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Abstract

Purpose

High performance polymer frameworks are marketed to clinicians as alternatives for removable partial dentures (RPD) though the evidence base to compare polymers with traditional metal frameworks is limited to case reports and laboratory studies. The aim of this trial was to investigate differences in performance in the domain of oral health-related quality of life. Further exploratory outcomes assessed were patient preference, periodontal indices and denture satisfaction.

Materials and Methods

Twenty-six participants were recruited to a randomised crossover-controlled trial and provided with poly-ether-ether-ketone (PEEK) and cobalt-chromium (CoCr) RPDs. Participants chose preferred RPD after four-weeks acclimatisation and reviewed with preferred RPD at 6-months and 1-year. Primary outcome was effect on OHIP-20 compared using repeated measures ANOVA. Secondary outcomes were participant preference compared with chi-squared analysis, plaque and bleeding index (PI, and BI) compared with repeated measures ANOVA and the McGill Denture Satisfaction Questionnaire (MDSQ) compared at 4-week follow-up with paired sample t-test.

Results

Both CoCr and PEEK frameworks made significant improvement to OHIP-20 score ($P < 0.001$), but material was not a significant factor in changes over 1-year

($p=0.87$). There were no statistically significant differences in participant preference at 1-year ($p=0.491$) nor between RPD materials in their effect on BI ($p=0.476$), PI ($p=0.967$) or the MDSQ ($p=0.368$).

Conclusion

Both CoCr and PEEK RPDs improved OHRQoL to a degree greater than the minimum clinically important difference (MCID) at 4-weeks, 6-months and 1-year compared to baseline. No significant preference or improved denture satisfaction score was seen for either material. PEEK frameworks seem to be associated with similar degrees of periodontal effects as CoCr frameworks.

Introduction

Tooth loss is associated with numerous deleterious clinical and patient centred outcomes. (1, 2) Measurement of oral health-related quality of life (OHRQoL) is a patient-centred outcomes that can be used to measure success for prosthodontic interventions.(3) Whilst improvements in OHRQoL measured by questionnaires such as the Oral Health Impact Profile (OHIP) are not as marked in RPDs compared to fixed prostheses, they have been shown to have a net beneficial impact on OHRQoL for patients.(1)

Studies suggest RPD wearers have worse OHRQoL than dentate, non-denture wearing, controls.(4, 5) 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 a RPD.(6) Suffice to say, the relationship between tooth loss, denture use and OHRQoL is complex and may be impacted by a number of variables such as number and position of missing teeth relative to the aesthetic zone, age and denture wearing experience to name but a few.(7) Indeed studies suggest that up to 25% of dentures are not used, particularly those that do not replace anterior teeth.(8) Clinicians should also consider the risks of introducing an RPD on the periodontal health of remaining teeth due to increased plaque retention predisposing to periodontal inflammation, gingival bleeding and attachment loss.(9) Strategies to mitigate effects of RPDs on the periodontium include prescription of a hygienic denture design, effective hygiene instruction and regular supportive periodontal therapy.(10, 11) A balance of harm versus benefit must be considered whenever RPDs are prescribed, a principle referred to as “the RPD equation”.(12)

One factor that may influence outcome is denture material. A commonly used RPD framework is Cobalt-Chromium alloy (CoCr), a rigid framework allowing masticatory forces to be distributed to supporting abutment teeth.(12, 13) Proponents of more flexible framework materials cite 'stress dissipation' as a potential advantage.(14-16) CoCr traditionally required a technique sensitive and labour-intensive fabrication process of lost wax casting. Alternative fabrication techniques such as milling, injection moulding are being introduced with a range of novel materials including non-metallic high performance polymeric materials (HPP). HPPs are marketed as suitable alternatives to metals for dental applications including: fixed crowns, fixed bridges, implant components and removable dentures.(15, 17) One such material is an aromatic semi-crystalline polymer known as poly-ether-ether-ketone (PEEK), which has been used as a spinal cage and joint replacement material.(18, 19)

