Design of a Multi-Degree-of-Freedom Traction and Stabilization Device for Open Reduction and Internal Fixation of Distal Radius Fractures

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DESIGN OF A MULTI-DEGREE-OF-FREEDOM TRACTION AND STABILIZATION DEVICE FOR OPEN REDUCTION AND INTERNAL FIXATION OF DISTAL RADIUS FRACTURES

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ABSTRACT

Open reduction and internal fixation (ORIF) is a surgical procedure performed with the objectives of restoring normal alignment and providing stability to broken bone fragments after a fracture. This procedure is increasingly used to treat fractures of the distal end of the radius. Reduction of the fracture into correct alignment is often achieved by the surgeon pulling and manipulating the hand while looking at real-time x-rays, and frequently requires large forces to distract impacted fragments from proximal bone. This can make the task of simultaneously aligning the fracture fragments and placing hardware to secure fragments into the correct position particularly challenging for surgeons. This study presents the design and preliminary testing of a multi-degree-of-freedom (DOF) device capable of performing both distraction and reduction of fractured bone fragments using a traction splint mechanism with locking joints that results in significantly reduced effort and greater accuracy in performing ORIF procedures on distal radius fractures. Quantitative force testing found an 80% reduction in the maximum force required to create needed traction, while qualitative tests with a hand surgeon found the device's ability to reduce and stabilize bone fragments while hardware is secured to be more intuitive and less obstructive than existing techniques.

1. INTRODUCTION

Accounting for up to 15% of all bone injuries, fractures of the distal radius most often occur during a fall in which a hand is outstretched to brace the body for impact, resulting in both dorsal and radial displacements of the distal end of the radius [1]. While traditional treatment involves closed reduction and immobilization with a cast or splint, ORIF is a procedure increasingly used to treat such fractures, as it allows the surgeon to more precisely align and stabilize the bone fragments and requires less time for the patient to be able to return to activities of daily living. The procedure is composed of four main steps performed by the surgeon: (1) exposure of the fracture site, (2) reduction of the fracture fragments into the correct position, (3) placement of a volar plate to secure the fragments, and (4) closure of the surgical site. One of the most challenging aspects of the procedure, however, occurs during the reduction phase. Due to the combination of dorsal and radial displacements of the distal fragment, this step most often entails pulling and manipulating the hand of the patient to first distract the distal fragment from the residual radius and then aligning the bone fragments while placing the hardware into position, all the while looking at real-time x-rays to ensure each component of the construct is in the correct position. Thus, to aid surgeons in completing this procedure, there is a need for a device capable of concurrently applying traction, reducing, and temporarily securing the fragments of a distal radius fracture into position, such that the hardware can be screwed into place with little effort and greater accuracy.

Current methods for stabilizing the distal fragments often rely on Kirschner wires (K-wires) to temporarily hold bone fragments in place while permanent hardware is screwed into position. These flexible wires are drilled into bone fragments during the operation and then removed following the procedure. K-wires have a variety of limitations that precludes their use in many cases. Due to their relatively thin diameter and flexibility, they can break if insufficient fixation is provided and can sometimes result in movement or shifts of the bone fragments during the surgery. Additionally, because the location of pin insertion is critical to holding the bone in the correct position, the surgeon may have to drill multiple times before the K-wire is inserted correctly. For elderly patients with weaker bones, there is also a high risk of further fracturing the bone when the pins

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are inserted. Surgeons sometimes find that the use of K-wires is not worth the potential complication and interference in workflow.

Accordingly, we present the design and testing of a multi-DOF device that overcomes the limitations of K-wires in stabilizing the bone fragments while simultaneously reducing and applying traction to the fracture site. The design was guided by hand surgeon and co-author Dr. Jay Connor. Similar to splints used by emergency medical personnel to distract and secure traction of femoral fractures, our mechanism uses a ratcheting system to amplify the force provided by the surgeon to distract the distal end of the radius from the proximal shaft and maintain traction throughout the procedure. Rotable and locking joints further allow for motion in all DOFs required by the surgeon. Thus, after establishing traction, the surgeon is able to manipulate the hand directly, moving the fractured fragments into the correct position, and then hold the alignment by locking the clamps. As a result, the fracture is stabilized in a hands-off state, which enables the surgeon to carefully inspect the alignment, making fine adjustments as needed and ensuring optimal placement of hardware onto the fracture site.

