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ORIGINAL ARTICLE / ОРИГИНАЛНИ РАД

Lithium disilicate and PEEK implant-retained single crowns – a randomized, prospective clinical study

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SUMMARY

Introduction/Objective Comparing two materials under the same conditions is the best way to define differences between them. Ceramic-reinforced polyether-etherketone (PEEK) is a polymer that has many possible uses in dentistry as already well-known lithium disilicate ceramics.
The aim of this study was to compare peri-implant soft tissue healing and evaluate patient satisfaction with esthetics in different observation periods, as well as the success and survival rate of both types of crowns.
Methods The study was conducted as a clinical, prospective, randomized split-mouth study on 17 patients with bilaterally missing upper teeth of the same type, replaced with dental implants. Study outcomes have been analyzed with subjective (visual analogue scale – VAS scale) and objective parameters (modified bleeding index – MBI, modified plaque index – MPI and peri-implant probing depth – PPD) baseline, six and twelve months after fixing crowns onto the implants.
Results Comparison of the results between PEEK and lithium disilicate crowns showed no statistical differences in terms of MPI, MBI, and PPD in the observed periods. Analyzing MPI during observation periods in the PEEK group of crowns, statistical significance was registered between baseline values and after six months. Also, statistical significance was noticed in terms of PPD during the observation time both in the study and control group of crowns. Results for VAS for the esthetics showed no statistically significant difference between the groups, while VAS for restoration satisfaction showed a statistically significant difference.
Conclusion This study showed that scores of the applied subjective and objective parameters can be a reliable tool to rate the clinical outcome of implant-retained single crowns over time.
Keywords: lithium disilicate; PEEK; single crowns; implants

INTRODUCTION

Nowadays, all-ceramic materials are frequently used for implant-retained single crowns to improve the esthetic result. As the esthetic demands in implant treatment have increased, the abutments started to be fabricated of ceramic materials, which are designed as one component and Titanium base (Ti-base) abutments. The most often used materials for this purpose are zirconia and lithium disilicate ceramic [1]. These materials are also used for implant-retained fixed restorations. Apart from ceramic materials, there are some new polymer materials on the market that are used for prosthetic restorations in conventional and implant prosthodontics. Lithium disilicate is a well-known material, which can be used for single crowns and all-ceramic fixed partial dentures framework veneered with ceramic [2, 3]. Crystals of lithium disilicate of 0.5–0.6 μm diameter are added to the glass matrix, depending on the technological method of fabrication. Lithium disilicate ceramic can be fabricated with a "press" technique in the laboratory, or CAD-CAM technique by the milling process, for chairside and laboratory settings. Both materials can be fabricated in full contour, stained and glazed in the cut back-body form layered with ceramics [4].

Also, there are some polymer materials on the market used for prosthetic restorations in conventional and implant prosthetics, and one of these materials is ceramic-reinforced polyether-etherketone (PEEK) with 30% of ceramic particles [5]. This material has constant homogeneity due to reinforced ceramic particles of 0.3 to 0.5 μm diameters [6, 7]. As crystalline thermoplastic resin is reinforced with ceramic particles, it withstands extreme forces [5, 6, 7]. It is biologically stable, so there are no reactions with other materials and ion exchanges. Also, there is no galvanic cell in the oral cavity and it does not cause pigmentation [5, 6, 7]. This material shows good biological properties in terms of biocompatibility; moreover, its elasticity is similar to human biomechanics [5, 6, 7]. As a base for prosthetic restoration, it satisfies the high esthetic criteria of contemporary implant dentistry. Due to its white color, it is an ideal base for veneering with conventional composite materials. It can be highly polished, so it does not cause abrasion of antagonist teeth [5, 6, 7].

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The aim of this study was to compare lithium disilicate and PEEK implant-retained single crowns, in terms of peri-implant soft tissue healing, esthetics and restoration satisfaction, as well as the success rate.

