MECHANICAL DEVICE FOR INCREASING THE RATE OF UNION IN OPEN FRACTURES OF THE TIBIA

WONG TECK HUI

Universiti Malaysia Sarawak

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Alamat tetap: 9 JALAN BERUS
96100 SARIKEI
SARAWAK

MR HA HOW UNG
Nama Penyelia

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This project report attached here, entitled " Mechanical Device for Increasing The Rate of Union in Open Fractures of The Tibia" prepared and submitted by Wong Teck Hui as a partial fulfillment of the requirement for the degree of bachelor of Engineering with Honors (Mechanical Engineering and Manufacturing System) is hereby read and approved by:

Dr. Ha How Ung	Date: 8/4/2000
(Project supervisor)	

MECHANICAL DEVICE FOR INCREASING THE RATE OF UNION IN OPEN FRACTURES OF THE TIBIA

MR WONG TECK HUI

Tesis Ini Dikemukakan Kepada
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ABSTRACT

Open fracture of the tibia is the common type of fracture happening almost everyday in the nation. Most of these cases are as result of road accidents. Researchers have proved that early axial dynamization of tibia can accelerate the fracture healing process through experiments done on animals. However, none of these related experiments have ever been conducted on human.

This study set as a milestone to investigate the accuracy of the theory by designing a mechanical device to provide axial force to the patient's lower limb, through actively exercising their legs while still bed-bound. Top-down hierarchical design approach was used in designing the device which would fulfill certain specifications. The device has to be of low cost, functional, light, safe and adjustable to suit patient's leg. Knowledge of dynamic, static, strength of material and manufacturing process were fully utilized. At this stage, emphasis was mainly on design of the device. It will then be tested intensively at the later stage for usability and reliability in Sarawak General Hospital. The result collected will provide valuables guideline for future modification and improvement of the final design of the device.

ABSTRAK

'Open fracture' pada bahagian tibia berlaku hampir setiap hari di negara kita. Kebanyakan kes berpunca daripada kemalangan. Para penyelidik melalui eksperimen mereka ke atas haiwan telah membuktikan bahawa dengan memberikan daya selari ke atas bahagian tibia kaki pada peringkat awal boleh membantu mempercepatkan kadar pemulihan. Namun demikian, masih tiada ekeperimen berkaitan pernah dijalankan ke atas manusia setakat ini.

Projek ini merupakan perintis bagi membuktikan kebenaran teori para penyelidik pada kaki manusia dengan mereka cipta satu alat senaman yang boleh memberikan daya selari kepada kaki pesakit semasa mereka masih terlantar di hospital. Pendekatan ciptaan ini adalah berdasarkan 'hiraki rekacipta atas-bawah'. Alat tersebut harus memenuhi beberapa specifikasi yang ditetapkan. Contohnya, ia harus dapat berfungsi sebaik-baiknya, kos penghasilan yang rendah, ringan, selamat digunakan dan panjang alat senaman boleh diselaras mengikut keselesaan kaki pesakit. Pada peringkat ini, tumpuan khusus diberikan kepada reka cipta alat senaman manakala pada peringkat seterusnya, ia akan diuji di Hospital Umum Sarawak untuk menentukan sejauh manakah keberkesanan alat tersebut. Data-data yang diperolehi hasil daripada percubaan penggunaan ini akan dijadikan panduan berguna untuk menghasilkan alat senaman yang terbaik pada masa akan depan.

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CHAPTER 1

INTRODUCTION

1.1 Background

A fracture is a break in the structural continuity of bone. It may be no more than a crack, a crumpling or a splintering of the cortex; more often the break is complete and the bone fragments are displaced. If the overlying skin remains intact it is a closed (or simple) fracture, if the skin or one of the body cavities is breached it is an open (or compound) fracture, liable to contamination and infection.

These fractures may result from a combination of causes, such as:

(i) a single traumatic incident;

(ii) repetitive stress; or

(iii) abnormal weakening of the bone.

The tibia and fibula have the highest incidences of diaphyseal fractures of all the long bones. These fractures are often caused by high-energy trauma. Because the shaft of the tibia is subcutaneous throughout its length and has a relatively poor blood supply, severe complications and major disability are common outcomes, particularly when the fractures are open. The average healing time in close fractures was 17.4 weeks and in open fractures 21.7 weeks.