2. BACKGROUND

2.1 Fracture Types and Treatment

The distal radius is one of the most commonly fractured bones in the human body, with over 640,000 fractures being treated each year in the United States. While such fractures have often been treated with closed reduction and casting, the number of surgical procedures performed has increased 500% over the past five years [2]. This is likely due to the development of anatomical plates (Figure 1) that result in better alignment and stabilization of the bones during healing, decreased pain, and a faster return to activities of daily living for the patient. With the advent of 3D printing enabling rapid creation of custom metal structures, the number of procedures will likely further rise.

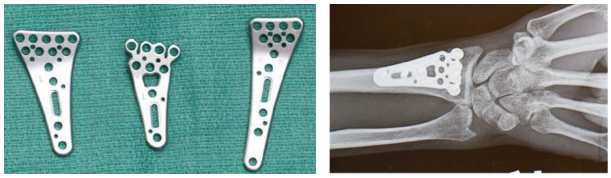
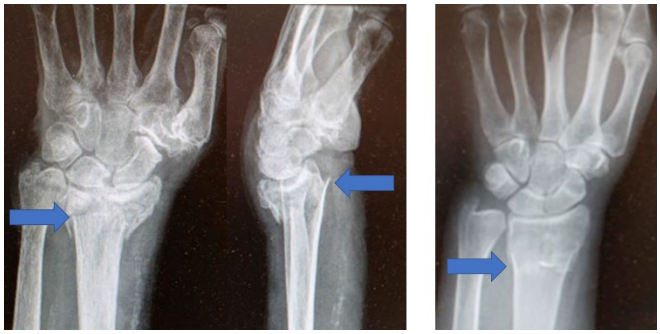


FIGURE 1: Volar Plate. These come in a variety of shapes and sizes to conform to the wrist of the patient and do not need to be removed following surgery.

These plates are particularly well suited for displaced fractures in which the anatomical alignment of the bones is compromised, such as that seen in Figure 2. Here, one can see the distal end of the radius angulated into the plane of the page in 2a and to the left in 2b. Figure 2c depicts a nondisplaced fracture in which traditional closed reduction and immobilization with a splint would be most commonly performed. Displaced fractures can be further categorized based on whether they were angulated toward the dorsal or volar side of the wrist, and each type will require a different set of movements and ranges of motion performed by the surgeon to reduce the fracture fragments.



(a) (b) (c)

FIGURE 2: Displaced (a and b) vs. Non-displaced (c) Fractures

2.2 Current Methods

K-wires enable surgeons to stabilize the fracture site while screwing the volar plate into place [3]. However, they come with distinct limitations that prevent them from being widely accepted in ORIF surgeries of the distal radius. As illustrated in Figure 3, the surgeon must drill multiple wires into position to secure the bones. Particularly for elderly patients with lower bone densities, this results in a high risk of further fracturing the initial fracture site, both when the wires are inserted and removed. Additionally, due to their thin and flexible nature, they are susceptible to breakage and slippage during the operation, which can result in further complications during the surgery.

The concept of applying traction to distract impacted or dislocated bone fragments to help realign and stabilize fractures has been applied to a variety of fracture types, and many techniques exist to pull and hold traction in place. For example, skin traction is often applied to femoral shaft fractures as early in a patient's treatment protocol as the initial response by emergency medical personnel.

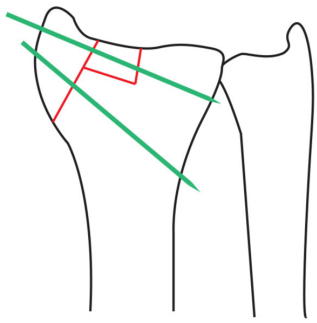


FIGURE 3: K-wires are drilled in to stabilize the bone fragments while the volar plate is screwed in position.

2.3 Device Functional Requirements

To our knowledge, no device currently exists to provide traction directly to the distal radius. Thus primary functional requirements were identified to enhance the current operational procedure of performing open-reduction and internal fixation surgery on distal radius fractures: 1) The device must be able to dislodge the impacted distal fragment from the proximal bone. The surgeon currently accomplishes this task by taking hold of the patient's hand and pulling on it, which often requires so much force that additional assistance in the form of another surgeon or assistant is required. The device therefore must provide this force with a mechanical advantage that reduces the input force required by the surgeon. 2) The device must hold the fragments in place after reduction and be appropriately transparent to x-rays while the surgeon examines images to install the volar plate and ensure correct alignment. 3) The components of the device must be either disposable or sterilizeable, as well as body-safe. For greatest adoption, the device must be compatible with existing technologies in the OR, such as bedside arm tables and the C-arm X-ray machine used throughout the operation.

