Reliable Performance

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

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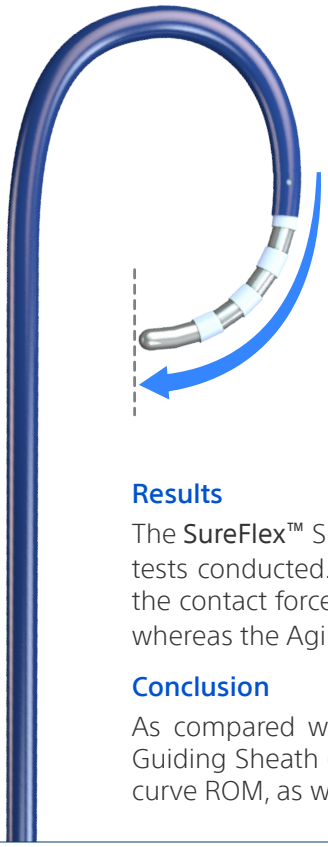
ABSTRACT



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 (Baylis Medical*) 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 (Baylis Medical*) 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.

METHODS

Two types of steerable transseptal sheaths were tested: The **SureFlex™** Steerable Guiding Sheath (Baylis Medical*) and the St. Jude Medical Agilis™ NxT Steerable Introducer. Sheaths were assembled with the **SureFlex™** Dilator (Baylis Medical*) and the **NRG™** Transseptal Needle (Baylis Medical*), 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 $p<0.05$.

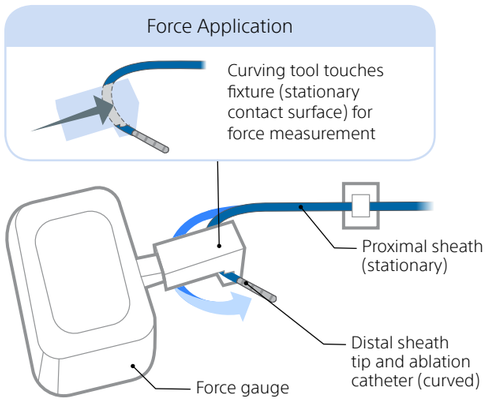


Figure 1. Contact force experimental setup

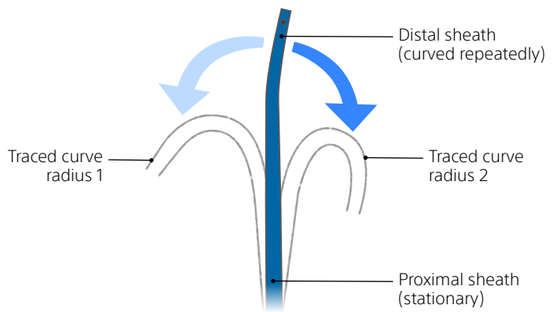


Figure 2. Curve range of motion experimental setup

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).

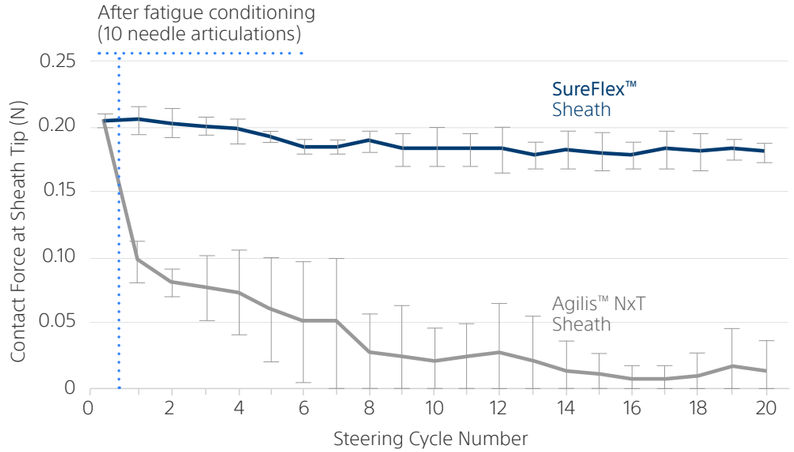
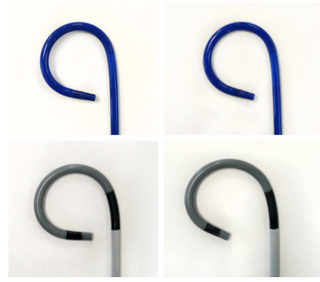


Figure 3. Average contact force over sheath steering cycles (data points are the mean ± standard error for 5 **SureFlex™** and 3 Agilis™ NxT sheaths)



