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Shapability, Memory, and Luminal Changes in Microcatheters after Steam Shaping: A Comparison of 11 Different Microcatheters

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PURPOSE: The purpose of this study was to compare the characteristics of shaped microcatheters, including shapability, durability, and luminal changes.

MATERIALS AND METHODS: Eleven brands of steam-shaped microcatheters and one brand of preshaped microcatheter were evaluated. There were 2 nonreinforced and 10 reinforced devices supported by coils. For evaluation of shapability, the tip angle of 6 samples of each brand were measured after steam-shaping for 20 seconds with a shaping mandrel bent at a 90° or 150° angle. The ability to maintain the shaped angle after guidewire insertion stress (durability) was compared by calculation of the change in the tip angle by using 3 samples of each brand. Luminal change after steam shaping was evaluated by calculation of narrowing rate of the smallest diameter and observation of the surface morphology of the mold of each catheter lumen by using a silicone polymer by means of a fluorescent projection method.

RESULTS: The nonreinforced microcatheters and the fiber-braided microcatheter showed higher shapability than the others. The degree of distal microcatheter straightening with the microguidewire insertion was less pronounced in the preshaped microcatheter and the fiber-braided microcatheter. Spontaneous recovery to the initial tip angle 5 minutes after the guidewire procedure was observed in 10 brands to various degrees (87%–98%). Irregular luminal surface morphology at the angled portion was found in 6 reinforced brands. One nonreinforced catheter and the fiber-braided catheter showed high narrowing rates >6%.

CONCLUSION: There are differences in shapability, durability, and luminal changes of steam shaping in 12 brands of microcatheters. These characteristics could be important factors in catheter choice for endovascular procedures.

The use of microcatheters shaped by steam is a common technique in neurointerventional procedures of endosaccular embolization of cerebral aneurysms, as well as in selective catheterization of arteries originating with an acute angle (1, 2). In some cases, shaping the microcatheter with an adequate angle is essential for a successful procedure. Therefore, characteristics of the shaped microcatheters—including shapability and durability, and changes of the luminal morphology—are important. According to recent developments in microcatheter material technology, various brands of microcatheter have been made commercially available worldwide. Because the shap-

ing characteristics of microcatheters depend on the catheter material, these characteristics differ. To the best of our knowledge, only 2 previous reports have mentioned the characteristics of durability of the shape and shortening in the length of steam-shaped microcatheters (3, 4). In this study, we evaluated the characteristics of shapability, durability of the shape, and luminal changes of widely used microcatheters.

Materials and Methods

Twelve brands of microcatheters were provided by 5 manufacturers for evaluation in this experimental study. Catheters evaluated include the Excelsior SL-10 (SL10; Target Therapeutics/Boston Scientific, Fremont, CA), Tracker Excel-14 (Ex14; Target Therapeutics/Boston Scientific), Excelsior 1018 (Ex; Target Therapeutics/Boston Scientific), FasTracker-10 (Fas10; Target Therapeutics/Boston Scientific), Renegade-18 (Rg; Target Therapeutics/Boston Scientific), Rebar 14 (Rb14), Progreat 2.0F (Pg2.0; Terumo, Tokyo, Japan), Progreat 2.4F (Pg2.4; Terumo), Rapid Transit (RT; Cordis Endovascular Systems, Miami, FL), Prowler Plus (PP; Cordis Endovascular Systems), Prowler Plus MX with a 90° (PP90; Cordis Endovas-

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TABLE 1: Characteristics of microcatheters

