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Original Article

Usability testing of a novel interlocking three-dimensional miniplate for mandibular angle fractures

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Background: We developed a novel interlocking three-dimensional (3D) miniplate design with an adjustable configuration. As this device is new, surgeons must become familiar with its application. This study evaluated the usability and learning curves associated with the novel interlocking 3D miniplate for mandibular fracture fixation.

Methods: The study participants, nine plastic surgeons, were asked to apply an interlocking 3D miniplate and a standard miniplate to polyurethane mandible models. The participants had completed the Basic Craniomaxillofacial Osteosynthesis course during residency and had operated on craniomaxillofacial fractures within the past 5 years. They were instructed to place the interlocking 3D miniplate three times and the standard miniplate once. We assessed the time required for implant placement, the comfort level of the surgeons, and the biomechanical stability of the plates. Biomechanical testing was conducted by subjecting the mandible to forces ranging from 10 to 90 N and the displacement was measured.

Results: The results indicate increasing comfort with each attempt at placing the interlocking 3D miniplate, with a significant difference between the first and third attempts. Additionally, a reduction in application time was noted with repeated attempts, suggesting improved efficiency. Biomechanical tests showed comparable stability between the tested plates.

Conclusion: Multiple attempts at applying the interlocking 3D miniplate resulted in increased comfort and reduced application time. These findings indicate that, despite its novelty, the interlocking 3D miniplate is relatively straightforward to apply and has a short learning curve. However, surgeons must have specific qualifications to ensure proper training and minimize errors during placement.

Abbreviations: ORIF, open reduction and internal fixation; 3D, three-dimensional

Keywords: Fracture fixation, internal / Mandibular fractures / Usability testing

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INTRODUCTION

The primary objective in managing mandibular fractures is to restore the anatomical shape and function. This can be accomplished using open reduction and internal fixation (ORIF) methods. The hardware utilized for internal fixation of these fractures has evolved since its introduction by Michelet et al. in 1973, which described the use of small plates and monocortical screws that could be placed through an intraoral approach. The method involves positioning a single miniplate with monocortical screws along the oblique line or the superior border of the mandible. Such a procedure avoids external skin incisions and minimizes the risk of damage to the inferior alveolar and facial nerves, while shortening the duration of surgery. However, subsequent studies have suggested that the Champy technique, as this method later became known, may not provide sufficient rigidity to ensure stable fixation of the fractured segments [1].

Consequently, some studies have recommended the use of two miniplates, one placed at the tension area and the other at the compression area of the mandible. This approach aims to achieve anatomical repositioning of the fracture segments while preventing their separation and rotation [2,3]. However, subsequent studies have reported inconsistent results, including improved stability, no significant difference, and a high complication rate [4-6]. To address this issue, Farmand and Dupoirieux introduced three-dimensional (3D) miniplates, which feature two miniplates interconnected by vertical cross struts. The design of these 3D miniplates is based on the geometric stability of the quadrangle [1,7].

Existing 3D miniplate designs must be made more flexible to accommodate complex fracture configuration [8]. The placement of screws in these designs presents a challenge, as the designated holes may intersect with fracture lines or lie directly over critical anatomical structures, such as dental roots and nerves. To overcome these issues, we developed a 3D miniplate design that can be adapted intraoperatively to meet specific challenges. We created interlocking 3D miniplates that enable customization through the adjustment of horizontal miniplates and vertical cross struts. This innovative design offers improved stability for angle fracture reduction compared to standard miniplates [9]. However, surgeons will need to familiarize themselves with the application of this new design, and its usability requires further evaluation.

Usability testing is an essential step in device innovation. This process corresponds to stage 0 in the IDEAL-D framework, which is analogous to phase 0 trials in the pharmaceutical sector. Stage 0 encompasses the preclinical evaluation of medical devices, providing a structured and rational method to balance innovation with safety, thereby facilitating the smooth transition of a medical device from the laboratory to first-in-human trials [10]. During usability testing, developers of medical devices gather feedback from clinicians to facilitate the device's integration into clinical practice. This testing assesses the effectiveness of the user interface and examines the user learning curve to ensure that the training provided is sufficient prior to clinical use [10].

