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FACULDADE DE MEDICINA DENTÁRIA
VISEU

THE USE OF CONNECTIVE TISSUE GRAFT IN IMMEDIATE IMPLANT PLACEMENT AT THE ESTHETIC AREAS: 6 MONTHS RESULTS FROM A PROSPECTIVE CROSS SECTION CLINICAL TRIAL.

Dissertação apresentada à Universidade Católica Portuguesa
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Por: Uxía García Torres

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Orientador: Prof. Dr. Tiago Borges

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RESUMO

Introdução

Tornou-se evidente nas últimas décadas que, após a extração dentária, ocorrem alterações dimensionais no volume local da maxila que são inevitavelmente produzidas devido à redução dos tecidos duros e moles, independentemente da estrutura dentária, que compromete o resultado estético.

Quando a espessura dos tecidos moles e duros peri-implantares é reduzida pela extração dos dentes, pode-se tentar manter o volume do local compensando a perda de material através do espessamento do tecido mole com a ajuda de enxertos conjuntivos.

Este estudo visa avaliar e quantificar as alterações dimensionais e volumétricas dos tecidos peri-implantares em pacientes tratados com implantes imediatos e pilares de cicatrização personalizados, com a utilização de enxertos de tecido conjuntivo na fase inicial de cicatrização, no sector maxilar anterior.

Materiais e métodos

O tipo de investigação que foi realizada é uma amostra de conveniência que faz parte de um ensaio clínico prospetivo randomizado, no qual foi necessário selecionar 32 pacientes com necessidade de extração de dentes na área anterior da maxila e a sua subsequente reabilitação. A seleção dos pacientes foi dividida em dois grupos, um em que o tratamento incluía a utilização de um enxerto de tecido conjuntivo após a colocação do implante e o outro em que não o fazia. Observações clínicas e recolha de dados foram realizadas em ambos os grupos antes, depois da cirurgia e em momentos subsequentes após a cirurgia e incluíram a medição da espessura da cortical vestibular (BT) e a distância entre o implante e a cortical vestibular (BID).

As impressões digitais foram executadas antes da extração em T0, a um mês T1 e a seis meses T2 após a inserção do implante.

Os modelos digitais foram sobrepostos com a ajuda de um software informático para medir as alterações dimensionais entre os dois grupos, das quais se destacam as variáveis lineares MBC (mm) e as variáveis volumétricas como Buccal Volume variation (BVv) em milímetros cúbicos e em percentagem relativa.

Resultados

Foram incluídos no estudo um total de 32 pacientes com uma idade média de 47,69 ± 10,822 anos. Foi observado que para os parâmetros MBC (mm), MBPC (mm), BVv (mm3), BVv (%), TVv (mm3) e TVv (%), os resultados não mostraram diferenças estatisticamente significativas entre os grupos. Contudo, quando se analisou a caracterização da variação relativa a BT, concluiu-se que em todas as variáveis estudadas, a interação entre o grupo (controlo/teste) e a medição de BT (≤ 1 mm / > 1 mm) foi significativa nos doentes com BT inferior a 1 mm.

Conclusão

Este estudo clínico demonstra que a utilização de enxertos de tecido conjuntivo em implantes imediatos com pilares de cicatrização personalizados é favorável na prevenção de alterações do tecido alveolar, mais especificamente em pacientes com um morfotipo fino da parede óssea vestibular.

Palavras chave

Implantes dentários, tecido peri-implantario, enxerto de tecido conjuntivo, remodelação de tecidos, perda óssea alveolar, pilar de cicatrização customizado.

ABSTRACT

Introduction

It has become evident in recent decades that, after tooth extraction, dimensional changes occur in the local volume of the maxilla that are inevitably produced due to the reduction of hard and soft tissues, regardless of the dental structure, that compromises the aesthetic result.

When the thickness of the peri-implant hard and soft tissues is reduced by tooth ex-traction, an attempt can be made to maintain the volume of the site by compensating for the loss of material by thickening the soft tissue with the help of connective grafts.

This study aims to evaluate and quantify the dimensional and volumetric alterations of peri-implant tissues in patients treated with immediate implants and customized healing abutments, with the use of connective tissue grafts at the early healing stage, in the anterior maxillary sector.

Materials and methods

The type of research that was carried out is a convenience sample that forms part of a prospective randomized clinical trial, in which it was necessary to select 32 patients with the need for extraction of teeth in the anterior maxillary area and their subsequent rehabilitation, attended in a private clinic by a Specialist in Oral Surgery. The selection of patients was divided into two groups, one in which the treatment included the use of a connective tissue graft after implant placement and the other in which it did not. Clinical observations and data collection were performed in both groups before, after surgery and at subsequent time points after surgery and included the assessment of the buccal bone plate thickness (BT) and the distance between the implant and the buccal bone plate (BID).

Digital impressions were taken before extraction at T0, at 1-month (T1) and at six-months (T2) after implant insertion.

The digital models were superimposed with the aid of a computer software to measure the dimensional alterations between the two groups and linear buccal changes (MBC) and volumetric variables like the Buccal Volume variation (BVv).

Results

A total of 32 patients with a mean age of 47.69±10.822 years were included in the study.

It was observed that for the parameters MBC (mm), MBPC (mm), BVv (mm^3), BVv (%), TVv (mm^3) and TVv (%), the results did not show statistically significant differences in the variations between the studied groups. However, when the characterization of the relative variation of BV was analyzed, it was concluded that in all studied variables, the interaction between the group (control/test) and the BT measurement (≤ 1 mm / > 1 mm) was significant in patients with BT less than 1 mm.

Conclusion

This clinical study demonstrates that the use of connective tissue grafts in immediate implants with customized healing abutments is favorable in the prevention of alveolar tissue alterations, more specifically in patients with a thin buccal bone plate morphotype.

Key words

dental implants, peri-implant tissues, connective tissue grafting, tissue remodeling, alveolar bone loss, custom healing abutment

Contents:

Table index

Figure index

List of abbreviations

CBCT - Cone Beam computer Tomography

SCTG - Sub-epithelial connective tissue graft

BID - Distance between implant shoulder and the buccal bone plate

KM - Mucosa queratinizada

DICOM - Digital Imaging and Communication in Medicine

BT - Buccal Bone Thickness

DBBM - Deproteinized bovine bone mineral

PMMA - Polimetilmetacrilato

ROI – Region of interest

MBC - Mean Buccal Change

MTC - Total alveolar changes

MBPC - Mean Buccal Palatal Change

mm - Milimeters

STL - Standard Tessellation Language

BVv – Buccal Volume variation

PVv – Palatal Volume variation

TVv – Total Volume variation

MGHv - Marginal gengiva height variation

MPHv - Mesial papilla height variation

DPHv - Distal papilla height variation

PHv - Papilla height variation

SPSS - Statistical Package for the Social Sciences

PH – Papilla Height

1. Introduction

It has become evident in recent decades that, after tooth extraction, dimensional changes occur in the local volume of the maxilla that are inevitably produced due to the reduction of hard and soft tissues, regardless of the dental structure. This event, generates numerous problems in the anterior sector of the jaws affecting the facial aesthetics of the patient. This lost in volume is due to factors such as the lack of functional stimulation or the lack of vascularization and blood supply of the periodontal ligament existing in the area when a tooth was present.(1) In general, the bone needs stimulation to maintain its density. When we extract a tooth the load levels, and consequently the bone stimuli, are reduced or even eliminated, which causes the bone in the area to be reabsorbed. The bone will adapt its shape through external remodeling and will also adapt its material properties with internal remodeling through the cellular activity of osteoclasts and osteoblasts. (2)

1.1. Immediate post-extraction implants

The lost of a tooth in the aesthetic maxillary area presents as situation that potentially leads to the reduction of soft and hard tissue around the lost tooth, which means a commitment for the restorative dentist to achieve a prosthetic outcome that is aesthetic, natural and fulfils the expectations of the patient regarding the treatment. The immediate placement of dental implants for dental replacement in the anterior maxilla demonstrated its efficacy and aesthetic success through the preservation of the bone and gingival anatomy present in the extraction alveolus. (3)

In 2003, the terminology for the immediate implant treatment options was defined according to the waiting time after the extraction.(4, 5) Hammerle et al proposed a list of four categories, classifying them from type I to type IV, defining the selection criteria and recommendations for different treatment options. (6)The immediate placement of the implant in the extraction cavity, defined as Type I in this classification, is a complex procedure that should only be performed by specialists. The placement of type I implants is for use only in ideal clinical conditions, and the requirements are the presence of a thick bone wall phenotype (> 1 mm) and a thick gingival biotype.

Traditionally, the patient should not have any type of infection at the extraction site, and should have sufficient volume of apical and palatine bone to allow the correct placement of the implant, ensuring the primary stability of the fixture. Implants classified as Type II, with soft tissue healing from 4 to 8 weeks after extraction, are

indicated in patients who have a thin facial wall or damaged by extraction, but maintain sufficient apical bone volume to stabilize the implant in the correct dimension with the help of increased contouring and guided bone regeneration. The Type III treatment option, considered as early placement of implants with partial bone healing, in which the healing period before implant placement is 12 to 16 weeks, is indicated in patients with a large periapical lesion, which requires bone regeneration prior to implant placement, which does not allow the use of Type I or II treatments; in these surgeries, bone contouring is increased with guided bone regeneration. As a last treatment option, type IV is considered a late implant placement, in which the patient must wait a minimum of 6 months of socket healing. The selection criteria for patients in this category include all young patients who have to reach the minimum age of 20 years, patients with extensive bone lesions in the apical or palatine bone, with insufficient bone volume, who will require guided bone regeneration and graft placement to increase bone contouring.(6)

1.2 Surgical and anatomical considerations for the placement of immediate dental implants

Several authors dedicated their time to study the variables and identify the factors they considered risky for bone loss and gingival recession in the placement of immediate implants in aesthetic areas.(7) In these studies, they identified as risk factors a thin facial bone wall or fractured facial bone plate that results from the surgical act of the extraction(8); an incorrect position or angulation of the implant when placed inside the socket (9); and the presence of a thin gingival biotype, an expression used to describe the thickness of the gingiva in an anatomical bucco-lingual orientation. (10).