	Proximal OD (French)	Distal OD (French)	Distal ID (inch)	Reinforcement	Materials
Small size					
Excelsior 1018	2.6	2.0	.019	SS coil	PEBAX
Tracker Excel-14	2.4	1.9	.017	SS coil	PEBAX
Excelsior SL-10	2.4	1.7	.0165	SS coil	PEBAX
Progreat 2.0F	2.7	2.0	.020	Tungsten coil	UE
Rebar 14	2.4	1.9	.018	SS coil	NA
FasTracker-10	2.6	2.0	.015	—	PP + PE
Large size					
Rapid Transit	3.0	2.3	.018	SS coil	Polyamide
Prowler Plus	3.0	2.3	.018	SS coil	Polyamide
Renegade-18	3.0	2.5	.021	Fiberbraid coil	PEBAX
Progreat 2.4F	2.9	2.4	.022	Tungsten coil	UE
Microferret	3.0	2.4	.021	—	PE
Prowler Plus MX	3.0	2.3	.018	SS coil	polyamide

Note.—SS coil indicates stainless steel coil; PEBAX, polyether block amides; UE, urethan elastomer; PP, polypropylene; PE, polyethylene; NA, no information available.

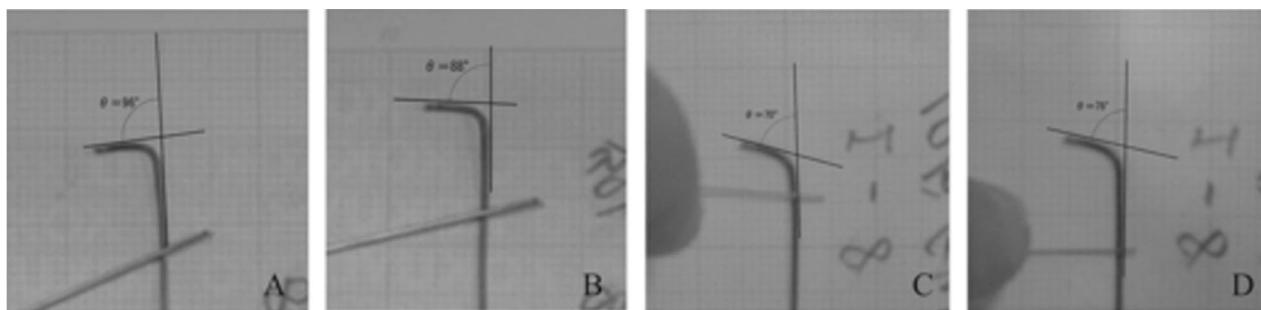


FIG 1. Change of tip angle of a microcatheter.

A, Initial tip angle. B, Tip angle following the water bath procedure for 10 minutes. C, Tip angle following guidewire procedure. D, Tip angle following the second water bath for 5 minutes.

cular Systems), and Microferret (MF; Cook, Bloomington, IN). Multiple lots of catheters were tested. General profiles of the brands are presented in Table 1. All catheters had hydrophilic coating. There were 2 nonreinforced catheters, Fas10 and MF. The others were reinforced devices supported by coils. Six microcatheters had an outer diameter ≥ 2.3 F at the distal portion (large-size group: RT, PP, PP90, Pg2.4, MF, and Rg), and the other 6 microcatheters had an outer diameter ≤ 2.0 F at the distal portion (small-size group: SL10, Ex14, Ex, Fas10, Rb14, and Pg2.0). One microcatheter with a tip angle of 90° was preshaped by the manufacture (PP90). The 0.012-inch or 0.016-inch microguidewires utilized were GT microwires (Terumo). The 0.012-inch microguidewire was used with the small-size group, and the 0.016-inch microwire was used with the large-size group. The characteristics of microcatheters were evaluated for shapability, durability of the shape, change of luminal diameter, and change of luminal morphology. Three samples of each brand were tested to evaluate shapability and durability, and 2 samples were tested for evaluation of luminal change.

Shapability

Each shaping mandrel included with the kit was bent manually at 90° or 150° angle by using a graduated. Each microcatheter was shaped with an intended angle of 90° or 150° by using a shaping mandrel 5 mm from the distal end of the microcatheter. Three samples were used for each angle. They were steamed for 20 seconds and were subsequently placed in cold (17°C) water for 20 seconds. After withdrawing the shaping mandrel, the tip angle of each catheter was recorded with a digital camera on 1-mm-square-section graph paper with a

resolution of 300 dots per inch. The data from the photograph were transferred to a computer, and the angle of the microcatheter was calculated by using computer-aided design software.

