CATÓLICA
FACULDADE DE MEDICINA DENTÁRIA
VISEU

THE USE OF CUSTOMIZED HEALING ABUTMENTS IN DENTAL IMPLANT PLACEMENT: A SYSTEMATIC REVIEW OF THE LITERATURE AND META-ANALYSIS.

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

Por:
Sham Aldagistani

Viseu, 2022

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Orientador: Prof Doutor Tiago Borges

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“Whether you think you can, or you think you can’t – you’re right” Henry Ford

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My sister, my binomial, and my partner in hard and good times. Thank you for always being there for me.

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Abstract:

Introduction: Advancements in oral implantology is a steady pace process and investigations constantly take place in order to achieve satisfying results in terms of function, durability and esthetic. The use of customized healing abutment (CHA) in clinical practice can follow implant placement in both anterior and posterior areas. CHA guides hard and soft tissue healing around implants, and it is considered a new method to optimize esthetic and condition soft tissue at implant site creating the desired emergence profile and favorable gingival tissue architecture. The aim of this study was to evaluate the peri-implant tissues response and treatment outcomes, after using custom healing abutments (CHA) as socket sealing option in comparison with standard healing abutments (SHA) in dental implant placement.

Materials and methods: An electronic search was performed in three databases: *PubMed/ Medline, Web of Science and Cochrane database*. The following keywords were used: "implant placement", "dental implantation", "dental implant", "customized healing abutment", "individualized healing abutment", and "standard healing abutment". The Boolean operators AND and OR were used. Articles were evaluated for eligibility according to the inclusion/exclusion criteria. Thereby, data was extracted from articles which fulfilled the inclusion criteria into predefined tables. Risk of bias assessment of included articles was evaluated using *The Cochrane Risk of Bias* tool 2 (RoB2). Statistical heterogeneity was measured by the *Cochran Q* test and *Higgins* I^2 statistic test. A meta-analysis using the random effect model was performed and a P value of 0.05 was set for significance.

Results: The present analysis included 4 randomized clinical trials., A 100% success rate was reported for all the implants with a total number of 114 patients (49 men and 65 women). The following variables were considered for the analysis: Pink Esthetic Score (PES), marginal bone loss, papilla height and midfacial height. PES evaluation was favorable for the test group, although the marginal bone changes were less intense with the use of standard abutments.

Conclusion: The use of customized healing abutments in oral implantology is a predictable treatment modality in terms of soft tissue stability and esthetic outcomes of the peri-implant mucosa. The immediate placement of customized healing abutments after implant insertion does not prevent the early marginal bone changes that eventually occur, when compared with the use of standard healing abutments.

Key words: implant placement, dental implant, customized healing abutment and standard healing abutment.

Resumo:

Introdução: Os avanços na implantologia oral são um processo de ritmo constante e as investigações ocorrem de forma a alcançar resultados satisfatórios em termos de função, durabilidade e estética. O uso de pilar de cicatrização customizado é uma prática recente, após a colocação do implante dentário tanto em sectores anteriores como na posteriores. O CHA orienta a cicatrização dos tecidos moles e duros ao redor dos implantes e é considerado um novo método para otimizar a estética e condicionar os tecidos moles no local do implante, criando o perfil de emergência desejado e uma arquitetura gengival favorável. O objetivo deste trabalho foi avaliar a resposta dos tecidos peri-implantares e os resultados do tratamento associados ao uso de pilares de cicatrização customizados (CHA) após a colocação de implantes dentários.

Materiais e métodos: Foi realizada uma pesquisa eletrônica em três bases de dados: *PubMed/Medline, Web of Science e Cochrane*, utilizando as seguintes palavras-chave: "implant placement", "dental implantation", "dental implant", "customized healing abutment", "individualized healing abutment" e "standard healing abutment". Foram utilizados os operadores booleanos AND e OR. Os artigos selecionados foram avaliados quanto à elegibilidade de acordo com os critérios de inclusão/exclusão previamente estabelecidos. O risco de vieses relacionados com os artigos escolhidos foi calculado através da ferramenta *The Cochrane Risk of Bias tool 2* (RoB2), e a heterogeneidade das publicações determinou-se através dos testes *Cochran Q* e *Higgins* I^2. Uma meta-análise utilizando o modelo de efeitos aleatórios e um valor de P de 0,05 foi executada para determinar se as diferenças entre as opções de tratamento eram estatisticamente significativas.

Resultados: A presente análise incluiu 4 estudos clínicos randomizados, dos quais algumas variáveis foram avaliadas e meta-analisadas. Uma taxa de sucesso de 100% foi relatada para todos os implantes com um número total de 114 pacientes (49 homens e 65 mulheres). As seguintes variáveis foram consideradas para análise: *Pink Esthetic Score* (PES), perda óssea marginal, altura da papila e altura médio-facial. Verificou-se que utilização de CHA está associada a melhores resultados estéticos relacionados com a estabilidade dos tecidos moles per-implantares. Verificou-se também que as alterações ósseas marginais são menos espectáveis na utilização de pilares standard em comparação com CHA.

Conclusão:

A utilização de pilares de cicatrização customizados é uma modalidade de tratamento previsível do ponto de vista de estabilidade dos tecidos moles periimplantares, mas não consegui estabilizar a perda óssea marginal, quando comparados com os pilares de cicatrização standard.

Palavras-chave: colocação de implantes, implante dentário, cicatrizador customizado e cicatrizador standard.

Index:

Tables and figures index:

Figures Index:

Tables index

Abbreviations:

IIP: Immediate Implant Placement

ITI: International Team for Implantology

CHA: Customized Healing Abutment

ARP: Alveolar Ridge Preservation

DBBM: Deproteinized Bovine Bone Mineral

SHA: Standard Healing Abutment

CAD-CAM: Computer- aided design and computer-aided manufacturing

DFT: Digitally Flip Technique

PMMA: Polymethyl Methacrylate

RCT: Randomized Controlled Trial

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-analysis

PICO: Population, Intervention, Comparison, Outcome

PES: Pink Esthetics Scores

MBL: Marginal Bone Loss

(RoB 2): Cochrane risk-of-bias 2 tool

CIs: Confidence Intervals

M1:4 to 6 months follow-up,

M2: 1 year period

PI: Papilla Index

NR: Not reported

FMBS: Full Mouth Bleeding Score

FMPS: Full Mouth Plaque Score

FIPS: the Functional Implant Prosthodontics Score

NRS: Numerical Rating Scale

BVv: Buccal Volume variation

SST: Socket Shield Technique

CTG: Connective Tissue Graft

pADM: porcine Acellular Dermal Matrix

I. INTRODUCTION

I. Introduction:

I.1 Biological aspects of implant placement

I.1.1 Dental Implants and timing of placement:

Dental implants have been used for more than 3 decades to rehabilitate patients with loss of one or more teeth. They are composed of inert alloplastic materials and titanium is the most common used one in implant fabrication.(1) Therefore implant-supported prosthesis is a very reliable option to substitute non-restorable or extensively damaged teeth. Furthermore, considering the high success rate of dental implants and their ability in replacing missing teeth without the loss of adjacent tooth structure, which often happens when a prosthodontic solution is planned, and their ability to maintain the existing alveolar process anatomy, we may state that implants are favored by clinicians over teeth-supported or removable methods of rehabilitation. (2-5).

Many surgical and prosthodontic protocols can greatly affect the long-term clinical outcome of implant-supported prosthesis. (6) From the surgical point of view, implant placement protocols have been classified by the healing period between tooth extraction and implant insertion. (6, 7) Traditionally, it is waited a period of 6 to 12 months after tooth extraction to place an implant. This waiting period has reduced gradually in recent years, up until implantation is undertaken after a couple of weeks or even immediately after tooth extraction, within the same surgical procedure. (7) *Hammerle et al.,* suggested a 4 type-classification system (I- IV) that defines Implant placement options based on the alveolar healing period time which include the following: (8)

a) Immediate implant placement on the day of tooth extraction (type 1),
b) early implant placement after 4–8 weeks of soft tissue healing (Type 2),
c) early implant placement after 12–16 weeks of partial bone healing (Type 3),
d) late implant placement after complete bone healing of at least 6 months (Type 4).

