OBJECTIVE LIFETIME DESIGN OF ORTHOPAEDIC JOINT REPLACEMENTS:
ARE WE THERE YET?

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ABSTRACT
A computation methodology to objectively predict the lifetime of orthopaedic joint replacements has been developed over the past 5 years. This methodology relies on accurate definitions of the joint kinematics, loads, and contact pressure coupled with experimentally determined wear rates. The validation process makes use of a joint retrieval program at the BioMotion Foundation.

INTRODUCTION
Implanted hip and knee joint replacements are now used in approximately one million surgical procedures each year in the U.S. First introduced in the late 1950’s, these devices have evolved to provide excellent relief of arthritic pain and reasonably good durability (10-15 years or more is common). Ironically, the success of joint replacements – which were originally meant to keep people out of wheelchairs and relieve their pain – now presents the greatest challenge: These devices are being implanted with increasing frequency in younger and more active patients who expect their treatment to provide superior mechanical function AND to last their lifetimes. Currently, about 10% of joint replacement surgeries are performed to replace another implant which has failed for mechanical, surgical, materials, and/or other reasons. As Baby-Boomers become joint replacement candidates, it is clear that reducing device/design related failures could yield substantial cost saving and quality of life improvements.

Unfortunately, joint replacement design remains largely an exercise in incrementalism – making modest changes to the shapes, materials, processing and methods associated with clinically proven implant designs. This conservative approach likely avoids major design errors, but likely also misses opportunities to make breakthrough improvements in performance and longevity. The reason for this state-of-affairs is the lack of integrated engineering tools providing the ability to create and reliably and rigorously evaluate novel designs without committing to expensive physical testing or clinical trials.

This type of engineering challenge is not unique to orthopaedics and joint replacements, but several factors contribute to make this an especially interesting problem:

- It is difficult to measure the service conditions (loads and kinematics) under which the implants perform.
- It is difficult and expensive to characterize new or existing materials in tests that are predictive of in vivo performance.
- It is difficult to predict the evolution of articular surface damage with years of use.
- It is difficult to obtain ‘used parts’ that have functioned in patients that can be used for design and model validation.

The purpose of this paper is to assess the current state of knowledge in these four areas of challenge and opportunity, trying to answer the question “Are we there yet?”

DEFINING SERVICE CONDITIONS
A computational design tool for joint replacements requires realistic motions and loads in order to provide reliable estimates of a novel design’s performance. Measurement of skeletal kinematics is accomplished using several techniques. Marker-based motion capture employs reflective or emissive
markers affixed to the skin surface and tracked using optical photogrammetry. These techniques are sufficient to define the kinematics of highly conforming joints like the hip, but are insufficient to define the translations and rotations that occur in the knee due to motion of the skin affixed markers with respect to the bones. We introduced radiographic observation techniques in 1992 that permit 3D measurement of implant and bone motion during dynamic activities (Figure 1). We and many others world-wide, now use either maker-based motion capture or radiographic techniques to define in vivo hip and knee kinematics for a wide variety of activities.

Direct measurements of joint forces and moments are not so readily available. To date, only a handful of patients have received strain-gauge instrumented implants with telemetry to give a direct measure of the loads or pressures occurring in the joints during dynamic motion. These devices have provided an important but limited set of data. Alternatively, force platform measures of ground reaction forces and inverse-Newton methods can be used to estimate the lower bounds for joint moments and forces. Biomechanical models of the lower extremity are now commonly employed to estimate joint loads from the measured ground reaction forces.

MATERIAL PROPERTIES

A computational tool for implant life prediction will require detailed models for the friction, wear rate, temperature sensitivity and directional sensitivity of the bearing couple. Typical material testing in the orthopaedic industry utilizes multi-station pin-on-disk and whole implant wear testing devices. These tests are extremely expensive to run, require months per test to accumulate millions of cycles, and provide results of limited generality. To support computational wear modeling and life prediction, we have developed experimental methods and tribometers to efficiently characterize bearing couples. These tribometers are designed for very low uncertainty, so that single specimen tests provide tribological parameters with high confidence.

IMPLANT RETRIEVAL FOR VALIDATION

No matter the complexity of the model or elegance of the physical test, computational tools need to be based on validated observations. For joint replacements, the ultimate test articles are implants retrieved from consenting patients after their deaths. These devices serve as the reference standard for successful device function against which all physical and computer models can be tested. Toward this end, one of our group maintains an Implant Donor Program to obtain consent and collect from willing donors, implants that have been in situ for extended periods of time.

PROOF OF CONCEPT

This holistic modeling concept, going from in vivo data through wear prediction and validation against real implants has now been performed. In vivo motion data were obtained from a 68 year old knee replacement patient two years after surgery. At four years post surgery the patient expired and the implant was retrieved for analysis. The in vivo data were used to predict implant wear for the duration of its time in situ, and this prediction was compared against measured wear on the retrieved bearing surface. The damaged region, locations of maximum damage, and distribution of wear were very quantitatively and qualitatively well predicted by the computational approach (Fig 2).

CONCLUSION

Computational tools for life prediction in joint replacements are developing rapidly and may soon provide design engineers powerful tools for virtual testing of their ideas in a time and cost efficient manner. The success of this approach will be based on the quality of the inputs: a representative range of in vivo data, accurate material models and the methods to obtain them, and comprehensive tribological models, all that have been tested and compared with reference to retrieved devices. First applications of this approach are extremely promising. So, are we there yet? …we’ve never been closer.