

REVIEW

Implantable sensor technology: measuring bone and joint biomechanics of daily life *in vivo*

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Abstract

Stresses and strains are major factors influencing growth, remodeling and repair of musculoskeletal tissues. Therefore, knowledge of forces and deformation within bones and joints is critical to gain insight into the complex behavior of these tissues during development, aging, and response to injury and disease. Sensors have been used *in vivo* to measure strains in bone, intraarticular cartilage contact pressures, and forces in the spine, shoulder, hip, and knee. Implantable sensors have a high impact on several clinical applications, including fracture fixation, spine fixation, and joint arthroplasty. This review summarizes the developments in strain-measurement-based implantable sensor technology for musculoskeletal research.

Introduction

Biomechanics plays a major role in orthopedic injury, disease, and treatment. The form and function of the musculoskeletal system is primarily mechanical in nature, supporting and protecting the rest of the body, and facilitating movement and locomotion. This system is made possible through the intricate interactions between bone, cartilage, ligaments, muscles and tendons. Stresses and strains are major factors influencing growth, remodeling and repair of these tissues. Therefore, knowledge of forces and deformation within bones and joints is critical to gain insight into the complex behavior of these tissues during development, growth, maturation, and aging; as well as the responses to injury, disease, and healing.

One of the most commonly used types of musculoskeletal sensor is one that measures strain [1-5]. By

monitoring strain one can determine local tissue deformations and stresses in bone and cartilage. Tissue strains have been measured *in vivo* in animals with implanted telemetry (wireless) systems or in humans with temporary (precutaneously wired) strain gages [1-3,6]. Orthopedic implants, such as joint arthroplasty components and spinal fixation devices, offer a convenient mechanism for sensor placement as well as to accommodate electronic components such as microprocessors, radiotransmitters, and power sources [7-11]. By calibrating strain against applied force, strain sensors in implants have been used to measure net joint loads. Sensors were initially wired and accessible only through percutaneous connections, which only permitted short-term data collection [1,12]. Radiotransmitters made it possible to develop fully implantable wireless systems (telemetry) that permitted longer-term data monitoring [9,13].

Implantable sensors have a high impact on several musculoskeletal clinical applications, including fracture fixation, spine fixation, and joint arthroplasty. Examples include monitoring the strength and progression of fracture healing and spine fusion; identifying risk for implant fatigue, migration and loosening; and monitoring of wear and damage in bearing surfaces. This review summarizes the developments in strain measurement-based implantable sensor technology for musculoskeletal research in general, with a special emphasis on the knee joint.

In vivo strain measurement in bone

Lanyon and colleagues measured bone strains *in vivo* as early as 1975 [1]. Strain magnitudes and orientation of principal strains varied widely based on activity as well as within each activity cycle. Later measurements in subjects performing activities at a higher level revealed higher than expected strain rates (reaching 0.05/second), although peak strain magnitudes remained below 2,000 microstrain and below those measured in animals [2]. The invasive nature of these strain gage measurements only permitted temporary implantation and sample sizes were limited to measurements in one or two subjects.

One challenge for long-term measurement of direct tissue strains *in vivo* is the debonding of standard strain

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sensors from the underlying tissue within a few weeks. On the other hand, sensors attached to porous tissue ingrowth surfaces can lose their original accuracy as the tissue ingrowth progresses [3]. One approach to overcome this challenge is coating sensors to enhance direct biological bonding to bone.

This approach of coating strain sensors was used for measurement of strains in the lamina of lower thoracic vertebrae and the rod of segmental fixation for scoliosis surgery (monitored postoperatively in one subject) [11]. These measurements provided a useful record of how the process of integration of calcium phosphate ceramic-coated strain gages to bone and progression of spinal fusion affected early postoperative strains. While these results appear to be specific to the individual tested, this approach may be valuable as a more sensitive, quantitative, and biomechanically relevant method of monitoring fusion than serial radiographs [14].

