Chapter 1
Introduction

Medical device companies and orthopaedic surgeons are constantly searching for alternative materials for total knee replacements (TKR). Most commonly, TKR consist of articulating surfaces of cobalt-chrome alloy (CoCr) and ultra-high molecular weight polyethylene (UHMWPE). Although UHMWPE has been the standard TKR bearing for many years, UHMWPE wear is a common problem of implanted TKR and has been linked to adverse biological conditions, bone resorption, and even bone death. Testing of the implant materials in the laboratory is crucial to the evaluation of the UHMWPE wear and to the development of new total knee implant materials.

Numerous *in vitro* (i.e., in an artificial environment outside the human body) testing devices have been developed in recent years in an attempt to mimic the wear and failure mechanisms of the UHMWPE in TKR. The most complex of these machines are knee simulators, which test actual total knee prostheses and have been shown to produce similar wear rates and UHMWPE damage as seen *in vivo* (i.e., within the human body). Nearly all knee simulators generate dynamic loading and can reproduce at least four of the knee's degrees of freedom (e.g., flexion/extension (F/E), tibial rotation, anterior-posterior (AP) sliding, and abduction/adduction). Unfortunately, knee simulators can be very expensive, some commercial models costing in excess of $200,000 (AMTI, 2000).

A common alternative to the knee simulator is the pin-on-disc wear testing machine, normally involving a flat pin of UHMWPE rotating on a CoCr disc. These relatively inexpensive devices can be very useful in simulating the cross-path stresses (at an angle of 90º) of the hip joint and their flat-on-flat contact closely mimics the hip's ball-in-socket contact. The knee, however, is more complex than the hip, normally experiencing a point-contact or a line-contact, and its small cross-path angle (about 10º) is often ignored entirely when simulating the joint.

The goal of several researchers has been to find an inexpensive compromise to the two previously mentioned types of wear testing devices. Their projects resulted in simple alternative prototype devices that did not test actual TKR, but rather a CoCr ring that was loaded and rotated upon a reciprocating UHMWPE block. While these apparatuses have been shown to produce somewhat similar wear rates and wear mechanisms as seen *in vivo* and with knee simulators, these designs are lacking. Specifically, none of the simple devices seen in the literature incorporate all of the knee's degrees of freedom or a physiologically correct loading curve.

1.1 Motivation – The Need for an Inexpensive Wear Screening Device

With the population's ever growing need for TKR due to increased life expectancy among other reasons, there is an increasing need for accurate TKR material testing. The motivation behind this research was to design and develop an inexpensive wear testing device that would incorporate the complex loading curve of the knee joint with only the most contributory knee-motion profiles in order to reproduce the wear rates and mechanisms seen with more expensive knee simulators and *ex vivo* TKR. Knee simulators have been shown to reproduce the degrees of freedom and wear mechanisms of implanted TKR quite well, but are very expensive and are limited to testing only actual TKR designs.

An inexpensive wear testing device capable of testing TKR materials in simple geometries would allow for quicker evaluation and screening of alternative materials for TKR usage. A device of this kind would eliminate the need to develop and test (in a knee simulator) TKR prototypes of unsatisfactory materials, saving time and money for orthopaedic device manufacturers and research facilities in industry and academia.

The objective of this investigation was to design, build, and validate a four-station wear testing device for current as well as future alternative TKR materials. The device has been designed to incorporate physiologically-correct loading and three of the knee's degrees of freedom (F/E, AP sliding, and tibial rotation) to test the wear characteristics of UHMWPE in contact with CoCr. This project required the combination of several engineering disciplines, including, but not limited to, machine design, tribology, finite element methods, materials science, instrumentation, data acquisition, and static and dynamic analyses.

1.2 Thesis Organization

This thesis has been organized in the manner subsequently described. Chapter 2 contains the literature review, focusing on the anatomy and physiology of the human knee, the need for TKR, the wear of TKR, and the wear testing devices used to evaluate TKR and their materials. A section outlining the research goals concludes the literature review.

Chapter 3 begins with a systematic review of all of the design criteria specified for the wear testing device. The System Design Section describes the selection of appropriate, commercially-available and/or fabricated components for the device. Each component used to fulfill the pre-specified design criteria is described in detail.

Chapter 4 expands upon the previous chapter and discusses the assembly of the device. Construction of the frame, integration of the purchased parts, and interfacing of the device to a computer are all described in depth and shown visually through photographs and schematics.

Chapter 5 reviews the steps taken to initially validate the device for use in actual wear testing. To meet the design specifications established in Chapter 3, the device's motions and forces are evaluated. The results of a preliminary wear test conclude Chapter 5.

Chapter 6 begins with future recommendations. Possible improvements in calibration, hardware, and the user interface are discussed. The final section of the thesis consists of conclusions and observations made during the design, development, and validation of the wear testing apparatus.