Distal-Tip Shape-Consistency Testing of Steam-Shaped Microcatheters Suitable for Cerebral Aneurysm Coil Placement

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BACKGROUND AND PURPOSE: **Although the selection of microcatheter for endovascular aneurysmal treatment is one important factor in patient outcome, the use of steam shaping for achieving safe entry and stability during coil placement has not, to our knowledge, been systematically evaluated. The goal of this study was to compare the durability of distal microcatheter steam shaping in five different catheters with typical intraprocedural stresses that are similar to those encountered during aneurysm coil placement.**

METHODS**: Distal tips of microcatheters were shaped into a 90° turn with distal straight-segment lengths of 3, 5, or 7 mm by using steam, performed according to the instructions for use included with each catheter. In a water bath kept at body temperature, the changes in catheter tip angle were recorded and measured following microcatheter insertion into a guiding catheter, microguidewire insertion through the microcatheter, and Guglielmi detachable coil (GDC) placement through the microcatheter.**

RESULTS: **The degree of distal microcatheter straightening with typical intraprocedural manipulations was more pronounced on braided microcatheters and on microcatheters with 3- or 5-mm distal-shaped segments. The degree of spontaneous recovery of the initially steamed shape was more pronounced with nonbraided catheters. The most significant single variable contributing to straightening of a steam-shaped catheter tip was the effect of microguidewire insertion. The catheter-tip straightening effect encountered with inserting GDCs was less than that encountered with microguidewire insertion. We demonstrated that the decreased catheter-tip angle encountered with a large-magnitude straightening stress spontaneously recovered once the stress was removed or when it was reduced to a smaller magnitude stress.**

CONCLUSION: **Our study shows that, although braided microcatheters are suitable for maintaining durable configurations when long distal-tip lengths are permissible, nonbraided microcatheters demonstrate the most durable distal-tip configurations when short distal-tip lengths are called for. This may be one of significant factors in catheter choice for endovascular treatment of aneurysm.**

Endosaccular aneurysm occlusion is often facilitated by steam shaping the distal microcatheter tip to optimize entry and stability while accessing and treating aneurysms with devices such as the Guglielmi electrically detachable coil (GDC; Target Therapeutics/Boston Scientific, Fremont, CA), which is widely used for intracranial aneurysm treatment (1, 2). Safely placing the catheter tip into the dome of the aneurysm depends on anatomic variables such as the size, configuration, and location of the aneurysm relative to daughter and parent vessels, in addition to variables such as the operator's technique and the performance of the hardware used for access including the microcatheter, guidewire, and guiding catheter. To account for some of the hardware and anatomic variables, microcatheters are often steam shaped, to custom configure the distal 3 cm of the catheter. We have been unable to find previous reports describing the objective stability and durability of such steam shaping in vitro, when evaluating straightening stressors such as those typically encountered during aneurysm coil placement.

