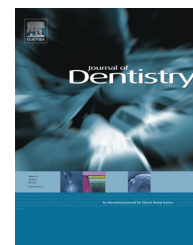


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## Cost-effectiveness of silicone and alginate impressions for complete dentures



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### ABSTRACT

**Objective:** The aim of this study was to assess the cost effectiveness of silicone and alginate impressions for complete dentures.

**Methods:** Cost effectiveness analyses were undertaken alongside a UK single centre, double blind, controlled, crossover clinical trial. Taking the perspective of the healthcare sector, effectiveness is measured using the EuroQol (EQ-5D-3L) which provides a single index value for health status that may be combined with time to produce quality adjusted life years (QALYs); and Oral Health Impact Profile (OHIP-EDENT). Incremental cost effectiveness ratios are presented representing the additional cost per one unit gained.

**Results:** Mean cost was higher in the silicone impression group (£388.57 vs. £363.18). Negligible between-group differences were observed in QALY gains; the silicone group had greater mean OHIP-EDENT gains. The additional cost using silicone was £3.41 per change of one point in the OHIP-EDENT. **Conclusions:** The silicone group was more costly, driven by the cost of materials. Changes in the EQ-5D and QALY gains over time and between arms were not statistically significant. Change in OHIP-EDENT score showed greater improvement in the silicone group and the difference between arms was statistically significant. Given negligible QALY gains and low level of resource use, results must be treated with caution. It is difficult to make robust claims about the comparative cost-effectiveness. **Clinical significance:** Silicone impressions for complete dentures improve patients' quality of life (OHIP-EDENT score). The extra cost of silicone impressions is £30 per patient. Dentists, patients and health care funders need to consider the clinical and financial value of silicone impressions. Different patients, different dentists, different health funders will have individual perceptions and judgements.

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## 1. Introduction

In common with many developed countries the proportion of adults in England who are edentate has fallen by 22% from 28% in 1978 to 6% in 2009.<sup>1</sup> However tooth loss is age related and these population wide figures mask the prosthodontic needs of an elderly population who require dentures; 15% of adults aged 65–74, 30% aged 75–84 and 47% aged >85 years are edentulous and require complete dentures.

Experts in prosthodontics concur that the quality of the dental impression is an important issue for improving the fit and comfort of a new denture. From the impression materials available, selection of material is left to the discretion of the dentist, who makes choices based on personal preference, experience, impression philosophy and the material used.<sup>2</sup> A survey of impression materials for complete dentures in the UK<sup>3</sup> demonstrated that the majority of dentists used alginate as the material of choice for the definitive impression material for complete dentures. This contrasts with the position both practiced and taught in USA dental schools where experts use silicon as a favoured alternative to alginate.<sup>2,4</sup> Although impression materials differ in many aspects, there was no evidence from randomised controlled trials (RCTs) to conclude that the clinical long-term outcome of dentures fabricated using varying materials and methods would differ significantly.<sup>5</sup> Similarly there is little evidence regarding the cost-effectiveness of different impression materials, which is important to assess which material provides the best value for money. Indeed, only two randomised controlled trials were found in the field of complete denture impression materials but neither built cost considerations into their analysis.<sup>6,7</sup>

A single-centre, randomised controlled cross-over trial was undertaken to establish the effectiveness and cost-effectiveness of the use of silicone vs. alginate, and to fill in the evidence gap for best practice. This paper reports on the cost-effectiveness analyses.

The aim of this study was to assess the cost effectiveness of silicone and alginate impressions for complete dentures.

## 2. Method

The cost effectiveness analysis (CEA) was conducted in parallel with the crossover RCT in the UK between October 2009 and December 2012. Full details of the RCT protocol and the clinical outcomes are reported elsewhere.<sup>8</sup> Within the RCT each patient received two sets of dentures; made using either alginate or silicone impressions.

The CEA takes the perspective of the UK NHS health care system. This includes the cost of resources used to construct the dentures, costs of adjustments made for both dentures and other health service costs resulting from problem with the dentures (for example, GP visits). Within the analyses, the effectiveness component of the cost effectiveness analysis is assessed in two ways; using the EQ-5D-3L, a measure of generic health related quality of life,<sup>9</sup> which provides a single index value for health status that is combined with time to produce quality adjusted life years (QALYs)<sup>10</sup>; and the Oral Health Impact Profile (OHIP-EDENT), a condition specific

health related quality of life measure adapted for use with edentulous individuals.<sup>11</sup> The second analysis was included due to concerns that the EQ-5D may not be sensitive enough to detect changes in this population.

