Medical Implants: The Cost of Failure

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Surgical implants are arguably one of the great scientific breakthroughs of all time. Artificial hips, knees, and shoulders are replacing deteriorated joints. Lap-bands, stents, and pacemakers are extending life; while ocular and dental implants are making life more enjoyable for countless others. Today as the global medical implant industry exceeds $200 Billion it is estimated that nearly 20% of all adults have received an implant of one type or another.

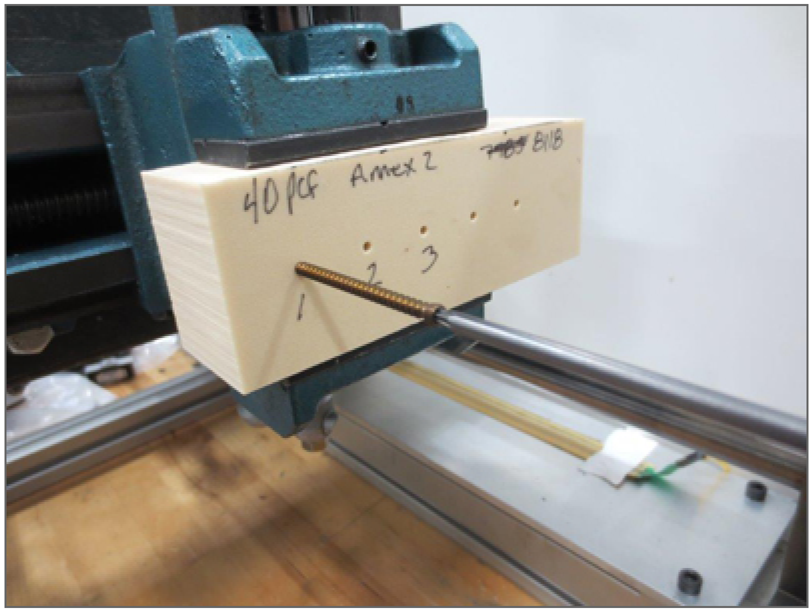
The Cost of Quality

Clearly implants have improved the quality of life for millions. But when these devices fail or pose health hazards, the ramifications can be disastrous for the recipient and manufacturer alike. Metal ions from artificial hips seeping into the blood stream has been linked to increased cancer risk, problems with eyesight and hearing, immune function disorder, cognitive impairment, and more have been linked to faulty medical implants. Today's court dockets are backlogged with lawsuits as medical device failure has surpassed mesothelioma as the most litigated cases.

Product Design Validation

Like all manufacturers, those producing medical implants face the constant challenge to accelerate product development. That pressure is further compounded by the need to create increasingly innovative products. Medical implant manufacturers must balance this race to market—quality; design, materials, and performance must be at the top of the list.

Below are some key points that every medical implant designer should consider.



- Any implant containing a sharp edge must be justified; especially inside an inside radii. They become stressors during implant activity and manifest in premature failure in a poorly designed implant.
- Tapers have been used extensively. However, many designers ignore the Morse tapers used successfully in the automotive and aerospace industry for decades. Why reinvent the wheel? Use a Morse taper with the commensurate angles and tolerances.
- Mechanical impedance balancing should be followed. A simple chain provides the theory: Every link along the stressed chain should carry the same load without breaking. The same concept goes for hip, knee and spine implants.

Computer generated models are a valuable tool in validating new designs. But, physical product testing remains the key to product integrity. Testing allows the experts to guide product development with years of practical experience. For example, metal plates and rods are being used with great success in stabilizing broken bones and supporting spinal injuries. Implants are fastened to the bone with screws. Although relatively simple by comparison, bone screw designs must undergo the same scrutiny and rigorous testing as any other more complex device. Self-tapping screws have been prone to tip breakage. Broken tips are not retrievable and may pose subsequent health risks. Additionally, when screws fail, the device fails. Screws and fasteners are tested for tip breakage, break angle, torque, and bending fatigue. Testing ensures that ASTM A540 standards are met and that the product meets structural and metallurgical specifications. In surgery provide a torque limiting screwdriver with fasteners as you never know how much torque might applied by the surgeon.

Failure Analysis: Explant Testing

Like all products medical implants have a natural lifecycle. Testing is called in when products fail prematurely or abruptly. Just as testing is used to in the early stages to predict product performance, it is also valuable in determining reason(s) for failure. Faulty implants are removed and analyzed to determine exactly why a part failed. This is especially critical in determining liability. Was the defect the result of a poor design? Was the wrong material used? Were errors made in the manufacturing process? Or, was the device incorrectly installed? Answers to these and other questions can be pinpointed during controlled laboratory testing.

Titanium is the metal of choice for many implants. When testing implanted screws watch that Ra at minor diameters, as the roughness may compromise the performance of the tests. (Titanium is notch sensitive.) Coatings for bone migration are required by the FDA. However, they are delicate and usually require pre and post-thermal treatments. Poorly performed thermal controls allows the Ti 6Al 4V ELI material to enlarge grains along the mating surfaces thereby creating micro stress that provide nucleation sites for fatigue fractures.

Conclusion

As an expert litigation witness I've been called on to perform a variety of tests to pinpoint areas directly and indirectly contributing to medical implant failure. Based on thirty years of experience I've drawn a lot of conclusions. But if I had to sum it up in one simple sentence it would be this: I cannot overstate the importance of testing. It is absolutely imperative to exhaust all testing and validation before releasing a product to market.

John McCloy is Founder and Owner of Engineered Assurance (www.engineeredassurance.com). He is a member of the American Society of Testing Materials (ASTM), the American Society of Metals (ASM), the American Welding Society (AWS) and maintains numerous industry and scholastic licenses and certifications including PE, CWI, and MBA.

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