"The fundamentals are the future."

**SPINE BIOMECHANICS: THE FUNDAMENTALS**

Perhaps the most fundamental of equations that describe rudimentary physical actions and reactions in the spine biomechanics arena is that which describes the relationship between bending moment, force, and moment arm length:

\[ M = F \times D, \]

where \( M \) is the bending moment, \( F \) is the force applied, and \( D \) is the distance from the point of force application to the axis of rotation (moment arm length).

This is perhaps best depicted in Figure 11.1. Using this equation, one can determine the bending moment applied in any given clinical circumstance. The bending moment has substantial clinical significance. The application of a bending moment results in the concentration of stresses that, in turn, increase the chance of failure at the site of maximum bending moment and force application. In the situation depicted in Figure 11.1, the site of maximum bending moment application is located at or near the ventral vertebral body (at the time of spinal column failure in the case of trauma). After the initiation of failure ventrally (due to the concentration of stresses induced by the applied bending moment), such failure usually propagates dorsally. In this example, all points ventral to the instantaneous axis of rotation (IAR) come closer together and all points dorsal become farther apart. The IAR at the moment of impact/failure is, in fact, located in the ventral/dorsal plane of the vertebral body in which the height of the vertebral body is equal to the rostral and caudal neighboring vertebral bodies. All points ventral to this point came closer together, whereas all points dorsal became further apart.

Spine surgeons have understood for years that there are fundamentally six mechanisms by which we can exert leverage on the spine to correct or prevent deformity and structural failure. These are 1) distraction, 2) three-point bending, 3) tension-band fixation, 4) fixed moment arm cantilever beam fixation, 5) non-fixed moment arm cantilever beam fixation, and 6) applied moment arm cantilever beam fixation. The use of cantilevers, in the form of screws attached to rods or plates, has greatly and positively affected the spine surgeon’s ability to stabilize the spine and prevent or correct deformity. Implant fracture, however, occasionally occurs (Fig. 11.2). Such a fracture always occurs at the point of maximum stress application. Hence, the surgeon either “asked” too much of the implant or fusion failed to ensue, thus fatigueing the implant at its most vulnerable point (the point of maximum stress application).

Dynamic spine fixation for cervical spine applications was popularized approximately one decade ago. By off-loading the implant from axial forces (by allowing the telescoping or subsidence of the spine to passively occur), while providing stability in rotation, flexion and extension, and lateral bending, such devices found clinical utility. Advantages of axial implant off-loading include the provision of bone healing enhancing axial loads to the interbody bone graft, while minimizing loads applied to the implant. Henceforth, the stresses applied to the implant are diminished as well. In spite of the advantages associated with dynamic fixators, constructs still failed.

Spine surgeons, thus, continued their quest to optimize spine stabilization via spinal instrumentation. They designed screws that were strengthened in the region of maximum stress application, thus decreasing the incidence of failure and shifting potential failure points to different locations along the spinal implant or screw, locations that expose the implant to a diminished chance for failure due to an enhanced ability to resist potential failure inducing loads and induced stresses (Fig. 11.3).

In addition to the aforementioned enhanced and bolstered implants, new surgical strategies have increasingly become more popular. These include the utilization of intermediate fixation points (screws placed into intermediate vertebral bodies in multi-segmental constructs) to add a three-point bending fixation force application. The addition of three-point bending forces to the construct enhances construct stability and diminishes the chance for fatigue failure at the bone-metal interface, as depicted in Figure 11.4, A–D. The application of three-point bending forces (Fig. 11.5, A and B).
results in force application in a manner that cannot be achieved by long bridging implants in which an intermediate point of fixation to the native or parent spine is not employed. (Fig. 11.5C). Such an application of intermediate points of fixation is depicted in Figure 11.4D.

The summation of the aforementioned advances improved, but did not eliminate, implant fracture, failure at the implant/bone interface, and overall construct failure. Many think that motion preservation technologies may provide the answer to these dilemmas.

Total disc arthroplasty is yet another new and innovative strategy for the management of patients with spinal disorders. It has found utility in the lumbar and cervical spine and theoretically preserves motion at the affected level and perhaps diminishes degenerative changes at levels adjacent to the arthroplasty. Total disc arthroplasty, however, has not yet been shown to decrease adjacent segment degenerative changes. Furthermore, the biomechanics of total disc arthroplasties are quite distinct and different from that of the normal motion segment. Most of the models available thus far are associated with a very high stiffness in axial loading and a very low stiffness in flexion, extension, rotation, and lateral bending. In other words, they are non-compressible axially and freely permit and do not restrict other motions. Some have a fixed center of rotation, whereas others do not. Therefore, some do not permit translation, whereas others do. Catastrophic complications secondary to implant expulsion have been observed in the clinical setting. Therefore, there remain many unanswered questions regarding motion preservation technologies. It is, however, becoming abundantly clear that the verdict is not yet in regarding their utility and safety.

