Title:

Analysis of marginal bone loss in implants placed at the soft tissue-bone tissue level.

Researchers:

Main: Ahmed Samir Mabrouk Oraby Elkattan

Collaborators:

- José López López
- Raúl Ayuso Montero
- Xavier Roselló Llabrés
- Monica Blázquez

Centers: Hospital Dentistry University of Barcelona (HOUB).

Faculty of Medicine and Health Sciences, Dentistry, University of Barcelona.

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SUMMARY

The subcrestal placement implant has a positive impact on papilla formation and allows an emergence profile suitable for an aesthetic restoration. Its placement allows the implant-abutment interface to be in a position that contributes to bone remodeling in the neck region of the implant, compared to implants placed at bone level (bone-level,crestal placement). Marginal bone loss from implants placedcrestal or subcrestal has shown conflicting results in recent studies.

1.- BACKGROUND OF THE SUBJECT

Dental implants have been introduced as an option for replacing missing teeth, since the initial studies of Professor Per-Ingvar Brånemark in the 1950s, there are multiple studies that support it, including (Andersson B, 1995; Arlin M, 1993; Noack et al, 1999; Jemt T, 2017; The accepted criteria for evaluating implant success were proposed by Albrektsson et al. (Albrektsson et al, 1986), who to identify clinical evidence of successful osseointegration and implant survival, suggested that a marginal bone loss of less than 1.5 mm in the first year and 0.2 mm in the following years, it is acceptable after implant loading (Díaz-Sánchez et al, 2019). Over the past three decades, implant success has been evaluated by survival rates, prosthesis stability, radiographic bone loss, and the absence of infection in the peri-implant soft tissues (Albrektsson et al, 1986; Smith and Zarb 1989; Buser et al, 1990, Albrektsson and Zarb 1998, Misch et al, 2008; The progressive knowledge of patients has increasingly required treatments that offer better aesthetics and comfort, making implantology a demanding field, where obtaining osseointegration or meeting the success criteria of implants highlighted by the lack of pain and infection, absence of radiolucency and mobility and possibility of restoration (Buser et al, in the 1990s). Thus, new parameters have been introduced to evaluate the long-term success of implant restorations. Including health status and natural-looking peri-implant soft tissues, prosthodontic parameters, aesthetics and patient satisfaction. However, osseointegration remains the predominant parameter in implantology (Furhauser et al, 2005; Meijer et al, 2005; Annibali et al, 2009; Belser et al, 2009).

Various authors describe that the position of the implant with respect to the crestal bone is a fundamental factor to preserve the bone in the future (Pontes et al, 2008; Novaes et al, 2009; De Siqueira et al, 2017; Wennerberb et al. al, 2003; Although, regarding this issue there continues to be controversy. Thus, some authors recommend placing the

implant below the crest of the bone (i.e., subcrustal placement). They argue that this position will contribute to the preservation of the mucosa (Pontes et al, 2008), helping to obtain an ideal emergence profile in aesthetic areas (Novaes et al, 2009; Di Siquerira et al, 2017) and preventing the surface of the implant is exposed; at the same time that the presence of mucositis or peri-implantitis is reduced (Wennerberg et, 2003). A possible reason for this could be bacterial colonization of the implant-abutment junction, where an inflammatory infiltrate occurs (Do-Nascimento et al, 2012; Hermann et al, 2000; Broggini et al, 2003). This characteristic, in conjunction with a low oxygen concentration, could create an ideal ecosystem for the proliferation of anaerobic bacteria (Piattelli et al, 2003). On the other hand, it could be speculated that deeper implant placement may correlate with deeper pockets and soft tissue inflammation (Siqueira et al, 2017).

In another order of things, the connection of the implant with the abutment involves microspaces. These microspaces (which facilitate the accumulation of bacteria) can influence peri-implant bone resorption along with other factors such as surgical trauma, the establishment of the biological width, the design of the implant and the position of the implant (Palacios-Garzón et al, 2019 ; Díaz-Sánchez, et al, 2019; Buser et al., 1990). Studies have shown that this microgap varies between 0 and 135 μm (Dellow et al, 1997; Callan et al, 1998). However, what deserves special attention is that, as in teeth, the biological width is formed around the implants, consisting of a junctional epithelium and connective tissue with an average dimension of approximately 2 mm and 1–1.5 mm. respectively (Berglundh et al, 1991). On the other hand, different risk factors can affect implant lifespan, such as anatomical characteristics, chewing dynamics, and proper implant selection, which are important for long-term prognosis. Today, we know that implants with rough surfaces show a statistically higher survival rate than machined implants at all intervals (Levin et al, 2006).