To avoid the risk of complications, the oral surgeon will have to access the anatomical structures of the aesthetic area with indication for the intervention: the dimensions and properties of the bone facial and palatine walls; the location of the naso-palatine nerves and blood channels, the apical remnant bone available above the socket; the size of the socket; and the type of bone defect that occurs at the site of extraction.(11) The characteristics for which the use of the immediate implant technique in aesthetic areas is indicated, starting with the skills of the dentist doctor before this type of surgery, should only be used when the specialist has experience in performing this type of techniques. The indications of this treatment are based on the

anatomical conditions presented by the patient, these would be ideal when: the patient has an intact bone wall, a thick bone biotype (>1mm), a thick gingival volume, the absence of infections in the extraction area and the presence of sufficient bone in the apical and palatine area of the future implant. (12) The use of this technique is contraindicated, provided that the above ideal conditions are not met, as well as when we do not reach the primary stability of the implant when it is placed inside the alveolus, which would mean waiting 4 to 8 weeks to obtain a minimum healing to ensure a partial formation of the bone within the alveolus, and the subsequent placement of the implant with the "early placement" technique. (12)

The knowledge of the residual space between the surface of the implant and the walls of the alveolar bone is an important feature to notice. (13) Researchers such as Wilson et al, based on human models, were able to affirm that the average degree of contact between the alveolar bone and the immediate implant is 50%, maintaining a gap between these two of approximately 1.5mm. (14). When bone resorption is reduced at the extraction site, by the immediate placement of implants, it is because of the position and angulation, in which the implant has been inserted into the alveolus. (15) The 3D position of the implant, the primary stability, the vestibular GAP and the type of surgical technique, are part of determining factors in the surgery of immediate implants in the upper jaw to minimize bone loss. Fabio Mazzocco et al, conducted a study in which he stated that surgical techniques performed with flap, presented a greater reduction of the periimplant tissues compared to the flapless extraction procedure. (16)

1.3. Healing of immediate implants

The primary stability of an implant is the basis of surgical success for the different types of implant supported rehabilitation; Osseointegration is generated at the bone and implant interface, through the growth of bone towards the porous and rough metal surface, where other factors such as the type of load and bone remodelling also influence this event. The formation of new bone towards the surface of the implant will be influenced by the type of implant material, its surface, its porosity, and the compounds and chemical reactions that it can produce in the body. (17)

The survival rate of the implant is related to the osseointegration of the bone, therefore, studying the conditions in which it is found is crucial. Normally, the condition

of the bone is evaluated by measuring its density and thickness, using cone beam computed tomography (CBCT) and is expressed with Honsfield units (HU). (18) Bone normally has a higher density in the jaw, and in anterior regions, than in the maxilla and posterior areas. In addition to the study of density, examining the thickness of cortical bone also affects the primary stability of dental implants. (18) Each parameter of the bone that relates its spongy bone density or the thickness of the cortical bone, will have an impact and influence. (19)

The science of the materials and the numerous techniques of manufacture and design of implants, generated a series of ideal characteristics that would improve the osseointegration, considering the design of the surface, the manufacture, the sterilization, its mechanical properties, its biocompatibility and the response generated by the human being when it comes into contact with this material. (20)

The placement of a post-extraction implant can prevent the loss of local bone, and therefore improves the aesthetic result of the patient. To achieve this clinical result, the dentist must take into account various characteristics, among which are differentiated, the processes of alveolar healing, and the need for regenerative procedures. (21) The healing of the implant will depend on several aspects to achieve a successful clinical result; the healing process of the alveolar bone, the anatomy of the chosen implant, the space present between the surface of the bone and that of the implant, or the primary stability, would be some of the aspects to be taken into account. (21)

The first weeks after surgery, the spaces between the implant and the bone heal by inter-membranous ossification; this bone formation begins with the formation of blood clots by the vascularization and migration of mesenchymal bone marrow cells, followed by the compaction of the new tissue formed. After a month, the remodeling of the bone begins, caused by the adaptation and adjustment of the density of the bone without the presence of mechanical load or functionality. (22)

The integrity of the implant in the bone is achieved through the process of remodelling and bone formation, the interaction between the local reabsorption of the bone by the osteoclasts, and the formation of new bone created by the osteoblasts. (23) The presence of the implant itself in living tissue, normally, promotes the formation of bone on the surface of the implant, therefore, studies have been carried out and proposed different improvements to increase this proliferation, including the manipulation and application of materials and biomimetic substances that cover the

surface of the implant, or the local administration of drugs that manage to increase bone formation or inhibit its reabsorption. (23)

1.4 Periodontal tissues

Dental implants have a very high rate of clinical success when their levels of osseointegration are observed, but this parameter is not the only important one when we talk about surgical success. There are aesthetic complications related to the remodeling of peri-implant soft tissues and the recession of the apical mucosa.(24)

The periodontium is defined as the region that surrounds the tooth giving it support and stability, anchoring the tooth to the bone and keeping it firm. Periodontal tissue encompasses a set of four differentiated tissues, the root cementum, the periodontal ligament, the alveolar bone and the gum. (25) All of them collaborate intimately and when one of them suffers a traumatic or pathological aggression, it directly affects the entire periodontal complex. (26) Cementum is an avascular tissue, which wraps around the roots of the teeth. It has the important function of serving as a junction between the root dentin and the periodontal ligament. (27) The periodontal ligament is a set of horizontal fibers anchored at one end to the root cementum, and at the other to the alveolar bone, absorbing occlusal forces and protecting the tooth and bone from masticatory forces. It also provides protection to the nerve and vascular cells present in this binding area. (28) The most important and abundant cells in the periodontal ligament are fibroblasts, responsible for synthesizing and removing collagen from the fibers to regenerate them continuously. (29) The gum is the area of the oral mucosa that surrounds the most cervical portion of the neck of the tooth, and is formed by connective tissue and gingival epithelium. (30) The alveolar bone, present in both the maxilla and the jaw of the human being, is the bony portion, which covers the roots of the erupted teeth. It can be subdivided into three areas; the alveolar wall, which is in direct contact with the periodontal ligament, the spongy bone and the cortical plates that externally limit the maxillary and mandibular bone. (31)

1.5 Gingival biotype

It is the thickness of the gum in the vestibule-palatine extension, of great clinical importance at the aesthetic and surgical level in the analysis of dental implant placement. (32) Clinically, patients with fine gingival biotype are more susceptible to

apical recessions in the gum and decreases in the volume of the surrounding alveolar bone when the area is surgically manipulated. Therefore, surgeons opt for the use of minimally invasive and traumatic techniques in which the vascularization of the soft tissues around the implant is preserved. They are recommended in this type of patients, procedures without flap or surgeries in which the use of soft tissue grafting is valued. (33)

-Fine gingival biotype: patients who present a very scalloped gingival anatomy, a scarce attached soft tissue, with a narrow and thin interdental papilla, thin bone and commonly, associated with triangular and narrow teeth, with a tendency to recession of gingival tissue. (34)

-Thick gingival biotype: it is presented by patients who suffer from a more voluminous anatomy and a wider interdental papilla, a denser and more robust bone; Patients who frequently suffer the appearance of periodontal pockets, and who have more square teeth. (34)

1.6 Customized healing abutments

The placement of immediate implants after extraction has been shown to present esthetic complications at the level of peri-implant soft tissues. Among the treatments to avoid these peri-implant esthetic problems, it has been demonstrated that the placement of a temporary restoration at the time of immediate implant placement favors the preservation of the volume and height of the soft tissues, avoiding large gingival recessions. (35) By gradually adapting the soft tissue to a temporary crown, the ideal peri-implant tissue architecture can be achieved.(36) On the other hand, the immediate placement of provisional screw-retained restorations requires a correct primary stability of the fixture and may increase implant loss caused by the excess of contact during the osseointegration period. Perez et al. demonstrated in a clinical trial that immediate restorations could be replaced by customized healing abutments, which would maintain an adequate soft tissue support anatomy. (37)

The function of custom healing abutments is to mimic the soft tissue profile of the lost tooth, facilitate soft tissue healing and seal the socket after an immediate implant placement. Customizing the diameter and anatomy of the healing abutment can decrease soft tissue recession. Both prefabricated and customized healing abutments prevent the occurrence of complications and maintain the implant survival

rate, although custom abutments have better results in guiding the soft tissue for the formation of the gingival profile. (38)

1.7 Connective grafting and its uses

The achievement of dental aesthetic outcomes after the placement of implants in the anterior area depends on the texture, colour and appearance of the soft tissues in the sites, after the tooth extraction.(39) With bone loss, a muco-gingival change is observed that compromises the dimensions of keratinized tissue, with a very important role in rehabilitation with immediate implants, since the absence of keratin prevents the good maintenance of oral hygiene.(40)

The healing and regeneration of these mucosal wounds, unlike the healing of skin wounds, present a healing capacity with minimal scar formation, an accelerated healing pattern, and a faster response and elimination to local inflammation, compared to wounds on the skin. (41)

It has been shown that thicker soft tissues have a greater amount of collagen, extracellular matrix, and greater vascularization, which helps in the local immune response. It has therefore been verified that thicker soft tissues respond favourably to wound healing, restorative trauma and graft management and placement in which multiple surgical techniques have been developed to significantly increase tissue volume. On the other hand, the thinner soft tissues present a greater degree of resorption.(42) The anatomy and shape of the gingival papilla around the implant also contributes to the final aesthetic result of the immediate post-extraction implant of a single tooth in the aesthetic zone.(43) The more cervical portion of the point of contact with adjacent teeth and the maintenance of the bone profile around the implant influences the adaptation of interdental papillae. The gingival recession supposes the loss of papilla, causing that the interproximal point of contact will compromise the aesthetics of the restoration due to the gingival asymmetry. (44)

Given this aesthetic concern, techniques are used in which connective tissue grafting is used in cases of immediate implants, in order to stabilize the facial gingival volume and compensate for the bone and gingival volume that has been lost in the extraction. In connective tissue grafting, it compensates for the collapse of gingival tissue in the apical area of the crown of the tooth and the gingival margin during a follow-up time. (45) Therefore, in aesthetically compromised areas, the objective of

using connective tissue grafting is to minimizes marginal recession of soft tissue areas. (46)

1.8 Indications for soft tissue grafting

A correct knowledge of the type of recession suffered by a patient is necessary for case planning. The recession of the soft tissues and consequent exposure of the roots of the teeth, can be a consequence of poor oral hygiene and the formation of bacterial plaque in contact with the gum, which will produce inflammation and irritation.

