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Performance Characteristics of Microcatheter Systems in a Standardized Tortuous Pathway

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BACKGOUND AND PURPOSE: Published reports of controlled experiments designed to evaluate the performance of over-the-wire microcatheter systems are rare and have often been based on subjective impressions from small clinical series. This investigation was designed to compare the load forces required to propel state-of-the-art, hydrophilically coated microcatheters from each of four manufacturers through a standardized tortuous pathway constructed of polytetrafluoroethylene tubing.

METHODS: Currently available hydrophilically coated microcatheters were provided by four manufacturers. A 20-cm long, three-dimensional pathway simulating the intracranial carotid circulation was constructed of 0.065-in. (inner diameter) polytetrafluoroethylene tubing and immersed in a water bath at 37°C. Testing was performed using an Instron tabletop load frame fitted with a 2-lb load cell. Durability and load force tests were conducted using a 0.014-in. stainless steel noncoated guidewire, with the wire tip protruding 1 cm beyond the catheter tip. At least four samples of microcatheters from each manufacturer were tested.

RESULTS: Extensive trackability testing of the guidewire alone established reproducible performance with maximum load forces of less than 8 g. Maximum gram forces for the four reinforced microcatheters were not greatly different, measuring between 9 and 14 g. Excessive buckling of the only nonreinforced catheter was initially overcome early in the pathway in a staccato, stepwise fashion. After reaching a critical load, however, the catheter and guidewire prolapsed.

CONCLUSION: All reinforced microcatheters tested established good and reproducible performance in our model. Reinforced microcatheters provided superior trackability over the one nonreinforced device tested.

Over-the-wire microcatheter systems are used in most intracranial neurointerventional vascular procedures. These catheters are produced by a number of manufacturers both within and outside the United States and incorporate a variety of design features. Demand from the neurointerventional community as well as competition in the marketplace have been the driving forces in the development of new and innovative products. Published reports of catheter performance are rare in the literature and most often are merely impressions derived from small clinical series (1–5).

In vitro studies reporting the performance characteristics of microcatheters are even more uncommon (6, 7).

Failure to access the distal intracranial circulation with an over-the-wire microcatheter is most commonly encountered in a tortuous vascular system. The ease with which a microcatheter follows a guidewire through a tortuous system has been termed "trackability." Innovations in material technology, hydrophilic coating, and mechanical catheter design have, at least subjectively, greatly improved the trackability of microcatheter systems during the past several years.

Microcatheters may be broadly divided into reinforced and nonreinforced devices. Reinforced devices are supported by an integral coil or braid. Most manufacturers offer at least one model of microcatheter with hydrophilic coating. These hydrophilic coatings are of proprietary formulation and are thought to be more lubricious than noncoated microcatheters.

The purpose of this study was to compare the load forces required to propel hydrophilically coated microcatheters from each of four major manufacturers
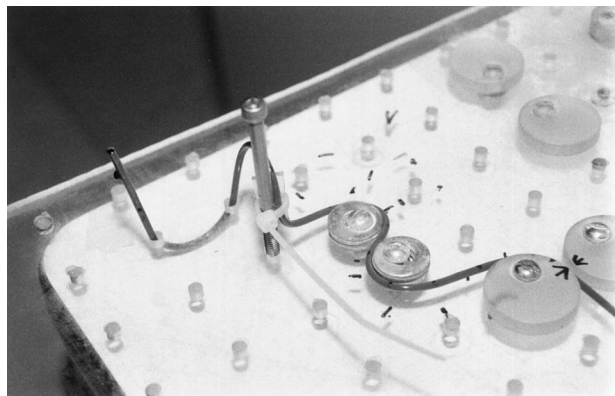
FIG 1. Three-dimensional model of pathway constructed of clear polytetrafluoroethylene tubing simulating the intracranial carotid circulation.

through a tortuous pathway constructed of Teflon tubing shaped to simulate the intracranial arterial circulation.

Methods

State-of-the-art microcatheters were provided by four manufacturers for evaluation in this study. Catheters tested include the FasTracker MX 18 (Target Therapeutics, Fremont, CA), the Jetstream 18 (Medtronic/Microinterventional Systems, Sunnyvale, CA), the Rapid Transit (Cordis Endovascular Systems, Miami, FL), the TurboTracker 18 (Target Therapeutics, Fremont, CA), and the Venture 2 (Meditech/Boston Scientific, Natick, MA). All test catheters were obtained from commercially available stock and, when possible, catheters of multiple lots were tested.