Maintaining the level of the crestal bone around dental implants is essential for their long-term success and survival (Mei et al, 2017; Al Amri et al, 2017; Marcelo-Machado, et al 2018). Factors that may showcrestal bone resorption in dental implants that affect the survival rate of the dental implant, such as the amount of overload stress (Stoichkov et al, 2018), micromotion (King et al, 2002), location and bacterial infiltration of the implant-abutment connection (Blanco et al, 2008; Kozlovsky et al, 2007; Tripodi et al, 2015), periodontal phenotype (Linkevicius et al, 2010), bone density (Hermann et al, 2001; Goiato et al, 2014), trauma surgical (Canullo et al, 2012) and maintenance of oral hygiene (Kozlovsky et al, 20007). In the actulaida, several treatment protocols have been proposed to reduce marginal bone loss around implants (Calvo-Guirado et al, 2015; Vohara et al, 2015; Romanos et al, 2014), including implant placement by below the level of the bony crest (subcrestal placement) (Kutan et al, 2015). Furthermore, the subcrestal implant also has a positive impact on papilla formation and allows for an adequate emergence profile for better aesthetic restoration (Vela-Nebot et al, 2006; Koutouzis et al, 2014). In this placement the implant-abutment interface is in a position that contributes to bone remodeling in the neck region of the implant compared to implants placed at bone level (crestal placement) (Outouzis et al, 2011; Charalampakis et al, 2014). On the other hand,

marginal bone loss from subcrustal implants compared to crests has shown contradictory results in recent studies (Gale et al 2013). Thus, some studies reported similar bone levels for both implant placement techniques (Casagrande et al, 2020). Therefore, we believe it is necessary to continue researching in this field, to make decision-making easier for the clinician.

2-JUSTIFICATION

Various treatment protocols have been proposed to reduce marginal bone loss around implants, including placement of implants below the level of the bone crest (subcrestal placement). The supracrestal implant also has a positive impact on papilla formation and allows an emergence profile suitable for an aesthetic restoration. Allowing the implant-abutment interface to be in a position that contributes to bone remodeling in the implant neck region compared to implants placed at bone level (crestal placement). Marginal bone loss from implants placed bestially/subcrestally has shown conflicting results in recent studies. In this study we intend to evaluate bone loss in 100 Tissue level implants from two different commercial companies: Straumann bone level® with the Bio horizon Tissue level® implant. Buying the data obtained with the existing literature.

3- HYPOTHESIS

3.1- Main hypothesis

Null hypothesis:

Two different brands of implants behave in the same way in terms of marginal bone loss, if they are placed based on the indications specified by the manufacturer.

Alternative hypothesis:

Two different brands of implants behave in the same way in terms of marginal bone loss, if they are placed based on the indications specified by the manufacturer.:

3- HYPOTHESIS

3.1- Main hypothesis

Null hypothesis: A brand of implant behaves in the same way in terms of marginal bone loss, if it is placed according to the indications specified by the manufacturer (crestal level or supracestal level).

Alternative hypothesis:

A brand of implant does not behave in the same way in terms of marginal bone loss, if it is placed according to the indications specified by the manufacturer (crestal level or supracestal level).

4-OBJECTIVES

4.1 Main objective:

To evaluate marginal bone loss in two different brands of implants placed at the bone level.

4.2 Secondary objectives:

• Relationship between marginal bone loss and suprabony soft tissue in mm.

• Relationship between marginal bone loss and ISQ value at the time of implantation.

• Relationship between marginal bone loss and torque (in Newton) at the time of implantation.

• Relationship between marginal bone loss and implant location.

• Relationship between marginal bone loss and the degree of periodontal disease.

• Relationship between marginal bone loss and systemic diseases.

• Relationship between marginal bone loss and smoking

5- MATERIAL AND METHOD

5.1- Study design

It is a prospective clinical study to compare two implants from two different brands of a similar design for their implantation [tissue level] and to evaluate the marginal bone loss of each dental implant in mm. 96 patients will be analyzed (an expected N of 48 per group, hoping to reach at least 100 implants per arm). See calculation of N in point 5.7.

5.2- Study population

The patients will be collected from patients who attend the master's degree in medicine, surgery and Oral Implantology, requesting implant-supported treatment. The study population will consist of patients who require treatment with dental implants, either partially or completely edentulous and who accept their placement and participation in the study.4.2.1 Inclusion / exclusion criteria

5.3-Inclusion/exclusion criteria

Inclusion:

• Patients of both sexes, over 18 years of age, who need dental implant placement for prosthetic rehabilitation. Whether partially or completely in both the maxilla and the mandible.

• Patients with residual alveolar ridge with at least 8 mm of bone height and 4 mm of width.

• Patients must have the ability to understand and decide at the time of voluntarily signing the informed consent before carrying out any intervention related to the study.

• Patients who, after being informed about the objectives and procedures of the research, agree, will sign the informed consent form. And they are ready to carry out the different study visits.

