Reliable Performance

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

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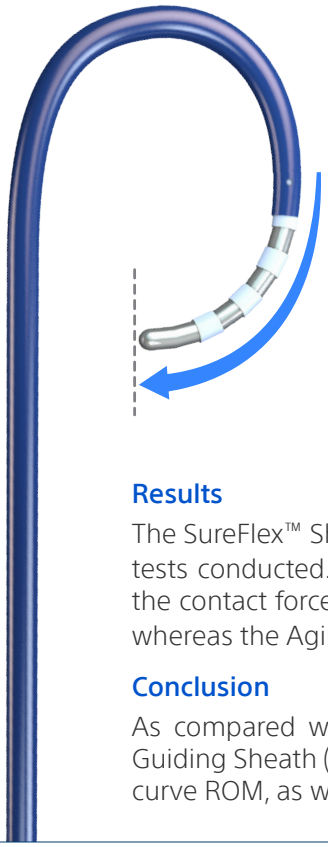
ABSTRACT



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 SureFlex™ Steerable Guiding Sheath (Boston Scientific) 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 up to 13 times the contact force at the sheath tip, three 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 SureFlex™ Steerable Guiding Sheath (Boston Scientific) offers more consistent sheath tip contact force, superior retention of curve ROM, as well as greater durability and resistance to failure.

INTRODUCTION

Transseptal 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 at the tip of fatigued sheaths was evaluated in the 0.1 – 0.2 N range. Sheath mechanical failure was tested to evaluate device durability.

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METHODS

Two types of steerable transseptal sheaths were tested: The SureFlex™ Steerable Guiding Sheath (Boston Scientific) and the St. Jude Medical Agilis™ NxT Steerable Introducer. Sheaths were assembled with the SureFlex™ Dilator (Boston Scientific) and the NRG™ Transseptal Needle (Boston Scientific), 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.

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 $p < 0.05$.

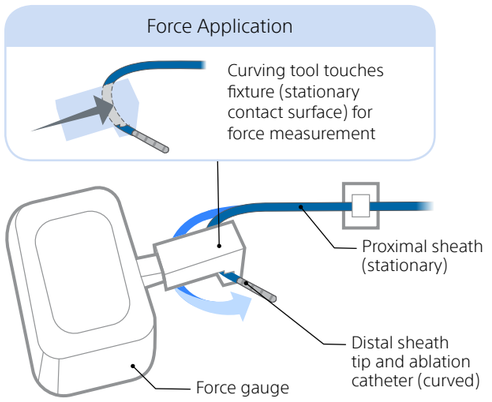


Figure 1. Contact force experimental setup

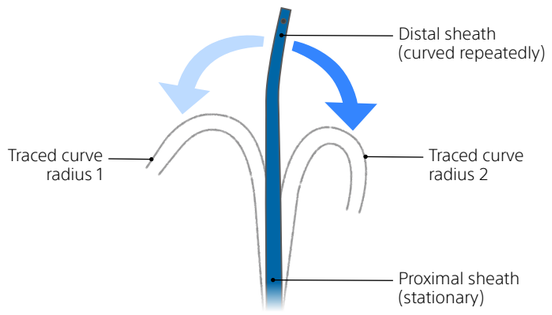


Figure 2. Curve range of motion experimental setup

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

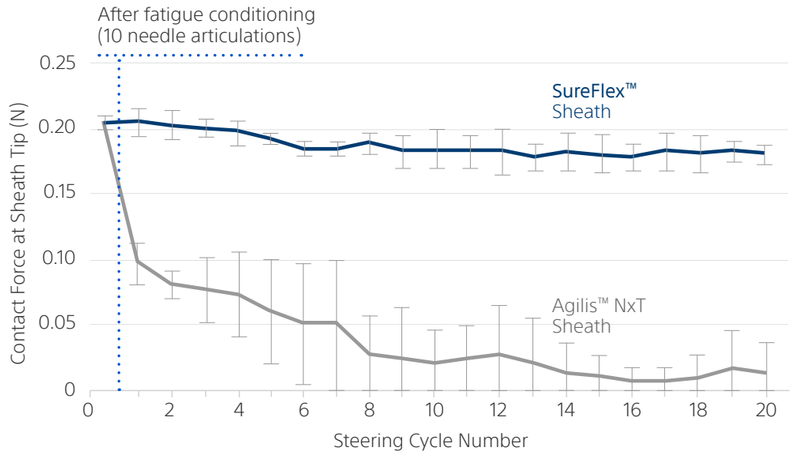
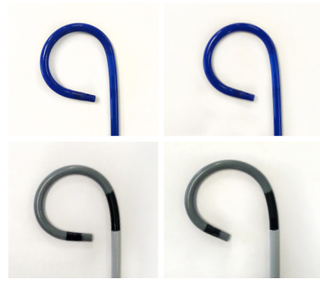


