Hernia Spoon for Pediatric Inguinal Hernia Repair

Samantha Sterling
Amin Adibi

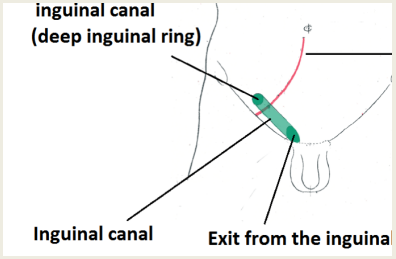
Supervised by
Dr. Geoffrey Blair

Need Statement

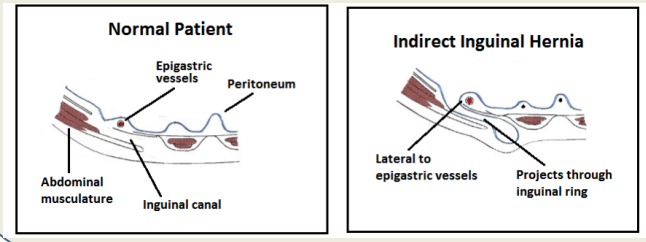
A low-cost method to manufacture hernia spoon retractors for pediatric inguinal hernia repair.

Disease State Fundamentals

Economic Impact
-Surgery done for about $90 in Uganda
-Reduces chance of complications and increased health care costs later in life

Inguinal Canal


Indirect Inguinal Hernia
Congenital- Peritoneal Sac Outside Body



Epidemiology
-1% to 5% of all newborns
-most common congenital abnormality
-most common pediatric surgery in newborns

Clinical Presentation
-Bulge near groin
-hard, red, painful lump
-vomiting, unwillingness to eat

Clinical Outcome: Incarcerated Hernia
-Sac= pathway for organs and fluid
-Trapped bowel => Intestinal necrosis/perforation
-Gonadal atrophy/necrosis
-Possibly fatal if untreated

http://teachmeanatomy.info/abdomen/areas/the-inguinal-canal/
http://www.pedsurg.ucsf.edu/conditions--procedures/inguinal-hernia.aspx
http://www.ncbi.nlm.nih.gov/pubmed/25270348

Treatment Options/Gaps

Current Treatment: Surgery

-Open: Local anesthetic, short procedure

-Laparoscopic: General anesthesia, longer procedure

The techniques exist, but the tools are hard to come by.

The Hernia Spoon

http://www.sages.org/wiki/pediatric-laparoscopic-inguinal-hernia-repair-a-review-of-techniques/
https://www.facs.org/~/media/files/education/patient%20ed/pediatricinguinal.ashx
http://www.pediatricurologybook.com/inguinal_hernia.html

Market Analysis

Criteria	Attribute
Market Size	- Half of elective pediatric surgeries in sub-Saharan Africa - Estimated at 75,000 annual cases in Uganda - 131 operating hospitals in Uganda (2010)
Market Dynamics	No competition. Small market. Low profitability. Potentially high healthcare impact. Regulatory requirements.
Market Needs	The need for the instrument is clearly there, but remains unmet due to financial barriers.
Willingness to Pay	Surgery costs ~$90. High rate of adoption expected only if the instrument is highly affordable (<$25).

Ohene-Yeboah, M., and F. A. . "Inguinal hernia disease in Africa: a common but neglected surgical condition." *West African journal of medicine*30.2 (2011): 77-83.
2015 Revision of World Population Prospects, United Nations. Accessible at http://esa.un.org/unpd/wpp/
http://onlinelibrary.wiley.com/doi/10.1002/bjs.9457/epdf
http://www.ubos.org/onlinefiles/uploads/ubos/pdf%20documents/PNSD/2010MOHStatAbst.pdf

Preliminary Stakeholder Analysis

Stakeholder	Primary Benefits	Primary Costs	Net Impact
Patients	Provides good retraction during the surgery, making the procedure easier to perform and thus less prone to complications.	none.	**Positive:** Expected to to improve recovery tome and decrease tissue damage and potential complications.
Pediatric Surgeons	Improved access, comfort and handling of the tissue during procedure makes to procedure significantly easier to perform.	none.	**Positive:** Improved access and handling of the tissue during procedure.
Facilities (Sterilization)	none.	none. The same sterilization procedure that is used for most common surgical instruments can be used.	**Neutral:** No need for any change in procedures.
Healthcare System	Improved care, reduced complication rate.	Increased cost.	**Positive:** If instrument is low cost (<$20)
Manufacturer	Positive Impact on Public and Community Relation.	Manufacturing cost.	**Positive:** If instrument is low cost (<$20)

Regulatory Requirements

FDA Class I Device, Subject to FDA General Controls:

- Establishment Registration
- Quality Control and GMP
- Product Listing
- Adulteration and Misbranding
- etc.

Device	Retractor
Regulation Description	Manual surgical instrument for general use.
Regulation Medical Specialty	General & Plastic Surgery
Review Panel	General & Plastic Surgery
Product Code	GAD
Premarket Review	Office of Device Evaluation (ODE) Division of Surgical Devices (DSD) General Surgery Devices Branch Two - Surgical (GSDB2)
Submission Type	510(K) Exempt
Regulation Number	878.4800
Device Class	1
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No

Uganda Requirements:

Three pathways:

- Track 1: Device licensed in EU, Australia, Japan, US or Canada.
- Track 2: Device Manufactured in EU, Australia, Japan, US or Canada in an QC accredited facility (ISO 13485, ISO 13488, QS1128 or 21 CFR part 82)
- Track 3: Preclinical Testing

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/ucm055910.htm
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm
http://www.nda.or.ug/docs/reg3.pdf

a place of mind

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