APPLICATION OF ENGINEERING FUNDAMENTALS IN THE DESIGN AND TESTING OF A COMPRESSIVE HIP CONSTRUCT

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ABSTRACT

The occurrence of Pauwel’s III fracture, which is a shear femoral neck fracture, continues to be problematic to the orthopedic community. Various methods are available to offer support during recovery either with the use of an orthopedic device or an assembly of screws. The assembly used to support a fracture is commonly referred to as a construct. Although many constructs are available, each contain certain deficiencies which regulate their application. A new prototype (PROTO) recently developed, aiming to improve on current constructs, was tested using the facilities of the UTC Biomechanics Lab. The results of the prototype were then compared with the performance of three traditional constructs currently used.

The results of the study comparing the existing construct to the prototype provided no evidence of improvement. The data collected contained valuable information which could be used to determine the design characteristics which influence construct performance. Using a fundamental design approach, the data was analyzed to determine the features which attribute to better performance for each of the tested parameters.

Four design features were determined to be beneficial. It was determined that reduction of the fracture gap, the use of locking head screws, and the incorporation of two parallel lags screws along with a transverse screw provided the most significant performance advantages. The new prototype (DHON) was designed that incorporated these features and underwent the same method of testing as used for the PROTO.

The test began with a torsion test of 0.005 kN-m. This was followed by a 10,000 cycle, -0.35 kN axial load. The test was then concluded with a final 0.005 kN-m torsion test. The data from the study was then compared to the stiffness values observed from the existing constructs including the PROTO.

The results of the DHON verification tests provided evidence of improved performance due to the design features. Proximal Distal stiffness showed a 25% increase, while Vera Valga stiffness resulted in a 100% increase. Each of the other parameters showed results equivalent to the mean value of the compared constructs. Medial Lateral stiffness resulted in the only decreased stiffness value being compared to the existing constructs.

One construct was tested during the study to determine if the design showed any trend of improvement. Preliminary results indicate that the DHON construct offers improved performance which supports further testing. It is recommended that the test be revisited to include 10 test specimens of the DHON construct so statistical results can be obtained.

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INTRODUCTION

The frequency of femoral neck factures is drastically increasing alongside the aging elderly population and is expected to continue as experts predict the number of fractures to triple by 2050[7]. Conditions such as osteoporosis and rheumatoid arthritis continually plague the elderly community leading to increased susceptibility to femoral neck fractures. The use of internal fixation for these fractures results in mortality rates as high as 25%, along with complications in as many as 36%[9]. This requires immediate attention to the development of superior methods of internal fixation.

A Pauwel's III fracture, a vertical shear fracture across the femoral neck, is a particular type of fracture that remains a troubling issue for post fracture stabilization. Several alternatives currently exist to support this type of fracture which include the cancellous screw (CS)[6], the cancellous screw supported by a transverse screw (XCS)[6], and the dynamic compression hip screw (AMBI)[6]. These alternatives develop various deficiencies after implantation due to the effects of loading and torsion during movement. These deficiencies of internal fixation include avascular necrosis[4], loss of fixation[4], non union[3], and secondary operations[4]. In an attempt to address the current performance issues, a major orthopedic supplier and a local surgeon combined efforts to develop an innovative locking plate design (PROTO).

The University of Tennessee College of Medicine and the University of Tennessee at Chattanooga Biomechanics Lab collaborated to compare the effectiveness of the PROTO construct to the CS, XCS, and AMBI. The study concentrated on the displacement of the femoral head during loading to obtain construct stiffness for each of the groups. This is one method that is often used for experimental comparison for construct performance[8]. The results, however, provided no evidence of improved performance from the PROTO.

The results obtained from the comparison study[6] contain information which relates construct design and performance. This information can therefore be used to extract the design characteristics which promote increased construct strength with the goal of incorporating these features into the designing, prototyping, and proof-testing a new hip plate construct (DHON). It is hypothesized that construct strength can be increased by including each of the advantageous design features into one design.

METHODOLOGY

The purpose of this project is to develop a new hip construct design which offers superior performance compared to current fixation methods. The design of the DHON hip plate is based on the design process which is standard throughout the engineering discipline. The design of the DHON construct is restricted to the initial stages of design and only proceeds through the enhancement stage of the design process. The comparison study provides the basis for the design features which improve performance. These features are incorporated into the device for the development of design alternatives. The best alternative is chosen and the preliminary construct design is developed. The design is then subjected to a verification test to ensure the goals of the product are met.

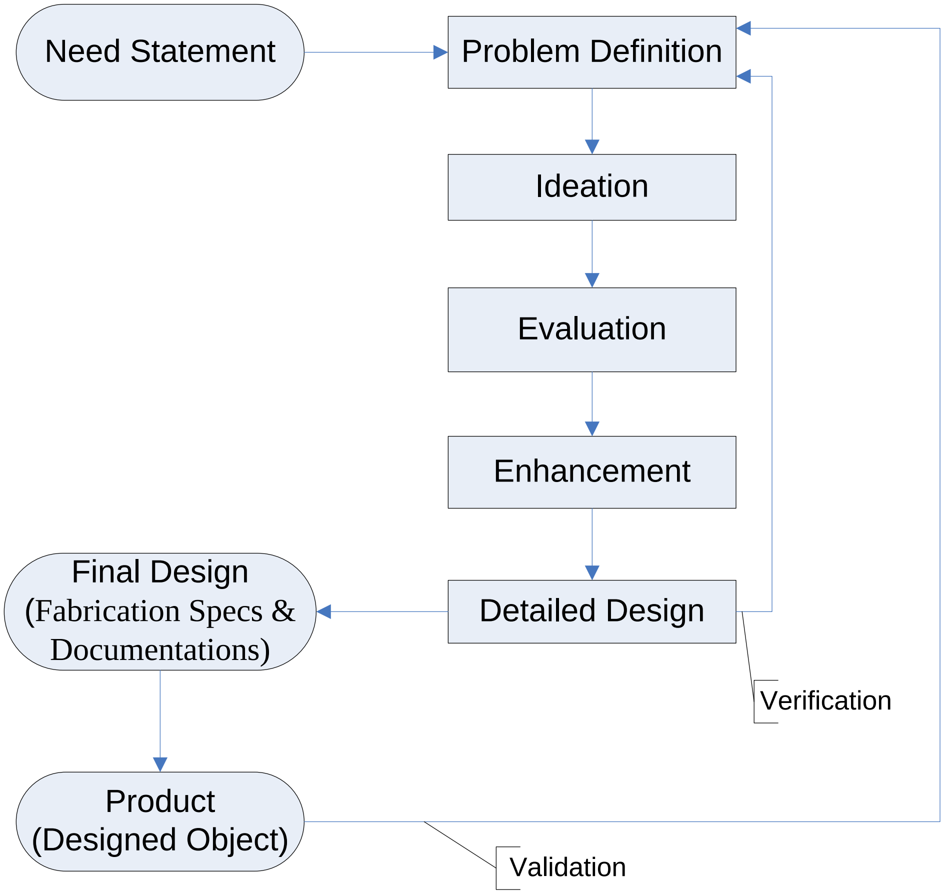


Figure 1: Design Process Diagram.

THEORY

Construct Performance

Various factors are attributed to the success and performance of an orthopedic construct. For success, a construct must aid in the healing process maintaining reduction under expected loads eventually leading to a full recovery. Reduction refers to the removal of the gap within the fracture. The performance of the construct is often associated with strength of the fixation method and the ability to restrict movement[5]. Performance is commonly tested by applying loads similar to those experienced during walking[7]. Axial and torsional loads are applied during activity and the construct stiffness, which is known to correlate well with strength[2], is therefore used as a valuable indication of performance[8]. Axial stiffness is defined as the slope of the load versus deflection curve and can be found using Equation 1.

$$k_A = \frac{\Delta F}{\Delta x} \qquad \text{Equation (1)}$$

Where:

k_A= Axial Stiffness (kN/mm)

ΔF= Change in Load (kN)

Δx= Deflection (mm)

Similarly, torsional stiffness is the slope of the moment versus rotational deflection curve (Equation 2).

$$k_T = \frac{\Delta M}{\Delta \theta} \qquad \text{Equation (2)}$$

k_T= Torsional Stiffness (kN-m/º)

ΔM= Change in Moment (kN-m)

Δθ= Angular Deflection (º)

The comparison of the stiffness values between groups is then used to determine which factors attribute to increased stiffness.

The movement occurring about the femoral neck is categorized by the anatomical direction of movement relative to the fracture plane. Six orientations of movement are used to describe femoral head relative motion and are represented in Figure 2. Medial Lateral (ML), Proximal Distal (PD), and Vera Valga (VV) each correspond to axial stiffness. ML movement corresponds to movement between the femoral head and femoral shaft within the x axis. PD movement is vertical movement along the y axis. VV is rotational deflection in the PD direction. Anterior Posterior (AP), Internal Rotation (IR), and Retro Anti (RA) are deflections associated with torsional stiffness. AP is movement along the z axis shown in Figure 6. IR is considered rotational deflection concentric with the femoral neck axis. RA corresponds to rotational deflection in the AP direction.

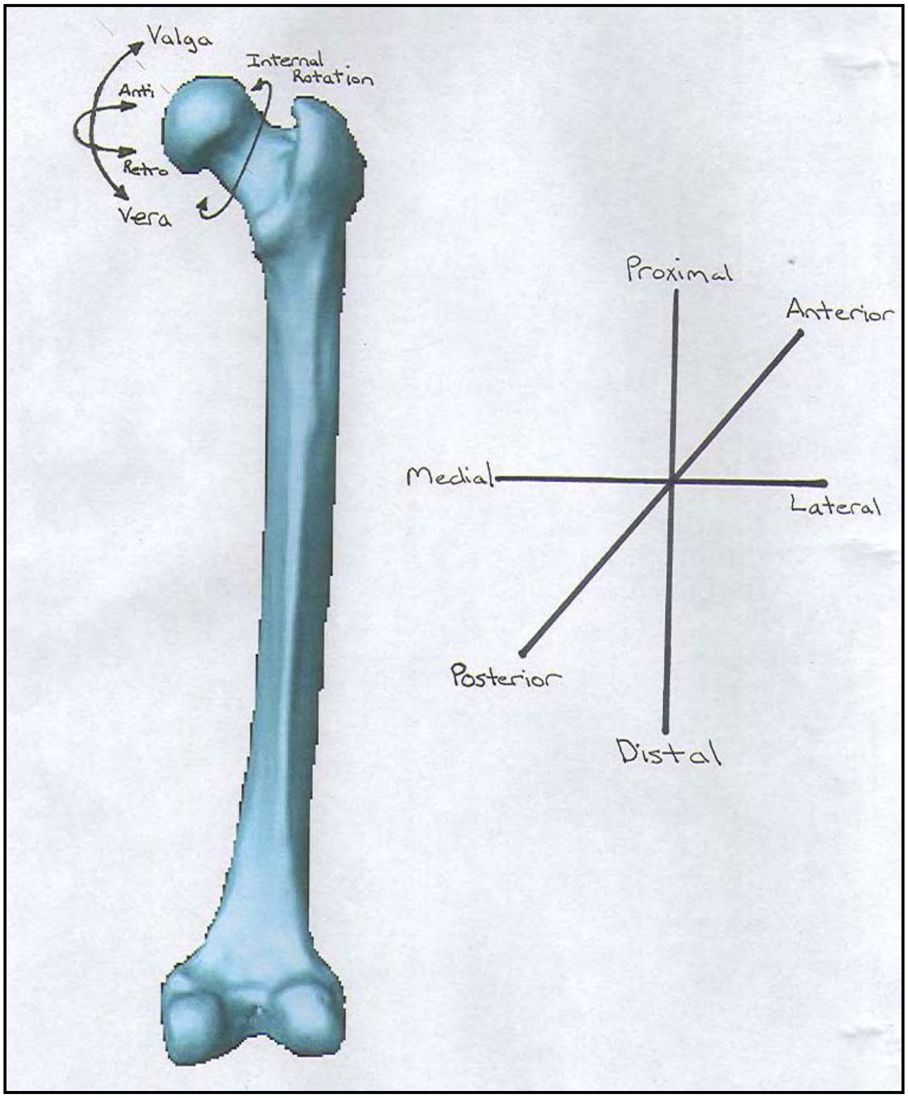


Figure 2: Orientation of Movement about the Femur.