A three-dimensional pathway simulating the intracranial carotid circulation was constructed of clear polytetrafluoroethylene tubing (Zeus, Orangeburg, SC) with an internal diameter of 0.065 in. (Fig 1). A total of four turns (two with a radius of 0.5 in. and two with a radius of 0.25 in.) were used to simulate the internal carotid artery circulation. The entire pathway, mounted on a plexiglass board, was immersed in an 8 × 14 × 28-in. water bath maintained at 37°C. Continuous circulation within the bath was maintained with the use of a Brinkman water pump (Brinkman Instruments, Westbury, NY). Water within the tubing was refreshed between each catheter pass by manual injection of water from the bath by using a hand-held syringe.

All load testing was performed using an Instron tabletop load frame (Model No. 4465) fitted with a 2-lb load cell. This device is designed to measure load forces as the catheter and guidewire combination is advanced at a constant, predetermined rate, selected to simulated rates of catheter advancement that would be reasonable in clinical practice.

A single 0.014-in. stainless steel noncoated guidewire was used for all testing. Preliminary testing of the guidewire consisted of 50 passes through a 22-cm segment of the pathway at a rate of 8 in. (203 mm) per minute. This same wire was then inserted into a microcatheter with the wire protruding 1 cm from the catheter tip. This microcatheter and guidewire system was advanced 50 times through the pathway at a rate of 8 in. (203 mm) per minute. The wire alone was next advanced through the pathway an additional 50 times under the same parameters. These preliminary tests were performed to determine whether a single guidewire could be used for the entire study or whether degradation and shaping of the wire would occur. Additional wire tests, consisting of multiple passes of the guidewire only, were performed after testing of each manufacturer's catheters. Because no changes in the characteristics of
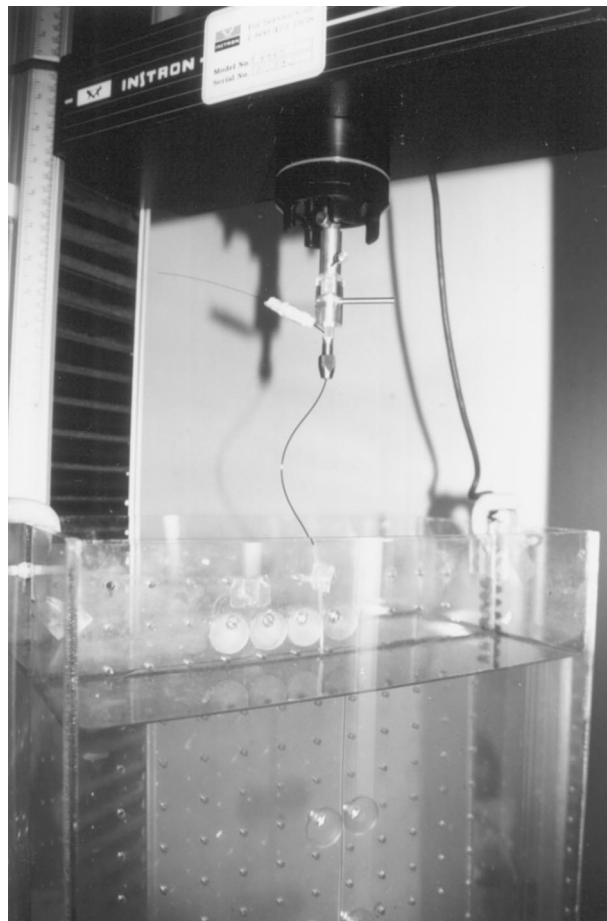

FIG 2. Proximal buckling of the FasTracker MX catheter because of excessive load forces.

the guidewire were detected, a single 0.014-in. wire was used throughout the study. Integrity of the guidewire was confirmed with multiple passes of the guidewire alone, performed after completion of all catheter testing.

At least four sample microcatheters from each manufacturer were tested. The guidewire tip was extended ½-in. beyond the microcatheter for all testing. All catheters except for the Rapid Transit were obtained from at least two different lots. The first of each manufacturer's catheters was passed through the 22-cm tortuous pathway 50 times at a speed of 2 in. (50.8 mm) per minute. Load forces were sampled at a rate of four points per second. At least three additional catheters from each manufacturer were passed through the pathway, three times each at a rate of 8 in. (203 mm) per minute. Load forces for these three sample catheters were recorded, statistically analyzed for variation between samples, averaged, and graphically displayed.

