Cementless Tibial Base Micromotion During Activities of Daily Living

Hayden Wilson
University of Denver

Follow this and additional works at: https://digitalcommons.du.edu/etd

Part of the Biomechanics and Biotransport Commons

Recommended Citation
https://digitalcommons.du.edu/etd/1471

This Thesis is brought to you for free and open access by the Graduate Studies at Digital Commons @ DU. It has been accepted for inclusion in Electronic Theses and Dissertations by an authorized administrator of Digital Commons @ DU. For more information, please contact jennifer.cox@du.edu,dig-commons@du.edu.
Cementless Tibial Base Micromotion During Activities of Daily Living

A Thesis

Presented to

the Faculty of the Daniel Felix Ritchie School of Engineering and Computer Science

University of Denver

In Partial Fulfillment

of the Requirements for the Degree

Master of Science

by

Hayden Wilson

June 2018

Advisor: Chadd W. Clary
Initial stability of cementless total knee replacement (TKR) components is directly related to long-term fixation and success, as excess motion hinders bony ingrowth. To assess implant stability, there is a need for more physiologically accurate loading conditions, incorporating forces and displacements in all 6 degrees-of-freedom found in the knee joint, as well as understanding the impact of femoral flexion on conformity of tibiofemoral articulation. Understanding how different activities of daily living generate tibial micromotion yields insight into surgical technique considerations, and rehabilitation strategies post-operatively. ASTM F3141-15, which specifies knee flexion, Internal-External moment, Medial-Lateral, Anterior-Posterior and Superior-Inferior forces during gait and stair descent activities, supplemented with abduction-adduction moments, as well as varied surgical alignment, was used to create loading profiles. Deep knee bending loading was extracted from the Orthoload database utilizing the same methods. These activities were simulated on Depuy Attune, Stryker Triathlon and ZimmerBiomet NexGen cementless tibial base tray designs implanted into biphasic synthetic tibia using the accompanying femoral component mounted in an AMTI VIVO joint simulator. Micromotions were observed on the anterior lateral, center and medial aspect of the tray with respect to the cortical tibia using digital image correlation to track displacements throughout the full cycle of each variation of each activity. Results
demonstrated increased tibial tray micromotions are primarily correlated with large femoral A-P translations coupled with high compressive loads, but not increased ad-ab moment, indicating initial fixation may be robust to frontal plane alignment of the implant. Gait and stair descent activities resulted in higher micromotions compared to deep knee bending activities, potentially indicating deep knee bending is not deleterious to initial fixation of cementless tibial trays. The findings of this experiment were used to create a validated finite element model to be used for pre-clinical implant development. Further work is currently under way to simulate the quadriceps muscle force, allowing for whole joint (tibiofemoral and patellofemoral) simulation. The addition of a muscle force driven mode represents a more anatomically accurate experimental method for evaluating native and implanted knee joint mechanics. The work presented in this thesis has strong medical device development and verification implications, as well as the ability to provide more clinically relevant information leading to increasingly successful patient outcomes.
ACKNOWLEDGEMENTS

First and foremost, I must thank my advisor, Dr. Chadd Clary, for his guidance and support on this work as well as his mentorship in and out of the academic setting.

I want to thank Dr. Paul Rullkoetter and Dr. Scott Barbee for serving as members of my defense committee.

I want to thank Yashar Behnam for his assistance on various projects throughout the course of my degree, particularly with the data collection for the micromotion study. I also thank Alessandro Navacchia for his help with MATLAB script development for the analysis of the micromotion study. I appreciate all of the members of our research group and extend my gratitude for assisting me throughout my time here.

I would like to thank Depuy Synthes for their funding of my project, particularly Abraham Wright for providing the necessary equipment along the way.

Finally, I would like to thank the Orthopaedic Research Society and AMTI Force and Motion Foundation for the award of 2018 FMF/ORS Young Scientist Scholarship, helping to fund the implementation of the quadriceps muscle force mechanism.
# TABLE OF CONTENTS

Abstract ......................................................................................................................... ii
Acknowledgements ......................................................................................................... iv

Chapter 1. INTRODUCTION ...................................................................................... 1
  1.1 Introduction ............................................................................................................ 1
  1.2 Objectives ............................................................................................................. 3
  1.3 Thesis Overview .................................................................................................. 4

Chapter 2. BACKGROUND INFORMATION AND LITERATURE REVIEW ........... 5
  2.1. Cementless Total Knee Replacement, Joint Loads and Alignment ............... 5
  2.2. Investigation of Cementless Fixation of the Tray-Bone Interface ................... 6

Chapter 3. CEMENTLESS TIBIAL BASE MICROMOTION DURING ACTIVITIES OF
  DAILY LIVING ........................................................................................................... 17
  3.1. Introduction ....................................................................................................... 17
  3.2. Methods ............................................................................................................ 19
  3.3. Results .............................................................................................................. 26
  3.4. Discussion ......................................................................................................... 34

Chapter 4. IMPROVED EXPERIMENTAL METHODS IN MUSCLE DRIVEN
  KNEE JOINT MECHANICS ....................................................................................... 60
  4.1. Relevance and Justification .............................................................................. 60
  4.2. Design Rationale and Process .......................................................................... 63

Chapter 5. CONCLUSIONS AND RECOMMENDATIONS ..................................... 71

BIBLIOGRAPHY ........................................................................................................... 74

APPENDICES .............................................................................................................. 80
  APPENDIX 3A: FULL-CYCLE MICROMOTION FOR ATTUNE D6,
  TRIATHLON AND NEXGEN ................................................................................... 80
  APPENDIX 3B: FULL-CYCLE MICROMOTION FOR ATTUNE D1-D6 ............... 84
  APPENDIX 3C: FULL-CYCLE MICROMOTIONS FOR ATTUNE D6 CR AND
  PS .............................................................................................................................. 90
  APPENDIX 3D: COMPOSITE MICROMOTION TABLE .................................... 96
  APPENDIX 3E: TABLE OF COMPLETED VERSUS FAILED SPECIMENS AND
  LOAD PROFILES .................................................................................................... 97
  APPENDIX 3F: TABLE OF STATISTICALLY SIGNIFICANT DIFFERENCES
  BETWEEN DESIGNS AND ACTIVITIES .............................................................. 98
LIST OF TABLES

Table 3.1 TIBIAL BASE TRAY GEOMETRY DETAIL DESCRIPTION ...............39
Table 3.2 LOADING CONDITIONS APPLIED TO EACH TIBIAL BASE ..........43
Table 3D COMPOSITE MICROMOTION TABLE AND STANDARD DEVIATION.96
Table 3E TABLE OF COMPLETED VERSUS FAILED SPECIMENS AND LOADING
PROFILES ..................................................................................................97
Table 3F.1 STATISTICALLY SIGNIFICANT DIFFERENCES FOR EACH DESIGN
PAIR FOR GAIT ACTIVITIES .................................................................98
Table 3F.2 STATISTICALLY SIGNIFICANT DIFFERENCES FOR EACH DESIGN
PAIR FOR STAIR DESCENT ACTIVITIES ..............................................99
Table 3F.3 STATISTICALLY SIGNIFICANT DIFFERENCES FOR EACH DESIGN
PAIR FOR DEEP KNEE BEND ACTIVITIES .............................................100

Table 4A.1 LIST OF PART DRAWING, PART QUANTITIES AND MATERIALS..101
LIST OF FIGURES

Figure 2.1: Porous Metallic Surface on Underside of Cementless Tibial Base Imaged Using Keyence VR White Light Microscope ........................................... 14
Figure 2.2: AMTI VIVO 6 Degree of Freedom Robotic Joint Simulator ............ 15
Figure 2.3: Optotrak Cetus and Infrared Rigid Body Markers .......................... 15
Figure 2.4: Biphasic Sawbones Resected Tibia, Pacific Research Labs, Part # 1522-912 ........................................................................................................ 16
Figure 2.5: GOM Aramis DIC Camera and Speckle Painted Foam Bone-Tray Construct .................................................................................................... 16

Figure 3.1: Tibial Base Tray Geometries for Attune D1-D6, Triathlon and NexGen .............................................................................................................. 38
Figure 3.2: Adduction and Abduction Profiles for Gait (Left) and SD (Right) extracted from Orthoload database. Black lines represent average of averaged patients, ± 1 SD ............................................................................................................. 39
Figure 3.3: A-P, S-I, Ad-Ab and I-E load profiles for gait (Top), SD (Middle) and DKB (Bottom) based on ASTM F3141 supplemented with extracted Orthoload data ......................................................................................................................... 40
Figure 3.4: Flexion and load profiles for DKB extracted from Orthoload database. Black lines represent average of averaged patients, ± 1 SD ............. 41
Figure 3.5: A-P, Ad-Ab and I-E load profiles for gait (Top), SD (Middle) and DKB (Bottom) based on Attune specific loading derived from computational simulation of the lower limb ......................................................................................................................... 42
Figure 3.6: AMTI VIVO Joint Simulator with Implanted Tibial Foam Bone construct. The DIC cameras (foreground) were used to track implant micromotion using matched pairs of targets affixed to the anterior face of the bone and tray .................................................................................................................. 43
Figure 3.7: The orientation of the various femoral components relative to the flexion axis of the femoral shaft on the VIVO simulator. Alignment was obtained via rapid prototype alignment ‘boxes’ ................................................. 44
Figure 3.8: The minimum distance between adjacent targets was subtracted from the maximum distance between adjacent targets to calculate a relative micromotion for the lateral, central, and medial aspects of the tibial base. The lateral, central, and medial micromotions were then averaged to determine an overall micromotion for the cycle ......................................................... 44
Figure 3.9: Peak loads applied during implantation of each tibial base designs (Left) and the amount of force required per 1-mm of tibial base advancement into the tibial bone as the base approached the tibial plateau (Phase II Slope, Right) .................................................................................................................. 45
FIGURE 3.10: FORCE DISPLACEMENT CURVES OF IMPLANTATION FOR EACH DESIGN ……….45
FIGURE 3.11: ANTERIOR POSTERIOR TRANSLATION LAXITY CONSTRAINT CURVES FOR
ATTUNE D6, TRIATHLON AND NexGen ……………………………………………………46
FIGURE 3.12: INTERNAL EXTERNAL ROTATION LAXITY CONSTRAINT CURVES FOR ATTUNE
D6, TRIATHLON AND NexGen…………………………………………………………..46
FIGURE 3.13: A-P LAXITY CHANGE AS A FUNCTION OF FLEXION ………………………47
FIGURE 3.14: I-E LAXITY CHANGE AS A FUNCTION OF FLEXION ……………………..47
FIGURE 3.15: CONDYLAN LOW-POINT A-P KINEMATICS OF THE LATERAL (LEFT) AND
MEDIAL (RIGHT) CONDYLES DURING ORTHOLOAD GAIT ACTIVITIES FOR ATTUNE D6 (TOP),
TRIATHLON (MIDDLE) AND NexGen (BOTTOM)……………………………………..48
FIGURE 3.16: LATERAL (LEFT), CENTRAL (MIDDLE), AND MEDIAL (RIGHT) MICROMOTION OF
THE TRAY RELATIVE TO THE BONE OVER THE COURSE OF THE ORTHOLOAD GAIT ACTIVITIES.
TOP ROW OVERLAYS THE NEUTRAL GAIT CYCLES FOR ATTUNE D6, TRIATHLON, AND
NexGen ………………………………………………………………………………….49
FIGURE 3.17: VISUALIZATION OF THE POSTERIOR-ANTERIOR FEMORAL LOCATION AND
RESULTING MICROMOTIONS DURING NEUTRAL GAIT CYCLE FOR ATTUNE D6 (TOP),
TRIATHLON (MIDDLE) AND NexGen (BOTTOM)………………………………………50
FIGURE 3.18: CONDYLAN LOW-POINT A-P KINEMATICS OF THE LATERAL (LEFT) AND
MEDIAL (RIGHT) CONDYLES DURING THE ORTHOLOAD STAIR DESCENT ACTIVITIES, FOR
ATTUNE D6 (TOP), TRIATHLON (MIDDLE) AND NexGen (BOTTOM)…………………..51
FIGURE 3.19: LATERAL (LEFT), CENTRAL (MIDDLE), AND MEDIAL (RIGHT) MICROMOTION OF
THE TRAY RELATIVE TO THE BONE OVER THE COURSE OF THE ORTHOLOAD STAIR DESCENT
ACTIVITIES. THE TOP ROW OVERLAYS THE NEUTRAL CYCLES FOR ATTUNE D6, TRIATHLON,
AND NexGen, WHILE ROWS 2-4 SHOW THE EFFECT OF ABDUCTION AND ADDUCTION ON THE
OBSERVED MICROMOTION FOR EACH TRAY DESIGN ………………………………………52
FIGURE 3.20: VISUALIZATION OF THE POSTERIOR-ANTERIOR FEMORAL LOCATION AND
RESULTING MICROMOTIONS DURING NEUTRAL STAIR DESCENT CYCLE FOR ATTUNE D6
(TOP), TRIATHLON (MIDDLE) AND NexGen (BOTTOM)……………………………..53
FIGURE 3.21: CONDYLAN LOW-POINT A-P KINEMATICS OF THE LATERAL (LEFT) AND
MEDIAL (RIGHT) CONDYLES DURING THE ORTHOLOAD DKB ACTIVITIES WITH A-P OFFSET
LOADING, FOR ATTUNE D6 (TOP), TRIATHLON (MIDDLE), AND NexGen (BOTTOM)……54
FIGURE 3.22: LATERAL (LEFT), CENTRAL (MIDDLE), AND MEDIAL (RIGHT) MICROMOTION OF
THE TRAY RELATIVE TO THE BONE OVER THE COURSE OF THE ORTHOLOAD DKB ACTIVITIES
WITH A-P OFFSET LOADING. THE TOP ROW OVERLAYS THE NEUTRAL CYCLES FOR ATTUNE
D6, TRIATHLON, AND NexGen, WHILE ROWS 2-4 SHOW THE EFFECT OF ANTERIOR AND
POSTERIOR LOADING ON THE OBSERVED MICROMOTION FOR EACH TRAY DESIGN ……..55
FIGURE 3.23: LATERAL (LEFT), CENTRAL (MIDDLE), AND MEDIAL (RIGHT) MICROMOTION OF
THE TRAY RELATIVE TO THE BONE OVER THE COURSE OF THE ORTHOLOAD DKB ACTIVITIES
WITH AD-AB LOADING. THE TOP ROW OVERLAYS THE NEUTRAL CYCLES FOR ATTUNE D6,
TRIATHLON, AND NexGen, WHILE ROWS 2-4 SHOW THE EFFECT OF ADDUCTION AND
ABDUCTION ON THE OBSERVED MICROMOTION FOR EACH TRAY DESIGN………………56
FIGURE 3.24: VISUALIZATION OF THE POSTERIOR-ANTERIOR FEMORAL LOCATION AND RESULTING MICROMOTIONS DURING POSTERIOR DKB AND ANTERIOR DKB CYCLES FOR ATTUNE D6 (TOP), TRIATHLON (MIDDLE) AND NEXGEN (BOTTOM) ........................................67


