

LITERATURE REVIEW

MICROSCOPIC FOREIGN BODY
CONTAMINATION IN THE
INTERVENTIONAL LAB AND THE
OPERATING ROOM

SYNTERVENTION INC



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1 Cotton Fiber Contamination in the Sterile Field: Related Publications

A literature review was conducted to review the literature related to lint contamination in the sterile field. This is a summary of key publications on lint contamination.

The following publications are summarized:

1. Laboratory tests = bench data such as light microscopy of equipment in tissue
2. Histological Studies = post mortem histological analyses
3. Pre-clinical studies = animal studies
4. Clinical Case Review = human clinical data

2 Laboratory Tests, Histological Studies, and Pre-Clinical Studies

2.1 Laboratory Tests

Walley VM, Stinson WA, Upton RT, Santerre JP, Mussivand T, Masters RG, Ghadially FN. Foreign Materials Found in the Cardiovascular System After Instrumentation or Surgery (Including a Guide to Their Light Microscopic Identification). Cardiovascular Pathology (1993); Vol. 2, No. 3, pp 157-185.

Walley et al (1993) acknowledge that foreign body contamination exists. The investigators conducted light microscopy examinations on multiple materials used during open surgical and percutaneous procedures for the purpose of educating the reader on the impact and the appearance of a variety of foreign materials if found on histological examination or autopsy. The manufacturers, materials used to manufacture the product, and a magnified photograph of the material were taken to illustrate the appearance of the foreign material.¹

Walley et al (1993) Laboratory Data	
Study Objective	Inform the reader of materials that may be recovered after cardiovascular procedures or surgery.
Study Design	Materials were analyzed using a Faxitron x-ray machine and the radiographic appearance of each material was tabulated. Radiographic comparison of the appearance of normal myocardium. The pictures of the materials studied were presented. Some products not intended for the cardiovascular system were included since they may be found there.
Study Results	Products #30-#45, pages 160-161 include lint producing materials.
Conclusion	Inform the reader of the appearance of materials that may be found in the cardiovascular system on autopsy that may be determined on light microscopy.
Why Is This Relevant?	The authors acknowledge that foreign body embolization is a problem to the extent they felt the need to educate the pathologist on the appearance of over 100 materials that can possibly embolize during a cardiovascular intervention or procedure.

Glasgow D and Sommers J. Lint Shedding Cannot Be Overlooked. The Clinical Services Journal (2003). 28-30.

Glasgow and Sommers (2003) reported on the link between airborne lint in the operating room and infection and contamination issues. They acknowledge that lint causing granulomas has been published multiple times in the 1970s and 1980s. The focus on lint decreased as the focus on powder from sterile gloves increased. There was a decrease in lint and cotton fibers in the air filters of operating rooms after the switch to polypropylene gowns and drapes. In 2001 King Edward Hospital lint study revealed that 90% of the lint particles found in one of the rooms was 90% cellulose, the cellulose materials were either wood pulp or cotton. A study was repeated in 2002 after the operating room switched products. Samples primarily contained cellulose fibers, of which cotton was the major portion. Samples were taken from 5 additional hospital operating rooms in the United Kingdom and the Netherlands and the majority of fibers were cellulose from cotton or wood pulp. The authors stress that airborne lint is not the only mode of transmission and that lint can be transferred via surgical instruments. The transfer of lint on surgical instruments is of paramount importance to prevent as the lint is a medium for transport of micro-organisms to the wound site as well as the potential to cause foreign body reactions. "The issue of lint shedding from surgical products in the operating suite environment should not be, nor cannot be, overlooked.

Summary: Glasgow et al (2003) Data	
Study Objective	To determine the impact on airborne lint particles after changing to polypropylene drapes and disposable gowns.
Study Design	Measurement of lint particles in the air filters in 6 operating rooms in the U.K. and the Netherlands.
Study Results	Significant "linting" was created by wood pulp, polyester, or cotton fabrics compared to polypropylene.
Conclusion	Lint is a medium for the transport of micro-organisms to the wound site as well as the cause of foreign body reactions. Measures to reduce or prevent lint contamination must be implemented. "The issue of lint shedding from surgical products in the operating suite environment should not be, nor cannot be, overlooked."
Why Is This relevant?	Operating rooms and cardiac cath labs have made partial changes to polypropylene disposable drapes and gowns. The prevention of shedding of cotton fibers needs to be taken a step further. The shedding of cotton fibers in direct contact with surgical instruments needs to be prevented. The current product, cotton gauze, causes lint particulate to be shed in the sterile field. Changing from use of gauze to a non-shedding product will reduce the possibility of lint contamination.

2.2 Histological Results (post mortem)

Silberman J, Cravioto H, Feigin I. Foreign Body Emboli Following Cerebral Angiography. Archives of Neurology (1960). Vol. 3, 119-126.