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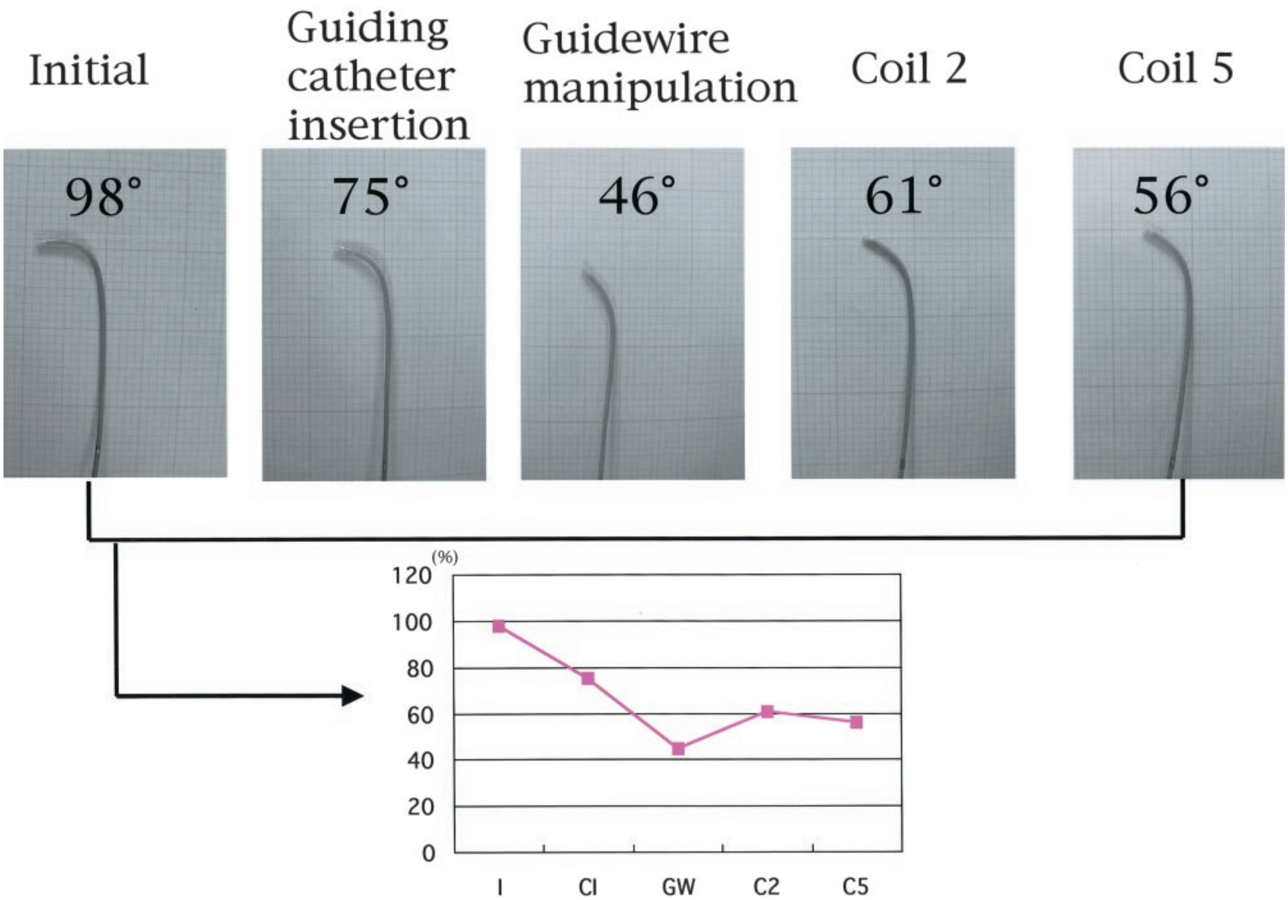

FIG 1. Excel 14 catheter, demonstrating 7-mm length and manually steam-shaped 90° angle curve. Although the initial measured tip angle measured 98° (I), the tip angle decreased to 75° following coaxial microcatheter insertion through a guiding catheter (CI). The tip angle was further reduced to 46° following guidewire manipulation (GW). The tip angle recovered to approximately 60° after the second (C2) and fifth GDC withdrawals and insertions (C5). The change rate of the catheter-tip angles, once exposed to straightening forces, is graphically depicted as a percentage straightening when compared with the initial baseline-shaped angle.

Methods

In this experimental simulation, currently available microcatheters that can be used in concert with the popularized GDC-10 system were selected for testing. The nonbraided test catheter was the FasTracker 10 (Target Therapeutics/Boston Scientific). The braided catheters tested included the Excel 14 (Target Therapeutics/Boston Scientific), Excelsior SL 10 (Target Therapeutics/Boston Scientific), Prowler 14 (Cordis Endovascular Systems, Miami, FL), and Prowler 14 Preshaped (Cordis Endovascular Systems) catheters. All test catheters were randomly removed from commercially available stock, and each microcatheter was steam shaped only once.