With a low Young's modulus of between 3-4GPa, PEEK is considerably more flexible than metal RPD framework materials with Young's moduli of between 100-220GPa.(15) Authors have argued that rigidity can be detrimental as clasps may distort under the stresses of normal function.(20, 21) On the other hand with reduced flexural strength in the region of 100MPa, the effectiveness of retentive clasps using PEEK are likely to be considerably weaker than metal clasps.(15, 20, 22) Reduced tensile strength of PEEK at approximately 80MPa, compared to that of metals such as titanium and CoCr in excess of 900MPa leaves the former more susceptible to fracture unless used in thicker section, which may be less tolerable for patients.(15, 20) For clasping elements minimum clasp thickness is suggested as 2mm and minimum height is 3mm.(23) Clearly these parameters create

potential for increased plaque retention and a concern for many clinicians may be that this will leave patients more prone to periodontal complications. A systematic review published in 2016 suggested that whilst no clinical studies could be found evaluating the use of PEEK dentures, they were likely to become a successful framework for RPDs in the future.(15) Clinicians are therefore in the difficult position of having a material on the market with limited evidence on which to base clinical decisions..

The aim of this study was to answer the research question: “For partially dentate patients, do PEEK frameworks improve OHRQoL?” The working hypothesis was that they do indeed improve OHRQoL. As this was the first opportunity to evaluate PEEK prostheses in a clinical trial, further exploratory questions were posed as follows: 1. “How do these improvements compare to those improvements made by CoCr RPDs?” 2. “ Is there a difference in denture satisfaction between PEEK and CoCr RPDs?” 3. “Is there a difference in the periodontal health impacts posed by PEEK RPDs compared to CoCr RPDs?” and 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 a UK Dental Hospital were invited to participate in a pilot randomised crossover controlled clinical trial comparing RPDs made with either PEEK or CoCr frameworks. Ethical approval for the trial protocol provided by the NHS National Research Ethics Service (REC reference 13/YH/0403). The clinical trial was registered with the U.S. National Library of Medicine (ClinicalTrials.gov identifier: NCT01953991).

The following inclusion criteria were applied:

- Adults aged 18 or over
- Absence of 3 or more teeth in one or both dental arch, excluding third molars, for which a removable partial denture would be a restorative option for one or both dental arches.
- 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 CoCr framework and one set made with PEEK framework. RPDs were fabricated in two specialist dental laboratories: in-house production laboratory at the Charles Clifford Dental Hospital and Reger Zahntechnik (Nürnberg, Germany).

Design parameters have been suggested for PEEK frameworks and have been evaluated in in-vitro studies. Design of both frameworks were similar though PEEK frameworks used more tooth support and generally avoided gingivally approaching clasps, favouring shorter clasp assemblies which engaged more undercut. Participants were randomly allocated to use either the PEEK denture or CoCr for a 4-week testing period before swapping to the other material. An investigator independent of the treatments provided computer generated block randomisation sequences for the study. Allocation concealment was ensured with the use of opaque sealed envelopes that were opened at the denture fit appointment. A wash-out protocol was fixed as removal of the denture, recording of data at review followed by full mouth prophylaxis after which the participants were given the other denture. After wearing each denture for the 4-week test period each participants chose their preferred RPD and were reviewed with their preferred denture at 6-months and 1-year.

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 (JUVORA Ltd, Thornton-Cleveleys, UK). CoCr frameworks were conventionally designed with wax patterns prior to investment and casting. Reinforced poly-methyl methacrylate teeth (Natura™, Schottlander Ltd., Letchworth, UK) 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 frameworks.

