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Will the New Circular External Fixator Ease the Surgeon's Burden?

Sri Lanka, like many other low-middle income countries, has been a victim of conflict for a long time. While the country is still recovering from the internal conflict that plagued it for over three decades, the shadows of these dark days still haunt these lands. The Sri Lankan soil is still not completely rid of antipersonnel landmines which were once weaponized against military and civilians alike. A more recent terrorist attack that happened in 2019 rekindled this age-old fear against explosions in the hearts of Sri Lankans. While prevention of such disasters is important, realistically, it is the duty of engineering researchers to equip medical professionals with devices that can aid and expedite the treatments if and when such unfortunate disasters occur.

Figure 1: CAD Model of the Uom-Imperial Circular External Fixator

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Treating blast injuries is especially problematic since they incur complex bone fractures which cannot be treated with traditional methods. In such scenarios, orthopaedic surgeons use circular external fixators as an effective method to stabilize the bone segments. However, these devices are currently imported to Sri Lanka and incur high costs. In addition, whenever a terrorist event, or other conflict event takes place, there can be the urgent and immediate requirement for many fixators that are not kept in stock to such a degree. Therefore, it is important to develop such technologies within the country at a lower cost, that can be manufactured locally, and, therefore, provide "surge" capacity in times of conflict. Bearing this target in mind, a team of researchers from the Bionics Laboratory of the Department of Mechanical Engineering, University of Moratuwa, is developing a novel circular external fixator with single-handed clamping capabilities under the guidance of experts in the medical field. This is one of the three collaborative projects between the University of Moratuwa and Imperial College, London, funded by the National Institute of Health Research of the United Kingdom.

Circular external fixators are a type of external fixation that has been in use for over fifty years in orthopaedics for the treatment of conditions such as complex bone fractures, limb deformity, limb length discrepancy, and fracture non-unions among others since they act as an alternative to amputation. Since its first introduction, there have been several generations of circular external fixators used in the medical field. However, the basic construct of these circular external fixators is the same. Generally, a circular external fixator comprises several ring-shaped structural components interconnected with vertical struts. Tensioned wires that pass through the fragmented bone segments are attached to each of these rings through wire-clamping components. These wires induce micromotions between the bone fracture interfaces while holding the bone segments in the desired positions. These micromotions promote a process called "distraction osteogenesis" which is the formation of new bone tissues inside a widening distraction gap in a fracture interface [1].

An important governing factor in the healing process is the wire pre-tension. The recommended wire pre-tension ranges between 90-130 kgf (882.6 – 1275 N) depending on the age and weight of the patient [2]. However, a common issue in many of the prevailing circular external fixators is the loss of wire tension due to wire slippage during dynamically loaded situations. In the commercially available circular external fixators, the wire clamping is achieved simply via the friction of a tightened bolt head. The research team identified a practical issue in this, which is the requirement of both hands of the surgeon to clamp the tensioned wire, restricting the surgeon's efficiency. The researchers addressed these issues in the development of the UoM-Imperial Circular External Fixator.

Several important factors were considered during this design. The ability for the wire to be tightened using one hand was the main consideration. Providing a sufficient clamping force from the wire clamps to retain the wire pre-tension as much as possible was another important factor that was tackled in this design. Minimizing the weight of the device was necessary to remove the burden on the

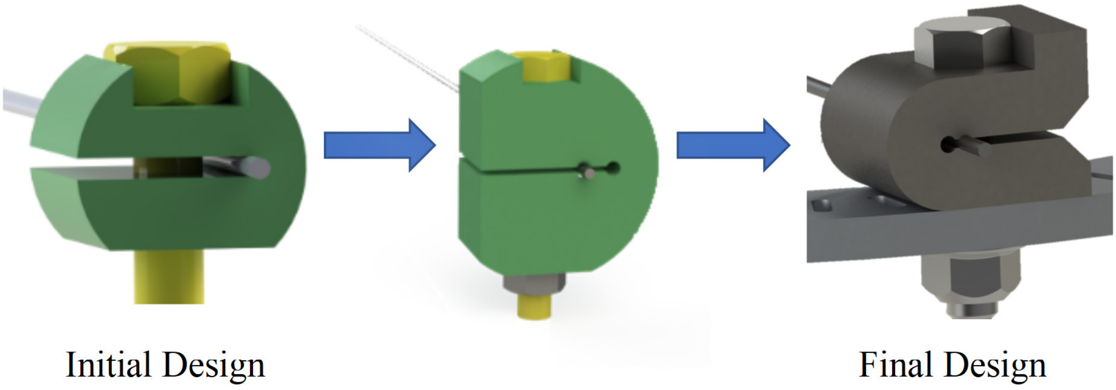

Figure 2: Design iterations of the clamp

wearer. This circular external fixator was developed targeting the low and low-middle income countries where blast injuries are relatively common due to various conflicts. Therefore, the cost played an important role in the design of the device.

Since the wire clamp of the device influenced the majority of the above factors, the research team focused on the design of the wire clamp at first. They came up with the initial design following a morphological analysis by considering the wire gripping capabilities, the ability to securely connect the wire and the ring, and limiting the relative motions between the wire and the clamp during wire tightening. The solution that best suited the requirements was a deformable friction clamp with a wire groove, tightened with a commercially available bolt. This enabled the possibility of replacing the most vulnerable part of the clamp with off-the-shelf fasteners.

