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Published in:
Clinical Neuroradiology

Link to article, DOI:
10.1007/s00062-023-01283-1

Publication date:
2023

Document Version
Peer reviewed version

Link back to DTU Orbit

Citation (APA):
Dahl, R. H., Larsen, R. W., Thormann, E., & Benndorf, G. (2023). Fragmentation of Hydrophilic Guidewire Coatings During Neuroendovascular Therapy. *Clinical Neuroradiology*, *33*, 793–799. https://doi.org/10.1007/s00062-023-01283-1

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Microguidewire Coating Delamination during Backloading

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Abstract

Purpose: Cerebral polymer coating embolism from intravascular devices may cause serious complications after endovascular therapy (EVT) for neurovascular diseases. Although polymer fragments are often created during endovascular procedures, exact mechanisms of their formation are largely unknown.

Method: Eight microguidewires (Asahi Chikai 200 cm, Asahi Chikai Black, Fathom™, Hybrid, Radifocus® Guide Wire GT, Synchro[2®], Transend™ EX, and Traxcess™) frequently used during EVT were investigated *ex vivo* using their dedicated metal or plastic insertion tools to assess for coating delamination after backloading of the microguidewires.

Results: Backloading caused damage to the coating of all microguidewires especially when guidewires bended during insertion. All studied microguidewires produced filamentous and/or band-like coating fragments. Few fragments had a diameter >150 µm. Spectroscopic measurements of polymer fragments and microguidewires identified various polymers.

Conclusion: Backloading of polymer-coated microguidewires during EVT should be minimized and pre-shaped wires should be used whenever possible. More stable hydrophilic coatings on microguidewires and less traumatic insertions tools are desirable.

Keywords

Attenuated-total-reflection Fourier transform infrared spectroscopy, microguidewire coating, hydrophilic polymer, cerebral polymer embolism, polyvinylpyrrolidone, delamination.

Introduction

Hydrophilic polymer coatings increase lubricity and improve navigability of intravascular devices during neuroendovascular therapy[1]. However, mechanical stress on surface coatings may cause delamination of polymer fragments which, if migrating into the cerebral circulation, can cause serious morbidity and even mortality[1–7].

In 2015, the U.S. Food and Drug Administration (FDA) reported, that damage to lubricious coatings on medical devices during endovascular procedures represents a safety concern, but also acknowledged, that the continued use of polymer-coated devices outweighed the risk of polymer emboli[8]. Although endovascular procedures carry a substantial risk of intravascular polymer fragment formation[9–11], only few studies have systematically assessed mechanisms responsible for coating damage[11,12]. Tight-fitting catheter systems may produce coating fragments[7,12,13] and some authors have observed coating fragments when inserting or torquing microguidewires[13–15]. The FDA has cautioned against the use of polymer-coated intravascular devices together with needles, metal cannulas, and other sharp-edged devices[8]. Notwithstanding, many polymer-coated microguidewires come in packages with a dedicated metal or plastic insertion tool, that may have relative sharp edges at their tips.

Recently we reported two cases of neurovascular procedures where polymer fragments were likely created during coaxial backloading of microguidewires through an insertion tool[15] – a practice often performed before insertion of a microguidewire, especially after bending to shape the wire tip. Although macroscopic coating fragments are rarely observed, we hypothesize that microscopic polymer coating fragments, invisible to the naked eye, are often created during backloading of microguidewires. Therefore, an experiment was performed to study the stability and integrity of the surface coating of eight currently used microguidewires.

Material and methods

Microguidewires

Eight commercially available microguidewires were investigated one at a time in a standardized setup. The 0.0014″ Asahi Chikai 200 cm (Asahi Intecc, Aichi, Japan), 0.0014″ Asahi Chikai black (angle 90°) (Asahi Intecc), 0.0016″ Fathom™ (Boston Scientific, Marlborough, MA, USA), 0.0012″ Hybrid (Balt Extrusion, Montmorency, France), 0.0014″ Radifocus® Guide Wire GT (angle 90°) (Terumo, Leuven, Belgium), 0.0014″ Synchro$^{2®}$ Standard (Stryker, Kalamazoo, MI, USA), 0.0014″ Transend™ EX (Boston Scientific) and 0.0014″ Traxcess™ (MicroVention®, Tustin, CA, USA) microguidewires were tested. All but

one wire was tested using their dedicated insertion tools (introducers). The Radifocus® microguidewire was tested using the insertion tool from the Goodtec Y-connector set (Asahi Intecc). Photographs of the tips of the insertion tools were obtained before testing (**Fig. 1**).