At present, external fixation remains the treatment of choice for open fractures of the tibia and is also useful for closed fractures that are very unstable and comminuted. The principle of external fixation is simple: the bone is transfixed above and below the fracture and proximal and distal transfixing pins, screws or wires are then connected to each other by rigid bar on both sides of the bone or on one side only. It allows small amounts of axial movement to promote callus and accelerate union.

External fixation avoids metal implants at the fracture site, requires minimal soft-tissue dissection and provides excellent stability. In addition, external fixation is very versatile. By altering the frame configuration, the fracture position can be changed, length can be regained and as healing progresses, an increasing load can be transferred to the bone, which encourages early union with mechanically sound callus. Active movement helps to pump away oedema fluid, stimulates the circulation, prevents soft-tissue adhesion and promotes fracture healing.

Fracture of the long bones results in a repair process that has the potential to restore the anatomic morphology and mechanical integrity of the bone without scar tissue. The repair process can occur in two patterns. In the first, under conditions of rigid stabilization, direct osteonal remodeling of the fracture line can occur with little or no external callus, a process known as direct bone repair. The second pattern of repair involves bridging of the fragments with external callus and formation of bone in the fracture site by endochondral healing.

This type of repair is known as indirect bone healing and occurs under less rigid interfragmentary stabilization. The rate of healing and the extent of callus in this type of repair can be modulated by the mechanical conditions at the fracture site. Applying cyclic interfragmentary micromotion for short periods has been shown to influence the repair process significantly, and characteristics of this stimulus influence the healing response observed.

1.2 Phases of Fracture healing

For simplification, fracture healing may be considered to consist of three overlapping phases: an inflammatory phase, a reparative phase and a remodeling phase. The inflammatory reaction immobilizes the fracture; pain causes the patient to protect the injured part and swelling hydrostatically splints the fracture. At the tissue level, the inflammatory phase is identical to the typical inflammatory response of most tissues to traumatic injury.

Vasodilation and hyperemia, presumably mediated by histamines, prostaglandins, and various cytokines, accompany invasion of the injury site by neutrophils, basophils and phagocytes that hematoma becomes organized as a developing fibrin network that provides pathways for cell migration. It is also presumed that during the inflammatory phase, various noncollagenous protein growth factors that regulate cell migration and differentiation and that normally are trapped in the bone matrix is released into solution, where they become active. The inflammatory phase peaks within 48 hours and is quite diminished by 1 week after fracture.

The reparative phase becomes activated within the first few days after fracture and persists for several months. Its chief feature is the development of a reparative callus tissue in and about the fracture site that gradually is transformed to bone. The callus may consist of cartilage, fibrous tissue, osteoid, woven bone and vessels.

The primary callus response is the direct response of bone to local inflammation, whether the inflammatory is caused by fracture, infection, foreign body or a neoplastic process and does not continue indefinitely. If the primary callus has failed to unite two sides of a fracture within a few weeks, it may cease to grow and be resorbed, as may be observed of the callus at the amputation stump or on one side of a large segmental defect.

If the primary callus is successful in connecting the fracture ends, healing progresses to the stage of bridging callus or hard callus. Although bridging callus seems to imply the directed growth of tissue outward from the viable regions distal and proximal to the fracture, the hard callus seems to differentiate simultaneously throughout its distribution, rather than growing as an advancing front. Calcification of the callus may be direct bone formation by osteoblasts or by endochondral ossification, depending on the local oxygen tension.

As the callus calcifies and becomes rigid, the fracture becomes internally immobilized and the examiner may consider the fracture to be healed, The initial calcification is remodeled by osteoclasts and osteoblasts, leading to the replacement of calcified cartilage and woven bone by lamellar bone in the final (remodeling) phase of fracture healing. This phase represents the normal remodeling activity of bone, although it may remain accelerated in the region of the fracture for several years, replacing each volume several times over.

