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## HOW CAN WE MAKE PRESS FIT ARTHROPLASTY MORE RELIABLE?

The Shoe Salesman, the Orthopedic Surgeon, and Force Sensing

When we buy a shoe, we always try it on to see if it has a proper fit. We don't always trust that a particular size fits us perfectly. In essence, we do a *force sizing* or *tactile sizing* of the shoe. The fit of the shoe is a function of both its geometry (size) and its stiffness property (Modulus of Elasticity). If the shoe is "too tight" we make an adjustment and get a half size larger, if the shoe is "too loose" we make and adjustment and get a half size smaller. These adjustments are based on tactile feel, pressure, and force phenomena, and not based on the actual size of the shoe. In this process, the shoe salesman gets critical feedback from the client.

In press fit arthroplasty, orthopedic surgeons preoperatively template the size of the implant by measuring the physical size of the bone cavity. However, intraoperatively we supersede this process by taking a *force* measurement of the cavity. We essentially size the bone cavity through the "tactile feel" of resistance to reaming and broaching. This intraoperative *force* assessment of the size of the cavity always trumps the preoperative measurements. Often, we perform this function of *tactile sizing* or *force sizing* unconsciously, without really being aware of it. The problem is that this type of assessment is prone to significant variability and error. During this process, there is no feedback from the patient, therefore the surgeon must rely on her own tactile senses.

Therein lies the disadvantage of the orthopedic surgeon. Orthopedics surgeons do not have the benefit of a tactile feedback loop from their patients as the shoe salesman has from her clients.

Over the last few years, studies around the globe have shown that there is a significantly higher risk of morbidity and mortality when hip replacements are done with cementless (press fit)

techniques. This has led the AAOS to recommend that in patients older than 65 years of age, surgeons use cemented technique for the femoral component.

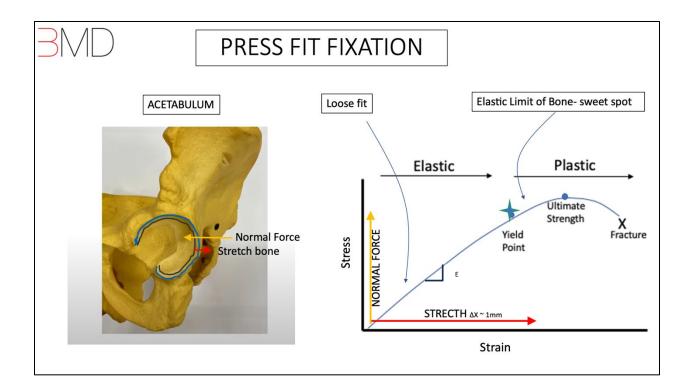
This recommendation by AAOS highlights a weakness in the current art of press fit arthroplasty. We should call it *art* rather than *technology* because even though we know the technique works, we don't quite exactly know how it works. According to Professor Leslie Valiant, professor of computer science and applied mathematics at Harvard, our current press fit technology should be called "Theory-less" as opposed to "Theory-full". That is, we have figured out how press fit arthroplasty works with minimal cognitive strain and have continued to use it for practical purposes, but we have never bothered to figure out exactly how it works, or the theory behind this concept. We do not have a formula that provides a consistent successful press fit arthroplasty every time. One may wonder why, because the solution to this problem is simple and related to classical mechanical concepts.

Broadly speaking when we press fit some bigger object into a smaller cavity, a compressive force is created that grasps the object. We call this press fit or interference fit. This compressive force is a function of the normal forces created at the rim of the cavity and the coefficient of static friction. For all practical purposes, this compressive or grasping force (press fit) is a function of two variables: 1. The amount of stretch placed on the smaller cavity ( $\Delta X$ ) 2. The material properties of the cavity (Modulus of Elasticity).

To do press fit correctly, we must know the *proper size of the bone cavity* and have a sense of its *stiffness property*.

This concept can be represented by the classical stress strain curve. The amount of strain placed on bone ( $\Delta X$ ), created by inserting a prosthesis into bone, multiplied by a conversion factor that represents the stiffness property of bone (Modulus of Elasticity), provides a value that represents press fit or stability of the implant, or simply the grasping force of bone. Figure 1.

Figure 1.



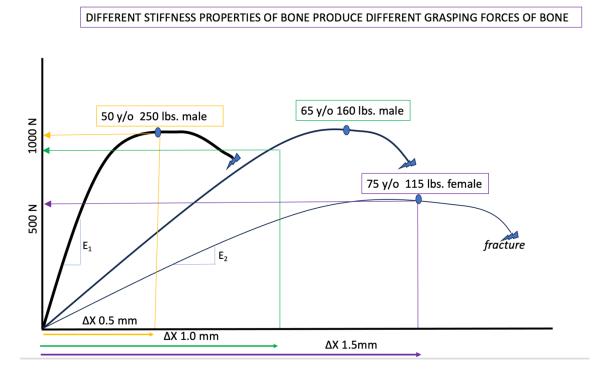
Our industry knows that the femoral cavity has is stiffer and more brittle than the acetabular cavity. In our current press fit technique, the medical device companies typically use a generic formula of under sizing the femoral cavity by  $\sim$  0.5mm and the acetabular cavity by  $\sim$  1.0 mm.