Type 1 implant or immediate implant placement (IIP) was first practiced by Professor Wilfried Schulte in 1978 from the University of Tubingen in Germany. He introduced the denomination of Tubingen Immediate Implant, which was made of aluminum oxide, a material that was eventually substituted with titanium due to recurrent implant fracture. IIP refers to implantation in fresh extraction sockets following tooth removal within the same

surgical procedure. (7) There is an increased interest for this approach considering the following advantages: shorter treatment protocol, a reduced number of surgeries up until the definitive restoration, decreased vertical and horizontal bone resorption and ideal esthetics of surrounding gingival tissues. (9, 10) It has been proposed that IIP- to some extent- might prevent alveolar bone resorption. (11, 12) Conversely, numerous clinical studies indicate that IIP does not prevent volumetric bone loss mainly at the buccal bony aspect and thus originating dehiscences and soft tissue recession, negatively influencing the esthetic outcome. (7, 13) The local anatomical individual features of the patient play also, an important role in terms of IIP treatment outcomes. The extent of dimensional changes can be influenced by the thickness of the buccal bony wall following tooth extraction. (14-16) Clinical studies indicates that the thickness of buccal bone crest between other factors, significantly influenced the extent of hard tissue alteration, however, the location of implant placement whether anterior or posterior and the horizontal buccal gap also were identified as possible factors to influence hard tissue changes. (17, 18) Also, less dimensional changes occur when a thicker buccal wall is present where the implant is placed, providing more predictable outcomes. (6) Dimensional ridge alterations can be notably visible when carrying out an early implant placement after 4-8 weeks of soft tissue healing. (19-26)

According to *Buser D et al.,* IIP is a complex procedure that only should be performed by an experienced implantologist, and many local factors should be considered before planning an immediate implant to attain a favorable prognosis. This includes: 1) a fully intact buccal bone wall at the extraction site with a thick wall phenotype (> 1 mm), 2) a thick gingival biotype, 3) Absence of acute infection at the extraction site, and 4) a sufficient volume of bone apical and palatal of the extraction site to allow correct 3D implant placement with sufficient primary stability. (27) When an immediate implant is planned, atraumatic surgical tooth extraction should be performed to minimize mechanical trauma onto the bone walls, caused by surgical instruments used in the routine procedures.(28) This minimally traumatic tooth removal, particularly in the anterior superior teeth, supports alveolar socket anatomy and both buccal and interproximal gingival contour. (28) Afterwards, osteotomy is carried out to place the implant in the correct position. (9) According to the *International Team for Implantology* (ITI) recommendations, when ideal local factors are not present, early implant placement after 4-8 weeks of soft tissue healing (type 2) is advisable. If implant primary stability is questionable after this period, then post-extraction healing period should be expanded to allow partial bone healing in the extraction socket (type 3). Thus, the clinician

has four options to choose from when an implant should be inserted, however, this clinical decision should be made according to the clinical and radiographic preoperative analysis to evaluate the patient risk profile. (27) According to *Grizas et al.,* (29) it is preferred that an implant is placed as early as possible after tooth extraction in order to prevent alveolar bone resorption and soft tissue collapse.

In terms of implant positioning, some studies (Rojas-Vizcaya 2008, 2013) suggest the principle of 3 mm apical and 2 mm buccal positioning of the fixture (principle 3A-2B). The final objective is to compensate marginal bone resorption that may occur during the alveolar healing period. (30, 31) *Ferrus et al.,* stated that anatomical location of implant placement (anterior or posterior) may affect ridge alterations. Accordingly, anterior sites are considered more susceptible to alveolar ridge changes than posterior site when carrying out an immediate implant procedure. The use of grafting material should be considered to fill large horizontal gaps and as a consequence improvement of treatment outcomes might be predictable. (18)

I.1.2 Peri-implant hard and soft tissue:

Peri-implant tissues are similar to the periodontal tissues around natural teeth which are comprised of epithelium and connective tissue, however the epithelium connection to the surface of an implant is mediated by hemidesmosomes.(32) The connective tissue fibers around implants run parallel to the connector or implant surface and it is worth to highlight that there are few blood vessels in the area which contribute to reduced resistance to both mechanical and microbiological stimuli. (33, 34) Also, peri-implant papilla management has been considered to be a challenging task in the esthetic area. (35) To maximize the height of peri-implant papilla, clinician must endeavor to maximize the blood supply and maintain the bone on the neighboring roots and around the implant.(36) Blanching of peri-implant soft tissue occurs when pressure upon inserting the abutment for instance, compromising blood supply of this fragile tissue and ultimately resulting in a reduction of the height of peri-implant papilla. (35)

As mentioned previously, reduced resistance of peri-implant soft tissue to detrimental factors is due to the fact that these tissues have the characteristics of scar tissue and are more predisposed to inflammation due to the bacterial plaque accumulation. Accordingly, it is very important to create the soft tissue anatomy around implants and design crowns and

bridges in agreement of natural soft tissue and dentition respectively, in order to maintain a high standard of oral cavity hygiene.(37)
It is noteworthy that peri-implant soft tissue are greater in volume and this increased volume permit an improved capacity to modify the position of tissue based upon the contours of the prosthetic component. (38)

I.2 Surgical approach in dental implant therapy

- ***Socket sealing options for optimizing emergence profile***

Over the past decades, persistent attempt by clinicians and researchers were pursued to improve clinical outcomes accomplished with dental implants concentrating on the anatomy of hard and soft tissues that should exist or be preserved throughout implant therapy. (39, 40)

A successful implant treatment is based on the assessment of implant and restoration survival, aesthetics of dento-gengival area, mechanical complications rate, bone level and health of surrounding soft tissues. (41-43) Achieving an aesthetic natural result is a challenging task in modern implantology. This can be accomplished by maximum preservation or reconstruction of peri-implant hard and soft tissues. (44)

Various methods have been used to prevent bone resorption and soft tissue collapse after tooth extraction and implant placement, that include the use of bone grafts, soft tissue grafts, xenogeneic collagen matrices for socket sealing and customized healing abutments (CHAs). (45) These treatment modalities also aim to preserve the emergence profile when an implant is placed, primarily in esthetic areas.

- ***Customized healing abutments (CHAs):***

The use of CHAs is a novel method to optimize esthetics, stabilize emergence profile and guide soft and hard tissue healing after implant placement. (46, 47) These abutments can be fabricated by CAD-CAM technology or clinically by incrementing composite materials to a prefabricated abutment. (47) CHA eliminates some need for provisional restoration, prepares the peri-implant tissues to directly receive the definitive implant-supported

prosthesis after peri-implant tissues healing and seals the socket that received an implant and a biomaterial for bone regeneration. (47) The use of CHA assumes its importance where immediate loading following immediate implant placement, particularly in posterior area, is not recommended and may lead to implant failure due to the masticatory forces that might disrupt the osseointegration process. (46, 47)

The gap between the implant surface and the bone plates of the extraction socket, that usually exists after IIP, is mainly located between the implant and the buccal bone wall. It was suggested that alveolar ridge preservation (ARP) technique using biomaterials to fill these gaps is a very viable approach in limiting bone remodeling after extraction and preservation, to some extent, alveolar ridge contour. (48) As mentioned previously CHA can provide mechanical closing of the extraction site containing any bone substitute used in voids between implant and buccal bone plate. (47) Care should be taken to not overfill particulate bone into socket gaps as this might imped the full seating of CHA. (49) Anyhow, after the abutment is screwed or torqued, further grafting can be performed to ensure full support of the gingival margin.(9) In posterior areas, CHA in combination with grafting material such as deproteinized bovine bone mineral (DBBM) in fresh extraction socket has been suggested when a flapless protocol is followed. (50) This protocol in posterior areas, according to *Akin 2016.,* is of vital importance for many reasons: 1) it involves a flapless tooth removal without osteotomy procedure; 2) Socket anatomy does not permit stock healing abutments seating easily; 3) when stock healing abutments are used after IIP, a flap elevation is needed to close around the abutment to keep grafting materials in place; 4) discrepancy of stock healing abutment emergence form is usually an issue, which calls for laboratory prediction of final restoration design complicating seating of a fully contoured final restoration unless further carving of the gingival tissues by clinician is planned. (9)

A customized emergence profile is beneficial since a potentially high pressure towards soft tissue, when inserting the definitive prosthesis, should be avoided. Furthermore, CHAs offer the possibility of skipping the reopening surgery which is usually performed by clinicians to expose the implant platform after osteointegration. (47, 51) When avoiding this second stage surgery following implant insertion, we can reduce morbidity for the patient and still ensuring alveolar contour preservation and optimized esthetics. (47)

Individualizing healing abutments helps preserving original contours of soft tissues allowing to match the contours of the original tooth with the final prosthesis. In other words, CHA offers a replica for the definitive restoration emergence profile to the patient´s gingival

architecture, making the fabrication of a properly contoured implant supported prosthesis more predictable. (52, 53)

- CHA and standard healing abutments (SHA)

Many heights and sizes are available of prefabricated standard healing abutments (SHAs). (53, 54) They have a circular shape and are usually fabricated from titanium. Owing to the fact that the base of the connector is round and smaller than the teeth roots which results from the fact that it has a maximum diameter of the degree of the implant. Ideally, the abutment should replicate the three-dimensional form of the tooth to be substituted, which is called the emergence profile, that extends apically from the head of an implant to the free gingival margin.(32, 35)

Healing of soft tissues can be achieved according to the contours of the definitive crown. (55) However, shaping tissues using standard healing abutment to mimic contours of natural dentition can be unpredictable. (56) Thus, to assure a satisfactory esthetic contours of peri-implant soft tissues, the form of the healing abutment should be similar to this of the future prosthesis.(53). When prefabricated healing abutment is applied, contours of soft tissue at time of prothesis insertion might be unfavorable requiring further recontouring. (57)

Stock abutments can be individualized by composite buildup to correspond to the gingival area where implant is placed. When composite materials are used for this purpose, abutment is sandblasted, or acid etched to create micro retentive areas for a better bonding. Microfilled composites are considered appropriate in its fabrication giving its ability to produce a highly polished surface which can be easily cleaned. This is a major key to obtain healthy peri-implant tissues without any kind of bacterial colonization preventing unfavorable complications. Further modifications to the healing abutment can be accomplished by adding or subtracting composite resin. (58) According to *Akin 2016* (9); avoiding addition of any composite materials in the first 1 millimeter of the supracrestal part of CHA is recommended to allow its full seating.

