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Implantable Sensor Technology: From Research to Clinical Practice

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Abstract

For decades, implantable sensors have been used in research to provide comprehensive understanding of the biomechanics of the human musculoskeletal system. These complex sensor systems have improved our understanding of the in vivo environment by yielding in vivo measurements of force, torque, pressure, and temperature. Historically, implants have been modified to be used as vehicles for sensors and telemetry systems. Recently, microfabrication and nanofabrication technology have sufficiently evolved that wireless, passive sensor systems can be incorporated into implants or tissue with minimal or no modification to the host implant. At the same time, sensor technology costs per unit have become less expensive, providing opportunities for use in daily clinical practice. Although diagnostic implantable sensors can be used clinically without significant increases in expense or surgical time, to date, orthopaedic smart implants have been used exclusively as research tools. These implantable sensors can facilitate personalized medicine by providing exquisitely accurate in vivo data unique to each patient.

Evolution of Smart Implant Technology

In orthopaedic applications of sensor technology, in vivo data collected with implantable sensors was first documented in the 1960s; force, pressure, and temperature were recorded using instrumented implants.¹⁻³ Use of the term smart implant in orthopaedics has been attributed to Franz Burny, who referred to his sensing implants as intelligent.¹

Historically, the strain gauge has been the mainstay of orthopaedic smart implant technology because it is robust, small (eg, submillimeter), and sensitive to minute changes in strain.⁴ However, the gauge requires

permanent bonding and hermetic encapsulation, which involves modification of the host implant. The strain gauge also requires electronics for power and signal transduction.

Early strain gauge systems used percutaneous leads for power and communication. These systems evolved into wireless, battery-powered, telemetry-based systems, which in turn evolved into wireless, telemetry-based systems that are powered passively (ie, no battery) (Figure 1). The latest-generation sensor systems are wireless with no telemetry and are powered passively. These systems are elegantly simple, robust, and inexpensive. Although this technology is promising for future widespread clinical use, to date, orthopaedic smart implants have been used

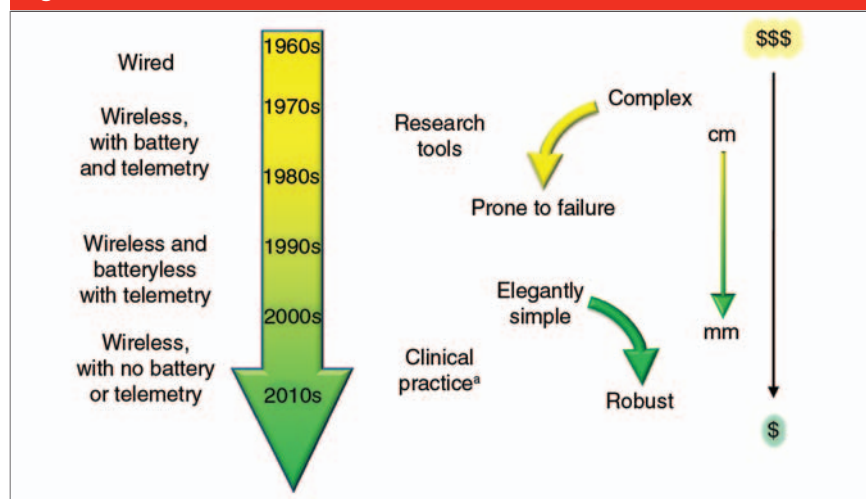
Figure 1

Illustration demonstrating the evolution of orthopaedic smart implants. Early smart implants were complex and bulky systems with signal conditioning electronics and telemetry that were prone to failure due to their complexity. The current passive sensors are simple and robust with no additional electronics. Size of the implantable components has been reduced from tens of centimeters to <10 millimeters. Fewer components and batch fabrication have dramatically reduced sensor cost, making the use of implantable sensors in clinical practice affordable.

^a None of these sensors has been used in clinical trials or clinical practice; however, the authors predict that the sensors may be used in clinical practice by the end of this decade.

exclusively as research tools, requiring Institutional Review Board approval before implantation.

