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Three-unit reinforced polyetheretherketone composite FDPs: Influence of fabrication method on load-bearing capacity and failure types

Running head: Flexural load of BioHPP bridges

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Abstract

To investigate the influence of different fabrication methods of three-unit reinforced polyetheretherketone composite (*PEEK/C*) fixed dental prostheses (*FDPs*) on fracture load. Forty-five three-unit anatomically supported *PEEK/C FDPs* were fabricated as follows: i. milled using a *CAD/CAM* system from an industrially fabricated *PEEK/C* blank, ii. pressed from industrially fabricated *PEEK/C* pellets, and iii. pressed from granular *PEEK/C*. Fracture load was measured and data were statistically analysed ($p<0.05$). *CAD/CAM* fabricated *FDPs* (2354N) presented a higher mean fracture load than those pressed from granular *PEEK/C* material (1738N) ($p<0.001$). *CAD/CAM* milled *FDPs* and those pressed from *PEEK/C*-pellets showed spontaneous and brittle fractures near the pontic without deformation of the *FDP*. In contrast, granulate pressed *FDPs* showed some plastic deformation without fracture. *CAD/CAM* fabricated *FDPs*, and *FDPs* pressed from *PEEK/C* pellets showed higher Weibull moduli compared to *FDPs* pressed in granular form. Industrial pre-pressing of blanks (*CAD/CAM*/pellet) increased the stability and reliability of *PEEK* restorations.

INTRODUCTION

Due to their specific mechanical properties including, *e.g.* damping effects, composite-based reconstructions are finding increased application, especially in implant borne restorations.[1,2] Industrial manufacturing of *CAD/CAM* (Computer Aided Design/Computer Aided Manufacturing) blanks for composite and *PMMA*-based reconstructions was shown to significantly improve mechanical properties.[3-5] Especially *CAD/CAM* composites can be applied as alternative materials to ceramic single tooth restorations.[3-8] In addition, a previous clinical study found that composite inlays had even a significantly better color match after three years than glass-ceramic inlays.[9] Although the *CAD/CAM* composite materials are very promising, there are also disadvantages, especially with regard to their abrasion resistance. In this context, laboratory and clinical studies report increased wear already after only a short loading periods.[8,10-12] To overcome the latter problem, a new generation of composites in dentistry, known as *PAEK* (polyaryletherketone) materials or as *PEEK* (polyetheretherketone) or *PEKK* (polyetherketoneketone) or reinforced *PEEK/PEKK* materials with inorganic fillers may be a suitable alternative with comparable wear properties in the range of ceramics as shown in some pilot trials (unpublished data). Additionally, *PEAK* is biocompatible and resistant to nearly all organic and inorganic chemicals and has also shown adequate mechanical properties.[13,14] Based on these excellent physical and biological properties - despite the lack of clinical long-term studies - this composite material seems to be suitable for superstructures in dentistry *i.e.* for dental implants, provisional abutments, fixed dental prostheses (*FDPs*), as well as implant-supported bars and clamps for removable prostheses.[15-19] *PEEK* represents a high performance thermoplastic polymer within this material group with a low melting temperature of 343°C and can therefore be processed in various ways. One possibility is pressing the material with a special vacuum-pressing device in a dental technical laboratory. For this purpose, *PEEK* is used either as industrially pre-pressed pellets or in granular form or. For the pressing process, the preheated muffle (with the press plunger) is placed into the vacuum-pressing device and pressed. Another option is the milling using *CAD/CAM* technologies where *PEEK* blanks are pressed industrially under standardized parameters such as pressure, temperature and time. All these fabrication methods can be applied using the same raw material for *PEEK FDPs*. So far, however, **results** of mechanical stress tests with these materials are limited and the available literature varies considerably in terms of investigated prosthetic applications. Therefore, the objective of this study was to test and compare the impact of three typical above mentioned different fabrication methods on the fracture load of 3-unit *PEEK/C FDPs*. The null hypothesis was that *CAD/CAM PEEK/C FDPs* show similar fracture load and failure types compared to *PEEK/C FDPs* pressed from granular or pellet material.

