
<tr>
<td>- Time</td>
<td>0.68 (0.8)</td>
<td>0.46 (0.7)</td>
<td>1.08 (0.7)</td>
<td>0.81 (0.7)</td>
<td>0.12 (0.6)</td>
<td>-0.08 (0.8)</td>
</tr>
<tr>
<td>- Cycle</td>
<td>-0.61 (0.1)</td>
<td>-0.16 (&lt;0.1)</td>
<td>-0.60 (0.1)</td>
<td>-0.76 (0.1)</td>
<td>-0.88 (&lt;0.1)</td>
<td>-0.24 (&lt;0.1)</td>
</tr>
<tr>
<td><strong>Random Variation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Subject</td>
<td>245.7 (89.0)</td>
<td>302.6 (109.4)</td>
<td>423.8 (151.5)</td>
<td>369.1 (132.2)</td>
<td>358.2 (128.0)</td>
<td>333.8 (120.3)</td>
</tr>
<tr>
<td>- Session</td>
<td>25.6 (5.7)</td>
<td>22.3 (4.2)</td>
<td>22.6 (4.5)</td>
<td>20.4 (4.6)</td>
<td>16.6 (3.5)</td>
<td>32.9 (5.8)</td>
</tr>
<tr>
<td>- Cycle</td>
<td>97.2 (4.6)</td>
<td>67.8 (2.1)</td>
<td>68.5 (2.8)</td>
<td>59.8 (3.3)</td>
<td>79.0 (3.0)</td>
<td>77.8 (2.1)</td>
</tr>
<tr>
<td><strong>Test</strong></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Treatment</td>
<td>2.19 0.14</td>
<td>1.56 0.21</td>
<td>5.30 0.02</td>
<td>0.05 0.82</td>
<td>7.00 0.01</td>
<td>5.11 0.02</td>
</tr>
<tr>
<td>- Sequence</td>
<td>0.32 0.57</td>
<td>1.52 0.22</td>
<td>0.06 0.81</td>
<td>0.29 0.59</td>
<td>1.13 0.29</td>
<td>0.46 0.50</td>
</tr>
<tr>
<td>- Period</td>
<td>0.02 0.89</td>
<td>0.32 0.57</td>
<td>3.54 0.06</td>
<td>0.06 0.81</td>
<td>1.50 0.22</td>
<td>1.44 0.23</td>
</tr>
<tr>
<td>- Time</td>
<td>0.77 0.38</td>
<td>0.47 0.49</td>
<td>2.56 0.11</td>
<td>1.37 0.24</td>
<td>0.04 0.84</td>
<td>0.01 0.92</td>
</tr>
<tr>
<td>- Cycle</td>
<td>37.27 &lt;0.01</td>
<td>45.07 &lt;0.01</td>
<td>117.22 &lt;0.01</td>
<td>52.36 &lt;0.01</td>
<td>398.54 &lt;0.01</td>
<td>236.78 &lt;0.01</td>
</tr>
</tbody>
</table>

N<sup>b</sup> 980 2090 1269 767 1520 2971

* Data from 16 subjects, 96 sessions.

<sup>b</sup> N = total number of cycles analyzed.
Table 8. Correlation coefficients for masticatory time and patients’ ratings of ease of chewing

<table>
<thead>
<tr>
<th>Item</th>
<th>LBO (N = 48)</th>
<th>HO (N = 48)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carrot</td>
<td>0.270</td>
<td>0.121</td>
</tr>
<tr>
<td>Cheese</td>
<td>0.199</td>
<td>0.191</td>
</tr>
<tr>
<td>Bread</td>
<td>0.062</td>
<td>-0.303*</td>
</tr>
<tr>
<td>Apple</td>
<td>0.002</td>
<td>0.081</td>
</tr>
<tr>
<td>Sausage</td>
<td>0.298*</td>
<td>0.253</td>
</tr>
</tbody>
</table>

*: P < 0.05
Table 9. Correlation coefficients for masticatory time and patients’ ratings of how well chewed the food was before swallowing

