

RELIABLE PERFORMANCE:

Contact force, curve retention and durability: A comparison study using the SureFlex® Steerable Guiding Sheath

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ABSTRACT



Purpose

Steerable sheaths have been shown to improve ablation procedure outcomes as compared with fixed-curve sheaths, partly due to their ability to access hard-to-reach areas and navigate complex anatomies. A key requirement of steerable sheaths is to support sufficient contact force of the ablation catheter against the cardiac tissue, for effective isolation of electrical signals. This study compares the ability of two types of steerable sheath to maintain contact force at the sheath tip over extensive use.

Methods

Two types of steerable transseptal sheath were evaluated: the Baylis Medical SureFlex® Steerable Guiding Sheath and the St. Jude Medical Agilis™ NxT Steerable Introducer. Sheath performance was assessed in three ways for both devices under various fatigue conditioning scenarios: consistency of contact force at sheath tip, retention of curve range-of-motion (ROM), and cycles-until-failure.

Results

The SureFlex® sheath performed better than the Agilis™ NxT sheath on all performance and durability tests conducted. Compared to the Agilis™ NxT sheath, the SureFlex® sheath retained as much as 13 times the contact force at the sheath tip, 3 times the initial curve ROM, and remained completely intact, whereas the Agilis™ NxT sheath failed after an average of 14 cycles.

Conclusion

As compared with the St. Jude Medical Agilis™ NxT Steerable Introducer, the Baylis Medical SureFlex® Steerable Guiding Sheath offers more consistent sheath tip contact force, superior retention of curve ROM, as well as greater durability and resistance to failure.

INTRODUCTION

Septal puncture is used to gain access to the left side of the heart for a number of cardiac procedures such as pulmonary vein isolation, mitral valve repair and left atrial appendage occlusion.¹ Once left heart access is established, catheters and other medical devices can be introduced through a transseptal sheath. Of particular interest, steerable sheaths provide control of the angle between the shaft and distal tip, facilitating access to target sites, especially in hard-to-reach areas and complex anatomies.² The use of steerable sheaths has been shown to improve outcomes of atrial fibrillation ablations.³ In pulmonary vein isolation, steerable sheaths have been correlated with a reduction in the frequency of acute pulmonary

vein reconnections, as well as procedural and fluoroscopic times.⁴

During ablation procedures, radiofrequency (RF) energy catheters rely heavily on contact force to generate adequate RF lesions, whereby best clinical outcomes are obtained using 0.2 N of force.⁵⁻⁶ Insufficient tissue contact (i.e. less than 0.1 N of contact force) may result in clinical failure and necessitate revision procedures.⁷

Although there have been no direct comparisons of commercially-available steerable sheaths, it is clear that clinical contact force relies on consistent curve range-of-motion (ROM) to establish tissue contact,

and on consistent mechanical force to support ablation catheters in generating adequate RF lesions. This benchtop study evaluates the ability of a sheath to retain full ROM over extensive use. Contact force

METHODS

Two types of steerable transseptal sheaths were tested: the Baylis Medical SureFlex® Steerable Guiding Sheath and the St. Jude Medical Agilis™ NxT Steerable Introducer. Sheaths were assembled with the Baylis Medical SureFlex® dilator and the Baylis Medical NRG® Transseptal Needle, and were pre-conditioned at 37°C for two hours to simulate physiological conditions for benchtop testing.

Contact force consistency – Contact force at maximum curve extension was evaluated using a benchtop model to represent mechanical fatigue (Figure 1). Five SureFlex® sheaths and three Agilis™ NxT sheaths were loaded with a dilator and transseptal needle, then fully articulated bidirectionally to maximum extension ten times to achieve mechanical fatigue. The needle and dilator were then replaced with an electrophysiology catheter (Biosense Webster ThermoCool SmartTouch® Catheter), and the sheath subsequently articulated unidirectionally twenty times while measuring the contact force at the tip with a force gauge after each articulation.

