A New Design of External Fixator for Long Bone Fracture Management

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SUMMARY

This thesis examines the sliding capability of external fixators under load and describes the development and testing of an external fixator capable of providing axial cyclic motion to a fracture site while a patient is walking.

Fracture healing by external callus formation or by modelling and remodelling is dependent on the rigidity of fracture fixation and is influenced by the application of mechanical loads through the fractured limb. Excessive mobility or rigidity of fracture fixation may adversely affect fracture healing. The importance of micromotion at a fracture site in promoting healing is now appreciated and there is considerable interest in the effects of controlling axial cyclic motion with external fixators during the early stages of fracture healing.

Others have shown benefits of axial cyclic loading forces applied at a later stage of fracture healing when greater mechanical stability has been regained and when there is little resultant movement at a fracture site. The relative benefits of early axial cyclic motion and later axial cyclic loading are unknown and further research is required.

A unilateral external fixator, used to provide micromotion by known displacements at a fracture site, must have a sliding mechanism capable of withstanding lateral bending moments under offset loading conditions when a patient is walking. Further, the fixator must be sufficiently stiff to insure that micromotion is provided by the sliding mechanism and not by instability of the fixator.

The mathematical concepts underlying mechanical bench testing of external fixators

were reviewed and a laboratory fracture model was developed that was suitable for testing the sliding properties of external fixators. Using this fracture model, laboratory tests showed that commercially available sliding fixators could not deliver consistent axial cyclic motion.

The absence of an appropriate commercially available external fixator necessitated the development of a suitable custom-made device. Sliding rods utilising different bearing surfaces were therefore made and tested. Metal on metal sliding parts were found to be unsuitable, but a bearing of polished stainless steel on Ertacetal, a plastic polymer, was shown to be capable of providing controlled axial displacements under offset loading conditions. Existing commercially available pin clamps were known to be mechanically inadequate for use with these custom made sliding rods, necessitating the design of a new clamp assembly. These combined requirements meant that a completely new external fixator had to be designed.

A design assurance pathway was used to design a new external fixator. The essential performance requirements of an ideal unilateral external fixator were identified as the capacity to apply known displacements and loads, rigidity, and versatility. Design specifications to achieve these requirements were identified and incorporated into the design of a new external fixator for long bone fracture management. Stiffness and cyclic testing confirmed that the performance of the fixator met the requirements for further investigation of the effects of modifying fracture healing by applying known loads and displacements to a healing fracture through an external fixator by the process of walking.

A preliminary clinical trial was conducted and a failure mode effects analysis was performed to identify possible failure modes. Failure mode solutions and tests were successfully implemented, completing the fixator design.

The new external fixator described in this thesis is suitable for clinical use and provides the means for further investigation of the modification of fracture healing by applying known displacements and loads to a healing fracture.