Mobile Bearing Total Knee Replacement Devices

JAI Guest Editors:
Kathy K. Trier
A. Seth Greenwald
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Mobile Bearing Total Knee Replacement Devices

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Foreword

THIS COMPILATION OF THE JOURNAL OF ASTM INTERNATIONAL (JAI), STP1531, Mobile Bearing Total Knee Replacement Devices, contains only the papers published in JAI that were presented at a symposium in St. Louis, Missouri, on May 18, 2010 and sponsored by ASTM International Committee F04 on Medical and Surgical Materials and Devices.

The JAI Guest Editors are Kathy K. Trier, Corin USA, Clearwater, FL, USA and A. Seth Greenwald, Orthopaedic Research Laboratories, Cleveland, OH, USA.
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Overview

Orthopedic knee replacement is a well accepted and clinically successful treatment procedure that provides pain relief and improved function for millions of people each year. Both fixed bearing and mobile bearing knee devices have well recognized success rates as a general category of device with the primary distinction between them characterized by whether the polyethylene tibial component is affixed in a stationary position in the metal tibial tray (fixed bearing) or whether the polyethylene tibial component is allowed to move on the tibial tray (mobile bearing).

While fixed bearing knee devices existed prior to the Medical Device Amendments of the Federal Food, Drug and Cosmetic Act of 1976, the mobile bearing knee devices were not in existence and thus, having no pre-amendment predicate device to support a Substantial Equivalence determination, were automatically classified as Class III devices.

The mobile bearing knee devices were first introduced in the late 1970s and since that time, several generations of mobile bearing knees have been developed and available on the international market. Designs include unicompartmental and bicondylar, with either platform-style or meniscal bearing design of the polyethylene articulating surface, with variations in the mobility of the polyethylene, type of constraint of the polyethylene and treatment of the PCL.

In the U.S., the first mobile bearing knee cleared for marketing through the FDA was the Low Contact Stress (LCS) Meniscal Bearing, Cemented, Tri-compartmental Knee (DePuy, Warsaw, IN) with PMA approval in 1985. The Rotating Platform version and cementless application gained PMA approval shortly thereafter. In comparison with the global market, the number of mobile bearing knee devices available in the U.S. has been limited in part as a result of the regulatory pathway to commercialization for a Class III device.

Reclassification of mobile bearing knee devices from Class III to Class II has been proposed since the late 1990’s with petitions submitted by the Orthopaedic Surgical Manufacturers Association (OSMA) to the FDA. The 1997 reclassification petition was reviewed by the FDA Advisory Panel on July 25, 1997 with the panel determination that there was insufficient evidence to provide reasonable assurance of safety and efficacy for the entire class of mobile bearing knees to be reclassified and recommended that tricompartmental and unicompartmental mobile bearing knees remain Class III devices. A second reclassification petition was favorably reviewed by the FDA Advisory Panel on June 4, 2004 but subsequently denied by FDA on October 28, 2004. Communications with FDA focused on the need for special controls, particularly pre-clinical bench tests that would distinguish
between clinically successful and unsuccessful designs and also recommended working with ASTM to develop consensus standards to address this need.

A determination for reclassification of mobile bearing knee devices from Class III to Class II requires that general controls and special controls, recognized by FDA, can provide reasonable assurance of the safety and effectiveness of the devices and that testing will be able to differentiate between good and bad designs and that test outcomes should be predictive of clinical outcomes. In 2007, ASTM standards development was initiated to incorporate testing for mobile bearing knee designs into existing ASTM knee standards for fixed bearing knee designs and include F1223 Test Method for Determination of Total Knee Replacement Constraint, F1800 Test Method for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee joint Replacements, and F2083 Standard Specification for Total Knee Prosthesis. In addition, four (4) new standards have been developed specifically for mobile bearing knee designs and include F2722 Evaluating Mobile Bearing Knee Tibial Baseplate Rotational Stops, F2723 Evaluating Mobile Bearing Knee Tibial Baseplate/Bearing Resistance to Dynamic Disassociation, F2724 Evaluating Mobile Bearing Knee Dislocation, and F2777 Evaluating Knee Bearing (Tibial Insert) Endurance and Deformation Under High Flexion. The goal of this work was to provide consensus standards that would address the required special controls to mitigate identified risks of all knee device designs. An added revision of F2083 is currently in process to provide a guidance document that covers all known clinical risks associated with the use of knee replacement devices and calls out relevant test methods across a wide range of generic knee designs, unicompound and bicondylar, fixed and mobile bearings.

