Controlled Crossing

A comparison study using the SureFlex™ Steerable Guiding Sheath

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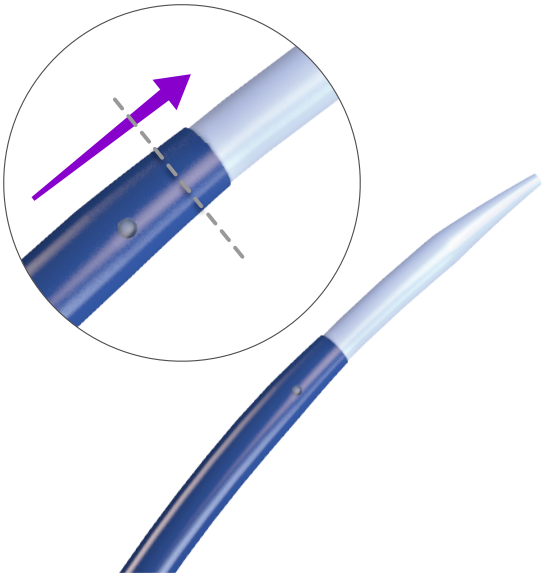
ABSTRACT



Purpose

The need to excessively push a steerable sheath forward during transseptal crossing may lead to uncontrolled movements, whereby the sheath tip may "jump" forward at the moment of accessing the left atrium. Elastic, aneurysmal, or thickened interatrial septa may increase the need for excessive crossing force and, subsequently, the risk of tissue injury. A smoother sheath-to-dilator transition may contribute to improved control during septal crossing. This study investigates the crossing performance of two types of steerable transseptal sheath.

Methods

Sheath-to-dilator transitions of the SureFlex™ Steerable Guiding Sheath (Baylis Medical*) and the St. Jude Medical Agilis™ NxT Steerable Introducer were measured using laser micrometry. Peak crossing force was measured using a benchtop model to assess sheath crossing performance.

Results

The sheath-to-dilator transition was 40% smoother in the SureFlex™ Sheath than the Agilis™ NxT Sheath ($p<0.001$). The smoother transition coincided with a 27% lower peak force to cross with the SureFlex™ Sheath as compared to the Agilis™ NxT Sheath ($p<0.001$).

Conclusion

The SureFlex™ Steerable Guiding Sheath offers a significantly smoother sheath-to-dilator transition and lower force to cross than the Agilis™ NxT Steerable Introducer.

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. Improved control as the sheath crosses the septum may contribute to predictable, atraumatic, left heart access with confidence.

In patients with elastic, aneurysmal, or thickened septa, or patients with repeat ablations, additional tissue tenting and mechanical force may be required for the sheath-dilator assembly to cross the septum.

Excessive force may cause the assembly to "jump" forward at the moment of tissue crossing, thereby increasing the risk of accidental perforation of the aortic root, left atrial appendage, left atrial wall, pulmonary vein, or pulmonary artery.[2] Pressure build-up from severe tenting, as well as accidental puncture of adjacent structures, may lead to life-threatening cardiac tamponade,[3-5] which has been shown to occur in up to 3% of atrial fibrillation

procedures.[6] Excessive force may also cause the device tip to slip from the target, thereby adding to the procedure time (due to repositioning).

In a sheath-dilator device assembly, a smoother sheath-to-dilator transition may provide improved control during transseptal crossing. This study investigates geometric and mechanical parameters affecting the crossing performance of steerable guiding sheaths in a benchtop septal model.

METHODS

Crossing performance was evaluated using the **SureFlex™** Steerable Guiding Sheath (Baylis Medical*) and the St. Jude Medical Agilis™ NxT Steerable Introducer.

Smooth transition – Five **SureFlex™** assemblies and five Agilis™ NxT assemblies were tested. The outer diameter of the sheath-dilator assembly was measured along the length of the sheath-to-dilator transition using a three-axis laser micrometer.

Crossing force – Ten **SureFlex™** assemblies and eight Agilis™ NxT assemblies were tested. In a benchtop model for transseptal access (Figure 1), a 0.020" thick 30 mm diameter silicone sample (35 Shore A durometer) was positioned at a 45° angle to mimic septal tissue, and mounted on an Instron® Testing System with a 2 kN force gauge. An **NRG™** Transseptal Needle (Baylis Medical*) was loaded inside each sheath-dilator assembly, which was then loaded into a custom fixture against the model silicone septum. A needle was used to puncture the silicone to model transseptal access. The force gauge was zeroed, and the entire device assembly was allowed to advance until the tip of the sheath fully crossed the model septum.

"...a 0.020'' thick 30 mm diameter silicone sample was positioned at a 45° angle to mimic septal tissue..."

Force application while crossing was recorded for each sample, and the average peak force was calculated.

Testing was performed using medium and large curvature sheaths. Data shown represents average performance measures of all sheaths tested. Statistical analysis was performed using Student's t-test, where significance was considered to be $p<0.05$.