Direct Percutaneous Wired Systems

The earliest implanted sensors used direct percutaneous connections tethered to implants to collect in vivo measurements. Rydell² mounted strain gauges to the femoral component of hip prostheses with wires passed through the skin for data collection. The wires were designed to be removed by pulling on the exposed

leads after data collection. In practice, incisions were made to remove the leads. Waugh³ used Harrington rods with gauges attached to percutaneous leads to measure axial forces transmitted through the rods postoperatively. The instrumented rods and leads were removed 2 weeks after the initial procedure, when a second surgical procedure was performed. Burny et al¹ and Perren and Boitzky⁵ both used fracture plates instrumented with strain gauges and percutaneous leads to measure strain during healing. These landmark ex-

periments provided key data that characterized the in vivo environment; however, use of percutaneous leads in human subjects has been limited because of the risk of infection. Direct percutaneous wired systems remain a simple and inexpensive alternative to telemetry-based systems for short-term preclinical studies.⁶

Battery-powered Telemetry Systems

To overcome challenges associated with use of percutaneous leads in the in vivo environment, battery-powered telemetry-based systems have been used with strain gauges to monitor force in nail plates,⁷ hip prostheses,⁸ and spinal cages.^{9,10} These systems facilitate long read ranges and allow data collection during dynamic activities, but the batteries have a finite life (typically weeks) and add bulk to the implanted systems (Figure 2).

Passively Powered Telemetry Systems

Smart implants that use passively powered telemetry have the longest track record of success. These systems use inductive coupling between an external source and an internal antenna to transmit power and data. An external antenna is placed superficial to the implant to make the inductive link. As early as 1971, wireless, passively powered telemetry systems were used in the spine¹¹ and hip¹² and in fracture fixation systems. Robust passively powered

Dr. Ledet or an immediate family member serves as a paid consultant to CardioMEMS; serves as an unpaid consultant to New Millennium Spine, CVS Medical, and ReVivo Medical; and has received research or institutional support from DePuy. Dr. D'Lima or an immediate family member serves as a board member, owner, officer, or committee member of the International Society for Technology in Arthroplasty; serves as a paid consultant to the National Institutes of Health (NIAMS and NICHD) and MAKO Surgical; serves as an unpaid consultant to Stryker, Zimmer, and Orthocyt; and has received research or institutional support from Stryker, Zimmer, Smith & Nephew, and Tornier. Dr. Westerhoff or an immediate family member has received research or institutional support from Synthes. Dr. Bergmann or an immediate family member has received research or institutional support from Zimmer. Neither of the following authors or any immediate family member has received anything of value from or owns stock in a commercial company or institution related directly or indirectly to the subject of this article: Dr. Szivek and Ms. Wachs.

Figure 2

Photograph demonstrating an early complex, bulky sensor with a battery-powered telemetry system. New implantable sensors are smaller and are passively powered (inset).

telemetry-based systems have been the foundation for ongoing studies, some of which have been active for more than a decade.¹³ These systems eliminate percutaneous leads and theoretically have an infinite life. Compared with battery-powered systems, passive telemetry systems are less bulky, but the electronics remain complex and must be protected in much the same way as the strain gauges to which they are attached (Figure 2). Housing electronics within the implant protects both the electronics and the in vivo environment.

Implantable Sensors

Smart implants have been used exclusively as research tools and have

provided critical data, characterizing the in vivo environment in ways that are not possible using other techniques. They facilitate optimal implant design, characterize the healing process, and provide a better understanding of the physical environment in the musculoskeletal system. Smart implants have been utilized in many orthopaedic applications, with significant contributions in the areas of shoulder, spine, hip, knee, bone, and cartilage.

Shoulder

In a recent study, the contact forces and moments that act in the glenohumeral joint were measured by placing six semiconductor strain gauges and an inductively powered

Figure 3

A, Photograph demonstrating an instrumented total shoulder implant. **B**, Photograph demonstrating a section view of the instrumented total shoulder. The electronics are housed in the internal cavity of the implant.

transmitter in the hollow neck of a titanium implant that was based on the Bio-Modular shoulder implant design (Biomet Deutschland GmbH, Berlin, Germany)¹⁴ (Figure 3). A nine-channel custom-made programmable telemetry chip was used to transmit strain, temperature, voltage, and a synchronized signal at a rate of approximately 125 Hz in three patients with shoulder endoprostheses.¹⁵ The signal was transmitted at radio frequency by an antenna located at the distal end of the prosthesis and connected by a pacemaker feedthrough to the telemetry system. Inductive power was transmitted at 4 kHz through the titanium implant. The patient's activities were video recorded and stored synchronously with the implant signals. Bench test-

ing indicated that the instrumented implant system had an accuracy rate of 1% for all load components and 2% for torque.¹⁵ Clinical application of this system has been limited to a small number of patients because of the costs associated with the prosthesis and recording and analyzing the data.

