Strut and Ring Connection System Design on External Fixator Based on Hexapod to Increase Bone Flexibility Reconstruction Using Finite Element Analysis

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Abstract. An external fixator is a medical device that supports bone reconstruction processes that require correction due to bone deformities. External fixator based on hexapod is the right device to do correction of complex deformities due to its ability to reconstruct bones in three dimensions. There are many external fixator based on hexapod products with varied designs, one of these variations is Taylor spatial frame which uses a universal joint for its connection system. So far, based on U. S. Patent 8,202,273, Taylor spatial frame has a good strut-ring angle (0°) and adjustments. The results of the correction process observations show that the frame has backlash problems due to the clearance between components. This study aims to improve the connection system of the strut and ring of the external fixator so as to produce a range of angles between the strut and the ring which were less than 30° with no backlash on its components. The improvements that will be made to the strut and ring connection system use a generic product development process based on Ulrich and Springer and finite element analysis. The results show that there are four alternative improvement concepts that can be produced. One of the four concepts can produce a range of angles between strut and ring for 32.04°. This research can be useful in the further development of external fixators based on hexapod.

1. Introduction

Bone is a member of the body that is very important for humans, where the body is very influential on the state of the human body. Fractures are separate bone continuity due to excessive pressure [1]. The number of traffic accidents that cause fractures in productive populations in Indonesia is relatively high. Based on recorded data, the average traffic accidents in Indonesia in 2012-2016 were 103,812 cases and 26.48% suffered severe injuries. [18]. Among those with severe injuries, 46.2% had a fracture of the lower extremity / complex lower bone deformity [19]. Based on recorded data, the number of people in Indonesia who are in the productive age (15 - 64 years) is 128 million or 69% of the total population of Indonesia. If the data is projected against the population of Indonesia, people who experience lower extremity fractures are estimated at 44 million people. Besides being caused by accidents, deformity problems can be caused by illness, congenital disorders, malnutrition, and stress [11].

The occurrence of these complex lower bone deformities can be handled by means of corrective actions. One of the corrective actions is bone reconstruction surgery, which is the withdrawal of bone tissue under controlled conditions using an external fixator to obtain the planned height and alignment of the bone [13][9]. People who experience lower extremity fractures require a long period of rehabilitation, namely 3 months after surgery. The length of the rehabilitation period makes people who
experience lower extremity fractures unable to move normally so that it results in a decrease in productivity of the company or institution where they work. The World of Medicine has attempted to reduce the length of the rehabilitation period, namely by using Illizarov [20]. Illizarov users can walk full body weight in 2 weeks after the use of the tool. However, this tool has the disadvantage of being less flexible in complex bone reconstruction. These problems have been resolved by the discovery of the hexapod system.

Ring type of external fixator with hexapod system can be used to reconstruct bone in three dimensions which are rotational, angulation, and lengthening. Hexapod is a six-rod system used in robotics [3]. This system has been applied by installing six struts on top ring and bottom ring, which are connected to a ball and socket joint or revolute joint [7]. This connection is arranged in such a way that the movement of each strut can change the position of the platform in six degrees of freedom [10]. This application is known as the platform platform system that has the advantage of being able to adjust the position to be more accurate [10].

The Taylor Spatial Frame has good strut-ring angle and adjustments. The results of the correction process observations show that the frame has backlash problems due to the clearance between components. Patent no. 6,030,386 concerning the Taylor Spatial Frame design shows the clearance of the shoulder bolt with the universal joint tip, and in each universal joint component. This clearance is needed so that the frame is able to move in three axes using a universal joint which is a two-axis connection system [3]. The clearance allows the strut to be installed in tight conditions but can still be rotated. However, uncontrolled clearance will cause backlash and make strut playback inaccurate. These two things will cause an unplanned bone shift so that even though the patient's bone reconstruction process is successful, the correction results remain less accurate. So it is necessary to develop a connection system to minimize backlash and make the external fixator save for the user and have angle of strut-ring 30°. If the angle range of the external fixator connection system can reach 30° values, it will be easier for doctors to be able to perform bone reconstruction process in patients who need an angle correction above 50°. Therefore, further consideration is needed regarding the use of universal joints as a connection system for external fixator.