<table>
<thead>
<tr>
<th></th>
<th>LBO (N = 48)</th>
<th>HO (N = 48)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carrot</td>
<td>0.236</td>
<td>0.100</td>
</tr>
<tr>
<td>Cheese</td>
<td>0.336*</td>
<td>0.281</td>
</tr>
<tr>
<td>Bread</td>
<td>0.089</td>
<td>-0.366*</td>
</tr>
<tr>
<td>Apple</td>
<td>0.076</td>
<td>0.072</td>
</tr>
<tr>
<td>Sausage</td>
<td>0.178</td>
<td>0.325*</td>
</tr>
</tbody>
</table>

*: P < 0.05
Figure 1—

Recording of vertical jaw movement, laryngeal movement and EMG activity of the right and left masseter, temporalis and digastric muscles, while one subject chewed a standard-sized piece of carrot with the long bar overdenture. The masticatory and cleaning periods have been identified. The arrows mark swallows.

Figure 2—

Part of the record from Figure 1 to show the division of the masticatory cycles into opening and closing phases.
1. The Design and Sample Size

The within-subject crossover design was used in the present study to allow us to use a small number of subjects. The great variability between subjects in edentulous history and masticatory performance means that a very large number would have been needed for a between group study. The within-subject design also allowed us to ask subjects to make a choice at the end of the trial.

The test foods used in the present study were selected from a variety of common foods from the softest (bread) to the hardest (carrot). Before the crossover study, patients underwent a practice function test with their conventional dentures to familiarize them to the test foods and the recording environment.

It is not possible to keep subjects blind to treatment assignment in the present study, as can be done in a randomized clinical trial of drugs. The obvious difference of number of implants and cost may influence patient preference. Having the opportunity to wear both of the implant prostheses in a within-subject study, subjects may be able to give the proper ratings of the prostheses regarding their satisfaction, comfort, retention, stability, chewing ability, etc.
The within-subject crossover trial is a very powerful design. It minimizes the effects of inter-subject variability and requires fewer subjects than a between-group study does. An estimation of sample size had been conducted previously (41). Minimal 14 subjects are necessary in identifying 10 mm effect size on 100 mm visual analog scales ($\alpha = 0.05, \beta = 0.20$) in a within-subject design of implant-supported prostheses.

Due to a clinical error, two subjects who should have received hybrid overdentures first were given long-bar overdentures instead. However, the age and gender of two different sequence groups were not different, and the multilevel analyses of both psychometric and functional data showed that there were no significant sequence effects. Moreover, an interim analysis of the functional test data conducted on the first ten subjects completed the trial (five subjects: The LBO first; five subjects: the HO first) showed the same result as the final analysis. Again, no sequence effects were detected.

2. The Administration of the Questionnaires

Patients came to our clinical laboratory twice within one month to complete the questionnaires before the start of the present study. The purpose of this step was to ensure that they understood all the items in the questionnaires and knew how to answer them. During the course of the study, we let patients completed the questionnaires by themselves. A research technician was
responsible for distributing the questionnaires, for explaining questions that caused difficulty, and ensuring that there were no missing items. This person was not involved in treatment.

We decided to let patients filled out the questionnaires themselves, instead of a trained interviewer to keep as simple and uniform as possible over time.

Patients were not allowed to see their previous responses to any of the questions before they completed other questionnaires. We believe that providing with previous responses may introduce the bias, such as (1) repeating the prior answers, even when real change has occurred, or (2) exaggerating the changes to please the investigator or clinician.

3. Comparison of Functional Tests and Patient-based Assessments

The results of laboratory tests show that there is no significant difference in masticatory or cleaning time between these two type prostheses when opposed by conventional dentures. This suggests that patients can eat as efficiently with a mandibular two-implant hybrid overdenture as with a long bar overdenture supported mainly by four implants.
However, this conclusion is not supported by the patient-based outcomes, which clearly show that edentulous patients feel their chewing ability is significantly better with the long bar overdenture than with the hybrid prosthesis for all the five test foods except cheese. As might be expected, correlation analysis showed a very weak association between these two measures of masticatory function.