Orthodontic movements or the exposure of the teeth to thermal, chemical or mechanical agents are also causes for soft tissue retraction.(47) There is a classification system of soft tissue recessions where they are divided into four classes according to their conditions. -Class I: Recessions that do not reach the muco-gengival line, teeth without loss of clinical insertion and with a root coverage of 100%.

-Class II: Recessions that reach or exceed the muco-gengival line, teeth without loss of clinical insertion and with 100% root coverage.

-Class III: Recessions that reach or exceed the muco-gengival line, teeth with loss of clinical insertion and with the root slightly exposed. The presence of poorly positioned teeth is common.

-Class IV: Fairly widespread recessions above the muco-gengival line, teeth with severe clinical insertion loss and with extremely exposed roots. (48)Based on this classification, the prognosis of exposed root cover with soft tissue grafts can be predicted. Class I and II recessions lead to full root coverage; In class III recessions, partial root cover is expected. In class IV recessions, root cover cannot be prevented. (48)

1.9 Principles of soft tissue grafts

The main concern of the tissue graft is whether it once placed will receive sufficient vascularization and nutrition from the reception room. Once placed, the excess movement of the graft prevents proper nutrition. That is why the initial adaptation and hemostasis are of great importance, since the active hemorrhage will impair the adequate adaptation. Taking into account these factors, it was concluded that the periosteum was the ideal reception area for soft tissue grafting, taking into account its abundant vascularization, its stability and the great ease of adaptation. (49)

An elaborate planning of the surgery and a delicate extraction of the soft graft from the donor area are necessary. This graft will have to present an adequate and uniform thickness for its comfortable handling and insertion. Normally, the usual place of tissue collection is the keratinized mucosa of the patient's own palate, being careful with possible damage to the palatine arteries. (50)

Usually, the sub-epithelial connective tissue graft (SCTG), a graft collected from the patient's own hard palate, is used for the increase of peri-implant soft tissues. (51)

Over time, new grafting techniques were introduced for this volume increase in relation to immediate implants; The modified palatal roll flap, split finger flap, apathetically placed flap, tunnel exposure, rotated palatal flap... among others. The surgical technique to graft sub-epithelial connective tissue is usually performed after the placement of the implant, following a waiting time for the healing of the implant.

Then, the implant is exposed to the oral cavity through a muco-periosteal flap and the connective tissue graft (SCTG) is collected from the palate with a complete incision technique and with the desired size, and placed in the implant area stabilizing it using suture techniques. The final thickness of keratinized mucosa will depend on the thickness of the flap displaced from the palate. Padhye et al., conducted recent research in which the authors studied the increase in volume of peri-implant soft tissues by the oral displacement of a flap of connective tissue graft. They concluded that the technique increased the thickness and width of the keratinized mucosa surrounding the implant after an observation period of one year, referring to the minimal discomfort in the patients. (51) On the contrary, other researchers found drawbacks in the available studies on this use of this technique. In a clinical study by Tavelli et al., the authors focus on the disadvantages of the use of connective tissue grafting of the deep palate. They state that it does not have enough potential to produce new keratinization due to the amount of adipose and glandular tissue present in the flap, which would act as a barrier in plasma diffusion and vascularization during the healing phase of the implant. (52)

This study aims to evaluate and quantify the dimensional and volumetric alterations of peri-implant tissues in patients treated with immediate implants and customized healing abutments, with the use of connective tissue grafts at the early healing stage, in the anterior maxillary sector.

2. Materials and methods

This study comprised the intervention and collection of data from 32 patients who underwent the placement of single dental implants after maxillary tooth extraction.

The type of research that was carried out is a convenience sample part of a prospective randomized clinical trial, where it was necessary to select patients with the need for tooth extraction in the anterior area of the maxilla and its subsequent rehabilitation, treated in a private clinic by a Specialist in Oral Surgery. The selection of patients was divided into two groups, one of them in which the treatment included the use of a connective tissue graft after the placement of the implant and another in which it did not. Clinical observations and data collection were made to both groups before, after surgery and at subsequent of time points after surgery.

All patients were selected using inclusion and exclusion criteria (Table 1) and evaluated by a specialist in the area of oral surgery. Those who met the conditions of the study accepted and signed an informed consent document before any intervention or treatment.

The research project number 139, has been approved by the CES-UCP, in May 2021.

The present investigation was registed at the ClinicalTrials.gov platform with the number NCT05060055.

2.1 Inclusion and exclusion criteria

Table 1. Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
- Patients of legal age. - Teeth of interest: one lost tooth between 15 and 25. -Teeth with adjacent and opponent tooth. -Presence of sufficient space for the placement of a single implant and a subsequent restoration. -Absence of bone lesions in the buccal bone wall.	- Medical contraindications (ASA ≥ III) - Presence of periodontal lesions. - Smoking patients. - Patients undergoing recent radiotherapy treatment in the head and/or neck. - Pregnancy

-Commitment and availability to fulfill to the follow-up apointments.	- Patients undergoing systemic drug therapy that potentially compromises bone healing.

2.2 Clinical observations and data collection

The digital and clinical assessment of the treatment outcomes was adapted from Borges et al 2020 and Fernandes et al. 2021.(53) (54) Patients were marked in pre-surgical and post-surgical appointments, for clinical observation and collection of data of interest; these observations and data collection was performed by the same dental practitioner in all cases. These data were assessed and used for research.

In the different appointments, the same data collection protocol was followed: the upper jaw arch of all patients was digitized with the help of an intra-oral scanner (Cerec Primescan, Dentsply Sirona Dental Systems GmbH), before the surgical intervention (T0), one month after surgery (T1) and six months after (T2).

Two clinical measurements were also made manually, through a periodontal probe (PCB 12, Hu-Friedy, Chicago, IL, USA); the distance between the inner wall of the vestibular cortical and the shoulder of the implant (BID) and the distance between the muco-gengival line and the gingival sulcus (KM).

2.3. Pre surgical radiographic analyses

Radiographic examination was performed with a volumetric dimension of 8 x 8 centimetres for 14 seconds with the XG 3D (Dentsply Sirona Dental Systems GmbH) tomography acquisition protocol, with a voxel size of 0.1 mm in high definition (HD) mode. The obtained CBCT images were imported in a Digital Imaging and Communications in Medicine (DICOM) format to a specific software for radiographic assessment (Materialise Mimics®, Materialise, Leuven, Belgium) in order to calculate Buccal Bone Thickness (BT). All measurements were obtained through coronal slice reconstructions, using an adjacent line to the sinus/nasal plate as a reference as described by Borges et al. 2020. BT was measured 1 mm above the coronal bone margin using a central slice, as well at the mesial and distal slices, ranging 1 mm from the central slice. Mean BT values were obtained as the average values of the three slices.

2.4. Intra-observer agreement

A protocol was elaborated to study the variables of interest in three distinct computer software. One examiner (U.T), blinded for the surgical procedure, was calibrated through an intra-examiner test (Dahlberg *d*-value), consisting in a double consecutive data collection of 10 randomly chosen patients included in this study. An intra-class coefficient of 0.92 was obtained.

2.5. Surgical protocol

All surgeries included in the research of this study were performed by the same specialist in oral surgery (TB) and under the same conditions.

All patients were treated with local anesthesia of the edentulous area using articaine with epinephrine 1/80000 and a flapless tooth extraction, sectioning the gingival fibers with a periostom, followed by odontosection and dislocation. The patients underwent an immediate implant placement with an internally connected cylindrical dental implant (OsseoSpeed EV™, AstraTech Implant System, Dentsply Sirona Implants, Möhndal, Sweden), placed in a slight palatal position with no contact with the buccal bone plate, following the surgical sequence protocol provided by the manufacturer. The space between the oral surface of the implant and the inner wall of the buccal bone plate was filled with deproteinized bovine bone material (DBBM) (Symbios®, Dentsply Implants, Möhndal, Sweden). To the patients of the test group was performed, apart from the surgery defined above, a connective tissue graft, which was obtained from the patient's own hard palate.

The socket was covered with a with a polymethyl methacrylate (PMMA) custom healing abutment made previously, screwed to the implant. No sutures where applied.

Patients were instructed to take postoperative medication; Amoxicillin 500mg three times a day for five days, Paracetamol 1000mg every 8 hours in the case of pain, and Ibuprofen 600mg every 12 hours for three days.

After surgery, patients were fitted with a temporary "Maryland" crown attached with adhesive to one of the adjacent teeth.