Beside this technique of composite incrementation, computer- aided design and computer-aided manufacturing (CAD-CAM) systems are also used to fabricate CHA. Many techniques were presented in the literature: Digitally Flip Technique (DFT) for one-step formation of supra-implant emergence profile (59), custom CAD-CAM healing abutment milled from PMMA block and bonded to a titanium insert (54) and a guided soft tissue healing technique

using CAD-CAM healing abutment. (60) When CAD-CAM system is used, an intra-oral scanning is usually done to obtain a virtual model previously to the surgical procedure, that allows to reproduce the original contour of the tooth and reproduce it to the CHA shape. (61)

- **CHA and provisional restoration**

Application of CHA and immediate provisional prosthesis have shown promising results in molding tissues during the healing period, providing also optimal esthetic results. (62)

Through the application of healing abutment or a temporary prosthesis, molding peri-implant tissues can be achieved to obtain a shape corresponding to the final future prosthesis emergence profile. This is considered crucial to the treatment outcomes because when peri-implant tissue healing is completed, further modification of the abutment probably is needed and prosthetic work might change the soft tissue surrounding the implant. (35)
Emergence profile creation is also performed through a dynamic compression utilizing a series of provisional crowns or consecutive adjustments of the existing provisional restoration. (63, 64) However, this technique needs time and entails additional costs.

The beneficial features of individualized healing abutments in obtaining the desired emergence profile which mimic the natural teeth soft tissue contours led clinicians to find out a way to obtain an emergence profile mimicking the natural teeth with the use of prefabricated anatomical healing abutments and to establish a method for developing a custom anatomical healing abutment without the need for further chairside procedures. (44)

The objective of this systematic review is to evaluate the peri-implant tissues response and treatment outcomes, after using custom healing abutments (CHA) as socket sealing option in comparison with standard healing abutments (SHA) in dental implant placement.

II. MATERIALS AND METHODS

II. Materials and methods:

II.1 Study protocol and registration:

Study type: Systematic review and Meta-analysis.

The followed protocol in this review was developed according to the PRISMA (Preferred Reporting Items for Systematic Review and Meta- Analyses) statement. (65)

This systematic review was registered in *PROSPERO (an international prospective register of systematic reviews)* under the number: CRD42022321048

II.2 PICO question:

PICO study design (Population, Intervention, Comparison and Outcome) was used as a template to formulate the clinical question. (Table 1):

Is there a clinical benefit from using custom healing abutment over standard healing abutment on peri-implant hard and soft tissues when an implant placement is performed?

Table 1: The focus question development according to the PICO study design

Component	**description**
Population (P)	Patients with a single edentulous site in both anterior or posterior areas of the maxillary or mandibular arches, who received a standard or a customized healing abutment
Intervention (I)	Implant placement with the use of custom healing abutment
Comparison (C)	Implant placement with the use of standard healing abutment
Outcome (O)	Soft and hard tissues response **measured by:** Marginal Bone Loss (MBL), Pink Esthetic Score (PES), Papilla height and Midfacial Mucosa Height (recession)
Focus question	Is there a clinical benefit from using custom healing abutment over standard healing abutment on peri-implant hard and soft tissues when an implant placement is performed?

II.3 Eligibility criteria:

Inclusion and exclusion criteria established for this review are described in table 2.

Table 2: Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
• Clinical studies in humans • Human trials with a minimum amount of 10 patients • Randomized clinical trials (RCTs) published in English language • RCTs which assessed the effect of customized healing abutments on peri-implant tissues • RCTs which included another type of socket sealing option other than SHA in the control group • Intervention location either in maxillary or mandibular arch, in both anterior and posterior sectors • Follow-up of at least 3 months	• Animal studies • Cohort studies • Non-randomized clinical studies • Studies in vitro • Case reports • Case series

II.4 Information sources and search strategy

An electronic search was performed by two investigators independently (TB and SA) using Google search engine in the following electronic databases: *Medline/PubMed, Web of Science* and *Cochrane Database* to identify controlled clinical trials that directly evaluate the effect of custom healing abutment on peri-implant tissues.

A PICO-style approach was adopted in the search strategy structure. No time limits were applied, although this electronic search was confined to English language as specified in the eligibility criteria. Table 3 summarizes search strategy and points out any filters that were used.

The 23rd of May of 2022 was the last date for databases consultation.

Table 3: Search strategy

database	Used terms	filters
PubMed/ Medline	(Dental Implant *[Mesh]* OR dental implantation *[Mesh]* OR implant placement *[text word]*) AND (customized healing abutment *[text word]* OR standard healing abutment *[text word]* OR individualized healing abutment *[text word]*).	none
Web of Science	(ALL=((Dental Implant OR dental implantation OR implant placement))) AND ALL=((customized healing abutment OR standard healing abutment OR individualized healing abutment))	none
Cochrane	((Dental Implant OR dental implantation OR implant placement)) AND ((customized healing abutment OR standard healing abutment OR individualized healing abutment))	Trials

II.5 Selection process:

Two reviewers worked independently at each stage of screening. Primarily, each obtained record after duplicates removal was assessed by its title and abstract, accordingly, multiple records were excluded. Secondarily, titles and abstracts of potentially eligible articles concerning CHAs were screened carefully for eligibility. Lastly, free full texts of clinical studies related to custom and standard healing abutments, were evaluated, however, only randomized controlled clinical studies were considered according to the well-defined inclusion criteria excluding any other type of studies. Differences between reviewers were resolved by discussion and consensus.

II-6 Data extraction and data items:

Two reviewers, independently, extracted data from the selected articles fulfilling the inclusion criteria. Extracted data were retrieved into pre-defined tables:

- General information: study design, year of publication, follow-up period, follow-up intervals, number of patients, test group, control group and patient-related information (including age, gender, smoking status, local factors (periodontal and gingival biotype)).
- Surgical and implant-related information: implants number, timing of placement, type of implant, implant placement location in mouth, medication, local anesthesia, insertion torque, surgical protocol, loading protocol, implant surviving rate, clinical outcomes.
- Treatment outcomes: Pink Esthetic Score (PES), Papilla height, Midfacial Mucosa Height, and Marginal Bone Loss (MBL):

- Pink Esthetic Score (PES from 0 to 10) include five factors: mesial papilla, distal papilla, curvature of the facial mucosa, level of the facial mucosa, and root convexity/soft tissue color and texture at the facial aspect of the implant site. (66) Whereas other authors report a scale from 0 to 14 point (seven parameter classification) that comprises similarly the following factors: Mesial papilla, distal papilla, tissue contours, gingival level and alveolar process, coloring and texture are considered separate factors in this classification. (67)
- Papilla height: the papillary level at implant site considering a reference point such as the cervical margin of adjacent teeth or muco-gingival junction.
- Marginal Bone Loss (MBL): bone changes that occur around the implant during a period of time.
- Midfacial Mucosa Height: changes that occur at the peri implant mucosa position around the final restoration.

II.7 Risk of bias assessment

The second Version of the Cochrane risk-of-bias tool for randomized trials (RoB2) was used (68). Two independent reviewers (TB and SA) assessed the risk of bias independently. **The methodological domains of the (RoB2) tool were:** Randomization process, Deviations from the intended interventions, Missing outcome data, Measurement of the outcome, Selection of the reported results.

II.8 Data synthesis:

In the synthesis of results, effect measures for the continuous outcomes evaluated in results is presented through standardized mean differences between two distinct groups (test and control).

Synthesized results were re-expressed by meta-analyzing mean differences. Meta-analysis that integrates the quantitative findings from separate but similar studies and provides a numerical estimate of the overall effect of interest, was performed. Under the fixed effects model, it is assumed that all studies come from a general population and that the size is not significantly different among the different trials. This assumption was tested by the heterogeneity test using the *Cochran´s Q* test.

The random-effects model was more appropriate to use considering that the included studies have enough in common that justifies data synthesis. However, no rationale exists to postulate that studies are "identical" in the sense that the true effect size is precisely the same in all the studies. (69). It was more appropriate to use this model since it took into account both the random variation within the studies and the variation among different studies. Therefore, individual trials were pooled, and the weighted mean differences for the following outcomes (MBL changes mesially and distally, PES, mid-facial level and papilla height), and together with their 95% confidence intervals (CIs), were calculated. P value=0.05 was selected to determine if differences were statistically significant.