Exclusion:

• Patients with uncontrolled systemic diseases (ASA ≥ III).

• Patients who do not have 8mm bone height and/or 4mm width

• Patients who require bone regeneration

• Patients with severe periodontal disease or acute pericoronitis.

• Pregnant and breastfeeding women.

• Patients with Deficient or Inadequate Oral Hygiene.

• Patients with severe bruxism.

• Patients taking bisphosphonates or other antiresority medications.

• Smoker of more than 10 cigarettes/day.

• Patients with uncontrolled diabetes mellitus.

• Psychiatric illnesses or unrealistic expectations.

• Immunocompromised or immunosuppressed patient.

5.4.-Recruitment

The sample will be for convenience and will be obtained from patients of the Hospital Odontològic Universitat de Barcelona (HOUB) who come to the service of the Master of Dentistry in Oral Medicine, Surgery and Implantology. Once the protocol is approved by the Ethics and Research Committee with Medicines and Health Products of the same HOUB (CEIm-HOUB), the recruitment of study participants will begin, estimated to take one year and 2 months, starting in November 2022.

5.5.- Procedures

5.5.1 First session and recruitment

In this first session, before starting surgery and prosthodontic treatment, a thorough medical history will be taken. Each patient will be examined by extra-oral and intra-oral examination, in addition to the evaluation of their respective orthopantomography and cone beam computed tomography (CBCT), to evaluate the level of height and width of the bone for the placement of dental implants. This process will be carried out by the main researcher and supervised by another expert in Dentistry. Study participants who meet the inclusion criteria will then be recruited and asked if they wish to participate. Each of them will be given the following records.

If the patient meets the criteria and is interested, they will sign the informed consent and will be randomized using a randomization table of 10 in 10 implants [e.g.: randomization table ABBAABBBAB] to place one type or another of implant:

5.5.2 Second session

The patient will come to the Hospital for primary impressions with alginate. Then a cast will made with gypsum for study the case and bite of the patient will be taken with wax to record it.

5.5.3Third session

The patient will come to the Hospital to operate the surgery within 15-20 days after having the study caste revised by a dentist and specialist from the fixed department. The patient will have temporary prothesis (Fixed or Removable) after the surgery of the implant. A periapical X-Ray will be taken immediately after the surgery to control the marginal bone loss. With the respect to accepted criteria for the assessment of implant success were proposed by Albrektsson and colleagues (Albrektsson *et al*., 1986), which to identify clinical evidence of successful osseointegration and survival of implants, suggested that a marginal bone loss of less than 1.5 mm in the first year and 0.2 mm in the following years is acceptable after implant loading.

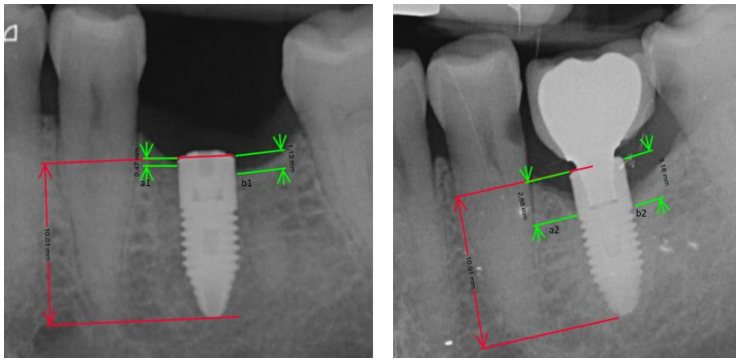
5.5.4 Fourth session

Once the osseointegration time has elapsed, 3 months ± 15 days (in the mandible) and 4 months ± 15 days (in the maxilla), new clinical and radiographic measurements will be taken and then the rehabilitation phase will begin. The visits will be those corresponding to the required prosthetic treatment (fixed or removable), carried out according to the usual procedures and techniques of the prosthodontic service.

5.5.5 Fith session

After placing the prosthesis on the patient, it will be reviewed every 3 months ± 15 days, for 2 years, to establish controls.

5.5.6 Sample's size calculation



Reference points for calculating marginal bone loss. Taken with permission from the author of Lina Dumanova's TFG. Red arrow, known mean of the implant. Green arrows reference the crestal bone and the marginal loss that occurred that allows us to compare at different times of the study.

5.6- Description of the treatment or intervention: drugs or techniques to be used.

- All patients will be anesthetized with 2% articaine with epinephrine,
- Regarding medication dispensed:
- Amoxicillin 1000 mg cps /8 hours for 7 days. (Patients allergic to Amoxicilllin, we prescribe Clindamicina 600 mg cps /8H / 7 days).
- Dexketroprofeno 25 mg cps /8 hours for 7 days.
- Omperazol 25 mg cps / 8H/ 7 days for the stomach.
- As rescue medication: Paracetamol 1000 mg cps /8 hours for 7 days and/or Metamizol 650 mg cps 1/8 hours.
- Rinse with 0.12% chlorhexidine 2 times/7 days.

