Minimizing Hemodialysis Vascular Access Trauma with an Improved Needle Design

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Abstract. The maintenance and longevity of hemodialysis vascular access remains one of the most problematic topics in the care of dialysis patients. Although much attention has focused on neointimal hyperplasia, the repetitive trauma to vessel walls by dialysis needles causes significant cumulative damage that has undergone little investigation. Commercial needles have beveled tips with intentional cutting surfaces to ease insertion. It was hypothesized that a pencil-point conical-shaped needle would cause less damage by taking advantage of the elasticity of native fistulae and produce an improved hole configuration in synthetic materials with minimal ability to stretch. A needle was subsequently designed with a removable pencil-point trocar and a side arm for the dialysis tubing. Once the trocar is removed, the blunt-ended cannula can be advanced or can be subject to inadvertent motion without causing damage to the luminal surface of the access. The new design as well as standard 15-gauge hemodialysis needles were tested on Gore-Tex® graft material and two bovine carotid artery preparations. Scanning electron microscopy was used to study the hole patterns. For all materials, the commercial needle holes had typical crescent shapes, and the cuts sliced sequentially through the various layers. For grafts, the new design caused a linear defect parallel to the axis of the graft that may preserve longitudinal strength. Interestingly, that tear line was nearly perpendicular to the linear hole in the thin polytetrafluoroethylene overwrap, which would be consistent with maintenance of hoop integrity. It is believed that these nonoverlapping defects would also improve hemostasis. The bovine specimens tested the importance of tissue stretching: Fresh carotid artery had experimental holes dramatically smaller than those from standard needles. In the denatured tissue, the experimental needle provided less benefit than that observed in fresh tissue, which is likely due to limited elasticity of the preserved artery. Improvement in needle design thus provides distinct advantages for native vessels and unique less traumatic holes in current synthetic materials. Pencil-point needle designs may be particularly applicable to the development of new elastomeric graft material.

The maintenance of hemodialysis vascular access has become one of the most important problems in the care of patients with end-stage renal disease. Much attention has focused on the superiority of native over synthetic materials (i.e., expanded polytetrafluoroethylene [ePTFE]), monitoring techniques, and interventions that may prolong their life span. In the particular case of synthetic grafts, it has been hoped that procedures which alleviate venous stenoses due to neointimal hyperplasia might be repeated as necessary to allow use for many years. Unfortunately, there has been relatively little investigation into the cumulative damage to the walls of the native or graft conduit by repeated needle sticks. The only commercially available dialysis needles have cutting surfaces, in that they have intentionally sharp edges at the beveled end of the thin-walled cannula. Cutting needles certainly facilitate insertion, but at the expense of significant damage to the wall and the sharp end remaining within the vessel during the entirety of the treatment. Advancing the needle or the inadvertent motion of the needle during the dialysis session can arc the sharp tip into the luminal walls and thereby cause further injury if not overt penetration through the other side. Charara et al. (1) clearly demonstrated the ultrastructure of the hole patterns and quantified the cross-sectional damaged surface area. By tallying the cut surfaces, they were able to project shredding of the graft as related to the needle size and available surface area of typical graft lengths.

We hypothesized that new less traumatic needle designs would be of benefit, especially for synthetic graft materials, because they would not have the reparative ability of native vessels. Interestingly, fine needles with conical ends and sharp tips have been available for interventional radiology purposes for decades. Because in that setting there was the clinical impression of less vessel injury (with minimal bleeding on insertion and removal), we devised a blunt-ended thin-walled needle with a removable pencil-point trocar for hemodialysis
purposes. We believed that there would be elastic stretching of the hole in native vessels and an improved hole configuration in synthetic materials. The new design was tested on the Gore-Tex® product as an example of ePTFE material with minimal ability to stretch. Two bovine carotid artery preparations were chosen to specifically address the issue of elasticity: fresh artery compared to commercially available “modified” tissue with its elastic quality attenuated by the manufacturing process. Ultrastructural analysis and quantification of the various hole patterns demonstrated superiority of the experimental device over that of standard commercial beveled cutting needles.

Materials and Methods

Materials

We designed the new needle (Figure 1) to have a trocar that once removed, through a self-sealing diaphragm, would allow blood to flow through a side port into the polyvinyl chloride dialysis tubing. If so desired, a groove could be placed along the axis of the trocar that would permit “flashback” of blood to indicate entry into the vessel lumen. The cannula itself is thin-walled and has a blunt end so that damage to the vessel’s luminal surfaces by needle motion would be minimized. For the purpose of the ultrastructural studies, we manufactured mock needles consisting of solid stainless steel shafts ground in a conical (pencil-point) shape to sharp points. The rods were purchased in a 15-gauge diameter, and this size was confirmed by measurement with a micrometer. The commercial comparison needles were of the same diameter and were made for hemodialysis (15-gauge; Terumo Corp., Elkton, MD).

