Team D3

Project Design Report

Device for the Controlled Reduction of Pediatric Intussusception

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IntussAssist

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II. Executive Summary

Intussusception is a life-threatening condition that affects thousands of infants each year and is characterized by the folding of the bowel over an adjacent segment, causing an obstruction that, if left untreated, can lead to tissue necrosis and patient death. However, if diagnosed early enough, intussusception may be resolved through pneumatic reduction, where the patient's bowel is pressurized with air in order to push out the obstruction.

Currently, reduction is performed using a Shiels Reduction Device, which is essentially composed of a hand aneroid pump, an enema tip, and a plastic tube connecting the two. While the pediatric radiologist would manually pump air to insufflate the patient's bowel, nurses and technicians would remain in the fluoroscopy room to constrain the child and squeeze the buttocks together in an attempt to provide a better seal. Through an extensive literature review of medical journals, multiple user interviews, and clinical observations, four major challenges were identified. Improper fit of the enema tip with the patient anatomy led to significant air leakage at the child device interface. A significant amount of fluid backflow into the plastic tubing was also observed. Additionally, the device provided barely any pressure regulation, with pressure fluctuations of 100mmHg occurring regularly. And lastly, due to the length and physically demanding nature of the tasks performed by the physician and nurses alike, the procedure resulted in significant user fatigue.

Team IntussAssist has set out to address these major challenges in order to create an improved solution for reduction of intussusception in children. Based on these challenges and other identified user needs, a design inputs table was created to narrow down the design space and establish clear metrics for success. The team generated multiple solutions through brainstorming and concept ideation stages. Patents of interest were searched for before and during the concept ideation stage. The concepts developed were narrowed down based on the potential to address the key identified challenges and a series of final designs were selected and improved upon to lead the team into the prototyping stage. The proposed solution consists of four components: an improved enema tip that can undergo conformational changes to allow for both an easy insertion and a better fit of patient anatomy, a fecal filtration system that

allows for one-way flow of air but prevents backflow of patient fluids, a pressure regulation unit that is compatible with hospital wall air sources and can automatically adjust air flow to deliver the desired pressure into the patient's bowel, and a handheld controller that allows the physician to adjust the set pressure, monitor the actual pressure and terminate the procedure in the case of an emergency. Future work required to validate the proposed design includes testing to the standards identified in the design inputs table and user interviews to determine what aspects could be improved upon before further iterations.

III. Project Description

Opportunity

Intussusception is a condition characterized by the invagination of one segment of the intestine into an adjacent segment, which typically presents in infants and toddlers between the ages of 6 months to 2 years[1]. The first line of treatment for this condition is pneumatic reduction, a procedure in which the bowel obstruction is physically pushed back by pressurizing the intestine with air[2]. The current device used in reduction, the Shiels Intussusception Air Reduction System, creates a physically-demanding procedure that requires the pediatric radiologist and assisting nurses to maintain pressure within the patient's bowel by manually pumping air into the intestine and holding the buttocks to create a tight seal for an extended period of time[3]. The multiple periods of physical exertion often lead to arm muscle fatigue in both physicians and their assistants, requiring these users to rotate positions through reduction attempts. In addition to experiencing physical exhaustion, the pediatric radiologists are constantly splitting their attention between multiple sources of information in the procedure room, including the fluoroscopy screen, the pressure gauge, the tubing from the pump, and the patient's physical cues[4]. Overall, the quantity and physically demanding nature of the tasks required to achieve a successful reduction create a chaotic and overwhelming environment prone to both error and stress. Based on this assessment, it is evident that any future solutions targeting this condition must focus on reducing the number of tasks the radiologist and nurses must perform as well as the physical exertion demanded by each task.

