SUPERIOR TORQUE MATTERS:
A Comparison of Transseptal Guiding Sheaths

Leung L, PhD, Rees DJ, MASc, Oldham L, BASc.

ABSTRACT

Purpose

Access to the left side of the heart is required for various therapies, including pulmonary vein isolation, mitral valve repair, and left atrial appendage closure. The role of a transseptal sheath, dilator and needle varies in every procedure; however, the ability to precisely control the distal end of the sheath by manipulating the proximal end is universally necessary. This characteristic, known as torque transfer, may be imperative to the success of the procedure. The goal of this study was to investigate and compare the torque transfer of commonly used transseptal sheaths.

Methods

Four commonly used transseptal sheath kits were tested: the Baylis TorFlex™ Transseptal Sheath, St. Jude Medical Swartz™ Braided Transseptal Guiding Introducer, St. Jude Medical Fast-Cath™ Guiding Introducer, and Biosense Webster Preface® Guiding Sheath. Three configurations of each sheath were tested: the sheath by itself, the sheath and dilator set, and the sheath, dilator and needle assembly. Torque testing was measured with a torque sensor and meter using a custom fixture to rotate each sample 90° clockwise and counter-clockwise from neutral.

Results

The braided 8F and 8.5F Baylis TorFlex™ Transseptal Sheaths had the highest torque transfer in all configurations tested ($p<0.01$).

Conclusion

In all configurations tested, the Baylis TorFlex™ Transseptal Sheath demonstrated significantly superior torque transfer, which provides control and maneuverability.

INTRODUCTION

Access to the left side of the heart is required for various therapies, including pulmonary vein isolation, mitral valve repair, and left atrial appendage closure. These procedures are typically performed through an atrial septal puncture.[1,2] After access to the left atrium is achieved, the role of a transseptal sheath and dilator set differs depending on the therapy being performed. Although the use of the sheath may vary, the ability to precisely control the distal end of the sheath during the atrial septal puncture is a common requirement.

Prior to dropping down the sheath, dilator, and needle assembly from the superior vena cava (SVC) to engage the fossa ovalis, the device assembly is clocked.[3,4] During this step, it is critical that the user can precisely control the distal end of the device assembly, by manipulating the proximal end (i.e. the device assembly has adequate torque transfer). This control is particularly important because the puncture location affects the trajectory of the therapy delivery device and thus is critical to the success of the subsequent procedure.[5-7] After gaining access to the left atrium, the user requires continued control of the distal end of the sheath in order to ablate at various target locations with RF energy. Due to the importance of torque transfer, the goal of this study was to investigate and compare the torque transfer of commonly used transseptal sheaths.

METHODS

Several commonly used transseptal sheath kits were tested: the Baylis TorFlex™ Transseptal Sheaths (8F & 8.5F, models TF8-32-63-55 & TF85-32-63-37), St. Jude Medical Swartz™ Braided Transseptal Guiding Introducer (8.5F, model 407454), St. Jude Medical Fast-Cath™ Guiding Introducer (8F, model 406840), and Biosense Webster Preface® Guiding Sheath (8F, model 301803M). A Baylis NRG® Transseptal Needle (model NRG-89-C0) was used to test the complete sheath, dilator, and needle assembly. All samples were soaked in a water bath at 37°C for at least 2 hours to mimic the body environment, and each sample was immediately tested upon removal from the water bath. Five samples of each model were tested to determine the mean torque transfer. Separate t-tests were used to compare the Baylis TorFlex™ sheath to the other devices. Statistical significance was considered to be $p<0.05$.

Three configurations of each sheath were tested: the sheath by itself, the sheath and dilator set, and the sheath, dilator and needle assembly.

> "All samples were soaked in a water bath at 37°C for at least 2 hours to mimic the body environment..."

These configurations were selected based on their importance during the various steps of left heart access, specifically while guiding therapy devices, tracking to the SVC, and controlling puncture location.

