PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

Title (Provisional)

Midpalatal suture osteotomy combined with microimplant-assisted rapid palatal expansion for adult maxillary transverse deficiency treatment: study protocol of a randomized controlled trial

Authors

Zhang, Wenyi; Chung, Miri; Zhu, Yanfei; Qian, Yifeng; Zhang, Lei; Jiang, Lingyong

VERSION 1 - REVIEW

Reviewer	**1**
Name	**Sanati-Mehrizy, Paymon**
Affiliation	**The University of Texas Southwestern Medical Center**
Date	**18-Nov-2024**
COI	**I understand and consent to the named publication of this review.**

This is an interesting study. Ultimately there are current no results and findings. I recommend submitting this once the study is complete rather than simply study design

Reviewer	**2**
Name	**Seifert , Lukas B**
Affiliation	**Goethe University, University Hospital Frankfurt**
Date	**07-Dec-2024**
COI	**I understand and consent to the named publication of this review.**

Dear editor, dear authors,

I would like to express my gratitude for providing me with the opportunity to review this manuscript. It is a well-crafted and thoughtful study protocol addressing a clinically significant topic in the field of orthodontics and maxillofacial surgery. I appreciate the authors' meticulous effort in designing the trial and presenting their work with clarity and

depth. I hope my feedback contributes constructively to the refinement of this valuable research.

Overall Comments

The manuscript presents a well-structured and comprehensive study protocol for evaluating the efficacy of a novel minimally invasive treatment, MSO-MARPE, compared to SARPE for adult maxillary transverse deficiency (MTD). The protocol adheres to SPIRIT guidelines and provides detailed methods, outcome measures, and statistical analyses. Below are my comments:

Strengths

1. Innovative Approach: The combination of midpalatal suture osteotomy with MARPE for adult MTD addresses a significant gap in orthodontic and maxillofacial surgical practice, offering a potentially less invasive and cost-effective alternative to SARPE.

2. Comprehensive Design: The trial uses robust methods, including randomization, CBCT imaging, and well-defined outcome measures, which enhance the reliability and reproducibility of results.

3. Focus on Patient-Centered Outcomes: Consideration of operative time, pain intensity (VAS), and cost-effectiveness is commendable, reflecting real-world applicability.

4. Ethics and Transparency: Ethical approval and trial registration are clearly stated, ensuring compliance with Good Clinical Practice and the Declaration of Helsinki.

Specific Comments

Introduction

- The introduction effectively outlines the clinical problem and rationale for the study. However, the hypothesis could be presented more succinctly to emphasize the novelty of the MSO-MARPE technique.

Methods

1. Sample Size:

- The rationale for the small sample size is well-explained, but the potential impact on the statistical power of subgroup analyses should be acknowledged.

2. Blinding:

- The manuscript notes that blinding is not feasible for participants and surgeons. Consider discussing how this limitation might affect bias and how it will be mitigated (e.g., independent assessors for CBCT analysis).

3. Outcome Measures:

- While comprehensive, some secondary outcomes (e.g., recurrence rates) are complex and may require further explanation regarding their clinical significance.

- Definitions of adverse events could be clarified, particularly for distinguishing between mild and severe complications.

Discussion

- The limitations section acknowledges the small sample size and lack of multicenter involvement. Consider elaborating on plans for scaling the study in future phases if results are promising.

Minor Suggestions for improvement

1. Grammar and Language:

- Minor grammatical errors and occasional wordiness could be improved for clarity.

- Example: Replace "So far, there has been no prospective clinical study to demonstrate..." with "To date, no prospective clinical study has demonstrated..."

2. References:

- Ensure all references are up-to-date and correctly formatted

- Some references, such as those for MARPE success rates, might benefit from additional context or newer studies.

Recommendations

The manuscript is suitable for publication after minor revisions addressing the points above. It presents a valuable contribution to the field of maxillofacial surgery and orthodontics by exploring an innovative treatment for a common and challenging condition.

VERSION 1 - AUTHOR RESPONSE

Responses to Specific Comments

Introduction

- The introduction effectively outlines the clinical problem and rationale for the study. However, the hypothesis could be presented more succinctly to emphasize the novelty of the MSO-MARPE technique.

Re：

Thank you for your comments. We have had a revision of the hypothesis in the Introduction section accordingly (see Page 41, Line 36-40).

Methods

1. Sample Size:

- The rationale for the small sample size is well-explained, but the potential impact on the statistical power of subgroup analyses should be acknowledged.

Re:

Thank you for your comments. We have added the content to the Discussion section (see Page 52, Line 43-47).

2. Blinding:

- The manuscript notes that blinding is not feasible for participants and surgeons. Consider discussing how this limitation might affect bias and how it will be mitigated (e.g., independent assessors for CBCT analysis).

Re:

Thank you for your comments. We have further enhanced the discussion on the limitations of open labelling in the Discussion section (see Page 52, Line 37-43). Blinding to CBCT/CT assessors is also not feasible due to the difference between the two surgical incisions, which is clearly visible on CBCT/CT (see Page 43, Line 41-44).

3. Outcome Measures:

- While comprehensive, some secondary outcomes (e.g., recurrence rates) are complex and may require further explanation regarding their clinical significance.

Re:

Thank you for your comments. We have further explained the clinical significance of the secondary outcomes to make them more understandable (see Page 46, Line 46 to Page 47, Line 54).

- Definitions of adverse events could be clarified, particularly for distinguishing between mild and severe complications.

Re:

Thank you for your comments. The description of the definition of adverse events has been added to Page 48, Line 9-13. And the criteria for distinguishing mild and severe complication has been added to Page 48, Line 17-23.

Discussion

- The limitations section acknowledges the small sample size and lack of multicenter involvement. Consider elaborating on plans for scaling the study in future phases if results are promising.

Re:

We would like to express our gratitude for the constructive feedback we have received. A further statement regarding the planning of the future multi-center, large-sample RCT has been incorporated into the Discussion section (see Page 53, Line 53-58 to Page 54, Line 3-5).

Minor Suggestions for improvement

1. Grammar and Language:

- Minor grammatical errors and occasional wordiness could be improved for clarity.

- Example: Replace "So far, there has been no prospective clinical study to demonstrate..." with "To date, no prospective clinical study has demonstrated..."

Re:

Thank you for your advice. We have corrected grammatical inaccuracies and ensured that the language is concise throughout the article.

2. References:

- Ensure all references are up-to-date and correctly formatted

Re:

Thank you for your comments. A thorough review has been conducted to ensure that all references are up-to-date and correctly formatted.

- Some references, such as those for MARPE success rates, might benefit from additional context or newer studies.

Re:

Thank you for your comments. We have incorporated several recent and pertinent references (see Reference 24, 25, 27-30) to make the protocol more scientific.
