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VISEU

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PRELIMINARY RESULTS WITH THE USE OF OSSIFYING COLLAGEN MEMBRANES IN THE HORIZONTAL ALVEOLAR DEFECTS TREATMENT AFTER DENTAL IMPLANT PLACEMENT

Dissertação apresentada à Universidade Católica Portuguesa
para obtenção do grau de Mestre em Medicina Dentária

Por:
João Mário Martins Lourenço Marques

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Orientador: Professor Doutor Tiago Borges

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“Luck is what happens when preparation meets opportunity” -

Seneca

Aos meus Pais

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A toda a minha família que unida como só nós conseguimos ser sempre me acompanharam durante esta jornada

Por fim, aos meus amigos, que tornam os momentos inesquecíveis e são a grande razão de memórias que levo comigo. Aos amigos mais “antigos” que sempre estiveram ao meu lado e aos amigos “de Viseu” que tornaram especiais estes 5 anos.

Resumo

Introdução: A reabilitação com implantes dentários é um tratamento que está associado a uma alta taxa de sucesso na reabilitação de pacientes parcial ou totalmente edêntulos. Doenças sistémicas, periodontais, trauma, tumores e extração dentária podem levar a uma perda de volume ósseo, que limitam o correto posicionamento dos implantes dentários.

Objetivo: O objetivo deste estudo é avaliar os resultados clínicos e radiográficos na colocação de implantes dentários em cristas edêntulas tratadas com uma membrana de colagénio com propriedades ossificantes para o aumento horizontal do volume alveolar perdido.

Materiais e Métodos: Este estudo avaliou as alterações volumétricas a nível vestibular através da sobreposição de impressões digitais, estudando as variáveis *Buccal Volume variation (BVv)* e *Mean Buccal Variation (MBV)*. Em termos de alterações ósseas marginais foram realizadas radiografias periapicais em dois tempos: *baseline* (T0) e 6 meses (T1) após colocação dos implantes em simultâneo com colocação da membrana de colagénio OSSIX Volumax™. Estas alterações foram caracterizadas em duas variáveis *mesial Marginal Bone Changes (mMBC)* e *distal Marginal Bone Changes (dMBC)*.

Resultados: O uso da membrana OSSIX Volumax™ em termos de variações volumétricas apresentou um aumento médio de 32,06% *(BVv)* e de 0,97mm *(MBV)*. Em termos de alterações ósseas marginais os resultados foram uma perda óssea marginal média de 0,75mm entre T0 e T1 para o *(mMBC)* e de 0,80mm para o (dMBC).

Conclusão: O uso da membrana OSSIX Volumax™ está associada a um ganho de volume vestibular nas zonas alveolares reabilitadas, contudo os resultados a nível de alterações ósseas marginais não mostraram uma vantagem concreta na utilização deste tipo de membrana comparativamente aos valores apresentados pela literatura.

Palavras-chave: Implante; Volume ósseo; Defeito ósseo; Perda óssea marginal; Regeneração óssea guiada; Membrana de colagénio.

Abstract

Introduction: Rehabilitation with dental implants is a treatment that has high success rate in the rehabilitation of partially or totally edentulous patients. Systemic diseases, periodontal diseases, trauma, tumors, and tooth extraction can lead to loss of bone volume and these bone defects limit the bone volume required for correct implant positioning.

Objective: The aim of this study is to evaluate the clinical and radiographic results of dental implant placement in edentulous ridges treated with a collagen membrane with ossifying properties for horizontal augmentation of the lost ridge volume.

Materials and Methods: This study evaluated the volumetric changes at the buccal level by superimposing digital files. The variables obtained were Buccal Volume variation (BVv) and Mean Buccal Variation (MBV). In terms of marginal bone changes, periapical radiographs were taken at two times: baseline (T0) and 6 months (T1) after implant insertion simultaneously with the placement of a OSSIX Volumax™ collagen membrane. These changes were characterized in two variables, mesial Marginal Bone Changes (mMBC) and distal Marginal Bone Changes (dMBC). Statistical significance was set at $P \leq 0,05$.

Results: The use of these cross-linked membrane showed an average increase of 32.06% in terms of volumetric changes (BVv) and 0.97mm at the linear measurements of the alveolar surface (MBV). In terms of marginal bone changes the results showed a mean bone reduction of 0.75mm between T0 and T1 for the mesial sites (mMBC) and 0.80mm for the distal sites (dMBC).

Conclusion: The use of OSSIX Volumax™ membrane is associated with a buccal volume gain, however in terms of marginal bone maintenance the results were not statistically significant and no improvement was noticed comparing with the literature outcomes.

Keywords: Implant; Bone volume; Bone defect; Marginal bone loss; Guided bone regeneration; Collagen membrane.

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List of Acronyms

GBR- Guided bone regeneration

e-PTFE- Expanded polytetrafluoroethylene

MBC- Marginal Bone Changes

mMBC- mesial Marginal Bone Changes

dMBC- distal Marginal Bone Changes

MBV- Mean Buccal Variation

BVv- Buccal Volume variation

ROI- Region of interest

1. Introduction

Rehabilitation with dental implants is a well-documented treatment in partial and fully edentulous patients (1,2) allowing for improvement in the quality of life by restoring esthetic needs and dental function. (3) When correctly performed, presents a high survival and success rate (4,5) although not all patients are indicated for implant placement mainly because of bone deficiencies.(1)

Systemic and periodontal diseases, trauma, tumors, and tooth loss can lead to decreased bone volume. (6) After tooth extraction, the alveolar ridge undergoes a remodeling process where alveolar bone is reabsorbed and consequently horizontal bone loss can be observed. (4,7) Horizontal bone loss takes place in the first six months preceding the loss of height (8,9) and limiting the bone volume required for correct implant positioning. (1)

It is of great importance to place the implant in a favorable position for rehabilitation, as this positioning is decisive to achieve favorable aesthetic and functional results. (10) This crucial requirement can only be fulfilled when there is an adequate volume of alveolar bone in the area to be rehabilitated. (11,12)

Initially, dental implants were positioned depending on the available bone in order to obtain adequate anchorage that would increase the predictability of osseointegration allowing a functional and more efficient rehabilitation, often at the expense of the esthetic component. (4,12) Recently, implants are positioned in a way that allows for greater certainty in planning the prosthetic reconstruction as well as in the rehabilitation itself. (4) The major factor that allowed this change was the high success rate associated with guided bone regeneration and augmentation techniques and correspondingly a higher predictability of osseointegration. (3,4)

Before implant therapy, it is necessary to plan the treatment to be executed and to analyze the need for hard and soft tissue augmentation in case of defects. (13) Pre-rehabilitation planning is essential as it allows for the decision of which is the best treatment option for the patient to achieve the desired prosthetic results and to assure that clinical procedures are prosthodontically driven. (4)

First and foremost, general and local contraindications must be assessed. Before proceeding with rehabilitation planning, it is vital to evaluate contraindications, both relative and absolute, in order to reduce and avoid dental implant treatment complications. (12) Afterwards, clinical and radiographic exams

need to be taken in order to assess the patient soft tissues and bone morphology. At this stage it is crucial for bone defects to be diagnosed for later selection of the most appropriate bone regeneration technique to be applied in order to increase the bone volume necessary for ideal tridimensional positioning of the implant. (4,12)

Analyses of the clinical case and an adequate prosthodontically driven diagnostic, considering the risks involved, allows for a categorization of a clinical case into a bone defect classification described by Hammerle and Benic (4) and, more specifically to horizontal bone defects, a four-class system proposed by Chiapasco and Casentini. (12) The categorization of a bone defect into a classification simplifies the choice of technique and treatment to be implemented.