In a study of contact shoulder forces associated with activities of daily living in four patients, *in vivo* measurements indicated that, during frequent high-demand activities, shoulder joint loads can reach up to approximately 150% body weight (BW).¹⁶ In very strong patients or in those with very low BW, the maximum loads exceeded 200% BW during activities such as forward flexion while lifting a weight. Data also indicated that precisely navigating an object (eg, placing a small object on an overhead shelf) requires additional muscular effort, which increases joint forces.

In a study of *in vivo* glenohumeral loading during activities of daily living, Bergmann et al¹⁷ found that, in many activities of daily living, joint loading is lower when the movement is performed quickly.¹⁷ The direction of force relative to the humerus was constant during most activities, as well. In contrast to previous model-based calculations, *in vivo* measurements demonstrated that loads on the glenohumeral joint increased when the arm was elevated beyond 90°. In addition, the measured moments were larger than those predicted by analytic models.¹⁷ This implies that the joint is not frictionless, as is often assumed in analytic models. Such high moments can be caused by friction, by an eccentric load application within the glenoid, or by forces acting outside the glenoid (eg, on the acromion).

In vivo measurements collected with instrumented implants are being used to validate new analytical mod-

els.¹⁶ The data are also being used to improve implant testing protocols and to counsel patients regarding activities that should be avoided in the first few weeks of the postoperative period.¹⁷

Spine

Measurement of *in vivo* forces acting on the spine presents unique challenges compared with measurement of forces in the shoulder, hip, and knee. Posterior spinal fixation devices, which engage the pedicles or laminae, are placed parallel to the spine, and are load sharing. Interbody implants are placed in series with spinal loads but are generally a fraction of the size of posterior spinal fixators and hip, knee, and shoulder prostheses. The size of interbody implants has limited measurement of *in vivo* forces in the spine. To date, only instrumented interbody implants with strain gauges and separate battery-powered telemetry or direct percutaneous wired connections have been used to measure forces in the spine in animal models.^{6,9,10} Posterior fixators¹⁸ and vertebral body replacements¹⁹ have been instrumented with strain gauges and implanted into the lumbar spine to measure applied forces and moments in a limited number of patients. Like the shoulder systems, power and data transmission have been achieved via inductively powered telemetry.

Instrumented posterior fixators were implanted in a cohort of patients with degenerative instability in the lumbar spine to measure forces during walking, sitting, lying down, stair climbing, and contraction of abdominal and back muscles; these findings were reported over several years in several studies.^{18,20,21} Data collected during walking, sitting, and lying down indicate that loads on the posterior fixator were primarily ax-

ial, with little force in the anterior-to-posterior or medial-to-lateral directions.²¹ Loads acting on the implant were similar when patients were sitting or lying down.²⁰ The lowest loads were recorded when patients were lying in a supine and relaxed position. In a study of two patients in which telemeterized spinal fixators were used to measure load, implant loads were higher when patients were walking than when they were lying down, sitting, or standing.²² Walking speed had little effect on implant loads, but stair climbing increased loading slightly.

Rohlmann et al²¹ found that the use of crutches reduced loads only slightly, whereas use of a walker reduced loads by 25%. Lifting a weight had little effect on implant loading, but flexion and extension increased loading on the fixator. In a later study, Rohlmann et al²³ analyzed the influence of muscle forces on loads in internal spinal fixation devices and found that implant loads substantially increased when the abdominal or back muscles were contracted.

In another study, Rohlmann et al²⁴ measured lumbar spinal forces acting on instrumented vertebral body replacements that were implanted in two patients who had lumbar fractures. Forces were measured while the patients were sitting, standing, climbing stairs, and lying in a relaxed position. Similar to data collected in a study of nonhuman primates,¹⁰ Rohlmann et al²⁴ found that loads on the anterior spine were generally high in upright positions, especially when the center of gravity of the upper body moved anteriorly, and that loads were low when patients were lying down. The authors also found that elevating the arms 90° in the sagittal plane resulted in high implant loads, particularly when additional weight was lifted.