Because of excessive buckling of the proximal catheter shaft (Fig 2), fewer runs were performed with the FasTracker MX, and several of these runs were aborted early. At the manufacturer's recommendation, multiple passes of the FasTracker MX catheters were attempted using a Mach-16 guidewire (Target Therapeutics) at displacement speeds of 2 and 8 in. per minute. Once again, buckling of the system prevented completion of the full testing protocol. Testing of a fifth microcatheter, the TurboTracker 18, was performed at a later date at the manufacturer's request. This reinforced catheter was not commercially available at the time of our original testing. The TurboTracker was subjected to the identical conditions as the other four manufacturers' catheters. Testing was performed using the original 0.014-in. stainless steel guidewire.

Differences between brands of catheters were analyzed using a one-way analysis of variance at specific displacement
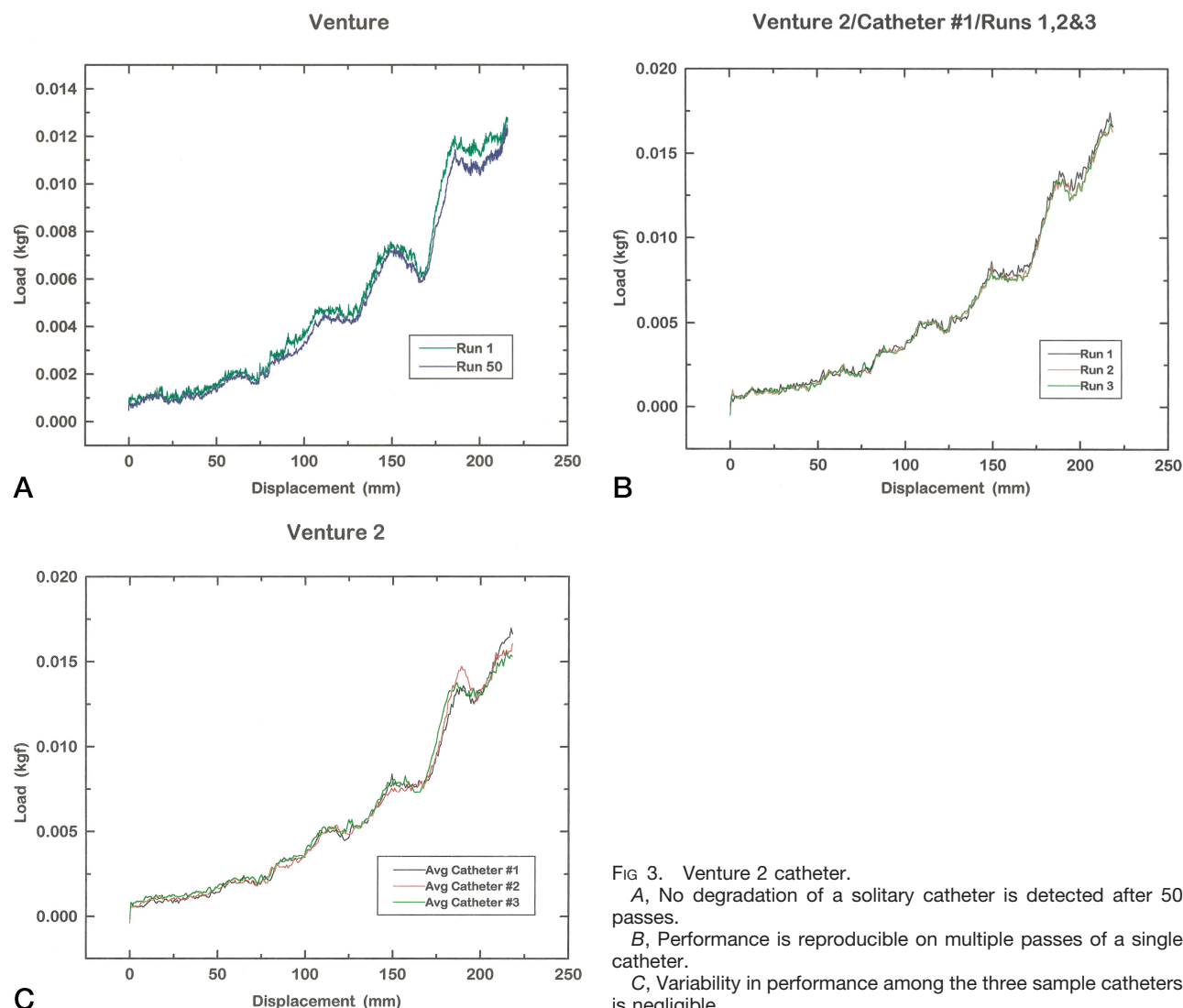
Fig 3. Venture 2 catheter.
A, No degradation of a solitary catheter is detected after 50 passes.
B, Performance is reproducible on multiple passes of a single catheter.
C, Variability in performance among the three sample catheters is negligible.

