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Design, Analysis and Manufacture a Prototype of the External Elbow Hinge Fixator a Bio-Mechanic Product

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Abstract: The simple design concept approach and the simple technique of installation of external elbow hinge fixator are used for the treatment of proximal interphalangeal (PIP) joint contractures without open surgery. This device has never been tested on any patient yet since it was a new design. Application of elbow hinge fixator is easy and effective in reducing contractures of the PIP joint by soft tissue distraction. An external elbow hinge fixators can be applied as a neutralization device after open or pericutaneous reduction. It will act as an active reduction device using universal hinge mechanisms between fixation blocks. Beside that it will also act as an external scaffold which incorporates the placement of multi-axial fixing element with shanz pin to apply force through humeral. The concept of fixation rod and multiaxial placement of pins is introduced. External elbow hinged fixators are used to provide some combination of easy mobilization, and stability, as well as gradual rotating elbow motion. In open procedure situations, the external elbow hinged fixator maintains a concentric motion of the humeral articulation throughout a full range of active elbow motion. During the postoperative period a controlled gradual stretch is applied using the stopper pin on the device. The device is turned smoothly in 0º till 135º and can be stop at interval of every 15º. The direction is alternated and the patient usually rests in extension overnight. The stopper pin mechanism can be released for active mobilization of the elbow.

Index Terms : External Fixator, Biomechanic, Mechanism, Multiaxial

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I. INTRODUCTIONS

Bio-medical equipments are one of the major needs in the medical industries today. The developed countries have their own research center to design new device for their nation. The involvement of the medical doctors, learning institution, industries and also technologies make their product or invention widely accepted around the world. Company such as Smith & Nephew from USA, Aesculap from Germany and Orthofix from Italy is a few examples of bio-medical industries. They are making billions of dollars every year helping people around the world by supplying the bio-medical equipments.

The bio-medical industries in Malaysia are still in the infant stage. Report from the MITI show that in 2005 alone Malaysia are importing more than RM 200 million of in-plant product where more than RM 40 million of it are in the orthopedic section.

This paper basically to present a brief report of design, analysis and fabricate the *external elbow hinge fixator*, one of the product in the bio-medical field. External elbow hinge fixator is the bio-mechanic equipment that will be used for the patient with the case of fracture elbow or dislocation of elbow. Figure 1 shows the external elbow hinge fixator that used as hinged at the external side of the fracture elbow and act as a fixator to provide stability and painless mobilization while curing. External elbow hinge fixator is a device used to the case of elbow dislocation and fracture-dislocation. Besides that it will also help to stabilize the elbow itself.

This project was done with the assist of an orthopedic surgeon and trauma from Hospital Universiti Kebangsaan Malaysia. The idea started from one of his patient that cannot afford to purchase a set of Illizarov fixator that cost thousands of Ringgit Malaysia. We begin this project by discussing about hinge concept and it ability to cure his patient. Everything started from ideas before into transfer into sketch, design and ended by FEA analysis. The fabrication of the prototype only begins once the material and method have been decided.

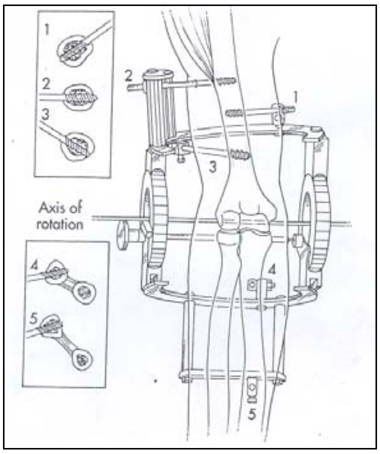

Figure 1: Compass elbow hinge (Smith & Nephew)

II. LITERATURE RIVIEW

There are several studies that prove the effectiveness of the elbow external hinge fixator. From the study of Dr M. D. McKee team of University of Toronto in 1997, they have defined elbow instability as non concentric articulation of the ulnohumeral joint. He said that previous authors have obtained poor results from conventional treatment of this condition.[12] [13]