Experimental setup

All equipment was handled in accordance with the manufacturer's instructions for use (IFU). Initially, deionized water was flushed through the dispenser tubes before removal of the microguidewires. No coating damage was visible before testing. To increase repeatability, backloading was performed by pulling each microguidewire through its dedicated insertion tool, that was fixed to the angiographic table. Backloading was first performed with a straight microguidewire and subsequently with moderate and severe bending of the microguidewire (radius of curvature of 30 cm and 17 cm, respectively) while pulling the microguidewire through the insertion tool. Immediately after backloading, the content of the insertion tool was flushed out onto a microscopic slide with deionized water and then dried by gentle heating. All fragments were radiolucent on radiography.

Microscopy and spectroscopy

The morphology and size of the fragments was examined by unstained polarized light microscopy (Axio Imager 2 Pol, Zeiss, Oberkochen, Germany). Microscopic images were obtained of the largest coating fragments visible on each microscopic slide. In addition, attenuated-total-reflectance (ATR) spectra of three microscopic coating fragments >150 µm in diameter were collected by a vacuum Fourier transform infrared (FTIR) spectrometer (VERTEX80v, Bruker Optics GmbH, Ettlingen, Germany) employing a single-reflection diamond ATR accessory[15]. Complementary ATR-FTIR spectra measured directly on the surface of intact microguidewire pieces were obtained for those three microguidewires using a germanium ATR accessory (IRIS, PIKE Technologies, Madison, USA).

Results

Microscopy

Microscopic fragments were observed after every attempt of microguidewire backloading regardless of manufacturer and whether the microguidewire was straight or bended. Fewest and smallest fragments were observed after backloading of straight (*unbend*) microguidewires, while bending increased the amount and size of fragments (**Fig. 2A-F**). All microguidewires

in this study produced filamentous and/or band-like fragments that were consistent with peeled off pieces of the microguidewire's coating. Thin filamentous fragments were most common. Single fragments usually measured 5-15 μm in diameter and had a length of up to 7 mm. Band-like fragments had a width of 35-115 μm and were more often created when microguidewires bended. These fragments were shorter and fragile often breaking into smaller pieces (**Fig. 3A-B**). Some fragments had a diameter >150 μm consisting either of multiple intertwined filaments or a single large fragment (**Fig. 2C, 3C-F**).

Spectroscopy

Spectroscopic measurements were obtained from three larger fragments from the Synchro$^{2®}$, Asahi Chikai 200 cm and Hybrid microguidewires (**Fig. 2C, 3E-F**, respectively). All other fragments were too small to be analyzed. The Asahi fragment consisted of polypropylene which was also detected in the Asahi plastic insertion tool (**Fig. 4A**), but not on the Asahi microguidewire, which was coated by polyvinylpyrrolidone (**Fig. 4B**). Low quality spectra from the Synchro$^{2®}$ and Hybrid fragments indicated that the fragments consisted of polyvinylpyrrolidone from the distal coating rather than polytetrafluoroethylene (PTFE) from the proximal coating (**Fig. 4C**). The PTFE coating additionally contained an unknown polystyrene-like copolymer containing aromatic ring structures.

Discussion

Hydrophilic polymer coatings improve navigability of intravascular devices and facilitate distal catheterization of the cerebral vasculature, which is often needed during neuroendovascular procedures[5]. These advantages have led to the routine use of various polymer materials such as polytetrafluoroethylene, polyvinylpyrrolidone and other proprietary polymer blends[16]. Polymer delamination and subsequent cerebral embolism of coating fragments was previously thought to be a rare phenomenon[5], but recent studies have shown that its occurrence is possibly underrecognized[2,9,10]. Characteristically, pathology is observed in the vascular bed downstream to the site of neurointervention[4,17]. Patients with cerebral polymer emboli may develop ischemic and hemorrhagic infarcts[2,4–6] or can present with delayed-onset non-ischemic cerebral enhancing lesions often with perilesional edema[3,7,13,17,18]. Furthermore, polymer coating fragments have been found in 30-50% of retrieved clots after mechanical thrombectomy for acute large vessel stroke[9,10].

