No Leg to Stand On

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With thousands of Total Hip Replacements (THRs) per year in America alone, the causes and prevention of THR failure are highly important. Though only 0.5-1.0% of THRs fail annually, these failures can be life-threatening and lead to great pain or even revision surgery. THR failure consequences range from failure-induced bone fractures to bone reabsorption surrounding the implant to metal ion release into the body (Katz, 2007). The three most common modes of THR failure are design imperfections, production errors, and damage during surgical implantation, all of which reduce device functionality (Barbosa, 2008). As these three modes of failure account for nearly 88% of THR failures, an improvement in any one would likely reduce failure rates (Katz, 2007). This is where engineers come in; it is up to THR implant engineers to design, test, and manufacture the highest-quality devices possible, which means continually learning from THR implant failures.

Most THR implants are made of metal alloys such as cobalt-chromium, stainless steel, or titanium. Regardless of the materials employed, THR implants must meet strict standards of strength, biocompatibility, corrosiveness, and even appearance to be considered acceptable for implantation (Barbosa, 2008). If standards are not met, failure potential rises and the device is not suitable for implantation. One of the most common implant design errors is the presence of stress concentrators. A stress concentrator is considered any structural element that causes stress to be unevenly distributed, thereby weakening the structure. By changing stress distribution across a structure, stress concentrators make it more difficult for an object to successfully withstand applied forces. Examples of stress concentrators include sharp corners, holes, and cracks (Figure 1a, b). If stress concentrators are present in a THR implant, it is more likely to fail at that specific point (Rimnac, 1991). On the design side, stress concentrators can be avoided by excluding sharp corners and holes from the implant. One way this can be

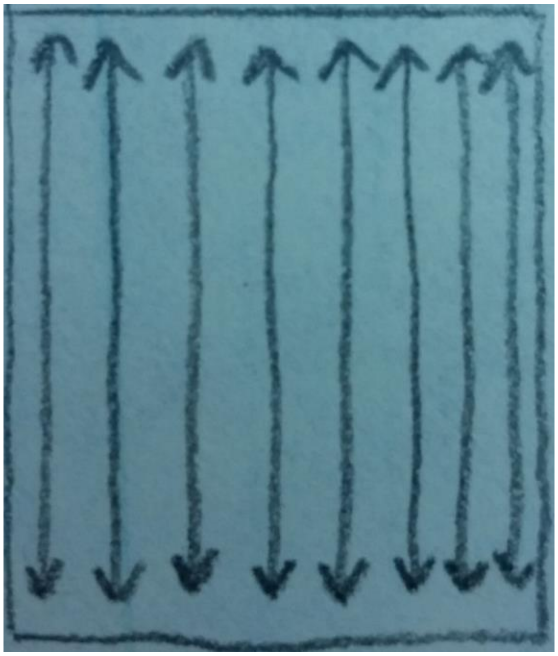

Figure 1a. *A uniform object with evenly distributed stresses*

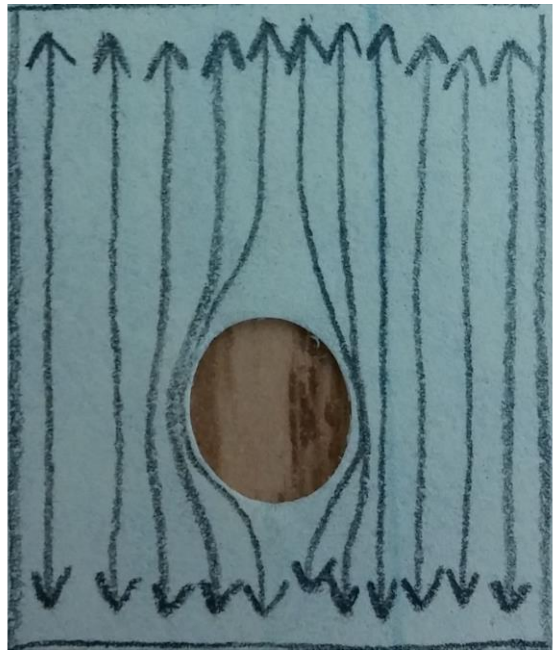

Figure 1b. *A non-uniform object: stress is concentrated around the edges of the hole*

accomplished is by choosing a design fixated with bone cement instead of screws so holes are not needed. Another option is rounding off edges so applied forces are distributed evenly across the contact surface instead of being focused at a point. It is critical for engineers to test new designs for stress-concentrating elements so no potentially dangerous implants go into production.

