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Trueness and marginal fit of implant-supported complete-arch fixed prosthesis frameworks made of high-performance polymers and titanium: An explorative *in-vitro* study

Samir Abou-Ayash [a,*], Martin Schimmel [b,c], Mutlu Özcan [d], Burak Ozcelik [e], Urs Brägger [f], Burak Yilmaz [g,h,i]

[a] *Senior Lecturer and Head of the Section of Digital Implant and Reconstructive Dentistry, Department of Reconstructive Dentistry and Gerodontology, University of Bern, Freiburgstrasse 7, 3007 Bern, Switzerland*
[b] *Department Head, Department of Reconstructive Dentistry and Gerodontology, University of Bern, Freiburgstrasse 7, 3007 Bern, Switzerland*
[c] *Senior lecturer, Extra muros, Division of Gerodontology and Removable Prosthodontics, University Clinics of Dental Medicine, University of Geneva, Geneva, Switzerland*
[d] *Head, Division of Dental Biomaterials, Clinic of Reconstructive Dentistry, Center of Dental, University of Zurich, Zurich, Switzerland*
[e] *Burak Ozcelik Professor, Baskent University Faculty of Dentistry Department of Prosthodontics, Ankara, Turkey*
[f] *Professor emeritus, Department of Reconstructive Dentistry and Gerodontology, University of Bern, Freiburgstrasse 7, 3007 Bern, Switzerland*
[g] *Associate Professor, Department of Reconstructive Dentistry and Gerodontology, School of Dental Medicine, University of Bern, Freiburgstrasse 7, 3007 Bern, Switzerland*
[h] *Associate Professor, Department of Restorative, Preventive and Pediatric Dentistry, School of Dental Medicine, University of Bern, Freiburgstrasse 7, 3007 Bern, Switzerland*
[i] *Adjunct Professor, Division of Restorative and Prosthetic Dentistry, The Ohio State University College of Dentistry, Columbus, Ohio 43210 United States*

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ABSTRACT

Purpose: To investigate the trueness and marginal fit of computer-aided design–computer-aided manufactured (CAD-CAM) complete-arch implant-supported screw-retained fixed prosthesis (CAISFP) made of polyetheretherketone (PEEK), polyetherketoneketone (PEKK) and titanium (Ti)

Material and methods: A typodont model with four implants, their multiunit abutments (MUAs), and MUA scanbodies were digitized by using a laboratory scanner. The generated CAD was used to mill CAISFP frameworks in Ti, PEEK, or PEKK (each $n = 10$). The frameworks were digitized with an industrial light scanner to superimpose resulting standard tessellation language (STL) file with the CAD file. Deviations at five points at the abutment-framework interface of each of the four abutment sites (1:left first molar, 2:left canine, 3:right canine, 4:right first molar sites) were calculated (trueness). Marginal gaps were measured using the triple scan technique. A nonparametric repeated measures ANOVA by Brunner and Puri with factors being *abutment location* and *material* was performed to assess the mean deviations for trueness and mean marginal gaps, followed by Mann-Whitney or exact Wilcoxon Signed-Rank tests (alpha=.05).

Results: Material type significantly affected the trueness ($p<0.0001$). PEEK had the lowest deviations (0.039 +/-0.01mm) followed by PEKK (0,049 +/-0.009mm), and Ti (0.074 +/-0.011mm). For marginal gaps, only abutment location's effect was significant ($p = 0.003$). Within PEKK, gaps at abutment 4 were significantly larger, compared with abutments 2 ($p = 0.04$) and 3 ($p = 0.02$).

Conclusions: The trueness of PEEK, PEKK, and Ti frameworks was different after milled. PEEK had the highest trueness. However, the marginal fit of the frameworks was similar and smaller than 90 μm in average.

Clinical Relevance: PEEK, PEKK, and Ti complete-arch frameworks had clinically acceptable gaps and may therefore be recommended when their fit is considered. Higher trueness after milling did not result in better marginal fit.