METHODS

The study was conducted as a clinical, prospective, randomized split-mouth study of implant retained lithium-disilicate and PEEK screw-retained crowns, and consisted on two groups - study and control group. Both of the groups consisted of the same 17 patients (70% females and 30% males, aged 24 to 62 years, mean age 44.33 ± 15.4) with bilaterally extracted teeth in the same region of the upper jaw. The study was conducted at the Clinic of Oral Surgery and Clinic for Prosthodontics, the School of Dental Medicine, University of Belgrade; it was approved by the Ethical Committee of the School of Dental Medicine, University of Belgrade.

The patients were recruited consecutively from the mentioned clinics. The inclusion criteria were: patients with already osseointegrated implants in the same region of the left and right upper dental arches, older than 18 years old, with maintained natural antagonists and vertical dimension of occlusion, and canine guided or group function occlusion. Exclusion criteria were the existence of bruxism and temporomandibular disorders, missing of the opposing teeth, and unmotivated patients for maintenance adequate oral care. The patients were fully informed about the protocol of the study, and all gave their written consent.

All the patients received Blue Sky implants (Bredent®, Senden, Germany), 4 mm diameter, and 10 mm length, on both sides. Implants were placed after planning with a cone-beam computed tomography (CBCT) scan, in a one-stage surgical procedure. Crowns were made of two different materials, put on osseointegrated implants with delayed loading protocol. Considering the split - mouth study design, each group of crowns was randomly assigned to either left or right halves of the upper jaw. The study group of crowns, PEEK based crowns (BioHpp®), were made on Sky Elegance abutment®, which consisted of a titan base coated with ceramic, reinforced with PEEK polymer. These crowns have been directly pressed on Sky Elegance abutment®, using For2press® system, made in a cut-back body form, and furtherly prepared for veneering with CreaLign® veneering material. The control group consisted of litihium disilicate crowns (IPS e.max) made on Sky Uni. fit® abutment, which consisted of a titan base and "burn out" cap as the modeling base. Core for the control group crowns was first modeled in wax on the Sky Uni. fit® abutment, shaped in a cut-back body form. After pressing in „Emax press system" (IPS e.max Press®), veneering was performed with Emax® veneering ceramics. After Emax crowns finishing, DTK® bonding material was used for connection with Sky Elegance® abutment (Figure 1). Both groups of crowns were fabricated on Ti-base, screw-retained abutment.