The torque testing was performed using a custom fixture, where the devices were clamped both at the proximal and distal ends (**Figure 1**). Torque transfer was measured using a torque meter and sensor (model numbers BGI and STH50OZ, respectively, Mark 10, NY, USA) attached to the fixture. Each sample was rotated 90° both clockwise and counter-clockwise from neutral at the distal end. The maximum torque measured in each direction of rotation was recorded, and the average of the readings in the two directions was calculated.

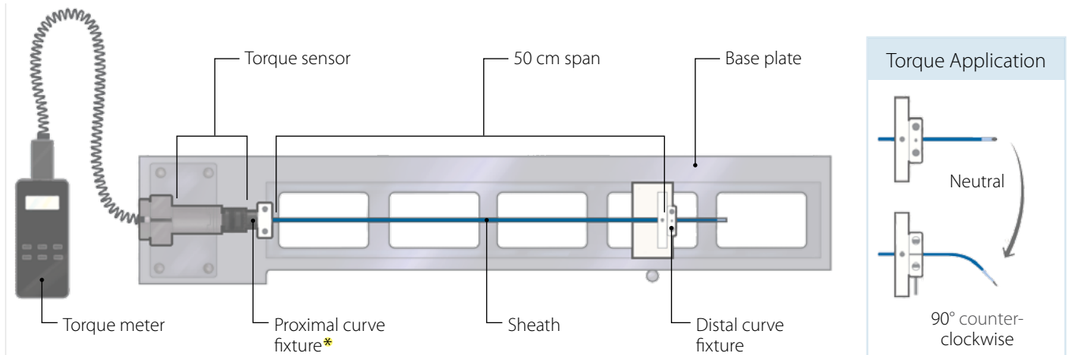

Figure 1 *Torque transfer test setup (superior view)*

RESULTS & DISCUSSION

SHEATH ALONE

When testing the sheaths without a dilator or needle, the 8F and 8.5F Baylis TorFlex™ braided sheaths were found to have the highest torque transfers.

When comparing the 8F sheaths, the braided design had a significant effect on the device's torque transfer. The St. Jude Medical Fast-Cath™ sheath is a non-braided construction, and as a result, had the lowest torque transfer of the sheaths tested. The braided 8F Baylis TorFlex™ sheath in comparison transferred 200% more torque than the St. Jude Medical Fast-Cath™ sheath ($p<0.01$). With the addition of a braid in the shaft, the torque transfer improves, but significant differences between the TorFlex™ sheath and the other sheaths were observed, showing that the material selection and braid design affect the device's torque transfer. Specifically, the 8F Baylis TorFlex™ sheath transferred over 35% more than the Biosense Webster Preface® sheath ($p<0.01$) and the 8.5F Baylis TorFlex™ sheath transferred 100% more torque than the St. Jude Medical Swartz™ sheath ($p<0.01$) (**Figure 2**).

> "...the 8F and 8.5F Baylis TorFlex™ braided sheaths were found to have the highest torque transfers."

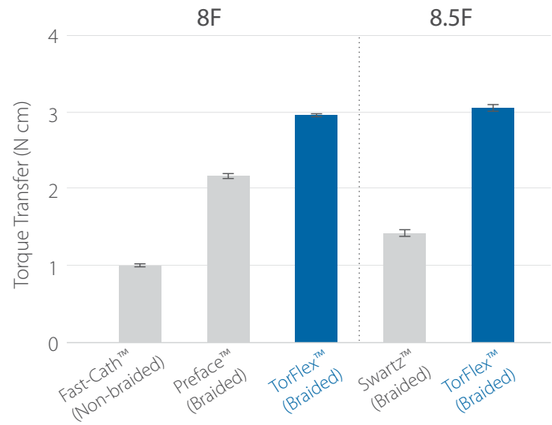

Figure 2 *Torque transfer of sheaths*

SHEATH & DILATOR

With the dilator inserted into the sheath, the 8F and 8.5F Baylis TorFlex™ sheath and dilator sets continued to transfer significantly more torque than the other sheaths (**Figure 3**). The 8F transferred over 200% more torque than the non-braided St. Jude Medical Fast-Cath™ sheath ($p<0.01$). Compared to the braided sheaths tested, the 8F Baylis TorFlex™ sheath transferred 30% more than Biosense Webster Preface® sheath ($p<0.01$) and the 8.5F Baylis TorFlex™ sheath transferred 82% more than the St. Jude Medical Swartz™ sheath ($p < 0.01$).

