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Avoiding Patient Injury Lawsuits— Design Team Tips

Introduction

My work for Robson Lapina involves reconstructing injury events, and explaining injury biomechanics including medical device technologies (orthopaedics) to assist either plaintiff or defense counsel in injury litigation. In this position, I have the opportunity to see, first hand, how plaintiff lawyers frame their cases against device manufacturers.

Reducing new product development litigation risk is critical to a healthy industry and will influence corporate entity survival. Since I continue to be involved in orthopaedic new product development projects for orthopaedic manufacturers and distributors, I am now even more careful about following appropriate and effective design processes. Having been fortunate enough to complete projects with over a dozen orthopaedic companies, I have been able to evaluate many variations of the "design control" system, and have established relatively efficient techniques now used by a few of my smaller clients. It is critical to "live" the design process and to effectively incorporate ISO/FDA Design Dossier practices into every development project. The following article shares a few insights that I hope will be helpful to other orthopaedic design teams.

Tort reform

Tort reform, limiting surgeon liability, is driving injury lawyers to the doorsteps of the orthopaedic industry. Patients with an orthopaedic procedure failure are encouraged to blame anyone except themselves for their pain, suffering, re-operation or other inconvenience. A portion of these failures result from surgical installation errors, caregiver errors, or design and manufacturing defects. Failures are mitigated or exacerbated by patient non-compliance or compromised health status (underlying disease or infection). Most orthopaedic device failures result from some combination of these factors. Other factors include: abnormal tissue loads, altered joint mechanics, known implant material limitations, and physiologic response to particulate implant debris and other degradation byproducts.

As an orthopaedic industry manufacturer or designer, your best defense against litigation is prevention of procedure failures. Be proactive. Be interactive. Be sure that surgeons, other caregivers, and patients each understand the general capabilities and limitations of your products.

Patient care is guided by orthopaedic surgeons. However, to minimize product liability litigation, the design team needs to address device related patient activity issues. Surgeon-authored patient care recommendations and activity limitations need to be included with the product, and in the educational materials provided to the surgeons, other care givers, and the patients. The team needs to document the performance characteristics of the device under all anticipated conditions.

Advertisement—a new twist

Performance test reports that are used to promote one device over another need to include a statement or discussion of the clinical relevance of the test, and any appropriate usage limitations.

Claiming that a new design is stronger and better than other devices can be misleading, especially when newer, more demanding indications are added. Surgeons and patients need to understand the physical limitations of the device *in a clinically relevant manner*. Today's design teams need to generate this information, and effectively communicate known limitations to both the patient and the surgeon.

Case Example—Intramedullary (IM) nail fracture and femur re-fracture at about six months in an unstable distal femoral fracture.

Company "X" has a new IM nail that has been designed to be inserted in either a hip-down (antegrade) or knee-up (retrograde) direction. The IM nail is stronger at the trailing end (end held by instrumentation and inserted last). Company "X"'s advertisement implies that their new IM Nail has increased strength compared to various other IM nails, **but it also needs to indicate whether the device is strong enough to withstand patient weight during ambulation or other activities for all indications.** Without this qualification, the surgeon perceives that the stronger product can be used for the new indications in a manner similar to original indications.

Patient presents with a very unstable spiral femoral fracture with a significant distal segment (within 75 mm of knee joint line) as measured on x-ray. The surgeon installs a small diameter nail (9

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mm x 380 cm long) in the traditional antegrade fashion, using proximal and distal locking screws, and three cerclage cables. Weight bearing is limited for 12 weeks, until radiographic evidence of callus formation is noted.

Implant failure occurred during ambulation at work at 23.5 weeks post treatment of initial fracture, and at 13 weeks of full weight bearing. This is about 875,000 gait cycles (middle-aged adult). The patient weighed 145 lb. Small IM nails in unstable fractures cannot withstand a significant number of weight bearing gait cycles, and even fewer cycles when including stair climb, and occasional stumbling.

The most proximal screw hole of the smaller diameter end of the IM nail was placed too close to the distal end of the unstable fracture fragment (within 25 mm). The implant fracture location was through the most proximal of the distal screws. This hole was located within 25 mm of the distal-most tip of the original fracture, so the nail and this screw hole experienced high bending moments.

Nails at or below 10 mm have a relatively high risk for overload and fracture. When a fracture is located within 50 mm of the most proximal distal locking screw, the peak stresses around the hole are known to frequently exceed the endurance limit of the metal, especially in smaller diameter implants. The fractured segment of the IM rod experienced repetitive axial compression, bending and torsion loading. The lowest strength cross-section and the second lowest stiffness cross-section of the IM rod were positioned at the highest stress position in this long spiral, unstable fracture.

Mechanical characterization testing for this type of device is frequently done at 3x BW using an average male weight of 176 lb (176 x 3 = 528 lb). Similar designs of this size/material IM nail have documented fatigue life range of 100,000 to 1,000,000 cycles (respectively, ten and 102 days of full weight bearing on a completely unstable fracture). Small IM nails cannot withstand a significant number of weight bearing gait cycles, and even fewer cycles when including stair climb, and occasional stumbling¹.

Industrywide, most smaller diameter IM nails are not able to withstand full weight bearing in an unstable fracture for longer than one to six months without overloading. **Most patients are not aware of any device strength limitations.**

Surgeon Issues

Surgeon took precautions to enhance fracture site stability in the difficult unstable fracture by applying three cerclage cables in addition to the IM rod, and by limiting weight bearing for 12 weeks (until evidence of callus formation). However, he did not place one of these stabilizing cables near the lower (distal) end of the fracture. Addition of one more cerclage cable at the distal most fracture site may have stabilized the fracture enough in bending to have accelerated healing and prevented implant cyclic bending overload.