2.4 Range of Motion Requirements

The current practice of reducing fracture fragments to their correct position entails the surgeon manipulating the hand of the patient directly through a variety of degrees of freedoms. This motion of the hand results in movement in the internal fractured bones of the wrist. Via this external motion of the hand, the surgeon is able to indirectly move the bone fragments into alignment. From measurements taken during conversations with Dr. Connor (co-author) as well as observations during live operations, five degrees of freedom were determined necessary to achieve alignment of the distal fragments during surgery. All degrees of freedom represent displacements of the hand relative to the forearm. Figure 4 presents the coordinate system utilized and the corresponding magnitudes of the five degrees of freedom identified. Note that controlling rotation about the x-axis was deemed unnecessary during the operation.

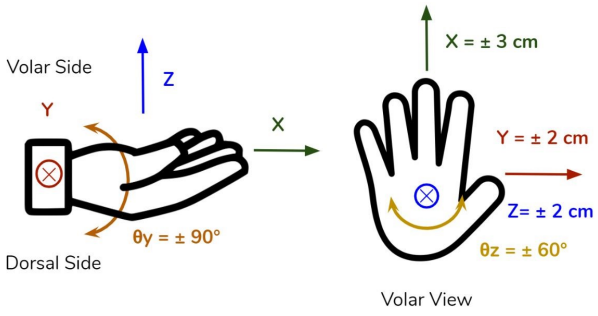


FIGURE 4: Range of motion requirements: 90° dorsal-volar angulation, 60° side-to-side rotation, 3 cm forward-backward translation, 2 cm side-to-side translation, 2 cm up-down translation.

3. DESIGN APPROACH

3.1 Strategy Selection

For maximal adoption in the clinical setting and ease of integration with current practices, we chose a design approach focused on meeting functional requirements while minimizing the number of changes a surgeon would need to make to their current operative procedure for distal radius ORIF surgeries. As a result, the surgeon is free to manipulate the hand through all degrees of freedom as they would do if the device were not present, and is able to do so by grasping the hand directly as opposed to external devices like wires or lead screws. Additionally, it was determined that the device would not interact with the bones of the fracture site directly, as doing so could cause the unwarranted risk of further fracturing the fragments. When the hand is in the desired position and the fracture is reduced, an assistant can then lock this position into place. This is achieved with locking ball joints. Additionally, traction is held throughout the procedure with a traditional ratchet system that the surgeon or assistant can tighten prior to performing the reduction. A proof-of-concept prototype is shown in Figure 5.

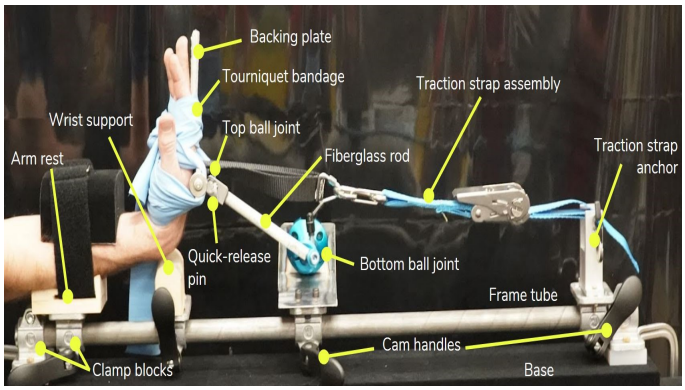


FIGURE 5: Proof-of-concept Prototype. It utilizes a traditional ratchet in combination with two locking ball joints. Each component is explained in further detail in the sections that follow.

3.2 Adjustability

In order for the device to be effective on a large range of arm sizes and shapes, many components were designed to be adjustable. The arm rest and wrist support are able to translate and rotate, while the wrist strap can be anchored at three vertical positions and is continuously adjustable along the horizontal axis. The use of a fabric strap and flexible tourniquet bandage allows hands and arms of multiple sizes to be secured to the device. A quick-release pin can be removed to detach the fiberglass rod from the top ball joint, so that the surgeon can perform -90°-rotation in the process of reduction, as required during some procedures.