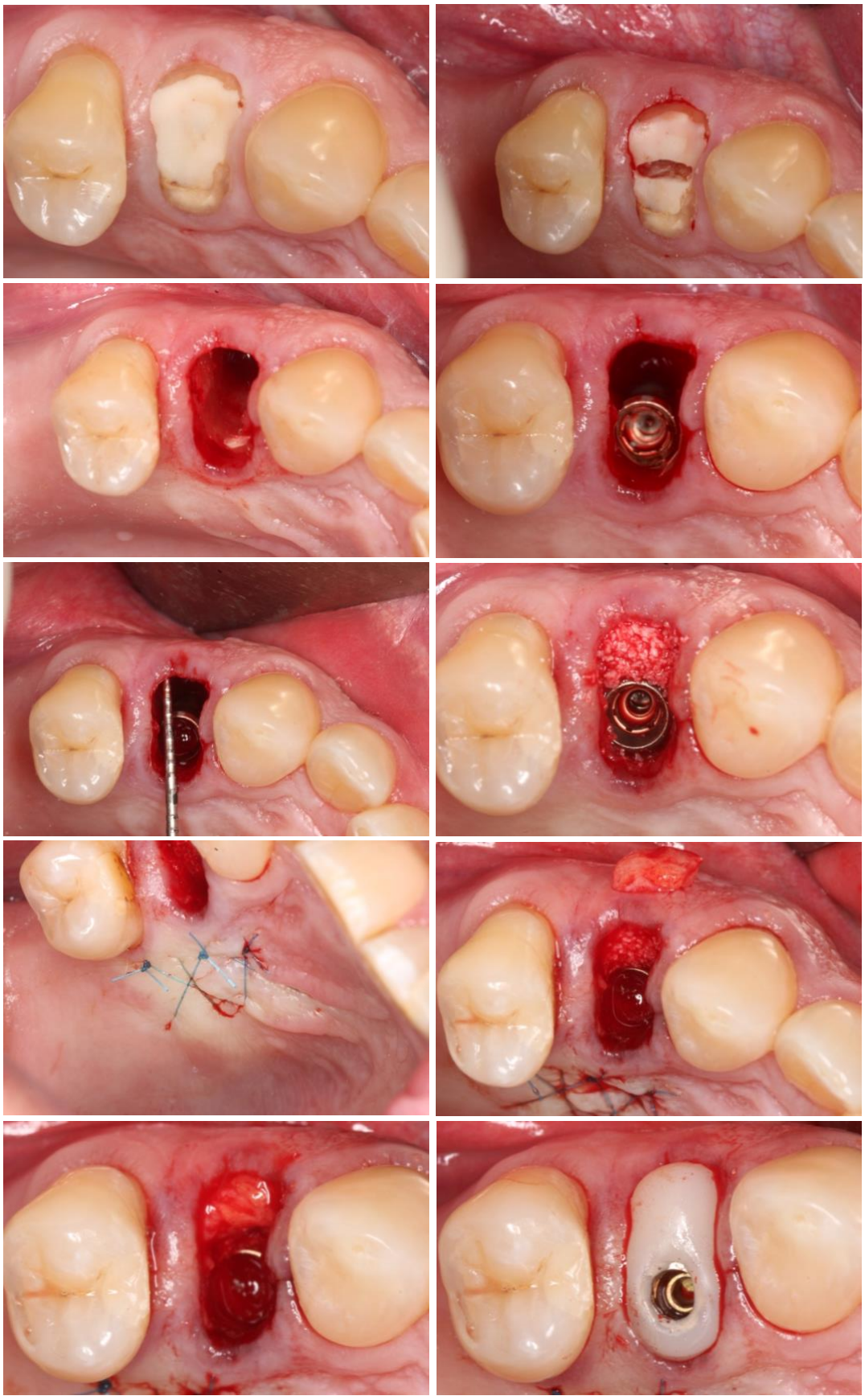

Figure 1: Surgical protocol of a patient included in the test group.

2.6 Digital evaluation

2.6.1 Study of digital models.

During the research, intra-oral scanners were taken from the upper arch to each of the patients at different pre and post-surgical time points: before surgery (T0), one month later (T1) and six months after implant insertion (T2). These models were exported in STL format for the computer program Geomagic Control X (Geomagic, Inc., North Carolina, USA) where they were aligned and superimposed to compare the changes at the peri-implant tissues. The final alignment was done through the *best fit* alignment algorithm for a perfect match of digital models.

2.6.2 Linear surface measurements

With the "3D Compare" tool, changes in thickness in T1 compared to T0 and in T2 compared to T0 were studied. Color maps were created by overlapping the models, where the change in color meant the variation in thickness in that area (Figure 2).

To assess thickness alterations in all models, it was necessary to ensure that the measurements were computed from the same place (“Align Between Measured Data Autoguess”, “local Based On Auto Guess” and “Best Fit Alignment). For this, a vertical line was defined along the axis of the tooth that served as a reference.

Subsequently, a rectangular area of interest was adjusted around this line, based on the free gingival margin of the tooth, and limited 5mm apical; Mesially and distally, a line passing through the interproximal area limited this region. it was divided into perpendicular lines with a separation of 0,5mm between them. This area was the study patronized region for each patient and was repeatedly used to determine the regions of interest (ROI) of the peri-implant tissue at the buccal and palatal surface (Figure 2).

The division of the area of interest in the models already superimposed, helped to calculate the buccal linear changes (MBC) and the total alveolar changes (MTC).

The Mean Buccal Change (MBC_{T0-T1}, MBC_{T1-T2}, and MBC_{T0-T2}) representing the buccal area and Mean Total Change (MTC_{T0-T1}, MTC_{T0-T1} and MTC_{T0-T2}) representing the buccal and palatal aspects were calculated in millimeters (mm) and allowed to evaluate the linear variations that occurred in the peri-implant area.

The relative percentages of the variables of interest began to be calculated allowing to compare them in the different post-operative times, and also to compare the different groups of patients.

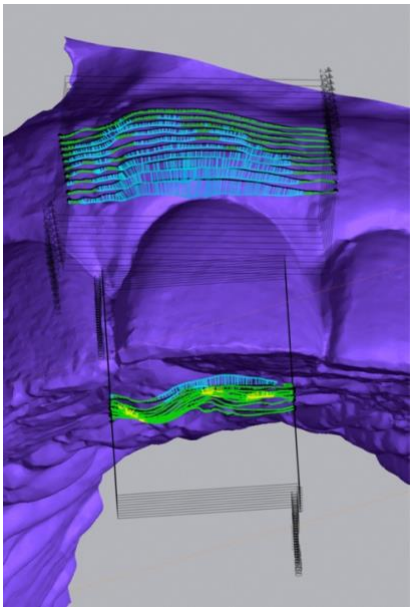

Figure 2: Linear digital assessment in buccal and palatal sections.

2.6.3. Volumetric dimensional measurements.

To volumetrically quantify the tissue changes, the STL models obtained at T0, T1 and T2 were imported to the Materialise Magics® (Materialise, Leuven, Belgium) computer program, where the function “Surface to Solid” was able to give volume to our models. A 3D volumetric ROI was manually selected with “Cut or Punch” function considering interproximal areas as mesial and distal limits (Figure 3). All cuts were performed in the same areas in all digital models ensuring that all measurements were carried out in the same regions. With the help of the “Boolean” section, the models were superimposed and it was possible to calculate the volume in the area of initial interest and compare it with the models in the post-operative follow-ups. In order to analyze the changes in the peri-implant volume, different variables such as Buccal Volume variation (BVv), palatal volume variation (PVv) and the total volume variation (TVv) were described and expressed in mm^3.

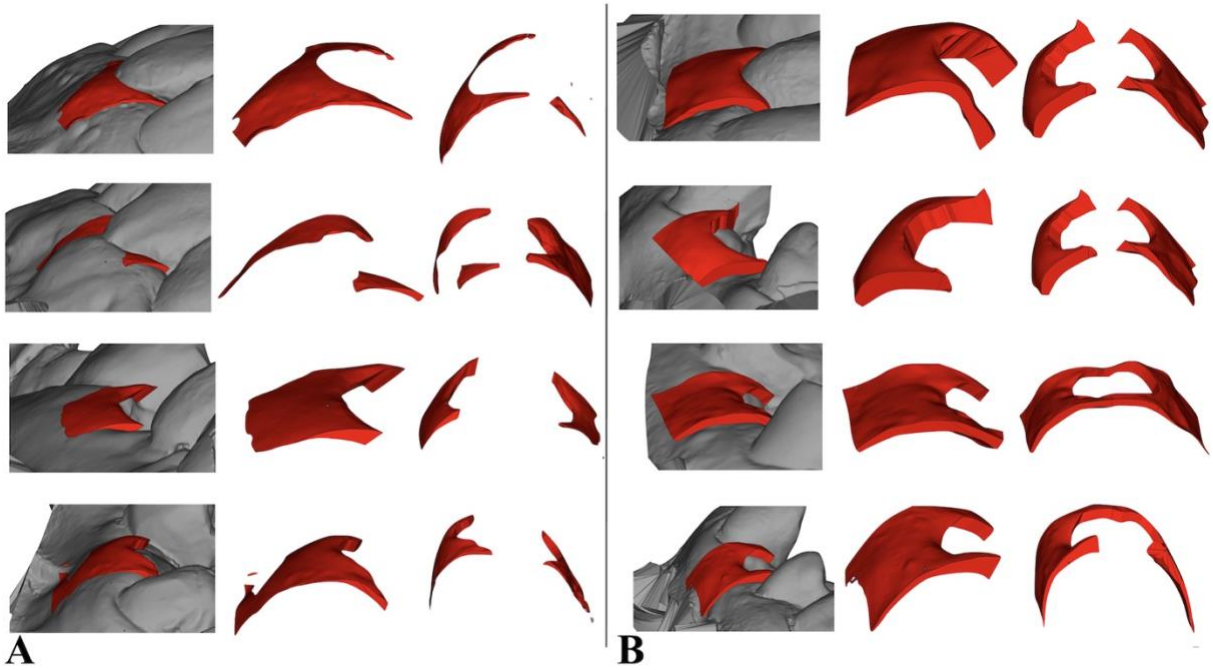

Figure 3: Comparison of volumetric variation between groups, at the first control visit.

2.6.4. Midfacial mucosa and papillae outcomes

Midfacial mucosa and papillae height variation at the 6-months follow-up were analyzed using the same computer software (Materialise Magics®, Materialise, Leuven, Belgium). After accurately coinciding the T0 and T2 STL files in a common coordinate system, a standardized line (red) was created connecting the marginal gingiva two most apical points of adjacent teeth, which served as a horizontal reference for the vertical measurements (Figure 4A). Three measurements were calculated in each STL file to access marginal gingiva mucosa and mesial and distal papilla height at T0 and T2 (Figure 4A and 4B). The mean differences of these measurements allowed to calculate variables representing MGHv (mm) related to the marginal gingiva height variation and MPHv (mm) and DPHv (mm), both associated to mesial and distal papilla height variation, respectively. PHv (mm) variable was established as the mean difference considering both papillae.

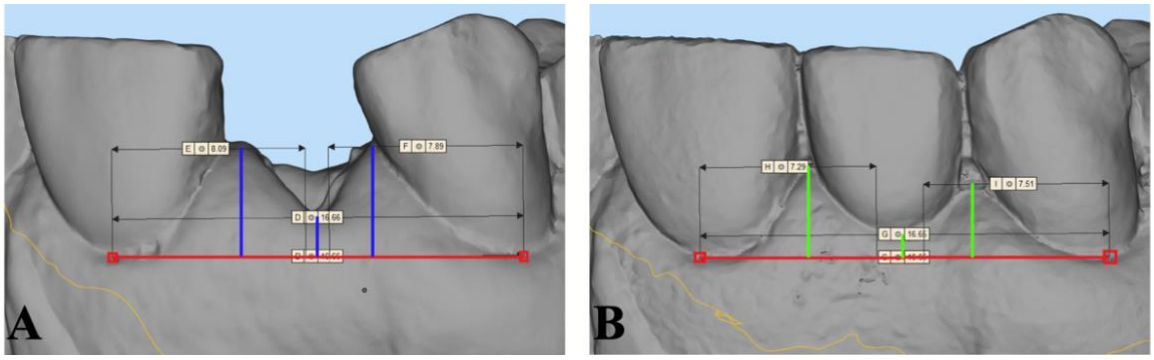

Figure 4: Digital midfacial mucosa and papillae measurements.

