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

Submission date	Recruitment status	[_] Prospectively registered
29/12/2025	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/12/2025	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
30/12/2025	Oral Health	[X] 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 osteotom

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
Jl. Prof. DR. Bahder Djohan, Pondok Cina, Kecamatan Beji, Kota Depok, Jawa Barat 16424
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Indonesia

Study participating centre
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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