This study was conducted to understand clinician perspectives on the usability and learning curves associated with the novel interlocking 3D miniplates. Usability was assessed based on comfort level and biomechanical studies. A short learning curve was indicated by the reduced time needed for miniplate placement and the progressively increasing comfort level with each repetition.

METHODS

As a preliminary phase of usability testing, this study aimed to gather baseline data on the novel interlocking 3D miniplate design and gain feedback from users to enhance its user-friendliness. Nine plastic surgeons were selected for their expertise to ensure consistency and minimize potential bias related to their background knowledge of mandibular fractures. For inclusion, participants were required to be plastic surgeons who had completed the Basic Craniomaxillofacial Osteosynthesis course during their residency training in Plastic and Aesthetic Surgery and to have operated on craniomaxillofacial fractures within the past 5 years.

Participants first received an introductory lecture and watched an instructional video that demonstrated how to apply the interlocking 3D miniplates. Then, they were given three opportunities to place the interlocking 3D miniplate system, compared to a single attempt using two standard miniplates, each secured with eight screws of 2×7 mm. This method was designed to increase their comfort with the interlocking 3D miniplates, with which they had no previous experience. In contrast, the participants were already acquainted with the standard plate due to their educational backgrounds and practice with synthetic models (Synbone) during the Basic Craniomaxillofacial Osteosynthesis course. This familiarity meant that no additional time or instruction was necessary for them to use the standard plate effectively. Thus, the study procedure ensured a consistent baseline for the assessment of the new plate design. To minimize bias and mitigate the effects of fatigue, the sequence in which participants applied the different plates was randomized. Fig. 1 details the plates used in the study.

Participants were instructed to apply the interlocking 3D

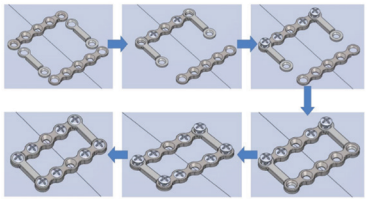
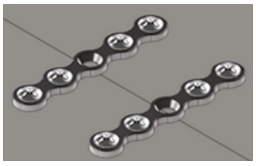
System	Plate thickness	Length	Screws used	Illustration
Interlocking 3D miniplate, consisting of: • SP • VS • IP	SP and IP: 1 mm and 0.5 mm at first and fifth holes VS: 1 mm and 0.5 mm at screw insertion	SP and IP: 25 mm VS: 15 mm	SP: Four screws of 2 × 7 mm VS: Two screws of 2 × 7 mm IS: Four screws of 2 × 7 mm	
Standard plate	1 mm	25 mm	Eight screws of 2 × 7 mm	

Fig. 1. Description of plates used in the study. 3D, three-dimensional; SP, superior plate; VS, vertical strut; IP, inferior plate.

miniplate and a standard plate onto synthetic polyurethane mandible models, which were designed to mimic the anatomy of a real mandible. A total of 36 polyurethane hemimandible models were utilized in the study. Following each application, participants were asked to complete a questionnaire about their comfort levels with both types of plates. Comfort was rated on a scale from 1 to 5, with 1 indicating "very uncomfortable and difficult to use" and 5 indicating "very comfortable and easy to use." This self-assessment was intended to gauge subjective outcomes, while for objective analysis, we measured the time required to perform osteosynthesis using all the miniplates on the model. Biomechanical testing on the synthetic mandibles served as an objective measure of performance.

Biomechanical testing of polyurethane mandible model

The biomechanical testing of the polyurethane mandible model, comparing the interlocking 3D miniplate with a standard plate, was conducted using universal force testing machine (MCT 2150; A&D Company, Limited) to apply the load. A hole was created in the premolar area to prevent the force tester from rolling off the tooth area (Fig. 2).

Biomechanical testing was incorporated to provide an additional objective assessment to complement the usability testing, rather than to perform an *in vivo* evaluation. The mandibles were subjected to continuous loading with a compression pressure speed set at 0.3 mm/min. The testing was concluded when damage occurred, defined as either implant failure or bone breakage. Vertical displacement (superior/inferior) and horizontal displacement (anterior/posterior) were measured at the inferior border of the mandible, while buccal/lingual displacement was assessed at the superior border (Fig. 3). These displacements were measured under loads that ranged from 10 N to 90 N. MSAT-Lite, a data processing software, was employed

Fig. 2. Position of the polyurethane mandible on the force tester.

to apply the load to the mandibles and display operation and processing results. The displacement of the mandibles under load was then measured using a Dino-Lite camera with Dinocapture software (Dino-Lite).