2.7 Statistical analysis

After collecting the interest data, they were grouped in the Excel software, version 16,6 (Microsoft Corporation, Redmond, USA) to be statistically accessed.

Statistical analyses were performed with the “Statistical Package for the Social Sciences (SPSS), version 26.0 for Windows (IBM Corporation, Armonk, NY, USA).

The established variables were presented as mean values, standard deviation, minimum, maximum and 95% confidence interval. When the initial sample was established a power test (G-power) was computed to test the power of the two arms sample. Variables related to participant´s characterization such as age, gender, implant site (incisive/premolar), BT, BID, KM, BVt and PVt were evaluated with *Chi-Square* test, *T-test* or *Mann-Whitney* test, to examine possible significant differences between the initial characteristics of the groups. The assumption of normality for these variables was computed using the *Kolmogorov-Smirnov* and *Shapiro-Wilk* tests.

Moreover, a two-way ANOVA analysis was computed to understand the buccal bone thickness effect on the linear and volumetric alveolar changes. Also, a two-way ANOVA test was computed to test the effect of the BT distribution and the changes found in the midfacial mucosa and papillae position. All hypothesis tests were considered at the 5% level of significance.

3. Results

3.1 Patients and implants

A total of 32 patients with a mean age of 47.69±10.822 years were included in the study. Randomly, these patients were distributed in two study groups; 16 patients in the control group (eight men and eight women) and 16 in the test group (three men and thirteen women).

Sample size and power calculation were computed taking into consideration a significance value of α = 0.08 (type I error) and the power at ß = 0.25 (type II error) obtaining a sample size power of 86,9%.

No patient presented clinical complications during surgery or in the 6 months post-operative period, obtaining a treatment success rate of 100%.

Not all patients complied with the initially established check-ups, resulting in absent data collected. At T1, 1 patient from the control group and 2 patients from the test group did not attend the appointment. Six months after surgery (T2), 2 patients from the control group and 3 patients from the test group were not present at the follow-up visit.

The characteristics of the patients and the implants used in the study are presented in table 2. All variables in this table are presented with a significance level of 5% and described by normal distribution.

Table 2: Patients demographic data and characterization.

Subject characterization	Group	N	Min	Max	$\overline{X}$	SD	Shapiro Wilk (p value)	*Chi* test *T* test Mann-Whitney test
Patients	Control	16	-	-	-	-	-	
	Test	16						
Gender (male/female)	Control	8♂/8♀ (50/50%)	-	-	-	-	-	*Chi* test p=0,137
	Test	3♂/13♀ (19/81%)						
Age	Control	16	37	69	51.25	9.125	0.926	T test p=0.061
	Test	16	23	65	44.13	11.477	0.788	

Implant site incisive / premolar	Control	7I/9PM (44/56%)	-	-	-	-	-	*Chi* test p=0,457
	Test	4I/12PM (25/75%)						
BT (mm)	Control	16	0.10	1.95	1.25	0.471	0.627	T test p=0.602
	Test	16	0.10	2.42	1.15	0.588	0.359	
BID (mm)	Control	16	2	5	3.12	0.885	<0.05	Mann-Whitney test p=0.305
	Test	16	3	5	3.44	0.629	<0.01	
KM (mm)	Control	16	3	5	4.13	0.806	<0.01	Mann-Whitney test p=0.171
	Test	16	3	5	3.63	0.957	0.065	
BVt (mm^3)	Control	16	136.54	457.03	246.85	90.832	0.916	T test p=0.625
	Test	16	181.67	477.47	293.94	83.039	0.510	
PVt (mm^3)	Control	16	142.16	377.61	246.85	76.857	0.226	T test p=0.110
	Test	16	195.77	428.64	288.64	67.455	0.528	

3.1.1 Treatment site distribution

Table 3 describes the site distribution of the lost tooth and IIP at the different groups and the total distribution of implants inserted.

Table 3- Implant sites distribution.

Tooth	Control N (%)	Test N (%)	Total N (%)
11	2 (12,5%)	1 (6,3%)	3 (9,4%)
12	2 (12,5%)	0 (0,0%)	2 (6,3%)
13	1 (6,3%)	0 (0,0%)	1 (3,1%)
14	1 (6,3%)	2 (12,5%)	3 (9,4%)
15	0 (0,0%)	2 (12,5%)	2 (6,3%)
21	1 (6,3%)	2 (12,5%)	3 (9,4%)
22	1 (6,3%)	1 (6,3%)	2 (6,3%)
24	6 (37,5%)	4 (25,0%)	10 (31,3%)
25	2 (12,5%)	4 (25,0%)	6 (18,8%)
Total	16 (100%)	16 (100%)	32 (100%)
Incisor	7 (43,8%)	4 (25,0%)	11 (34,4%)
Premolar	9 (56,3%)	12 (75,0%)	21 (65,6%)
Total	16 (100%)	16 (100%)	32 (100%)

3.1.2 Type of implants

The type of implants used, regarding the diameter and length, in each group, are presented in table 4.

Table 4 – Type of Implant distribution.

Implant	Control N (%)	Test N (%)	Total N (%)
3.6x11	9 (56,3%)	8 (50,0%)	17 (53,1%)
3.6x13	4 (25,0%)	5 (31,3%)	9 (28,1%)
3.6x9	1 (6,3%)	0 (0,0%)	1 (3,1%)
4.2x11	2 (12,5%)	2 (12,5%)	4 (12,5%)
4.2x13	0 (0,0%)	1 (6,3%)	1 (3,1%)
Total	16(100%)	16 (100%)	32 100%)

3.2 Alveolar changes

Table 5 shows the results on the evolution of the linear and volumetric changes in the IIP sockets, comparing the two groups. Regarding Mean Buccal Change (MBC) it can be observed that in T0-T1 the individuals from both groups presented identical results. From T0 to T2 the MBC register for the control group was -0.19 mm±0.224 mm of linear loss, and for the test group was -0.36 mm±0.329 mm of linear loss, not showing a statistically significant difference between the two groups.

Regarding Total Mean Buccal Change MBPC (mm) it was observed that at T0-T1 the control group subjects had a mean linear loss of -0.29 ± 0.348 mm and the test group subjects had a mean linear loss of -0.33 ± 0.298 mm. On the other hand, at T0-T2 it was recorded that the individuals from the control group had an average loss of -0.38 ± 0.279mm and the individuals from the test group had an average of -0.49 ± 0.473mm of total linear loss. The results showed no statistically significant differences in the linear variations between groups.

Regarding the Buccal Volume Variation (BVv) parameter (mm^3), at T0-T1 it was observed that control group subjects had a volumetric loss of -15.89 ± 15.068 mm^3 and test group subjects had a mean volumetric loss of -12.84 ± 8.923 mm^3. In the T0-T2 range, the record of vestibular volumetric change for Control Group was a mean loss of -19.78 ± 17.608mm^3 and for Test Group, a mean volumetric loss of -23.43 ± 17.995mm^3. The differences observed were not statistically significant.

As for Buccal Volume Variation relative percentage (%) it was observed that at T0-T1 the control group had a mean volume loss of -5.59 ± 5.006 % and the test group had a mean loss of -4.35 ± 2.257%; at T0-T2 the control group had a mean volume loss of -6.98%±5.544% and the test group had a mean volume loss of -7.38 ± 4.021%. The differences observed were not statistically significant.

Regarding the parameter T Volume Variation (TVv)(mm3) it was observed in T0-T1 that individuals from the Control Group presented volumetric losses of -26.16 ± 28.983mm3 and individuals from the Test Group had a mean register of total volumetric variations of -24.11 ± 18.956 mm^3. In the T0-T2 variation the mean record of losses for Control Group was -37.50 ± 29.072 mm^3 and for Test Group was -32.52 ± 23.020 mm^3. The differences observed were not statistically significant.

As for Total Volume Variation relative percentage (%) it was observed that at T0-T1 the control group subjects registered mean volume losses of -4.69 ± 4.461% and the test group subjects had mean losses of -4.26 ± 2.869%; at T0-T2 the control group subjects registered volume losses of -6.85 ± 4.371% and the test group subjects had losses of -5.38 ± 2.761%. The differences observed were not statistically significant.

Table 5 - Evolution of alveolar changes between groups.