Silberman et al (1960) reported foreign body emboli following cerebral angiography. Five cases reported foreign bodies 10-20 microns in thickness and from 80 to 200 microns in length that were found in the lumens of the cerebral arteries. In 2 of the 5 subjects, the reactions to the foreign bodies completely occluded the arteries involved, and infarcts were present in the areas of their distribution. The material was found to be cotton fibrils identical to those found in gauze pads present in the angiography set. These complications can be prevented with the use of wipes that do not contain a soft meshwork of short cotton fibers.³

Summary: Silberman et al (1960) Data	
Study Objective	Report on the findings of foreign bodies in human brains.
Study Design	Post mortem autopsy examinations reported, N=5.
Study Results	<p>Case #1: 10 microns x 150 microns foreign body found in leptomenigeal artery, which measured 0.8mm in diameter.</p> <p>Case #2: Almost a completely occluded artery in the left corpus striatum with a foreign body measuring 10 microns by 80 microns.</p> <p>Case #3: 2 arteries 300 microns in diameter, occluded by fibrous connective tissue, with a recent infarct present. Focal infarcts were noted.</p> <p>Case #4: Recent embolic occlusion of the main trunk and several branches of the right middle cerebral artery. Left middle cerebral artery was occluded. Foreign fibrils with connective tissue were blocking the lumen. Focal infarcts were noted.</p> <p>Case #5: One leptomenigeal artery, about 300 microns in diameter, showed foreign fibrils and multi-nucleated foreign body giant cells.</p>
Conclusion	The foreign bodies in all 5 of these cases on histologic comparison were known to be cotton fibrils obtained from gauze pads usually present in the angiography set. In each case they were found within the cerebral arteries in the distribution of the vessel injected.
Why Is This Relevant?	Brain injury resulted in 2 of the 5 cases due to foreign emboli being introduced into the patients at the time of angiography. Eliminating the use of gauze in cerebral angiography was advised by the investigators.

Dimmick JE, Bove KE, McAdams AJ, Benzing III G. Fiber Embolization – A Hazard of Cardiac Surgery and Catheterization. Medical Intelligence (1975). Vol. 292, No. 13, 685-687.

Dimick et al (1975) reported on the hazard of fiber embolization during cardiac surgery and catheterization. Over the previous 10 years, prior to this report, cotton fibers were commonly found on post mortem exams in patients who had undergone cardiac catheterization or cardiac surgery. This investigation was prompted by two subjects who had recent thrombosis associated with these fibers, indicating the presence of foreign materials is not innocuous, and has a profound impact on the clinical outcomes of patients. Materials worn and used during cardiac catheterization were microscopically examined and compared to those in the pathological specimens. The ease by which the fibers were shed was assessed, and saline from the bypass pump oxygenator was examined for fiber content. 14/173 (8%) of patients who underwent cardiac catheterization or cardiac surgery or both had fiber emboli in routine autopsy sections.

All 14 had cardiac catheterizations, 8 had intracardiac surgery, and three had extracardiac surgery such as pulmonary artery banding. Fibers occurred in pulmonary arteries (8), renal arteries (4), cerebral (1), and mesenteric arteries (1). When patients died during or immediately after the procedure, fibers found were not associated with inflammation, and there may or may not have been thrombus. At a later stage the fibers elicited a standard foreign body inflammatory reaction. Regardless of the reaction, the fibers were associated with narrowing or occlusion of the vascular lumen. Shed cotton fibers ranged from 3.3 to 22.2 microns. The incidence and morbidity of fiber embolization demonstrated in this study in addition to the morbidity previously documented suggest that preventative measures should be considered.

Summary Dimick et al (1975) Data	
Study Objective	Retrospective study to understand the prevalence of cotton or cellulose fibers inadvertently introduced into the subjects' cardiovascular systems.
Study Design	Retrospective study post mortem. Autopsy records were reviewed from 1964-1973 for all subjects who had undergone cardiac surgery or catheterization or both. N=173. All 14 had undergone prior angiography, 8 had intracardiac surgery, and 3 had extracardiac procedures, and 3 did not undergo surgery.
Study Results	14/173 (8%) were found to have fiber emboli in routine autopsy sections. Fiber locations included pulmonary artery (n=8), renal artery (n=4), Cerebral artery (n=1), and mesenteric artery (n=1). These were found in subjects who died during or immediately following intracardiac procedures. Regardless of the type of reaction, the embolized fiber resulted in a narrowing for occlusion of the vascular lumen. Multiple foci of cerebral necroses were present (n=1) with numerous fiber emboli within small cerebral vessels. Recent cases (n=2), a pulmonary infarct from a cotton fiber, and an occluded radial artery, 24 hours after radial artery cannulation during angiography, due to a thrombus formation from a cotton fiber resulted in amputation of the hand.
Conclusion	Measures need to be taken to eliminate inadvertent introduction of cotton fibers into patients.
Why Is This Relevant?	Fiber emboli continue to increase morbidity and mortality following cardiac diagnostic procedures and surgery.