Target Users and Conditions

Pediatric radiologists are the primary users for this medical device, given that they are the physicians trained to properly carry out this procedure. They are tasked with pumping air into the patient's intestines, monitoring the pressure measured by the gauge, and observing the fluoroscopy screen to determine whether reduction or perforation have occurred. Usually, these physicians stand next to the fluoroscopy table and although they have a clear view of the screen, often times their view of the patient is obstructed by the fluoroscopy machine itself. The secondary users are the assisting technicians and nurses who set the device in place for the

physician to use, switch enema tips as needed, secure the child during the procedure, and ensure a proper seal at the child-device interface. As mentioned before, the physically demanding nature of the many tasks required from both users can lead to a chaotic environment as well as physical fatigue.

Market Analysis

The U.S. incidence of this condition is approximately 1 per 2,000 infants, whereas there is a slightly higher global incidence, with about 1 per 1,250 children under one year of age [5]. This incidence merits the presence of reduction devices in every pediatric hospital capable of performing follow up bowel surgery, with most pediatric radiology wards possessing at least two devices. The Shiels Device, which consists of a hand aneroid pump with a pressure gauge and an enema tip, is only sold as such through GRI Medical, selling for approximately $200. The disposable portion of the device (the enema tip) is sold in bulk and currently sells for approximately $225 per 10 units. Alternatively, the hand aneroid is sold commercially for use with blood pressure cuffs. Depending on the degree of automation and overall quality of the product, the prices for these bulbs can range between $100-300 [6]. Based on these market considerations, it has been determined that the target price should be less than $350 for the capital item and between $20-30 for the disposable portion.

IV. Research Methodologies

User Interviews

Upon project assignment, contact with the client, the chief of Pediatric Radiology at Children's Healthcare of Atlanta (CHOA) at Scottish Rite, Dr. Damien Grattan-Smith, was established. Through communication with Dr. Grattan-Smith, the team not only obtained a first-hand account of the procedure and the main problems encountered while performing it, but also gained access to other physicians and medical personnel within the department. Before carrying out user interviews, a set of standardized questions was developed in order to gather the same information from every user. Eight users were interviewed, including nurses, technicians and pediatric radiologists both at CHOA Scottish Rite and CHOA Eggleston. Through user interviews, the team identified that major recurring issues with the procedure included air

leakage out of the child-device interface, failure to generate and maintain the desired pressure, and user fatigue among the nurses, technicians and pediatric radiologists alike.

Clinical Observation

During the first meeting with Dr. Grattan-Smith, the team was able to observe and examine the fluoroscopy room, where this procedure is normally carried out, while listening to an account of where the professionals stand during the procedure. From this preliminary observation and explanation, the team took note of the radiologist's obstructed view of the patient given the position where he or she stands, the poor packaging of the tubing and device which showed potential for entanglement, the availability of a wall air source in the room, and the sizing of the current device. In addition, a nurse gave an account of the physical difficulty of maintaining a seal between the enema tip and the child. During a second visit to Scottish Rite, the team observed sequential fluoroscopy images detailing a successful reduction in an anonymous patient, which allowed for a more complete understanding of the procedure. Lastly, the team was able to observe this emergency procedure while Dr. Grattan-Smith was on call. During this observation, the team identified major issues that could compromise the integrity of the procedure and narrowed them down to four: leakage at the child-device interface, backflow of bodily fluids, faulty pressure generation and maintenance, and user fatigue.

Literature Review

A literature review of medical journals was performed to complement our user interviews in terms of understanding the history of intussusception management. Additional sources, such as scholarly books containing anthropometric data, were used to estimate or determine characteristics that might be useful in designing a device for this purpose, including children's anatomical dimensions and mechanical properties of the bowel. Additionally, ASTM and other similar standards organizations were used to determine acceptable standards for design and testing, and Google Patents was used to identify patents of interest pertaining to the design task at hand. The relevant standards were included in the Design Inputs table and the relevant patents & prior art are included below.