Each patient was followed from baseline to the end of the second denture adjustment period. Data was collected prospectively and retrospectively. Prospectively, clinical dental staff recorded the procedures undertaken and the time taken. This included assessment, undertaking the impressions and any adjustments. Data on patients' use of other healthcare as a result of their dental care were collected using patient self-reported questionnaires administered within the dental clinic at baseline, 2 weeks assessment and at the end of each 8 weeks assessment periods. Costs were obtained from national sources and where necessary adjusted to 2012 prices using the CCEMG–EPPi Centre Cost Converter.<sup>12</sup> Details are given in Table 1.

Patient responses to the EQ-5D, at baseline, the end of period 1 and the end of period 2, were converted to health-state utility values using the UK tariff values<sup>13</sup> and an area under the curve approach. These values were then multiplied by duration (56 days) of using each denture and divided by 365 to estimate QALYs. QALYs represent a quality-weighted survival value in which 1 QALY is the equivalent of 1 year of full health. The OHIP-EDENT questionnaire has 19 items that are rated on five-point Likert-type scales (range: 0 = never to 4 = very often). The total score of the scale ranges between 0–76 points, with lower scores indicating better oral health-related quality of life (OHRQoL). Sum scores were calculated without item weighting.<sup>14</sup>

There were no missing values of EQ-5D over time. For the small number of missing OHIP-EDENT data the missing items were imputed using the overall medians by treatment over time. One patient was excluded in our OHIP-EDENT analysis because the percentage of missing items was greater than 50%. Similarly missing data for costs was minimal; we applied mean imputation by treatment to deal with these missing data. Descriptive statistics of costs, EQ-5D and OHIP-EDENT scores were calculated for each arm of the trial. Crossover statistical analysis was performed using the *pkcross* routine in STATA 12 software (StataCorp LP, College Station, TX) to evaluate differences in health-related quality-of-life scores between groups. One-way analyses of variance (ANOVA) and Fisher's least significant difference were applied to estimate overall mean, period effects, treatment effects, and carry-over effects.

All patients who did not withdraw in the trial were included. The outcome of the CEA was an incremental cost per QALY/OHIP-EDENT point. We present incremental cost-effectiveness ratios (ICERs) representing the ratios of the incremental cost and incremental benefits (QALYs/OHIP-EDENT points) between silicone and alginate impressions. The ICER represents the additional cost per one unit of outcome gained, in this case per QALY gained (OHIP-EDENT lost) for silicone vs. alginate. In the UK as a guideline, the National Institute for Health and Care Excellence (NICE) accepts as cost-effective those interventions with an ICER of <£20,000 per QALY. NICE states that, in general, if a treatment costs >£30,000 per QALY it would not be considered cost-effective.