Tinker MA, Teicher I, Burdman D. Cellulose Granulomas and Their Relationship to Intestinal Obstruction. The American Journal of Surgery (1977). Vol. 133, 134-139.

Tinker et al (1976) reported 45 cases of cellulose granulomas specimens from surgical mortalities over a 2.5 year period. Morphologic comparisons were made to known fibers from laparotomy pads, and disposable paper gowns. Out of 7500 surgical specimens and autopsies, 45 cases of cellulose foreign body granulomas were identified. The 45 specimens were from patients who had at least one surgical procedure involving the same area.

Summary: Tinker et al (1976) Data	
Study Objective	Report a collected series of 45 consecutive cases of cellulose foreign body granulomas, estimate the incidence of lesions, determine origin, and evaluate its clinical significance in regards to intestinal obstruction.
Study Design	45 specimens from approximately 7500 surgical specimens from surgical mortalities reviewed by one pathologist during a 2.5 year period. A comparison was made to the cellulose fibers found in laparotomy pads and in paper gowns.
Study Results	<p>All subjects had surgery in the area of where the granuloma specimens were retrieved within 3 years prior.</p> <p>Group 1: Intraperitoneal – 18/45 were found within the peritoneal cavity. N=8 who were symptomatic with 2 having granulomatous peritonitis and 6 having small bowel obstructions.</p> <p>Group 2: Extraperitoneal – 27/45 granulomas were outside the peritoneal cavity. N=8 – symptomatic with 5 requiring surgery, and 3 possibly related to the indication for surgery.</p> <p>All autopsy material from surgical mortalities was classified as asymptomatic as the granulomas were not the cause of death.</p>
Conclusion	A true incidence rate cannot be determined unless those subjects who undergo re-operation have surgical specimens sent to pathology for histological examination to determine the presence of cellulose fibers. Disposable paper fabrics make a significant contribution to the formation of cellulose granulomas.
Why Is This Relevant?	While this paper did not report on the impact of gauze, it continues to emphasize the seriousness of the impact of inadvertent introduction of cotton fibers on patient outcomes.

Shannon P, Billbao JM, Marotta T, Terbrugge K. Inadvertent Foreign Body Embolization in Diagnostic and Therapeutic Cerebral Angiography. American Journal of Neuroradiology (2006). Vol. 27, 278-282.

Shannon et al (2006) reported a 5 year retrospective study of available post mortem cases of post angiographic neurologic complications and histological exams of surgically resected arteriovenous malformations (AVMs) at a single institution in the United States. One of the AVM cases had the diagnostic angiogram performed at another institution, which illustrates that this problem is not confined to one institution. Unintentional cotton fiber embolization can occur and should be included in a differential diagnosis of post cerebral angiographic complications.

Summary: Shannon et al (2006) Data	
Study Objective	To conduct a comprehensive and systematic retrospective review of all available post mortem cases of post angiographic neurologic complications following cerebral angiography as well as review the histological data from all resected AVMs at a single institution.
Study Design	Post mortem retrospective review over 5 years. N=61
Study Results	N=3 Embolic material found (3/61, 4.9%) following diagnostic cerebral angiography in the AVM group. The number of neurologic complications out of 2900 consecutive diagnostic cerebral angiograms cases was 39 (1.3%), of which 20 (0.7%), were transient, 5 (0.2%) were reversible, and 14 (0.5%) were permanent.
Conclusion	While the complications are usually asymptomatic, foreign body embolization has the potential to have a lethal impact in patients.
Why Is This relevant?	Reduction of the use of cotton in the sterile field will reduce the chance of foreign emboli form cotton fibers being introduced into the patient, and resulting in a lethal outcome.

2.3 Preclinical Testing

Von Glahn WC, Hall JW, Sun S. Arteritis in Guinea Pigs, Produced by Emboli of Cotton, Resembling the Arteritis of Hypersensitivity. American Journal of Pathology (1954), Vol. 30, No.6, 1129-1139.

Von Glahn et al (1954) conducted a controlled experiment to determine if there is an antigen-antibody reaction to cotton fibers when injected into the venous circulation of guinea pigs. Sterilized cotton soaked in physiologic saline was injected into the jugular vein using sterile technique. The animals were sacrificed at 12, 24, and 48 hours. After 12 hours foreign body granulomas began to form, necrosis formed adjacent to the cotton emboli, and the necrosis was seen where no foreign body granulomas had formed. The cotton fibers produced lesions in the pulmonary arteries, arterioles and precapillary ranches at the sites where the fibers lodged. Foreign body granulomas formed in many areas where the cotton lodged. Lesions induced by cotton closely resembled arteritis.