* Corresponding author at: Department of Reconstructive Dentistry and Gerodontology, University of Bern, Freiburgstrasse 7, 3007 Bern, Switzerland.
E-mail addresses: samir.abou-ayash@zmk.unibe.ch (S. Abou-Ayash), martin.schimmel@zmk.unibe.ch (M. Schimmel), mutlu.ozcan@zzm.uzh.ch (M. Özcan), tbozcelik@yahoo.com (B. Ozcelik), urs.braegger@zmk.unibe.ch (U. Brägger), burak.yilmaz@zmk.unibe.ch (B. Yilmaz).

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1. Introduction

Complete-arch fixed implant-supported prostheses (CAFISPs) have been commonly used particularly following the outcomes of clinical studies, which showed promising results even with only four implants supporting the prostheses [1–3]. The frameworks of CAFISPs have been commonly cast in metal and veneered with acrylic resin. However, prosthetic complications have also been observed when these conventional materials were used [4–6].

With the advances in computer-aided design and computer-aided manufacture (CAD-CAM), titanium became the standard framework material, which was followed by zirconia and chromium cobalt, and more recently, high-performance polymers have been introduced [7–9]. Polyaryl ether ketone (PAEK) materials are high-performance polymers, which are alternatives to metal and zirconia frameworks [10]. For their application in dentistry, PAEK materials are veneered with composite resin or polymethyl methacrylate resin (PMMA) due to their unfavorable optical properties [11,12]. PEEK (Polyetheretherketone) is a semi-crystalline polymer with noncorrosive properties in the PAEK family [13]. PEEK is available without any fillers, but modified versions with fillers are also manufactured. A specific type of PEEK is modified incorporating 20% nano-ceramic fillers (BioHPP, Bredent, Senden, Germany) to increase its strength [11].

Polyetherketoneketone (PEKK) was also introduced as a framework material, and consists of titanium dioxide particles (20%) and an additional ketone group when compared with PEEK. PEKK has a higher compressive strength and fatigue properties than PEEK [14,15]. PEEK and PEKK have a lower elastic modulus compared with metals and zirconia, which may be a limitation in frameworks with distal extensions [16,17]. Clinical studies on the performance of PEEK when used for complete-arch situations are scarce [18], and authors of the present study are unaware of any clinical studies on the performance of PEKK when used for CAFISPs. Although there are case reports on the use of PEKK or PEEK as CAFISP frameworks [19], to the authors knowledge, the milling trueness and fit of PEEK and PEKK when used for CAFISPs haven't been investigated.

The aim of the present study was to investigate the milling trueness and marginal fit of CAD-CAM PEEK and PEKK CAFISP frameworks on four implants comparing with titanium (Ti) frameworks. The primary null hypothesis of the present study was that the milling trueness would not be different depending on the framework material (PEEK, PEKK, or Ti) and the abutment location. The secondary null hypothesis was that the marginal fit of frameworks would not be affected by the framework material and the abutment location.

2. Materials and methods

2.1. Framework fabrication and superimposition

A screw-retained complete-arch acrylic resin (Pattern resin LS, GC America, Alsip, USA) framework prototype was fabricated on a typodont model with 2 straight implants (Nobel Active RP 4.3 × 13 mm; Nobel Biocare AG, Zurich, Switzerland) in the anterior region and 2 implants (Nobel Active RP 4.3 × 13 mm, Nobel Biocare AG, Zurich, Switzerland) with a 30-degree distal tilt in the posterior region (Fig. 1). Straight multiunit abutments (Multi-unit Abutment Plus Conical Connection RP 2.5 mm, Nobel Biocare AG, Zurich, Switzerland) were used in the anterior, and 30-degree angulated abutments (30°Multi-unit Abutment Plus Conical Connection RP 3.5 mm, Nobel Biocare AG, Zurich, Switzerland) were used on the posterior implants. The prototype's passive fit was improved sectioning and luting by using the same resin (Pattern resin LS). After all 4 screws were tightened to get the best fit possible, a 3-dimensional (3D) laboratory laser scanner (Zirkonzahn Software, Zirkonzahn GmbH, Gais, Italy) was used to digitize the typodont model with the framework and then with scan bodies (Elos Lab Sb, Elos Medtech Dental). The resin prototype was also scanned from all surfaces to generate a virtual 3D CAD framework (ICAM V5, Imes-Icore GmbH, Eiterfeld, Germany). The present study followed the methodology of a previous publication for the generation of the CAD of the prototype, which was also utilized in the present study because the frameworks design fit in the aims [20]. A CAM milling unit (Coritec 550i, Imes-Icore GmbH, Eiterfeld, Germany) was used to fabricate 10 frameworks of the CAD file in Ti (LOT 107,757 for all blanks, rematitan; Dentauraum GmbH & CoKG, Ispringen, Germany), PEEK (LOT 483,954 for all blanks, BioHPP, bredent, GmbH & Co KG, Senden, Germany) and PEKK (LOT 000,038,509 blanks, Pekkton ivory; Cendres+Métaux Biel/Bienne, Switzerland) (Fig. 1). Two frameworks were milled from each blank. The milling settings were selected according to the milling