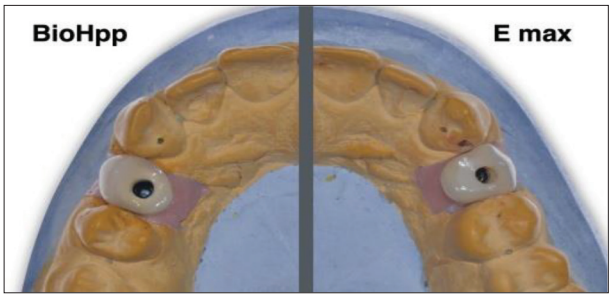

Figure 1. BioHpp® and Emax® crowns

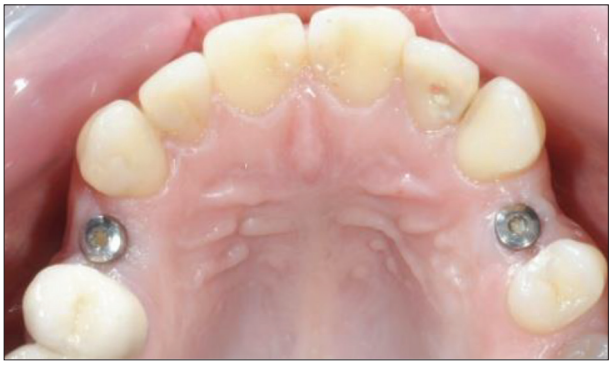

Figure 2. Osseointegrated implants and healing abutments

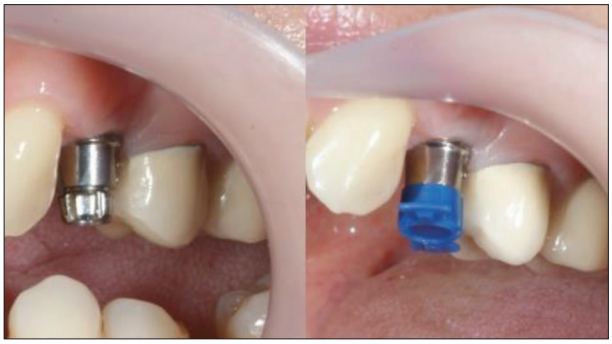

Figure 3. Transfers for closed tray impression technique

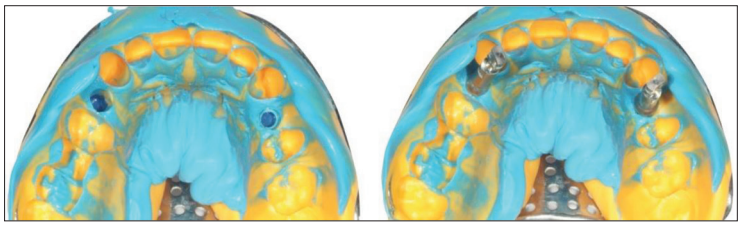

Figure 4. a) Closed tray technique impression; b) analogue reposition

After implant placement, healing abutments were placed on the implants in order to create a profile and to protect the implants (Figure 2). Full arch impression on implant level was obtained using the closed tray method with esthetic transfer (Esthetic transfer closed tray) - Figure 3. Impressions were taken with a silicone material (Elite HD+ Putty Soft Normal Set, Zhermack®, Italy), by use of a standard tray, in a single-step technique (Figure 4). Impressions of the opposite jaw were made with alginate (Hydrogum 5, Zhermack®, Italy) in standard steel trays. Finally, inter-occlusal registration in centric relation was made in Silicon A material. After defining vertical

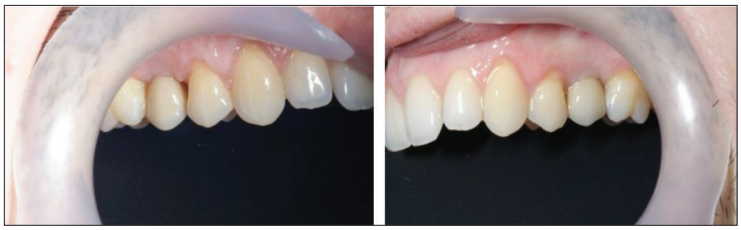

Figure 5. a) BioHpp®crown; b) IPS e.max® crown

dimension, models were transferred into an articulator (Artex CR, Amman® Girrbach, Austria) with a face bow.

The crowns were put in the mouth for analysis of occlusal relation in maximum inter-cuspation and eccentric movements, evaluating contour and aesthetic parameters. After finishing laboratory procedures and glazing (Figure 4), crowns were placed onto the implant and tightened with the manual screw-driver. A resilient material, such as teflon tape was placed in the screw access channel and closed with a temporary filling. Within a week, the previous temporary filling was removed and the abutment screw was re-tightened to the recommended torque of 25 Ncm [8]. Teflon was placed again into the screw access channel and filled with a composite resin (Figure 5).