***In vivo* strain measurement in fracture fixation**

Instrumenting external fixation systems with strain gages provides a convenient, although temporary, method of measuring displacement and stiffness of the fracture site. Increasing stiffness during fracture healing allows quantitative monitoring of the process. A threshold for bending stiffness of 15 N-m/degree for tibial fractures and 20 N-m/degree for femoral fractures has been established as a marker of acceptable healing and to permit removal of the fixator [15-17]. In the early 1970s, Burny and co-workers used percutaneous leads to measure loads during fracture healing by instrumenting fracture plates with strain gages [18]. Brown and coworkers used battery powered telemetry-based systems to monitor forces in proximal femoral nail plate fixation systems [9]. Peak bending moments of 20 N-m about the anteroposterior axis were reported for walking during the early postoperative period (within 4 weeks of surgery) before fracture healing. Of note were the relatively higher than expected axial moments (up to 12 N-m). Since fracture healing significantly reduced the forces and moments on the nail-plate, long-term monitoring of hip forces was not relevant. A femoral intramedullary nail instrumented with sensors and a telemetry system were used to monitor femoral forces during the fracture healing process and reported a 50% decrease in loading over the first 6 months after fixation [19].

***In vivo* pressures in cartilage**

Metal-on-cartilage contact pressures were measured using a hemi-arthroplasty femoral component, with pressure sensors on the articular surface of the head [10,20]. Peak pressures were much higher (up to 18 MPa) than those measured previously *in vitro* and were attributed to dynamic events and muscle co-contraction.

Percutaneous pressure sensors have been inserted during arthroscopy to temporarily monitor medial compartmental cartilage-on-cartilage pressures [21]. However, direct measurement of cartilage strains *in vivo* with more permanent implants has, to date, been possible only in animals. These *in vivo* measurements of cartilage stresses in canines revealed subtle alterations in force that would have been difficult to detect with external (non-implanted) measurements [6,22,23]. For example, changes in joint loading induced by anterior cruciate ligament transection could be quantified. The individual contributions of pain and instability were also independently identified by measuring the change in loading response to anti-inflammatory treatment, which supports the translational relevance of such preclinical studies.

Implantable sensors in the hip joint

Forces acting on implanted femoral components were measured *in vivo* by Rydell as early as 1966 [12]. While the implants were permanent, the precutaneously wired connections were temporary and were designed to be removed after early postoperative data collection. In the mid to late 70s, passive (powered by inductive coupling) telemetry (wireless) systems were used to measure metal-on-cartilage pressures in a hemiarthroplasty [24,25]. Battery-powered telemetry has also been used to measure forces in a total hip arthroplasty femoral component, which peaked at nearly 2.5 times body weight (xBW) during walking on the 12th postoperative day [13].

Sensors that measure hip pressures or forces have been implanted in the hip joint by several research groups, making *in vivo* hip forces one of the most widely reported joint forces [10,26-28]. The underlying principles of strain gage measurement of forces and inductive electromagnetic powering of the telemetry system have remained the same. However, three generations of hip components have been developed and implanted, resulting in the current capability of measuring three components of force and three moments acting across the femoro-acetabular joint [29].

During walking, hip joint forces peaked between 2.2 to 3.3 xBW [27]. Hip forces were sensitive to the velocity of walking and peaked at 5 xBW during jogging, but were much less sensitive to the type of footwear or to the type of walking surface [27,30]. The importance of involuntary muscle contraction was emphasized when forces approaching 9 xBW were recorded during an episode of stumbling [31]. The direction of the peak force vector relative to the acetabulum was found to be consistent between subjects supporting the conventional wisdom of adaption and development of the musculoskeletal system in response to external forces [32]. These measurements directly support the need to more precisely reconstruct the center of the hip joint after arthroplasty and to avoid

deviation from normal femoral anteversion in order to reduce the risk of abnormal forces on the implanted components. Experimental results from implanted hip sensors have been widely cited and used for validation of, and as data input into, several computer models and have advanced the *in vitro* and preclinical assessment of hip implants [33-36].

Implantable sensors in the spine

Around the same time as Rydell's attempt to measure hip forces, Waugh used Harrington rods instrumented with strain gages for spine fixation to measure forces *in vivo* [37]. As with Rydell's femoral component, the strain gages on the Harrington rods connected via percutaneous wires allowed measurement for only one day. By the early 1970s, telemetry systems were temporarily implanted to measure early postoperative forces in the spine [38,39]. Since then forces in the spine have been measured over longer durations using instrumented spine fixation devices [40], strain gages on the lamina [11], and instrumented vertebral body replacement [41].

