ATRIUM

Thoracic Catheters

TECHNICAL DATA

BIOCOMPATIBILITY

Do Atrium HydraGlide™ Thoracic Catheters help minimize infection and reduce postoperative catheter adhesions?

Using the latest in biomaterial technology and drug delivery techniques, Atrium Medical Corporation has developed a thoracic catheter with superior clinical properties over existing products. The driving force behind Atrium's research has been to improve patient drainage and enhance patient recovery and comfort. To accomplish this, Atrium Medical Corporation developed a smooth, flexible thoracic catheter and heparin release coating process to help improve the natural foreign body response, reduce the risk of infection, and minimize mechanical irritation to the heart, pericardium, and pleural surface which can occur by the mere presence of a catheter to these delicate tissues.

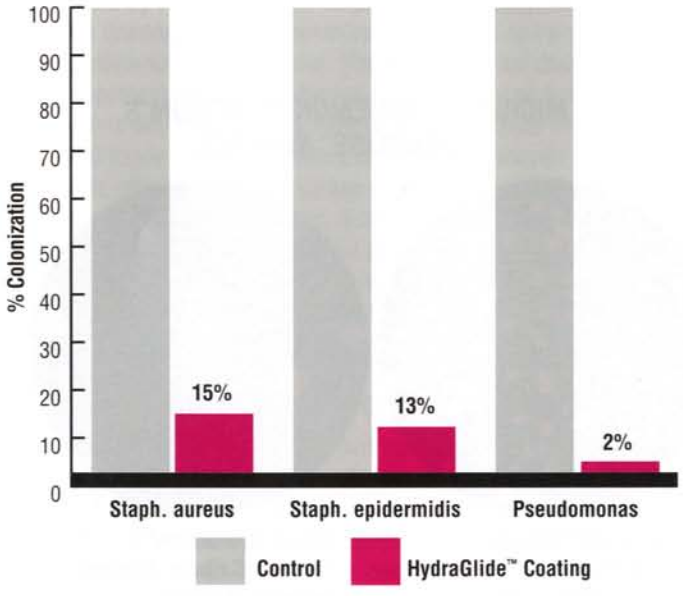
Biocompatibility Overview

Although a thoracic catheter is a short term implantable device, the biological interactions stimulated by the foreign catheter material must be considered as they do have a direct influence on patient recovery, drainage efficiency, catheter removal, and patient discomfort. The complex interactions involve cell-to-cell and cell-to-polymer interactions, including inflammation and complement activation. The response of tissues at the implant site involves a myriad of mediators including chemotactic substances and growth factors that modulate cell functions such as activation, proliferation, and protein production[1]. Bacteria, tissue, and cell-to-biomaterial interactions are directed not only by specific receptors and outer membrane molecules on the cell surface, but also the atomic geometry and electronic state of the biomaterial surface. Modifications to a biomaterial's surface even at the atomic level can influence cell-to-substratum events, diminishing infection by directly inhibiting bacterial adhesion.

The Atrium HydraGlide™ thoracic catheter has undergone standard *in vitro* and *in vivo* testing and demonstrated no toxicity or biocompatablity problems. In addition, several specialized tests have also been performed which demonstrate significantly improved properties related to reduced infection and tissue adhesions.

Figure 1

INHIBITION OF BACTERIAL COLONIZATION



Do Atrium HydraGlide™ thoracic catheters help minimize infection and reduce postoperative catheter adhesions?