Actions to reduce loads on implant and reduce fracture motion:

- Initially install larger diameter IM nail (only if femur can be reamed further without undue compromise)
- Insert this style IM nail in knee-up (retrograde) direction vs. traditional hip-down (antegrade) direction
- Cerclage cable or wire around/near lowest end of fragment
- Restrict weight bearing
- Brace thigh

Design Related Issues

If this nail had been inserted in the retrograde direction, with the stronger, stiffer cross-section located at the distal end of the original fracture, the IM nail fracture and femur re-fracture may have been prevented.

The smaller IM nail used had proportionally large screw holes. The remaining cross-section is too small to take significant long-term loading, especially in bending or combined load scenarios. The combination of a 5 mm screw hole, a large inner diameter, and external grooves weakened this small diameter IM nail, leaving too little material to support loads in an unstable fracture with delayed distal union.

What could a design team do to prevent a future lawsuit in this situation?

1. Reduce hazards.

- Geometrically, the smaller IM nail strength can be increased by: (1) elimination of grooves in the outer diameter of the shaft near the screw holes; and (2) reduction of the inner diameter longitudinal hole size (cannulation ID)
- The manufacturer's literature indicates that the material in the IM nail is Ti6Al4V alloy titanium with type II anodize. Include a solution treating and aging (STA) heat treatment process to impart maximum fatigue strength for this alloy in smaller diameter IM nails; and (2) render screw hole more fatigue resistant via processes such as shot peening or laser shock peening.

2. Stress the directional performance and strength characteristics of the device in usage instructions.

- a. Instruct surgeons that the nail should be inserted in a retrograde fashion to prevent overload when used to stabilize unstable distal femoral fractures. Include installation instructions for specific unstable femur fractures.
- b. Warn against use of the nail in the more traditional hip-down (antegrade) insertion direction for unstable fractures with distal components.
- c. Include screw hole placement limitations relative to fracture fragment location

3. Restrict patient weight and activity levels;

i.e., recommend external brace use for patients at certain weight and activity levels.

4. Educate patients.

Provide patient information and include activity limitations and warnings for "at risk" indications.

Development Processes Pointers

Fine-tune your team Design Dossier skills by making sure your Design Inputs include clinically relevant, measurable performance requirements. Do a thorough failure modes and effects analysis (FMEA) including risk and hazard analyses.

Always summarize the clinical significance of testing in terms of user activities. What can the device withstand? What activities must be avoided, and why?

Revisit your device performance specifications. Are they compatible with current patient populations? For example, in the 1970's and 1980's the typical joint implant recipient was an elderly, retired and minimally active individual, possibly returning to golf, walking or swimming. Today's patients are younger, and significantly more active. Many are still working. Some are engaged in higher leg impact sports such as jogging, basketball, racquetball, and tennis. Others are returning to activities requiring deeper knee flexion such as cycling, yoga, or squatting. Today's patient is also, on average, heavier. Trends indicate more frequent, higher loads and greater range of motion.

Hip and knee fatigue/wear testing was initially standardized on uniaxial gait motion simulation at about one to three million cycles, at peak loads of 3x body weight (about 160 lb average man). Current simulators are capable of multiaxial motion and simulation of multiple activities including stair climb, walking and jogging.

Today's total hip arthroplasty (THA) patients average 9,688 steps per day, for a combined average of 3.54 million steps per year (range of .438 to 12.96 million steps per year)^{2,3,4}. 40- and 50-year olds receiving total hips have a higher than average activity level, or over 3.5 million gait cycles per year. Many also climb over 264 stair steps per day (96,380 steps per year)⁵. A hip or knee simulation of ten million cycles, including about 300,000 stair climbs, equates to less than three years of walking in these younger patients. 30 million cycles are needed to characterize ten years of implant duration. Peak loads on these joints are occasionally higher than 7x body weight (stumbling, possibly stair climb or descent). Is your joint simulation protocol in line with these more rigorous load and motion requirements?

A company that designs, manufactures, or offers any product for sale has a responsibility to protect people from hazards that may be present in their products.

Hazard — Potential source of harm

Harm — Physical injury and/or damage to health or property

Risk — Probable risk of occurrence of a hazard causing harm and degree of severity

Safety — Freedom from unacceptable risk of harm

Mitigation — To reduce or eliminate risk of hazard less severe and to increase safety.

The design process must take into account the types of actions that people make under reasonably foreseeable conditions of

service, including intended use, as well as reasonably foreseeable misuse. Hazards should be designed out of the product through engineering means. If the hazard cannot be eliminated, guards must be provided. In all cases in which the hazard cannot be eliminated or guarded against, clear and prominent warnings or instruction as to the dangers of the product must be provided. These three steps form the fundamental principles and rules of practice for safe and appropriate engineering of products. Hazard analysis rests with the manufacturer.

Medical device manufacturers have a responsibility to characterize the mechanical performance of a device in typical and foreseeable worst-case clinically relevant conditions. In products like IM nails, where overload is both possible and relatively common under certain circumstances, the manufacturer has a responsibility to educate the users (surgeons, patients and other caretakers) concerning the device limitations, including methods users can adopt to assure effectiveness and prevent injury from device overload, misuse or failure. In many of these devices, warnings and precautions regarding patient weight, weight bearing limitations, and related stability are needed to prevent failures.

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