UNIVERSITI PUTRA MALAYSIA

AN INVESTIGATION OF THE PERFORMANCE OF NiTi SHAPE MEMORY ALLOY BASED BONE FIXATION DEVICE

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By

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Thesis Submitted to the School of Graduate Studies, Universiti Putra Malaysia, in Fulfilment of the Requirements for the Degree of Master of Science

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Abstract of thesis presented to the Senate of Universiti Putra Malaysia in fulfilment of the requirement for the degree of Master of Science

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By

YONG THIAN HAW

September 2015

Chair: Mohd Roshdi Bin Hassan, PhD

Faculty: Engineering

This project has involved design of a new bone fixation device made of NiTi shape memory alloy. Conceptual designs were generated by using Product Design Specification (PDS) and brainstorming methods. The concept evaluation of the conceptual designs has been carried out by means of weighted objective method and the conceptual design that scores highest was chosen as the best design concept. The concept of Nitinol Stitch was the most suitable for bone fixation device because of large size of fracture coverage and excellent adaptability to bone geometry when compared to other design concepts.

The new bone fixation device model was fabricated by using NiTi shape memory alloy as its main constituent. Performance of the newly designed bone fixation device model made of NiTi shape memory alloy was evaluated. Meanwhile, commercial finite element analysis (FEA) software, Abaqus was used to analyze the mechanics of model as well as its behavior, so that the installation process during orthopedic surgery can be simulated. A prototype has been fabricated. Heat test was conducted in laboratory to investigate the actual performance of the prototype. Experimental data were compared to the simulation data for result validation.

From simulation, it is found that the gap between two bone fragments has been reduced from 2mm to 0.2mm. However, slipping occurred during experiment, the gap has increased up to 6.54mm. The simulation result was further explored to justify the device's feasibility. The findings of this research will provide one of the possibilities that can be made to solve shortcomings of a few existing SMA based bone fixation devices as reviewed in literature. The research has led to a conclusion that the newly designed device, Nitinol Stitch, has shown its potential advantages in orthopedics by offering a new alternative in fixing bone fracture. The design and experimental processes throughout the project can be used as a reference for future development of other SMA based bone fixation devices.

Abstrak tesis yang dikemukakan kepada Senat Universiti Putra Malaysia sebagai memenuhi keperluan untuk ijazah Sarjana Sains

KAJIAN TERHADAP PRESTASI PERANTI PENETAPAN TULANG BERASASKAN ALOI INGATAN BENTUK NiTi

Oleh

YONG THIAN HAW

September 2015

Pengerusi: Mohd Roshdi Bin Hassan, PhD

Fakulti: Kejuruteraan

Projek ini telah melibatkan reka cipta sejenis alat penetapan tulang patah baru yang diperbuat daripada aloi ingatan bentuk NiTi. Konsep reka bentuk telah dijana dengan menggunakan Product Design Specification (PDS) dan kaedah brainstorming. Penilaian konsep reka bentuk telah dijalankan dengan kaedah weighted objective dan konsep reka bentuk yang mencapai markah tertinggi telah dipilih sebagai konsep reka bentuk terbaik. Konsep Jahitan Nitinol adalah paling sesuai untuk alat penetapan tulang kerana saiz liputan retakan yang besar dan penyesuaian pada geometri tulang yang bagus berbanding dengan konsep reka bentuk yang lain.

Alat penetapan tulang yang baru telah dihasilkan dengan menggunakan aloi ingatan bentuk NiTi sebagai bahan utamanya. Prestasi alat penetapan tulang yang baru direka cipta ini telah dinilai. Sementara itu, perisian analisis unsur terhingga (FEA) komersial, Abaqus telah digunakan untuk menganalisa mekanik model serta kelakuannya, supaya proses pemasangan semasa pembedahan ortopedik dapat disimulasikan. Sebuah prototaip telah dihasilkan. Ujian pemanasan telah dijalankan di dalam makmal untuk menyiasat prestasi prototaip yang sebenar. Data experiment telah dibandingkan dengan data simulasi untuk pengesahan hasil keputusan.

