Foreign Debris And Post-Surgical Issues

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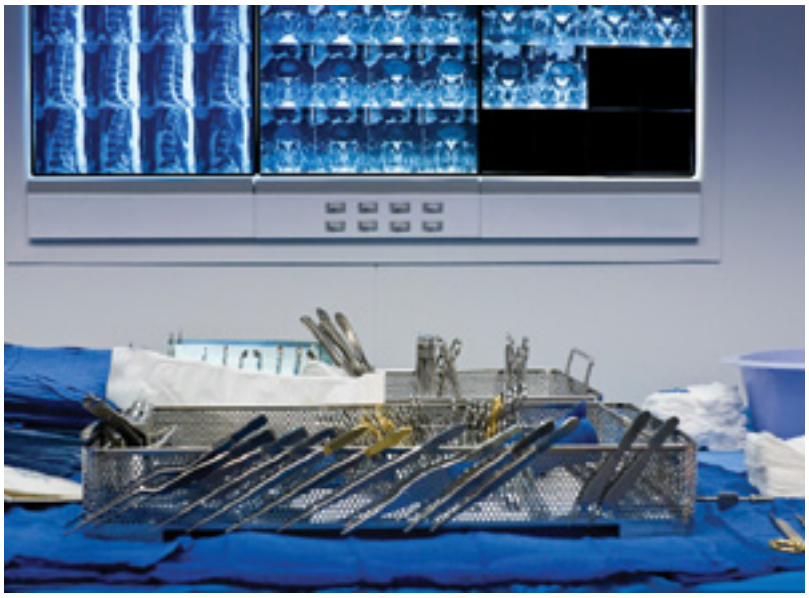
What happens when lint, or other foreign debris, contaminates your surgical instruments, devices, or implants? And is a suboptimal outcome because of your product or due to the “linty” drape upon which your device was placed?



One of the most important attributes of living organisms is the capacity to self-repair. This ability is expected and observed every time a patient undergoes a major or minor invasive procedure. Needless to say, lack of this healing ability would render surgery useless and every injury, whether large or small, would be a potential death sentence. Instead, a surgeon removes an appendix, sets a fracture, or performs brain surgery expecting normal wound healing, without infection or other complications within a fairly predictable period of time. Simplistically, to keep microbial contamination of the site to a minimum, all which is necessary is to make the necessary repairs, keep the tissues moist, and properly align the wound margins. Although the auto-pilot repair process initiates to some degree in any individual, the quality of the healing can vary substantially depending on many factors. These include the patient’s general health, degree of trauma sustained, level of microbial contamination, and the presence or absence of foreign bodies in the wound.

Unfortunately, the important role that these foreign particles can play in post-surgical complications does not receive enough attention. Lint is composed of fine fibers that separate from the surface of fabrics including gowns, drapes, sterilization wrap, and huck towels. Fibers also abrade off paper fenestrations and drapes, cardboard and poorly laminated or embrittled sterilization pouches. In practice,

such debris is generally referred to as lint. Associated pathologies depend upon the composition, size, and number of fibers, as well as the tissues in which they are deposited, and include:

- Increased incidence/severity of infections
- Blood clots
- Amplified inflammation
- Poor quality wound healing
- Granulomas
- Adhesions
- Infections

Lint and debris in the surgical wound increase the risk of infection both as a transport for microorganisms and as an immune distraction.

Transporter: Lint and debris can be carried on air currents throughout the operating room (OR). They can fall on any surfaces, including the floors, exposed skin of surgical staff, and monitor screens, where bacteria can cling to them. As staff move and equipment pieces are repositioned, the now contaminated debris can be airborne again, potentially landing on surgical instruments, drapes, gloves, or directly into the open surgical wound. (AORN)

A study conducted by Verkkala demonstrated that reducing lint reduces surgical site contamination and that cellulose containing fabrics generate significant amounts of lint. In a series of 66 coronary artery bypass surgeries performed by the same team in the same OR, he found that replacing cellulose (cotton and paper) containing gowns and drapes with those made of 100 percent polypropylene reduced airborne lint and fibers from 850 particles/m3 to 50 particles/m3. Sternal wound bacterial contamination was reduced by 46 percent and those at the vessel harvest site in the leg by over 90 percent.

Immune distraction: When lint or fibers are present with bacteria in the same surgical area, the immune system perceives them as a much larger threat to the body than tiny bacteria. Thus, while the white cells are working to wall off the lint or fibers, they ignore the bacteria. The few bacteria that contaminate any surgical wound then multiply unimpeded; gaining a strong presence that is difficult for the immune system to overcome. An example of the effectiveness of the mechanism of “immune distraction” is a study performed by Elek, where he was able to demonstrate that the presence of a suture fiber reduced the number of bacteria needed to cause an infection by 100,000 times.

Blood Clots

Lint- or fiber-associated thrombogenesis is initiated when platelets trigger the clotting cascade to wall off the debris introduced into the bloodstream. Fibrin is deposited, forming a net to trap the foreign threat. Blood cells are ensnared and trapped in the net forming a clot. This cycle continues, essentially “snow-balling” in size until the clots (lint emboli) become large enough to block narrowing blood vessels. An important distinguishing feature of a lint or fiber-initiated blood clot is

the failure of the entire embolus to dissolve when anti-thrombolytic treatments are used. Lint fibers are attracted to guidewires, pacemaker leads, and catheters by static cling.