1.1 Classification of bone defects

1.1.1 Classification of bone defects proposed by Hammerle and Benic(4)

Contour deficit: Class 0

The situation that is presented in class 0 is that of an implant that can be placed in the ideal prosthetic position, however, since there is a ridge contour deficit bone augmentation is indicated.

Intra alveolar defect: Class 1

Class 1 is characterized by an intra-alveolar defect between the implant and the intact bone walls due to the resorptive processes that occur after tooth extraction.

The choice of treatment for class 1 depends on the gap between the implant and the bone wall, as well as whether the rehabilitation is in a more posterior or anterior area. If the defect presented is in a posterior site and the gap between the implant surface and the bone wall is less than 1 to 2 millimeters no bone regeneration is needed, however, if the defect is bigger than 1 to 2 millimeters a bone substitute is used in conjunction with a resorbable membrane.

In esthetic areas the treatment of choice is bone regeneration of the residual socket and over augmentation of the buccal bony wall. (4)

Dehiscence-type defect: Class 2

Class 2 encompasses cases of dehiscence defects in which the volume stability of the augmentation site is provided by adjacent bone walls.

The treatment for dehiscence defects class 2, both for posterior and anterior areas is the combination of resorbable membranes with a particulate bone substitute. (4)

Dehiscence-type defect: Class 3

As well as class 2, class 3 is characterized by dehiscence defects, although different from the former the volume stability of the augmentation site is not provided by adjacent bone walls.

One possible treatment for class 3 defects is the use of a titanium reinforced e-PTFE membrane and a particulate bone substitute. (4)

Horizontal defect: Class 4

In class 4 defects, the reduced ridge width does not allow for implant primary stability.

For the treatment of large horizontal defects autogenous bone blocks, bone substitutes and resorbable and non-resorbable membranes can be used. (4,8,12)

Vertical defect: Class 5

Vertical defects are characterized by a reduction in ridge height.

Bone augmentation is necessary, autogenous bone blocks, bone substitutes and resorbable membranes can be used. (4,8)

1.1.2 Classification of horizontal defects according to a prosthetically driven diagnostic protocol and surgical options proposed by Chiapasco and Casentini (12)

The authors intended with this classification to assess horizontal defects and then divide them into classes according to a prosthetically driven protocol, also providing for each class a therapeutic suggestion for its regeneration.

Class 1

In class 1 no bone augmentation is required as there is sufficient bone volume to place the implant in the ideal, prosthodontically driven position allowing for an adequate bone volume of 1.5mm-2mm to cover all implant surfaces. This type of class is uncommon and is found in post-extraction and recently healed sockets treated with ridge preservation techniques. (14)

Although the bone anatomy is adequate, ensuring the ideal positioning of the implant without the need for hard-tissue regeneration a connective tissue graft may be suggested for a better esthetic result.(12,15)

Class 2

Class 2 is characterized by a moderate horizontal defect, the thickness of the buccal wall is less than 1mm and sometimes a fenestration or a dehiscence of the buccal plate can be present. In class 2, implants can be placed in the ideal prosthetic position, however bone augmentation is indicated.

The main treatment options include guided bone regeneration using autogenous bone or alloplastic materials combined with a resorbable or non-resorbable barrier membranes, sagittal osteotomy, or the use of osteotomes to increase bone volume. This bone regeneration can be complemented by soft tissue augmentation when a more esthetic result is expected. (12,15)

Class 3

Class 3 represents the cases with a significant horizontal defect, where primary stability cannot be achieved and the implant is not placed in the ideal position for the rehabilitation due to lack of bone volume.

The treatment for advance horizontal defects includes guided bone regeneration using autogenous bone or alloplastic materials combined with a barrier membrane and autogenous or non-autogenous bone blocks, both options are commonly used combined with soft tissue grafts, a healing period of 4 to 9 months is expected before proceeding with implant placement. (12)

Class 4

Class 4 presents as the most complex situation, involving both horizontal and vertical bone defects. Vertical defects increase the complexity of treatment and consequently the possible complications. (16,17) All potential complications and risks must be discussed with the patient before beginning rehabilitation. (12)

The treatment includes guided bone regeneration using autogenous bone or alloplastic materials combined with a barrier membrane, bone blocks and in more severe cases of maxillary atrophy Le Fort I osteotomy with advancement and lowering of the maxilla and interpositional bone grafts. (12)

After a bone defect is classified, it becomes clear which techniques such as bone grafting and guided bone regeneration are best suited for a successful bone augmentation. (12)

1.2 Guided bone regeneration

Resorption of alveolar bone compromises the structural, functional and esthetic results of implant placement, however guided bone regeneration seems to be predictable and successful in the treatment of horizontal defects. (6)

The key principle of guided bone regeneration is aiming to achieve bone regeneration using barrier membranes, (18) supporting the concept that using a resorbable or non-resorbable membrane that prevents soft tissue invasion of the wound space, thus allowing only osteogenic cells to repopulate the bone defect. (6,18–20)

The membranes used in guided bone regeneration, resorbable or non-resorbable, are an essential factor of the treatment. (6,21) Different materials can compose them, each one having its clinical indications, advantages and

disadvantages and the choice of the material depends on the size and configuration of the bone defect. (6)

The ideal characteristics of the membranes include biocompatibility, cell-occlusion properties, integration by the host tissues, clinical applicability, space-making ability, adequate mechanical and physical properties. (6,18)

1.2.1 Non resorbable membranes

The first, well-documented, generation of barrier membranes used in guided bone regeneration were expanded polytetrafluoroethylene membranes (e-PTFE). (4) These membranes can be reinforced with titanium (20,22) or titanium meshes. (12) E-PTFE membranes need to be immobilized using titanium pins or microscrews for perfect adaptation to the anatomical site to treat. (12)

