ELECTRICAL SIGNATURES AND FORCE/TORQUE SENSORS AS METHODS FOR QUANTITATIVELY SIZING BONE IN PRESS FIT ARTHROPLASTY

Kambiz Behzadi
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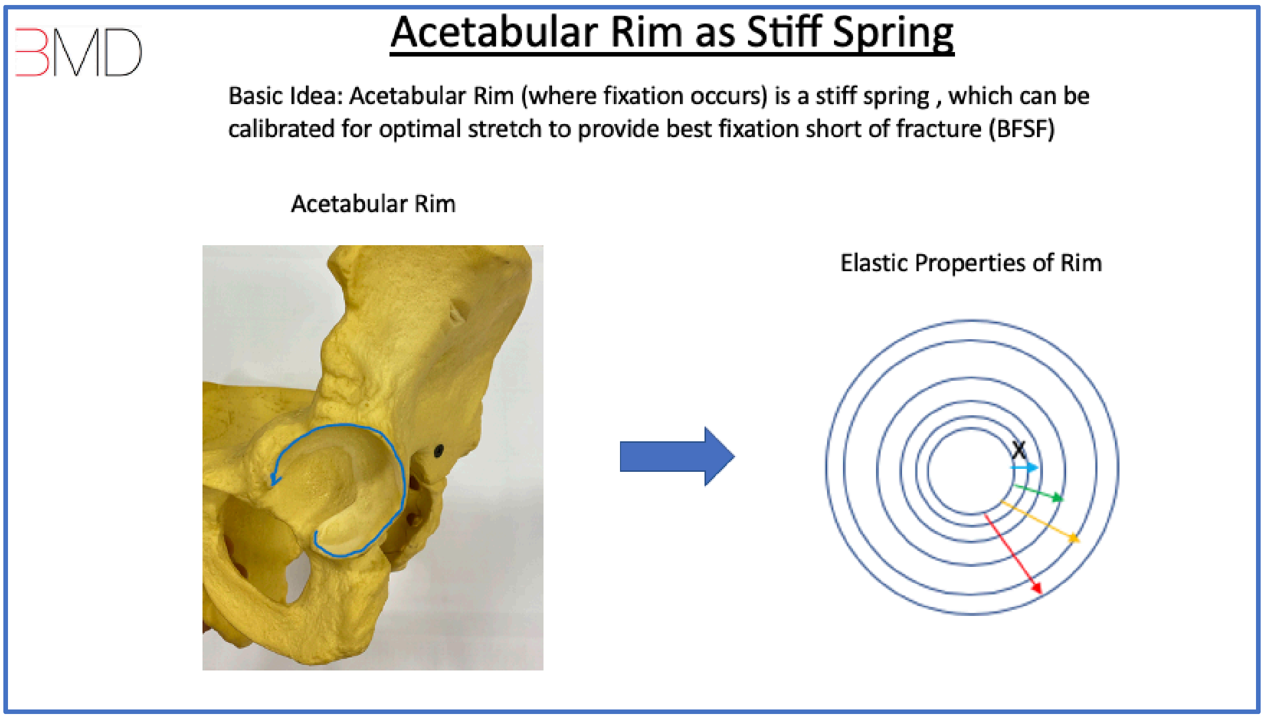
In total hip arthroplasty, orthopedic surgeons use a press fit technique to obtain primary stability of implants in bone. This technique uses the bone's elastic property to grasp the implant. In this process the bone cavity is prepared approximately 1mm smaller than the implant, and an oversized implant is impacted into place with dynamic impacts.

The success of the press fit arthroplasty is dependent on this primary implant stability. Generally, this means that the bone's grasp of the implant must be tight enough, such that there is less than 50µm of micromotion between the implant and bone. If the implant experiences greater than 50µm of micromotion, the implant will eventually get loose and fail. Therefore, optimal primary implant stability is critical to the success of total hip arthroplasty.

Three distinct factors affect primary implant stability: 1. Press fit process 2. Material properties of the implant (stiff or flexible) 3. Geometric properties of the implant (straight, angled). Beyond the material and geometric properties of the implant, the process of *press fitting* is crucially important to the longevity of the implant. The ability to get a good press fit is related to the surgeon's ability to properly size the bony cavity. This type of *tactile sizing* is not unlike what occurs when you buy shoes or pants. Too tight and too loose are both inadequate, and you can only assess the *proper size* by trying the shoes or pants on and *feeling* for the tightness or looseness of the shoe or pants. This is a type of tactile or *force sizing* process.

Currently, the only way we can quantitatively size bone cavities is through pre-operative templating, which is achieved by the surgeon's visual assessment of X-rays. The surgeon performs a distance measurement of the size of the cavity on the X-ray. However, the act of press fit is a force phenomenon. We need a method that sizes bone through *force measurements* as opposed to *distance measurements.* Currently, surgeons rely on their own tactile and auditory senses during the bone preparation process (reaming and broaching) to qualitatively size the bone cavity. These techniques are non-standardized and subject to the surgeon's biases and personal experience.

The sizing of the bone cavity is basically a simple Newtonian problem. How much should we stretch the bone to get the best elasticity or grasping force at the rim, without causing fracture and/or *bone strain deformation*?



Current practice of bone preparation involves reaming the acetabulum to a bleeding surface; or broaching the femur until a firm tactile fit is felt. Frequently, the surgeon has no clear idea how much to ream or to broach the bone. After the reaming is complete, based on pre-operative templating, the acetabular bone may show partially subcortical and partially bleeding trabecular bone. Should the surgeon remove all the dense subcortical bone? There is no clear answer to this question. The whole process of bone preparation and sizing in orthopedic arthroplasty is *non-standardized and qualitative.* There is no good quantitative process of sizing bone intra-operatively.

A fundamental problem with current art is that the tactile feel of the size of the bone does not always match what the surgeon has preoperatively templated on X-rays. There is frequently conflict between what the surgeon perceives as proper size from the felt “chatter “due to changes in the tactile sensation of the reamer or broach and what the surgeon has preoperatively templated on Xray’s.

