Tooth loss is associated with numerous deleterious clinical and patient-centered outcomes. Measurement of oral health–related quality of life (OHRQoL) is a patient-centered outcome that can be used to measure the success of prostho-dontic interventions. While improvements in OHRQoL measured by questionnaires such as the Oral Health Impact Profile (OHIP) are not used as frequently for removable partial dentures (RPDs) as for fixed prostheses, RPDs have been shown to have a net beneficial impact on OHRQoL for patients.

Studies suggest that RPD wearers have worse OHRQoL than dentate, non–denture-wearing controls. However, patients with fewer than 20 remaining natural teeth and no dentures are half as likely to enjoy OHRQoL above the national median than people with fewer than 20 natural teeth who wear an RPD. Sufficient to say, the relationship among tooth loss, denture use, and OHRQoL is complex and may be impacted by a number of variables, such as the number and position(s) of missing teeth relative to the esthetic zone, age, and denture-wearing experience, to name but a few. Indeed, studies suggest that up to 25% of dentures are not used, particularly those that do not replace anterior teeth. Clinicians should also consider the risks of
introducing an RPD to the periodontal health of the remaining teeth due to increased plaque retention, which predisposes the dentition to periodontal inflammation, gingival bleeding, and attachment loss. Strategies to mitigate the effects of RPDs on the periodontium include prescription of a hygienic denture design, effective hygiene instruction, and regular supportive periodontal therapy. A balance of harm vs benefit must be considered whenever RPDs are prescribed, a principle referred to as “the removable partial denture equation.”

One factor that may influence outcome is denture material. A commonly used RPD material is cobalt-chromium alloy (Co-Cr), which is a rigid framework that allows masticatory forces to be distributed to the supporting abutment teeth. Proponents of more flexible framework materials cite stress dissipation as a potential advantage. Co-Cr traditionally requires the technique-sensitive and labor-intensive fabrication process of lost-wax casting. Alternative fabrication techniques, such as milling and injection molding, are being introduced for a range of novel materials, including nonmetallic high-performance polymeric materials (HPPs). HPPs are marketed as suitable alternatives to metals for dental applications, including fixed crowns, fixed partial dentures, implant components, and removable dentures. One such material is an aromatic semi-crystalline polymer known as polyether ether ketone (PEEK), which has been used as a spinal cage and joint replacement material.

With a low Young’s modulus of between 3 and 4 GPa, PEEK is considerably more flexible than metal RPD framework materials, which have a Young’s modulus of between 100 and 220 GPa. Authors have argued that rigidity can be detrimental, as clasps may distort under the stresses of normal function. On the other hand, with reduced flexural strength in the region of 100 MPa, the effectiveness of retentive clasps using PEEK are likely to be considerably weaker than metal clasps. The reduced tensile strength of PEEK at approximately 80 MPa compared to that of metals such as titanium and Co-Cr, which are in excess of 900 MPa, leaves the former more susceptible to fracture unless used in thicker sections, which may be less tolerable for patients. For clasp elements, minimum clasp thickness is suggested to be 2 mm, and the minimum height 3 mm. These parameters create the potential for increased plaque retention, and a concern for many clinicians is that this will leave patients more prone to periodontal complications. A systematic review published in 2016 suggested that while no clinical studies could be found evaluating the use of PEEK dentures, PEEK was likely to become a suitable alternative to Co-Cr RPDs.

The aim of this study was to answer the research question: In partially dentate patients, do PEEK frameworks improve OHRQoL? The working hypothesis was that they would improve OHRQoL. As this was the first opportunity to evaluate PEEK prostheses in a clinical trial, further exploratory questions were posed:

1. How do these improvements compare to improvements made with Co-Cr RPDs?
2. Is there a difference in denture satisfaction between PEEK and Co-Cr RPDs?
3. Is there a difference in the periodontal health impacts posed by PEEK RPDs compared to Co-Cr RPDs?
4. Which of the two materials do patients prefer?

