A FRAMEWORK FOR DESIGNING, ANALYZING AND CLASSIFYING CEMENTLESS FEMORAL STEM FOR MALAY POPULATION

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Thank you ALLAH SWT for your help and guidance.

This work is dedicated to my beloved parents and sister who constantly supports me throughout these years.

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ABSTRACT

Asian hip morphology differs from western populations due to their lifestyle and physical stature. This was confirmed by the modification of commercial hip implants to address these differences and to improve the primary fixation stability inside the femoral canal. This study provided a framework for designing, analyzing and classifying cementless femoral stem for Malay population. The process began with a three dimensional (3D) morphology study, followed by a femoral stem design, fit and fill analysis, and nonlinear finite element analysis (FEA). Various femur parameters for periosteal and endosteal canal diameters were measured from the osteotomy level to 150 mm below, to determine the isthmus position. The 3D morphology study provided accurate dimensions that ensured primary fixation stability for the stem – bone interface and prevented stress shielding at the calcar region. The results showed better total fit (53.7%) and fill (76.7%) in the canal for this newly designed metaphyseal loading with mediolateral flared femoral stem. The FEA showed the maximum equivalent von Misses stress was 66.88 MPa proximally with a safety factor of 2.39 against endosteal fracture, and micromotion was 4.73 µm, which promotes osseointegration. The prototype was fabricated using 316L stainless steel by using investment casting techniques to reduce manufacturing cost without jeopardizing implant quality. Most researchers validated FEA with biomechanical testing but this increases computational time with different preset parameters. Any changes to these parameters will lead to different results, which are not in compliance with the experimental results. A new method for primary stability classification using support vector machine classifier and several time domain features for feature extraction (TDF – SVM) was proposed to overcome this FEA limitation. Thirteen different time domain features feed the classifier with polynomial kernel that mapped the datasets into separable hyper planes. Multiclass support vector machines considered three classes of micromotion and four classes of strain by mapping the original data into a feature space. A one-against-all method was chosen because of its easy application, reduced computational time, and accurate results. The results demonstrated more than 97% classification accuracy using several time domain features (mean absolute value, maximum peak value, mean value, root mean square) for both strain and micromotion. This indicated that TDF – SVM could be applied as preclinical tool to provide functional information for implant stability prior clinical use.

ABSTRAK

Morfologi pinggul bagi penduduk di Asia dan Barat adalah berbeza kerana perbezaan cara hidup dan bentuk fizikal. Fakta ini disokong dengan pengubahsuaian implan pinggul komersial bagi mengatasi masalah ini dan meningkatkan kestabilan penetapan utama implan di dalam femur. Kajian ini menyediakan kerangka kerja bagi rekabentuk, analisis dan pengelasan linggi femur tanpa simen bagi penduduk Melayu, bermula daripada analisis morfologi secara tiga dimensi (3D), diikuti dengan rekaan linggi femur, analisis padan dan isi, dan analisis unsur terhingga (FEA). Pelbagai parameter bagi bahagian dalam dan luar femur telah diukur dari aras osteotomi ke 150 mm ke bawah bagi menentukan kedudukan istmus. Analisis morfologi 3D memberikan dimensi yang tepat bagi memastikan kestabilan penetapan utama bagi permukaan tulang – linggi femur dan menghalang perisaian tegasan pada bahagian kalkar. Keputusan menunjukkan keputusan lebih baik bagi padanan keseluruhan (53.7%) dan pengisian (76.7%) bagi rekabentuk baru linggi femur yang mempunyai pembebanan metafisial dan suar mediolateral. FEA menunjukkan nilai maksimum tegasan setara von Misses adalah 66.88 MPa di bahagian proksimal dengan faktor keselamatan 2.39 menentang kepatahan endosteal, dan pergerakan miko sebanyak 4.73 µm yang menggalakkan pertumbuhan tulang. Prototaip telah difabrikasi menggunakan kekuli tahan karat 316L dengan mengaplikasikan teknik penuangan lilin yang mengurangkan kos pengilangan tanpa mempengaruhi kualiti implan. Kebanyakan penyelidik mengesahkan FEA dengan pengujian biomekanik yang secara umumnya mengambil masa yang lama dengan pelbagai parameter praset. Perubahan pada parameter ini akan membawa keputusan yang berbeza yang tidak selari dengan keputusan eksperimen. Kaedah baru bagi pengelasan penetapan utama menggunakan mesin sokong vektor sebagai pengelas dan beberapa sifat domain masa bagi mengekstrak sifat (TDF – SVM) telah dicadangkan bagi mengatasi kekangan FEA ini. Tiga belas sifat domain masa berbeza menyuap pengelas dan kernel polinomial yang memetakan set data kepada hiper satah berlainan. Pelbagai kelas mesin sokong vektor telah digunakan untuk mengkategorikan tiga kelas pergerakan mikro dan empat kelas terikan dengan memetakan data sebenar kepada ruang sifat. Kaedah satu-lawan-semua telah digunakan kerana teknik ini mudah digunakan, tempoh masa pengiraan yang cepat dan menghasilkan keputusan yang tepat. Keputusan menunjukkan lebih daripada 97% ketepatan pengecaman corak menggunakan beberapa sifat domain masa (nilai mutlak min, nilai maksimum puncak, nilai min, punca min kuasa dua) bagi kedua-dua terikan dan pergerakan mikro. Ini menunjukkan TDF – SVM boleh digunakan dalam menentukan kestabilan penetapan linggi femur dengan memberikan maklumat berkenaan kestabilan implan sebelum digunakan secara klinikal.

