CLINICAL STUDY OF BIOLOGICAL AND MECHANICAL COMPLICATIONS IN SINGLE IMPLANT PROSTHESIS WITH OR WITHOUT INTERMEDIATE ABUTMENT

March 24th 2022

HYPOTHESIS AND OBJECTIVES

As Null Hypothesis (H0) the investigator assumes that marginal bone loss is similar in all implants, regardless of the type of restoration performed.

The Alternative Hypothesis (H1) is that marginal bone loss does depend on the type of restoration performed.

Formulated the hypothesis, the investigator states the objectives that we have set:

1.- Clinical monitoring of marginal bone loss in various types of prostheses on implants on a sample of patients at one and six months after placement.

2.- Clinical follow-up of other mechanical and biological complications that may occur on these unitary implants.

MATERIAL AND METHOD

Initially, a referal review is carried out based on a bibliographic search through various Medline EMBASE, COCHRANE databases, to locate the state of scientific knowledge at this time on the subject to be investigated.

The keywords used are:

Removal torque, Mechanical complications, Abutment screw, Screw loosening, Cyclic loading, Preload, Technical complications, Abutment angulation, Prosthetic screw, Untightening torque, Biological complications, Survival

This study will analyze the mechanical and biological complications of single implant prostheses. A controlled and randomized clinical trial will be carried out in unitary prostheses. Screw-retained prostheses will be compared on unitary implants subdivided into three groups:

1. Prosthesis on interface (unit) + CAD/CAM structure.

2. Direct implant prosthesis + Cad/CAM.

3. Direct prosthesis to implant overcasting techniques.

The assignment of groups will be carried out using a randomized table of numbers.

Main variable: Marginal bone loss.

As secondary variables the investigator will analyze: Implant and prosthesis survival, prosthetic complications, soft tissue stability, type of antagonist, crown height space (the distance between the marginal bone crest and the occlusal plane), demographic variables, social habits (smoking , alcohol).

Sample size according to the article by Galindo Moreno 2015:" We are planning a study of a marginal bone loss from independent control (prosthesis direct to implant) and experimental (prosthesis on interface) subjects with 1 control(s) per experimental subject. In a previous study (Galindo-Moreno) the response within each subject group has a true difference in the experimental and control means of 0.77. Considering a normal distribution with a standard deviation of 0.77. If , we will need to study 17 experimental subjects and 17 control subjects to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis is 0.05.

Therefore, we need 17 implants * 3 groups * 15% "drop outs" this leads to a sample size of 59 implants.

We will study their biological complications by means of a radiographic study of the crestal bone loss at 0, 3 and 6 months after prosthodontic rehabilitation. For this, we will protocolize the taking of periapical radiography using the parallelism technique and an invariable personalized positioner.

The loads on the different elements of the implant-prosthetic system will be studied using the finite element technique: crown-connection screw, intermediate abutment interface, if used, and intermediate abutment-implant.

The adjustment between the CAD/CAM structures and the intermediate abutments with or without interface will also be studied using electron microscopy.

A prospective clinical study will be carried out at 3 and 6 months, extendable up to a year, in patients recruited in the Léon Master of Surgery in whom BTI unitary implants have been placed in any location, with a universal platform. The informed consent of the patient will be previously obtained in order to be included in the study, also complying with the agreement reached with the ethics committee for the same. In this trial, the prosthesis will be loaded, dividing the cases into the previously described subgroups.

The CAD/CAM part will be carried out at the BTI Institute, with the porcelain being loaded at the Carretero Dental laboratory.

We will analyze the changes produced in this period of time on the soft tissues, scanning them with an intraoral scanner, being able to make the comparison at 0, 3 and 6 months. Likewise, among the possible mechanical complications that may occur, chipping, fractures, debonding or loosening of the screw will be studied. We will analyze the latter by digital ratchet.

AVAILABLE MEANS TO CARRY OUT THE PROJECT:

The facilities of the solidarity clinic will be used, where the clinical and theoretical practices of the Master's Degree in Surgery, Periodontics and Implantology of the University of León (C/ Alfonso IX, nº 11-13) are carried out.

The BTI implant house will provide us with the transepithelial and CAD/CAM structures as well as the facilities and technologies necessary for the study of finite elements and electron microscopy.

APPLICABILITY AND PRACTICAL USE:

Implants are increasingly used in daily practice. Their long-term survival and prognosis depend largely on the type of restoration carried out on them. We must analyze the design parameters of our restorations that can influence the appearance or not of biological or mechanical complications on our implants, in order to be able to transfer this information to the decisions that we must carry out in our clinical practice as dentists.

KEY POINTS FOR THE ETHICS COMMITTEE:

• Study patients will sign a consent in which they will be aware that they are part of it.

• The restorations on implants that we are going to carry out are part of our usual clinical practice, what we intend is to evaluate which one gives the best results.

• For the radiological control of the prostheses we use a digital periapical radiography device with very low radiation (0.005mSV in conventional, and 0.003mSV in digital, that is: comparable to the natural background radiation of one day)

• The intraoral scanner, It registers based on photographs, not being harmful to patients. Contact Co-promoters

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This study is has been aproved b yan Ethic Committe

universidad de león

Vicerrectorado de Investigación
Comité de Ética

Ms Sonia Martínez Martínez, as Secretary of the Ethics Committee ofthe University of León

CERTIFIES:

That the ETICA-ULE-002-2020 application, entitled "Clinical study of biological complications and mechanics in unitary prosthesis with or without intermediate abutment" presented by Dr. Jesús A. Seco Calvo has received a favorable evaluation by the Ethics Committee of the University of León.

To issue the report, the members of this Committee have verified that the request complies with the requirements set forth in article 4 of the Regulations of the University Ethics Committee de León and which are, as the case may be:

- Check the adequacy of both the model and the procedure used to obtain the informed consent of the person participating or from whom it is obtained the biological material.
- Ensure the guarantee of the confidentiality of the personal data of the subjects who participate in the procedure.
- Supervise the suitability and accreditation of all participants in the protocols.

And for the record for the appropriate purposes, I sign this certificate in León on January 23, 2020.

Fdo.: Dra. Sonia Martínez Martínez
Secretaria del Comité de Ética
Universidad de León

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