INPLASY PROTOCOL

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The authors have stated explicitly that there are no conflicts of interest.

Xenograft materials in maxillary sinus floor elevation surgery: a systematic review and network meta-analysis protocol

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Review question / Objective: **What xenograft material produces greater new bone formation in maxillary sinus floor elevation procedure?**
Condition being studied: **Two-stage sinus floor elevation technique using different xenograft materials before dental implant surgery. The dental implant rehabilitation of the posterior maxillary region is frequently inhibited by the amount of available bone. Bone-substitute materials from animal source are commonly used to increase bone volume in the deficient posterior maxilla.**
Information sources: **We will search the following electronic bibliographic databases: EMBASE, PubMed, Cochrane Central Register of Controlled Trials (CENTRAL), LILACS database, Scopus database, Web of Science database, and ClinicalTrial.gov. We will conduct manual searches in the reference list of the eligible studies, and a comprehensive manual search in the relevant journals.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 June 2020 and was last updated on 01 February 2021 (registration number INPLASY202060106).

INTRODUCTION

Review question / Objective: **What xenograft material produces greater new bone formation in maxillary sinus augmentation?**

Rationale: **Tow-stage sinus floor elevation using a lateral window technique represents the most widely technique to perform bone augmentation in the maxillary posterior region. Because intra-oral donor sites provide a limited quantity of bone and the extra-oral site is not well accepted by the patients, various types of bone-substitute materials have been suggested for maxillary posterior augmentation procedure. Previews studies**

showed that xenograft materials are the most used bone substitutes. However, no previous systematic reviews comparing the available xenograft materials using direct and indirect evidence are available. Therefore, the authors will be performed a frequentist network meta-analysis to provide evidence for comparing different xenograft materials used for maxillary sinus augmentation.

Condition being studied: Two-stage sinus floor elevation technique using different xenograft materials before dental implant surgery. The dental implant rehabilitation of the posterior maxillary region is frequently inhibited by the amount of available bone. Xenograft materials are commonly used to increase bone volume in the deficient posterior maxilla.

METHODS

Search strategy: Search strategy: Pubmed and Cochrane (((((Sinus Floor Augmentation[MeSH Terms]) OR "sinus floor elevation") OR "Sinus lift") OR "sinus lifting procedures" OR "Sinus elevation" OR "maxillary augmentation" OR "lateral window technique" OR "sinus grafting")) AND ((((((((Randomized controlled trial[Publication Type]) OR controlled clinical trial[Publication Type]) OR randomized[Title/Abstract]) OR placebo[Title/Abstract]) OR randomly[Title/Abstract]) OR trial[Title])) OR "Clinical Trials as Topic"[Mesh:NoExp])) NOT ((animals[MeSH Terms]) NOT humans[MeSH Terms]). Embase: sinus floor augmentation'/exp OR 'sinus floor elevation' OR 'sinus lift' OR 'sinus lifting procedures' OR 'sinus elevation' OR 'lateral window technique' OR 'maxillary augmentation' OR 'sinus grafting' AND 'randomized controlled trial'/exp AND topic OR 'controlled clinical trial' OR randomized:ab,ti OR Scopus: (TITLE-ABS-KEY ("Sinus Floor Augmentation") OR TITLE-ABS-KEY ("sinus floor elevation") OR TITLE-ABS-KEY ("Sinus lift") OR TITLE-ABS-KEY ("sinus lifting procedures") OR TITLE-ABS-KEY ("Sinus elevation") OR TITLE-ABS-KEY ("maxillary augmentation") OR TITLE-ABS-KEY ("lateral window technique") OR TITLE-ABS-KEY ("sinus grafting")) AND ((TITLE-ABS-KEY (randomized AND controlled AND trial) OR TITLE-ABS-KEY (controlled AND clinical AND trial) OR TITLE-ABS-KEY (randomized) OR TITLE-ABS-KEY (placebo) OR TITLE-ABS-KEY (randomly) OR TITLE (trial))) AND NOT ((TITLE (observational AND study) OR TITLE (meta-analysi) OR TITLE (retrospective) OR TITLE (systematic AND review) OR TITLE (animal AND study) OR TITLE (rats) OR TITLE (mouse) OR TITLE ("Canine Model") OR TITLE (rabbit))) Web Of Science TS=("sinus floor augmentation" OR "sinus floor elevation" OR "sinus lift" OR "sinus lifting procedures" OR "sinus elevation" OR "lateral window technique" OR "maxillary augmentation" OR "sinus grafting") AND TS=("Bone biopsies" OR "trephine biopsies" OR "histomorphometry" OR "histologic" OR "histological techniques" OR "newly formed bone") AND TS=(randomized clinical trial OR controlled clinical trial OR randomized OR clinical trial OR randomly OR trial).