Study outcomes were analyzed with subjective and objective parameters six and twelve months after placing crowns onto the implants. Subjective parameters, such as esthetics and patient satisfaction with the restoration, were evaluated with standardized questionnaires on visual-analogue scales (VAS) [9]. This scale was presented as a line length of 10 cm, followed by verbal descriptions, where the beginning of the scale was defined with "totally unsatisfied," and the end as "totally satisfied" [9]. Patients were asked to vertically mark their opinion concerning the comfort, general chewing possibility, and aesthetics, and results were notified and measured from the null point to the marked line. Objective parameters in crown comparing were based on characteristics of soft tissues around dental restorations with a periodontal probe, done in observation periods at baseline, after six and 12 months. These clinical findings were recorded according to the following criteria [10]: 1) Modified Bleeding Index - MBI (0 – no bleeding on probing; 1 – isolated bleeding spots present; 2 – blood forms a red line on the gingival margin; and 3 – heavy profuse bleeding); 2) Modified Plaque Index (MPI) (0 – no detection of plaque; 1 – plaque only recognized by running a probe across the smooth marginal surface of the implant; 2 – plaque can be seen by the naked eye; 3 – the abundance of soft matter); and 3) peri-implant probing depth (PPD) measured by probing with a periodontal probe with millimeter graduation (Hu Friedy® periodontal probe) on all four sides of the osseointegrated implant, with the controlled force of 0.25N to resistance appearance.

Statistical analysis

All collected data were organized and evaluated using the dedicated software (SPSS Statistics, Version 17.0; SPSS Inc., Chicago, IL, USA) and were analyzed by descriptive statistical methods, by the measures of central tendency (mean and median), measure of variability (standard deviation and variation interval – minimum, maximum). Testing differences of numerical data between groups was done by the Mann–Whitney test (between two observed groups) and numerical data in each group during time by the Wilcoxon test (in one of the groups during observation periods). The level of significance was set at $p \leq 0.05$.

RESULTS

Clinical examination of the MBI and MPI at baseline, after six and 12 months among the observed groups did not show statistical significance in mean values (Tables 1 and 2). Additionally, analyzing mean values of MPI during observation time in the study group of crowns, statistical significance was registered at baseline (0.12 ±0.33; from 0 to 1) compared to the period after six months (0.35 ± 0.49; 0–1) – Table 1.

Table 1. The values of MBI during the time between groups of crowns

Clinical parameter	Study group of crowns		Control group of crowns		[b]p
	X ± SD; med (min–max)	[a]p	X ± SD; med (min–max)	[a]p	
MBI at baseline	0.12 ± 0.33; 0 (0–1)	(1:2) 0.046 (2:3) 0.705 (1:3) 0.083	0.06 ± 0.24; 0 (0–1)	(1:2) 0.317 (2:3) 1.000 (1:3) 0.317	0.551
MBI after six months	0.35 ± 0.49; 0 (0–1)		0.12 ± 0.33; 0 (0–1)		0.111
MBI after 12 months	0.29 ± 0.47; 0 (0–1)		0.12 ± 0.33; 0 (0–1)		0.210

MBI – modified bleeding index; X – mean value; SD – standard deviation; med – median; a – Wilcoxon test; b – Mann–Whitney test; p – significance;
* – statistically significant

Table 2. The values of MPI during the time between groups of crowns

Clinical parameters	Study group of crowns		Control group of crowns		[b]p
	X ± SD; med (min–max)	[a]p	X ± SD; med (min–max)	[a]p	
MPI at baseline	0.29 ± 0.59; 0 (0–2)	(1:2) 1.000 (2:3) 0.739 (1:3) 0.705	0.18 ± 0.39; 0 (0–1)	(1:2) 0.157 (2:3) 0.180 (1:3) 0.564	0.551
MPI after six months	0.29 ± 0.47; 0 (0–1)		0.06 ± 0.24; 0 (0–1)		0.111
MPI after 12 months	0.24 ± 0.44; 0 (0–1)		0.24 ± 0.44; 0 (0–1)		0.210

MPI – modified plaque index; X – mean value; SD – standard deviation; med – median; a – Wilcoxon test; b – Mann–Whitney test; p – significance;
* – statistically significant