FIGURE 4.1: VIVO MUSCLE FORCE QUADRICEPS MECHANISM ......................................................81

FIGURE 4.2: IMPLEMENTATION OF THE QUADRICEPS MECHANISM IN A PREVIOUSLY VALIDATED FINITE ELEMENT MODEL (CLARY) ........................................................82

FIGURE 4.3: FEMORAL COMPONENT ATTACHED IN LINE WITH FLEXION AXIS ..................82

FIGURE 4.4: FEMORAL FIXTURE ADJUSTABILITY ................................................................82

FIGURE 4.5: MODIFIED VIVO AD-AB ARM CONFIGURATION ........................................83

FIGURE 4.6: NEUTRAL AND 45 DEGREE FLEXION OFFSET POSITION TO ALLOW DEEP FLEXION ....................................................................................................................83

FIGURE 4.7: QUADRICEPS MUSCLE FORCE ACTUATOR ADJUSTABILITY .......................84

FIGURE 4.8: FIXTURING DESIGNED FOR TOTAL KNEE JOINT TESTING WITH THE ADDITION OF A QUadriceps Muscle Force (BLUE) IN THE AMTI VIVO (GRAY) ................85

FIGURE 4.9: LOGIC DIAGRAM FOR MUSCLE FORCE FEEDBACK CONTROL ................85

FIGURES 3A 1-13: FULL-CYCLE MICROMOTION FOR ATTUNE D6, TRIATHLON AND NEXGEN .................................................................89

FIGURES 3B 1-19: FULL-CYCLE MICROMOTION FOR ATTUNE D1-D6 .................................93

FIGURES 3C 1-19: FULL-CYCLE MICROMOTIONS FOR ATTUNE D6 CR AND PS. 97

FIGURE 4A. 1: SI ARM 4 HOLE PATTERN WASHER MECHANICAL DRAWING ................101

FIGURE 4A. 2: SI ARM CONNECTION PLATE MECHANICAL DRAWING ........................102

x
FIGURE 4A. 3: VV ROTATION BOTTOM ARM 1 MECHANICAL DRAWING ...................... 104
FIGURE 4A. 4: VV ROTATION BOTTOM ARM 2 MECHANICAL DRAWING .................. 105
FIGURE 4A. 5: VV ROTATION BOTTOM BASE MECHANICAL DRAWING .................. 106
FIGURE 4A. 6: VV ROTATION TOP MECHANICAL DRAWING .................................. 107
FIGURE 4A. 7: ACTUATOR ROTATION PLATE ARM MECHANICAL DRAWING .......... 108
FIGURE 4A. 8: ACTUATOR ROTATION PLATE BASE MECHANICAL DRAWING .......... 109
FIGURE 4A. 9: ACTUATOR ROTATION PLATE BASE DETAIL MECHANICAL DRAWING .... 110
FIGURE 4A. 10: ACTUATOR SLIDE PLATE MECHANICAL DRAWING .................... 111
FIGURE 4A. 11: ALTERED AD/AB ARM PART 1 MECHANICAL DRAWING ................. 112
FIGURE 4A. 12: ALTERED AD/AB ARM PART 1 ARC SLOT DETAIL MECHANICAL DRAWING .................................................................................................................. 113
FIGURE 4A. 13: ALTERED AD/AB ARM PART 2 MECHANICAL DRAWING ................. 114
FIGURE 4A. 14: CONNECTION TOP PLATE MECHANICAL DRAWING ..................... 115
FIGURE 4A. 15: FEMORAL FIXTURE MECHANICAL DRAWING ............................. 116
FIGURE 4A. 16: FEMORAL IE COUPLE MALE MECHANICAL DRAWING ............... 117
FIGURE 4A. 17: SI ARM MECHANICAL DRAWING ............................................ 118
CHAPTER 1. INTRODUCTION

1.1 Introduction

Cemented total knee replacement components have shown superior fixation durability, but their long-term performance is of cause for concern (Crook et al., 2017). With advances in additive manufacturing and porous metallic surface coatings, cementless fixation is seeing a rise in popularity. It has been found that initial fixation of the component to the bone through the first 6 weeks is crucial to ensure bony ingrowth and long-term survivorship (Chong et al., 2010). Therefore, evaluating the contribution of different fixation features and surgical preparation to initial fixation under worst-case anatomical loads of activities of daily living is critical in the design and verification of future cementless tray designs.

Cementless fixation has been investigated both in vivo or in vitro, each of which has benefits and shortcomings. In vivo testing allows observation of implant performance in the patient, but limits invasive exploration. In vitro testing allows for invasive experimentation, but accurate reproduction of anatomic loading conditions becomes a challenge. Efforts have been made to characterize and standardize knee loads during activities of daily living (ADLs) for use in in vitro studies of knee mechanics (Van Valkenburg et al., 2016).
Previous studies investigated the effects of micromotion on bone ingrowth (Jasty et al., 1997; Pilliar et al., 1986), as well as the fixation of the bone-tray interface in vivo (Harwin et al., 2013; Kutzner et al., 2010). In vitro testing of the contribution of tibial tray fixation features on micromotion has been done in cadaveric tissue (Chong et al., 2010), but more commonly a synthetic representation of the tibia is used in fixation evaluation and comparative studies (Bhimji and Meneghini, 2014, 2012; Crook et al., 2017; Yildirim et al., 2016). These studies serve as strong examples of predicate research, but their use of simplified loading conditions and the small scope of activities and variations leaves room for more in-depth investigation.

The primary focus of this thesis is to characterize the relationship between loading during activities of daily living and tibial micromotion with current total knee replacement systems, while accounting for potential variability due to surgical philosophy. Micromotion was characterized under a variety of loading conditions, including stair descent, gait, deep knee bend, and under various levels of medial-lateral load distribution representing anatomic alignment and mal-alignment, which has been shown to greatly impact implant survival (Kutzner et al., 2017). The work presented in this thesis has significant medical product development and clinical relevance given the renewed interest in cementless fixation. Additionally, this experiment was used to validate the accompanying finite element model, capable of computationally simulating all 6 degrees-of-freedom and directly measuring micromotions across the whole implant-bone interface (Navacchia et al., 2018).
1.2 Objectives

The objectives of this thesis are to:

1) Design an experiment capable of characterizing micromotion at the tray-bone interface of cementless total knee replacement tibial trays during activities of daily living

2) Develop loading profiles that simulate variations in frontal plane alignment (or malalignment) of the total knee replacement (anatomic alignment)

3) Compare tibial base tray fixation feature geometries

4) Provide verification for a finite element computational model of the experiment

5) Develop improved methods for joint testing through the experimental simulation of muscle forces.

Anatomic loads, in all six degrees of freedom of the knee joint, were applied to cementless tibial trays implanted into biphasic simulated bone to 1) assess prototypes and iterate to a final design, and 2) to compare the performance of the final prototype design to two commercially available trays. The experimental setup was reproduced in a finite element framework, and the results were used to verify the accuracy of the computational simulation.
1.3 Thesis Overview

Chapter 2 provides a brief background on *in vitro* biomechanical testing, as well as a review of published literature on micromotion effects on initial fixation of cementless tibial implants.

Chapter 3 presents *Cementless Tibial Base Micromotion During Activities of Daily Living* that aims to investigate the effects of different fixation features on tray-bone micromotion during three activities of daily living: gait, stair descent and deep knee bending.

Chapter 4 presents *Improved Experimental Methods in Muscle Driven Knee Joint Mechanics*, which outlines the part designs, process and important features around the addition and implementation of a quadriceps actuator to allow for testing of the whole natural and implanted knee joint.

Chapter 5 discusses the importance of the findings of this thesis as they pertain to cementless implant design, as well as recommendations for future exploration and works.
Aseptic loosening has been shown to be the leading cause for revision in cemented and cementless total knee replacement surgery (Crook et al., 2017). While cemented tibial trays are the most prevalent, in recent years there has been a rise in cementless TKR due to advancements in porous metallic surfaces (Figure 2.1), and additive manufacturing technologies (Ranawat et al., 2012). Cementless implant components rely on a greater interference fit into bone than cemented counterparts for early stability, and utilize initial press fit to allow bone growth. Initial stability over the first 10,000 cycles, or roughly 6 weeks of regular activity, is critical for bony ingrowth into the porous structures of the implant, which dictates the likelihood for long-term success (Yildirim et al., 2016), therefore understanding the effects of fixation features and the loads in the knee during activities of daily living (ADLs) on tray micromotion is paramount when developing and evaluating new tibial tray designs.

In order to better understand the loads at the knee, instrumented TKR components have been implanted in living patients to record the 6 degree of freedom (DoF) loads within the knee joint caused by active muscles, soft tissue, external forces and contact.
Kutzner also investigated the effects of frontal plane varus or valgus alignment on increased knee adduction moments, finding a strong correlation between varus malalignment and increased medial compartment forces (Kutzner et al., 2017). This study, combined with others performed by the Julius Wolff Institute of the Charité in Berlin (Orthoload Database) informed the loading standards for tribological testing of total joint replacement, but also shed light on the importance of the abduction-adduction moments and varus-valgus alignment when testing and evaluating the knee joint. Howell et al. has performed numerous investigations on the impact of surgical alignment of knee implants, particularly varus-valgus alignment, on patient outcomes, further highlighting the importance of understanding these loads (Howell et al., 2013a, 2013b).

2.2. Investigation of Cementless Fixation of the Tray-Bone Interface

*In Vivo Testing*

Understanding the relationship between micromotion and fixation of cementless tibial implants requires *in vivo* studies. From Wolff’s Law, bone remodeling occurs due to mechanical stimulus (Huiskes et al., 2000). Many investigations have explored what degrees of loading and motion enable bone-implant fixation. The effects of different magnitudes of micromotions, (0, 20, 40 and 150 μm) on implant-bone ingrowth and resulting fixation was explored *in vivo* in a study on 20 canines (Bragdon et al., 1996; Jasty et al., 1997). The results showed excellent bone growth into the implants from no-motion to 20μm, and statistically significantly less growth for each iteration thereafter. The implants experiencing 150μm exhibited dense fibrous tissue and trabecular fractures
rather than trabecular bone growth. These findings strongly reinforce results from two additional independent canine in vivo studies, which found motions in excess of 150μm to negatively affect bony ingrowth (Pilliar et al., 1986). In vivo studies are performed in human subjects as well. Harwin et al. implanted 108 subjects with cementless TKR and followed up over 2.5 years with radiographs, pre- and postoperative Knee Society pain and function scores, and ranges of motion (Harwin et al., 2013). The radiographs showed no signs of loosening via the absence of osteolysis, stress shielding or radiolucent lines. While in vivo experiments have great clinical relevance and are the only means by which to test bone in-growth, they are less useful during the design phase of new TKRs, as one is unable to experiment with investigational designs.

In Vitro Testing

In vitro evaluation of cementless total knee replacement requires experimental methods to load the knee joint and measure the resulting knee kinematics and implant micromotion. Multiple configurations of knee testing rigs have been described in the literature. Testing rigs vary from static to dynamic loading and with multiple controllable DoFs. One rig that has proven successful in biomechanical evaluation is the Oxford rig (Zavatsky, 1997), which led to the creation of more complex loading systems such as the Kansas Knee Simulator (Clary et al., 2013). The Kansas knee simulator, as well as others, allow for complex multi-axial loadings at the knee by applying loads at the hip and ankle, which physiologically loads the knee joint. Robotic arm rigs are the gold standard in human motion simulation (Maletsky et al., 2016), as they allow the knee to be unconstrained in all 6-DoFs. These machines can be controlled in a number of ways,
from load to displacement control of the joint, and have become the best way to analyze both native and implanted joints. The AMTI VIVO (Figure 2.2) (AMTI, Watertown, MA) is among the most advanced implant testing machines, allowing for axis independent force or position control, as well as fully supporting the Grood and Suntay (Grood and Suntay, 1983) coordinate system used by major biomechanics joint testing standards organizations such as ASTM, ISB and ISO\textsuperscript{1}.