Orthopedic Construct Overview

Three commonly used fixation methods for the Pauwel's III femoral neck fracture are the CS, XCS, and AMBI constructs. Each of these methods contain favorable design characteristics, yet fail in differentiating themselves due to superior performance[6]. Studies indicate high measures of torsional stiffness for the XCS setup, along with superior measures of axial stiffness with the AMBI[6], however clinical failures remain common. Studies have shown serious complications requiring a second operation as high as 36% in patients receiving support from internal fixation methods[9]. The incorporation of the features which show increases in stiffness into one design could aid in reducing the high failure rates associated with internal fixation. A basic understanding of each of the constructs must first be developed to begin critiquing the design characteristics.

CS Construct: The CS construct consists of three 6.5 mm diameter cannulated lag screws which are arranged in an inverse triangular pattern. Each parallel screw extends through the fracture surface into the femoral head. The lag screws function to supply reduction by threading into the cancellous bone of the femoral head. Reduction occurs as the head of the screw meets the lateral cortical bone. The angle between the screw and the femoral shaft varies from one bone to another, but averages 135°. Figure 3 depicts the arrangement of this setup.

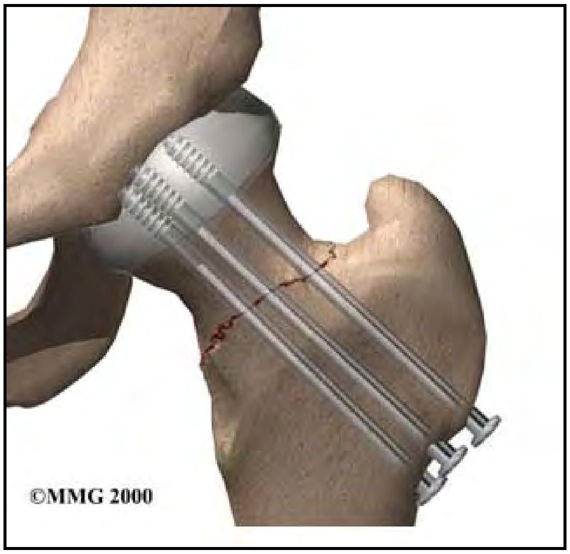


Figure 3: CS Construct.

XCS Construct: The XCS arrangement consists of two parallel cannulated lag screws which extend through the femoral neck and initiate reduction. A transverse screw enters perpendicular to the femoral shaft and extends just beyond the fracture surface threading into the cortical bone. By threading into the cortical bone, the transverse screw restricts torsional movement and also functions to supply compression to the distal end of the fracture. This can be seen in Figure 4.

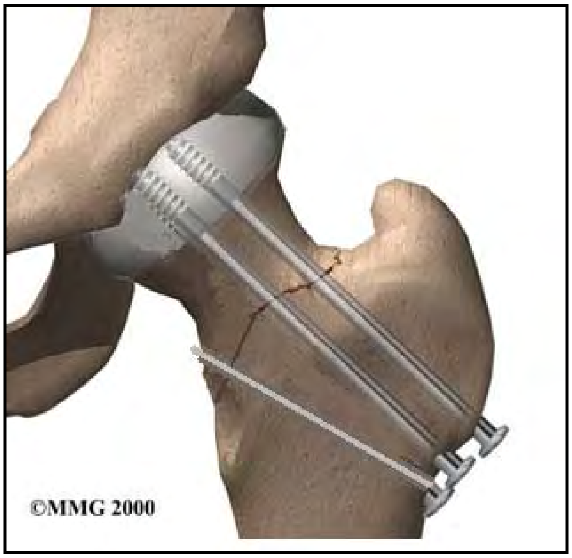


Figure 4: XCS Construct.

AMBI Construct: The AMBI construct is a more advanced design which incorporates the use of a plate which attaches to the lateral side of the femur. A 12.7 mm barrel extends from the plate entering into the femoral neck. An oversized 9.0 mm lag screw enters through the barrel and threads through the femoral head. A set screw is then entered into the lag screw. Reduction is applied by the set screw which treads into the 9.0 mm lag screw. This acts to draw the lag screw into the barrel resulting in closure at the fracture. A derotation screw is then inserted parallel to the lag screw, independent of the plate. Figure 5 offers a more detailed view of this construct.

Figure 5: AMBI Construct.

PROTO Construct: A fourth design (PROTO) is a prototype that was developed which attempts to improve on the existing designs. Three locking head lag screws are used in combination with a plate to lock the screws into place. The locking head screws are inserted to create a crossing pattern at the fracture surface. A transverse screw is also used which replicates the XCS screw arrangement. The intention of the design is for compression to be achieved by first inserting the transverse screw which only threads into the distal end of the femoral neck. This acts to compress the fracture which prepares for the insertion of the locking head screws. The assembly of the Proto plate for the comparison was not performed in the manner creating a gap between the fracture surfaces. This construct is represented in Figure 6.

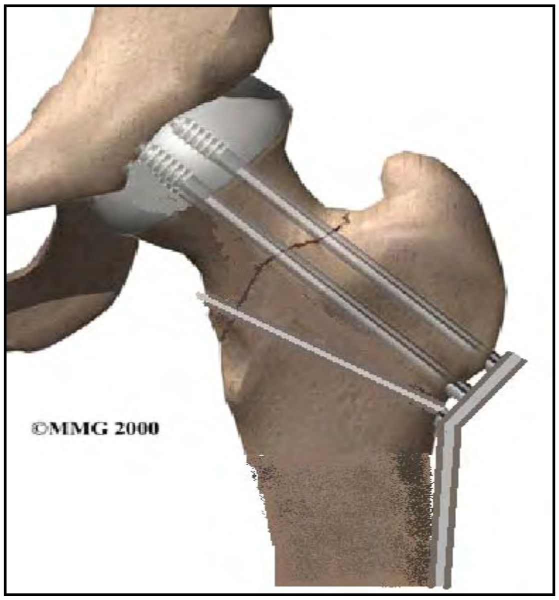


Figure 6: PROTO Construct.

APPLICATION OF DESIGN PROCESS

The design process shown in Figure 1 represents a holistic view of product development. The objective of this type of project is the development of a product which fulfills all of the defined objectives for the device to be considered marketable. The first requirement is a description of the need for the product. The need refers the purpose of the project. This could be a revision of an existing design or the development of a new product.

The problem definition is used to develop the requirements for the design. The first step in the problem definition is a statement of the goals. A goal is traditionally a statement of intent for the project. The goals can refer to the overall purpose of the design or to a specific sub goal within the project that must be satisfied.

The definition of the project continues by focusing on the objectives of the product. The objectives concentrate on specific commitments upon which the product must fulfill. Objectives are expressed as measurable quantities that can be used to ensure achievement of the goal. The next step in the design definition is to determine what must be done to fulfill the objectives, which is expressed by defining functions of the design.

Functions are broken down into primary, secondary, and unwanted classifications. The primary functions establish the principal task of the product. Secondary functions are often a byproduct in the fulfillment of the primary function. These can be considered beneficial or unrelated to the fulfillment of the objectives. Unwanted functions are undesirable byproducts of primary and secondary functions. These are unavoidable but need to be recognized in an attempt to minimize the undesirable effects.

The final requirement of the project definition is a declaration of the constraints. The constraints outline criteria which place restrictions on the design. Constraints are used to confine a project within a certain boundary that is deemed acceptable to the application of the product. These include factors such as safety, materials, and size.

The design process continues by beginning the ideation stage of the design. Ideation is the development of a conceptual design and initiates the groundwork for which the design can build upon. This stage promotes the exploration of current designs to determine advantages and disadvantages, along with the generation of ideas to supplement the design. As the development of a conceptual design continues, a variety of alternatives must be explored. These alternatives will each fulfill the objectives of the project; however they offer various approaches to the design.

The next stage of the design process is evaluation. In this step the alternatives are evaluated to determine which design proves advantageous based on detailed criteria. The criterion allows the design to be differentiated based on perceived strengths. The design found to be superior must then enter the enhancement stage of the process.

Enhancement begins the development of the preliminary design which describes initial specifications that are shown to be favorable. The function of the design is described in detail and assigned preliminary dimensions. Upon completion of the preliminary design, the product must revisit the requirements defined by the need and project definition. This verification process must conclude that the design meets each of the defined objectives. If the objectives are not met, the design must be adjusted or a new conceptual design must be developed.

The detailed design follows the successful completion of enhancement. All objectives must be met and all constraints must be satisfied. The detailed design entirely specifies the product to prepare for final design and manufacturing.

Design Requirements

The complete design approach previously described outlines the development of a completed product. This approach is outside the context of the DHON design which is only intended for the understanding and development of a design based on mechanical performance. The application of the process is therefore a sub goal which focuses on mechanical improvement. Due to the narrow focus of the design, the process proceeds only through the enhancement stage of the design process to ensure the design provides evidence for continued development.

Need Statement: The need of the project is a superior orthopedic device for the internal fixation of a Pauwel's III femoral neck fracture.

Problem Definition: The development of a superior fixation method is based on the mechanical performance of the device. This requires the goal of the project to be the development of a construct that offers improved mechanical performance for the support of a Pauwel's III femoral neck fracture.

> <u>*Device Objectives, Constraints, and Functions*</u>*:* Stiffness is one method of measuring construct performance due to the correlation between increased stiffness and construct success[8]. This requires the design objectives to be based on the improvement of construct stiffness. The objectives of the device

are to improve both axial and torsional stiffness beyond what is seen in traditional fixation methods. The objective tree is shown in Figure 7.

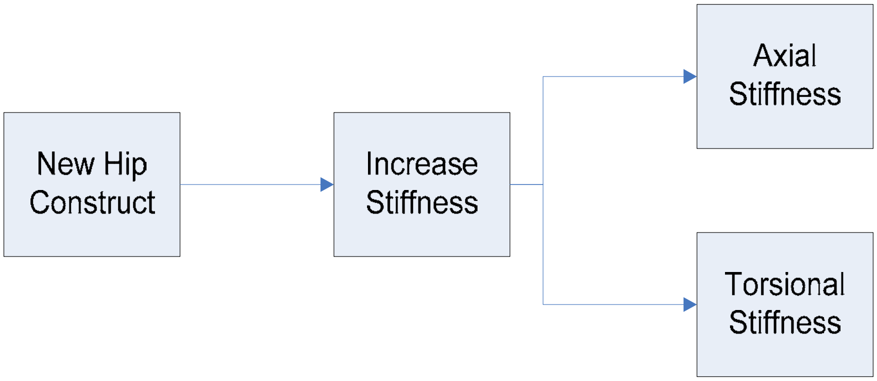


Figure 7: Objective Tree.

