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# Comparison of pre- and post-implantation of Indonesian-made plates in fracture patients: Functional, radiological, biomechanical and chemical analyses

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## Abstract

Bone implants are important in the recovery of fractures and degenerative diseases. Although many implants have been marketed, study on Indonesian-made plates is still limited. The aim of this study was to assess the patients' functional and radiological improvements and biomechanical and chemical changes of Indonesian-made plates used in long bone fractures. retrospective study was conducted at Semen Gresik Hospital, Gresik, Indonesia. This study included adult patients with long bone fractures who had surgeries with Indonesian plates. Functional improvement (assessed using disabilities of arm, shoulder, and hand (DASH) or lower extremity functional scale (LEFS)) and radiological data (assessed using radiographic union score (RUS)) were assessed in week 4 and month 6, 12, and 15 after surgery. Biomechanical changes (hardness and roughness test) and chemical analysis were assessed after 15 months of use. The normality of the data was tested with Shapiro-Wilk while data analysis was conducted using paired Student t-test or Friedman test as appropriate with type of data. Our data indicated that the DASH and LEFS functional scores had significant improvement over the follow-ups indicating functional recovery. RUS scores also improved over time, indicating a good healing process. Hardness tests on post-surgery implants showed a decrease in hardness of 7.3% and an increase of 3.3% in roughness. Chemical analysis showed a reduction in chemical levels in the implant of 7.8%, indicating durability and minimal toxicity. This study highlights that Indonesian implants have been proven safe to use in fractures. Further examinations with a larger sample and a longer duration of monitoring are recommended for stronger validity.

**Keywords**: Bone fracture, Indonesian-made plate, functional analysis, biomechanics analysis, chemical analysis



## Introduction

Bone consistency and function are crucial aspects of skeletal health. Bones provide structural support to the body and play a pivotal role in various physiological functions such as mobility, protection of vital organs, and hematopoiesis. Understanding bone consistency involves examining its composition, including minerals like calcium and phosphorus, as well as collagen, which contributes to its strength and flexibility is critical. Moreover, bone density and architecture significantly influence its mechanical properties, impacting its ability to withstand

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external forces without fracturing [1,2]. Fractures, or breaks in the continuity of bones, can occur due to various reasons, such as trauma from accidents, falls, or sports injuries. Additionally, factors like age, gender, genetics, lifestyle choices, and underlying medical conditions can predispose individuals to fractures [3]. Epidemiological data underscores the significance of bone fractures, with millions of cases reported globally each year [4,5]. These numbers highlight the substantial burden fractures pose on healthcare systems and emphasize the importance of preventive measures and effective management strategies to mitigate their impact on individuals' health and well-being [1,3,4].

Long bone fractures present significant complications, often leading to severe consequences. These complications include delayed healing, nonunion, malunion, infection, and nerve or vascular damage [6,7]. Prompt and appropriate treatment is crucial to prevent these adverse outcomes. Currently, available treatment options range from conservative measures like immobilization with casts or splints to surgical interventions such as open reduction and internal fixation using plates and screws [8,9]. To date, there has been limited exploration into the outcomes associated with the use of Indonesian-made plates. Therefore, further investigation is warranted to evaluate the characteristics of Indonesian-made plates. This assessment could serve as a valuable reference for their application in treating fracture patients in Indonesia.

Monitoring postoperative patients with long bone fractures treated with plates is crucial. This involves assessing functional recovery, radiological evidence of bone healing, biomechanical stability of the implants, and chemical integrity of the plates. Comprehensive analysis ensures optimal patient outcomes and early detection of any complications [2]. According to a study, the mechanical performance of Indonesian plates was inferior to that of Association of Osteosynthesis (AO) plates [10]. These observations may serve as a catalyst for the enhancement of domestically manufactured dynamic compression plates (DCP) in Indonesia to attain properties similar to widely utilized plates, such as the standard European AO plates [10]. The aim of this study was to compare conditions before and after the installation of Indonesian-made plates in fracture patients, with a focus on functional, radiological, biomechanical, and chemical analysis. This study is expected to make a valuable contribution to the improvement of Indonesian-made plates, clinical practice, and the development of more effective treatment methods for fracture patients.