High vertebral body loads have been measured even during the first postoperative month after implantation with a vertebral body replacement. These forces ranged from 100 N when lying down, to over 700 N when carrying weights or exercising against resistance [41]. Vertebral laminar strains peaked at nearly 2,000 microstrain while climbing stairs: an unexpected finding suggesting that trunk flexion to reduce knee moments may place high strains on posterior elements of the spine [11]. Up until these instrumented implants made *in vivo* measurements possible, laboratory experiments were limited to cadaver experiments. *In vivo*, muscular effort was a major factor influencing the loads on the implant. However, the difficulty inherent in accurately simulating the effect of muscle forces explains the significant differences found between cadaver measurements and *in vivo* measurements [42].

Nachemson measured intradiscal pressures for the first time *in vivo* using an external pressure transducer connected to a temporary intradiscal needle [43]. Since then several reports of *in vivo* disk pressures using similar percutaneous techniques have been made, but longer-term monitoring of intervertebral body forces using fully implantable sensors has not been successfully accomplished in humans [44-46]. In baboons, even sitting with the spine flexed generated forces exceeding 4 xBW, which underscores the high magnitude of forces generated [47,48]. In humans too, sitting generated higher vertebral body forces than standing [49]. However, given the sensitivity of measured loads to the location of sensors in the spine, it appears likely that intervertebral forces or intradiscal forces may be different from loads measured in the posterior fixation or vertebral body.

In addition to the experimental observations, such as the effect of chair design on spinal forces [50], or changes in spinal fixator forces after a staged anterior interbody fusion [51], these data have been used to validate computational models [52], as well as to inform on developing more realistic *in vitro* models for spine testing [53].

Implantable sensors in the shoulder joint

The shoulder is one of the most complex of the major joints in the human body. The hip resembles a ball-and-socket joint; therefore, the stability is primarily governed by the bony anatomy. The shoulder, on the other hand, has an extensive range of motion and is stabilized primarily by muscles during most activities. Forces in and around the shoulder are directly related to many common shoulder disorders such as instability, tendinitis, rotator cuff tears, and arthritis: involving repetitive activities of daily living or athletic actions such as throwing. Shoulder arthroplasty therefore provides a convenient opportunity to implant sensors and telemetry systems in the shoulder to monitor forces during complex activities.

Forces in the shoulder were first measured *in vivo* using a shoulder arthroplasty humeral stem instrumented with a six-sensor, multichannel telemetry system [8]. Comparing across activities of daily living, the highest joint forces were recorded while steering a car with one hand, setting down 1.5 kg on a table, and lifting a 2 kg weight to a high shelf (all over 100% bodyweight) [54]. Despite the classification of the shoulder as a non-weight bearing joint, forces in the shoulder peaked over 2.0 xBW during forward flexion while holding a 2 kg weight [5]. For comparison, walking generates similar peak forces in the hip [27] and knee (Table 1). Activities requiring a high degree of control increased joint forces presumably due to increased muscular co-contraction. An unanticipated experimental finding was the increase in glenohumeral contact forces when the arm was raised above the shoulder [5]. Before *in vivo* experimental forces were available, most computational models that use muscle forces to balance the external adduction moments were unable to predict this increase. The speed of movement did have an effect on the magnitude of motion; however, contrary to expectations, faster movements decreased peak forces [5]. These results underscore the need for more accurate predictions of shoulder forces and highlight an inherent weakness of common approaches to musculoskeletal modeling, which makes it difficult to predict muscle agonistic and antagonistic co-contraction with a high degree of accuracy. Additionally, most computational models of the shoulder ignore articular friction, assuming it to be negligible, but the magnitude of moments recorded in the head of the humerus indicates that friction is likely to be an order of magnitude