2. Material and methods

In this study, the fracture load of anatomically constructed *PEEK FDPs* was tested. For all *FDPs*, the identical raw reinforced *PEEK* composite (*PEEK/C*) material containing 20 wt% inorganic fillers was used, but *FDPs* were fabricated differently as follows: i) *CAD/CAM* milled from a *PEEK/C* blanks which were originally pressed from granular *PEEK/C* (breCAM Bio HPP blank; Bredent, Senden, Germany, LOT 381115), ii) pressed from industrially fabricated pellets which were also pressed from granular *PEEK/C* (Bio HPP Pellets; Bredent, LOT 381125), and iii) pressed from granular *PEEK/C* (Bio HPP Granular; Bredent, LOT 379806) (Fig. 1).

In order to produce standardized *FDPs*, a steel model with two abutments simulating a bridge between a canine and a first molar was used. The abutments of this model had flat occlusal surfaces and a ball end. They were cylindrically shaped (height: 5 mm; diameter canine: 7 mm; molar: 8 mm) with a 1-mm circular shoulder and 6° taper, and were surrounded by a 0.75 mm thick plastic covering, which simulated the periodontal ligament. The holder of the test set-up was made of aluminium alloy with cylindrical holes with a distance of 16.5 mm. After scanning (Ceramill Map 400; AmannGirrbach, Koblach, Austria), an anatomically supported *FDP* was constructed (Ceramill Mind; design software, AmannGirrbach). The connectors had a cross-sectional area of 16 mm², an occluso-gingival height of 4.45 mm, and a bucco-lingual width of 3.60 mm. The pontics showed a cavity in their middle congruent to the loading stainless steel ball (diameter 5 mm) ensuring a 3-point-contact between the steel ball and the occlusal surface at loading.

In total, fifteen *PEEK/C* (breCAM Bio HPP, Bredent, LOT 381115) and thirty wax *FDPs* (breCAM.wax; Bredent, LOT 380089) were milled (ZENO 4030 M1; Wieland+Dental, Pforzheim, Germany). The wax *FDPs* were randomly divided into two groups (*n*=15 per group), *i.e.* pressed using either *PEEK/C* pellets (Bio HPP Pellets; diameter: 20 mm, Bredent, LOT 381125) or granular *PEEK* (Bio HPP Granular; Bredent, LOT 379806). Afterwards, wax *FDPs* were embedded (Brevest for 2 press investment material; Bredent, LOT 121012) in a muffle according to the manufacturer's instruction. After 20 min, the muffle was heated up to 630°C for 60 min (for *PEEK/C* granular) or 90 min (for *PEEK/C* pellets) and then cooled to 400°C at a cooling rate of 8°C/min. Subsequently, the pre-heated muffle was filled with *PEEK/C* granular/pellets, and kept in the preheating oven for 20 min at 400°C. As the next step, *FDPs* were pressed at a pressure of 2.3 bar (for *PEEK/C* granular) or 4.5 bar (for *PEEK/C* pellet) in a special vacuum-pressing device (Vacuum pressing device for 2 press; Bredent). For this pressing process, one plunger for each muffle was used and the pressing process lasted for 25 min. After cooling, the investment material was removed in an aluminium oxid blasting unit (Fine-blaster type FG 3; Sandmaster, Zofingen, Switzerland) using 105 µm Al_2O_3 (Hasenfratz, Sandstrahltechnik, Aßling, Germany) at a pressure of 2 bar. The *FDPs* were finished using a silicone polisher (Ceragum Wheel; Bredent) and polishing paste (Abraso-Starglanz; Bredent) for 3 min. Before fracture load testing, all *FDPs* were ultrasonically cleaned in distilled water for 5 min (Ultrasonic T 14, Kearny, NJ, USA). Subsequently, the uniformity of all different fabricated FDPs was checked using a silicon mold, which was based on a *CAD/CAM* fabricated *FDP,* which served as the master model for the silicon mold. Thus, all *FDP*s showed comparable overall thickness.