# Methods

## Study design and patients

A retrospective study was conducted at the orthopedic and traumatology outpatient clinic of Semen Gresik Hospital, Gresik, Indonesia, from June 2020 to June 2022. According to Cochran's Formula [11], the minimum sample was 15 patients. This study included patients: (a) aged 16 to 65 with long bone fractures; (2) underwent surgery using Indonesian-made plates in Semen Gresik Hospital; (c) had not removed any plates from June 2020 to June 2022; and (d) had no pre-existing limb function abnormalities. Patients with comorbidities that can affect fracture healing outcomes such as diabetes mellitus, congenital diseases, or other chronic metabolic conditions; patients with multi-trauma requiring care from more than two specialized fields; and patients who lost for follow-up for at least one year were excluded from the study.

## Study variables and data collection

Demographic data, including age, gender, location of the fractured extremity, and trauma mechanism, were collected from each patient. Functional data (assessed using disabilities of arm, shoulder, and hand (DASH) and lower extremity functional scale (LEFS)) and radiological data (assessed using Radiographic Union Score (RUS) were measured by interviews and collected from medical records, respectively, during week 4, and month 6, 12, and 15 after surgery. We did not collect data related to functional analysis (DASH and LEFS) and radiology (X-ray) before the fracture.

Biomechanical data (hardness and roughness test) and chemistry test data using plates that had been used on the patients (after 15 months of use) were assessed by the Department of

Mechanical Engineering, Faculty of Industrial Technology and Systems Engineering, Institut Teknologi Sepuluh Nopember, Surabaya, Indonesia.

## Functional and radiology assessments

DASH and LEFS scores were assessed through direct interviews with one orthopedic specialist. The DASH score questionnaire measures upper extremity disabilities and disorders. It is designed to provide specific outcomes, enabling self-assessment by individuals. DASH consists of 30 assessment items with scoring 0 (no defects) to 100 (normal) [12]. The LEFS questionnaire consists of 20 questions designed to assess an individual's capability to accomplish daily tasks. LEFS was used to evaluate functional impairment in patients with disorders of one or both lower extremities. The minimum score is 0 and maximum score is 80 [13].

The radiological data were presented in the form of bone union and radiographic union scores, which have been validated by two orthopedic specialists. RUS assesses the integer score for each cortex imaged on anteroposterior (medial and lateral cortex) and lateral (anterior and posterior cortex) X-ray as follows: 1 = no healing; 2 = no callus, no bridging callus; 3 = there is a bridging callus, but the fracture line is still visible; 4 = there is a bridging callus without a visible fracture line. Scores for all four cortices were summed to give a final score ranging from 4 (not healed) to 16 (maximum healed) [14,15].

## Biomechanics and chemical analyses

The biomechanical test was conducted using a hardness test and roughness test. The hardness test was to assess the surface hardness of an implant. This involved applying a Vickers indenter onto the implant surface using a machine. The size of the resulting indentation indicated the hardness level of the surface under examination. Measurements were carried out using both a manual Leitz micro hardness system and an automatic micro indentation testing system, LecoAMH43 (Leco Corporation, Lakeview, St. Joseph Michigan, USA), with a 200 g weight. The roughness test evaluates surface texture, with the average roughness (Ra) representing the surface's average vertical deviation from an imaginary baseline. The surface roughness of the plates was gauged using a Profilometer (Scantron Industrial Product Ltd., Taunton, UK). Measurements were taken at 3 points surrounding the deepest hole, on both convex and concave surfaces, each measuring 0.5×0.5 mm [10,16] (**Figure 1**).


Figure 1. Hardness and roughness test plate sample before and after implantation. The hardness test was carried out at point A, while the roughness test was conducted at points 1, 2 and 3, which are between the plate holes.