Table 1. Peak tibial forces during activities of daily living

Activity	Peak tibial forces (xBW)	Notes
Walking [4,7,70,71,76]	2.5-2.8	Laboratory floor
Stair ascent [4,76]	2.9-3.2	N = 9
Stair descent [4,76]	3.2-3.5	N = 9
Treadmill walking [71]	2.1 ± 0.2	1 to 3 miles per hour (N = 4)
Power walking [71]	2.8 ± 0.4	4 miles per hour on treadmill (N = 4)
Jogging [68]	3.1-3.6	Tumor replacement prosthesis (N = 1)
Jogging [71]	4.2 ± 0.2	5 miles per hour on treadmill (N = 4)
Stationary bicycling [71]	1.0-1.5	Level 1-5; 60-90 rpm (N = 4)
Golf (lead knee) [71]	4.4 ± 0.1	Left knee in a right handed golfer (N = 4)
Golf (trailing knee) [71]	3.0 ± 0.2	N = 4
Tennis serve [71]	4.2 ± 0.1	N = 4
Tennis forehand [71]	4.3 ± 0.4	N = 4
Tennis backhand [71]	3.5 ± 0.6	N = 4
StairMaster Level 1 [71]	2.4 ± 0.1	N = 4
StairMaster Level 3 [71]	3.3 ± 0.3	N = 4
Elliptical level 1 [71]	2.3 ± 0.2	N = 4
Elliptical level 11 [71]	2.2 ± 0.3	N = 4
Leg press [71]	2.8 ± 0.1	Foot reaction force = 1 xBW (N = 4)
Knee extension [71]	1.5 ± 0.0	Resistance = 0.2 xBW (N = 4)
Rowing machine [71]	0.9 ± 0.1	N = 4

xBW, times body weight. Adapted from [81].

greater (coefficient of friction 0.1 to 0.2) than estimated (0.01), and more important than previously thought [5].

Implantable sensors in the knee joint

The knee joint is a critical load-bearing joint that is often affected by injury and disease. Osteoarthritis, one of the most common forms of arthritis, has a strong bio-mechanical component. Forces and moments about the knee joint have been correlated with the severity and progression of osteoarthritis [55-67]. Knee forces have even greater significance after knee arthroplasty and can directly affect the wear and damage of the artificial materials used in knee replacement components, as well as influence the remodeling of the underlying bone, and can impact the integrity of the interface between the implants and the bone. The complexity of the knee joint makes it difficult for computer models to accurately predict knee forces. Therefore, direct measurements are critical to better understand the progress and modulation of diseases, such as osteoarthritis, as well as to enhance the design, surgical implantation and postoperative care of the reconstructed knee.

In 1998, a massive (tumor replacement) distal femoral prosthesis was instrumented to measure the forces and moments in the femoral shaft. These measured forces

were then used to calculate the joint forces at the hinged knee joint [68,69]. Anderson and colleagues measured medial compartment pressures intraoperatively using percutaneous pressure sensors inserted during arthroscopy [21]. However, the human knee joint was the last of the major joints to be implanted with permanent sensors (after the spine, hip, and shoulder) [4,7,70,71]. This was in part due to the technical challenges of incorporating the sensors and telemetry system within the smaller footprint of a knee arthroplasty tibial tray. The first *in vivo* knee forces were measured in 2004 using an early generation device that only measured uniaxial forces [4,70,72]. From the measured uniaxial forces at four quadrants in the tibial tray, the center of pressure and the mediolateral distribution of forces could also be calculated [4,72]. However, this device could not measure anterior shear and axial torque, both of which are important components of force in the knee joint. In 2005, a second-generation device that measured all six components of forces and moments of the tibial tray was implanted [7,71,73]. The second-generation sensor design consisted of a redundant array of 12 strain gages that collectively yielded the three components of force and three moments [73]. Independently, the team led by Bergmann subsequently instrumented a tibial tray that

measured all six components of forces, which increased the total number of patients with implanted sensors in the knee joint to ten [74-77].

Tibial forces were monitored over the first postoperative year: with peak knee forces progressively increasing before eventually reaching an average of 2.8 xBW at the end of the first postoperative year [4,74]. Forces through the medial compartment averaged 55% of total force [78]. During the stance phase of walking, the axial force through the medial compartment averaged 73% for the first peak and 65% for the second peak [79]. This mediolateral distribution of forces was correlated with limb alignment with a 1° varus deviation increasing the medial loading by 5%. A summary of the tibial forces for other activities of daily living are provided in Table 1. These instrumented knee implants have been used to test the efficacy of deliberately altering knee forces, for example, as one potential approach to the prevention and treatment of osteoarthritis.