Prior Art & Patents of Interest

Current Device

The current device that is indicated for use in pneumatic reduction of intussusception has been patented as the Shiels Intussusception Air Reduction System, which consists of a hand aneroid, similar to the hand pump used to inflate blood pressure cuffs, connected to an enema tip by a plastic tube. The device is customizable to the patient to a certain degree, given that there are multiple enema tip sizes available, with the most common being between 20-40 French plastic enema tips. A Foley or balloon catheter may also be used in lieu of the approved tip to better match the patient anatomy. Although the catheter or enema tip portion is disposable and can be switched from patient to patient, the bulb remains a reusable piece.

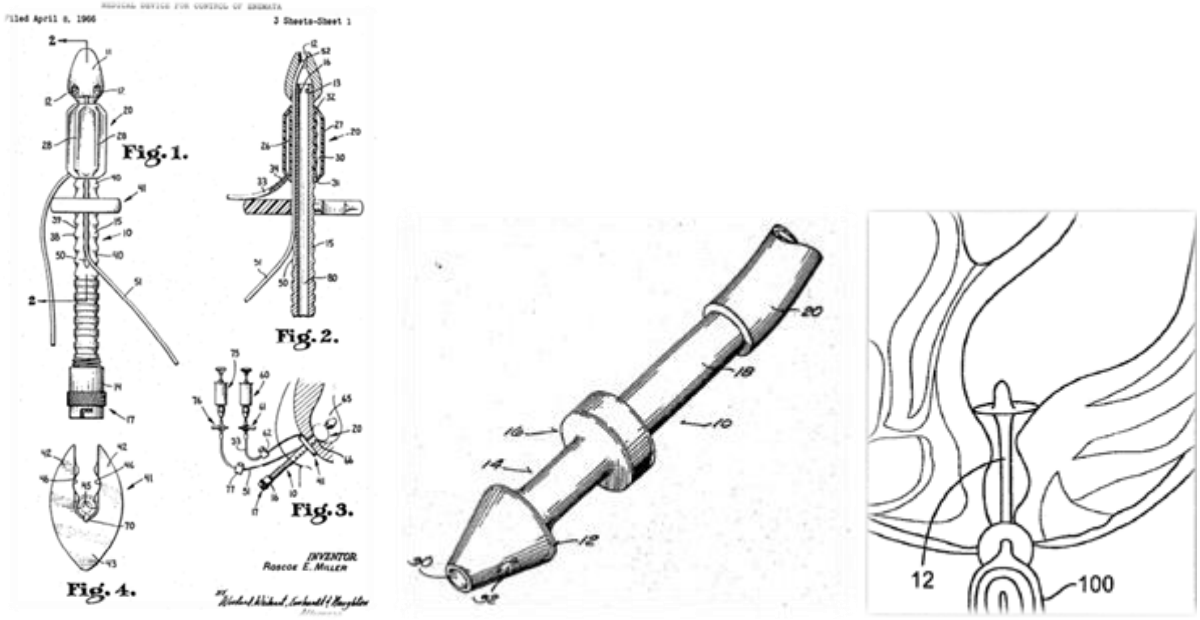
Patents of Interest

A group of researchers in India has previously designed an air insufflation device for the reduction of intussusception that incorporates various desirable features[7]. It is portable, relying on a rechargeable battery to pump air, has a release valve to relieve the excess pressure, and incorporates a pressure drop alarm to notify the users of a systematic leak. Although no patent was found, this device's existence should be included in novelty considerations for the design task at hand. The patents of interest are organized by ideation concepts below:

Child-device interface

In the subcategory of child-device interface, three patents of interest were identified. All three pertained to the design of enema tips. The first, patent 175 titled “Medical device for control of enemata” (Figure 1a), detailed a series of different designs involving balloons and external abutments for the purpose of measurement and sealing[8]. The patent could potentially limit the ability to operate with a new design which relies on balloons. The second patent of interest is 448 titled “Enema Tip” (Figure 1b), which describes the basic shape and profile of an enema tip. It is worth noting because every enema tip is of similar shape to the designs presented[9]. However, significant innovation will distance any new design from those laid out in this patent. The third patent of interest is 448 titled “Fecal incontinence device, systems and methods” (Figure 1c), which describes an enema tip which undergoes a conformational change

after insertion[10]. This patent is of interest because a number of the proposed enema tip designs undergo conformational changes post insertion.