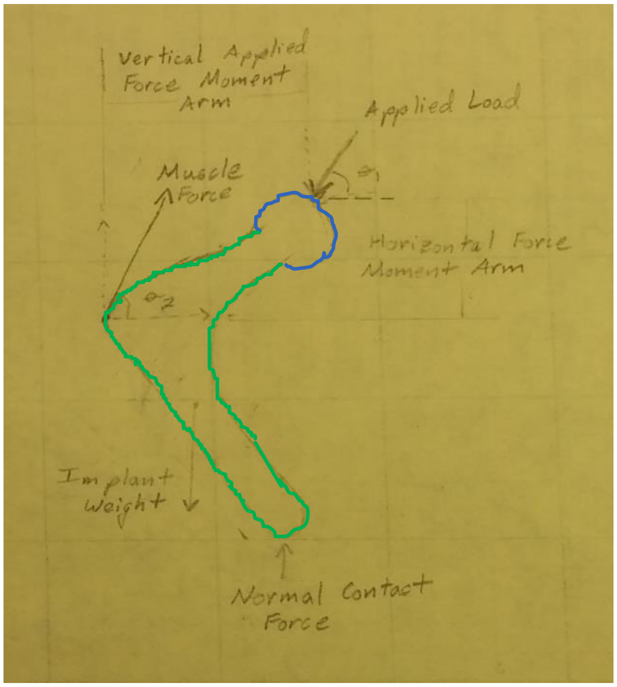

Figure 2a. *A typical THR implant and the stresses acting on it*

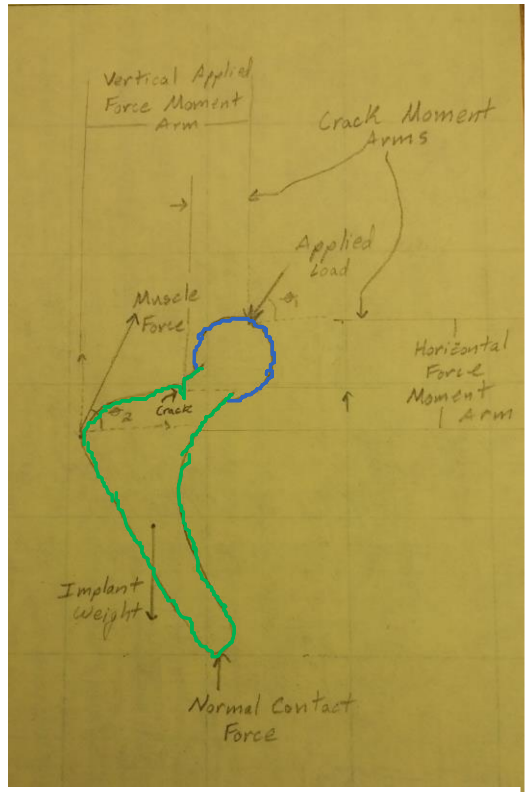

Figure 2b. *A THR implant containing a crack in the upper femoral stem. This may lead to stress concentration and even device failure*

Femoral Head:

Femoral Stem:

Stress-concentrating cracks and scratches occur in the post-design phase (Figure 2a, b), often due to manufacturing errors. If a THR implant is machined incorrectly, and even a tiny crack appears, it is no longer functional. This because the hip is cyclically (repeatedly) loaded at an angle, which causes crack propagation over time and can ultimately lead to implant loosening or fracture depending on the crack location (Barbosa, 2008). The angular force acting on the hip is called a moment, which is considered the tendency of an object to rotate about an axis at a certain perpendicular distance from that axis, called the moment arm. A more common name for a moment is torque. When a crack is present, a moment occurs about the crack's tip, causing it to deepen, which can lead to implant weakening and failure. The presence of a crack in the upper femoral stem (Figure 2b) also shortens the moment arm of the joint and muscle forces on the implant, which changes force distribution and concentrates stress at the crack. Other flaws can occur due to manufacturer negligence regarding implant machining standards. For example, a weld causes a material change that can weaken the device at the weld sight, so welding is not an acceptable THR manufacturing method. If a device manufactured using welding techniques and were implanted, the sight of the weld would be susceptible to cracking, and would likely fracture (Barbosa, 2008). Engineers must partner with manufacturers to ensure all THR implants are machined correctly using techniques that guarantee safe production and reduce the risk of flaws. Implant manufacturing must be careful monitored and each batch of devices thoroughly inspected by production engineers to ensure quality standards are met.

The other main occurrence of cracks is during implantation surgery (Figure 2a, b). Often, THR devices can be scratched or damaged by implantation surgeons, creating a stress concentrator and often leading to failure. Operative error failures are largely due to ethical shortcomings of surgeons who fail to remove the damaged implant whether for lack of understanding of the structural integrity loss associated with a crack or scratch, lack of time, or lack of a back-up device. Many such failures could likely be prevented by having an implant engineer join the operating team to inspect the device during implantation and confirm continued functionality as well as providing a potential back-up device should the first become damaged.

Though many potential implant failure onsets are fairly well-known, many more remain yet undiscovered, putting design engineers in a position to try to design against every imaginable mode of failure. Duke University professor of engineering, Henry Petroski, called this concept “defensive engineering,” (Petroski, 2003) stating that the only way to achieve total design success would be, theoretically, to plan for and design against every possible form of failure (Petroski, 2003). Realistically, however, envisioning and designing for every type of failure is highly impractical, so engineers are tasked with coming as close to this standard as possible making them, “naturally conservative in their expectations of technology,” (Petroski, 2003) according to Petroski.

To take on the challenge of engineering new implantable devices or any engineered structure, is to accept the inevitable failures that come with innovation. With the continually developing medical technologies, it is up to engineers to ensure medical devices, such as THR implants, are held to the highest quality and safety standards from design to implantation. When a design feat has never before been attempted, there is no sure way to predict its abilities aside from imagining all possible failures and testing its limits. In this way, failure is an essential part of engineering and a vital tool for technological advancement, which engineers must embrace in order to keep building a better world.

References

Barbosa, C., do Nascimento, JL., Caminha, IMV., and Abud, IC. (2008) *Premature Failure in Orthopedic Implants: Analysis of Three Different Cases*. Retrieved from: http://link.springer.com.proxy.lib.uiowa.edu/article/10.1007/s11668-008-9192-z/fulltext.html

Katz, JN., Wright, J., Wright EA., and Losina, E. (2007). *Failures of Total Hip Replacement: A Population-Based Perspective*. Retrieved from: http://www.orthojournalhms.org/volume9/manuscripts/ms11.pdf

Petroski, H. (2003, August, 29) *Failure is Always an Option*. Retrieved from: http://www.nytimes.com/2003/08/29/opinion/29PETR.html

Rimnac, CM., Wright TM., Bartel, DL., Klein, RW., Petko, AA. (1991, June). *Failure of orthopedic implants: Three case histories*. Retrieved from: http://www.sciencedirect.com.proxy.lib.uiowa.edu/science/article/pii/104458039190012S