Heterogeneity was evaluated through the use of *Cochran´s Q* test and *Higgins I^2* statistic test. Forest plot is produced to graphically display the difference among results of the evaluated outcomes.

Collected data from studies were documented in an Excel spreadsheet for afterwards synthesis in which the standardized mean differences were used among studies that applied the same effect measure for the same outcome over the follow-up period.

III. RESULTS

III. Results:

III.1 Study selection

The initial electronic search in the three databases resulted in the identification of 1019 records. Duplicates and triplicates removal was done before screening. Afterwards, titles and abstracts were evaluated and accordingly, 819 publications were excluded. The remaining 62 articles were evaluated. The reasons for exclusion were as follows: 1) case reports, 2) Dental techniques, and 3) non-randomized clinical trials. Finally, 4 articles were included into the analysis. The summarized selection process is presented in figure 1.

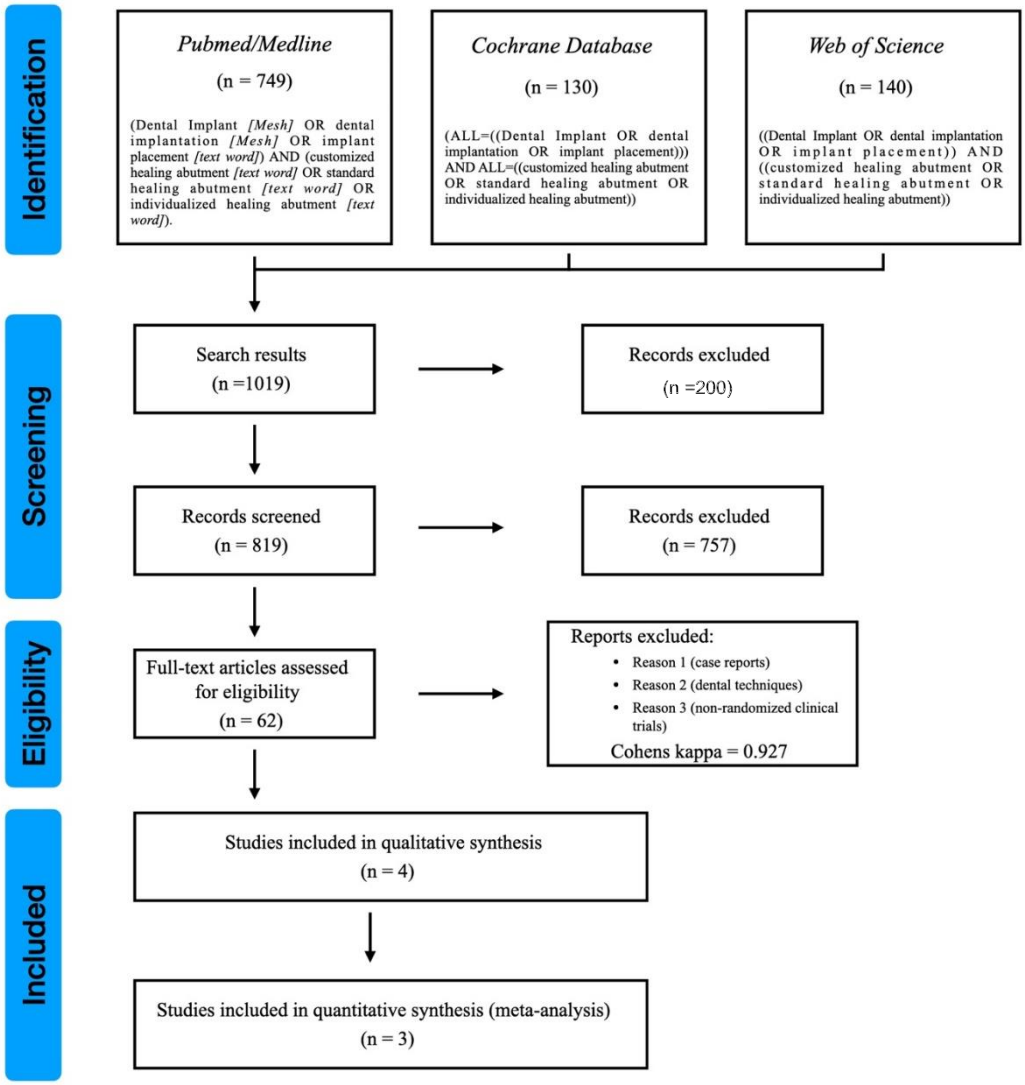

Figure 1: Flow diagram for selection process according to PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses). (65)

III.2 Study characteristics

Characteristics of included studies are described in tables. (4-10) A total of 4 randomized clinical trials were analyzed with a total number of 114 patients (49 men and 65 women) where 51 belonged to the test group and 49 to the control group and 14 to a third group established by *Fernandes et al.* (45) Regarding implant placement location, implant placement in the anterior maxillary arch including premolars was performed in 3 RCTs. (45, 66, 70). However, besides premolars, molar sites in both maxillary and mandibular arches were included in *Beretta et al* study. (71) A total of 114 implants were inserted, from which 91 were placed in the maxilla and the remaining 13 implants in the mandible.

Uncontrolled or untreated periodontal disease was an exclusion criterion in two studies. (66, 70) For *Fernandes et al* (45), individuals diagnosed with periodontal disease were also excluded whereas in *Beretta et al*, (71) no information is reported in this regard. Heavy smokers (more than 10 cigarettes a day) were excluded from included studies. Individuals with poor oral hygiene (full mouth plaque index > 25% and full mouth bleeding score > 25%) were also excluded. (66, 70, 71)

The type of implant placement in both *Fernandes et al (45),* and *Perez et al (66),* was immediate implantation as opposed to *Wang et al*, (70) and *Beretta et al,(71)* in which delayed implant placement in patients' papulation where teeth were missing, was performed. Regarding the surgical protocol, a flapless tooth extraction and IIP was performed in both *Fernandes et al*, and *Perez et al,* studies. (45, 66) Whereas mucoperiosteal flap was elevated in *Beretta et al, (71)* study to place the implant and posteriorly the healing cap. A surgical guide was utilized in *Wang et al,* (70) study when executing the osteotomy procedure to place the implant.

III.3 The reported clinical outcomes of the implants

Implant survival rate was 100% for the test and control groups.
The following clinical outcomes were also reported:

III.3.1 Marginal Bone Loss (MBL)

MBL was calculated in *Perez et al,* and *Wang et al,* (66, 70) and for both, no significant differences were reported for any group when describing marginal bone level changes at

mesial and distal sites separately, at 1-year follow-up. In *Wang et al* study, (70) significant differences were reported when mesial and distal marginal bone level was calculated for both groups (customized and standard) at three time points (Implant placement, loading and after 1-year). However, marginal bone loss at mesial site for standard (0.6mm) vs (0.0) in the customized group at the 1-year follow-up was described in *Perez et al*, study (66) and this difference proved to be significant.

III.3.2 Papilla Height:

After 1-year follow-up, there was no statistical differences taking into consideration papilla height variation at mesial and distal sites. Anyhow, slightly less height variation was observed in the customized group when compared to the collagen matrix group established by *Fernandes et al*, (45). They found papilla height variation at mesial site of -0.35 mm in customized group compared to -0.54 mm in the collagen matrix group and height variation at the distal site of (-0.38 mm) for customized group and (-0.60 mm) for collagen matrix group. After 12 months of loading, a slight increase in papilla height from the 6-month follow-up was observed in both groups of *Wang and colleagues 'study* .(70) Their findings reported that mesial papilla height increased from 3.93 (6 months) to 4.06 (1 year), as well as, the distal papilla height also increased from 3.50 (6 months) to 3.65 (1 year) in the customized group. Mesial papilla height also increased in standard group from 2.59 to 2.64 at 6 months and 1-year follow-up respectively. Nevertheless, distal papilla height decreased from 2.22 (6 months) to 2.09 (1 year). These differences proved to be statistically significant for all the time points listed earlier.