Durability of the Shape

The microcatheters shaped with an angle of approximately 90° at 5 mm from the distal end and a preshaped microcatheter (PP90) were used in this evaluation. After the initial tip angle was calculated (Fig 1A), they were put in a digital temperature-controlled water bath maintained at 37°C for 10 minutes. The tip angle of each shaped microcatheter was then calculated (Fig 1B). After the second calculation, a 0.012-inch or a 0.016-inch microguidewire was advanced through the microcatheter. The microguidewire was pushed until the tip of the wire was positioned 3 cm beyond the tip of the catheter and withdrawn. This microguidewire procedure was repeated 5 times, and the tip angle was then calculated (Fig 1C). After the third calculation, the microcatheter put in the water bath for an additional 5 minutes and the angle was calculated again (Fig 1D).

Change of Luminal Diameter and Luminal Morphology

Two samples of each brand of microcatheter shaped with an intended angle of 150° were used for this evaluation. One sample of each brand without shaping was used as a control. Silicone polymer liquid was infused into the microcatheter from its tip to obtain the mold of the lumen of each microcatheter. After fixing the silicone polymer for 12 hours, it was picked out with teardown of the microcatheter. The surface

TABLE 2: Tip angle of each brand with intended angles of 90° and 150°

	90°	150°
Small size		
Excelsior 1018	51–57 (54)	54–68 (62)
Tracker Excel-14	54–56 (55)	70–74 (72)
Excelsior SL-10	51–57 (55)	87–91 (89)
Progreat 2.0F	46–51 (48)	86–93 (90)
Rebar 14	49–54 (51)	88–92 (90)
FasTracker-10	64–77 (72)	124–136 (130)
Large size		
Rapid Transit	40–43 (41)	58–66 (62)
Prowler Plus	44–47 (45)	76–80 (78)
Renegade-18	58–70 (62)	111–117 (114)
Progreat 2.4F	47 (47)	72–80 (76)
Microferret	64–77 (70)	115–121 (117)

Notes.—Values are expressed as ranges followed by mean in parentheses.

morphology of the silicone mold was observed by a fluorescent projection method by using a profile projector (Profile projector PJ 300, Mitutoyo Corp. Tokyo, Japan). The profile projector consisted of a screen with horizontal and vertical reference lines and was equipped with a light source to project a magnified image of the object onto the screen in the form of a shadow. Each sample was secured in the horizontal axis of the measuring table, and by using rear illumination its silhouette was focused on the display screen (50×). All distances were displayed on 2 digital counters (A-Counter, Mitutoyo Corp.); the counters were accurate to ± 0.001 mm. The smallest axial diameter of both shaped and nonshaped microcatheters was calculated at 5 mm (the curved portion) and at 2 mm (the straight portion) proximal from the distal end.

Results

Shapability

The average angle for the 3 samples of each brand with intended angles of 90° and 150° are summarized in Table 2. In the small-size catheter group (Fig 2), the mean angle was increased according to increasing the intended angle in all catheters; Fas10 showed the

highest shapability. In the large-size catheter group (Fig 3), MF and Rg showed higher shapability than the others.

Nonreinforced microcatheters and fiber-braided catheters had higher shapability than the other reinforced microcatheters in both the small- and large-size catheter groups.

Durability of the Shape

Because the initial angles of the microcatheters are different, durability of the microcatheters was evaluated in change rates of catheter-tip angle.

Initial angles of the microcatheters and their change rates are summarized in Table 3 and Figs 4 and 5.