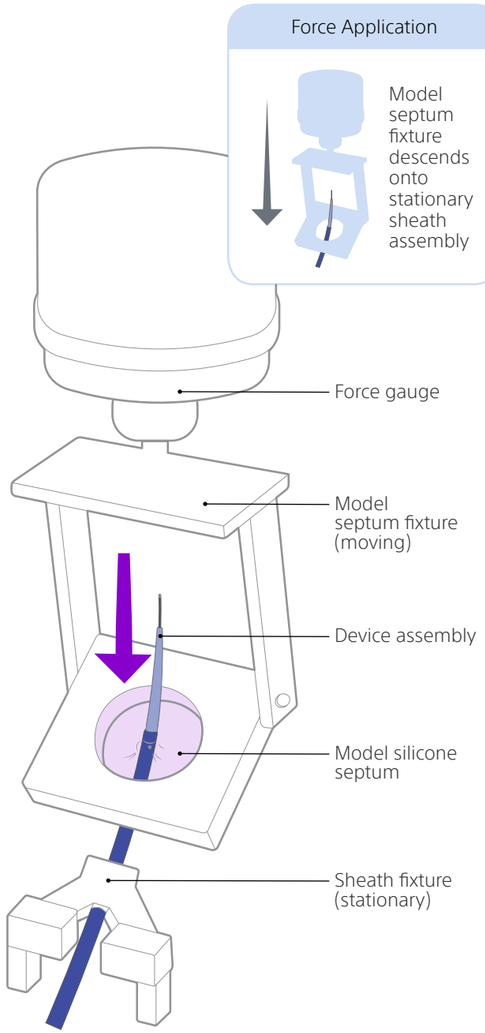


Figure 1. Benchtop model for transseptal access

RESULTS AND DISCUSSION

Smooth transition

The outer diameter along the transition from dilator to sheath tip was more streamlined in the **SureFlex™** assembly than the Agilis™ NxT assembly (Figure 2; representative sample data shown).

The sheath-to-dilator transition was 40% smoother in the **SureFlex™** Sheath than the Agilis™ NxT Sheath ($p<0.001$), suggesting an easier, smoother crossing.

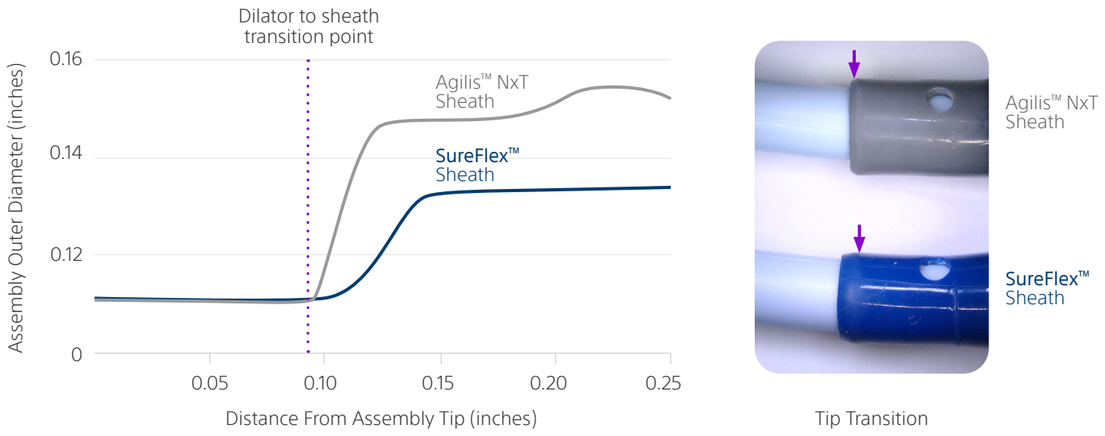


Figure 2. Dilator-to-sheath transition comparison (left: outer diameter measurements; right: device photographs)

Crossing force

Consistent with the hypothesis that a smoother sheath-to-dilator transition facilitates crossing, the crossing force was indeed significantly lower using the **SureFlex™** assembly than the Agilis™ NxT assembly. The peak crossing force was 27% lower using the **SureFlex™** assembly than the Agilis™ NxT assembly (Figure 3; mean ± standard error, $p<0.001$). Lower peak crossing force suggests a lower risk of device tip "jumping."

"The peak crossing force was 27% lower using the **SureFlex™** assembly..."

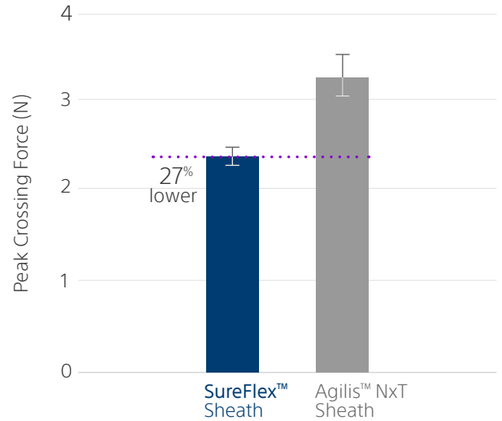


Figure 3. Peak crossing force comparison (mean ± standard error for 10 **SureFlex™** sheaths and 8 Agilis™ NxT sheaths, $p<0.001$)

CONCLUSION

The **SureFlex™** Steerable Guiding Sheath offers a significantly smoother sheath-to-dilator transition and a significantly lower force to cross than the Agilis™ NxT Steerable Introducer.

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