

Efficacy of the Maxillary Anterior Segmental Distraction Osteogenesis in Patients With Cleft Lip and Palate: A Systematic Review and Meta-Analysis

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Pu, PJ; Bao, SY; Jiao, YH; Wang, FY; Hou, YX; Gao, JB; Zhan, YL; Zhao, HX.

Corresponding author:

Huaxiang Zhao

huaxiangzhao@xjtu.edu.cn

Author Affiliation:

College of Stomatology, Xi'an Jiaotong University.

ADMINISTRATIVE INFORMATION

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Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 18 June 2024 and was last updated on 18 June 2024.

INTRODUCTION

Review question / Objective To provide evidence and reference regarding the Efficacy of the Maxillary Anterior Segmental Distraction Osteogenesis in Patients With Cleft Lip and Palate.

Condition being studied Maxillary hypoplasia is a more common symptom in patients with cleft lip and palate. In addition to this, they also show anterior or posterior teeth crossbite, severe dental crowding, and a concave face due to maxillary hypoplasia. Collapsed dental arch due to alveolar cleft and speech disorders due to velopharyngeal insufficiency. These clinical symptoms seriously affect the oral function, facial aesthetics, speech level and psychological health of patients with cleft lip and palate. The lefort I osteotomy combined with distraction osteogenesis could lengthen the maxilla to improve maxillary hypoplasia. Since it also lengthens the soft, vascular, and neural tissues, it reduces the pulling of scarring tissues,

which in turn reduces the recurrence rate and increases the extent of maxillary advancement.

METHODS

Search strategy We searched relevant studies published before February 18, 2024 in Medline (via Pubmed), Embase, Web of Science, Cochrane Library, Scopus. Combinations of Mesh terms, free text words, appropriate truncations and filters were used without language restriction. The search terms were obtained by searching MEDLINE and were modified accordingly for other databases.

Participant or population Cleft Lip and Palate patients with maxillary hypoplasia.

Intervention Maxillary anterior segmental distraction osteogenesis with internal distractor.

Comparator The study compared the maxilla, mandible, the anterior tooth position and the facial soft tissue before and after Maxillary anterior

segmental distraction osteogenesis with internal distractor.

Study designs to be included (1) Clinical controlled trials (randomized/non-randomized/prospective or retrospective cohorts with control groups).(2) Population: Cleft Lip and Palate patients with maxillary hypoplasia.(3) Intervention: Maxillary anterior segmental distraction osteogenesis with internal distractor.(4) Comparison: Measuring the changes of maxillary cephalometric landmarks before and after maxillary anterior segmental distraction osteogenesis.(5) Outcome: Mid-facial skeletal, dentoalveolar and soft-tissue measurements.

Eligibility criteria The exclusion criteria were: systematic reviews, reviews, opinion articles, letters to the editor, case series, case report, animal studies; studies including syndromic patients; dual publications.

Information sources A total of 1513 publications were included in the database search (MEDLINE N = 184, Embase N = 372, Cochrane Library N = 18, Web of Science N = 519, Scopus N = 420), and no additional results were obtained by manual search of reference lists.

Main outcome(s) The SNA angle increased by $6.43^\circ \pm 0.08^\circ$ (95% confidence level, 4.11° to 8.74°), A-McNamara increased by $7.29 \text{ mm} \pm 0.08 \text{ mm}$ (95% confidence level, 6.21 mm to 8.37 mm), and ANS-PNS increased by $8.30 \text{ mm} \pm 0.08 \text{ mm}$ (95% confidence level, 5.44 mm to 11.15 mm), which meant a significant increase in length of the maxilla. The FH-ANS decreased by $0.82 \text{ mm} \pm 0.08 \text{ mm}$ (95% confidence level, -2.03 mm to 0.38 mm), FH-A decreased by $1.22 \text{ mm} \pm 0.08 \text{ mm}$ (95% confidence level, -2.73 mm to 0.29 mm), the SN-PP angle decreased $0.97^\circ \pm 0.08^\circ$ (95% confidence level, -2.12° to 0.18°), but these variations were not statistically significant. The SNB change was not statistically significant ($-0.20^\circ \pm 0.08^\circ$, $p=0.77$), and the ANB angle increased by $4.84^\circ \pm 0.08^\circ$ (95% confidence level, 4.01° to 5.66° , $p < 0.00001$). The Overjet increased by $9.20 \text{ mm} \pm 0.08 \text{ mm}$ (95% confidence level, 6.93 mm to 11.47 mm , $p < 0.00001$), the U1/SN angle increased by $5.35^\circ \pm 0.08^\circ$ (95% confidence level, -0.10° to 10.80° , $p < 0.00001$), and the Overbite decreased by $2.09 \text{ mm} \pm 0.08 \text{ mm}$ (95% confidence level, -2.87 mm to -1.32 mm , $p < 0.00001$). The Nasolabial angle increased by $10.23^\circ \pm 0.08^\circ$ (95% confidence level, 8.27° to 12.19° , $p < 0.00001$), and the Upper lip to E-line increased by $4.87 \text{ mm} \pm 0.08 \text{ mm}$ (95% confidence level, 2.84 mm to 6.90 mm , $p < 0.00001$).

Additional outcome(s) Due to differences between studies in DO methods, distractors, patients, DO amounts and during times, the meta-analysis revealed that there was considerable heterogeneity in the composite results of many measures. The heterogeneity of data was relatively low for FH-A ($I^2 = 0\%$, $p=0.11$), FH-ANS ($I^2 = 0\%$, $p=0.18$), SN/PP ($I^2 = 0\%$, $p=0.10$), SNB ($I^2 = 0\%$, $p=0.77$), ANB ($I^2 = 0\%$, $p < 0.00001$), Nasolabial angle ($I^2 = 0\%$, $p < 0.00001$), Overbite ($I^2 = 27\%$, $p =0.11$). The heterogeneity was regarded as very high for SNA ($I^2 = 93\%$, $p < 0.00001$), A-McNamara ($I^2 = 88\%$, $p < 0.00001$), ANS-PNS ($I^2 = 79\%$, $p < 0.00001$), Overjet ($I^2 = 97\%$, $p < 0.00001$), U1/SN ($I^2 = 82\%$, $p=0.05$), Upper lip to E-line ($I^2 = 74\%$, $p < 0.00001$).

Quality assessment / Risk of bias analysis The risk of bias of every included study was assessed by the ROBINS-I tool, and the studies assessed with a critical risk of bias were excluded from further analysis and synthesis. Pu Panjun and Bao Shanying reviewed these studies, and if there is a difference of opinion, consulting the advice of the third reviewer.

Strategy of data synthesis Mean difference (MDs) and 95% confidence interval (CIs) were shown. I^2 statistic and p-value were used to assess heterogeneity. $I^2 \leq 50\%$ and $p \geq 0.1$ was considered as no or low heterogeneity, and a fixed-effects model was used. $I^2 > 50\%$ and $p < 0.1$ was considered as high heterogeneity, and descriptive analysis was applied. All statistical analyses were performed using the RevMan 5.4.1 software.

Subgroup analysis None.

Sensitivity analysis None.

Country(ies) involved China.

Keywords Maxillary Anterior Segmental Distraction Osteogenesis; cleft lip and palate.

Contributions of each author

Author 1 - Panjun Pu.
Email: 1247617658@qq.com
Author 2 - Shanying Bao.
Author 3 - Yuhua Jiao.
Author 4 - Feiyu wang.
Author 5 - Yuxia Hou.
Author 6 - Jianbo Gao.
Author 7 - Yalin Zhan.
Author 8 - Huaxiang Zhao.