This process is extremely inaccurate and insufficient in determining the frictional forces at the implant-bone interface. The surgeon’s brain cannot quantitatively assess the frictional forces experienced at the implant-bone interface. Nor should the success of the patient’s arthroplasty have to rely on the surgeon’s feel.

This concern is significant because 80% total hip replacements are done by surgeons who do less than 10 per year. The younger and inexperienced surgeons will never be able to get the experience they need to get the proper feel for a reliable press fit.

Too much implant-bone contact leads to fracture or destruction of the dense cortical bone that provides the interference fit (*bone strain deformation)*. Too little implant-bone contact leads to a poor initial fit and eventual loosening. Surgeons want the highest implant-bone contact that provides optimal primary implant stability (best press fit), but without destroying the natural elastic limit of bone.

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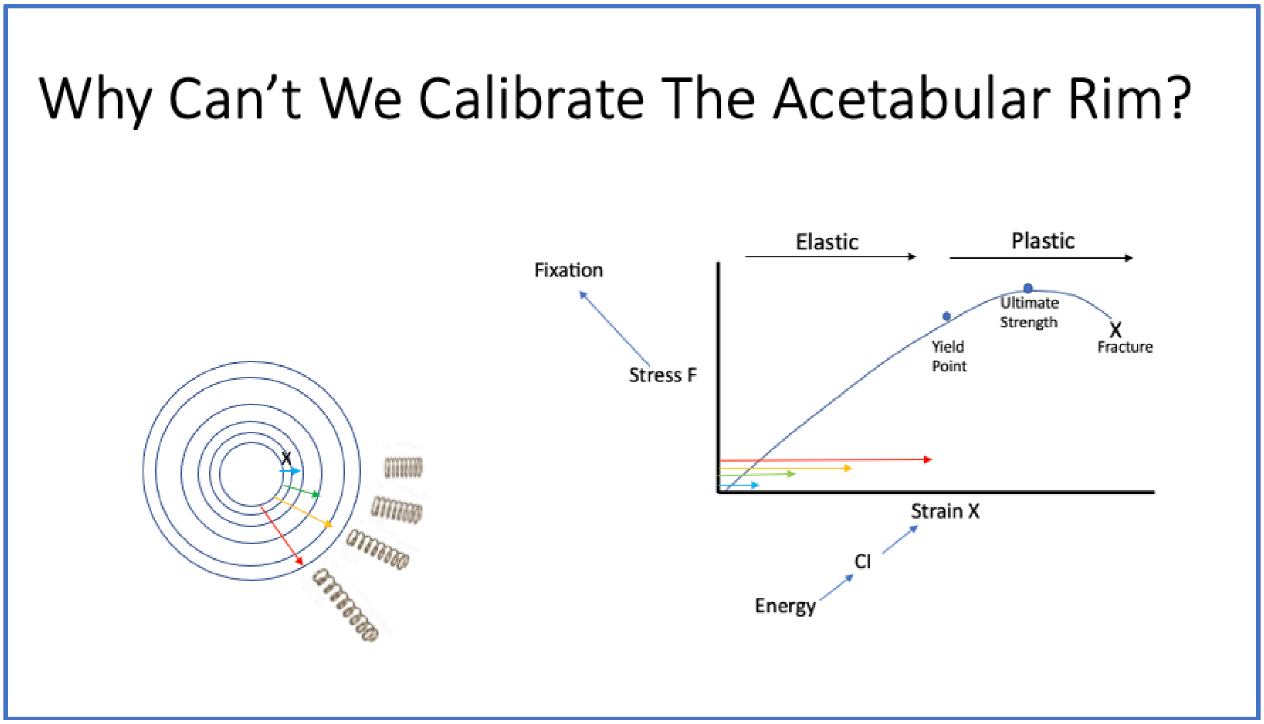
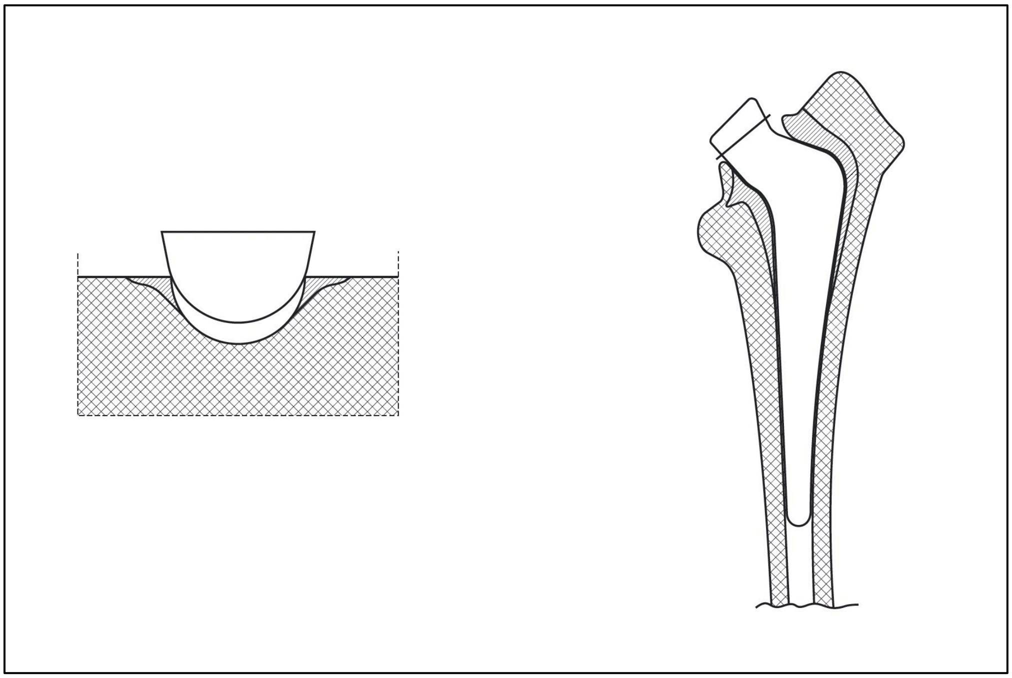


This is a goldilocks problem. Bone behaves like a stiff circular composite spring.
Proper press fit for total hip arthroplasty implants is usually in the range of 0.5mm to 1.0mm. If surgeons under size the cavity and installs too small an implant, the implant will get loose or subside. If surgeons oversize the cavity and use excessive force to impact the implant, then they will damage bone cells, bone vascularity, and create fractures.

