Precise Steering:

A comparison study using the **SureFlex™** Steerable Guiding Sheath

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ABSTRACT

Purpose

Through dial and handle rotation, steerable sheaths function to facilitate access to target sites inside the heart, which is especially useful in hard-to-reach areas and complex anatomies. It has been suggested that the precise movements offered by steerable sheaths contribute to improved outcomes in atrial fibrillation procedures, as compared to non-steerable sheaths. The steering precision of a transseptal sheath may therefore contribute to the success of a procedure. This study measures and compares the steering precision of two types of transseptal steerable sheaths.

Methods

The Baylis Medical* **SureFlex™** Steerable Guiding Sheath and the St. Jude Medical Agilis™ NxT Steerable Introducer were assessed on three aspects of steering precision: 1) torque transfer (axial rotation), 2) tip deflection, and 3) tactile dial feedback. Benchtop studies were used to replicate the torque applied to both the handle and dial of steerable sheaths.

Results

Compared to the Agilis™ NxT Sheath, the **SureFlex™** Sheath 1) delivered a more precise 1:1 torque transfer along the length of the sheath from handle to tip, 2) demonstrated a more linear force-rotation profile, with two times more consistency in force-to-turn the dial, and 3) required 61.6% less force-to-turn the dial in the neutral zone, while demonstrating a more consistent neutral zone.

Conclusion

The **SureFlex™** Steerable Guiding Sheath offers more precise handling, more responsive steering, and a more consistent neutral zone as compared to 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.

Both fixed and steerable sheaths can be used for these procedures; however, steerable sheaths have been shown to possess superior maneuverability. 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 precise movements demonstrated by steerable sheaths may contribute to improved patient outcomes and require significantly less fluoroscopy time during a procedure.[3,4]

STEERABLE SHEATH TECHNIQUES

This study will explore three distinct aspects of steering precision:

1) Torque Transfer (Axial rotation) – Precise handling

Torque transfer is achieved when rotation of the sheath's proximal handle translates to a corresponding degree of rotation at the distal tip. A direct 1:1 ratio contributes to precise handling via control and maneuverability of the distal tip.

2) Tip deflection – Responsive steering

Tip deflection is achieved via dial rotation. A linear relationship between dial rotation and force-to-turn the dial contributes to smooth steering. A responsive steering mechanism allows physicians to navigate complex anatomies and reach target locations.

3) Tactile dial – Consistent neutral zone

The user receives tactile feedback via resistance in the dial. In steerable sheaths with tactile dial feedback, the force-to-turn the dial increases when steering towards maximum deflection. The dial neutral zone is a range in which the dial can be turned (in either direction) before the distal tip of the sheath begins to deflect. The tactile feedback provided by a consistent neutral zone allows physicians to intuitively confirm tip deflection, which may reduce their reliance on fluoroscopy during sheath delivery and positioning.

METHODS

The Baylis Medical* **SureFlex™** Steerable Guiding Sheath and the St. Jude Medical Agilis™ NxT Steerable Introducer were assessed on three aspects of steering precision: torque transfer (axial rotation), tip deflection, and tactile dial feedback.

1) Torque Transfer (Axial rotation) – Precise handling

A physical, to-scale model of a human circulatory system was used to test axial torque transfer in each sheath. Rotation of the sheath's proximal handle (input) was measured relative to the degree of rotation at the distal tip (output) within the model circulatory system (Figure 1). Handles were rotated a full 360° to assess the maximum rotational capabilities of each sheath. Five **SureFlex™** Sheaths and three Agilis™ NxT Sheaths (medium curve size) were tested.

2) Tip deflection – Responsive steering

The degree of dial rotation and corresponding force-to-turn the dial were measured when deflecting the tip from straight to maximum deflection. Data was plotted as a force-rotation graph. Mathematical analysis† was used to determine how much each plot deviates from a linear profile. The more linear the profile, the more consistent and smooth the steering response. Testing was performed on five **SureFlex™** Sheaths and five Agilis™ NxT Sheaths (medium curve size).