III.3.3 Pink Esthetic Score (PES)

An improvement in pink esthetic score was outlined in the customized group (11.44, 12.50 and 11.67) compared with the standard group (9.18, 9.91 and 10.82) at Implant placement, loading and 1-year follow respectively. PES significantly changed within either group during these three time points. (70)

PES changes in the control group at 1-year follow-up were not statistically significant. Interestingly, PES score showed an improvement only on the distal aspect of the five assessed clinical parameters in the customized group (1.6) when compared to the

standard group (0.9). (66)

III.3.4 Mid-facial mucosa level

No significant differences were found upon evaluating midfacial mucosa variation at 1-year follow-up. *Fernandes et al*, observed a more coronal position of midfacial mucosa at the collagen matrix group compared to the customized abutment group (-0.37 ± 0.55 mm and -0.55 ± 0.64 mm, respectively). (45) In the study of *Perez et al*, the mid-facial mucosal level showed a recession of 0.2 ± 0.4 mm for the customized group at 12-month examination and the standard group showed a gain of mucosal level of 0.1 ± 0.5 mm. This difference was statistically significant. (66)

Table 4: Demographic Data

AUTHOR	YEAR	STUDY DESIGN	PATIENTS NUMBER	AGE RANGE	GENDER (MALE: FEMALE)
PEREZ ET AL, (66)	2019	RCT	36 Test group: 18; control group: 18.	23-77 Test group: 50.8 ± 19.5 control group: 59.0 ± 15.4	19:17
BERETTA ET AL, (71)	2019	RCT	20 Test group: 10; control group: 10.	60.75 ± 12.58	08:12
FERNANDES ET AL, (45)	2021	RCT	28 Test group: 14; control group: 14	54.00 ± 12.20 Test group: 53.43 ± 12.33 control group: 54.57 ± 12.51	13:15
WANG ET AL, (70)	2021	RCT	20 Test group: 9; control group:11.	30.15 ±5.25	09:11

Table 5: General information 1

AUTHOR	YEAR	SMOKING HABIT	LOCAL FACTORS (PERIODONTAL AND GINGIVAL BIOTYPE)
PEREZ ET AL, (66)	2019	28 patients (77.7%) non-smokers 8 patients (32.3%) light smokers	(Type 1 extraction socket and favorable periodontal biotype, gingival phenotype of adequate thickness (>2 mm)
BERETTA ET AL, (71)	2019	NR	NR
FERNANDES ET AL, (45)	2021	100% non-smokers	**Type 1 extraction socket** **Buccal thickness:** test: 1.11± 0.48 control: 0.98± 0.73 **Keratinized mucosa:** test: 4.07± 0.73 control: 3.79± 1.53
WANG ET AL, (70)	2021	< 10 cigaretts per day	medium thick gengival biotype intact buccal bone plate

Table 6: General information 2

AUTHOR	YEAR	TEST GROUP	CONTROL GROUP	FOLLOW-UP	FOLLOW-UP INTERVALS
PEREZ ET AL, (66)	2019	Custom healing abutment	Standard healing abutment	1 year	T0: baseline; T1: after 4 months; T2: 1 ano.
BERETTA ET AL, (71)	2019	Custom healing abutment	Standard healing abutment	3 months	1 month 3 months
FERNANDES ET AL, (45)	2021	Custom healing abutment	Collagen matrix for socket sealing	1 year	T0: baseline; T1: 1 month, T2: 4 months, T3: 1 year.
WANG ET AL, (70)	2021	Custom healing abutment	Cylinderical prefabricated abutment	1 year	T1; 1 month; T2; 6 months T3: 1 year.

Table 7: Implant-related information

AUTHOR	YEAR	IMPLANTS NUMBER	TIMING OF PLACEMENT	TYPE OF IMPLANT	IMPLANT PLACEMENT LOCATION IN MOUTH
PEREZ ET AL, (66)	2019	36 implants	Immediate	Bone level tapered implants (BLT implants, Straumann, Basel, Switzerland)	Anterior region of maxilla including premolars
BERETTA ET AL, (71)	2019	20 implants	Delayed	(iSy Implant System®, Camlog Biotechnologies, Basel, Switzerland)	Gaps in maxillary or mandibular arch distal to canines
FERNANDES ET AL, (45)	2021	28 implants	Immediate	cylindrical shape implants (osseoSpeed EV, Astra Tech Implant System, Dentsply Implants, Mohndal, Sweden)	Maxillary anterior teeth form premolar to premolar
WANG ET AL, (70)	2021	20 implants	Delayed	3.5x11 mm (Ankylos C/X, Dentsply)	Maxillary incisors

Table 8: Surgical considerations

AUTHOR	YEAR	MEDICATION	LOCAL ANESTHESIA	INSERTION TORQUE
PEREZ ET AL, (66)	2019	**Preoperative:** 2 g of amoxicillin or 600 mg of clindamycin 1 hour before surgery. **Postoperative:** 1 g amoxicillin 2x daily for 5 days or 300 mg of clindamycin 3x daily for 5 days	Articaine with adrenaline 1:100,000	test group: 37.9 ± 12.1 control group: 39.9 ± 10.8
BERETTA ET AL, (71)	2019	**Preoperative:** 2 g of amoxicillin and clavulanic acid 1 h before surgery	2% mepivacaine with 1:100,000 epinephrine.	NR
FERNANDES ET AL, (45)	2021	**Postoperative:** Amoxicillin 1 g 2x per day for 7 days and paracetamol 1000 mg 3x per day	4% articaine with adrenaline 1:100000	NR
WANG ET AL, (70)	2021	NR	Primacaine (Articaine 68 mg, adrenaloine 17 µg)	≥ 25 Ncm

Table 9: Surgical and prosthetic protocols

AUTHOR	YEAR	SURGICAL PROTOCOL	LOADING PROTOCOL	IMPLANT SURVIVING RATE
PEREZ ET AL, (66)	2019	Flapless extraction with fine periotomes. Implant bed was prepared for its placement. Hardening alloplastic bone graft substitute was placed in peri-implant bony defects so that standard or customized healing abutments be finally applied.	Temporary or final restorations were delivered 4 months after implant placement	100%
BERETTA ET AL, (71)	2019	Incision, mucoperiosteal flap, osteotomy and implant placement were executed. Customized and standard healing abutments were applied.	1 month in the maxilla 3 months in the mandible	NR
FERNANDES ET AL, (45)	2021	Flapless tooth extraction by sectioning the tooth. Periotomes and elevators were used to separate the two parts of the tooth. Afterwards, osteotomy was performed to place implants in the correct 3- dimensional position. DBBM material was grafted in gaps of at least 2mm.	Provisional crown was delivered after 4 months. Definitive restoration was delivered after 6 months	100%
WANG ET AL, (70)	2021	Implant socket preparation using surgical guide. Afterwards, immediate individualized or conventional healing abutments were placed each in its group.	6 months after implant placement	100%

Table 10: Clinical outcomes of the selected studies

AUTHOR	YEAR	CLINICAL OUTCOME
PEREZ ET AL, (66)	2019	**Primary outcome:** Compare soft tissue outcomes through Papilla Index (PI) or Jemt Index & Pink Esthetic Score (PES). **Secondary outcome:** 1. Changes in the mid-facial mucosal/ changes in the width of keratinized gingiva. 2. Changes of the peri-implant bone level or Marginal Bone Loss (MBL). 3. Comparison of implant success rate 4. Comparison of implant failure and complication rate. 5. Full Mouth Bleeding Score (FMBS) 6. Full Mouth Plaque Score (FMPS)
BERETTA ET AL, (71)	2019	Clinical evaluation of the peri-implant soft tissue response among the two groups through: 1. The Functional Implant Prosthodontics Score (FIPS) - FIPS is defined by 5 variables: 1) interproximal, 2) occlusion, 3) design, 4) mucosa, and 5) bone. 2. Perceived pain after crown insertion was also assessed by the Numerical Rating Scale (NRS)
FERNANDES ET AL, (45)	2021	Evaluate peri-implant tissues dimensional changes (hard & soft tissues) between the two groups by comparing: Linear Buccal Changes, Buccal Volumetric Variation (BVv), papilla presence and midfacial mucosa height.
WANG ET AL, (70)	2021	Compare the clinical influence of the 2 types of abutments on peri-implant soft and hard tissue in shaping the emergence profile through: 1. The pink esthetic score, papilla height, papilla proportion and radiographic marginal bone level. 2. The visual analog scale (patient self-assessment scores).

