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Comparison of Transseptal Puncture Using a Dedicated RF Wire Versus a Mechanical Needle With and Without Electrification in an Animal Model

HIGHLIGHTS

- In an ex vivo study, mechanical puncture using the FlexCath Cross™ (formerly known as AcQCross™)* Transseptal Solution (FC) required more force and device advancement than purpose-built radiofrequency (RF) puncture with the **VersaCross™** RF Transseptal Solution (VC).
- VC (~10 W) achieved 100% transseptal puncture (TSP) success.
- FC required more power (30 W) to achieve 91% TSP success, and was associated with tissue charring, larger septal defects, and tissue coring in 57% of punctures.

INTRODUCTION

- The application of electrocautery to needles and guidewires for TSP as an alternative to dedicated RF systems may be associated with increased safety risks, such as tissue coring and thermal damage.
- This study compared the safety and efficacy of two commercially available transseptal systems:
  - **VersaCross™ RF Transseptal Solution (Boston Scientific):** An RF wire with a discrete, rounded electrode powered by the dedicated RFP-100A Generator†
  - **FlexCath Cross™ Transseptal Solution (Medtronic)*:** An open-ended, deployable mechanical needle powered by a standard electrosurgical generator.

METHODS

- **In vivo experiments:** RF puncture was performed on live swine with intracardiac echocardiography and fluoroscopy guidance, and evaluated for possible tissue cores.
- **Ex vivo experiments:** Punctures were performed on freshly excised swine septa (Table 1) in 100% egg white solution, which has similar electrical conductivity as human blood.
  - Mechanical force and device displacement were measured using an Instron mechanical tester (Instron).
  - Qualitative assessment of defect size and tissue charring was performed post-puncture using an optical microscope.
  - Tissue coring was confirmed using Masson's trichrome staining and blinded pathology analysis.

Transseptal Device	Puncture Method
VersaCross RF Transseptal Solution	RF: 1 s constant mode (~10 W)
FlexCath Cross Transseptal Solution*	Mechanical force RF: 10 W (up to 5 attempts) 20 W, 30 W (up to 2 attempts each)

Table 1. TSP settings for ex vivo experiments.

RESULTS

Efficacy

- VC achieved 100% TSP success with ~10 W power and required only 1.0 ± 0.0 attempts (Figure 1A).
- FC required a greater amount of power (30 W) and 1.53 ± 0.51 attempts to achieve 91% puncture success (FC failed to puncture at 10 W and 20 W) (Figure 1A).

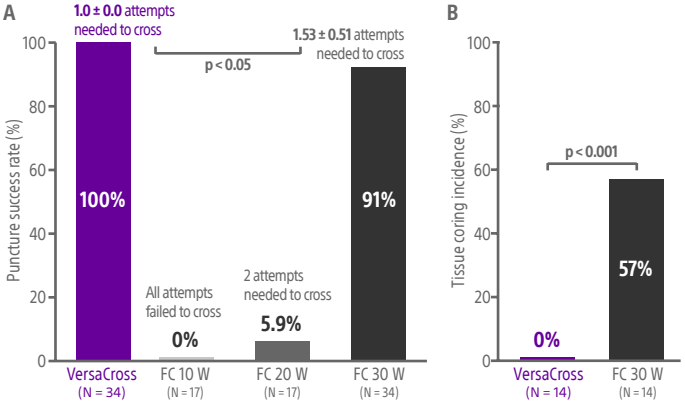

Figure 1. Compared to the FlexCath Cross (FC) system, (A) the VersaCross system required fewer puncture attempts and less power to achieve transseptal puncture, and (B) had zero incidence of tissue coring.

Safety

- In vivo TSP in swine using FC at 30 W resulted in multiple particulates that may have included tissue cores.
- Mechanical puncture with the FC needle required 6x more force and 8 mm more device advancement compared to RF puncture using VC ($p < 0.05$).
- FC needle punctures with 30 W of energy were associated with more tissue charring and larger defects.
- Tissue cores (0.5 – 3.2 mm) were observed in 57% of successful punctures using electrified FC needles (Figure 1B).

DISCUSSION AND CONCLUSIONS

- Excessive force and displacement using a sharp-tipped mechanical needle risks unintended puncture and injury.
- For energy-assisted TSP, electrode current density at the tissue interface and RF generator energy waveform impact TSP efficacy and safety.
  - 100% TSP success was achieved with 1 energy application using the purpose-built VersaCross system.
  - The open-ended FlexCath Cross needle required higher power and multiple energy applications for RF TSP, and was associated with tissue coring.
- These findings corroborate previous studies showing purpose-built RF devices improve TSP consistency and reliability in patients with varying anatomies[1,2], and have lower risk of thermal damage and tissue coring vs. non-dedicated devices.[3,4]

* This study was performed using the AcQCross™ Transseptal Access System, which is now rebranded as the FlexCath Cross™ Transseptal Solution, Medtronic.
† Baylis Medical Company Radiofrequency Puncture Generator RFP-100A. Baylis Medical Company is a wholly-owned subsidiary of Boston Scientific Corporation.

