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Original Article

Procedure time and patient perception for ceramic endocrowns or partial coverage ceramic restorations: a double-blind randomized clinical trial

Tempo de procedimento e percepção do paciente para endocrowns de cerâmica ou restaurações de cerâmica de cobertura parcial: um ensaio clínico duplo-cego randomizado

Tiempo del procedimiento y percepción del paciente para endocoronas cerámicas o restauraciones cerámicas de cobertura parcial: un ensayo clínico aleatorizado doble ciego

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Abstract

Objetive: This study aimed to compare procedure time and patient discomfort and satisfaction between endocrowns or partial coverage ceramic restorations with fiber post and filling (PCCR+Post). Materials and Methods: A double-blind RCT was carried out according to eligibility criteria: 1) Endodontic treatment; 2) Molars or premolars; 3) Minimum of one cusp with 3-mm thick; 4) Dental antagonists; 5) Supragingival margins; 6) Good oral hygiene; and 7) Minimum of 18 years. Patients were allocated to two groups: Endocrown or PCCR+Post. Each session was timed; discomfort and satisfaction were assessed. Poisson regression analysis and two-way repeated-measures analysis of variance were performed. Results: Forty patients were selected (20 per group). 90% and 82.5% of participants in the PCCR+Post and Endocrown group, respectively, reported little or no discomfort. There was no association between the explanatory variables and the discomfort reported by patients. The level of satisfaction was 100%. Procedure time in the Endocrown (129.7 min±29.78) was similar to PCCR+Post (134.1 min±29.64). Endocrown and PCCR+Post had similar procedure time and patient perception, however, endocrowns allow less clinical steps. Conclusions: Endocrown and PCCR+Post had similar procedure time and patient perception, however, endocrowns allow less clinical steps.

Trial registration- clinicaltrials.gov (NCT03064516).

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Descriptors: Dental Cavity Preparation; Patient Reported Outcome Measures; Patient Satisfaction; Ceramic; Operative Time.

Resumo

Objetivo: Comparar o tempo operatório, o desconforto e a satisfação de pacientes restaurados com endocrowns cerâmicas ou com restaurações parciais (inlays/ onlays/ overlays) cerâmicas com pino de fibra e preenchimentos e os possíveis fatores relacionados. Métodos: Um ensaio clínico controlado randomizado, duplo-cego, foi conduzido por um operador, dentro dos critérios de elegibilidade: 1) Tratamento Endodôntico 2) Molares ou pré Molares 3) Mínimo de Presença de dentes antagonistas; 4) 1 cúspide com espessura adequada de 3 mm; 5) Margens Supra Gengivais e 6) Boa higiene oral 7) Idade mínima de 18 anos. Os pacientes incluídos foram distribuídos aleatoriamente em dois diferentes grupos: Endocrown Vs. Rest. parcial +Pino, tendo apenas 1 dente por paciente. O tempo foi cronometrado em cada sessão, a mensuração do desconforto foi realizada por meio da escala VAS e a satisfação foi medida por meio de escala numérica. Análise de regressão de Poisson foi utilizada para avaliar a associação de variáveis explicativas com o desconforto. Análise de variância de dois fatores com medidas repetidas foi utilizado para calcular a diferença do tempo clínico de atendimento entre os grupos experimentais. Resultado: Um total de 40 pacientes para cada grupo foi incluído, sendo 20 para cada grupo. Em relação aos resultados de desconforto, no grupo Rest. parcial +Pino, 90% dos participantes relataram nenhum/ mínimo desconforto, enquanto no grupo Endocrown 82.5% apontaram respostas similares. Não houve associação entre as variáveis explicativas e o desconforto relatado pelo paciente. A taxa de satisfação foi 100% excelente. O tempo gasto para as Endocrowns (129.7min ± 29.78) foi estatisticamente semelhante ao tempo dispensado para as Rest. parcial + Pino (134.1 min ± 29.64). Conclusão: Endocrowns são uma alternativa para as restaurações parciais cerâmicas com pinos, uma vez que ambas técnicas apresentaram alta satisfação, baixo desconforto e tempo clínico operacional similar.

Descritores: Preparo da Cavidade Dentária; Medidas de Resultados Relatados pelo Paciente; Satisfação do Paciente; Cerâmica; Tempo Operatório.