MATERIALS AND METHODS

Study Design

Patients who required provision of new RPDs in the Department of Restorative Dentistry at the Charles Clifford Dental Hospital, Sheffield, UK, were invited to participate in a pilot randomized controlled crossover clinical trial comparing RPDs made of PEEK vs Co-Cr frameworks. Ethical approval for the trial protocol was provided by the NHS National Research Ethics Service (REC reference 13/YH/0403). The clinical trial was registered with the US National Library of Medicine (ClinicalTrials.gov identifier: NCT01953991).

The following inclusion criteria were applied:

- Adults aged 18 or over
- Absence of three or more teeth in one or both dental arches (excluding third molars) for which an RPD would be a restorative option
- Patients with a stable oral condition with absence of active primary disease and peri-radicular pathology
- Patients with or without experience of denture use

Patients with active primary disease, pulpal or peri-radicular pathology, and those without capacity to consent for treatment were excluded from the trial. All participants were provided with one set of RPDs made with a Co-Cr framework and one set made with a PEEK framework. RPDs were fabricated in two specialist dental laboratories: an in-house production laboratory at the Charles Clifford Dental Hospital and at Reger Zahn-technik in Nürnberg, Germany.

Design parameters have been suggested for PEEK frameworks and evaluated in in vitro studies. The designs of both Co-Cr and PEEK frameworks are similar, though PEEK frameworks use more tooth support and generally avoid gingivally approaching clasps, favoring shorter clasp assemblies that engage more undercuts. After a 2-week acclimation period to ensure quality of
Denture Fabrication
Denture design was carried out prior to the fabrication of any framework materials and after setting the desired path of denture insertion. PEEK frameworks were digitally designed and milled using JUVORA Dental Discs. Co-Cr frameworks were conventionally designed with wax patterns prior to investing and casting. Reinforced polymethyl methacrylate teeth (Natura, Schottlander) were used for both dentures. Consistency of tooth positions was assured by indexing the same tooth set-up after try-in on the working cast for each denture prior to fabrication of the frameworks.

Outcome Measures
OHRQoL was measured using the 20-item Oral Health Impact Profile (OHIP-20). The OHIP-20 includes items about difficulty chewing, discomfort when eating, and comfort with dentures and is considered to be sensitive to changes resulting from RPD provision. Each item on the OHIP-20 is scored with a Likert scale ranging from 0 to 4 (0 = never, 4 = very often). Total scores range from 0 to 80 points, with higher scores indicating worse OHRQoL. In accordance with the best evidence from confirmatory factor analysis of the OHIP-20 and to avoid erroneous findings resulting from multiple tests, individual domain scores were not separately analyzed; therefore, the changes in total OHIP-20 score from baseline to 4 weeks for both framework testing periods was used for comparative analyses.

The McGill Denture Satisfaction Questionnaire (MDSQ) was completed by the participants at the 4-week follow-ups for both the Co-Cr and PEEK RPDs. The MDSQ includes 17 items and is scored using a Likert scale ranging from 0 to 4 (0 = not at all satisfied/great difficulty, 4 = extremely satisfied/very easy). The MDSQ total score ranges from 0 to 68, with higher scores indicating better satisfaction.

Periodontal outcomes were measured at baseline and the 4-week, 6-month, and 1-year follow-ups. Periodontal indices were taken at six points: the mesial, mid, and distal points on both the buccal and lingual surfaces per each remaining tooth in each arch being restored. These measures included mean probing pocket depth (PPD) in millimeters measured using a clearly marked UNC-15 periodontal probe (Hu-Friedy), percentage of periodontal sites with pockets measuring ≥ 4-mm depth (% ≥ 4 mm), Gingival Bleeding Index (% sites with bleeding) (GBI), and Plaque Index (% sites with plaque) (PI), with measurements taken at 6 sites per remaining tooth.

Finally, patient preference was recorded as a binary choice between Co-Cr and PEEK.

Intrarater Reliability
A single calibrated examiner measured all periodontal indices. Test-retest reliability was calculated in a cohort of patients using intraclass correlation coefficient (ICC). ICC was greater than 0.9 for all continuous measures: PPD (0.98); % ≥ 4 mm (1.0); GBI (0.96); and PI (0.97).