(a (b (c)

Figure 1: (a) Medical device for control of enemata[8], showing a patent drawing with a number of enema tips utilizing balloons and abutments. (b) Enema tip[9], patent showing the basic design for an enema tip. (c) Fecal incontinence device, systems and methods[10], patent which displays an enema tip which undergoes conformational changes post insertion

Pressure regulation

Three patents of interest were identified in the field of pressure regulation. The first is "Pneumatic device for treating intussusception" (587), which describes a computer based control system to maintain the pressure for an intussusception reduction procedure (Figure 2a)[11]. The system is built with a number of solenoid valves and pressure transducers attached to a pressure source, outputting to an enema tip and controlled by a digital control system. However the patent does not describe any mechanism for interfacing with a physician, or allowing set pressures. In addition, although there are diagrams showing a proposed system layout, the claims are highly general, not defining a layout, or even a number of components. The second patent of interest for pressure regulation is "Intussusception air reduction system" (239) which is the patent for the predicate device, the Shiels Intussusception reduction device (Figure 2b)[12]. The patent describes a device which is composed of a hand aneroid, a stop cock, tubing, and an enema tip. This patent represents the current device and is therefore important

for understanding the way that the current procedure is done, what works, and what does not. The third patent of interest is “Insufflation Device” (546), which describes a computer controlled device for the insufflation of a gas into a bodily cavity[13]. The patent describes a system which uses a variable orifice solenoid valve (similar to a proportional valve, although that is not explicitly stated). This differs from the designs presented by IntussAssist in that this team proposes to use a series of digital solenoid valves.

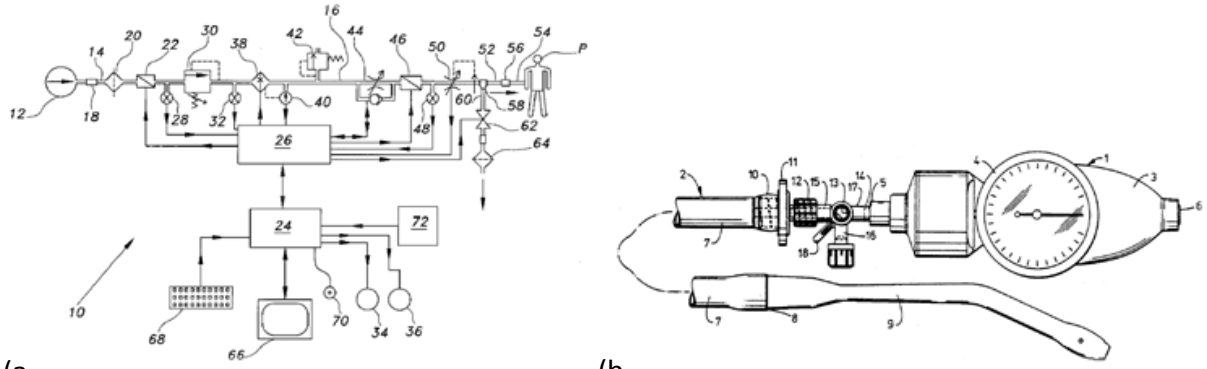
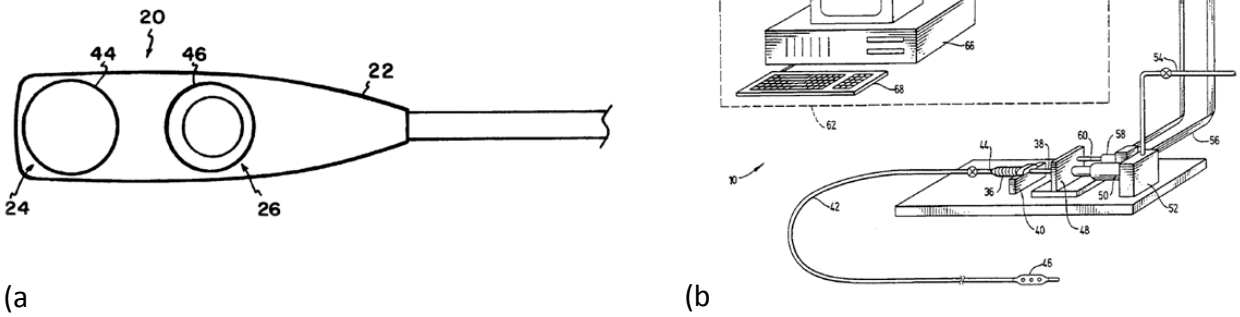