Josefsson et al [1989] reported four cases of recurrent dislocation associated with fractures of the radial head. Regan and Morrey [1989] found a satisfactory outcome in only 20% of a large number of patients with type-III coronoid fractures.[15][18] Adler and Shaftan [1988] reported that although fractures of the radial head associated with elbow dislocations comprise only 10% of all fractures of the head in a large series, they were responsible for over half the poor results. Bennett et al [1996] reported a failure rate of 50% in the treatment of unstable fracture-dislocations by conventional techniques.[2] Broberg and Morrey [1997] described how prolonged casting, undertaken in an attempt to maintain reduction following fracture-dislocation of the elbow, led to a high incidence of stiffness.[1]

In the only directly comparable series reported, Cobb and Morrey successfully treated six of seven patients with unstable fracture-dislocations of the elbow by applying the Mayo hinged external fixator[5]. In their patients the mean arc of flexion after surgery was 88 degrees. The external fixator gave stability and mobility so that the joint could be subjected to immediate postoperative continuous passive movement without disturbing the healing fractures and ligaments.

Using the same device as McKee , Wyrsch et al [1996] reported having restored stability in seven of nine unstable fracture-dislocations, although the complication rate was 50%. Others have described preliminary good results with similar dynamic external fixators. In Dr M.C Kee[1996] series, in which the difficulties of restoring stability were compounded by the failure of previous operations, 12 patients (75%) achieved a Morrey elbow score of good or excellent. There was only one poor result (6%).

They do not recommend the use of the hinged external fixator for the treatment of complex fractures of the distal humerus.[1][12] The nature of the fracture makes it difficult to insert the Steinmann pin at the centre of rotation. The clinical problems seen with complex proximal fractures of the ulna and radius do not often arise: accurate reduction and rigid fixation of the fracture of the distal humerus usually restore stability.

The Compass Universal Hinge Fixators shown in figure 2 rely on accurate placement of the hinge co-linear with the axis of rotation of the joint. In the elbow, this is a line passing through the center of the capitellum and exiting medially just anterior and inferior to the medial epicondyle. A controlled gradual stretch is applied using the worm gear of the Compass Hinge device. The gear is turned in small increments every 15 to 30 minutes. The direction is alternated and the patient usually rests in extension overnight (Hasting 1997). The worm gear mechanism is released three times a day to allow active mobilization of the elbow.

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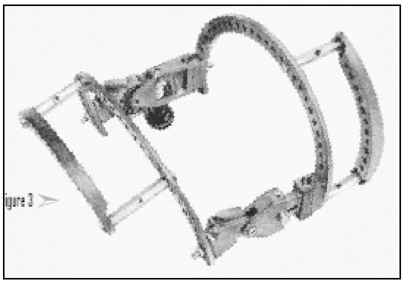

Figure 2:Combination of Universal compass with Ilizarov Hinge (Smith and Nephew, Memphis, TN)

In spite of the high complication rates, which have been noted by other author, Dr M.C Kee findings prompt to advocate the use of a hinged elbow external fixator in the treatment of recurrent, complex elbow instability, especially when conventional techniques failed. By providing adequate stability, it allows early movement after fixation and repair of soft tissues and this advance improves the ultimate functional outcome.[12]

Base from these reports and literatures, it is assumed that the highly effective and versatile elbow external hinge fixator still cannot be found on the shelved. Another aspect is most of these equipments produced come form Europe or USA. This will give a big impact in term of pricing and will be too costly due to the tax, transportation and currency. It will also consume lot of time in term of delivery. If the equipment can be produced locally, the cost will be much cheaper and also shorten the time of delivery whereby it is understood in most accident that involved fracture cases, the faster treatment time the better it is. Hopefully this design will become one of the devices that can assist the treatment of the elbow fracture not only in Malaysia but also being accepted worldwide.