The design of the construct is guided by the functions which it must fulfill. The primary function of the device is to improve stiffness of the fracture. For fracture stiffness to increase, the femoral head movement must be restricted, which requires the axial and torsional stiffness parameters to increase. The device must also fix to the bone to enable the construct to support the load.

Supplemental functions are a byproduct of the required functions and tend to offer additional benefits. Reduction of the fracture and patient mobility are functions of this type. Reduction aids in the recovery process by reducing recovery time and complications. The function of mobility is also one that supplements the requirements. Increased stiffness results in the ability to support increased loads with less deflection allowing load bearing motion.

A device requiring surgery is one that will also contain unwanted functions, with the most notable being the creation of pain due to the incision. The occurrence of pain, along with the many risks such as infection and blood loss, create a multitude of unwanted functions that could arise. Another unwanted function is the removal of cancellous bone. This weakens the natural stability of the bone upon removal of the construct and increases the likelihood of a repeated fracture. A summary of the functions are shown below in Figure 8.

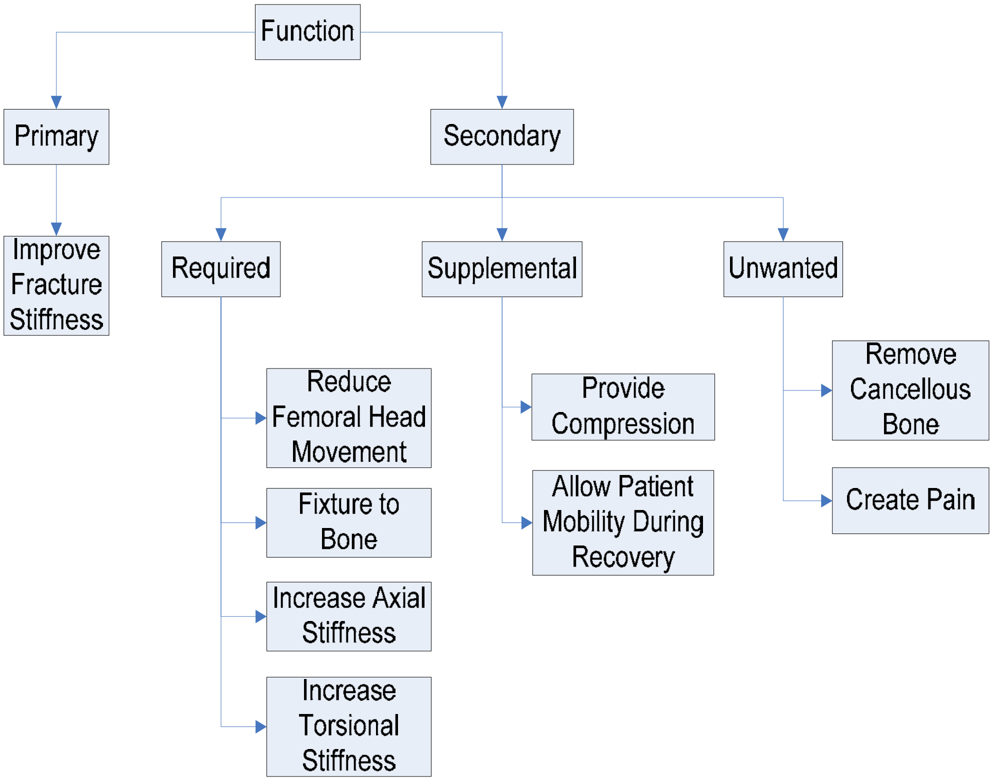


Figure 8: Function Tree

Another requirement for the successful design of the new construct is the fulfillment of design constraints. Due to the environment in which this device performs, special precautions must be taken to ensure the safety of the patient. To ensure safety, the construct must be medically feasible for implantation. Feasibility refers to the understanding that the accessible area is limited to the lateral side of the fracture and location of the fracture is dependant on the use of scanners. The construct must use standard assembly techniques to reduce the training of physicians due to difficulty of use. The final constraint requires a maximum of a one inch diameter for the cross-section extending beyond the fracture to avoid obstruction with the cortical bone surrounding the femoral neck.

Ideation

The objective in the new design is to ensure an increase in axial and torsional stiffness. This will be accomplished by incorporating design features which indicate performance advantages from the results of the comparison study.

Interpretation of the source data is restricted to relative movement about the fracture surface to concentrate on movement allowed by the construct. The stiffness results from axial loading are summarized first in Figures 9-11. The stiffness results for torsional loading are shown in Figures 12-14. A summary of the results along with the ANOVA results can be seen in Appendix B.

Axial Stiffness Design Features:

<u>Medial-Lateral</u>*:* A summary of the Medial Lateral stiffness results are shown below in Figure 9. Each of the constructs displayed similar measures of stiffness with the exception of the XCS construct which was slightly lower. A trend indicates slightly better performance by the PROTO with a 20% increase in stiffness compared to XCS. Attention is now drawn to the differences between the XCS and PROTO construct. Both setups use the same screw orientation with the primary difference being the use of locking head screws with the PROTO. Due to the orientation of the medial-lateral movement, the presence of locking head screws, which restricts movement perpendicular to the plate, helps to explain why increased stiffness is observed. The AMBI also uses a plate and set screw setup which act to restrict movement to or from the femoral shaft and is found to have the second best performance with a stiffness of 5200 N/mm.

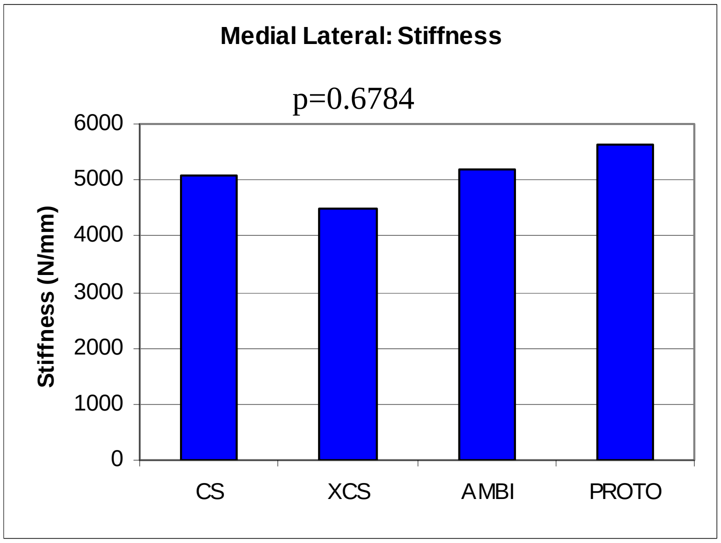


Figure 9: Medial Lateral Stiffness.

<u>*Proximal-Distal*</u>*:* Proximal Distal movement corresponds to a shear failure within the construct. Factors that are attributed to shear failure include the projected cross-sectional area of the members resisting the shearing loads and the presence of friction. The results in Figure 10 indicate increased stiffness among the CS, XCS and AMBI constructs (p=0.0034). One feature common to the CS, XCS, and AMBI is the reduction that the constructs offer. The Proto plate offers no mechanism to cause reduction. Continued reduction generates a compressive force at the fracture surface. Compression is a feature which acts to increase the friction between two surfaces. This idea helps to explain the 15 % increase in stiffness from XCS to AMBI, which is known to supply significantly more compression than the remaining constructs[2]. The AMBI also exhibits the largest lag screw diameter which also attributes to increased stiffness.

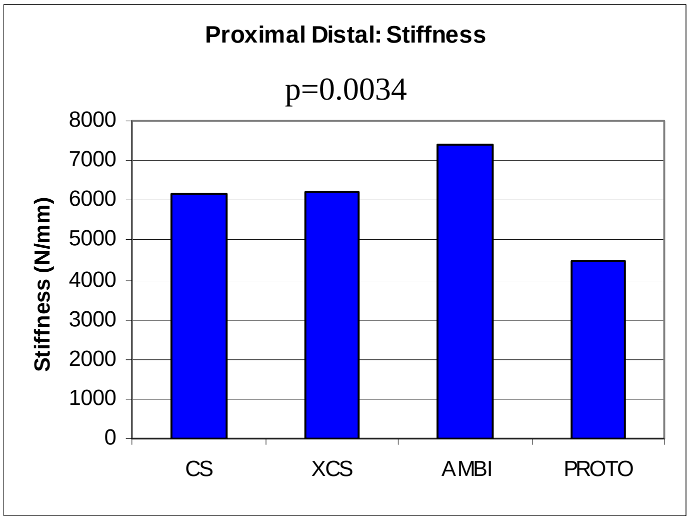


Figure 10: Proximal Distal Stiffness.

<u>*Vera-Valga*</u>*:* The PROTO Plate was found to have the lowest stiffness in Vera Valga movement ($p<0.001$), shown in Figure 11. Again, it is suspected that the lack of reduction at the fracture surface contributed to the inferior performance due to this being the only feature that is different between XCS and PROTO. Attention must also be drawn the results between the XCS and CS constructs. The difference in the two constructs is the presence of the transverse screw in the XCS. The method of implantation requires that the transverse screw only thread into the strong cortical bone at the base of the femoral neck. This allows the transverse screw to compress the distal end of the femoral neck restricting Vera-Valga movement.

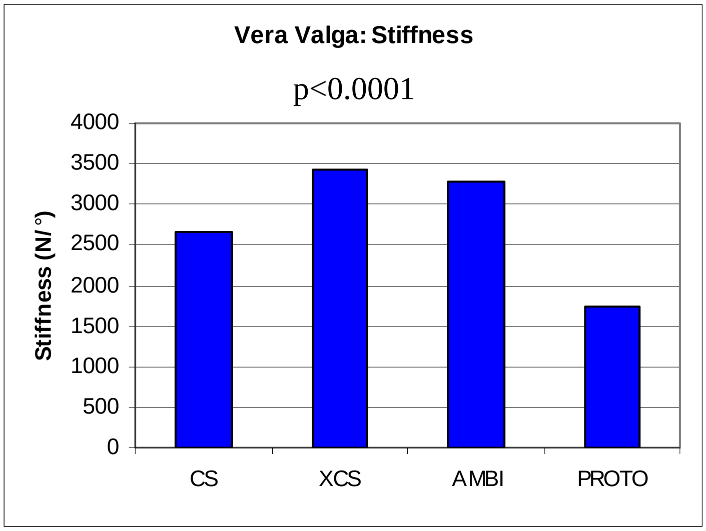


Figure 11: Vera Valga Stiffness.

<u>*Summary of Axial Stiffness Results*</u>*:* Intuitively one can reason that the projected cross-sectional area of the construct at the fracture plays a significant role in the axial stiffness, which is evident in the superior axial

stiffness in the AMBI design. However, the additional stiffness afforded by increasing cross sectional area is offset by the quantity of bone removal. For this reason the cross sectional area of the members needs to be less than what is used with the AMBI, which is acceptable in practice. Attention to limiting bone removal allows continued strength upon construct removal and requires only minimal growth of cancellous bone.