Fig. 1. Typodont model and frameworks: Evaluated frameworks milled from PEEK, PEKK and titanium (left to right), and the typodont model.

machine manufacturer's recommendations established for each material. The supports were placed distant from the margins to not damage the margins when separating the frameworks from the blanks. The milling burs varied depending on the material to be milled and new burs were used for each blank milled. After milling, the frameworks were separated from the blanks by using separating burs and material remnants, particularly within the screw access channels, were gently removed with a small bur paying utmost attention to not damage the abutment interfaces of the frameworks. The digitization and post-milling adjustments were performed by one experienced laboratory technician. The frameworks were then digitized with a high-precision industrial structured-light scanner (ATOS Compact Scan 5M, GOM GmbH, Braunschweig, Germany) to superimpose the resulting STL file with the CAD file using a metrology software (GOM Inspect V8 SR1, GOM GmbH, Braunschweig, Germany). After manual prealignment, the software's best-fit algorithm was used for the superimpositions, and all superimpositions were in the same coordinate system, which enabled the selection of the same points on the frameworks. Deviations at five points at each of the four abutment sites (abutment 1, abutment 2, abutment 3, abutment 4) were calculated after alignment to measure the trueness (Fig. 2). The points were located on the buccal, lingual, mesial and distal of the abutment interface of the framework and one point was selected on the margin.

2.2. Fit assessment

After trueness measurements, the frameworks were placed on the abutments by using the one-screw test tightening the prosthetic screws at left first molar (abutment 1) and right canine by using a hand screw driver (Screwdriver Manual Multi-unit 25 mm; Nobel Biocare AG, Zurich, Switzerland) to enable the initial positioning of the framework on implants [20–24]. After further tightening of the prosthetic screw at the terminal location (TL) to 15 Ncm torque with a wrench (Manual Torque Wrench – Prosthetic; Nobel Biocare AG, Zurich, Switzerland), the screw at right canine abutment was unscrewed and 3D marginal gaps at framework-abutment interfaces at this state were measured by using the triple-scan protocol [25]. The framework, when secured on the model with one screw, was scanned by using an industrial, metrology-grade structured-light scanner (ATOS Compact Scan 5M; GOM GmbH, Braunschweig, Germany) (key scan). The framework‘s occlusal and intaglio surface scans and the model's scan performed during the trueness tests were also used for pre- and final-alignment by using best-fit algorithm (GOM inspect V8 SR1; GOM GmbH, Braunschweig, Germany), which generated a single framework scan (merged). Also, pre- and final alignment of the key scan on the model scan was performed followed by the pre- and final alignment of the merged framework scan on the key scan.

To measure the gaps at abutment-framework interfaces, four virtual sectional cuts were made at maxillary left canine (abutment 2), right canine (abutment 3), and right first molar (abutment 4) sites. Gaps at eight different points in four cross-sections were measured and averaged at each abutment-framework interface by using a software (3shape 3D Viewer 2014.1, 3Shape AG). The section cut locations were standardized by using the identical section for each scan of each material (Fig. 3). Because the same master model scan was used as the basis for alignment, all scans were superimposed in the same coordinate system, as well as the locations of the section cuts. After the image of the abutment-framewotk interface was enlarged, one point on the abutment and one point on the framework were selected to determine the closest visual distance. The points were then moved until the closest possible distance between the abutment and the framework was found. This procedure was repeated for all measurments, so that the smallest distance was always measured at the respective sectional cuts in a standardized manner.