Based on the problems that arise from the connection system with the universal joint in the Taylor Spatial Frame, one solution that can be given is to make improvements to the strut and ring connection systems. The product development process generally consists of stages or often also referred to as phases. The overall product development process consists of 6 phases, namely product planning, concept development, system level design, detailed design, testing and repair, and initial production. A subsection Some text.

2. Methods
The completion step in this study was adapted from the generic product development process in the development concept section which can be seen in Figure 1:
2.1. A Identifying Costumer Needs
Identification of needs is done to determine the needs needed to improve the existing external fixator design, so that the results of identification needs are expected to be a technical need when designing connection system improvements from external fixators.

2.2. Product Specification
Specifications and targets are obtained after identifying the needs of users. At this stage the decomposition of user needs is carried out to become a technical need to know the specifications needed according to the design improvement targets.

2.3. Concept Generation
After setting the specifications and targets, the design of an external fixator fixing concept is carried out using spherical plain bearings according to specifications and targets that have been determined. So the goal of this stage is to explore concepts and generate alternative design concepts that are appropriate to the needs, in order to meet the target specifications by turning them into technical needs. Generation of alternatives design concepts are done using morphological charts.

2.4. Concept Selection and Evaluation
After the morphological chart results are obtained, then there is a selection of the existing product configuration, there are several stages, namely:
   1. Screening design concepts by filtering design concepts based on reliable
   2. Evaluation of concept design that have been filtered using software autodesk inventor 2016: finite element analysis
   3. Assessment of the concept design using Pugh Matrix
   4. Ranking of concept design
3. Result and Discussion

3.1. Identifying Costumer Needs

This stage describes the problem of using the Taylor Spatial Frame using universal joints. Description of the problem is obtained through literature studies on the use of Taylor Spatial Frames for orthopedic surgeons and practitioners in the field of fixation tool design through available patents. The results of the literature study indicate that the range of the strut and ring angles can reach 90° but in the correction process shows that the frame has backlash problems due to the clearance between components. Patent no. 6,030,386 concerning the Taylor Spatial Frame design shows the clearance of the shoulder bolt with the universal joint tip, and in each universal joint component. This clearance is needed so that the frame is able to move in three axes using a universal joint which is a two-axis connection system [3]. Provision of clearance allows the strut to be installed in tight conditions but can still be rotated. However, uncontrolled clearance will cause backlash and make strut playback inaccurate. These two things will cause an unplanned bone shift so that even though the patient’s bone reconstruction process is successful, the correction results remain less accurate. Therefore, further consideration is needed regarding the use of universal joints as a connection system for external fixators. The universal Taylor Spatial Frame universal component can be seen in Figure 2.

![Figure 2. Universal Joint Taylor Spatial Frame](image)

Figure 2 presents connection system of Taylor Spatial Frame. The universal joint which used in Taylor Spatial Frame is a custom single universal joint so that the shape of the yoke / fork and connection of each component is not in accordance with the standard. Custom joints are used so that the angles that can be formed are larger. The FAST Taylor Spatial Frame diagram is used to evaluate information on frame usage constraints that aim to identify the root of the problem in each obstacle. Identification of the root problem from each obstacle using Taylor Spatial Frame can be seen in Figure 3.

![Figure 3. Identify the Root Backlash Problem](image)

Figure 3 presents identification of the root problem from each obstacle. Backlash is the distance or space or confusion that exists between two or more elements [15]. The backlash is caused by the clearance between the center block hole and the small pin and large pin. In addition, the backlash occurs due to a clearance on the universal joint tip that is connected to the ring. Clearance in small quantities is needed in these components to support the Taylor Spatial Frame movement mechanism [6]. However, excessive
clearance can cause damage to the frame, especially on struts that are directly connected to universal joints.