Another study reported that, com-

pared with standing, spinal loading increased during sitting.²⁵ In general, activities that induced abdominal or spinal muscular activation resulted in increases in implant loads. Differences in load during activities were dependent on several factors, including arm position. Use of a walker or supporting the upper body with the hands substantially reduced spinal loading.

Spinal loading is dynamic and highly dependent on posture and activity.^{20,21,24,25} Muscle activation is a significant contributing factor to spinal loading, particularly in the anterior column. The highest forces acting on posterior implants have been measured during unexpected events such as stumbling, coughing, and vomiting.^{3,11} During dynamic activities (eg, running), peak forces appear to correlate with extensor muscle activation.⁶

Hip

Since 1988, multiple instrumented implant systems have been used to measure loads that act on hip joints.¹³ Like the sensor systems used in the shoulder and spine, the hip systems are powered inductively, and data transmission is achieved with telemetry. Early-generation hip implants allowed measurement of forces in three dimensions but did not allow measurement of bending moments. Electronics were placed in the hollow cavity of the implant stem.¹³ Current-generation implanted sensors are now capable of measuring moment and thus the friction occurring within the joint.²⁶ These sensors can measure temperature within the joint, as well.

In a decade-long clinical series, nine instrumented hip endoprostheses were implanted in seven patients.²⁷ All implants measured three-dimensional forces acting on the joint as well as the temperature in

the femoral head. Five of these implants also measured temperature along the shaft.

Bergmann et al²⁸ examined hip implant temperatures associated with activities such as walking. The authors reported that, in a patient with low BW and an implant with a polyethylene cup, peak temperature in the cup (43.1°C [109.6°F]) was reached after an hour of walking, whereas in an implant with a ceramic cup, the peak temperature was 1.5°C (2.7°F) lower. In patients with lower joint loads, peak temperatures were lower during cycling than during walking. The material-dependent temperature differences emphasize the advantage of ceramic-on-ceramic hip implants in terms of friction in the joint. In patients with poorly lubricating synovia or those with a metal-on-polyethylene implant, temperatures even higher than 43°C (109.4°F) are expected.

In a later study, Bergmann et al²⁹ reported that typical hip contact forces averaged 270% BW (range, 220% to 330% BW) during walking. They also found that forces increased to approximately 500% BW with fast walking and slow jogging. Neither the floor properties nor the type of footwear had a significant influence on contact forces, and the lowest hip forces were found during barefoot walking. Use of walking aids (eg, crutches) had less influence on hip contact forces than expected, even when patients were trained on their proper use.

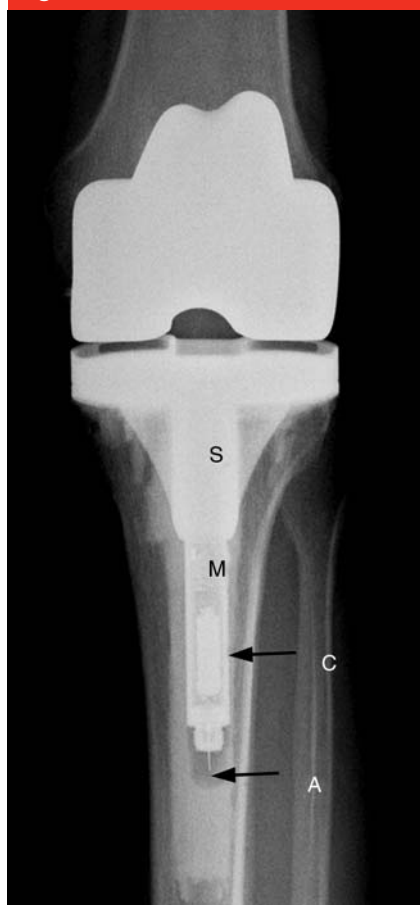
Bergmann et al²⁷ measured hip contact forces with implantable sensors and analyzed synchronous gait patterns in four patients during activities of daily living, including standing, sitting, walking, and ascending stairs. The authors found that the direction of highest forces relative to the femur were constant during all types of activity. Loads with the highest absolute values (up

to 870% BW) were measured by chance when a patient stumbled. Although it was not possible to simulate or reproduce stumbling, these extreme loads were assumed to be caused by involuntary maximal muscle contraction. Therefore, higher forces are expected in younger and more active patients who are likely to have more intense muscle activity. The extreme loads measured during stumbling should be considered when testing the stability of implant fixation, especially the stability of cementless prostheses, during the first weeks postoperatively. These extreme loads further emphasize that walking cautiously during the first few postoperative weeks is more important for fracture consolidation than the use of walking aids.