Small-Size Catheter Group

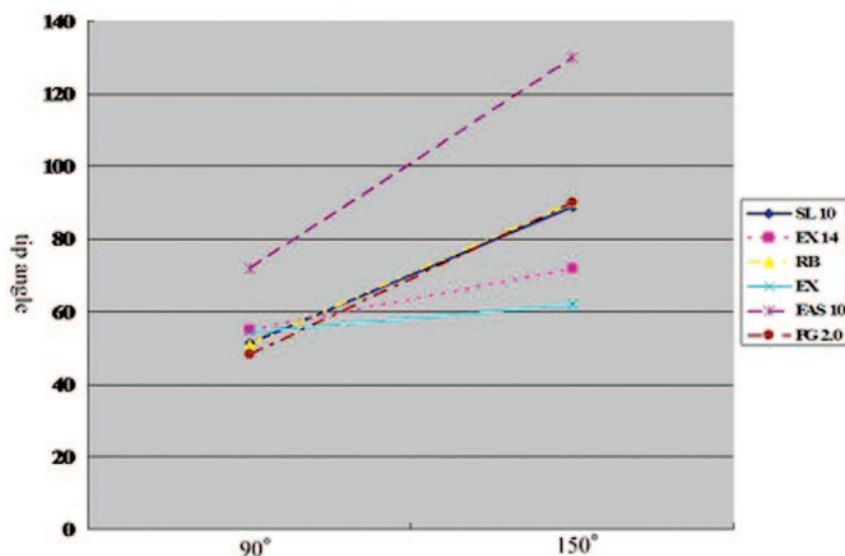
All microcatheters showed reduction of tip angle after the microguidewire procedure. The change rates were $<10\%$ in 4 brands, Rb, Ex, Ex14, and SL10, and $>10\%$ in 2 brands, Fas10 and Pg 2.0. At the final calculation 5 minutes after the microguidewire procedure, the tip angle of all microcatheters of each brand showed a tendency to return to the initial angle to various degrees. Nonreinforced catheter Fas10 showed high angle-recovery rates, and its rate of change at the final calculation was $<10\%$. All reinforced microcatheters except for Pg2.0 showed similar change rates, and the final change rates were $<10\%$. Pg2.0 showed change rates $>10\%$ at the final calculation.

Large-Size Catheter Group

Two brands of microcatheters of RT and PP showed reduction of the tip angle before the guidewire procedure. All microcatheters showed reduction of the tip angle following the microguidewire procedure. The change rates were $<10\%$ in 4 brands, Rg, PP90, MF, and Pg.2.4, and were $>10\%$ in 2 brands,

FIG 2. Shapability of small-sized catheters.

Although the mean tip angle is increased according to increasing the intended tip angle in all catheters, Fas10 shows the highest shapability.



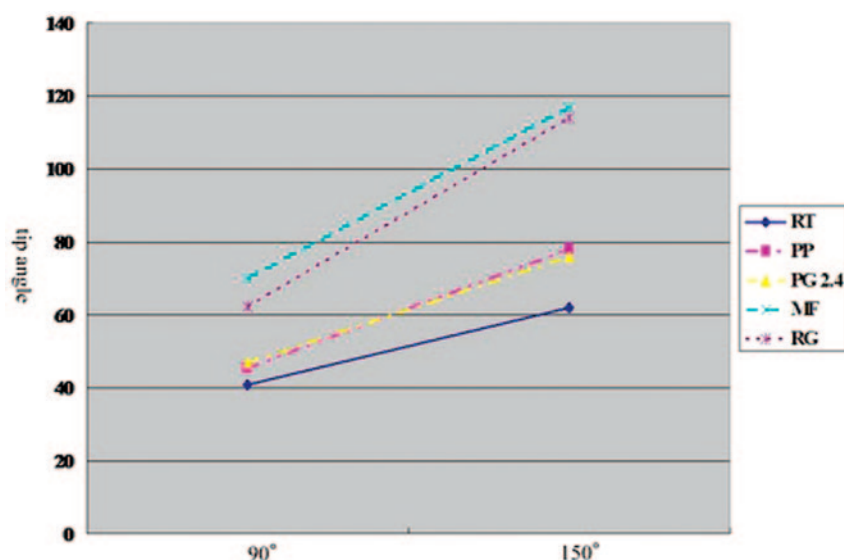


FIG 3. Shapability of large-sized catheters. MF and Rg show higher shapability than the others.

