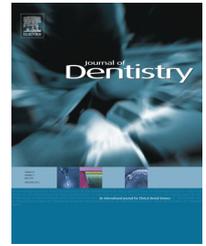


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A Randomised Controlled Trial of complete denture impression materials

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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 Jokstad⁷ and of Harwood⁸ 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 UK¹² 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 or 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 way¹⁷ 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, 3MESPE) 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 Drago¹⁹ 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.

The casts were allocated a number (blind to the clinician) which allowed the later identification of the dentures. At all subsequent stages of denture construction the clinician was blind to the impression material used.

The completed unadjusted dentures were labelled by random allocation with blue and red dots. The randomisation was blocked by variable block sizes to ensure balance between groups and concealed in sequentially numbered envelopes created by the statistician and securely stored in the randomisation locker at DenTCRU. Half the red dot dentures were from alginate impressions and half from silicone; similarly for the blue dot dentures. Patients were given both sets of unadjusted dentures and asked to follow a structured programme of alternate wearing of the dentures, starting with the red dentures, for a two-week 'Habituation Period'. Thus the dentures worn first during this period was determined by the randomisation defined by the colour code allocation. The 'Habituation Period' allowed patients to become accustomed to the new dentures and assess their preference for the unadjusted dentures (primary outcome).

Following the initial assessment of the dentures (primary outcome) the dentures were relabelled by green or yellow coloured dots by randomised allocation. It was blocked (variable block sizes) and balanced for order of testing in the initial 'Habituation Period'. This was administered centrally by the CTRU using an automated 24-h telephone system. Patients then wore the newly coded dentures sequentially in 2 periods of 8 weeks each ('Adjustment Period'), during which time, the patients returned to the DenTCRU for any adjustments they required. All necessary adjustments were made by a second independent, blind clinician. The 1:1 randomisation coded by the yellow or green dots established the order of testing during the 'Adjustment Periods'. The patients and the clinical team were blind to these allocations. Finally, patients took both sets of dentures for a final two week period ('Confirmation Period') at the end of which they returned for the final assessment.

The primary outcome assessed was:

1. The patients' preference for the unadjusted dentures following the 2 weeks 'Habituation Period'.
Secondary outcome assessments were:
 1. Patient perception of denture comfort, stability and chewing efficiency of the dentures using 5-point Likert scales.
 2. Patients' preference for the adjusted dentures following the 2 week 'Confirmation Period'.
 3. OHIP-EDENT questionnaires assessing the patient oral health related quality of life following each Adjustment Period.
 4. Patient perception of comfort and taste of each impression material using 5-point Likert scale at the impression stage.
 5. Patient preference for the impression of materials at the impression stage. Baseline OHIP-EDENT questionnaires were completed by the patients prior to denture construction.

2.1. Statistical methods

The comparison of the proportions of patients preferring dentures made from alginate impressions to those preferring

dentures made from silicone impressions was presented in a 2×2 table for paired data and analysed using McNemar's test. This analysis was used at both the primary end point (after the habituation period, for the unadjusted dentures) and at the end of the trial (for the adjusted dentures). OHIP-EDENT scores were analysed using a Wilcoxon Rank Sum test to compare scores between denture impression materials (due to non-normality of the data). The period and carry-over effects were also tested using Wilcoxon Rank Sum tests. Assessments of the Likert scale assessments of the dentures used the Wilcoxon test for matched pairs.

3. Results

Eighty-five patients were recruited from April 2010 to April 2012; follow-up finished January 2013. 59 (69.4%) of the patients were female, 77 (90.6%) white, with a mean age of 69.4 (SD 10.87). Fig. 1 shows a flow diagram of patients' progression through the trial. There were no serious unexpected adverse events that were related to trial procedures.

3.1. Primary outcome

78 (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 who 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%, $p < 0.0001$ McNemar's test) Table 1.

3.2. Secondary outcomes

1. After the 'Habituation Period' (i.e. before substantial denture adjustment), the patient reported assessment of the 'Comfort', 'Stability' and 'Chewing Efficiency' of the dentures showed significant evidence that unadjusted dentures made from silicone impressions were rated as more comfortable ($p = 0.0039$), more stable ($p = 0.0047$) and more efficient for chewing ($p < 0.0001$) than unadjusted dentures made from alginate impressions (Table 2).
2. After the confirmation period there was a 33.8% difference in preference rates for the adjusted dentures (in favour of silicone) (95% CI 14.3–53.3%, $p = 0.0016$) (see Table 1).
3. After the 'Confirmation' period, the patient reported assessment of the 'Comfort', 'Stability' and 'Chewing Efficiency' of the dentures showed there was again no evidence of a difference in comfort rating between silicone and alginate impression materials ($p = 0.5417$). However, there was significant evidence that dentures made from silicone impressions were rated as more stable ($p = 0.0066$) and more efficient ($p = 0.0010$) than dentures made from alginate impressions after adjustment (see Table 2).
4. After wearing the dentures for the two 8 week Adjustment Periods, there was significant evidence that the OHIP-EDENT score was lower (better oral health related quality of life) after wearing dentures made with silicone impressions materials with a median reduction in score of 5.5 units