Guided bone regeneration with e-PTFE membranes is indicated in irregular and severe defects, particularly in cases where a vertical component is present. (12)

Non-resorbable membranes are effective in the treatment of class 3 and 4 defects in partially edentulous patients according to the classification of horizontal defects proposed by Chiapasco and Casentini. (12) When using this type of membranes, it is suggested the use of a mixed graft combining autogenous bone and a bone substitute. (12)

Polytetrafluoroethylene membranes, a synthetic polymer, are considered one of the most inert and stable polymers for medical use. (6) It has a porous structure, resists enzymatic and microbiological degradation, does not induce immunologic reactions, (4,18) maintains its structural integrity and, when compared with resorbable membranes, this material presents superior space-maintaining properties and cell occlusion capacity. (19)

Exposure of e-PTFE membranes to the oral cavity leads to the colonization of the porous surface of the membranes by oral bacteria (23,24) leading to potential infections and the need for early removal of the membrane (11,25) which compromises bone augmentation and osseointegration. (25–27)

Another disadvantage of non-resorbable membranes is the need for a second surgery for membrane removal. This usually takes place six to nine months after membrane placement and re-entry presents a risk for the newly

formed tissue and is associated with patient morbidity. (12,19) The use of e-PTFE membranes is also a technically demanding procedure and often requires experienced surgeons to perform it. (12)

To surpass some of these disadvantages and to simplify surgical protocols, resorbable membranes have been developed. (4)

1.2.2 Resorbable membranes

There are two kinds of resorbable membranes: polymeric and collagen membranes. (21)

Polymeric membranes are synthetic membranes made up of synthetic polyesters, polyglicolides, polylactides or co-polymers, whereas collagen membranes are derived from collagen type I or a combination of collagen type I and III, which can have human origin or be derived from bovine or porcine tendon, skin, or pericardium. (21,28)

Biodegradable membranes are indicated for treatment of small peri-implant defects like dehiscence or fenestration, but they can also be used in class 3 cases by associating particulate autogenous bone with the membrane. (12)

Resorbable membranes present advantages when compared with e-PTFE membranes such as decreased patient morbidity, the possibility of avoiding a second surgery (since there is no need for membrane removal and thus not exposing the newly regenerated bone), simplified protocol, and better cost-effectiveness. (4,18,19,21,29) Also, these membranes present good tissue integration as well as fast vascularization and degradation with reduced foreign body reaction. (30)

Complications with the use of resorbable membranes such as exposure of the membrane are not common and are easily managed. (12) However, these membranes also have some disadvantages, most of them described in the literature such as unfavorable mechanical properties, lack of rigidity and space-making abilities. These membranes, both collagen and synthetic, are usually used in conjunction with support materials, such as bone grafts, thus preventing the collapse of the bone defect space. (21,28,31) Another major drawback is correlated with fast degradation which results in difficulties with maintaining barrier function for a proper length of time. (4)

1.2.2.1 Cross-linked and non-cross-linked collagen membranes

Native non-cross-linked collagen membranes, maintain the natural collagen structure and their properties. (32) The major disadvantages of non-cross-linked collagen membranes are faster degradation and the difficulty in providing enough integrity for the whole process of bone augmentation. (33) On the contrary, cross linking of collagen increases bio-durability and allows for the control of its degradation kinetics and barrier function. (34,35)

Ribose is used to cross-link collagen fibers simulating the glycation process that happens in a natural way. (35,36) Ribose cross-linked membrane show superior results in lateral augmentation when compared with native collagen membranes. (37) However, in Garcia *et al.* review (2017) it was concluded that GBR with cross-linked and non-cross-linked collagen membranes showed no statistical relevance in terms of volumetric changes, whereas in relation to biocompatibility and complications non-cross-linked membranes showed better results. (38)

Ossix Volumax™, a resorbable collagen membrane, is based on sugar cross-linking of collagen using Glymatrix® technology. This new membrane was developed for the purpose of both soft and hard tissue augmentation in periodontal and implant surgeries. The clinical applications of Ossix Volumax™ are guided bone regeneration and guided tissue regeneration, having the potential to augment thin tissue, esthetic deficiencies and residual dehiscence's. (34)

1.3 Bone grafts

A bone graft can be described as the material used in the treatment of bone deficiencies of contour or volume. Bone grafts are used in bone regeneration since they can have osteogenic properties (cells with potential to grow bone), osteoinductive capacity (bone inducing substance), or are osteoconductive (serve as a support for bone regeneration). (39)

Bone grafts can be divided into four categories, autograft, allograft, alloplastic and xenograft. (39)

1.3.1 Autograft

Autograft is bone collected from the same individual which accelerates bone formation. (40)

When bone augmentation is needed autogenous bone graft is considered as the gold standard, since it is the most predictable graft for osseous tissue regeneration. (41–43)

In addition to osteoconduction and osteoinduction, autogenous grafts have osteoblast-like cells with the ability to proliferate and express bone cell markers. (41) Autografts do not cause an immune response, eliminate the risk of disease transmission, as well as allow the penetration of blood vessels and the migration of osteoprogenitor cells. (44)

The main disadvantages with the use of autogenous bone are associated with donor site morbidity and unpredictable resorption. (39,40,45)

1.3.2 Allograft

Allograft is bone from the same species, including free frozen bone, freeze dried bone, deproteinized bone and demineralized freeze-dried bone. (39,40,43) Allografts were developed to overcome the existing limitations of autografts.

Allografts have the advantage of being available in larger quantities and of eliminating the morbidity associated with the harvesting of bone. (39,46)

1.3.3 Xenograft

Xenografts are tissue grafts obtained from a different species. They come from equine, porcine, or bovine sources after being deproteinized and processed. Organic components are removed so that it doesn’t induce an immune response or pathogen transmission. (43,47) This type of graft is biocompatible and have osteoconductive properties. (40)

1.3.4 Alloplastic

Advances in biomaterials and the limitations that are imposed by the use of autografts and allografts have made the use of alloplastic grafts necessary. (39)

Alloplastic materials are fully synthetic and synthesized from non-organic sources. (43)

Alloplastic graft has advantages such as less morbidity when compared to autogenous bone since there is no need for harvesting bone, no restrictions on the amount of graft available, and no risk of disease transmission. (39)

1.4 Objective

The aim of this study is to access the clinical and radiographic outcomes of dental implants placed in edentulous mandibular ridges with non-critical horizontal defects, treated with a high-volume glycose cross-linked collagen membrane for the horizontal augmentation of the lost alveolar volume.