Orthopedic surgeons do not have a standardized quantitative method to properly size bony cavities for press fit fixation during the actual operative procedure.

There is a need for a better method for sizing bone cavities in press fit arthroplasty.
There is a need for *a quantitative process for sizing bony cavities* intra-operatively.

The mechanical points of interest in acetabular and femoral fixation in primary hip replacements (as opposed to revision hip replacements) focus on the *rim* of the acetabulum and the proximal aspect of the femur.



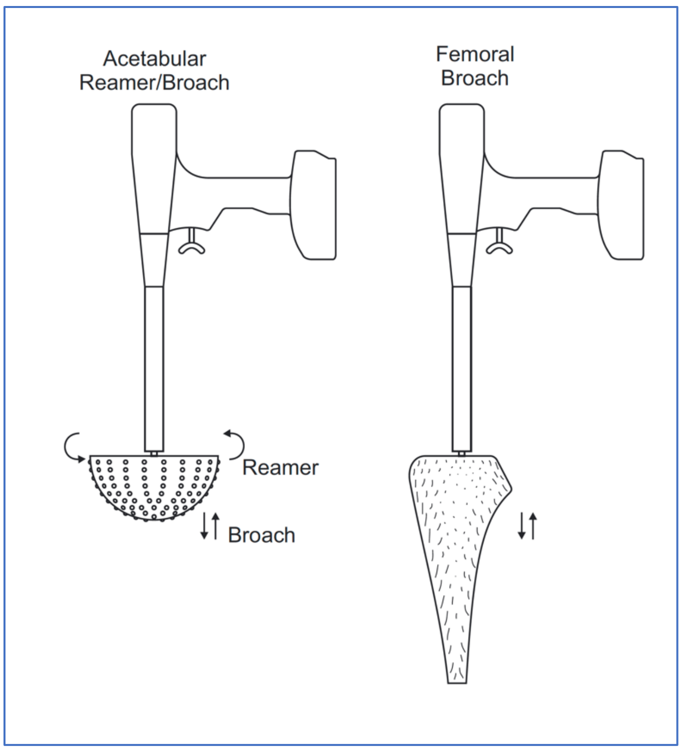
To monitor the frictional forces between the bone and implant in arthroplasty, direct measurement methods have been tried, including measuring forces in bone and within the impaction rods, with a variety of force sensors and accelerometers. However, these methods are difficult and expensive to implement in the OR.

Indirect methods of measuring frictional forces between bone and implant can also be obtained by using dynamometers with load cells that can provide a measure of the sensed strain in the system, in terms of electrical charge and electrical resistance.

Dynamometers measure force, torque, power, and rotational speed of an engine. Basic dynamometers can be of two types: power absorption and power transmission. Power absorption dynamometers measure the output of absorbed power. Power transmission dynamometers have a set of strain gauges that measure the strain of an object.

With respect to power transmission dynamometers, force-torque sensors have application in the concept of *force sizing* of the elastic limit of bone. A way to obtain a quantitative measurement of the frictional forces at the implant bone interface is with the use dynamometers, force gauges, and force-torque sensors. The strain gauges are placed along a moving motor shaft-wheel, and torque is measured by the angular deformation of the motor shaft. Therefore, dynamometers can be used to directly measure force experienced at the bone-implant interface.

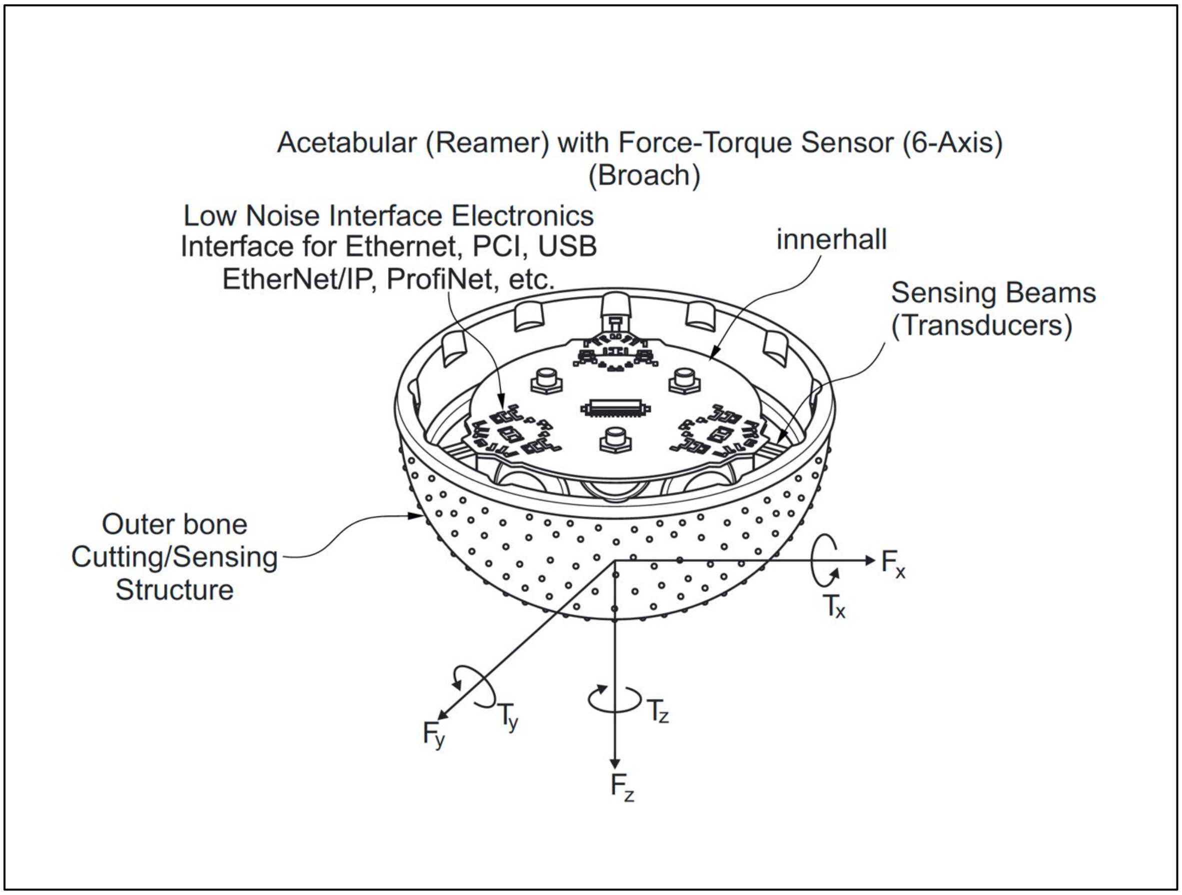
Force-Torque sensors use a variety of strain gauges such as silicon strain gauges that convert mechanical loads into force-torque measures simultaneously in all of 6 degrees of freedom (multi-axis force-torque transducer). In the case of an orthopedic bone resecting instruments such as a reamer or a broach, the sensing structure can be *the actual cutting surface of the reamer or broach.*