The guiding catheters used were 6F Guider catheters (Boston Scientific, Natick, MA). The 0.014-inch microguidewires used were Transcend Floppy Microwires (Boston Scientific). The GDC coils tested in the microcatheters were GDC-10 SR coils, 6 mm in diameter by 6 cm in length. All testing was performed by using a digital temperature-controlled water bath (86 × 26 × 26 cm) heated with a heat pump to 37°C.

The distal catheter tips were steam shaped according to the instructions for use included with each catheter. Distal catheter-tip angle was set at 90° for all catheters, although the length of the straight segment distal to the steam-shaped curve was manually set at 3, 5, or 7 mm in length. During the testing phase, the tip angle of each catheter was recorded with a digital camera and was superimposed live on graph paper with 1-mm squares. The various filmed catheter-tip angles were measured manually with Scion Image software (Scion Corporation, Frederick, MD). The rate of change of the catheter-tip angles, once exposed to straightening forces, was graphically depicted as a percentage straightening when compared with the initial baseline-shaped angle (Fig 1).

All microcatheters were inserted into the guiding catheters with microguidewires and assembly performed in a temperature-controlled water bath during the placement and manipulations. We denoted these series of experiments as "catheter measurement without stress." In this control group of catheters that were not exposed to any of the angle stressors, the catheter tip angles were measured at 5, 15, and 30 minutes.

There were two types of stress imparted to the tested catheters that were "measured with stress:" one type was induced by the microguidewires, and the second type was induced by the GDCs. The microguidewires that were passed to the microcatheter tip 10 times were allowed to remain in place extending to the distal tip of the microcatheter for 30 seconds and were then withdrawn approximately 10 cm proximal to the microcatheter tip, where they remained for an additional 30 seconds. GDC placement consisted of GDC positioning, which was achieved with five total passages of the GDCs through the tip of the microcatheter, followed by 5 minutes of coil placement within the tip of the microcatheter and then withdrawn. Angle measurements were performed following the second and fifth GDC withdrawals.

Results

Angle Change without Stress

Catheter-tip angle change rates were measured without stress in temperature-controlled water baths