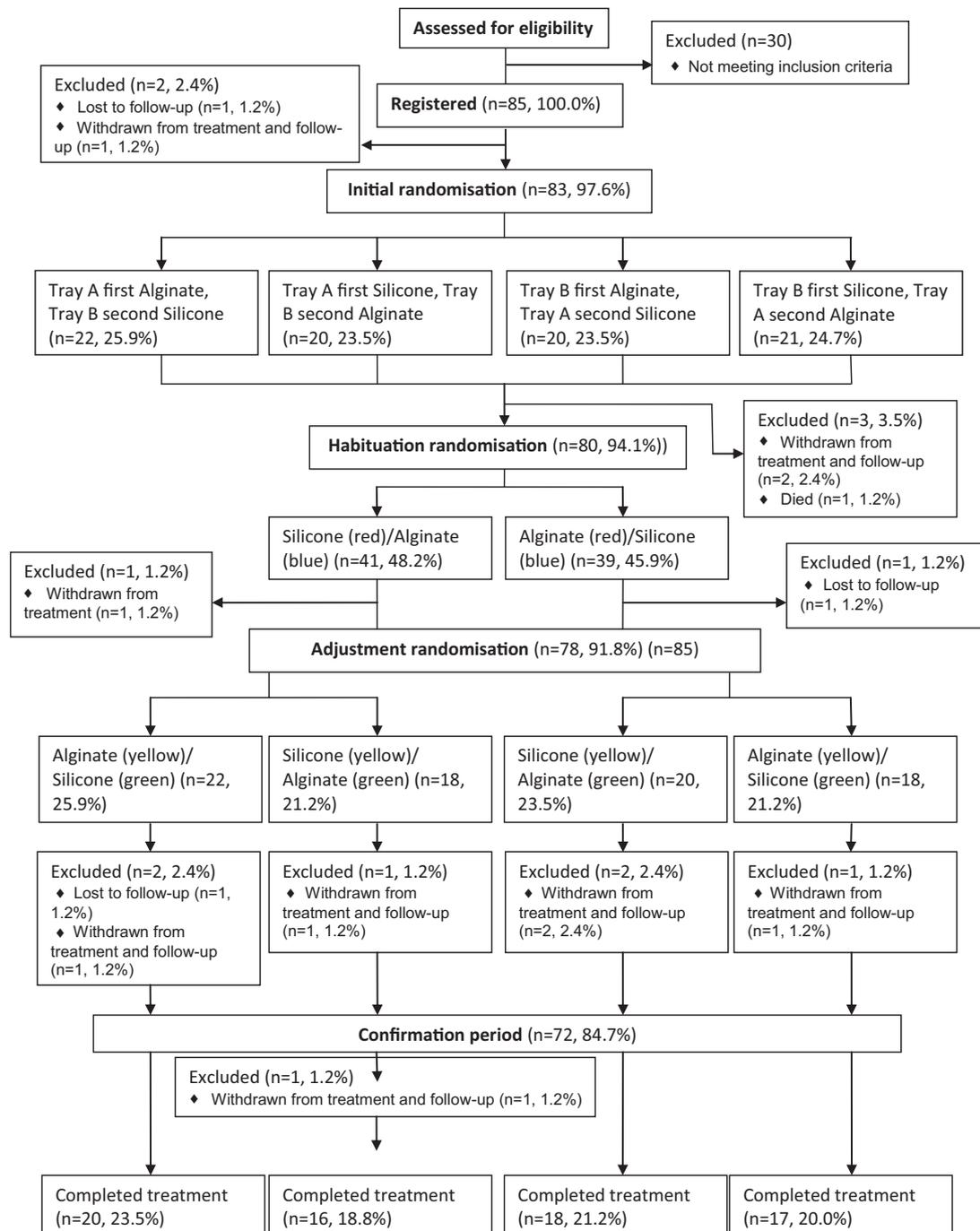


Fig. 1 – CONSORT flow diagram showing patients progression through the phases of the trial.

($p = 0.0014$) (see Table 3). There was no evidence of a period effect ($p = 0.2105$) or carry-over effect ($p = 0.5295$).