Fracture load measurement

FDP specimens were then cemented with a resin composite cement (Variolink II, Vivadent-Ivoclar, Schaan, Liechtenstein, LOT R35481/P84939) on corresponding steel abutments according to the manufacturer's instructions. Before cementation, the inner surfaces of the restorations were treated as mentioned above in the text (air-abrasion and cleaning ultrasonically). The metal abutments were not pre-treated. Variolink II was mixed in a 1:1 ratio for 10 s and then applied on the inner surfaces of FDPs. The restorations were placed on the model and excess cement was removed. A special cementing device was used to ensure that the pontic was loaded centrally at a force of 0.98 N for 10 min.

After 24 h water storage (37°C), the cemented *FDPs* were subjected to testing and were loaded in a universal testing machine (Zwick/Roell 1445; Zwick, Ulm, Germany) at a cross-head speed of 1 mm/min with a steel ball (diameter 5 mm) placed on the centre of the pontic. To achieve an even force distribution, a 0.5 mm tin foil (Dentaurum, Ispringen, Germany) was placed between the pontic and the loading ball. The measurement stopped as soon as fracture load decreased by 10% of the maximum load (Fmax). An illustration of the test set-up is shown in Figure 2.

Afterwards, a fracture types analysis was performed. Failure modes were defined has having occurred either as “complete fracture” or by deformation.

Statistical analysis

Fracture load results were presented descriptively by means, standard deviation (*SD*) and the corresponding 95% confidence intervals (95% *CI*). Normality of data distribution was tested using Kolmogorov-Smirnov and Shapiro-Wilk tests and one-way *ANOVA* together with the Scheffé post-hoc test was applied in order to investigate the fracture load differences between the groups. In additional, Weibull statistics (shape, scale) were computed. In all tests *p*-values smaller than 5% were considered to be statistically significant. The data were analysed using a software package for statistical analysis (SPSS Version 20, SPSS INC, Chicago, IL, USA).

3. Results

The fracture load results of each group are presented in Table 1 and Figure 3. Figure 4 shows a typical load-displacement curve for each *PEEK/C* material. Kolmogorov-Smirnov and Shapiro-Wilk tests indicated no violation of the assumption of normality for all tested groups. The milled *CAD/CAM FDPs* (2354±422 N) showed significantly higher fracture load than those pressed from granular *PEEK/C* (1738 ± 439 N) ($p<0.001$). No differences were observed between *FDPs* pressed using *PEEK/C* pellets (2011±353 N) and the other groups.

According to the Weibull statistics, *CAD/CAM* milled *FDPs* (2527 N) showed significantly higher ($p<0.001$) characteristic fracture load (scale) than bridges pressed from granular *PEEK/C* (1902). No further differences were found. *PEEK/C FDPs* pressed with granular *PEEK/C* (4.63) showed a significantly lower (*p*<0.001) Weibull modulus (shape) compared to *CAD/CAM* milled *PEEK/C* (6.27) and pellet-pressed *PEEK/C* (6.49).

During fracture load tests *CAD/CAM* milled *FDPs* and pellet-pressed *FDPs* usually fractured at the pontic whereas the *FDPs* pressed from granular *PEEK/C* usually showed plastic deformation of the bridge, without complete fracture (Fig. 5).