3.2. Product Specification

Specifications and targets are obtained after identifying the needs of users. At this stage the decomposition of user needs is carried out to become a technical need to know the specifications needed according to the design improvement targets.

To overcome the problem of smooth strut movement, a custom universal joint component should be replaced with another connection system because it is difficult to carry out joint production with a high degree of accuracy. Universal joint components can be replaced with standard components that can accommodate universal joint systems and are able to overcome backlash constraints.

![Figure 4. Improvement Concept](image-url)

Figure 4 presents improvement concept that can be able to overcome the existing problems. To overcome this problem technically it can be stated that the user needs a joint replacement with a joint that is able to overcome the problem when using universal joint (backlash). After discussions with doctors and practitioners in the field of designing external fixation, the concept of improvement was determined by using a ball joint, where the joint chosen was spherical bearing. Spherical bearings are chosen because they are capable of rotating with a wider angle so that they are suitable to be an alternative to universal joint replacement.

Spherical plain bearings are standard mechanical components that allow movement in various directions and are able to align the bearing itself. This bearing consists of two components, namely the inner ring which has an outer surface such as a ball and outer ring that has a concave inner surface that adjusts the inner ring [12]. The advantages of spherical plain bearings as joint external fixators are:

- Able to accommodate misalignment & high reliability
- Accommodate deformation from surrounding components
- Accommodate broad manufacturing tolerance
- Suitable for slow and precise rotating movements
- Long economic life
The bearings used in this alternative are spherical radial plain bearings with GE 10 steel material E. Specifications from GE 10 E can be seen in Figure 5.

3.3. Product Specification

After setting the specifications and targets, the design of an external fixator fixing concept is carried out using spherical plain bearings according to specifications and targets that have been determined. So the goal of this stage is to explore concepts and generate alternative design concepts that are appropriate to the needs, in order to meet the target specifications by turning them into technical needs. Generation of alternatives design concepts are done using morphological charts.

Figure 6 presents the morphological chart that determine the design concept obtained based on the division of existing solutions and sub-functions. the concepts obtained are 12 design concepts. the difference from the 12 design concepts is the use of parts in each function. for example, in the design concept 1 (arrows with full lines and blue), to support the function of moving the joint system, the design concept 1 uses the standard strut lock screw. the part uses aluminum 6061 and no adjustment is made in the form of thinning thickness, whereas when using "modified" it means that the part uses stainless steel and some adjustments are made in the form of thinning. Furthermore, in the design concept 1, to support the function of angular changes in the connection system, the design concept 1 uses a standard spherical plain bearing and installs the part right in the middle of the ring and no adjustment is made in the form of chamfering an cut off on the inner and outer from bearing. when using the "modified" type, the bearings used will be installed parallel to the ring and adjustments will be made to how much chamfer is 45° and the cut off is 1.5 mm on the inner and outer bearing. nd finally, to support the function of holding the bearing stable, the design concept 1 uses a single ring. when using a double ring, each top row and bottom ring consists of 2 rings which are joined together with the help of bolts.
3.4. Concept Generation
The concept selection is done in order to determine the best design concept and that suits to the needs. At this stage an evaluation of alternatives to get the best alternative is carried out. Evaluation is carried out by assessing alternatives based on the results of angles of strut-ring, displacement, safety factor, and tolerance joint fitting using stress analysis with software inventor 2016. From the filtering results it is found that out of the twelve design concepts, it can only be reduced to four alternatives, namely the concept design VI, design concepts IX, concept X, and design concepts XII. In the next stage an assessment is carried out to determine the ranking and selection of the highest ranking results.

