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Clinical Efficacy of Acellular Dermal Matrix for Soft Tissue Augmentation around Implants: A Systematic Review

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KEYWORDS

Keratinized Mucosa Width,

Implants,

Acellular Dermal Matrix Allograft,

Connective tissue graft,

Free gingival graft

ABSTRACT:

BACKGROUND: Dental implants offer a reliable therapeutic option for tooth replacement therapy. However, biological, prosthetic and aesthetic complications are not rare events. Adequate width of keratinized gingiva is required for periodontal health and prevention of progressive recession of connective tissue attachments. An insufficient amount of Keratinized Mucosa width (KMW) around dental implants is associated with more plaque accumulation, tissue inflammation, mucosal recession and/or attachment loss. It has been demonstrated that a recently developed acellular dermal matrix can facilitate the regeneration of keratinized gingival tissue around implant. The aim of this review is to determine the clinical efficacy of acellular dermal matrix(ADM) for soft tissue augmentation around implants.

METHODOLOGY: An electronic search of the following databases MEDLINE (NCBI PubMed and PMC), Cochrane Central Register of Controlled Trials (CCRCT), Science Direct, Google Scholar, EMBASE, EBSCO, K Hub was done along with a hand search of peer reviewed journals for relevant articles. The following combinations of title, abstract, Medical Subject Heading Terms (MeSH) and keywords were used to search through the above-mentioned database. (Keratinized Mucosa Width) AND (Implants) AND (Acellular Dermal Matrix Allograft) AND (Connective tissue graft) AND (Free gingival graft).

RESULTS: A total of 9 articles were included in this systemic review. Acellular dermal matrix was carried out in the included studies as an al ternative options to different soft tissue augmentation methods for the treatment of implants.

CONCLUSION: The use of Acellular Dermal Matrix is a viable alternative to various soft tissue augmentation techniques around implant.

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INTRODUCTION

The implants are used to anchor prosthetic replacement teeth in the edentulous jaw. Implant designs, surgical placement techniques, healing times, and restorative protocols continue to evolve with the goal of improving outcomes. For tooth replacement therapy dental implants offer a reliable therapeutic option.[1]

The esthetic aspect of peri-implant soft tissue is crucial as it contributes to the natural appearance of the implant-supported tooth. Ideally, the soft tissue should mimic the color, contour, and texture of the adjacent natural teeth. However, achieving optimal esthetics with peri-implant soft tissue can be challenging.[2]

One complication that can arise is peri-implant mucositis, which is an inflammatory condition affecting the soft tissue around the implant. This can lead to redness, swelling, and bleeding, similar to gingivitis. If left untreated, peri-implant mucositis can progress to peri- implantitis, which involves not only inflammation but also bone loss around the implant. Another complication is recession of the peri-implant soft tissue, where the gum tissue around the implant recedes, exposing the implant surface. This can result in an unaesthetic appearance and may also lead to implant sensitivity or implant failure if not addressed timely.To address these complications, various techniques have been developed to enhance peri- implant soft tissue esthetics and health.[3]

Proper soft tissue management is crucial in preventing and treating these complications. Various surgical techniques, such as soft tissue augmentation, can be utilized to enhance the esthetic outcome and maintain the health of the peri-implant soft tissue Additionally, adequate maintenance and regular professional cleanings are imperative to ensure the long- term stability of the soft tissues surrounding the implant. Mucogingival surgery for implants, also known as peri-implant plastic surgery or soft tissue augmentation around implants, is a set of procedures aimed at enhancing the health and aesthetics of the soft tissues (gingiva and mucosa) surrounding dental implants. Here are some common mucogingival surgical procedures related to dental implants:[4]

1. **CONNECTIVE TISSUE GRAFT**: This procedure involves taking a small piece of tissue, often from the roof of the mouth, and grafting it onto the site where soft tissue augmentation is needed. It helps to increase the thickness of the peri- implant mucosa and improve its overall health.

2. **FREE GINGIVAL GRAFT**: Similar to CTG, FGG involves harvesting a pieceof tissue from the palate and placing it onto the implant site. This procedure is often used to increase the width of the keratinized tissue around implants, providing better protection against inflammation and trauma.

3. **PEDICLE GRAFT:** These grafts involve repositioning nearby gingival tissue to cover the implant site. This can be achieved through techniques such as the Coronally Advanced Flap (CAF) or the lateral sliding flap. The goal is to improve the quality and quantity of soft tissue around the implant

4. **VESTIBULOPLASTY:** Sometimes, the depth of the vestibule (the space between the teeth and the lips/cheeks) may be insufficient. Vestibuloplasty is a surgical procedure that aims to increase the depth of the vestibule, providing betteraccess for oral hygiene and improving the aesthetics around the implant.

5. **PAPILLA RECONSTRUCTION**: In cases where the papilla (the gum tissue between two adjacent teeth or implants) is deficient, surgical techniques may be employed to reconstruct and enhance the appearance of the papilla.

6. **SOFT TISSUE CONDITIONING:** This involves procedures to optimize the soft tissue architecture and contour around implants. Techniques may include flap management, tissue sculpting, and other approaches to create a harmonious and esthetically pleasing result.

TREATMENT FOR SOFT TISSUE AUGMENTATION AROUND IMPLANTS:

In accordance with the techniques, various soft tissue augmentation methods and periodontal plastic procedures have been introduced around implants. The primary objective of periodontal plastic surgery is to achieve a stable and complete tissue margin attached at the cementoenamel junction (CEJ), increase the dimensions of keratinized gingiva, such as thickness and width, and maintain a healthy gingival sulcus.[5] In recent decades, various surgical approaches have been

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evaluated to achieve soft tissue augmentation around implants. Soft tissue augmentation around dental implants is a valuable procedure for enhancing esthetics and functional outcomes. By following a systematic treatment protocol and considering patient-specific factors, clinicians can achieve predictable results and improve patient satisfaction with their dental implant restorations. Ongoing monitoring and long-term follow-up are essential to assess the stability and longevity of soft tissue augmentation achieved.[6] Over the years, various approaches have been employed to augment and increase the volume of soft tissues surrounding dental implants. One such technique that has gained significant attention is the use of acellular dermal matrix (ADM). ADM is an allograft material derived from human or animal dermis that has been processed to remove cellular components while preserving the extracellular matrix. This derivative is then reinforced with a natural or synthetic scaffold to provide structural support for tissue regeneration.[7]

Firstly, the ability of ADM to improve peri-implant soft tissue thickness and volume is widely acknowledged. The acellular nature of ADM minimizes host immune response and enhances tissue integration, leading to successful soft tissue regeneration. ADM acts as a scaffold, providing a three-dimensional structure that guides cell migration and promotes neovascularization, resulting in the formation of robust and well-vascularized soft tissue.[8]