> "...the 8F and 8.5F Baylis TorFlex™ sheath and dilator sets continued to transfer significantly more torque than the other sheaths."

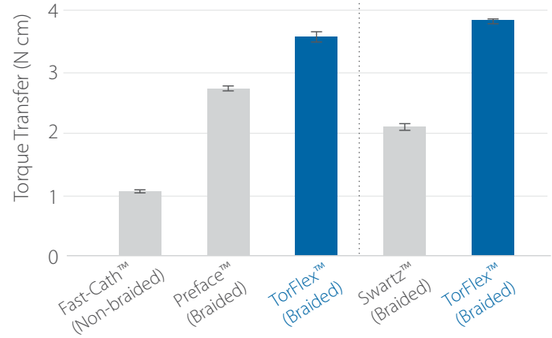

Figure 3 *Torque transfer of sheath and dilator set*

SHEATH, DILATOR & NEEDLE

Lastly, with the dilator and NRG® transseptal needle inserted into the sheath, the 8F Baylis TorFlex™ sheath, dilator and needle assembly had a torque transfer that was 41% more than the St. Jude Medical Fast-Cath™ sheath ($p<0.01$) and 15% more than the Biosense Webster Preface® sheath ($p<0.01$) (Figure 4). The 8.5F Baylis TorFlex™ sheath, dilator and needle assembly had 32% more torque transfer than the St. Jude

Medical Swartz™ sheath ($p<0.01$).

To provide a comparison to the NRG® transseptal needle, the St. Jude Medical BRK™ transseptal needle was tested and the same trends and statistical significance were observed. This indicates that the results were not affected by the needle used during testing.

> "...the 8F Baylis TorFlex™ sheath, dilator and needle assembly had a torque transfer that was 41% more than the St. Jude Medical Fast-Cath™ sheath."

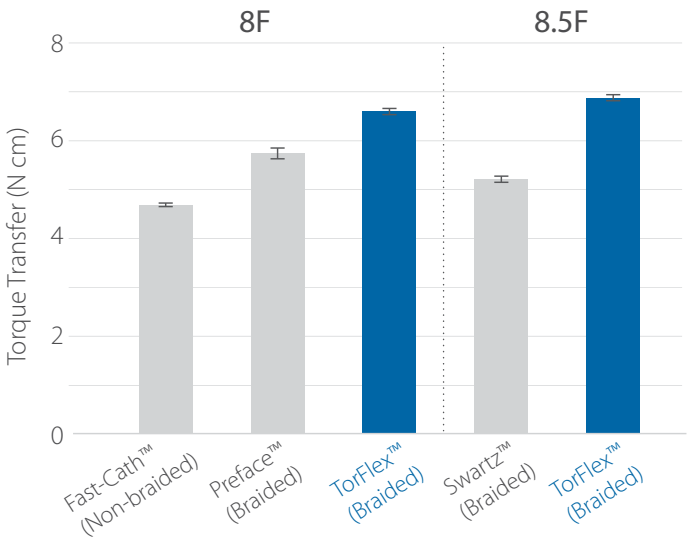

Figure 4 *Torque transfer of sheath, dilator and needle assembly*

CONCLUSION

Four transseptal guiding sheath kits were tested via direct comparison, for their ability to transfer torque from the user to the distal tip of the device. In all configurations tested, the Baylis TorFlex™ Transseptal Sheaths (8F & 8.5F) demonstrated significantly superior torque transfer, which provides control and maneuverability.

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Baylis MEDICAL

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

Tel.: (514) 488-9801 / Fax: (514) 488-7209
www.baylismedical.com / info@baylismedical.com