Osteoarthritis remains intractable with no known disease-modifying therapy. Because of the biomechanical factors contributing to the onset and progression of osteoarthritis, several therapies have targeted reduction in knee forces and in adduction moments. Examples of these approaches include shoe orthotics, braces, walking aids, gait modification, and treadmills. External measurements incorporating motion analysis and ground reaction forces have only provided indirect evidence to support these techniques. Directly measuring the effect of these biomechanical modifications on the magnitude and distribution of tibial forces *in vivo* is therefore very attractive.

A gait-modification technique that exaggerated the medial thrust at the knee in an attempt to generate a valgus moment during walking was found to reduce medial compartmental loads by 7 to 28% [80]. Hiking poles were even more effective, reducing medial compartmental force by up to 45% [80]. The benefit of a cane depended on which side the cane was used: reducing peak abduction moment on the tibial tray by 43% on the contralateral side, while increasing the abduction moment by 9% on the ipsilateral side [81].

Lateral wedges in the soles of shoes have been shown to reduce the external adduction moment at the knee in some studies and therefore reduce medial knee loads in an attempt to relieve medial compartmental osteoarthritis. However, not all studies consistently reported successful changes in adduction moment. In an attempt to resolve conflicting reports, the mediolateral distribution of knee forces was directly measured in six subjects with instrumented tibial trays [75]. Wedges alone were found to reduce average medial forces by only 1 to 4%, although one subject benefited from a 15% medial force reduction. A variable stiffness shoe simulates the

effect of a dynamic lateral wedge with the potential for less subjective discomfort than a static wedge. Since the lateral half of the sole is stiffer than the medial half, the medial sole compresses more on weight bearing, producing a similar effect as a lateral wedge. A variable stiffness shoe reduced the peak external adduction moment of the knee in subjects with medial compartmental osteoarthritis [82]. Medial compartment joint contact force was also reduced compared to wearing a shoe without the variable stiffness sole [83].

Valgus knee braces were used in an attempt to relieve medial compartmental forces by reducing the external adduction moment. Direct measurement of medial compartment pressures using arthroscopically inserted temporary percutaneous pressure sensors in 11 subjects could not detect any significant benefit of unloading braces [21]. Knee forces were therefore measured *in vivo* in instrumented trays for more direct assessment [77]. Both the design of the brace and the degree of valgus adjustment were found to affect medial tibial forces. Using an extreme valgus adjustment of 8° in one brace design was found to reduce peak medial forces by up to 30% during walking and stair climbing (although this extreme valgus setting was considered too uncomfortable for prolonged use).

Lower body-positive pressure chambers can reduce net ground reaction forces and can relieve postoperative pain during ambulation. Placing a treadmill inside a pressurized chamber can reduce the effect of gravity on the lower extremities during walking. The patient is positioned with his or her lower body within the chamber. A neoprene seal at the waist maintains the pressure differential between the lower and upper body. A positive pressure (that is, higher pressure within the chamber) lifts the patient and reduces the ground reaction force on the treadmill. Knee forces monitored *in vivo* were reduced and correlated with the reduction in treadmill reaction forces [84].

In summary, knee forces have been recorded for a variety of activities ranging from postoperative rehabilitation to activities of daily living, recreation, and athletic exercise (Table 1). One benefit of directly measuring the forces includes the assessment of therapeutic approaches to modulate knee forces. The effect of these techniques can be monitored in instrumented implants and the precise effect on knee forces quantified. An additional value of *in vivo* experimentally measured knee forces is to validate computational models predicting knee forces. In general, measured knee forces were at the lower range of those predicted, and most mathematical predictions overestimated knee forces compared to those measured *in vivo* (reviewed in [81,85]). Using experimental data to support development and validation of mathematical models substantially broadens the utility of these

electronic implants and extends the value far beyond the small sample size. In addition, the supporting data that are collected in parallel, such as MRI and CT scans, video and fluoroscopic motion analysis, electromyography, and external reaction forces, makes it possible to develop subject-specific models that could drive personalized medicine [85]. These datasets are being released annually for a Grand Challenge Competition held at the ASME Summer Bioengineering Conference and are made available to the musculoskeletal modeling community at [86].