The results indicate that the lack of reduction at the fracture surface contributes to the poor performance of the PROTO. The results also indicate that continued reduction to induce compressive forces promotes increased stiffness. The use of locking head screws by the PROTO is shown to increase Medial-Lateral stiffness.

Overall, the AMBI and XCS display the best measure of performance when dealing with axial stiffness. This requires future design attention towards the use of a transverse screw along with the ability to reduce and compress the fracture surfaces.

Torsional Stiffness Design Features:

<u>Anterior-Posterior</u>: XCS and PROTO are shown in Figure 12 to have the highest level of torsional rigidity for AP movement. The XCS and Proto exhibit the same screw orientation and include the use of a transverse screw.

The transverse screw is also the only difference between the CS and XCS which results in a 35% increase in torsional stiffness.

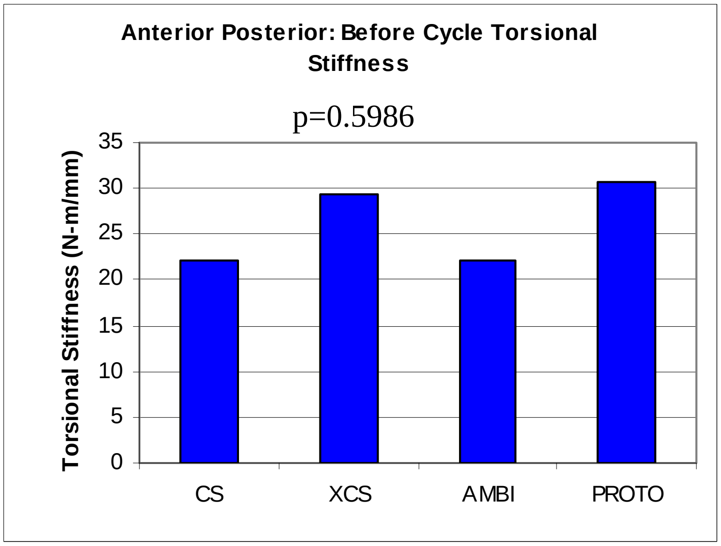


Figure 12: Anterior Posterior Stiffness.

Internal-Rotation: The trend shown in Figure 13indicates a 100% increase in stiffness due to the reduction offered by CS, XCS, and AMBI.

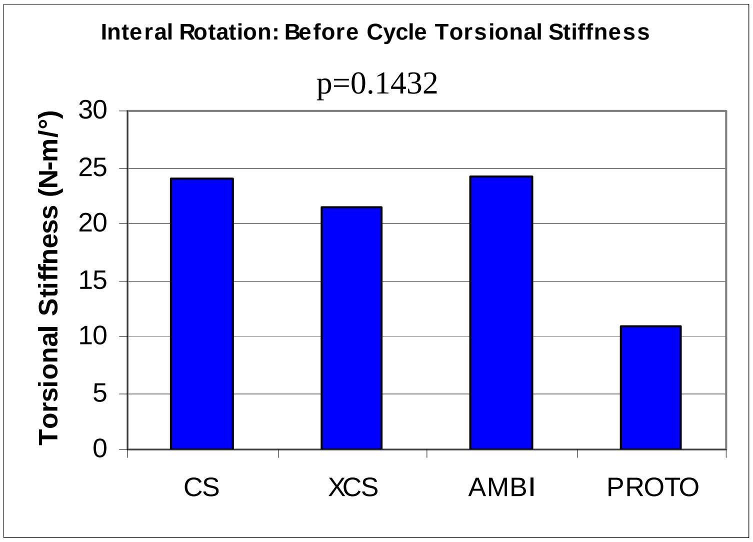


Figure 13: Internal Rotation Stiffness.

Retro-Anti: XCS and the PROTO have the highest measure of torsional rigidity about this orientation. The CS and XCS only differ in the addition of the transverse screw that is used with the XCS. This transverse screw is shown to increase the torsional stiffness 30%. This further reinforces the importance of the transverse screw that is used in these two constructs.

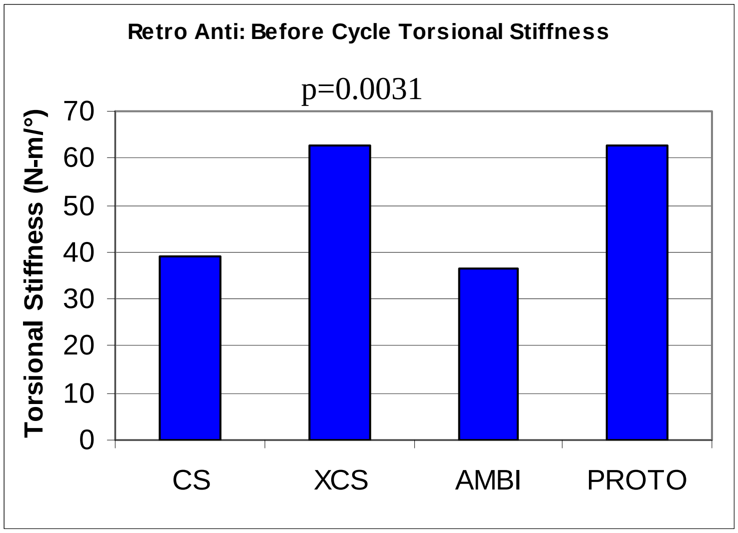


Figure 14: Retro Anti Stiffness.

Summary of Torsional Stiffness Results: The high torsional rigidity demonstrated by the PROTO originates from two design characteristics; the use of the transverse screw and reduction of the fracture gap.

Design Features: Based on the analysis from the CS, XCS, AMBI, and PROTO test results, the addition of a transverse screw, reduction of the fracture gap, and the presence of a locking screw aid in increasing construct stiffness. The orientation of the construct is selected based on the results from the comparison study, which conclude that the XCS provides the best torsional resistance. Therefore the use of two parallel screws with a transverse screw is used for each of the design alternatives. Design focus is placed on incorporating these features into the design of the DHON construct.

Design Alternatives: Several possibilities exist which incorporate the required design characteristics. Below are four alternatives that were developed to explore different methods of reduction, compression, and assembly.

*Alternative 1**:*** The design of Alternative 1 arises from the traditional approach of supplying compression similar to what is used in the AMBI construct. This includes a plate and barrel assembly along with lag screws. Several changes were made this assembly mechanism to include the defined design characteristics. To allow the use of the two parallel lag screws, the size of the barrel and lag screw assembly was reduced. This also allows for the use of a transverse screw. The requirement of locking head screw was then applied to the barrels with are screwed into the plate.

This setup allows the barrels to be fixed on the lateral side of the femur. A lag screw extends through the barrel and threads into the cancellous bone at the femoral head. A set screw is used to thread into the lag screw from the lateral side which draws the lag screw into the barrel reducing the fracture gap and generating compressive forces. This design is displayed in Figure 15.

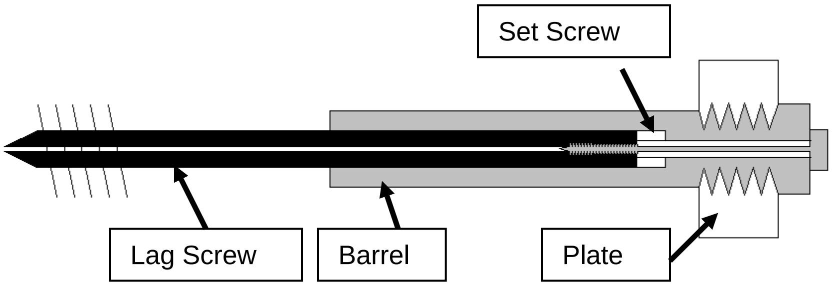


Figure 15: Compression Mechanism of Alternative 1.

Alternative 2: The design of alternative 2 results from the incorporation of functionality shown by Alternative 1 with a slight deviation in the reduction mechanism. The primary difference in the design is the barrel itself supplies the reduction by threading onto the outside of the lag screw, removing the need of the set screw. The reason for this design is a method of increasing the thread diameter to reduce the possibility of deformation of the threads during loading. This compression mechanism can be seen in Figure 16.

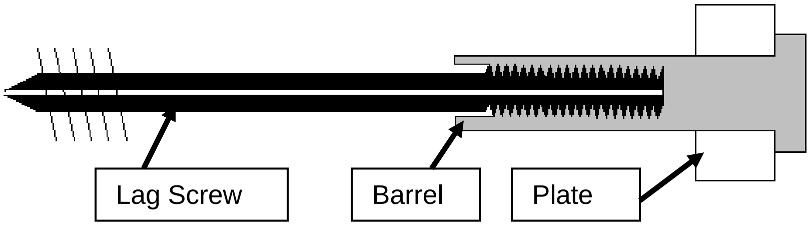


Figure 16: Compression Mechanism of Alternative 2.

Alternative 3: Alternative 3 explores a new method of reduction that combines the use of a plate, a bolt, and a new type of cancellous nut. The idea with this design is a method of reduction without a barrel and lag screw assembly. An alternative method to induce reduction is the placement of a device within the femoral head which can support a screw or bolt. The device is only intended as a fixture and not to resist deflection. The method of accomplishing this idea was the use of a nut and bolt assembly. The nut incorporates a large outer thread which enables it to lock into the cancellous bone at the femoral head. A 5/16” bolt then threads into the cancellous nut drawing the fracture surfaces together and therefore reducing the fracture gap. This design is illustrated in Figure 17.

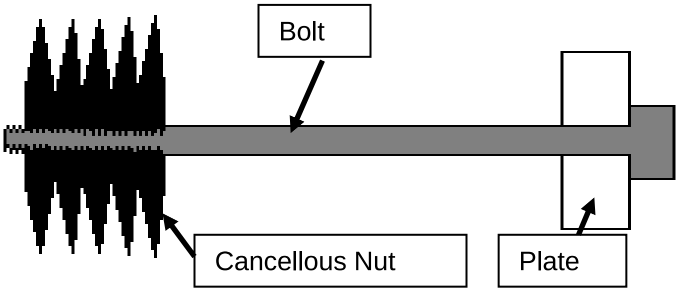


Figure 17: Compression Mechanism of Alternative 3.

Alternative 4: Due to the high torsional performance offered by the XCS construct, a design was employed to replicate the construct with the intention of increasing axial stiffness. Alternative 4, shown in Figure 18, uses the standard XCS setup with the addition of a plate along the lateral side of the femoral shaft. The lag screws function to reduce the fracture while the screw orientation provides the torsional resistance.

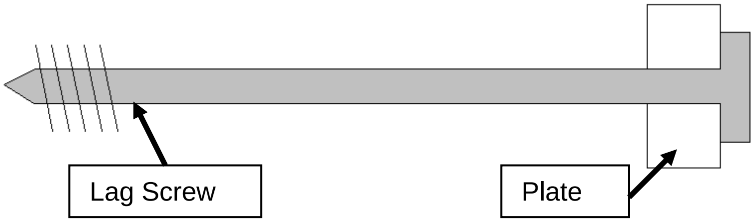


Figure 18: Compression Mechanism of Alternative 4.

