



Development of a Prototype Trocar for Transluminal Therapeutic Interventions Using EUS



Shyam Varadarajulu MD,¹ Kenneth Binmoeller MD,² John Lunsford,³ Hoang Phan,³ Fiona Sander³

¹University of Alabama, ²California Pacific Medical Center, ³Xlumena, Inc.

Aim: This study compared a standard 19G FNA needle to three versions of a prototype (“Extending Blade”) trocar based on: (1) the force required to puncture porcine GI luminal tissue, and (2) the force required to subsequently pass large caliber catheters through the resulting puncture site.

Introduction

For EUS-guided therapeutic interventions such as pancreatic pseudocyst drainages, current techniques rely on the use of a 19 gauge FNA needle to gain initial access across the GI lumen. However, advancement of catheter-based devices through the incision created by these needles is technically difficult thereby necessitating progressive dilation of the luminal wall prior to undertaking endotherapy.



Partially deployed trocar blade

The EUS 2008 Working Group recommended development of specific devices to facilitate easy endotherapy. An echoendoscope-compatible prototype 19 gauge trocar was designed to create a tissue puncture, significantly larger than its own profile, to facilitate easier passage of larger catheter-based devices for one-step endotherapy.

Catheter Puncture & Insertion Forces

	19G	Trocar
Primary Puncture Force (g)	194	167
Insertion Force (g) 4mm balloon	357	24
Insertion force (g) 10mm balloon	381	218

Methods

Ex-vivo porcine stomachs were used to compare puncture forces of a 19 gauge EUS-FNA needle with 1, 2 and 3-blade versions of the prototype trocar passed via the biopsy channel of an echoendoscope. Subsequently, the force required to pass a 2.2mm dilating catheter and a 6mm balloon catheter through the punctures created by the FNA needle and prototype trocars were compared.

Results

The force required for initial puncture of the tissue using all three prototype trocars was equal to that applied using a 19 gauge FNA needle.

The force required to advance the 2.2mm dilating catheter through the tissue punctured using the prototype trocars was 8 times (range, 6-11) less than the force required to advance them via the 19 gauge needle puncture site.

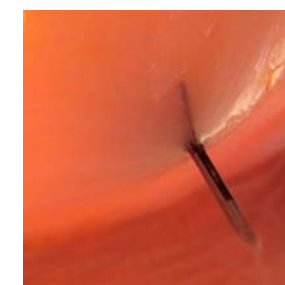
Also, the force required to advance the 6mm balloon catheter through the tissue punctured by the prototype trocars was 9 times (range 7-11) less than the force required to advance them via the 19 gauge needle puncture site.



Fully-deployed trocar blade

Conclusion

Initial access created by the echoendoscope-compatible prototype trocar obviates the need for progressive dilation of the GI luminal wall and could potentially facilitate easier one-step transluminal endotherapy.



Trocar tip and blade during incision



Trocar tip and blade after incision

Disclosures: Drs. Varadarajulu and Binmoeller serve as Advisors to Xlumena.