Summary: Von Glahn et al (1954) Data	
Study Objective	To determine if antigen-impregnated cotton fibers cause an antigen-antibody reaction in test animals.
Study Design	Guinea pigs: 65 Test animals injected with R salt egg-albumin impregnated cotton and 44 control, 4 sensitized to albumin and injected with untreated sterile cotton, 25 received R salt egg-albumin soaked cotton, and 11 received cotton soaked in egg albumin. Reactions were observed at 12, 24 and 48 hours.
Study Results	Gross changes in the lungs were directly related to amount of cotton injected. Small hemorrhages were seen. At 12 hours media was found to be necrotic proximally and distally adjacent to the cotton. Foreign body granulomas were beginning to form. End of 24 hours entire media was often necrotic and no foreign body granulomas were seen. Where granulomas had formed, vessel walls were stretched, large mononuclear cells were found between the necrotic muscle cells, and edema was present. All stages of arteritis were noted in single animals. Arteritis was present in 38/65 (58.5%) of the animals.
Conclusion	No relationship between previous sensitization and the arteritis (no antigen-antibody reaction), as identical lesions were found in the control group. Damage to the vessel walls occurred independent of the presence of granulomas. Granulomas were present in some lesions and not others. Medial necrosis occurred without granulomas present. Lesions resembled arteritis.
Why Is This Relevant?	Demonstrates in the animal model the reactions due to foreign body emboli, specifically the foreign body made of cotton.

Sturdy JH, Baird RM, Gerein AN. Surgical Sponges: A Cause of Granuloma and Adhesion Formation. Annals of Surgery (1967), Vol. 165, No. 1, 128-134.

Sturdy et al (1967) conducted an experiment to show that cotton gauze could cause foreign body granulomas and review cases of foreign body granulomas at a single institution. Four groups of rats, treatment groups varied depending on test article, and control groups were treated with various substances that are commonly used during surgical procedures. Group 1, 29 animals, treated by vigorously rubbing a dry laparotomy sponge over a wound to allow lint to fall into the abdominal cavity. Group two, three animals, the treatment consisted of placing a laparotomy sponge in the abdominal cavity. Group 3 consisted of six animals where a small piece of gauze sponge was placed in the abdominal cavity, and group 4 consisted of six animals where starch powder was sprinkled in the abdominal cavity. Group five, the control group underwent opening and closure of the abdominal cavity without the addition of foreign material. The experiment confirmed that gauze fragments cause granulomas similar to those seen in humans. The granulomas caused adhesions. Gauze fragments came from both four gauze sponges and laparotomy sponges made of cotton.

Summary: Sturdy et al (1967) Data	
Study Objective	Demonstrate that cotton gauze could cause foreign body granulomas formation, and report cases of foreign body granulomas at a single institution.
Study Design	Rat model used, in an animal operating room (to reduce contamination) 4 treatment groups, one control group. Group 1: N=29 tested by rubbing a dry laparotomy sponge over an open abdominal cavity to allow lint to fall into the cavity, sacrificed at 4-81 days; Group 2: N=3 tested by placing a small piece of sponge in the abdominal cavity, sacrificed at 7-20 days; Group 3: N=3 tested by placing a small piece of gauze sponge in the abdominal cavity, sacrificed at 7-15 days; Group 4: N=6 tested by sprinkling starch powder in the abdominal cavity, sacrificed at 7-74 days; Group 5: N=10 control group was not tested with foreign materials and underwent the abdominal cavity being opened and closed, sacrificed at 9-69 days.
Study Results	Group 1: 21/29 microscopic and gross granuloma formation; 15/29 contained gross granulomas that formed between 1 and 12 weeks, and 21/29 had microscopic granulomas that formed between 1 and 12 weeks. Groups 2 and 3: These groups were not large enough for interpretation, granulomas were produced by both sponge and gauze placed in abdominal cavity. Group 4: Granulomas in 5/6 animals. Group 5: No granulomas, 1 contained an adhesion at time of sacrifice.
Conclusion	Rat experiments confirmed the development of granulomas and adhesions are gauced by lint particulate from gauze from gauze sponges and laparotomy sponges.
Why Is This Relevant?	Reinforces the consistency in the reactions observed when gauze sponges are utilized during sterile procedures.

Zimmerli W, Low DP, Waldvogel FA. Pathogenesis of Foreign Body Infection: Evidence for a Local Granulocyte Defect. Journal of Clinical Investigation (1984). Vol. 73, 1191-1200.