Figure 2: (a) Pneumatic device for treating intussusception[11]; (b) Intussusception air reduction system[12].

User controllers

There are many patents for handheld remote controllers. Only the one which is most relevant is chosen for exhibition here. “Pneumatic controller and method” (165) describes a handheld device with a pair of buttons for the controlling of air flow (Figure 3a)[14]. An additional patent of interest is “Automatic fluid pressure control system” (295), which shows a system which has a remote computer controlling a pressure system (Figure 3b)[15]. Although initially similar in appearance, neither of these appear to cover IntussAssist's proposed solution which includes an HMI and hand-held controller to adjust a set pressure and visualize both the set and current pressures.



(a (b

Figure 3: (a) Pneumatic controller and method[14] ; (b) Automatic fluid pressure control system[15].

V. Engineering Design Specification

Engineering requirements were established in order to meet the major identified user needs, as organized into four major categories: pressure regulation, child-device interface, ease-of-use, and safety. Only the metrics deemed critical are described below. A complete list of engineering metrics is included in the Design Inputs table found on page 11.

Pressure delivery error

Fluctuations in pressure created with the current reduction procedure present a large problem when attempting to standardize this procedure and provide consistent, predictable outcomes for patients. After observing the reduction procedure at Scottish Rite Children's' Hospital, it became clear how difficult it is to maintain a consistent pressure, with the hand aneroid used by the radiologist often measuring fluctuations in pressure of exceeding 100 mmHg. After speaking with radiologists, a pressure regulation error of ± 10 mmHg has been established as an acceptable range for this metric.

Pressure retention in intestine

Retaining pressure in the intestine is critical for providing an uninterrupted pressure to the occluded portion of the bowel. For this, a sufficient seal must be created at the interface between the child and the device. The current approach of using an enema tip sized to the child is ineffective because the compliance of the anus changes after insertion and because the patient's anus relaxes over time. To ensure the proposed solution creates a sufficient seal, it

will be tested in a test bed anus to ensure the device can seal to a pressure of 140 mmHg, 20 mmHg above the intended value.

Enema tip slip-out pressure

The enema tip must be able to withstand a certain pressure before slipping out of the anus and relieving the remaining pressure in the intestine. Having a consistent slip out pressure will allow radiologists to understand the limitations of the child-device interface and will provide an additional safety factor in the event of large, unanticipated increases in pressure. The designated slip-out pressure is set at 500 mmHg to ensure the functional pressure range needed is well below the pressure at which the interface with the child fails.

Status indicator

The design solution must incorporate a status indicator that can be read from a minimum of six feet away [IEC 60601-1-6 (usability of medical electrical equipment); ISO 9241 (ergonomics of human-system interaction)]. To ensure we have met these standards, we will conduct a survey amongst users to ensure the proposed solution better indicates status in comparison to the predicate device.

Device health indications

The design solution must include indications for device health to ensure the device is only used when fully functional and calibrated. Because the radiologist and nurse must focus on other tasks during the procedure, it becomes critical that the proposed design is able to assess its own ability to function and relay that information to the user. To establish that this design input has been met, system simulations will be conducted to ensure appropriate notification is delivered to the user if the system becomes dysfunctional.