2. Materials and Methods

2.1 Study design

The present study was designed as a retrospective analysis, comprising adult patients treated with dental implants and a glycose cross-linked collagen membrane in edentulous class 0 mandibular alveolar crests. (4) Patient´s recruitment was executed independently of the investigation, accordingly with the inclusion criteria listed below. All patients were treated in a private clinic and all the surgical procedures were executed by a specialist in Oral Surgery (TB). The study protocol was approved in January 2022 by the CES-UCP under the register number 183/2022.

2.2 Inclusion and exclusion criteria

The inclusion criteria included patients (>18 years old) with a mandibular edentulous area, American Society of Anaesthesiologists (ASA) status I, class 0 of the bone defect classification described by Hammerle and Benic (4) and class 1 or class 2, when no fenestration or dehiscence is present, of the classification proposed by Chiapasco and Casentini (12) and who personally signed and agreed with the informed consent declaration and with the treatment plan that was previously delivered.

The patients with systemic bone diseases capable of influencing bone healing, smokers, patients under pregnancy and who declared to be under treatment with drugs that potentially alter the bone metabolism were excluded.

2.3 Surgical procedure

The surgical procedure included: local anesthesia of the edentulous area using articaine with epinephrine 1/80000; linear muco-periosteal incision of the alveolar crest and muco-periosteal flap elevation; insertion of the dental implants (Astra Tech EV, Dentsply Implants, Dentsply Sirona, USA) at the edentulous area in accordance with the manufacturer surgical protocol; placement of a collagen membrane (Ossix Volumax™, Datum Dental Ltd, Bat Sheva, Israel) between the muco-periosteal flap and the buccal bone wall, after the implant insertion;

immediate placement of the final prosthetic abutment (with 2mm height); and the flap was sutured with a 5/0 polyamide suture (Seralon™, Serag-Wiessner, Nalia, Germany). Postoperative instructions were given to the patients, which included oral hygiene procedures, chlorhexidine 0.12% rising and medication (Paracetamol 1000mg, as needed, and amoxicillin 1g twice a day for seven days). The sutures were removed after 8 days.

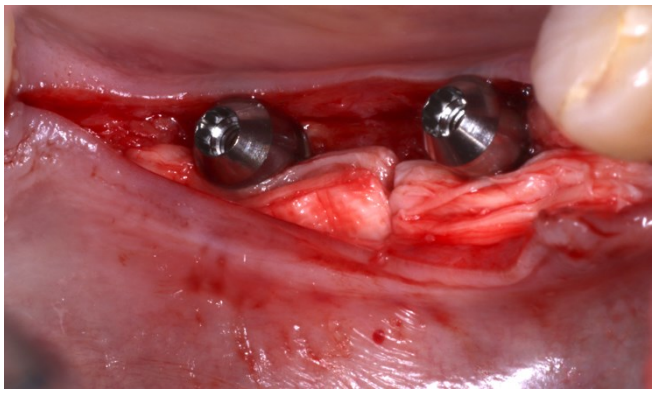

Figure 1- Membrane insertion between the facial area of the muco-periosteal flap and the buccal bone wall (Surgical procedure and image by Professor Tiago Borges)

2.4 Outcome Assessment

2.4.1 Matching digital models

Digital impressions were taken prior to implant placement (T0) and six months after implant insertion (T1), using an intraoral optical scan (Primescan®, Dentsply Sirona, USA). All digital models were exported from the intraoral optical scan in STL format (Figure 2A) and were viewed with Geomagic Control X® (Geomagic, Inc., North Carolina, USA), allowing to superimpose the digital files and to evaluate volumetric changes between different time points at peri-implant tissue areas like Buccal Volume variation (BVv) and Mean Buccal Variation (MBV) (48). The digital assessment protocol was adapted from Borges *et al.* (2020) (48) and Fernandes *et al.* (2021) (49) and consisted in two different measurements methods: one linear analysis of the alveolar surface next to the treated area and a volumetric assessment of the alveolar volumetric changes that occurred at the peri-implant tissues.

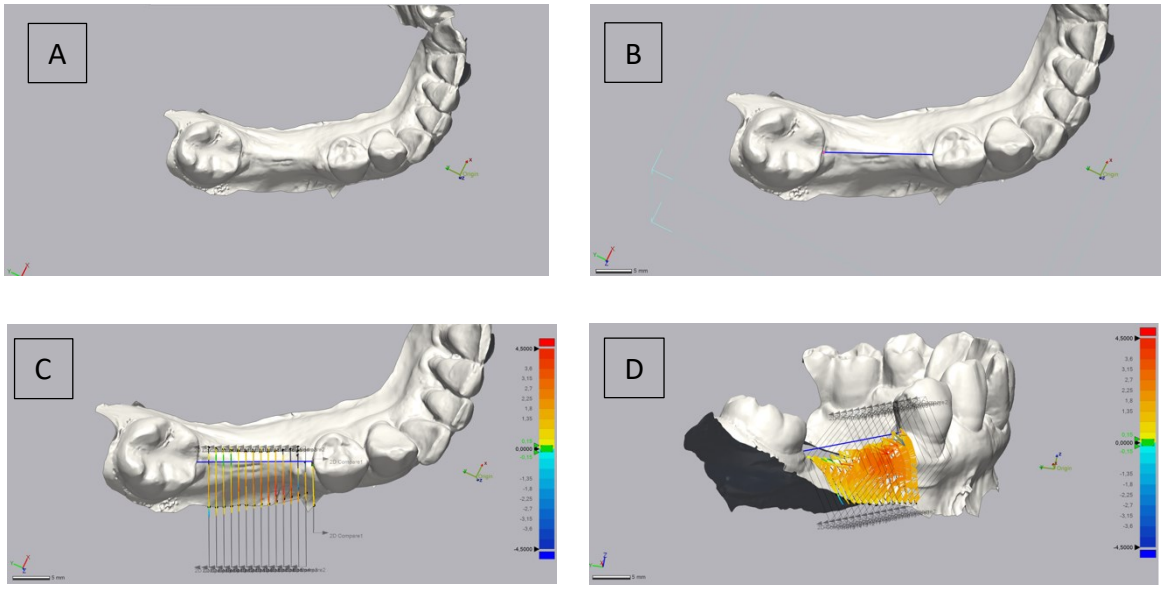

Figure 2- A- STL file use for digital analysis; B- horizontal reference line for linear analysis; C-Region of interest (ROI) creation; D- comparison of the different files at the ROI, using the color map

2.4.1.1 Linear surface measurements

With the "3D Compare" tool, changes in thickness in T1 were compared to T0. Color maps were created by overlapping the models, where the change in color meant the variation in thickness at that area.

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 horizontal line was defined along the alveolar crest that served as a reference (Figure 2B). Subsequently, a rectangular area of interest was adjusted around this line, based on the free gingival margin of the adjacent 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 surface (Figure 2C and 2D).