2.3. Statistical analysis

For descriptive analyses, means and standard deviations were calculated. A nonparametric repeated measures (rm) ANOVA by Brunner and Puri with factors *abutment location* (repeated measurement) and *material* was performed to assess mean deviations on a global context for both trueness and marginal gaps. Post hoc exact Mann-Whitney tests (for differences between materials by abutment position) or exact Wilcoxon Signed-Rank tests (for differences between abutment position within a material) were performed in situations the rm ANOVA showed a significant impact of a factor. Effect values for materials were estimated as median difference (incl. 95%-confidence intervals (CI)) between two groups. Effect values for the abutment positions were estimated using the Hodges-Lehmann median (incl. 95%-CI). Throughout, p-values less than 0.05 were considered statistically significant. Due to the explorative nature of the present study, p-values were not corrected for multiple testing. Finally, a post-hoc sample size calculation was performed to determine the minimum sample size to detect significant differences in terms of the effect of material on trueness, with a statistical power of at least 80%. The post-hoc sample size was calculated using the Bootstrapping method based on the observed values within the present study.

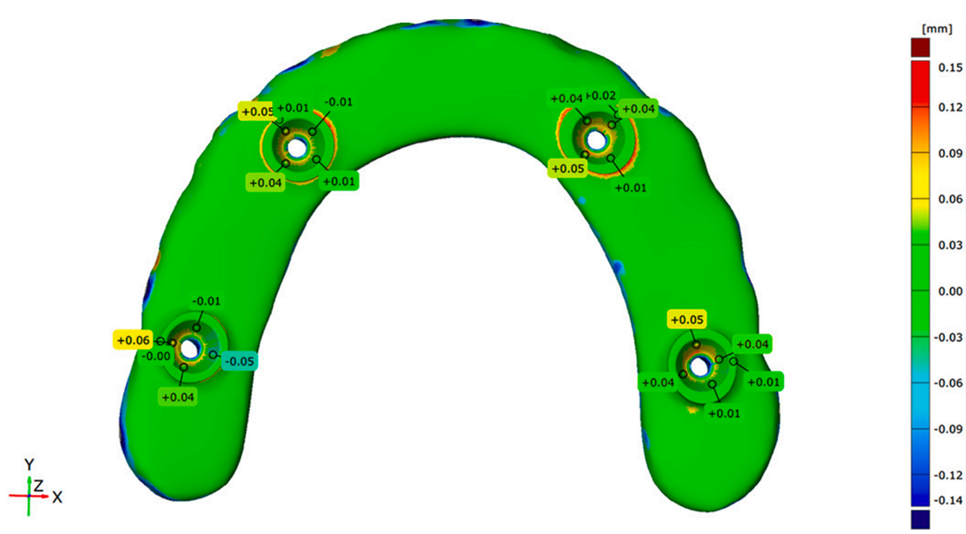

Fig. 2. Evaluation of trueness: Trueness was evaluated at five points at each framework-abutment connection. Abutment positions: Left molar = Abutment 1, left canine = Abutment 2, right canine = Abutment 3, right molar = Abutment 4.