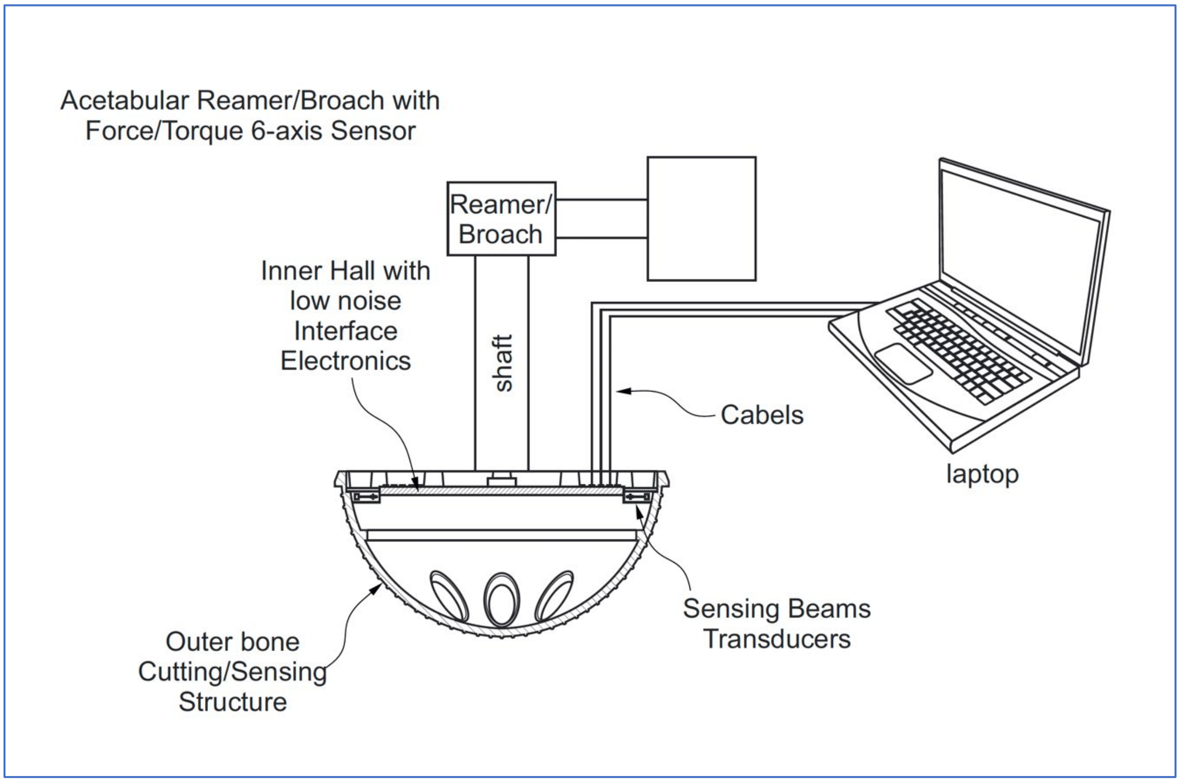
With respect to bone resection and *force sizing* of the elastic limit of bone. The resecting surface of a reamer or broach that meets bone becomes the actual sensing structure. In one exemplary form the cutting surface is housed in an outer wall and is connected to an inner hull with spokes or sensing beams and flexures that have force strain gauges, such as silicon force strain gauges. These force gauges function as transducers, the output of which is 6 channels of strain gauge voltages. This output is digitized and converted into Force and Torque through a matrix calculation.

The benefit of the force/torque sensor over a single load cell is that it provides a full picture of all the forces acting on the transducer, instead of just a single force measurement in a single axis.