III. PROJECT SCOPE

The project will focused on design of the external elbow hinge fixator for which is used for elbow injuries with and possible to apply for other joint in the human body such as knee, legs hand or even finger. The principle of the hinge with one join was used as a design concept. Design is concentrated on a few aspects such as product functionalities, ergonomics on the human body especially elbow, material selection, and also the possibilities to assemble this product with other standard part

Finite elements analysis has been applied to the selected components to compare stress and weight between different materials. It focused on static analysis to generate stress distribution. The results obtained will illustrate either the design is applicable or not to carry certain amount of load given. In this case 220 lb of load is used. Simulation carried out using COSMOSXpress® provided by SolidWork® .

During prototype fabrication, job is focus on producing prototype using both aluminum and stainless steel. Some of the components using the standard part while the rest of it will be fabricated in house. CAD/CAM software MasterCAM® V9.1 used to produce CNC program while machining processes being performed using CNC milling, EDM wire cut, lathe and drilling.

IV. DESIGN STAGE

Design concept mainly concern about basic function of the product as an external elbow hinged fixator. Therefore, existing product were compared and used as referenced since this kind of product has already available and proven to be functioned.

The basic principles that were outlined before need to be achieved during designing and creating the external elbow hinged fixator. This equipment must capable to reduce or cure the fracture at the elbow and also act as a fixation for both joint on the knee. It will stabilize the elbow by reducing the un-unilateral movement to the left and right. It maintained elbow stability during the treatment and only allow the radial movement.

In principles, it should preserve the blood supply into the normal circulation and also not interrupt the formation of the soft tissue. In other words it should reduce the contact between the components and skin or body.

Another aspects need to be considered is the materials used. The materials should be able to sterile and inert to the entire chemical used during the treatment. It should be easy and safe for installation and maintain to be comfortable to the patient while using this equipment on their elbow. It should also facilitate the patient's needs of mobilization especially during their moving around by walking or even when they lift their arm purposely for having their meals.

In order to make this product become more universal and versatile, the development of the component should be fully integrated with the current available product such as SHANZ pin and Stuhler Heise system. Elements from this basic equipments allow external fixation operate with universal applicability, high stability, comprehensive adjustments and axial functional compression. The main objective of the product is to allow the motion happen between the joint and it should be able to use at the elbow and other joint.

Basics criteria's need to be fulfill are :

- Able to be rotate.
- Can be locked.
- Radiolucent.
- Applicable to shanz pin.

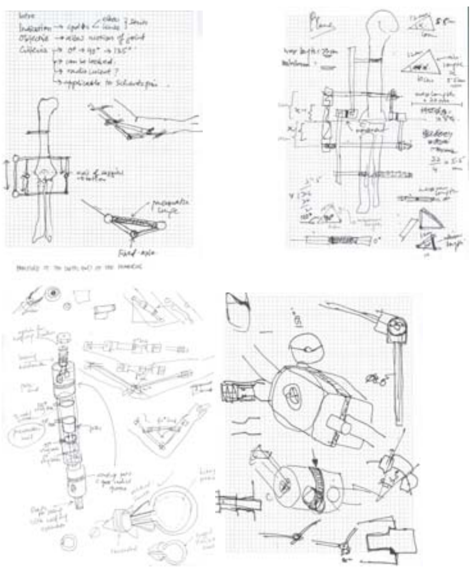

Figure 3: The initial ideas and sketches

First of all, this equipment is designed to be used at various joint fractures e.g. elbow, knee, feet, hand or may be even fingers at later stage. At present, the only constraint is the size. Base on the same concept and principle, the external hinge fixator actually applicable to most of the joint in the human body.