Motion capture tracking systems are used for measuring knee kinematics during the experiment. Measuring \textit{in vitro} kinematics is similar to collecting \textit{in vivo} kinematics, and many of the same methods are used, such as instrumented spatial linkages (ISLs), electromagnetic systems, and marker-based optical tracking. Marker based tracking can be performed using active or passive markers (e.g. Vicon, Denver, CO and Optotrak, Northern Digital, Canada respectively), with active marker systems being the more accurate of the two (Maletsky et al., 2016). The Optotrak Certus system (Figure 2.3) has been tested extensively for both accuracy and repeatability, resulting in kinematics accurate to ± .1-degree rotation and .008 to .03mm in translation accuracy and high repeatability (Maletsky et al., 2016). Literature suggests that Optotrak is the premier active marker system, and has also undergone extensive complex navigation testing, proving to be most accurate when compared to similar systems such as those offered by Polaris (Rudolph et al., 2010).

\textsuperscript{1} AMTI VIVO Information Page (http://www.amti.biz/vivo.aspx)
Another important aspect in implant evaluation is the motion of the components relative to the bone during loading. Implant-tibial stability has been measured with linear variable differential transducers (LVDTs) (Bhimji and Meneghini, 2012). More recently, digital image correlation (DIC) has been used to measure implant micromotion. DIC is a non-contact stereo-camera system able to measure 3D micromotion and microstrain of biological tissue, providing information on both local and global strain fields at micrometer accuracy (Sutton et al., 2008). DIC has also been validated in correlation with inverse finite element models. DIC was used to characterize the 3D deformations of a gel tissue phantom, then compared to the deformations of a Neo-Hookean hyperplastic model. The model showed the ability to determine the bulk material properties of human soft tissue within 95% accuracy between computation simulation and in vivo testing (Moerman et al., 2009). This verification is important, as the validation of computational models is a vital aspect of in vitro testing.

Cementless Tibial Tray Loading and Micromotion Measurement Methodologies,

Findings and Limitations

The initial fixation and micromotion between implant and bone for cementless total hip and total knee replacement components is commonly examined in vitro, either in cadaveric bone or synthetic bone. While studies using cadaveric tibiae provide the most realistic fixation conditions, they often require an experienced orthopaedic surgeon to implant the component, and a range of implant sizes to insure proper cortical support across the specimen population (Chong et al., 2010). Synthetic biphasic models of the resected tibia (Figure 2.4) are common across published investigations of the cementless
implant-bone interface micromotion and subsidence studies. Synthetic bones can be customized to mimic human bone in a variety of diseased conditions, from healthy to severely osteoporotic (Yildirim et al., 2016). Synthetic bone models are useful for comparative studies between different designs and surgical preparations, due to the control of the material properties unavailable in cadaveric specimen. These bone constructs allow for the use of the implant specific preparation in the same way as is done in real bone, but with repeatable placement and implant sizing across all prepared specimen (Crook et al., 2017). Bhimji and Meneghini used Sawbone tibiae (Pacific Research, Vashon, Washington) to minimize variability within test groups (Bhimji and Meneghini, 2014, 2012). Across most of the literature reviewed, the bone models consisted of 40 pounds per cubic foot (pcf) foam to represent the cortical shell, and a lower density (12.5-pcf) foam to represent the cancellous bone. Both the density of the interior cancellous material, and the thickness of the cortical rim were selected based on guidance from a panel of orthopedic surgeons, deeming 12.5-pcf foam the best likeness to human cancellous bone (Bhimji and Meneghini 2012; Yildirim et al., 2016; Crook et al., 2017).

To access micromotion of the tray relative to the bone, a variety of measurement techniques and loading conditions are presented in the literature. The axial compressive force of the gait cycle was evaluated by Crook et al. through the loading of cemented and cementless tray implants in foam bones with the matching femoral component, such that the lateral-medial forces were near 30%-70% full load, respectively. Tray motion was captured via four LVDTs mounted to the anterior, posterior, medial and lateral
peripheries of the tray. These applied loads were axial and cycled from 20 to 2000 N at 1 Hz for 10,000 cycles, while taking measurements at the 1st, 5000th and 10000th cycles. There were significantly higher micromotions at all four locations when comparing the first cycle to the 5,000th, but minor differences from 5,000th to 10,000th. Results indicated negligible difference between cemented and cementless fixation due to the small micromotion magnitudes (<150 µm) for both tray types, but the anterior and medial regions of the tray appear most vulnerable to increased micromotions. While this study isolated potential significant regions for micromotion investigation, it was hindered by simplified axial loading of the implants (Crook et al., 2017).

Implanted cadaveric tibiae have been tested in 2100 N of pure compression by an accompanying femoral component that is unconstrained in adduction-abduction to equally distribute loads to the medial-lateral condyles (Chong et al., 2010). LVDTs were also used to measure relative motions of the tray at the anterior, medial and lateral regions. A three-dimensional finite element representation of the experiment had poor agreement with the experimental test due to variations between cadaveric specimen. Again, the greatest micromotions occurred at the anterior aspect of the tray and only axial loads were applied.

Prior investigations have determined that stair descending and ascending generate the highest knee forces, 346% BW and 316% BW, respectively (Kutzner et al., 2010). For that reason, Yildirim investigated the motions of uni-condylar knee replacements (URK) generated by 10,000 cycles of the compressive loads of the stair ascent activity scaled to 60% (the lower bound of the standard deviation found clinically). These loads
were applied to the implant via the accompanying femoral component axially pressing down on the implant and insert at a fixed flexion angle. The tibial construct (foam bone and tray) was coated with a random pattern of black and white dots to use digital image correlation (DIC) to track displacements between the tray-bone interface (Figure 2.5). A GOM ARAMIS stereo-camera system (GOM mbh, Braunshweig, DE) was used to track the micromotion of three points in the coronal, sagittal and axial axes. The results of this study were compared to historical data of successful cementless UKR to show equivalent or superior fixation, reporting that both designs experienced the greatest motions on the anterior aspect in the superior-inferior direction. The historically successful implant was not included in the experimental study, but rather just compared to published data, leaving room for differences in the testing protocols from each study, and only evaluating the fixation given axial loads from a single activity (Yildirim et al., 2016).

Bhimji and Meneghini’s investigations of tibial tray micromotion in keeled versus pegged fixation trays were among of the first to incorporate multi-axis loadings. First, implanted foam bone constructs were mounted into a testing rig in which axial compressive loads from 115 to 1,150 N were applied directly to the tray on the posterior third of the lateral and medial sides, neglecting the insert or femoral component, for 100 cycles each. Six LVDTs were mounted to four spheres attached to the anterior, posterior, medial and lateral peripheries of the tray to calculate peak to peak micromotion every 10th cycle. A loading profile simulating stair descent was then applied through the insert and femoral component. This loading profile consisted of a compressive load, anteroposterior load, and internal-external rotation torques through the cycle, while
leaving the adduction-abduction constraint free and locking the flexion angle at 72°. 10,000 cycles of this activity were run at 0.25 Hz, as this is the approximate amount of time estimated to allow initial fixation and bone ingrowth \textit{in vivo}. The LVDTs collected data every 1,000\textsuperscript{th} cycle and peak-to-peak motion was averaged across the final 9,000 cycles. The result from the two tests showed a far greater magnitude of micromotion in 5 of 6 locations for the stair descent activity compared to simple axial loading, especially anteriorly, suggesting that more complex loading condition led to greater tray motions. (Bhimji and Meneghini, 2012). This same method was used to evaluate the high shear forces at low compressive loads seen in gait, focusing on the deleterious nature of tray liftoff from the bone both anteriorly and posteriorly (Bhimji and Meneghini, 2014). Both of these studies demonstrate the need for more complex loading conditions, but still neglect the abduction-adduction moment at the knee.

Future studies of cementless tibial tray micromotion should implement key findings from previous investigations and improve upon their shortcomings. The most critical takeaway from the literature reviewed is the need for more clinically relevant loading conditions for different activities of daily living, incorporating loads in all 6-DoF. The importance of the Ad-Ab moment, as well as impacts of surgical alignment, particularly within the frontal plane, has been demonstrated and should be studied in future evaluations. Prior results indicate that the anterior aspect of the tibial tray is the most susceptible to micromotions, in the form of lift-off, thus this region should be the focus for peak tray-bone motion. DIC was shown to be a more robust and accurate method for measuring micromotion compared to LVDTs, which are hindered by the
effects of the offset between the device and baseplate. LVDTs are also unidirectional and only take a measurement on the exact location at which they are fixed to on the baseplate, where DIC takes full field measurements in 3-dimensions. Most studies neglected the femoral component and insert, but no studies included the effects of articular constraint on loading, which likely influences tray micromotions.

Figure 2.1: Porous Metallic Surface on Underside of Cementless Tibial Base Imaged Using Keyence VR White Light Microscope
Figure 2.2: AMTI VIVO 6 Degree of Freedom Robotic Joint Simulator

Figure 2.3: Optotrak Cetus and Infrared Rigid Body Markers
Figure 2.4: Biphasic Sawbones Resected Tibia, Pacific Research Labs, Part # 1522-912

Figure 2.5: GOM Aramis DIC Camera and Speckle Painted Foam Bone-Tray Construct
CHAPTER 3. CEMENTLESS TIBIAL BASE MICROMOTION DURING ACTIVITIES OF DAILY LIVING

3.1. Introduction

As manufacturing technology improves, cementless tibial baseplates are seeing a rise in popularity. Initial fixation of the tibial base to the host bone in cementless total knee arthroplasty (TKA) is critical to long-term bony ingrowth (Bragdon et al., 1996) and is influenced by the patient’s bone quality, surgical technique, baseplate fixation features, and loads applied to the tray via the articulating surfaces. *In vivo* studies in canines showed that micromotions as small as 20 µm would elicit bony ingrown into porous coated surfaces, but saw micromotions of 150 µm or more would be deleterious to fixation, leading to failure through the creation of fibrous tissue at the implant-bone interface (Jasty et al., 1997; Pilliar et al., 1986). Total knee and total hip replacement implant component micromotion relative to bone has been evaluated *in vitro* in cadaveric specimens (Enoksen et al., 2014; Kraemer et al., 1995), but synthetic bone structures are often used for comparative assessment to mitigate variability within cadaveric bones, which may confound the results (Bhimji and Meneghini, 2014, 2012; Crook et al., 2017; Geraldes et al., 2017; Yildirim et al., 2016).

Understanding how different activities of daily living generate tibial micromotion yields insight into surgical technique considerations, activity restrictions, and rehabilitation strategies during the intermediate post-operative period. Previous
experimental methods to assess tibial fixation utilized peak loads during gait (Chong et al., 2010) or a simplified combination of compression and anterior-posterior loading coupled with internal-external tibial torques applied to the tibial articulating surface to assess tibial micromotion for a stair descent cycle (Bhimji and Meneghini, 2014), but neglected the effects of femoral flexion-extension and adduction-abduction moments. Femoral flexion changes the conformity of the tibiofemoral articulation, altering the femoral condylar translation on the articulating surface. Furthermore, forces within the knee joint are sensitive to surgical variations in frontal plane alignment and the associated adduction moment (Kutzner et al., 2010), but it is unclear how other common activities of daily living (ADLs), like the gait or deep knee bending (DKB), affect implant micromotion.

The aim of this study was to characterize the relationship between loading during ADLs and tibial micromotion with contemporary total knee replacement (TKR) systems, while accounting for potential variability due to frontal plane alignment. Micromotion of the Attune (DePuy Synthes, Warsaw, IN) cementless fixed bearing tibial base prototype designs were characterized during ADLs and benchmarked against micromotion of commercially available cementless TKA designs. Micromotion was characterized under a variety of loading conditions, including stair descent, gait, and a deep knee bend, and under various levels of adduction moment and variation in frontal plane alignment. This experiment was used to validate a finite element model, capable of computationally simulating all 6 degrees-of-freedom (DoF) and directly measuring micromotions across the whole implant-bone interface (Navacchia et al., 2018).
3.2. Methods

**Implant Configurations**

Eight fixed-bearing cementless tibial base trays were evaluated in this study. Initially, a group of four prototype designs of the Attune cementless tray (D1, D2, D3, and D4) were evaluated, and based on their preliminary results, two additional Attune prototype iterations (D5 and D6) were assessed. Two commercially available designs: Zimmer NexGen Trabecular Metal fixed bearing tibial base (Zimmer Biomet, Warsaw, IN) and the Stryker Triathlon Tritanium fixed bearing tibial base (Stryker Corporation, Kalamazoo, MI), were also assessed for comparison. The Attune prototype designs were equivalent in size to the Attune size 5, and the tibial base sizes for the Triathlon and NexGen implant system that most closely aligned with the medial-lateral width of the Attune size 5 tibial base were selected (size 5 and size 4 for the Triathlon and NexGen tibial bases, respectively). Triathlon’s design included a large central keel with four spikes on the anterior-medial, anterior-lateral, posterior-medial, and posterior-lateral aspects of the tray. The underside of the tray, was a porous metallic matrix. The underside of the NexGen tibial base and the entirety of the fixation features have a rough metal texture. NexGen has two hexagonal pegs under the medial and lateral condyles, as well as a hemispherical dome on the anterior aspect of the tray. Attune designs D1-4 had a 3D titanium matrix underside but varied in their stem length, stem shape, and inclusion of keels. All four designs included four peripheral pegs to enhance fixation. Attune D5 and D6 represented a progression towards a final implant design. D5 incorporated an intermediate length cruciform stem without a keel structure and D6 was comprised of the
same stem design, but with a modified peg design that incorporated a scalloped feature to ease implantation. The configuration of each tibial base design is shown in Table 3.1 and Figure 3.1. Three samples (n=3) of each design were evaluated with their respective cruciate-retaining tibial insert and femur. The Attune prototype design D6 was also evaluated with an Attune posterior stabilized femur and insert in addition to the cruciate retaining configuration.