Statistical analyses

Statistical analyses were performed to compare comfort levels and placement times using repeated measures analysis of variance. The significance of differences in displacement values at each 10 N increment, up to 90 N, was assessed using a *t*-test. For data that exhibited a non-normal distribution, the Mann-Whitney *U* test was employed, and the data were analyzed separately.

Ethical clearance

This study was approved by the Research Ethics Committee of the Faculty of Medicine at Universitas X, number: KET-1609/UN2.F1/ETIK/PPM.00.02/2021.

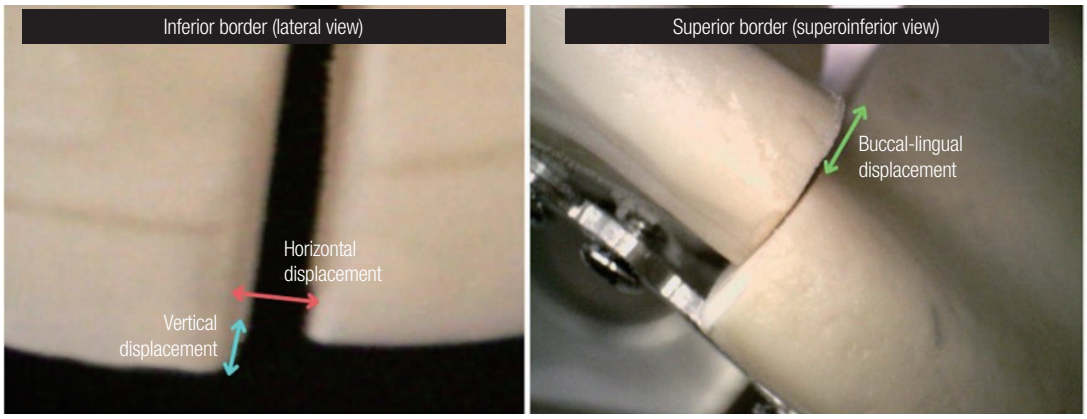


Fig. 3. Measurement of displacement of the polyurethane mandible model.

Table 1. Participant characteristics

Variable	No. (%)
Sex	
Male	2 (22.2)
Female	7 (77.8)
Years of experience	
9	2 (22.2)
8	1 (11.1)
7	3 (33.3)
6	1 (11.1)
5	2 (22.2)

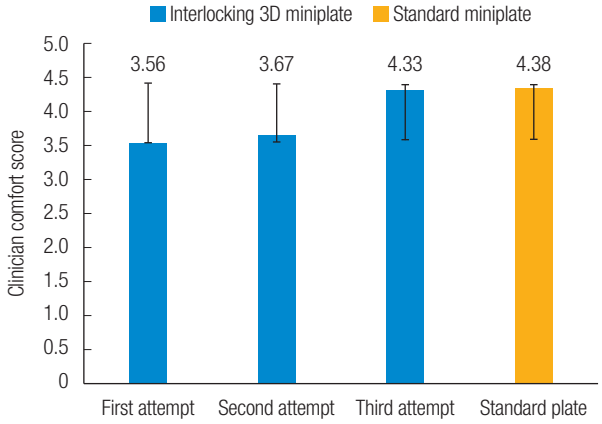


Fig. 4. Comparison of comfort levels between the interlocking three-dimensional miniplate and the standard miniplate. Clinician comfort score: 5 (very comfortable and easy to use), 4 (comfortable and easy to use), 3 (neutral), 2 (uncomfortable and difficult to use), 1 (very uncomfortable and difficult to use).