This study confirms that backloading of microguidewires produce significant amounts of microscopic fragments as have previously been suggested[13–15]. Fragments were created at the insertion tool's tips due to peeling of the coating by the relative sharp edges, which worsened when microguidewires bended. Fragments were observed with both metal and plastic insertion tools. A polypropylene fragment was found after backloading the Asahi microguidewire through the polypropylene insertion tool, indicating that plastic insertion tools may also be a source of fragments as well as contamination from dispenser tubes or packaging materials[9].

In clinical practice, coating delamination is only rarely observed by the naked eye which is likely due to 1) wetting of microguidewires and catheters, and 2) the transparency and extremely small size of most fragments. Furthermore, fragments created during backloading were often lodged within the lumen of the insertion tool, which made them difficult to detect and thereby increasing the risk of pushing them into the microcatheter during the introduction step with subsequent migration into the vasculature. Coating fragments were observed for all studied microguidewires and likely occur far more frequently than anticipated. Thus, backloading of microguidewires during neurointerventional procedures should be minimized and if necessary, caution should be taken not to actively bend the main body microguidewire during backloading. Nevertheless, backloading may be the only option if the angle of the microguidewire's tip is shaped to more than 90 degrees. The acute curve of the microguidewire tip may possibly increase the friction during loading into the introducer causing damage to the distal polyvinylpyrrolidone coating. Frontloading is always preferable because it reduces the length of the microguidewire being exposed to the insertion tool's edge. Therefore, the use of

pre-shaped microguidewires is an alternative option as those can usually be inserted directly into the introducer or Y-connector.

Several authors have reported that manipulation of guiding sheaths and microcatheters may cause coating delamination especially when tight-fitting co- and triaxial systems are navigated in tortuous anatomy increasing intracatheter friction[5,6,11,12] (**Table 1**). Kan et al. 2020[12] recently evaluated combinations of microcatheters and rotating hemostatic valves (RHV) for coating delamination and found significant amounts of polymer fragments after insertion and extraction of microcatheters through the RHV side ports especially when a guidewire was inserted coaxially. Stanley et al. 2016[11] observed avulsion of coating material from a guiding sheath incubated in saline for only 15 minutes. This material had similar microscopic appearance as cerebral foreign material emboli found in 54% of study animals after carotid and iliac artery stenting in an *in vivo* shine model[11].

Non-ischemic enhancing lesions have been reported after endovascular treatment of cerebral aneurysms with regular, stent-assisted and balloon-assisted coiling, and after flow diversion[6,17–20]. The use of triaxial catheter systems together with intravascular devices are thought to increase the risk of friction and polymer delamination. Flow diversion has also been associated with polymer delamination from the pusher wire[19]. Although not tested here, we speculate if the widely used techniques to correct flow diverter malapposition[21], such as the practice of massaging a J-shaped wire against the wall of the device to fully expand it, may be another potential source of polymer delamination. Thus, other systematic *ex vivo* investigations are necessary to assess the risk of coating delamination from other mechanisms and device combinations.

Mehta et al.[9] showed that intrathrombus coating fragments varied widely in shape and size measuring 10-150 µm in diameter similar to our observations. We furthermore observed filamentous fragments of up to 7 mm in length. Embolization of such coating fragments could potentially lead to infarction from occlusion of small intracranial arteries, possibly not identifiable in control angiograms.

Histopathological characteristics of polymer fragments have been thoroughly described[2], but polymer fragments are often heterogenous in shape and composition. Abbasi et al.[10] recently classified coating fragments in retrieved clots into four types based on their color and texture in hematoxylin and eosin-stained slides. These authors compared harvested polymers to foreign materials in retrieved clot and found that PTFE was more frequently observed in clot tissue than other polymer coatings[10]. This observation and our previous finding of PTFE coating

delamination[15] suggest that PTFE coatings employed on the proximal segment of most microguidewires could be an important source of polymer fragments.