Foam bones representing the proximal tibia (Sawbones, Pacific Research Labs, Part # 1522-912) were prepared using the implant specific tibial preparation instrumentation for each implant construct. The synthetic foam bone tibiae used a 12.5 pound/cubic foot (pcf) density polyurethane foam core, representing the cancellous bone, inside of a 50 pcf solid cortical shell. This simulated resected tibia is commercially-available for fixation studies and is consistent with those used in previous estimations of tray-bone micromotion (Bhimji and Meneghini, 2014, 2012; Yildirim et al., 2016). Placement of the tray was prescribed using a custom guide that fit over the periphery of the foam bone with an internal template that guided the position of the tibial base relative to the bone to reduce variations in implantation. After preparation of the foam bone, each tibial base was press fit into the foam bone using either a hydraulic press or an Instron 5982 Dual Column Screw Frame driven at a displacement rate of 3mm/min. Force-displacement curves were recorded during the implantation.
Loading Conditions

Loading conditions representing variations of gait, stair descent (SD), and deep knee bending (DKB) were derived from a combination of published Orthoload database telemetric TKA implant data and Attune-specific loadings produced by previous finite element models of the lower limb. The knee loading data contained in the Orthoload database was compiled into ASTM standard F3141-15, which included knee flexion (F-E), Internal-External (I-E) moment, Medial-Lateral (M-L) force, Anterior-Posterior (A-P) force, and Superior-Inferior (S-I) force profiles for both gait and stair descent activities (Van Valkenburg et al., 2016). ASTM F3141-15 does not include Adduction-Abduction (Ad-Ab) moments, nor the 6 degree-of-freedom loads at the knee during a deep knee bending activity. To supplement the standard, all gait, stair descent, and deep knee bending loading data and videos were downloaded from the Orthoload dataset for patients K1L, K2L, K3R, K4R, and K5R. These are the same subjects used by Van Valkenberg, as the group adequately captured the variability of the dataset. The approximate knee flexion angle was extracted from the activity videos by calculating the angles between lines connecting the hip and knee and the knee and ankle in the sagittal plane and synchronized with the reported loading data.

For the gait and stair descent activity cycles, each load measurement sequence for each patient was manually parsed to determine the individual cycle by identifying heel strike and toe-off events in the knee compressive load profile. The time-based length of each cycle was normalized to % cycle and the average loading across all cycles for each individual patient were calculated for both gait and stair descent. Subsequently, the
average and standard deviation of the average loading profiles across all five patients were calculated. These average Ad-Ab moment profiles (Figure 3.2) were used in conjunction with the loading profiles for gait and stair descent in ASTM F3141 to form the “Orthoload – Neutral” loading conditions. “Orthoload – Adduction” and “Orthoload – Abduction” profiles were generated in the same form, by either adding or subtracting one standard deviation of the Ad-Ab loading profile to the average profile from the Neutral condition (Figure 3.3). To enable compatibility of the stair descent profiles with the mechanical constraints of the test setup, the maximum flexion angles of the profiles were truncated from 100° to 75° knee flexion.

An analogous method was used to compile the deep knee bending load profiles. Each trial for each patient was parsed based on knee flexion angle and the length of the cycle was normalized so that the first 50% of the cycle was knee flexion while the final 50% of the cycle was knee extension. Average loading was calculated across all trials for each patient, then the average and standard deviations were calculated across all five patients (Figure 3.4). The average knee flexion, Ad-Ab moment, I-E moment, M-L force, A-P force, and S-I force were compiled to form the “Orthoload – Neutral” DKB load profile. “Orthoload – Adduction” and “Orthoload – Abduction” profiles were generated in the same form, but by either adding or subtracting one standard deviation of the Ad-Ab loading profile to the average profile from the Neutral condition. Likewise, “Orthoload – Anterior” and “Orthoload – Posterior” profiles were generated by either adding or subtracting one standard deviation of the A-P loading profile to the average profile from the Neutral condition. This was done to capture variability in posterior
cruciate ligament tension and posterior tibial slope on A-P loading. Because the “Orthoload – Posterior” profile was observed to cause posterior dislocation of the femur in low-conformity designs (e.g. Triathlon), two additional variations of the load profile were created by adding 0.5 and 0.75 times the AP standard deviation to the average profile, “Orthoload – 50% Posterior” and “Orthoload – 75% Posterior” respectively. To enable compatibility of the DKB flexion profile with the mechanical constraints of the test setup, the maximum extension angles of the profiles were truncated from 15° to 40° knee extension.

Attune specific boundary conditions for gait, stair descent, and deep knee bending were developed based on the contact mechanics of the Attune Fixed-Bearing Cruciate Retaining knee system implanted into a previously established dynamic finite element model of the lower limb while performing these activities (Fitzpatrick et al., 2016). This computational model is limited to the stance phase of activities, so a transition phase of the cycle was added which included a parabolic ramp for each load profile connecting the load at the end of stance phase to the load at the beginning of stance phase. Like the “Orthoload – Posterior” DKB profile, the Attune CR DKB profile cause posterior subluxation of the femur in low conforming designs. Thus, scaled version of the Attune CR DKB were created which applied 0.5 and 0.75 times the posterior loading to the tibia. Similarly, an Attune Cruciate Substituting (CS) profile was created which simulated a resected PCL (Figure 3.5). The variations of each activity and associated naming convention can be seen in Table 3.2.
**Mechanical Testing**

In preparation for micromotion measurement during mechanical testing, a single coat of white acrylic paint was applied to the anterior face of the implanted tibial constructs (tray and foam bone). A random speckle pattern was applied to the construct by misting black acrylic paint over the surface. Target stickers were applied on the anterior-medial, center, and anterior-lateral aspects of the tibial base tray surface just above the implant-bone interface. Corresponding targets were placed directly below the tibial base markers on the cortical face of the foam bone. The anterior side of the tray-bone interface was the focus of the analysis due to the susceptibility of tray liftoff and high micromotions observed in previous studies (Crook et al., 2017; Yildirim et al., 2016).

Each implant construct, including the implanted tibial base and foam bone, the articulating insert, and the femoral components were mounted into the AMTI VIVO simulator (AMTI, Waterton, MA), where the previously described loading conditions were applied (Figure 3.6). Femoral mounting blocks were rapid prototyped to position the axis of rotation for each femoral component consistently across knee systems (Figure 3.7). Infrared emitting diode arrays were mounted to the tibia fixture, ab-ad arm, flexion arm and bench top, and the location of the implanted components were digitized relative to their respective rigid body arrays using an infrared stylus (Optotrack Certus, NDI, Ontario, Canada). The three-dimensional location of these arrays were tracked through the loading activities, capturing the relative position of the femur on the tibia. The rigid body transformations between the tibia and femur were resolved into Grood and Suntay
(Grood and Suntay, 1983) kinematics and femoral lowest-point kinematics using custom Matlab scripts.

To ensure consistent application of loading cycles and an overall duty cycle for the construct, 50 cycles of each activity were performed. On the fortieth cycle, a GOM Aramis (GOM, Braunschweig, DE) digital image correlation camera system was used to capture strain on the surface of the tibial foam bone and micromotion between the tibial base and foam bone at a rate of 20 Hz synchronized with the tibiofemoral kinematic measurements via an external trigger.

The DIC images were post-processed to extract the relative distance of the lateral, central, and medial pairs of tracking targets. To estimate the micromotion between the tibial base and tibial bone, the minimum distance between the corresponding targets were subtracted from the maximum distance between the targets over the course of a cycle (Figure 3.8). This difference was averaged across all three target sets (lateral, central, and medial) to determine a composite average micromotion for each specimen and activity, and then averaged across groups of specimens with the same implant construct.

A-P and I-E tibiofemoral articular constraints for each implant were quantified through laxity assessments specified by ASTM F1223. A-P laxity was measured over the range of anterior (+) and posterior (-) translations (mm) between the maximum articular constraint force prior to subluxation. Similarly, I-E laxity was measured over the range of internal (+) and external (-) rotations (degrees) between the maximum articular constraint torques prior to subluxations. Laxity ranges for each design were obtained manually at 60° knee flexion, the midpoint of the flexion angles tested. Sinusoidal loading profiles
were created which oscillated across the A-P and I-E ranges, respectively, under 200 N of compressive load. M-L motion was free to maintain 0-N of force, while the other degrees of freedom were fixed in displacement. Laxity was assessed from 0° to 40° flexion in 5° increments, 50° to 90° flexion in 10° increments, and finally at 120° of flexion.

3.3. Results

Implantation Results

Peak implantation forces, the slope of the force displacement curve during final seating of the implant, and the full force displacement curves for each tibial construct are available in Figures 3.9 and 3.10. There were minimal differences in the peak implantation forces between the various Attune designs (D1-D6), and the force required to advance the tray into the foam bone increased as the tray approached the fully seated position, with the peak load occurring at final seating. The average peak press in forces for designs D1-D6 are 3080-N, 2540-N, 4060-N, 3720-N, 3140-N, and 3430-N, respectively. The Triathlon design had a similar peak implantation force to the Attune designs at 2850-N, which also occurred at final seating, but the Triathlon tray advanced with less force (lower slope of the force displacement curve) until the peripheral pegs engaged just prior to full seating. Triathlon’s pegs were designed with a significant level of press-fit that led to a dramatic increase in the slope of the force displacement curve over the last few millimeters of seating. Unlike the other designs, the NexGen design required a relatively low and constant force of ~500-N to advance the tray to final seating. Multiple methods (hydraulic press, load-controlled Instron, displacement-controlled Instron) were used to press in the trays as experimental protocols evolved.
through the course of the study, making distinct claims about relative implantation forces of different designs inconclusive.

*Implant Articular Constraint*

The excursion ranges were manually determined to be ±13 mm A-P translation and ±20° I-E rotation for Attune. For NexGen and Triathlon, which have a more drastic change in conformity through the range of flexion, ±10 mm A-P was used for flexion angles 0° to 25°, and +10/-20 mm for flexion angles 30° and greater. ±25° I-E rotation was used to assess I-E laxity for both NexGen and Triathlon. The A-P and I-E laxity curves for each of the implants are displayed in Figure 3.11 and 3.12 respectively. Attune had the highest articular constraint, 32% higher and 15% lower anteriorly and posteriorly, and 60% higher and 11% lower for interior and external rotations compared to NexGen at a flexion angle of 60°. Attune was 79% and 39% higher anteriorly and posteriorly, and 57% and 14% higher for interior and external rotations compared to Triathlon at 60°. The A-P and I-E articular conformity as a function of increasing flexion for all designs as can be seen in Figures 3.13 and 3.14.

*Loading, Kinematics and Micromotion during the Orthoload Gait Simulations*

The Orthoload Neutral Gait cycle applied a two-peaked compressive load during stance phase (~2,200-N and ~2,600-N) coupled with a 21-N-m adduction moment and oscillating I-E torque. During swing phase, the compressive load dropped to 200-N with minimal adduction or internal moments applied. In addition, a posteriorly directed 213-N load was applied over the first 15% of the cycle, which shifted to a 77-N anterior load
over the remainder of the stance phase of gait (15% - 60% of the entire cycle) and was minimal during swing phase.

The kinematic response of the three knee systems tested (Attune, Triathlon, and NexGen) exhibited consistent motion patterns resulting from the gait loading profile (Figure 3.15). In general, the medial and lateral condyles initially translated posteriorly at heel strike, followed by an anterior slide, particularly on the medial condyle, that continued through toe-off. This anterior slide of the medial condyle was largest for Triathlon at ~10-mm compared to ~8-mm for NexGen and ~5-mm for Attune. The differences in the magnitude of the anterior slide are due to the significant differences in the A-P constraint provided in the articular surfaces of the three designs, with the Attune providing the highest level of constraint and Triathlon the lowest.

The initial posterior translation of the condyles coupled with the increase in compressive load at heel strike led to a lengthening between the lateral, central, and medial markers as the anterior aspect of the tray decompressed (Figure 3.16). When the medial condyle slid forward during mid and terminal stance phase, the anterior aspect of the tray was once again compressed against the bone. As the compressive load was relieved during swing phase, the anterior aspect of the tray decompressed, primarily on the medial side, prior to the subsequent heel strike. In general, the maximum distances between the tray and bone occurred during either the middle of stance phase or the middle of swing phase, while the minimum distance occurred during the heel strike and...
toe-off. Visualization of the posterior-anterior femoral location and resulting micromotions during neutral gait cycle for each designs can be seen in Figure 3.17.

