Image Analysis on Clavicle Bone for Indonesian Clavicle Implant Design

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Abstract. Implant is a medical device created by humans and implanted in the human body to replace or enhance the biological structure in the human body. In this study, we performed an image analysis of the clavicle bone with the aim of estimating the latest clavicle implant design obtained for Indonesians. The data was collected from 6 computed tomography (CT) thorax data with a specific age range of 18-25 years old women patient. The data was loaded into three-dimensional (3D) multiplanar reconstruction, followed by segmentation process and measuring the predetermined parameter. After getting the numbers from several measurements, an approximation is made to be applied to the latest designs of clavicle implant. This study concludes that the image analysis using 3D Slicer and Radiant Viewer can give a specific number in the parameter of diameter, length, and curve that can be a recommendation for designing and manufacturing the clavicle implants based on the patient data.

1. Introduction

An implant is a medical device created by humans and implanted in the human body to replace or enhance the human body's biological structure. Implants are sometimes needed in many diseases, one of them is for clavicle fractures. Clavicle fracture itself is a common fracture [1]. There are 2.6% of all fractures cases for clavicle fractures [2] and 29.3% of 100,000 among adult population [3]. One of the treatments for clavicle fractures is by placing implants on the clavicle bone, which is commonly called the clavicle fixation. There are a few methods of surgical treatment for clavicle fractures, namely intramedullary fixation, plates and screws, partial-claviculectomy, and external fixation [4, 5].

One of the clavicle fracture treatment is plating as standard fixation. Using a fixation plate, allowing the patient to become recovered early post operatively. The fixation plate based on the principle of direct reduction of fracture fixation and added stress to the fracture to achieve biomechanical stability[6]. The clavicle fixation plate itself at the beginning used bone plate in general. This makes installation difficult because the plate shape and bone shape are not synchronized. There are currently many innovations in the clavicle fixation plate by adjusting the clavicle bone shape [7].
According to some recent studies on clavicle bone anatomy, clavicle bone between races is different. It can be seen from several previous journals that examined the anatomy of their clavicle bone region [8–14]. From previous study said, there is no anatomical study of the Chinese population. It led the researcher to carry out this research so that it could be applied to contemporary clavicle plate modifications or new developments for the Chinese population [9].

Another study comes from the Korean population. A research of clavicle in Korean population, conducted a study on clavicle fractures based on age and gender. In this research, he tested the suitability of the clavicle and pre-contour anatomical plates. There were 126 men and 60 women who showed good results on plate placement in 50% of the clavicle, and 84 men and 41 women fit in the area of 60% -70% [13].

Meanwhile, another research is based on plates that are often used, which are plates designed based on western sizes, so an anatomical study of the clavicle for the Indian population is needed [10]. As in previous studies, the anatomical study of the clavicle in the Indonesia population is the focus of this study. It is because there is no study of clavicle bone in Indonesia before. So it is expected that the size of the clavicle bone can be applied to the fixation plate.

2. Method

2.1. Data Acquisition

The data was collected from Saiful Anwar Hospital, Malang, in 2019 until 2020. This study used thorax CT scan data for normal female patients aged 18-25 years old. There are 6 CT Scan data with 11 clavicles total data. The data format used is digital imaging and communications in medicine (DICOM). DICOM is the standard format for medical imaging. The data consists of hundreds of images where the slice thickness is 0.5 millimeters (mm).

2.2. Image Analysis

This image analysis uses the Radiant DICOM Viewer software to measure the predetermined parameters. In this software, the data collected can be loaded and can use the 3D multiplanar reconstruction (MPR) technique. Data usually appears with the axial view, but, in 3D MPR, the data can be seen in three different views, such as coronal, axial, and sagittal. From 3D MPR, it can get clavicle bone images after setting the image specifically by changing brightness/contrast and changing thickness. After rotating and moving axes on the 3D MPR, the clavicle bone images can be found, as in the figure 1, the bone length, angle, and bone diameter can be calculated. Length measurements are made by drawing a line from the sternal extremity to the acromial extremity. The angle calculation can be divided into the measure of the medial angle (near the sternum) and the lateral angle. As for the diameter, the measurements were taken at the distal, medial, and proximal parts. The measurement method is shown in the figure 2.
3. Results and Discussion