THE SPINE BIOMECHANICS LABORATORY

The spine biomechanics laboratory is usually involved with the testing of implants alone or in combination with a biological (usually cadaveric) specimen, such as a human or calf spine. Significant deficiencies are associated with all models used in the biomechanics laboratory. These are related to many factors, ranging from the stripping of muscle...
from the spine, the age of the spine, the anatomical fit of the non-human specimen tested to the human clinical scenario, etc. These are but a few of the nuances associated with spine biomechanics testing that result in the obligatory introduction of assumptions into the experimental milieu. This leads to the significant potential for error regarding the interpretation of the results and the importation of the results into the clinical arena for their clinical application.

The following represents a hypothetical situation. If a spine biomechanist were to make 10 assumptions during a biomechanics experiment (a conservative estimate), and if each of these assumptions were associated with a 20% error (or an 80% accuracy; 80% applicability to the analogous clinical situation under investigation), also a conservative estimate, the overall accuracy (clinical applicability) would be very low. The clinical applicability could be calculated in this circumstance by the following equation:

$$0.8^{10} = 11\% \text{ overall accuracy (clinical applicability)}$$

Therefore, it is clear that the biomechanics laboratory presents insufficient relevant information to the clinician and that many gaps in knowledge must be filled, often erroneously. Therefore, the question is raised, “Can we optimize constructs further and can we predict failure by eliminating or diminishing the obligatory gaps in knowledge associated with the assumptions made in the biomechanics laboratory?”

**BIOMECHANICS: THE FUTURE**

It would indeed be wonderful if spine surgeons could measure the parameters, currently only assessed the in vitro laboratory setting, in the human in vivo state. Each patient might then become a biomechanics laboratory and the new science of in vivo biomechanical testing would emerge. This new “frontier” may be nearly upon us with the advent of microelectromechanical systems (MEMS) technology. This technology integrates micromachines or “systems” on a chip. They may have gears, motors, levers, fluidic channels, and/or a variety of other hydraulic or biomechanical interfaces that allow for and facilitate measuring, assimilating, and transmitting physical parameters. They can perform complex tasks, in spite of their small size, which is in the range of micrometers to millimeters.²

MEMS is an enabling technology. MEMS devices harbor the ability to read and respond to the environment in which they are placed, either as a stand-alone device or in combination with an implanted device, such as a spinal implant.

If a tool, measurement technique, or smart system is conceivable in the macro-world, it is possible to construct the same in the micro-world. The technology and resources currently exist to accomplish this. The only additional requirement is money, and lots of it!

Such devices in their simplest form can measure strains, loads, and pressures. Off-the-shelf MEMS pressure sensing devices are available today. In fact, MEMS technology has been available and has found significant application opportunities for some time in non-biological arenas, such as the automotive and aerospace industries.

**SPINE APPLICATIONS**

Theoretically, the pressure within bone, within cages, or under plates may be useful in determining and assessing the progression of healing following a surgical fusion procedure. Figure 11.6 depicts a hypothetical trend of strains (loads) and pressures that may ensue after a successful fusion using an interbody fusion cage. The strain along the cage may diminish as the bone fusion matures and solidifies. Fluctuat-
ing pressures within the cage would dampen with time, stabilize, and possibly rise as the bone structure matures. Therefore, it is conceivable that such devices could be attached to screws, plates and rods or be placed within cages or within body cavities or structures. Such an implant with associated microsensors is depicted in Figure 11.7.3

THE MERGING OF THE PHYSICAL AND BIOLOGICAL SCIENCES

The Generation of a Hypothesis

We, at the Cleveland Clinic Spine Institute Spine Research Laboratory (CCSI SRL), capitalizing on a significant experience with MEMS technology and a special interest in the biological application of such technologies, began “proof of concept” studies regarding the use of pressure sensors in orthopedic and spinal applications.4 The hypothesis that drove the aforementioned research was “that the (telemetric) assessment of pressure is useful for the monitoring and management of spine and orthopedic conditions and treatment paradigms.” In order for this hypothesis to be ultimately confirmed and validated, MEMS devices must be shown to have the capacity to accurately telemetrically monitor clinically significant variables, transmit information to an external receiver and have no internal power requirements. First, however, it is necessary to demonstrate that the variables, such as pressure, are worthy of in vivo measurement in the clinical environment; hence, the derivation of the aforementioned hypothesis. Measuring intradiscal pressure may be analogous to the measurement of blood pressure in the early sphygmomanometer development era. Measuring blood pressure seemed like a good idea. However, it was a difficult concept to “sell” to cautious and suspicious clinicians of the time. It was even more difficult to validate.