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

Figure 4. Tip curvature (photographs)

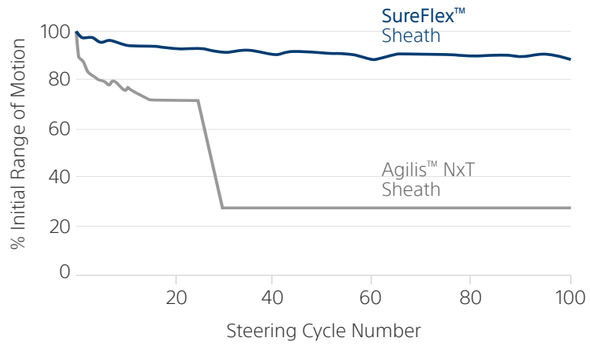


Figure 5. Percent of initial range-of-motion retained over 100 steering cycles with dilator and needle

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..."

CONCLUSION

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

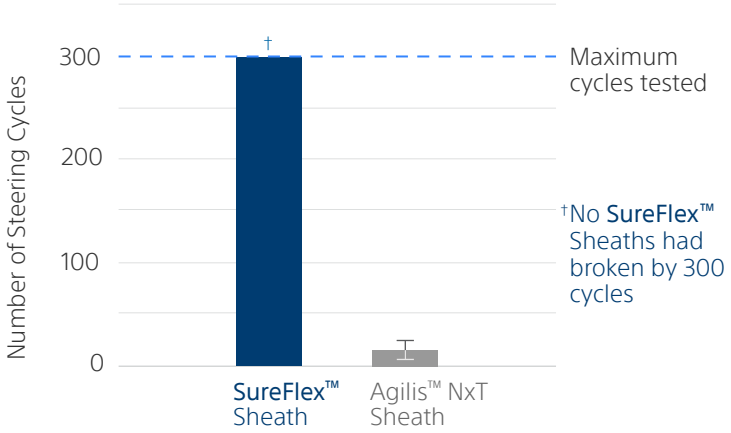


Figure 6. Number of cycles to failure (data are the mean ± standard error for 5 **SureFlex**™ Sheaths and 6 Agilis™ Sheaths)

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SureFlex™ Steerable Guiding Sheath

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INDICATIONS FOR USE: The SureFlex™ Steerable Guiding Sheath kit is indicated for introducing various cardiovascular catheters to the heart, including the left side of the heart through the interatrial septum.

CONTRAINDICATIONS: There are no known contraindications for this device.

WARNINGS: • Laboratory staff and patients can undergo significant x-ray exposure during interventional procedures due to the continuous usage of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure. The use of echocardiography is recommended. • The SureFlex™ Steerable Guiding Sheath kit is intended for single patient use only. Do not attempt to sterilize and reuse the SureFlex™ Steerable Guiding Sheath kit. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another. • Care should be taken to ensure that all air is removed from the sheath before infusing through the side port. • Do not attempt direct percutaneous insertion of the sheath without the dilator as this may cause vessel injury. • Maintain continuous hemodynamic monitoring throughout procedure • Provide continuous heparinized saline infusion while the introducer remains in vessel. • DO NOT attempt to insert or retract the guidewire through a metal cannula or a percutaneous needle, which may damage the guidewire and may cause patient injury.

PRECAUTIONS: • Careful manipulation must be performed to avoid cardiac damage, or tamponade. Sheath, dilator and guidewire advancement should be done under fluoroscopic guidance. Echocardiographic guidance is also recommended. If resistance is encountered, DO NOT use excessive force to advance or withdraw the device. • Avoid deflecting distal end of sheath during delivery and removal, otherwise damage to vessels may occur. • Do not attempt to use the guidewire with electrocautery tools. • Do not reshape distal tip or curve of the guidewire. Excessive bending or kinking of the distal curve may damage the integrity of the wire or coating and lead to patient injury.

ADVERSE EVENTS: Adverse events that may occur while using the SureFlex™ Steerable Guiding Sheath include: • Infection • Air embolus • Local nerve damage • Vasovagal reaction • Dissection • Vessel spasm • AV fistula formation • Atrial septal defect • Pseudoaneurysm • Aortic puncture • Arrhythmias • Perforation and/or tamponade • Hematoma • Hemorrhage • Catheter entrapment • Embolic events • Stroke • Valve damage • Myocardial infarction • Pericardial/pleural effusion • Pacemaker/defibrillator lead displacement • Pulmonary edema • Coronary artery spasm and/or damage • Vessel trauma

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