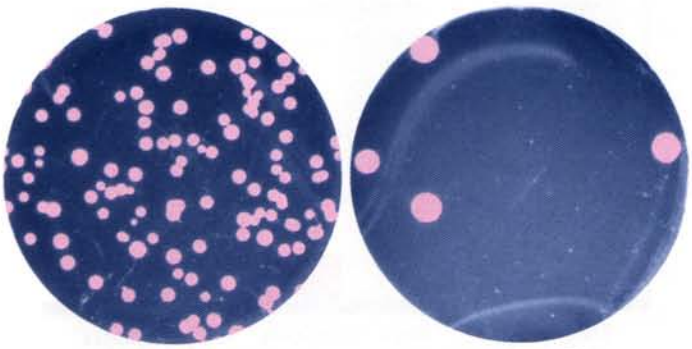
Infection Control

"Foreign body" or biomaterial centered infections are casually related to the highly adaptive ability of bacteria to colonize on the surfaces of inert biomaterials *or* adjacent damaged tissue cells. Bacteria in biomaterial or damaged tissue-centered infections have a common survival mode based on the adhesion colonization of substrata. Thus, bacterial adhesions and its denominators direct the pathogenesis of damaged tissue and biomaterial infections. Biomaterials are physiochemically active and may directly modulate adhesions or interact with host defenses.[2]

The process chosen to coat the Atrium HydraGlide™ thoracic catheter reduces the absorption and colonization of bacteria. The assay of Christensen et al *[J. Clin. Microb. 22(6): 996 (1985)]* was used to test the inhibition of bacterial colonization by the Atrium HydraGlide™ thoracic catheter coating. The results are given in **Figure 1**. Adherence of *Pseudomonas sp was* reduced *98%, Staph. epidermidis 87%, and Staph. aureus 85%*. **Figure 2** gives a visual depiction of the reduced colonization seen with *Staph. epidermidis*. In addition to the bacterial colonization assay, a bacterial adherence assay which compares the adherence of *Staph. epidermidis* to thoracic catheters was performed. Several commercially available thoracic catheters were tested **(Figure 3)**. It was determined that *Staph. epidermidis* had a lower level of adherence to Atrium HydraGlide™ thoracic catheters than to all other catheters tested.

Figure 2

MICROBIAL ADHESION TO ATRIUM'S HYDRAGLIDE™ SURFACE

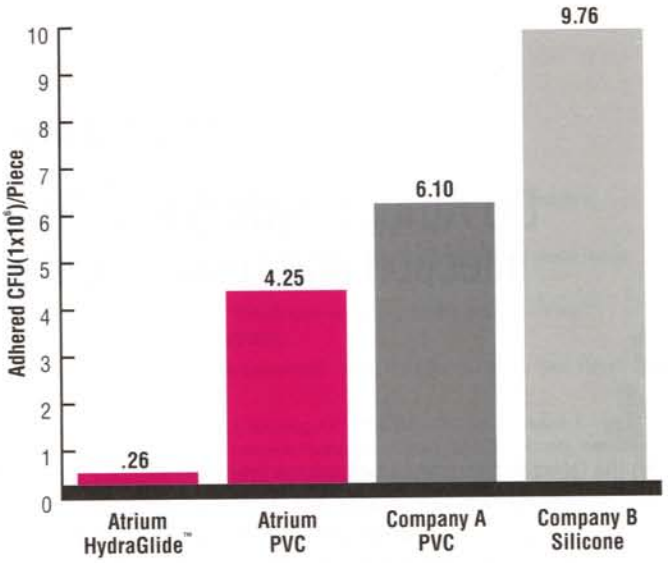


Uncoated Material Exposed To Staph. Epidermidis

Atrium HydraGlide™ Thoracic Catheter Coating Exposed To Staph. Epidermidis

Figure 3

STAPH. EPIDERMIDIS ADHERENCE



In addition to the attachment of bacteria, trauma at the thoracic catheter-tissue interface can promote infection. Traumatized tissue is represented by amorphous organic fragments of cellular tissue and matrices which are rich in microbial nutrient material and receptors. This traumatized tissue provides a surface for colonization by bacteria that possess the appropriate adhesives. Thus, in addition to low cell adhesion, trauma reduction plays an important role in reducing infection, controlling the inflammatory response, and reducing implant complications associated with long term abrasive tissue-implant interactions. Atrium Medical Corporation has incorporated a trauma reduction design with an extremely low coefficient of friction to minimize this effect.

