Radiation free Micron resolution Monitoring of Orthopaedic Implant Displacement

OrthoDX has developed the first iteration prototype of a powerful diagnostic tool that can monitor the displacement of surgically placed orthopedic hardware in response to changes in load bearing. Our system uses no ionizing radiation and measures load-induced displacement of an implant relative to a sensor affixed to the host bone with an accuracy of 20 microns. Measurements are non-intrusive and may be performed as often as desired in either a clinical or non-clinical environment, and without patient discomfort or undue inconvenience. A full measurement sequence can be performed in 5 to 10 minutes and could be transmitted to the orthopaedist or therapist over the internet. We think this is a superior scalable and widely applicable solution that can potentially become the standard method for postoperative monitoring of orthopaedic implants.

Our desktop prototype consists of an isolated wireless sensor mounted within a hollow acrylic tube, a loop antenna external to the tube, and a cobalt-chromium rod representative of an implant. The CoCr rod descends into the tube from a fixture atop the tube. The fixture has a precise manually controlled mechanism to adjust the distance in microns between the CoCr rod and the sensor. Our antenna loop, electronics and software operate to measure and display in microns the displacement between one manually set distance and the next. This prototype provides a realistic desktop demonstration of an arrangement representative of a sensor deployed *in-vivo* within the femoral canal as part of a total hip replacement. This exemplary case represents one of the more challenging of many possible uses and locations of our sensor as it requires several millimeters of clearance between a sensor of 10 mm diameter and the distal implant tip.

The closer to the implant the sensor is affixed to the bone, the smaller it can be. This means our system can be scaled to apply in areas such as spinal implants, knees and other joints, and fractures stabilized with a fixation plate or intramedullary rod. No modifications to the implant itself are

needed, provided the surface of the implant proximal to the sensor is electrically conductive, i.e., made of a metal. There is no battery and nothing to wear out so it is expected our sensor can remain usable within a patient for the entire expected service time of the prosthesis.

Clinical Scenarios:

With our system, patient monitoring may begin immediately after surgery. Measurements may be taken at regular intervals throughout the course of therapeutic exercises. During a typical exercise session, measurements would be made continuously while loading and unloading the leg with a specified weight or exercise device. As the supporting bone grows into the implant, such ongoing measurements of the ensuing clinical progress would be expected to reveal a gradual decrease in the displacement of the implant relative to the femur in response to load. An unexpected reversal of this trend would alert the therapist to possible problems or perhaps indicate changes to physiotherapy, for example delaying the application of full weight bearing so as not to compromise osseointegration. With the matter resolved, subsequent checkups should then show a continuation of implant integrity. Our system will provide data for such insights. Physiotherapy could be tailored to each patient to produce more uniformly successful results.

Long term monitoring should continue indefinitely on a relaxed but regular schedule, perhaps monthly or quarterly. With the patient's individual measurement history as a baseline, our system would detect implant loosening at the micron level by flagging any increase in implant displacement relative to the femur in response to a given change in the load supported by the patient's leg. Such monitoring could identify later stage problems much earlier than current technology allows, perhaps well before the patient experiences pain and other symptoms of implant failure. If there is to be remedial surgery, it is best performed before the remaining bone has been damaged by the action of a loosened implant.

Please note that in the scenarios outlined above, our system does not depend upon the prior collection of measurement data from multiple patients. This makes the OrthoDx system tactically superior to any competing system that requires the accumulation of a large and diverse set of patient data before its measurements can be interpreted in a clinically useful way. Our system is expected to be clinically useful with the very first patient to receive our sensor implant. It uses only the patient's own ongoing measurement data as its baseline. It is of course expected that much will be

learned through collecting case data over time from a large and diverse population of patients, but for our system this is a bonus, not a requirement.

A Brief Explanation of our Technology:

Recent advances in technology have made the use of *in vivo* inductive proximity sensors more practical as a novel approach to precise measurement of orthopaedic implant micro-motion. A proximity sensor as simple as a tank circuit consisting of a coil and capacitor is placed within a few millimeters of a conductive implant to form a coupled system. An external antenna driven by a controlled power source generates a brief wireless transmission which passes through the intervening soft tissues and excites the sensor's LC tank circuit into oscillation at its resonant frequency. The distance between implant and sensor affects the damping rate of the sensor circuit oscillation because coupled energy is lost in the implant due to eddy current dissipation. The greater the damping, as measured by a feedback loop to the external antenna, the closer the implant is to the sensor. These effects occur in the near field. The power involved is far too small to produce any measurable thermal effects. Depending upon the resting distance between the implant and the sensor, micro-motion specificity of 20 microns can be reliably achieved.[1]

This principle of operation is well understood. Our application of these physics is novel. Our proprietary circuit and signal processing extract precise high-resolution measurements from miniscule signals hidden within much higher amplitude raw data that are quite noisy. With our technology these measurements are substantially invariant against changes in the position of the external antenna with respect to the patient and can be made without compromise to accuracy while the patient is moving and in the presence of normal blood flow and pulse.

