# Redesign of OrthoLPPDUNS External Fixation for Bone Reconstruction Using the Function Analysis System Technique (FAST) Method

Lobes Herdiman[1a◆], Ilham Priadythama[1b], Susy Susmartini[1c], Yusuf Priyandari[1d],

I Nyoman Suci Anindya Murdiyantara[2e], Durkes Herlina Apriani[1f]

**Abstract.** *Taylor Spatial Frame (TSF) is better known as an external fixation product from several fixation devices in the orthopedic field. The Laboratory of Product Planning and Design has manufactured TSF or called OrthoLPPDUNS external fixations. The OrthoLPPDUNS design found that frame instability forming ring-strut angles caused by strut screw rotations was feeling rough due to backlash. The purpose is how to redesign an OrthoLPPDUNS with a Function Analysis System Technique (FAST). The FAST method is applied at each stage of starting from the information stage to interpreting the results. The OrthoLPPDUNS design with the joint system uses custom components that cause weakness in frame stability. The use of standard components in joint systems can provide solutions to external fixations, although there are still weaknesses in the ring-strut angle. The OrthoLPPDUNS redesign has a better success rate in terms of stability parameters, allowing more precise bone reconstruction.*

**Keywords:** *OrthoLPPDUNS; FAST; external fixation; stability.*

## I. INTRODUCTION

External fixation techniques were popularized in the mid-20th century when Hoffman introduced a tool that used bars Steinman and half-pins to stabilize long fracture bones (Drijber et al., 1990). External fixation is a metal frame designed to hold and stabilize the bones in place (Dubowy and Nichols, 2018). External fixation to reconstruct boned limbs due to fractures or abnormalities in the bone and has an adjustable bar (called strut) is rotated slowly in reconstructing the bone. In other words, external fixation is a method for treating bone or joint injuries and for correcting bone deformities by attaching external devices to the bones that aim to stabilize injured limbs (Solomin, 2008). In addition, it allows for the manipulation of limb segments to do the planned length and alignment.

In 1989 Behrens explained that three basic concepts governing the use of external frames safely and effectively for bone trauma, namely K-wire and half-pin, are vital mechanical structures and must be protected from damage, allow access to the area of injury, and must meet mechanical demands patient. In general, there are three types of external fixations widely used in bone reconstruction (Solomin, 2012). Ilizarov's external fixation is a circular fixation consisting of a metal ring or carbon fiber-connected by metal bars and sliders (Fig. 1a). The Ilizarov fixation is connected to the bone with thin wire and thick half-pins used to hold the bone in place. A monolateral external fixation is a fixation bar that consists of metal bars connected to bones with thick pins (Fig. 1b). This device is used to extend or hold the bone in place after it is straightened. Use screws to hold the bar in place when the bone extends over the bar. Taylor's Spatial Frame (TSF) is a circular fixation consisting of two metal rings and six telescopic struts at universal joints, creating a hexapod device system (Fig. 1c). TSF is a circular external fixation system, allowing

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[1] Industrial Engineering Department, Faculty of Engineering, Sebelas Maret University, Surakarta, 57126

[2] Orthopedic Surgery and Traumatology Department, Dr. Soeradji Tirtonegoro Hospital, Klaten, 57424

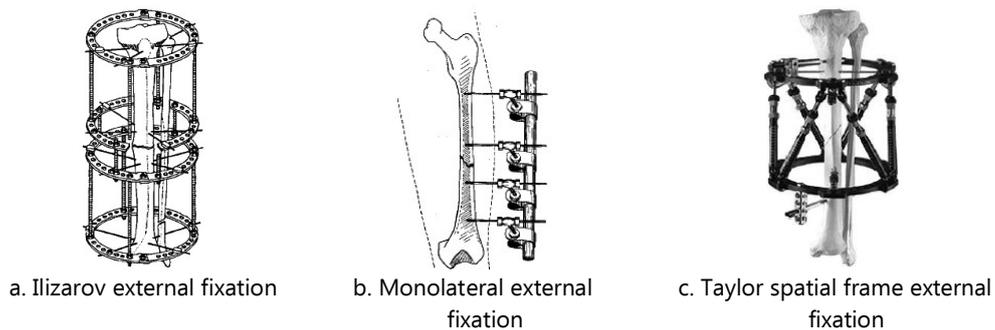[a] email: lobesh@gmail.com
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[d] email: priyandari@ft.uns.ac.id
[e] email: idnsuci@gmail.com
[f] email: durkesherlina@gmail.com
◆ corresponding author

| a. Ilizarov external fixation | b. Monolateral external fixation | c. Taylor spatial frame external fixation |

**Figure 1.** Types of external fixation among orthopedic physicians.

correction of skeletal deformity from the simplest to the most complex using the same frame. This frame has two full circles or two per thirds of the rings connected by six struts. Use thin wire and thick half-pins to connect to the bone.