Spectroscopy allows detection of characteristic spectra that may permit identification of exact polymer types. The wide heterogeneity of polymer coatings and the use of proprietary polymer blends complicate the identification of specific polymer types, but also imply that many devices may have a unique spectroscopic fingerprint. Thus, we found that PTFE coatings on microguidewires may contain a polystyrene-like copolymer or polydimethylsiloxane depending on the manufacturer[15]. Spatially resolved FTIR and Raman micro-spectroscopic technologies supported with atomic force microscopy (AFM), which have recently been used to study retrieved clots after mechanical thrombectomy[22], are new techniques with an excellent spatial resolution of up to 10 nm. These techniques could potentially be used to identify the source of polymer fragments in future *ex vivo* and *in vivo* studies.

Conclusion

This study demonstrates that backloading of polymer-coated microguidewires through both metal and plastic insertion tools create considerable amounts of polymer coating fragments. Delamination occurs at the relative sharp edges of the insertion tools, especially if microguidewires bend during backloading. Polymer micro fragments can present in various morphologies and polymer compositions, and can migrate into the distal cerebral vasculature during neuroendovascular procedures and result in clinical consequences. Backloading of current hydrophilic microguidewires after shaping should be minimized and pre-shaped wires should be used whenever possible instead. More stable hydrophilic coatings for microguidewires are desirable.

Legends

Figure 1.

Photographs of tips of insertion tools in anterior and oblique views. The insertion tools have relative sharp edges at their tips. From left to right: Asahi, Fathom™, Hybrid, Goodtec Y-connector set, Synchro$^{2®}$, Transend™ EX and Traxcess™ insertion tools. The image frame is approximately 2 x 2 mm for the Asahi plastic insertion tool and 1 x 1 mm for the metal insertion tools.

Figure 2.

Polarized micrographs show filamentous fragments created by backloading the Synchro$^{2®}$ (**A-C**) and Asahi Chikai Black (**D-F**) microguidewires. Smaller fragments were observed when backloading a straight microguidewire (**A, D**) compared to backloading a microguidewire with moderate (**B, E**) and severe (**C, F**) bending. Multiple smaller fragments with diameter less than 15 μm was visible after all attempts of backloading.

Figure 3.

Polarized micrographs of polymer coating fragments created during backloading with a bended microguidewire. **A-B.** Band-like fragments from the Fathom™ (**A**) and Transend™ EX (**B**) microguidewires that seemed to break into smaller pieces. **C-D.** Large fragments with diameter >150 μm from the Synchro$^{2®}$ (**C**) and Traxcess™ (**D**) microguidewires. **E-F.** Intertwined filamentous fragments from the Asahi Chikai 200 cm (**E**) and Hybrid (**F**) microguidewires.

Figure 4.

Reference ATR-FTIR spectra between 500 cm^{-1} and 1800 cm^{-1} obtained using a germanium ATR accessory. **A.** Polypropylene was identified in the Asahi fragment and Asahi plastic insertion tool. **B.** Polyvinylpyrrolidone was detected on the full length of the Asahi microguidewire and on the distal Hybrid and Syncro$^{2®}$ microguidewires. Low quality ATR-FTIR spectra of the Hybrid and Syncro$^{2®}$ fragments employing a diamond ATR accessory indicated that both fragments consisted of polyvinylpyrrolidone due to absorption bands around 2000-3000 cm^{-1} (not shown). **C.** Polytetrafluoroethylene (PTFE) with an unknown polystyrene-like copolymer was identified in the proximal coating of the Hybrid and Syncro$^{2®}$ microguidewires.

Table 1: Experiments of coating delamination from neurovascular devices.

Study	Type	Experiment	Result	Source
Barnwell et al. 1997[5]	Ex vivo	Manipulation of microcatheter through Berenstein catheter tip.	Coating delamination.	Microcatheter
Hu et al. 2014[6]	Ex vivo	Manipulation of guiding sheath and withdrawal of catheter.	Coating delamination.	Guiding sheath and/or catheter
Stanley et al. 2016[11]	In vivo*	IA and CA stenting.	Cerebral foreign material emboli.	Guiding sheath
	Ex vivo	Guiding sheath incubated in saline.	Coating delamination after 15 min.	
Kan et al. 2020[12]	Ex vivo	Manipulation of single and double microcatheters through RHVs.	Coating delamination using RHV side ports.	Microcatheters
Present study	Ex vivo	Backloading of microguidewires through insertion tools.	Coating delamination.	Microguidewires and insertion tools

* Swine model. CA: Carotid artery; IA: Iliac artery; RHV: Rotating hemostatic valve;

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