The division of the area of interest in the models already superimposed, helped to calculate the buccal linear changes (MBV).

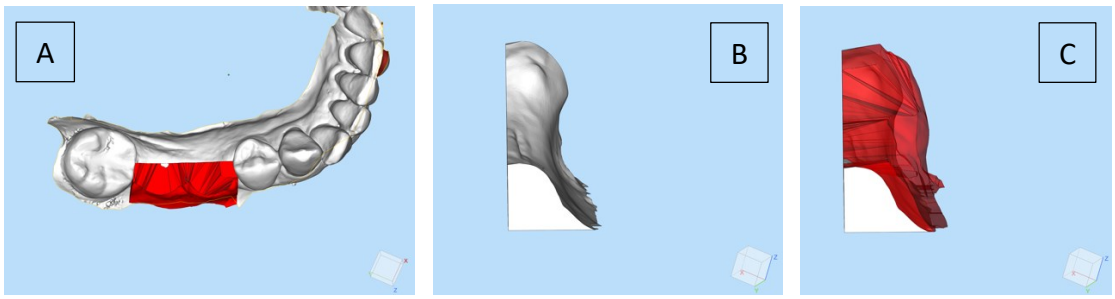

Figure 3- A- 3D volumetric ROI; B- Volumetric ROI at T0; C- Volumetric ROI at T1

2.4.1.2 Volumetric dimensional measurements

To volumetrically quantify the tissue changes, the STL models obtained at T0 and T1 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, the variable Buccal Volume variation (BVv), was computed in mm^3 and expressed in percentage (%) of volume change.

2.4.2 Marginal bone changes

Peri-apical radiographs were taken at the implant surgery (baseline) and six months after implant insertion (T1), using a silicone customized bit block to assure the reproducibility of the radiographic measurements at the different time points. The crestal bone changes at the peri-apical radiographs were assessed by an independent examiner that was not involved in the study, using software for radiographic analysis (SIDEXIS™, Sirona Dental Systems Inc., NY, USA).

Final MBC values were presented as the mean measurements obtained at the mesial (mMBC) and distal (dMBC) aspect of each implant from the implant platform uppermost point of the micro threaded part to the adjacent crestal bone.

The parameter chosen to calibrate the measurement system were the distance between the implant platform and the most apical point of each fixture, along an ideal line running parallel to the long fixture axis. Intra-examiner calibration was achieved by Dahlberg d-value through a double consecutive data collection of a number of implants included in the study. (50,51)

2.5 Statistical analysis

After data collection, 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. Variables related to participant´s characterization such as age, gender, implant site (molar/premolar), MBV, BVv, mMBC and dMBC were evaluated.

The assumption of normality for these variables was computed using the *Shapiro-Wilk* test. Finally, a Pearson´s correlation test was conducted in order to study the influence between variables and their outcomes. All hypothesis tests were considered at the 5% level of significance.

3. Results

3.1 Patients and implants

The data related to the demographic characterization of the sample is described in Table 1. Briefly, the sample consisted of eight patients (7 women and 1 man; n=8) with a mean age of 54.13 ± 8.08 years. Seventeen implants (n=17) (Astra Tech EV, Dentsply Implants, Dentsply Sirona, USA) were enrolled in this study. All implants were placed in the posterior area of the mandible, eleven in molar regions and six in the pre-molars site.

Table 1- Demographic data of the sample of the study

Patient	Gender	Implant site	Age	Implant
#1	F	46; 45	58	3.6x6mm; 3.6x6mm
#2	F	47; 45	56	3.6x6mm; 3.6x8mm
#3	F	47; 46	58	3.6x8mm; 3.6x8mm
#4	F	37; 35	59	3.6x8mm; 3.6x8mm
#5	M	47; 46	64	3.6x6mm; 3.6x8mm
#6	F	46; 45	44	3.6x6mm; 3.6x9mm
#7	F	37; 35; 34	54	3.6x6mm; 3.6x8mm; 3.6x8mm
#8	F	47; 46	40	3.6x6mm; 3.6x8mm
N=8	7F/1M	N=17	54.13 ± 8.08	

3.2. Variables computing and distribution

Table 2 shows the assessed data regarding the different variables defined for the study as well as its normal distribution. Normality test was conducted with the *Shapiro-Wilk* normality test and a normal distribution of the data at all the studied variables was obtained for all the study participants.

Table 2- Variables assessment and normal distribution.

Patient	MBV T0-T1 (mm)	BVv T0-T1 (%)	mMBC- imp ant (mm)	mMBC- imp post (mm)	dMBC- imp ant (mm)	dMBC- imp post (mm)
#1	1,68	77,15%	-2,64	-0,41	-2,30	-0,84
#2	1,11	22,86%	-2,01	-0,45	-1,01	-0,94
#3	1,55	57,25%	-0,42	0,07	0,00	0,00
#4	0,82	16,84%	-0,68	0,00	-0,75	-0,21
#5	0,40	6,34%	-1,11	-0,33	-1,24	0,11
#6	0,47	9,60%	-0,80	-1,04	-0,72	-1,53
#7	1,01	36,71%	-0,03	-0,64	0,00	-0,26
#8	0,74	29,74%	-0,79	-0,65	-1,10	-1,89
Shapiro-Wilk (p)	0,603	0,382	0,308	0,789	0,390	0,386

Shapiro-Wilk normality test ($p \leq 0,05$ for statistical significance); mm: millimeters; %: percentage.

3.3. Digital evaluation of the alveolar changes

Table 3- Characterization of the digital variables during the 6-months follow-up

Variable	Min	Max	Mean	SD	CI (95%)
MBV (mm)	0.40	1.68	0.97	0.47	[0.584; 1.361]
BVv (%)	6.34	77.15	32.06	24.43	[11.639; 52.483]

The characterization of the variables over the follow-up period of 6 months is shown at table 3. Mean Buccal Variation (MBV) is presented in mm and represents the mean linear change of the alveolar surface at the treatment area from T0 to T1. A linear average gain of 0.97 ± 0.47mm was observed during the first 6 months of treatment. Buccal Volume variation (BVv) presents a notorious increase during the 6 months observation period. At T1 the mean increase of volume was 32.06 ± 24.43% (min: 6.34%; max:77.15%).

3.4 Marginal bone changes

Marginal bone changes were computed by the assessment of the mesial and distal bone variations that occurred in the most anterior implants and the posterior implants. This assessment was completed through the comparative analysis of two peri-apical radiographs taken at T0 and T1 (Figure 4).