The value of the *in vivo* measurement of forces and strains is high; however, extrapolation to other total knee arthroplasty patients or to other populations, such as normal subjects, has yet to be validated due to the small sample size. Of all the instrumented orthopedic implants covered in this review, an instrumented tibial tray may be feasible for commercial use. Electronic sensors, which can monitor the distribution of tibiofemoral forces intra-operatively, are now available to supplement surgical instrumentation and computer-aided navigation to quantify the soft-tissue balance of the knee (eLIBRA[®], Synvasive Technology, Inc.; and Orthosensor[™]). An attractive feature of the Orthosensor[™] Knee Trial is the complete encapsulation of sensors, telemetry, and powering system within the trial insert. Combining this with low-cost manufacturing of disposable units increases economic feasibility. This technology can also be used to instrument tibial trays that have the same dimensions, shape, and structural performance as off-the-shelf arthroplasty components. The availability of *in vivo* force data from large cohorts of patients is a tremendous advantage to the scientific community, the operating surgeon, and the implant manufacturer. Knowledge of forces within one's knee would also be valuable to the patient in identifying activities at risk and beneficial in modifying postoperative behavior.

Conclusions, potential benefits and future directions

As technological advances reduce the size and invasiveness of sensors and telemetry systems, measurement of forces in individuals with less surgical reconstruction may become feasible, which will permit extrapolation to normal populations with greater validity. *In vivo* measurements of stresses and strains have potential value at several levels. The most immediate benefit is to the research and scientific communities in their respective fields: testing and validating conventional wisdom regarding the performance of implants within the body and generating fresh insights into the behavior of musculoskeletal tissues in response to injury, repair, and surgery, as well as the biomechanics of the healing process. *In vivo* force data for hip, spine, shoulder and knee are freely available at [87]; while datasets combining CT scans, video and fluoroscopic motion analysis,

electromyography, and external reaction forces are available at the link referenced in the following citation [86].

The next level of benefit is to the designers and manufacturers of the medical devices and implants as they incorporate the newly acquired data into developing the next-generation devices. *In vivo* data are also being used to develop more clinically relevant laboratory and computer models for preclinical testing of medical devices as a basis for improving international standards of testing of these devices, and informing regulatory agencies (such as the FDA in the USA, or EU directives governing CE marking) in establishing guidelines with respect to the safety of new medical devices.

A third level of benefit is in providing biofeedback to patients. Direct measurement of implant strain during activity is an unambiguous and quantitative signal. One example is the monitoring of activity that places the implant or surgery at risk for biomechanical failure. This risk of failure was 15 times higher in patients that did not follow recommended postoperative restrictions and when experimentally measured deformation was above the fatigue limit for the implant material [88].

A final benefit, which effectively tightens the design, development, and testing loop, is the analysis of unsupervised data collected under field conditions, which will yield direct assessment of implant efficacy and performance as well as generate early biomarkers of success and failure [89]. These data will greatly enhance evidence-based medicine.

To realize all these benefits, several technical and safety bottlenecks have to be overcome. Sensor and telemetry systems have to be miniaturized to fit within the footprint of standard medical devices without modifications that would jeopardize the performance or reducing the safety of the implants. Another issue is providing long-term power in the form of enhanced and safer battery technology, unobtrusive electromagnetic induction, or alternative approaches such as energy harvesting from applied forces or body temperature. The additional cost of these modifications has to be low enough to make these devices commercially competitive, at least until the value of all the benefits can be established and balanced against cost. Wireless data transmission protocols have to be standardized and approved, and integration with electronic medical records has to be carefully considered. Finally, one has to deal with the massive amounts of data being generated and bandwidth, storage, retrieval, and protection of patient privacy will all be of critical concern.

Abbreviations

CT, computed tomography; MRI, magnetic resonance imaging; xBW, times body weight.

Competing interests

The authors declare that they have no competing interests.

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