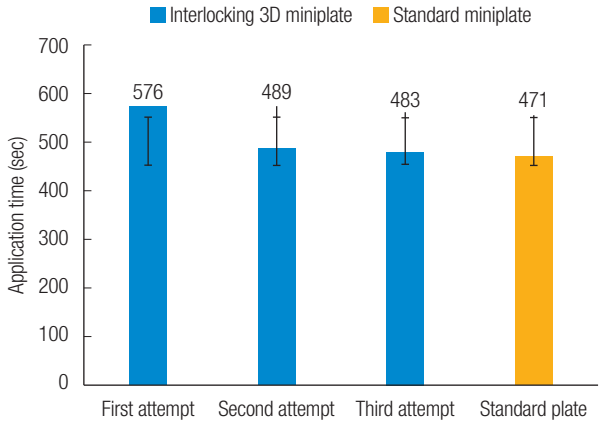


Fig. 5. Comparison of the time required to apply the interlocking three-dimensional (3D) miniplate and the standard miniplate.

RESULTS

Participant characteristics

Most participants in the usability test were women (77.8%), and all were plastic surgeons who had graduated between 2018 and 2023. The highest percentages of participants were those who graduated in 2023 and 2018, each constituting 22.2% of the total (Table 1).

Clinician comfort score

Participants reported increased comfort with each successive attempt, from their initial to their third, when applying the interlocking 3D miniplates to the mandible model (Fig. 4). A significant improvement was noted between the first and third attempts. Furthermore, no significant difference in comfort score was observed between the third attempt with the interlocking 3D miniplate and the placement of the standard miniplate.

Time required for the application of internal fixation systems

A consistent trend emerged, revealing a progressive reduction in the time required for plate placement across the first, second, and third trials. The mean application time decreased from 576 seconds to 489 seconds, then further to 483 seconds. Although statistical analysis revealed no significant difference between at-

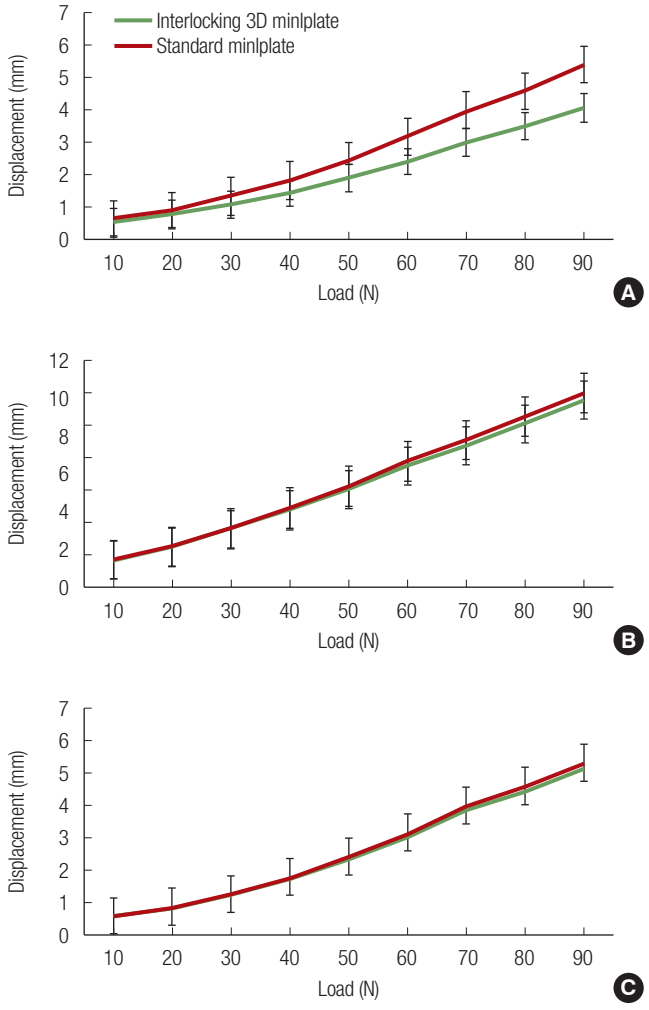


Fig. 6. Displacement versus load on the mandible model. (A) Horizontal displacement. (B) Vertical displacement. (C) Buccal-lingual displacement. 3D, three-dimensional.

tempts, the reduction in time from the first to the third attempt demonstrated an improvement in efficiency ($p = 0.076$). Additionally, no significant difference was noted in the time required for the third attempt compared to that for the standard plate ($p = 0.835$), as shown in Fig. 5.