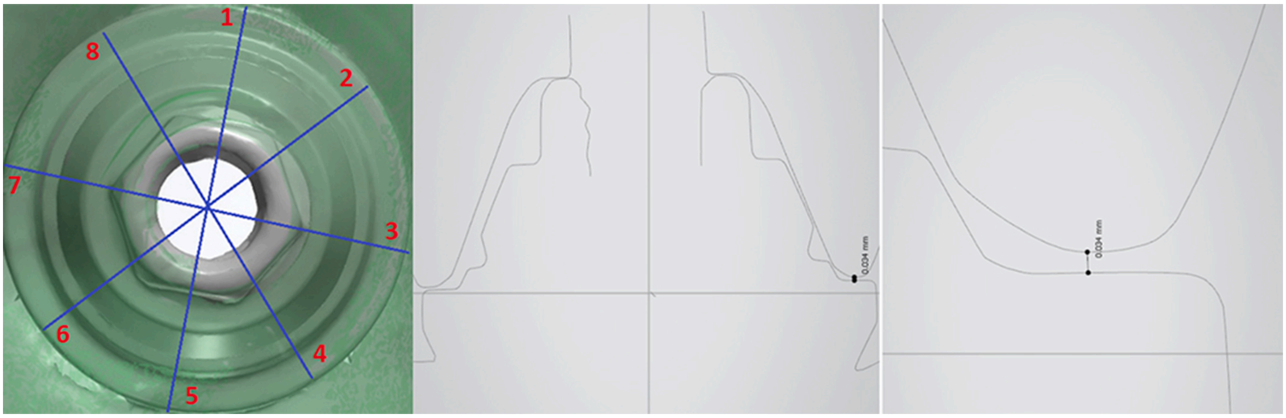

Fig. 3. Evaluation of marginal fit: Four cross-sections and eight points (left) to evaluate the marginal fit. The closest distance was between the implant and abutment was visually determined (middle) on the enlarged cross-section (right).

3. Results

For trueness after CAM, a highly statistically significant effect of material was observed ($p<0.0001$; Fig. 4). All comparisons among materials at each abutment site, except for one comparison, were statistically significant ($p \leq 0.03$). PEEK had the lowest deviations (0.039 +/−0.01 mm) followed by PEKK (0.049 +/−0.009 mm), and Ti (0.074 +/−0.011 mm). The difference between the PEEK and the PEKK was not significant at abutment 4 ($p = 0.16$). Table 1 gives an overview of the pairwise comparisons including the effect sizes. For marginal gaps, there was a significant effect of the abutment location ($p = 0.003$), but not of the material ($p = 0.057$). The overall mean marginal gap sizes were 0.057 +/- 0.04 mm (PEEK), 0.083 +/- 0.05 mm (Ti), and 0.085 +/- 0.038 mm). Within PEKK, gaps at abutment 2 were significantly smaller than those at abutment 4 (effect size: 0.057 (95% CI: 0.003, 0.077; $p =$ 0.04), and gaps at abutment 3 were significantly smaller than those at abutment 4 (effect size: 0.032 (95% CI: 0.003, 0.039; $p = 0.02$; Table 2). Fig. 5 gives an overview of gap sizes at abutments 2 – 4 for each material. The post-hoc sample size analysis revealed a minimum sample size of 10 specimens per group.

4. Discussion

The trueness of frameworks was significantly influenced by the material and the abutment location. Therefore, the null hypothesis that the milling trueness would not depend on the material and the abutment location was rejected. The marginal fit was not significantly affected by the material, however, the abutment location affected the fit. Therefore, the null hypothesis that the abutment location would not affect the marginal fit was rejected.

To the authors' knowledge, no study has evaluated the trueness of CAFISP frameworks milled from different polymers. In the present study, the highest trueness after milling was found with PEEK followed by PEKK, and Ti. Various factors can affect the correct transfer/transition of CAD file to the physical milled framework during milling process including the milling machine, burs, the milling strategy, the prosthetic material, and the interaction of these factors [26–29].

Smaller gaps were found with PEEK, however, no significant difference among the materials was found. The anticipated marginal fit depending on the trueness after milling was not completely observed. However, the p value for the effect of material was small which warrants testing of more number of specimens to possibly detect a statistical