Outcome measures

OHRQoL was measured using the twenty-item Oral Health Impact Profile (OHIP-20).(24) OHIP-20 includes items about difficulty chewing, discomfort when eating, comfort with dentures and is considered to be sensitive to changes resulting from RPD provision.(25) OHIP-20 was scored with a Likert scale ranging from 0-4 (0 = “never”, 4 = “very often”). Total scores ranged from 0-80-points with higher scores indicating worse OHRQoL. In accordance with best evidence from confirmatory factor analysis of the OHIP and to avoid erroneous findings resulting from multiple testing, individual domain score were not separately analysed. Therefore, a total change from baseline to 4-weeks was compared with OHIP-20

The McGill Denture Satisfaction Questionnaire (MDSQ) was recorded at 4-week follow-up for both the CoCr and PEEK RPDs. The MDSQ includes 17-items and is scored using a Likert scale ranging from 0-4 (0=“Not at all satisfied”/“Great difficulty”, and 4=“Extremely satisfied”/“Very easy”). The MDSQ total score ranged from zero to 68, with higher scores indicating better satisfaction.

Periodontal outcomes were measured at baseline, 4-weeks, 6-months and 1-year follow-up. Periodontal indices were taken at six-points: mesial, mid and distal on both the buccal and lingual surfaces, per remaining tooth in each arch being restored. These measures included mean probing pocket depths (mm) (PPD) measured using a clearly marked UNC-15 periodontal probe (Hu-Friedy, Chicago, IL, USA), percentage of periodontal pockets measuring greater than or equal to 4mm depth ($\geq 4\text{mm}$), Gingival Bleeding Index (GBI) and Plaque Index (PI). (26, 27)

Finally, patient preference as a binary choice between CoCr and PEEK was recorded.

Intra-rater reliability

A single, calibrated examiner measured all periodontal indices. Test re-test reliability was calculated in a cohort of patients using intra-class correlation coefficient (ICC). ICC was greater than 0.9 for all continuous measures: PPD (0.98), % \geq 4mm (1.0), GBI (0.96) and PI (0.97).

Sample size

Based on the primary research question “For partially dentate patients, do PEEK frameworks improve OHRQoL?” the minimum clinically important difference (MCID) in OHIP-20 was used as the determinant of “improving OHRQoL”.(25) This is determined as nine-points (SD: 14.8) in partially dentate patients provided with RPDs which indicates an anticipated effect size of 0.61 to demonstrate a MCID in PEEK RPDs before to after treatment. (25) Further, assuming $\alpha=0.05$ and $1-\beta=0.8$, 24 patients would be required to demonstrate this difference.

Statistics

Normality of OHIP-20 and MDSQ scores was measured using Shapiro Wilk test for normality. Both were normally distributed, OHIP-20 (SW=0.963, df=52, p=0.107), MDSQ (S-W=0.972, df=50 p=0.271).

A two-way repeated measures ANOVA was used to investigate the impact of framework material and time (baseline, 4-weeks) on 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 1-year follow-up.

Repeated-measures ANOVA was used to investigate differences in periodontal measures between denture materials over the one-year of follow-up.

Comparison of MDSQ scores at 4-week follow-up was made using a paired sample t-test. Chi-squared analyses were used to investigate differences in participant preferences. To account for multiple testing the threshold for statistical significance was moved to $p < 0.01$.

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

Results:

Thirty participants were assessed for eligibility. Four were excluded due to advanced levels of periodontal attachment loss rendering them unsuitable for tooth-supported removable partial dentures. Twenty-six participants gave written, informed consent for participation. The CONSORT flow diagram in Figure 1 shows the numbers 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 CoCr dentures for the same case.

OHRQoL

There was a significant main effect of time when evaluating trends from baseline to 4-weeks ($F(df)=31.30(1)$ $p<0.001$) and baseline to 1-year ($F(df)=16.92(3)$, $p<0.001$) indicating that both materials showed a statistically significant improvement in OHIP consistent with the MCID.

Material was not a significant factor when evaluating trends from baseline to 4-weeks ($F(df)=0.106(1)$, $p=0.746$) or from baseline to 1-year ($F(df)=0.24(3)$, $p=0.87$) indicating no significant difference between the two types of material in their effects on OHRQoL. Table 2 shows the mean change scores in OHIP-20 at 4-weeks, 6-months and 1-year follow-up. In all cases the change scores demonstrated improvement in OHRQoL compared to baseline.