In 1998 H.S. and J.C. Taylor first created the Taylor Spatial Frame (TSF, Smith & Nephew, Memphis, TN, USA) and applied this method to orthopedic (Taylor H.S. and J.C., 2000; Tan et al., 2014). This frame consists of a ring and a strut (Bone Fixation, 2018), a ring made of aluminum, titanium, or carbon fiber, available in various ring sizes determined by internal diameters, 80 mm, 105 mm, 130 mm, 155 mm, 180 mm, 205 mm, 230 mm, 255 mm, and 300 mm. Strut is available in four long groups, namely extra short (75-96 mm), short (90-125 mm), medium (116-178 mm) and long (169-283 mm). The frame's attachment to the bone is equipped with wire from stainless steel or titanium alloy with a diameter of 1.6 or 1.8 mm (called K-wire) that penetrates the skin and enters the bone. This frame is paired with a half-pin (called a pin) on the ring that penetrates the skin and enters the bone using stack rancho cubes, available in diameters of 4, 5, and 6 mm. The two ring construction (top for proximal and bottom for distal) can simulate single-level deformity; a three-ring construction with six struts in each ring pair can simulate two-level deformity (Paley, 2011). Modification of universal joint of strut lengths by changing strut sizes in frame configurations allows changes in one ring's orientation (Keshet and Eidelman, 2017), leading to simultaneous correction of each deformity (differences in leg length, angulations, translation, and rotation). The position of the computer-generated ring is based on measurements taken from X-rays and clinical examination. After all deformity parameters in the software, a daily set schedule can be proposed and printed, and a strut is rotated every day to straighten or extend the bone.

Construction of a six strut angle on the TSF with each strut's axial weight without applying bending forces to the tilt of the strut attached to the ring when we look at the attachment point strut on the ring, they are shaped like a triangle, not a circle. Paley, 2011 explained that all structures in this construction, strut configurations that form side triangles, have the same shape as the diamond crystal structure (octahedron). This construction is robust. Manual mechanical accuracy for adjusting the strut's position in the correction of the six-axis deformity has been measured up to 0.7 degrees and 2 mm. The TSF fixation is able to correct all aspects of the six-axis deformity simultaneously (Keshet and Eidelman, 2017). Components of deformity divide it into angulations, rotation, translation, and shortening or lengthening (Heidari et al., 2013). Angulations and rotation are angular deformities, measured in degrees. Translation and length are displacements, measured in units of distance (e.g., millimeters, inches). According to Paley (2002), the six parameters of deformity needed to define clinical deformity include anterior-posterior plane angulations, lateral plane angulations, axial plane angulations, anterior-posterior plane translational, lateral plane translational, and axial plane translational. Correction of deformity between two bone segments can be characterized by three projected angles (rotation) and three projected

displacements (translational). Therefore, six parameters of deformity are needed to decide the place of bone deformity in a patient.

In 2015 researchers from Industrial Engineering, the Laboratory of Product Planning and Design at Universitas Sebelas Maret, Solo, and an orthopedic doctor succeeded in making a TSF replica product called OrthoLPPDUNS external fixation or OrthoLPPDUNS. The making of this product is to assist orthopedic doctors in correcting tibia bones in a patient with Blount's disease or known as another tibia vara at Rumah Sakit Unggulan Pendidikan (RSUP) Kabupaten Klaten Jawa Tengah, Indonesia. These patients need osteotomy surgery to correct Blount's disease; this deformity can occur in infancy, childhood, and adolescence (Putra, 2018; Sabharwal, 2016). Osteotomy surgery in these patients aims to improve deformity, equalize both legs' length, and improve symptoms. Acute corrective osteotomy in patients has been complicated by peroneal nerve palsy, compartment syndrome, residual deformity (Eralp et al., 2016), long limb imbalance (Henderson et al., 1992), delayed unification of bone, or events with emergence fixation device failures (Birringer et al., 2016). The results of a review of several journal pieces of literature that the use of circular frames has shown the ability to gradually correct angulations, translation, rotation, and lengthening or shortening, thereby minimize the incidence of postoperative complications.

Before an osteotomy surgery is performed on the patient, the Ortho-LPPDUNS device is first assessed on the joint system at the ring-strut angle. The study results of the design of the OrthoLPPDUNS are made from custom components through the manufacturing process. After several motion simulation tests using the Fusion 360 software, it was found that the rotational motion with displacement values for strut screw components appeared to be rougher or not smooth. The reason is that the threads on the strut components are worn out. The foundation of this weakness results in unstable frames at a certain distance, seen from the mass of the mass using an inner ring diameter of 155 mm and a combination of six struts with a medium length of 150 mm. The configuration of the frame at the ring-strut angle shows this instability due to backlash. The appearance of backlash on the joint system between the ring-strut angels due to the external fixation design requires a clearance between components. This design results from considering the TSF design patent no. US6,030,386 (Taylor H.S. and J.C., 2000) explains that giving clearance is required for the connection between components on the edge shoulder bolt and the edge of the universal joint, applied to every component of the universal joint.

The provision of clearance between components aims to enable the frame configuration to move into a three-axis system (Shah et al., 2012). In contrast, the universal joint component is a two-axis joint system (Wijaya et al., 2019). Giving clearance allows strut mounted on the ring under tight conditions but can still be rotated by the patient. However, giving clearance out of control will cause a backlash and make the strut twist process heavy and the correct size specified in the previous around the schedule inaccurate. If this condition is not a concern, it will cause undesired bone shifts during bone reconstruction in the patient. Although the process of bone reconstruction in a patient is successful, the results of correction remain inaccurate. Several studies have evaluated the parameters that affect the stability of the circular fixation. These factors, such as ring size and material, wire type, diameter, and voltage; the number, size, and location of half-pins, have been shown to have the same effect on the stability of TSF fixation. However, studies of frame stability related to ring-strut angles have not been reported in the literature. We redesigned this device, gave attention to the changes, instability in the joint system between the ring-strut angles due to the use of alternative components on the external fixation using the Function Analysis System Technique (FAST) to overcome backlash and struts screw that wear out quickly.