This increased soft tissue thickness not only improves aesthetic outcomes but also aids in the prevention of implant exposure and subsequent complications.[9]

Additionally, ADM has proven to be an effective solution in cases where the esthetic zone lacks adequate soft tissue biotype. Thin or recessed soft tissues around implants often result in a compromised aesthetic appearance, with exposed implant components and unaesthetic gingival contours.[10]

ADM provides a biological reserve of tissue that can be used to augment the deficient soft tissue biotype, leading to improved esthetic outcomes. By effectively increasing the thickness and bulk of peri-implant soft tissues, ADM offers a viable solution for cases with challenging esthetic demands.[11]

Furthermore, the stability of augmented soft tissues with ADM has been well-documented. Long-term success relies not only on initial tissue augmentation but also on the preservation of the augmented soft tissue volume over time.[12]

Various studies have shown that ADM contributes to stable and long-lasting peri-implant soft tissue profiles. The matrix provides mechanical stability and rigidity, preventing tissue shrinkage and maintaining the desired tissue volume. The predictable and sustainable outcomes of ADM-supported soft tissue augmentation make it a valuable tool in implant dentistry.[13]

However, despite its numerous advantages, ADM does present some limitations. The availability of ADM can be a challenge, as large quantities may be required for extensive soft tissue augmentation cases. Additionally, the cost associated with the use of ADM may limit its accessibility for some patients. It is essential to consider these practical aspects when weighing the benefits of ADM.[14]

The popularity of ADM for soft tissue augmentation around implants has grown remarkably due to its unique properties and clinical efficacy. Numerous studies have reported favourable outcomes with regards to soft tissue volume, contour, and stability when ADM is used in conjunction with implant placement. This introduction aims to review the clinical efficacy of ADM for soft tissue augmentation around dental implants, highlighting its benefits and limitations.

AIM AND OBJECTIVES

AIM: To answer the following PI(E)COS question.

In soft tissue augmentation around implants, what is the efficacy of ADMA, in terms of Keratinized Mucosa Width (KTW) and Mucosal Thickness (MT)?

Where,

PARTICIPANTS/POPULATION(P) - Patients who underwent soft tissue augmentation on at least one dental implant site.

INTERVENTION(S), EXPOSURE(S) – Studies evaluating ADM as soft tissue augmenting material, keratinized mucosa width around implants will be reviewed.

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COMPARATOR(S)/CONTROL(C) – Other soft tissue regenerating material other than ADM

STUDY DESIGN- In-vivo human randomized and/or controlled clinical trials

PRIMARY OUTCOME- Keratinized tissue width (KTW)

MEASURES OF EFFECT OF PRIMARY OUTCOME- The parameters evaluated in each of the eligible randomized and/or controlled clinical trial, should have been evaluated at baseline and at the subsequent follow-up visit/s as per the criteria specified in each trial.

SECONDARY OUTCOME(S)- Wound healing index (WHI), Plaque index (PI), Probing depth (PD), Bleeding index (BI)

MEASURES OF EFFECT OF SECONDARY OUTCOME(S)- The effects of the additional outcome of each of the eligible clinical trials, should have been evaluated at baseline and at the subsequent follow-up visit/s as per the criteria specified in each trials

OBJECTIVES:

1. To systematically review the literature in order to produce a database of outcome variables that have been utilized for Clinical parameters.
2. Critical appraisal of the primary and secondary outcome variables assessed in the literature with respect to acellular dermal matrix (ADM).
3. To analyze the clinical efficacy of Acellular dermal matrix for soft tissue augmentation around implants over primary and secondary outcomes(s).

MATERIAL AND METHODS

PROTOCOL: A protocol developed following the PRISMA (Preferred Reporting Items for Systematic Review and Meta Analyses) statement (Moher,Liberati,Tetzlaff & Altman, 2009) is followed to report the present systematic review.

ELIGIBILITY CRITERIA: The establishment of eligibility criteria preceded the literature search. The controlled vocabulary Medical Subject Headings (MESH) terms and free keywords for search strategy based on the aforesaid PI(E)COS question were applied.

STUDY CHARACTERISTICS: Parallel or split mouth randomized and/or controlled clinical trials which have evaluated the efficacy of Acellular Dermal Matrix(ADM) as an alternative option to different soft tissue augmentation methods for increasing keratinized mucosa width (KMW) around implants, in terms of clinical or microbiological or immunological profiles were rendered 'eligible' for present systematic review. Narrative literature reviews, case reports, case series, in vitro studies, in vivo animal studies, commentaries, interviews, updates were rendered 'non-eligible' for present systematic review.

REPORT CHARACTERISTICS: A comprehensive search was undertaken from the year of origin of the earliest study to identify and collect evidence from studies which have evaluated the clinical efficacy of acellular dermal matrix(ADM) for soft tissue augmentation around implants in order to answer the PI(E)COS question. Studies published from their earliest records until the date of the searches are run were obtained. The searches were re-run just before the final analyses and further studies, if any, were sought for inclusion. No language restrictions were laid for the search. An attempt to obtain unpublished studies was sought by a formal screening through https://ClinicalTrials.gov/ by entering the same keywords of the search strategy. Correspondence was established with the respective researchers to obtain their study data for grey literature thereby obtained.

STUDY SELECTION:

IDENTIFICATION: The articles were first selected from the database by reading titles and abstracts. The duplicate records were identified and removed.

SCREENING: Two independent reviewers screened the identified publications based upon the following criteria.

STUDIES TO BE INCLUDED:

1. Patients with the presence of implant placement.
2. Randomized Controlled Trials and/or Controlled Clinical Trials comparing the clinical efficacy of acellular dermal matrix(ADM) for soft tissue augmentation around implants.
3. In-vivo human randomized and/or controlled clinical trials with parallel and/or split-mouth designs.
4. Patients between 18-80 years of age
5. Patients with no prior experience of implant.

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6. Studies reporting at least one of the following parameters as an outcome variable: Patient with clinical outcome at least 3 months follow up showing gain in keratinized mucosa width (KMW), Wound healing index (WHI), Plaque index (PI), Probing depth (PD), Bleeding index (BI).