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N	-	Newton
Pa	-	Pascal
μm	-	micrometre
kV	-	kilovolts
mAs	-	milli Ampere seconds
ε	-	Strain
σ	-	Stress
E	-	Young's Modulus
ν	-	Poisson's ratio
ρ	-	Density
Ω	-	Ohm
ξ	-	Distance of misclassified point from hyper plane

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CHAPTER 1

INTRODUCTION

1.1 Background

The development of hip arthroplasty began in 1962 and was initiated by Sir John Charnley which showed tremendous results in orthopaedic surgery. Hip joint arthroplasty has increase in popularity as a way to restore the function of the hip joint damage by degenerative diseases such as osteoarthritis and rheumatoid arthritis (Ethgen et al., 2004, Learmonth et al., 2007). Osteoarthritis is normally related to the deterioration of cartilage, while rheumatoid arthritis is associated with autoimmune responses. In 2006 alone, Europe reported 650 000 hip replacement cases and revision surgeries, followed by the United States with 420 000 cases, and 70 000 cases in Japan and South Korea (Kiefer, 2007). The high prevalence of hip arthroplasty encouraged implant manufacturers to produce better designs that optimized fixation stability based on advice from orthopedic surgeons.

However, there is no universal design for hip implants that will fit all femoral types (Noble et al., 1988, Husmann et al., 1997, Laine et al., 2000). Noble et al. (1988) classified the endosteal canal into three different shapes according to the canal flare index (CFI). These categories are stovepipe shape (CFI < 3.0), normal shape ($3.0 <$ CFI < 4.7) and champagne flute shape (CFI > 4.7) (Noble et al., 1988). Even if universal stems were suitable for a variety of sizes, the possibility of an implant being over or under sized are high. Oversized implants risk more bone stock due to over reaming during surgery. In the worst cases, it can lead to bone fractures. On the other hand, undersized implants cause micromotion, fibrous tissue formation, loosening, and thigh pain. The common problems that lead to the hip arthroplasty failure are dislocation, stress shielding, and aseptic loosening (Karrholm, 2010). These problems can be solved by well-designed hip implants that fit optimally inside the femoral canal (Cristofolinia et al., 2003).

Several studies have shown the differences in femoral morphology between Asian and Western populations (Mahaisavariya et al., 2002, Hoaglund and Low, 1980, Mishra et al., 2009). Typically, Asians have a small stature (Siwach and Dahiya, 2003), and peculiar endosteal canal characteristics, especially in metaphyseal region (Ando et al., 1999, Kawahara et al., 2010) that contribute to the biological fixation of the hip implant. Ignoring this fact jeopardizes stability and shortens the lifespan of the implant. Mismatched prosthesis were reported due to these morphological differences (Leung et al., 1996, Mishra et al., 2009).

Currently, implant manufacturers try to produce hip implants with smaller femoral head offsets and stem lengths (Sivananthan et al., 2003, Fang et al., 2010, Kaya et al., 2008, Ohsawa et al., 1998, Cheh et al., 2009, Chiu et al., 2011). Although the implant had excellent medium and long term results (Sivananthan et al., 2003, Cheh et al., 2009, Chiu et al., 2011), a few cemented hip stem failures were reported in young and active patients (Joshi et al., 1993, Chandler et al., 1981). This phenomenon lead to the development of cementless hip stems for Asian populations that were better designed for their peculiar femoral morphology (Fang et al., 2010, Kaya et al., 2008, Ohsawa et al., 1998).