## II. RESEARCH METHOD

Techniques in limb reconstruction continue to show significant progress, largely due to external

fixation devices. The design details of the external fixation device are produced with the manufacturer's consideration in creating the external fixation. The emergence of backlash and strut screw problems that wear out quickly requires the redesign stage in OrthoLPPDUNS. The discussion covers the information stage, the functional stage, the evaluation stage, the redesign stage, the assessment design, and the design interpretation (Figure 2).

**Information stage**

The information phase was carried out by means of interviews through discussions with
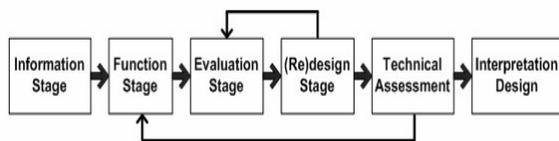


**Figure 2.** The stage of the methodology is the redesign of the external fixation and feedback loop.

orthopedic surgeons who had recognized and operated the external fixation limb of RSUP Dr. Soeradji Tortonegoro Klaten and the external fixation product design team at the Industrial Engineering from Laboratory of Product Planning and Design at Universitas Sebelas Maret Solo. Look up information from the type of TSF external fixation functions, and describe the device's workings. The results of this discussion will be obtained from an overview and notes from the OrthoLPPDUNS design. This information is then stated in the form of a description of the need to ease the steps' preparation when redesigning the external fixation.

**Function stage**

The description of the external fixation mechanism using the FAST method aims to map and sort each frame component's functions during operation. This method also aims to visualize the relationship between all the frame functions, making it easier to check how the frameworks. Compilation of functions with two questions between how and why it's, namely how the external fixation works and why a bone correction is performed. In the first stages, the FAST method is described in the flow diagram.

FAST is made in general to decide each component's work function as to why a bone correction is done.

**Evaluation stage**

At this stage, the design of OrthoLPPDUNS examines in more detail. By evaluating the flow of FAST diagrams on each frame component function, the component functions can be traced clearly to weaknesses in the design. Determination of technical requirements, as recommendations for what it's, should be made to redesign the external fixation, which is a consideration in bone reconstruction.

**Redesign stage**

It's having known the weaknesses of the use of components in the OrthoLPPDUNS design. Then the external fixation design is compared with the use of components and provides recommendations using other components. The external fixation design is explained in the form of three-dimensional images using Autodesk Inventor 2016. The FAST diagram flow again explains the external fixation redesign using other components as a replacement.

**Technical assessment**

The technical assessment is the detailed process of designing an external fixation device that will be produced to help monitor the technical progress of the design. It also provides status information to support detailed tool system design assessments, product realization, and technical management decisions. The assessor will analytically change the output of status reporting in a better form than the expected results can be understood.

**Interpretation Design**

This stage is conducted on a simulation test on OrthoLPPDUNS design between custom components and standards. Compares the characteristics of the two frames based on physical dimensions and stability parameters, including the value of the safety factor, displacement, and the range of the ring-strut angle. Constraints and further study of the external fixation design to get the best ring-strut angle.

## III.  RESULT AND DISCUSSION

The information phase aims to decide the user needs of doctors and patients from the OrthoLPPDUNS design. This study involved an orthopedic surgeon and two designers from an external fixation device at the Laboratory of Product Planning and Design. OrthoLPPDUNS products are custom-made with all components through a manufacturing process with manual machining. The results of discussions with an orthopedic physician involved in this study illustrate in his explanation that the OrthoLPPDUNS design focuses on the ability to rotate the screw strut. This indication is feared that the frame will experience undesired movements after the patient's strut head rotations. The frame in the OrthoLPPDUNS design will experience mechanical instability originating from the achievement of the ring-struts angle. Henderson et al., 2008 recommend that long struts be selected when installing TSF so that the ring-strut angle can reach 30 degrees, avoided less. The clinical relevance is related to the use of TSF in atypical confirmation, especially in the pediatric population who need correction of the deformity. After obtaining a response from an orthopedic doctor and information from several journal articles, a thorough review of this design was carried out by the external fixation design team. This study's results note that there are still indications of the emergence of undesired movements originating from the coarse motion of the strut screw components (Figure 3).

The results of a motion simulation test using the Fusion 360 software show that there are several strut components in the strut screw section that look worn; this condition affects the frame's movement. The next step is to redesign OrthoLPPDUNS with the rotating motion of the strut screw being smooth, and the threaded component does not wear out quickly. The two stability parameters in this frame are needed for immediate repair to produce a correct bone correction.

Analysis of the external fixation component's functional stage using the FAST method is related to when operating the frame, followed by arranging these functions into the FAST flow diagram. The first step in this analysis is to describe the flow of the FAST diagram in an external fixation in general (Figure 4).