Participant preference

Table 3 shows the number of participants preferring each denture material at 4-week, 6-months and 1-year follow-up. There were no statistically significant differences in preference for the two dentures being investigated at 4-week ($X^2(df)=0.04(1)$, $p=0.841$), 6-months ($X^2(df)=0.43(1)$, $p=0.513$) or 1-year ($X^2(df)=0.47(1)$, $p=0.491$).

Denture Satisfaction

At 4-week follow-up mean MDSQ score was 19.8-points (SD 12.7) for PEEK RPDs and 17.9-points (SD 10.0) for CoCr dentures. Whilst this indicates improved denture satisfaction scores for the PEEK dentures, there were no statistically

significant differences between the two RPD materials $t(df=24)=0.753$, $p=0.459$, mean difference=1.8 points; 99% CI -5.0 to 8.7 points.

Periodontal Health

Mean PPD, $\% \geq 4\text{mm}$, BI and PI at baseline, 4-weeks, 6-months and 1-year follow-up are shown in Table 4. There was no difference in the PPD ($F(df)=0.82(2.3)$, $p=0.461$), $\% \geq 4\text{mm}$ ($F(df)=1.35(2.4)$, $p=0.269$), BI ($F(df)=1.43(2.1)$, $p=0.249$) or PI ($F(df)=0.07(2.4)$, $p=0.956$) between materials.

Discussion

The primary aim of this study was to determine whether RPDs made from PEEK frameworks improve OHRQoL. The change in OHIP-20 score seen with both denture materials was of a magnitude equivalent to at least the OHIP-20 MCID of a nine-points. RPDs made with frameworks of both CoCr and PEEK made improvements to OHRQoL to a degree greater than the minimum clinically important difference (MCID) at 4-weeks, 6-months and 1-year follow-up.

This was the first study to compare the use of high performance polymer RPD frameworks against traditional CoCr alloy frameworks. As such it provided an opportunity to explore secondary research questions and provide an estimate of potential difference between materials, which may be used to appropriately power a comparative study to detect a true difference. Secondary research questions related firstly to the difference in effect on OHRQoL between materials. Denture material was found not to be a significant factor in the magnitude of OHRQoL improvement. One must emphasise that this was a

secondary outcome and therefore the study was not powered make such a direct comparison though it does provide an estimate of difference for future research.

Other secondary question related to participant preference, denture satisfaction and periodontal effects. Preference was observed at 4-week, 6-month and 1-year follow-up. The findings suggest that there was no difference between patients preferring CoCr or PEEK materials. There were also no significant differences between denture frameworks in respect of denture satisfaction score measured by the MDSQ. This suggests that performance of PEEK denture frameworks was as good as that of CoCr. The MDSQ has been widely used to measure both masticatory and denture satisfaction outcomes in fixed and removable prosthodontics research.(28-30) In most cases it has been scored with a VAS on a scale of 0 to 100mm. In this study a Likert scale was used, which has been shown to be comparable to the VAS.(31) One potential limitation of the methods used in this study include 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.(31)

The four key domains in OHRQoL relate to orofacial appearance, function, pain and psychosocial impact.(32) Whilst one of proposed advantages of PEEK is that of improved aesthetics in comparison to CoCr there were no significant differences between the two types of framework in OHRQoL. It is not possible to say a. whether there were improvements in perception of appearance, or b. whether any such improvements were offset by a reduction in function or an increase in pain. In-depth analysis of the differences between frameworks in the

various domains of OHRQoL was not possible due to limitations to 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 differs between the two treatment materials.

In this study mean PPD, percentage of pockets ≥ 4 mm depth, bleeding index and plaque index scores did not significantly differ between PEEK dentures versus CoCr at any follow-up period. All participants were caries free and had either no active periodontal disease or had undergone a period of disease control prior to enrolment into this study. They were recalled at regular intervals and provided with supportive periodontal therapy including oral hygiene instruction, supra- and sub-gingival scaling and root surface instrumentation. Considering this status as a pre-requisite, it seems that the use of PEEK framework RPDs are no more detrimental to the periodontal health of remaining teeth than CoCr framework RPDs over one 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 CoCr RPDs on periodontal health.