The major factors determining the mechanical milieu of a healing fracture are the rigidity of the selected fixation device, the fracture configuration, the accuracy of fracture reduction and the amount and type of stresses occurring at the bone ends dictated by functional activity and the loading at the fracture gap. Of these effects of these factors on fracture healing and remodeling in the canine tibia under unilateral external fixation, amount of physiologic loading as dictated by the body weight is the most significant factor in promoting periosteal callus formation.

1.2.1 Mechanical Environment of Fracture Healing

Bone is a dynamic tissue that is highly sensitive to change in mechanical demand. The early observations of Wolff [1] led to his law of bone remodeling which incorporates the concept that prevailing forces determine bone tissues. Mechanical conditions are one of the most important factors governing not only whether a fracture will heal, but also the mechanism through which bone union will take place.

More recently, many researchers have proved that fracture healing benefit from certain amount of controlled axial loading and micro motion, although the optimal conditions for different stages of healing have not been defined. The timing of when fixation should be dynamized for maximum beneficial must also be determined for different fracture types. As fracture heals, loads ideally should be borne related personnel of Faculty of Engineering, Faculty of Medical and Human Science and other related faculty before coming out with the most appropriate proposal. This research will be the first of its kind done in Malaysia. Focus will mainly be on patients with fractured leg and external straight fixator fixed to the tibia and with open wound since it is the most common type of fracture recorded.

The device will provide patient with fresh fractured leg wound who lies on the bed a chance to exercise their leg. Even after dismissal from the hospital, the patient can still rent the device for continued exercising at home. Hence, the criteria considered in producing the device include generally its production cost, easiness for transportation, ergonomics, safety and flexibility. The challenge is the continuity of improvement on the device in future. The project is only the beginning to understand how the device and theory can be applied in a practical and economic way.

1.4 Report Structure

The report will be divided into five different chapters as below: -

Chapter 1: Introduction

Chapter 2: Literature review

Chapter 3: Methodology

Chapter 4: Result and discussion

Chapter 5: Conclusion and recommendation

Chapter 1 will introduce to the reader about fracture healing and some related medical fields generally. It will explain how the fracture healing patients are treated on admission to the hospital and how the mechanical environments are able to help patients with fractured leg to recovery quickly. Then it will be followed by an explanation of the project objectives and lastly outline of the report structure.

Chapter 2 will discuss mainly on the works or research done by others related to this project. The information gathers through journal, Internet and other related materials would provide essential ingredient for doing this chapter.

Chapter 3 explains the basic design process taken in designing the device. The consideration about the strength, device feature, material selection, cost, ergonomic aspects, and easiness for transport, safety and others are the main focus here.

Chapter 4 will introduce concept origin, manufacturing process for producing the device, improvement on design prototype until the final revised model. Apart from that, it also provides structural analysis of the orthodic device and explanation of the spring used. Is the device has been successfully designed, what the weakness and strength will be discuss in this chapter.

Last but not the least the conclusion and recommendation chapter. It will specify whether the objectives of the project are achieved. Recommendations will also be made to improve the project or further works so that the project will give others a step stone or guideline in carrying out similar project.

CHAPTER 2

LITERATURE REVIEW

2.1 Introduction

The literature review for the project was very much limited since this exercising device is not available in the market even though its concept has already been proven by many researchers. Their experiments were mainly based on animals such as dog and rabbit and have not ever on human. Most of the literatures reviewed were from journals and reference books.

2.2 Clinical Orthopaedics & Related Research

Early axial dynamization of external fixation had been proposed to change the pathway of healing to encourage early callus proliferation and thereby secondary bone union by simulating increased endochondral ossification. Most studies demonstrated increased periosteal callus formation by changing the fracture's mechanical environment had done so by inducing or allowing increasing interfragmentary motion of a large gap fracture model. This model was usually compared with one in which fixation is extremely stiff, allowing virtually no motion of the gap.

Kenwright J. and Gaardner T. in the paper 'Mechanical Influences on Tibia Fracture' measured interfragmentary fracture displacements in 6 degrees of freedom at intervals throughout healing in groups of patients with tibial diaphyseal fractures treated by external skeletal fixation. The results were compared with those obtained from experimental studies in which the ideal mechanical conditions for fracture healing were predicted. A finite element analysis model of the healing tibial fracture was also developed. Measured data were used for the analysis, and stress and strain patterns were defined for different stages of healing.