Parameter indications

The design solution must incorporate indications that provide proper direction and instruction for understanding the parameters used by the device (pressure, leakage, time, on vs. off). User trials will be used to ensure the radiologist and nurse can follow device indications to accurately assess the system's parameters.

	Category	Parameter	Comment	Functional	Performance	Constraint	Physician	Nurse	Patient	Hospital	other	Metric	Critical	Need	Want	Reference	Test	Analysis	Demonstration	Inspection	Verification Description
		Product Requirements					User						Rating				Method of Verification				
A1	Pressure Regulation	pressure generation range	how much pressure do we need to generate in system	■			■		■			[20 mmHg, >=240 mmHg)			■	standard procedure used today goes to 120mmHg, this is double; (Shiels, 1993)	■	■			hook system up to gauge pressure indicator and read max pressure capable of being generated
A2		pressure delivery error	how much fluctuation?		■						■	estimate: +/- 10 mmHg	■			interviews suggest that fluctuations are large (as high as 100 mmHg). We hypothesize that smaller fluctuations will lead to better outcomes. This will require post prototype construction testing	■	■			hook system up to gauge pressure indicator and read error at various pressure settings
A3		pressure cut-off	what causes perforation? mechanical blowout valve; this is the worst case scenario; there should be 2 pressure safety systems in place before this safety feature will be reached	■			■		■			estimate: 500 mmHg			■	this will be a mechanical pressure blow out, which should only ever kick in if there is a failure mode. Shiels 1993 suggests that pressure should be <270 mmHg, so we increase the value for system failure	■	■			intentionally over-pressure system. Insure that system dumps pressure
B1	Rectal Device Interface	pressure retention in intestine	must be capable of holding/sealing against a pressure in intestine such that our flow rate can maintain pressure	■				■				should seal to 140 mmHg	■			standard procedure used today goes to 120mmHg, this adds a slight safety factor for spikes due to coughing, etc.. Some leakage above that pressure is acceptable; (Shiels, 1995), (Shiels, 1993), (Kaiser, 2007)	■				ensure that pressure is held in test bed intestine (ASTM D1456 - rubber elongation)
B2		enema tip size	must be insertable into rectum of child, should come in multiple sizes to satisfy patient diversity	■			■	■	■			at minimum 24 French and 40 French sizes			■	tips which satisfy B2 and B3 for the full range of infant anus sizes from 0-2 years old; prior art offers 24 and 40 French sizes (Grattan-Smith, 2015; Shiels, 1991)	■		■		ensure that tip can be inserted into test bed rectum and conforms to expected dimension
B3		enema tip/catheter slip-out pressure	how much pressure can be applied prior to tip/catheter slip out	■				■				500 mmHg	■			standard 140 mmHg + significant safety factor for tugging on line, child movement, Valsalva maneuver, etc... will require additional testing post prototype fabrication to determine exact value necessary (Shiels, 1995; Shiels, 1991; Mahaffey, 2015)	■				pressurize test bed rectum and ensure that tip stays inserted without user intervention
B4		enema tip insertion length	must be capable of being inserted at least 3 inches	■				■	■			>3 inches			■	current insertion length is generally 3 inches or less (Grattan-Smith, 2015; Mahaffey, 2015)	■	■			measure insertable length
C1	Physical Embodiment	storage and portability	must be capable of being stored and easily moved			■		■			■	weight is comfortable for transport by nurses (<10lbs); size is no more than prior art case (11inx9inx4in)			■	must be easy to use and fit in the same space as prior art. Interview with Grattan-Smith and visit to hospital allowed physical contact with Shiels device case (Grattan-Smith, 2015; Shiels, 1995)	■	■	■		will ensure size and weight are no larger than prior art case; will survey nurses for comfort level moving device
C2		compatiblity with non-specified tips	connectors out of pressure control system should be industry standard	■			■		■		■	luer lock compatible			■	ISO 594 (luer-lock)	■	■		■	inspection to ISO specifications
C3		visual intimidation	should minimize fear and intimidation		■		■	■	■			by survey would person (patient parent, physician, nurse) be less comfortable than with the predicate device			■	(Grattan-Smith, 2015; Mahaffey, 2015)			■		survey