TABLE 3: Changes of the tip angle of each brand

	Initial Angle (°)	10-min Waterbath	Guidewire	5-min Waterbath
Small size				
Excelsior 1018	93–107 (97.2)	90–104 (97.2)	85–99 (90.6)	92–106 (93.2)
Tracker Excel-14	94–105 (101.0)	97–112 (102.7)	91–98 (93.6)	92–101 (96.3)
Excelsior SL-10	96–101 (99.0)	90–103 (96.3)	86–90 (88.3)	95–99 (97.0)
Progreat 2.0F	96–105 (100.6)	91–108 (99.3)	70–98 (84.6)	78–97 (87.0)
Rebar 14	96–109 (105.6)	96–105 (101.7)	98–103 (100.0)	94–107 (101.6)
FasTracker-10	110–115 (111.6)	107–114 (109.6)	93–100 (97.3)	105–106 (105.3)
Large size				
Rapid Transit	90–94 (93.0)	84–91 (87.0)	81–86 (83.0)	75–81 (78.6)
Prowler Plus	87–98 (91.3)	73–77 (75.6)	65–74 (70.6)	72–74 (73.0)
Renegade-18	86–102 (94.3)	90–120 (105.0)	91–117 (100.6)	87–114 (99.0)
Progreat 2.4F	93–95 (94.0)	90–102 (94.6)	82–91 (87.6)	92–96 (94.3)
Microferret	99–104 (102.8)	99–113 (109.2)	91–103 (99.7)	93–110 (104.7)
Prowler Plus MX	80–82 (80.7)	81–90 (86.0)	79–88 (84.6)	82–84 (83.3)

Note.—Values are expressed as ranges followed by mean in parentheses.

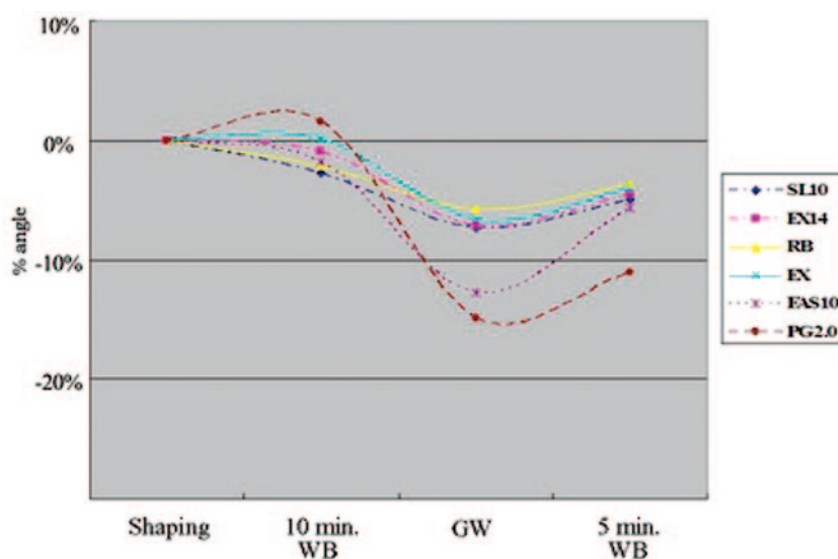


FIG 4. Durability of the shape of small-sized microcatheters. All microcatheters show reduction of tip angle after the microguidewire procedure (GW). The change rates are >10% in Fas 10 and Pg 2.0. At the final calculation, the Fas10 nonreinforced catheter shows high angle-recovery rates. All reinforced microcatheters except for Pg2.0 show similar change rates, <10%. Pg2.0 shows change rates >10% at the final calculation.