Resumen

Objetivo: Comparar el tiempo operatorio, el malestar y la satisfacción de los pacientes restaurados con endocoronas cerámicas o restauraciones parciales (inlays / onlays / overlay) con postes y rellenos de fibra y los posibles factores relacionados. Métodos: Un operador realizó un ensayo clínico controlado, aleatorizado, doble ciego, dentro de los criterios de elegibilidad: 1) Tratamiento endodóntico 2) Molares o premolares 3) Presencia mínima de dientes antagonistas; 4) 1 cúspide con un espesor adecuado de 3 mm; 5) Márgenes supragingivales y 6) Buena higiene bucal 7) Edad mínima 18 años. Los pacientes incluidos fueron asignados aleatoriamente a dos grupos diferentes: Endocrown Vs. Rest. Parcial + Pin, teniendo solo 1 diente por paciente. El tiempo se cronometró en cada sesión, el malestar se midió mediante la escala EVA y la satisfacción se midió mediante una escala numérica. Se utilizó el análisis de regresión de Poisson para evaluar la asociación de las variables explicativas con el malestar. Se utilizó un análisis de varianza bidireccional con medidas repetidas para calcular la diferencia en el tiempo de atención clínica entre los grupos experimentales. Resultado: se incluyó un total de 40 pacientes para cada grupo, con 20 para cada grupo. Respecto a los resultados de malestar, en el grupo Descanso. parcial + Pino, el 90% de los participantes informó ninguna / mínima molestia, mientras que en el grupo Endocrown el 82,5% indicó respuestas similares. No hubo asociación entre las variables explicativas y el malestar reportado por el paciente. La tasa de satisfacción fue 100% excelente. El tiempo empleado por las Endocrowns (129,7min ± 29,78) fue estadísticamente similar al tiempo empleado por el resto. parcial + Pin (134,1 min ± 29,64). Conclusión: Las endocoronas son una alternativa a las restauraciones cerámicas parciales con clavijas, ya que ambas técnicas mostraron alta satisfacción, baja incomodidad y similar tiempo operatorio clínico.

Descriptores: Preparación de la Cavidad Dental; Medidas de Resultado Reportadas por el Paciente; Satisfacción del Paciente; Cerámica; Tempo Operativo.

INTRODUCTION

Current scientific literature has gradually expanded its field of study so as to look at restorative treatment from a broader perspective, rather than to analyze it primarily

from the longevity standpoint. Patient-reported outcome measures (PROMs) in randomized controlled trials (RCT) are primary or important secondary endpoints[1-3], and they can not only serve as tie-breaking criteria for the selection of a treatment, but also as a way to elucidate key points for the treatment of dental diseases[4]. As these outcomes are a recent trend in dentistry, they have been poorly investigated so far, and the quality of publications in this area has to be improved[2-6].

Restoration of endodontically treated teeth is a challenge because of extensive structure loss and its consequent weakening. Thus, when an endodontically treated tooth still has a certain amount of tooth structure, several restorative treatment options are available, depending on the amount and resistance of the remaining coronal structure[7-14]. Prosthetic treatments often include lengthy, complex, and costly procedures, which could negatively affect patients' perception of this kind of intervention. Understanding acceptability after dental interventions is essential so that dentists can choose among the possible procedures and increase patient compliance with treatments.

The design of this study is important in prosthetics for gathering scientific evidence about the restorative treatment of endodontically treated teeth, as there is no randomized clinical trial in the literature comparing endocrowns to partial coverage ceramic restorations (inlays, onlays, overlays, and three-quarter crowns) with fiber posts, or assessing patient-centered outcomes, which could provide an overview of these procedures and allow patients to analyze whether ceramic endocrowns are a feasible alternative, laying a foundation for better clinical decisions.

The aim of this study is to evaluate immediate outcomes, addressing questions concerning procedure time and patients' satisfaction and discomfort between ceramic endocrown restorations or partial coverage ceramic restorations with fiber post. The null hypothesis is that both restorative techniques have similar procedure time and levels of satisfaction and discomfort.

