EVALUATION OF ENAMEL WEAR ANTAGONIST TO MONOLITHIC ZIRCONIA, LITHIUM DISILICATE AND METAL-CERAMIC RESTORATIONS. PROSPECTIVE RANDOMISED STUDY.

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STUDY PROTOCOL

1. Introduction

The study will be carried out on patients who will be candidates for treatment with full coverage restorations on teeth, using the different materials: translucent monolithic zirconia (TMZ), monolithic lithium disilicate (LMD) and metalceramic (MC) in order to establish a comparison between them on the wear they produce on the antagonist tooth, and to evaluate if this wear is significant with respect to the wear of the natural tooth itself.

Numerous *in vitro* studies have been conducted to determine enamel wear against the different ceramic materials most commonly used today **(Kim, 2012; Sripetchdanond, 2014; Zandparsa, 2016; Rupawala, 2017; Ashtiani, 2019; Habib, 2019; Yang, 2019; Rosentritt, 2020).** However, such studies do not take into account that human tooth tissues show variations in the geometry or thickness of enamel layers and may become brittle due to storage conditions **(Habib, 2019).**

Intraoral wear is a complex phenomenon affected by physical, chemical and biological factors. The pattern of enamel wear is influenced by the material and surface texture of the antagonist restoration; dietary habits (acidic diet), masticatory force, temporomandibular dysfunction, bruxism and/or unilateral chewing habits of the patient **(Kim, 2012; Mundhe, 2015; Hartkamp, 2017).**

Furthermore, these studies are difficult to compare with each other due to differences in the type of material and surface finish of the restorations, the method of wear employed and the type of analysis to measure it **(Esquivel-Upshaw, 2018).** Therefore, *in vitro* studies do not faithfully reproduce oral cavity conditions and cannot fully simulate real clinical wear **(Gou, 2019).**

Therefore, clinical evaluation in patients is necessary. There are a limited number of clinical studies on this topic **(Esquivel, 2012; Mundhe, 2015; Stober, 2016; Lohbauer, 2017; Hartkamp, 2017; Esquivel, 2018; Yang, 2019; Solá-Ruiz, 2020)** compared to their *in vitro* design counterparts. Only four of them compare antagonist enamel wear to natural tooth wear itself **(Esquivel-Upshaw, 2012; Mundhe, 2015; Stober, 2016; Yang, 2019)** and none of them integrate in the same study the three materials we want to analyse in our work in order to be able to make a comparison between them (translucent monolithic zirconia, monolithic lithium disilicate and metal-ceramic). It is therefore clear that further evidence from clinical research is needed to substantiate the results of existing laboratory simulation studies **(Koletsi, 2019).**

2. Objectives

1. To evaluate the wear produced in the short and medium term by translucent monolithic zirconia, metal-ceramic and monolithic lithium disilicate restorations on the antagonist tooth in patients with fixed prostheses.
2. To assess the factors that may influence such wear.
3. To analyse whether the wear of the antagonist tooth differs significantly between the following groups.
   a. Group 1: Monolithic zirconia restorations.
   b. Group 2: Metal-ceramic restorations.
   c. Group 3: lithium disilicate restorations.
   d. Group 4: natural tooth (control group).
4. To analyse whether the wear of the tooth antagonistic to monolithic zirconia (group 1), metal-ceramic (group 2) or lithium disilicate (group 3) restorations differs significantly from the wear of the natural tooth (group 4 or control group).

3. Inclusion and exclusion criteria

INCLUSION CRITERIA:

- Patients in need of single tooth restorations on posterior teeth.
- Age range: between 18 years of age.
- No contraindications for dental treatment.
- Good oral hygiene.
- No periodontal disease or treated periodontal disease.
- Absence of temporomandibular disorder and/or untreated habits or parafunctions.

Inclusion criteria for abutment teeth:

1) Posterior tooth requiring placement of a single tooth restoration. Restorability: with a crown:root ratio of at least 1:1.
2) The presence of an unrestored or minimally restored natural antagonist tooth (teeth with no more than a Class II restoration), in the same quadrant as the treated tooth (G1,2,3).
3) The presence of two unrestored or minimally restored antagonist teeth (in the same quadrants or on the contralateral side) (G4 or control).
4) Minimum height of the dental stump: 3mm.

EXCLUSION CRITERIA:

Exclusion criteria for abutment teeth:

1) Antagonist tooth with a full coverage restoration.
2) Opposing arch with fixed or removable partial denture.
3) Lack of occlusal contact points in the enamel of the control teeth.

4. Variables to be studied

- Type of material used (monolithic zirconia, metal-ceramic, lithium disilicate).
- Glazed surface finish.
- Age.
- Sex.
- Position of the restoration, molars vs. premolars, maxilla or mandible.
- Type of occlusion (classes according to Angle).
- Parafunction treated (use of splint).
- Diet (whether or not you drink acidic beverages, etc).
- Periodontal status (probing, bleeding and recession).
- Wear, fracture and fissure and debonding.
- Survival.

5. Fabrication of the restorations

5.1. Preparation of the abutment tooth

Three investigators will prepare all teeth to receive the restoration based on the design criteria for their preparation. Temporary material (ProtempTM Plus, 3 M ESPE) will be used to fabricate the temporaries, which will be cemented with eugenol-free zinc oxide temporary cement (Temp-Bond NE TM, Kerr) on the prepared teeth prior to cementation of the final crowns.

The abutment teeth shall be prepared to receive monolithic zirconia, metal-ceramic and lithium disilicate restorations according to the randomisation list.

Translucent monolithic zirconia restorations
An axial reduction of 0.6 mm, an occlusal reduction of 1 mm and a juxtagingival chamfer margin design shall be performed.