RT and PP. At the final calculation 5 minutes after the microguidewire procedure, the tip angles of 4 brands (Rg, MF, PP90, and Pg2.4) showed a tendency

to return to the initial angle to various degrees. RT and PP showed high reduction rates, and final change rates were >10%. PP90 and Rg showed low reduction

Fig 5. Durability of the shape of large-sized microcatheters. RT and PP show reduction of the tip angle before the guide-wire procedure. All microcatheters show reduction of the tip angle following the microguidewire procedure (GW). The change rates are $>10\%$ in RT and PP. At the final calculation, RT and PP show high reduction rates and final change rates $>10\%$. PP90 and Rg show low reduction rates throughout the examination. The nonreinforced catheter MF shows the highest angle-recover rate.

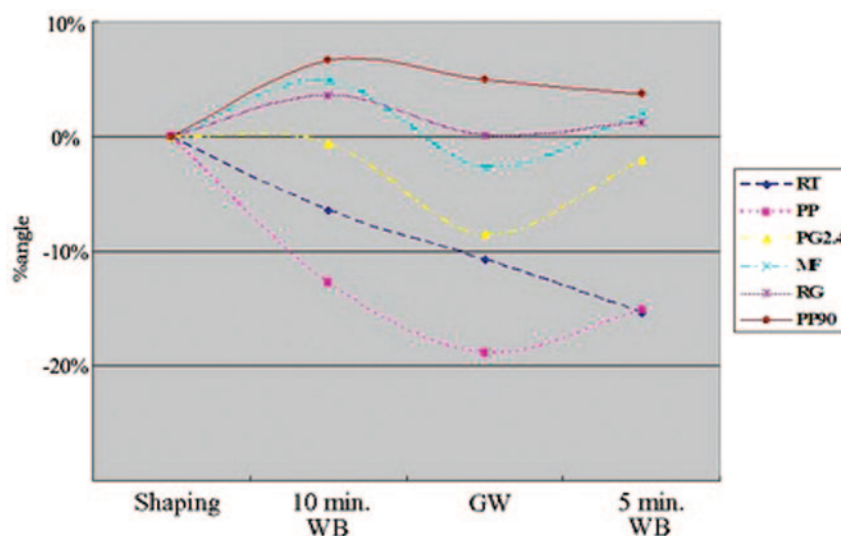


TABLE 4: Changes of the luminal diameter

	% Axial Diameter of Control	% Axial Diameter of Shaped Catheters at Angled Portion
Small size		
Excelsior 1018	100.7	95.5
Tracker Excel-14	100.1	99.2
Excelsior SL-10	99.3	99.5
Progreat 2.0F	99.4	99.1
Rebar 14	100.3	97.3
FasTracker-10	100.3	97.3
Large size		
Rapid Transit	99.3	93.1
Prowler Plus	99.8	98.8
Renegade	98.9	90.5
Progreat 2.4F	100.0	95.4
Microferret	99.4	88.3

Note.—% axial diameter = (axial diameter at 5-mm proximal portion/axial diameter at 2-mm proximal portion) $\times$ 100.

rates throughout the examination. The nonreinforced catheter, MF, showed the highest angle recovery rate and its change-rate at the final calculation was $<10\%$.

Luminal Changes

In one sample of both nonreinforced catheters of Fas10 and MF with 150° tip angle, silicone polymer liquid could not be infused sufficiently into the catheter lumen because of high resistance. Therefore, data of luminal changes could be available from one sample for these 2 brands. In the other brand, a silicone mold could be obtained.

Luminal Diameter

In the control group, differences in the shortest axial diameter between the 5-mm and 2-mm portions were $<1.1\%$ (Table 4). To various degrees, all shaped microcatheters showed reductions of the shortest axial diameter at the curved portion. The narrowing rate of the diameter ranged from 0.5% to 11.7%.

In the small-size group, all microcatheters showed narrowing rates $<5\%$. In the large-size group, the narrowing rates of the diameter were $<7\%$, except those of Rg and MF, which showed the high narrowing rate of 9.5% and 11.7%.

Luminal Morphology

Irregular surface morphology on the lesser curvature at the curved portion was observed in 6 brands. In these brands, 2 microcatheters, Rg and RT, showed moderate irregularity >0.03 mm in peak-to-valley measurement, and 4 microcatheters showed mild irregularities <0.02 mm in peak-to-valley measurement (Fig 6). The other microcatheters showed smooth luminal morphology.