Dari simulasi, adalah didapati bahawa jurang antara dua bahagian tulang patah telah dikurangkan dari 2mm hingga 0.2mm. Akan tetapi, disebabkan oleh berlakunya tergelincir dalam eksperimen, jurang telah bertambah sehingga 6.54mm. Keputusan simulasi telah diteroka untuk membincangkan kebolehgunaan alat tersebut. Hasil carian penyelidikan ini akan memberi salah satu kemungkinan yang boleh digunakan untuk menyelesaikan kelemahan-kelemahan dalam beberapa alat penetapan tulang berasaskan SMA yang wujud sekarang sebagaimana yang telah dibincangkan dalam hasil bacaan. Penyelidikan ini telah membawa kepada kesimpulan iaitu alat penetapan tualng yang baru, Nitinol Stitch, telah menunjukkan potensi kelebihannya dalam bidang orthopedik dengan menyedikan satu alternatif baru dalam perihal penetapan rekahan tulang. Proses reka bentuk dan eksperimen sepanjang projek ini boleh digunakan sebagai rujukan untuk perkembangan alatan penetapan tulang yang baru pada masa depan.

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Finally, the student would like to express gratitude to other faculty members of Universiti Putra Malaysia for their intellectual support throughout the course of this project.

I certify that a Thesis Examination Committee has met on 18 September 2015 to conduct the final examination of Yong Thian Haw on his thesis entitled "An Investigation of The Performance of NiTi Shape Memory Alloy Based Bone Fixation Device" in accordance with the Universities and University Colleges Act 1971 and the Constitution of the Universiti Putra Malaysia [P.U.(A) 106] 15 March 1998. The Committee recommends that the student be awarded the Master of Science.

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This thesis was submitted to the Senate of Universiti Putra Malaysia and has been accepted as fulfilment of the requirement for the degree of Master of Science. The members of the Supervisory Committee were as follows:

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LIST OF NOMENCLATURES

AAA	Abdominal Aortic Aneurysms
A_f	Austenite Start
A_s	Austenite Finish
ATMFS	Acetabular Tridimensional Memory Alloy-Fixation System
CAE	Computer Aided Engineering
CT	Computed Tomography
FEA	Finite Element Analysis
GUI	Graphical User Interface
HSS	High Speed Steel
M_f	Martensite Finish
M_s	Martensite Start
MIS	Minimally Intrusive Surgery
Nitinol	Nickel Titanium Naval Ordnance Laboratory
PDS	Product Design Specification
PE	Pseudoelasticity
PTFE	Polytetrafluoroethylene
σ_f	Detwinning Finish Stress
σ_s	Detwinning Start Stress
SMA	Shape Memory Alloy
SMAHC	Shape Memory Alloy Hybrid Composite
SME	Shape Memory Effect

CHAPTER 1

INTRODUCTION

1.1 Overview

Bone fracture is an injury where the bone forms cracks, fragments and breakage. It occurs when the bone is subjected to excessive stress or impact. Bone fracture is diagnosed via x-ray or computed tomography (CT scan) before any treatment is performed. If required, surgical procedure is performed to treat bone fracture. In some cases, bone fixation devices (orthopedic implants) are used to hold the fractured bones together to assist bone healing. There have been many designs of orthopedic implants, for example, metal rods and screws. Stainless steel and titanium are common materials that are suitable for orthopedic implants.

Nevertheless numerous metal alloys have been explored and investigated for their suitability to make bone implants. Nitinol is a type of titanium alloy which is suitable to be implanted to human body for various benefits. One of the most significant characteristics Nitinol possess is the Shape Memory Effect (SME). An orthopedic implant with SME can be designed in such a way that it is capable to hold the fractured bones together by exerting an amount of compressive force through the shape transformation process. Such compressive force is beneficial to bone healing. A carefully designed orthopedic implant should be able to provide an optimum compressive force to the fracture while avoiding unnecessary buildup of stresses on the fractured bones which may jeopardize bone healing process.