Metal-ceramic restorations
A 1.2 mm axial tooth reduction with a juxtagingival chamfer margin line and 1.5 to 2 mm occlusal reduction shall be performed.

Lithium disilicate restorations
An axial reduction of 0.5 - 0.8 mm with chamfer and juxtagingival termination line and an occlusal reduction of 1 - 1.5 mm shall be performed.

5.2. Fabrication technique

The final impression shall be made after gingival displacement with retraction wires, using addition silicone. The definitive model will be made in plaster type IV.

The manufacture of the crowns will depend on the type of material used, differentiating in the 3 groups of the study.

- G1: The crowns will be made of 88% - 95.5% yttria-stabilised (> 4.5% - ≤ 6.0 %) translucent monolithic zirconia (IPS e.max ZirCAD, Ivoclar Vivadent), and will be fabricated in the laboratory using CAD/CAM computer-aided design and fabrication. The crowns will be designed using the design software (Dental System; 3Shape Dental System; Denmark). By means of a milled plastic try-in the proximal and occlusal fit will be clinically evaluated and subsequently produced by a milling machine (Roland DWX-50 DGSHAPE; Roland DG Iberia©). After the sintering step at 1450 - 1520°C for 3 hours in a high-temperature sintering furnace (Programat® CS4), the crowns will be stained/characterized (IPS e.max CAD Crystall./Shades/Stains; Ivoclar Vivadent) in a ceramic furnace (Programat® CS4).

- G2: The metal frameworks will be made of laser-sintered 90% Cr-Co (Wirobond C; BEGO; Barcelona) and will be completely veneered with ceramic. The fabrication process will be completed by firing the glaze at 850 °C for 2 min (Vitamat 2500; Vita Zahnfabrik, Bad Sackingen, Germany / Zenostar Magic Glaze Spray; Wieland Dental).

- G3: All lithium disilicate restorations will be fabricated on the basis of CAD/CAM computer-aided design and fabrication. A milled plastic try-in will be used to clinically assess the proximal and occlusal fit. Subsequently, the lithium disilicate framework will be milled from a block (IPS e.max CAD, Ivoclar Vivadent, Schaan, Liechtenstein). Once the IPS e.max blocks have been milled (Roland DWX-42W DGSHAPE; Roland DG Iberia©), they are polished with fine-grained, water-cooled diamond burs and medium-fine diamond polishers (OptraFine®; Ivoclar Vivadent). Subsequently, the restoration is cleaned with ultrasound in a water bath or an air gun. If necessary, the restoration is stained (IPS e.max CAD Crystall./Shades/Stains; IvoclarVivadent) followed by crystallization and one-step stain firing (Programat CS, IvoclarVivadent; Liechtenstein) at 850 °C for 20-25 minutes.

5.3. Cementation

For the preparation of the tooth prior to cementation, a selective enamel etching (or total etching) with 35% orthophosphoric acid and universal adhesive, light-curing 20s will be carried out.

The preparation of the restorations prior to cementation will depend on the type of restoration and material used, differentiating between the 3 groups in the study.

- G1: sandblasting of the inner surface of the crowns (1 bar, 35 μm alumina), cleaning with ethanol or orthophosphoric acid and drying, universal adhesive and cementing with a dual resin cement, light-curing for 20s on each surface.
- G2: Cemented with a self-adhesive dual resin cement, light cure for 20 seconds on each surface.
- G3: Internal side etched with 4.2% hydrofluoric acid for 20s, neutraliser 5s, silane 1 min, universal adhesive and cemented with a dual resin cement, light cured for 20s each surface.

6. Measuring wear method

<u>Intraoral scan:</u> at the beginning of restoration placement and at 6, 12 and 24 months.

- Scanning of both arches (upper and lower), where the crown, the operative tooth and the control teeth are located, to record the occlusal surfaces of each cemented crown, its antagonist tooth and the enamel controls.
- Prior to each scanning step, the tooth surfaces will be thoroughly cleaned with a non-abrasive rotating synthetic brush under water cooling using a micromotor and contra-angle handpiece and then air-dried.
- Image superimposition with software.

7. Study groups

a. GROUP 1:
- Study: translucent monolithic zirconia crowns - natural tooth.

b. GROUP 2:
- Study: metal-ceramic crowns - natural tooth.

c. GROUP 3:
- Study: lithium disilicate crowns - natural tooth.

d. GROUP 4:
- Control: natural tooth - natural tooth.

8. Statistical study for sample size estimation

The sample size estimation was performed using a two-sample t-test calculated for a confidence level of 95% and a standard deviation ± 7.25, assuming a normal distribution.

Following the similar 2017 study "Randomized clinical study of wear of enamel antagonists against polished monolithic zirconia crowns". by J.F. Esquivel-Upshaw, M.J. Kim, S.M. Hsu N. Abdulhameed, R. Jenkinsb, D. Neal, F. Ren, A.E. Clarka published in Journal of Dentistry
http://dx.doi.org/10.1016/j.jdent.2017.10.005

Randomisation and masking of allocation

Using the enclosed clinical protocol, a record will be made of the type of crown in relation to the tooth or teeth to be treated, the fabrication material, the bonding and cementation method, the position of the abutment tooth (molar/premolar, maxillary/mandibular) as well as the type of antagonist. Before placing the restorations, the sample will be randomised into 3 groups according to the restorative material used, using the online randomisation software www.alazarinfo.es.

All patients will be pseudonymised, assigning each patient a number from 1 to 75 according to the chronology of inclusion in the study. Thus, the first patient to be included in the study will be assigned the number 1, relating it to the number in his or her clinical history. In this way, if it is necessary to know the identity of the patient, this will be done without undermining their personal data protection.

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