STUDIES TO BE EXCLUDED:

1. Subjects with any systemic disease.
2. Current smoking.
3. Randomized Controlled Trials and/or Controlled Clinical Trials not involving the efficacy of any other regenerative material than acellular dermal matrix in the treatment of soft tissue augmentation around implant.
4. Pregnant or lactating women.
5. Subjects who have undergone any periodontal therapy and/or antibiotic therapy in the last 6 months.
6. Adolescents (under 18 years of age) and elderly people (over 80)
7. No outcome variable of interest
8. Narrative literature reviews, case reports, in vitro studies, in vivo animal studies, commentaries, interviews, updates, case series.

ELIGIBILITY: The full texts of selected studies were acquired and the reference lists of all the primary articles were screened for any additional relevant studies. All the full text articles were analysed by two independent reviewers for final eligibility in the systematic review.

DATA COLLECTION PROCESS: After a manual and electronic search, studies found through duplicate searches were eliminated and the title and abstract of possibly eligible studies were noted. Further, studies which do not fulfill the eligibility criteria were eliminated. Then, full-text detailed reading of the narrowed-down studies was carried out, and studies that do not fulfill the eligibility criteria were excluded. This formal screening was performed independently by two individual review team members. Any disagreement between them was resolved by a third reviewer. All the eligible studies were assessed for study quality and evidence synthesis.

DATA ITEMS: Each study was assigned an exclusive Reference ID for easy identification and simplification of data collection procedure. The Reference ID was prepared with the initials of first author and alphabetic order

1. Name of the authors.
2. Year and origin of the study
3. Journal of publication
4. Study population
5. Study design
6. Sample size
7. Demographics of the participants
8. Baseline characteristics
9. Intervention and comparator groups.
10. Acellular dermal matrix used
11. Clinical parameters
12. Follow-up duration
13. Statistical tests performed
14. Results
15. Conclusion.

A similar search strategy and eligibility criteria will be applied to obtain grey literature (unpublished data). In case of missing data in any of the eligible trials, it will be requested through formal correspondence with the respective study authors.

RISK OF BIAS ASSESSMENT IN INDIVIDUAL STUDIES: Bias refers to the tendency of a measurement process to over or underestimate the value of a population parameter. Assessment of bias is mainly concerned with the issues that are likely affect the ability to draw reliable conclusions from the study. So, it forms an integral part of qualitative analysis of the evidence in a systematic review.

- All the eligible studies were subjected to a qualitative assessment, performed for every eligible study independently using risk of bias (quality) assessment. The Revised Cochrane Risk-of-Bias tool for Randomized trials, Version 2.0 (RoB 2)102 was used to perform the quality assessment of eligible studies.
- ROB 2 tool provides a framework for considering the risk of bias in the findings of any type of randomized trial. It assesses each trial intricately under five major domains whose name clearly describes the causes of bias addressed by that particular domain. The assessment is performed at an individual study level.
- Bias arising due to randomization process
- Bias due to deviations from intended interventions

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- Bias arising due to missing outcome data
- Bias in measurement of the outcome
- Bias in selection of the reported result.

A template constructed according to the design of the randomized trial was used to address the above-mentioned domains. Response of two individual reviewers were recorded. Free textboxes were utilized to provide information to support the response. Risk of bias judgement was assigned for each domain. Optional judgements provided in the tool was utilized to ascertain the direction of the bias for each domain. Finally, an overall risk of bias was determined for each study considering individual risk of bias judgement for each domain and an overall risk of bias judgement and direction of the bias was concomitantly determined. (Annexure)

Disagreements between the review authors over the risk of bias in particular studies were resolved by discussion, with the involvement of a third review author, wherever necessary.

SUMMARY OF MEASURES/MEASURES OF EFFECT: The parameters evaluated in each of the eligible clinical trials, should have been evaluated at baseline and at the subsequent follow-up visit/s as per the criteria specified in each trial.

SYNTHESIS OF RESULTS: The extracted data were analyzed and numeric values in the studies for the measured variables were recorded and compared. The studies reporting clinical data were segregated. The numeric values of all the assessed parameters were recorded. Details about Acellular dermal matrix used were also recorded.

RESULT

STUDY SELECTION:

A full search from multiple databases resulted in 2567 articles. Relevant articles were identified by two independent reviewers, 2371 duplicates were removed. 196 articles were selected for full text evaluation after screening the title and abstracts. For publications in which only abstracts were available, full texts were requested and obtained. For publications in languages other than English, the corresponding authors were contacted and requested for translated version of the manuscript. 90 articles of in vitro and animal studies were excluded. Only In-vivo human studies were included. 106 articles of in vivo human studies were found. By applying the inclusion criteria, 86 articles were excluded. Total articles fulfilling the inclusion criteria were 9. Therefore 9 articles fulfilled the criteria to be included in the current systematic review. Data was extracted from these publications and was critically analyzed for efficacy of acellular dermal matrix for soft tissue augmentation around implants

CHARACTERISTICS OF INCLUDED STUDIES:

All the included studies were in-vivo trials conducted on human subjects. Randomized clinical trials were included. Out of 9 included studies, 4 were conducted in accordance with the guidelines by the World Medical Association Declaration of Helsinki. All authors of the included studies sought approval of the protocol from Ethical Committee. Amongst the included randomized clinical trials, one was split mouth design. (TABLE 1) Out of 9 studies, 4 studies were conducted in Turkey, Brazil, San puol, Ann harbour and 1 in Pune India; rest of them were conducted in Lowa, Bejing, Germany, etc. Average sample size of the included studies was 12-45 participants. Mean age of the participants was 18-80 years. The participants in each trial were selected as per the inclusion criteria of individual trial based upon age and periodontal status. Written informed consent was obtained by participant population as reported in 9 of the included studies.(TABLE 2)

SUMMARY OF METHODOLOGICAL CHARACTERISTICS OF STUDIES ON ACELLULAR DERMAL MATRIX IN SOFT TISSUE AUGMENTATION AROUND IMPLANTS:

Acellular dermal matrix was carried out in the included studies as an alternative option to soft tissue augmentation method around implants. All the included studies used different brands of acellular dermal matrix available to them for the treatment of soft tissue augmentation around implants. 1 study used coronally advanced flap(CAF) technique, 3 studies used acellular dermal matrix with immediate implant placement, 5 studies used acellular dermal matrix after placing implant. 2 studies included free gingival graft (FGG) in the control group while 2 studies only had acellular dermal matrix in test group and no graft was placed in the control group. 5 studies included connective tissue graft (CTG) in the control group. 3 studies did not specified

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the no. of implants treated with acellular dermal matrix while in other 6 studies in range 7-36 implants were treated with acellular dermal matrix. (Table 3)

SUMMARY OF PRIMARY AND ADDITIONAL OUTCOMES MEASURED:

Clinical Parameters were measured in 9 studies which included keratinized tissue width (KTW), wound healing index (WHI), plaque index (PI), gingival index (GI), probing depth (PD), bleeding index (BI).

