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Does the Nature of the Definitive Impression Material Influence the Outcome of (Mandibular) Complete Dentures?

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Abstract - *The effects of impression materials on the outcome of complete dentures are poorly understood. This double-blind cross-over randomized controlled trial investigated eleven adult edentulous patients. Each received a maxillary denture and three mandibular dentures (which differed only in the three materials used to record the definitive impressions). The three manbibular dentures were given in a random order. Patients' opinions of each denture were recorded using a Linear Analogue Scale. There was a statistically-significant difference between the outcome of the dentures constructed when zinc-oxide eugenol was used, this material being least favoured ($p<0.001$). It would therefore appear that care should be exercised when selecting impression materials when constructing mandibular complete dentures.*

KEY WORDS: Dentures; Outcome; Double blind, Cross-over randomised control trial

INTRODUCTION

Complete dentures Prosthodontics has a long history and there is now a clear understanding of many of the physical, physiological and psychological considerations fundamental to this branch of clinical dentistry. Evaluation of many of the techniques used, however, is anecdotal and not evidence-based. For example, many complete denture patients would appear to be satisfied with their prostheses but there remains a clinically significant percentage that experiences difficulties wearing their dentures although the dentures are normatively perceived to satisfy current prosthodontic criteria for acceptability.

Successful provision of (conventional) complete dentures demands that the dentures satisfy the requirements of support, retention and stability[1]. Support is derived from residual alveolar bone and the covering mucosa. Retention is achieved by accuracy of fit and seal around the periphery of the denture. Stability requires a balance between the muscles surrounding the dentures, especially the mandibular denture[2,3]. While the support and retention of dentures should be catered for via the definitive impression, stability is more variable and is a paradigm of occlusal balance, peripheral form and patient neuromuscular control[4].

From the patient's perspective, if complete dentures are to be worn satisfactorily they are required to be stable and retentive[5]. Unfortunately the mandibular denture bearing area lacks the shape and size of the maxillary denture bearing area and a mandibular complete denture, not surprisingly, is the most problematic clinical prosthesis to provide successfully. Clinically speaking, the problems of prescribing mandibular complete dentures are predominantly those of stability and any inherent lack of stability often overrules the factors involved in retention and support, rendering them ineffective[5]. Implant-retained/supported prostheses are clearly a significant way to maximize stability, but not all edentulous patients are in a position to receive such a treatment option and they must rely on conventional prosthodontic techniques.

Several investigators have measured patient satisfaction and these cover aspects such as general satisfaction, comfort, appearance, ability to speak, stability, ease of cleaning and ability to chew a variety of foods[6]. Thomason et al.[6] investigated all of these parameters in two groups of edentulous patients, one with conventionaI dentures and one with implant-stabilised mandibular dentures. It was concluded that overall satisfaction with completed prostheses was 36% higher in the group with implant-stabilised mandibular dentures. However, another study, in which patients wearing complete dentures were asked to rate their chewing ability, the findings showed that only 6 to 8% rated their chewing performance poor[7]. It is interesting to note that Wolff *et al.*[8] reported that the major factors affecting patient satisfaction with replacement mandibular complete dentures were submandibular /sublingual salivary flow rate.

Clearly, there are many factors which might potentially influence patient satisfaction to replacement complete mandibular dentures. One treatment – related factor was reported by McCord and Tyson[6]. They reported the clinical success resulting from the recording of definitive (mandibular) impressions with a viscous impression material. Their report was at variance with other clinicians who recommended that "mucostatic" impressions should be preferred. McCord and Tyson recommended that a randomised control study should be conducted to test the effects, on outcome of treatment, of impression

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materials in the provision of conventional mandibular complete dentures.

A cross-over randomized controlled trial was therefore undertaken to determine if the nature of the impression material, used to record the mandibular definitive impression, influenced the outcome of the treatment by recording the views of patients.

MATERIALS AND METHODS

Eleven edentulous patients were enrolled onto the study, which had approval of the Local Ethical Committee. The eleven comprised six male and five female patients and all were referred to the University Dental Hospital of Manchester (UDHM) for replacement complete dentures. All patients included in the study had an Atwood Class V mandibular ridge[7] and all had worn complete maxillary and mandibular dentures for at least five years.

All examinations, and subsequent treatment, were conducted in the Unit of Prosthodontics, UDHM. A history and examination was conducted on each patient included in the sample and a baseline questionnaire completed to determine the denture-wearing history of each patient. Each patient was prescribed a replacement maxillary complete denture and three mandibular complete dentures. The replacement dentures were set up to the same occlusal vertical dimension (OVD), for each patient, and each of the three mandibular complete dentures was constructed to have identical forms of the occlusal and polished surfaces by using plaster indices. They differed only in the form of the denture-bearing surface (*vide infra)* as all dentures for all patients were made by the same technician.

The mandibular dentures were each coded for the impression material used to record each definitive impression and these dentures were allocated to each patient. The order in which each of the three mandibular dentures was given to each patient was determined via the randomization process The nature of the three impression materials recording the mandibular arch differed slightly (*vide infra*).

