IntelliJoint System for Monitoring Displacement in Biologic Systems

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A system of wireless sensors implanted in biological tissue is being developed for dynamic measurements of distances *in vivo*, in real time. The system is designed for clinical use – namely, for monitoring orthopedic procedures, such as healing complicated fractures and evaluating the performance of artificial implants of hip, knee and shoulder joints.

Following laboratory evaluation of the wired system, the electromagnetic sensors are currently being tested for efficacy and safety in experimental surgery using two animal models [Figures 1 and 2].

The sensors are expected to monitor the progress of union in the case of fracture and supply information unobtainable from X-rays. Periodic follow-up provides a graph that shows the gradual decrease of relative motion of the fragments until union occurs.

In joint replacements, the sensors are expected to monitor loosening and progressive instability of the fixation of the implant in bone. Progressive wearing down of the articulating surfaces of the prosthesis, which precedes the deterioration in their performance, is graphically shown on the surgeon's computer.

Conventional imaging modalities fail to diagnose subtle changes in prosthetic joints. The resolution of X-rays, computed tomography and magnetic resonance imaging is lower than 1 mm. X-rays can detect changes in bone structure only after loss of about 20% of bone mass, and dual energy X-ray absorptiometry (DEXA) can detect changes in bone density only after loss of about 5% of bone mass. Bone isotopes have the capacity to provide only qualitative value and are diagnostically non-specific. Special techniques that have been described to

Figure 1. Animal model of the Sensor monitoring motion (displacement) at the fracture site. Note the curved shape Sensor placed within the proximal fragment and the stainless steel rod placed in the distal fragment.

Figure 2. Animal model of the Sensor monitoring the extent of wear (change of distance from the metallic head) of the polyethylene cup in a total hip implant. Note the curved shape Sensor firmly placed at the periphery of the cup.

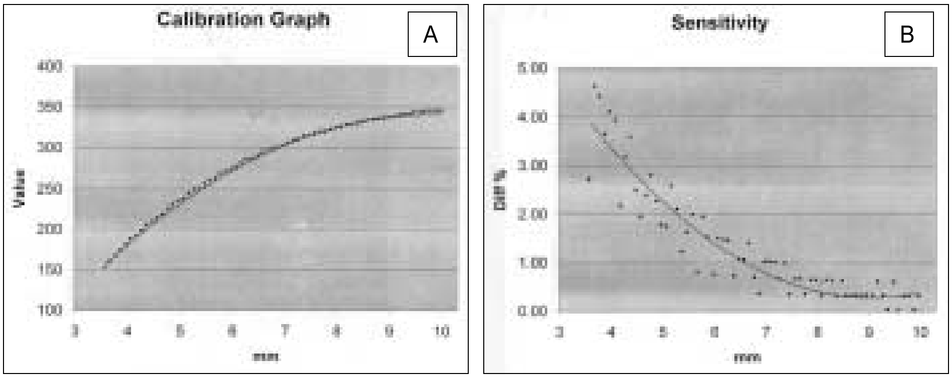

Figure 3. Display of the accumulated data from a laboratory test of the wired Sensor. The rate of attenuation of the oscillating amplitude was measured at various distances at 100 μ increments. **[A]** The measured attenuation related to distance. **[B]** Derivative of [A] displaying the sensitivity of this measurement related to the distance from the Sensor.

improve the resolution of X-rays are not suitable for routine clinical assessment, particularly when the material used for the components of the implants is radio-opaque.

Since the report of Rydell [1] over 30 years ago on the use of wired sensors to measure the distribution of pressures in an artificial hip implant of a volunteer, occasional studies have appeared in the literature on the use of sensors in joint implants. Recently, Elvin et al. [2] developed a wireless tool to monitor pressure in joint implants. However, since all of these sensors were designed for research purposes only, none was able to monitor displacement.

For the clinician, the continuous information on the performance of implanted joints is crucial, as two deleterious processes begin the day after surgery:

- The wearing down of the materials from the articulating surfaces accumulates as microscopic particles.
- During the years of use, the worn particles accumulate in astronomic numbers and cause an ever-increasing inflammatory process of macrophage activity and release of biochemical mediators, including interleukin-1 and tumor necrosis factor, which enhance osteoclastic activity and absorption of bone from the bed of the implant [3].

As a result of this process, the fixation of the prosthesis in bone loosens, the joint pain returns, and the implant requires re-operation and revision. The surgical revision procedure is difficult and lengthy, requires reconstruction of the lost bone with massive bone graft, necessitates a special kind of implant, and is followed by an increased incidence of major complications and mortality.

The benefit of close follow-up, which includes monitoring the performance of the prosthetic joint, is that it enables the physician to take the appropriate measures in the event of an imminently failing implant – prior to bone loss and gross loosening of the prosthesis. The benefit of monitoring the process of union in cases of complicated fractures is the accuracy in determining the final stage of the healing period. This clearly has social and financial implications.

The laboratory research and the development of our project have focused on three aspects: the development of the electromagnetic sensor, the portable wireless transmitter/receiver, and the software for display of data on a PC. Pulses of 50–150 volts are transmitted to the sensors, 3–5 μsec long at a repetition rate of several pulses per millisecond. A signal of 50–200 millivolts is received from the sensor and computed by the software; it displays the frequency and the attenuation rate of the resonance of the sensor, which are a function of the distance between the sensor and the implant.

The three components of the tiny sensor are being developed to be biocompatible and are enclosed within a sealing biocompatible polymer coating (Galaxyl D, Advanced Coating Polymer Ltd., Kiryat Shmoneh, Israel). The sensors are inert, robust, and contain no source of energy. Furthermore, they do not require maintenance or replacement and are therefore suitable for long-term medical applications. Their shape and size can be modified to fit the required application and can be miniaturized by appropriate technology.

The initial laboratory data of the wired system confirm the high accuracy and resolution of 100 μ of the data [Figure 3]. Conversion of the wired system into a wireless one required that the sensors be refined and the transmitter/receiver capacity increased.

In conclusion, the laboratory data and first stage of animal experimental study show encouraging results. Further refining of the receiver to improve the accuracy of obtained information is currently underway, as is improvement of the sensor's core. It is anticipated that this unique system will suit further applications into other medical fields as well.

References

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