(Table 4)

SUMMARY OF CLINICAL PARAMETERS EVALUATED AND METHOD OF EVALUATION:

All the studies evaluated the clinical parameters keratinized tissue width (KTW), wound healing index (WHI), plaque index (PI), gingival index (GI), probing depth (PD), bleeding index (BI) UNC 15 type periodontal probe (Hu-Friedy, Chicago, IL, USA).

RESULT OF INDIVIDUAL STUDIES

COMPARING KERATINIZED TISSUE WIDTH:

9 studies compared keratinized in the test group (acellular dermal matrix) with the control group of which all the studies showed better results in test group and control group, where as in three studies (Basegmez C et al, Naddafpour N et al, Panwar M et al) showed more better results in control group.

COMPARING WOUND HEALING INDEX:

Out of 9 studies, 2 studies compared wound healing index in test group(acellular dermal matrix) with control group of which one study (Anderson LE et al) showed better result in control group than test group. While another study (Hutton CG et al) showed significant result both in test and control group.

COMPARING PLAQUE INDEX:

Out of 9 studies, 3 studies (Basegmez C et al, Naddafpour N et al, Zang J et al) compared plaque index in test group (acellular dermal matrix) with control group of which all the three studies showed better results in test group than control group.

COMPARING GINGIVAL INDEX:

2 studies out of 9 studies compared mean gingival index in the test group (acellular dermal matrix) with the control group out of which both the studies (Basegmez C et al, Naddafpour N et al) showed significantly better results in test group than control group.

COMPARING PROBING DEPTH:

Out of 9 studies, 4 studies compared probing depth in test group (acellular dermal matrix) with the control group out of which 3 studies (Naddafpour N et al, Zang J et al, Abbas WM et al) showed significant difference in the values of both groups. In one of the study (Basegmez C et al) probing depth showed increased values during the follow up in the control group than the test group.

COMPARING BLEEDING INDEX:

2 studies (Zang J et al, Abbas WM et al) out of 9 studies compared bleeding index in test group (acellular dermal matrix) with the control group of which both the studies showed significant results in test group and control group.

RISK OF BIAS WITHIN THE INCLUDED STUDIES

The risk of bias of the included studies was evaluated using the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions. An overall assessment for the Risk of Bias showed a high risk for 2 studies, risk of some concerns for 2 studies while low risk of bias for 5 studies. Domain 1 of the Risk of Bias Assessment tool checks for bias arising from randomization process within the studies. It was found to be of low for 7 studies, some concerns for 1 study while it was high for 1 study. Domain 2 analyses the trials to check bias arising due to deviation from intended intervention and assesses the effect of adherence to interventions. It was found to be low for 7 studies, high for 1 study while some concerns for only 1 study. Domain 3 judges the trials based upon availability or missingness in reporting data related to outcomes. Risk of bias arising due to missing outcome data was low for 7 studies and risk of some concerns for 1 study. Domain 4 of the tool focuses on reporting bias arising in measurement of outcome. It was some concerns for 1 study while it was low risk for 7 studies. Domain 5 reports the risk of bias arising in selection of the reported result. It was low risk for 7 studies, high risk for 1 study while 1 study showed some concerns. (TABLE 5)

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DISCUSSION:

Treating soft tissue augmentation around implants is challenging and tough for both clinicians and patients, mainly due to the inconsistent success rates of various treatments. Furthermore, the predictability of treatment outcomes can vary significantly depending on the specific surgical technique employed and the type of soft tissue augmentation method or biomaterial used. Biomaterials have been developed as a replacement for traditional gingival grafts in order to minimize surgical risks, morbidity, clinical time, and enhance patient compliance. Traditional methods of soft tissue augmentation, often involving autogenous grafts, present challenges such as donor site morbidity and limited graft availability. ADM, being a collagen-based scaffold devoid of cellular components, provides an alternative that addresses these limitations.[15]

ADM finds applications in a range of dental implant procedures, with its primary role being in soft tissue augmentation. Its versatility extends to addressing challenges such as inadequate keratinized tissue, gingival recession, and achieving harmonious peri-implant esthetics. ADM serves as a scaffold for new tissue formation, promoting the integration of host cells and contributing to the development of a stable and functional soft tissue environment around dental implants. As research on ADM in dental implants continues to evolve, future directions should focus on refining processing techniques, establishing standardized protocols, and conducting large-scale, long-term clinical trials.[17]

Innovations in ADM technology, such as the incorporation of growth factors or bioactive agents, hold potential for enhancing tissue regeneration and further improving clinical outcomes. In present systematic review, results showed a significant increase in KMW when soft tissue grafts, either autogenous or substitutes, were used in combination with ADM, while no statistically significant KMW gain was obtained following any of the bilaminar techniques. All of the APF(Apically positioned flap) treatment groups (FGG, CTG and ADM) showed superior KMW compared to non-augmented control sites.

The present systematic review has been evaluated an RCTs on clinical efficacy of Acellular dermal matrix for soft tissue augmentation around implants. This study follows a protocol in order to avoid potential bias in the data. In the RCTs, two types of study designs have been used one is a split -mouth design and another is a parallel-arm study design. From the electronic search, the data was obtained from the year of origin till the year 2023.

Nine RCTs fulfilled the inclusion criteria with systemically healthy patients in need for implant placement and with a minimum follow-up period of 3 months. These RCTs have evaluated the effectiveness of Acellular dermal matrix for soft tissue augmentation around implants. Out of nine, one study was split-mouth design, one was parallel-group design and other were single blinded studies.

The heterogeneity among the studies may be due to differences in the types of grafts used. No significant adverse effects of acellular dermal matrix were noted in treatment of soft tissue augmentation around implants.

The results of the present systematic review indicates that acellular dermal matrix produces statistically significant improvements in terms of outcomes variables such as BI, PI, GI, WHI, KMW and PD when compared with other grafts. In some studies it showed more significant improvements in terms of soft tissue augmentation around implants for a longer follow up when compared to CTG, SCTG and FGG.

In present systematic review, 9 studies compared keratinized tissue width, 2 studies compared bleeding index, 4 studies compared probing depth, 2 studies compared gingival index, 2 studies compared plaque index, 2 studies compared wound healing index. Probing depth, Gingival index, Plaque index showed nearly non-significant results between the test and control group in the included studies.