The operation of the external frame fixation begins with how to lengthen and shorten the struts. Where turning the strut cap to the right (+) will increase the struts screw and push down the strut tube, then the struts will be elongated. Otherwise, the strut cap turning to the left (-) will decrease the struts screw and pull the strut tube, and the struts will shorten. Changing the length of the struts can change the joint's position; the angle of the joint can be changed.  Changing the
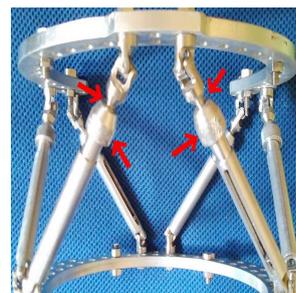


**Figure 3.** Frame OrthoLPPDUNS with all custom component manufacturing.

joint angle changes the shoulder bolt position attached to the ring so that the place of the ring changes. Changing the position of the ring will automatically adjust the place of the

K-wire fixation bolt mounted on the ring, which will affect the position of the K-wire. Changes in bone place due to K-wire attached to the bone. This frame's operation is done periodically until a bone correction can be achieved according to the planned schedule. FAST diagram flow shows that the frame component's stability factor between the ring-strut for external redesign fixation is an essential component.
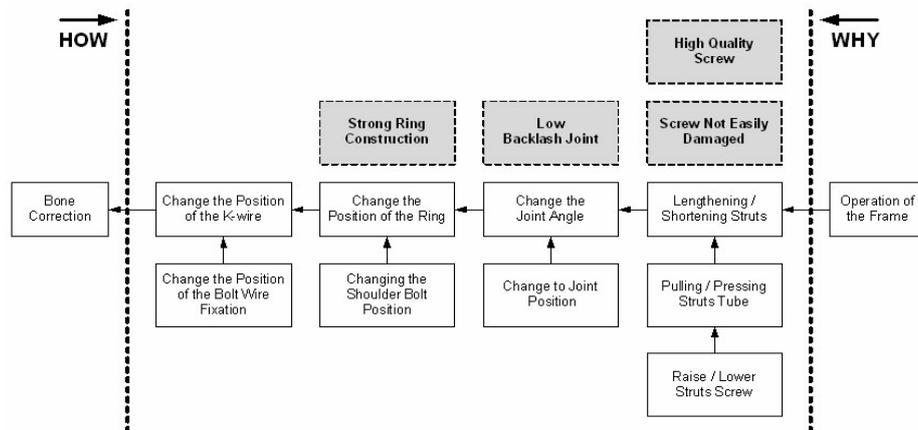
**Figure 4.** The general operation of the external frame fixation.
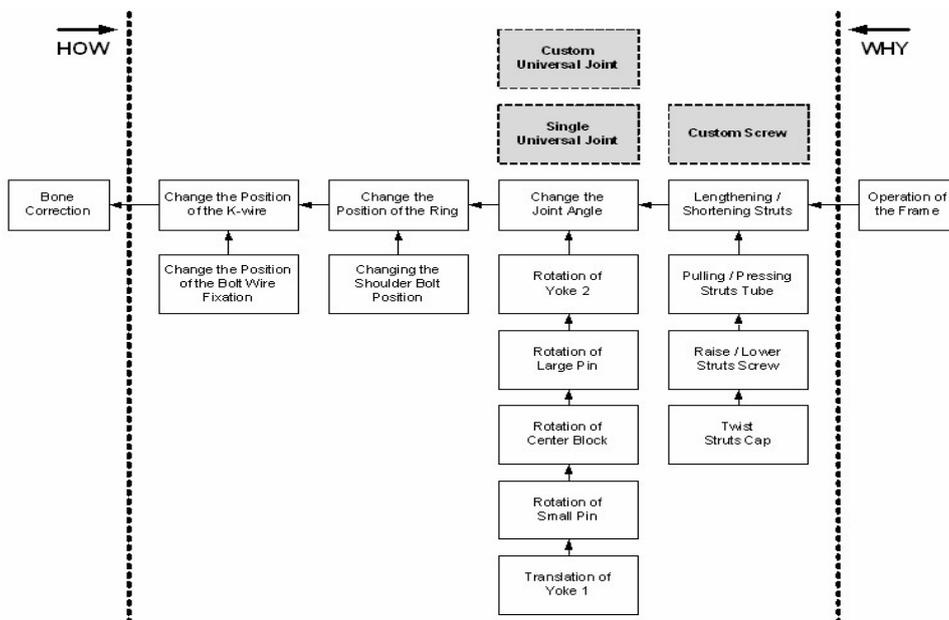


**Figure 5.** The operations on frame external fixation.

In the evaluation phase, by depicting the flow of the FAST diagram on the external frame fixation, tracing the root of the problem occurs when operating the frame relating to frame stability (Figure 5).

OrthoLPPDUNS design, the universal joint is a connecting component between ring-strut angles, which is placed in the strut section. The motion simulation results, which states that the rotational motion of the strut becomes coarse, can be traced from the flow diagram below (Figure 6).

The OrthoLPPDUNS design frame uses custom universal joint components. Vesali et al. (2012) explain that the universal joint component consists of two hinges connected by a crossbar, allowing the bar to turn in any direction (Figure 7). Adjusting the frame's position on the strut will change the ring struts angle; strut rotation direction influences this change. At the time of a strut, tube twist arises as if the rotation is not smooth.