Chemical composition analysis involved assessing changes in chemical content post-plating using scanning electron microscopy energy dispersive spectroscopy (SEM-EDS) Hitachi FlexSEM 100 (Hitachi Ltd., Ibaraki, Japan) [17]. The Indonesian-made plates are divided into surface, middle, and inner parts. In this study, chemical tests were carried out on the surface (parts exposed to soft tissue) and the middle (parts that were minimally exposed). The inner part was not checked since in this study, the entire plate inspection was carried out on the surface only. Chemical changes were done only on 2 plates (one sample was a new plate and another sample was the plate that had been used on the patient). However, these plates were chosen randomly to reduce the risk of bias (**Figure 2**).

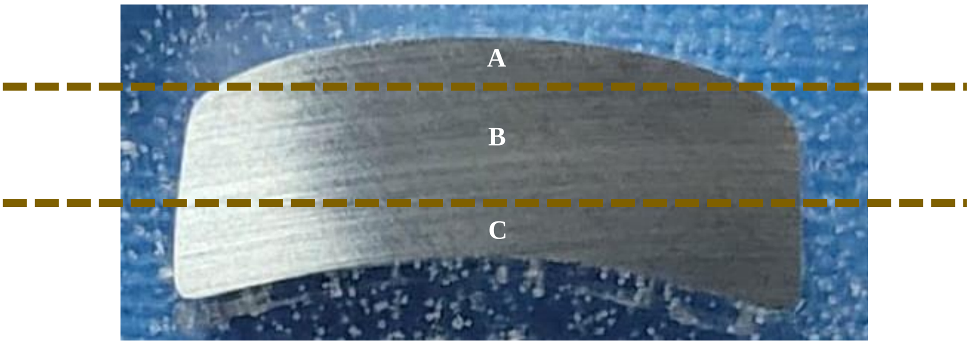


Figure 2. Coronal section of the plate A: surface, B: middle, and C: the inner part.

Follow-up assessments were conducted to evaluate functional and radiological changes. However, this study focused on comparing newly acquired Indonesian-made plates designated for bone placement with those removed at or after month 15. Researchers regarded new Indonesian-made plates as having similar characteristics and manufacturing standards.

### Statistical analysis

The normality of data was assessed using the Shapiro-Wilk test. For radiological evaluation (RUS) and functional evaluations (DASH and LEFS scores), the repeated ANOVA/General Linear Model or Friedman test was used as appropriate to compare the improvements between the follow-ups. For biomechanical evaluation (using hardness and roughness) and chemical composition (using SEM-EDS), the paired Student t-test or the Wilcoxon test was used to assess the changes between pre and postoperative implant conditions. All data were processed using SPSS 27.0.0 for Windows edition 64-bit, 2023 (SPSS Inc. Chicago, IL, USA).

## Results

### Characteristics of the patients

A total of 20 patients (14 males and 6 females) who were monitored regularly over 15 months were included in the study (**Table 1**). Among them, 9 had upper extremity fractures and 11 lower extremity fractures fixed with the Indonesian plates. The average age of the patients was 38.1 years, with the majority falling within the 41–50 age group, comprising 45% of the total sample. The primary mechanisms of trauma were falls from greater than standing height and low-speed motor vehicle collisions, accounting for 65% of cases.

Table 1. Characteristics of the patients included in the study (n=20)

| Characteristics | Frequency | Percentage |
|---|---|---|
| Gender | | |
| Male | 14 | 70 |
| Female | 6 | 30 |
| Age (year) | | |
| <30 | 4 | 20 |
| 31–40 | 7 | 35 |
| 41–50 | 9 | 45 |
| >50 | 0 | 0 |
| Location of fracture extremity | | |
| Upper | 9 | 45 |
| Lower | 11 | 55 |
| Trauma mechanism | | |
| Fall from standing height/lower | 2 | 10 |
| Fall from more than standing height | 6 | 30 |
| Low-speed motor vehicle collision | 7 | 35 |
| High-speed motor vehicle collision | 5 | 25 |

### Functional analysis

DASH scores for upper extremity fractures showed significant improvement. The mean DASH score in patients with upper extremity fractures at week 4 was 17.2, month 6 was 13.1, month 12 was 8.6, and the DASH score at month 15 was 1.8 (**Table 2**). The data had a normal distribution based on the Shapiro-Wilk test, and therefore the repeated measures ANOVA test was conducted. Mauchly's test indicated similar variances (*p*=0.056), while the Sphericity assumption yielded a significance level of *p*<0.001. These data indicated a significant improvement in mean score of DASH scores between follow-ups (**Table 3**).