The discrepancy between the masticatory function rated with questionnaires and that measured by chewing tests is in agreement with many other reports (67, 12, 72). Lindquist and Carlsson (67) demonstrated that both patients' ratings of chewing ability and the chewing efficiency measured in the laboratory were improved after insertion of mandibular fixed prostheses. However, they only found a very weak relationship between patient-based ratings of masticatory ability and the chewing variables that they used, such as chewing efficiency index, chewing time and bite force. They indicated that some psychological effect of implant treatment might have influenced patient-based ratings of masticatory ability.

In an investigation of masticatory function after surgical reconstruction of the mandibular ridge, Renaud et al. (12) reported that both subjects' ratings of chewing difficulty and laboratory variables of chewing tests based on the size of chewed almond particles, and on the time required to masticate food before swallowing, improved. However, they found discrepancies between the patients'
ratings and the chewing tests, and concluded that the two methods of evaluation for the masticatory function served two different purposes and should be used simultaneously to study rehabilitation. In their view, masticatory efficiency tests are a useful tool for identifying the masticatory handicap and evaluating the impact of the treatment. On the other hand, the psychometric method reveals patient's own level of satisfaction.

Slagter et al. (72) have different explanation of the discrepancy. In an investigation of the relationships between the ability of 38 complete denture wearers to comminute a tough artificial test food and their answers to questions about their chewing experience, they reported that subjects' chewing experience was weakly related to the results of chewing tests. They indicated that masticatory ability is conceivably determined by many other factors and dentists could not rely on asking denture wearers about their chewing problems for predicting those patients' masticatory abilities. They stated that the ability of complete denture wearers to comminute tough foods should be determined individually by a series of chewing tests.

The low correlation between the two measures and the controversial interpretations of this, means that we have to reconsider the reliability of these two measures, and their significance in appraising the effectiveness of implant-supported prostheses.
Masticatory efficiency is loosely defined as the ability to prepare food for swallowing. It has been evaluated by measuring several physiological variables that are presumed to be directly related to masticatory function, such as the size of chewed particles, masticatory time, number of strokes and bite force. As early as 1940s, investigators reported that chewing efficiency based on the measurement of chewed particle size decreased as the natural dentition deteriorated (73). It was later shown that the masticatory efficiency of denture wearers was worse than that of people with natural teeth in terms of particle size, chewing time and number of strokes, and bite force (57, 61, 65).

Helkimo et al. (57) demonstrated clear associations between patients' dental state and their chewing efficiency index using almonds as test food and a system of sieves. They reported that individual with fewer teeth, complete or removable partial dentures, had a lower masticatory efficiency than those with natural teeth. Furthermore, denture wearers usually chewed for a longer time before swallowing. Mahamood et al. (61) reported that dentate subjects had significantly higher efficiency than did complete or immediate denture wearers, by the means of measurement of chewed particle size. Gunne (65) estimated the masticatory efficiency of subjects with a complete national dentition, those with complete maxillary and removable partial mandibular dentures, and those with complete dentures. Two masticatory materials were used, gelatin and almonds. Size of particles were calculated by dye absorption test and fractionated sieving, respectively. Significant differences of chewing efficiency were observed among...
the three groups irrespective of the method used, and subjects with complete dentures and removable partial dentures compensated for the impaired masticatory efficiency by chewing for a longer time.

It is evident that masticatory efficiency estimated by chewing tests is closely related to the state of the dentition, and to the type of prosthetic replacement for missing teeth. However, it has also been noted that patients who received new dentures or had their old ones improved had no improvement or only slight improvement in their masticatory efficiency. Vinton and Manly (74) reported some improvement in masticatory performance during the first 6 months after edentulous patients received their first complete dentures, but no such improvement showed up for patients who had worn complete dentures. These estimates were based on the measurement of chewed particle size. Lundquist et al. (75) conducted an investigation concerning the changes in chewing efficiency after receiving new removable dentures in edentulous patients with denture adaptation difficulties. With almonds and a sieve-system, they reported that no significant improvements were found in terms of chewing efficiency index, chewing time, number of chewing strokes and bite force comparing with their original complete dentures. The correlation between the physiological variables measured in their studies was significantly high and consistent. They suggested that there were possible psychological implications since the subjects in their study represented the special population who were not satisfied with their
present dental situation and were waiting for being treated with osseointegrated oral implant bridges in the mandible.

