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The Use of Hydrophilic Catheters in Small Arteries

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In this issue of the *AJNR*, Dr Barnwell and coworkers (1) discuss the histologic findings in four instances of microscopic filamentous materials after interventional procedures. Several devices and agents were used during these procedures, including a Target Therapeutics (Fremont, Calif) catheter. They have said that the material looked “strikingly similar to the hydrophilic coating” that is present on the Fastracker-18 infusion catheters. Although the authors state that there were “no known adverse clinical results of this foreign intravascular material,” Target Therapeutics nonetheless takes this issue very seriously. The purpose of this commentary is to provide an additional perspective on the situation as well as to describe steps that Target has taken to improve its hydrophilic coating as part of its continuous improvement program for its products.

Hydrophilic coatings that are presently applied to both catheters and guidewires are generally agreed to improve the ability of these devices to access a desired target site while simultaneously decreasing the potential for vascular trauma. These coatings in general, and Hydrolene in particular, have also been shown to improve the thromboresistance of the devices and to diminish the force of adhesion of liquid embolic agents to their surfaces (2–5). Both of these qualities have potential significant impact on improving the safety of procedures done with devices to which such coatings have been applied. These hydrogel-type coatings absorb large amounts of water, so they are considered low-strength materials (6). Given sufficient force, a hydrogel can be abraded from the surface to which it has been attached.

Figure parts 3A and B in the article by Barnwell et al are photomicrographs of the specimens that demonstrate the reason for the authors’ concern. Figure 3A shows the reduction in thickness of the hydrophilic coating on a catheter after the catheter has been subjected to

a maneuver designed to cause the abrasion of its surface. This can indeed happen to the coating on a catheter that is subjected to sufficient force; in fact, repeated cycling of Hydrolene-coated catheters through a sharply angled guiding catheter was the first friction/durability test used at Target to evaluate these devices. Figure 3B shows peeling of the hydrophilic coating on the surface of another such catheter. It is this separation of the coating from the surface of the catheter that has led the authors to suspect that strips of coating might shed themselves from a catheter and thus become intravascular foreign bodies. Target Therapeutics disagrees with this notion.

An equally compelling argument could be made that most of the separations of the coatings from the catheters observed by Barnwell et al were not caused by the abrasion test that the authors used but rather were the result of the technique used to cut the catheters to prepare them for microscopic examination. Figure 1A and B (provided courtesy of Dr Barnwell) show two sections of Fastracker 18 infusion catheters. It can be seen from these illustrations that coating separation has occurred on both the nonabraded (Fig 1A) and the abraded (Fig 1B) samples. Figure 1B (the abraded sample) also shows a reduction in the thickness of the coating on this catheter. A gradual wearing away of a hydrophilic coating is expected to occur on the surface of catheters or wires that are subjected to repeated abrasion. However, Target’s own particulate testing after repeated cycling of coated catheters through a tortuous path has not shown particles such as those in the histologic specimens described by Barnwell and colleagues. Target’s hydrophilic coatings have passed US Pharmacopeia testing for the amount of particles permissible for intravascular injection (USP XXII sec 788).

Despite our best efforts, we too have been unable to identify chemically the foreign mate-

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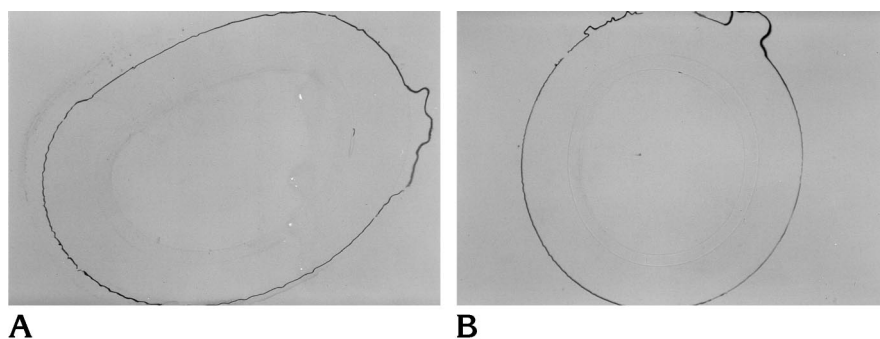


Fig 1. Cross sections of Fastracker infusion catheters: nonabraded (A) and abraded (B) (courtesy of Stanley L. Barnwell).

rial in the specimens described by Barnwell et al. This makes a definitive resolution of this issue difficult if not impossible. Despite Target's conviction that long strips of coating will not come off its hydrophilic-coated devices, we are committed to improving our products continually and have an active and ongoing program to advance the characteristics of our hydrophilic coatings. In this regard, an improved hydrophilic coating process that improves the durability without compromising the improved lubricity associated with microcatheter use has just been completed.

In conclusion, I would like to reinforce the authors' point that there were "no known adverse clinical results of this foreign intravascular material" and also add that Target Therapeutics does not have any other information in our complaint database regarding this type of situation

in more than 100 000 Fastracker catheters used since the product was introduced in 1993.

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