The Adduction and Abduction variations of Orthoload Gait cycles caused minimal changes in the observed micromotion for Attune when compared to the neutral cycle, but the increase in adduction moment (reduced lateral plateau loading) caused increased opening on the lateral and central aspects of the tray for the Triathlon design, again likely due to the lower conformity.

**Loading, Kinematics and Micromotion during the Orthoload Stair Descent Simulations**

The Orthoload Neutral Stair Descent cycle applied a two-peaked compressive load during stance phase (~3,100-N and ~3,300-N) coupled with a 19 N-m adduction moment and 8 N-m internal torque. A posteriorly directed 227-N load was applied at heel strike that transitioned to a 106-N anteriorly directed load by toe-off. All three knee systems exhibited a corresponding posterior condylar translation at heel-strike followed by an anterior sliding of both condyles through toe-off (Figure 3.18). Like in the gait simulations, the anterior slide was largest for Triathlon and lowest for Attune.

The posterior translation of the condyles coupled with the large compressive load at heel-strike led to a lengthening between the lateral, central, and medial markers as the anterior aspect of the tray decompressed (Figure 3.19). The elongation was most dramatic for Triathlon, which also had the highest amount of posterior slide at heel strike. As the condyles slid forward during stance phase, the anterior aspect of the tray
compressed through toe-off, then decompressed once again during swing phase. In general, the maximum gapping between the tray and bone occurred during heel strike (or in some cases during swing phase), while the minimum distance occurred during toe-off. The stair descent cycles with increased adduction and abduction moments had minimal effects on the observed kinematics or micromotion across all designs. Visualization of the posterior-anterior femoral location and resulting micromotions during the neutral stair descent cycle for each designs can be seen in Figure 3.20.

*Loading, Kinematics and Micromotion during the Orthoload Deep Knee Bend Simulations*

The Orthoload Neutral DKB applied a compressive load (~2000-N) and a minimal A-P load, coupled with abduction (~12.5 N-m) and internal (~3.7 N-m) moments with increasing flexion. The load combination in flexion led to rollback of the lateral condyle with minimal anterior translation of the medial condyle (Figure 3.21). The motion pattern reversed with knee extension, whereby the lateral condyle translated anteriorly, although remaining posterior relative to the medial condyle throughout the entire deep knee bend cycle. The Orthoload DKB profiles with a small anterior load (~111-N) or posterior load (~195-N) caused significant A-P shifts in the condylar positions throughout the cycle. The posterior shift of both condyles from the anteriorly to posteriorly loaded cycles were between 5 and 10-mm for all three designs.

All designs showed a closing of the lateral side of the tray with increasing flexion, coupled with less closing centrally and minimal motion medially as the compressive load
ramped up with flexion in the neutral DKB cycle (Figure 3.22). The maximum distances between the lateral, central, and medial markers occurred in extension, with the minimum distance occurring in flexion under maximum compression and adduction moments as the knee began to extend. Increasing the anterior force applied during the DKB increased the amount of compression, or closing of the gap, that occurred across the entire anterior aspect of the tray. Shifting the forces posterior led to a lengthening of the distance between the markers indicating a decompression along the anterior aspect of the tray. In a similar fashion, increased adduction moments applied in the “Orthoload adduction” cycle had more closing laterally and centrally than the “neutral” or “abduction” cycles (Figure 3.23).

These results seem to indicate that the DKB boundary conditions caused a teetering effect on the motion of the tray relative to the bone, whereby the increasing compressive load caused the entire tray to compress against the bone, but moving the contact point posteriorly caused the anterior aspect of the tray to compress less, or even decompress, in some loading conditions. This is supported by the observations that a more posterior application of the compressive load in the “Orthoload Posterior DKB” cycle minimized the closing that occurred on the anterior aspect of the tray with flexion and that the increased abduction moment (increased loading of the lateral condyle) caused less closing of the lateral plateau. Despite their differences in conformity and the resulting condylar translations, all designs demonstrated a similar motion pattern with increasing posterior and abduction loading during the various Orthoload DKB
simulations. Visualization of the femoral location and resulting micromotions for anterior and posterior deep knee bending cycles for each designs can be seen in Figure 3.24.

It should be noted that ‘adduction’ variations of gait and stair descent caused lateral subluxation of NexGen, while ‘posterior’ deep knee bending caused subluxation of Triathlon. Neither of the two performed the Attune specific cruciate retaining deep knee bending activity. This is likely due to the lesser constraints of the tibial inserts.

**Effects of Fixation Features on Micromotion**

The range of micromotion (maximum distance minus minimum distance for marker pairs) on the lateral, central, and medial aspects of the tray averaged across three specimens tested for each Attune prototype design are shown in Figure 3.25 during the Attune-specific Gait, Stair Descent, and DKB (CR and CS) activities. In addition, a composite micromotion, which is the average of the range of micromotions on the lateral, central, and medial aspects of the tray, are also reported.

The largest composite micro-motions occurred during the stair-descent and gait cycles, followed by the CR and CS DKB cycles. Design 1 consistently exhibited the highest levels of micromotion, followed by designs 3 and 4 (the designs with the shortest stem lengths). The smallest micromotions were exhibited by designs 2, 5, and 6, which all had a medium or long length cruciform shaped keel. A slight increase in micromotion was noted from D5 to D6 despite minimal changes to the implant geometry. The slight increase was likely due to a change in tibial prep that occurred between the design iterations.
Attune Design 6 was deemed the best design and as a result was tested with both a CR and a posterior-stabilized (PS) tibial insert. The PS insert elicited higher composite micromotions for the gait and CS DKB activities while the CR insert elicited higher micromotions for the stair descent and CR DKB activities.

Comparison with Contemporary Designs

The range of micromotion (maximum distance minus minimum distance) for marker pairs on the lateral, central, and medial aspects of the tray averaged across the three specimens tested for Attune D6, Triathlon, and NexGen are shown in Figure 3.26 during the Neutral Orthoload gait, stair descent, and deep knee bend activities. The composite micromotion, which is the average of the range of micromotions on the lateral, central, and medial aspects of the tray, are also reported.

During gait, Triathlon exhibited the highest micromotions on the lateral and central aspects of the tray leading to the highest composite micromotion, while the Attune D6 design exhibited the lowest micromotions on the lateral and central aspects of the tray, leading to the lowest composite micromotion. During stair descent, Triathlon had the highest micromotions on the lateral and central aspects of the tray leading to the highest composite micromotion. The NexGen tray exhibited the lowest micromotions centrally and medially leading to the lowest composite micromotion. During the neutral DKB, Attune D6 had the highest micromotions on the lateral and central aspects of the tray leading to the highest composite micromotion. However, the overall micromotions during the DKB were much smaller those observed during gait and stair descent.
Full micromotions for the lateral, central, and medial aspects of each tray for each loading condition performed can be found in Appendix 3A, 3B, and 3C, along with a table reporting the range of micromotions reported in the figures referenced above (Appendix 3D). A comprehensive table of the tested specimens, including which specimens failed to run or experienced errors during the experiment are available in Appendix 3E. Appendix 3F denotes all of the designs with statistical differences for each activity.

3.4. Discussion

Micromotions across the anterior aspect of six different Attune prototype trays and two contemporary designs were evaluated under various activities of daily living, including gait, stair descent, and deep knee bending. In general, the observed micromotions of the trays relative to the simulated bones were consistent with the applied loading conditions and resulting implant kinematics. The results demonstrated that the implant micromotion is sensitive to both the configuration of the fixation features and the loading transferred to the interface by the conformity of the articulating surfaces.

Based on the Attune designs, the results seem to indicate that a longer central stem reduces the amount of micromotion during activities of daily living. However, there is a ceiling affect, as both medium and long central stems provide a similar benefit to reducing micromotion. It is more difficult to draw specific conclusions about how the fixation features on Triathlon and NexGen affect the micromotion relative to the Attune designs, as the results are confounded by corresponding changes in the level of articular constraint. The Triathlon design has a very flat polyethylene insert, while the NexGen is
slightly more conforming, with the Attune insert providing the highest conformity and thus, stability. As a result, the condylar translations of the femur on the insert are different for each configuration. The results suggest that the flexion moment applied to the tray, imparted by a large compressive load applied posteriorly on the tibial insert, tends to open the gap on the anterior aspect of the tray. Lower conformity designs like Triathlon allow for increased rollback under posterior loads, but also allow greater anterior condylar translations as the AP loading fluctuates during the stance phase of activities. These greater oscillations in condylar AP position lead to a fluctuation in the flexion movement applied to the tray, and thus increase the observed micromotions.

These results demonstrate that increased tibial base micromotions are primarily correlated with large A-P translations of the femoral condyles coupled with high compressive loads, but not with increased ad-ab moments. This indicates that initial tibial fixation may be robust to variations in the frontal plane alignment of knee implants. Micromotions were markedly higher during both gait and stair descent than during DKB, potentially indicating that DKB would not be deleterious to tibial initial fixation. Future studies may consider using a consistent articular surface to better isolate the effects of the fixation features on observed micromotions. In addition, the influence of the articular mechanics should be included when comparing multiple competitive implant geometries.

It should be noted when evaluating the results that while the distance between corresponding marker sets on the tray and bone is taken to be the micromotion between the tray and bone, the change in distance is truly a combination of both deformation of cancellous bone underlying the tray and the motion of the tray relative to the bone.
Delineation of true micromotion at the interface of the implant and bone cannot be directly determined from the experimental measurements taken in this study, but given that all trays were placed in a consistent location in the foam bone and that the foam bones tested had uniform mechanical properties, it is reasonable that the change in distance between markers is indicative of the micromotion taking place at the implant-bone interface. Simultaneously, a finite element representation of the experiment, capable of accurately predicting the true micromotion at the implant bone interface, was developed and verified (Navacchia et al, 2018).

This study had several limitations. The distance between corresponding target marker pairs was normalized relative to the start of the measurement cycle. This has the benefit of normalizing the micromotion across the various designs using a common loading condition but doesn’t elucidate how the relative distance between the corresponding markers has changed relative to the unloaded state. As a result, it is difficult to say whether the anterior aspect of the tray ever goes from compressive loading to tensile loading, which would be deleterious to implant fixation. Future experiments will reference the distance between corresponding markers to an unloaded frame taken at the beginning of the experiment. The computational representation of this experiment addresses this limitation by predicting the contact pressure at the implant-bone interface. Additionally, fifty cycles of each activity were simulated and data was collected on the fortieth, where similar investigations ran 10,000 cycles (Bhimji and Meneghini, 2014, 2012; Crook et al., 2017; Yildirim et al., 2016), and increased micromotions were seen to be higher at cycle 5,000 compared to those seen at the first cycle (Crook et al., 2017).
Due to the number of activities performed, and the interest in relative micromotion across designs and activities, less cycles were justified for this study. It is also unknown whether increased motion at higher cycles is indicative of in vivo results, or if it is rather a measure of the degradation of the foam as it fatigues. Finally, while this experimental method incorporates loading in all 6 DoF, it still represents a simplified loading scenario of actual joint loading through the simulation of soft tissue and muscle forces. The experimental setup does not allow for full joint simulation, only tibiofemoral, as it uses the proximal tibia and only the articular surface of the femur, neglecting the patella due to constraints of the VIVO. This limitation manifests in the different conformities of the implants, as the same loads are applied to each implant neglecting the fact that more conforming inserts will have likely higher A-P and I-E loading. By incorporating a full knee with soft tissue structures which restrain motion, a more realistic comparison could be made between different implants. Subsequent testing should include the addition of a quadriceps muscle force applied to the patellar tendon, and soft tissue structures through the inclusion of the distal femur and patella to better assess both native and implanted knee joint mechanics.
Figure 3.1: Tibial Base Tray Geometries for Attune D1-D6, Triathlon and NexGen
Table 3.1: Tibial Base Tray Geometric Detail Description

<table>
<thead>
<tr>
<th>Tibial Base Design</th>
<th>Stem Length</th>
<th>Stem Shape</th>
<th>Extended ML Keels</th>
<th>Pegs</th>
<th>Number of samples</th>
</tr>
</thead>
<tbody>
<tr>
<td>D1</td>
<td>Long</td>
<td>Cone</td>
<td>Keels</td>
<td>Standard</td>
<td>3</td>
</tr>
<tr>
<td>D2</td>
<td>Long</td>
<td>Cruciform</td>
<td>No Keels</td>
<td>Standard</td>
<td>3</td>
</tr>
<tr>
<td>D3</td>
<td>Regular</td>
<td>Cruciform</td>
<td>Keels</td>
<td>Standard</td>
<td>3</td>
</tr>
<tr>
<td>D4</td>
<td>Regular</td>
<td>Cone</td>
<td>No Keels</td>
<td>Standard</td>
<td>3</td>
</tr>
<tr>
<td>D5</td>
<td>Intermediate</td>
<td>Cruciform</td>
<td>No Keels</td>
<td>Standard</td>
<td>3</td>
</tr>
<tr>
<td>D6</td>
<td>Intermediate</td>
<td>Cruciform</td>
<td>No Keels</td>
<td>Scalloped</td>
<td>3</td>
</tr>
<tr>
<td>Triathlon</td>
<td>None</td>
<td>None</td>
<td>Keels</td>
<td>4 Peripheral Cruciform</td>
<td>3</td>
</tr>
<tr>
<td>NexGen</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>2 Posterior, 1 Anterior</td>
<td>3</td>
</tr>
</tbody>
</table>

