

Superior Torque Matters

A comparison of Transseptal Guiding Sheaths

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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 **TorFlex™** Transseptal Sheath (Baylis Medical®), 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 **TorFlex™** Transseptal Sheaths had the highest torque transfer in all configurations tested ($p < 0.01$).

Conclusion

In all configurations tested, the **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. that 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 **TorFlex™** Transseptal Sheaths (8F and 8.5F, models TF8-32-63-55 and 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). An **NRG™** Transseptal Needle (model NRG-89-C0, Baylis Medical*) 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 **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 STH500Z, 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.

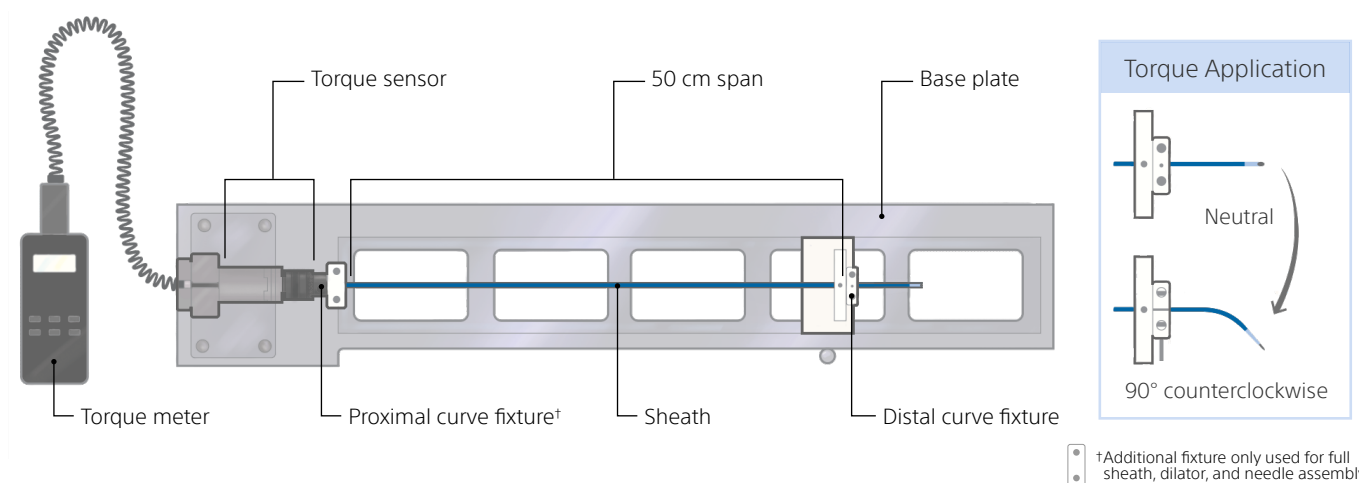


Figure 1. Torque transfer test setup (superior view)

RESULTS AND DISCUSSION

SHEATH ALONE

When testing the sheaths without a dilator or needle, the 8F and 8.5F **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 8F **TorFlex™** Braided Sheaths in comparison

“...the 8F and 8.5F TorFlex™ Braided Sheaths were found to have the highest torque transfers.”

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 **TorFlex™** Sheath transferred over 35% more than the Biosense Webster Preface® Sheath ($p < 0.01$) and the 8.5F **TorFlex™** Sheath transferred 100% more torque than the St. Jude Medical Swartz™ Sheath ($p < 0.01$) (Figure 2).

SHEATH AND DILATOR

With the dilator inserted into the sheath, the 8F and 8.5F **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 **TorFlex™** Sheath transferred 30% more than Biosense Webster Preface® Sheath ($p < 0.01$) and the 8.5F **TorFlex™** Sheath transferred 82% more than the St. Jude Medical Swartz™ Sheath ($p < 0.01$).

“...the 8F and 8.5F TorFlex™ Sheath and dilator sets continued to transfer significantly more torque than the other sheaths.”

SHEATH, DILATOR, AND NEEDLE

Lastly, with the dilator and the **NRG™** Transseptal Needle inserted into the sheath, the 8F **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 **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.

