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Stepwise Development & Commercialization of a Modern Navigable Tubular Access Assembly System Through a Multidisciplinary Startup-Academic Collaboration

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DISCLOSURES:

Elizabeth Hagerman and Brian Dougherty are employees of Rose-Hulman Ventures & received consulting fees from NICO Corporation.

Martina Cartwright, PhD has received employee compensation and consulting fees from NICO Corporation and has been a co-author of NICO publications. Dr. Cartwright is also on the Abbott Nutrition speaker's bureau and receives consulting fees from Cassiopea SpA Dermatology.

Joseph Mark is an employee and shareholder of NICO Corporation.

INTRODUCTION:

The conceptual benefits of using a cylindrical tube for brain retraction was introduced 30 years ago. However, the ability to place the tube accurately and safely without damage to brain tissues remained elusive. Hence, a minimally disruptive trans sulcal access system was invented; it utilizes a navigable tubular retractor that creates a non-disruptive trans sulcal surgical corridor, simultaneously protecting the cortex, white matter, vasculature & fascicular anatomy via tissue displacement. This system approach lends to functional preservation & improved outcomes.

We describe the steps & timeline involved in creating a navigable tubular access assembly system (NTAAS) from vision to commercialization, address design, regulation, patent & production challenges.

METHODS:

A scientist/inventor, neurosurgeon & academic engineers collaborated to create a NTAAS that follows the natural sulcal folds of the brain to reach tumors/vascular abnormalities. Initial prototypes were tested in pigs & human cadavers. The patented NTAAS is made from a light-weight aluminum alloy & plastic. Through live surgical observations & clinician feedback more than 20 individual product characteristics were considered before the NTAAS was ready for commercialization.

RESULTS:

Several prototyping & manufacturing runs were required to demonstrate consistent reproducibility. The NTAAS patent application was filed 1/24/2011 & issued 9/26/2017 (Pat .No. 9,770,261). FDA 510K was filed 3/7/2012 & granted 6/5/2012.

The patented NTAAS consists of an inner obturator & outer sheath. (Figure 1).

The obturator tip is configured to gently dilate the sulcal opening from 1.9 to 13.5mm in a single pass while the obturator & sheath glide along the sulcus, limiting abrasive damage. The uniquely designed sheath advances without trapping tissue or disrupting the pia. The distal outer sheath is contoured, mitigating potential parenchyma breech during manipulation. (Figure 2). It is ergonomically designed & made of materials compatible with all imaging modalities. The NTAAS has been used in over 6,500 patient cases.

FIGURE 1: A. Sheath (clear) and obturator (blue). B. NTAAS device with obturator inserted into the sheath.

- Trans-sulcal access
- Image guided trajectiory-centric cannulation
- Designed to allow fluid to pass during access, creating a venting mechanism
- Reduces negative pressure
- Exoscopic visualization
- Degrees of freedom