MATERIAL AND METHOD

○ *Study design – ethical and methodological aspects*

This study is an integral part of an umbrella project, in which the primary outcome is the longevity of prosthetic treatments, whereas patient-centered secondary outcomes are dealt with in the current study. The study protocol was approved by the Research Ethics Committee of São Paulo University (CAAE no. 73845317.2.0000.0075), following the Consolidated Standards of Reporting of Trials (CONSORT and CONSORT PRO) guidelines[1,15], and registered at clinicaltrials.gov (NCT03064516). This double-blind, parallel-arm randomized clinical trial, with a 1:1 allocation ratio, was conducted by a previously trained operator (RMF), who performed all the restorative procedures.

Survival rate of inlay/onlay ceramic restorations (96.6% after 24 months) was the primary outcome considered for sample size calculation[13]. Therefore, a clinically significant difference of 15% is expected for longevity between the groups. So, adopting a significance level of 0.05 and a 0.80 power, considering one tooth per patient, and using a two-tailed test for noninferiority trials, adding 20% for possible losses (dropout), the final number of teeth per group was 20, corresponding to a total of 40 teeth.

○ *Participants - recruitment, eligibility, randomization, and allocation*

The patients were recruited by one of the researchers (SM) based on history-taking, clinical examination, and radiographic exams using a sample of patients from the Military Police Dental Center (São Paulo, Brazil) treated in 2017. The clinical steps were carried out in a private dental office from July to December 2018.

There was no distinction between sex, race, or ethnicity and patients were selected according to the following inclusion criteria: 1) Endodontic treatment; 2) Molars or premolars; 3) Minimum of one cusp with 3-mm thick; 4) Dental antagonists; 5) Supragingival margins; 6) Good oral hygiene (without white spot lesions and with good biofilm control); and 7) Minimum of 18 year The exclusion criteria were as follows: 1) Patients who did not agree to sign the free informed consent form; 2) Teeth with painful symptoms, unsatisfactory endodontic treatment, or signs of periapical lesions at the time of radiographic or clinical examination; 3) Pregnant women; 4) Volunteers who did not fit into the research; 5) Teeth with restorations, cracks, hypoplasia, or carious lesions on the adjacent remaining surfaces; and 6) Patients wearing orthodontic braces. Endodontic treatments had been carried out by different dentists on dates that could not be clearly specified by the patients.

Eligible patients were randomly assigned to one of the parallel arms of the study. The randomization sequence was generated (www.sealedenvelope.com) and allocation concealment was ensured by the use of sealed

brown envelopes numbered serially and kept in possession of an independent researcher until they were opened by the operator at the beginning of treatment. The contents of the envelope indicated the experimental group to which the patient would be assigned: Endocrown group (test) or Partial coverage ceramic restoration + fiber post group (PCCR+post- control).

○ *Restorative techniques for the experimental groups*

All participants received instructions on oral hygiene and diet. Radiographs were taken at baseline and after cementation. Photographs were taken at baseline, after removal of the carious tissue and of old restorations, after cavity preparation, and after cementation. Procedure time was recorded in sessions 1 and 2, beginning with preoperative mouth rinsing and ending with occlusal adjustment (session 1) and beginning with preoperative mouth rinsing and ending with final radiograph (session 2).

○ *Session 1- Cavity preparation and casting*

Endocrown group – Well-defined cervical chamfered finish lines should be created to facilitate the impression and technical procedures, thus a 2-mm round-ended chamfer finish line was created along the margin using tapered inverted cone diamond burs, at high rotation and under cooling, against a 1:5 contra angle multiplier (S-MAX M95L- NSK). No filling was used, the space of the pulp chamber is included in the preparation (Figure 1).

Figure 1- Endocrown group- A: removal of restoration and gingival retraction; B: Glazed specimen; C: Occlusal view of the cemented endocrown; D: Radiographic view.

PCCR+Post group – A fiber post (White post, FGM) whose size was compatible with the main canal was luted, reaching approximately half of the canal. The post was cleaned with alcohol, dried, and treated with Monobond (Ivoclar Vivadent); Multilink was applied to the tooth (Ivoclar Vivadent), mixing it with primer A+B at a 1:1 ratio, without previous acid etching, with a brief air jet. After that, the post was luted with Multilink resin cement (Ivoclar Vivadent), followed by photopolymerization for 20 seconds and filling with composite resin – shade A2 (Tetric N Ceram bulk fill- Ivoclar Vivadent), in 1-2 mm increments and photopolymerization for 20 seconds per layer. Occlusal and proximal boxes were prepared, not exceeding 2 mm in ceramic thickness. A 2-mm round-ended chamfer finish line was created along the margin of extracoronal areas using tapered inverted cone diamond burs, at high rotation and under cooling, against a 1:5 contra angle multiplier (1:5 S-Max M95L, NSK) (Figure 2).