4. Discussion

This study assessed the influence of different fabrication methods of three-unit reinforced *PEEK/C FDPs* on fracture load. The data obtained in this study support the rejection of the null-hypothesis, since the fracture load of differently fabricated *FDPs* was statistically different. **In general, the industrially pre-pressed and consequently milled *CAD/CAM FDPs* showed higher fracture loads than those pressed from granular *PEEK*. It can therefore be assumed that the industrial pre-pressing process for the *CAD/CAM* blanks and for the pellets increases the mechanical properties. Additionally,** *CAD/CAM* blanks after industrial fabrication under optimal conditions display a reduced risk of porosities within the restorations and therefore show improved mechanical properties. In contrast, the mechanical properties of pressed *FDPs* are more operator-dependent: The preheating method, the vacuum pressing device and other factors may influence the overall quality of the specimens. According to the fracture types, information regarding the brittleness of the material can be won: *FDPs* fabricated from pre-pressed *CAD/CAM* blanks and *FDPs* pressed from pellet *PEEK/C* showed complete fractures at the pontic, whereas *FDPs* pressed from granular *PEEK/C* usually displayed a plastic deformation without complete fracture. Hence, it can be supposed that an additional industrial pre-

pressing of *PEEK/C* blanks/pellets does not only increase the flexural strength of the material, but also reduces its elastic deformability.

Despite of its relatively rigid molecular chain structure, thermoplastic *PEEK* material demonstrated considerable ductility and can accommodate a wide range of plastic deformation, in both uniaxial tension and compression.[14)] However, the material used in this study was optimized in its mechanical properties due to the combination with inorganic fillers (20 wt%). The mean fracture load for the granulate group was deformed at 1738 N, however plastic deformation and no fracturing was found and slight deformation was initially observed at approximately 1600 N. Maximum occlusal forces between posterior teeth have been measured up 909 N.[20)] Of course, this function depends on varying factors such as restoration type, measurement process, diet, and gender variation.[20)] However, it can be assumed that the *FDPs* analyzed in this study would withstand clinical applications without restrictions.

In the present study, the connector area of the *FDPs* was set at to 16 mm^2. An increased connector surface area would have probably additionally increased the results.[21)] Another study investigating the fracture load of *CAD/CAM* milled non-veneered three**-unit *PEEK FDP* frameworks with a connector area of 7.36** mm^2 **observed a fracture load of 1383 N with a deformation at approx. 1200 N.[19)] The *CAD/CAM* milled *PEEK/C FDPs* in the present study showed a higher mean fracture load of 2354 N.** The manufacturer published data regarding C*AD/CAM* milled three-unit *PEEK FDPs*, veneered with resin composite, **which showed a mean fracture load of 2055 N.[22)]** These values are comparable to those in the present study (1738 N- 2354 N). This was even higher than values found for three-unit-*FDPs* made of lithium disilicate glass-ceramic (950 N),[23)] In-Ceram Alumina (851 N),[24)] In-Ceram Zirconia (841 N),[24)] and **zirconia (981-1331 N).[23,25)]** In contrast, composite- and *PMMA*-based three-unit *FDPs* showed much lower mean fracture loads ranging from 268 N to 467 N.[5)]

In the present study, Weibull statistics were also applied to characterize the structural reliability of the materials.[20,26)] In doing so, a **lower** Weibull modulus indicated a greater variability and thereby less reliability in strength, most probably due to flaws and defects in the material.[20)] **Significant differences in Weibull moduli were observed: *FDPs* pressed from granulate showed a lower modulus compared to *CAD/CAM* milled *FDPs* and *FDPs* pressed from *PEEK/C* pellets.** Again, the statement can be confirmed that an additional industrial pre-pressing of *PEEK/C* increases the Weibull moduli and thus leads to improved reliability of the material.

An increase in fracture load was found when *FDPs* were non-rigidly mounted[27,28)] and when the elastic modulus of the abutment was higher.[27-29)] The clinical situation could be simulated by investigating non-rigidly mounted abutments with an elastic modulus similar to that of natural teeth.[4,30)] Although the physiological mobility of teeth was simulated with a emulated periodontal ligament, it must still be emphasized that steel abutments with an elastic modulus of 180 GPa were used, whereas natural teeth only have an elastic modulus of approximately from 15 (dentin) to 85 (enamel) GPa. It could therefore be assumed that the stability of the *FDPs* in a clinical situation might therefore be slightly lower. As the specimens in this study were not aged, further investigations with additional aging through chewing simulation or thermal cycling are required for more longitudinal clinical aging data or at least trends. Of course, clinical studies are also needed to support the use of *PEEK* for long-term restorations.