Zimmerli et al (1984) acknowledge that foreign bodies are highly susceptible to pyrogenic infections and represent a major problem. The investigators postulated that local host defense mechanisms might not be able to defend against local invasion of microorganisms. Most foreign body infections have been caused by *S. aureus* and are controlled by the phagocytic response to the infection. Zimmerli et al used a guinea pig model with implanted Teflon cages as the foreign body and studied the function of phagocytes near or around a foreign body in this guinea pig model. Interaction of polymorphonucleocytes (PMNs) with Teflon fibers was observed. The PMNs showed defective bactericidal activity and granular enzyme content. This may be part of the reason for high susceptibility to infection of foreign bodies.⁹

Summary: Zimmerli et al (1984) Data	
Study Objective	Study the pathogenesis of infections from foreign bodies: Determine some of the steps responsible for the abnormal bactericidal activity of PMNs surrounding an implant and the mechanisms leading to the acquired granulocyte defect, and its pathogenic significance by preventing infection with local infusion of peripheral PMNs. They sought to quantitatively evaluate the microbiologic, immunologic, and cellular events preceding or associated with a foreign body infection.
Study Design	Guinea pig model - foreign body: implanted Teflon cages infected with <i>S. aureus</i> used to study phagocytic function at the location of the foreign body. 1-3 weeks after cage implants, fluid was aspirated using sterile technique and sterility and PMN counts were analyzed.
Study Results	Reduced PMN function as a result of granular enzymes and decreased functionality (unable to produce a respiratory burst).
Conclusion	The combination of PMN defect and increased bacterial adherence act in concert to favor infection and foreign material.
Why Is This Relevant?	This is a very complex article, mostly understood by pathologists. Looking beyond the complexity, the results emphasize that when a foreign body is introduced (and this can be a deliberate implantable device or inadvertent foreign emboli) the ability to fight infection can be altered putting the patient at greater risk for complications.

Bookstein JJ, Arun K. Experimental Investigation of Hypercoagulant Conditions Associated with Angiography. Journal of Vascular and Interventional radiology (1995), Vol. 6, No. 2, 197-204.

Bookstein et al (1995) conducted an experiment of hypercoagulant conditions associated with angiography. The purpose of their experiment was to evaluate changes in blood coagulability after high velocity intravascular fluid injections under conditions relevant to angiography. This investigation was initiated due to stroke rate after arch aortography, occasional rapid progression of thrombus at stenotic sites, increase in thromboembolic complications and competing procoagulant effects of pulse spray during thrombolysis, and following two deaths after aortography and inferior vena cavography. Previous inconsistencies in the coagulative effects of injected intracatheter blood caused the investigators to suspect that particulate foreign matter on the guidewire or within the guidecatheter might influence hypercoagulance. High velocity injections alter coagulability but there is a greater effect when particulate matter is involved. The procoagulant effects of injection of 1mL of blood that resided in the catheter for 3 minutes were much greater after the blood had been exposed to a guidewire that had been wiped down with gauze and powdered surgical gloves. The ACT was 106 seconds (± 12 seconds) without injections, intracatheter blood that resided for 3 minutes dropped the ACT to 74 seconds (± 17 seconds) and intracatheter blood with exposure to particulate dropped the ACT to 25 seconds (± 25 seconds).

The investigators concluded that coagulant complications from angiography are probably, for the most part, preventable. It has become standard to inject a bolus of heparin (2,000 – 3,000 units prior to any angiographic injections), and eliminating all blood from catheters prior to injection of contrast materials, but additional attention should be paid to other meticulous techniques such as careful washing of glove powder off gloves, and using wiping materials that do not produce particulate residue.

Summary: Bookstein et al (1995) Data	
Study Objective	Quantify hypercoagulant conditions that might be associated with high velocity intravascular fluid injections under conditions relevant to angiography.
Study Design	Rabbit model used, rationale for this model explained. Contrast injections into the aorta using an injector were performed. Blood samples were aspirated and ACT was tested on each sample. Pilot study using 4 rabbits was conducted to demonstrate consistency in ACT determination with little variance. The study design pertinent to this report of the literature is regarding the testing of blood exposed to a guidewire handled with gauze and powdered surgical gloves. N=4; 3 minute intracatheter blood with no exposure to particulate was compared to intracatheter blood for 3 minutes exposed to particulate.
Study Results	The following results are relevant to this report of a literature review: ACT 74 \pm 17 seconds. 3 minute intracatheter blood with exposure to particulate: ACT 25 \pm 25 seconds.
Conclusion	Attention should be paid to techniques such as washing glove powder off gloves and use of wiping materials that do not produce particulate residue.
Why Is This Relevant?	Inadvertent introduction of particulate during a percutaneous intervention can cause hypercoagulant conditions and put the patient at greater risk for complications.

Whelan DM, van Beusekom HMM, van der Giessen WJ, Foreign Body Contamination During Stent Implantation. Catheterization and Cardiovascular Diagnosis (1997), Vol. 40, 328-332.

Whelan et al (1997) reported on foreign body contamination during stent implantation. A preclinical study involving swine was conducted to assess contamination factors during stent implantation. The implanted stents were studied at various time intervals from hours to 12 weeks post implant. 46 animals were divided into 2 groups. Group A included short term follow-up. Group B consisted of longer-term follow-up. Group B showed 8.8% fiber contamination. Particulate contamination may influence the wound healing response, and this may increase the period where subacute thrombosis can occur. The investigators conclude that contamination can possibly be a problem during stent implantation, but until proven or disproved, measures should be implemented to reduce the chance of foreign body contamination.