Results

Ease of Cannulation

Compared with the commercial cutting needles, the experimental devices were subjectively only slightly more difficult to insert into Gore-Tex® material. The modified bovine material provided somewhat more resistance to pencil-point needle puncture, but at a level easily acceptable for patient use. The fresh carotid artery material, however, was quite difficult to puncture with the experimental device, consistent with it lacking the cutting surfaces.

Gore-Tex® Microscopy Findings

The commercial cutting needles produced a hole pattern consistently similar to that reported previously (1). As illus-
trated in Figure 2a, there was a crescent-shaped hole with small tear marks on each side in some views. In addition, there was a small flap corresponding to the location of the elliptical opening at the end of the needle. The needle thus sliced through the thin PTFE overwrap and then into the underlying main structure of the conduit, thereby producing an identical corresponding hole pattern in both layers. Because the cutting surface was in the shape of a crescent, the arc sliced through the main layer of the graft in a configuration that would disrupt both its longitudinal and circumferential integrity. This was in marked contrast to the experimental needle. Because the PTFE had negligible elasticity, the conical point spread and then tore the layers of the material in their structurally weakest directions. Because the thin overwrap is applied circumferentially at an approximate 45° angle to the longitudinal conduit, the tear patterns of the two layers are in different directions and do not overlap. As depicted in Figure 3, the holes appear grossly to be straight slashes, running nearly perpendicular to the axis of the conduit for the thin overlay and parallel to the axis for the main underlying tubular graft. Figure 2b demonstrates the latter linear puncture pattern, which does not appear to disrupt the longitudinal integrity. Higher magnification in Figure 2c shows the node pattern of the extruded PTFE substructure and allows an appreciation of the plane of node disruption at the edge of the hole. Quantification of the hole sizes revealed similar measurements for the experimental and commercial devices (mean of 1.4 versus 1.2 mm² for surface area, and 6.8 versus 5.1 mm for the perimeters). However, the effective surface area of the standard needle’s crescent defect may have been much higher because of the potentially limited structural value of the unsupported flap.

**Modified Bovine Carotid Artery Heterograft Microscopy Findings**

Because the serosal surface of the bovine product was so obscured by connective tissue, images were limited to views...
obtained from the intimal surface. The standard beveled cutting needles demonstrated their typical crescent-shaped hole patterns (Figure 4, panel a with the intima and panel b without it), which were again markedly different from those produced by the experimental device. The pencil-point needle caused rather irregular hole patterns that appeared different in the intima and media layers, suggesting varying degrees of elastic stretch before the nearly linear tearing of the tissue. Notably, the linear direction of the hole in the intima was nearly perpendicular to that in the media. The result of these nonoverlapping tear patterns was that there was only a small opening traversing both layers (Figure 4c), which was much smaller than that caused by the commercial needle (Figure 4a). Removing the intima revealed the previously obscured defect in the media (Figure 4d).

**Fresh Bovine Carotid Artery Microscopy Findings**

Figure 5a demonstrates the crescent configuration of the hole produced by the commercial needles with the intima intact. Two examples of the dramatically smaller holes produced by the experimental design are shown in Figure 5, b and c. Interestingly, the experimental holes were so small that it was difficult finding them without the use of a field microscope to properly dissect the tissue for electron microscopy. The striking difference in hole size persisted after the intima was removed (two examples of the commercial needle cut in Figure 6, a and b, and the experimental hole in Figure 6c).

**Discussion**

Gross anatomic study of excised hemodialysis vascular accesses demonstrates the cumulative damage to the native or synthetic vessel walls caused by repetitive needle punctures (2). Appreciation of the progressive weakening of the graft wall and ultimate development of pseudoaneurysms has also been of help in the design of new PTFE materials. Proprietary modifications of ePTFE have sought to address circumferential (or hoop) strength, although there are limited data in support of any particular material design. For example, the Gore-Tex® access product has a thin PTFE film wrapped around the main tubular conduit. Although the overlay may provide support, it is subject to the same needle trauma and may be lifted off from the underlying structure at the site of cannulation. Charara et al. (1) reported on the pattern of damage to ePTFE caused by current designs of commercial beveled edge (cutting) hemodialysis access needles. We confirmed their observation that there is a crescent-shaped slice with a contralateral tongue. With an angled needle insertion, the circular shaft would cause an elliptical hole distortion. Then, on removal of the needle, the displaced flap could theoretically recoil into place. The flap, along with any minor inherent elastic recoil to the material,
would decrease the defect’s size and perhaps improve hemo-
stasis. Careful rotation of 15-gauge needle sites to make use of
the entire length of a 25-cm graft could theoretically allow up
to 5 yr half-life of available access material; however, this
would be dramatically decreased by the reality of not using (or
not being able to use) the entire surface, pseudoaneurysm
formation, stenoses leading to low flow or thrombosis, and
synergistic weakening by unintentional contiguous connecting
holes.