points. *P* values for multiple comparisons tests were adjusted using the Bonferroni correction. Displacements of 60, 90, 117, 150, and 190 mm were chosen for the analysis, since these displacement points seem to correspond to load peaks related to curves in the tortuous path.

Results

Extensive testing of the guidewire established reproducible performance throughout the pathway, with maximum load forces of approximately 8 g. The load profile and maximum load forces were not significantly changed, even at the termination of the experiment. No evidence of permanent deformity or shaping was noted regarding the solitary guidewire used throughout the entire experiment.

Testing of the Venture 2 microcatheter established a profile that paralleled that of the guidewire alone, but with slightly higher load forces. The average maximum load force for the three sample catheters measured at 190 mm of displacement was 13.8 g. No degradation in catheter performance was noted after 50 passes of the first sample (Fig 3A). There was no discernible variation between several runs of the same

catheter (3B), nor was there any perceptible variation in the performance of three additional Venture 2 sample catheters (3C).

Testing of the Rapid Transit and Jetstream 18 microcatheters produced similar performances to the Venture 2, but with even lower average maximum gram forces for the three sample catheters at 190 mm displacement, measuring 9.7 and 9.3 g, respectively. Once again, no degradation of either brand microcatheter was noted after 50 passes, nor was there any significant variability between individual catheters from the same manufacturer.

Testing of the FasTracker MX was complicated by excessive catheter buckling, which was overcome early in the pathway in a staccato, stepwise fashion (Fig 4). After reaching a critical frictional force, however, the catheter and guidewire buckled irrecoverably, necessitating the termination of the test. This characteristic was observed with each of five FasTracker microcatheters at rates of both 2 and 8 in. per minute. The maximum load at the termination of these runs was measured as high as 69.9 g. Excessive buckling was again encountered, even when the study
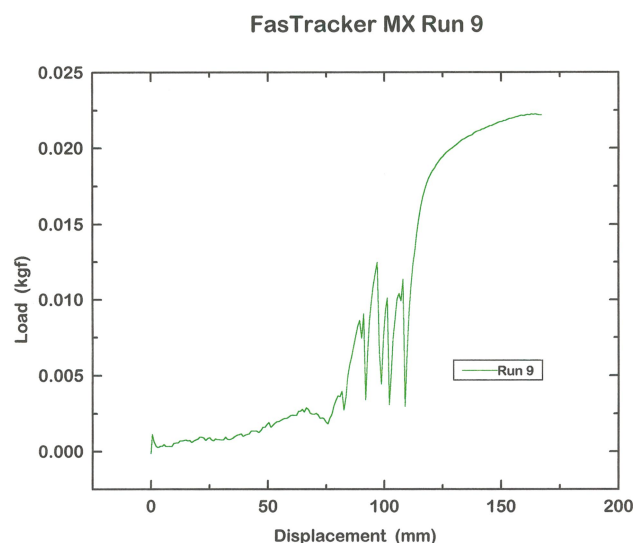
FasTracker MX Run 9

FIG 4. FasTracker MX catheter. Multiple load peaks corresponding to multiple successive episodes of buckling and paroxysmal advancement of the catheter are observed between 75 and 110 mm of displacement. Above 110 mm of displacement, the catheter buckled in an irrecoverable manner, with an excessive increase of load forces to over 20 g.
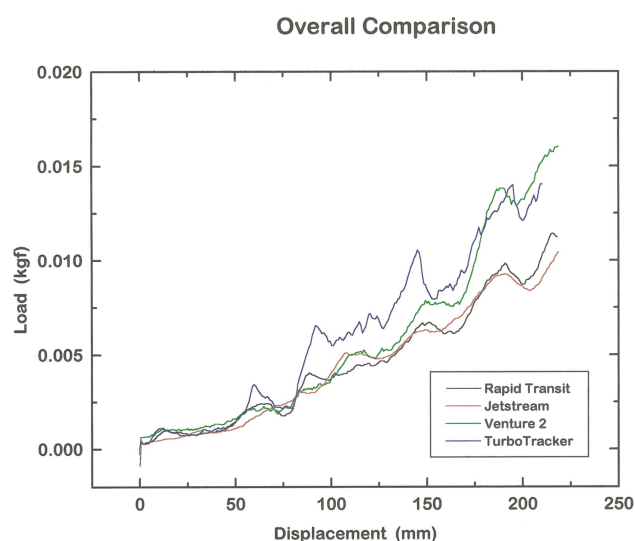
Overall Comparison

