Research Protocol

Date: Jan 10th, 2018

Title: Survival of Endocrowns Made from Different Ceramics

NCT number: NCT03542019

Background: Endodontically treated teeth often lose a significant amount of tooth structure due to caries or trauma, which renders them at risk of catastrophic fractures[1]. Their restoration requires a means to protect the cusps from the wedging forces of occlusion. Cuspal coverage using full metal or porcelain crowns has been traditionally used and has been demonstrated to improve their survival rate[2, 3].

Recently, the demand for more aesthetic and conservative restorations has grown, and the introduction of CADCAM technology has allowed the preparation and cementation of indirect restorations at the same day. Adhesive indirect restorations have become popular and their application in dentistry has involved the restoration of endodontically treated teeth. Full and partial onlays and full coverage crowns have been used successfully to provide cuspal protection[4]. The endocrown is another form of adhesive indirect restorations that incorporates the core and cuspal coverage in one unit which is then bonded to the remaining tooth structure [5]. Endocrowns can be made from different types of ceramics. Lithium disilicate ceramic has been used extensively for this purpose due to its favourable physical properties, good aesthetics and its predictable bonding to tooth structure [6]. However, when milled from ingots, it requires an additional step of crystallization which will increase marginal gaps [7, 8]. This step is also time consuming and in a busy practice may be considered a draw back to the material.

Zirconia has become a popular option in dentistry due to its superior toughness and fracture resistance compared with other types of ceramics. When the CAD/CAM technology is used, zirconia restorations are usually milled from pre-sintered blocks which must be sintered after milling in order to achieve their maximum strength. This step is time consuming.

Hybrid ceramics are a new category of ceramics with a dual ceramic-polymer network that incorporates the benefits of ceramic and composite materials offering strength, flexibility, crack prevention properties and a superior abrasion behaviour [9]. Furthermore, hybrid ceramics require no additional steps following their milling from CAD/CAM blocks. They can be bonded to the tooth straight after its milling which is a favourable property in a busy dental practice.

Clinical data on the longevity of this type of restorations is scarce [10]. The aim of this study is to assess the short and long-term outcomes of endocrowns made from three different materials; Lithium disilicate ceramic (IPS e.max ®), monolithic translucent zirconia and a hybrid ceramic (Vita Enamic®).

Material and methods:

Sample size calculation:

Sample size per each group was set at 20 restorations based on similar studies investigating the outcome of different restorations on root canal treated teeth.

Inclusion criteria:

Root canal treated molars with significant loss of tooth structure and supra-gingival margins that are scheduled for cuspal-covering indirect restorations are included in this study.

Exclusion criteria:

Teeth with extensive cracks or fractures
Teeth with deep subgingival margins
Non-functional teeth (no opposing dentition)
Teeth with advanced periodontitis

Following root canal treatment, teeth will be randomly allocated into one of three groups according to the material of the endocrown they will receive; group A (n= 20): IPS e.max lithium disilicate ceramic, group B (n= 20): monolithic translucent zirconia, and group C (n= 20): Vita Enamic hybrid ceramic. Preparation of all teeth will be performed by the same operator. Impressions will be made using a conventional 2-stage putty and wash silicone impression material (We'll choose one) and the same dental technician will provide all the endocrowns by milling them from CAD/CAM blocks. Cementation will be done under rubber dam isolation using the recommended protocol for each material.

Clinical follow-up assessment will be made at 6 months, 1 year, 2 years and 5 years post-operatively. This will include assessment of the restoration integrity, marginal integrity and marginal discoloration, pink and white aesthetic scores and pocket probing depths.

Radiographic assessment will be made at 1 year, 2 years and 5 years post-operatively to detect the presence of restoration defects and recurrent caries.

Patient satisfaction will be assessed on a visual analogue scale (0-10)

All assessments will be done by an experienced independent clinician unaware of the material used.

Statistical analysis

Non-parametric tests will be used to discern any statistically significant difference between groups. Wilcoxon signed-rank and Mann-Whitney tests will be used for tooth integrity, marginal integrity and discoloration, PES&WES and patient's satisfaction. Non-parametric T-test will be used for radiographic parameters.

Weibull distribution will be used o predict long-term survival rates per each group.

Funding:

This research needs funding to cover the cost of a) the lab fees of fabricating 60 endocrowns and b) the resin cement systems. Please see attached sheet.

Data collection form (appendix 1):

Patient: _____

DOB: _____

Tooth: _____

Material (coded): _____

Date: _____

ID: _____

Phone no.: _____

e-mail: _____

_____

a- Clinical examination:

Endocrown failure: Yes / No (Specify type of failure) _____

Weeks from cementation to failure: _____

Modified USPHS criteria (*use Alpha, Bravo, Charlie and Delta as in the key*)

Margins: _____

Anatomic form: _____

Texture: _____

Colour match: _____

BoP/ pockets: _____

b- radiographic examination:

Secondary caries (0: absent, 1: present) _____

Proximal caries in adjacent teeth (0: absent, 1: enamel, 2: dentine) _____

Excess cement (0: absent, 1: detectable, 2: gross): _____

Periapical infection: (0: absent, 1: present/ improving, 2: present/ not improving or getting worse) _____

c- Patient-reported satisfaction *(use the VAS below):*

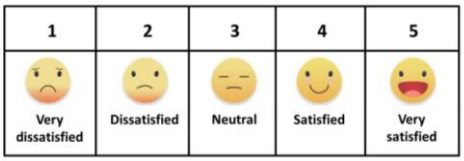
Shade: _____

Shape: _____

Quality of proximal contacts
(Food impaction/ ability to floss) _____

Chewing ability _____

Overall satisfaction _____



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