Conclusions

Within the limitations of this in-vitro study, it can be summarized that, based on the findings in this study, milled *PEEK/C FDPs* displayed advantages over *FDPs* pressed from granular *PEEK/C*. Therefore, it can be concluded that

- *PEEK/C* reinforced with other inorganic fillers can be potentially used as crown and bridge material
- Industrial pre-pressing of blanks (*CAD/CAM*/pellet) increases the stability and reliability of *PEEK/C* restorations.

Acknowledgments

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Figure 1: Study design, division of specimens according different pretreatments, veneering resin composites and adhesive systems.

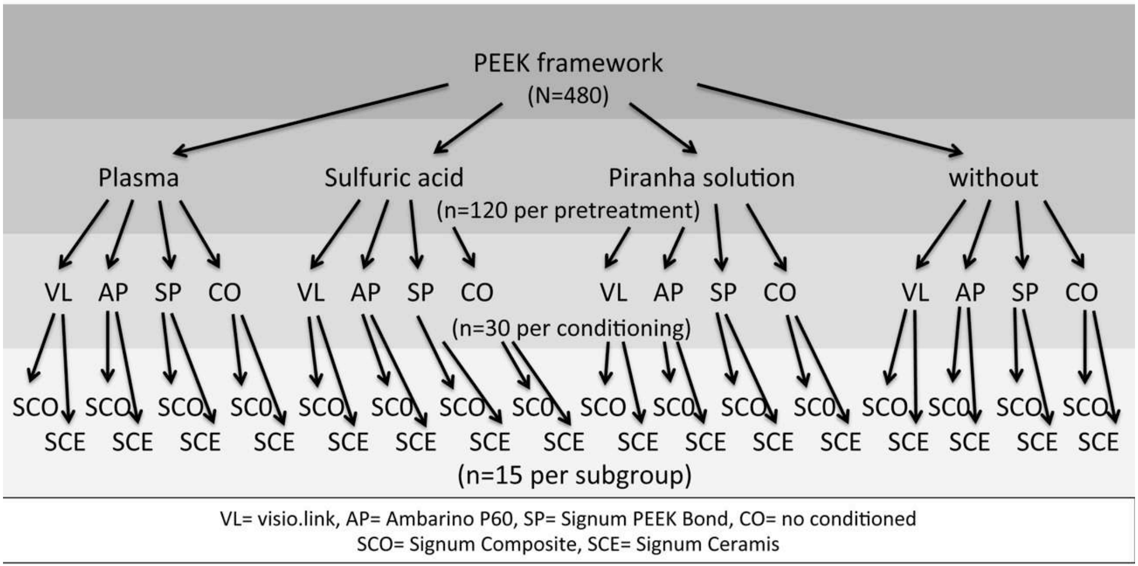

Figure 2: Veneered PEEK FDPs positioned in the universal testing machine with teflon foil between the pontic and the loading jig.

Figure 3: Boxplots for fracture load of veneered FDPs [N] of all tested groups.

