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A Randomised Controlled Trial of complete denture impression materials

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ABSTRACT

Objectives: There is continuing demand for non-implant prosthodontic treatment and yet there is a paucity of high quality Randomised Controlled Trial (RCT) evidence for best practice. The aim of this research was to provide evidence for best practice in prosthodontic impressions by comparing two impression materials in a double-blind, randomised, crossover, controlled, clinical trial.

Methods: Eighty-five patients were recruited, using published eligibility criteria, to the trial at Leeds Dental Institute, UK. Each patient received two sets of dentures; made using either alginate or silicone impressions. Randomisations determined the order of assessment and order of impressions. The primary outcome was patient blinded preference for unadjusted dentures. Secondary outcomes were patient preference for the adjusted dentures, rating of comfort, stability and chewing efficiency, experience of each impression, and an OHIP-EDENT questionnaire.

Results: Seventy-eight (91.8%) patients completed the primary assessment. 53(67.9%) patients preferred dentures made from silicone impressions while 14(17.9%) preferred alginate impressions. 4(5.1%) patients found both dentures equally satisfactory and 7 (9.0%) found both equally unsatisfactory. There was a 50% difference in preference rates (in favour of silicone) (95%CI 32.7–67.3%, $p < 0.0001$).

Conclusion: There is significant evidence that dentures made from silicone impressions were preferred by patients.

Clinical significance: Given the strength of the clinical findings within this paper, dentists should consider choosing silicone rather than alginate as their material of choice for secondary impressions for complete dentures.

Trial Registration: ISRCTN 01528038.

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1. Introduction

Although the treatment of edentulous patients has been transformed by the introduction of implants, the barriers to implant treatment are known and have been explored in the literature.[1,2] The barriers are related to the cost of treatment, the fear of surgery and ageism. Even when implants were offered free, more than a third of the patients rejected this option.[3] 28% of edentulous patients were not suitable to receive implants in a clinical trial.[4] Although the best treatment option for patients often involves implants,[5,6] the current reality is that a majority of patients are unsuitable for implants or opt for non-implant treatment due to cost or fear of surgery. The option of traditional prosthodontics remains the staple provision for tooth replacement for many patients.

Given the high incidence in the use of non-implant treatment, there is a continuing need for high quality research evidence to inform the dentist and patients of the best methods of producing the required prosthesis. The systematic reviews of Jokstad[7] and of Harwood[8] show that it is in this area of clinical technique for traditional prosthodontics that there remains a particular paucity of high quality Randomised Controlled Trial's (RCTs). This lack of research has been highlighted by Carlsson.[9–11] Much of our knowledge of current ''best practice'' in prosthodontics is based on experience and tradition argued from a position of first principles rather than high quality evidence from RCT research. As a result our belief in what constitutes ''best practice'' can vary from one teaching tradition, one dental school, one culture, to another.

A survey of impression materials for complete dentures in the UK[12] demonstrated that the majority of dentists report the use of alginate as the material of choice for the definitive secondary impression material for complete dentures. This contrasts with the position both practiced and taught[13,14] in USA dental schools and found in UK private denture laboratories.[15] It is implied by these surveys that experts use alternatives to alginate. Dentists have a choice of materials for making dental impressions but there is a dearth of RCT evidence to inform their choice, highlighting the need for robust RCT research.

The primary aim for this RCT is to establish whether there is a patient preference for dentures produced from alginate or silicone impressions.The secondary objectives are

1. To assess the impact of dentures produced from alginate and silicone impressions on oral health related quality of life.
2. To assess comfort, stability and chewing efficiency for dentures produced from alginate or silicone impressions.
3. To assess patients' experience of having impressions made using alginate and silicone impression materials.

2. Method

This research was carried out in the Dental Translational Clinical Research Unit (DenTCRU) at Leeds Dental Institute, University of Leeds under the auspices of the Leeds Clinical Trial Research Unit (CTRU). It was a single centre, double-blind, randomised, controlled, crossover clinical trial of alginate and silicone impressions for complete dentures. Full details of the trial protocol can be found in the pre-published protocol paper.[16] There were no major deviations from the published protocol. Ethical approval was obtained through the UK Integrated Research Application System (IRAS) system from Leeds (West) Research Ethics Committee in February 2010 and written informed consent was obtained from all patients.

Eligible participants were edentulous adults aged 18 or over who required new complete dentures, were available for follow up and able and willing to complete the informed consent process. Patients were excluded if they had an oral tumour, required an obturator, had extreme xerostomia, had a known hypersensitivity to silicone or alginate or would benefit from selective pressure impressions.

A sample size calculation revealed that 76 patients would have 80% power to detect a difference in preference rates of 30% between the two dentures (30% versus 60%) at a significance level of 5%, assuming that 10% of patients express no preference. A total of 85 patients were recruited overall to allow for a dropout rate of 10%, consistent with previous studies.

All 85 patients were recruited from primary care referrals to the Leeds Dental Institute. Patients received two sets of dentures, one set of dentures made from impressions taken with silicone the other set made from alginate impressions.

Two sets of acrylic, spaced, and customised impression trays with stub handles and acrylic ''stops'' were constructed for each patient. The spacing of the customised trays was achieved in the usual way of adapting a layer of denture wax over the primary cast and constructing the customised trays over the wax.[17] Where there was deep hard tissue undercut on the casts this was reduced by blocking out the undercut in wax prior to laying down the spacer. The trays were identical and labelled A and B. During impression making, the trays which were used first (A or B) and the impression material which was used first (alginate of silicone) was randomised. The randomisation was blocked by variable block sizes to ensure balance between groups and concealed in sequentially numbered sealed envelopes by the CTRU statistician and securely stored in the randomisation locker at DenTCRU. The envelope containing the tray randomisations was opened by authorised members of the research team after the 'blind' adjustment of both sets of impression trays to remove over extensions.

The trays to be used for the alginate impression were border moulded with green stick impression compound (Kerr) in the usual way[17] and the alginate impressions taken (Xantalgin, Heraeus). The trays used for silicone impressions were border moulded in silicone, using heavy bodied for the upper (Extrude, Kerr) and regular bodied for the lower (Express, 3M ESPE) and the impression taken with light bodied silicone (Express, 3M ESPE). The border moulding materials selected were those advocated by expert opinion for each impression material.[17,18] A retrospective audit by Drago[19] was unable to detect a difference in the use of these materials for border moulding. The quality of the impressions was assessed by the clinician and by a second independent inspector. If either the clinician or the second independent assessor felt an impression was below an acceptable standard, the clinician re-took the impression.

The master casts were poured in the dental laboratory and the casts cleaned to remove all traces of impression material.