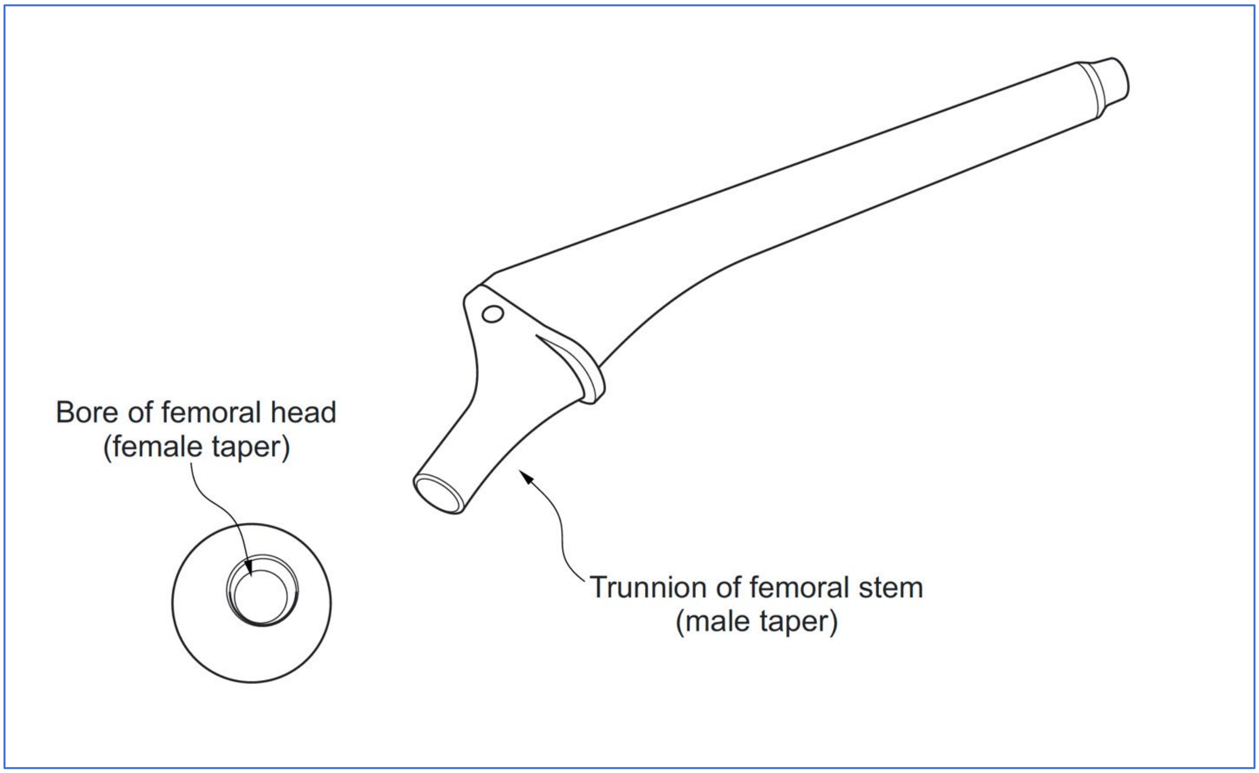
This system consists of a transducer, high flex-cable, and an intelligent data acquisition system, Ethernet/DeviceNet interface or force-torque controller. Force-torque sensors have application in bone resection by providing a quantitative tactile sense of the frictional and radial forces at the bone-implant interface.


Acetabular (Reamer) with Force-Torque Sensor (6-Axis)
(Broach)
Low Noise Interface Electronics
Interface for Ethernet, PCI, USB
EtherNet/IP, ProfiNet, etc.
innerhall
Sensing Beams
(Transducers)
Outer bone
Cutting/Sensing
Structure
F_x
T_x
F_y
T_y
T_z
F_z

Recent advances allow sensors to be directly integrated into desktop and laptop computers using off the shelf data-acquisition cards DAQ, which results in higher data speeds, easier installation, and flexibility in bus selection and operation systems. DAQ force-torque sensors work with any desktop and laptop computer on the market. The six-axis DAQ force-torque sensor consists of a transducer, high-flex cable, DAQ card, and software tools. Proprietary interface cards, on the market, placed on or near the transducer produce a low-noise seven channel signal that can be read by most off the shelf analog input DAQ cards with at least seven available channels. PC based software converts the signal to force and torque output. The computer, through the DAQ card, powers the interface card and transducer. Bundled software includes a reusable, hardware-independent Windows ActiveX component that configures the transducer system and converts raw voltages into forces and torques.