- There was significant evidence from the patient reported Likert scores that silicone impressions were more comfortable than alginate impressions ($p = 0.0021$) but no evidence of a difference in taste between the two impression materials ($p = 0.1128$). An additional post hoc statistical analysis using McNemar's test showed there was a 28.9% difference in patient preference rates for having their impression taken in silicone (95% CI 11.1–46.8%, $p = 0.0027$).

4. Discussion

This trial has produced definitive answers to a pertinent clinical question. Previous attempts at RCTs for dental impression materials have been scarce^{20,21} and have not yielded definitive answers to their research questions. Thus the lack of RCTs of impression materials is compounded by the inability of previous RCTs to find a clinically significant difference between the impression materials. This inability of

Table 1 – Patient preference of the dentures before and after adjustment.

	Silicone		Total
	Prefer/satisfactory	Not prefer/unsatisfactory	
<i>Patient denture preference before denture adjustment (after Habituation Period)</i>			
Alginate			
Prefer/satisfactory	4 (5.1%)	14 (17.9%)	18 (23.1%)
Not prefer/unsatisfactory	53 (67.9%)	7 (9.0%)	60 (76.9%)
Total	57 (73.1%)	21 (26.9%)	78 (100.0%)
	Silicone		Total
	Prefer/satisfactory	Not prefer/unsatisfactory	
<i>Patient denture preference after denture adjustment (after Confirmation Period)</i>			
Alginate			
Prefer/satisfactory	7 (9.9%)	17 (23.9%)	24 (33.8%)
Not prefer/unsatisfactory	41 (57.7%)	6 (8.5%)	47 (66.2%)
Total	48 (67.6%)	23 (32.4%)	71 (100.0%)

Table 2 – Differences in comfort, stability and chewing efficiency of dentures by Likert scores.

A total of 80 patients reached Habituation	Comfort N (%)	Stability N (%)	Efficiency N (%)
<i>Before denture adjustment (after Habituation Period):</i>			
Difference in score (Silicone–Alginate)			
–4 to –2	19 (23.8%)	15 (18.8%)	18 (22.5%)
–1	21 (26.3%)	16 (20.0%)	16 (20.0%)
0	25 (31.3%)	38 (47.5%)	40 (50.0%)
1	4 (5.0%)	3 (3.8%)	0 (0.0%)
2–3	9 (11.3%)	6 (7.5%)	4 (5.0%)
Missing	2 (2.5%)	2 (2.5%)	2 (2.5%)
Total	80 (100.0%)	80 (100.0%)	80 (100.0%)
A total of 72 patients reached Confirmation	Comfort N (%)	Stability N (%)	Efficiency N (%)
<i>After denture adjustment (after Confirmation Period):</i>			
Difference in score (Silicone–Alginate)			
–4 to –2	10 (13.9%)	10 (13.9%)	12 (16.7%)
–1	12 (16.7%)	16 (22.2%)	12 (16.7%)
0	30 (41.7%)	35 (48.6%)	39 (54.2%)
1	12 (16.7%)	7 (9.7%)	6 (8.3%)
2–3	7 (9.7%)	3 (4.2%)	2 (2.8%)
Missing	1 (1.4%)	1 (1.4%)	1 (1.4%)
Total	72 (100.0%)	72 (100.0%)	72 (100.0%)

Table 3 – Overall and domain OHIP-EDENT scores by impression material.

		Alginate N = 78	Silicone N = 78
<i>Overall OHIP-EDENT score</i>			
Overall score:	Median (range)	38.5 (2, 75)	27.0 (0, 69)
	Missing	6	6
<i>Domain OHIP-EDENT score</i>			
Function limitation:	Median (range)	9.0 (0, 12)	7.0 (0, 12)
	Missing	5	5
Pain:	Median (range)	11.0 (0, 16)	8.0 (0, 16)
	Missing	6	5
Psychological discomfort:	Median (range)	3.0 (0, 8)	2.0 (0, 8)
	Missing	5	5
Physical disability:	Median (range)	7.0 (0, 12)	5.0 (0, 12)
	Missing	6	6
Psychological disability:	Median (range)	2.0 (0, 8)	2.0 (0, 8)
	Missing	5	6
Social disability:	Median (range)	2.0 (0, 12)	0.0 (0, 11)
	Missing	5	6
Handicap:	Median (range)	0.0 (0, 8)	0.0 (0, 8)
	Missing	5	6

prosthodontic RCTs to detect a difference extends to areas beyond RCTs of impression materials.