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

Figure Legends

Figure 1 CONSORT participant flow diagram

Figure 2 Examples of both PEEK and CoCr RPDs for the same case

Figure 2a Example of Lower CoCr RPD

Figure 2b Example of Lower PEEK RPD

Figures and Tables

Figures:

Figure 1 CONSORT participant flow diagram

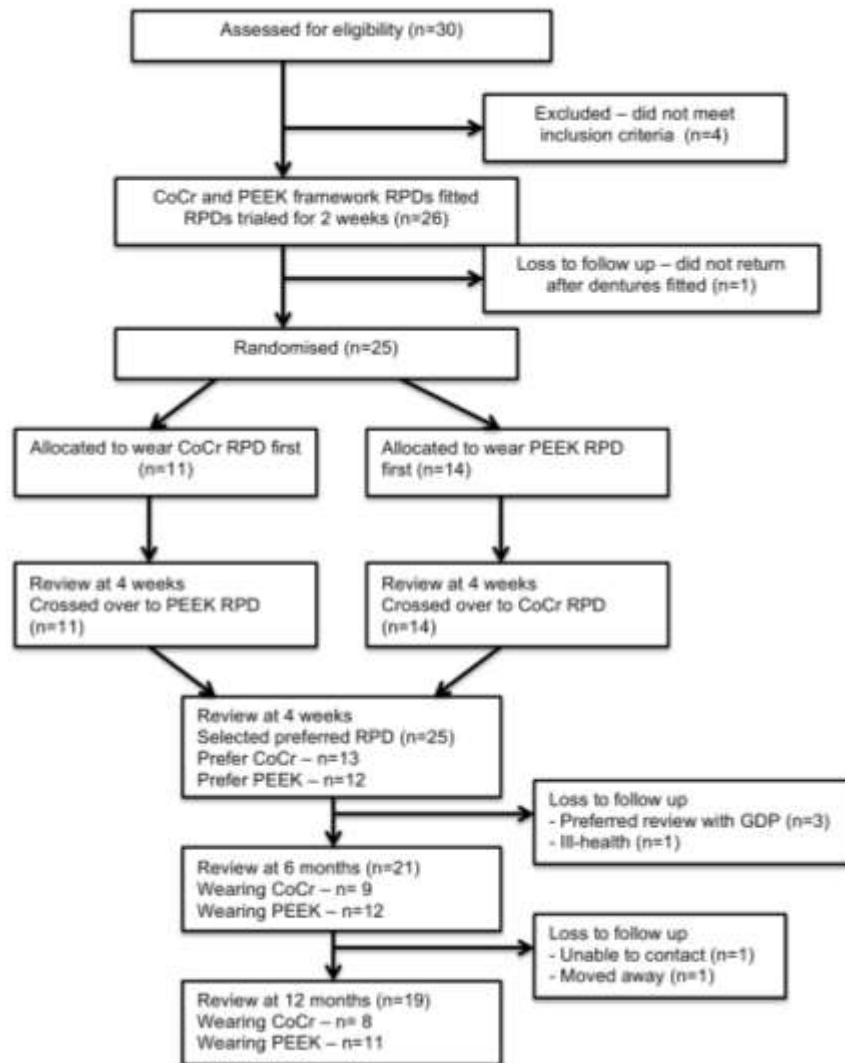


Figure 2 Examples of both PEEK and CoCr RPDs for the same case

Figure 2a Example of Lower CoCr RPD



Figure 2b Example of Lower PEEK RPD



Tables:

Table 1 Baseline characteristics: participant level and denture level

		Mean, [range], (SD)	N=
Age		64.8, [39-85], (12.4)	
Gender	Female		11
	Male		15
History of RPD use	Never worn RPD before		5
	Worn RPD before		21
RPD provided in the study	Lower RPD only		7
	Upper RPD only		6
	Upper and Lower RPD		13
Total number of remaining teeth (participant level)		14, [5-25]	
Total number of abutment teeth (participant level)		7, [3-13]	
Baseline OHIP-20 Total Score (points)		31.9, [2-73], (19.2)	
Kennedy Classification (denture level)	Kennedy Class 1		15
	Kennedy Class 2		11
	Kennedy Class 3		11
	Kennedy Class 4		2
No. remaining teeth per arch (denture level)		7, [3-11]	
No. abutment teeth per arch (denture level)		4, [3-9]	

