

A new transeptal solution for enabling left atrial access of large delivery sheaths

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INTRODUCTION

- ▶ Obtaining transeptal access for delivery sheaths may be hindered by tissue resistance against the sheath-dilator stepped interface, which necessitates additional force that can:
 - Increase the risk of injury
 - Reduce procedural efficiency
 - Lead to procedural termination
- ▶ ExpanSure® Large Access Transeptal Dilator is a 12.5F single introducer and dilation device with a smooth sheath-dilator transition that can be used to advance transeptal needles and dilate the septum for left heart access of large sheaths.

METHODS

In Vitro Force Comparison:

- ▶ A pre-punctured 0.03" thick silicone membrane was used to model the interatrial septum.
- ▶ Crossing force was measured using an Instron® Testing System (Instron) as the ExpanSure® transeptal dilator or 8.5F Swartz™ SL1™ sheath and dilator (Abbott) were advanced through the silicone to model 'transeptal access'.
- ▶ The transeptal systems were exchanged for a WATCHMAN™ delivery sheath (Boston Scientific), and force was measured for both cases.

Case Series:

- ▶ ExpanSure® transeptal dilator was evaluated in its first clinical experience in a series (n=19) of left atrial appendage closure (LAAC) procedures.
- ▶ ExpanSure® transeptal dilator was used to introduce the NRG® Transeptal Needle (Baylis Medical) for transeptal puncture.
- ▶ ProTrack™ Pigtail Wire (Baylis Medical) was used to exchange the ExpanSure® transeptal dilator for WATCHMAN™ or Amulet™ (Abbott) implant delivery systems.
- ▶ Procedure time, success, fluoroscopy use, and complications were assessed in this series.
- ▶ Operator experience was surveyed for ease of septal crossing and integration into typical LAAC workflows.

RESULTS

- ▶ While advancing through the silicone model, 38% less work was required with the ExpanSure® transeptal dilator than the SL1™ dilator (p<0.001; Fig. 1-A).

- ▶ While advancing the WATCHMAN™ sheath through the silicone model, 20% less work was required when the silicone had been pre-dilated with ExpanSure® transeptal dilator than the SL1™ dilator (p<0.001; Fig. 1-B).
- ▶ Clinical experience showed smooth crossing of the ExpanSure® transeptal dilator regardless of the septal anatomy (e.g., fibrotic and aneurysmal) in addition to well integration with LAAC workflows.
 - Procedures were 100% successful, with no complications
 - Procedure time for delivery sheath access into the left heart was 16.8±11.4min

DISCUSSION & CONCLUSIONS

- ▶ Smooth sheath-dilator transition of the ExpanSure® transeptal dilator and reduced crossing force provides a potential solution to reduce septal tearing and tissue injury.
- ▶ Large (12.5F) diameter allowed tissue dilation to facilitate advancement of a large delivery sheath.
- ▶ Easy advancement of the delivery sheaths was achieved using the NRG® needle, ProTrack™ wire and ExpanSure® transeptal dilator which enabled the puncture, exchange, and effective dilation of the septum.
- ▶ The ExpanSure® transeptal dilator may be a key tool for improving efficiency of left atrial access for procedures requiring large sheaths.

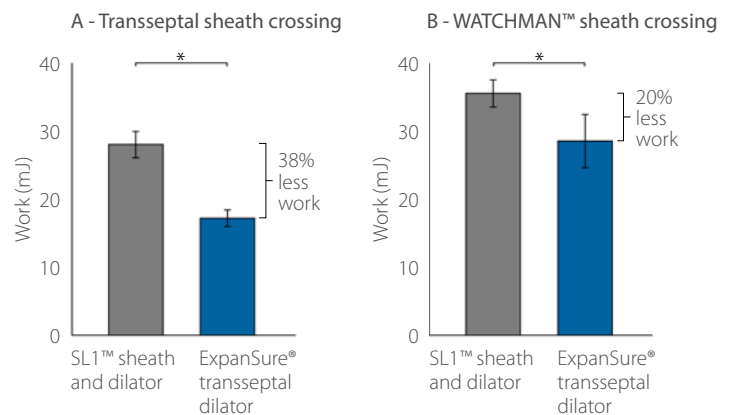


Figure 1: (A) Bench study showed 38% less work required to cross using the ExpanSure® transeptal dilator than a standard SL1™ sheath. (B) 20% less work was required to advance the WATCHMAN™ sheath after pre-dilating with the ExpanSure® transeptal dilator than a SL1™ sheath (n = 12; * p < 0.001).