Brief Summary | **VersaCross™** RF Wire

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 VersaCross™ RF Wire is indicated for creation of an atrial septal defect in the heart.

CONTRAINDICATIONS: The VersaCross™ RF Wire is not recommended for use with any conditions that do not require the creation of an atrial septal defect. The Connector Cable is not recommended for use with any other Baylis RF Generator or any other device.

WARNINGS: • Laboratory staff and patients can undergo significant x-ray exposure during RF 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 VersaCross™ RF Wire and Connector Cable are intended for single patient use only. Do not attempt to sterilize and reuse either devices. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another. Reuse may result in patient complications. • The VersaCross™ RF Wire must be used with the Connector Cable provided. Attempts to use it with other connector cables can result in electrocution of the patient and/or operator. • Do not use the VersaCross™ RF Wire with electrocautery or electrosurgery generators, connector cables or accessories as attempted use can result in patient and/or operator injury. • The Connector Cable must only be used with the RFP-100A Baylis RF Generator and the included VersaCross™ RF Wire. Attempts to use it with other RF Generators and devices can result in electrocution of the patient and/or operator. • The VersaCross™ RF Wire must be used with 0.035" compatible transseptal sheath and/or dilator devices. Use of incompatible accessory devices may damage the integrity of the VersaCross™ RF Wire or accessory devices and may cause patient injury. • The VersaCross™ RF Wire has only been validated for transseptal puncture use through VersaCross™ dilators which have been demonstrated to provide the required support for optimal function. • The VersaCross™ RF Wire is not intended for use with neonatal patients (i.e. less than one month of age). Do not attempt to treat neonatal patients with the VersaCross™ RF Wire.

PRECAUTIONS: • In order to prevent the risk of ignition, ensure that flammable materials are not present in the room during RF power application. • Careful manipulation of the VersaCross™ RF Wire must be performed to avoid vessel trauma. If resistance is encountered, DO NOT use excessive force to advance or withdraw the VersaCross™ RF Wire or ancillary sheath and/or dilator assembly. Excessive force may lead to bending or kinking of the device limiting advancement and retraction of sheath and/or dilator device. • The Baylis RF Generator is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the VersaCross™ RF Wire and/or DIP electrode, particularly when operating the device. • During power delivery, the patient should not be allowed to come in contact with ground metal surfaces. • If using electroanatomical mapping guidance, it is recommended to use it along with alternative imaging modality in the event there is loss of visibility of the device.

ADVERSE EVENTS: Adverse events that may occur while creating an atrial septal defect 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 • Arteriovenous fistula • Pericardial effusion • Tachycardia • Vascular Trauma • Additional Surgical Procedure • Wire entrapment/ entanglement • Foreign body/wire fracture

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Brief Summary | **VersaCross™** Transseptal Dilator

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 VersaCross™ Transseptal Dilator 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 VersaCross™ Steerable Sheath kit is intended for single patient use only. Do not attempt to sterilize and reuse the VersaCross™ Steerable Sheath kit. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another. Failure to follow this instruction may result in patient complications • Maintain continuous hemodynamic monitoring throughout procedure • Provide continuous heparinized saline infusion while the introducer remains in vessel.

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 VersaCross™ 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 • Thromboembolic events • Stroke • Valve damage • Myocardial infarction • Pacemaker/defibrillator lead displacement • Pulmonary edema • Coronary artery spasm and/or damage • Vessel trauma • Pericardial/pleural effusion

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Brief Summary | **VersaCross™** Transseptal 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 VersaCross™ Transseptal 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 VersaCross™ Transseptal Sheath kit is intended for single patient use only. Do not attempt to sterilize and reuse the VersaCross™ Transseptal Sheath kit. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another. • 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. • The VersaCross™ Transseptal Sheath is compatible with introducer sheaths 11Fr or larger. • The VersaCross™ Transseptal Sheath and Dilator are compatible with transseptal devices and guidewires .035" or smaller. • The VersaCross™ Transseptal Sheath kit is NOT compatible with transseptal needles such as the "NRG™ Transseptal Needle".

ADVERSE EVENTS: Adverse events that may occur while using the VersaCross™ Transseptal 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

EP-1506605-AA

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