Several studies have been performed regarding cementless femoral stems using finite element analysis (FEA) and experimental methods (Dopico-Gonzalez et al., 2010, Pettersen et al., 2009a, Pettersen et al., 2009b). Dopico – Gonzalez et al. (2010) presented a robust tool for probabilistic FEA for cementless stems that focused on femur characteristics and the implant design geometry between the Proxima short stem and IPS stem which showed good agreement with the in-vitro study (Dopico-Gonzalez et al., 2010). In addition, Pettersen et al. (2009a) and Pettersen et al. (2009b) supported the excellent correlation between an actual human cadaver and FEA while investigating the feasibility of subjects specific to stress shielding and micromotion using a cementless Summit stem (Pettersen et al., 2009a, Pettersen et al., 2009b). Ando et al. (1999) also performed FEA to compare their stems for Japanese dysplastic hip (FMS and FMS-anatomic) with other commercial stems such as Omnifit, Omniflex, and IDS (Ando et al., 1999). They focused on contact stress, relative motion, and load transfer prior to clinical use. Their results showed that the load was transferred mostly in the proximal region with low micromotion value, which explained the excellent success rate of this implant (Kawahara et al., 2010, Kokubo et al., 2013). Furthermore, Rawal et al. (2012a) manufactured an Indian femoral stem using a 3 axis CNC machine after finding that the equivalent von Misses stress result from FEA was below 160 MPa and prevented endosteal fractures (Rawal et al., 2012a). In this study, a similar method was used as a nonlinear three dimensional FEA in the design process of a cementless stem for Malays. Finite element analysis has become a useful tool for researchers for predicting early and medium term results (O'Toole et al., 1995).

Although FEA can predict the results for implants, there are several limitations that influence this in-silico method, such as boundary and loading conditions, material properties, contact bodies, and mesh convergence. Any changes to these parameters will lead to different results, which are not in compliance with the experimental results. Pattern recognition of the primary stability of the cementless femoral stem is a new field of study and it could determine the stable phase during biomechanical testing. In this study, digital signal processing (DSP) was applied to the strain and micromotion signals for feature extraction and pattern recognition of primary stability when the active features were clearly differentiated. This DSP method was not only easily applied, but it also saved computation time, and achieved reasonable results. In addition, the results of the DSP were in compliance with FEA. This suggests that DSP could be used for determining primary stability and could become an efficient preclinical tool for newly designed implants.

1.2 Research Scope

This study covered the development of cementless femoral stems for the Malay population. Data was acquired from 60 healthy subjects after receiving approval from the hospital committee and the National Medical Research Register (NMRR). A femur was then reconstructed into three dimensional (3D) models from raw computed tomography (CT) datasets using commercial medical imaging software. The dimensions were carefully measured according to the standard measurements for periosteal and endosteal canal diameters using computer aided design (CAD) software. These anatomical features were then used for designing the cementless femoral stem for the Malay population. Computational simulation was performed through finite element analysis (FEA) to study stress distribution, displacement, and micromotion of the cementless femoral stem inside the medullary canal. The prototype was fabricated using 316L stainless steel and an investment casting technique. FEA was experimentally validated using composite femoral. Micromotion was measured using a linear variable direct transducer (LVDT) proximally and distally, while the strain was measured using four tri axial rosette medially and laterally. The data was then processed using thirteen time domain features for feature extraction and a support vector machine classifier with a polynomial kernel. This new method discovered each strain and micromotion signal that could be used as a preclinical tool before clinical trials. The information benefit researchers by determining the stable phase of the femoral stem, thus preventing loosening and stress shielding from occurring post-surgery. Conventional method validated FEA and experimental testing consumed a great deal of time as it dealt with a variety of preset parameters that could create different results, whereby the proposed TDF – SVM classification demonstrated better pattern recognition accuracy for the implant's primary stability during biomechanical testing.

1.3 Objective of the Study

The goal of this study was to develop a cementless femoral stem for the Malay population tailored with the morphology study, which was subsequently analyzed using computational simulation and was experimentally validated using the composite femora. The objectives of this study were as follows:

a) To model the three dimensional femoral morphology and analyze using finite element method for femoral stem design of Malays.

b) To develop a systematic framework for the development of a cementless femoral stem for the Malay population.

c) To extract features and classify the primary stability of the newly designed femoral stem using a proposed method time domain features – support vector machine (TDF – SVM) that could be used as a preclinical tool for biomechanical testing.