Although beveled cutting needles are appealing because of
the ease of insertion, other designs are possible. Small pencil-
point needles, typically 19-gauge size, were popular with some
radiologists in the 1970s for arterial and venous radiocontrast
media injections. Although there were no convincing data, the
impression was that there was less vessel trauma as manifest by
little bleeding after needle removal. The conical design has
largely been supplanted by the easier-to-use beveled needles,
with hemorrhage being minimized by the use of much smaller
diameters.

We hypothesized that pencil-point needles would have dis-

tinct advantages in the hemodialysis setting. In the case of
native fistulae, we hoped for significant stretching rather than
tearing of the vessel with subsequent elastic recoil and only a
small defect. With synthetic grafts (apart from a small compo-

\[\text{Figure 5. Fresh bovine carotid artery, intima intact, luminal views. (a) Cutting needle puncture. (b and c) Two examples of experimental needle punctures. Magnification: } \times 31.\]

\[\text{Figure 6. Fresh bovine carotid artery, intima removed, luminal views. (a and b) Two examples of cutting needle punctures. (c) Experimental needle puncture. Magnification: } \times 21.\]
structure could theoretically lead to tears along the the lines of preexisting weakness that could be in different directions in the separate layers. Our findings support a dramatic difference in hole patterns that is consistent with this concept. Interestingly, the manner in which the graft material tore was not what we had anticipated. The ePTFE tubing is extruded in a manner which creates circumferential rings of dense material that have a characteristic periodicity along the length of the conduit. These dense rings, or nodes, are connected by fine filaments and result in the alternating band/filament/band/filament repeating substructure that comprises the long tubular conduit wall. We had originally considered the possibility that because of only minimal stretching ability, the conical needle tip would cause tearing of the very fine longitudinal filaments. This would thereby allow separation of the dense rings and give the gross appearance of a slice perpendicular to the length of the tube. The observed hole pattern was opposite to this, namely a grossly linear defect parallel to the long axis of the conduit, which is consistent with rupture of the circumferential nodes and separation of adjacent fine filaments. Higher magnification of the ePTFE substructure away from the needle site provides an explanation for this phenomenon. Figure 2d demonstrates that in the manufacturing process, the nominally circumferential rings of material are often discontinuous or of irregular width, and these gaps or weaknesses would be the foci of the tear.

In the case of Gore-Tex®, the shape of the experimental needle hole was dramatically different from that of the typical standard needle’s crescent slice. This makes it difficult to measure and interpret the finding of similar experimental hole perimeters and surface areas for the new and old devices. Because the flap of material contralateral to the crescent cut would be expected to have lost its hoop and longitudinal strength, the effective defect size may have been much larger than that measured by morphometry. We believe that much more important was the observation that the pencil-point needle hole in the main tubular Gore-Tex conduit had a different stretch-tear pattern than that in the overlap. Thus, the holes in the layers did not coincide as they do with the cutting needle. The linear tears were at a nearly 90° angle, so that the openings did not overlap, and this may infer an additional hemostatic benefit, as opposed to the “modified” artery, which had been somewhat difficult with fresh bovine carotid artery), this has yet to be determined for arterialized veins.

The benefit of noncutting needles may also be of importance for newer graft materials currently under design or just recently marketed. An appreciation of how structurally weak planes within synthetic materials determine tear patterns could help in the fabrication of better conduits. Of greater relevance would be the pursuit of elastomeric materials with maximum stretch and minimal tear characteristics that would be superb candidates for this pencil-point needle approach. There also is the need for additional studies of the pencil-point design’s effect on native shunts, including the ultrastructural analysis of hole patterns in arterialized veins of native fistulae in animal models after single and repetitive punctures. In summary, these preliminary gross and ultrastructural findings support the further investigation of pencil-point needle designs to minimize trauma to native and synthetic hemodialysis vascular accesses, which may be an important factor in improving their longevity.

References

Access to UpToDate on-line is available for additional clinical information at http://www.lww.com/JASN.