Evaluation

Each of the alternatives shown previously offers the ability to increase stiffness. Selection of the best alternative must also meet other objectives such as reduction, machinability, and ease of assembly. To decide on the best alternative, a metrics table was developed which applies a weight to each of the criteria. The highest weight is applied to reduction. This is the major function of the design and therefore requires the most significant weight. A measure for this value is based on the reduction potential of the design. For example; Alternative 1 can reduce a gap up to the full length of the lag screw, whereas Alternative 4 is restricted to the distance allowed before contact is made with the medial cortical bone of the femoral head. Machinability is a measure of the skill level and tools required to manufacture the construct with the available shop facilities. This design must be prototyped to verify completion of the objectives and the manufacturability must be considered. The final criterion is simplicity of assembly which deals with the skill set required to implant the construct. The design must not incorporate foreign techniques which will limit the application of the device. The metrics described have been approved by Dr. Ron Goulet, who offers experience in the field of biomechanics and strength of materials. The results of the alternative selection are shown in Table 1, with the metrics defined in Tables 2-4.

Table 1: Weighted Alternative Selection

Criteria	**Relative Weights**	**Alternative 1**			**Alternative 2**		
		Score	Value	Weighted	Score	Value	Weighted
Reduction	0.5	Exc.	3	1.5	Exc.	3	1.5
Machinability	0.3	Adeq.	2	0.6	Adeq.	1	0.3
Assembly	0.2	Adeq.	2	0.4	Poor	2	0.4
Total				**2.5**			**2.2**

Table 1 (cont.): Weighted Alternative Selection

Criteria	**Relative Weights**	**Alternative 3**			**Alternative 4**		
		Score	Value	Weighted	Score	Value	Weighted
Reduction	0.5	Adeq.	2	1.0	Adeq.	1	0.5
Machinability	0.3	Adeq.	2	0.6	Exc.	3	0.9
Assembly	0.2	Exc.	3	0.6	Exc.	3	0.9
Total				**2.2**			**2.3**

Table 2: Conversion Metrics-Reduction

Score	**Value**	**Range**
Excellent	3	Reduction of 8mm.
Adequate	2	Reduction of 4 mm.
Poor	1	Reduction of 2 mm.

Table 3: Conversion Metrics-Machinability.

Score	**Value**	**Range**
Excellent	3	Machinable with moderate experience with the available shop equipment.
Adequate	2	Machinable with advanced experience with the available shop equipment.
Poor	1	Requires assistance of professional machine shop.

Table 4: Conversion Metrics-Assembly.

Score	**Value**	**Range**
Excellent	3	Standard techniques
Adequate	2	Semi-advanced techniques
Poor	1	Advanced techniques

*Based on use of current tools and techniques associated with traditional constructs.

Based on the results in Table 1, the best design is Alternative 1 with a weighted score of 2.5. This design is expected to provide significant reduction, manufactured with only moderate experience, and uses standard assembly techniques. With the optimal design chosen, the details of the preliminary design must be developed.

Enhancement

Alternative 1 must be verified to ensure achievement of the stated objectives. This requires the development of preliminary specifications for the design which can be used to prepare for prototype fabrication and testing.

Preliminary Specifications: The plate is designed to fit the lateral contour of the femoral shaft and needs to incorporate the XCS screw orientation at the head of the plate. Two prototype plates were cut using a CNC mill to ensure correct dimensioning and an adequate contour when placed on the femur. The final dimensions of the plate are 20x90x4 mm with a 155° bend at 58 mm from the distal end of the plate. A drawing with associated dimensions of the plate can be seen in Figure 20.

The compression barrel is a hollow cylinder with an inside diameter of 5 mm and an outside diameter of 8mm. The lateral end of the barrel incorporates a tapered thread which allows the barrel to lock securely into the plate. A 6.5 mm cannulated lag screw then extends through the barrel and threads into the cancellous bone. A 4-40 machine screw enters the lateral side of the plate, through the barrel, and threads into the lag screw. This draws the cancellous screw into the barrel and supplies compression to the fracture surfaces. The dimensions of the barrel can be seen in Figure 21. A solid model rendering of the DHON construct can be seen in Figure 19.

Figure 19: DHON Construct Assembly.

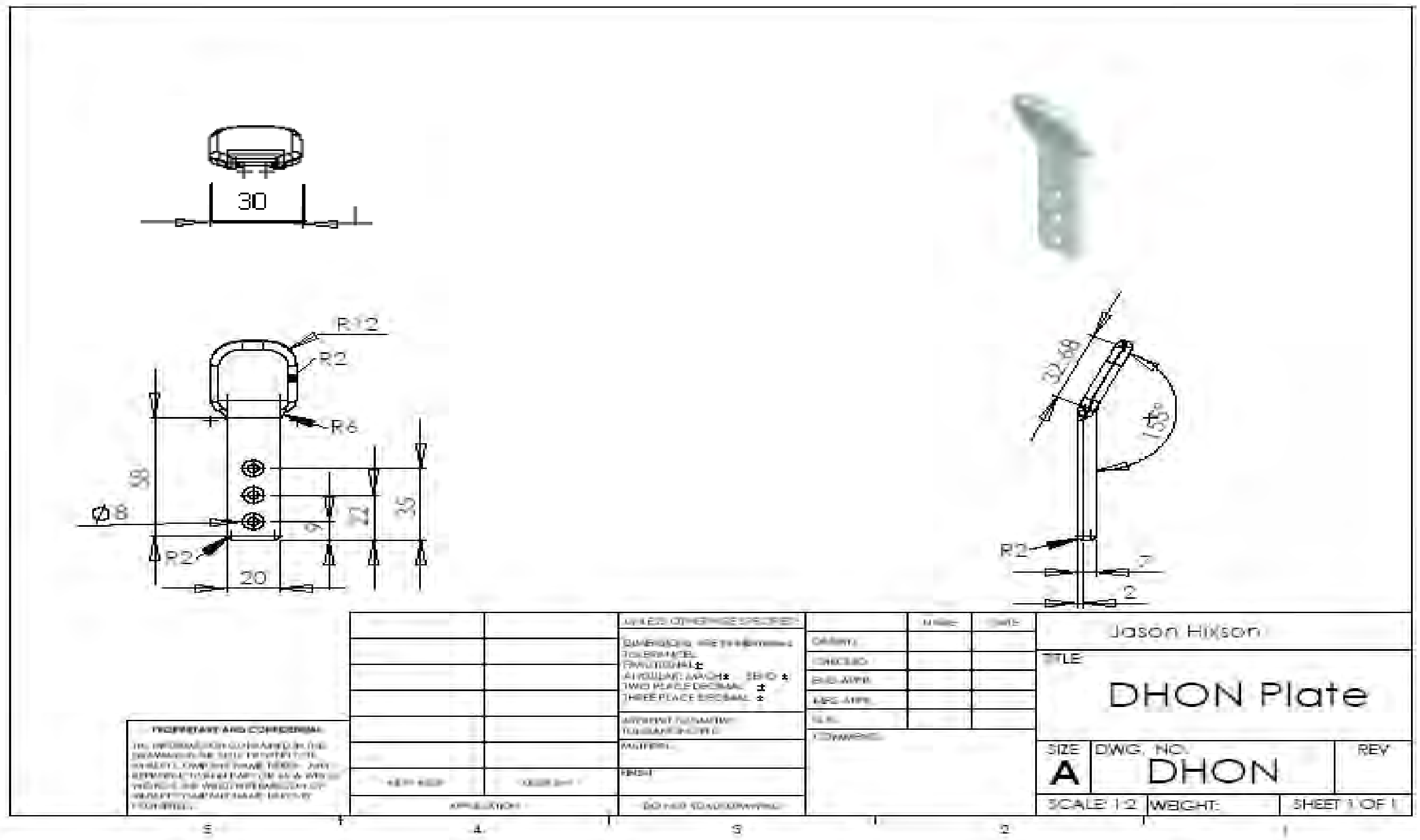


Figure 20: Plate Design and Dimensions.

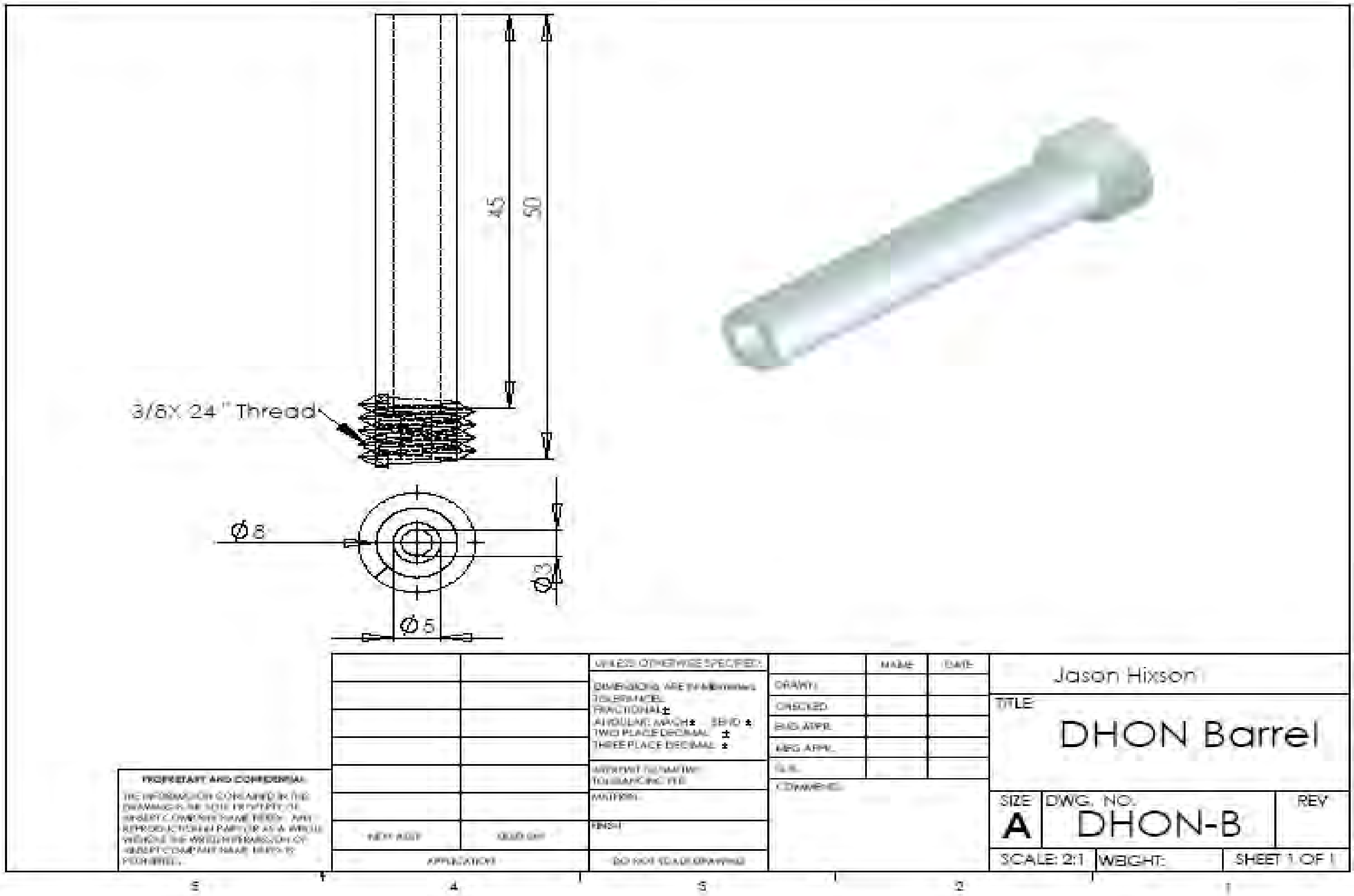


Figure 21: Barrel Design and Dimensions.