1.2 Problem Statement

Devices for fractured bone fixation with rigid structure such as metal plates and bone screws are able to provide stability to the bone fracture. Their rigidity will fix bone fragments in place and prevent any further movement on the bone fracture after surgery. However, there are some issues that medical personnel must not overlook when rigid bone fixators are used. One of the issues involved is cortical bone loss near the implant region. Cortical bone loss will inhibit the union of bone fragments. This is because rigid fixators typically create stress shielding around the bone fracture, which slows down the regrowth process of bone cells for cortical perfusion. So, there is a risk for the treated bone to fracture again after the rigid fixator is removed. The remedy for this issue is to have the rigid fixator remain inside the patient's body for at least 15 to 18 months in order compensate for slow cortical perfusion before removal (Müller et al, 1965). Despite the precaution taken, there have been reported cases where bone refractures still occurred after implant was removed for an average of 20.1 months (Kessler et al, 1992). In other words, rigid bone fixators are not effective in facilitating the regrowth of bone cells around the bone fracture.

Besides that, such designs lack the ability to exert a continuous compressive force, which is important for faster bone healing. The device that only provides rigid mechanical fixation may loosen up after usage for a long period. The screws that are being used to tighten the metal plate on to bone fracture may gradually become loose due to micro motion of the screw thread relative to bone (Taljanovic et al, 2003). Consequently the metal plate will be able to shift away from its intended location. So, the whole implant will lose its ability to stabilize the fracture site. This will cause poor bone contact across the fracture line, which will increase the failure rate of the implant. If the device is found to be displaced after surgery, revision surgery will be required. Such procedures are time consuming and complicated. Many efforts have been put into solving this problem with modified rigid bone fixation design and one of them have almost succeeded. Uhthoff has conducted a canine pilot experiment with axially compressible plates or ACP (Uhthoff et al, 2006). ACP, modified based on his previous design called axially flexible plates (AFP), was expected to enable faster healing than conventional plates by introducing dynamic compression to the bone fracture (Foux et al, 1997). Although it has been found that ACP can reduce stress shielding effect, unfortunately the experiment has ended in failure due to early degradation in one of its component (Uhthoff et al, 2006).

There are many implants based on shape memory alloy exist in the market today. Nitinol is commonly used in manufacturing of these implants. So, they are generally more biocompatible compared to steel implants and are able to utilize shape memory effect to compress the bone fragments against each other. They come in various shapes and sizes, depending on the area of application. Some implants are designed to treat general bone (rod shaped) fractures such as fractures to the femur bones and forearm bones, while others are designed for fractures on specific bones (irregular shaped) such as pelvic bones and skull. Some of them provide discontinuous clamping to the bone fracture (Song et al, 1999; Naohiro et al, 2007), while others provide a regional clamping to bone fracture (Song et al, 2002; Dai et al, 2002). However, there are still no devices designed to treat long-spanned and irregular-shaped bone fractures. Currently, this type of bone fracture is still most effective being treated with steel bridge plating or external fixation device, which doesn't exert continuous compression to the fracture.

1.3 Objectives

There are two objectives in this project:

1. To design and fabricate a new bone fixation device model using NiTi shape memory alloy.
2. To assess the performance of a newly designed, NiTi shape memory alloy based bone fixation device.

1.4 Scope of Study

This study is limited to the design, fabrication and evaluation of a new bone fixation device model. Material used to fabricate the model is NiTi shape memory alloy. Commercial finite element analysis (FEA) software, Abaqus is used for analysis of the mechanics of model as well as forces exerted by the model, simulating the installation process during orthopedic surgery. Nevertheless, its performance on the fractured bones is also predicted using the FEA software. If forces exerted by the model are found to be inadequate for bone healing, the model will be redesigned.

1.5 Significance of Study

This study would contribute to the biomedical researchers who want to seek for more ideas or methods to apply fixation devices to bone fracture. A good method to apply fixation device to a patient's fractured bone would benefit the patient and medical institution in terms of reduced pain after surgery, shorter bone healing time required and reduced number of revision surgery.

Also, developers would be benefited from various design methods, design evaluation as well as design concepts presented in this study. Decision making in choosing the best design and finite element method can assist the developer to evaluate their design before the fabricating a prototype, hence reduces the time consumption, labor cost and material cost when developing a new product (in this case, the bone fixation device). In addition, this study may inspire several ideas and concepts to future researchers in designing other types of bone fixation devices in their work.

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