Biomechanical evaluation

Fig. 6 presents the displacement (vertical, horizontal, and buccal/lingual) versus load for the mandible models. As shown in these figures, the interlocking 3D miniplates exhibited lower displacements compared to the standard plate for all three measurements. However, statistical analysis revealed no significant differences in displacement across all loads ($p > 0.05$).

DISCUSSION

The existing 3D plate design features a stable rectangular structure, consisting of two horizontal plates joined by two vertical plates at fixed angles. However, this rigid configuration can present difficulties in avoiding fracture lines or key anatomical structures. To address this issue, an adjustable 3D plate, termed the interlocking 3D plate, was developed. This innovative design permits adjustment of the angles between the horizontal and vertical plates, representing a single cohesive unit without increased plate thickness at the joints.

To evaluate this novel design, a usability test was conducted with nine plastic surgeons. Nielsen and Landauer have reported that testing with five users is sufficient to uncover most usability issues in a design, typically uncovering around 85% of usability problems [11]. Such an approach is both practical and cost-effective, offering a rapid means of improving products without extensive testing. This is especially beneficial in a dynamic development environment.

In the present study, the participants were plastic surgeons who had completed the Basic Craniomaxillofacial Osteosynthesis course during their residency. This criterion meant that all participants had a consistent understanding of ORIF techniques and demonstrated familiarity with standard internal fixation devices used in surgical procedures. Furthermore, participants were required to have recent experience in craniomaxillofacial surgery, including the placement of internal fixation devices. This background ensured that they were well-acquainted with the routine challenges encountered in facial fracture surgery, such as incision placement, tissue handling, bone fragment reduction, and fixation. Thus, the participants were well-positioned to evaluate the usability of the novel 3D interlocking miniplates in comparison to standard plates.

Our study employed polyurethane mandible models, which can mimic the structure and material of the mandible. The outer layer provides hardness, like cortical bone, while the inner layer is softer, resembling cancellous bone. The participants were already familiar with the application of miniplates to the model, having gained experience during the Basic Craniomaxillofacial Osteosynthesis course. Utilizing a polyurethane mandible model is advantageous over the use of cadavers as it minimizes anatomical variability, thus reducing bias [12]. Despite these advantages, the use of a synthetic bone model cannot fully replace real bone, as it lacks the morphological characteristics necessary to replicate the maximal load experienced *in vivo* [13].

Previous studies have indicated that in the first week following mandibular fracture surgery, the maximum bite force is approximately 70 N. This force increases to between 130 and 135 N after 6 weeks. Notably, the bite force exerted during food consumption may be less than the maximal bite force. For instance, the average bite force when chewing a biscuit is 16.5 N,

for whole wheat bread it is 22.2 N, for sausage with dense meat it is 16.7 N, and for smoked beef it is 34 N [14,15]. Based on these observations, we chose a load range of 10 N to 90 N for biomechanical testing. This range encompasses the lower spectrum of forces that the implants are likely to experience during normal function, ensuring testing under conditions that simulate the typical chewing forces encountered in the human mandible. This methodology offers a relevant assessment of implant stability and functionality under load conditions that reflect those of daily oral function [16].

To assess usability, we evaluated the comfort level, time efficiency, and biomechanical aspects of interlocking 3D miniplates compared to standard plates. Since the clinician comfort level was evaluated subjectively, typical usability testing practices necessitated a complementary objective assessment. We incorporated objective evaluation by measuring the time required for fixation system placement and performing biomechanical tests. This approach aligns with the findings of a systematic review by Smith et al. [17], which emphasized the vital role of clinicians in the early stages of medical technology development. The review underscored the importance of assessing device performance, clinical needs, and user requirements before marketing a device. It also stressed the value of incorporating both objective and subjective evaluations in usability testing.

Our study provided participants with three opportunities to become acquainted with the new interlocking 3D miniplate model, as they had no prior experience with this type of miniplate. This approach is supported by the research of Hopper et al. [18], which indicates that repetitive learning and experience can significantly improve performance. Furthermore, we allowed multiple attempts at applying the interlocking 3D miniplates to ensure that participants could become as familiar with this technique as they were with the standard plates, which they had used during their training. By the third attempt, we anticipated that participants would achieve a level of proficiency with the interlocking 3D miniplates that was comparable to their established proficiency with standard plates, thereby ensuring a fair comparison during testing.