Figure 3.2: Adduction and Abduction profiles for gait (left) and SD (right) extracted from Orthoload database. Black lines represent average of averaged patients, ± 1 STD
Figure 3.3: A-P, S-I, Ad-Ab and I-E load profiles for gait (top), SD (middle) and DKB (Bottom) based on ASTM F3141 supplemented with extracted Orthoload data
Figure 3.4: Flexion and load profiles for DKB extracted from Orthoload database. Black lines represent average of averaged patients, ± 1 STD
Figure 3.5: A-P, Ad-Ab and I-E load profiles for gait (top), SD (middle) and DKB (Bottom) based on Attune specific loading derived from computational simulation of the lower limb
Table 3.2 Loading Conditions Applied to Each Tibial Base

<table>
<thead>
<tr>
<th>Activity</th>
<th>Variation</th>
<th>Naming Convention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gait Cycles</td>
<td>Orthload - Neutral</td>
<td>GTON</td>
</tr>
<tr>
<td></td>
<td>Orthload - Adduction</td>
<td>GTOAD</td>
</tr>
<tr>
<td></td>
<td>Orthload - Abduction</td>
<td>GTOAB</td>
</tr>
<tr>
<td></td>
<td>Attune CR Specific</td>
<td>GTATTCR</td>
</tr>
<tr>
<td>Stair Descent Cycles</td>
<td>Orthload - Neutral</td>
<td>SDON</td>
</tr>
<tr>
<td></td>
<td>Orthload - Adduction</td>
<td>SDOAD</td>
</tr>
<tr>
<td></td>
<td>Orthload - Abduction</td>
<td>SDOAB</td>
</tr>
<tr>
<td></td>
<td>Attune CR Specific</td>
<td>SDATTCR</td>
</tr>
<tr>
<td>Deep Knee Bending Cycles</td>
<td>Orthload - Neutral</td>
<td>DKBON</td>
</tr>
<tr>
<td></td>
<td>Orthload - Adduction</td>
<td>DKBOAD</td>
</tr>
<tr>
<td></td>
<td>Orthload - Abduction</td>
<td>DKBOAB</td>
</tr>
<tr>
<td></td>
<td>Orthload - Anterior</td>
<td>DKBOAN</td>
</tr>
<tr>
<td></td>
<td>Orthload - 50% Posterior</td>
<td>DKBOPO50</td>
</tr>
<tr>
<td></td>
<td>Orthload - 75% Posterior</td>
<td>DKBOPO75</td>
</tr>
<tr>
<td></td>
<td>Orthload Posterior</td>
<td>DKBOPO</td>
</tr>
<tr>
<td></td>
<td>Attune CS Specific</td>
<td>DKBATTCS</td>
</tr>
<tr>
<td></td>
<td>Attune CR Specific</td>
<td>DKBATTTCR</td>
</tr>
<tr>
<td></td>
<td>Attune CR Specific - 50% Posterior</td>
<td>DKBATTTCR50</td>
</tr>
<tr>
<td></td>
<td>Attune CR Specific - 75% Posterior</td>
<td>DKBATTTCR75</td>
</tr>
</tbody>
</table>

Figure 3.6: AMTI VIVO joint simulator with implanted tibial foam bone construct. The DIC cameras (foreground) were used to track implant micromotion using matched pairs of targets affixed to the anterior face of the bone and tray.
Figure 3.7: The orientation of the various femoral components relative to the flexion axis of the femoral shaft on the VIVO simulator. Alignment was obtained via rapid prototype alignment ‘boxes’

Figure 3.8: The minimum distance between adjacent targets was subtracted from the maximum distance between adjacent targets to calculate a relative micromotion for the lateral, central, and medial aspects of the tibial base. The lateral, central, and medial micromotions were then averaged to determine an overall micromotion for the cycle.
Figure 3.9: Peak loads applied during implantation of each tibial base designs (left) and the amount of force required per 1-mm of tibial base advancement into the tibial bone as the base approached the tibial plateau (Phase II Slope, right)

Figure 3.10: Force Displacement Curves of Implantation for each Design
Figure 3.11: Anterior Posterior Translation Laxity Constraint Curves for Attune D6, Triathlon and NexGen

Figure 3.12: Internal External Rotation Laxity Constraint Curves for Attune D6, Triathlon and NexGen
Figure 3.13: A-P Laxity Change as a Function of Flexion

Figure 3.14: I-E Laxity Change as a Function of Flexion
Figure 3.15: Condylar low-point A-P Kinematics of the lateral (left) and medial (right) condyles during Orthoload Gait Activities for Attune D6 (top), Triathlon (middle) and NexGen (bottom)
Figure 3.16: Lateral (left), central (middle), and medial (right) micromotion of the tray relative to the bone over the course of the Orthoload gait activities. Top row overlays the neutral gait cycles for Attune D6, Triathlon, and NexGen
Figure 3.17: Visualization of the posterior-anterior femoral location and resulting micromotions during neutral gait cycle for Attune D6 (top), Triathlon (middle) and NexGen (bottom)
Figure 3.18: Condylar Low-point A-P kinematics of the lateral (left) and medial (right) condyles during the Orthoload Stair Descent activities, for Attune D6 (top), Triathlon (middle) and NexGen (bottom)
Figure 3.19: Lateral (left), central (middle), and medial (right) micromotion of the tray relative to the bone over the course of the Orthoload stair descent activities. The top row overlays the neutral cycles for Attune D6, Triathlon, and NexGen, while rows 2-4 show the effect of abduction and adduction on the observed micromotion for each tray design.
Figure 3.20: Visualization of the posterior-anterior femoral location and resulting micromotions during neutral stair descent cycle for Attune D6 (top), Triathlon (middle) and NexGen (bottom)
Figure 3.21: Condylar Low-point A-P kinematics of the lateral (left) and medial (right) condyles during the Orthoload DKB activities with A-P offset loading, for Attune D6 (top), Triathlon (middle), and NexGen (bottom)
Figure 3.22: Lateral (left), central (middle), and medial (right) micromotion of the tray relative to the bone over the course of the Orthoload DKB activities with A-P offset loading. The top row overlays the neutral cycles for Attune D6, Triathlon, and NexGen, while rows 2-4 show the effect of anterior and posterior loading on the observed micromotion for each tray design.
Figure 3.23: Lateral (left), central (middle), and medial (right) micromotion of the tray relative to the bone over the course of the Orthoload DKB activities with Ad-Ab loading. The top row overlays the neutral cycles for Attune D6, Triathlon, and NexGen, while rows 2-4 show the effect of adduction and abduction on the observed micromotion for each tray design.
Figure 3.24: Visualization of the posterior-anterior femoral location and resulting micromotions during posterior DKB and Anterior DKB cycles for Attune D6 (top), Triathlon (middle) and NexGen (bottom)
Figure 3.25: Range of micromotion (maximum distance minus minimum distance) for marker pairs on the lateral, central, and medial aspects of the tray averaged across the three specimens tested for Attune D1-D6 during the Attune specific gait, stair descent, and deep knee bend activities. The composite micromotion represents the average of the range of micromotions on the lateral, central, and medial aspects of the tray.
Figure 3.26: The range of micromotion (maximum distance minus minimum distance) for marker pairs on the lateral, central, and medial aspects of the tray averaged across the three specimens tested for Attune D6, Triathlon, and NexGen during the Neutral Orthoload gait, stair descent, and deep knee bend activities. The composite micromotion represents the average of the range of micromotions on the lateral, central, and medial aspects of the tray.
CHAPTER 4. IMPROVED EXPERIMENTAL METHODS IN MUSCLE DRIVEN KNEE JOINT MECHANICS

4.1. Relevance and Justification

Motivation

Osteoarthritis (OA) is the leading cause of disability in the United States\(^2\), and is estimated to cost our economy more than $128 billion dollars annually by 2040\(^3\). Orthopedic surgeons and medical device companies are working to improve clinical outcomes for patients who suffer from OA, but extensive evaluation of new devices is necessary to bring innovation to the market. The need for multi-axis testing has increased in attempts to recreate more anatomically correct loading conditions, as a single-axis loading is too drastic of a simplification and does not capture loading \textit{in vivo}. \textit{In vivo} kinematics of the knee are characterized by 6 degrees-of-freedom (DoF), thus multi-axis \textit{in vitro} testing is required for more accurate and realistic results. While advanced loading rigs are a start, there is a need for muscle force simulation to better evaluate whole joint mechanics. The addition of a quadriceps muscle force to a 6 DoF machine such as the

\(^2\) National and state medical expenditures and lost earnings attributable to arthritis and other rheumatic conditions--United States, 2003

\(^3\) Hootman et al. Updated Projected Prevalence of Self-Reported Doctor-Diagnosed Arthritis and Arthritis-Attributable Activity Limitation Among US Adults , 2015 – 2040
AMTI VIVO (AMTI, Watertown, MA) will narrow the gap between in vivo and in vitro testing.

**Introduction**

Realistic multi-axis loading representing activities of daily living is critical to better assess the mechanics of healthy knees and total knee replacements (TKR). In vitro experiments and computational models that apply realistic multi-axis loads to the joint can provide insight into tibiofemoral (TF), patellofemoral (PF), and soft tissue mechanics. Previous experimental methods to assess total knee joint mechanics, like the Oxford knee simulator, have been limited to simplified boundary conditions that are not representative of the actual loading at the knee (Ali et al., 2017). The specific aim of this study is to develop a multi-axis in vitro test using the AMTI VIVO knee simulator that includes a supplemental quadriceps actuator to allow simultaneous simulation of TF, PF, and soft tissue mechanics in healthy and implanted knees under realistic quadriceps loads. The hypothesis of this study is that this experiment and associated validated finite element model can be used to derive multi-axis, activity-specific contact loads and quadriceps forces that can be applied in the VIVO.

**Methods**

Loading conditions representing variations of gait, stair descent, and deep knee bend (DKB) have previously been derived from ASTM standard F3141-17, which specifies knee force profiles in five degrees of freedom (flexion-extension, internal-external moment, and medio-lateral, antero-posterior, and superior-inferior) for gait and
stair descent based on the Orthoload database (Van Valkenburg et al., 2016). In addition, adduction-abduction (Ad-Ab) moment profiles for gait and stair descent were extracted from the Orthoload database along with loading conditions for a DKB activity to develop a full suite of 6-DoF loading during these activities of daily living.

Fixturing to attach a supplemental linear actuator to the femoral fixture of the VIVO has been designed and fabricated for applying loads to the knee through the quadriceps tendon (Figure 4.1). A PID control system has been proposed which will operate via the Optotrack Certus camera system and Application Programmer’s Interface (NDI, Ontario, Canada) to apply dynamic quadriceps loading profiles. In parallel, a finite element representation of the quadriceps actuator will be incorporated into a previously validated model of the VIVO (Figure 4.2) (Fitzpatrick et al., 2016). The model will be used to derive a coupled set of VIVO TF and quadriceps loading profiles that will recreate the desired 6-DoF loading at both the TF and PF joints for the activities described above. To validate that the loading profiles are generating the desired TF and PF loading conditions, a previously designed instrumented TKR tibial tray capable of measuring reaction forces on the medial and lateral tibial plateaus will be mounted into the experimental set-up. TF forces measured during the experiment will be compared to the target TF forces described above and the accuracy quantified. The outcome of this work will be a validated coupled experimental and computational multi-axis loading model that can be used to investigate novel knee surgical techniques and implant designs for treating patients with orthopedic disease or injuries affecting the knee joint.
The muscle-loading framework would be universal and could be adapted for evaluation of different joints as well. The enhanced experimental capabilities, along with the accompanying verified finite element model, could lead to many beneficial outcomes from journal publications to the possibility of a Food and Drug Administration (FDA) approved Medical Device Development Tool (MDDT). This would also have direct impacts on the procurement of external funding for further orthopaedic research.

4.2. Design Rationale and Process

_Femoral Fixture & VIVO Alteration_

First, the necessary functions and requirements of the total joint mechanism were explored. It was determined that fixtures needed to rigidly hold a cadaveric femur from the abduction-adduction (Ab-Ad) arm of the VIVO. Previously, the articular surface of a femoral component attached in line with the Ad-Ab axis (Figure 4.3), but this does not allow the inclusion of the femoral shaft, preventing the use of cadaveric bone. The current design would allow for the femur to be mounted to a modified Ad-Ab arm and a tibia to be mounted to the X-, Y-, Z- stage of the VIVO (as done in previous experiments). The fixturing must incorporate adjustability to align the femur and tibia to the flexion axis of the simulator. The design includes adjustment in the A-P and M-L directions, as well as V-V and I-E rotations. Superior-inferior adjustability will come from the Z-axis of the VIVO stage (Figure 4.4). The re-designed Ad-Ab arm arcs towards the inside of the VIVO’s flexion arm, granting an un-obstructed view of the joint during testing, and attaches to the flexion arm via a modular pinned rod connection used in previous experiments (Figure 4.5). The new arm has two ‘neutral’ positions: the first
being at 0 degrees relative to the flexion arm, and the other being offset to 45 degrees of
flexion relative to the flexion arm (Figure 4.6). This enables simulation of deeper flexion
ranges than the VIVO is currently able to perform due to its mechanical constraints.