MEMS Technology

From a historical perspective, MEMS technology is the outgrowth of strain gauge development in the 1950s. This technology was heralded by the discovery of the piezoresistivity of silicon in 1954. Metal diaphragms were developed in the 1960s and commercial MEMS pressure sensors were introduced in 1973 by National Semiconductor.

The telemetric application of MEMS sensor technology to biological systems has two component requirements: sensing and data transmission. If no internal power source is to be used, external powering of the system becomes a requirement, as well. This can be accomplished via inductive coupling, using radiofrequency transmission from an external source, the charging of a capacitor located on the implanted MEMS chip, and the releasing of the energy to power the MEMS chip and circuit in order to transmit sensed data to an external receiving source. An alternate, and even simpler, scheme is suitable for capacitive MEMS sensors in which changes in the sensing parameter can be translated into capacitance variations of the MEMS sensor (Fig. 11.8). In such cases, the MEMS sensor can be configured into a passive tank circuit that is comprised of the variable capacitor and a fixed inductor. This tank circuit exhibits a characteristic resonant frequency that varies as the capacitance changes. An external probe can be used to detect the resonant frequency of the implanted sensor without the use of any circuit in the implanted chip.5

There are obvious pitfalls associated with the use of MEMS technology in biological systems. The larger the antenna, the greater the distance permitted between the MEMS sensor and the receiving device. The degradation of

FIGURE 11.6. The strain on an intervertebral cage and the pressure within a cage could theoretically fluctuate with time, as depicted.

FIGURE 11.7. Chips applied to a spinal implant.
transmission with distance and its relationship to the size of the antenna (acquired from research performed in our laboratory, using passive circuitry, whereby the sensor forms a variable capacitor) is depicted in Figure 11.9.

PRESSURE MATTERS

Before pursuing the clinical application of MEMS technologies in the spine and orthopedic arenas, it seemed prudent to demonstrate that the real-time assessment of variables, such as pressure and strain, would be of clinical utility. Therefore, human cadaveric wired-sensor studies were begun in the CCSI SRL. Small fluid pressure sensors were placed into the intervertebral disc and strain gauges over the annulus fibrosis (Fig. 11.10A). Fluctuations in pressure were observed to be commensurate with loads applied and to be substantially blunted by the placement of a rigid pedicle screw fixation device (Fig. 11.10B). Because load (compression), in general, correlates with bone remodeling and healing and intradiscal pressure correlates with applied loads, it can be safely assumed that the pressure at the bone graft/endplate correlates with load applied. This, in turn, should correlate with bone remodeling and bone healing ala Wolff.

Intraosseous pressures were studied in both cadaveric spine and femur models. Minimal fluctuations in intraosseous pressures in both models, even with significant axial loading, were observed. Pressures at varying points within the medullary cavity of the same bone were observed to be equal. The former observation was, at least in part, due to the ingress and egress of blood or, in the laboratory model case, infused saline to replicate the normal low capacitance/low-pressure venous-like channels that connect the intra- and extraosseous spaces. This low resistance egress and ingress of blood between the intra- and extraosseous spaces most certainly results in the blunting of intraosseous pressure fluctuations that may have been expected to be associated with the loading of bone. In addition, the protection of the interstices of bone (intraosseous compartment) by the rigid cortical margins of the femur and vertebral body most certainly further dampens the transmission of pressure into the intra-osseous spaces. The latter observation further substantiates the fact that the medullary cavity of bone should be considered as fluid filled vessel, a vessel within which pressures are equal throughout.