Discussion

According to recent technological developments, most microcatheters are supported by integral coils or braid to give higher resistance against kinking; however, shapability and durability are higher in nonreinforced devices than in reinforced devices. In some cases, steam shaping the tip of the microcatheter with an acute angle is essential for successful procedures. Reduction of the initial tip angle during the procedure is often observed in clinical use. Abe et al (3) demonstrated a higher consistency in the tip angle of the nonreinforced device than reinforced devices in their experimental study. Our results also show the high shapability and consistency of the shape in nonreinforced microcatheters. We found, however, there were various degrees of shapability and durability in reinforced devices. The differences of shapability and durability of each reinforced brand depend on the materials and thickness of the catheter wall and the reinforcing coils. Techniques to make a particular shape could also affect the shapability and the consistency of the tip angle. We used steam shaping for 20 seconds to make the tip angle. The consistency of the tip angle of preshaped microcatheters (PP90) was higher than that of steam-shaped angles of the same

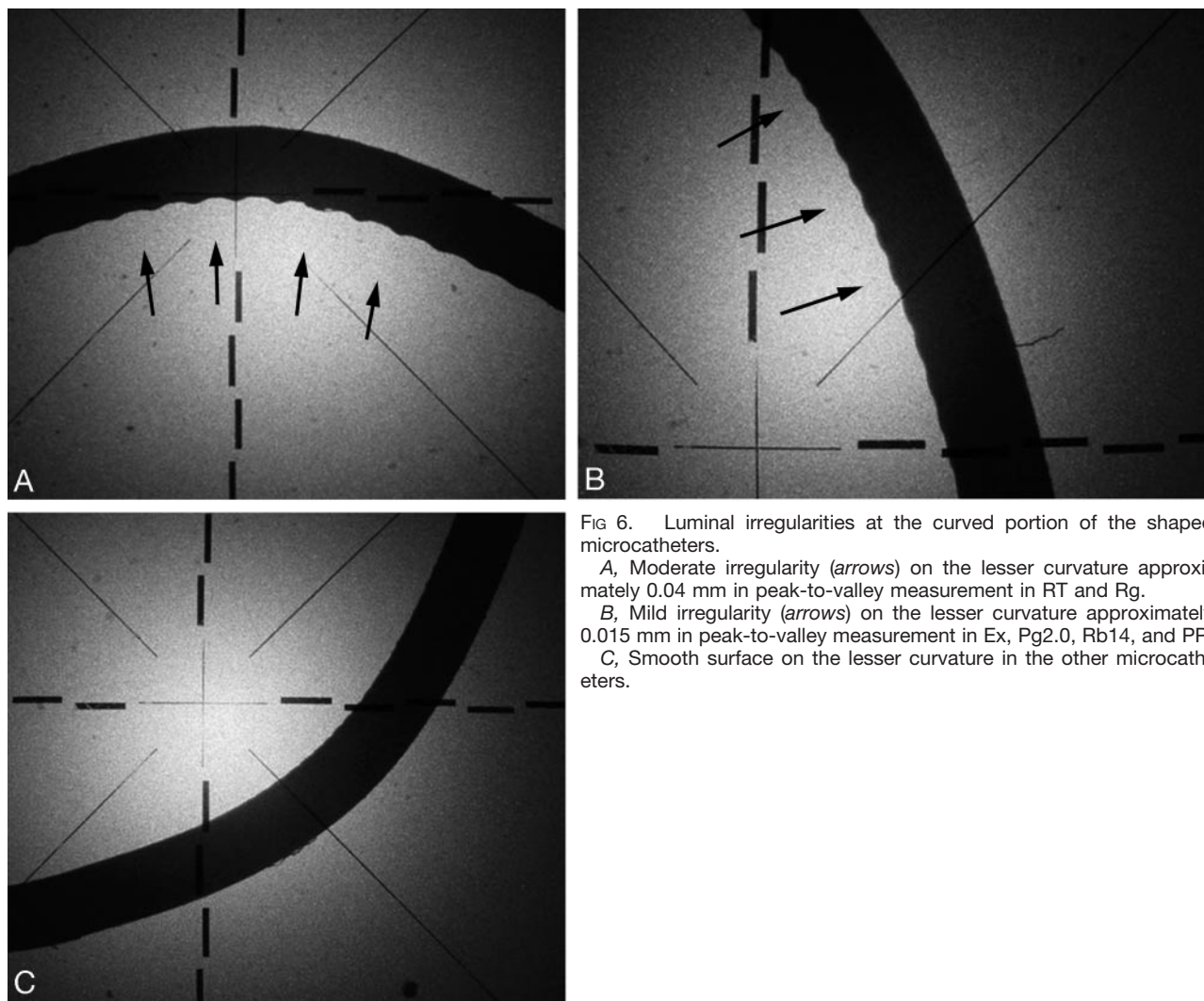


FIG 6. Luminal irregularities at the curved portion of the shaped microcatheters.

A, Moderate irregularity (arrows) on the lesser curvature approximately 0.04 mm in peak-to-valley measurement in RT and Rg.

B, Mild irregularity (arrows) on the lesser curvature approximately 0.015 mm in peak-to-valley measurement in Ex, Pg2.0, Rb14, and PP.

C, Smooth surface on the lesser curvature in the other microcatheters.

brand (PP). Although variations of the tip angle of preshaped devices are limited, the use of a preshaped device is requested when the tip angle is adequate for the case. Three brands—MF, Rg, and PP90—had increased angulation after the water-bath procedure. The reason of increasing angulation is unclear, but one hypothesis is a possibility of stretching the microcatheters during withdrawal of the shaping mandrels for steam-shaped catheters (as a guidewire procedure). We performed all procedures as gently as possible, though nonreinforced or fiber-braided catheter are soft and could be stretched. Although we performed a cooling procedure for 20 seconds after steam shaping, the