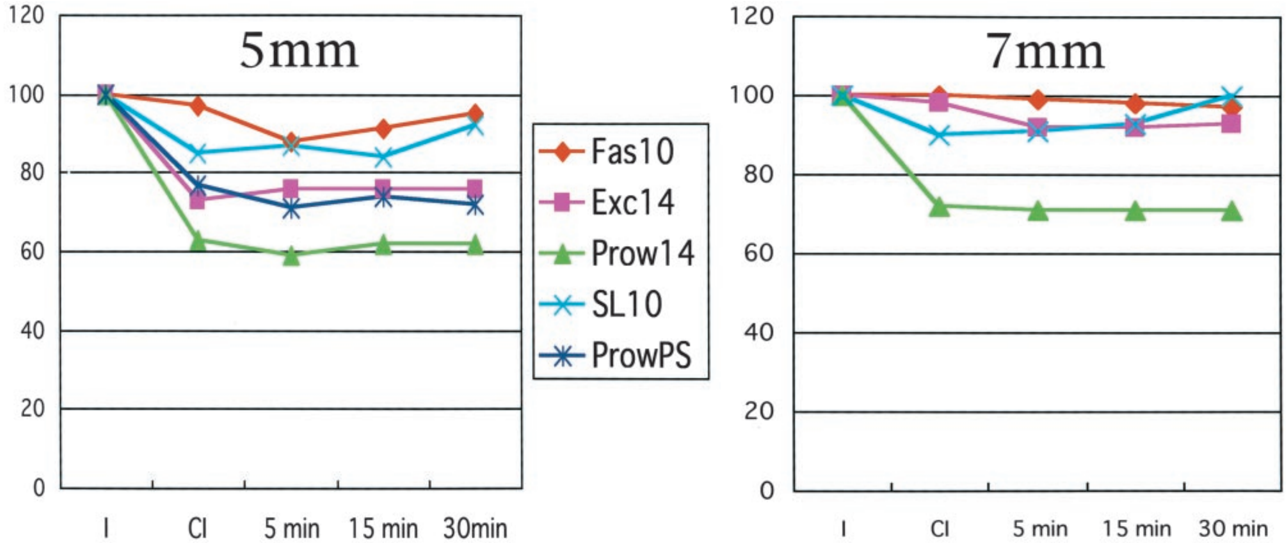

FIG 2. Change rate without stress on 5- and 7-mm lengths of steam-shaped catheter tip. After insertion through a guiding catheter (CI), measurement was performed at 5, 15, and 30 minutes. Exc14 indicates Excel 14; Fas10, FasTracker 10; I, initial measurement; Prow14, Prowler 14; ProwPS, Prowler 14 Preshaped; and SL10, Excelsior SL 10.

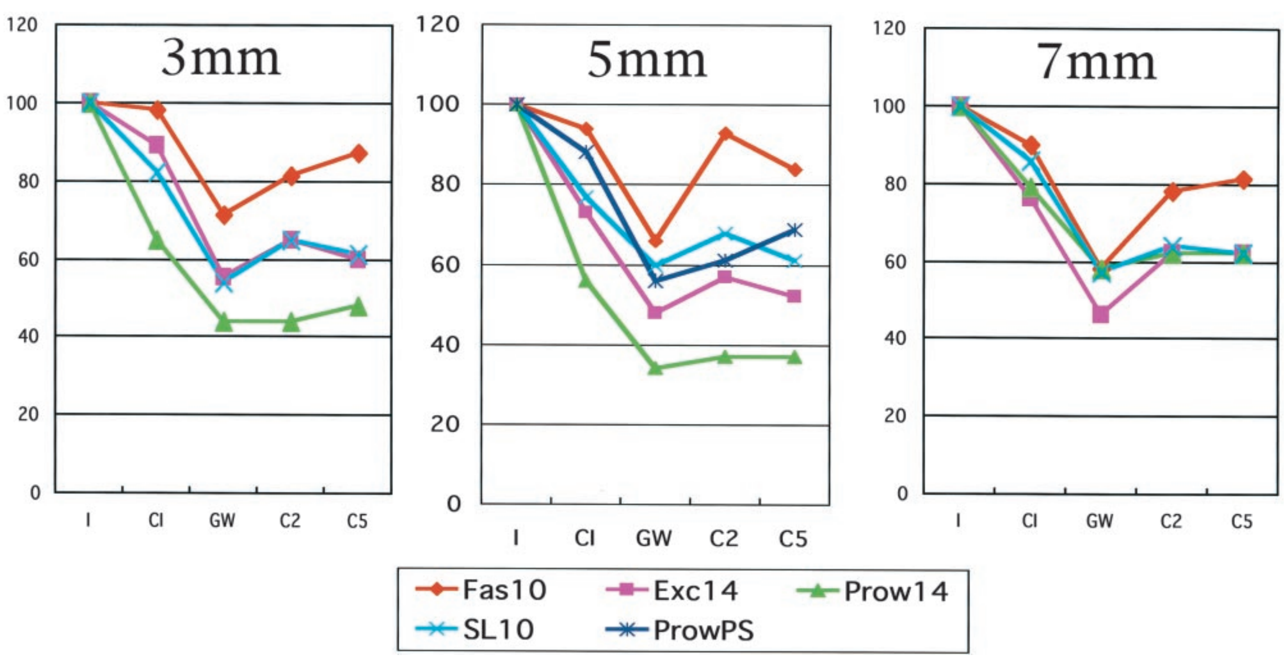

FIG 3. Change rate with stress on 3-, 5-, and 7-mm lengths of steam-shaped catheter tip. CI indicates coaxial microcatheter insertion through a guiding catheter; C2, after second GDC insertions and withdrawals; C5, after fifth GDC insertions and withdrawals; Exc14, Excel 14; Fas10, FasTracker 10; GW, microguidewire manipulation; I, initial measurement; Prow14, Prowler 14; ProwPS, Prowler 14 Preshaped; and SL10, Excelsior SL 10.