3.1. Clavicle Measurement
The results of measurement parameters are listed in the Table 1.
### Table 1. Measurement Results

| Parameters          | Left         | Total       | Mean  |
|---------------------|--------------|-------------|-------|
| **Length (cm)**     |              |             |       |
|                     | Left         | 13.09       | 13.74 |
|                     | 13.85        | 13.50       | 13.15 |
|                     | 13.56        | 14.05       | 13.74 |
|                     | Right        | 13.59       | 13.27 |
|                     | 14.50        | 13.65       | 13.73 |
|                     | 13.66        | -           |       |
| **Medial Angle**    |              |             |       |
|                     | Left         | 148.9°      | 148.45° |
|                     | 153.3°       | 150.2°      | 148.66° |
|                     | 139.8°       | 157.9°      |       |
|                     | 140.6°       | 148.45°     |       |
|                     | Right        | 146.2°      | 145.2° |
|                     | 159°         | 146.8°      | 148.86° |
|                     | 147.1°       | -           |       |
| **Lateral Angle**   |              |             |       |
|                     | Left         | 157.5°      | 144.28° |
|                     | 144.3°       | 148.5°      | 146.45° |
|                     | 148.5°       | 134.3°      |       |
|                     | 146.7°       | 137.4°      |       |
|                     | Right        | 149.1°      | 148.62° |
|                     | 148.9°       | 154.3°      |       |
|                     | 142.4°       | -           |       |
| **Diameter (cm)**   |              |             |       |
|                     | Distal       |              |       |
|                     | L            | 2.01        | 1.79  |
|                     | 2            | 1.58        | 1.84  |
|                     | 1.75         | 1.71        |       |
|                     | R            | 2.01        | 1.79  |
|                     | 1.95         | 1.55        |       |
|                     | 1.70         | -           |       |
|                     | Medial       |              |       |
|                     | L            | 1.10        | 1.13  |
|                     | 1.21         | 1.07        | 1.57  |
|                     | 1.08         | 1.08        |       |
|                     | R            | 1.12        | 1.13  |
|                     | 1.34         | 1.11        |       |
|                     | 1.02         | -           |       |
|                     | Proximal     |              |       |
|                     | L            | 1.79        | 1.87  |
|                     | 1.83         | 1.76        |       |
|                     | 1.76         | 1.99        |       |
|                     | R            | 1.55        | 1.85  |
|                     | 2.10         | 1.62        |       |
|                     | 1.59         | -           |       |

#### 3.1.1. Length
Length measurements have been done with the 11 clavicles with a mean of 13.74 ± 1.1 cm. The largest length in this study was 14.50 cm and the smallest length was 13.09 cm. Between both clavicle, there was no significant difference. It is assumed that the right and left clavicle are the same. In a study conducted about anatomic variation of the clavicle, the length of the clavicle in women was a mean of 142.17 mm[12]. Whereas in the study of anatomy of the clavicle and its medullary canal, the mean length of the clavicle in women is 145.79 mm[14]. Seeing the measurements in several previous studies are different, explaining that the length of each clavicle is different in women, especially white women[13].

#### 3.1.2. Angle
As for the angle measurement, the mean results for the medial angle are 148.66° ± 15.95°, and the mean for the lateral angle is 146.45° ± 17.55°. From the results of the angle measurement, the medial angle is 2° wider than the lateral angle. Similar to previous research, the two angles are not very significant. The differences will look different when the gender is different, where the angle of women is bigger than men[12].

#### 3.1.3. Diameters
In measuring the diameter, it appears that the three parts of the clavicle. The mean of the distal diameter was 1.8 ± 0.44 cm. The largest distal diameter recorded in this study was 2.01 cm and the smallest distal diameter recorded was 1.55 cm. The mean of the medial diameter was 1.14 ± 0.26 cm. The largest medial diameter recorded was 1.34 cm and the smallest distal diameter recorded was 1.02 cm. Last, the mean of the proximal diameter was 1.77 ± 0.51 cm with the largest
proximal diameter recorded was 2.10 cm and the smallest proximal diameter was 1.52 cm. Similar to the previous study, the diameter have various sizes in every part[15].