The maxillary complete denture and all three mandibular complete dentures were processed using an injection moulding technique and, at the time of insertion, the mandibular denture delivered was determined using a table of random numbers (*Table I*). Each mandibular complete denture was worn in turn for one month.

A further examination was carried out after a period of one month from the provision of each mandibular complete denture and a relevant questionnaire completed by each patient. This process was repeated for all three mandibular complete dentures.

The clinical procedures were as per those advocated by Ogden *et al.*[8]. The specific details of the mandibular impressions were:

Three impression materials were selected to record the mandibular denture-bearing areas:

- A light-bodied polyvinylsiloxane material (Provil – Heraeus, Dormagen, Germany).
- An admix of impression compound and tracing compound in the ratio of three parts by weight of impression compound to seven parts by weight of greenstick placed in water at 60°C and kneaded into a homogeneous mass (McCord and Tyson[5]).
- A two-paste system of zinc oxide and eugenol (SS White Mfg., Gloucester, England).

Table 1. *Random allocation of dentures.*

Patient No.	*Inserted 1st*	*Inserted 2nd*	*Inserted 3rd*
1	C	T	S
2	C	S	T
3	T	C	S
4	S	C	T
5	T	S	C
6	C	T	S
7	C	S	T
8	C	S	T
9	C	S	T
10	T	C	S
11	S	C	T

Where:
T = definitive impression recorded in zinc oxide and eugenol
S = definitive impression recorded in Admix
C = definitive impression recorded in Provil

Each master cast was coded by a senior dental instructor according to each definitive impression material used. The codings were not revealed to the clinicians until the end of the study, and the clinicians were not aware of which denture was made on which cast. The codings used to identify the casts were :
T = zinc oxide and eugenol
S = Admix
C = Provil

All maxillary casts were transferred to the articulators via a facebow transfer and the intermaxillary relations were recorded via a central bearing device (PTC UK Ltd. Bolton, England). Three central bearing apparatus tracings were recorded, one per each of the three mandibular "master" casts for each patient. The OVD for each patient was constant and, in all cases identical moulds for each mandibular denture (to suit the upper arch (Senator, Wright Oral Health, Dundee).

The forms of the polished surfaces and the occlusal surfaces were standardized by use of plaster indices.

All trial dentures were assessed by two clinicians, JFM and LMM, (and each patient) to ensure acceptable appearance and occlusion of the maxillary and mandibular dentures. When all parties were satisfied with the trial dentures, the dentures were sent for processing in acrylic resin (Trevalon, Dentsply, Weybridge, England). Each processed mandibular denture was coded according to the impression material used to record the mandibular definitive impression (*vide supra)*

The insertions were performed according to standard prosthodontic practice[8], to ensure that no obvious problems of support, retention or stability were present.

The random allocation of dentures for each patient, and the frequency overall of the order of insertion of the dentures are illustrated in *Table 1.*

One month after wearing each of the first-provided

Table 2. *Digital Analogue box used to record patient opinion of each mandibular denture.*

1. Most comfortable	2. Neither 1 nor 3	3. Least comfortable

mandibular denture, a second patient questionnaire was recorded for the denture worn over the first month. A second mandibular denture was then allocated, the first denture retained by the researchers and the patient reviewed after one month of wearing the second denture. At that time, a third questionnaire was completed for the second mandibular denture and the third mandibular complete denture provided; again the researchers retained the second worn denture.

One month after wearing the third denture, a final questionnaire was completed and the patient given all three dentures, with the instruction to wear the denture he/she preferred most. This was conducted via a digital analogue box (*Table 2*). The preference of each patient for each mandibular denture was recorded and the results analysed.

Collection of data and data assessment

The questionnaires were in the form of digital analogue boxes and all scores were recorded . The three types of impressions used, coded as T, S or C (marked on the casts as a Triangle, Square or a Circle) plus the order of insertion were each addressed in statistical detail. The data were recoded in two ways as 1) most preferred or not and 2) least preferred or not. A general estimating equation (GEE) model was fitted to each of these dichotomous dependent variables using the 'xtgee' command in Stata 8 (like logistic regression) with impression and order as independent variables, clustering for patient, with family binomial and logit link.

RESULTS

The number of patients included in the study was eleven, six males and five females. The age range was from 49 to 93 years and the average age was 76.7 years. With regard to the dentures worn by the patients at first presentation, the following facts were determined:

Seven per cent of patients experienced difficulty with their maxillary dentures, 55% of patients experienced pain from their mandibular dentures, 55% experienced loose maxillary dentures, 91% experienced loose lower dentures and 55% of patients did not take their dentures out at night. In addition, all the patients wore their dentures at meal times

Results of randomization of mandibular dentures

The denture marked C (Provil impression) was provided first on six occasions, the denture marked T (Zinc oxide and eugenol impression) was provided first on three occasions, the denture marked S (Admix impression) was provided first on two occasions.