III.4 Risk of bias assessment

Using *The Cochrane Risk of Bias 2 (RoB 2)* tool, the overall study-risk of bias assessment is presented in figure 2, as well as the risk of bias assessment of each included study individually using the same tool in figure 3 . (68)

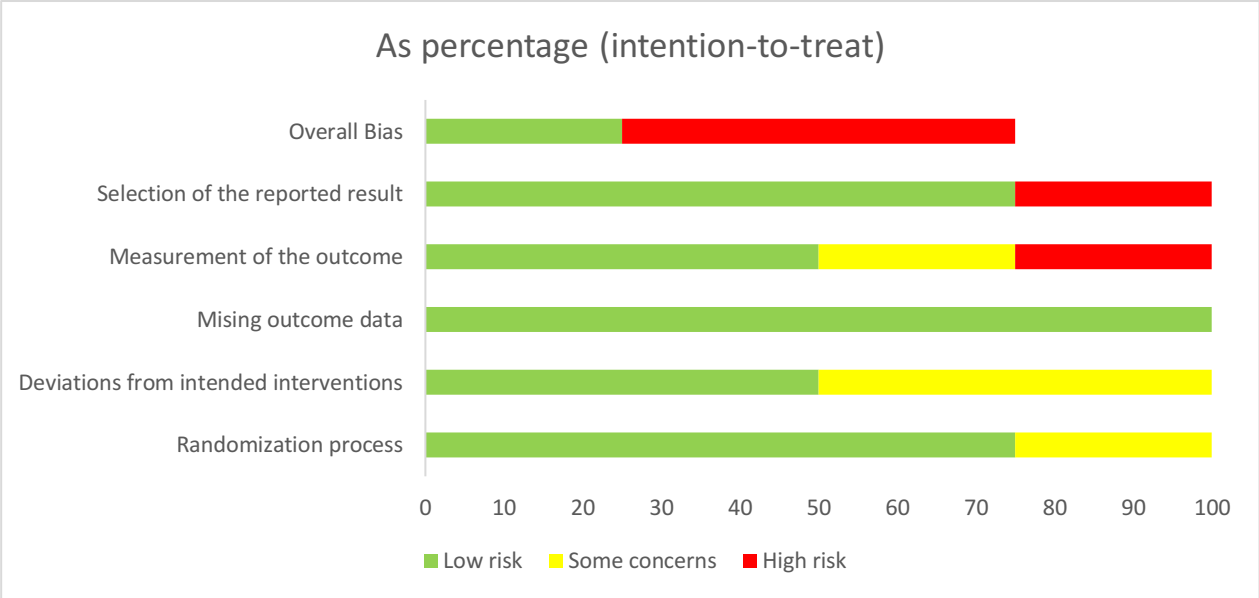

Figure 2: Overall Risk of bias assessment using The Cochrane Risk of Bias 2 (RoB 2) tool.

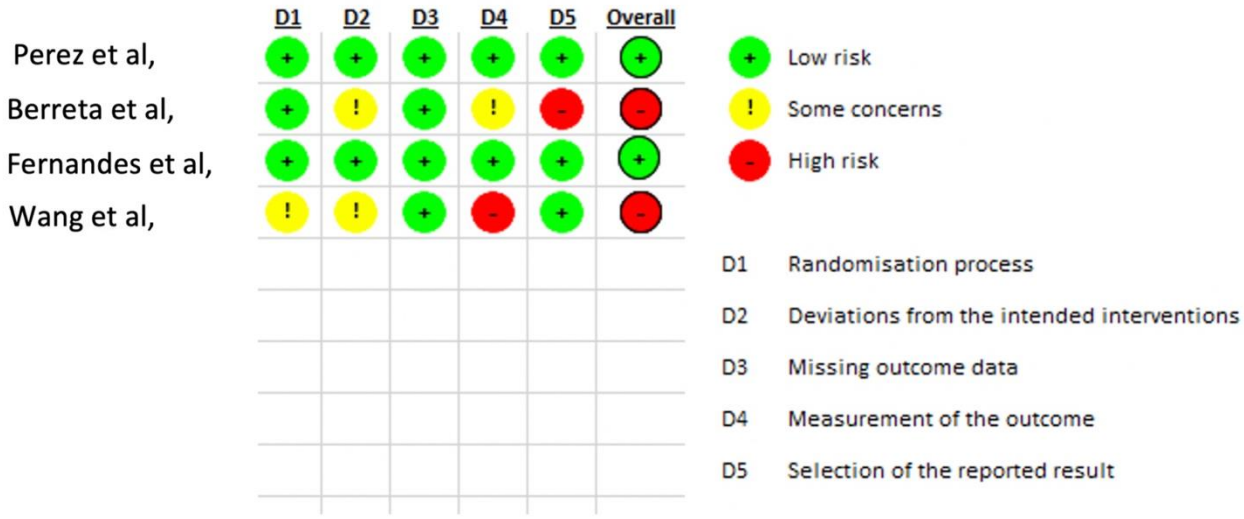

Figure 3: Overall Risk of bias assessment using The Cochrane Risk of Bias 2 (RoB 2) tool.

III.5 Results of meta-analysis

Wang et al. (70), *Fernandes et al.* (45) and *Perez et al* (66) studies were included in meta-analysis. 95% confidence interval was used in the estimation and statistical heterogeneity was measured by the *Cochran Q* test and *Higgins* I^2 statistic test.

Results of statistical syntheses are reported in the following table 11, and figures (4 to 13):

Table 11: Demographic data comparison among studies

Variable	Group	Perez et al	Beretta et al	Fernandes et al	Wang et al
year		2019	2019	2021	2021
Patients number	Test	18	10	14	9
	Control	18	10	14	11
	Total	36	20	28	20
Age range	Test	50.8 ± 19.5		53.43 ± 12.33	
	Control	59.0 ± 15.4		54.57 ± 12.51	

	Total		60.75 ± 12.58	54.00 ± 12.20	30.15 ±5.25
Gender (male/female)	Test	11/18		8/14	
	Control	8/18		5/14	
	Total	19/17	8/12	13/15	9/11
Method	Test	custom healing abutment	custom healing abutment	custom healing abutment	custom healing abutment
	Control	Standard healing abutment	Standard healing abutment	collagen matrix for socket sealing and cover screw	cylindrical prefabricated abutment
Follow-up		1 year	3 months	1 year	1 year

III.5.1 Age and sex

For *Perez et al* and *Fernandes et al* studies, the analysis of age and sex variables was performed in order to infer about the homogeneity of the studies. (Figures 4 and 5).

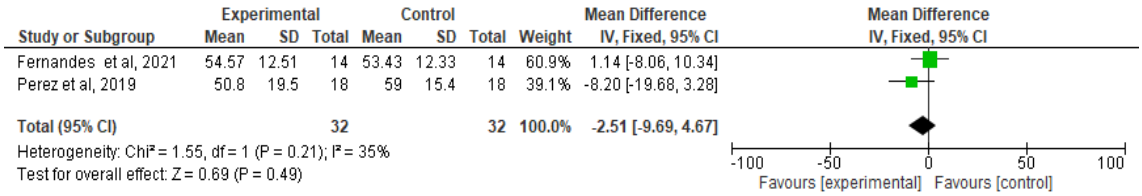

Figure 4: Meta analysis results for age

- Taking into account the results of Figure 4, *Cochran's Q* (p=0.21>0.05) and I^2=35%, it was concluded that the **studies were homogeneous in terms of age**. Observing the forest plot, age tends to be lower in the test group.

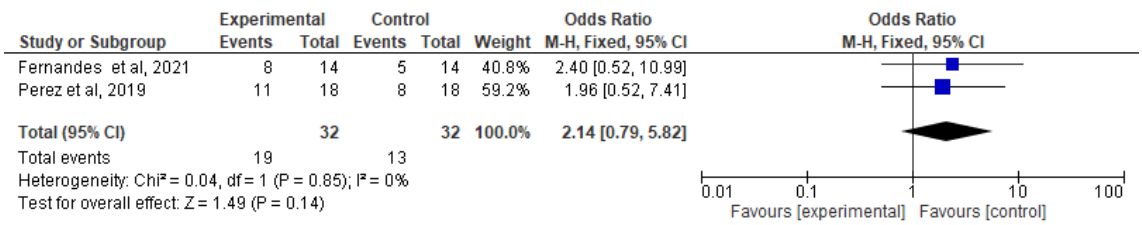

Figure 5: Results of the meta-analysis for sex

- Taking into account the results of Figure 5, *Cochran's Q* (p=0.85>0.05) and I I^2=0%, it was concluded that the studies were homogeneous in terms of sex. Observing the forest plot, it can be seen that in each study **men and women are balanced by group.**

III.5.2 Marginal bone loss

For *Wang et al,* and *Perez et al,* studies**,** the mesial marginal bone loss and distal marginal bone loss variables were analyzed in the evaluation between four and six months (M1) and one year (M2) in order to infer about the homogeneity of the studies. (Figures 6 and 7).