This condition occurs due to backlash on the connection component. Backlash, according to

Solon (2010), explains the required distance or space or the mess between two or more components. Backlash at the ring-strut connection is required for clearance in the center block hole between the small pin and large pin. In addition, clearance is also needed at the end of the universal joint connected to the ring. Clearance space requirements on components a small size to support the mechanism of motion of the mechanism on the external fixation (Karidis, 2012). However, clearance with excessive size causes arousal to occur in the frame, especially strut components that relate to the universal joint between the center block and pin, as well as the joint and ring. Seherr-Thoss et al. (2006) explain that excessive clearance will reduce the accuracy of the dimensions. The universal joint in the OrthoLPPDUNS design is custom with a single component, where the dimensions of the yoke and connections in each component are not adjusted according to standard products available in the market (Figure 8).

The purpose of a custom universal joint is that the ring-strut angle is more significant so that tolerance between components is not required even though. As a result, the distance between the components becomes greater. So, it is increasingly clear that strut twists' movements of frames that are not smooth due to backlash from the use of custom universal joints.

Position the displacement in the frame by lowering and raising the strut screw to change the ring struts joint angle. When strut tube playback is not smooth within a certain time, the strut screw will wear faster (Figure 9).
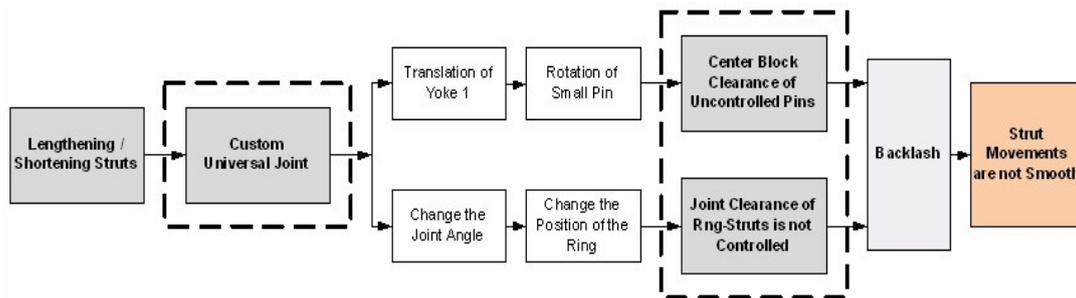


**Figure 6.** The tracing twist strut becomes rough.



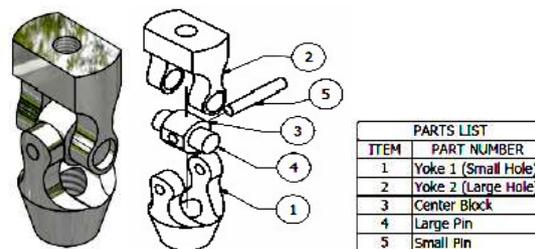**Figure 7.** The single universal joint standard.



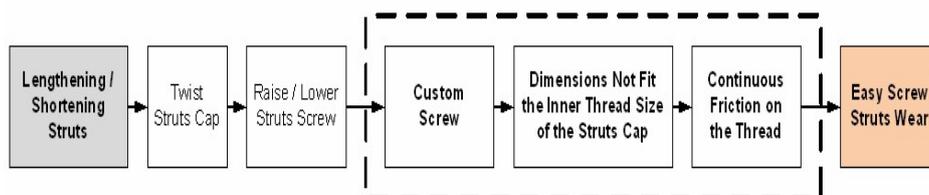**Figure 8.** The single custom universal joint.



**Figure 9.** The tracing on the strut screw wears out quickly.

The screw rod design on the strut component is a custom screw from another manufacturer's external fixation dimensions. The strut screw (threaded rod) design is not according to product standards available in the market but is a custom product. The screw pitch in the OrthoLPPDUNS design is 1 mm with a major diameter of 5 mm, designed not to affect the twist system. The threaded rod's design is not yet seen as a weakness; after the simulation test, evaluating the displacement value shows a great value. This test involves turning the manual threading process parameters at a specific time with several iterations in the simulation without tool changes. The diameter of the rod is reduced, and the results are inconsistent. Even though the threaded strut's inaccurate dimensions will cause

continuous friction on the strut cap component, the threaded strut becomes easily worn. According to the standard metric screw thread (ISO 724, 1993), the pitch size of the threaded rod is 1 mm with a major diameter of 6 mm. Allowing this error potential to be more significant when of production, let alone lack of supervision at every step of the production process (Evans, 2014). So, it is increasingly clear that the problem of the strut screw is easily worn due to the use of custom screw components.