*Quadriceps Actuator Mounting*

With the ability to mount both the femur and tibia discussed above, the next step
was to mount an actuator capable of applying loads to the quadriceps tendon, allowing
for full PF and TF investigation. An actuator was specified with a peak load of 3,200-N,
to simulate loads generated by the quadriceps muscles. The actuator will mount to the
femoral fixture on the new Ad-Ab arm, and is designed to allow adjustment in the
medial, lateral, superior and inferior directions, as well as rotation in the frontal plane to
adjust the line of action of the quadriceps force (Figure 4.7).

The above designs have been prototyped via 3D printing, reviewed, finalized and
fabricated in house. Figure 4.8 shows a rendering of the altered VIVO configuration set
up to allow for the evaluation of the total knee joint with the addition of a quadriceps
muscle force. Detailed mechanical drawings for each part are compiled in Appendix 4A.

*Control Systems*

The muscle force framework consists of two main components: 1) a linear
electromechanical actuator and associated controller to apply muscle loading and 2) the
optical tracking system and proportional integral derivative (PID) control software to
control the applied load magnitude. The first piece of equipment necessary for the control
system is an ADK series servo driver to control the quadriceps actuator’s Kollmorgen
Servomotor. Secondly, the Optotrak Application Programmer’s Interface (OAPI) software package (Northern Digital) is required to output real-time 3D marker position coordinates to calculate knee flexion angle via the Optotrak’s data acquisition unit. This flexion angle will be processed by a LabView PID controller to determine the muscle loads as a function of flexion and the associated load will be output to the servo driver to be applied by the actuator (Figure 4.9).

Future Work

Although the focus was on the mechanical system of the quadriceps mechanism, work beyond the scope of this thesis includes development and tuning of the control system. Further work will also be necessary to implement this experimental setup into a finite element model which can be validated and used as a pre-clinical design tool.
Figure 4.1: VIVO Muscle Force Quadriceps Mechanism
Figure 4.2: Implementation of the Quadriceps Mechanism in a Previously Validated Finite Element Model (Clary)

Figure 4.3: Femoral Component Attached in Line with Flexion Axis

Figure 4.4: Femoral Fixture Adjustability
Figure 4.5: Modified VIVO Ad-Ab Arm Configuration

Figure 4.6: Neutral and 45 Degree Flexion Offset Position to Allow Deep Flexion
Figure 4.7: Quadriceps Muscle Force Actuator Adjustability
Figure 4.8: Fixturing Designed for Total Knee Joint Testing with the Addition of a Quadriceps Muscle Force (Blue) in the AMTI VIVO (Gray)

Figure 4.9: Logic Diagram for Muscle Force Feedback Control
CHAPTER 5. CONCLUSIONS AND RECOMMENDATIONS

The work presented in this thesis contributes to the orthopaedic research community by advancing the accuracy of medical device design and validation testing. As renewed interest in cementless total knee replacement components continues, the importance of understanding activities of daily living on initial fixation is paramount, as it is directly related to boney ingrowth and thus success of the implant.

As detailed in the Chapter 2, previous investigations in the literature have characterized the effects of implant motion of fixation, as well as aimed to quantify tibial base trays micromotion in vitro, but are hindered by the over-simplified loading conditions used. The study presented in this thesis addresses shortcomings in loading conditions used previously in ASTM standard F3141-15 with supplemental varus-valgus torques, as well as a full suite of activities and loading variations. This allowed for loading in all 6 degrees-of-freedom with an AMTI VIVO joint simulator. Kinematics were tracked using active marker rigid body clusters mounted to each of the free axes, which were compared to machine feedback files for accuracy comparison. Micromotion was calculated via state-of-the-art digital image correlation measurements of target locations on the anterior- lateral, central and medial aspects of the tray-bone construct. Five prototype cementless tibial base tray designs were evaluated in simulated bone, giving way to finalized 6th design, which was tested both in the cruciate retaining and posterior stabilized configuration. Two competitive tibial base trays currently on the
market were also tested, as a baseline for comparison to the finalized prototype design. This experiment also served as the validation a computational model, which can be used as a tool in early implant development.

Work is currently under way to mount an additional actuator to the VIVO, which allows for the simulation of muscle forces. This permits the testing of both the natural and implanted total knee joints through the inclusion of the distal femur and the patella, along with the proximal tibia. This muscle driven loading is more indicative of the anatomic loads put on the knee in vivo.

The aforementioned study was not without limitations. The distance between corresponding target marker pairs was normalized relative to the start of the measurement cycle. This has the benefit of normalizing the micromotion across the various designs using a common loading condition, but doesn’t elucidate how the relative distance between the corresponding markers has changed relative to the unloaded state. Also, compared to similar published data, a low amount of cycles of each activity were run. This is due to the sample size and the high number of separate movements performed.

Future development of this work could investigate the effects of higher cyclic loading on implant micromotion. This same experimental setup may easily be adapted to run loading profiles on trays implanted in cadaveric tibiae through the raising of the flexion arm stage and the use of previously designed cadaveric tibial fixtures mounted to the tibial stage. The author’s recommendation is the continued development and eventual implementation of the quadriceps mechanism discussed in Chapter 4, as it provides improved capabilities in full knee joint evaluation through the addition of muscle driven
loads and inclusion of the patella. This work is finite-element ready, and a validated model could lead to a Food and Drug Administration (FDA) approved Medical Device Development Tool (MDDT), directly boosting the procurement of external funding for further orthopaedic research, and more rigorously testing new medical devices.
BIBLIOGRAPHY

https://doi.org/10.1016/j.jbiomech.2017.04.008

https://doi.org/10.1016/j.jbiomech.2011.11.052


https://doi.org/10.1016/j.arth.2011.06.010


https://doi.org/10.1302/0301-620X.99B6.BJJ-2016-0713.R1

https://doi.org/10.1016/j.jbiomech.2010.03.046


https://doi.org/10.1016/j.jbiomech.2009.02.016


APPENDICES

APPENDIX 3A: FULL-CYCLE MICROMOTION FOR ATTUNE D6, TRIATHLON AND NEXGEN

Figures 3A 1-13: FULL-CYCLE MICROMOTION FOR ATTUNE D6, TRIATHLON AND NEXGEN
APPENDIX 3B: FULL-CYCLE MICROMOTION FOR ATTUNE D1-D6

Figures 3B 1-19: FULL-CYCLE MICROMOTION FOR ATTUNE D1-D6
APPENDIX 3C: FULL-CYCLE MICROMOTIONS FOR ATTUNE D6 CR AND PS

Figures 3C 1-19: FULL-CYCLE MICROMOTIONS FOR ATTUNE D6 CR AND PS
APPENDIX 3D: COMPOSITE MICROMOTION TABLE
APPENDIX 3E: TABLE OF COMPLETED VERSUS FAILED SPECIMENS AND LOAD PROFILES

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Load Profile 1</th>
<th>Load Profile 2</th>
<th>Load Profile 3</th>
<th>Load Profile 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimen A</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Specimen B</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Specimen C</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Specimen D</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Specimen E</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Specimen F</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Data Collection Summary

- FIR = Failed in Run
- D/N = Did Not Attempt
APPENDIX 3F: TABLE OF STATISTICALLY SIGNIFICANT DIFFERENCES BETWEEN DESIGNS AND ACTIVITIES

Table 3F.1: Statistically significant difference between each design pair of designs for the Gait activities. Note: only statistically significant differences are noted, design pairs not listed were not significantly different.

<table>
<thead>
<tr>
<th>Lateral</th>
<th>Design A</th>
<th>Activity</th>
<th>P Value</th>
<th>Design A</th>
<th>Activity</th>
<th>P Value</th>
<th>Design A</th>
<th>Activity</th>
<th>P Value</th>
<th>Design A</th>
<th>Activity</th>
<th>P Value</th>
<th>Design A</th>
<th>Activity</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.023</td>
<td>GTOAD</td>
<td>D1</td>
<td>0.002</td>
<td>GTOAD</td>
<td>D1</td>
<td>0.006</td>
<td>GTOAD</td>
<td>D1</td>
<td>0.004</td>
<td>GTOAD</td>
<td>D1</td>
<td>0.007</td>
<td>GTOAD</td>
<td>D1</td>
<td>0.008</td>
</tr>
<tr>
<td>0.002</td>
<td>GTON</td>
<td>T</td>
<td>0.001</td>
<td>GTON</td>
<td>T</td>
<td>0.003</td>
<td>GTON</td>
<td>T</td>
<td>0.006</td>
<td>GTON</td>
<td>T</td>
<td>0.007</td>
<td>GTON</td>
<td>T</td>
<td>0.007</td>
</tr>
<tr>
<td>0.039</td>
<td>GTON</td>
<td>D6_PS</td>
<td>0.004</td>
<td>GTON</td>
<td>D6_PS</td>
<td>0.006</td>
<td>GTON</td>
<td>D6_PS</td>
<td>0.007</td>
<td>GTON</td>
<td>D6_PS</td>
<td>0.008</td>
<td>GTON</td>
<td>D6_PS</td>
<td>0.009</td>
</tr>
<tr>
<td>0.001</td>
<td>GTATTCR</td>
<td>D1</td>
<td>0.002</td>
<td>GTATTCR</td>
<td>D1</td>
<td>0.003</td>
<td>GTATTCR</td>
<td>D1</td>
<td>0.004</td>
<td>GTATTCR</td>
<td>D1</td>
<td>0.005</td>
<td>GTATTCR</td>
<td>D1</td>
<td>0.006</td>
</tr>
<tr>
<td>0.018</td>
<td>GTATTCR</td>
<td>D3</td>
<td>0.003</td>
<td>GTATTCR</td>
<td>D3</td>
<td>0.005</td>
<td>GTATTCR</td>
<td>D3</td>
<td>0.006</td>
<td>GTATTCR</td>
<td>D3</td>
<td>0.007</td>
<td>GTATTCR</td>
<td>D3</td>
<td>0.007</td>
</tr>
<tr>
<td>0.006</td>
<td>GTON</td>
<td>D6_PS</td>
<td>0.007</td>
<td>GTON</td>
<td>D6_PS</td>
<td>0.007</td>
<td>GTON</td>
<td>D6_PS</td>
<td>0.008</td>
<td>GTON</td>
<td>D6_PS</td>
<td>0.009</td>
<td>GTON</td>
<td>D6_PS</td>
<td>0.01</td>
</tr>
<tr>
<td>0.004</td>
<td>GTATTCR</td>
<td>D3</td>
<td>0.005</td>
<td>GTATTCR</td>
<td>D3</td>
<td>0.006</td>
<td>GTATTCR</td>
<td>D3</td>
<td>0.007</td>
<td>GTATTCR</td>
<td>D3</td>
<td>0.008</td>
<td>GTATTCR</td>
<td>D3</td>
<td>0.008</td>
</tr>
</tbody>
</table>

98
Table 3F.2: Statistically significant difference between each design pair of designs for Stair Descent activities. Note: only statistically significant differences are noted, design pairs not listed were not significantly different.