Figure 2- PCCR + post group- A: Occlusal view of tooth with post placement and filling with composite resin; B: Glazed specimen; C: Occlusal view of the cemented partial coverage ceramic restoration; D: Radiographic view.

In both groups, the cusps were preserved, whenever possible, but in cases where veneering was needed, the occlusal surface was abraded to allow for a 1.5-to-2 mm space. If necessary, the proximal contact point was removed with metal files.

The double-cord technique (Ultrapack-Ultradent) and double molding technique were used (Virtual heavy and regular body - Ivoclar Vivadent). The color was chosen using the Vita classical shade guide (Vita Zahnfabrik). The provisional restorations were fabricated with acrylic resin and cemented with Temp Bond NE (Kerr Corporation).

○ *Laboratory phase – ceramic restoration manufacture*

The specimens were fabricated with lithium disilicate glass ceramic (IPS e.max CAD-Ivoclar Vivadent) and milled (Cerec In Lab Mcxl), producing a monolithic restoration, which was tinted and glazed.

○ *Session 2- Testing, fitting, and cementation of the ceramic restoration*

After testing and fitting of the specimen in the mouth, rubber dam isolation was used for adhesive cementation in both groups, as follows:

the enamel and dentin were etched with 37% phosphoric acid gel (N-etch; Ivoclar Vivadent) for 15-20 seconds, followed by copious rinsing and brief air jets. The specimens were etched with 5% hydrofluoric acid (IPS Ceramic Etching Gel; Ivoclar Vivadent), silanized for 1 min (Monobond N; Ivoclar Vivadent) and luted with Tetric N-bond and Multilink N dual cement (Ivoclar Vivadent). Photoactivation was performed with a Radii-Cal device (SDI- 1200 mW/cm2) for 20 seconds on each surface. Occlusal adjustment was performed and the restorations were polished with rubber points (Optra Fine Ivoclar Vivadent) at low speed, under cooling.

- *Patient outcomes*

Patient-reported outcome measures (PROMs) include self-administered questionnaires, with the purpose of evaluating psychometric data, in addition to history taking and demographic and clinical data. The questionnaires described next were handed out to participants by an external examiner, in the absence of the operator:

- Patient satisfaction questionnaire[16] - The patient was asked to give his/her real opinion about the treatment and to indicate how satisfied he/she was on a 0-3 scale: 0 – excellent; 1- good; 2- acceptable; 3- not satisfied.
- Visual analog scale – Used to assess patient discomfort/pain immediately after the end of sessions 1 and 2. This scale consists of a 10-cm (100-mm) horizontal line, with “no sensitivity" written on one end and "maximum sensitivity" on the other one. The patient was asked to draw a vertical line on the horizontal scale to indicate his/her level of discomfort/pain. After that, the distance (in mm) from the starting point (no sensitivity) to the vertical line drawn by the patient was measured with a ruler (0 to 100 mm). The recorded values were interpreted as follows: 0-4 mm no discomfort; 5-44 mm mild discomfort; 45-74 mm moderate discomfort; 75-100 maximum discomfort.

- *Statistical analysis*

The data were assessed by SPSS V16 for Windows (SPSS; Chicago, IL, USA). Poisson regression analysis was used to compare patient discomfort between the groups and to evaluate the influence of explanatory variables on the discomfort reported by patients (age and sex, tooth, type of restorative treatment, number of treated surfaces, presence of endodontic lesion, and procedure time). At first, an unadjusted Poisson regression analysis was performed for each explanatory variable, and values with $p<0.20$ were included in the adjusted regression model. Only those variables with $p\leq0.05$ were kept in the final model. Prevalence ratios (PR) were calculated using a 95% confidence interval (95%CI). As the level of satisfaction was 100% for score 0, it was not possible to conduct a statistical analysis. Two-way repeated-measures analysis of variance – experimental group and time – was used to estimate the difference in procedure time between the experimental groups. In all analyses, the significance level was set at 5%.

RESULTS

The phases and distribution of participants are shown in the flowchart (Figure 3).