Summary: Whelan et al (1997) Data	
Study Objective	To assess the impact of inadvertent foreign bodies being introduced during stent implantation.
Study Design	Pig model was used to place stents in the coronary arteries. Implanted stents studied up to 12 weeks post implant. 125 random samples of stained sections from stented coronary arteries from 46 animals were examined for contamination with starch granules and textile fibers. These 46 animals were randomly sampled from 11 animals used in various studies where a total of 147 stents had been implanted. Group A- short term follow-up (due to stent thrombosis), Group B long-term follow-up.
Study Results	Group A: 41.6% starch contamination; 0% textile contamination. Group B: 11.8% starch contamination; 8.8% textile contamination.
Conclusion	Contamination of equipment with a textile fiber is probably from gauze and may occur during cleaning, handling, wiping of the equipment. Deposition of gauze results in granulomas formation. Microscopic fibers can adhere to stents, balloons, wires, and be carried into the vessel where they can be lodged. Gauze leads to a long and persistent foreign body reaction. Contamination can occur during stent implantation. It would be prudent to implement measures to prevent contamination.
Why Is This Relevant?	Pre-clinical work that continues to emphasize the importance of preventing contamination with particulate and inadvertent introduction into the patient.

Sari A, Basterzi Y, Karabacak T, Tasdelen B, Demirkan F. The Potential of Microscopic Sterile Sponge Particles to Induce Foreign Body Reaction. International Wound Journal (2006). Vol. 3, 363-368.

Sari et al (2006) report that a sterile gauze sponges that are widely used in medicine lose a significant amount of lint during their routine use in surgery. This experiment evaluated the potential to lose lint and induce a foreign body reaction in surgically created wounds. Sari et al acknowledge that the true incidence of the situation is not reported in the literature due to legal issues. The investigators stressed that any foreign substance infiltrating the organism; whether large, or invisible to the eye, have the potential to invoke an inflammatory response. A surgical gauze sponge is composed of a cellulose structure that cannot be ingested by tissue macrophages and results in foreign body granulomas. The results of this study showed that small gauzes particles and lint lost from gauze by rubbing it on a surgical wound might induce the formation of intra-abdominal granulomas and adhesions.

Summary: Sari et al (2006) Data	
Study Objective	Evaluate if surgical sponges have a potential to lose microscopic lint, and if the retained particles have the ability to produce a foreign body reaction and later the intensity of the inflammatory response already initiated by surgical trauma.
Study Design	Rat model, N= 15. Two pockets created on the right and left abdominal wall in each rat. Sterile sponges utilized in the operating room, made of cotton, were used for this experiment. The free cut edges of the sponges were folded inward to prevent the edges from being exposed to the pockets. The left pockets were each packed with a folded sterile sponge, while the right side pockets remained empty. Sponges remained in the pockets for 15 minutes. Sponged removed, pockets were irrigated with sterile saline. Irrigation material was collected in sterile glass tubes, and surgical wounds were closed. Animals were operated on at 4 weeks and tissue samples were removed. Investigators recognized the difference between rat hair and lint from sponges under light microscopy.
Study Results	N=15 with 1-2 macroscopic gauze remnants in left pocket, 0 in right. N=14 with microscopic gauze particles in left pocket, 0 in right. The intensity of the inflammatory reaction was reported: The intensity was graded Mild=1, Moderate=2 or Severe=3. N=9 out of 15 (60%) with an increased intensity of inflammatory reaction in left pocket compared to own control (right pocket). N=5 out of 15 had the same intensity in reaction on the left as the right. N=1 out of 15 that had a lower intensity grade on the left compared to the right pocket. The difference in the results between the left and right side was significant (p< 0.05).
Conclusion	Surgical sponges used today are disposable (no longer re-sterilizable) and still loose particles may fall on the sterile field particularly when sponges with free cut edges are vigorously used. Surgical sponge lint is made of cellulose and cannot be digested by tissue macrophages; therefore, a cascade of inflammatory reactions occur forming foreign body granulomas. Not only do small gauze particles invoke this reaction, but also microparticles from the gauze can invoke this same reaction.
Why Is This Relevant?	Pre-clinical data continues to demonstrate the increased severity in the inflammatory response caused by particulate from gauze in the surgical setting.

Ramot Y, Amir G, Willenz EP, Nyska A. Foreign Body Granulomas within Intramyocardial Arteries in a Transcoronary Safety Assessment in Pigs. Toxicologic Pathology (2008), Vol. 36, 385-387.