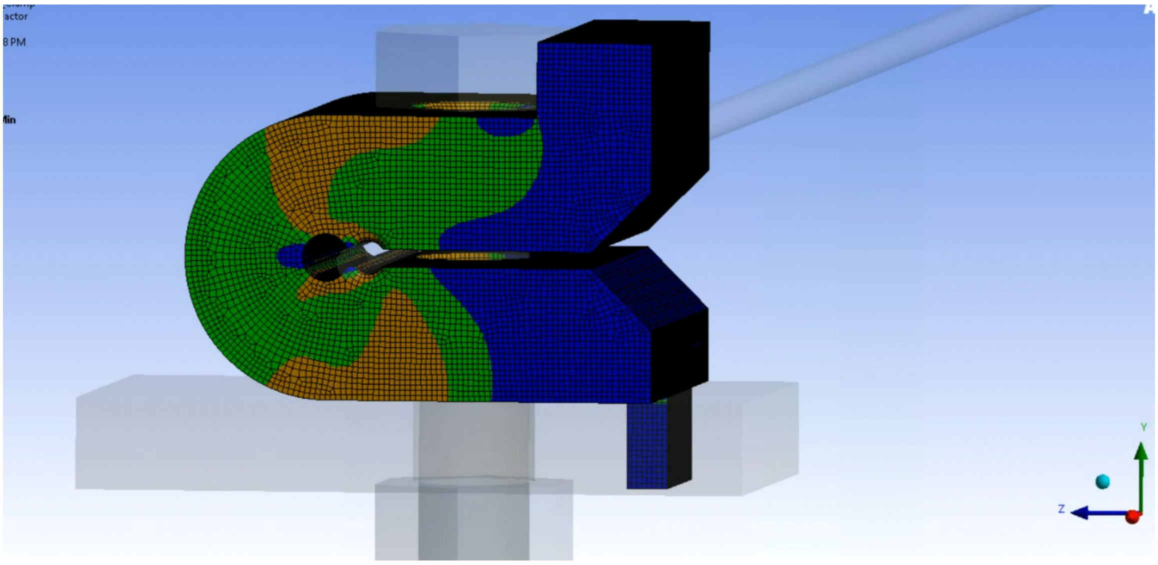

Figure 3: Simulation results of the final clamp design

The team qualitatively performed shape-wise optimization for the initial design considering the low-weight requirement. They identified several independent geometrical parameters that influence the clamp's wire retaining capability. Ansys software enabled the optimization of these parameters by using improved clamping force, reduced mass, and optimized safety factor as targets. They carried out numerical simulations for different design iterations and selected the final design as shown in Figure 2. These simulations showed that the final design can safely withstand the expected loads. The researchers presented these simulation results in a poster demonstrated at the Blast Injury Conference 2021 [3].

The final clamp design shaped the design of the ring, which was a derivation of the traditional circular external fixator ring, was modified with improved anchor points. Manufacturability was the main consideration in this aspect.

The material of the first prototype was selected based on the availability in the local market and the information gathered from the literature. The team utilized medium carbon steel for the clamp due to its strength, availability and manufacturability, and Aluminum for the ring for its light-weight and low cost.

After finalizing the design, the research team successfully manufactured the first prototype using the manufacturing facilities available at the Department of Mechanical Engineering, University of Moratuwa. To validate the functionality of the designed components, the team developed a specifically modified test-bed, to mimic the natural loads occurring in the wire-clamp-ring subassembly. To simulate the dynamic loads on the clamp, they incorporated the test-bed with Testometric™ Universal Testing Machine. The research is currently at the testing stage where the performance of the first prototype is being validated.

The UoM-Imperial Circular External Fixator is proof of what can be achieved via collaborations between developed and under-developed nations to improve the quality of life of humans around the world. While addressing a common and multidisciplinary problem is important itself, we hope this will inspire other researchers to strengthen the collaborations with different nations to further advance scientific and technological progress.

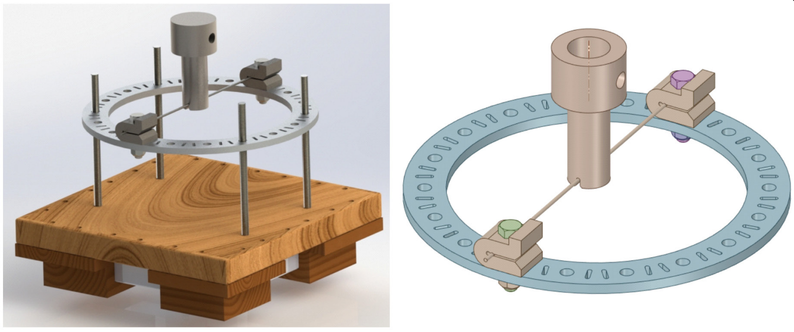

Figure 4: CAD models of the designed test-bed

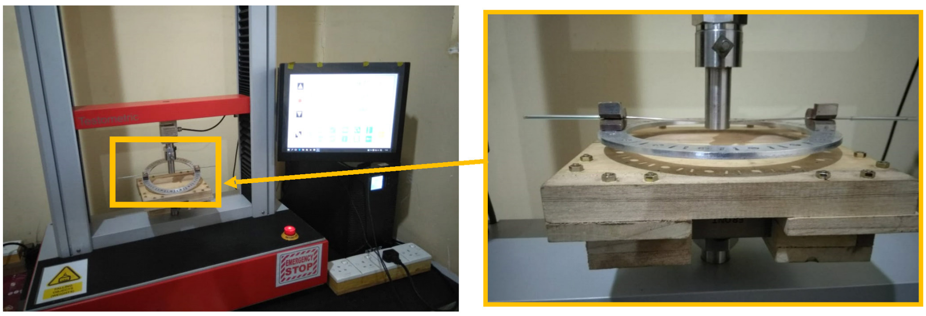

Figure 5: Testing setup

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