Table 2 OHIP-20 outcomes over 1-year follow-up

Follow-up Period	Mean OHIP-20 points change compared to baseline (SD)	
	PEEK	CoCr
Baseline to 4-weeks	12.4, (SD 17.6)	14.0, (SD 16.3)
Baseline to 6-months	17.1, (SD 15.8)	14.4, (SD 21.7)
Baseline to 1-year	18.8, (SD 14.6)	14.1, (SD 20.3)

Table 3 Participant RPD preferences

Design Group	Preference at 4-weeks (N(%))		Preference at 6-months (N(%))		Preference at 1-year (N(%))	
	CoCr	PEEK	CoCr	PEEK	CoCr	PEEK
Groups Combined	12 (48%)	13 (52%)	9 (43%)	12 (57%)	8 (42%)	11 (58%)

Table 4 Periodontal health measures from baseline to follow-up

Follow-up	Baseline	Mean (SD)					
		4-weeks		6-months		1-year	
Preferred framework	N/A	PEEK	CoCr	PEEK	CoCr	PEEK	CoCr
PPD (mm)	1.7mm (0.5)	1.4mm (0.4)	1.8mm (0.4)	1.4mm (0.4)	1.6mm (0.6)	1.4mm (0.4)	1.6mm (0.4)
≥4mm pocketing (%)	3.8% (5.5)	1.7% (2.8)	3.6% (5.1)	1.4% (3.6)	3.0% (5.3)	1.2% (2.6)	1.3% (2.2)
Bleeding Index (%)	10.7% (13.0)	6.4% (6.1)	9.3% (13.6)	5.4% (5.2)	11.3% (21.9)	5.5% (6.0)	7.6% (12.3)
Plaque Index (%)	58.8% (20.0)	59.3% (21.5)	52.3% (24.1)	59.6% (19.2)	52.3% (30.3)	54.8% (22.1)	46.6% (21.3)

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Baseline to 4-weeks	12.4, (SD 17.6)	14.0, (SD 16.3)
Baseline to 6-months	17.1, (SD 15.8)	14.4, (SD 21.7)
Baseline to 1-year	18.8, (SD 14.6)	14.1, (SD 20.3)

Table 3 Participant RPD preferences

Design Group	Preference at 4-weeks (N(%))		Preference at 6-months (N(%))		Preference at 1-year (N(%))	
	CoCr	PEEK	CoCr	PEEK	CoCr	PEEK
Groups Combined	12 (48%)	13 (52%)	9 (43%)	12 (57%)	8 (42%)	11 (58%)

Table 4 Periodontal health measures from baseline to follow-up

Follow-up	Mean (SD)						
	Baseline	4-weeks		6-months		1-year	
Preferred framework	N/A	PEEK	CoCr	PEEK	CoCr	PEEK	CoCr
PPD (mm)	1.7mm (0.5)	1.4mm (0.4)	1.8mm (0.4)	1.4mm (0.4)	1.6mm (0.6)	1.4mm (0.4)	1.6mm (0.4)
≥4mm pocketing (%)	3.8% (5.5)	1.7% (2.8)	3.6% (5.1)	1.4% (3.6)	3.0% (5.3)	1.2% (2.6)	1.3% (2.2)
Bleeding Index (%)	10.7% (13.0)	6.4% (6.1)	9.3% (13.6)	5.4% (5.2)	11.3% (21.9)	5.5% (6.0)	7.6% (12.3)
Plaque Index (%)	58.8% (20.0)	59.3% (21.5)	52.3% (24.1)	59.6% (19.2)	52.3% (30.3)	54.8% (22.1)	46.6% (21.3)



Fig. 2.a.



Fig. 2.b.