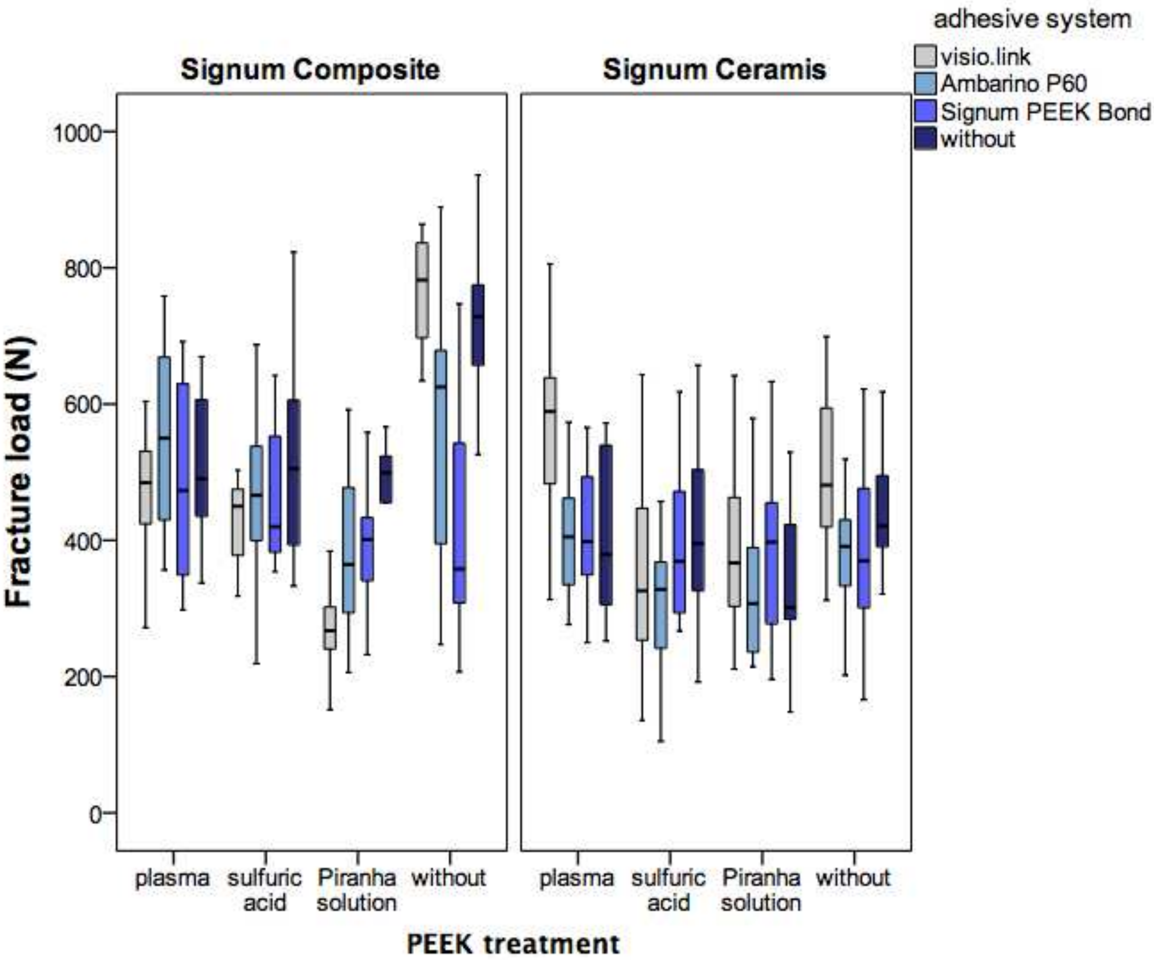

Figure 4: Failure types A. after thermal cycling - cracks in veneering resin composite, B. after fracture load measurements - adhesive failures between PEEK framework and veneering resin composite.