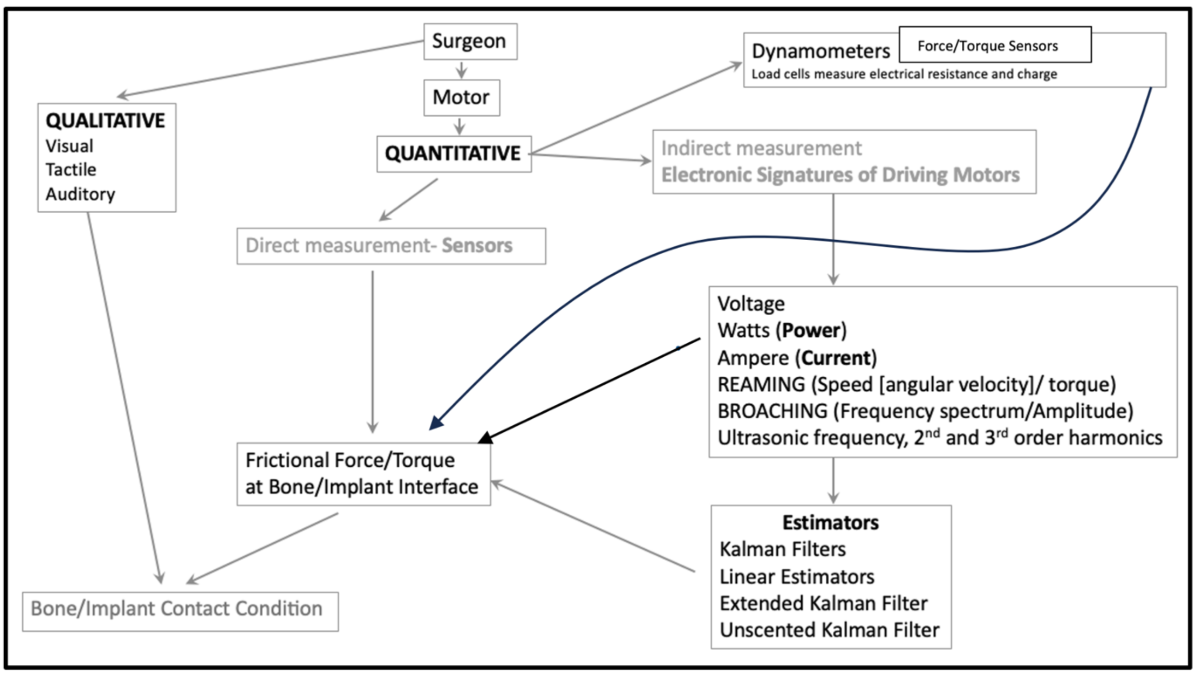


Force-torque sensors also have valuable application in assembly of orthopedic *implants into bone* as well as assembly of *modular orthopedic implants*. The force-torque sensors can assemble the femoral head on to the trunnion, in the modular assembly process, with a level of quantitative exactness that cannot be reproduced by humans. With this method surgeons can use robotic tools to assemble the femoral head unto the trunnion, applying the exact force required to produce a *cold weld* at the head/trunnion interface, preventing any type of metal debris, metalosis and trunnionosis from ever occurring.

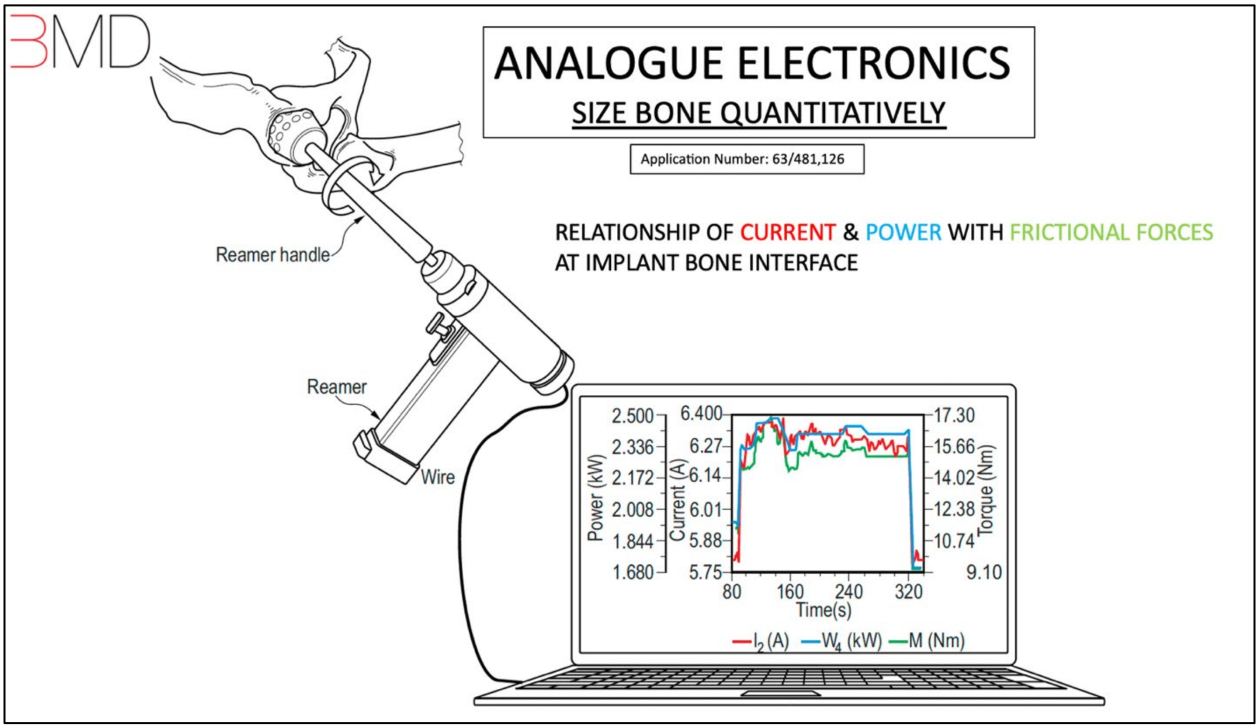


Force-torque sensors also allow surgeons to have a sense of exactly how much force to apply to press fit the implants into bone. For example, the resistive frictional force at the rim of the acetabulum may be 4KN. Surgeons may use up to 14KN of force to impact (press fit) the acetabular cup into bone. A good portion of the extra 10KN of applied force is absorbed by the pelvis, frequently resulting in fractures, occult fractures, osteocyte death, loss of vascularity and bone strain deformation. This system allows the surgeon to know the exact amount of force required to to overcome the resistive frictional forces at the implant bone interface, thereby preventing use of excessive force.

