

Evaluation of a custom 3D surgical guide in mandibular sagittal split osteotomy

Submission date 29/12/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 31/12/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/12/2025	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Plain English summary of protocol not provided at time of registration.

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Study information

Scientific Title
Patients undergoing mandibular sagittal split osteotomy: comparison of custom three-dimensional surgical guide versus conventional technique on lingual split pattern, lateral osteotomy end, and inferior alveolar nerve exposure — a split-mouth randomized controlled trial

Study objectives
The primary objective of this study is to evaluate the effect of a customized 3D-printed surgical guide on split pattern characteristics during bilateral sagittal split osteotomy (BSSO) of the

mandible. Specifically, this randomized controlled trial aims to compare lingual split patterns, lateral osteotomy end position, and inferior alveolar nerve exposure between mandibular sides operated with and without the use of a custom 3D surgical guide within the same patient.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 31/05/2025, Dental Research Ethics Committee, Faculty of Dentistry, Universitas Indonesia (Jln. Salemba Raya No. 4 Jakarta Pusat, Jakarta, 10430, Indonesia; +(62-21) 31906289; etikrisetfkg@ui.ac.id), ref: 78/Ethical Approval /FKGUI/V/2025

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Blinded (masking used)

Control

Active

Assignment

Crossover

Purpose

Basic science

Study type(s)

Health condition(s) or problem(s) studied

Correction of dentofacial deformities in adult patients with skeletal Class II or Class III mandibular discrepancies undergoing bilateral sagittal split osteotomy

Interventions

The intervention consisted of a custom 3D-printed surgical cutting guide–assisted mandibular sagittal split osteotomy (BSSO). It was developed to improve osteotomy accuracy and control split patterns by translating virtual surgical planning into precise intraoperative guidance, reducing unfavorable splits and variability associated with freehand techniques. Patient-specific acrylic cutting guides were fabricated using 3D printing based on cone-beam CT or multislice CT imaging and virtual planning software (3D Slicer, Meshmixer, Blender). Preoperative CT data were segmented to create a 3D mandibular model, and osteotomy lines were virtually planned following the Obwegeser–Dal Pont–Hunsuck–Epker modification. During surgery, the guide was positioned intraorally and secured with miniscrews to guide medial and lateral osteotomies. The procedure was performed face-to-face under general anesthesia during a single orthognathic surgery session, applied individually to each mandibular side according to split-mouth randomization. All surgeries were carried out by board-certified Oral and Maxillofacial Surgeons experienced in orthognathic surgery, supported by radiologists and biomedical engineers trained in virtual surgical planning and CAD/CAM workflows. The intervention took

place in operating theatres at Universitas Indonesia Hospital and Universiti Malaya Medical Centre, equipped with standard orthognathic surgical and digital planning infrastructure. Each surgical guide was tailored to the patient's anatomy and osteotomy trajectory based on preoperative imaging. No modifications to the protocol were made during the study. Fidelity was ensured through adherence to a standardized digital planning and guide fabrication protocol, with intraoperative verification of guide fit and stability. All guides were successfully positioned and used as planned, with no intraoperative fractures or failures reported.

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. lingual split patterns measured using three-dimensional mandibular models reconstructed from CT scans at 2 weeks postoperatively

Key secondary outcome(s)

1. Lateral Osteotomy End (LOE) position measured using axial CT images and 3D virtual mandibular models at 2 weeks postoperatively

2. Inferior alveolar nerve exposure measured using the nerve exposure scale of Lee et al. (2016): NE1: No visible nerve exposure, NE2: Partial nerve exposure within the distal segment, and NE3: Complete nerve exposure detached from the distal segment at the intraoperative assessment

Completion date

15/12/2025

Eligibility

Key inclusion criteria

1. Age ≥ 18 years
2. Mandibular skeletal Class II or Class III deformities
3. Signed informed consent

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

80 years

Sex

All

Total final enrolment

30

Key exclusion criteria

1. Non-SSO orthognathic procedures
2. Medically compromised patients
3. Refusal to sign the informed consent

Date of first enrolment

01/05/2024

Date of final enrolment

15/12/2025

Locations**Countries of recruitment**

Indonesia

Malaysia

Study participating centre**University of Indonesia**

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Indonesia

Study participating centre**Universiti Malaya**

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Sponsor information**Organisation**

University of Indonesia

ROR

<https://ror.org/0116zj450>

Funder(s)

Funder type

Funder Name

Direktorat Riset and Pengembangan, Universitas Indonesia

Alternative Name(s)

Directorate of Research and Development, Directorate of Research and Development of the University of Indonesia, R&D Directorate, Directorate of Research and Community Engagements Universitas Indonesia, Directorate of Research and Community Engagement UI, Directorate for Research and Development - Universitas Indonesia, Direktorat Riset & Pengembangan, Risbang, Risbang UI, Directorate of Research and Community Engagement UI, Direktorat Riset dan Pengabdian Masyarakat UI, DRPM UI

Funding Body Type

Government organisation

Funding Body Subtype

Research institutes and centers

Location

Indonesia

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files			30/12/2025	No	No