Table 2. Disabilities of arm, shoulder, and hand (DASH) score (n=9)

| Gender | Disabilities of arm, shoulder, and hand (DASH) score follow-up | | | |
|---|---|---|---|---|
| | Week 4 | Month 6 | Month 12 | Month 15 |
| Male | 18 | 15 | 8 | 1 |
| Male | 19 | 15 | 7 | 0 |
| Male | 17 | 13 | 10 | 4 |
| Male | 20 | 13 | 6 | 4 |
| Male | 15 | 10 | 7 | 2 |
| Male | 16 | 12 | 10 | 0 |
| Female | 15 | 14 | 10 | 0 |
| Female | 20 | 14 | 9 | 4 |
| Female | 15 | 12 | 10 | 1 |
| Mean±SD | 17.2±1 | 13.1±0.9 | 8.6±0.9 | 1.8±1.1 |

Table 3. Disabilities of arm, shoulder, and hand (DASH) score analysis between follow-ups

| Time of follow-up | Shapiro-Wilk | Mauchly test | Sphericity assumed |
|---|---|---|---|
| | *p*-value | *p*-value | *p*-value |
| Week 4 | 0.110 | 0.056 | <0.001 |
| Month 6 | 0.481 | | |
| Month 12 | 0.052 | | |
| Month 15 | 0.054 | | |

LEFS scores for lower extremity fractures also had significant increases across monitoring periods. The mean LEFS score in patients with lower extremity fractures at week 4 was 48, month 6 was 51.3, month 12 was 55.8, and the LEFS score at month 15 was 58.9 (**Table 4**). The data was tested for normality using Shapiro-Wilk and was found that the data was normally distributed. Following the Repeated Measures ANOVA test, Mauchly's test showed *p*=0.191, suggesting comparable variances, while the assumed Sphericity significance yielded a *p*<0.001. Therefore, it can be concluded that there was a significant difference in mean improvement (LEFS scores) between groups (**Table 5**).

Table 4. Lower extremity functional scale (LEFS) score

| Gender | Lower extremity functional scale (LEFS) score based on follow-up | | | |
|---|---|---|---|---|
| | Week 4 | Month 6 | Month 12 | Month 15 |
| Male | 50 | 52 | 57 | 58 |
| Male | 48 | 53 | 57 | 60 |
| Male | 46 | 50 | 57 | 59 |
| Male | 46 | 51 | 53 | 58 |
| Male | 45 | 51 | 55 | 60 |
| Male | 46 | 51 | 56 | 59 |
| Male | 50 | 53 | 57 | 60 |
| Male | 48 | 50 | 56 | 60 |
| Female | 49 | 52 | 57 | 58 |
| Female | 50 | 51 | 53 | 57 |
| Female | 50 | 51 | 56 | 59 |
| Mean±SD | 48±1 | 51.3±0.6 | 55.8±0.8 | 58.9±0.6 |

Table 5. Lower extremity functional scale (LEFS) score analysis between follow-ups

| Time of follow-up | Shapiro-Wilk | Mauchly test | Sphericity assumed |
|---|---|---|---|
| | *p*-value | *p*-value | *p*-value |
| Week 4 | 0.059 | 0.191 | <0.001 |
| Month 6 | 0.100 | | |
| Month 12 | 0.300 | | |
| Month 15 | 0.079 | | |

## Radiological analysis

Radiological outcomes, including bridging callus observations, were assessed. RUS scores averaged 4.95 at week 4, 6.5 at month 6, 8.95 at month 12, and 12.8 at month 15 (**Table 6**). The Shapiro-Wilk test presented normal distribution ($p<0.05$). The results of the Friedman test revealed a $p=0.739$, suggesting no notable differences in RUS scores across the monitoring periods (**Table 7**).