FIG 5. Overall comparison of the four reinforced catheters. Average load forces required by three catheters (three passes of each) are plotted against displacement. Lower maximum load forces are required by the Jetstream and Rapid Transit catheters but may not be clinically significant.

Average load forces (g) for three samples of each brand of reinforced catheter at selected displacement values

	Displacement, mm				
	60	90	117	150	190
Jetstream	1.7	3.0	5.0	6.3	9.3
Rapid Transit	2.3	3.9	4.5	6.7	9.7
TurboTracker	3.4	6.0	6.3	8.5	13.1
Venture 2	2.1	3.2	5.3	7.7	13.8

was repeated using a Mach-16 guidewire at the manufacturer's suggestion.

No degradation in performance was noted in the TurboTracker after 50 passes. The average load force for the three samples of this microcatheter at 190 mm of displacement was 13.1 g, approximating the performance of the Venture 2.

At 60 mm of displacement into the pathway, statistically significant differences in load force ($P < .05$) were found between the Rapid Transit and the Jetstream, between the TurboTracker and the Jetstream, between the TurboTracker and the Rapid Transit, and between the TurboTracker and the Venture 2. At a displacement of 90 cm, significant differences in load force were found between the TurboTracker and all other catheters. At 117 mm of displacement, significant differences in load force were found between the TurboTracker and the Jetstream, and between the TurboTracker and the Rapid Transit. At very distal displacements of 150 and 190 mm, no significant difference between catheters could be statistically determined (Fig 5; see Table).

Discussion

Factors that impact in vivo microcatheter performance include lubricity, stiffness, and durability. Different manufacturers use various catheter materials, hydrophilic coatings, and mechanical designs to optimize the safety and trackability of their catheter systems. Designing an in vitro model that does not fatigue or change with use, but that simulates the intracranial carotid circulation, is a difficult task. The shape of our model was designed to provide a reasonable degree of frictional resistance against catheter advancement and to roughly simulate the curvature of the intracranial carotid circulation. Poly-

tetrafluoroethylene tubing was chosen as a moderately rigid, nonfatiguing material. Although a similar model might have been constructed from cadaveric human or animal arterial specimens, such a model would be difficult to standardize throughout a lengthy and repetitive testing protocol and might have introduced errors into our experiment. Although it lacks some of the distensibility of an in vitro arterial segment, we thought that polytetrafluoroethylene tubing was a reasonable material from which to construct a pathway that would not confound our measurements of catheter performance. Potential transfer of hydrophilic coating from the multiple microcatheters to the Teflon could occur; however, the tubing was manually flushed after passage of each catheter. Furthermore, the lowest average gram forces were recorded with passage of the Jetstream microcatheter. This catheter was passed through the system 50 times in the preliminary phase of guidewire testing and again as the third of five manufacturers' catheters being tested. No appreciable difference in performance of this brand of microcatheter was detected at these various times in the study, suggesting that our results are in fact due to intrinsic properties of the catheters rather than to any change in the tortuous pathway.

The Jetstream 18, Rapid Transit, TurboTracker,

and Venture 2 microcatheters are all supported by an integral braid or coil. Performance between and within the sample groups of the Jetstream, Rapid Transit, and Venture 2 was good and reproducible, paralleling performance of the guidewire alone. Performance of the TurboTracker established more run-to-run variability for each catheter, as well as variability in performance between different sample catheters of the same brand.

Diminished load forces were actually required by the Jetstream and Rapid Transit catheters after the first pass of each sample (Fig 6). This phenomenon may be the result of the softening of the catheter in the water bath, the softening of the hydrophilic coating with hydration, or the microfracture of the hydrophilic coating with the first pass. This first-pass effect was not noted with the TurboTracker or Venture 2 catheters.

