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

Date of the document: 01 - 02 - 21

INFORMED CONSENT DOCUMENT
AND COMMITMENT TO CONFIDENTIALITY

1.- INFORMATION TO THE EXPERIMENTAL SUBJECT.

The research project for which we are requesting your participation is entitled:
"Evaluation of enamel wear antagonistic to monolithic zirconia, lithium disilicate and metalceramic restorations. Prospective randomised study".

In order for you to participate in this study, it is necessary that you give your consent and that you are aware of the basic information necessary for this consent to be considered truly informed. Therefore, please read the following information carefully. If you have any questions, please express them before signing this document to the principal investigator of the project, either in person, by telephone or by e-mail. The details of the principal investigator of the project also appear in this document.

Principal Investigator: Dr. Mª Fernanda Solá Ruiz
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The basic information you should know is as follows:

a) Aim of the study:

1. To evaluate the short- and medium-term wear produced by monolithic zirconia, metal-ceramic and 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.MZ: monolithic zirconia restorations.
    b. Group 2.MC: metal-ceramic restorations.
    c. DSL Group 3.DSL: 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).

b) Methodology to be used for the study, type of collaboration expected of you and duration of such collaboration:

After signing the informed consent the patient will start to take part in the study. Your treatment will be carried out in the same way as if you were not part of this study. In no case will this study influence your treatment; it will only be monitored periodically, so that your participation in the study will not cause you any possible discomfort or risk.

On the day treatment begins, everything related to your treatment (material, cementing technique, etc.) will be noted down, as well as a basic oral exploration of the current state of the oral cavity, following the methodological criteria of the WHO (1987). The material used for this will be: oral mirrors, examination probes, articulating paper, disposable gloves, masks, paper napkins, plastic cups, dental equipment illumination lamp, cold spray, camera and intraoral scanner.

At follow-up appointments (1 month, 6 months, 12 months and annually thereafter) for 2 years, a complete intraoral scan will be carried out again to monitor the evolution of the treatment. In all cases, the evaluation protocol shall be complied with.

c) Preventive, diagnostic and/or therapeutic procedures available as alternatives to those investigated in this study: Not applicable in this type of study to be carried out.

d) Possible inconveniences and risks of participation in the study:

Only periodic monitoring of the patient will be carried out, so that participation in the study will not cause any possible discomfort or risk to the patient.

e) Measures to respond to adverse events:

If any patient in the study should have any problems related to the treatment carried out (placement of a restoration in the molar or premolar area) they will be attended to and solved in the clinic on the 3rd Floor of the dental clinic, in the Master's Degree in Dental Prosthetics of the Prosthodontics and Occlusion Unit by Dr. Mª Fernanda Solá Ruiz and their cost will be assumed at €0.00.

f) Measures to ensure adequate compensation in the event that you suffer any damage:

There is no risk of any kind of damage due to the regular follow-up of the patient.

g) Expected benefits of the research:

The results of this research project may contribute to the improvement in the diagnosis and treatment of diseases, as well as the knowledge of the clinical evolution of such treatment with the different materials supported by scientific literature, possible complications and improvements.

h) Consequences of non-participation:

If you prefer not to participate in said research, this will not affect your right to healthcare and the relationship with the people who have proposed you to participate will be just as cordial and dedicated with those who refuse to participate as with those who do participate.

i) Possibility of withdrawal at any time and consequences:

You may withdraw from the project at any time by signing the revocation of consent included at the end of the document. Your withdrawal will not have any negative consequences for you, and will be accepted by the research team without any problems.

j) Who has funded the study: No funding.

k) Which institution is carrying it out: It is being carried out at the University of Valencia.

l) Free of charge for participation:

The patient will not receive any financial or other type of compensation for participating in this research.

m) Foreseeable subsequent use of the results:

The results will be used for research and scientific publication purposes.

n) Research team:

1. Mª Fernanda Solá Ruiz
2. Mª Alejandra Baima Moscardó
3. Rubén Agustín Panadero
4. Ana Roig Vanaclocha

o) Contact details of the principal investigator for clarifications or queries:

- Dr. Mª Fernanda Solá Ruiz
- E-mail: m.fernanda.sola@uv.es.
- Master's Degree in Dental Prosthetics. U.D. in Prosthodontics and Occlusion. Department of Stomatology. Faculty of Medicine and Dentistry UV. Clínica Odontológica Universitaria (clinic of the master's degree 3rd floor).
- Telephone number: 609048198.

p) The project will be carried out in accordance with the international ethical criteria set out in the Declaration of Helsinki.

2.- COMMITMENT TO CONFIDENTIALITY.

a) Measures to ensure respect for privacy and confidentiality of personal data:
Appropriate measures have been adopted to guarantee the complete confidentiality of the personal data of the experimental subjects participating in this study, in accordance with the Personal Data Protection Act (LOPD) 3/2018, of 5 December.

b) Measures to access information relevant to you arising from the research or the overall results:
Know that you have the right to access the information generated about you in the study. To do so, you should contact the principal investigator, who will give you access to each of your protocols completed during the periodic controls.

3.- CONSENT

In the event that the experimental subject is of legal age:
Sr/Ms _____,
of legal age, holder of National Identity Card: _____, hereby declare that
I hereby declare that:

In the event that the experimental subject is a minor or incapable of acting:
Sr/Ms
_____
_____,
of legal age, holder of identity card: _____,
☐ father, ☐ mother, ☐ legal guardian
of_____
_____,
hereby declare that:

I have been informed of the characteristics of the Research Project entitled: "Evaluation of enamel wear antagonistic to monolithic zirconia, lithium disilicate and metalceramic restorations. Prospective randomised study".
I have read both section 1 of this document entitled "information to the experimental subject" and section 2 entitled "commitment to confidentiality", and I have been able to formulate the doubts that have arisen in this respect. I consider that I have understood this information.

I am informed that I may withdraw from the study at any time.

By virtue of these conditions, I consent to participate in this study.

In witness whereof, I have signed this document at the place and on the date indicated below.

Valencia, _____ of _____ of 20___.

Name and surname of the participant:	*Name and surname of the father, mother or guardian (in the case of minors or incapacitated persons):*	*Name and surname(s) of the principal investigator:*
Signature:	Signature:	Signature:

If the study subject is an intellectually and emotionally capable adolescent between 12 and 16 years of age, their opinion must be heard and they must authorise their participation in the study by also signing this consent. In the case of minors who are not incapable or incapacitated, but who are emancipated or 16 years of age, consent cannot be given by proxy and the subject of the study must sign the consent (Law 41/2002)

REVOCATION OF CONSENT

I revoke the consent given on _____ to participate in the project entitled "_____" and, for the record, I sign this revocation.

In Valencia, at _____ of _____ of 20___.

Name and surname of the participant:	*Name and surname of the father, mother or guardian (in the case of minors or incapacitated persons):*	*Name and surname(s) of the principal investigator:*
Signature:	Signature:	Signature:

Notes to be taken into account:

1) The information shall always be adapted to the comprehension capacities of the experimental subject.
2) In the case of minors, the information sheet should be written in language that is as comprehensible as possible for them, in order to inform them of its contents, even if their representative has to sign in the end.
3) There should be one copy of this document signed for the experimental subject or, in the case of minors, for their representative, and another for the research team.
4) Depending on the design of the proposed study, specific aspects may be included, both in the patient information document and in the consent document, to cover the essential and specific aspects of the study.