Torsional loads also can affect implant fixation, especially fixation of uncemented implants in bone; hip sensor systems can be used to collect data on torsional moments about the axis of the implant stem. Load is dependent on the angle of anteversion achieved during surgery. Torsional moments measured about the axis of the femoral shaft are very high; therefore, use of cross-sectional stem geometries that resist failure in torsion is advantageous.²⁷

Knee

Implantable sensors have been used to measure forces acting on the knee joint. In several series, tibial prostheses have been modified and instrumented with load cells, microtransmitters, and antennae.³⁰⁻³² In one clinical series, load cells were placed at the four corners of the tibial tray to measure total force, anteroposterior and mediolateral distribution of forces, and the center of pressure.³¹ In another study, a second-generation instrumented tibial prosthesis was used to measure all six components of force³⁰ (Figure 4).

Figure 4

Postoperative AP radiograph of the knee joint demonstrating implantation of a second-generation instrumented tibial prosthesis that was used to measure forces acting on the joint. The strain gauge (S) is located superior to the microprocessor (M) in the tibial stem, with the internal coil (C) and transmitting antenna (A) located at the distal end of the implant. (Adapted with permission from D'Lima DD, Patil S, Steklov N, Chien S, Colwell CW Jr: In vivo knee moments and shear after total knee arthroplasty. *J Biomech* 2007; 40[suppl 1]:S11-S17.)

The telemetry system of this implant was composed of a microtransmitter and antenna that was powered by magnetic field coupling via an external electromagnetic coil.

D'Lima and colleagues^{31,32} were the first to report on in vivo tibial force measurements collected following

Table 1**Peak Tibial Forces Measured During Activities of Daily Living**

Activity	Peak Tibial Forces (× BW)	Notes
Walking ³¹⁻³³	2.5–2.8	Laboratory floor
Stair ascent ³¹	2.9–3.0	—
Stair descent ³¹	3.2–3.5	—
Treadmill walking ³²	2.1 ± 0.2	1 to 3 miles per hour
Power walking ³²	2.8 ± 0.4	4 miles per hour on treadmill
Jogging ³²	4.2 ± 0.2	5 miles per hour on treadmill
Stationary bicycling ³²	1.0–1.5	Level 1–5; 60–90 rpm
Golf (lead knee) ³²	4.4 ± 0.1	Left knee in a right-handed golfer
Golf (trailing knee) ³²	3.0 ± 0.2	—
Tennis serve ³²	4.2 ± 0.1	—
Tennis forehand ³²	4.3 ± 0.4	—
Tennis backhand ³²	3.5 ± 0.6	—
StairMaster ^a level 1 ³²	2.4 ± 0.1	—
StairMaster ^a level 3 ³²	3.3 ± 0.3	—
Elliptical level I ³²	2.3 ± 0.2	—
Elliptical level II ³²	2.2 ± 0.3	—
Leg press ³²	2.8 ± 0.1	Foot reaction force = 1 × BW
Knee extension ³²	1.5 ± 0.0	Resistance = 0.2 × BW
Rowing machine ³²	0.9 ± 0.1	—

× BW = times body weight

^a Core Fitness, Vancouver, WA

Adapted with permission from D'Lima DD, Patil S, Steklov N, Chien S, Colwell CW Jr: Knee joint forces: Prediction, measurement, and significance. *Proc Inst Mech Eng H* 2012;226[2]: 95-102.

primary total knee arthroplasty. In the first study, one patient received a first-generation device instrumented with four force transducers.³¹ In a later study, three patients received a second-generation device instrumented with strain gauges capable of measuring all six components of force acting on the prosthesis.³² Both studies measured knee forces, knee kinematics, and ground reaction forces during rehabilitation and activities of daily living; the later study also measured forces during athletic and recreational activity (Table 1). In the patient who received the first-generation instrumented implant, peak axial contact forces increased substantially during rehabilitation in the first 3 weeks postoperatively.³¹ At 1-year follow-up, average peak

forces measured 2.8× the patient's BW (ie, 67 kg [147.7 lbs]). Stair climbing generated high forces, as well: 1.9× BW on postoperative day 6 and 2.5× BW at 6 weeks. In the study of the second-generation implant, stationary bicycling, exercise on an elliptical trainer, and rowing were found to generate lower forces than those measured during walking.³² Tennis is a high-impact activity that generated knee forces comparable to those generated during treadmill jogging. Golf swing was considered a low-impact activity; however, it generated high peak tibial forces in the leading knee that approached those of jogging.³²