Sample Size
Based on the primary research question (In partially dentate patients, do PEEK frameworks improve OHRQoL?), the minimum clinically important difference (MCID) in the OHIP-20 was used as the determinant of improved OHRQoL. This is determined as 9 points (SD 14.8) in partially dentate patients provided with RPDs, which indicates an anticipated effect size of 0.61 for demonstrating an MCID in PEEK RPDs from before to after treatment. Further, assuming α = .05 and 1 – β = 0.8, 24 patients would be required to demonstrate this difference.

Statistical Analyses
Normality of OHIP-20 and MDSQ scores was measured using Shapiro-Wilk (SW) test for normality. Both were normally distributed: OHIP-20 (SW = 0.963, degrees of freedom [df] = 52, P = .107), MDSQ (SW = 0.972, df = 50, P = .271).

Two-way repeated measures analysis of variance (ANOVA) was used to investigate the impact of framework material and time (baseline, 4 weeks) on the OHIP-20. After participants selected their preferred denture, a second repeated-measures ANOVA using preferred material and time (baseline, 4 weeks, 6 months, and 1 year) as factors was used to investigate changes in OHIP-20 over the 1-year follow-up.

Repeated-measures ANOVA was used to investigate differences in periodontal measures between denture materials over the 1-year follow-up. Comparison of MDSQ scores at the 4-week follow-up was made using paired-samples t test. Chi-square analyses were used to investigate differences in participant preferences. To
RESULTS

Thirty participants were assessed for eligibility. Four were excluded due to advanced levels of periodontal attachment loss rendering them unsuitable for account for multiple testing, the threshold for statistical significance was moved to \( P < .01 \).

Missing data were treated using the intention-to-treat protocol with missing values imputed using the last observed value carried forward.
Clinical Research

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Tooth-supported RPDs. Twenty-six of the participants gave written informed consent for participation. The CONSORT (Consolidated Standards of Reporting Trials) flowchart in Fig 1 shows the number of participants seen at each stage of follow-up and reasons for any loss to follow-up. Baseline participant characteristics are shown in Table 1. Figure 2 shows examples of both the PEEK and Co-Cr dentures for the same case.

OHRQoL

There was a significant main effect of time when evaluating trends from baseline to 4 weeks ($F \{df\} = 31.30 \{1\}, P < .001$) and from baseline to 1 year ($F \{df\} = 16.92 \{3\}, P < .001$), indicating that both materials showed a statistically significant improvement in OHRQoL consistent with the MCID.

Material was not a significant factor when evaluating trends from baseline to 4 weeks ($F \{df\} = 0.106 \{1\}, P = .746$) or from baseline to 1 year ($F \{df\} = 0.24 \{3\}, P = .87$), indicating no significant difference between the two types of material in their effects on OHRQoL. Table 2 shows the mean score changes in the OHIP-20 at the 4-week, 6-month, and 1-year follow-ups. In all cases, the score change demonstrated improvement in OHRQoL compared to baseline.

Participant Preference

Table 3 shows the number of participants who preferred each denture material at the 8-week, 6-month, and 1-year follow-ups. There were no statistically significant differences in preference between the two dentures at 8 weeks ($\chi^2 \{df\} = 0.04 \{1\}, P = .841$), 6 months ($\chi^2 \{df\} = 0.43 \{1\}, P = .513$), or 1 year ($\chi^2 \{df\} = 0.47 \{1\}, P = .491$).