If a need arises in the future, the sensor circuit can be enhanced to harvest energy to power concomitant diagnostic sensors such as temperature, chemical, acoustic or photometric microelectronics. [2]

1: Hamed Mohammadbagherpoor , Student Member, IEEE, Paul Ierymenko, Meghan H. Craver, Jim Carlson, David Dausch, Edward Grant , Senior Member, IEEE, and John D. Lucey: "An Implantable Wireless Inductive Sensor System Designed to Monitor Prosthesis Motion in Total Joint Replacement Surgery", IEEE TRANSACTIONS ON BIOMEDICAL ENGINEERING, VOL. 67, NO. 6, JUNE 2020

2. US Patent Number US 10980419 B2, April 20, 2021., other patents pending.

Comparison to the Radiostereometric (RSA) Method:

RSA has been used for decades primarily as a research tool to forecast the survival rates of various implant designs. In cementless fixation, there is evidence that the amount of acceptable early migration should be small and at least less than 1 to 1.5 mm within 2 years to avoid early and midterm revisions.[3,4] But RSA is unable to provide real time motion measurements without sophisticated x-rays.

RSA involves the insertion of many small beads of tantalum into the bone surrounding the implant to act as markers. This insertion process and gaining access to the bone to do it will increase the surgical burden of the implant surgery. We expect the process of mounting a single OrthoDx sensor per each monitored site will be significantly simpler and easier to achieve.

The complex process of obtaining RSA studies involving patient inconvenience, x-ray exposure and multiple expenses, constitutes a significant impediment to collecting prosthetic motion data. The OrthoDx system will allow unlimited weight bearing data collection with micron precision from day one of surgery throughout the lifetime of the prosthesis, using portable equipment, a simple process and with no x-ray exposure.

Studies suggest the amount of micro-motion in the early post-operative period after joint replacement surgery should not exceed 150 microns to promote solid osseointegration and lessen the possibility of fibrous union formation.[5] Research on the efficacy of pharmacologic intervention to slow down or stop osteoclastic activity to avoid the need for revision surgery secondary to aseptic loosening is progressing. If OrthoDx can help bring easy simple, reliable real-time measurements to bear on this challenge an estimated financial burden of some 8 billion dollars in annual expense can possibly be lowered and patient outcomes can be generally improved.

3. Marcus R. Streit MD, MSc, Daniel Haeussler MD, Thomas Bruckner PhD,Tanja Proctor BSc, Moritz M. Innmann MD, Christian Merle MD, MSc, Tobias Gotterbann MD, PhD, Stefan Weiss MD, PhD., Early Migration Predicts Aseptic Loosening of Cementless Femoral Stems: A Long-term Study.,Clin Orthop Relat Res (2016) 474:1697-1706 DOI 10.1007/sl1999-016-4857-5

4. Karrhohn J, Herberts P, Hultmark P, Malchau H, Nivbrant B, Thanner J. Radiostereometry of hip prostheses. Review of methodology and clinical results. Clin Orthopaedics Relat Res. 1997 Nov;(344, 94-110)

5. Murali Jasty, MD, Charles Bragdon, BS, Dennis Burke, MD, Daniel O'Connor, AST, Jay Lowenstein, William H Harris, MD, Boston Massachusetts, “In Vivo Skeletal Responses to Porous-Surfaced Implants Subjected to Small Induced Motions* , The Journal of Bone and Joint Surgery, VOL. 79-A, NO. 5, MAY 1997.

Further Development:

OrthoDx is still in the early stages of development. We feel quite encouraged by our progress to date and confident we can advance the technology further. The next stage of development beyond our existing prototype is to address the implanted sensors. The metallic coil must be encased in a biologically inert material, such as PEEK. The encased sensor must be designed to lock into place within the bone. Experimentation will be carried out to determine the optimum placement of the sensors, whether in the intramedullary canal and/or more proximally within the trochanteric region of our hip model. Three-dimensional orientation is also necessary, and we know how to accomplish this with three sensors. We have arrangements in place for encasement expertise and animal testing as well as FDA consultants. This will require a substantial capital investment.

Although our present focus has been on total joint arthroplasty, this technology can be also applied to monitoring the stability of any orthopaedic construct, be it fracture care, arthrodesis, joint reconstruction, dental implants, and veterinary medicine.

There is no question that this is the way of the future. We are convinced this technology is destined to be within the mainstream of orthopaedics. Perspicacious investment will make it so.

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