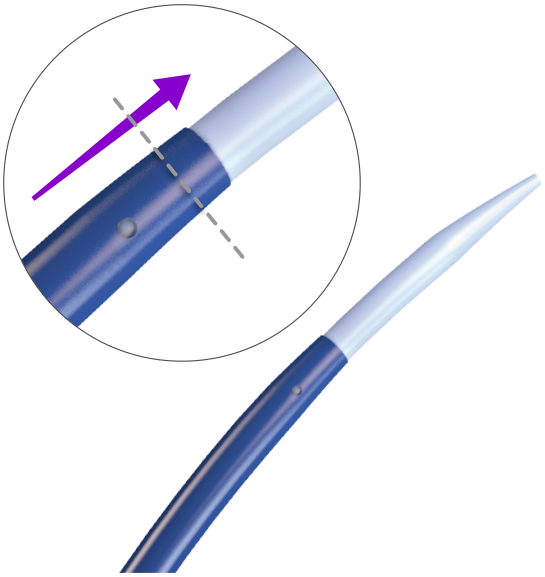
Controlled Crossing

A comparison study using the SureFlex™ Steerable Guiding Sheath

Al-Dujaili, S., PhD, Chan, A., BASc, Couture-Tremblay, J., MEng, Keaveney, L., BEng, Lau, K.H., BASc, Zhang, A.B., BASc, and Chen, J.H., PhD

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 $p<0.05$.

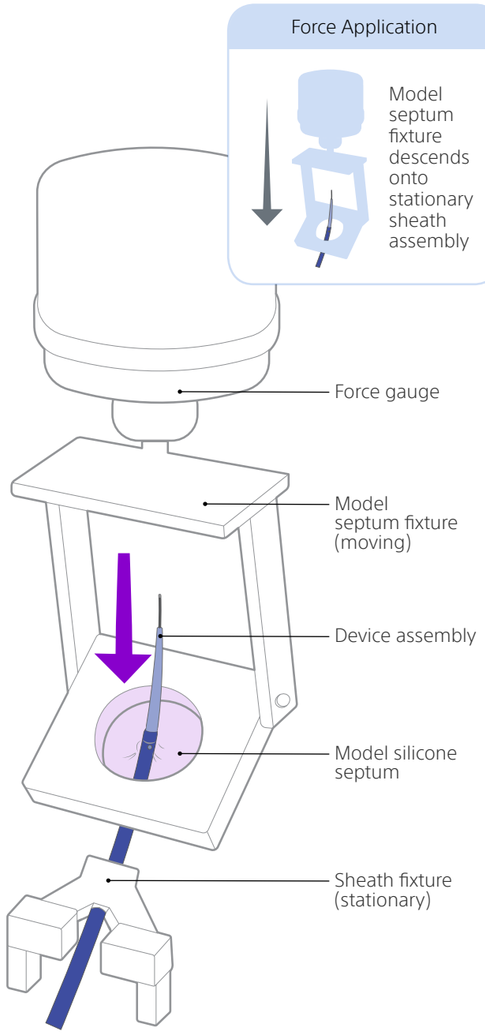


Figure 1. Benchtop model for transseptal access

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.

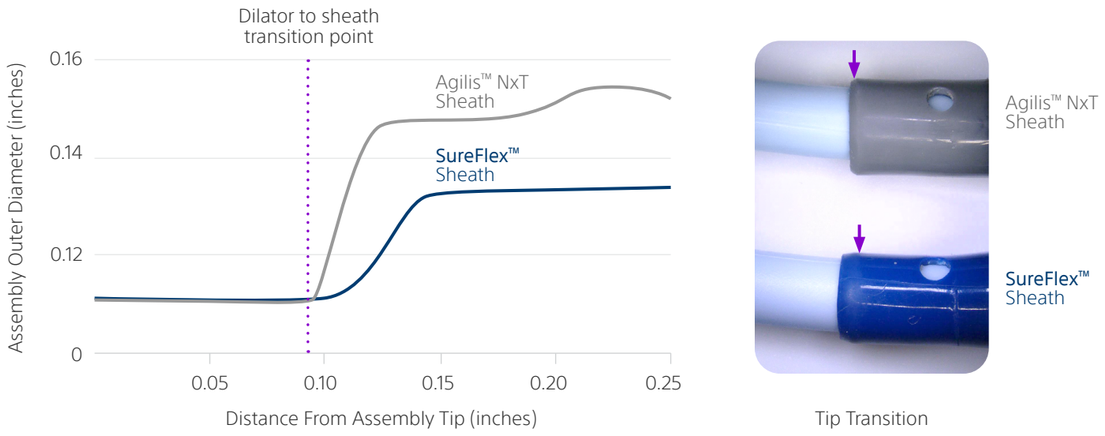


Figure 2. Dilator-to-sheath transition comparison (left: outer diameter measurements; right: device photographs)

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..."

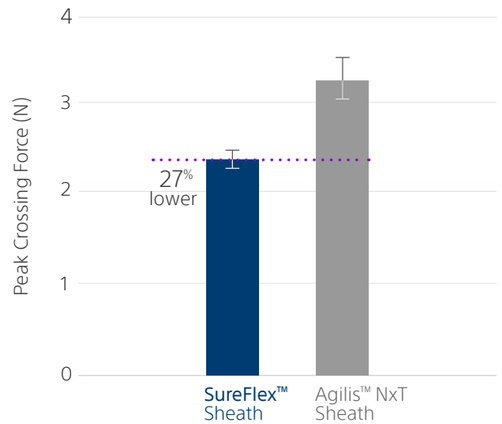


Figure 3. Peak crossing force comparison (mean ± standard error for 10 **SureFlex™** sheaths and 8 Agilis™ NxT sheaths, $p<0.001$)

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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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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Baylis Medical Company Inc.
5959 Trans-Canada Highway
Montreal, QC Canada H4T 1A1

www.baylismedical.com
info@baylismedical.com

General Inquiries
(514) 488-9801

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