Basegmez C et al 2013[16] investigated the clinical efficacy to increase the dimension of peri-implant keratinised mucosa. Postoperative outcomes one month after the procedures were found to be similar with both grafting techniques. However, there was a 50% postoperative relapse in the amount of attached mucosa around implants at 6 months with ADM application. **Karring et al (1975)**[18] suggested that only connective tissues have the ability to induce epithelial keratinization, and the characteristics of the formed epithelium are determined by the genetics of the connective tissue. Plaque and gingival indices significantly decreased in

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both groups at 1, 3, and 6 months post-surgery. Nonetheless, the ADM group exhibited higher plaque and inflammation scores, and the reduction in probing depth was less at 6 months. While all subjects in the FGG group reported severe pain at the donor site, none of the patients in the ADM group complained about pain. It was observed that ADM allograft application resulted in better tissue blending and color match compared to FGG delivery.

Anderson LE et al 2014 reported the first pilot study investigating SCTG and ADM grafting techniques for implant application in a randomized controlled manner. They discovered that a thicker biotype did not consistently result in better outcomes for recession or concavity correction. To address horizontal bone deficiencies or concavity defects, researchers employed guided bone regeneration, onlay block grafts, or ridge split techniques before implant therapy. An average horizontal gain of 1.72 ± 0.59 mm, which represented a 58.9% correction of concavity (1.22 ± 0.46 mm or 41.4% shrinkage) at 6 months, was observed. Bone thickness was not assessed or defined in this study. At 1 year, coverage was achieved in 96.3% of cases, with complete coverage found at 75% of the sites. Due to the nature of the pilot protocol, there are no comparative studies examining the impact of bone thickness on implant soft tissue grafting outcomes.[19,20] Increasing the width of keratinized mucosa with free gingival grafts was shown to reduce soft tissue recession and resorption of crestal buccal bone in the short term.[21] This study revealed that the average buccal plate thickness of implants with compromised esthetics is 0.58 mm. Research assessing esthetics using ADM generally demonstrates better results compared to free gingival grafts.[22] Wound healing was incomplete at 6 weeks in ADM-treated sites, whereas complete healing was observed at this time around SCTG sites. When ADM was compared with free gingival grafts and SCTG, the likelihood of swelling and bleeding was significantly reduced. ADM was recommended as a grafting material because it reduced surgical time and consequently, swelling and bleeding.[23]

Riberio S et al 2015 histologically evaluated the use of ADM without vertical releasing incisions to attempt primary closure, not only preserved the MGL on its original position, but also led to an increase in the zone of keratinized tissue. The teeth chosen for this investigation were mandibular single molars and bicuspids, where the mucogingival line (MGL) is clearly delineated on both the buccal and lingual aspects. In this research, it appeared that ADM became integrated into the host tissues around the fifth week. Soft tissue enhancement was notably greater in the test group, with an average of 4.40 ± 1.45 mm, compared to 1.40 ± 1.40 mm in the control group. The ADM effectively maintained ridge thickness while simultaneously increasing the zone of keratinized tissue. Augmenting the zone of keratinized mucosa as a preparation for implant placement is an important consideration for long-term implant health. [24]

Hutton CG et al 2018 assessed the soft tissue compensation in response to alveolar bone. In non-grafted sites with an initially thin bone phenotype, the soft tissue thickness increased an average of 4.8 mm. Similarities were observed between groups in terms of changes in mid-buccal keratinized mucosa width (KMW), wound healing, and patient-reported outcomes. Implants inserted in sites with thin crestal tissue (< 2 mm) that were simultaneously thickened with a soft tissue allograft exhibited comparable behavior to sites with initially thick tissue. Sites with initially thin tissue that did not receive grafting experienced a significantly greater amount of bone loss (1.2 ± 0.08 mm) compared to the thin-grafted and thick groups (0.22 ± 0.06 mm).[25]There was a lesser increase in soft tissue thickness at measurements taken 1 mm apical to the planned restorative margin. Changes in peri-implant mucosal thickness (PMT), which was the primary outcome, did not significantly differ between treatment groups but showed slight variations depending on the apico-coronal height relative to the mucosal margin. In this study comparing thin (≤ 2 mm) versus thick (> 2 mm) mucosal thickness, a statistically significant difference was observed in peri-implant bone loss (0.6 ± 0.5 mm vs. 0.2 ± 0.4 mm), favoring sites with thicker tissue. The reduction in KMW was relatively small, less than 1 mm in all instances where a correlation was noted. The researchers acknowledged that thicker PMT is positively correlated with esthetic outcomes and carries a lower risk for tissue recession, particularly around immediate implants.[26]

Naddafpour N et al 2019 clinically evaluated significant increase in width of attached gingiva at three months in both groups; however, the increase in attached gingiva was significantly greater in FGG group. Despite utilizing

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wider grafts in the ADM group, there was observed to be a smaller increase in the width of attached gingiva and greater graft shrinkage, which aligns with our own findings. It was concluded that ADM was less effective than FGG, and the treatment outcomes with ADM were less predictable due to the higher degree of graft shrinkage. However, the use of ADM offers several advantages, including the absence of a need for a second surgical site for graft harvesting, resulting in less pain and discomfort for the patient, shorter surgical duration, and favorable aesthetic results.[27] The final width of attached gingiva at three months was reported to be 2 mm. The increase in width of attached gingiva was greater in the FGG group at both three and six months. Additionally, relapse of plaque index (PI) and gingival index (GI) occurred more frequently in the ADM group. In our study, CenoDerm was placed on non-keratinized tissue, whereas FGG is harvested from the keratinized tissue of the palate and therefore, would possess similar properties at the recipient site. The periodontal parameters at three months did not exhibit significant differences between the two groups. The probing depth (PD) at three months significantly improved in the CenoDerm group; however, it was only statistically significant and not clinically significant, as both values were within the clinically acceptable range for periodontal health. The level of postoperative pain and discomfort experienced by patients was not measured in the current study.