Participant or population: Participants are adults with insufficient bone volume in the maxillary posterior region, making dental implant rehabilitation unfeasible. No restrictions on age, ethnicity, gender will be applied.

Intervention: Two-stage Sinus floor elevation technique using Bio-Oss as bone-substitute.

Comparator: Two-stage Sinus floor elevation technique using a different xenograft material, or a different association including Bio-Oss.

Study designs to be included: Parallel and split-mouth randomized clinical trials.

Eligibility criteria: Studies will be selected according to the PICOS criteria (Participant, intervention, comparator, outcomes, and study design) outlined in the referred sections. Additionally, we will

include only studies that performed the biopsies six months after sinus lift surgery. We will exclude studies with no description of the biomaterial trademark or using experimental grafting. Similarly, studies using a one-stage sinus floor elevation technique, studies without new bone formation data, or with incomplete results will be excluded. Studies with more than one biopsy per sinus will also be excluded.

Information sources: We will search the following electronic bibliographic databases: EMBASE, PubMed, Cochrane Central Register of Controlled Trials (CENTRAL), LILACS database, Scopus database, Web of Science database, and ClinicalTrial.gov. We will conduct manual searches in the reference list of the eligible studies, and a comprehensive manual search in the relevant journals.

Main outcome(s): The percentage of newly formed bone measured by histomorphometric analysis. 2) The percentage of residual bone-substitute measured by histomorphometric analysis. The main outcomes must be measured after a healing period of 6 months.

Additional outcome(s): The authors will analyze the following clinical outcomes: 1) implant survival and peri-implant bone resorption at least 12 months after functional loading; 2) Implant success rates.

Data management: The studies will be imported into Endnote X9 software (Thompson Reuters, Philadelphia, PA, USA) where duplicates will be automatically removed. All analyses will be performed using the software R version 3.6.2 or updated Mac OS X computer system. The package "netmeta" will be used to run network meta-analysis. This package is available from the Comprehensive R Archive Network (CRAN).

Quality assessment / Risk of bias analysis: Two review authors will independently assess the risk of bias. We will use the Cochrane tool for assessing the risk of bias. Sequence generation - Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups. Allocation concealment - Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrollment. Blinding of participants, personnel, and outcome assessors - Describe all measures used, if any, to blind study participants and personnel from the knowledge of which intervention a participant received. Incomplete outcome data - Describe the completeness of outcome data for each main outcome, including attrition and exclusions, from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group, reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by the review authors. Were incomplete outcome data adequately addressed? Selective outcome reporting - State how the possibility of selective outcome reporting was examined by the review authors, and what was found. Other sources of bias - State any important concerns about bias not addressed in the other domains in the tool.

Strategy of data synthesis: A frequentist network meta-analysis using direct and indirect evidence of eligible comparisons will be accomplished. We will provide a quantitative and narrative synthesis. We will provide summaries of intervention effects for each study by calculating standardized mean differences or mean differences. We will pool the results using a fixed or random-effects meta-analysis. Heterogeneity will be assessed using both the tau² test and the I^2 statistic. We will consider an I^2 value greater than 50% indicative of substantial heterogeneity. The heterogeneity within designs and between designs will be analyzed. Additionally, the assumption of transitivity and similarity based on clinical and methodological characteristics will be assessed. The inconsistency will be explored using the

Net Heat Plot. We will also assess evidence of publication bias.

Subgroup analysis: None.

Sensibility analysis: None.

Language: No language restrictions will be applied.

Country(ies) involved: Brazil and The United States of America.

Other relevant information: This study will be performed by a frequentist approach, which will enable us to estimate which intervention has the highest probability to be the best using net rank function.

Keywords: maxillary sinus augmentation; Bio-Oss; xenograft; systematic review; network meta-analysis.

Dissemination plans: The results of this systematic review will be disseminated through peer-reviewed journal.

Contributions of each author:
Author 1 - João Vitor Canellas - The author will draft the protocol and the manuscript. Contributed to the development of the selection criteria, the risk of bias assessment strategy, and data extraction criteria. The referred author developed the search strategy and provided statistical expertise. The risk of bias assessment and screening of search studies against eligibility. The author will read and approve the final manuscript.
Author 2 - Luciana Drugos - The author will draft the manuscript. The risk of bias assessment and screening of search studies against eligibility criteria. The author will read and provide feedback.
Author 3 - Fabio Gambôa Ritto - The author will read, perform the risk of bias assessment, supervise, provided feedback. The author will read and approve the final manuscript.
Author 4 - Ricardo Guimarães Fischer - The authors will read, supervise, provided feedback. The author will read and approve the final manuscript.
Author 5 - Paulo Jose Medeiros - The authors will read, supervise, provide feedback, and approve the final manuscript.