<table>
<thead>
<tr>
<th></th>
<th>Lateral</th>
<th>Central</th>
<th>Medial</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Activity</td>
<td>P Value</td>
<td>Activity</td>
<td>P Value</td>
</tr>
<tr>
<td>Design A Design B</td>
<td>Design A Design B</td>
<td></td>
<td>Design A Design B</td>
<td>Design A Design B</td>
</tr>
<tr>
<td>02 01 SDATTCR</td>
<td>0.037</td>
<td>D2 01 SDATTCR 0.018</td>
<td>D2 01 SDATTCR 0.021</td>
<td>D2 01 SDATTCR 0.027</td>
</tr>
<tr>
<td>06 01 SDATTCR</td>
<td>0.024</td>
<td>D5 01 SDATTCR 0.017</td>
<td>D5 01 SDATTCR 0.024</td>
<td>D5 01 SDATTCR 0.021</td>
</tr>
<tr>
<td>06 01 SDATTCR</td>
<td>0.048</td>
<td>D6 01 SDATTCR 0.041</td>
<td>D6 01 SDATTCR 0.025</td>
<td>D6 01 SDATTCR 0.030</td>
</tr>
<tr>
<td>06 01 SDON</td>
<td>0.038</td>
<td>Z 01 SDATTCR 0.038</td>
<td>D3 02 SDATTCR 0.031</td>
<td>Z 01 SDATTCR 0.029</td>
</tr>
<tr>
<td>05 03 SDATTCR</td>
<td>0.011</td>
<td>D3 03 SDATTCR 0.011</td>
<td>D4 02 SDATTCR 0.032</td>
<td>D3 02 SDATTCR 0.044</td>
</tr>
<tr>
<td>05 03 SDATTCR</td>
<td>0.026</td>
<td>D6 03 SDATTCR 0.016</td>
<td>D5 03 SDATTCR 0.035</td>
<td>D3 03 SDATTCR 0.025</td>
</tr>
<tr>
<td>05 04 SDATTCR</td>
<td>0.039</td>
<td>D6 PS 03 SDATTCR 0.041</td>
<td>D6 03 SDATTCR 0.023</td>
<td>D6 03 SDATTCR 0.026</td>
</tr>
<tr>
<td>05 04 SDATTCR</td>
<td>0.020</td>
<td>Z 03 SDATTCR 0.031</td>
<td>D5 04 SDATTCR 0.031</td>
<td>Z 03 SDATTCR 0.033</td>
</tr>
<tr>
<td>05 04 SDATTCR</td>
<td>0.031</td>
<td>D6 PS 04 SDATTCR 0.043</td>
<td>D6 04 SDATTCR 0.011</td>
<td>D6 04 SDATTCR 0.026</td>
</tr>
<tr>
<td>02 01 SDONAB</td>
<td>0.003</td>
<td>D2 01 SDONAB 0.006</td>
<td>D2 01 SDONAB 0.025</td>
<td>D5 01 SDONAB 0.032</td>
</tr>
<tr>
<td>06 01 SDONAB</td>
<td>0.000</td>
<td>D6 01 SDONAB 0.001</td>
<td>D6 PS 01 SDONAB 0.025</td>
<td>T 01 SDONAB 0.034</td>
</tr>
<tr>
<td>06 01 SDONAB</td>
<td>0.007</td>
<td>D6 PS 01 SDONAB 0.007</td>
<td>T 01 SDONAB 0.018</td>
<td>T 01 SDONAB 0.031</td>
</tr>
<tr>
<td>02 01 SDONAB</td>
<td>0.010</td>
<td>D2 01 SDONAB 0.011</td>
<td>D1 02 SDONAB 0.018</td>
<td>D2 01 SDONAB 0.006</td>
</tr>
<tr>
<td>05 03 SDONAB</td>
<td>0.011</td>
<td>D5 03 SDONAB 0.011</td>
<td>D6 PS 03 SDONAB 0.025</td>
<td>D6 03 SDONAB 0.026</td>
</tr>
<tr>
<td>05 03 SDONAB</td>
<td>0.021</td>
<td>D5 03 SDONAB 0.009</td>
<td>Z 03 SDONAB 0.048</td>
<td>Z 03 SDONAB 0.032</td>
</tr>
<tr>
<td>05 03 SDONAB</td>
<td>0.050</td>
<td>D6 03 SDONAB 0.009</td>
<td>D2 01 SDONAB 0.011</td>
<td>D6 04 SDONAB 0.040</td>
</tr>
<tr>
<td>06 06 SDONAB</td>
<td>0.001</td>
<td>D6 06 SDONAB 0.002</td>
<td>D5 06 SDONAB 0.001</td>
<td>D2 01 SDONAB 0.020</td>
</tr>
<tr>
<td>06 06 SDONAB</td>
<td>0.010</td>
<td>Z 06 SDONAB 0.100</td>
<td>D6 PS 06 SDONAB 0.007</td>
<td>D6 06 SDONAB 0.033</td>
</tr>
<tr>
<td>06 06 SDONAB</td>
<td>0.010</td>
<td>Z 06 SDONAB 0.100</td>
<td>D6 PS 06 SDONAB 0.100</td>
<td>T 06 SDONAB 0.033</td>
</tr>
<tr>
<td>02 01 SDON</td>
<td>0.006</td>
<td>D2 01 SDON 0.001</td>
<td>D6 PS 01 SDON 0.001</td>
<td>D6 03 SDON 0.026</td>
</tr>
<tr>
<td>03 01 SDON</td>
<td>0.000</td>
<td>D3 01 SDON 0.000</td>
<td>D6 PS 01 SDON 0.000</td>
<td>D6 03 SDON 0.038</td>
</tr>
<tr>
<td>06 04 SDON</td>
<td>0.002</td>
<td>D6 PS 04 SDON 0.006</td>
<td>D5 01 SDON 0.002</td>
<td>D2 01 SDON 0.011</td>
</tr>
<tr>
<td>05 03 SDON</td>
<td>0.001</td>
<td>D5 03 SDON 0.001</td>
<td>D6 PS 03 SDON 0.006</td>
<td>S 04 SDON 0.037</td>
</tr>
<tr>
<td>05 03 SDON</td>
<td>0.001</td>
<td>D5 03 SDON 0.001</td>
<td>D6 PS 03 SDON 0.006</td>
<td>D6 03 SDON 0.003</td>
</tr>
<tr>
<td>05 03 SDON</td>
<td>0.008</td>
<td>D5 03 SDON 0.008</td>
<td>Z 03 SDON 0.004</td>
<td>Z 03 SDON 0.036</td>
</tr>
<tr>
<td>05 03 SDON</td>
<td>0.000</td>
<td>D5 03 SDON 0.000</td>
<td>D6 PS 03 SDON 0.002</td>
<td>D6 03 SDON 0.007</td>
</tr>
<tr>
<td>05 05 SDON</td>
<td>0.002</td>
<td>D5 05 SDON 0.002</td>
<td>D6 PS 05 SDON 0.002</td>
<td>D6 03 SDON 0.007</td>
</tr>
<tr>
<td>05 04 SDON</td>
<td>0.004</td>
<td>D5 04 SDON 0.004</td>
<td>Z 04 SDON 0.004</td>
<td>Z 04 SDON 0.039</td>
</tr>
<tr>
<td>05 04 SDON</td>
<td>0.001</td>
<td>D5 04 SDON 0.001</td>
<td>D6 PS 04 SDON 0.001</td>
<td>T 05 SDON 0.002</td>
</tr>
<tr>
<td>05 05 SDON</td>
<td>0.001</td>
<td>D5 05 SDON 0.001</td>
<td>D6 PS 05 SDON 0.001</td>
<td>D6 05 SDON 0.005</td>
</tr>
<tr>
<td>05 05 SDON</td>
<td>0.006</td>
<td>D5 05 SDON 0.006</td>
<td>D6 PS 05 SDON 0.006</td>
<td>D6 05 SDON 0.005</td>
</tr>
<tr>
<td>05 05 SDON</td>
<td>0.008</td>
<td>D5 05 SDON 0.008</td>
<td>D6 PS 05 SDON 0.008</td>
<td>D6 05 SDON 0.005</td>
</tr>
<tr>
<td>05 05 SDON</td>
<td>0.000</td>
<td>D5 05 SDON 0.000</td>
<td>D6 PS 05 SDON 0.000</td>
<td>D6 05 SDON 0.005</td>
</tr>
<tr>
<td>Z 05 SDON</td>
<td>0.018</td>
<td>Z 05 SDON 0.018</td>
<td>Z 05 SDON 0.018</td>
<td>Z 05 SDON 0.018</td>
</tr>
<tr>
<td>05 05 SDON</td>
<td>0.004</td>
<td>D5 05 SDON 0.004</td>
<td>Z 05 SDON 0.004</td>
<td>Z 05 SDON 0.004</td>
</tr>
<tr>
<td>05 05 SDON</td>
<td>0.004</td>
<td>D5 05 SDON 0.004</td>
<td>Z 05 SDON 0.004</td>
<td>Z 05 SDON 0.004</td>
</tr>
<tr>
<td>05 05 SDON</td>
<td>0.001</td>
<td>D5 05 SDON 0.001</td>
<td>Z 05 SDON 0.001</td>
<td>Z 05 SDON 0.001</td>
</tr>
</tbody>
</table>

99
<table>
<thead>
<tr>
<th>Design A</th>
<th>Design B</th>
<th>Activity</th>
<th>$P$ Value</th>
<th>Design A</th>
<th>Design B</th>
<th>Activity</th>
<th>$P$ Value</th>
<th>Design A</th>
<th>Design B</th>
<th>Activity</th>
<th>$P$ Value</th>
<th>Design A</th>
<th>Design B</th>
<th>Activity</th>
<th>$P$ Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>D1</td>
<td>D2</td>
<td>0.042</td>
<td>0.049</td>
<td>D1</td>
<td>D2</td>
<td>0.042</td>
<td>0.049</td>
<td>D1</td>
<td>D2</td>
<td>0.042</td>
<td>0.049</td>
<td>D1</td>
<td>D2</td>
<td>0.042</td>
<td>0.049</td>
</tr>
<tr>
<td>D4</td>
<td>D3</td>
<td>0.020</td>
<td>0.060</td>
<td>D4</td>
<td>D5</td>
<td>0.035</td>
<td>0.020</td>
<td>D4</td>
<td>D5</td>
<td>0.035</td>
<td>0.020</td>
<td>D4</td>
<td>D5</td>
<td>0.035</td>
<td>0.020</td>
</tr>
<tr>
<td>D5</td>
<td>D6</td>
<td>0.000</td>
<td>0.000</td>
<td>D5</td>
<td>D6</td>
<td>0.000</td>
<td>0.000</td>
<td>D5</td>
<td>D6</td>
<td>0.000</td>
<td>0.000</td>
<td>D5</td>
<td>D6</td>
<td>0.000</td>
<td>0.000</td>
</tr>
<tr>
<td>D6</td>
<td>D7</td>
<td>0.001</td>
<td>0.001</td>
<td>D6</td>
<td>D7</td>
<td>0.001</td>
<td>0.001</td>
<td>D6</td>
<td>D7</td>
<td>0.001</td>
<td>0.001</td>
<td>D6</td>
<td>D7</td>
<td>0.001</td>
<td>0.001</td>
</tr>
</tbody>
</table>

Table 3F.3: Statistically significant difference between each design pair of designs for the Deep Knee Bend activities. Note: only statistically significant differences are noted, design pairs not listed were not significantly different.
APPENDIX 4A: MECHANICAL PART DRAWINGS FOR QUADRICEPS
ACTUATOR MECHANISM

Table 4A.1: List of Part Drawings, Part Quantities and Materials

<table>
<thead>
<tr>
<th>Drawing Name</th>
<th>Quantity</th>
<th>Material</th>
</tr>
</thead>
<tbody>
<tr>
<td>SI Arm 4 Hole Washer</td>
<td>1</td>
<td>Aluminum</td>
</tr>
<tr>
<td>SI Arm Connection Plate</td>
<td>2</td>
<td>Aluminum</td>
</tr>
<tr>
<td>VV Rotation Bottom- Arm 1</td>
<td>1</td>
<td>Aluminum</td>
</tr>
<tr>
<td>VV Rotation Bottom- Arm 2</td>
<td>1</td>
<td>Aluminum</td>
</tr>
<tr>
<td>VV Rotation Bottom- Base</td>
<td>1</td>
<td>Aluminum</td>
</tr>
<tr>
<td>VV Rotation Top</td>
<td>1</td>
<td>Aluminum</td>
</tr>
<tr>
<td>Actuator Rotation Plate- Arm</td>
<td>2</td>
<td>Aluminum</td>
</tr>
<tr>
<td>Actuator Rotation Plate- Base</td>
<td>1</td>
<td>Aluminum</td>
</tr>
<tr>
<td>Actuator Rotation Plate- Base Detail</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Actuator Slide Plate</td>
<td>1</td>
<td>Aluminum</td>
</tr>
<tr>
<td>Altered Ad/Ab Arm- Part 1</td>
<td>1</td>
<td>Aluminum</td>
</tr>
<tr>
<td>Altered Ad/Ab Arm- Part 1 Detail</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Altered Ad/Ab Arm- Part 2</td>
<td>1</td>
<td>Aluminum</td>
</tr>
<tr>
<td>Connection Top Plate</td>
<td>1</td>
<td>Stainless Steel</td>
</tr>
<tr>
<td>Femoral Fixture</td>
<td>1</td>
<td>Stainless Steel</td>
</tr>
<tr>
<td>Femoral IE Couple Male</td>
<td>1</td>
<td>Aluminum</td>
</tr>
<tr>
<td>SI Arm</td>
<td>1</td>
<td>Aluminum</td>
</tr>
</tbody>
</table>
Figure 4A. 1: SI Arm 4 Hole Pattern Washer Mechanical Drawing
Figure 4A. 2: SI Arm Connection Plate Mechanical Drawing
Figure 4A. 3: VV Rotation Bottom Arm 1 Mechanical Drawing
Figure 4A. 4: VV Rotation Bottom Arm 2 Mechanical Drawing
Figure 4A. 5: VV Rotation Bottom Base Mechanical Drawing
Figure 4A. 6: VV Rotation Top Mechanical Drawing
Figure 4A. 7: Actuator Rotation Plate Arm Mechanical Drawing
Figure 4A. 8: Actuator Rotation Plate Base Mechanical Drawing
Figure 4A. 9: Actuator Rotation Plate Base Detail Mechanical Drawing
R=0.13 through holes for 1/4-20 bolts, 
R=0.2 countersunk for head clearance 
2.5" deep off of front face

top and bottom slot countersunk 
by .20" from back face

Actuator slide plate

Figure 4A. 10: Actuator Slide Plate Mechanical Drawing
Figure 4A. 11: Altered Ad/Ab Arm Part 1 Mechanical Drawing
Figure 4A. 12: Altered Ad/Ab Arm Part 1 Arc Slot Detail Mechanical Drawing
Figure 4A. 13: Altered Ad/Ab Arm Part 2 Mechanical Drawing
Figure 4A. 14: Connection Top Plate Mechanical Drawing
Figure 4A. 15: Femoral Fixture Mechanical Drawing
Figure 4A. 16: Femoral IE Couple Male Mechanical Drawing
Figure 4A. 17: SI Arm Mechanical Drawing