Several methods of reducing knee forces and external adduction moments have been analyzed, including

gait modification, walking aids, and shoe orthoses. Fregly et al³⁴ monitored mediolateral distribution of tibial forces in one patient 3.5 years after primary total knee arthroplasty for osteoarthritis. The authors analyzed normal, medial thrust, and walking-pole gait patterns and found that a medial thrust gait, in which the knee is deliberately medialized to generate an external abduction moment, effectively reduced medial loads on the tibia by 7% to 28% relative to normal gait. Walking with hiking poles stabilized moments in the frontal plane and reduced medial compartmental forces by 15% to 45%,³⁴ presumably because ground reaction forces were transferred to the poles. Another study demonstrated that walking with a cane in the contralateral hand decreased peak adduction moments by 43%, whereas walking with a cane in the ipsilateral hand increased peak adduction moments by 9%.³⁵ Erhart et al³⁶ found that a variable-stiffness shoe reduced peak external adduction moment and medial compartment joint contact force in a patient with medial compartment osteoarthritis who underwent knee arthroplasty with an instrumented prosthesis.

The knee forces reported on here were in the lower range of those predicted by analytical models. Gait modification can help to modulate distribution of knee forces.^{34,35} External devices such as shoe wedges and walking aids can be used to reduce medial compartmental or total knee force during level walking.³⁴⁻³⁶

Bone

Strain gauges attached to bone have been used to measure strain in several *in vivo* studies. The material properties of bone have been well characterized; thus, strain gauges combined with engineering theory

have been used to determine loads during activities such as walking and exercising. Several materials have been used to bond strain gauges to bone, including adhesives and bioactive coatings.³⁷ Because bone is a dynamic tissue, bonding strain gauges to be used *in vivo* for long periods of time remains a technical challenge, with limited success reported beyond 1 year.³⁸ Protocols for waterproofing gauges and wire junctions with implant-grade epoxy or a multilayer coating have been described, but gauge failure due to moisture absorption remains common.

In early studies, strain gauges were used to improve understanding of regulation of bone remodeling and healing. Studies that used various animal models³⁹ or examined individual patients³⁸ focused on collecting peak bone strain and loading frequency measurements during gait and exercise. In human studies, strain gauges were bonded to bone to establish healing time near spine fusion^{38,40} and to monitor fracture healing.

Studies have demonstrated that load-induced bone remodeling is modulated by the magnitude and frequency of dynamic loading, not by static loads.⁴¹ Strain gauge data have demonstrated that stress shielding causes focal bone loss near stiff metal bone fixation plates and hip stems.⁴² Strain gauge monitoring of spinal fusion has successfully provided a means of assessing bony healing and has also allowed direct measurement of bone strain during activities such as rising out of a hospital bed, rising from a chair, climbing stairs, and lifting an object.⁴⁰

In vivo measurement of bone strain has demonstrated the effect of load frequency on bone maintenance and has been used to validate theories of bone remodeling. Cumulatively, *in vivo* bone strain data have helped to elucidate the effects of stress shield-

Figure 5



Photograph of an implantable osteochondral scaffold instrumented with a single strain gauge to measure cartilage loads *in vivo*.

ing and have changed approaches to implant design.⁴³ Strain measurement has also provided a better understanding of load-induced bone remodeling and loading during bone healing, which in turn has allowed for risk assessment of specific activities performed during healing.

Cartilage

Placement of sensors onto cartilage is not currently possible without damaging the surface of the cartilage and significantly changing its properties; therefore, collection of *in vivo* measurements is rare and requires that sensors be embedded in or placed immediately below the cartilage surface.