4. ENGINEERING DESIGN

4.1 Forces and Moments

To quantify the force a surgeon must exert to distract the distal fragment from the proximal radius, we used a Futek LCM300 load cell to measure a surgeon's maximum pulling force. Each end of the load cell had a steel rod which was used as a gripping surface and was gripped similarly to how the surgeon grips the hand and forearm of the patient when performing distraction. We conducted tests where the subject pulled with their maximum

force and with a steady state force for 1 minute. Dr. Connor estimated that he pulls with this maximum force when performing the distraction step of the operation. Results of the maximum pulling force test revealed a maximum pulling force of 200 N, while the steady-state pulling force was approximately 100 N. We chose to design for a distraction force of 220 N.

Other degrees of freedom of the wrist produce reaction forces that are smaller in scale but still significant. These forces were estimated by assuming the reaction force is equivalent to a force couple. Force inputs were taken from the wrist force transformations, as well as estimates for the weight of the arm and additional force for installing the volar plate (Figure 6, Table 1).

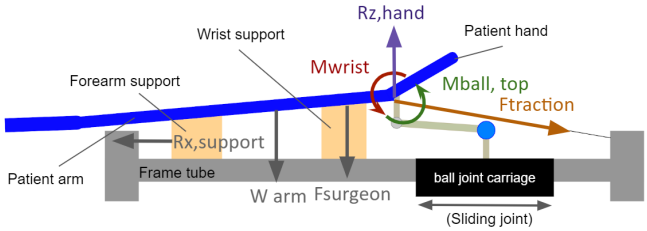


FIGURE 6: Forces and moments in the system.

TABLE 1: Force and moment inputs in the system.

Force Input	Value
$F_{traction}$	220 N
M_{wrist} (Y angle couple + Z translation couple)	17 Nm
$F_{surgeon}$ (acts at $L_{arm}/4$)	30 N
W_{arm} (acts at $L_{arm}/2$)	30 N

Force and moment balances on the patient's arm and hand were performed to find the moment experienced for the top and bottom ball joint, and the z-direction reaction force at the wrist. The required torques for the top and bottom ball joints were 10 N-m and 27 N-m, respectively. We chose a factor of safety of two, designing for required torques of 20 N-m and 54 N-m.

4.2 Ball Joint Testing

We conducted tests to determine if off-the-shelf ball joints could hold the required torque for our system. Each ball joint was tightened fully and the amount of weight each joint could support prior to failure was measured using a mechanical force gauge. Maximum holding torques were then calculated and are displayed in Table 2 below.

TABLE 2: Maximum ball joint torques.

Ball Joint	Weight (N)	Distance to force (m)	Max holding torque (Nm)
Thorlabs	111	0.025	2.8
Springfix	111	0.10	11
Thorlabs-sandblasted	156	0.025	3.9
McMaster	156	0.076	12

All ball joints failed at less than 12 N-m of torque applied, motivating the need for a custom ball joint capable of providing a greater holding torque.

4.3 Custom Ball Joint Design

The required radius for a ball joint capable of providing the required holding torque at minimum coefficient of friction is about 1 inch, much larger than anything available off-the-shelf. As a result, we decided to design a custom ball joint with dimensions that provide for the requisite clamping force. While a commercially available ball joint can be used for demonstration purposes, a custom ball joint is optimal. The custom ball joint consists of an aluminum ball inside a steel housing with a spherical seat. The large ball joint is two inches in diameter and the small ball joint is one inch in diameter. The design is shown in Figure 7. One side of the housing is free to rotate, so that the cutout for the threaded stud can be small. This preliminary design meets force requirements and is easily integrated into the assembly; however, we chose to use the lower holding torque commercially available ball joints for the first prototype in order to expedite completion of an entire assembly that could be preliminarily tested by the doctor. The next iteration will include custom ball joints.

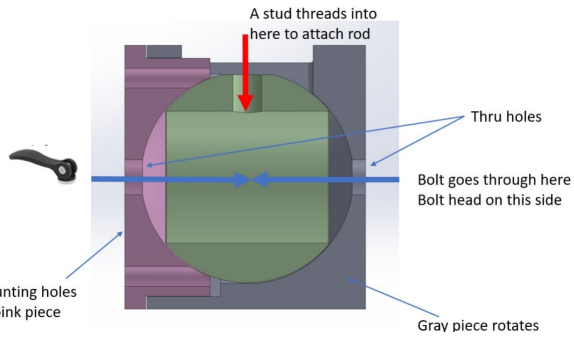


FIGURE 7: Design of Custom Ball Joint.