Variable	Group	N	Minimum	Maximum	Mean	Std. Deviation	95% Confidence Interval		Test -*t* (p value)
							Lower Bound	Upper Bound	
MBC T0-T1 (mm)	Control	15	-0,72	0,10	-0,16	0,205	-0,28	-0,05	-0.284 (0.777)
	Test	14	-0,56	0,16	-0,16	0,181	-0,26	-0,05	
MBPC T0-T1(mm)	Control	15	-1,01	0,16	-0,29	0,348	-0,48	-0,09	0,341 (0,736)
	Test	14	-1,00	0,03	-0,33	0,298	-0,50	-0,16	
BVv T0-T1 (mm^3)	Control	15	-46,55	-1,40	-15,89	15,068	-24,23	-7,54	-0.218 (0.827)
	Test	14	-38,14	-2,32	-12,84	8,923	-17,99	-7,69	
BVv T0-T1 (%)	Control	15	-18,40	-0,69	-5,59	5,006	-8,37	-2,82	-0,870 (0,395)
	Test	14	-9,21	-0,84	-4,35	2,257	-5,66	-3,05	
TVv T0-T1 (mm^3)	Control	15	-98,00	6,03	-26,16	28,983	-42,21	-10,11	-0,224 (0,825)
	Test	14	-63,71	-2,51	-24,11	18,956	-35,05	-13,17	
TVv T0-T1 (%)	Control	15	-15,90	0,85	-4,69	4,461	-7,16	-2,22	-0.310 (0.759)
	Test	14	-9,77	-0,29	-4,26	2,869	-5,91	-2,60	

Table 6 (Continuing)

MBC T1 -T2 (mm)	Control	14	-0,25	0,08	-0,07	0,096	-0,13	-0,02	2,939 (0,056)
	Test	13	-0,76	0,05	-0,28	0,233	-0,42	-0,14	
MBPC T1 - T2 (mm)	Control	14	-0,41	0,12	-0,12	0,142	-0,21	-0,04	1,166 (0,263)
	Test	13	-1,38	0,32	-0,27	0,439	-0,54	-0,01	
BVv T1 -T2 (mm^3)	Control	14	-11,65	2,88	-4,40	4,555	-7,02	-1,77	-1,456to (0.145)
	Test	13	-40,86	2,62	-11,31	12,598	-18,92	-3,70	
BVv T1 -T2 (%)	Control	14	-4,08	0,93	-1,57	1,593	-2,49	-0,65	1,945 (0,063)
	Test	13	-9,87	0,84	-3,54	3,411	-5,60	-1,48	
TVv T1 -T2 (mm^3)	Control	14	-21,48	4,80	-9,16	7,737	-13,63	-4,69	-0,087 (0,931)
	Test	13	-41,26	24,07	-8,68	18,210	-19,69	2,32	
TVv T1 -T2 (%)	Control	14	-5,42	1,05	-1,83	1,711	-2,82	-0,84	-0,555 (0,584)
	Test	13	-5,87	4,05	-1,34	2,814	-3,04	0,36	
MBC T0-T2 (mm)	Control	15	-0,64	0,26	-0,19	0,224	-0,31	-0,06	-1,911th (0.049)*
	Test	15	-1,15	0,16	-0,36	0,329	-0,54	-0,17	
MBPC T0-T2 (mm)	Control	15	-0,91	-0,05	-0,38	0,279	-0,54	-0,23	-0.789th (0.430)
	Test	15	-1,55	0,19	-0,49	0,473	-0,75	-0,23	
BVv T0-T2 (mm^3)	Control	15	-56,86	-3,23	-19,75	17,608	-29,50	-10,00	0,567 (0,575)
	Test	15	-79,00	-5,52	-23,43	17,995	-33,40	-13,47	
BVv T0-T2 (%)	Control	15	-22,47	-1,06	-6,98	5,544	-10,05	-3,91	-0.892th (0.373)
	Test	15	-19,08	-2,32	-7,38	4,021	-9,61	-5,16	
TVv T0-T2 (mm^3)	Control	15	-105,85	-7,09	-37,50	29,072	-53,60	-21,40	-0.062nd (0.950)
	Test	15	-104,97	-3,22	-32,52	23,020	-45,27	-19,78	
TVv T0-T2 (%)	Control	15	-17,18	-2,01	-6,85	4,371	-9,27	-4,43	-1,107 (0,278)
	Test	15	-12,46	-0,47	-5,38	2,761	-6,90	-3,85	

* - significant at 5%

By analysing the table 7, it was shown that for all the variables under study, the interaction between group and BT measurement is statistically significant. The buccal volume variation is clearly influenced by the thickness of the buccal bone plate and the type of treatment. We can notice that the test group presents less reduction of the buccal volume, either in volume units or relative percentage, when compared with the control group.

Table 7– BT influence over the volumetric tissue variation at the two groups.

	Group	Statistical measures	BT		Two-way ANOVA
			BT (<= 1mm)	BT (> 1mm)	
BVv(mm^3) T0-T1	Control	Mean	-32,25	-9,94	**Group factor:** ET=4,149 p=0,052 **BT factor:** ET=3,935 p=0,058 **Group/BT interaction** ET=12,422 **p=0,009****
		Std.	10,840	11,689	
	Test	Mean	-9,72	-15,96	
		Std.	5,676	10,844	
BVv(mm^3) T0-T2	Control	Mean	-36,47	-13,67	**Group factor:** ET=0,080 p=0,780 **BT factor:** ET=1,662 p=0,209 **Group/BT interaction** ET=4,930 **p=0,04***
		Std.	16,431	14,162	
	Teste	Mean	-20,20	-26,26	
		Std.	12,606	22,179	
BVv(%) T0-T1	Control	Mean	-10,26	-3,90	**Group factor:** ET=4,111 p=0,047* **BT factor:** ET=3,014 p=0,095 **Group/BT interaction** ET=8,987 **p=0,006****
		Std.	5,179	3,662	
	Test	Mean	-3,51	-5,20	
		Std.	1,978	2,333	
BVv(%) T0-T2	Control	Mean	-11,55	-5,31	**Group factor:** ET=0,395 p=0,535 **BT factor:** ET=1,537 p=0,226 **Group/BT interaction** ET=5,284 **p=0,030***
		Std.	7,479	3,854	
	Test	Mean	-6,39	-8,26	
		Std.	2,871	4,838	

Std: standard deviation; p: significance; *-sig to 5%; ** - sig at 1%.

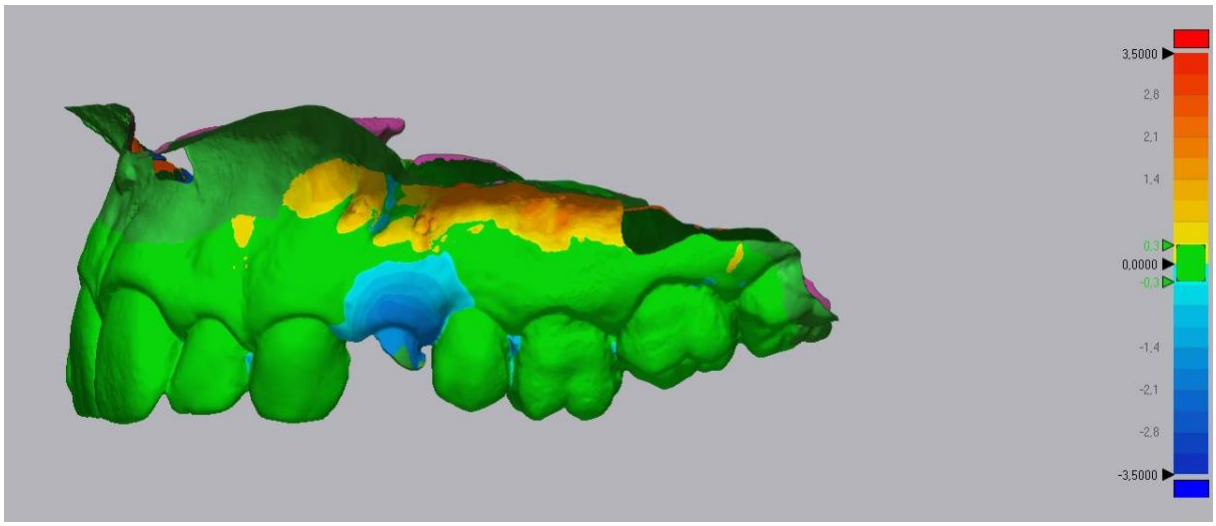

Figure 5: Representation of the areas with dimensional changes relative to temporal change, produced by a three-dimensional evaluation.

Table 8 shows the interaction between the different groups and BID measurements. is not statistically significant. The variation in buccal volume is not influenced by the space between the implants and the alveolar bone.

Table 8- BID influence over the volumetric tissue variation at the two groups.

	Group	**Statistical measures**	**BID**		**Two-way ANOVA**
			BID <=3 mm	**BID >3 mm**	
BVv(mm^3) T0-T1	Controle	Mean	-13,33	-21,00	**Fator grupo:** ET=0,574 p=0,456 **Fator BID:** ET=1,447 p=0,240 **Interação grupo/BID** ET=0,126 p=0,725
		Std.	13,345	18,573	
	Teste	Mean	-11,35	-15,52	
		Std.	4,688	14,172	
BVv(mm^3) T0-T2	Controle	Mean	-15,78	-27,69	**Fator grupo:** ET=0,071 p=0,792 **Fator BID:** ET=0,915 p=0,348 **Interação grupo/BID** ET=0,620 p=0,438
		Std.	15,402	20,813	
	Teste	Mean	-22,97	-24,13	
		Std.	10,161	27,213	
	Controle	Mean	-4,98	-6,81	**Fator grupo:**

BVv(%) T0-T1		Std.	4,043	6,940	ET=0,876 p=0,358 **Fator BID:** ET=0,553 p=0,464 **Interação grupo/BID** ET=0,176 p=0,679
	Teste	Mean	-4,17	-4.68	
		Std.	1,753	3,193	
BVv(%) T0-T2	Controle	Mean	-5,83	-9,27	**Fator grupo:** ET=0,010 p=0,921 **Fator BID:** ET=0,768 p=0,389 **Interação grupo/BID** ET=0,968 p=0,334
		Std.	4,191	7,626	
	Teste	Mean	-7,46	-7,27	
		Std.	2,366	6,023	

Std: standard deviation; p: significance; *-sig at 5%; ** - sig at 1%.

3.3 Midpoint mucosa and papillae height variation.

Table 8 shows the parameters of the evolution of the changes in the vestibular midpoint and papillae height comparing the two groups. Regarding the marginal variation of gingival height, MGHv (mm), it was observed that individuals in the control group had a mean linear loss of -0.60 ± 0.723mm and individuals in the test group had a mean loss of -0.38 ± 0.446mm. In the variation of mesial papilla height, MPH (mm) the mean record for the control group was -0.29 ± 0.369 mm linear loss and for the test group -0.07mm±0.544mm loss. In the variation of distal papilla height, DPH (mm) the mean record for the control group was -0.38 ± 0.498mm linear papilla loss and for the test group -0.13 ± 0.688mm loss. In the variation of the mean difference of several papillae, PH (mm) the mean record of the control group was a loss of -0.34mm±0.358mm and in the test group, a linear loss of -0.10 ± 0.544mm. The observed differences are not statistically significant.

Table 9 – Midpoint mucosa and papillae height variation at T2.