**Table 1 – Unit costs.**

Services	Unit cost	Source	Note
GP, surgery visit (face to face)	£43.29	(Curtis, 2012) <sup>21</sup> – p183 – with qualification per minute (£3.70). Including direct care staff costs	Average visit time is 11.7 min (PSSRU p. 182) (£3.70 × 11.7)
GP, surgery visit (tel/email)	£26.27	(Curtis, 2012) <sup>21</sup> – p183 – with qualification – lasting 7.1 min	
GP, home visit	£110.00	(Curtis, 2012) <sup>21</sup> – p183 – with qualification – per visit (Inc. travel time)	Per out of surgery visit lasting 23.4 min
District nurse, home visiting	£27.30	(Curtis, 2012) <sup>21</sup> – p175/183 – with qualification – per visit (Inc. travel)	£70 per hour. Assume visit time is same as GP out of surgery, i.e. 23.4 min (70/60*23.4)
District nurse, patient-related work	£6.86	(Curtis, 2012) <sup>21</sup> – p175 – with qualification – per contact	Assume contact is telephone call and is same length as GP = 7.1 min (58/60*7.1)
Hospital inpatient stay	£586.00	(Curtis, 2012) <sup>21</sup> – p109. Non-elective inpatient stays (short stays)	
Hospital A&E – leading to admitted	£152.00	(Lloyd-Jones et al., 2009) <sup>22</sup> – dental care – HRG code: VB10Z	
Hospital A&E – not leading to admitted	£68.00	(Lloyd-Jones et al., 2009) [22] – dental care – HRG code: VB10Z	
Hospital general outpatient clinic – dental medicine specialties	£105.00	(Lloyd-Jones et al., 2009) <sup>22</sup> – outpatient attendances – service code: 450	
Lab cost: full upper or lower only with standard teeth (2× for F/F)	£167.05	Mgill website ( <a href="http://www.mgill.co.uk/Price_list/index.html">http://www.mgill.co.uk/Price_list/index.html</a> ), November 2012	
Salary	Per hour	Year	Source
Dentist (NHS, England)	£32.87	2011	2012 (adjusted for inflation) (CCEMG – EPPI-centre cost converter, 2013)
			Pay circular (M&D) 1/2011 and PSSRU p. 182
Overheads			
		% of income	Dentist (NHS, England) as above
Wages and NI (per hour)		17.42%	£33.69
Overheads (per hour)		12.77%	£24.70
Cost of materials	Per bag/box	Per patient	Item
1	£10.99	£0.79	Heraeus/Kulzer Xantalgin select refill bag 500 g (10.99/14)
2	£16.89	£2.41	Impression compound stick Kerr Greenper box (16.89/7)
3	£24.59	£1.64	GC Europe iso functional stick Pink 120 g box (24.59/15)
4	£77.29	£7.73	3 M Espe Express 2 regular body Quick set 4 × 50 ml (77.29/10)
5	£45.99	£6.57	Kerr Extrude Purple 2 × 50 ml & tips (45.99/7)
6	£77.29	£19.32	3 M Espe Express 2 light body standard Quick set 4 × 50 ml (77.29/4)
Total		Per patient	Notes
Alginate (1,2,3)	£4.84		(Green stick and pink stick impressions cost (2.41 + 1.64 + 0.79)
Silicone (3,4,5,6)	£35.26		(Heavy medium and light) and pink stick impression cost (1.64 + 6.57 + 19.32 + 7.73)

Sensitivity analyses were carried out to account for uncertainty in the cost values. We performed the sensitivity analysis by adding and subtracting 20% of the cost and assessing the subsequent impact on the ICERs. The value of 20% is essentially arbitrary but it was considered likely to represent any uncertainty that might exist in parameter values.

### 3. Results

85 patients were recruited, of which, 13 patients withdrew (2 prior to the randomisation, 4 at baseline, 4 at the 2-week assessment period, 2 at the first 8-week assessment period, 1 at the second 8-week assessment period), and 1 patient died unrelated to trial procedure. Thus 71 participants are included,

34 were randomised to the silicone group and 37 to the alginate group in period 1; groups received the treatment in the reverse order in period 2. Cost data at baseline was available for all 71 participants. At the first 8-week assessment period EQ-5D and OHIP-EDENT were available for all 71 participants (34) silicone, (37) alginate. At the second 8-week follow-up, EQ-5D were available for all participants (37) silicone, (34) alginate. OHIP-EDENT were available for 70 participants (36) silicone, (34) alginate. The participants had a mean age of 72 (range: 40–89) and 70.4% were female. The ANOVA showed no period effect in costs, EQ-5D or OHIP-EDENT ( $P = 0.24, 0.28$  and  $0.12$ , respectively).

Table 2 shows the mean time spent by the dentist together with the mean cost for construction and adjustment of the dentures. The time for primary impression, jaw registration, try in and fit is common to both the silicone and alginate arms

**Table 2 – Procedures and costs.**

Resource	Silicone		Alginate	
	Time (min)	Cost (£)	Time (min)	Cost (£)
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
<b>Baseline</b>				
Primary impression	5.74 (2.42)	5.75 (2.33)	5.74 (2.42)	5.75 (2.33)
Secondary impression	17.05 (3.64)	16.59 (3.54)	16.63 (4.29)	16.19 (4.18)
Jaw registration	12.84 (5.13)	12.49 (4.99)	12.84 (5.13)	12.49 (4.99)
Try in	7.52 (5.60)	7.32 (5.45)	7.52 (5.60)	7.32 (5.45)
Fit	8.27 (6.14)	8.05 (5.98)	8.27 (6.14)	8.05 (5.98)
Other	8.58 (6.16)	8.35 (5.99)	8.58 (6.16)	8.35 (5.99)
<b>Adjustment periods</b>				
Trimming and polishing	7.88 (5.44)	7.68 (5.30)	7.77 (6.49)	7.56 (6.31)
Rebase/reline (1st appointment)	0.29 (1.74)	0.29 (1.69)	0.00	0.00
Rebase/reline (2nd appointment)	0.01 (0.04)	0.01 (0.04)	0.59 (4.51)	0.58 (4.39)
Chairside adjustment of occlusal errors	0.15 (0.72)	0.14 (0.70)	0.28 (1.29)	0.27 (1.26)
Check record (adjustment of occlusal errors)	0.00	0.00	0.00	0.00
Lab based occlusal adjustment	0.00	0.00	0.00	0.00
Other	0.83 (2.80)	0.81 (2.73)	0.19 (0.45)	0.18 (0.44)
Subtotal	8.97 (5.13)	8.73 (4.99)	8.75 (7.16)	8.52 (6.97)
Material	N/A	35.26	N/A	4.84
Total		44.09		13.36
(SD)		(4.99)		(6.97)
N		71		71