| Alternative Design Concept | Angles of Strut-Ring (°) | Max Displacement (mm) | Min Safety Factor (ul) | Joint Fitting Tolerance (µm) |
|-----------------------------|--------------------------|-----------------------|------------------------|----------------------------|
| Design Concept VI           | 34,116                   | 0,09081               | 1,53                   | 68                         |
| Design Concept IX           | 38,77                    | 0,1047                | 1,93                   | 68                         |
| Design Concept X            | 36,52                    | 0,1059                | 2,88                   | 68                         |
| Design Concept XII          | 32,04                    | 0,08097               | 2,16                   | 68                         |
| Initial Design (Taylor Spatial Frame) | 0             | 0,09712               | 1,71                   | 1150                       |

Table 1 presents technical factor value for each alternative concept and for initial design (Taylor Spatial Frame). There are 4 criteria used as a comparison, namely angles of struts, displacement, safety factor, and joint fitting tolerance. angles of strut-ring is the angle range between strut and ring, the smaller the angle that can be produced, the more flexible the frame is. initial design has the best angle range value between the existing alternative design concepts. Displacement is the level of ability of the frame of each alternative when given a number of burdens, whether experiencing a shift or not, when experiencing a shift, how much the shift. the smaller the displacement value, the better the stability of the frame. The displacement value is obtained by applying the finite element analysis to each alternative design concept. Design concept XII has the best displacement value among all the other alternatives. Safety factor is the ability to accept loads from each alternative frame, the value of safe and feasible safety factors must be in the range of 1.25 - 4. Value of safety factor is obtained by applying the finite element analysis to each alternative design concept. All design concepts have good safety factor values (within the recommended range). and finally, joint fitting tolerance is the tolerance given to each component of the joint system used. The smaller the value of joint fitting tolerance, the better the stability of the frame (backlash can be avoided by applying a small joint fitting tolerance).

| Alternative Design Concept | Design Concept VI | Design Concept IX | Design Concept X | Design Concept XII |
|-----------------------------|-------------------|-------------------|-------------------|-------------------|
| Angles of Strut-Ring        | -                 | -                 | -                 | -                 |
| Stability (Displacement)    | +                 | -                 | -                 | +                 |
| Safety Factor               | -                 | +                 | +                 | +                 |
| Joint Fitting Tolerance     | +                 | +                 | +                 | +                 |
| Amount (+)                  | 2                 | 2                 | 2                 | 3                 |
| Amount (0)                  | 0                 | 0                 | 0                 | 0                 |
| Amount (-)                  | 2                 | 2                 | 2                 | 1                 |
| Final Score                 | 0                 | 0                 | 0                 | 2                 |
| Ranking                     | 2                 | 2                 | 2                 | 1                 |
Table II presents design concept evaluation using Pugh Matrix (The concept-screening matrix). For the syringe example, the pugh’s matrix rated the concepts against the reference concept (initial design: Taylor Spatial Frame) using a simple code (+ for "better than," 0 for "same as," - for "worse than") in order to identify some concepts for further consideration. Design concept XII is ranked first among the other three design concepts which received 2 for its final score. Note that the three concepts ranked "2" all received the same net score.

Ring fixator models for Taylor Spatial Frame and frame of design concept VI, IX, X and XII were created using Autodesk Inventor 2016. Ring fixator models for Taylor Spatial Frame created designs were full ring-type with internal diameter 155mm as a moderate ring internal diameter. Aluminum 6061 T6 was used as main material, as Taylor Spatial Frame used the same material for its rings [14], and frame of design concept VI, IX, X and XII created designs were full ring-type with internal diameter 180mm as a large ring internal diameter. Aluminum 6061 T6 was used as main material. As for numerical modeling, key wire attachment positioning was indicated by wire fixation bolts mounted on inner ring holes, while strut end attachment positioning was indicated by shoulder bolts mounted on outer ring holes for Taylor’s ring and frame of design concept VI, IX, X and XII. External load was determined from wire tensioning and weight given from normal human body. The reference force of the wire strain in the ring is 900-1100 N [9][5] and axial load applied to 700 N as maximum weight load for average human weight [2]. In this study, we applied maximum wire strain and to weight using average human body weight. The wire load is placed in the same direction as the position of key wire attachment position while the weight load is placed on the wire fixation bolt.