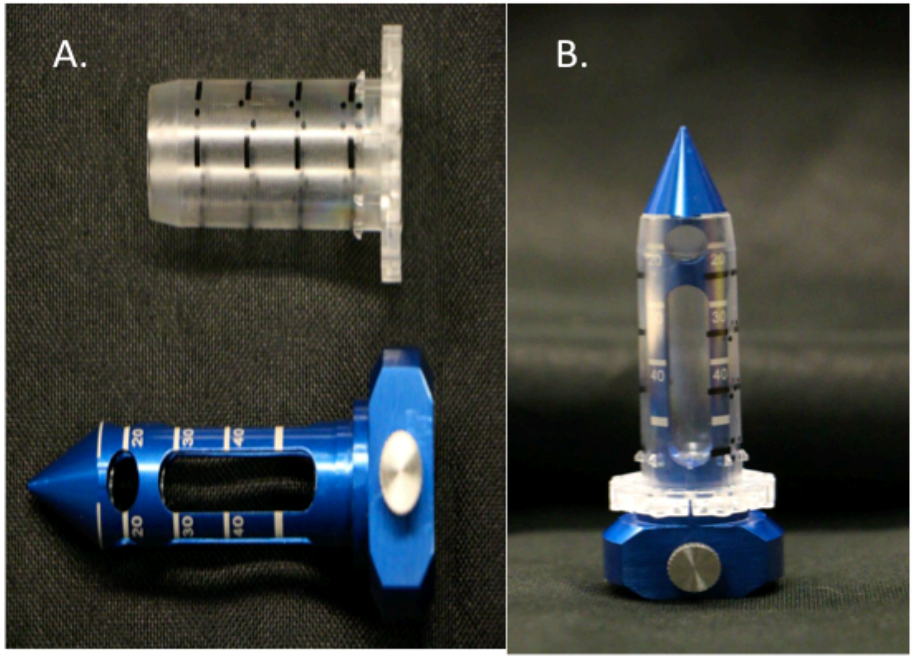
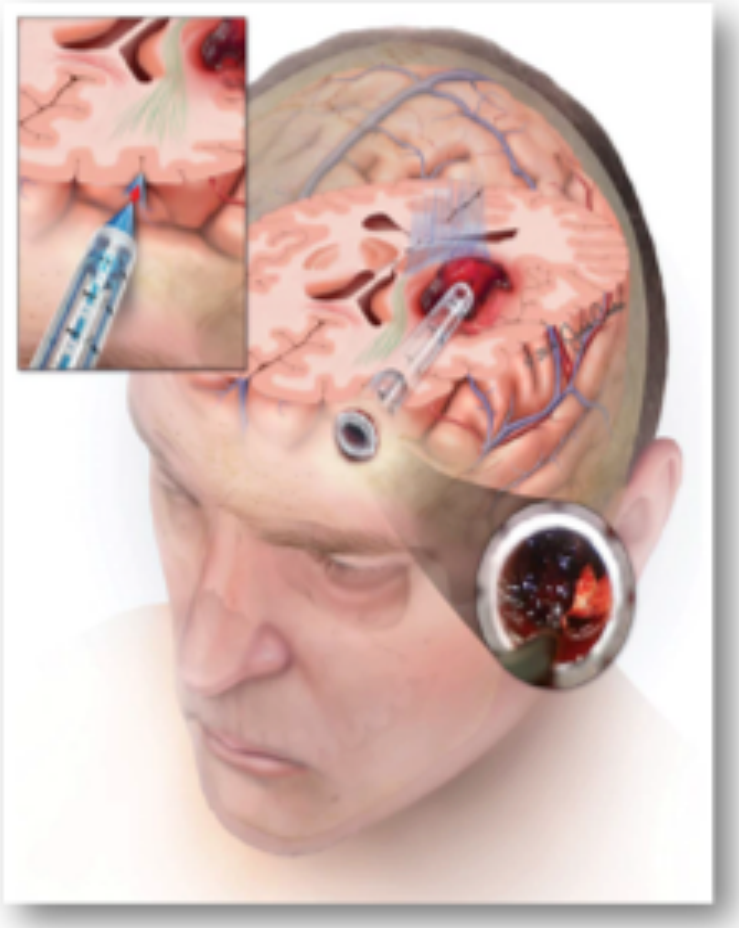
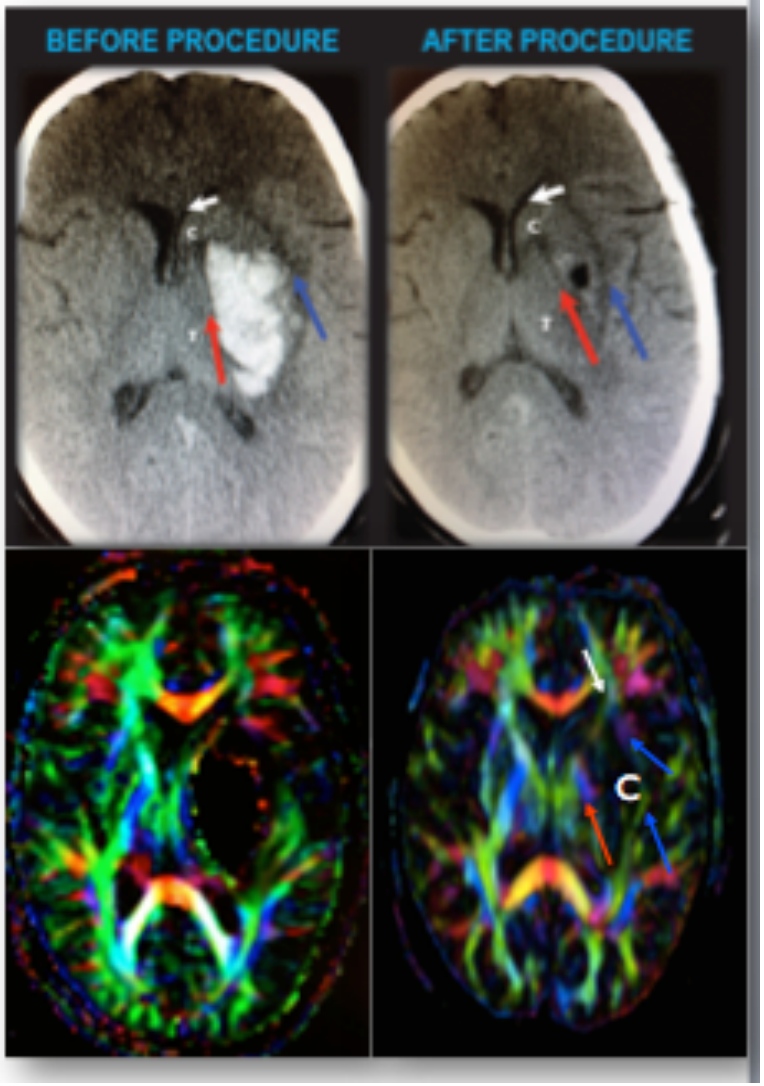


FIGURE 2





Source: Labib et al.. *Neurosurgery*. 2017;80(4): 515-524.

DISCUSSION:

The process of inventing, manufacturing, & commercializing life changing medical devices can be rewarding. Traditional academic-venture capital funded startup company partnerships often encounter barriers to funding, regulatory approval challenges and research delays. Seeking to streamline innovation while controlling costs & risks, we describe the evolution of a medical device engineered to reach deep-seated brain tumors & vascular lesions. The successful engineering of prototypes & final commercialized products were achieved through partnership with a unique academic-affiliated professional cooperative of engineers committed to streamlining medical innovation.

SUMMARY POINTS:

- **Creating & commercializing innovative, clinically relevant devices requires collaboration between scientists, clinicians & engineers**
- **The process from idea to commercialization may take months to years**
- **Familiarity with the manufacturing, engineering, commercial and regulatory processes is beneficial to streamlining the overall process**