Variable	Group	N	Minimum	Maximum	Mean	Std. Deviation	95% Confidence Interval		Test -*t* (p value)
							Lower Bound	Upper Bound	
MGHv (mm)	Control	16	-1,68	0,51	-0,60	0,723	-0,98	-0,21	-0,923 (0,356)
	Test	16	-1,08	0,80	-0,38	0,446	-0,62	-0,14	
MPHv (mm)	Control	16	-0,88	0,73	-0,29	0,369	-0,49	-0,10	-1,414 (0,157)
	Test	16	-0,63	1,34	-0,07	0,544	-0,36	0,22	
DPHv (mm)	Control	16	-1,45	0,53	-0,38	0,498	-0,64	-0,11	-0,377 (0,706)
	Test	16	-0,96	1,99	-0,13	0,688	-0,50	0,24	
PHv (mm)	Control	16	-0,96	0,44	-0,34	0,358	-0,53	-0,15	-0,943 (0,345)
	Test	16	-0,66	1,51	-0,10	0,554	-0,40	0,19	

Table 10 – BT influence over the midpoint mucosa and papillae height variation at T2.

	Group	Statistical measures	BT		Two-way ANOVA
			BT <= 1mm	BT > 1mm	
MGHv (mm)	Control	Mean	-0,36	-0,68	**Group factor:** ET=0,336 p=0,567 **BT factor:** ET=0,361 p=0,553 **Group/BT interaction:** ET=0,588 p=0,450
		Std.	0,583	0,770	
	Test	Mean	-0,40	-0,36	
		Std.	0,330	0,562	
MPHv (mm)	Control	Mean	-0,53	-0,21	**Group factor:** ET=2,890 p=0,100 **BT factor:** ET=1,328 p=0,259 **Group/BT interaction:** ET=0,377 p=0,544
		Std.	0,249	0,376	
	Test	Mean	-0,12	-0,02	
		Std.	0,648	0,457	
DPHv (mm)	Control	Mean	-0,45	-0,35	**Group factor:** ET=1,310 p=0,262 **BT factor:** ET=0,434 p=0,516 **Group/BT interaction:** ET=0,074 p=0,788
		Std.	0,232	0,567	
	Test	Mean	-0,24	-0,02	
		Std.	0,393	0,912	
PHv (mm)	Control	Mean	-0,49	-0,29	**Group factor:** ET=2,496 p=0,125 **BT factor:** ET=1,001 p=0,326 **Group/BT interaction:** ET=0,017 p=0,897
		Std.	0,199	0,390	
	Test	Mean	-0,18	-0,02	
		Std.	0,462	0,657	

Std: standard deviation; p: significance; *-sig at 5%; ** - sig at 1%.

Regarding the variables MGHv, MPHv, DPHv and PHv, there were no statistically significant differences in the two-factor Anova models (group and BT). However, it is worth noting the high values of standard deviation especially in the BT class greater than 1mm and especially in the test group.

4. Discussion

This study was designed to compare the behavior of the peri-implant soft tissues after the placement of immediate implants and customized healing abutments with connective tissue grafting.

When an immediate implant placement technique is used, the peri-implant hard and soft tissues initiate a remodeling process, including morphological changes in periodontal tissues and alveolar bone. According to Borges et al, patients with a thinner buccal bone table (<1mm) will suffer a large reduction in the thickness and volume of the peri-implant alveolar tissues when compared with patients who present thick facial bone wall morphotypes. These authors state that, during the first year after immediate implant placement surgery, the tissues undergo continuous remodeling and reduction in thickness, which will occur mainly during the first month, and which will become more stable four months after surgery. (53)

As a result of the loss of thickness and volume in the bone table after tooth extraction, periodontal tissue recession and remodeling occurs. The loss of this soft tissue severely compromises the clinical outcome at the aesthetic level. According to Migliorati et al, when the thickness of the peri-implant hard and soft tissues is reduced by tooth extraction, an attempt can be made to maintain the volume of the site by compensating for the loss of material by thickening the soft tissue with the help of connective grafts. Migliorati, demonstrated the effectiveness of these connective tissue grafts in immediate implant surgeries, with a two-year follow-up, where his test group showed better aesthetic results than the control group. (55)

On the other hand, in immediate implant placement, other surgical treatment variants have demonstrated their potential benefit in preventing tissue shrinkage and improving aesthetic outcomes. Fernandes et al. demonstrated the use of customized healing abutments as a solution to aesthetic peri-implant soft tissue problems, aiding tissue healing, volume maintenance and also the prevention of dimensional soft tissue alterations; conducted a 1-year randomized clinical trial in which two groups of patients were studied, one group had an immediate implant and a collagen matrix as a sealing option, and the other group used a guarded healing abutment; after one year of study, they found significant evidence that patients with a final buccal bone table (<1mm) suffered greater volumetric variations. (54) Authors, such as Perez et al, stated that

the use of customized abutments showed better papilla maintenance and less loss of bone volume when compared to standard healing abutments. (37) In our table 8, we can see that papillary variations were residual, and that no variant presented statistically significant values; even so, through the analysis of PHv (mm), we were able to affirm that the use of connective tissue grafts contributes to the loss of papillary recession.

When the evolution of alveolar alterations was studied by comparing the two groups (Table 6), it was observed that for the parameters MBC (mm), MBPC (mm), BVv (mm^3), BVv (%), TVv (mm^3) and TVv (%), the results did not show statistically significant differences in the variations between the studied groups. However, when the characterization of the relative variation of BV was analyzed, it was concluded that in all studied variables, the interaction between the group (control/test) and the BT measurement (≤ 1 mm / > 1 mm) was statistically significant in patients with BT less than 1 mm. The result of this interaction for Bvv (%) varies between small and moderate (Table 7). These observations are in agreement with the clinical results presented by Jiang et al, who studied hard and soft tissue alterations in immediate implant placement with and without connective tissue grafting; in this investigation, they were able to compensate for facial tissue collapse with connective tissue grafting; After immediate implant surgeries, Jiang et al. noticed buccal bone resorption in both groups and highlighted that in patients with a thicker buccal bone plate (>1mm) bone resorption was more limited when compared to patients with a thicker buccal bone plate (45)

Characterizing the evolution parameters of the papillae height alterations (Table 8), no significant statistical differences were observed. Comparing the two groups investigated, it was shown that test group presented better linear results with a lesser amount of soft tissue lost after surgery, and therefore, better surgical and aesthetic results. Regarding MGHv (mm), the control group presented a mean value of -0.60 ± 0.723 mm whereas test group patients -0.38 ± 0.446 mm. In the MPH variation (mm), the control group had a mean value of -0.29 ± 0.369mm and the test group -0.07 ±0 .544 mm. In the DPH study (mm), the control group had a mean value of -0.38 ± 0.498mm and the test group -0.13 ± 0.688 mm. When taking in consideration both papillae mean value control group had a mean of -0.34 ± 0.358mm and the test group -0.10 ± 0.544mm. Ferrantino et al, conducted a study comparing a total of 59 patients

who had immediate implants placed in post extraction sockets and a non-functional provisional restoration with a connective tissue graft (Test group) or without (Control group). The main variable used was the implant Crown Aesthetic Index. This multicenter randomized clinical trial concluded that the use of connective tissue grafting and a non-functional provisional restoration is not mandatory nor does it present a notable relevance to achieve a more differentiated aesthetic outcome. (57)

Volume variation variables were also studied in relation with the group and the buccal bone wall thickness (Table 7). regarding these variables significant statistical differences were observed in the BT≤ 1 mm class in the test group, which helps to affirm that patients with a thin buccal wall will present better clinical results and less loss of peri-implant tissue when a connective tissue graft is used in them.

In a 12-month follow-up study, Ninwegen et al. compared the soft tissue volume after implant placement and connective tissue grafting in the esthetic area. The authors found considerable tissue loss in the facial mucosa of the test group. Investigators also stated that the use of connective tissue grafts in immediate implant surgeries should be limited to cases of mucosal defects.(58)

In 2021, Zuiderveld et al, stated the benefits of peri-implant connective tissue grafting of peri-implant mucosa on the thickness of the buccal bone present in each patient's esthetic zone, using cone beam computed tomography (CBCT) as a data collection mechanism. The clinical trial included 60 patients divided in two groups who underwent immediate implants and provisionalization with or without CTG Authors concluded that connective tissue grafting, when placed with an immediate implant, results in a greater loss of bone volume in the aesthetic area when compared to patients who did not receive connective tissue grafting. However, it was demonstrated that connective tissue grafting does improve the aesthetic outcome by helping to decrease peri-implant mucosal recession. (59)

The variable BVv was also studied in relation to the gap between the implant and the alveolar buccal bone wall by means of a two-way Anova model study. It was concluded that these variables did not present significant statistical differences, and that the variable BID had no influence on the final BVv volume.

For many years, the study of peri-implant soft tissue alterations was performed through clinical evaluations and aesthetic classifications. An example of this was the use of the PES (Pink Esthetic Score) index, a mechanism to evaluate the appearance of peri-implant soft tissue. (56) This analytical method, despite being widely used, has the limitation that the data can be interpreted differently depending on the examiner, which is why advances in technology have allowed us to carry out our study using an intra-oral scanner, where we can collect three-dimensional images of the anatomy of the soft tissues and analyze them digitally collecting objective data. (53)

Regarding this study, we can highlight some limitations related to the data collection methodology. The use of an intraoral scanner that provides us STL files only provides us with a superficial evaluation capacity, being impossible to differentiate hard from soft tissue dimensional changes. By obtaining a more exhaustive analysis of the deeper tissues we could also evaluate the relationship of these recessions with bone tissue loss and determine more thoroughly the soft tissue alterations occurring after the use of connective tissue grafts, knowing how to differentiate the percentage of recession caused by bone remodeling separately from gingival recession.

Also, we can highlight as a major limitation of our study the follow-up period of the patients selected. Prolonging the study time and increasing the long-term observations of the patients, adding more moments of evaluation and data collection, would help to increase the study impact and determine whether the remodeling that took place in peri-implant tissues will undergo more changes or will stabilize over time from the sixth month after implant placement. Likewise, an increased number of included patients and a larger data collection could be relevant in order to obtain more statistically significant results.

5. Conclusion

This clinical study demonstrates that the use of connective tissue grafts in immediate implants with customized healing abutments is favorable in the prevention of alveolar tissue alterations, more specifically in patients with a thin buccal bone plate morphotype.

The two groups studied presented predictable outcomes that constrain the tissue remodeling leading to linear and volumetric losses of the aesthetic zone.