Frame stability was significantly compromised in compression and bending when shorter struts were used and the ring-strut angles were less than 30 degrees. Torsional stability was not significantly affected [6]. Each Universal Joint of Taylor Spatial Frame can be rotated 90° [4] or it can be assumed that the angle of strut-ring is 0°. Design concept XII has the most a angle of strut-ring that can approach 30° although that angle of strut-ring was not better than what initial design (Taylor Spatial Frame) can produce. Stability is the main criteria to generate an safety bone reconstruction. Less displacement of an object represents higher stability. Table I shows that ring of design concept XII had the smallest score for max displacement among others with 0.08097mm. The smaller of max displacement’s value will make the stability level of the external fixator better, may cause a long-term effect to bone reconstruction. Fixator rings must be designed to withstand a “design overload” larger than the normally expected load. Safety factor allows to evaluate the design ability to withstand amount of load applied to that design [16]. Modern engineering design gives a rational safety factor within the range of 1.25 to 4 [17]. Based on that, all of the design concept and Taylor’s were still able to withstand normal load, although design concept X has the biggest score of safety factor among others.

Based on table II, design concept XII was ranked first among the other. That concept is using modified strut lock screw (one part of the strut which located at both ends of the strut), single ring, and using modified ball joint (spherical plain bearing) which is mounted parallel in the bottom or top of the ring. Design concept XII may provide the solutions on Taylor’s (backlash) with better design performance, especially in providing stability and safety for the users although the angle of strut-ring can’t reach 30° yet. The detail of design concept XII is presented in Figure 7 and Figure 8.
Figure 7. Design Concept XII: External Fixator based Hexapod using Ball Joint

Figure 8. Detail Of Connection System Using Ball Joint (Spherical Plain Bearing)

Figure 8 presents detail of connection system using ball joint of external fixator based on hexapod. The angle range between the strut and ring that can be produced is 32.04°, even though the value cannot reach the recommended angle value, but with an angle range of 32.04°, this Frame is able to take corrective actions for extreme angles, namely correction of angles above 50°. For further research, it is necessary to consider the provision of slots in the connection system to accommodate a larger ring-strut angle.

### Table 3. Comparison Between Design Concept XII (Selected Design) And Initial Design (Taylor Spatial Frame)

| Alternative Design Concept       | Angles of Strut-Ring (°) | Max Displacement (mm) | Min Safety Factor (ul) | Joint Fitting Tolerance (µm) |
|----------------------------------|--------------------------|-----------------------|------------------------|-----------------------------|
| Design Concept XII              | 32.04                    | 0.08097               | 2.16                   | 68                          |
| Initial Design (Taylor Spatial Frame) | 0                        | 0.09712               | 1.71                   | 1150                        |

Table III presents comparison between design concept XII (selected design) and initial design (taylor spatial frame). In the table, cells that are shaded in gray indicate that the value is the best value. So, the design concept XII has displacement values, safety factor values and joint fitting tolerance values that are better than the initial design. While the initial design is only superior to the value of angles of...
the struts. This proves that in terms of design and in terms of finite element tests, design concept XII can improve and develop the disadvantages of Taylor spatial frames (backlash on connection system components).

3.5. Conclusion

External fixator based hexapod using ball joint provide the solutions on Taylor’s (backlash) with better design performance, especially in providing stability and safety for the users. Although the angle of strut-ring can only reach 32.04°. Angle of Ring-strut is a critical factor in truss mechanics, seems to have the greatest influence on stability for the external fixator. The recommendation is adequate length struts be chosen when constructing a external fixator so that ring-strut angles of 30 degrees or less are avoided.

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