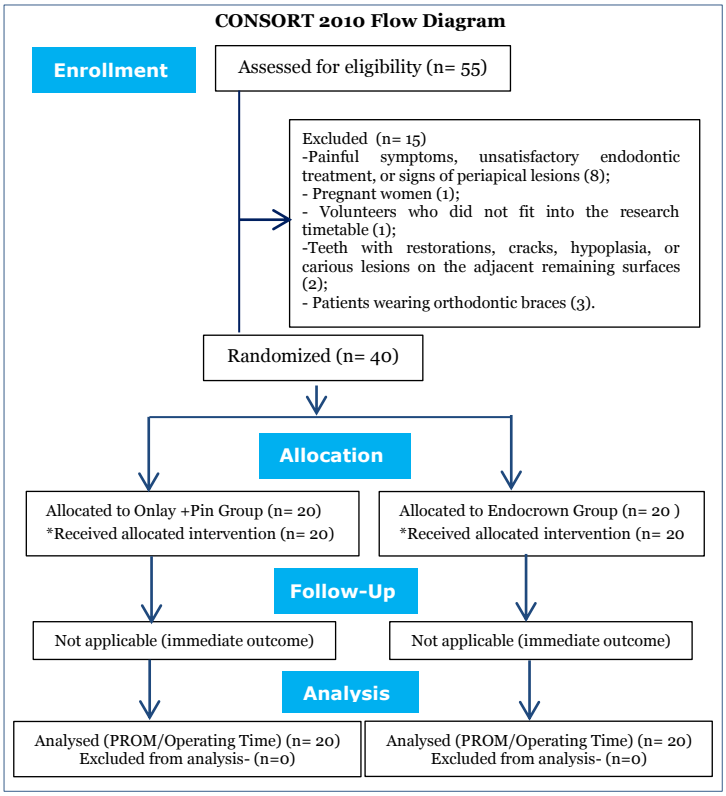

Figure 3: Flow diagram of the progress through the phases of a parallel randomized trial of two groups15

Patient ages ranged from 26 to 59 years. The analysis of variance did not reveal any significant difference between the procedure time needed for Endocrowns (129.7±29.78 min) and that necessary for PCCR+post (134.1±29.64 min), regardless of the session.

The characteristics of participants are displayed in Table 1, with no significant difference in the characteristics between the groups ($p<0.05$). Most participants were male (65%), with high caries experience (97.5%) and older than 40 years (65%).

Endocrowns and PCCR+Post were equally used in 19 molars and in 1 premolar (total of 20 patients/group). Nine endocrowns were placed in the maxilla and 11 in the mandible, whereas eight PCCR+Post were placed in the maxilla and 12 in the mandible. On

occlusal surfaces, endocrowns consisted of one inlay and 19 onlays, while PCCR+Post included one inlay, 18 onlays, and one overlay.

Table 1. Characteristics of participants in the experimental groups on baseline – n (%)

Characteristics		PCCR+post	Endocrown	p value
Sex	Female	6 (15)	8 (20)	0.184
	Male	14 (35)	12 (30)	
DMFT index	DMFT <3	0 (0)	1 (2,5)	0.549
	DMFT ≥3	20 (50)	19 (47,5)	
Age	20 - 39	5 (12.5)	9 (22.5)	0.507
	≥ 40	15 (37.5)	11 (27.5)	

The mean for patient discomfort was 0.25 (±0.74) for the control group and 0.60 (±0.74) for the endocrown group. In addition, 90% of the participants reported little or no discomfort in the control group. Likewise, 82.5% reported little or no discomfort in the endocrown group. The results of Poisson regression analysis are presented in Table 2.

Table 2. Poisson regression analysis between patient's self-reported discomfort and independent variables