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7. Annex

Annex I

UNIVERSIDADE CATÓLICA PORTUGUESA

Parecer sobre o projeto nº 139
Comissão de Ética para a Saúde da Universidade Católica Portuguesa
Mandato 2019/2023

Projeto de Investigação
Na reunião do dia 27 de maio de 2021 a CES-UCP esteve reunida e apreciou do ponto de vista ético os elementos submetidos pelo investigador principal, em resposta ao parecer prévio da CES. Após apreciação redige o parecer que agora se apresenta.

Título: Volumetric digital analysis on the effect of a customized healing abutment with or without connective tissue graft in maxillary immediate implant sites – A randomized clinical trial

Investigador Principal: Tiago Ferreira Borges
Orientadores: Não aplicável

ELEMENTOS SOLICITADOS PELO PARECER DA CES-UCP
Aspetos a merecerem atenção:
1. O valor social do estudo em particular no que concerne à clarificação da bondade do estudo, da sua fundamentação (que estudos foram realizados neste domínio e quais os seus resultados a nível internacional e a nível nacional) do novo conhecimento que os resultados deste estudo poderá demonstrar. **Resposta:** Os investigadores fundamentarem adequadamente o valor social e científico e sustentaram-no através de revisão bibliografiaca satisfatória;

2. Interessaria clarificar os aspetos relacionados com as modalidades de recrutamento dos participantes;
Resposta: Mediante o cumprimento dos critérios de elegibilidade e prévia obtenção de consentimento

3. Interessaria que fosse explicitada a dimensão amostral bem como os pressupostos para o seu cálculo.
Resposta: Dimensão amostral : 30 doentes.

4. Seria de clarificar se se prevê a possibilidade de serem envolvidos doentes vulneráveis (ex: alterações cognitivas) bem como como será assegurado o respeito pela dignidade humana nestes doentes?
Resposta: Não serão incluídos doentes vulneráveis.

RESPOSTA DOS INVESTIGADORES

1. A utilização de pilares customizados, bem como de enxertos de tecido conjuntivo apresentam-se como modalidades de tratamento viáveis no que concerne ao tamponamento do alvéolo em implantes imediatos, tendo demonstrado já resultados benéficos em diferentes investigações (Perez et al. 2020; Hosseini et al 2020). Pretende-se com este estudo realizar uma análise volumétrica digital (Borges et al. 2020) dos tecidos peri-implantares em implantes pós-extracionais comparando ambas as técnicas, de forma a aferir possíveis vantagens/desvantagens associadas às mesmas e determinar se alguma se destaca favoravelmente face à outra. Assim, pretende-se também acrescentar evidência científica atualizada na área de Implantologia Oral, de modo a que o profissional de saúde possa exercer a melhor opção de tratamento do ponto de vista do paciente.

2. Neste estudo serão determinados diversos critérios de inclusão e exclusão
   A utilização dos mesmos irá condicionar o recrutamento de pacientes para participar no estudo, sendo que os participantes o farão de forma livre e informada, tendo indicação expressa para serem submetidos aos tratamentos em estudo.

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Critérios de Inclusão	Critérios de Exclusão
• ≥18 anos; • O dente abordado trata-se de um incisivo, um canino ou um pré-molar da arcada maxilar superior; • O dente em foco apresenta dentes adjacentes e oponente natural; • Espaço mesio-distal e inter-oclusal suficiente para a colocação de um implante unitário e respetiva restauração definitiva; • Ausência de deiscências ou fenestrações ósseas da cortical vestibular; • Disponibilidade de comparência aos controlos previamente estipulados.	• Contraindicações médicas e gerais para o procedimento cirúrgico, expressado por ASA ≥ III; • Presença de doença periodontal; • Fumador; • Tratamento recente com radioterapia na zona da cabeça e pescoço; • Pacientes medicados com fármacos que potencialmente possam estar associados a alterações do metabolismo ósseo.

3. Tem-se como objetivo poder aleatorizar cerca de 30 pacientes potencialmente passíveis de serem incluídos nesta investigação, de modo a alocar 15 pacientes em cada um dos grupos. Após o início do estudo será aplicado um teste estatístico de potência da amostra para determinar o numero mínimo de pacientes necessários para obtenção de inferência estatística nos resultados futuros.

4. Não se prevê a possibilidade de serem envolvidos doentes vulneráveis (ex: alterações cognitivas) no presente estudo.

APRECIAÇÃO SOBRE OS ESCLARECIMENTOS SUBMETIDOS PELO INVESTIGADOR PRINCIPAL: Este projeto cumpre preceitos éticos essenciais, quer no que respeita à dignidade humana e quer ao seu valor social e científico, clarificados os aspetos a merecer melhor atenção, por parte dos investigadores, nomeadamente, no que concerne aos aspetos acima mencionados.

Estiveram presentes na reunião nº 29 da CES-UCP

Presidente: Doutora Mara de Sousa Freitas
Doutor Jerónimo Santos Trigo
Doutor Pedro Garcia Marques
Dr. Eugénio Fonseca
Mestre António Faria Vaz
Doutora Ana Mineiro Zaky
Doutora Marta Brites
Mestre Ivone Gaspar

Conclusão

Ouvido o Relator, e o plenário da reunião do dia 27 de maio de 2021, realizada por videoconferência, esta CES delibera, por unanimidade, a emissão de **Parecer Favorável.**

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Esta CES solicita ao Investigador Principal que, aquando da conclusão do estudo, lhe seja enviada uma síntese dos resultados obtidos e respetivas conclusões, via eletrónica, para o correio eletrónico da CES UCP.

A Presidente,

Mara de Sousa Freitas

Mara de Sousa Freitas
27/05/2021

Annex II:

CATÓLICA
FACULDADE DE
MEDICINA DENTÁRIA
VISEU

Termo de Consentimento Informado

DECLARAÇÃO DE CONSENTIMENTO INFORMADO, LIVRE E ESCLARECIDO PARA PARTICIPAÇÃO EM INVESTIGAÇÃO

Por favor, leia com atenção a seguinte informação. Se achar que algo não está claro, não hesite em solicitar mais informações. Se concorda com a proposta que lhe foi feita, queira assinar este documento.

Título do estudo: Análise volumétrica digital das alterações dimensionais dos tecidos peri-implantares após a utilização de um pilar customizado com ou sem enxerto de tecido conjuntivo em colocações de implantes imediatos – um ensaio clínico randomizado.
Volumetric digital analysis on the effect of a customized healing abutment with or without connective tissue graft in maxillary immediate implant sites – A randomized clinical trial.

Enquadramento: Investigação de âmbito académico a efetuar na Clínica Dentária da Universidade Católica Portuguesa tendo como responsável o Prof. Dr. Tiago Borges, Professor Auxiliar da Faculdade de Medicina Dentária da Universidade Católica Portuguesa.

Explicação do estudo e do tratamento: O estudo pretende avaliar a evolução do volume alveolar durante e após o tratamento com implantes dentários colocados em alvéolos frescos pós-extraccionais, recolhendo dados sobre as alterações ósseas marginais peri-implantares, volume de tecido gengival e sua relação com diferentes variáveis e hábitos dos pacientes. Este estudo vai recolher dados clínicos obtidos através do tratamento com implantes dentários que lhe foi proposto e que consiste na extração de um dente, que foi diagnosticado como perdido, e na colocação imediata de um implante dentário no mesmo local e no mesmo momento cirúrgico. O tratamento descrito não consiste em nenhuma técnica experimental nem pretende testar dispositivos ou produtos sem registo ou certificação pelas entidades competentes. O estudo não pretende recolher amostras biológicas dos seus participantes. A recolha de dados será efectuada através de um scanner óptico que não está sujeito à emissão de radiação.

Condições: Este estudo não envolve procedimentos que não se enquadrem na prática clínica normal. A participação neste estudo é totalmente voluntária, não acarretando quaisquer custos, podendo o paciente retirar o seu consentimento em qualquer etapa do estudo, sem necessidade de facultar qualquer explicação aos seus responsáveis e com total ausência de prejuízos caso não queira participar. Ao decidir

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participar pode colocar todas as questões que considerar necessárias para o seu esclarecimento ou facultar informações aos responsáveis do estudo em qualquer etapa do mesmo.

Achados acidentais: Qualquer achado acidental não relacionado com a anatomia do alvéolo dentário, cuja descoberta foi efectuada durante o estudo, será obrigatoriamente e imediatamente comunicada ao paciente participante. O paciente pode expressar a vontade de a mesma informação ser comunicada ao seu médico assistente, informando-o da condição de saúde do participante.

Confidencialidade: Os dados recolhidos para o presente estudo são de uso exclusivo do investigador e tratados de modo a garantir a sua máxima confidencialidade de modo a promover o seu anonimato. A análise dos dados recolhidos será efetuada em ambiente que garanta a privacidade dos mesmos, sendo estes utilizados exclusivamente pelo investigador envolvido no projeto. A identificação do participante será realizada por meio de código que identifica as iniciais e código numérico do mesmo, não sendo identificável por terceiras partes além do investigador responsável. Serão respeitadas todas as disposições legais relacionadas com a nova Lei Geral de Proteção de Dados de 25 de Maio de 2018.

Assinatura(s) dos responsáveis pelo projeto:

O INVESTIGADOR: _____

_____

Declaro ter lido e compreendido este documento, bem como as informações verbais que me foram fornecidas pela(s) pessoa(s) que acima assina(m). Foi-me garantida a possibilidade de, em qualquer altura, poder recusar participar neste estudo sem qualquer tipo de consequências. Desta forma, aceito participar neste estudo e permito a utilização dos dados que de forma voluntária forneço, confiando em que apenas serão utilizados para esta investigação e nas garantias de confidencialidade e anonimato que me são dadas pelo investigador.

Nome: _____

Assinatura: _____ Viseu, ___ /___ /_____

ESTE DOCUMENTO É COMPOSTO DE 2 PÁGINAS E FEITO EM DUPLICADO: UMA VIA PARA O INVESTIGADOR, OUTRA PARA A PESSOA QUE CONSENTE

Membros do Júri das Provas Públicas

Presidente: Prof. Doutora Mariana Seabra

Arguente: Prof. Doutor Tiago Marques

Orientador: Prof. Doutor Tiago Borges

Data das provas públicas: 19 / 07 / 2022

Classificação: 18

Validação e confirmação pelos serviços escolares:

_____

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