Table 3. The values of PPD during the time between groups of crowns

PPD	Study group crowns		Control group of crowns		[b]p
	X ± SD; med (min–max)	[a]p	X ± SD; med (min–max)	[a]p	
At baseline	1.99 ± 0.70; 2 (1–3.25)	(1:2) 0.002 (2:3) 0.004 (1:3) 0.001	2.10 ± 0.85; 2 (1–4)	(1:2) 0.006 (2:3) 0.006 (1:3) 0.003	0.865
After six months	2.28 ± 0.73; 2.25 (1.25–3.75)		2.28 ± 0.85; 2 (1–4)		0.973
After 12 months	2.47 ± 0.73; 2.75 (1.25–3.75)		2.47 ± 0.88; 2.25 (1–4)		0.973

PPD – peri-implant probing depth; X – mean value; SD – standard deviation; med – median; a – Wilcoxon test; b – Mann–Whitney test; p – significance; * – statistically significant

Table 4. The values of visual analogue scale for esthetics and restoration satisfaction in both groups of crowns

Visual analogue scale	Study group of crowns	Control group of crowns	[a]p
	X ± SD; med (min–max)	X ± SD; med (min–max)	
Aesthetic outcome	9.95 ± 0.11; 10 (9.7–10)	9.84 ± 0.30; 10 (9.1–10)	0.357
Satisfaction with the restoration	9.88 ± 0.18; 10 (9.5–10)	9.37 ± 0.92; 9.7 (7.3–10)	0.002*

X – mean value; SD – standard deviation; Med – median; a – Wilcoxon test; b – Mann–Whitney test; p – significance; * – statistically significant

In terms of mean values of the PPD, there was no statistically significant difference between crown groups during the time (Table 3). However, statistical significance was found in intragroup comparison during the time both in the study and control group of crowns (baseline *vs*. after six months, after six months *vs*. after 12 months, and baseline *vs*. after 12 months) – Table 3.

The mean value of VAS testing for esthetic outcome in both groups of crowns showed no statistical difference (Table 4). The mean scores for VAS referring to satisfaction with the restoration indicate a statistically significant difference between groups, where study group restorations were valued by patients with the higher score (Table 4).

During the implant observation period, no implant was lost, resulting in an implant survival rate of 100%. The restoration cumulative survival rate in both groups was 100%. The fracture of the veneer material occurred in one single crown in the study group, while in the control group, two fractures were registered. The cumulative success rate was 94.12% for the study group of crowns and 88.23% for the control group of crowns.

DISCUSSION

In the conducted study, the split-mouth design was used for randomization, which is previously described as a very popular design in oral health research [11]. The advantage and the attractiveness of this study design compared to the whole-mouth design is that all variabilities within the subjects are removed [11]. On the other hand, some authors indicated disadvantages of this study design, referring to the problem of the patient recruitment due to the need for symmetrical patterns of randomization, and the "carry-cross effect," in which the main problem is that it compromises the possible confusion concerning treatment effect from one side to the other [12, 13, 14].

This study shows that patients were more satisfied with crowns made of PEEK material, which is very important parameter in the oral rehabilitation process and it should be used for the evaluation of the specific therapy [15]. Previous studies did not analyze patient's satisfaction with these types of crowns, but many of them refer to the efficiency of the implant therapy based on patient satisfaction, wherein most of the cases patients claimed that they were satisfied [16–20]. Chang et al. [21] established that patients have marked implant-retained crowns as "very satisfying" concerning esthetics, while clinicians were "less satisfied" with the same crowns. The findings in a three-year follow-up study showed no significant difference for VAS analysis of patient satisfaction about function and esthetic appearance, between the two groups – single implant screw-retained monolithic lithium disilicate and veneered zirconia crowns [22].

Our study has shown no statistically significant differences among the soft tissue parameters (MBI, MPI and PPD) between the observed groups of crowns, which is in correlation with the previous three-year follow-up study for the anterior implant screw-retained IPS e.max crowns, where similar results were demonstrated [23]. In the mentioned study, the mean values of MPI and MBI at baseline, after six months, one year and three years showed no statistically significant differences [23]. In addition, another study which compared clinical performances of screw-retained, monolithic, zirconia, and cemented porcelain-fused-to-metal implant crowns, showed no statistically significant difference between the study and the control groups in terms of the soft tissue parameters such as bleeding on probing and plaque index at the third, sixth, ninth, and 12th month after prosthetic loading [24].