In addition to the trials of impression materials, there have been a number of prospective RCTs which have addressed the issue of 'simplified' denture impression techniques compared to conventional techniques.²²⁻²⁵ The 'simplified' single stage impression in a stock tray compared with various two stage impression techniques showed no significant difference between the trial arms. Of course the inability to detect a difference should not automatically lead to the assumption of equivalence; absence of evidence is not evidence of absence.²⁶ None of these trials were designed as an equivalence study (which have particular design issues to avoid establishing equivalence through poor adherence and underpowering amongst other issues²⁷). It may also be that the protocols used were incapable of detecting a clinically significant difference. Protocols for prosthodontic trials would benefit from a wider discussion in academic literature.

Currently, there are a number of issues with prosthodontic protocols that may provide underlying reasons why clinically significant differences are not produced in RCTs. Prosthodontic trials can have numerous specific confounding variables such as patient related factors (e.g. ridge form, saliva flow, mucosal quality, patient expectation, psychological profile, perceived aesthetics), technical construction factors (e.g. occlusal form, impression technique, processing methods, different technicians/technical procedures, the full use, or not, of the recorded sulcus depth) and dentist related factors (e.g. ability, education, number of clinicians, velocity of seating of the impression).

Randomisation by minimisation will usually reduce the potential impact of these variables, however the particular nature and volume of potential prosthodontic confounders does mean this problem is more pronounced in this field and parallel group RCTs will need very large numbers of patients to eliminate the problem. Alternatively, a cross over protocol (where patients effectively become their own control) using a very careful denture duplication protocol²⁸ will eliminate many potential confounders, ensuring that the only difference between the two sets of dentures is the single issue under investigation.

The results reported within this paper have shown that patients' perceptions of their dentures in relation to comfort were changed after the adjustment of the dentures; this was anticipated as a potential effect of adjustment. The results show that before adjustment the patients rated the silicone dentures as more comfortable than the alginate dentures, whereas after adjustment the trial was unable to detect a significant difference in the patients' assessment of comfort. Adjusting the dentures effectively eliminated a difference in comfort ratings between the dentures. In other trials,^{22,24,25} the use of assessment at the post-adjustment stage alone (e.g. at 3 months and 6 months) coincides with a failure to differentiate between groups. Post adjustment assessments when reported on their own may not adequately describe the clinical situation. It is appropriate to report assessments both pre and post adjustment since both are clinically relevant. Where post adjustment assessments are reported on their own, it would be good practice to also report the extent of the adjustments required on each side of the trial, to allow the reader to assess if any preferential adjustment of the dentures has taken place.

Use of expert opinion and/or expert assessment of the quality of dentures in RCTs have been ineffective^{23,29} and may be inappropriate. There is a paradox here in using expert opinion (which is regarded as having low evidence value) to determine an outcome of an RCT (which is regarded as having high evidence value). Instead, it is proposed that blind, patient derived and patient centred outcome measures (for example, patients preferred denture, or OHIPs) are used as a more selective and clinically relevant primary outcome in future crossover trials.

The issue of simplified versus conventional dentures may be usefully broken down into two separate areas; the first related to simplified impressions and the second related to simplified occlusion. Doing so is useful since the two issues can and should be addressed separately. For instance it may be that separate investigations find that simplified occlusions are superior but simplified impressions are not (or vice versa). If the 'simplified technique' improves one aspect of denture construction but makes another aspect worse, the effects will cancel out and investigating both issues simultaneously in a single study will lead to confounded results. This is an area of potential future investigations and when correctly powered the protocols, from Heydecke³⁰ (for occlusion), Gray¹⁶ and Hyde³¹ provide a potential way forward.

In summary, there are problems designing effective protocols in the field of prosthodontic research. The authors of this paper take the view that the inability of prosthodontic RCTs to detect a clinical difference can be limited by a careful protocol design which includes:

1. a cross over randomisation,
2. a careful denture duplication process,
3. the blinding of clinicians and patients,
4. the reporting of both pre and post adjustment assessments and
5. a primary outcome measure centred on patient preference.

Following these principles this trial has differentiated between dentures constructed on secondary impression taken with either silicone or alginate. This protocol has potential to be a useful tool to look at other areas of prosthodontic treatment.

4.1. Clinical implications

In view of the strength of the outcomes of this trial, dentists should consider replacing alginate with silicone as the material of choice for secondary impressions for complete dentures.

5. Conclusions

1. Dentures made from silicone impressions were preferred by patients over dentures constructed from alginate impressions, both before and after the dentures were adjusted.
2. Overall patients preferred the experience of having impressions taken in silicone, finding silicone impressions more comfortable; however there was no preference for the taste of either material.
3. Patients' oral health related quality of life was better after wearing dentures made from silicone impressions.

4. Unadjusted dentures made from silicone impressions were more comfortable, stable and efficient for chewing.
5. After adjustment, the dentures made from silicone impressions remained more stable and efficient for chewing. However, the adjustment of the dentures resulted in no detectable difference in comfort between the dentures.

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