It is known that avascular necrosis (AVN) of the hip is a progenitor of hip degenerative changes that may ultimately necessitate total hip arthroplasty. The management of such pathologies has plagued orthopedic surgeons for years. AVN provides a simple paradigm for assessing intraosseous pressures. As stated, intraosseous pressure, in general, does not fluctuate significantly with the loading of bone. If, however, a cavity is created in the femoral head, just beneath the chondral margin of the head, and fluid pressure is monitored under loaded and unloaded conditions, significant fluctuations in pressure were observed. This is most likely related to the cavity created and the deformability of the chondral margin of the femoral head that was created by the removal of subchondral bone (Fig. 11.11, A–C). This may be an issue

FIGURE 11.8. A, fundamental operating principle of a MEMS telemetric pressure sensor. In this case, the sensor comprises a deformable capacitor and a fixed inductor, which together exhibit a characteristic resonant frequency (B). As pressure varies, the capacitance changes and results in a change of resonant frequency. The resonant frequency is detected with an antenna that couples with the sensor.

of clinical significance. For example, intramedullary pressure fluctuations probably occur to a much greater extent (due to the deformability of the femoral head) with loading of the femoral head in the pathological state (AVN) than in the non-pathological state. This may also have significant implications in the spine care and spine surgery arenas due to similar failures of chondral or chondral-like integrity in the form of end-plate failure that may accompany symptomatic degenerative diseases of the spine.

**Implant Failure**

In order to study spine pathology and spine implant failure, a simple model using the human femur was first used. Fluid pressures were initially measured beneath plates, before and after implant loosening, after the creation of small divots (cavities) in the bone to accommodate the sensor. This did not demonstrate predictable fluctuations in pressure. Subsequently, contact pressure sensors were used (Fig. 11.12, A–C). Contact pressure measurements clearly heralded implant loosening and predicted lift-off of the implant. This most certainly correlates with the clinical situation in which failure and lift-off of an implant is observed following failure of spinal fusion (Fig. 11.13). Such measurements, if available in the in vivo clinical scenario, may even be used to predict catastrophic failure, such as that associated with expulsion of the devices following implantation (Fig. 11.14). Such was demonstrated in our laboratory in the femur model, as well in a total disc arthroplasty model.

**STRAIN MATTERS TOO**

Vertebral body strain was measured during axial loading, flexion and extension. Strain varied with loading and was reduced when a rigid pedicle screw fixator was applied to the vertebrae (Fig. 11.15). Implant and bone strain, which can be readily assessed telemetrically, are also objective and predictable “biomechanical” metrics that will most certainly provide clinically relevant information.

**THE HYPOTHESIS REVISITED**

It was hypothesized that “that the (telemetric) assessment of pressure is useful for the monitoring and management of spine and orthopedic conditions and treatment para-
digms." The data and observations derived from the series of limited (but focused) experiments presented herein support the hypothesis; i.e., proof of concept. Physical parameters, such as intradiscal or intraosseous pressure, are reflective of biomechanical and clinically significant parameters. Pressure (as well as strain and load) does matter.

**WHAT WE KNOW**

Pressure matters. Intraosseous pressure is, in general, low and fluctuates little with loading under normal conditions. It does seem that intraosseous pressure does not vary significantly from region to region within the medullary cavity of the same bone. Similarly, when an intraosseous cavity is created and the cortical surface becomes deformable, as is the case with the AVN model described herein, the intraosseous pressure does fluctuate with the application of external forces. Plate contact pressure decreases, as one might expect, with plate loosening, thus, providing significant implication for the prediction of implant failure. Finally, vertebral body wall strain is affected by spine loading and is modified by the application of spinal fixators.

**WHERE ARE WE GOING?**

Intradiscal pressure, intraosseous pressure, and, in certain pathological conditions, strains, loads, and contact pressures between implants and the spinal column, can most likely be used to detect early implant failure and failure of fusion. This information can be correlated with clinical information and perhaps used to optimally design treatment strategies. Such measurements may be used to detect and protect patients from catastrophic injury that may result from expulsion or catastrophic failure of implants.

Perhaps, more importantly, MEMS technology can be used as a diagnostic tool to determine optimal treatment strategies. Indeed, the fundamentals (the measurements of simple parameters, such as pressure, strain, or load) are the future! The simple real-time measurement of intradiscal pressure may radically affect diagnostic algorithms and, in fact, the way we manage patients with spinal disorders.

Each patient with an implanted MEMS device may become, in a sense, a freestanding “in vivo biomechanics laboratory” that benefits both the patient and his/her physician. With the accumulation of data from multiple patients, databases will be populated with an accumulating and meaningful dataset, diagnostic and treatment paradigms designed and validated, and ultimately, the treatment of patients with spinal disorders optimized.

**ACKNOWLEDGMENTS**

This work was partially supported by grants from OrthoMEMS, LLC and the Ohio Technology Third Frontier Action Fund. The authors are grateful to Douglas Lee, CEO of OrthoMEMS, LLC, for his insight.

**Disclosure**

The authors disclose a potential financial relationship with OrthoMEMS, a Cleveland Clinic spin-off company.
REFERENCES