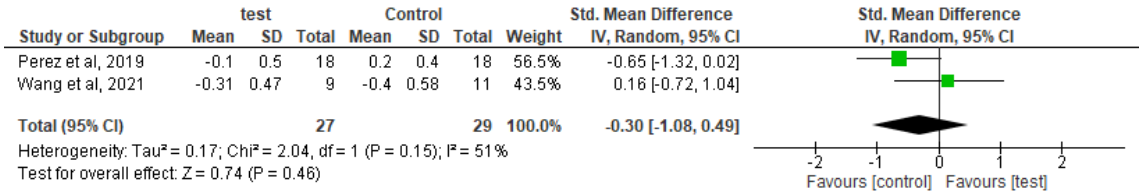

Figure 6: Meta analysis results for Mesial marginal bone loss M1

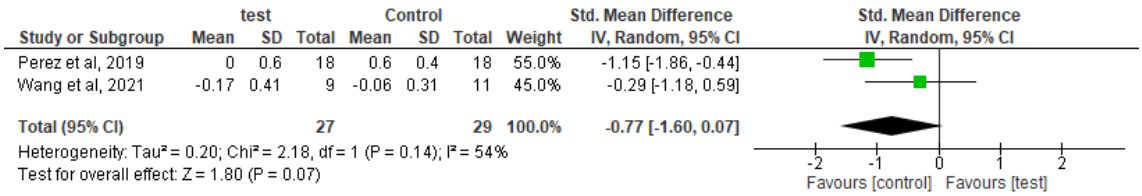

Figure 7: Meta analysis results for Mesial marginal bone loss M2

- Taking into account the results of figures 6 and 7, I^2=51% and I^2=54%, respectively, it was concluded that there was low heterogeneity between studies regarding the mesial marginal bone loss in the two evaluation moments. By the observation of the forest plot, we can verify that the study of *Perez et al,* is statistically significant to one year and that **after one year of treatment both studies lead to results that favor the control group.**

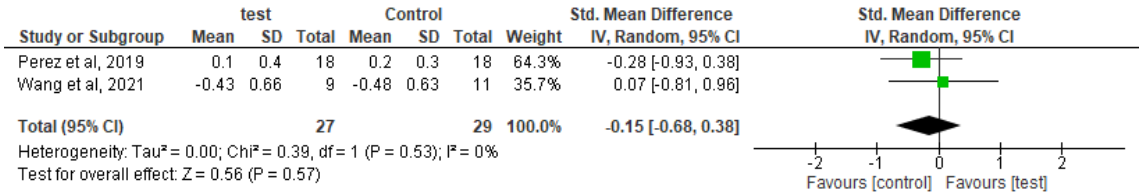

Figure 8: Meta analysis results for Distal marginal bone loss M1

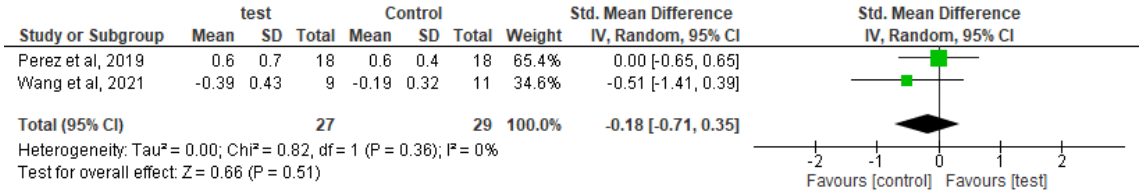

Figure 9: Meta analysis results for Distal marginal bone loss M2

- Regarding the results of figures 8 and 9, I^2 =0%, it was concluded that there was homogeneity between studies regarding the distal marginal bone loss in the two evaluation moments. Observing the forest plot, it is verified that there are no significant differences and after one year of treatment, *Wang et al,* results are in favor of the control group and the results of *Perez et al,* are not in favor of any of the groups.

III.5.3 Papilla height:

For the studies of Wang et al and Fernandes et al, the analysis of the variables **mesial papilla height and distal papilla height** was performed in the evaluation between four and six months in order to infer about the homogeneity of the studies.

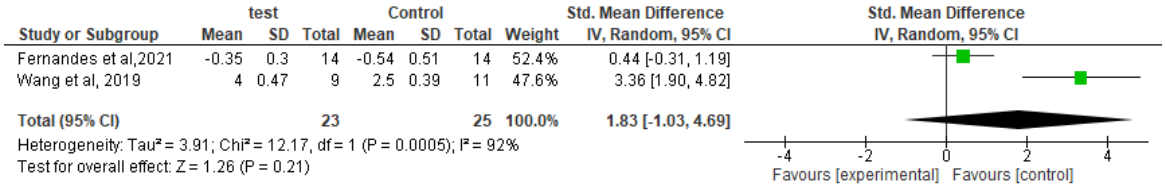

Figure 10: Meta analysis results for mesial papilla height M1

- Considering the results of Figure 10, Cochran's Q ($p<0.001$) and I^2 =92%, it was concluded that there was high heterogeneity between studies regarding the mesial

papilla height. Observing the forest plot, it appears that the study *Wang et al* is statistically significant.

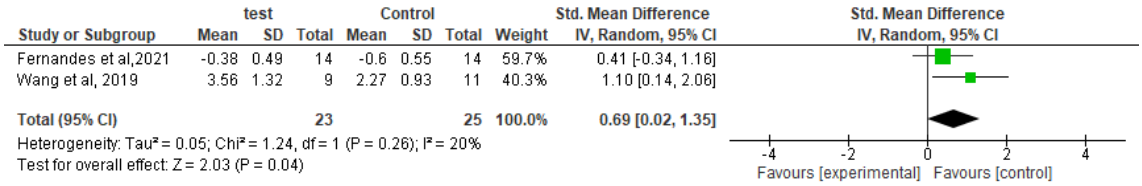

Figure 11: Meta analysis results for distal papilla height M1

- From the results of Figure 11, Cochran's Q (p=0.26>0.05) and I^2 =20%, it was concluded that the studies were homogeneous in relation to the distal papilla height. Observing the forest plot, it appears that the study *Wang et al,* is statistically significant.

III.5.4 Pink Esthetic Score (PES):

For the studies Wang et al and Perez et al, the analysis of the variable PES was performed in the one-year evaluation in order to infer about the homogeneity of the studies.

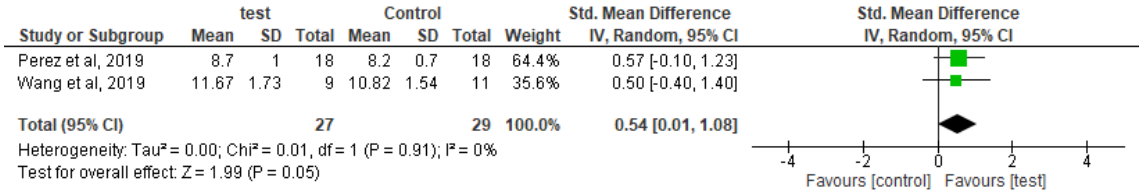

Figure 12: Meta analysis results for PES M2

- Taking into account the results of Figure 12, Cochran's Q (p=0.91>0.05) and I^2 =0%, it was concluded by the homogeneity between studies regarding PES score. Observing the forest plot, it is verified that the studies are statistically identical to each other and the results favor the test group.

III.5.5 Mid-facial mucosal level:

For the studies *Fernandes et al*, and *Perez et al,* the analysis of the variable Mid-facial mucosal level (recession) was performed in the one-year evaluation in order to infer about the homogeneity of the studies.

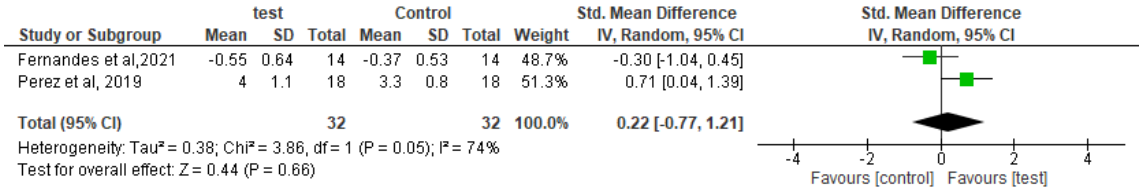

Figure 13: Meta analysis results for Mid-facial mucosal level / recession M2

- From the results extracted of Figure 13, Cochran's Q ($p<0.05$) and I^2 =74%, it was concluded that there was moderate heterogeneity between studies regarding the Mid-facial mucosal level / recession. Observing the forest plot, it is verified that the studies are statistically identical to each other and the results favor the test group in *Perez et al*, study.

IV. DISCUSSION

IV. Discussion:

This systematic review aimed to evaluate hard and soft tissue response when using customized healing abutments after immediate or delayed implant placement.

Numerous techniques beside the use of CHA, were cited in the literature that focus on stabilizing or augmenting peri-implant tissues, preservation of emergence profile and optimizing gingival architecture.