---

**Table 1** Baseline Characteristics at the Participant and Removable Partial Denture (RPD) Levels

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Mean, range (SD)</th>
<th>No. of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>64.8, 39 to 85 (12.4)</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>History of RPD use</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never worn RPD before</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Worn RPD before</td>
<td>21</td>
<td></td>
</tr>
<tr>
<td>RPD provided in the study</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mandibular RPD only</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Maxillary RPD only</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Maxillary and mandibular RPD</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>Total no. of remaining teeth (participant level)</td>
<td>14, 5 to 25</td>
<td></td>
</tr>
<tr>
<td>Total no. of abutment teeth (participant level)</td>
<td>7, 3 to 13</td>
<td></td>
</tr>
<tr>
<td>Baseline OHIP-20 total score</td>
<td>31.9, 2 to 73 (19.2)</td>
<td></td>
</tr>
<tr>
<td>Kennedy classification (denture level)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class 1</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>Class 2</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Class 3</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Class 4</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>No. of remaining teeth per arch (denture level)</td>
<td>7, 3 to 11</td>
<td></td>
</tr>
<tr>
<td>No. of abutment teeth per arch (denture level)</td>
<td>4, 3 to 9</td>
<td></td>
</tr>
</tbody>
</table>

OHIP-20 = Oral Health Impact Profile.

**Table 2** Mean Change (SD) in Oral Health Impact Profile (OHIP-20) Scores Over 1-Year Follow-up

<table>
<thead>
<tr>
<th>Follow-up period</th>
<th>PEEK</th>
<th>Co-Cr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline to 4 wk</td>
<td>12.4 (17.6)</td>
<td>14.0 (16.3)</td>
</tr>
<tr>
<td>Baseline to 6 mo</td>
<td>17.1 (15.8)</td>
<td>14.4 (21.7)</td>
</tr>
<tr>
<td>Baseline to 1 y</td>
<td>18.8 (14.6)</td>
<td>14.1 (20.3)</td>
</tr>
</tbody>
</table>

**Table 3** Framework Preferences of the Participants

<table>
<thead>
<tr>
<th></th>
<th>8 wk (n = 25)</th>
<th>6 mo (n = 21)</th>
<th>1 y (n = 19)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Co-Cr PEEK</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participants, n (%)</td>
<td>12 (48)</td>
<td>13 (52)</td>
<td>9 (43)</td>
</tr>
<tr>
<td></td>
<td>12 (57)</td>
<td>8 (42)</td>
<td>11 (58)</td>
</tr>
</tbody>
</table>

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Fig 2 Mandibular (a) Co-Cr and (b) PEEK RPDs for the same patient.
Table 4  Periodontal Health Measures From Baseline to Follow-up

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>4 wk</th>
<th>6 mo</th>
<th>1 y</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N/A</td>
<td>PEEK</td>
<td>Co-Cr</td>
<td>PEEK</td>
</tr>
<tr>
<td>PPD (mm), mean (SD)</td>
<td>1.7 (0.5)</td>
<td>1.4 (0.4)</td>
<td>1.8 (0.4)</td>
<td>1.4 (0.4)</td>
</tr>
<tr>
<td>% ≥ 4-mm PPD</td>
<td>3.8 (5.5)</td>
<td>1.7 (2.8)</td>
<td>3.6 (5.1)</td>
<td>1.4 (3.6)</td>
</tr>
<tr>
<td>Gingival Bleeding Index, %</td>
<td>10.7 (13.0)</td>
<td>6.4 (6.1)</td>
<td>9.3 (13.6)</td>
<td>5.4 (5.2)</td>
</tr>
<tr>
<td>Plaque Index, %</td>
<td>58.8 (20.0)</td>
<td>59.3 (21.5)</td>
<td>52.3 (24.1)</td>
<td>59.6 (19.2)</td>
</tr>
</tbody>
</table>

Denture Satisfaction
At the 4-week follow-ups, the mean MDSQ score was 19.8 points (SD 12.7) for PEEK RPDs and 17.9 points (SD 10.0) for Co-Cr dentures. While this indicates improved denture satisfaction scores for the PEEK dentures, there were no statistically significant differences between the two RPD materials (t [df] = 24 [0.753], P = .459; mean difference = 1.8 points; 99% CI –5.0 to 8.7 points).

