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Kanwalpreet, K; Ravinder, S; Rajesh, V; Artak, H.

Corresponding author:
Kanwalpreet Kaur

drkanwalpreet@yahoo.co.in

Author Affiliation:
King Khalid University.

ADMINISTRATIVE INFORMATION

Support - King Khalid University.

Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202610033

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 9 January 2026 and was last updated on 9 January 2026.

INTRODUCTION

Review question / Objective To evaluate the diagnostic accuracy and geometric performance of AI-based systems used for diagnosis and virtual surgical planning in pediatric craniofacial and maxillofacial surgery.

Rationale AI is increasingly used in craniofacial care, there is insufficient evidence on its real-world reliability for children.

Condition being studied Pediatric craniofacial and maxillofacial deformities, including craniosynostosis, mandibular dysmorphism, and complex craniofacial asymmetries.

METHODS

Search strategy A comprehensive search conducted in PubMed/MEDLINE, Scopus, Web of Science, ScienceDirect, and Cochrane Library from inception to November 2025 using MeSH and free-text terms related to AI and craniofacial surgery.

Participant or population Pediatric patients with craniofacial or maxillofacial conditions, as investigated in included studies.

Intervention AI-based systems for diagnostic assessment, image segmentation, reconstruction, or virtual surgical planning.

Comparator Expert clinical judgment, manual segmentation, or conventional diagnostic methods as the reference standard.

Study designs to be included Studies evaluating AI-based diagnostic or surgical planning applications, including diagnostic accuracy studies, retrospective validations, prospective feasibility studies, and computational modeling studies.

Eligibility criteria Studies included were those reporting quantitative diagnostic accuracy in pediatric craniofacial/maxillofacial contexts.

Exclusions covered non-English papers, animal research, and incomplete reports.

Information sources Electronic databases (PubMed, Scopus, Web of Science, ScienceDirect, Cochrane Library) and manual searching of reference lists.

Main outcome(s) Segmentation accuracy and diagnostic accuracy.

Additional outcome(s) Predictive performance, clinical feasibility, osteotomy accuracy, and workflow efficiency.

Data management Two independent reviewers performed study selection, data extraction, and quality assessment using piloted forms. Discrepancies were resolved through discussion or a third reviewer. Data were analysed using Comprehensive Meta-Analysis software.

Quality assessment / Risk of bias analysis Risk of bias was assessed using QUADAS-2 for diagnostic accuracy studies and ROBINS-I for non-randomized segmentation/surgical planning studies.

Strategy of data synthesis Results were combined using random-effects models, accounting for study differences. Heterogeneity and publication bias were statistically examined.

Subgroup analysis Planned but not performed due to limited studies and inconsistent reporting of key variables.

Sensitivity analysis Conducted by excluding studies with serious risk of bias to ensure robustness of pooled estimates.

Language restriction Included only English-language publications.

Country(ies) involved Saudi Arabia, United States of America, India.

Keywords Artificial intelligence; Craniofacial surgery; Maxillofacial surgery; Diagnostic accuracy; Image segmentation; Virtual surgical planning; Meta-analysis.

Dissemination plans Findings will be disseminated through peer-reviewed publication and conference presentations.

Contributions of each author

Author 1 - Kanwalpreet Kaur - Conceptualization, methodology.

Email: drkanwalpreet@yahoo.co.in

Author 2 - Ravinder Singh - Visualization, Project implementation.

Email: rsaini@kku.edu.sa

Author 3 - Rajesh Vyas - Statistical expertise, draft writing.

Email: rvyas@kku.edu.sa

Author 4 - Artak Heboyan - Final draft writing and publications.

Email: heboyan.artak@gmail.com