Both of these problems can be identified and are considered as recommendations for the OrthoLPPDUNS redesign of frame stability parameters, namely joint component specifications with low or even zero backlashes, use f screws that do not wear out quickly, and a
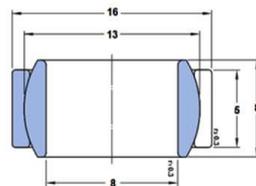


**Figure 10.** Radial spherical plain bearing GE 8E (in mm).
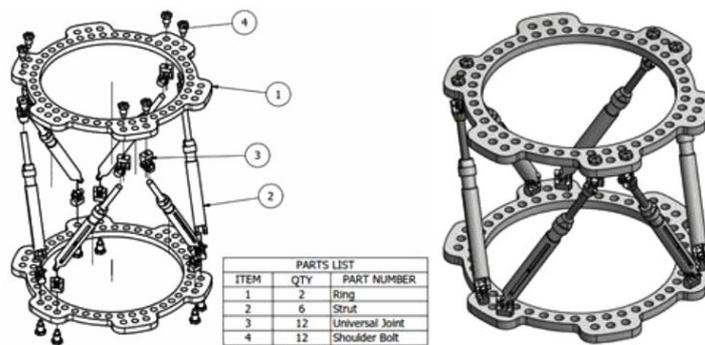


**Figure 11** The OrthoLPPDUNS design uses custom components.
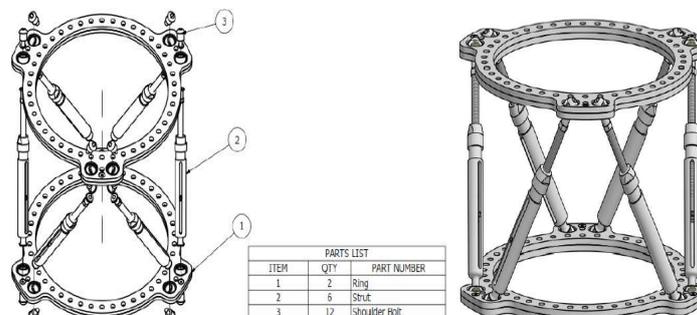


**Figure 12** The OrthoLPPDUNS design uses standard components.

robust ring construction design.

Redesign stage for the need for an external frame fixation, where strut movements must be smooth and avoid excessive backlash events. After discussing with orthopedic doctors and practitioners in designing an external fixation, the concept of repair is done by replacing custom universal joint components using standard components with ball joint components, where the selected joint is spherical bearing. The selection of spherical bearings is based on the SKF catalog because it can make rotational movements at a wider angle, suitable to be a substitute for a custom universal joint. The spherical plain bearing is a standard mechanical component that allows movement in various directions and is able to align the bearing itself. This bearing consists of two parts, an inner ring with an outer surface such as a ball and an outer ring with a concave-shaped inner surface that adjusts the inner ring (SKF, 2011). The advantages of spherical plain bearings as an external joint fixation can accommodate misalignments, high reliability because there is almost no pressure from the edge and the load exceeds the limit, accommodate the deformation of the surrounding components, accommodate wide manufacturing tolerances, able to carry high capacity loads, suitable used for slow and precise rotating movements, long economic life (INA, 2008). The bearing used is radial spherical plain bearing with GE 8E type steel material (Figure 10).

The redesign of the strut component is that the screw does not wear out technically. It is stated that the screw has high-quality material. The concept of repairing screws is done by replacing custom threaded rod components with standard threaded rods, the standard metric screw threads used according to ISO 724 (ISO, 1993). A standard threaded rod has a pitch of 1 mm with a major diameter of 6 mm. This standard product has advantages, where manufacturing efficiency, reliability, and quality are guaranteed (Evans, 2014) and easily obtained at a cheaper price (Nicholas, 2010). Replacement of components with standard products is done, hoping that these components have a

guaranteed quality standard size and are not easily worn or damaged. The evaluation stage results in the OrthoLPPDUNS design of the joint system can be determined by comparing the use of custom and standard components (Figure 11 and Figure 12).

The ring component is part of the frame is the main component that serves as a

K-wire buffer made of aluminum 6061A material that is radiopaque (difficult to penetrate X-rays). Frame construction is completed in a circle with the aim to produce stability in the frame. The hole in the outer ring is used to install the strut components; the inner ring hole is used to install other components such as K-wire and half pin attached to the bone to support the frame's rigidity (Smith & Nephew, 2011). The strut component is a part of the structure consisting of a cylinder with a threaded rod in it, where the rod can be raised or lowered on the cylinder by turning the strut cap. The threaded rod used in this fixation a pitch of 1 mm and major diameter of 5 mm. One turn of the strut head can change the length of the strut by 1 mm. This component is connected to the universal joint component, where the support at the bottom is modified to be yoke 1. The threaded rod component is made of stainless steel material, and the cylinder component and strut head are made of Al. 6061A, which is radiopaque. The strut's length can be changed at specific intervals so that the position of one ring can switch to another ring (Paley, 2002).