4.4 Rod and Backing Plate Sizing

Fiberglass was chosen for the material of the rod that connects the two ball joints, as it is X-ray transparent. The required diameter of the rod is such that the rod does not yield in bending due to the imposed moment on the end. A factor of safety of 5 was chosen to determine the maximum load the rod will need to support. A rod diameter of 0.5 inches (0.0127 m) was determined appropriate.

The backing plate is splinted to the hand to keep it rigid while being locked in place. The backing plate is roughly modeled as a cantilevered beam with a fixed end and a distributed load from the hand. It is necessary to ensure the backing plate is of sufficient size to prevent any significant deflection under load during the operation. Plate dimensions of 0.25 in. by 1 in. were determined to be sufficient to obtain a deflection of less than 10^{-4}m.

5. FABRICATION

The cam handles, clamp blocks, traction belt and ratchet, large ball joint, and arm strap and fasteners were sourced from McMaster-Carr. The small ball joint was sourced from Springfix. See Appendix for part numbers. The tourniquet bandage is standard operating room equipment. The remaining parts were custom fabricated. The arm rest and wrist support were made from pine wood and sanded to the contours of the phantom arm, and in production such a rest can be made from molded plastic or stainless steel. The arm straps were shortened. The frame tube was made from 1-inch (2.54 cm) diameter steel round tube with 0.049-inch (0.124 cm) wall thickness. Although steel is not x-ray transparent, it was chosen to expedite fabrication for early ergonomic testing. A carbon fiber or fiberglass tube of the same size and stiffness can be used to replace it. The strap anchor and part of the backing plate were machined from aluminum by Protolabs. The remainder of the backing plate consists of a DIN rail, which was chosen for its versatile mounting options and stiffness. The DIN rail was covered in silicone to create a soft, grippy surface to contact with the back of the hand. Finally, the mounting bracket for the large ball joint was made from welded 4130 steel sheets cut on a waterjet to save cost and material.

6. TESTING

6.1 Quantitative

To determine the mechanical advantage obtained using the device to distract and hold traction during the operation, an NK-500 Mechanical Analog Push Pull Force Gauge was attached to the ratchet of the device and used to determine the pulling force required to bring the rope to full tension. Multiple tests were performed, and the force required to bring the device to full traction (maximum tension in rope) was recorded at various arm positions and ball joint locations. A value of approximately 45 N was calculated as the average force required to maneuver the ratchet and bring to full tension. This is an 80% reduction when compared to the force required of the surgeon during a conventional procedure.

6.2 Qualitative

Dr. Connor, a practicing hand surgeon, had the opportunity to test the device using a phantom arm of latex casing filled with ballistics gel and a 3-D printed fractured distal radius. He was most pleased with its performance, but had concerns regarding the sterilizability of the device as well as the overall length. The issue of sterilizability will be addressed in future iterations of the device, while the length can be shortened by using a shorter strap in conjunction with the ratchet. Figure 8 provides a detailed description of the prototype and the steps a surgeon would take to utilize the device during a surgical procedure.

7. FUTURE WORK

While the current prototype is fully functional, a number of developments must be made before entering the OR. Firstly, the custom ball joint whose design is detailed above must be fabricated to provide sufficient holding force and ensure slippage of the ball joints does not occur during the procedure. Secondly, the current prototype uses a metal rod as the base component upon which all other components are attached. This will need to be replaced with a carbon-fiber rod to ensure x-ray transparency. In addition, while the process of locking the ball joints when the hand is in the desired position can currently be carried out by an assistant, it would be desirable if the ball joints could be actuated by a foot pedal (e.g., like hydraulic disk brakes) controlled by the surgeon. For example, the surgeon would press the pedal to unlock the joints and manipulate the hand, and then release the pedal when the hand is in the desired position, and the ball joints would lock. Additionally, methods to improve the sterilizability of the device will be explored. Finally, to allow the setup to be compatible with a larger variety of operating environments, a shorter traction strap should be added to the system. By reducing the length of the strap, the length of the entire system could be reduced significantly. Following the development of this next prototype, an appropriate IRB can be submitted such that user