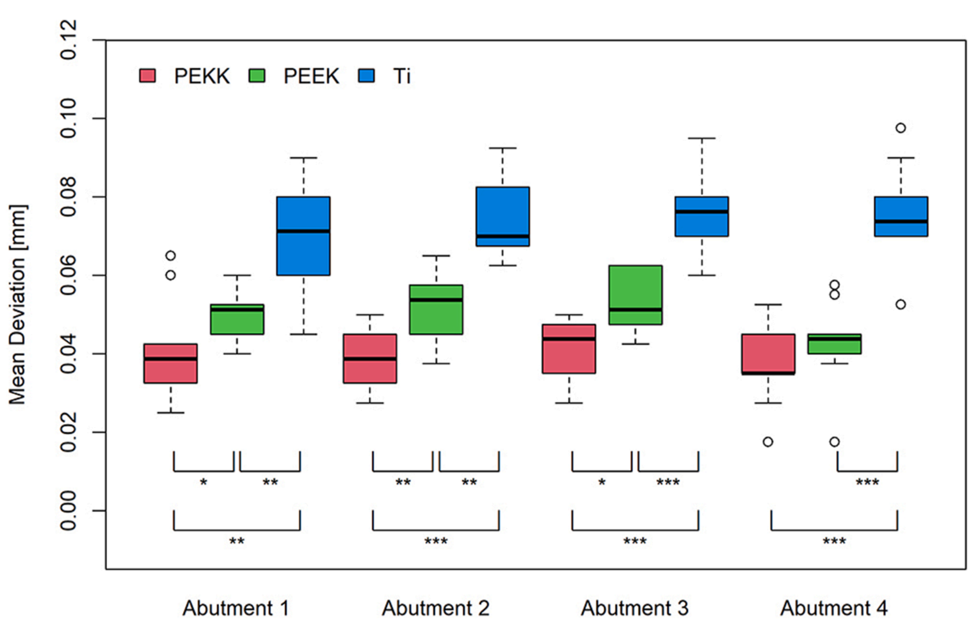

Fig. 4. Trueness: Median deviations of milled frameworks evaluated at four abutment locations. Significances shown as *: $p \leq 0.05$, **: $p < 0.01$, ***: $p < 0.0001$. Abutment positions: Left molar = Abutment 1, left canine = Abutment 2, right canine = Abutment 3, right molar = Abutment 4.

Table 1
Comparison of deviations (mm) of frameworks (trueness) at each abutment location.

Abutment	Baseline Group	Comparison Group	Effect (95%-CI)	p-value
A1	PEKK	PEEK	−0.010 (−0.018, −0.003)	0.03
A1	PEKK	Titanium	0.020 (0.010, 0.028)	0.001
A1	PEEK	Titanium	0.030 (0.015, 0.043)	0.0003
A2	PEKK	PEEK	−0.015 (−0.023, −0.005)	0.004
A2	PEKK	Titanium	0.020 (0.013, 0.030)	0.0002
A2	PEEK	Titanium	0.035 (0.025, 0.043)	<0.0001
A3	PEKK	PEEK	−0.013 (−0.018, −0.003)	0.01
A3	PEKK	Titanium	0.023 (0.015, 0.033)	<0.0001
A3	PEEK	Titanium	0.035 (0.028, 0.045)	<0.0001
A4	PEKK	PEEK	−0.005 (−0.015, 0.005)	0.16
A4	PEKK	Titanium	0.033 (0.025, 0.043)	<0.0001
A4	PEEK	Titanium	0.038 (0.028, 0.048)	<0.0001

Pairwise comparisons of applied materials in terms of trueness, including effect sizes and 95% confidence intervals (CIs) [mm]; p values from Wilcoxon Signed-Rank tests. Negative values indicate lower trueness in the baseline group. Abutment positions: Left molar = A1, left canine = A2, right canine = A3, right molar = A4.

Table 2
Comparison of gaps [mm] at different abutment locations.

Material	Baseline Group	Comparison Group	Effect (95%-CI)	p-value
PEKK	A2	A3	0.025 (−0.003, 0.042)	0.11
PEKK	A2	A4	0.057 (0.003, 0.077)	0.04
PEKK	A3	A4	0.032 (0.003, 0.039)	0.02
PEEK	A2	A3	0.008 (−0.011, 0.025)	0.36
PEEK	A2	A4	0.038 (−0.037, 0.074)	0.20
PEEK	A3	A4	0.029 (−0.029, 0.054)	0.25
Titanium	A2	A3	0.020 (−0.003, 0.041)	0.11
Titanium	A2	A4	0.034 (−0.030, 0.110)	0.19
Titanium	A3	A4	0.021 (−0.025, 0.068)	0.32

Materialwise comparisons in terms of gap size [mm], including effect sizes and 95% confidence intervals (CIs); p values from Wilcoxon Signed-Rank tests. Positive values indicate smaller gap sizes in the baseline group. Abutment positions: Left canine = A2, right canine = A3, right molar = A4.