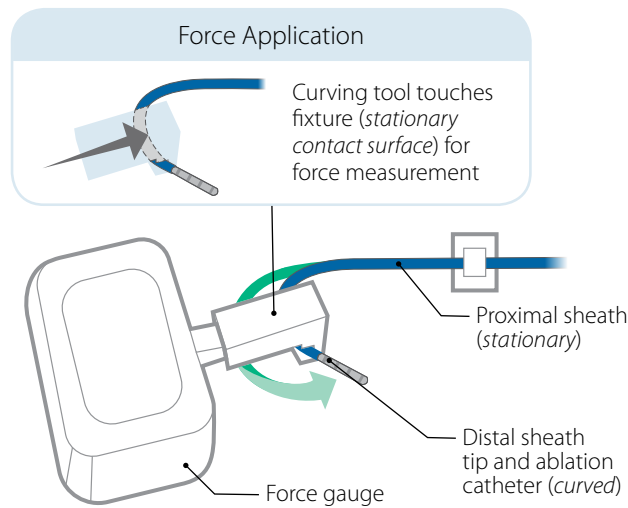


Figure 1 Contact force experimental setup

at the tip of fatigued sheaths was evaluated in the 0.1 - 0.2 N range, discussed above. Sheath mechanical failure was tested to evaluate device durability.

Retention of curve range-of-motion – To evaluate a sheath’s ability to maintain full ROM, five SureFlex® sheaths and three Agilis™ NxT sheaths were curved bidirectionally to their full extent of articulation. Extended sheaths were traced on a paper to measure curve size. Sheaths were then assembled with a dilator and transseptal needle, placed in a 37°C water bath to simulate clinical-use conditions, and curved repeatedly up to 100 cycles while tracing the curve radius in both directions at each step (Figure 2). Traces were analyzed to measure the curve angle at maximum articulation, and determine curve retention capacity as a function of the percentage drop in ROM at each cycle.

Durability – Durability was assessed by repeatedly articulating sheaths unidirectionally to their maximum curvature extension until failure, or up to 300 cycles, using an Instron® Testing System. Five SureFlex® sheaths and six Agilis™ NxT sheaths assembled with needle and dilator were tested.

Figures represent average performance data of multiple samples. Statistical analysis was performed using Student’s t-test, where significance was considered to be $p < 0.05$.

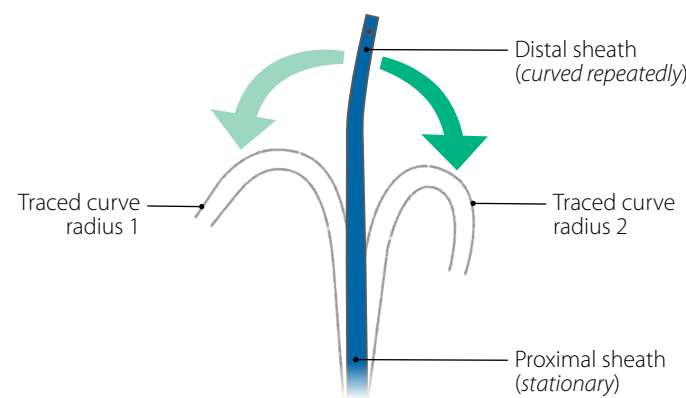


Figure 2 Curve range of motion experimental setup

RESULTS & DISCUSSION

CONTACT FORCE CONSISTENCY

After fatigue conditioning, the SureFlex® sheath maintained its contact force, whereas the Agilis™ NxT sheath lost 52% of its initial contact force, and dropped below 0.1 N on average. (Figure 3).

Continuing up to 20 articulation cycles, the SureFlex® sheath showed significantly higher contact force than the Agilis™ NxT sheath ($p = 0.007$). The SureFlex® sheath