of the trial; as is the cost of construction of the dentures. The difference lies in the time taken for the secondary impression (the difference between the time taken for the secondary impression by each arm is not significant ( $P = 0.897$ )). There is no statistically significant difference in the total number of visits for adjustments between the silicone group and the alginate group: 62 in the silicone group (61 in the alginate group) visits for trimming and polishing, 11<sup>8</sup> visits for the first appointment of rebase/reline, 7<sup>8</sup> visits for the second appointment of rebase/reline, 9<sup>9</sup> visits for chair side adjustment of occlusal errors, and 17<sup>15</sup> visits for other issues, respectively.

Commercial construction of the dentures was £334.1 which includes laboratory cost (full upper or lower only with standard teeth, 2 × FF). Table 2 gives details of the procedures undertaken and associated costs. The extremely short time reported in the adjustment periods was not for individual time. This is a range of values for the mean time containing all the values of zero spent in remedial treatment for all patients in which the majority of patients required little adjustment or remedial work.

There was little reported use of healthcare associated with problems with dentures. Two GP visits were recorded in the silicone group (one face to face and 1 telephone) and 1 outpatient visit, and 2 GP visits (face to face) and 4 outpatient visits in the alginate group.

The total mean per patient costs (including the initial cost of construction) is 388.57 (16.33) for the silicone arm and £363.18 (44.56) for the alginate arm. The difference in total costs between two arms is statistically significant at 99% level (mean difference 25.39, CI: -288.47 to 103.87).

Wilcoxon rank-sum test indicated that changes in EQ-5D over time were not statistically significant, but changes in OHIP-EDENT score were at 95% level. In general, the results indicated small fluctuations in EQ-5D throughout the trial period, making it difficult to draw conclusions about the impact of denture materials on generic health-related quality

of life. Table 3 shows the mean difference between baseline OHIP-EDENT scores and follow-up was around 15 in the silicone group and 8 in the alginate group.

Differences in QALY gains between groups were minimal. Within ICER calculations if the intervention costs are higher and the intervention is less effective than the comparator, the intervention is said to be dominated by the comparator. In this case the silicone group was dominated by the alginate group because the silicone group had the lower QALY gains and the higher mean total cost over the trial. Table 4 provides the cost-effectiveness results, showing the incremental costs and benefits as well as the ICERs for each group. Interpretation should be tempered given negligible between group differences observed in QALY gains. In respect of the OHIP-EDENT the silicone group had the more OHIP-EDENT gains and higher mean total costs. The ICER shows a cost of £3.41 per change of one OHIP-EDENT point.

**Table 3 – EQ-5D and OHIP-EDENT scores.**

		EQ-5D	
		Silicone	Alginate
Baseline	Mean (SD)	0.73 (0.27)	0.73 (0.27)
	N	71	71
Follow-up	Mean (SD)	0.71 (0.34)	0.77 (0.26)
	Change	Mean (SD)	-0.02 (0.23)
		OHIP-EDENT	
Time point		Silicone	Alginate
Baseline	Mean (SD)	44.20 (17.61)	44.07 (17.52)
	N	70 <sup>a</sup>	71
Follow-up	Mean (SD)	28.64 (18.92)	36.17 (19.58)
	Change	Mean (SD)	-15.56 (20.51)

<sup>a</sup> One patient with missing values of >50% items was excluded.