Table 6. Bone union and radiographic union score (RUS)

| Gender | Bone union and radiographic union score (RUS) based on follow-up | | | |
|---|---|---|---|---|
| | Week 4 | Month 6 | Month 12 | Month 15 |
| Male | 5 | 8 | 10 | 16 |
| Male | 4 | 4 | 7 | 13 |
| Male | 5 | 5 | 7 | 12 |
| Male | 4 | 6 | 8 | 14 |
| Male | 5 | 6 | 8 | 12 |
| Male | 4 | 4 | 8 | 12 |
| Male | 4 | 6 | 8 | 16 |
| Male | 5 | 4 | 7 | 15 |
| Male | 5 | 8 | 10 | 12 |
| Male | 4 | 6 | 8 | 13 |
| Male | 5 | 8 | 10 | 15 |
| Male | 6 | 8 | 10 | 12 |
| Male | 4 | 8 | 10 | 15 |
| Male | 6 | 6 | 10 | 12 |
| Female | 6 | 8 | 8 | 12 |
| Female | 5 | 4 | 8 | 13 |
| Female | 6 | 5 | 10 | 10 |
| Female | 6 | 10 | 12 | 12 |
| Female | 4 | 10 | 12 | 10 |
| Female | 6 | 6 | 8 | 10 |
| Mean | 4.95 | 6.50 | 8.95 | 12.8 |

Table 7. Bone union and radiographic union score (RUS) score analysis

| Time of follow-up | Shapiro-Wilk | Friedman test |
|---|---|---|
| Week 4 | 0.001 | 0.739 |
| Month 6 | 0.041 | |
| Month 12 | 0.006 | |
| Month 15 | 0.042 | |

## Biomechanical analysis on pre- and post-implantation of plates

In all specimens, there were a total of 20 samples, showing an average decrease in hardness of 0.1%. The normality test using Shapiro-Wilk indicated a $p=0.022$, suggesting a non-normal distribution of the data. Subsequently, the Wilcoxon test was conducted to compare pre- and post-implantation plate hardness, yielding a $p=0.083$ indicating no significant disparity in hardness between pre- and post-implantation plate specimens (**Table 8**). The average increase in roughness was 2.2%. The Wilcoxon test revealed a $p=0.083$ demonstrating that there was no significant difference in pre- and post-implantation plate specimens in terms of roughness tests (**Table 8**).

Table 8. Hardness and roughness test and analysis

| Samples | Hardness test (HV) | | Roughness test (Ra) | |
|---|---|---|---|---|
| | Pre-implantation | Post-implantation | Pre-implantation | Post-implantation |
| 1 | 229 | 228 | 0.47 | 0.48 |
| 2 | 218 | 217 | 0.39 | 0.40 |
| 3 | 212 | 212 | 0.53 | 0.55 |
| 4 | 214 | 214 | 0.33 | 0.33 |
| 5 | 274 | 273 | 0.45 | 0.45 |
| 6 | 289 | 289 | 0.48 | 0.48 |
| 7 | 246 | 246 | 0.38 | 0.38 |
| 8 | 196 | 196 | 0.40 | 0.41 |
| 9 | 214 | 214 | 0.33 | 0.33 |
| 10 | 204 | 203 | 0.36 | 0.38 |

| Samples | Hardness test (HV) | | Roughness test (Ra) | |
|---|---|---|---|---|
| | Pre-implantation | Post-implantation | Pre-implantation | Post-implantation |
| 11 | 225 | 225 | 0.11 | 0.11 |
| 12 | 217 | 217 | 0.09 | 0.12 |
| 13 | 214 | 214 | 0.07 | 0.07 |
| 14 | 193 | 193 | 0.42 | 0.44 |
| 15 | 270 | 270 | 0.34 | 0.34 |
| 16 | 240 | 240 | 0.32 | 0.33 |
| 17 | 178 | 178 | 0.38 | 0.39 |
| 18 | 192 | 192 | 0.84 | 0.84 |
| 19 | 321 | 321 | 0.24 | 0.25 |
| 20 | 339 | 339 | 0.33 | 0.34 |
| Mean | 234.25 | 234.05 | 0.363 | 0.371 |
| Change (%) | (-) 0.1 | | (+) 2.2 | |
| Wilcoxon test | 0.083 | | 0.083 | |