Nevertheless, in our research, statistically significant difference was registered in terms of the mean values of MPI between baseline and after 6 months in the study group of crowns. Also, statistically significant intragroup differences were noticed in terms of PPD during the time, both in the study and control group of crowns, which is in correlation with the results of previous studies [23, 24, 25].

Suggested clinical parameters are commonly used as an evaluation method in the clinical trials for implant-retained restorations [26]. The peri-implant soft tissue is very important, and always must be evaluated, not only for the esthetics but also for the long-term stability of the implant-retained restorations. Our results of soft tissue parameters between the observed groups indicate that

the new system, that has been recently launched into the market (BioHpp®) can clinically perform as well as lithium disilicate material used in the For2press system (IPS e.max Press®), which has been marketed for many years.

The soft tissue around the implants has a similar role as soft tissue around natural teeth. Besides, dense soft tissue forms a protective barrier for crestal bone, as it creates contact with the abutment surface [27]. Previous studies have shown that there are some differences in anatomical characteristics of the soft tissue surrounding the implant and natural dentition; natural teeth are connected with perpendicular Sharpey's fibers, while the weaker connection is formed with parallel and circumferential fibers around the abutment surface [26, 28, 29].

CONCLUSION

The findings of this study showed that scores can be a reliable tool to rate the clinical outcome of implant-retained single crowns over time. MBI, MPI, PPD, and VAS scores can also be useful to monitor any possible early failure and to standardize follow-up recalls. Furthermore, the two materials tested in this randomized controlled trial showed comparable clinical performances, with a high success rate after one year of service. Nevertheless, future studies should be conducted to show clinical advantages or disadvantages referring to this new material for the solo crown in prosthodontics.

Conflict of interest: None declared.

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Литијум-дисиликатне и ПЕЕК имплантатно ношене шрафом ретиниране соло крунице – рандомизована, проспективна клиничка студија

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САЖЕТАК

Увод/Циљ Поређење два материјала под истим условима најбољи је начин за дефинисање разлика између њих. ПЕЕК је полимер који има много потенцијалних употреба у стоматологији, исто као и већ добро позната литијум-дисиликатна керамика.

Циљ овог истраживања био је да се, између два типа круница, упореди зарастање периимплантатног меког ткива у различитим периодима посматрања, процене естетска својства и задовољство пацијената зубним надокнадама, као и успех и стопа преживљавања.

Методе Студија је спроведена као клиничка, проспективна, рандомизована студија подељених уста на 17 пацијената са билатерално недостајућим горњим зубима исте врсте и уграђеним имплантатима у том пределу. Процена је извршена субјективним (визуелна аналогна скала) и објективним параметрима (модификовани индекс крварења, модификовани плак индекс и дубина сондирања).

Резултати Поређење резултата између ПЕЕК и литијум-дисиликатних круница показало је да нема статистички значајних разлика у погледу модификованог плак индекса, модификованог индекса крварења и дубине сондирања у посматраним периодима. Анализирајући модификовани плак индекс током периода посматрања у студијској групи круница, регистрована је статистичка значајност између почетне вредности и вредности након шест месеци. Такође, уочена је статистичка значајност у погледу дубина сондирања током времена, како у студијској тако и у контролној групи круница. Резултати визуелне аналогне скале за естетику нису показали статистички значајну разлику између група, док је визуелна аналогна скала за задовољство зубним надокнадама показала статистички значајну разлику.

Закључак Ова студија је показала да примењени субјективни и објективни параметри могу бити поуздан алат за оцењивање клиничког исхода појединачних круница на имплантатима током времена.

Кључне речи: литијум-дисиликат; ПЕЕК; соло крунице; имплантати