stretched tip angle of these catheters may not recover completely. Increasing tip angle of preshaped catheters (PP90) after water bath procedure may be due to reduction of the angle during packing and transferring process. The initial tip angle of 3 samples of PP90 ranging from 80° to 82° were significantly less than that supplied by the manufacturer (90° tip angle).

Regarding luminal changes, narrowing at the curved portion was seen in a nonreinforced device (MF) and a reinforced device with fibered coils (Rg).

In one sample of both nonreinforced catheters of Fas10 and MF with 150° tip angle, silicone polymer liquid could not be infused sufficiently into the catheter lumen, because of high resistance. Although these infusion failures could be caused by an immature infusion technique or high viscosity of the silicone polymer liquid, we suggest that they were probably due to narrowing of the catheter lumen by steam shaping. During an embolization procedure by using large particles or coils, the embolic materials may be clogged at the narrow portion of these catheters shaped with an acute angle. Regarding the luminal morphology, moderate luminal irregularity was found on the lesser curvature in 2 brands of reinforced device. Secondary to steam shaping, the catheter wall on the lesser curvature of the angled portion was compressed longitudinally. The irregularity is probably caused by protrusion of the catheter wall material between the coil loops of the reinforced microcatheter. The distance between each reinforcing coil loop and the softness of the catheter material could be associated with the degree of luminal irregularity. Moderate luminal irregularity may also cause trouble in embolization procedures.

Commercial microcatheters have various characteristics due to the steam shaping of the distal tip. These characteristics could depend on material of catheter wall, reinforcing coils, and method of shaping. Our results showed the nonreinforced device and a reinforced device with fibered coils showed higher shapability and durability of the shape than the reinforced device with metallic coils as reported elsewhere (3). Those catheters having high shapability, however, tend to be narrowed at the curved portion by steam shaping. Knowledge of these properties is useful for the selection of an adequate microcatheter for each case.

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