### Chemical analysis on pre- and post-implantation of plates

The chemical contents examined were oxygen, chromium (Cr), ferrous (Fe), and nickel (Ni). Post-implantation, oxygen content on the surface area increased by 52.55%, while Cr, Fe, and Ni decreased by 10.08%, 10.11%, and 2.14%, respectively. It has also been observed that the oxygen yield has risen by 16.47% in the middle area and the levels of Cr, Fe, and Ni declined by 10.41%, 0.03%, and 0.35%, respectively (**Table 9**). The data normality test resulted in a value of $p$=0.002, suggesting that the data was not normally distributed. The Wilcoxon test yielded a result of $p$=0.273 indicating no significant difference between pre- and post-plate implantation (**Table 9**).

Table 9. Chemical content of plate pre- and post-implantation in surface area

| Section of plate | O (Oxygen) | Cr (Chromium) | Fe (Ferrum) | Ni (Nickel) |
|---|---|---|---|---|
| Surface area | | | | |
| Weight pre-implantation (%) | 1.37 | 19.73 | 59.31 | 9.77 |
| Weight post-implantation (%) | 2.09 | 17.74 | 53.31 | 9.56 |
| Change percentage (%) | 52.55 | (-10.08) | (-10.11) | (-2.14) |
| Middle area | | | | |
| Weight pre-implantation (%) | 0.85 | 21.50 | 60.95 | 11.60 |
| Weight post-implantation (%) | 0.99 | 19.26 | 60.75 | 11.19 |
| Change percentage (%) | 16.47 | (-10.41) | (-0.03) | (-0.35) |
| Shapiro-Wilk test | 0.002 | | | |
| Wilcoxon test | 0.273 | | | |

## Discussion

RUS serves as an assessment tool for fracture healing, aiming to standardize radiographic evaluations of fractures. The primary radiological criteria involve identifying the bridging callus at the fracture site, the presence of a bridging callus on three cortices, and cortical persistence. Generally, successful bone union is indicated by the absence of pain in weight-bearing areas, no false movement along the fracture line, and observable callus formation on radiographs of the fracture line [18]. The accuracy of radiological evaluations in assessing bone fracture healing is debated due to the lack of a gold standard method. This evaluation system applies to various fixation techniques, including screw fixation, plating, and external fixation. However, factors during fracture union, such as callus tissue formation, endosteal bone formation rate, and loss of the fracture line, can vary based on the specific technique used in the procedure [18,19]. Our study found that RUS values steadily increased each week or month of monitoring without significant differences.

The DASH score is widely used to assess upper extremity pathology outcomes, specifically designed for wrist and hand evaluation. It has demonstrated reliability, reproducibility, and validity in various studies, correlating well with other outcome scales [20,21]. Our study observed a significant functional improvement in the upper extremities. A different study presented generally good and satisfactory DASH scores for 45 patients during an average 17-month follow-up [22]. Similarly, other studies indicated favorable DASH scores for patients with fractures treated with volar plate fixation [23,24]. A cohort study reported satisfactory to excellent results matching DASH scores for patients with shoulder and wrist complaints [25]. The LEFS is a widely recognized and validated patient-reported outcome measure designed to assess lower extremity

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function. LEFS has proven effective in evaluating lower extremity function across various conditions and treatments [26-29]. Our study found an increasing mean LEFS score in patients with lower extremity fractures, indicating significant improvement over time. In summary, both DASH and LEFS scores in our study demonstrated significant functional improvement in the upper and lower extremities over the observation periods. These findings align with previous studies, showcasing the reliability and effectiveness of these scoring systems in evaluating functional outcomes across various orthopedic conditions and treatments [30,31].