Periodontal Health
Mean PPD, % ≥ 4 mm, GBI, and PI at the baseline, 4-week, 6-month, and 1-year follow-ups are shown in Table 4. There was no difference between materials in:

- PPD (F [df] = 0.82 [2.3], P = .461)
- % ≥ 4 mm (F [df] = 1.35 [2.4], P = .269)
- GBI (F [df] = 1.43 [2.1], P = .249)
- PI (F [df] = 0.07 [2.4], P = .956)

DISCUSSION
The primary aim of this study was to determine whether RPDs made from PEEK frameworks would improve OHRQoL. The changes in OHIP-20 scores seen with both denture materials were of a magnitude equivalent to at least the OHIP-20 MCID of 9 points. RPDs made with both Co-Cr and PEEK frameworks made improvements to OHRQoL to a degree greater than the MCID at the 4-week, 6-month, and 1-year follow-ups.

This was the first study to compare the use of high-performance polymer RPD frameworks against traditional Co-Cr alloy frameworks. As such, it provided an opportunity to explore secondary research questions and provide an estimate of the potential difference between the materials, which may be used to appropriately power a comparative study to detect a true difference. Secondary research questions related first to the difference in effect on OHRQoL between the materials. Denture material was found not to be a significant factor in the magnitude of OHRQoL improvement. It must be emphasized that this was a secondary outcome, and therefore the study was not powered to make such a direct comparison, though it does provide an estimate of difference for future research.

Other secondary questions are related to participant preference, denture satisfaction, and periodontal effects. Preferences were observed at the 4-week, 6-month, and 1-year follow-ups. The findings suggest that there was no difference between patients preferring Co-Cr or PEEK materials. There were also no significant differences between denture frameworks with respect to the denture satisfaction scores measured by the MDSQ. This suggests that the performance of PEEK denture frameworks was as good as that of Co-Cr. The MDSQ has been widely used to measure both masticatory and denture satisfaction outcomes in fixed and removable prosthodontics research. In most cases, it has been scored with a visual analog scale (VAS) on a scale of 0 to 100 mm. This study used a Likert scale, which has been shown to be comparable to the VAS. One potential limitation of the methods used in this study is the use of a Likert scale, as it may be argued that this would not have been as sensitive to differences between materials as a VAS scale. Awad et al, however, found that this was not the case and that VAS scores were comparable to Likert scoring for measures of OHRQoL.

The four key domains in OHRQoL relate to orofacial appearance, function, pain, and psychosocial impact. While one of the proposed advantages of PEEK is the improved esthetics in comparison to Co-Cr, there were no significant differences between the two types of framework in OHRQoL. It is not possible to say whether there were improvements in perception of appearance or whether any such improvements were offset by a reduction in function or increase in pain. In-depth analysis of the differences between the frameworks in the various domains of OHRQoL was not possible due to the limitations of sample size in this pilot study. Future clinical studies that compare outcomes between these materials using larger sample sizes should investigate which, if any, of the OHRQoL domains differ between the two treatment materials.

In this study, mean PPD, % ≥ 4 mm, GBI, and PI scores did not significantly differ between PEEK and Co-Cr dentures at any follow-up. All participants were free of caries and had either no active periodontal disease or had undergone a period of disease control prior to...
enrollment in this study. They were recalled at regular intervals and provided with supportive periodontal therapy, including oral hygiene instruction and supra- and subgingival scaling and root surface instrumentation. Considering this status as a prerequisite, it seems that the use of PEEK framework RPDs are no more detrimental to the periodontal health of remaining teeth than Co-Cr framework RPDs over 1 year of follow-up. Recall of participants at longer follow-up periods would be required to determine the longer-term effects of PEEK compared to Co-Cr RPDs on periodontal health.

A benefit of a crossover design is the ability to control for other confounders associated with RPD provision. There are limitations, however, in that after 4 weeks with each framework, the participants were asked to choose their preferred denture. All participants therefore wore both dentures up to the end of the crossover period of 8 weeks; however, any conclusions drawn for follow-up beyond that point were limited by participants being grouped according to their preferred denture.

CONCLUSIONS

PEEK denture frameworks seem to have similar effects on OHQoL, patient satisfaction, and periodontal outcomes as Co-Cr denture frameworks.

ACKNOWLEDGMENTS

The authors report no conflicts of interest.

REFERENCES