E1	Environmental	environmental impact	should minimize impact on the environment			■				■	■	conform to ISO 14040 and ISO 14044 (Envirenmental Managment / Lifecycle analysis)			■	ISO 14040 and ISO 14044 (Envirenmental Managment / Lifecycle analysis)		■			process and design review
F1	Sterility	aseptic catheter/enema tip and tube	enema tip and tube should be clean			■				■	■	conform to ISO 13408 (asptic processing of healthcare products)			■	ISO 13408 (asptic processing of healthcare products)	■			■	bioburden, visual inspection
F2		flow back of liquid from patient	no fluid should return from the patient into the device with a pressure gradient up to 500 mmHg			■					■	zero flow of liquid water from patient into device at A3 pressure (500 mmHg)			■	dirty fluid is exiting the child, this must not be passed into the device and onto the next patient (Mahaffey, 2015)	■				will verify by colored water liquid and vapor being pushed through filter mechanism at A3 pressure
G1	Performance	reduction time	should be equivalent or better to current device when used on test bed		■			■	■	■	■	time to reduction of intussusception on device less than or equal to prior art when compared on our test bed			■	device must be better than the prior art; data will be comparative on test bed (Shiels, 1992)			■		have a trained physician perform reduction on test bed using existing device and new device compare time to successful reductions
G2		subjectively preferred by physicians	by survey of physicians, use is preferred by physicians on test bed		■			■				by survey physicians statistically prefer our device to the prior art when compared on a test bed			■	device must be better than the prior art; data will be comparative on test bed (Shiels, 1992)			■		user trial/survey
G3		subjectively preferred by nurses	by survey of nurses, use is preferred by nurses on test bed		■				■			by survey nurses statistically prefer our device to the prior art when compared on a test bed			■	device must be better than the prior art; data will be comparative on test bed (Shiels, 1992)			■		user trial/survey
G4		reduction rate	should have a higher rate of successful reduction than prior art		■			■	■	■	■	should have a higher rate of successful reduction than prior art			■	device must be better than the prior art; data will be comparative on test bed (Shiels, 1992)			■		have a trained physician perform reduction on test bed using existing device and new device compare number of successful reductions
H1	Safety	perforation prevelance	should not lead to increased perforations compared to current device; ideally would notify if a perforation does occur		■			■		■	■	mathematically, pressure should be delivered in a more controlled fashion; tests on test bed should show no increase in perforations when compared to previous art.			■	device must be better than the prior art; data will be comparative on test bed (Shiels, 1992)	■				have a trained physician perform reduction on test bed using existing device and new device compare number of perforations. Guarantee mathematically that the pressure we deliver is in no way more likely cause perforations
H2		emergency stop	drops air pressure to zero immediately after activation	■				■			■	compliant with ISO 13850 (emergency stops) / will depressurize intestine at system max exit flow rate; kill all power to system			■	ISO 13850 (emergency stops)	■				will measure pressure output from device, time to depressurize, proper electrical state
H3		parameter indications	clear indication of set parameters and easy adjustment of said parameters		■			■				easy for a new user to understand the set parameters	■			ISO 9241 (ergonomics of human-system interaction), ISO 11581 (symbols for computer interfaces)			■		user trials
I1	Reliability/Maintenance	device health indication	comparative testing using multiple sensors to ensure accurate sensor readouts. Self test solenoids		■			■	■		■	able to detect failure of critical components	■			the device should minimize the affects of relevant failure modes		■	■		verify that system has been designed in a way as to minimized affects of relevant failure modes. Test simulated failure modes.