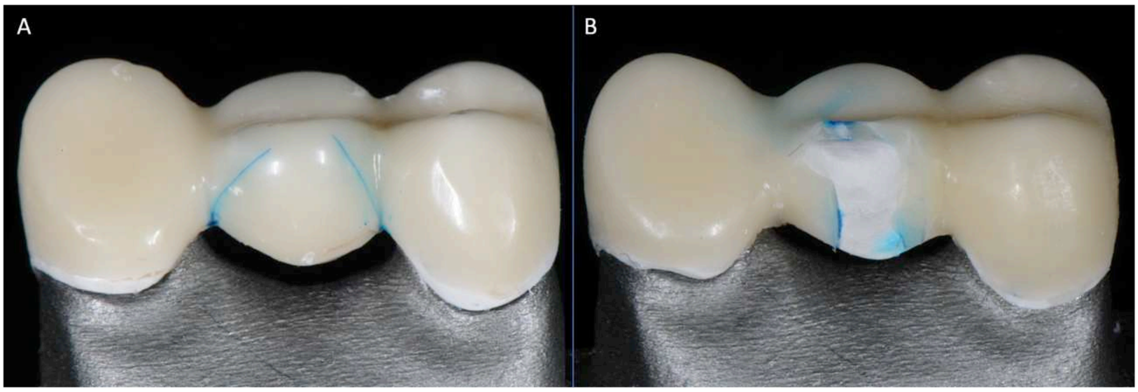

Figure 5: Surface topography after a: plasma treatment, b. etching using sulfuric acid, c: etching using piranha solution and d: no treated PEKK surface (50,000 × magnification).

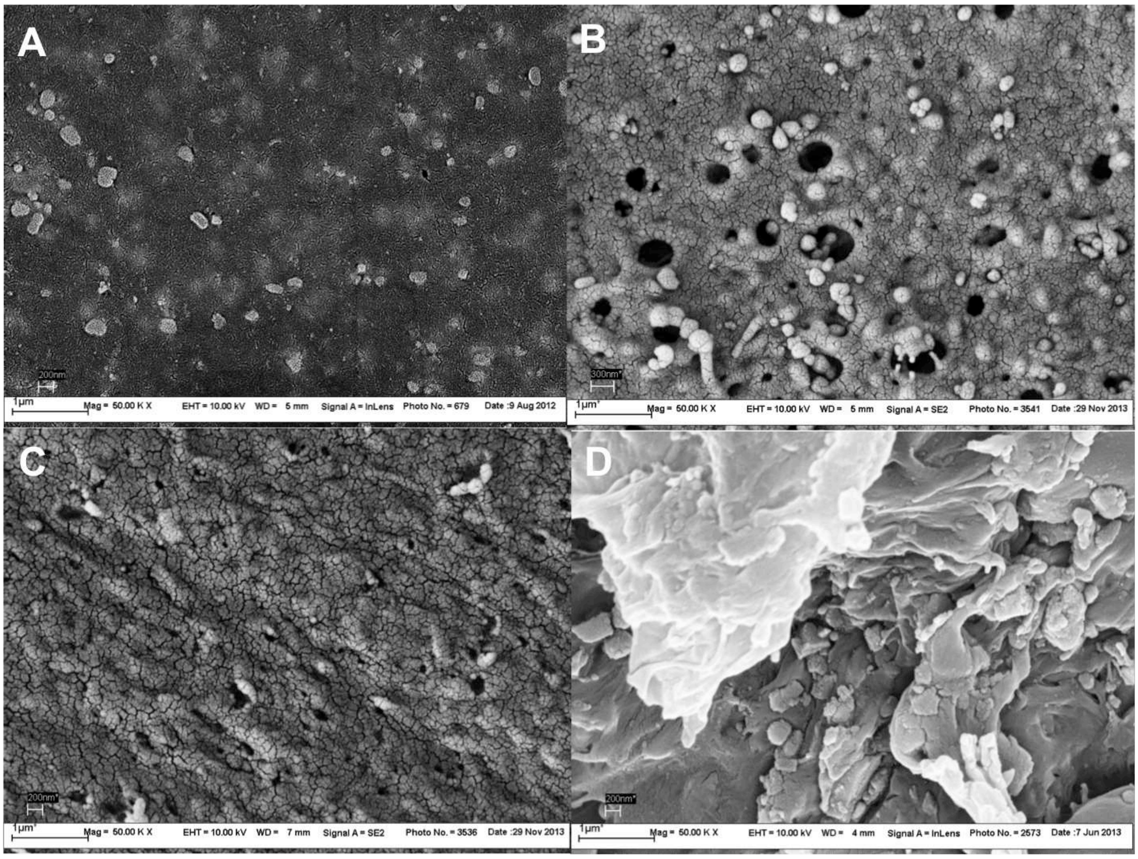

Figure 6: Boxplot of measured surface roughness values after different pretreatments of air-abraded PEEK surfaces.