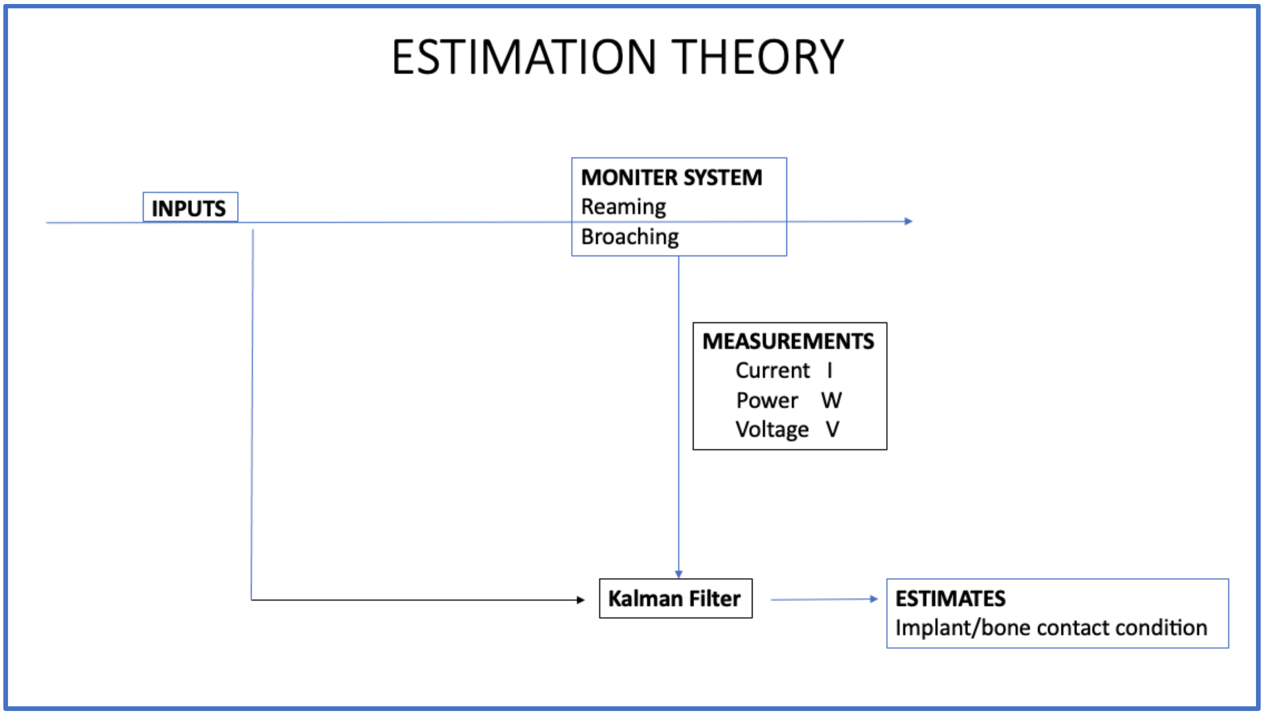
Another *indirect method* of monitoring the frictional forces at the implant-bone interface is to use *electronic signatures of driving motors.* This provides similar information by showing how much power is absorbed during the bone preparation process. The transient electric power and electric current of the driving motors used in tools to ream and/or broach the acetabular and femoral bones can provide a reliable estimate of the frictional force sensed at the implant bone interface. This provides an accurate representation of the implant bone contact condition.



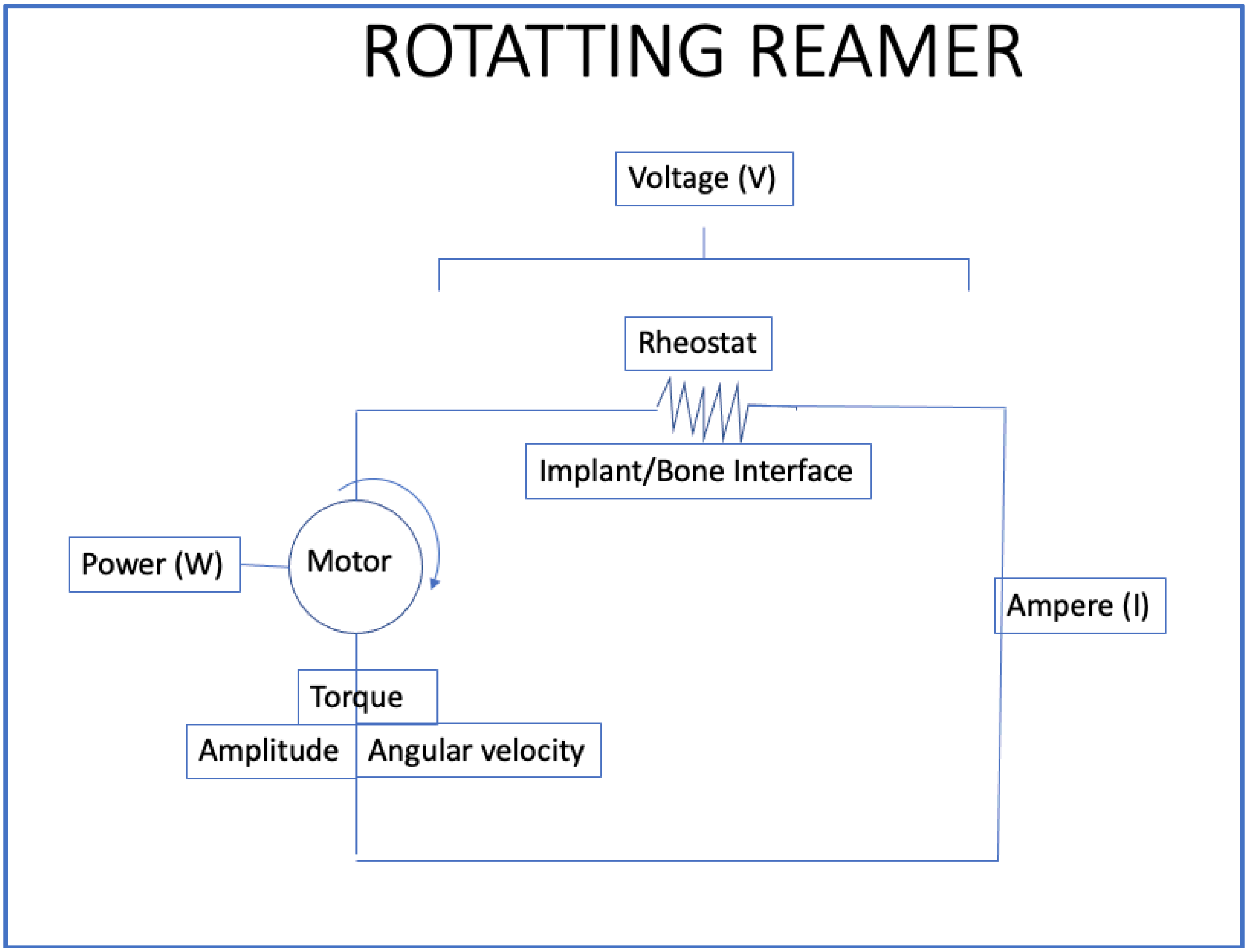
This estimated value of frictional force can be shown to the surgeon in digital or numerical form providing guidance as to when reaming and or broaching should stop to prevent irreparable damage to the bone. In this manner the surgeons can quantitatively assess the Newtonian elastic limit of any bony cavity, without having to rely on their own tactile senses, and without having to rely on the pre-operative templating process.