Adhesion Prevention

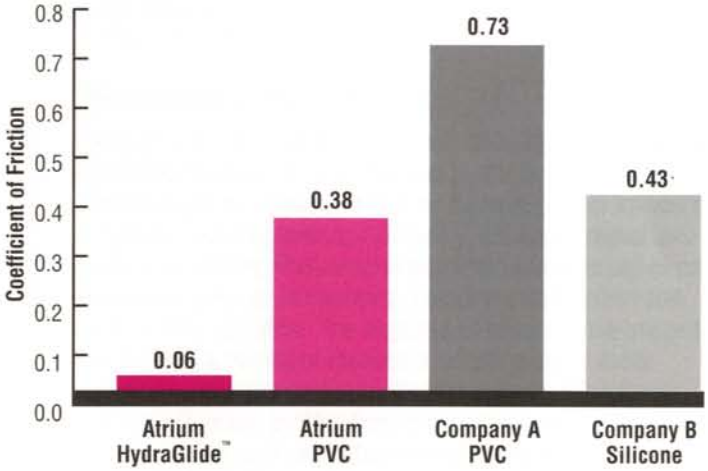
The incidence of reoperation continues to steadily increase with repeat coronary artery surgery comprising the majority of reoperations today. During reoperation, postoperative pericardial adhesions can subject patients undergoing repeat cardiac surgery to substantial risks including potential injury to the heart, great vessels, and extra cardiac grafts during resternotomy and elongated operation times. It has been reported that resternotomy is associated with a 2-6% incidence of major vascular injury. A 37% mortality has also been reported in patients experiencing major hemorrhage during resternotomy,

and the mortality increases to 50% for those patients experiencing major hemorrhage during resternotomy after aortocoronary artery graft procedures[3,4]. Three main steps appear to be associated with post-operative adhesion formation: injury to the surface endothelium, coagulation of the exudated and accumulated blood causing fibrin formation, and fibrous tissue formation with adhesive properties that cause adjacent structures to stick together.

Once Atrium's HydraGlide™ coating comes in contact with fluid, the heparin polymer matrix becomes hydrated and exhibits a very smooth surface to the touch. One should be careful not to abrade the surface in the dry state, however, as this will damage the coating. Upon hydration, the Atrium HydraGlide™ thoracic catheter has a coefficient of friction significantly lower than that of both PVC and silicone thoracic catheters **(Figure 4)**. The low coefficient of friction for the Atrium HydraGlide™ thoracic catheter results in far less trauma at the catheter-tissue interface. Consequently, this should provide clinical advantages by reducing the traumatic events to the surface endothelium that may lead to adhesions.[5] The Atrium HydraGlide™ thoracic catheter's low coefficient of friction and anticoagulant properties also reduce adhesions resulting from blood coagulation and fibrin formation.

Figure 4

THORACIC CATHETER FRICTION DATA

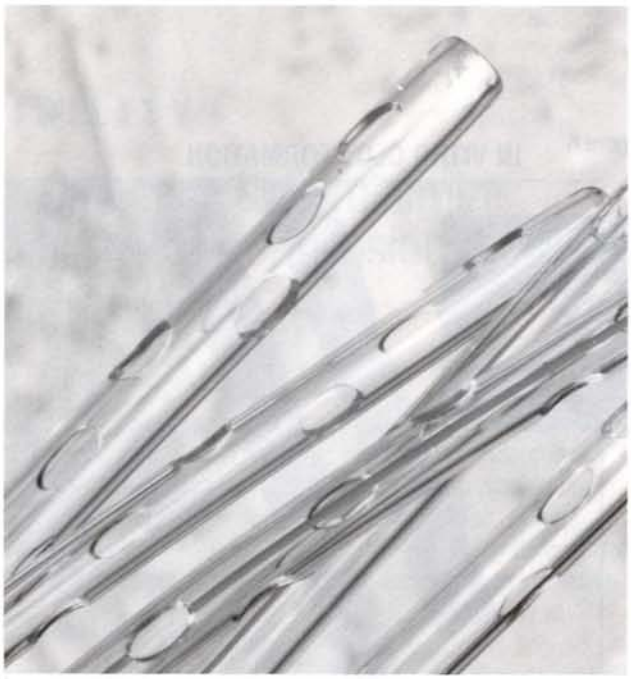


Trauma Reducing Design

The formation of adhesions at the tissue-catheter interface may be a cause for a high percentage of the observed sensations and discomfort to patients. In a recent study, the most frequently reported sensations during chest tube removal included burning, pain, and pulling.[6] It was also reported that