Variables		N (%)	Self-reported discomfort			
			Unadjusted RR (95% CI)	p value	Adjusted RR (95% CI)	p value
Groups	PCCR+post	20 (50)	Ref	0.100	Ref	0.131
	Endocrown	20 (50)	2.400 (0.846-6.812)		2.574 (0.754-8.782)	
Age	20 - 39	14 (35)	Ref	0.016	Ref	0.113
	≥ 40	26 (65)	0.294 (0.109-0.794)		0.408 (0.135-1.237)	
Sex	Female	14 (35)	Ref	0.630		
	Male	26 (65)	1.292 (0.455-3.668)			
Arch	Maxilla	17 (42.5)	Ref	0.912		
	Mandible	23 (57.5)	1.056 (0.402-2.774)			
Type of restoration	Overlay	1 (2.5)	Ref	1.000		
	Onlay	37 (92.5)	20.601 (-89620.415-89661.617)			
	Inlay	2 (5)	1.024E-5 (-109786.75-109786.75)			
Endodontic lesion	No	24 (60)	Ref	0.693		
	Yes	16 (40)	0.818 (0.303-2.212)			
Number of surfaces	Mean (SD)	3.62 (0.838)	0.612 (0.340-1.102)	0.102	0.897 (0.422-1.908)	0.778
Time	Mean (SD)	131.44 (32.24)	1.008 (0.997-1.019)	0.166	1.009 (0.997- 1.021)	0.162

ϕ Variables maintained in final model.

In the unadjusted analysis, only age was associated with discomfort reported by the patients. However, experimental groups, number of treated surfaces, and procedure time had a p <0.20 and were also included in the adjusted analysis. No variable was kept in the final model. There was no association between independent variables and discomfort reported by the patients. The level of satisfaction was 100% for score 0 (excellent).

DISCUSSION

Several dentists often choose the most conventional method for restoring endodontically treated teeth, i.e., placement of crowns and metal core, as they believe this type of intervention plays an important role in increasing treatment longevity. This approach, however, require excessive loss of remaining tooth structure and lengthier clinical treatment. The decision as to whether or not to use post and core systems does not seem to substantially influence tooth longevity when there is a considerable amount of remaining dentin, but preservation of the coronal structure appears to be the most critical factor for long-term longevity of endodontically treated teeth[10].

Taking into account the need to preserve the coronal structure, our study addressed two conservative techniques; nevertheless, partial coverage restorations with post or core systems are more conventional than endocrowns, the latter of which have emerged as an alternative method, possibly bringing some benefits such as easy placement, cost, patient satisfaction and, consequently, better compliance with the restorative treatment[7-9,11-14,16]. Furthermore, endocrowns remove smaller amounts of healthy tissue as compared to other techniques (e.g., full crowns). Even though procedure time has been shown to be much shorter for endocrowns[14], our study demonstrated that both techniques required a similar procedure time. This may have occurred because we compared two conservative techniques between themselves rather than comparing conservative techniques with more invasive ones, such as the placement of full crowns either combined or not with metal posts.

Techniques that promote less discomfort and more satisfaction and are less time-consuming and less costly, with increased longevity should be preferred and considered in clinical decisions. It is widely known that some minimally invasive treatments are targeted at reducing anxiety, discomfort, and fear in patients[4-6.16-18].

To date, no study has compared both techniques (endocrowns and partial coverage ceramic restorations with fiber posts) from the perspective of patient-reported outcome measures (PROMs) or of survival. A systematic review on endocrowns[14] included three clinical trials for qualitative analysis only, with a follow-up period of 6 to 36 months, success rate of 94% to 100%, and a total of 55 posterior teeth assessed. The authors stated that the available literature suggests that endocrowns may work similarly to or better than conventional treatments using post and core systems, direct composite resin, or inlay/onlay restorations, but the findings should be viewed with caution, as further studies are needed to confirm whether endocrowns are a feasible option.

Our study sought to assess which technique (endocrowns or partial coverage ceramic restorations with fiber posts) would be more suitable for the restorations of endodontically treated teeth; however, no difference was observed between the groups regarding procedure time and self-reported discomfort or satisfaction. Patient satisfaction was excellent in both groups. Little or no

discomfort was reported by most patients in both groups. The null hypothesis was accepted.

Therefore, the findings of this study encourage new alternative approaches that are both preventive and minimally invasive, since endodontically treated teeth have already had remarkable structural losses and preservation of the remaining tooth structural is essential[18].

A limitation of this study concerns the failure to follow up the levels of satisfaction over time. As both techniques depend on the operator, and as we decided for standardization, using a single operator, his perception was not obtained. Cost effectiveness will be assessed together with survival rate at 2 years follow up.

CONCLUSION

Endocrown and PCCR+Post had similar procedure time and patient perception, however, endocrowns allow less clinical steps.

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CONFLICTS OF INTERESTS

The authors declare no conflict of interest with respect to the conduct, authorship and/ or publication of this article

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