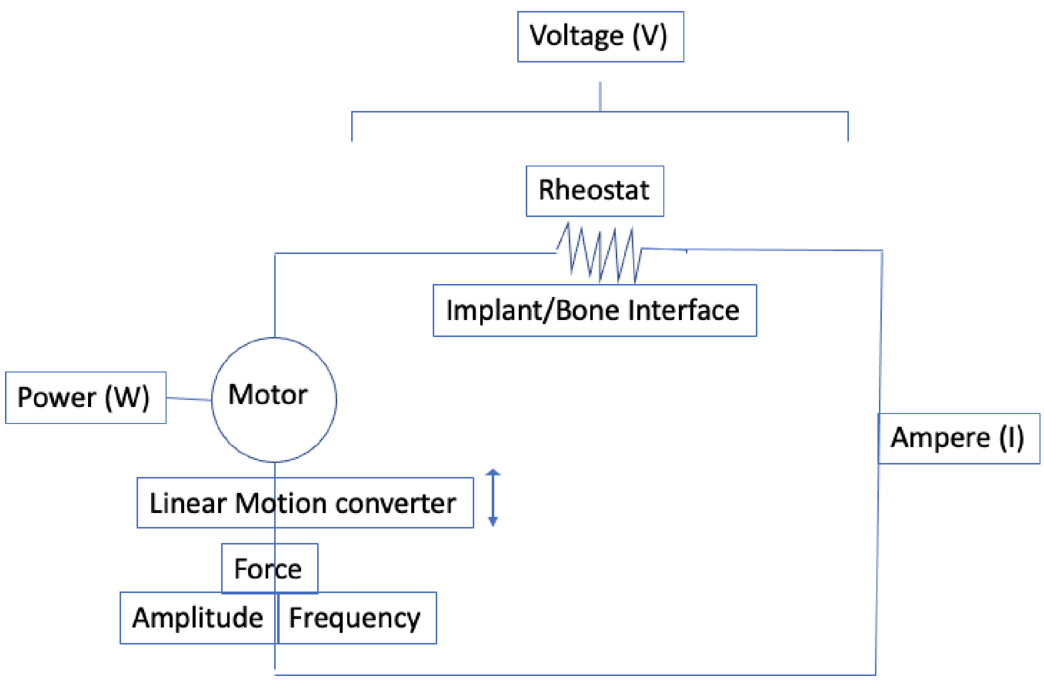
Furthermore, Estimation Theory concepts such as Kalman Filter, Extended Kalman Filter and Unscented Kalman Filter can be utilized to optimize the values of frictional force and torque obtained through electronic signatures, further enhancing the quality of the estimates of the frictional forces at the implant-bone interface.



The Implant-Bone interface basically acts as a variable rheostat causing decrease or increase in current and power consumption within the system. At certain stage during the reaming and broaching process, as the frictional forces and torque increase, current and power consumption will reach an inflection point/limit which suggests that the elastic limit of the bone has been reached and therefore reaming and/or broaching should stop. This state may be represented by the changes in current, power, active power, voltage, speed (angular velocity), torque, amplitude, and frequency. When ultrasonic energy is used the change may be represented in the harmonics, specifically 2nd and 3rd order harmonics.

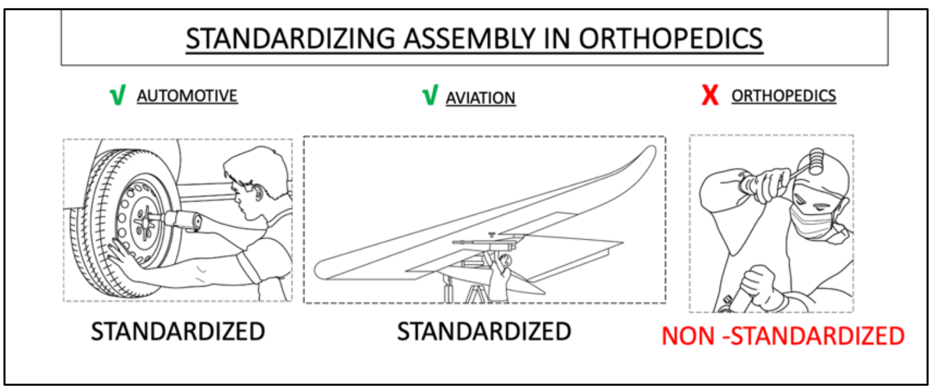

ROTATTING REAMER
Voltage (V)
Rheostat
Implant/Bone Interface
Power (W)
Motor
Ampere (I)
Torque
Amplitude
Angular velocity

VIBRATING BROACH



The ability to quantitatively *force size* bone cavities intra-operatively using *electrical signatures of the driving motors*, or with Force/torques sensors embedded in reamers and broaches is a game changer in total hip arthroplasty. Surgeons will no longer undersize bone cavities and install too small of an implant, which leads to aseptic loosening; or oversize bone cavities and install too large of an implant, which leads to fracture.

These concepts provide for a *STANDARDIZATION PROCESS* for orthopedic implant assembly.



The benefits include:

1. Decreased morbidity, fewer complications, and revision surgeries for patients.
2. Decreased stress for surgeons and tools that help them do a better job.
3. Tens of billions of dollars in savings for insurance companies and National Health Cares.