5.7.- Sample calculation

According to data obtained in the study by Natalia Palacios-Garzon et al, 2020 (taking into account that both are internally connected implants), in order to detect changes of 0.2mm we would need: Accepting an alpha risk of 0.05 and a beta risk of 0.2 in a bilateral contrast, 48 subjects (implants) in the first group and 48 (Implants) in the second are needed to detect a difference equal to or greater than 0.2 units.

The common standard deviation is assumed to be 0.34. A loss to follow-up rate of 5% has been estimated.

5.8.- Statistical analysis

The variable data will be entered into the Excel program of the Microsoft Office 2019 Package (Microsoft Corporation, Washington, USA, 2013) and will be analyzed with the SPSS 26.0 program for Windows (SPSS, Illinois, USA, 2019).

The data collected will be processed using the STATA 14.0 statistical package. A descriptive analysis of the qualitative and quantitative variables will be carried out. The Kolmogorov-Smirnov test will be used to analyze the normality of the measurements.

The relationship between bone loss and implant position will be analyzed using parametric t-test.

The level of statistical significance chosen is 5% (α = 0.05). To evaluate the association between the dependent variable bone loss from T0 to T2 and successive Ts and the independent variables implant A, Implant B placement, a multiple linear regression analysis will be used.

All variables considered to potentially affect the study relationship, such as sex, age, and smoking, will be used as control variables in the regression; the number of cigarettes per day, maxilla or mandible, ISQ [implant stability value] and contact of the mesial and distal implant (penseic ade dinets and/or implants by mesial and distal)

5.9- Schedule

	2022												2023											
	En	Feb	Mar	Abr	May	Jun	Jul	Agos	Sep	Oct	Nov	Dic	En	Feb	Mar	Abr	May	Jun	Jul	Agos	Sep	Oct	Nov	Dic
Reclutamiento de participantes																								
	2024												2025											
	En	Feb	Mar	Abr	May	Jun	Jul	Agos	Sep	Oct	Nov	Dic	En	Feb	Mar	Abr	May	Jun	Jul	Agos	Sep	Oct	Nov	Dic
Recopilación de datos																								
	En	Feb	Mar	Abr	May	Jun	Jul	Agos	Sep	Oct	Nov	Dic	En	Feb	Mar	Abr	May	Jun	Jul	Agos	Sep	Oct	Nov	Dic
Análisis de los datos																								

5.0- Specification of the acceptance of the national and international ethical norms

The researchers agree that each participating subject will be treated and controlled following the protocol authorized by the Ethics and Research Committee for Medicines and Health Products of the Hospital Odontològic of the University of Barcelona (CEIm-HOUB) and the Declaration of Helsinki of ethical principles for medical research in humans by the World Medical Association (64ª General Assembly, Fortaleza, Brazil, October 2013).

5.1- Economic report

- Cost of rehabilitative prosthetic treatment paid by the patient.
- Administrative costs: in charge of the Master of Dentistry in Medicine surgery and Implant and the doctoral student.
- Material costs: by the Master of Dentistry in Medicine surgery and Implant and the doctoral student.

  - Ortopantograhia: 31€.
  - CBCT para un cuadrante: 97€.
  - CBCT para un mono-implant(Dependente en el caso): 81 €.
  - Impressional Alginato Aligsul: 10€.
  - Encerarlo (wax up) GEO CLASSIC gris-OPCA 75GR:20 €.
  - Dental Gypsum (Snow White plaster): 46€.

- Implanto Tipo A: 690€.
- Protesis:830€.
- Articulado papel (PAPEL BK 01 AZUL 300 HOJAS 0,2mm): 21€.
- Silicona Optosil P Plus (Heraeus Kulzer GmbH, Hanau, Germany): 80€.
- Silicona Zetalabor hard 85 shore A (Zhermack, Badia Polesine, Italy): 120€.
- Guantes de látex (Medicaline, Castellón, España): 180€.

5.2- Data collection sheet

PERSONAL DATA

CODE: IN SESSION:

NUMBER: SURNAMES:

DATE: EXAMINER:

DATE OF BIRTH (AGE): SEX: Man□ Woman □

PHONE: E-MAIL:

TYPE OF PATIENT: ASA I □ ASA II □ ASA III □ ASA IV □ ASA V □

PRIMARY DIAGNOSIS (DATE: mm / yyyy):

_____
__

_____
__

SURGERY TREATMENT (DATE: mm / yyyy):

_____
__

_____
__

Nº TEETH TO BE REHABILITATED WITH A PROSTHETIC: __prosthetic units.

TYPE OF PROSTHESIS:_____.

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