Verification:

Verification of the design objectives requires the assembly and testing of the construct. The details of the construction of the DHON prototype can be seen in Appendix C. An explanation of the assembly method along with the method of testing is shown below.

Construct Assembly: The first step to begin the assembly of the construct is to simulate the femoral neck fracture. A vertical cut is made at the base of the femoral neck. This cut allows a visual to ensure that the drilled holes extend through the femoral neck avoiding any contact with cortical bone.

Six test bones are cut and drilled in preparation for testing. The first step in assembly is to clamp on the drill template and drill a guide hole to determine where the holes align in relation to the femoral neck. Once the plate is aligned properly, an 8 mm bit is used to drill holes for the barrels and the plate barrels slide into the predrilled holes. Each of the barrels extend beyond the fracture approximately 12 mm, which requires the femoral head to also be drilled. The femoral head is drilled by extending the existing holes present in the femoral shaft.

Once all the required holes are drilled, the lag screws are inserted into the barrels and the barrels are inserted into the femur. The lag screws are then screwed into the femoral head and fully secured. The plate is place on the bone and the remaining holes locking the plate to the femoral shaft are drilled. Three 4.5 mm cortical screws are used to fix the plate to the femoral shaft. Once the plate is secured, the 4-40 machine screws are threaded into the lag screw creating the necessary compression at the fracture surface. Finally, a 4.5 mm transverse screw is tapped into the bone perpendicular to the femoral shaft. The method of assembly can better be understood by the exploded view of the construct shown in Figures 22 and assembly diagram shown in Figure 23.

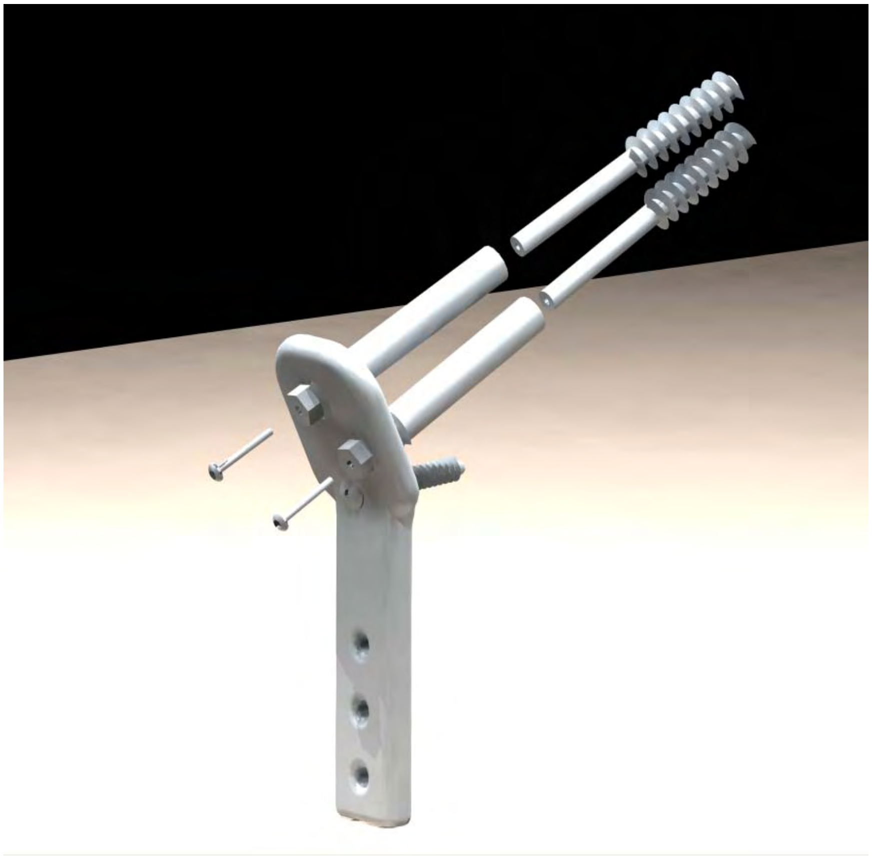
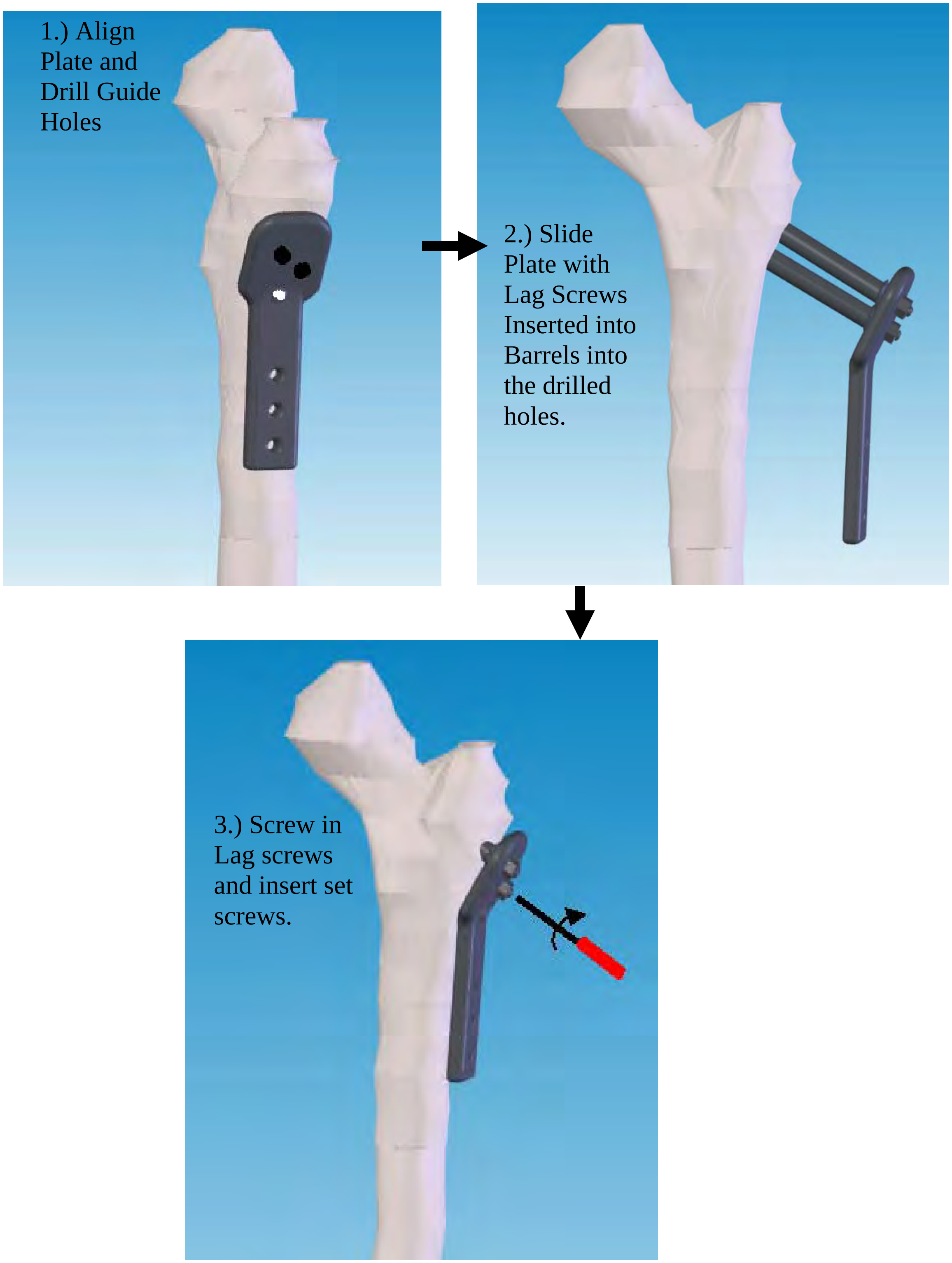


Figure 22: DHON Construct- Exploded View.



1.) Align Plate and Drill Guide Holes

2.) Slide Plate with Lag Screws Inserted into Barrels into the drilled holes.

3.) Screw in Lag screws and insert set screws.

Figure 23: Construct Assembly Diagram.

Testing: The original testing strategy was to use partial femurs readily available in the lab, which allows several constructs to be tested so statistical results can be obtained. Data was collected using this method but after analyzing the stiffness values, several unsuspected results were obtained in medial lateral stiffness. To verify that the testing strategies were equivalent, an intact femur along with an intact partial femur were tested for stiffness which should result in equivalent values. The results of this test provided evidence that errors are present in the testing strategy. Another test was performed to verify that the results from the former study could be repeated. It was determined that the testing strategy that was employed was not repeatable for medial lateral and anterior posterior movement. Upon further investigation, it was found that the sensor mount for the femoral head had begun degrading and is therefore recording movement that is not representative of femoral head movement. This evidence requires an exact replication of the former study to allow the collection of comparable data. Due to the inconsistency of Medial Lateral and Anterior Posterior stiffness results, the validity of comparable data will be restricted to Proximal Distal, Vera Valga, Internal Rotation, and Retro Anti stiffness. A single full femur is therefore tested using the same test sequence and mounting strategy to determine if evidence is available supporting an increase in performance from the DHON construct.

The test sequence begins with a torsion cycle of 0.005 kN-m. This is followed by a ten thousand cycle axial load of -0.35 kN at a rate of 2 Hz. The test is then concluded with another torsion cycle of 0.005 kN-m.

Several steps are required before testing the construct. The first task is to assemble the construct according to the method previously described. This is followed by drilling the hole for each of the sensor mounts. The first mount is located on the greater trochanter and the second is located on the on the distal end of the femur. This is done by using an existing jig which enables a replicable hole for each new bone. During testing, the head and shaft of the bone are fixed to restrict movement. A low melting point metal is used for this where the distal end of the bone is submerged in the liquid metal forming a mold which is used for each of the constructs. The femoral head mount is available from the previous study and is again used. The bone is then placed in the gimble mounts to begin testing. The experimental setup can be seen in Figure 24

Analysis and Discussion: To accurately measure the displacement during testing, the Fastrak sensoring system is used. This system uses a transmitter to detect the relative location of the connected sensors. A program was developed to aid in analyzing the data and output the deflection and stiffness results. The details of the program are outside the context of this study and will not be discussed. The primary objective of the software is to align the Fastrak and Instron data so that the load and displacement curves will correlate. Once this is done, the displacement among each axis is found which is used to find the stiffness. The results are shown below in Figures 25-30.

Figure 24: Experimental Instron Setup.