Hardness testing is a crucial method for analyzing material properties in engineering design and material development. It measures a material's resistance to permanent deformation, such as bending, wear, abrasion, and scratches. Vickers hardness testing, involving diamond indentation under loads of 1 to 100 kg for 10 to 15 seconds, is a common method. Measured with a microscope, hardness is calculated from the indentation area [10,16,32]. Our test results revealed no significant difference in hardness between pre- and post-implantation plates, indicating a good hardness quality.

Surface roughness, measured by parameters like average roughness (Ra) and root mean square roughness (Rq), is crucial for material texture evaluation. Surface roughness affects bacterial adhesion and biofilm formation, correlating with the hydrophilicity required by cells and bacteria. An implant with Ra 1.2–1.5 μm is considered ideal for bone integration, while Rq provides a significant estimate of roughness. Surface hydrophilicity supports protein adsorption and cell adhesion, enhancing bone integration. Studies suggest that increased surface implant hydrophilicity improves protein adsorption, including the arginine-glycine-aspartic acid (RGD) sequence, contributing to cell adhesion and osteoblast differentiation, and promoting bone integration [33-36]. A previous study reported that increased roughness in implants or plates can lead to peri-implantitis and ion leakage, hindering bone integration [35]. Our study showed no significant difference in roughness between pre- and post-implantation plates, concluding that there is no significant difference in roughness between pre- and post-implantation plate specimens. The average roughness values for pre-plating and post-plating were 0.368 μm and 0.378 μm, respectively, falling within the good Ra range (1.2–1.5 μm) considered ideal for bone integration and resistant to biofilm-forming bacteria [35,36].

Orthopedic implants, especially load-bearing ones, demand superior corrosion resistance, high strength, low elastic modulus, corrosion resistance, and no cytotoxicity. Material selection is crucial, especially in load-bearing devices like hip and knee joints, requiring biocompatibility, optimal mechanical properties, ease of fabrication, and cost-effectiveness. Metal biomaterials like stainless steel, cobalt-chromium alloys, titanium, nickel-titanium alloys, and magnesium are widely used for their strength and toughness [17,37]. Stainless steel, despite lower biocompatibility, remains popular due to competitive pricing, good mechanical properties, and corrosion resistance aided by self-healing oxide layers. Alloying elements like chromium, carbon, manganese, and silicon influence the biomaterial's properties. Recent studies have explored Ni-free alternatives like high-nitrogen (N) steel, titanium (Ti) alloys, and cobalt-chromium (Co-Cr) alloys. The debate on Ni ion cytotoxicity in metal biomaterials continues, driving investigations into alternative compositions [38,39]. The addition of Cr to alloys enables the formation of a protective chromium oxide layer, known as the passive film, effectively reducing corrosion rates. Ni contributes to improved mechanical performance without causing brittleness. Ni exhibits a more significant overall beneficial effect on toughness transition temperature than similar alloying elements. Oxygen also acts as a significant alloying element in steel, enhancing strength at both ambient and low temperatures [40]. Although our study showed chemical structure changes in the plate, they were not significantly different.

## Conclusion

Patients demonstrated considerable functional and radiological improvements after plate implantation. Although there were some changes in plate hardness, roughness, and chemical levels post-implantation, these changes were not deemed significant when compared to pre-implantation values. In summary, the plates exhibited satisfactory functionality, radiographic performance, and chemical composition. Nonetheless, additional studies are advisable for a more comprehensive analysis.

### Ethics approval

This research has been given ethical approval by the Ethics and Legal Committee of Semen Gresik Hospital, East Java, Indonesia (11/KERS/2003/6.2020).

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### Competing interests

All the authors declare that there are no conflicts of interest.

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### Underlying data

Derived data supporting the findings of this study are available from the corresponding author on request.

## How to cite

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