It seems that the chewing tests may be not sensitive enough to identify slight changes in mastication after a denture therapy, or that treatment may not have any effects on the variables that a chewing test evaluates, although patients may report differences in function. In a review of the methods used in measuring masticatory function, Boretti (42) suggested that denture therapy remains more as an art than as a science, and that chewing tests could not provide a solution for patients unless they included an assessment of the patients' quality of life. He urged that patient-based assessments of masticatory ability and other psychosocial effects should be emphasized more than a biomedical approach based on chewing tests.

Indeed, the results of our study and of many earlier studies (12, 67, 72) indicate that patients' own impression of their masticatory ability are different from those gained from the laboratory tests. The data from functional tests may be accurate and reliable, but they may not be very relevant to the concerns of patients. The two implant-supported overdenture may allow a patient to prepare food for swallowing as efficiently as with a prosthesis supported by four implants, but this was not reflected in the patients' self-ratings of masticatory ability and nor their psychosocial well-being.
There is an increasing agreement that patients should take an active role in the decisions about their health care and that patients' self-assessment of treatment should be given more importance in today's clinical trials. Feine et al. (40) suggested that patient-based ratings of treatment be considered as the most valid outcome measure in prosthetic rehabilitation, since the major goal of treatment is to improve the patients' quality of life. The results of the present trial support this claim. The subjects gave significantly higher ratings to the long bar overdenture in chewing ability, as well as in stability, retention, comfort, esthetics, confidence, quality of meal and quality of life. Consequently, all subjects preferred to keep the long bar overdenture, despite the fact that the functional tests indicate that the hybrid overdenture can function just as efficiently.

There is a concern that patients may overestimate treatment efficiency in some circumstances. However, the risk of overrating was low in the present study. First, the assessors who were in charge of collecting questionnaire data provided none of the treatment. Thus, patients' tendency to show gratitude for the time and effort expended by doctors has been avoided. Secondly, patients were asked to evaluate their chewing ability using the same five test foods before and after each chewing test. This avoids problem of distortion in memory. Furthermore, and most important, patients' self-ratings of the two prostheses are consistent with the behaviors, i.e., the long bar overdenture was rated to be better than the hybrid and all subjects preferred to wear it.
In conclusion, the study show that when patients are given the opportunity to compare the two types of mandibular implant-supported overdentures, they assess their chewing ability is significantly better with the long bar overdenture than the hybrid. On the other hand, no difference was shown between these two prostheses in terms of masticatory efficiency measured by laboratory tests, and patients’ self-assessment of masticatory ability was found to have little relationship to laboratory tests of chewing efficiency.

4. Speech

No difference was found in patient-based assessment of speech between these two mandibular implant-supported prostheses. This may prove the assumption that the changes of speech are mainly related to maxillary prostheses, as other authors have claimed (71, 76), because the upper prosthesis did not change during the present study. However, this conclusion has to wait until the accomplishment of the ongoing clinical trials focusing on maxillary implant prostheses: (a) maxillary implant-supported long bar overdentures with and without palates; (b) maxillary fixed bridges vs. long bar overdentures. Of interest is that preliminary analysis of these speech data has shown some differences between the upper maxillary implant-supported prostheses.

5. Future Studies
The present clinical trial is only one of a series of comparisons of the most commonly used types of implant-supported prostheses. So far, our research group has compared mandibular fixed bridges and long bar overdentures (24, 26, 32), which was followed by this study of mandibular long bar and hybrid overdentures. In both trials, a within-subject design was used. We are also carrying out a between group comparison of hybrid overdenture and conventional dentures because an appropriate well-controlled comparison of them was needed, despite the fact that many people believe that patients are more satisfied with mandibular implant-supported removable overdentures than with conventional dentures.

The comparisons between maxillary implant-supported prostheses are especially important because the various designs may have very different effects on speech and esthetics, as well as on masticatory efficiency. With the accomplishment of the series studies, we hope provide much more information for clinicians so that they can prescribe the most beneficial implant-supported prostheses for each edentulous patient.


40. Feing JS, Awad MA, Lund JP. The impact of patient preference on the design and interpretation of clinical trials. (submitted)


60. Christiansen EG (1924). Note on «chewing power of teeth.» *Br dent J* 45:318