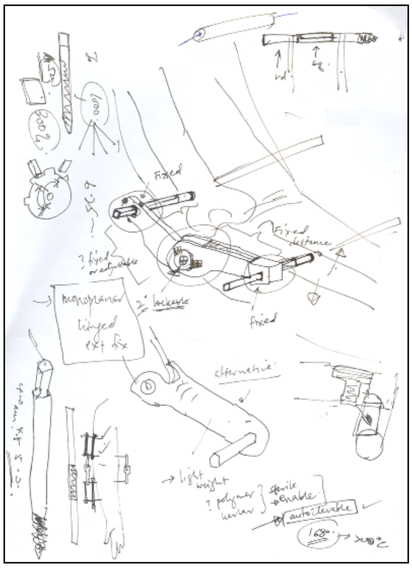

Figure 4: First concept design of the external elbow hinged fixator

One of the most important criteria required for this product is; it should be able to be rotated and adjustable within certain degree of angle. The angles are 0º during elbow being straighten, 90º when elbow will be place for rest and 135º is for the elbow being bend to the maximum allowable range. This equipment must be able to be hold rigidly at certain desired angle such as at every 15º to facilitate the treatment of the elbow and therapy during curing process. The product weight also needs to be as light as possible. This equipment will be attached to the bone using readily available Shanz screw (manufacture by Aesculap). It needs to come with the fixing element that will suit the guide rods and shanz screw which will be drilled into the bone.

This equipment will be used in pair and will be fixed on the left and the right side of patient's elbow. It will be linked between left and right components by 'C' shape part and must be stabile and rigid to hold the fractured elbow. Distance between hinges will be determined by the size of 'C link' and will be wide enough to place the arm between it.

The degree of freedom of the shanz pin is important because during the drilling process we cannot actually locate or specified the place to be drill. We can only choose or locate the point to be drilled base on the suitability of the bone

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and injuries condition. That why it is important for the fixing element to be adjusted with less restriction.

V. PRODUCT DESIGN

The product design 1 produced after first concept determine. Part will rotated on the shaft that will act as hinge and it also functioned to hold the male and female part together. On the male part it has semi circle slots that allow the stopper pin to move and stop when reach the end. On the female part it has eight threaded holes distributed evenly at 45 degree each. The stopper pin will be inserted through any of these holes. Importunely it is found that this design was too bulky and most importantly it won't allow the SHANZ screw to move and rotate freely.

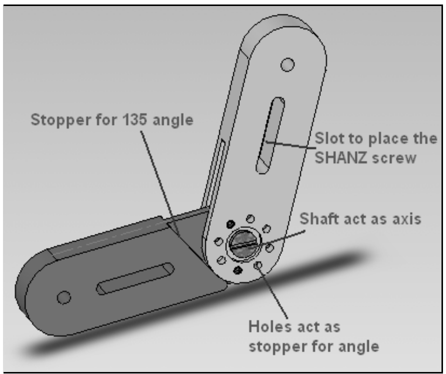

Figure 5: Product design 1

The second product design developed using the same concept. Part will rotate on shaft act as hinge and there were be eight holes for stopper pin on female part while on the male part there will be a semi circular slot. The second product design was improved by considering the free movement for the Shanz pins. The modification was done by reducing the lengths of male and female part and addition of a guide rod at the end of the flat faces. Another two holes were added for the purpose of assembling the 'C link" components.

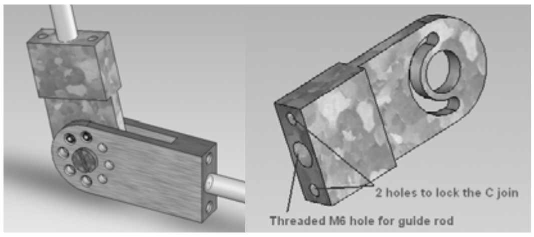

Figure 6 : Product Designs 2

Product design 2 seems to be more reliable and results through the kinematics simulation analysis showed that it was function as expected. The fabrication of prototype 1 begins once everything is satisfied by fulfilling criteria set earlier.

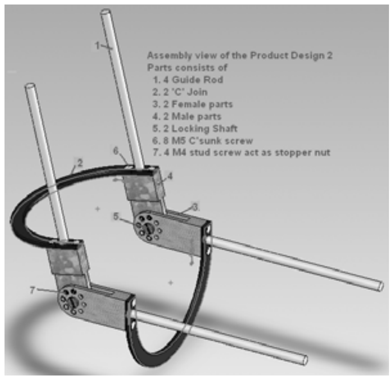

Figure 7: Isometric view of the Product design 2 assembly drawing.