difference. Two previous studies first analyzed the trueness and then the fit of zirconia and Ti CAFISP frameworks and showed no difference in trueness between materials, but smaller marginal gaps with the Ti framework [22,30]. One of the factors that could be related to the difference in the fit of zirconia and Ti may be the material's ductility, which is much lower for zirconia (Young modulus (YM): 200 GPa) compared to Ti (YM: 100 GPa). In the present study, all tested materials were rather ductile, especially when compared to zirconia, and their ductility may have compensated for the difference seen in trueness when the one-screw test was implemented. The maximum misfit was measured at abutment 4 and was below 120 µm for all materials. Although a clinically tolerable gap value is unknown, gaps < 120 µm have been reported as clinically acceptable [31]. In addition, similar gap values with complete-arch fixed frameworks have been reported previously [22,32]. In terms of marginal bone level alterations, a similar degree of misfit has been described as tolerable [33]. It was not possible to make direct comparisons with previous studies, which assessed the fit of high-performance polymers for CAFISPs as none was found in the literature. In this respect, the present study is the first that evaluated the fit of polymer CAFISP frameworks.

In the present study, gap values were measured after tightening the screw in the terminal implant location. Previous studies, which used the one-screw test, have shown that the gap values also increased when they were distant from the abutment with the tightened screw [20,22,34]. The same trend was seen in the present study, however, significant difference in gap relative to the abutment position was only observed with PEKK frameworks. It has been demonstrated that in a clinically relevant scenario, where all abutment screws are tightened, the gap values would get smaller [34]. Therefore, utilizing the applied milling machine, all tested materials can be considered suitable for framework fabrication in terms of fit.

The assessment of fit of milled constructions on implants is a complex process. Model and scan body digitization can negatively effect the outcome; accuracy of the scanner, use of scan spray, distance between the implants, length of the edentulous ridge, or the precision of the scan bodies may impact results [35–40]. The software used for the superimpositions and for the triple-scan protocol to analyze the gap values at abutment-framework interface has been used in previous studies [22,41]. All frameworks were digitized with a high-precision industrial scanner, which provides an accurate basis for the analysis of the fit of the frameworks [42].

The precision of the data stored in implant libraries is crucial. Unlike with tooth-borne restorations, where the prepared die is digitized directly, the implant-prosthis interface is transferred with a scanbody that is aligned relative to the implant shoulder [43,44]. The coordinates of the transition between the implant and the prosthetic construction must be transferred to the CAD software precisely [43]. The fit of the framework on multi-unit abutment is defined by so-called “library file” or "base file", which is responsible for the interface contour of the planned construction and is specified by the library provider. Therefore, the base file is a decisive factor within the implant library and cannot be altered in the CAD design by the user [45]. It has a predefined gap and also specifies the contour of the inner geometry of the milled framework because the inner contour is milled based on the base file and not the intraoral scan itself [43]. Additionally, the base file defines the center and shape of the screw channel, and the screw head contact surface inside the screw channel relative to the implant axis. Depending on the CAD system, this information could also be provided by the abutment screw file, which is implemented in the library [46]. Hard materials, such as Ti, can displace the milling bur towards the center when machining the inner contour and the screw channel than when milling softer materials. This displacement may reduce the distance between the milled inner contour and the abutment, which is predefined in the implant library by the base file influencing the fit of the framework. Various studies have shown that the frameworks milled in softer materials using the same milling machine had smaller gaps than those milled in harder materials [47,48]. This is one of the reasons why many manufacturers predefine a larger gap when using hard materials (CoCr, Ti, etc.) for fixed partial dentures (e.g. CoCr, Ti, etc.). After milling, the predefined gap is usually smaller due to the displacement of the milling bur when milling a hard material. For the materials used in the present study, the hardness of PEKK is about 1.4 times greater than that of PEEK, and the hardness of Ti is about 14 and 10 times greater than the hardness of PEEK and PEKK, respectively. This could be another explanation why the best fit was found with PEEK, followed by PEKK, and then Ti. In addition, milling burs vary depending on the material to be milled. New burs specific to each material (same type for PEEK and PEKK) were used