The purpose of the ASTM Symposium on Mobile Bearing Knee Devices, May 2010, and this compilation of the papers as presented (STP1531) are to provide a scientific discussion on mechanical testing with regards to their relevance to clinical outcomes and clinical failures. The call for papers requested discussion of clinical data that is relevant to bench performance on the following topics related to mobile bearing total knee replacement devices:

- Mobile bearing knee tibial baseplate/ bearing resistance to dynamic disassociation.
- Mobile bearing knee tibial baseplate rotational stops.
- Dislocation, spin out, spit out.
- Determination of constraint for mobile bearing total knee replacements
- Cyclic fatigue testing of metal tibial tray components for mobile bearing total knee joint replacements.
• Knee bearing (tibial insert) endurance and deformation under high flexion for mobile bearing knee replacements.
• Knee bearing (tibial insert) wear including backside wear.
• Contact area, contact pressure distribution for mobile bearing knee joint replacements.
• Range of motion testing for mobile bearing knee joint replacements.

All presenters were encouraged to submit their work for inclusion and were peer reviewed using independent qualified reviewers. Given the specific goal of the symposium, peer review criteria to meet editorial requirements were liberal.

Two papers serve to provide a context for the remaining papers presented here (STP1531). The first provides an overview of the standards development as described and the second provides an updated review of the literature on clinical outcomes of mobile bearing knee devices. The following symposium papers have been organized under four themes that address the above specified clinical risks. For obvious reasons, while papers are organized under the key themes, they may overlap across themes.

Component Disassociation

The intent of this section is to present clinical papers that address ASTM F2724 and F2723 test methods, mobile bearing knee dislocation and tibial tray/polyethylene bearing disassociation respectively. Papers describe clinical results related to spin out, polyethylene dislocation and subluxation related to differing implant designs. One paper describes implant design modifications which were implemented to address spin out. Other papers report results of the relationship of polyethylene dislocation on revisions and a comparison of crepitation and pain following TKA with posterior stabilized designs, both rotating platform and fixed bearing.

Mechanical Fracture

Test methods to evaluate rotational stop (F2722) and polyethylene bearing deformation/fracture (F2777) are newly developed standards while testing for tibial tray fatigue/fracture (F1800) has been used with regards to fixed bearing knee designs. The papers in this section include a discussion of validated computational models using finite element (FE) methods to visualize the magnitude and location of stresses on the polyethylene bearing and identify parameters that vary with in vivo movement. Results demonstrate that FE models successfully predict clinically observed results.
**Functional Performance**

Papers in this section look at clinical outcomes as they relate to alignment and range of motion, measuring intraoperative rotation (F1223 constraint) and postoperative revisions as a result of spinout and dislocation. Wear simulator and wear particle analysis, clinical and radiographic results, and evaluation of the impact of the tibio-femoral bearing on abrasive wear, tibio-femoral kinematics and particle release across different designs are discussed. The focus of these papers are on knee devices with rotational mobility (rotational and linear motion) between the polyethylene bearing and tibial tray with one paper suggesting that the benefit the mobile bearing devices offers is self alignment to accommodate small rotational misalignments.

**Longevity and Wear**

F2083 addresses the specification of test methods for knee replacement devices and covers known clinical risks associated with the use of knee replacement devices, both fixed and mobile bearings. Focus in this section is on contact area, backside wear and total wear. Two papers addressing backside wear in mobile bearing rotating platform total knee designs evaluate the distinction between bearing wear and bearing damage suggesting that damage is not a proxy for polyethylene wear and the rate of wear over time with a mobile bearing device compared to a fixed bearing knee device. Papers also discuss a conservative measurement of total wear penetration and penetration rate in one mobile bearing design and a method for simulation of wear in mobile bearing unicompartmental knee replacement. Comparisons of total wear for many different knee device designs, both fixed bearing and mobile bearing and total and unicompartmental in a wide range of sizes, are reported. Key questions address “Do mobile bearing knee devices produce less total wear than fixed bearing devices? Is the difference found across knee devices a result of materials and implant designs?”

**Significant and Future Work**

Central to the discussion during the symposium was the fundamental question – “Are the standards sufficient to differentiate across mobile bearing device designs and predict clinical outcomes?” It is clear that some mobile bearing knee designs have long successful clinical history. A number of papers provided test results specific to a particular device design while others covered a wider range of designs. A common thread throughout the papers and symposium discussions is that few knee devices (fixed and mobile) today experience clinical failures making it difficult to validate ASTM test methods by testing both “good” and “bad” device designs via round robin
testing. It is appropriate to suggest that testing completed on the currently successful mobile bearing devices can serve as a measure of validation for the knee device standards. It is important to remind that these knee standards have been developed by consensus of the members of the ASTM F04 Arthroplasty subcommittee and that the collective experience and knowledge of the breadth of knee device design is extensive.

Kathy K. Trier  
Corin USA  
Clearwater, FL, USA

A. Seth Greenwald  
Orthopaedic Research Laboratories  
Cleveland, OH, USA

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