After prototype 1 was completed, it is discovered that not all of the eight holes at the female part design earlier is needed so with minor modifications on the female part, it reduced from eight into five holes. During assembly of the parts the threaded shaft for joint axis being replaced by hard shaft with diameter of 6mm and force fit into the holes. On the male part, bearing is added to reduce the friction. The small bearing with OD of 12mm in diameter and ID of 6mm is used.

VI. STRESS ANALYSIS

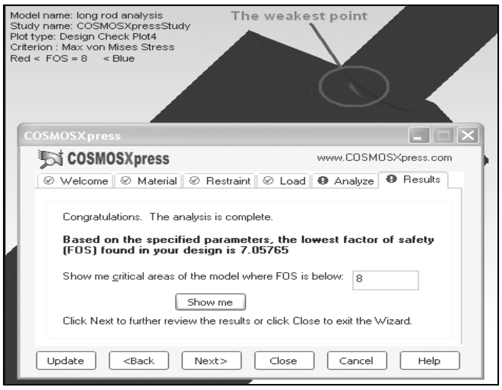

Figure 8: Analysis result show the safety factor

The purpose of the analysis is to find the stress distribution on the guide rod. Few assumptions were made before run this analysis. It is assumed that the guide rod is the main component that will received force/load given from the movement of patient arm/hand is solid components with the male or female body. In this analysis 220lb of load is applied to the shaft and distributed evenly through out the rod. The weakest point should be at the joint between the male/female part since this is the place where smallest diameter (M6 thread) located.

Table 1: Material properties

Property Name	Value	Units
Elastic modulus	6.9e+010	N/m^2
Poisson's ratio	0.33	NA
Mass density	2700	kg/m^3
Yield strength	5.5149e+007	N/m^2

From the analysis result it shows that the guide rod can stand the load of 220 lb given to it by more than seven times. The 220 lb load actually is the maximum load can be produced from the patient arm. Figure 8 shows that the maximum (7.814e+006 N/m^2) stress at the diameter 6mm near the joint between rod to the female part. The yield point for this material is 5.515e+007N/m^2. With the load of 220 lb given to this rod, it still capable producing safety factor of seven.

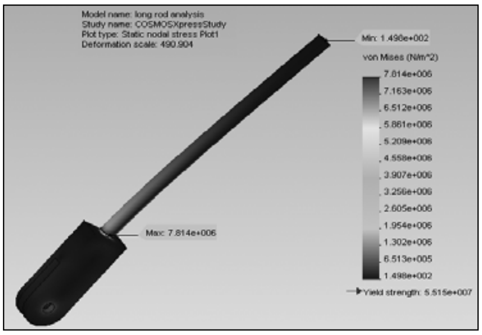

Figure 9: Analysis result show the stress distribution

Result from this analysis showed that the size and the dimension of the guide rod are suitable. There will still be a possibilities to reduce the rod's diameter to reduce weight but with another constraint define earlier where this product need to be fully integrated with another widely used component from Stuhler-Heise or to make it standardizes.

VII. CONCLUSIONS

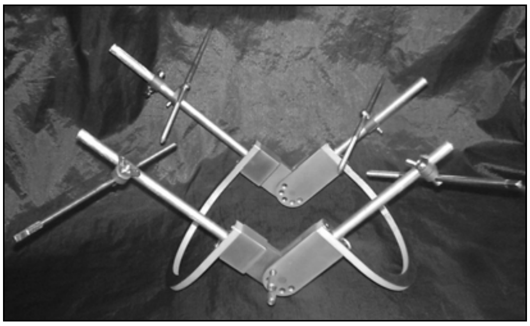

Figure 11 : Complete Prototype of Product

This project has achieved all of the objective set earlier. It fulfills the principle and criteria which were set at the beginning. Even though it is completed but still cannot be used to actual patient. Since this external hinge fixator is considered as bio-mechanic product and will be use on the human, further testing needed. The next process will be mechanical test such as three points bending, and fatigue test and it will be also being fabricated using different material and tested equally.

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