Figure 5

DRAINAGE EYELET SPIRAL CONFIGURATION



analgesics may not be effective in relieving or preventing such sensations. It should be noted that thoracic catheters made by Atrium Medical Corporation are designed such that the drainage eyes are positioned in a gentle spiral configuration to minimize tissue trauma. (**Figure 5**). Precise drainage hole placement serves to minimize vacuum induced tissue invagination in any one location, thereby helping reduce inflammation and tissue damage. Atrium's smooth, oval shaped drainage eyes offer maximum drainage performance with less mechanical irritation. Each drainage hole is carefully tapered and polished to minimize clot adhesion and delicate tissue erosion. Thus, the catheter design in combination with superior heparin surface properties can significantly improve the response at the catheter-tissue interface **(Figure 6)**.

Advantages Over Silicone

Recent studies have confirmed that there is greater inflammation surrounding silicone catheters than there is surrounding catheters made of polyvinylchloride (PVC), suggesting that silicone produces a greater chemotactic gradient than other materials. When complement opsonization assay and radioimmunoassays were performed to compare the relative abilities of silicone and PVC to activate complement, silicone exhibited a tenfold increased ability for complement activation

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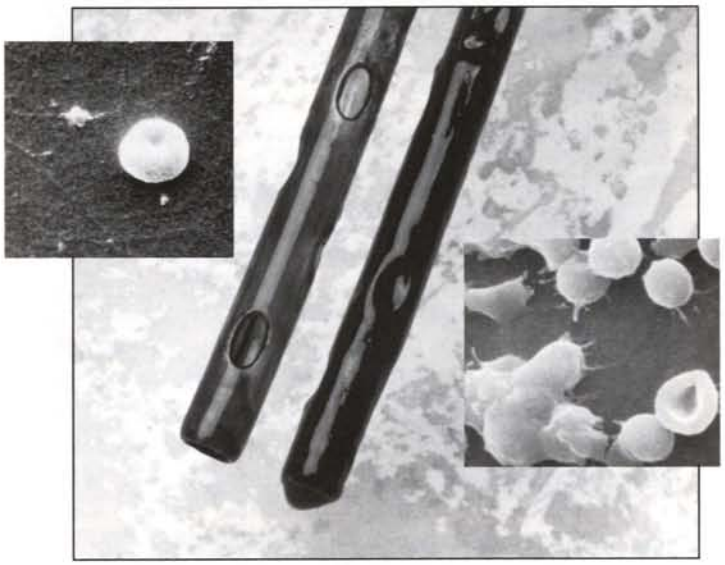
Figure 6 **IN VITRO CLOT FORMATION**



Atrium HydraGlide™ **Company A PVC**

than PVC. These studies found that excessive complement activation by silicone may explain the greater inflammation seen around silicone catheters in vivo[7] and might play a role in silicone's creating a greater risk of infection.

Atrium's novel HydraGlide™ PVC thoracic catheter is processed with a state-of-the-art drug delivery surface. Its unique surface chemistry exhibits an extraordinary low coefficient of friction in addition to preventing adherent clot formation. When it comes to uninterrupted patient drainage for either cardiac, thoracic, or trauma, Atrium's complete family of HydraGlide™ PVC thoracic catheters provide a superior alternative to today's catheter offerings. Coupled with a more desirable resistance to infection, these advanced drainage catheters can offer a truly significant advance in the clinical outcome of any thoracic drainage patient.

References

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