Abbas WM et al 2020 showed that implants placed in fresh extraction sites can provide a safe and successful treatment procedure. This study demonstrated a 100% survival rate of immediate implants. However, immediate implant placement with simultaneous soft tissue augmentation using either SCTG or ADMA did not lead to improvements in the width of keratinized mucosa. Regarding changes in keratinized mucosa width (KM) in this study, the SCTG group experienced a loss of 0.858 ± 1.199 mm, while the ADMA group lost an average of 0.357 ± 1.488 mm. Both groups exhibited a Pink Esthetic Score (PES) of 7.00 at the 4-month follow-up interval. The uniform thickness of ADMA, especially when compared to SCTG, may positively influence flap and graft adaptation. A statistically significant difference in the mean bleeding index (BI) was observed between both groups at the 12-month follow-up intervals, where the mean BI associated with implants placed immediately following tooth extraction with SCTG was significantly higher than that associated with implants placed immediately following tooth extraction with ADMA. The advantages of ADMA include avoiding the need for a second surgery to harvest autogenous soft tissue at the donor site, reduced operative time, and not requiring a skilled clinician. However, the high cost of ADMA could be considered a disadvantage of this material. Limitations of the present study include its short-term follow-up and small sample size

Panwar M et al 2022 reported that on intragroup comparison, there was a statistically significant decrease in papillary height postoperatively in mesial and distal locations of group A and the distal location of group B, whereas decrease was non-significant in mesial papillary height in group B. Group B exhibited a statistically significant increase of 0.65 ± 0.0411 mm in keratinized tissue width (KTW). Conversely, in group A, a statistically significant decrease of 0.250 ± 0.2635 mm in KTW was observed. The postoperative gingival thickness in both groups was statistically significant; however, it was not sufficient to produce a change in the gingival biotype in either group. The observed loss was partly attributed to flap advancement to submerge the immediate implant but predominantly due to the frequent occurrences of graft exposures resulting from wound dehiscence. Interestingly, in some case reports, ADM has shown an increased width of keratinized mucosa when placed under a partial thickness flap.[28] The absence of immediate provisionalization in the study resulted in papillary collapse.[29] Long-term studies have revealed that a thin gingival biotype is often associated with a significantly lower dimension of peri-implant gingiva compared to thicker tissue biotypes.[30]

Happe A et al 2022 concluded that cumulative implant success rate following single immediate tooth replacement and soft tissue augmentation with a xenograft or autogenous graft was 100%.The ADM group exhibited a pink appearance for all grafts after a 2-week period. Within the constraints of this study, the findings indicate that utilizing ADM as an alternative to CTG alongside immediate implant placement demonstrated favorable biocompatibility and clinical performance. All patients reported the absence of pain 14 days after surgery. A common complication of immediate implant placement in fresh extraction sockets is the three-dimensional volume change that occurs

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during healing, potentially leading to recession and aesthetic concerns.[31,32] In this study, the horizontal ridge change 12 months post-implant placement was less than 1 mm for all cases, with no significant difference observed between the groups in terms of volume change. Limitations of this study include the small number of patients and the relatively short 1-year follow-up period. The results suggest that using ADM resulted in significantly less postoperative morbidity for patients, with comparable outcomes in terms of volume stability. The utilization of ADM in dental implantology may alleviate patients' postoperative morbidity and facilitate treatment

Zang J et al 2022 clinically and histologically evaluated the efficacy of using acellular dermal matrix (ADM) for peri-implant vertical soft tissue augmentation at implant placement over 6 months. The findings revealed that soft tissue thickness was similar between the two groups at the second-stage surgery (3.20 ± 0.42 mm vs. 3.50 ± 0.58 mm), and a mean increase of 1.85 mm in vertical soft tissue was noted at 3 months postoperatively in the ADM group. The incremental thickness gain observed in this study was adequate for the ADM group to achieve comparable clinical outcomes to the control group. When used to address a deficiency of keratinized tissue, the ADM group exhibited a lower proportion of cellularity and blood vessels but a higher presence of inflammatory infiltrates compared to the free gingival graft (FGG) group. The current study examined the histological outcomes of peri-implant increased vertical mucosa, revealing that the soft tissue in the ADM group appeared mature and organized, similar to the control group. The expression level of VEGF in tissue reflects angiogenesis stimulation during wound healing, while the degree of angiogenesis can be assessed by MVD.[33] The results indicated that there was no significant difference in the percentage of VEGF-positive cells between the ADM group and the control group (37.2 ± 3.09 vs. 37.7 ± 3.79), and the MVDs were also comparable between the two groups (29.12 ± 4.34 vs. 32.73 ± 3.78). VEGF and PDGF-BB levels were notably lower in the ADM group compared to the control group at T0 (1 week after second-stage surgery). However, at subsequent time points (1 month and 5 months after second-stage surgery), both cytokines exhibited similar low levels in the two groups. VEGF and PDGF-BB play crucial roles in the wound healing process.[34]

Arthur BN et al 2001 conducted a case report to evaluate the use od the ADM material as a membrane for bone regeneration. Planned extraction was undertaken, with consideration given to immediate implantation in the bicuspid area. Full-thickness flaps were raised both buccally and palatally.[35] After careful debridement, a longitudinal fracture on the distal-buccal surface of the cuspid, along with a resorptive process of the buccal plate, was identified. The tooth was extracted meticulously without buccal-palatal luxation.[36] The buccal and palatal flaps were repositioned and sutured without coronal displacement, deliberately leaving the mid-portion of the ADM graft exposed to promote an increase in the width of keratinized tissue.[37] Four weeks after the procedure, the exposed surface of the Alloderm graft demonstrated successful healing. The ADM material met the necessary criteria for this case, facilitating bone regeneration while enhancing the width of keratinized tissue in the cuspid area. The healing process progressed smoothly, surpassing the observed healing patterns with other membrane materials.[38] The outcomes observed in this case warrant further investigation through controlled clinical studies to explore the potential routine clinical utilization of ADM material as a GBR membrane.

P. Papi et al 2020 conducted a prospective cohort study to evaluate the 2-year follow-up results of early implant placement with simultaneous peri-implant augmentation using an acellular dermal matrix (ADM) and a synthetic bone substitute in the aesthetic zone.[39] In this investigation, a biphasic alloplastic material comprised of 60% hydroxyapatite (HAP, Ca10(PO4)6OH)2 and 40% β-tricalcium phosphate (β-TCP, β-Ca3(PO4)2) was utilized. **Di Raimondo et al (2020)[40]** demonstrated the efficacy of a synthetic bone substitute graft consisting of 60% HA + 40% β-TCP in lateral bone augmentation alongside dental implant placement, yielding comparable outcomes to deproteinized bovine bone material. The primary benefits of integrating implant placement with guided bone regeneration (GBR) and soft tissue peri-implant augmentation using an ADM are to minimize patient invasiveness, eliminate the need for palatal harvesting and its potential postoperative complications, streamline surgical procedures, and reduce the frequency of surgical interventions. A notable increase in soft tissue thickness of 1.9 mm was achieved after 2 years, with no

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decline observed between the 12- and 24-month intervals.