Similar results were reported by Eversbusch and Grantcharov [19], who assessed the impact of training on virtual colonoscopy performance. Their study demonstrated a significant improvement by the third attempt at the procedure, even among participants lacking prior experience in colonoscopy. This finding underscores the importance of repetition in cultivating expertise and reducing the learning curve.

Despite the significant difference in clinician comfort levels between the first and third attempts at applying the interlocking 3D miniplate, statistical analysis revealed no significant difference in the time required for these attempts (576 ± 178 seconds vs. 483 ± 117 seconds, $p = 0.076$). This result underscores the importance of objective evaluation in usability testing of new medical devices. While subjective assessment indicated a significant improvement in comfort level, the objective measure—time taken to complete the application—displayed no substantial difference. This implies that participants did not find the application of the interlocking 3D miniplate to be particularly challenging or uncomfortable, despite its novel design.

Although the time required to apply the interlocking 3D miniplate on the third attempt was 12 seconds longer than that for the standard plate, this difference was not statistically significant. Such a disparity was anticipated, since the interlocking miniplate has more components than the standard plate. The need for precise placement of the vertical strut, which connects the superior and inferior plates, likely contributed to the increased application time. Future developments should prioritize designing a surgical tool that simplifies the assembly of interlocking 3D miniplates, potentially decreasing the time needed for their application.

Despite the longer application time observed for interlocking 3D miniplates initially, biomechanical evaluation indicated no statistically significant difference in stability compared to standard miniplates. This finding suggests that, although a learning curve is required, the novel design offers comparable stability to the conventional approach. Previous studies have supported interlocking 3D miniplates as a more stable alternative to standard plates [7,20].

Minimizing displacement in fracture fixation is essential for bone healing [21]. Consequently, internal fixation systems that demonstrate minimal displacement under load are preferable. Under a 90-N load, a clear difference was observed in horizontal displacement between the standard miniplate and the interlocking 3D miniplate, with the latter showing greater stability that may better support bone healing. The biomechanical testing in this study provided objective evidence of the interlocking 3D miniplate's superior performance. Notably, however, these findings are derived from a synthetic model and do not directly translate to clinical practice. Further biomechanical analysis of the interlocking 3D miniplate, including tests on a goat mandible, is presented in a separate study [9]. Research on the biocompatibility, bone healing, and outcomes associated with the interlocking 3D miniplate is also underway.

During this study, the participants were asked to provide feedback on the interlocking 3D miniplates. They suggested that the plates should have distinct codes or colors; for instance, using different identifiers for the superior and inferior plates may facilitate easier recognition during surgery. Such input is valu-

able for supporting product development. Furthermore, we recognize the need to develop an interlocking miniplate system specifically for the midface. This system should be designed considering the need to preserve critical anatomical features, including sinus walls and tooth roots, thus maximizing its clinical utility and safety. Future research on the usability of interlocking 3D miniplates should include diverse specialties to thoroughly assess the device's effectiveness and suitability in various clinical settings. Beyond the present usability study, it is imperative to test the design in a clinical environment with human participants to fully evaluate its performance and practicality in real-world clinical scenarios.

In this study, we focused on evaluating the usability of the interlocking 3D miniplate design. Previous research has shown that this design is significantly more stable than the standard miniplate [9]. Our findings provide insight into clinicians' perspectives on the novel interlocking design, revealing a comfort level comparable to that of the standard plate. Furthermore, repeated applications of the interlocking 3D miniplate led to increased comfort and a reduction in application time. This suggests that, despite its novel nature, the interlocking 3D miniplate is relatively straightforward to apply and has a short learning curve. The time required to apply the interlocking 3D miniplate was only 12 seconds longer than that for the standard plate, with comparable stability.

NOTES

Conflict of interest

No potential conflict of interest relevant to this article was reported.

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Ethical approval

This study was approved by the Research Ethics Committee, Faculty of Medicine, Universitas Indonesia Nomor: KET-1609/UN2.F1/ETIK/PPM.00.02/2021.

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