The denture marked C was provided second on four occasions, the denture marked T was provided second on two occasions and the denture marked S was provided second on five occasions

Table 3. *Recorded analogue scores.*

Patient	*Zinc oxide and*	*eugenol (T)*	*Admix (S)*	*Provil (C)*
1	3		1	2
2	3		1	2
3	3		1	2
4	3		2	1
5	3		1	2
6	3		2	1
7	2		1	3
8	3		2	1
9	3		1	2
10	2		1	3
11	2		3	1

Rankings:
1 = "highest" score on this analogue scale and indicates the greatest comfort.
2 = between 1 and 3
3 = indicates the least comfort

The denture marked C was provided third on one occasion, the denture marked T was provided third on six occasions and the denture marked S was provided third on four occasions.

The scorings for patient opinion are listed in *Table 3*.

The denture marked T was never the denture that was most preferred. It was the least preferred on eight out of eleven occasions.

The denture marked S was the denture most preferred on seven occasions. It was least preferred on one occasion.

The denture marked C was the denture that was preferred on three occasions. On two occasions, it was the least preferred

For most preferred, both dentures S and C were preferred to T ($p<0.001$), there being no difference between S and C ($p=0.32$), and no order effect was found ($p=0.48$). Denture T was least preferred, more often than S ($p=0.02$), otherwise no significant differences were found.

DISCUSSION

Many techniques have been advocated in an attempt to provide functionally acceptable prostheses for patients with atrophic mandibular ridges[5]. Implant supported dentures have been prescribed in some cases although for the majority of edentulous patients this may not be a viable option in the United Kingdom owing to financial constraints. Copy denture techniques are a valid prosthodontic option to consider yet they tend not to cater for those patients who have both atrophic mandibles and soft tissue support problems[5] Better guidelines and more scientifically-based clinical research are therefore required to assist the dentist to provide complete dentures with the confidence of evidence-based studies.

Some studies have determined the opinions of patients to certain occlusal forms and to the adaptability of patients to copying the form of polished surfaces[6]. There are no studies, however, which record how patients have perceived the outcomes of replacement mandibular dentures using a variety of materials to record the definitive mandibular impression.

All research studies require competent control and planning if meaningful results are to be achieved. Where clinical studies involving complete dentures are concerned, considerable care is required in controlling three distinct yet inter-related areas; these are:

Clinician-related factors. It is often assumed that clinicians are entirely consistent in their actions and that certain clinical factors such as pressure applied when recording impressions are standardised. This clearly is not always easy to control but every effort was made in this study to eliminate operator error by having one operator (LM) record the mandibular impressions.

Technician-related factors. Again, it is assumed that the technician will perform his/her skills in a consistent way and for this reason, only one senior technician was allowed to undertake all of the technical stages.

The third factor is related to the patient. Clearly the physical, social and psychological aspects of denture-making are specific to each individual and there is merit in having trials constituted on a statistically-sound basis. Equally, there is also merit in having the patient serve as a control for certain factors being investigated[12].

In this cross-over randomized-controlled study, the clinical factors were controlled by one clinician recording all mandibular impressions using three identical mandibular trays. The technical factors were controlled by using one technician to fabricated all stages of each denture.

The patient factors were controlled by having one replacement maxillary denture and three replacement mandibular dentures. As the mandibular dentures were identical (in the forms of their occlusal and their polished surfaces) for each patient, this allowed each patient to be a control for each mandibular denture. In addition, the assessment of denture after one month was selected as Kalk and de Baat[13] stated that the majority of problems with replacement dentures could be anticipated by this time.

This study represents some of the difficulties inherent in performing such a randomized controlled study in this clinical specialty. Many patients are over the age of 65 and not prepared to attend for additional visits; this was evidenced by the fact that 25 patients were invited to participate in the study but only 11 agreed. Within this study, however, the Null hypothesis was disproved. There is a statistical difference between the outcome of delivery of dentures according to the nature of the impression material used to record the definitive impression. Perhaps the more hydrophilic, light-bodied paste system of the zinc-oxide-eugenol impression material was more accurate and therefore the impression surface of the denture was microscopically more rough than the other two materials is a possibility. This clearly merits further consideration. It is also surprising that it was clinically significant finding that the first worn denture initially caused most discomfort but this perhaps substantiates the need to have the denture-bearing area, polished surfaces and occlusal surfaces of controlled forms. As a result, only the nature of the impression surface of the dentures might be a variable and this may well be what resulted in the differences in perception reported by patients.

What these findings do indicate, however, is that there may well be a need for clinicians to spend greater time in evaluating the nature of the edentulous ridge. This assessment may help in gaining a greater understanding of factors affecting the impression surfaces of dentures to be prescribed for patients with atrophic mandibular (and possibly maxillary ridges). As a result, there may well be valid reasons for prescribing certain impression materials for atrophic ridges (e.g. the admix technique) where preliminary assessment indicates that the ridges are tender to palpation.

The need for larger randomized controlled trials is clear from the findings of this study and, on the basis that the first-worn denture always produced most discomfort, the need for robust statistical planning is apparent.

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