P. Algirdas et al 2014 conducted a case series to evaluate the efficiency of acellular dermal matrix membrane to augment vertical peri-implant soft tissue thickness during submerged implant placement. The utilization of allograft alongside implant placement in a two-stage procedure led to a statistically significant elevation of peri-implant soft tissue height, as assessed during the connection of the healing abutments.[41] This approach facilitated the conversion of thin soft tissues, with an average thickness of 1.54 mm, to thick soft tissues measuring approximately 3.75 mm on average. **Wei et al (2000)[42]** demonstrated the successful use of ADM for various purposes, including increasing keratinized tissue, root coverage procedures, deepening the vestibular fornix, and augmenting localized alveolar defects. **Silverstein et al (1999)[43]** in a clinical trial, the acellular dermal alloplastic graft material exhibited clinical and histological characteristics similar to the patient's own palatal donor tissue after 3 months of healing. ADM membranes can effectively be employed for vertical soft tissue augmentation concurrently with submerged implant placement, resulting in an average gain of 2.34 mm, depending on the initial mucosa thickness. Favorable clinical integration of the material and complete resemblance to the adjacent healthy mucosal tissues can typically be anticipated as early as 3 months postoperatively.[44]

Piero. P et al 2020 conducted a prospective cohort study to report clinical and volumetric three-dimensional changes in mucosal thickness (MT) 1 year after treatment with an acellular dermal matrix (ADM).[45] This study also demonstrated an increase in buccal contour through both volumetric and linear digital measurements. A recent systematic review of randomized controlled clinical trials concluded that the utilization of collagen matrix is as effective as connective tissue grafting in augmenting both mucosal thickness (MT) and keratinized mucosa (KM) width.[46] A recent randomized controlled trial (RCT) assessed the effects of acellular dermal matrix (ADM) in preserving soft tissue thickness during alveolar ridge preservation with buccal overlay using a xenograft. According to their findings, there were no statistically significant differences in the gain of soft tissue thickness after 4 months between the ADM and no-membrane groups (1.1 ± 1.0 mm versus 0.9 ± 0.8 mm, respectively).[47] Digital linear and volumetric measurements indicated an increased area of the region of interest (ROI), with subsequent shrinkage between the time-points, consistent with previous research. The application of ADM during the second-stage surgery appears to be an effective approach for achieving peri-implant soft tissue augmentation, with all implants surpassing and maintaining their outcomes throughout the study duration..

The present systematic review included an evaluation of the various studies selected for inclusion, in accordance to the Revised Cochrane Risk Bias Tool for Randomized Trials edited by " Julian PT Higgins and their co-authors in 2019" which is more modified and highly considered as RoB2 tool. The majority of studies were rated as "Low risk of bias" i.e. 10 of the included studies. There was lack of information regarding blinding of participants, personnel, outcome assessment, data of missing patients, size and placement of acellular dermal matrix, sample size calculation was observed in the studies

CONCLUSION

Acellular Dermal Matrix has demonstrated its efficacy in addressing soft tissue deficiencies around dental implants, offering a viable alternative to traditional grafting methods. Its unique properties, coupled with positive clinical outcomes, position ADM as a valuable tool in the armamentarium of implant dentistry. As the field continues to advance, ongoing research and innovations will likely refine the application of ADM, contributing to improved esthetic and functional outcomes in dental implant procedures. The properties of ADM, including its collagen-rich composition and customizable thickness, contribute to its adaptability in addressing various challenges associated with peri-implant soft tissues. Studies assessing the clinical efficacy of ADM consistently demonstrate positive outcomes, with improvements observed in parameters such as soft tissue thickness, gingival recession, and overall patient satisfaction. While ADM presents a compelling alternative to traditional grafting methods, it is essential to acknowledge potential challenges and considerations. Variability in matrix properties, the remote possibility of disease transmission, and cost factors may influence its widespread adoption. Looking ahead, future directions in ADM research should focus on refining processing techniques, establishing

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standardized protocols, and conducting robust, long-term clinical trials. Innovations, such as incorporating growth factors or bioactive agents, hold the potential to further enhance tissue regeneration and improve overall clinical outcomes.[48]

TABLE 1: STUDY CHARACTERISTICS

SR NO.	AUTHOR NAME (Year of the study)	JOURNAL NAME	STUDY DESIGN	APPROVAL OF PROTOCOL	CONDUCTED IN ACCORDANCE WITH
1	Basegmez C et al 2013	European journal of oral implantology	Randomised, controlled, double-blinded trial	NS	Helsinki Declaration of 1975, as revised in 2000.
2	Anderson LE et al 2014	The official journal of the international congress of oral implantologists	A single center, randomized controlled clinical trial	Approved by the Institutional Review Board for the Medical Sciences at the University of Michigan, Ann Arbor, MI	NS
3	Ribeiro S et al 2015	The official journal of the international congress of oral implantologists	Randomized controlled trial	Independent committee on the Ethics of Human Research of Fluminense Federal University (CEP/HUAP #068/06),	Declaration of Helsinki
4	Hutton CG et al 2018	Journal of Periodontology	Single-masked, parallel arm, non-inferiority randomized clinical trial	Institutional Review Board approval from the University of Iowa (Hawk IRB Approval #201407810)	NS

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5	Naddafpour N et al 2019	Journal of International Dental and Medical Research	Randomized controlled trial	The ethics committee of Qazvin University of Medical Sciences (Ethical code: 28/20/10038)	Declaration of Helsinki
6	Abbas WM et al 2020	Egyptian Dental Journal	Comparative Randomized controlled trial	The ethical committee for clinical studies of Faculty of Dentistry, Ain Shams University	NS
7	Panwar M et al 2022	Medical Journal Armed Forces India	Randomized controlled trial	NS	NS
8	Happe A et al 2022	International Journal of Periodontics & Restorative	Randomized controlled trial	Approved by the local ethical committee (2012-513-b-S)	Declaration of Helsinki
9	Zang J et al 2022	Clinical Oral Implants Research	Randomized controlled trial	Approved by the Institutional Review Board of Peking University School and Hospital of Stomatology (No. PKUSSIRB-202057114)	CONSORT guidelines

TABLE 2: PARTICIPANT CHARACTERISTICS

SR NO	AUTHOR NAME	GEOGRAPHIC AREA	MEAN AGE (in years)	GENDER	CONSENT	SAMPLE SIZE	TYPES OF GRAFT USED

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1	Basegmez C et al 2013	Turkey	35-65	NS	Obtained	36 patients	ADM FGG
2	Anderson LE et al 2014	Ann Arbor, MI	30-70	NS	Obtained	13 patients	SCTG ADM
3	Ribeiro S et al 2015	Rio de Janeiro, Brazil	20-48	Female-22 Male-8	Obtained	30 patients	ADM
4	Hutton CG et al 2018	Low a city	18-80	Female-9 Male-11	Obtained	20 patients	CTG ADM
5	Naddafpour N et al 2019	Qazvin, Iran	25-70	NS	Obtained	16 patients	FGG ADM
6	Abbas WM et al 2020	Ain Shams University	22-45	NS	Obtained	14 patients	SCTG ADM
7	Panwar M et al 2022	Pune	18-60	NS	Obtained	20 patients	CTG ADM
8	Happe A et al 2022	Germany	33-71	Female-9 Male-11	Obtained	20 patients	ADM CTG
9	Zang J et al 2022	Beijing, China	21-80	NS	Obtained	20 patients	ADM