In a recent animal study, an implantable scaffold that supports cartilage regeneration was combined with an integrated calibrated strain gauge array, allowing axial and shear load measurement⁴⁴ (Figure 5). During activity, strain measurements were collected with implanted sensors and telemetry to confirm that

Figure 6

Photograph of the first implantable sensor approved by the US Food and Drug Administration. It is a passive resonator-based system manufactured using microfabrication techniques. The resonators are functionally simple; the complex portion of the system is housed in the external electronics. (Courtesy of CardioMEMS, Atlanta, GA.)

the system was capable of detecting subtle differences in force during passive loading activities and to confirm that loads increase during healing.⁴⁴ Chaudhari et al⁴⁵ examined cartilage morphology following anterior cruciate ligament injury and found that disruption of the ligament was associated with an increase in impact loading and a decrease in peak mid-stance loads, thus verifying results from prior gait and motion analysis studies.⁴⁵

Data from these early studies have been used to verify analytical models of strain loading and improve their fidelity. The in vivo data have also helped define loading regimens for use in cartilage bioreactors to improve tissue engineering. In the future, patients could monitor their own activities to prevent reinjury to the joint. For patients who have undergone cartilage regeneration procedures, real time in vivo measurement of loading and strain can be used to alert them if they overload cartilage tissues during sporting activities. This type of feedback could be used to develop postoperative patient-

specific activity modification and exercises.

Future Applications

To achieve the goal of using sensors in clinical practice, the devices must be inexpensive, robust, and require little to no modification of the host implants.^{1,4} Technology now exists to realize the final step in the evolution of sensors from research tools to devices usable in clinical settings. Microfabrication techniques have facilitated development of implantable passive resonator-based sensors that are fundamentally simple electronic circuits composed of only two components. No telemetry, no signal conditioning electronics, and no on-board power are involved in these circuits. In some cases, there are no electrical connections between components.⁴⁶ Resonator function is simple: when the resonator is exposed to radiofrequency energy from an external antenna, it resonates at a characteristic frequency that can be measured by the external antenna. Resonator-based sensors are designed so that the characteristic resonant frequency is modulated when the sensor is exposed to a stimulus, such as load.

Resonator-based implantable sensors were described as early as the 1960s;⁴⁷ however, advances in microfabrication have renewed interest in passive resonator-based sensors.⁴⁸ This technology provided the basis for the first implantable sensor approved by the US Food and Drug Administration, a passive resonator-based system (Figure 6). Major advantages of this system include the lack of lead wires, batteries, and telemetry systems. The sensors are small, simple implantable electronics that are inexpensive (<\$10 per sensor based on batch fabrication cost) and, importantly, require little or no mod-

ification to the host implant. The complexity and cost of these systems lie in the external antennae and external electronics.

Simple, robust, and inexpensive implantable sensors have clinical applications in fracture healing, spine fusion, and arthroplasty. This technology can aid assessment of fracture healing and spine fusion by monitoring load sharing between the implant and bridging bone. This can allow for earlier detection of pseudarthrosis and nonunion as well as early intervention (eg, bone stimulator, dynamization) or revision. Union can also be detected earlier, which can result in a quicker return to work and reduction of lost wages.

Intraoperative measurement of forces in a knee implant or trial can facilitate intraoperative soft-tissue balancing for optimal implant placement. Likewise, early detection of prosthesis migration or loosening by measuring micromotion between the implant and bone may permit early intervention, reduction of osteolysis, and better long-term outcomes. Other applications may include detection of infection with a pathogen-specific sensor. In each application, onboard data storage and patient feedback technology can provide an early warning directly to the patient to prompt activity modification.

Summary

Smart implantable sensors have evolved from complex and bulky technology with signal conditioning electronics and telemetry systems that were prone to failure to simple and robust passive microsensors that require no additional electronics. The size of the implantable components has been reduced from tens of centimeters to <10 millimeters. Fewer components are required in the new sensors, and batch fabrica-

tion has dramatically reduced their cost. Implantable sensor technology continues to drive changes in implant design and surgical technique. This technology has been used to develop and validate laboratory testing protocols that are clinically relevant and could be used to advise patients on safe levels of activity following surgery. Large-scale manufacturing of new systems may permit the use of implantable sensors in clinical practice, thus improving patient outcomes. This technology also can be used to collect quantitative data for evidence-based medicine by monitoring cohorts of patients to identify early markers of orthopaedic disease and to optimize treatment regimens.

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Evidence-based Medicine: Levels of evidence are described in the table of contents. In this article, references 1-3, 5, 7, 8, 11, 16, 20, 21, 24, 25, 28, 29, 31, 32, 34, 35, and 40 are level II studies. Reference 4 is level V expert opinion.

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