Medial Lateral:

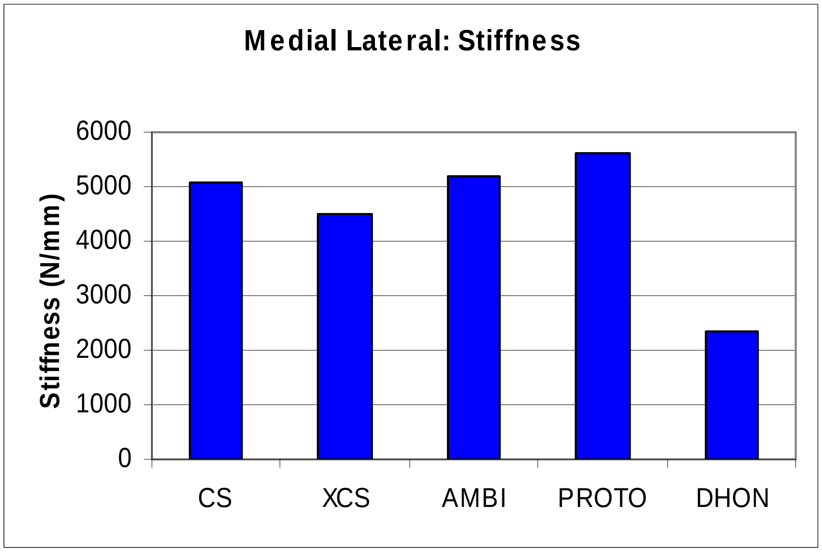


Figure 25: Medial Lateral Stiffness.

The medial lateral stiffness for the DHON construct, shown above in Figure 25, is approximately 50% lower than each of the alternative methods.

Proximal Distal:

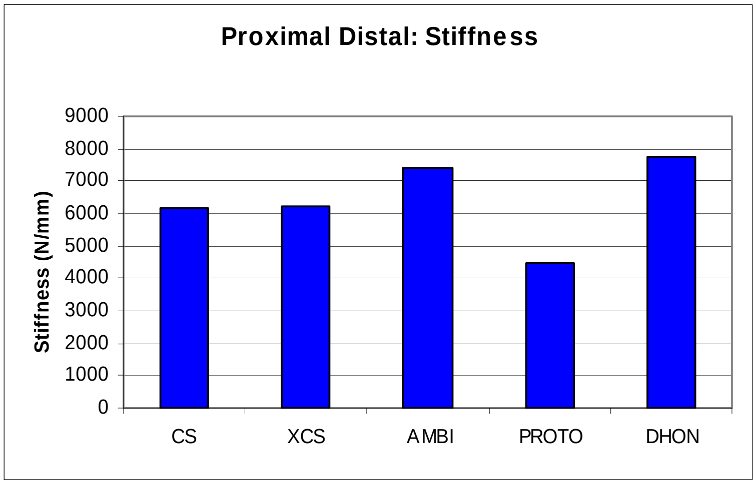


Figure 26: Proximal Distal Stiffness.

The DHON construct displays the highest measure of stiffness compared to the CS, XCS, AMBI, and PROTO. The average stiffness between each of the compared methods is approximately 5500 N/mm. The trend shown in the results of Figure 26 indicate a 25% increase in stiffness when compared to this average.

Vera-Valga:

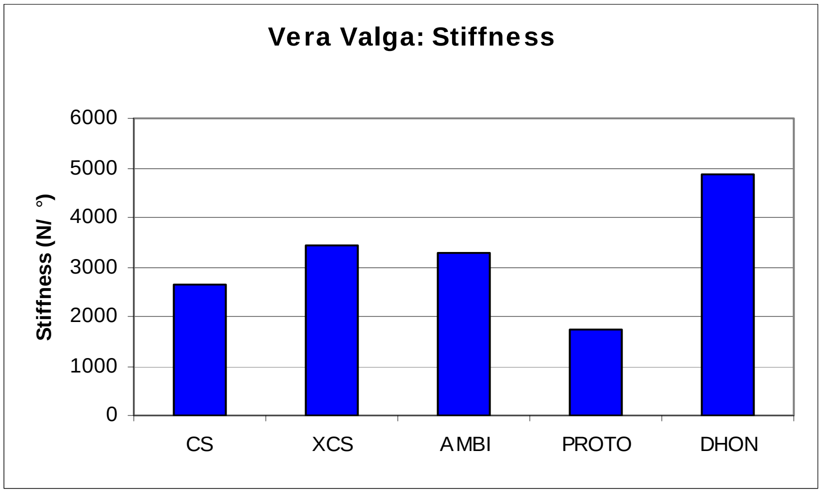


Figure 27: Vera Valga Stiffness.

The DHON construct displayed the highest measure of Vera Valga stiffness when compared to each of the traditional constructs, Figure 27. The average stiffness between the alternative groups is 2500 N/mm. The measured stiffness of 4950 N/° represents a 100% improvement in construct stiffness.

Anterior Posterior:

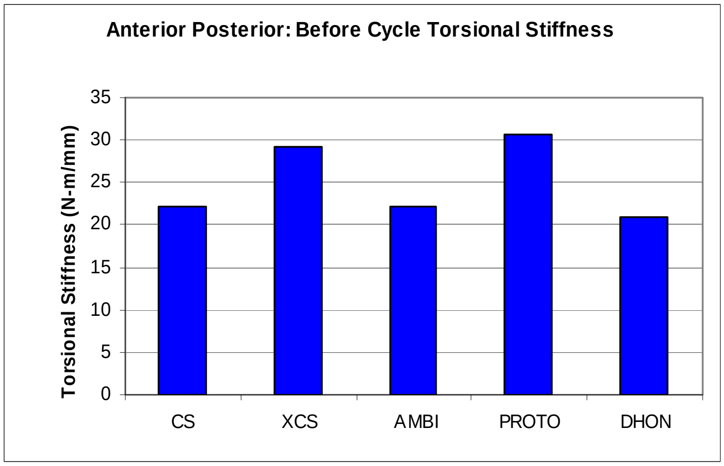


Figure 28: Anterior Posterior Before Cycle Torsional Stiffness.

The DHON construct performed equivalent to the results seen by the CS and AMBI methods with a stiffness of 21 N-m/mm, shown in Figure 28. The results show a 33% decrease in torsional stiffness compared to the XCS and PROTO.

Internal Rotation:

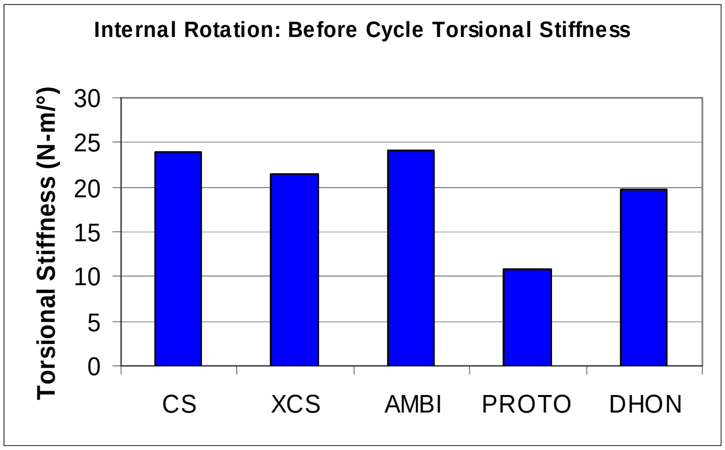


Figure 29: Internal Rotation Before Cycle Torsional Stiffness.

The results in Figure 29 indicate a 20% decrease in torsional stiffness compared to CS and AMBI.

Retro-Anti:

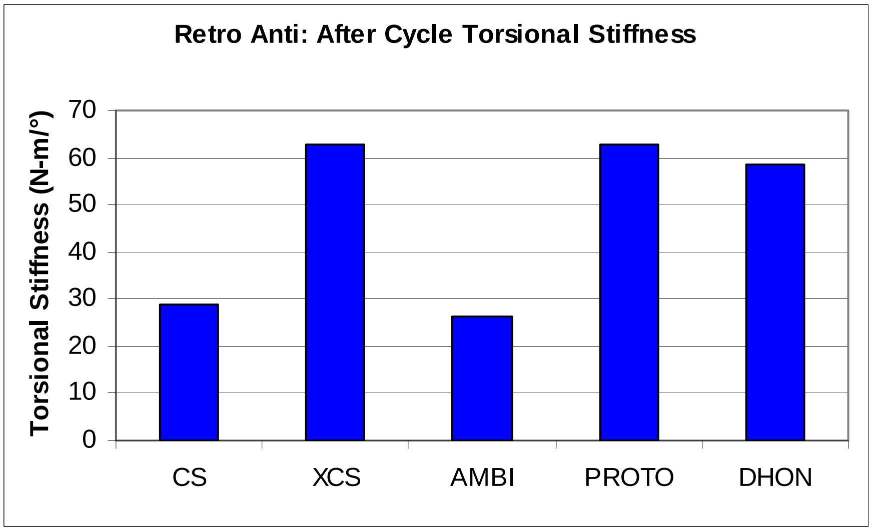


Figure 30: Retro Anti After Cycle Torsional Stiffness.

The Retro Anti stiffness indicates equivalent performance with the similar screw arrangements present in XCS and PROTO. This signifies an improvement when compared to the CS and AMBI constructs.

The results of the axial stiffness tests indicate poor performance of the DHON construct along the Medial Lateral orientation. This orientation, however, is known to produce results of little validity. The results of the Proximal Distal and Vera Valga movement indicate improved performance due to the new design. The results for torsional stiffness show comparable values in each of the three categories. This indicates that the new design had little or no significant role in increasing torsional stiffness.

CONCLUSION

Summary

The method used for the design of the DHON construct followed the systematic design process taught throughout the engineering curriculum. A clear definition of the project goal was presented describing the need, objectives, and constraints. The aid of the previous hip study provided the necessary information to gain an understanding of the influence of certain design advantages and a basis for experimental comparison.

The design eventually chosen included each of the design characteristics that were experimentally shown to be beneficial. The design included two parallel lag screw, a transverse screw, and a mechanism to reduce the fracture gap and supply a considerable amount of compression. The design satisfies all of the defined constraints and ensures the implant is surgically feasible from the lateral side of the femur.

The experimental testing replicated the original study to ensure comparable results. Each of the applicable movement orientations were considered and analyzed using the software developed for the original study. Proximal Distal stiffness is shown to increase by 25%, while Vera Valga stiffness shows an increase of 100%. Each of the torsional movement orientations represented comparable stiffness results.

The results indicate that the DHON construct shows increases in Proximal Distal, Vera Valga, and Retro Anti stiffness. This signifies that the hypothesis being tested, which expressed construct performance could be increased by combining existing features, is valid. The results, however, have no statistical significance and are only based upon observed trends. These results are further weakened by the known deficiency of the femoral head mount which represents movement that is not reflective of the femoral head. The deficiencies in the data lie most directly in Proximal Distal and Anterior Posterior movement. The remaining results are considered reliable. For the hypothesis to be fully verified, statistical significance needs be obtained in further studies.

Recommendations

The design of the DHON construct is based on the assumption that the stiffness results obtained previously were reliable and repeatable. The degradation of the femoral head mount has compromised the validity of the results, which requires each of the traditional constructs to be retested. Once the tests are verified to be accurate and repeatable, the same testing strategy then needs to be employed for several specimens of the DHON construct. This will verify the increased stiffness results that were obtained, and clarify the confusion that is present with Medial Lateral stiffness and each of the torsional stiffness results.

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APPENDIX A

DEFINITIONS

Construct – Orthopedic devise or screw arrangement which sis used to support a fracture.

Pauwel’s III- A shear femoral neck fracture associated with osteoporosis and high impact accidents.

Reduction- Closure of the fracture gap.

Axial stiffness - The resistance of an elastic body to deflection by an applied force.

Torsional stiffness - The resistance to rotational deflection by an applied moment.

ANOVA- Analysis of variance between groups of data.

p-value- Value which signifies whether the results are by random chance within a confidence interval.