Performance of the FasTracker MX, the only non-braided catheter we tested, was markedly inferior in this model. We believe that the lack of integral reinforcement leads to buckling of the microcatheter when the tip encounters the points of greatest resistance within the tortuous pathway (ie, the curves). This effect is transmitted in a retrograde fashion along the microcatheter, resulting in severe buckling of even the stiffer proximal portion of the shaft. Early in the pathway, the still relatively low frictional forces are overcome by the catheter in a staccato fashion, resulting in small forward jumps of the distal tip. This performance characteristic may have implications for intracranial catheterization, in which unexpected forward advancement of the microcatheter may result in perforation of small vessels or a cerebral aneurysm. Although differences in hydrophilic coatings could be implicated to account for the performance difference between the reinforced catheters and the FasTracker, we think that the basic differences in catheter shaft construction are far more important. Further testing is planned to compare the lubricity of these different catheters and hydrophilic coatings and the forces required to overcome static friction.

Various techniques are used in clinical practice to facilitate the advancement of the microcatheter/guidewire combination. One of the most commonly used techniques has been to take advantage of the catheter slack that accumulates in tortuous vascularity by withdrawing the guidewire a significant distance into the catheter and then advancing it again in a smooth fashion. This often propels the catheter tip forward as the guidewire is being advanced. Various catheters may respond differently to this maneuver. This type of complex manipulation could not be reliably simulated by the load frame device and was not assessed in our model. Such maneuvers may significantly contribute to the clinical performance of certain types of microcatheters and may account for the clinical acceptance of nonreinforced microcatheters, such as the FasTracker.

Statistical analysis among brands of catheters disclosed significant differences between the Turbo-Tracker and the other catheters at displacement val-
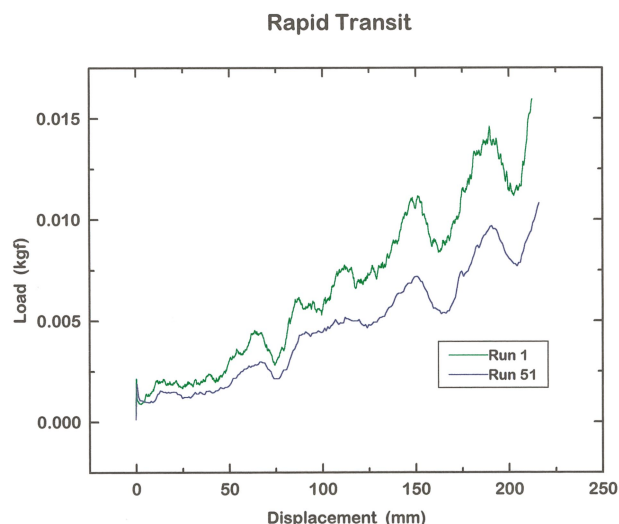

Rapid Transit

Fig 6. Load forces required by the Rapid Transit catheter actually diminish with multiple passes. This effect, which can be observed after only one or two passes, also occurred with the Jetstream catheter. Improvement may be the result of the softening of either the catheter or the hydrophilic coating.

ues of 60, 90, and 117 mm. Nevertheless, no statistical model can accurately predict the clinical performance of a particular brand of catheter. Load forces were relatively small for all reinforced catheters, and the actual clinical performance of all catheters tested is acceptable to various groups of skilled interventionists.

Lower load forces may cause less vascular trauma during intracranial catheterization. Rupture of a cerebral aneurysm proximal to the tip of a microcatheter has been attributed to stretching and displacement of the proximal vasculature during attempted embolization of an arteriovenous malformation (AVM) (8). Unexpected, rapid advancement of the microcatheter tip during intraaneurysmal catheterization for diagnostic evaluation or coil embolization may result in perforation of the dome. Smooth and predictable advancement of the microcatheter tip is necessary to avoid this complication. The potential for perforation of an arterial feeder to an AVM during superselective catheterization has been acknowledged by some authors (9). Subarachnoid hemorrhage resulting from catheter perforation of a feeding artery during AVM embolization has also been documented by several investigators (10–12).

Conclusion

Testing of five state-of-the-art hydrophilically coated microcatheters was performed in a standardized tortuous pathway designed to simulate the intracranial carotid circulation. All reinforced microcatheters tested established good and reproducible performance in our model, requiring relatively small load forces to achieve smooth and predictable advancement. Thorough testing of a single brand of nonreinforced microcatheter could not be accomplished because of excessive buckling. The use of a catheter system with optimal trackability may en-

hance the safety of superselective intracranial catheterization.

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