Custom universal joint components are mounted on the end of the strut cylinder and the end of the threaded rod as a component of the ring-strut connector. This component consists of the main cross axle, cross axle pin, and two yokes. Yoke 1 and the cross axle pin are connected in a fix, while yoke 2, the main cross axle and cross axle pins are connected so that they can rotate with each other. Using a joint to support changes in the ring's position to another ring, this joint system provides the ability to "turn" in any direction, made of Al. 6061A, which is radiopaque. The shoulder bolt component is a component that connects the yoke two parts to the custom universal joint against the ring, made
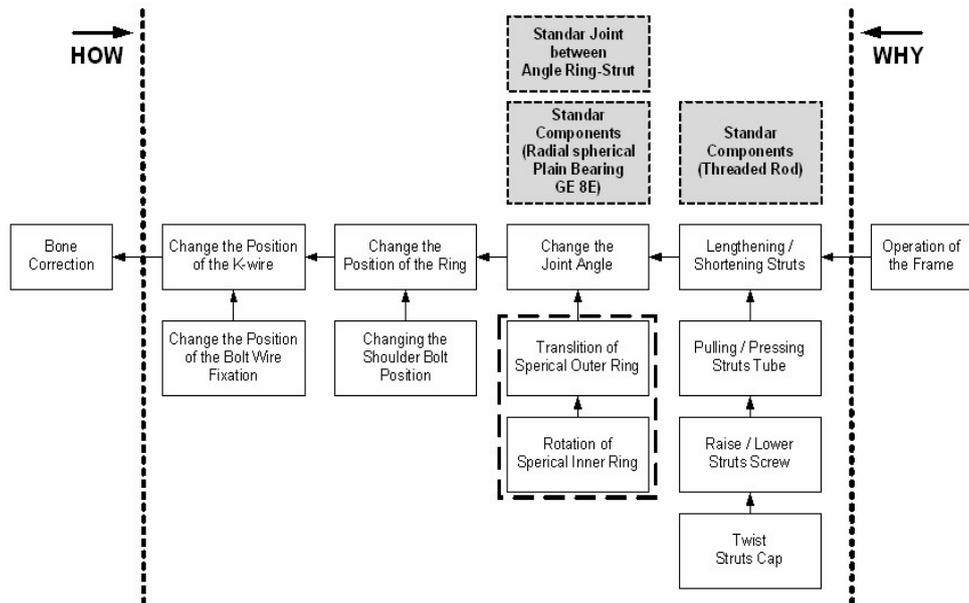
**Figure 13.** The operation of the external frame fixation uses standard components.

of stainless steel with a standard head diameter of 10 mm. The use of shoulder bolt components is done so that the strut can still rotate to the ring even if it is connected tightly enough (Norrish, 2013).

The ring component consists of two rings with a diameter of 155 mm with a thickness of 3.75 mm made of Al. 6061A and connected with three countersink screws. This component has a cavity that serves as a bearing housing and a hole with a ring diameter to install other components, such as K-wire and half pin. Struts components made of Al. 6061A materials, consisting of 6 strut tubes and six strut screws arranged in such a way. Strut screw made of stainless steel material in this design uses a standard M6 threaded rod metric. Bearing components, this design use 12 plain spherical bearings with a diameter of 8 mm with GE 8E specifications. This bearing is installed in a cavity in the ring. Button head shoulder bolt component that serves to connect the strut with bearings mounted in the ring. The shoulder bolt head is modified into a button shape to be mounted on the bearing without limiting the bearing space.

The FAST flow diagram for the OrthoLPPDUNS design with standard components such as plain spherical bearings and threaded rods can be described again to determine how to operate this frame to achieve bone correction (Figure 13).

The joint system in plain spherical bearings is a ball-type joint that aims to overcome the need for clearance at the joint ends of the ring-strut with three degrees of freedom. The use of standard components on the external fixation has met smooth strut movements; the need for clearance can be minimized. Spherical plain bearing SKF products with clearance as a benchmark tolerance of connections between components have a relationship, tolerance of 68 µm and a custom component of 1150 µm. Spherical plain bearings are installed in the ring, where the shoulder bolt is attached to the bearing. The strut is mounted directly on the shoulder bolt and bearing without touching the ring, and the installation does not need clearance. The support can rotate freely. This external fixation uses a standard threaded rod to meet the needs of a threaded strut that is not easy to wear; the risk of wear can be minimized.

**Table 1.** Comparison of characteristics and simulations on the stability parameters of the frame

| No | OrthoLPPDUNS | unit | Custom component | Standard component | Difference |
|----|--------------|------|------------------|--------------------|------------|
| 1 | Mass weight | kg | 0.855 | 0.749 | 0.106 |
| 2 | Width | mm | 217 | 225 | -8 |
| 3 | Height | mm | 174.7 | 139.74 | 34.96 |
| 4 | Safety factor | ul | 1.93 | 4.21 | -2.28 |
| 5 | Displacement | mm | 0.388 | 0.115 | 0.2727 |
| 6 | Maximum elongations ring and strut angle | degree | 0 | 42.08 | |

In the technical assessment, it was found that the use of plain spherical bearings in external fixation was considered not difficult compared to replica TSFs with universal joint modification of the strut length. This is because the frame installation process is relatively similar to the Taylor Spatial Frame installation. The advantage of external fixation is that the shoulder bolt's attachment and strut to the ring are tight because it does not require tolerance. Therefore, orthopedic doctors can install the frame without the need to estimate the rings and struts' tolerance. The operation of external fixation with plain spherical bearings by the patient was considered not as difficult as replica TSF. This is because the strut can be rotated freely so that the size label on the support can be seen easily by the patient while doing the strut winding process. In addition, the process of turning the strut head does not experience obstacles such as the strut head in the universal joint modification, which is sometimes difficult to turn because the joint system is not supported.

The interpretation design is simulated through finite element analysis using Fusion 360 software in the OrthoLPPDUNS frame design. This test gives loading at points on the ring that receive direct loads, where this point is where the installation of K-wire, there are eight points spread on both rings. The magnitude of the load is based on the ability of material Al. 6061A with an average adult weight of 700 N with a withdrawal load on the K-wire of 1100 N, the result is shown in Table 1.