Ramot et al (2008) reported the occurrence of granulomas-type reactions to cotton gauze fragments following coronary interventions in three domestic swine. The investigators' concern was that during toxicological studies, granulomatous inflammation can occur from drug therapy, thus determining the origin of the inflammatory reaction is of utmost importance during toxicological studies. Foreign body granulomas may lead to an inflammatory response and misinterpretation of drug safety results. The experiment was conducted in the following fashion: Myocardial infarctions were induced by occluding blood flow using an angioplasty balloon. Three days following, the test material was injected into the coronary artery followed by saline and coronary angiography. Inflammatory response occurred in the test animals. The investigators concluded that foreign body embolization can occur during interventions, and this can cause misinterpretation of drug safety results and impact patient outcomes. During studies, appropriate measures should be taken to reduce the chances of contamination.¹³

Summary: Ramot et al (2008) Data	
Study Objective	Report the results of a pre-clinical study to illustrate the importance of histological data in drug safety studies due to the impact that granulomatous reactions to cotton gauze fragments can have on the results.
Study Design	Pig model, N=3. Each underwent catheterization of the left anterior descending (LAD) artery using non-ionic contrast. Angioplasty balloon inflated for 60 minutes induced an acute myocardial infarction (AMI). Day three, a second catheterization was performed and the test material was injected into the infarcted artery. Day 8, the animals were sacrificed and tissue samples were taken.
Study Results	3 out of 5 study animals developed foreign body granulomas.
Conclusion	Foreign body embolization can occur and that the foreign body reaction can lead to misinterpretation of drug safety results. During the study (and always) appropriate measures need to be taken to reduce contamination.
Why Is This Relevant?	Pre-clinical data as recent as 2008 is consistent with previous studies dating back to the 1940s illustrating the reactions caused by foreign body embolization from gauze fragments.

3 Clinical Case Reviews

Heath D and Mackinnon J. Case reports: Cotton-Wool Granuloma of Pulmonary Artery. British Heart Journal (1962). Vol. 24, Issue 4, 518-520.

Heath et al (1962) report a case of an unusual disturbance of the pulmonary circulation. On cardiac catheterization, a patient was found to have a patent ductus arteriosus (PDA) and underwent repair. In addition, a small portion of the lung was removed for histologic exam. After a 3 week hospitalization, the patient was discharged and tolerated an increase in exercise tolerance. One of the pulmonary arteries, on biopsy showed a peculiar change. A granuloma was present which protruded outward into the adventitia and into the lumen of the vessel. The granulomas were comprised of fibrous tissue and inflammatory cells. The changes in the blood vessel were similar to hypertensive pulmonary vascular disease. The lesion was similar as described previously by Von Glahn (1949). Cotton-wool fibers were inadvertently injected during the cardiac catheterization. The storage of catheters was changed by the cardiac catheterization unit.¹⁴

Summary: Heath et al (1962) Data	
Study Objective	Present the results of a biopsy to inform the reader of a peculiar change in the muscle structure of a pulmonary artery that may present a problem in the interpretation of future lung biopsies.
Study Design	Case review presented with emphasis on specific results of a lung biopsy taken at the time of a PDA repair.
Study Results	A cotton-wool fiber was inadvertently introduced into the patient where it became lodged in the pulmonary artery. A granulomatous response was invoked, as documented in the literature many times over.
Conclusion	The catheter contamination was most likely the cause of the fiber in the pulmonary artery.
Why Is This Relevant?	Contamination with a cotton-wool fiber caused a lesion to form in the pulmonary artery of a patient. The fiber was probably introduced into the circulation during a cardiac catheterization. Inadvertent introduction of contaminants can be prevented.

Sturdy AH et al. Surgical Sponges: A Cause of Granuloma and Adhesion Formation. Annals of Surgery 1967, Vol 165, No. 1;pp. 128-134.

Sturdy et al (1967) reported on a clinical case series of 61 patients divided into 4 groups based upon the site of granulomas formation. Thirty-two post surgical cases were found to have granulomas formation in the peritoneum, of which 23/32 gauze was considered to be the cause. One patient died due to a persistent bowel obstruction. The material found in this patient included gauze, talc, starch powder, suture material, Lipiodol and a mixture of these. Group 2, 10 out of 23 cases required a secondary operation at 2 weeks to 11 months following the original surgery due to granulomas formation in skin and subcutaneous tissue. The third group included 6 cases of granuloma formation in the area of the cervix, none caused morbidity. The fourth group included a sponge left in a knee joint post surgery.⁸

Summary: Sturdy et al (1967) Data	
Study Objective	Report cases of foreign body granulomas at a single institution
Study Design	A retrospective review of subjects who experienced granulomas formation was reported. The location of the granulomas formation, the material type that caused the formation and the time period from 1 st operation to granulomas formation were reported.
Study Results	Group 1: N=32 Peritoneal, n=15/32 0- 5 years, n=12/32 with adhesions resulting in morbidity and additional surgery. 23/32 etiology was gauze. Group 2: N=23 Subcutaneous, n=18/23 0-1 year, n=10 requiring secondary surgery. N=1 where granulomas resembled recurrent malignant disease. 21/23 granulomas were caused by gauze. Group 3: N=6; 5/6 granulomas caused by gauze. Group 4: N=1 intra-articular granulomas caused by gauze.
Conclusion	A retrospective review of clinical cases indicated that gauze was the etiological factor in foreign body granuloma formation.
Why Is This Relevant?	Retrospective study of human clinical data shows similar results to previous reports for both pre-clinical and clinical outcomes from the impact of cellulose at the surgical site.