The socket shield technique (SST) was introduced by Hurzeler in 2010 and is widely used nowadays. As alveolar bone resorption is more evident on the buccal aspect rather than the lingual one, particularly in the esthetic area, originating unpleasing esthetic result and interfering with ideal implant positioning, SST can help in stabilizing the alveolar ridge dimensions after IIP. *Hurzeler et al*, evaluated partial root retention keeping the buccal bone plate, combined with IIP. (72) *Abd-elrahman et al,* in their RCT, reported that SST is a reliable technique to be combined with IIP, however it is also a sensible technique and requires practice to be duly executed. (73) A recent systematic review by *Atieh et al., 2021* concluded that SST is a good technique with regard to stabilization of the marginal bone level, preservation of alveolar bone and obtaining esthetically pleasing results. However, further clinical studies are needed to state the long-term outcomes and the prevention of complications. (74)

Connective tissue grafting (CTG) has been advocated in order to minimize soft tissue recession, particularly in the anterior maxilla where a thin gingival biotype is frequently observed. In a systematic review and meta-analysis by *Seyssens et al*, it appears that CTG contribute to midfacial soft tissue stability, and this procedure should be considered when high risk for midfacial recession is anticipated in the esthetic zone considering these local factors (thin gingival biotype and < 0.5 mm thickness of the buccal bone). CTG is also considered a reliable procedure to augment the height of keratinized mucosa to enable performing properly hygiene measures that can be difficult when keratinized mucosa height is reduced and consequently, peri-implant health is assured preventing soft tissue inflammation. (75) *Obreja et al,* corroborate this statement in a cross-sectional observational study, indicating that CTG is a beneficial procedure in maintaining healthy peri-implant tissues. (76)

IIP and immediate provisionalization in the esthetic area have been advocated taking into consideration its efficacy in providing good esthetic results by maintaining the alveolar bone and gingival tissue architecture. (77) The dynamic compression technique was proposed to condition soft tissue architecture through the use of a provisional restoration after the removal of the healing cap in the esthetic area in order to obtain the desired gingival tissue emergence profile. (64)

Another option that has been described for alveolar ridge preservation is the use of xenogeneic non-cross linked extracellular resorbable collagen matrix. This biomaterial has been indicated for this propose due to its safety, feasibility and effectiveness for alveolar ridge preservation when associated with the use of bone grafts. (78) Additionally, xenogeneic, porcine non-cross linked resorbable collagen matrix can also be used in alveolar ridge preservation (ARP) procedures providing a reliable alternative to autogenous and other soft tissue grafts. (78) A recent RCT by *Happe et al,* that evaluate peri-implant soft tissue esthetic outcome after using porcine acellular dermal matrix (pADM) or connective tissue graft when IIP protocol is followed. They found that pADM is an effective approach considering the pink esthetic score and mucosal color match as much as autogenous CTG. Conversely, pADM offers an advantage that is does not necessitate a second surgical site with an overall esthetic outcome comparable to this obtained with CTG. (79)

Regarding our review, various articles were evaluated for eligibility, the majority of those describing the manufacturing techniques of CHA and case reports. (46, 52, 53, 59-61) Due to the lack of clinical trials in this topic, only four recent randomized clinical trials that fulfilled the inclusion criteria and thus included in this review. Eligible RCTs evaluated CHAs and SHAs in the test and control groups respectively. Exception for *Fernandes et al*, where xenogeneic collagen matrix and implant level healing caps were used in the control group. IIP in both *Fernandes et al (45),* and *Perez et al (66) studies,* was performed as opposed to *Wang et al*, (70) and *Beretta et al,(71)* in which delayed implant placement was executed. Regarding the surgical protocol, a flapless tooth extraction and IIP was performed in both *Fernandes et al* and *Perez et al* studies,(45, 66) Whereas a more invasive procedure was carried out with mucoperiosteal flap elevation in *Beretta et al (71)* study to place the implant and posteriorly the healing cap. A surgical guide was utilized in *Wang et al* (70) study when drilling the osteotomy procedure to place the implant. We assume a flapless approach was adopted since authors did not refer any data about a flap elevation or suturing.

The loading protocol was appropriate for all included studies where either provisional or definitive crown was inserted after at least 1 month (in the maxillary arch) of implant placement procedure.
Regarding antibiotic use, all patients received either amoxicillin or clindamycin (in case of allergy). The use of amoxicillin associated with clavulanic acid in *Beretta et al*, study is not justified, the prescription of prophylactic antibiotic of amoxicillin solely is preferred.
Light smokers were accepted in our study sample whereas patients with uncontrolled periodontitis were excluded in two studies,(66, 70). Fernandes and colleagues did not accept patient papulation diagnosed with periodontal disease.(45) It is evident that periodontal status should be evaluated carefully as it is an extremely important parameter in the clinical outcome and success of implant therapy in terms of hard and soft tissue stability. *Beretta et al (71)* did not refer periodontal status of included patients in their study.
Patient papulation was carefully selected (type 1 extraction socket, favorable periodontal biotype, thick gingival biotype and without soft tissue defects or recession). (45, 66) Wang and colleagues also included patients where buccal bone plate is intact and medium thick gingival biotype is present.(70) These local factors were not considered in *Beretta et al,* study (71). It might be justified that these parameters are less relevant in their study sample since implants were placed in the posterior area of maxillary and mandibular arches where periodontal/gingival biotype is generally favorable.

Considering results of our meta-analysis. Homogeneity regarding age whether in control and test group in the selected studies (45, 66) was verified with tendency to be inferior in the test group. Therefore, no biases concerning age were detected. In other words, surgical interventions were executed in similar populations in terms of age. Homogeneity considering sex of included patients was established and it was observed that, in each evaluated study men and women are balanced by group. (45, 66) Taking into consideration this homogeneity in these two demographic variables (age and sex) of our sample, comparison between studies with the same profile is plausible.

Considering the statistical analysis carried out for mesial marginal bone loss in *Wang et* al. *and Perez et* al. studies (66, 70) at two moments (M1:4 to 6 months follow-up, M2: 1 year period), low heterogeneity was observed between studies. For mesial marginal bone loss, *Perez et al.* study is statistically significant at one year and that after one year of treatment

both studies led to results that favor the control group.(66, 70) therefore, lower mesial bone loss is found when using SHAs over CHAs after 1-year period.
Regarding distal marginal bone loss at M1 and M2, homogeneity between studies in the two evaluation moments was verified. After the 1-year follow-up only *Wang et al,* study was in favor for the control group with lower distal marginal bone loss in comparison with the test group. Results of *Perez et al,* were not explicitly favor one of the groups over the other, in terms of distal MBL.

Considering mesial and distal papilla height at one time point (M1). It was possible to perform a meta-analysis for *Wang et al (70)* and *Fernandes et al (45)* studies that revealed high heterogeneity regarding mesial papilla height and *Wang et al* (70) study proved to be statistically significant. Therefore, favorable results in the control group were found with a better mesial papilla height in one study. (70)
Homogeneity with regard to distal papilla height at M1 between the two studies *(45) (70)* indicates that *wang et al (70)* is statistically significant and better distal papilla height was found when SHAs are used.

For the studies *Wang et al* and *Perez et al,* (66, 70) the analysis of the variable PES was performed in the one-year evaluation. homogeneity between studies regarding PES was verified and studies are statistically identical to each other, and the results favor the test group with better PES. It is noteworthy to mention that PES is a reliable tool in assessing esthetic results, however, it is a subjective outcome measure.

For the studies *Fernandes et al* and *Perez et al*, (45, 66) the analysis of the variable Mid-facial mucosal level / recession was performed at one-year period. Moderate heterogeneity between studies regarding the Mid-facial mucosal level / recession was observed and studies are statistically identical to each other, and the results favor the test group in *Perez et al* study. (66) However, we cannot conclude that CHA is beneficial in term of mid-facial recession considering only one study.

Differences regarding the anatomical location of implant placement were verified, since included studies involved implantation in both maxilla and mandible. The quality of bone is different among the two jaws which raises questions regarding the accurate effect of custom healing abutments. Conversely, meta-analysis was only performed on implants placed in

the anterior maxilla. Implant placement in the mandible was only performed in *Beretta and colleagues'* study (71) whose implant outcomes results were not evaluated in the meta-analysis.

Both immediate and delayed implant placement are performed in our study sample, even it not specified in *Wang et al* (70) and *Berretta et al* (71) studies whether implantation was performed in partially or fully healed alveolar bone. Results can be confounding in terms of marginal bone loss, PES, mid-facial recession and papilla height in this aspect.

Generally, follow-up period of included clinical studies in this systematic review is considered short, moreover, a 3 month-follow-up period in *Berretta et al (71)* study is indeed very short, and we cannot take conclusions in such a short follow-up period. However, we could not meta-analyze results from this study as it presented results using FIPS which appears to be a vague outcomes measure. This made it difficult to compare outcomes of this study with the other included RCTs. Anyhow, this study, interestingly, used the numerical rating scale (NRS) to evaluate the perceived pain by patients upon inserting the definitive abutment which is considered an important parameter to assess patient´s satisfaction regarding implant treatment. Patient satisfaction parameter was also assessed in *Wang et al,* study and better results were reported in the customized group over the standard group, but no significant differences were found between the two groups.

Markedly, Fernandes and colleagues (45) measure linear and volumetric dimensional changes using digital files. Through this digital approach we can obtain objective results without observer subjectivity.

Since our review is based on a very recent subject, the literature is scarce and few studies are carried out in this domain. A limited number of patients were included in our study sample. Short follow-up period is a major limitation besides the limited number of RCTs included in this review. One of the main limitations of this systematic review is that it was restricted to English language and only 3 databases were searched out. Large discrepancy is verified among studies which made it difficult to make a comparison among all of them.

Another major limitation is that meta-analysis was applied only on three RCTs.

V. CONCLUSION

V. CONCLUSION

The use of customized healing abutments in oral implantology is a predictable treatment modality in terms of soft tissue stability and esthetic outcomes of the peri-implant mucosa. The immediate placement of customized healing abutments after implant insertion does not prevent the early marginal bone changes that eventually occur, when compared with the use of standard healing abutments.

VI. BIBLIOGRAPHY

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