Surgeons use this method irrespective of the patients age, sex, and metabolic condition. For example, they use the same press fit technique to install a prosthesis in a 75-year-old 115 lbs. female that they do in a 55-year-old 250 lbs. male. That is, if both above patients have a 56mm size acetabulum, surgeons will underream both patient's acetabula by 1mm to (55mm) and impact a 1mm larger (56mm) cup.

Correct sizing of the bone cavity is an important factor in the success of press fit arthroplasty. If you undersize the bone, you don't stretch the bone enough to get the optimal reactive force of bone. If you over size the bone, you basically destroy the elastic property of the bone. Additionally, the stiffness property of bone is equally important in determining the quality of press fit. Most surgeons have no insight as to how the stiffness quality of bone affects the quality of press fit.

In this hypothetical scenario, the younger male bone is much denser, stiffer, and more brittle. It has a higher modulus of elasticity. The older female bone is less dense, less stiff, and more ductile. It has a lower modulus of elasticity. A 1mm  $\Delta X$  for the 50-year-old 250 lbs. male is too much, and would cause a fracture, however, a 0.5mm  $\Delta X$  produces maximum press fit.

Conversely, a 1mm  $\Delta X$  does not produce optimum press fit for the 75-year-old 115 lbs. female; a 1.5mm  $\Delta X$  maybe more desirable. Figure 2.



Therefore, surgeons need a method that allows them to treat these hypothetical patients differently. There is a need for a method that incorporates the stiffens property of bone during the sizing process, hence the terminology *force sizing*.

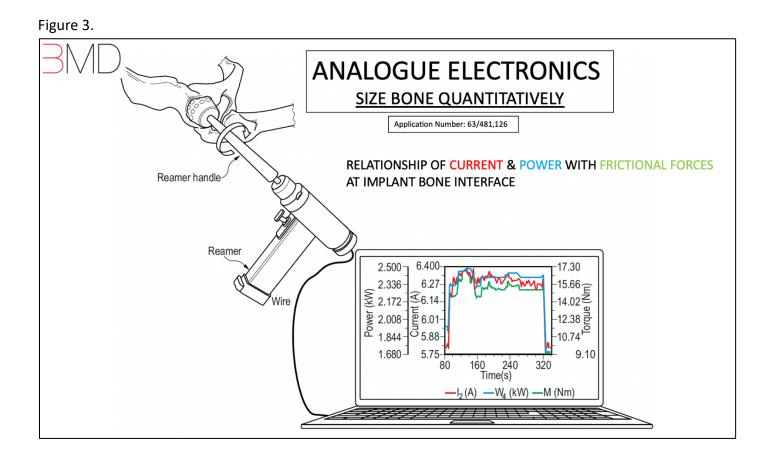
Studies have shown large variations in templating even between experienced surgeons. Experienced surgeons are off (+/-) one size, up to 75% of times. Which means that the surgeon's intraoperative tactile sizing of the bone frequently disagrees with the same surgeon's preoperative templating.

This is significant because even small variations in sizing can lead to failure, causing loosening or fracture, as has been described by Dr Morlock's group at University of Hamburg. To get proper press fit, one has a small margin of error in the sizing process.

To intelligently press fit implants, surgeons need accurate information about the bone's size and the bone's mineral density (stiffness). They have neither. The only value they have is a distance measurement of the cavity obtained preoperatively. No matter how accurately or precisely this value is obtained, with 2-D or 3-D scans, it does not provide an actual *force sizing* of the bony cavity or any representation of the stress response of bone. Ultimately, press fit is a force phenomenon. It cannot be properly assessed through a distance measurement. This may be one reason why robotic platforms, which generally disregard this haptic sizing process, with overreliance on visual templating, have not gained wide popularity.

Is it possible to develop a quantitative metric of sizing bone that represents both the size and stiffness properties of bone?

The answer is yes. We can obtain a quantitative measurement of the mechanical stress response of bone along with its physical size during the bone preparation process, by utilizing analogue electronics to measure current and power consumption. These variables have a direct relationship with the frictional forces that exist at the implant/bone interface, and therefore have utility in providing a method of *force sizing* of the bony cavity. This relationship can be utilized to quantitatively identify the elastic limit of bone, and therefore the sweet spot of optimal stability for each individual patient. Figure 3.



With the development of ultrasonic assisted femoral (US 10905456) and acetabular (10463505) broaches the process of bone preparation and force sizing becomes even more precise.

Once we have a quantitative means of *force sizing* bone cavities, we can install implants gently, and with significantly less force, minimizing damage to bone cells (osteocytes) and bone vascularity. This allows us to standardize assembly technique in orthopedic surgery, eliminating the plague of aseptic loosening and periprosthetic fractures.

Figure 4.