TABLE 3: METHODOLOGICAL CHARACTERISTICS

SR NO	AUTHOR NAME	NO. OF PATIENTS IN TEST/ CONTROL GROUP	NO. OF IMPLANTS TREATED WITH ADM	INTERVENTION GROUP (ACELLULAR DERMAL MATRIX)	CONTROL GROUP	FOLLOW UP
1	Basegmez C et al 2013	18/18	36	ADM + classic procedure	FGG	1,3 And 6 months
2	Anderson LE et al 2014	6/7	12	ADM+ CAF	SCTG	14days, 6weeks, 3 and 6 months
3	Ribeiro S et al 2015	15/15	15	ADM	NO GRAFT	14 days and 3 months

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4	Hutton CG et al 2018	10/10	NS	ADM	CTG	14 days and 3 months
5	Naddafpour N et al 2019	8/8	NS	ADM	FGG	3 months
6	Abbas WM et al 2020	7/7	7	ADM+IIP	SCTG+IIP	4months and 12 months
7	Panwar M et al 2022	10/10	10	ADM+IIP	CTG+IIP	3months
8	Happe A et al 2022	10/10	10	ADM+IIP	SCTG+IIP	4months and 12 months
9	Zang J et al 2022	10/10	NS	ADM	NO GRAFT	3months

TABLE 4: SUMMARY OF PRIMARY AND ADDITIONAL OUTCOMES

SRNO	AUTHOR NAME	CLINICAL PARAMETERS						
		KERATINIZED MUCOSA WIDTH (KTW) (BASELINE/ FOLLOW UP)	WOUND HEALING INDEX (WHI) (BASELINE/ FOLLOW UP)	PLAQUE INDEX (PI) (BASELINE/FOLLOW UP)	GINGIVAL INDEX (GI) (BASELINE/ FOLLOW UP)	PROBING DEPTH (PD) (BASELINE/ FOLLOW UP)	BLEEDING INDEX (BI) (BASELINE/ FOLLOW UP)	
1	Basegmez C et al 2013	Test (0.89 ± 0.31 /2.47 ± 0.32†) Control (1.01 0.34 (1.02 3.58 ± 0.40†)	-	Test (1.12 ± 0.15/0.35 ± 0.29†) Control (1.38 ± 0.45/0.12 ± 0.16†)	Test (1.71 ± 0.19/0.29 ± 0.33†) Control (1.57 ± 0.32/0.19 ± 0.17†)	Test (4.06 ± 0.30 /3.22 ± 0.15 †) Control (4.80 ± 0.58 /3.33 ± 0.27 †)		

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2	Anderson LE et al 2014	Test (1.75/2.17) Control (1.00/1.86)	Test (1.5/1) Control (2.5/1)	-	-	-	-	
3	Riberio S et al 2015	Test (2.40 ±0.54/ 4.40 ±1.45) Control (0.48 ±0.32/1.40 ± 1.40)	-	-	-	-	-	
4	Hutton CG et al 2018	Test (4.95 ± 1.38/ 4.50 ± 0.94) Control (5.30 ± 1.16 /4.45 ± 1.14)	Test (1.90±0.57/ 1.00±0.00) Control (1.70±0.48/ 1.00±0.00)	-	-	-	-	
5	Naddafpour N et al 2019	Test (0.17 ± 0.39/ 2.58 ± 0.9) Control (0.12 ± 0.35/ 4.38 ± 0.744)	-	Test (1.5 ± 1.0/ 0.9 ± 0.8) Control (1.12 ± 0.6/ 1.06 ± 0.6)	Test (0.4 0 ± 0.5/ 1 ± 0.0) Control (0.62 ± 0.75/0.15 ± 0.75)	Test (1.5 ± 0.5/ 1 ± 0.0) Control (1.38± 0.5/ 1 ± 0.0)		
6	Abbas W M et al 2020	Test (4.786/4.429) Control (4.429/3.571)	-	-	-	Test (2.850/2.506) Control (2.806/2.903)	Test (0.866/0.666) Control (0.738/0.929)	
7	Panwar M et al 2022	Test (3.200 ± 0.4216/2.950 ± 0.2838) Control (2.8 ± 0.788 /3.4 ± 0.864)	-	-	-	-	-	
8	Happe A et al	Test (– 0.23 ± 0.128 /–	-	-	-	-	-	

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	2022	0.55 ± 0.330) Control (– 0.22 ± 0.116 /– 0.60 ± 0.491)						
9	Zang J et al 2022	Test (1.35 ± 0.47/ 3.20 ± 0.42) Control (3.45 ± 0.64/ 3.50 ± 0.58)		Test (1.10 ± 0.46/1.05 ± 0.37) Control (1.30 ± 0.59/1.45 ± 0.44)		Test (3.23 ± 0.48 /3.08 ± 0.41) Control (3.08 ± 0.41 /3.25 ± 0.24)	Test (0.85 ± 0.41 / 0.70 ± 0.35) Control (1.05 ± 0.37 /0.85 ± 0.53)	

TABLE 5: RISK OF BIAS ASSESSMENT FOR INCLUDED STUDIES

SRNO	AUTHORNAME	RISK OF BIAS ASSESSMENTS					OVERALL ASSESSMENT
		DOMAIN 1	DOMAIN 2	DOMAIN 3	DOMAIN 4	DOMAIN 5	
1	Basegmez C et al 2013	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk of bias
2	Anderson LE et al 2014	Low risk	Low risk	Some concern	Low risk	Some concern	Some concern
3	Ribeiro S et al 2015	High risk	Low risk	High risk	Low risk	Low risk	High risk of bias
4	Hutton CG et al 2018	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk of bias
5	Naddafpour N et al 2019	Some concern	Some concern	Low risk	Some concern	Low risk	Some concern
6	Abbas WM et al	Low risk	High risk	Low risk	High risk	Low risk	High risk

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	2020						
7	Panwar M et al 2022	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk of bias
8	Happe A et al 2022	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk of bias
9	Zang J et al 2022	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk of bias

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