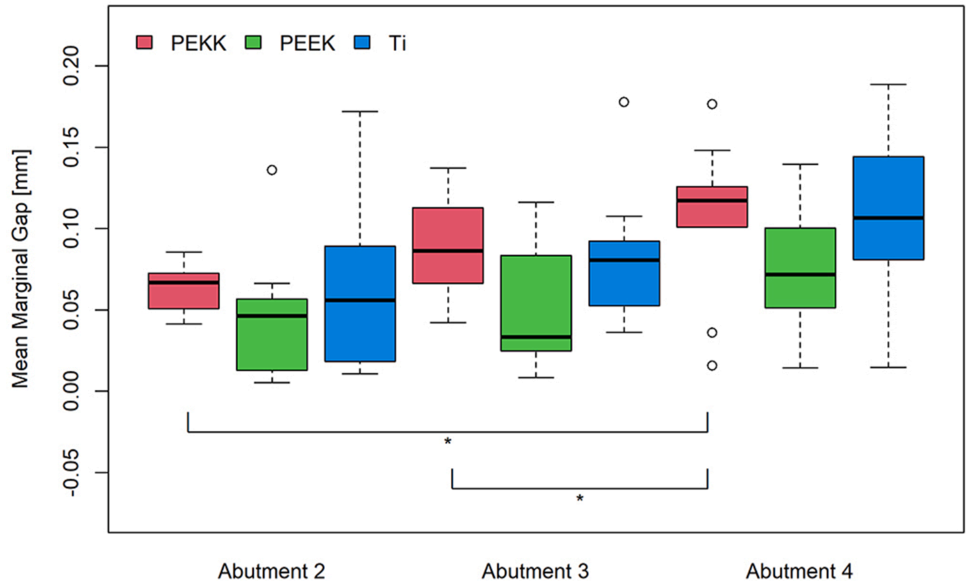

Fig. 5. Marginal fit: Median marginal gaps at three abutment-framework interfaces without prosthetic screws. Significance shown as *: $p \leq 0.05$. Abutment positions: Left canine = Abutment 2, right canine = Abutment 3, right molar = Abutment 4.

for the materials milled in the present study.

Another challenge to be considered is the state of milling with respect to the drilling of the screw channel and the screw head contact surface. An eccentrically manufactured screw channel can cause a lateral offset when tightening the abutment screws. Also, if the screw channel was manufactured exactly centric to the abutment axis, the framework can generate tension when tightening due to insufficient machining of screw head's contact surface with the screw channel. Residual material inside the screw channel or on screw head's contact surface area can influence the fit negatively. The effect of such factors can be minimized by carefully implementing milling strategies in the CAM software, using stable and suitable milling tools, and the experience and competence of the user, who is responsible for these processes [29,49].

The frameworks were designed to directly fit on the abutments without the inclusion of a Ti base to standardize the fabrication of frameworks in the present study. High-performance polymers require a Ti base to reinforce the polymer-screw head junction [50], which would add a cement interface that may affect the outcomes and prevent standardization of fabrication and comparisons of polymers with the Ti frameworks, which do not require a Ti base. Different results may be achieved when a Ti base is included in the design and cemented in the polymer.

Only one milling machine and one specific material for each group were used in the present study. Only the trueness and the fit but not the overall quality of the frameworks was analyzed, which should be further studied. One experienced software engineer carried out the trueness and marginal gap measurements for standardization. Bonding to high-performance polymers is a technique-sensitive procedure with limited scientific evidence available. Although a positive effect of various surface pretreatments, including airborne particle abrasion, plasma treatment, and different bonding agents, has been demonstrated, there is currently no gold-standard procedure that can be recommended for all types of high-performance polymers [51].

5. Conclusions

The trueness of PEEK, PEKK, and Ti frameworks was different after milled. PEEK had the highest trueness. However, the marginal fit of the frameworks was similar and smaller than 90 μm in average.

CRediT authorship contribution statement

Samir Abou-Ayash: Conceptualization, Data curation, Investigation, Methodology, Project administration, Supervision, Validation, Writing – original draft, Writing – review & editing. **Martin Schimmel:** Methodology, Project administration, Resources, Writing – review & editing. **Mutlu Özcan:** Conceptualization, Resources, Writing – review & editing. **Burak Ozcelik:** Investigation, Methodology, Validation, Visualization, Writing – review & editing. **Urs Brägger:** Methodology, Project administration, Resources, Writing – review & editing. **Burak Yilmaz:** Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing.

Declaration of Competing interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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