for both the 5- and 7-mm tip-length samples (Fig 2). Following coaxial microguidewire-reinforced microcatheter passage through the guiding catheters, reductions in microcatheter tip angles were observed in all catheters. The 7-mm tip samples demonstrated less angular reduction than did the 5-mm tip samples. The angle reduction rate was less in nonbraided catheters than in braided catheters. The non-preshaped Prowler 14 microcatheter had less stability than the other tested microcatheters. The preshaped Prowler, however, had stability and angle-reduction characteristics similar to those of the Excel 14 microcatheter. The SL10 microcatheter demonstrated greater stability and fewer tip-angle changes than the other braided catheters.

Angle Change with Stress

Catheter-tip angle change-rates were measured with stress in temperature-controlled water baths for the 3-, 5-, and 7-mm tip-length samples (Fig 3). The largest reductions in angle were demonstrated following microguidewire manipulation. Partial correction in tip-angle effects with a partial return closer to the original steamed-shaped angle were measured during the coil manipulation phase of the experiment. The catheter samples with 7-mm distal straight portions had greater curvature reductions than did the catheters with 3- or 5-mm distal straight portions, following microguidewire manipulation. The tip-angle reduction rate was less in nonbraided catheters than in braided catheters. In addition, nonbraided catheters demonstrated better angular correction than did braided catheters by demonstrating a greater tendency to return to the steam-shaped configuration. The varieties of angle change were greater with the catheters having 3- or 5-mm tip length. As with the angular changes measured without stress, the nonpreshaped Prowler 14 microcatheter had less stability than that of the other tested microcatheters. The preshaped Prowler, however, had stability and tip angle–preservation characteristics similar to those of the Excel 14 and SL 10 microcatheters.

Discussion

To secure stable catheter-tip positioning within a cerebral aneurysm, distal portion of microcatheters are frequently steam shaped. The question of catheter-tip shape stability following such steam shaping has not been directly addressed with experimental techniques in the clinical literature. Although shifting intra-aneurysmal catheter shapes are clinically seen, changes in catheter-tip curve configuration are noticed with instrumentation and manipulation, and changes in catheter-tip shape after coil placement are frequently observed, the individual experimental influences and causative factors have not, to our knowledge, been previously reported. Microcatheter shaping with steam can cause slight shortening of the distal 3 cm of the microcatheter, which can lead to mismatching of the marker bands of the microcatheter with the detachable coil (3).

In our modest experimental study, the greatest distorting force and influence on microcatheter-tip angle with resulting angular reduction was guidewire manipulation. It is interesting to note that, following coil manipulation, there is a tendency for the catheter to return to the steam-shaped configuration. With respect to the length of the distal straight catheter portion distal to the steam-shaped curvature, we found less of a tendency to return to the steam-shaped configuration with 7-mm straight-tip lengths than with the shorter 3- and 5-mm distal straight-tip lengths. Although catheter braiding confers significant advantages to use, such as increased axial rigidity and improved cross-sectional stability in a tortuous circulation, the braided catheters demonstrated less of a tendency to retain steam-imparted shape than did the nonbraided catheters. To use the braided catheter's tip in the ideal shape, over-angled shaping or preshaping of the product may be requested.

In our experimental simulation, the nonbraided catheters had a greater tendency to retain steamed shape following instrumentation. We suppose that the nonbraided microcatheters may be optimal when large steam-shaped angles and short distal tip stability is desired.

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