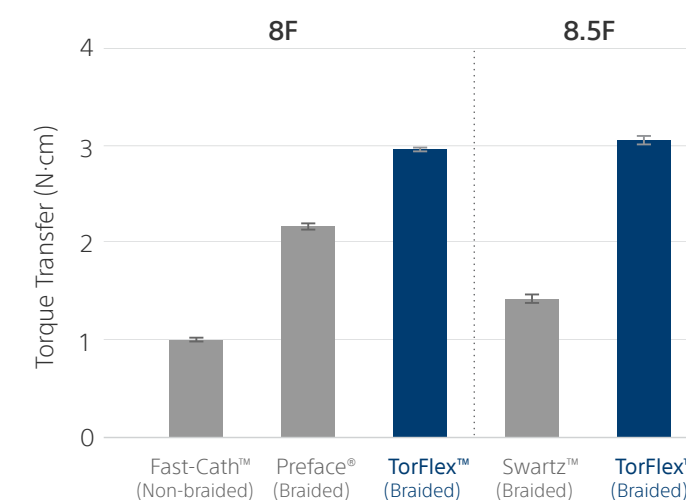


Figure 2. Torque transfer of sheaths

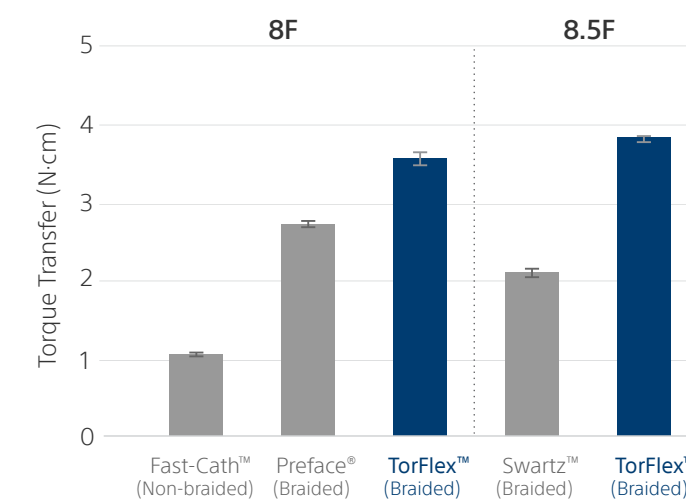


Figure 3. Torque transfer of sheath and dilator set

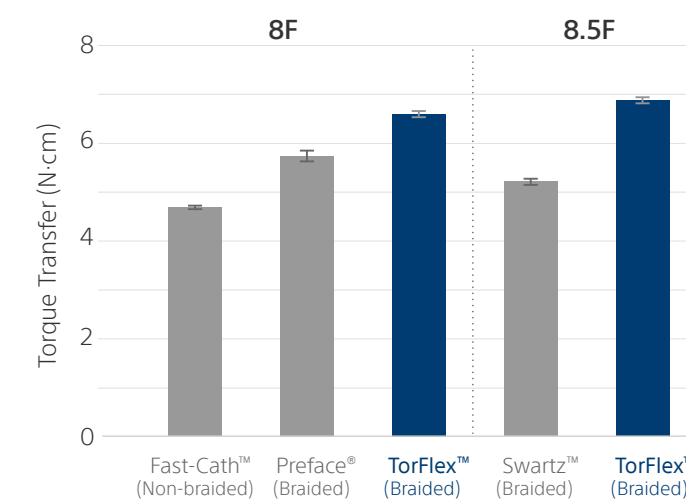


Figure 4. Torque transfer of sheath, dilator, and needle assembly



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 8F and 8.5F TorFlex™ Sheath demonstrated significantly superior torque transfer, which provides control and maneuverability.

“...the 8F TorFlex™ Sheath, dilator, and needle assembly had a torque transfer that was 41% more than the St. Jude Medical Fast-Cath™ Sheath...”

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TorFlex™ Transseptal 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 TorFlex™ Transseptal Guiding Sheath kit is used for the percutaneous introduction of various types of cardiovascular catheters and guidewires to all heart chambers, including the left atrium via transseptal perforation / puncture.

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 TorFlex™ Transseptal Guiding Sheath kit is intended for single patient use only. Do not attempt to sterilize and reuse the TorFlex™ Transseptal Guiding Sheath kit. Reuse can cause 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. • Careful manipulation must be performed to avoid cardiac damage or tamponade. Sheath advancement should be done under fluoroscopic guidance. Echocardiographic guidance is also recommended.

PRECAUTIONS: • Careful manipulation must be performed to avoid cardiac damage, or tamponade. Sheath, dilator and guidewire advancement should be done under fluoroscopic guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the device.

ADVERSE EVENTS: Adverse events that may occur while using the TorFlex™ Transseptal Guiding Sheath kit include: • Infection • Air embolus • Local nerve damage • Hemorrhage • Embolic events • Vessel spasm • AV fistula formation • Atrial septal defect • Pseudoaneurysm • Perforation and/or tamponade • Arrhythmias • Pericardial/pleural effusion • Hematoma • Vessel trauma • Valve damage • Catheter entrapment

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NRG™ Transseptal Needle

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 NRG™ Transseptal Needle is used to create an atrial septal defect in the heart. Secondary indications include monitoring intracardiac pressures, sampling blood, and infusing solutions.

CONTRAINDICATIONS: The NRG™ Transseptal Needle is not recommended for use with any conditions that do not require cutting or coagulation of soft tissue.

WARNINGS: • Laboratory staff and patients can undergo significant x-ray exposure during radiofrequency puncture 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 NRG™ Transseptal Needle is intended for single patient use only. Do not attempt to sterilize and reuse the needle. • During power delivery, the patient should not be allowed to come in contact with ground metal surfaces. • Thoroughly flush the NRG™ Transseptal Needle with heparinized saline solution prior to use. • If using electroanatomical mapping guidance it is recommended to confirm tip placement on the fossa ovalis and septal tenting before RF puncture with graphic imaging or another imaging modality.

PRECAUTIONS: • Placement of the dispersive electrode on the thigh or hip could be associated with higher impedance. • In order to prevent the risk of ignition make sure that flammable material is not present in the room during RF power application. • Careful needle manipulation must be performed to avoid cardiac damage, or tamponade. Needle advancement should be done under image guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the needle. • During power delivery, the patient should not be allowed to come in contact with ground metal surfaces. • Thoroughly flush the NRG™ Transseptal Needle with heparinized saline solution prior to use. • If using electroanatomical mapping guidance it is recommended to confirm tip placement on the fossa ovalis and septal tenting before RF puncture with graphic imaging or another imaging modality.

ADVERSE EVENTS: Adverse events that may occur while using the Baylis Medical Radiofrequency Puncture System include: • Tamponade • Sepsis/Infection • Thromboembolic episodes • Vessel perforation • Atrial Fibrillation • Myocardial Infarction • Vessel spasm • Sustained arrhythmias • Atrial Flutter • Hemorrhage • Vascular thrombosis • Perforation of the myocardium • Hematoma • Allergic reaction to contrast medium • Ventricular Tachycardia • Pain and Tenderness • Thermal damage to tissue • Arteriovenous fistula • Pericardial Effusion

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