Bookstein conducted a study to understand the formation of clots during angiography after an increase in cases of thromboembolic complications, including strokes and two deaths. With magnification, he was able to see the smooth clean surface of guidewires immediately removed from the package become contaminated with lint from sterile drapes, and powder from gloves, either during preparation or the procedure itself. The clinging debris (sterile or non-sterile) can then be deposited directly into the bloodstream or into the inside of the catheter, soon to be injected into the bloodstream. The investigator determined that foreign debris on the guidewire or within the catheter may influence hypercoagulance and amplify the thrombosis impact of high velocity injections. He concluded that coagulant complications resulting from angiography are probably, in large part, preventable.

Shannon conducted a 5-year retrospective study of the postmortem cases of postangiographic neurologic complications, performing histologic examination on all associated clot formations. Particulate embolization, usually initiated by cotton fibers, was present in as many as 25 percent of the resected arteriovenous malformations. The author concluded that unintentional foreign body emboli remain common in modern angiographic practice and are probably underappreciated clinically. When postangiographic ischemia or infarction occurs, lint, or other foreign debris should be included in the differential diagnosis.

Chapot reported that thromboembolic events are the most frequent complications of endovascular treatment of intracranial aneurysms. The author reported a case where he was able to ensnare a non-dissolvable clot from the middle cerebral artery and identify the fibers at the center of the clot as coming from unsealed gauze in the vascular set used during the procedure.

Whelan had similar findings when lint from drapes and powder debris from gloves were attracted to intravascular stents during preparation were found to be responsible for thrombogenic events in the coronary artery and an unsuspected contributor to restenosis. He reduced the complication by addressing the sources of contamination.

Amplified Inflammation

When particles are deposited in tissues at the surgical site, cell injury is initiated due to direct cellular damage from physical abrasion, collateral damage from neutrophilic enzymes and oxidative radicals, and from chemicals sometimes leached from lint, fibers and particles over time. Each of these contributors is associated with inflammation that can spread beyond direct contact as the body tries to protect itself from the foreign “invasion.” For example, neutrophils (PMN) are energetic white blood cells representing one of the body’s first lines of defense when something enters the tissues. As soon as they arrive, they expel destructive enzymes and oxidative radicals in efforts to “kill” the foreign invader. They spray

the area much like shotgun pellets directed at a target hit items in the periphery. In doing so, the enzymes and oxygen radicals harm healthy tissues in the vicinity of the lint and particles. The injured tissues signal an inflammatory response in an expanding area that, depending on the nature of the foreign debris, may continue for an extended period.

Poor Wound Healing

After uncomplicated surgery, normal healing commences almost immediately and proceeds in very well-orchestrated interdependent sequential events. However, the presence and persistence of amplified inflammation caused by foreign debris sends mixed signals such that areas farther away from the debris may heal rapidly and well, while others lag behind or only partially complete the sequential phases. It may take longer for new blood vessels to be constructed in the swollen, inflamed area. This means less oxygen delivered, signaling that impacted areas are not yet ready for collagen, thus delaying healing. The delay in healing could potentially result in a regional mosaic of weak and strong areas with mixed levels of optimal alignment and contracture. Complications have included increased scar volume possessing decreased center strength, toughness, resilience, and flexibility of the repaired tissues, delayed healing, an increased risk of dehiscence, and reduced functionality.

Granulomas

A granuloma is a very small “pearl” formed when the body tries to wall-off foreign debris. This foreign body reaction starts with white blood cells (macrophages) surrounding the perceived invader. Unable to dissolve it, the white cell encapsulated fibers are then encased by more white cells including T-lymphocytes and with more fibrin. Tinker reported 45 consecutive cases of cellulose fiber granuloma with mild to severe consequences. Analysis of specimens suggested that cellulose foreign body granulomas may be a significant cause of intestinal obstruction as adhesions strangling the intestines often had cellulose-granulomas as probable initiators. His conclusion was that new drapes containing paper were the source of the cellulose fibers.

Adhesions

Adhesions can be potentially devastating complications. Fibrin strands are deposited by the body to stop movement of invading debris. The fibrin strands anchor themselves around nearby structures. Because lint and other fibers do not dissolve, the fibrin strands persist, and they become thicker and more permanent. They may contract, causing mild to severe pain, impeding optimal function of organs to which they are attached. Cases include impaired ovaries, fallopian tubes, kidneys and intestines. It is estimated that 50 percent of post-surgical abdominal pain is due to adhesions. In 1997, Duron performed an extensive study in which he excised chronic adhesions from patients and performed histopathology on the masses. He found 80 percent contained lint and fibers.

Implementation

Lint and fibers come from natural and synthetic sources. As Belkin's studies have emphasized, paper and cotton are cellulose based (from plants and trees) and are generally the higher linting and bio-reactive materials. Whether natural or synthetic, source materials may contain dyes, glues/adhesives, and fire-resistant treatments that can be leached into the wound. The fibers themselves do not dissolve. For example, cotton fabrics are washed in washing machines and do not dissolve. Similarly, paper will eventually degrade and fall apart in water, but the fibers are still there. In tissues, most lint and fibers remain and are associated with many different post-surgical complications.

The best way to make certain that complications associated with lint and fibers do not adversely impact post-surgical procedures performed with your medical product is to ensure the users are conducting their procedures in low lint/foreign debris-containing environments. If your product is included in a custom pack, make certain the contents are low linting and powder-free. Add the appropriate recommendations in your directions for use. Make certain all in-vivo safety or clinical studies performed on your product are conducted in a foreign debris-controlled environment.