The value of the safety factor in the frame design should be considered when designing the frame. The ability to accept or safety factor is the value of the structure's power to design statically in receiving loads, which is measured when the higher the value, the better the acceptance of the load (Ullman, 1986). The simulation in the safety factor test aims to determine whether the frame is still capable of receiving heavy loads from a predetermined person, whether this frame can accept a greater or lesser burden on the allowable strength. In modern engineering that the value's of the safety factor in design ranges from 1.25 to 4.0. Safety factor simulation results on the standard component frame of 4.21 ul, showing that this external frame fixation has better strength than frames using custom components.

The displacement value indicates the maximum value of the shift that is still allowed in the frame. The displacement value is the benchmark in the design for frameshifting. It's the same as a benchmark for shifting between unwanted bone fragments or Inter-Fragmentary Shear (IFS). Until now, the value of IFS is still controversial, and some studies suggest this value can have positive side effects. According to Betts and Muller (2014) explained, most studies on the importance of displacement in frame fixation stated that IFS could inhibit bone reconstruction. IFS can also delay bone formation in osteotomy between the bones, decrease callus in the periosteal, and stiffness in bone tissue that should be flexible (Augat et al., 2003).

Meanwhile, Steiner et al. (2014) state that the allowable value of IFS during bone reconstruction is the maximum value of inter-fragmentary movement/IFMmax (movement between bone

fragments) of 1.5 mm. Based on most of these studies, an IFS value that exceeds regulatory limits should be avoided because it can inhibit bone reconstruction. IFS must be calculated to a minimum to anticipate obstructed bone reconstruction. The displacement value of the frame within the safe limit is in the range of 0.115 to 0.388 mm (Figure 14).

Standard components in the external frame fixation have a small displacement value of 0.115 mm or only 10% of the maximum displacement allowed. These results indicate that this frame is still possible for IFS to occur in bone, but with a minimal value for the occurrence of bone reconstruction obstructions. Frames with small displacement values are declared relatively safe. This simulation test explains that green has a smaller displacement and red has a large displacement. Large displacement frames are on two earrings due to the loading point of the K-wire. This loading point is still at a safe level, where the surface area around the loading becomes uniform. The results of the evaluation and redesign recommendations are produced by the OrthoLPPDUNS frame with the use of standard components (Figure 15).

The ring-strut angle reach of the joint system of the OrthoLPPDUNS uses custom and standard components (Figure 16). Custom components can form an angle of 96.08 degrees or a 0 degree ring-strut angle; the dimensions of the yoke have been modified so that it does not obstruct other yokes when rotating. The maximum angle uses a standard component of 42.08 degrees or a ring-strut angle of 47.92 degrees. Although both of these frame fixations with ring-strut angles formed, they cannot reach the recommended angle of approaching 30 degrees (Henderson, 2008).

The limitation of this angle's formation is the impact of mounting the joint in the ring so that the strut can only rotate as broadly as the ring hole. This condition affects the limitations of the free-angle in reconstructing bone later. However, its problem can be overcome by replacing the longer strut. But strut replacement is also experiencing problems because the frame has been formed by certain strut angles, making the
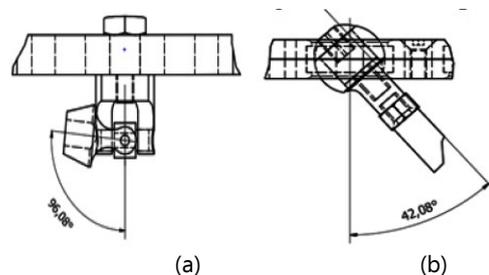
attached shoulder bolt difficult to remove. The next frame study should be noted by considering the tolerance of each component in the external frame fixation to avoid backlash again. The limitation of this angle's formation is the impact of mounting the joint in the ring so that the strut can only rotate as broadly as the ring hole. This condition has an impact on the limitations of the free-angle in reconstructing bone later. However,



**Figure 14.** Displacement is on the external frame fixation with standard components.



**Figure 15.** The OrthoLPPDUNS frame uses several standard components.



(a)        (b)
(a). Custom universal joint components
(b). Standard spherical plain bearing components
**Figure 16.** The ring-strut angle is the joint system on the external fixation.

its problem can be overcome by replacing the longer strut. But strut replacement is also experiencing problems because the frame has been formed by certain strut angles, making the attached shoulder bolt challenging to remove.

The next frame study should be noted by considering the tolerance of each component in the frame external fixation to avoid backlash. The ring-strut angle should achieve the recommended angle. Stability of the frame to replace struts for longer or shorter struts.

## IV. CONCLUSION

The use of standard components in OrthoLPPDUNS, spherical ball plain bearings GE 8E components can eliminate backlash and threaded rods ISO 724 to ensure uniform thread quality. The spherical plain bearing connection system for external fixation makes it easier for patients and doctors to use the frame. The frame construction with ring-strut has a minimum safety factor value, and the displacement value with IFS is below the maximum value. The range of the ring-strut angle in the frame still needs to be reexamined as it has not reached an angle of nearly 30 degrees. It is also important to consider changing the combination of strut sizes from medium to long or short with all configurations in the frame.

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