Table 4- Marginal bone changes

Variable (mm)	Implants (N)	Min	Max	Mean	SD	CI (95%)
mMBC Implant 1 (T0-T1)	9	-2.64	-0.03	-1.06	0.86	[-1.778; -0.342]
mMBC Implant 2 (T0-T1)	8	-1.04	0.07	-0.43	0.36	[-0.733; -0.130]
dMBC Implant 1 (T0-T1)	9	-2.30	0.00	-0.89	0.74	[-1.506; - 0.274]
dMBC Implant 2 (T0-T1)	8	-1.89	0.11	-0.70	0.73	[-1.308; -0.082]

mMBC: mesial marginal bone changes; dMBC: distal marginal bone changes; N: number of implants; Implant 1: anterior implants; Implant 2: posterior implants; SD: standard deviation; CI: confidence interval.

The mean mesial MBC at the anterior implants, after 6 months of follow-up, was -1.06 ± 0.86mm and -0.43 ± 0.36mm at the posterior implants. At the distal sites, the assessed mean MBC was -0.89 ± 0.74mm and -0.70 ± 0.73mm at the anterior and posterior implants, respectively.

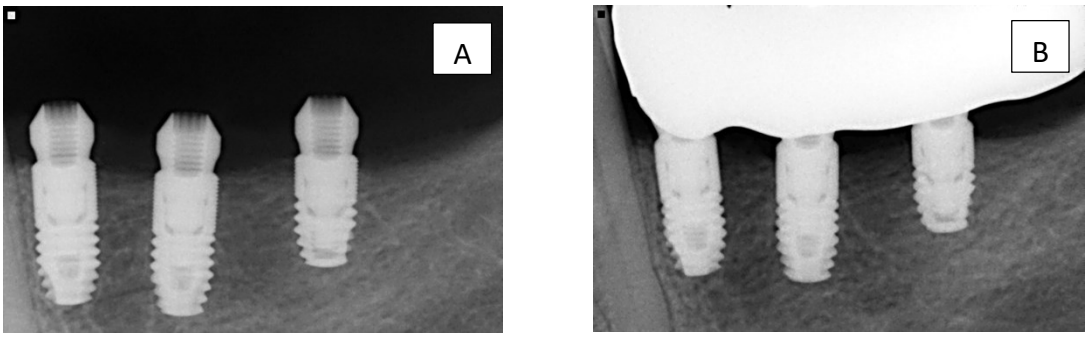

Figure 4- Peri-apical radiograph at T0 (A) and T1 (B)

3.5 Variables correlation

Table 5- Pearson correlation

	BVv (%)	mMBC ant	mMBC post	dMBC ant	dMBC post
BVv (%)	1	-0.358	0.289	-0.257	0.069
mMBC ant		1	0.015	0.878**	0.218
mMBC post			1	0.108	0.713*
dMBC ant				1	0.300
dMBC post					1

The following table shows Pearson's correlation coefficients. It can be seen that BVv does not show significant correlation with any variable.

The variable mMBC for the anterior implant is strongly correlated with dMBC at the same implant (r=0.878) and mMBC of the posterior implant is moderately correlated with dMBC of the same implant (r=0.713).

4. Discussion

The aim of this study was to access the clinical and radiographic outcomes in edentulous ridges treated with dental implants and high-volume cross-linked collagen membranes for the horizontal augmentation of the lost ridge volume.

Literature shows that implants present high success and survival rates. Buser *et al.* (2002) in a 5-year prospective study of 66 implants described an implant survival rate of 100% and success of 98.3%. (52) Another investigation that assessed survival and success rates after a 10-year follow-up of 511 titanium implants showed rates of 98.8% and 97%, respectively. (53)

Partially edentulous ridge sites frequently present alveolar tissue volumetric reduction. The time lapse between teeth extraction and implant-supported rehabilitation and the surgical trauma during teeth extraction are two factors that can influence soft and hard tissue shrinkage over time. (9)

Guided bone regeneration has been documented as being predictable and successful to augment bone in sites where insufficient bone volume is present. (29) However, some complications should be taken into account in accordance with the GBR procedure that was chosen to regenerate bone. Some investigations found a higher incidence of dehiscence in resorbable membranes (8,54,55) although Schneider *et al.* (2014) concluded that while a non-resorbable e-PTFE membrane had to be removed in case of exposure, resorbable membranes showed a tendency for healing. (55) Another study also found that e-PTFE had a higher incidence of premature exposure, but the statistical difference was not significant. (11)

Despite the previously referred complications, polytetrafluoroethylene membranes have clinical evidence of successful treatment of vertical and horizontal bone defects. (52,54,55) Schneider *et al.* (2014) described in his study a mean defect resolution of 96% using non-resorbable membranes. (55) Several studies also show the success of resorbable membranes in guided bone regeneration. (56,57) A randomized clinical trial comparing guided bone regeneration using a resorbable membranes vs a titanium-reinforced non-resorbable membrane demonstrated that both membranes were successful in bone regeneration regarding vertical defect compensation and horizontal thickness increase (54). Other studies also stated no differences in bone volume augmentation using resorbable vs non-resorbable membranes. (11,58,59)

Collagen scaffolds are mostly used in guided bone regeneration and guided tissue regeneration. (60) The cross-linked collagen membrane used in this study (Ossix Volumax™, Datum Dental Ltd, Bat Sheva, Israel) uses ribose, a natural and non-toxic sugar to cross-link collagen fibers. (36)

In a study that compared the resistance to degradation in the oral cavity of three types of membranes (a ribose cross-linked membrane, a glutaraldehyde and a non-cross-linked membrane) the results showed that all membranes lost some degree of integrity, however ribose cross-linked collagen membranes maintained a higher degree of integrity when compared with the other two experiment membranes. (61) Tal *et al.* (2008) also concluded that cross-linked collagen membranes were more resistant to degradation when compared with non-cross-linked barriers. (62)

Friedmann *et al.* (2011) tested the effectivity of ribose cross-linked collagen membranes and non-cross-linked membranes through a randomized clinical trial. The results showed that both membranes improved the bone volume at the regenerated sites and are predictable in guided bone regeneration of dehiscence and fenestration defects. However, the authors concluded that the use of the ribose cross-linked membrane presented superior results in lateral augmentation, mainly in soft tissue healing. (37)

These results are in line with the ones assessed by our investigation since we could notice a proper healing in all the studied patients, with no record of post-surgical infection, membrane exposure and wound dehiscence.

To assess the outcomes related to the use of this membrane for mandibular class 0 alveolar defects treatment, (4) the following variables were computed: Mean Buccal Variation (MBV), Buccal Volume Variation (BVv) and Marginal Bone Changes (MBC), before implant insertion and six months after implant placement.