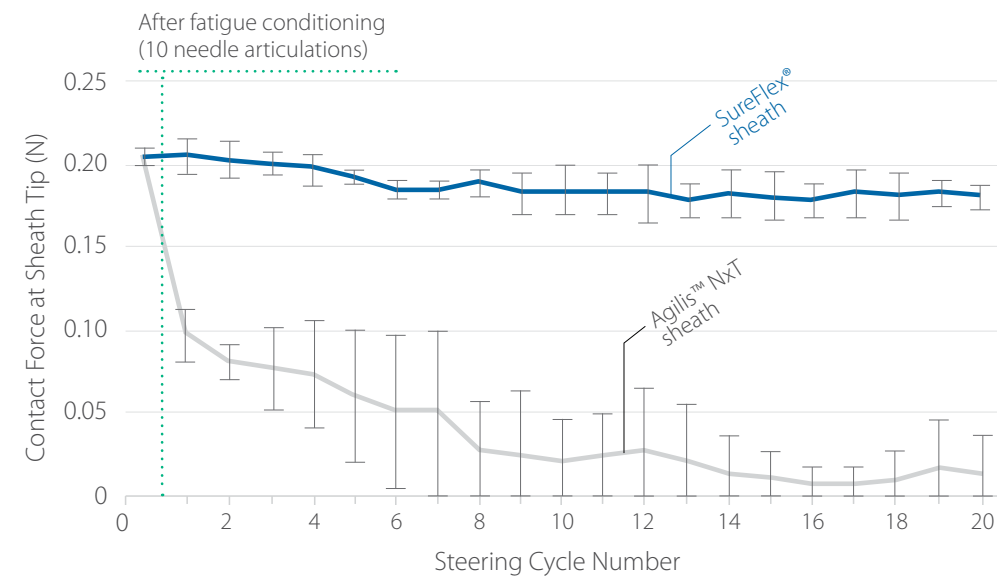


Figure 3 Average contact force over sheath steering cycles

retained 88% of its initial contact force (still remaining above 0.1 N, on average) whereas the Agilis™ NxT sheath only retained 7% of its initial contact force.

Findings from contact force testing also suggested that the SureFlex® sheath retains more curve ROM after fatigue conditioning and 20 articulation cycles with an ablation catheter (Figure 4).



Figure 4 Tip curvature (photographs)

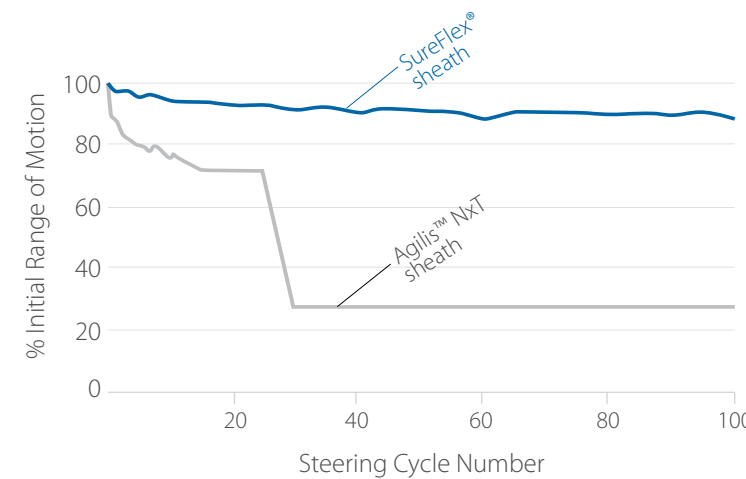


Figure 5 Percent range-of-motion retained over 100 steering cycles with dilator and needle

RETENTION OF CURVE RANGE-OF-MOTION

Additional testing indicated that after 100 articulation cycles with dilator and needle, the SureFlex® sheath retained significantly more of its initial ROM than the Agilis™ NxT sheath ($p < 0.001$), retaining 89% of its ROM compared to only 27% with the Agilis™ NxT device.

Aggregate data shown in Figure 5.

DURABILITY

The SureFlex® sheath remained intact after 300 cycles of articulation with dilator and needle, whereas the Agilis™ NxT sheath failed after an average of 14 cycles (Figure 6).

“The SureFlex® sheath remained intact after 300 cycles...”

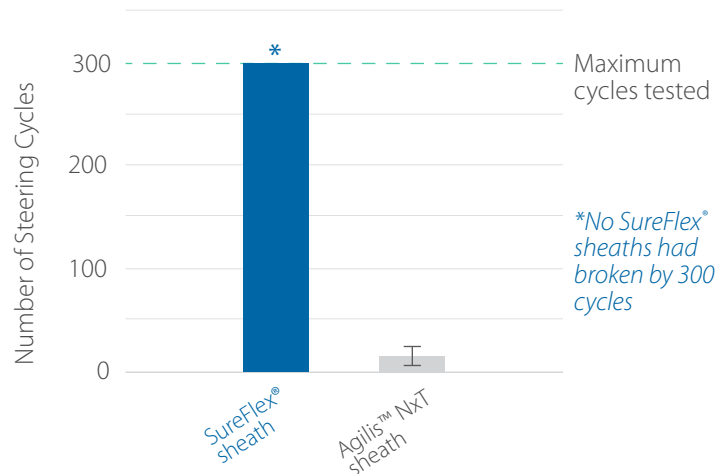


Figure 6 Number of cycles to failure

CONCLUSION

As compared with the St. Jude Medical Agilis™ NxT Steerable Introducer, the Baylis Medical SureFlex® Steerable Guiding Sheath offers more consistent sheath tip contact force, superior retention of curve range-of-motion, as well as greater durability and resistance to failure.

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Based on bench testing conducted at Baylis Medical Company Inc. R&D labs. Results may not be indicative of clinical performance.

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