3.2. Analysis for Placement Fixation
According to three previous studies of clavicle measurement, the measurement technique on this study are related to them [1,2,3]. These techniques then can be implemented for a new design of the fixation plate to fit the clavicle bone better. The most common and frequently used fixation plate is a fixation with eight holes with a 3.5 mm screw. In contrast, a plate with a 2.7 mm screw can only be used on thinner clavicle bones [5, 16].

Fixation plate placement must be appropriate when implanted in the clavicle bone so that the fracture can be resolved properly. When the fracture is in the middle of the clavicle, the plate application is better in the middle of the clavicle bone in about 40-60% [17]. Meanwhile, according to a research of clavicle's anatomy in Indian population, fractures in the middle can determine the application of plates in mm with the clavicle's total distance minus the distance of superior clavicle bow from the acromial end. The distance of superior clavicle bow from acromial end was 38.15 mm [10]. If the distance of superior clavicle bow is assumed to be the same for Indonesian people, then the best zone for plating is 9.925 cm. The ideal fractures were in the middle of the best zone for plating. As to the fixation plate's size, the surgeon chose depending on subjective best fit. An anatomical fit is defined as the easy positioning of the plate to the clavicle bone [1].

The data used all came from women living in East Java. The gender of several studies had a strong influence on clavicle bone size. From this study, it can be seen that the East Java region tends to have almost the same clavicle size. This is different from other sexes, such as Greek men who have a clavicle length of about 15.8 cm [18], which has a difference of 2.06 cm with the obtained data. Another study also researched differences in the clavicle bone size according to gender in the Iranian population. There are differences in the length of the clavicle between women and men in the Iranian people. Men have a clavicle length of 7 mm greater than women [19]. However, Iranian women's clavicle bone length was 7 mm smaller than the data obtained in this study. In addition, in other studies, a comparison of the clavicle's anatomy based on gender and age was also conducted in the Spanish population. In the Spanish population, the male clavicle is longer than the female clavicle. Spanish women had a smaller clavicle length of 5 mm compared to the data obtained in this study [20]. A further study from the Czech Republic, where data were obtained from the University of Athens, showed that gender greatly influenced the clavicle's size and shape. The male clavicle is more curved horizontally than the female clavicle. The female clavicle is also less robust and has less muscle attachment. The length of the clavicle in women is 19.12 mm shorter than the clavicle's length in men [19]. The male clavicle is 16.12 mm longer than the data in this study.

The size and shape affect the fixation to be used. The fixation on the market is designed for westerns. Compared to previous studies, the data used in this study is very limited. This is because anatomical studies of bone in Indonesia are still very rare. Besides, no studies were found in studying clavicle bone. Although need further improvement in data quantities, this study is very good as a preliminary study to initiate the learning of clavicle bones in the Indonesian population to develop a fixation plate suitable for Indonesian clavicle bones.

Further, more data is needed with variations in age and gender in the Indonesian population. It makes learning can be deeper and measurements are more representative of the population. Width measurement also needs to be done to determine the plate that is more fit during installation [15].

4. Conclusion
The measurement of the clavicle bone in the Indonesian population has been successfully conducted. Then the measurement parameters that have been measured has a mean clavicle length was 13.74 ± 1.1 cm, the mean medial angle was 148.66° ± 15.95 °, the mean lateral angle was 146.45° ± 17.55°. Then, the distal diameter was 1.8 ± 0.44 cm, the medial diameter was 1.14 ± 0.26 cm, and the proximal diameter was 1.77 ± 0.51 cm. The best zone for plating was 9.925 cm from acromial end.
with ideal fractures between them. In other words, this study can be concluded that image analysis can give a specific number in the parameter that can be a recommendation for designing and manufacturing the clavicle implants based on the patient data.

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