**Table 4 – Between-group comparisons of cost-effectiveness.**

Treatment	Costs (£)			QALY			Cost/effectiveness ratio (£/QALY)
	Mean	SD	Between-treatment increment	Mean	SD	Between-treatment increment	
<b>Overall</b>							
Alginate (N = 71)	363	43	26	0.06	0.02	-0.004	-5.758 (alginate dominates)
Silicone (N = 71)	389	16		0.05	0.02		
Treatment	Costs (£)			OHIP points			Cost/effectiveness ratio (£/OHIP)
	Mean	SD	Between-treatment increment	Mean	SD	Between-treatment increment	
<b>Overall</b>							
Alginate (N = 71)	363	43	26	36.17	19.58	7.53	3.41
Silicone (N = 70)	389	18		28.64	18.92		

To address uncertainty around mean incremental costs and effectiveness, we conducted sensitivity analyses and non-parametric bootstrapping. Univariate sensitivity analysis varied the cost of one material by 20% at a time while keeping the other constant at base-case value. In order to assess how a simultaneous change of costs of two materials affected the ICER, we also varied the costs of both materials by 20%. Only two scenarios showed silicone to dominate; where the costs of the alginate were increased by 20%, and where the costs of the silicone were decreased by 20%.

#### 4. Discussion

Overall, the mean healthcare costs associated with provision of the dentures and associated healthcare use by the patients was higher in the silicone impression arm than the alginate arm (£388.57 vs. £363.18). This difference was almost entirely driven by the higher cost of the silicone impression materials (£35.26 vs. £4.84); this was reflected in the sensitivity analyses. Few patients reported use of other healthcare services as a result of problems with their dentures and there was little difference between the number of dental appointments for adjustment or time required within dental appointments during the assessment periods. This is in line with previous studies.<sup>7</sup> Wilcoxon rank-sum test indicated that the changes in EQ-5D over time were not statistically significant but changes in OHIP-EDENT score were, with silicone showing the better results. The EQ-5D instrument has been reported to have adequate construct and convergent validity, but may not be as sensitive as specific measures of oral health-related quality of life.<sup>15-17</sup> The differences reported here between general health and oral health shed light on the relatively few previous studies that relate oral health to health utility and to cost utility. In general, the results indicated small fluctuations in EQ-5D throughout the trial period, making it difficult to draw conclusions about the impact of denture materials on generic health-related quality of life. Given the apparent insensitivity of the generic preference based measure (EQ-5D) future research should explore development of an oral health related quality of life measure for use in cost-effectiveness analysis.

Dental care professionals may be unfamiliar with the interpretation of OHIP-EDENT scores, therefore an attempt to ascertain the magnitude of change that corresponds to a minimal important difference (MID) would interpret the clinical relevance of treatment effects. The MID is defined as “the smallest difference in scores in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient’s management”.<sup>18</sup> Allen et al.<sup>19</sup> suggest a 9 point difference in OHIP-20 score could be considered the MID for partially dentate patients. However, for a cross section of prosthodontic patients, including edentulous patients, John et al.<sup>20</sup> calculated the MID for the full OHIP-49 as 6 OHIP points (95% confidence interval of 2-9). In this trial, the mean difference between baseline OHIP-EDENT scores and follow-up was around 15 in the silicone group and 8 in the alginate group. Thus, differences in OHIP-EDENT gains between groups can be seen as beneficial to the patient. Moreover, the analysis showed an additional cost using silicone per patient of £3.41 per change of one point in the OHIP-EDENT and a MID is achieved within the additional cost of using silicone.

The clinical significance of these findings is a balance between the competing pressures of cost and delivering improved patient quality of life. Silicone impressions for complete dentures improve patients’ quality of life (OHIP-EDENT score). The extra cost of silicone impressions is £30 per patient. Dentists, patients and health care funders need to consider the clinical and financial value of silicone impressions. Different patients, different dentists, different health funders will have individual perceptions and judgements. The long-term outcome of patients with complete dentures is not known. Future research in this area is required to clearly project maintenance costs and effects observed over a longer time horizon as well as from a broad societal perspective by combining productivity loss and loss of earnings due to work absence and out of pocket expenses.

#### 5. Conclusion

The silicone arm was more costly, driven by the cost of materials. Little change was observed in generic health related quality of life; however, the change in OHIP-EDENT score



showed great improvement in the silicone arm and the difference between arms was statistically significant. Given the negligible QALY gains and low level of resource use, results must be treated with caution making it difficult to make robust claims about the comparative cost-effectiveness of either material.

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