In terms of Mean Buccal Variation, an improvement of the linear thickness of the alveolar tissues could be observed between T0 and T1 ranging from 0.40mm to 1.68mm (mean increase of 0.97 $\pm$ 0.47mm). In terms of Buccal Volume variation, the mean increase was 32.06 $\pm$ 24.43% between T0 and T1 (ranging from 6.34% to 77.15%). These findings show an improvement in terms

of percentage of volume variation prior and 6 months after implant insertion in conjunction with OSSIX Volumax™.

The linear and volumetric variations variables previously referred were assessed throughout a fully digital protocol using a computer software to superimpose STL files as described by Borges *et al.* (2020) (48). This method allowed to objectively observe dimensional changes in the alveolar ridge avoiding an observer-dependent analysis like periodontal probe measurements or the *pink esthetic score*. (48)

Regarding linear and volumetric changes of the peri-implant tissues at the different observational periods, before implant placement associated with OSSIX Volumax™ membrane and after the six month follow-up, there was clearly an improvement in terms of alveolar volume. These results are in agreement with those found in the literature that demonstrated volume improvement after guided bone regeneration. A study (63) that evaluated peri-implant changes after implant placement and bone augmentation after six months, observed an increase in volume of the buccal aspect of the ridge of 0.72 ± of 0.47mm. The same investigation also assessed the effect after soft tissue augmentation finding an increase of 0.55 ± 0.53mm. Authors concluded that GBR had a bigger contribution to volume increase compared to soft tissue augmentation. In the present investigation a mean buccal variation of 0.97mm was observed, results similar to the study conducted by Schneider *et al.* (2011). (63)

Another study by Smidt *et al.* (2019) using the same collagen membrane as this one showed that the use of ribose cross-linked membrane was successful in restoring the deficient buccal volume, (64) concluding that, as in our investigation the use of OSSIX Volumax™ when placing dental implants on horizontal reduced alveolar crests, has a positive impact on the buccal volume restoration.

Marginal bone changes and distal marginal bone changes, as described in the materials and methods of this study, are presented as the mean measurements obtained at the mesial (mMBC) and distal (dMBC) aspect of each implant (anterior and posterior). Measurements were taken from the implant platform uppermost point of the micro threaded part to the adjacent crestal bone.

Several studies have used the marginal bone changes that occur around the dental implant as an outcome related to the prediction of success of the implant treatment. Due to this, the method that assesses the bone variations around the implant platform have been published widely and proven to be an indicator for long term implant survival. (50,51)

On average, marginal changes in the mesial aspect were bone loss of -1.06 ± 0.86mm and -0.43 ± 0.36mm at the anterior and posterior implant, respectively. At distal sites, anterior implants had a marginal bone loss of -0.89 ± 0.74mm and posterior implants experienced a reduction of marginal bone of -0.70 ± 0.73mm. Although we cautiously need to look at the early bone loss as the probable result of the bone remodeling that might follow implant insertion, (65) we also can accept that the use of this regenerative solution did not improve the upholding of the bone reduction at the studied implants.

These results related to marginal bone variations can be explained by a major limitation of this study, which is the short follow-up period of six months. As described in the study by Borges *et al.* (2018), after placement of dental implants initial bone remodelling occurs and stabilizes at around four months after implant placement. (50)

We can highlight some limitations related to our investigation. These limitations are associated with the low number of treated patients and as stated above, the reduced follow-up period of six months, which may not be enough to access the ossifying potential of this type of membrane nor the effect that the membrane may have in the marginal bone loss reduction.

Another drawback was the fact that when evaluating the marginal bone changes a two-dimensional peri-apical radiograph was taken, which only allows assessment of marginal bone changes in the mesial and distal aspects of the implant. We must state that an improved study sample with a higher number of patients and a longer follow-up period would be necessary for consistent clinical results and outcome measurements.

5. Conclusion

We can conclude that the use of this type of membrane is related to a stable and predictable alveolar volume increase in mandibular areas treated simultaneously with dental implants.

Six months after implant placement the membrane did not show improved results in terms of marginal bone changes.

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Appendix

Appendix I
Consentimento informado:

CATOLICA
INSTITUTO DE CIÊNCIAS DA SAÚDE
LISBOA·PORTO·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: ***Resultados preliminares do uso de membranas de colagénio ossificantes para o tratamento de defeitos ósseos alveolares horizontais na colocação de implantes dentários.***

Preliminary results with the use of ossifying collagen membranes in the horizontal alveolar deffects treatment after dental implant placement.

Enquadramento: Investigação de âmbito académico a efetuar na disciplina de Projeto I e II da Universidade Católica Portuguesa tendo como responsável o Prof. Dr. Tiago Borges, Professor Auxiliar do Instituto de Ciências da Saúde da Universidade Católica Portuguesa.

Explicação do estudo e do tratamento: O estudo pretende recolher dados demográficos e clínicos obtidos após o tratamento a que já foi submetido. Os dados demográficos recolhidos serão a idade, o género e o local anatómico do tratamento efetuado. Os dados clínicos recolhidos serão as imagens volumétricas obtidas através de scanner ótico. O mesmo pretende avaliar a evolução do volume alveolar após o tratamento com implantes dentários colocados em áreas edêntulas cicatrizadas, 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 usar dados clínicos obtidos através do tratamento com implantes dentários que lhe foi efectuado. O tratamento descrito não pretendeu testar dispositivos ou produtos sem registo ou certificação pelas entidades competentes. O estudo não pretendeu 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 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 alveolar, 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. Os dados serão mantidos em anonimato, em documento criado para o efeito e destruídos após a conclusão do estudo, prevista para Julho de 2021.

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

Contacto do Encarregado de Proteção de Dados (DPO - Data Protection Officer) da UCP:

Dra. Frederica Campos de Carvalho
Contacto telefónico: +351 217214179
E-mail: compliance.rgpd@ucp.pt

Appendix II:

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Parecer sobre o projeto nº 183
Comissão de Ética para a Saúde da Universidade Católica Portuguesa
Mandato 2019/2023

Projeto de Investigação
Na reunião do dia 21 de janeiro de 2022 a CES-UCP esteve reunida e apreciou do ponto de vista ético os elementos submetidos pelo investigador. Sobre a apreciação redige o parecer que agora se apresenta.