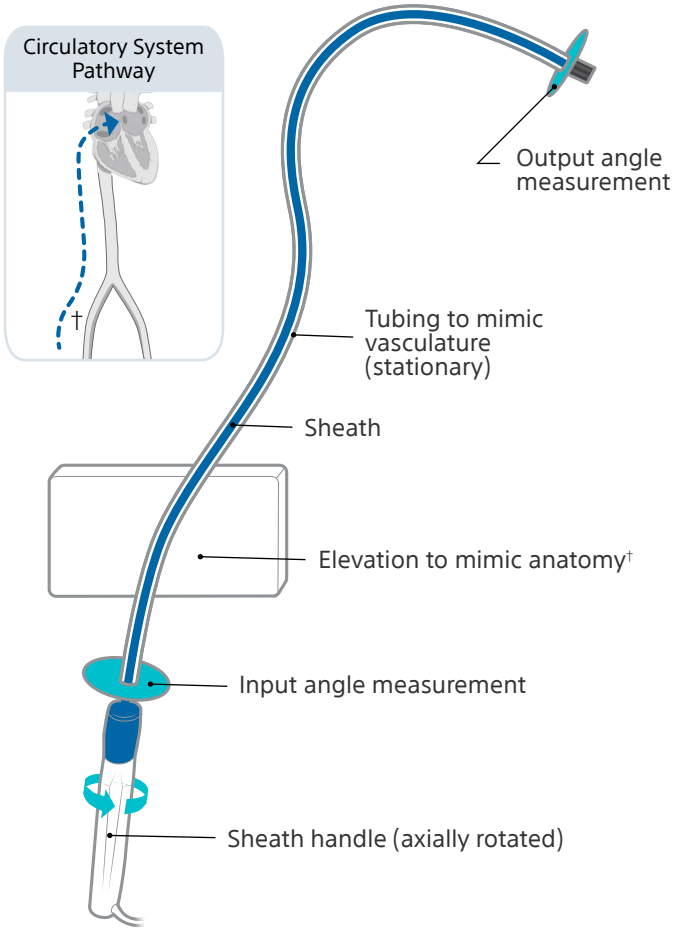

Figure 1. Axial rotation test setup

3) Tactile dial – Consistent neutral zone

The force-to-turn the dial in the neutral zone was measured to determine consistency in a sample of 15 **SureFlex™** Sheaths and 10 Agilis™ NxT Sheaths (medium curve size). Force-to-turn was measured using a custom rotational fixture (Figure 2).

Unless otherwise noted, figures represent the average performance in a data set with standard deviation error bars. Statistical analysis was performed using Student's t-test, where significance was considered to be $p<0.05$.

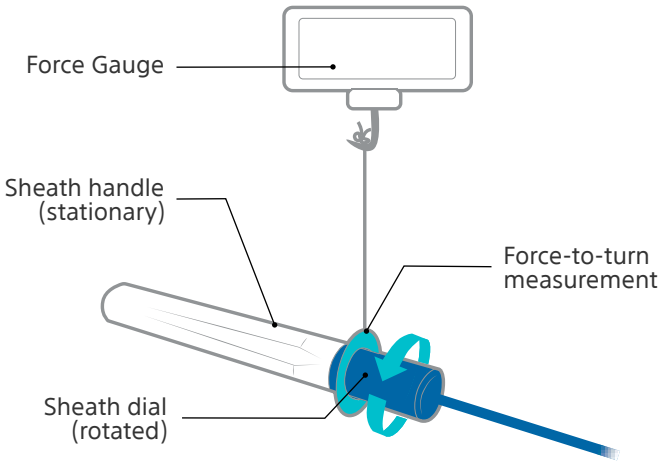

Figure 2. Tip deflection and dial tactile feedback test set-up

RESULTS AND DISCUSSION

1) Torque Transfer (Axial rotation) – Precise handling

The **SureFlex™** Sheath consistently delivered a 1:1 torque transfer along the length of the sheath, over a 360° rotation of the handle, whereas the Agilis™ NxT Sheath broke in two out of three cases at a rotation as low as 135° (Figure 3). Upon breaking, the Agilis™ NxT Sheaths no longer responded to input. Less efficient torque transfer may result in abrupt catheter movements, which have the potential to extend procedure time through increased difficulty reaching and remaining at target ablation sites.[5]

"The **SureFlex™** Sheath consistently delivered a 1:1 torque transfer [...] over a 360° rotation of the handle..."