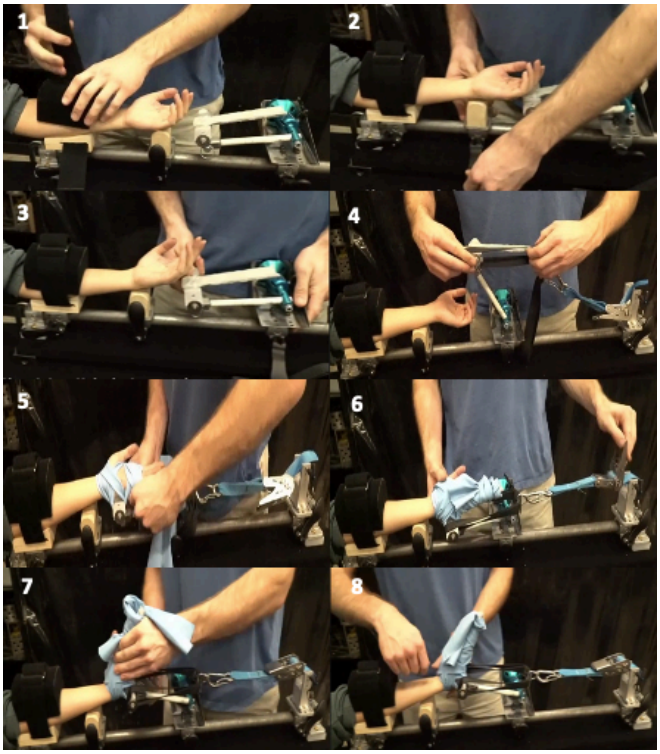


FIGURE 8: Detailed use case in ORIF surgery of distal radius. 1. Patient's forearm is strapped down. 2. Wrist support is adjusted and moved into position. 3. Ball joint carriage is adjusted and moved into position. 4. Traction strap is installed. 5. Hand is splinted to backing plate. (Not shown: An incision is made on the volar side of the patient's wrist, revealing the fracture site where the hardware is to be installed.) 6. Impacted bone fragments are distracted by pulling traction using the device's ratchet mechanism. When traction is established, ball joint carriage is locked in place. 7. The surgeon manipulates the hand through multiple DOFs in order to reduce the fragments into their correct position. For example, the surgeon may place the wrist in flexion as shown here. Once the fragments are reduced, ball joints can be locked, securing the position of the hand. 8. Hardware is screwed into place and the incision is closed (not shown).

testing with several surgeons may be conducted in a laboratory environment with broken bone phantoms and/or cadaver bones to compare methods and results. Both traditional methods involving manual pulling and K-wires as well as the new design would be tested and compared. Finally, a clinical trial could be designed and conducted to evaluate the efficacy of the design in the operating environment.

8. CONCLUSION

A prototype of a device to aid surgeons in open-reduction and internal-fixation surgeries of the distal radius was engineered, built, and tested with a phantom. Quantitative tests confirmed a significant reduction in the force required by the surgeon to distract the distal fragment from proximal bone. This was enabled by the use of a ratchet-based multi-DOF design that provides a mechanical advantage to the surgeon and reduces the required distraction force when compared to the current method of pulling on the hand of the patient directly. Qualitative end-user testing with a hand surgeon revealed the device was preferable to current methods of stabilizing bone fragments during reduction, as it does not require additional drilling of wires into bone fragments and may better hold the fractured fragments into position while hardware is secured than existing techniques such as the use of K-wires. Due to the presence of two coupled degree of freedom locking ball joints, the surgeon is able to manipulate the hand (and thus indirectly the fractured bone fragments) into the correct position and then secure the entire system by locking the ball joints. Thus the design presented here possesses the potential to not only improve surgeon satisfaction, but also decrease surgical time and enhance patient care by allowing easier and more precise alignment of fractured bone fragments during the reduction phase of ORIF surgeries.

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APPENDIX

TABLE 3: Part numbers for pre-made components.

Item	Vendor & Part Number
Cam Handles	McMaster-Carr 5720K37
Clamp Blocks	McMaster-Carr 9578T66
Traction Belt and Ratchet	McMaster-Carr 31025T721
Large Ball Joint Base	McMaster-Carr 1530N11
Large Ball Joint Locking Handle	McMaster-Carr 1530N14
Large Ball Joint Mount	McMaster-Carr 1530N29
Arm Strap Fasteners	McMaster-Carr 9273K96
Small Ball Joint	Springfix R3540.MF010