Título: Resultados Preliminares com o uso de membranas de Colagénio Ossificante no tratamento de defeitos alveolares horizontais após colocação de implantes dentários
Projeto inserido no Mestrado Integrado em Medicina Dentária
Instituições: Faculdade de Medicina Dentária da UCP e CMEB, Advanced Oral Care Clinic

Investigador responsável: Lic. João Mário Marques
Orientador: Prof Doutor Tiago Gonçalves Ferreira Borges /FMD UCP

Resumo
O estudo pretende recolher dados demográficos e clínicos obtidos após o tratamento a que já foi submetido. Os dados demográficos recolhidos serão a idade, o género e o local anatómico do tratamento efetuado. Os dados clínicos recolhidos serão as imagens volumétricas obtidas através de scanner ótico. O mesmo pretende avaliar a evolução do volume alveolar após o tratamento com implantes dentários colocados em áreas edêntulas cicatrizadas, 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 usar dados clínicos obtidos através do tratamento com implantes dentários que lhe foi efetuado. O tratamento descrito não pretendeu testar dispositivos ou produtos sem registo ou certificação pelas entidades competentes. O estudo não pretendeu recolher amostras biológicas dos seus participantes. A recolha de dados efetuada através de um scanner óptico que não está sujeito à emissão de radiação.

Objetivos
Determinar o efeito da utilização de membranas de colagénio com propriedades ossificantes na regeneração de defeito alveolares horizontais, no tratamento com implantes dentários.

Metodologia
Estudo retrospetivo observacional.
A recolha de dados clínicos e tratamento dos pacientes teve lugar no CMEB, Advanced Oral Care Clinic e o tratamento dos dados será realizado na Faculdade de Medicina Dentária da Universidade Católica Portuguesa.

Instrumentos de recolha de dados
Um exame radiográfico inicial, consistindo numa radiografia periapical, foi realizado exclusivamente com um propósito de diagnóstico da área de tratamento. Uma impressão digital com um Scanner intra-oral foi realizada previamente ao início do tratamento (T0), 1 mês (T1) e 6 meses (T2) depois do início do tratamento, permitindo sobrepor os ficheiros digitais obtidos de forma a avaliar as alterações ocorridas na anatomia alveolar após a aplicação da técnica em estudo. As variáveis estudadas foram a variação do volume vestibular (BVv), a variação do volume total (TVv e as alterações lineares vestibulares (MBC). Os dados digitais obtidos serão posteriormente introduzidos num software (Geomagic ControlX) que permitirá comparar as alterações ocorridas ao longo do tempo (Borges T. et al, 2020).

Procedimentos
O procedimento cirúrgico consistiu em: Anestesia local da área a tratar mediante a administração de articaína; incisão linar muco-perióstea na crista alveolar e descolamento do retalho muco-periósteo; colocação dos implantes dentários na crista alveolar edêntula de acordo com o protocolo cirúrgico estabelecido pelo fabricante; colocação de uma membrana de colagénio (Ossix Volumax™, Datum Dental Ltd, Bat Sheva, Israel) entre o retalho muco-periósteo e a cortical óssea vestibular, depois da colocação dos implantes; colocação imediata dos pilares protéticos definitivos (com 2 mm de altura); sutura do retalho com pontos simples através da utilização de uma sutura de nylon 5/0.

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População e amostra

Pacientes adultos (>18 anos) tratados com implantes dentários de acordo com o plano de tratamento descrito posteriormente. Os pacientes selecionados serão escolhidos de acordo com tratamento efetuado atendendo aos critérios de inclusão listados na seção Material e Métodos, presente no protocolo de estudo.

Potenciais incómodos

Não se identificam potenciais riscos relacionados com a recolha de dados dos pacientes uma vez que a captação de imagens com impressão digital com um Scanner intra-oral não emite radiações ionizantes, sendo um meio de diagnóstico indolor e não invasivo. Não foram recolhidas amostras biológicas. O procedimento cirúrgico ao qual os pacientes foram submetidos pode estar relacionado com o aparecimento de sinais inflamatórios como o edema ou desconforto no local da ferida cirúrgica. Aos pacientes foi administrada a terapêutica medicamentosa usual neste tipo de situações clínicas, que incluiu a toma de um anti-inflamatório e de um analgésico para controlo da sintomatologia inflamatória. Os pacientes não foram submetidos ao tratamento descrito para efeitos do estudo, mas como procedimento clínico normal. Não foram testados novos dispositivos, materiais ou fármacos nos pacientes tratados. Os dispositivos e materiais usados no tratamento dos pacientes encontram-se devidamente certificados pelas entidades europeias e portuguesas de regulamentam a utilização e comercialização de dispositivos médicos. Os participantes do estudo foram tratados com os mais altos padrões de tratamento e boa prática clínica em relação ao tratamento com implantes dentários em zonas edêntulas, consistindo na reabilitação da área com coroas implanto-suportadas e tratamento da reabsorção óssea vestibular.

Confidencialidade dos Dados e RGPD

Uma vez que o estudo vai ser realizado através da recolha de dados de pacientes tratados pelo investigador principal, um Médico Dentista registado e com licença profissional pela Ordem dos Médicos Dentistas, os aspetos éticos e legais relacionados com a prática clínica, dos quais se destacam a confidencialidade dos dados clínicos e pessoais dos pacientes, estão assegurados pelo dever deontológico do profissional em causa (Tiago Borges, cédula profissional OMD 5063). Estes dados não serão transmitidos a terceiras partes das quais se incluem entidades ou pessoas externas ao estudo. Os pacientes incluídos na amostra em estudo serão identificados através de um código numérico, único dado de identificação fornecido para o tratamento de dados. Todos os dados estão de acordo com a Lei Geral de Proteção de Dados de 25 de Maio de 2018.Todos os dados estão de acordo com a Lei Geral de Proteção de Dados de 25 de Maio de 2018. Aos participantes no estudo será fornecido o contacto do responsável do Gabinete de Proteção de Dados da Universidade Católica Portuguesa (GPD) para qualquer explicação ou dúvida adicional que os intervenientes no estudo creiam necessária. Esse contacto é parte integrante do documento de Consentimento Informado fornecido a cada um dos participantes.

Em suma, o Protocolo de investigação preenche os requisitos pedidos pela CES. No estudo não estão incluídos menores, nem outras populações vulneráveis e não existem práticas de natureza invasiva. A confidencialidade dos dados está enunciada, bem como o compromisso de proteção dos dados por parte do investigador, tendo sido enviadas as respetivas declarações de conflito de interesses, confidencialidade e proteção de dados. Foi enviado o formulário devidamente preenchido, foram enviados os CVs do investigador e do respetivo Orientador, bem como os documentos referentes à aprovação do projeto pela Clínica CMEB e pelo Conselho Científico da Faculdade de Medicina Dentária da UCP.

Estiveram presentes na reunião nº 36 da CES-UCP

Presidente: Doutora Mara de Sousa Freitas
Vice-Presidente: Doutora Teresa Marques
Doutor Jerónimo Santos Trigo
Doutora Marta Brites
Doutora Ana Mineiro Zaky
Mestre Ivone Gaspar

Conclusão

Ouvido o Relator, e o plenário da reunião do dia 21 de janeiro de 2022, 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
21/01/2022