Interfragmentary movement measured in the first 6 weeks after injury usually was a magnitude smaller in patients treated by external fixation than in patients treated with cast immobilization. This movement could be much smaller than that predicted to be optimal by experimental studies. Greater amplitude could be achieved, even in stable fractures, by ensuring patient activity. The interfragmentary movement was elastic during loading activity and was generally sinusoidal during steady walking. At the time of dynamization (the unlocking of the frame), a permanent set occurred at the fracture site in all planes. The cyclical movement range in each plane often decreased immediately after unlocking.

The model analysis study of fracture healing predicted that tissue damage might occur in the later (hard callus) phase of healing, even while the fixation device was in place, because of abnormally high stresses and strains. This study indicated that fracture mechanics should be controlled more rigorously to provide amplitudes of movement in the first 4 to 6 weeks after fracture. The rigidity of fixation should be increased in the subsequent weeks until the fracture had healed and the frame was removed.

From the Biomechanics Laboratory, Department of Orthopedics, Mayo Clinic / Mayo Foundation of Rochester Minnesota, study was carried out on the effects of early dynamization (physiologic axial compression) on dogs' canine fracture healing at six weeks by creating bilateral transverse mid-tibial osteotomies and initially stabilized with a 2 mm gap using rigid external fixators. External fixation was an ideal means of applying axial dynamization since a telescoping frame mechanism could be used to control rotational and bending forces and yet allowed free axial compression of the fracture when physiologically loaded.

The telescoping mechanism of one of the fixators on each dog was released (dynamized) seven days after osteotomy, resulting in physiologic loading of the osteotomy while the contralateral fixator remained locked as a rigid control. The dynamized osteotomy closed and increased functional weight bearing resulted from three weeks on. Radiographically the amount of periosteal callus increased over time indicating accelerated remodeling. Torsional mechanical testing found the dynamized osteotomies to be stiffer and tolerate more maximum torque. A significantly greater proportion of the dynamized osteotomy gap was also filled with new bone. These results suggested that dynamization improved fracture healing by reducing fracture gap size and increased weight bearing without altering the basic pathway of healing. Thus the timing of dynamization might not be critical as long as the fracture gap can be narrowed with axial loading. [3]

Another similar research by Biomechanics Laboratory was investigating the effect of early physiologic dynamic compression on bone healing under external fixation. The paper had been read in part at the 34th Annual Meeting of the Orthopaedic Research Society on 1-4 February 1988 at Atlanta Georgia. They performed transverse midtibial osteotomies on dog and rigid external fixation system was used for stabilization in a neutralization mode (800 μm) to prevent compression of the osteotomy ends during weight bearing. On the 15th day, one osteotomy in each animal was subjected to dynamic compression through weight bearing by release of the fixator-telescoping mechanism (axial dynamization), while other side remained unchanged as control.

The analysis of sequential roentgenograms showed that the callus distribution was more symmetric on the dynamic compression side. There were no statiscal differences in new bone formation, bone porosity or maximum torque between sides. The fixation fixation had maintained the initially created osteotomy gap on the control side and tended to unite through a gap-healing mechanism. The dynamic compression side showed reduction in gap size and union by more of a contact-healing mechanism. [5]

2.3 Systems Design Approach

There are two broad approaches to systems design: structure-oriented design and object-oriented design.

a) Structure-oriented design approach

The structure-oriented design approach applies modern methodologies such as prototyping, modeling tools, RAD and various other techniques to employ an engineered, disciplined approach to systems development. The essence of the structure-oriented approach is top-down decomposition.

The structure-oriented design approach involves two sub-approaches. The process-oriented approach is applied for well-defined systems in which the output, input and process requirements are fairly well established. The data-oriented approach is used for ill-defined systems that support a variety of decision-making tasks.

b) Object-oriented design approach

The object-oriented approach uses all the methodologies, modeling tools and techniques employed by the structure-oriented approach. The key objective of the object-oriented approach at the general systems design level is to identify: -

a) object classes
b) relationships
c) attributes
d) inheritance