1.4 Importance of Research

A rapidly aging population leads to a higher prevalence of the hip fractures, bone diseases, and other musculoskeletal disorders, which required more hip arthroplasty. The Malaysia Informative Data Center (MysIDC) reported that the Malay population in Malaysia, 50 years of age or older, increased from 1.37 million in 2000, to 2.21 million in 2010. This phenomenon also occurred in Western countries where the growing aging population is increasing the demand for hip replacement for primary osteoarthritis (Kiefer, 2007).

The orthopaedic community in Malaysia has mutually agreed that the bone morphology of Malay skeletal systems is different from those found in American and European countries. Hip prostheses are mostly designed and manufactured by

European and American implant manufacturers. The size as well as other parameters, such as the collo diaphyseal angle (CDA), femoral head offset, femoral head position, and endosteal canal diameters particularly for the isthmus canal, were developed according to their respective morphology.

The physical size and stature of Asians are smaller than Western populations. Asian femora morphology also differs from the Western morphology in the metaphyseal region where proximal fixation is essential for the primary and secondary stability of the implant. This was further confirmed by new implant designs developed by global implant manufacturers to cater to the Asian market (Kaya et al., 2008, Ohsawa et al., 1998). An optimized hip implant ensures the stability of the implant inside the femoral. Kaya et al. (2008) reported that a modification to the Anatomic Medullary Locking (AML) stem (Depuy, Warsaw, IN, USA) at the metaphyseal (called medial modified aspects (MMA) was due to the narrower and shorter hips of Japanese patients (Kaya et al., 2008).

The universal hip stem with its number of sizes is not applicable for all types of femur and it might cause the varus or valgus position of the femoral stem inside the medullary canal. A few cases of implant mismatch were reported to be caused by the peculiar morphology of the Asian population (Reddy et al., 1999, Koval, 2007, Gadegone and Salphale, 2007). A mismatched implant could complicate surgeries while implanting the stem inside the femoral canal, and hamper the function of the implant, which could affect post-surgery outcomes. Several studies have developed new implants to cater to the unique hip morphology of different populations (Fang et al., 2010, Ando et al., 1999, Kawahara et al., 2010, Kokubo et al., 2013, Rawal et al., 2012a). Kokubo et al. (2013) reported a 100 % success rate in anatomic fit after 7.1 years for an implant that was specially designed for Japanese dysplastic hip patients (Kokubo et al., 2013). This implant optimized fixation stability between the bone – stem interface, promoted osseointegration, and prolonged the lifespan of the implant. Furthermore, the implant also prevented unnecessary removal of bone stock for future revision surgery (Mishra et al., 2009).

1.5 Organization of the Thesis

This thesis consists of six chapters. The introduction in Chapter 1 explained the background study, research scope, objectives, and importance of this research. Chapter 2 provided a brief review of the literature that could help readers comprehend this study, the anatomical structure of the femur, cementless femoral stems, and the analysis methods used.

Chapter 3 describes the methodology implemented in the development of the cementless femoral stem for the Malay population. The computed tomography images were acquired prior to designing the cementless femoral stem in accordance with the morphology for an Asian population. The fabrication process used an investment casting technique before sand blasting with a silicon carbide mesh for surface roughness. For validation purposes, strain was measured with four tri-axial rosettes at the metaphyseal region, and micromotion was measured using linear variable direct transducers proximally and distally on the composite femora.

In Chapter 4, the results from the analysis completed in Chapter 3 are discussed. The morphology study showed that Asian femurs are smaller than Western femurs, except in the metaphyseal region. The newly designed femoral stem had a better total fit (53.7%) and fill (76.7%) canal, with more load distributed proximally to prevent stress shielding in the calcar region. The stem demonstrated lower displacement and micromotion (less than 40 μm) promoting osseointegration between at the stem–bone interface and provided primary fixation stability.

Chapter 5 proposes a new method for the application of various time domain feature extractions and support vector machine classifiers (TDF – SVM) to classify different states of an implant's primary stability using interface micromotion and strain signals. The conventional method used experimental validation with finite element analysis (FEA) to evaluate the fixation stability of the implant, which generally took more computational time and involved different preset parameters. Finally, the conclusion of this study and a discussion of future work to improve the methodical and quality of the femoral stem are discussed in Chapter 6.

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