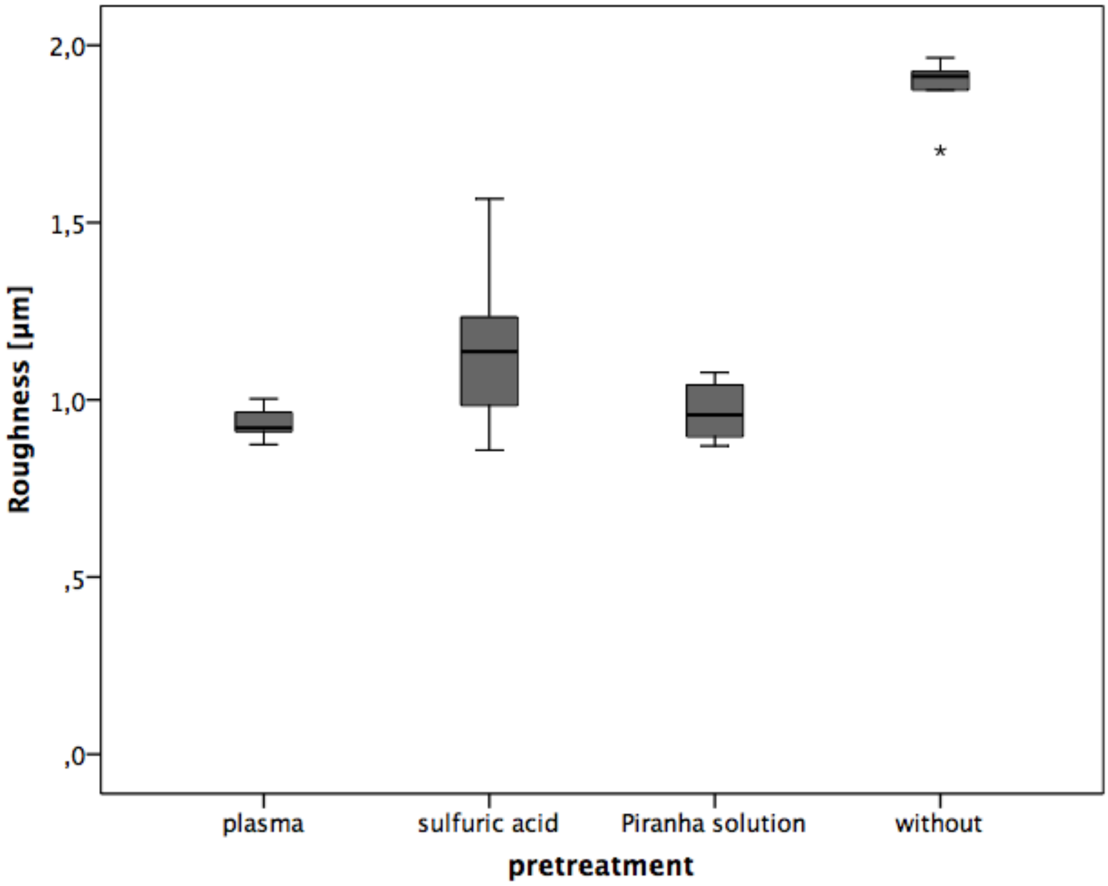

Table 1. Results of the fracture load evaluation and Weibull statistic analyses for all tested groups.

Normal distribution (N)						
	mean	SD	95% CI	min	median	max
CAD/CAM milled PEEK	2354^{b}	422	2118;2588	1571	2384	3169
pressed pellet PEEK	2011^{ab}	353	1814;2208	1388	2026	2660
pressed granular PEEK	1738^{a}	439	1494;1981	1187	1591	2631
Weibull distribution						
	scale (N)			shape		
CAD/CAM milled PEEK	2527^{b}			6.27^{b}		
pressed pellet PEEK	2155^{ab}			6.49^{b}		
pressed granular PEEK	1902^{a}			4.63^{a}		

***** Different superscript letters (a, b) represent a significant difference according to post hoc test between the different fabricated *FDP*s.