Janoff K, Wayne R, Huntwork B, Kelley H, Alberty R. Foreign Body reactions Secondary to Cellulose Lint Fibers. The American Journal of Surgery (1984). Vol. 147, 598-600.

Janoff et al (1984) reported 24 cases of cellulose fiber granulomatous reactions in three area hospitals over a 5 year period. Six resulted in acute granulomatous peritonitis, and one death as a result of this complication. 22 additional operations were performed on these patients due to complications directly associated with the granulomatous reaction. An additional 400 days of hospitalization were required secondary to complications from foreign body reactions. Measures should be taken to prevent lint contamination being introduced into a patient.¹⁵

Summary: Janoff et al (1984) Data	
Study Objective	Report on 24 cases identified as cellulose fiber granulomatous reactions in three area hospitals that occurred over a 5 year period. Etiologic considerations and preventable measures are discussed. Some cases were discussed in detail.
Study Design	Retrospective Study and Case reviews
Study Results	<p>Case #1: Modified radical mastectomy – 3-4 days following surgery, subject experienced pain, erythema, serous drainage, deep retraction of the scar, and unattractive appearance. Patient underwent excision of the scar and suffered 10 additional days in the hospital. A cellulose fiber granuloma was revealed on histological exam of the specimen, an extraperitoneal granulomatous reaction.</p> <p>Case #2: A complex case where a patient total proctocolectomy for ulcerative colitis at age 16. Patient presented at age 26 with symptom of a small bowel obstruction. No obstruction was found on exploration, large bilateral ovarian cysts were resected, and patient was discharged 8 days later. Patient was readmitted 2.5 weeks later with an intestinal obstruction. A celiotomy was performed. The bowel was adhered to all surrounding structures. Patient was hospitalized for 4 weeks and the histological exam showed foreign body reactions to cellulose, known as intraperitoneal granulomatous peritonitis.</p> <p>6 additional cases of intraperitoneal granulomatous peritonitis resulted in significant morbidity and 1 mortality.</p>
Conclusion	The true incidence of granulomatous peritonitis is unknown. An estimated 400 days of additional hospitalization in this study were required secondary to foreign body reactions.
Why Is This Relevant?	Cellulose products are the cause of increased morbidity and mortality in the operating room. Gauze and gauze sponges are made of cellulose. This article is relevant as the intra-operative use of all cellulose products needs to be reduced.

Fischi M and Narins CR. Coronary Embolization of a Gauze Fragment: A Cautionary Case Report. Catheterization and Cardiovascular Interventions (2005). Vol. 66, 570-572.

Fischi and Narins (2005) reported on a case of an iatrogenic embolization of exogenous material into the coronary artery during a percutaneous procedure. A patient developed chest pain after an intervention. The patients returned to the cardiac catheterization lab for angiography. The angiogram showed a filling defect in the mid-LAD. Saline soaked sterile gauze pads are commonly used to wipe equipment during angiography and interventions. It was determined that the saline injected into the patient's coronary artery during the use of a pressure wire inadvertently caused a gauze fiber to be injected as well. It was determined that the bowl of sterile saline used for injection during the procedure was also the bowl where gauze pads were kept for use during the procedure. A fiber came loose from a gauze pad and was aspirated into a syringe for injection into the coronary arteries.

Summary: Fischi et al (2005) Data	
Study Objective	To inform the reader of a potential mechanism by which foreign material can be inadvertently introduced into the circulation of patients undergoing coronary angiography.
Study Design	Case Review; N=1
Study Results	Patient underwent repeat angiography after undergoing a diagnostic angiogram and pressure wire assessment of an ostial circumflex artery lesion and experiencing chest pain 10 minutes after completion of the diagnostic procedure. The second diagnostic procedure shoed a new filling defect in the LAD and the patient underwent thrombus aspiration.
Conclusion	The specimen removed from the LAD was a thrombus that had formed around a gauze cotton fiber. The author concluded that it had inadvertently been injected into the coronary artery during the assessment with the pressure wire.
Why Is This Relevant?	A case that clearly demonstrates the complications and the severity of the complications that can arise from the use of gauze in the cardiac catheterization lab.

Thank you to



for assistance with this literature review