Figure 3. Average contact force over sheath steering cycles (data points are the mean ± standard error for 5 SureFlex™ and 3 Agilis™ NxT sheaths)



Before fatigue conditioning (cycle 0) | After fatigue conditioning and 20 steering cycles

Figure 4. Tip curvature (photographs)

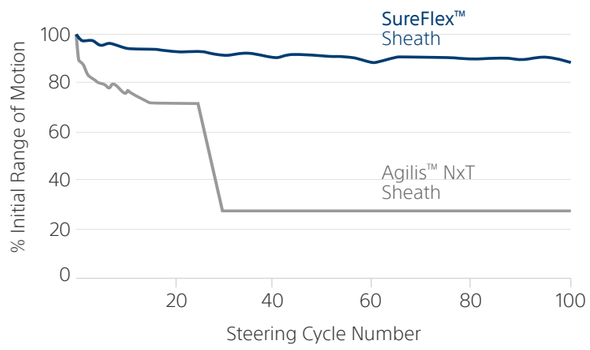


Figure 5. Percent of initial range-of-motion retained over 100 steering cycles with dilator and needle

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..."

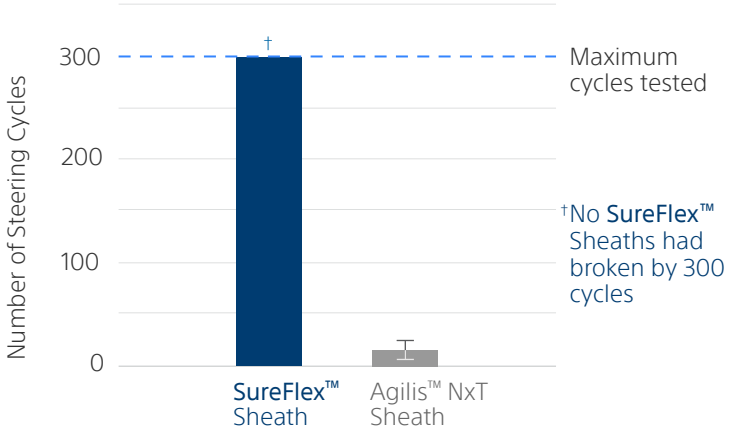


Figure 6. Number of cycles to failure (data are the mean ± standard error for 5 SureFlex™ Sheaths and 6 Agilis™ Sheaths)

CONCLUSION

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

REFERENCES

1. Babaliaros VC, Green JT, Lerakis S, Lloyd M, Block PC. Emerging applications for transseptal left heart catheterization: Old techniques for new procedures. *J Am Coll Cardiol.* 2008. 2116-22. doi: 10.1016/j.jacc.2008.01.061
2. Brunelli M, Raffa S, Grosse A, Wauters K, Menoni S, Schreiber M, et al. Influence of the anatomic characteristics of the pulmonary vein ostium, the learning curve, and the use of a steerable sheath on success of pulmonary vein isolation with a novel multielectrode ablation catheter. *Europace.* 2012. 331-40. doi: 10.1093/europace/eur333
3. Piorkowski C, Eitel C, Rolf S, Bode K, Sommer P, Gaspar T, et al. Steerable versus nonsteerable sheath technology in atrial fibrillation ablation: A prospective, randomized study. *Circ Arrhythm Electrophysiol.* 2011. 157-65. doi: 10.1161/CIRCEP.110.957761
4. Masuda M, Fujita M, Iida O, Okamoto S, Ishihara T, Nanto K, et al. Steerable versus non-steerable sheaths during pulmonary vein isolation: Impact of left atrial enlargement on the catheter-tissue contact force. *J Interv Card Electrophysiol.* 2016. 99-107. doi: 10.1007/s10840-016-0135-4
5. Reddy VY, Shah D, Kautzner J, Schmidt B, Saoudi N, Herrera C, et al. The relationship between contact force and clinical outcome during radiofrequency catheter ablation of atrial fibrillation in the TOCCATA study. *Heart Rhythm.* 2012. 1789-95. doi: 10.1016/j.hrthm.2012.07.016
6. Kimura M, Sasaki S, Owada S, Horiuchi D, Sasaki K, Itoh T, et al. Comparison of lesion formation between contact force-guided and non-guided circumferential pulmonary vein isolation: A prospective, randomized study. *Heart Rhythm.* 2014. 984-91. doi: 10.1016/j.hrthm.2014.03.019
7. Park CI, Lehrmann H, Keyl C, Weber R, Schiebeling J, Allgeier J, et al. Mechanisms of pulmonary vein reconnection after radiofrequency ablation of atrial fibrillation: The deterministic role of contact force and interlesion distance. *J Cardiovasc Electrophysiol.* 2014. 701-8. doi: 10.1111/jce.12396

Indications, safety, and warnings for SureFlex™ Steerable Guiding Sheath

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