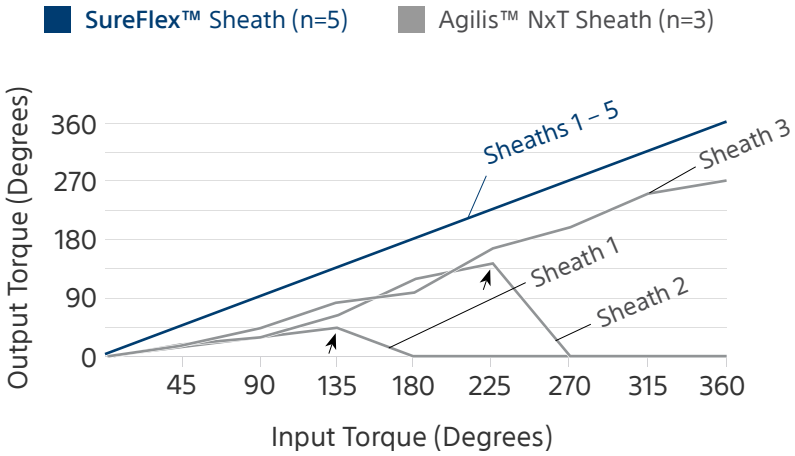

Figure 3. Individual sheath torque transfer (axial rotation) performance (arrows indicate sheath breakage)

2) Tip deflection – Responsive steering

The **SureFlex™** Sheath demonstrated a more linear force-rotation profile (Figure 4), with two times more consistency in force-to-turn the dial compared to the Agilis™ NxT Sheath ($p<0.05$). A consistent linear force-rotation profile suggests more responsive steering, fewer uncontrolled movements, and smoother dial rotation. This may contribute to greater control of distal tip deflection and overall steering precision.

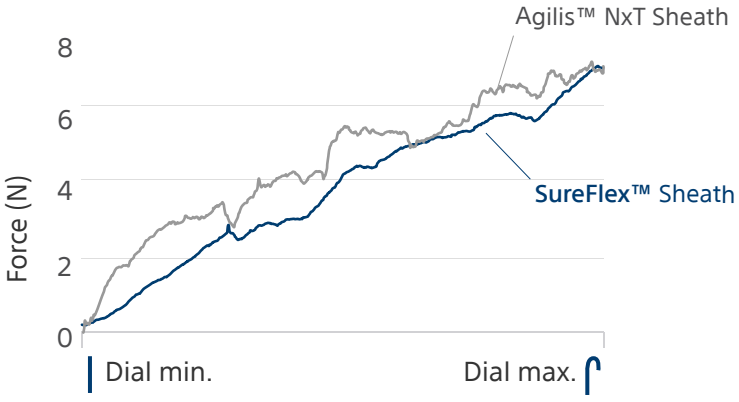

Figure 4. Force-rotation profiles from representative sample sheaths

3) Tactile dial – Consistent neutral zone

Compared to the Agilis™ NxT Sheath, the **SureFlex™** Sheath required 61.6% less force-to-turn the dial in the neutral zone.

The **SureFlex™** Sheath also demonstrated significantly more consistency in force-to-turn the dial in the neutral zone, compared to the Agilis™ NxT Sheath (Figure 5, $p<0.05$).

Less force-to-turn the dial and greater consistency in force-to-turn the dial allow physicians to more reliably detect the neutral zone. As a result, physicians can more reliably confirm sheath tip position and reduce their reliance on fluoroscopy.

"The **SureFlex™** Sheath also demonstrated significantly more consistency in force-to-turn the dial in the neutral zone..."

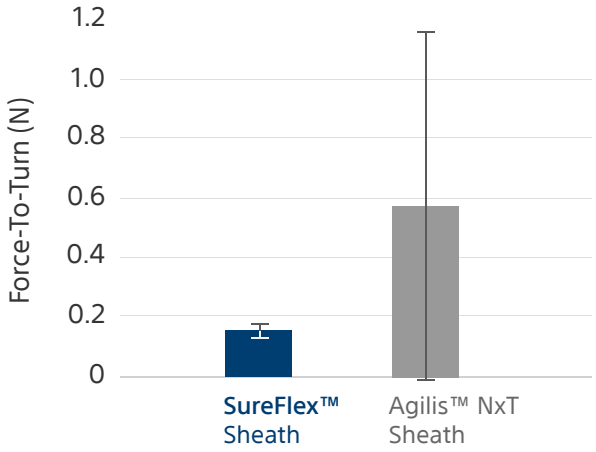

Figure 5. Average force-to-turn the dial in the neutral zone

CONCLUSION

The **SureFlex™** Steerable Guiding Sheath offers more precise handling, more responsive steering, and a more consistent neutral zone as compared to the Agilis™ NxT Steerable Introducer.

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† In bench testing conducted at Boston Scientific, a 'Maneuverability Factor' analysis was developed to mathematically determine the deviation from a linear profile for each plot.

Bench testing or pre-clinical study results may not necessarily be indicative of clinical performance. The testing was performed by or on behalf of Boston Scientific. Measurements taken by Boston Scientific. Actual values may differ. Data on file.

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