APPENDIX B

COMPARISON STUDY RESULTS

Summarized Statistics

Test Parameters			Fisher's PLSD
Test	**Movement**	**Set**	**Significant Relationships/p-values**
Cyclic Axial	Medial-Lateral Fracture	Stiffness	None
		Retained Stiffness	None
	Proximal-Distal Fracture	Stiffness	AMBI,Proto/0.0003;CS,Proto/.0246;Proto,XCS/0.0225
		Retained Stiffness	AMBI,Proto/0.0003;CS,Proto/.0246;Proto,XCS/0.0225
	Vera-Valga Fracture	Stiffness	AMBI,Proto/0.0001;CS,Proto/0.0092; CS,XCS/0.0240;Proto,XCS/0.0001
		Retained Stiffness	AMBI,Proto/0.0001;CS,Proto/0.0092; CS,XCS/0.0240;Proto,XCS/0.0001
Single Torsional	Anterior-Posterior Fracture	Before Cycle Tor Stiff	ANOVA not Significant @ 95% CI
		After Cycle Tor Stiff	ANOVA not Significant @ 95% CI
	Internal Rotation Fracture	Before Cycle Tor Stiff	None
		After Cycle Tor Stiff	CS,Proto/0.0051
	Retro-Anti Rotation Fracture	Before Cycle Tor Stiff	AMBI,XCS/0.0139;CS,XCS/0.0245; Proto,XCS/0.0292
		After Cycle Tor Stiff	AMBI,XCS/0.0094;CS,XCS/0.0129; Proto,XCS/0.0080

Medial Lateral

Means Table for ML Frac
Effect: Type
Split By: Set
Cell: STIFF

	Count	Mean	Std. Dev.	Std. Err.
AMBI	10	5207.280	2405.669	760.739
CS	10	5087.242	2141.568	677.223
Proto	10	5632.482	1733.756	548.262
XCS	10	4500.891	1933.745	611.504

ANOVA Table for ML Frac
Split By: Set
Cell: STIFF

	DF	Sum of Squares	Mean Square	F-Value	P-Value	Lambda	Pow er
Type	3	6539457.697	2179819.232	.509	.6784	1.528	.141
Residual	36	154069521.062	4279708.918				

Fisher's PLSD for ML Frac
Effect: Type
Significance Level: 5 %
Split By: Set
Cell: STIFF

	Mean Diff.	Crit. Diff.	P-Value
AMBI, CS	120.038	1876.334	.8975
AMBI, Proto	-425.202	1876.334	.6486
AMBI, XCS	706.389	1876.334	.4501
CS, Proto	-545.240	1876.334	.5593
CS, XCS	586.351	1876.334	.5302
Proto, XCS	1131.591	1876.334	.2292

Proximal Distal

Means Table for PD Frac
Effect: Type
Split By: Set
Cell: STIFF

	Count	Mean	Std. Dev.	Std. Err.
AMBI	10	7396.409	2401.575	759.445
CS	10	6173.887	1891.278	598.075
Proto	10	4450.212	669.499	211.714
XCS	10	6200.944	997.779	315.526

ANOVA Table for PD Frac
Split By: Set
Cell: STIFF

	DF	Sum of Squares	Mean Square	F-Value	P-Value	Lambda	Power
Type	3	44101557.436	14700519.145	5.451	.0034	16.352	.919
Residual	36	97094586.865	2697071.857				

Fisher's PLSD for PD Frac
Effect: Type
Significance Level: 5 %
Split By: Set
Cell: STIFF

	Mean Diff.	Crit. Diff.	P-Value	
AMBI, CS	1222.522	1489.530	.1047	
AMBI, Proto	2946.197	1489.530	.0003	S
AMBI, XCS	1195.465	1489.530	.1123	
CS, Proto	1723.675	1489.530	.0246	S
CS, XCS	-27.057	1489.530	.9708	
Proto, XCS	-1750.732	1489.530	.0225	S

Vera Valga

Means Table for Vera/Valg Frac
Effect: Type
Split By: Set
Cell: STIFF

	Count	Mean	Std. Dev.	Std. Err.
AMBI	10	3286.252	781.211	247.040
CS	10	2652.967	612.150	193.579
Proto	10	1747.575	482.880	152.700
XCS	10	3427.838	971.479	307.209

ANOVA Table for Vera/Valg Frac
Split By: Set
Cell: STIFF

	DF	Sum of Squares	Mean Square	F-Value	P-Value	Lambda	Power
Type	3	17580161.746	5860053.915	10.842	<.0001	32.526	.999
Residual	36	19457665.394	540490.705				

Fisher's PLSD for Vera/Valg Frac
Effect: Type
Significance Level: 5 %
Split By: Set
Cell: STIFF

	Mean Diff.	Crit. Diff.	P-Value	
AMBI, CS	633.285	666.802	.0620	
AMBI, Proto	1538.677	666.802	<.0001	S
AMBI, XCS	-141.586	666.802	.6693	
CS, Proto	905.392	666.802	.0092	S
CS, XCS	-774.871	666.802	.0240	S
Proto, XCS	-1680.263	666.802	<.0001	S

Anterior Posterior

Means Table for AP Frac
Effect: Type
Split By: Set
Cell: BTT

	Count	Mean	Std. Dev.	Std. Err.
AMBI	10	19.076	8.258	2.611
CS	10	22.222	11.255	3.559
Proto	10	15.767	32.509	10.280
XCS	10	8.199	32.215	10.187

ANOVA Table for AP Frac
Split By: Set
Cell: BTT

	DF	Sum of Squares	Mean Square	F-Value	P-Value	Lambda	Power
Type	3	1086.933	362.311	.633	.5986	1.899	.166
Residual	36	20605.103	572.364				

Fisher's PLSD for AP Frac
Effect: Type
Significance Level: 5 %
Split By: Set
Cell: BTT

	Mean Diff.	Crit. Diff.	P-Value
AMBI, CS	-3.146	21.699	.7704
AMBI, Proto	3.309	21.699	.7589
AMBI, XCS	10.877	21.699	.3161
CS, Proto	6.455	21.699	.5501
CS, XCS	14.023	21.699	.1983
Proto, XCS	7.568	21.699	.4839

Internal Rotation

Means Table for Inter Rot Frac
Effect: Type
Split By: Set
Cell: BTT

	Count	Mean	Std. Dev.	Std. Err.
AMBI	10	-.091	33.627	10.634
CS	10	17.358	23.113	7.309
Proto	10	10.820	6.198	1.960
XCS	10	21.441	11.500	3.637

ANOVA Table for Inter Rot Frac
Split By: Set
Cell: BTT

	DF	Sum of Squares	Mean Square	F-Value	P-Value	Lambda	Power
Type	3	2648.472	882.824	1.924	.1432	5.771	.446
Residual	36	16520.492	458.903				

Fisher's PLSD for Inter Rot Frac
Effect: Type
Significance Level: 5 %
Split By: Set
Cell: BTT

	Mean Diff.	Crit. Diff.	P-Value	
AMBI, CS	-17.449	19.430	.0769	
AMBI, Proto	-10.911	19.430	.2623	
AMBI, XCS	-21.532	19.430	.0308	S
CS, Proto	6.538	19.430	.4993	
CS, XCS	-4.084	19.430	.6725	
Proto, XCS	-10.622	19.430	.2749	

Retro Anti

Means Table for Retro/Anti Fact
Effect: Type
Split By: Set
Cell: BTT

	Count	Mean	Std. Dev.	Std. Err.
AMBI	10	-36.461	23.795	7.524
CS	10	-16.365	40.196	12.711
Proto	10	21.802	36.818	11.643
XCS	10	34.048	64.894	20.521

ANOVA Table for Retro/Anti Fact
Split By: Set
Cell: BTT

	DF	Sum of Squares	Mean Square	F-Value	P-Value	Lambda	Power
Type	3	32295.174	10765.058	5.557	.0031	16.671	.925
Residual	36	69739.162	1937.199				

Fisher's PLSD for Retro/Anti Fact
Effect: Type
Significance Level: 5 %
Split By: Set
Cell: BTT

	Mean Diff.	Crit. Diff.	P-Value	
AMBI, CS	-20.095	39.920	.3141	
AMBI, Proto	-58.262	39.920	.0054	S
AMBI, XCS	-70.509	39.920	.0010	S
CS, Proto	-38.167	39.920	.0604	
CS, XCS	-50.414	39.920	.0148	S
Proto, XCS	-12.247	39.920	.5377	

APPENDIX C

PROTOTYPE CONSTRUCTION

Plate Construction: One advantage of modeling the plate in SolidWorks is the ease to manufacture using a CNC mill. This allows a very accurate cut for the plate and reduces weakening of the metal due to any bending. A mild steel was selected for the plate to aid in the milling process, whereas in actual construction a surgical steel would be required. It is not expected that this substitution affects the performance due to the modulus of elasticity being much higher in steel compared to bone. This results in a failure in the femoral shaft of the bone rather than in the plate.

The complex geometry of the femoral neck requires the holes for the barrels to be drilled after the plate is milled. Several ideas were generated to best place the tap holes, with the final resulting in a reverse approach by drilling from the femoral neck. A femur is first cut along the neck and the plate is mounted to the shaft. Each of the test bones have a manufactured hole extending through the center of the femoral neck, which is used to align the mill head. With the orientation of the mill head secure, the location of the barrel holes were determined so that each of the barrels could extend through the neck without interfering with the cortical bone. Two parallel holes are then drilled and extended through the head of the plate. This approach ensures that entrance from the lateral side of the femur results in correct alignment with the femoral neck.

Barrel Construction: The entire assembly process needs to be possible from the lateral side of the femur to be applicable in a surgical environment. This requires the barrel to first slide through the plate to lock with the threads at the head of the barrel. A lathe is used to reduce the barrel diameter to 8mm, allowing it to slide through the plate. The head of the barrel is left a larger diameter to incorporate the threads. The original intention for the barrels was a locking head using a tapered thread design. This, however, is not possible due to the need of specialized equipment, which is not available. Instead, a 3/8" machine thread is cut for the barrels.

Once the barrel was screwed into the plate, it became apparent that the standard 3/8" thread was not going to provide the strength necessary for the construct. The close proximity of the parallel barrels restrict the size of the barrel head, and with no overlapping head, the threads are unable to lock and restrict movement. To alleviate this problem, the barrels are instead welded to simulate the performance of the tapered locking head design. This provides the rigidity that was expected from the original design.

For the barrels to function properly, a hole is needed to extend through the entire length of the barrel. The diameter of this hole is dependent on the diameter of the lag screw that would be used, which was determined to be equivalent to a #15 drill, or approximately 5 mm. The lathe was again used to ensure that the hole was located in the center of the barrel. This provides a smooth channel for the lag screw to draw into.

Lag Screw Construction: The lag screws being used in the DHON construct are a 6.5 mm cannulated Smith & Nephew design. The cannulated screw provides a hole through the entire screw length that act as guide during implantation. To incorporate the screws into the new design, the screw heads are removed. A 4-40 machine thread is tapped into the guide hole that is used with the set screw. To insert the lag screw into the cancellous bone, torque must be applied through the barrel. The simplest method is to alter the lag screw so that a flat head screw driver can be used. This allows the lag screw to thread into the cancellous bone and the set screw to thread into and draw the lag screw through the barrel from the lateral side of the femur.

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