I3		cleanability	should be sealed against wash-down			■		■			■	must be designed for cleanability			■	current ASTM WK31799 (medical device cleanability) is in progress; will have to develop in house method		■			contaminate and mark device surface; wash down device; Does any fluid enter the case? Is there any damage? Is there any remaining marking or bioburden?
J1	Life Span	disposable shelf life	disposable component should be able to last for 10 years			■					■	disposable component should be able to last for 10 years			■	current BARD catheter lifespan		■			accelerated aging
J2		capital device lifespan	primary device should be able to last for 10 years			■					■	primary device should be able to last for 10 years			■	based on Welch Allyn hand aneroid (competitive product) warranty period		■			accelerated aging combined with simulated cycles
K1	Packaging	packaging should not compromise device	it should be easy to open packaging and move straight to use. Should adequately protect device from mechanical and biological attack		■			■	■			conforms to ISO 11607 (packaging for terminally sterilized medical devices), including adequate protection for the device; also allows ease of use of packaging			■	ISO 11607 (packaging for terminally sterilized medical devices)	■		■		conformance to standard for protection and user testing for ease of use.
K2		labeling should allow intuitive use	easy to read, short instructions for use (IFU)		■			■	■			conforms to ISO 15223 (symbols for medical device packaging) standard with clear labeling			■	ISO 15223 (symbols for medical device packaging)		■	■		user trials and spec conformance
L1	Interfacing Devices	electro-magnetic interference (EMI)	conforms to IEC 6060; ensure electro-magnetic interference is at a safe level; does not interfere with fluoroscopy or other relevant devices in the fluoroscopy suite			■						conforms to IEC 60601 (guide for electronic medical devices)			■	IEC 6061 (guide for electronic medical devices)	■	■			will test per standard
L2		should interface with standard hospital air source	quick disconnect to interface with 1/4 NPT and barb for tube			■		■	■		■	must interface with 1/4 NPT and soft tube (barb fitting), ISO 228 (BPT) fitting			■	ANSI B1.20.1 (NPT), ISO 228 (BPT), ASME B16 (pipe fittings)	■	■			test against specifications
M1	User Experience	intuitive use	a standard trained radiologist should be able to figure out the interface with no instruction; we will allow a basic IFU on the device		■			■	■			conforms to standard practices for interface design; by survey (physicians statistically agreeing on device being intuitive to use)			■	ISO 11581 (symbols for computer interfaces); ISO 20282 (ease of operation of everyday devices); ISO 9241 (ergonomics of human-system interaction); IEC 62366:2007 (medical device usability); AAMI-HE75 (human factors for medical devices)		■	■		user trials/standard verification
M2		glove compatibility	minimize static touch interfaces, maximize tactile feedback		■			■				all systems must function fully with gloves			■	interviews suggest that all users are fully gloved and that the environment becomes very messy with bowel fluid exiting the patient (Grattan-Smith, 2015; Mahaffey, 2015)		■	■		intelligent design and user trials
M3		status indicator	should have clear status indicator which can be read from at least 6 feet, along with more detailed data up close		■			■				indicator which can be read from at least 6 feet	■			IEC 60601-1-6 (usability of medical electrical equipment); ISO 9241 (ergonomics of human-system interaction)		■	■		design for easy reading of status, survey users
M4		distractions	no alarms; no flashing		■			■	■		■	no alarms or flashing lights; simple notification of blow off			■	IEC 62366:2007 (medical device usability); AAMI-HE75 (human factors for medical devices); Kaye, 2000 (FDA)		■			design per standards
M5		physical work	currently physicians and nurses are required to exert themselves significantly to perform a successful reduction; this causes fatigue		■			■	■			should reduce physical exertion when compared with the predicate device	■			interview with nurse and physician indicated excessive physical exertion (Grattan-Smith, 2015; Mahaffey, 2015)			■		user trials on test bed comparing new and predicate device for fatigue
M6		tactile feedback	a way for the physician to make real the pressure via feedback and perhaps interact directly		■			■				should provide adequate tactile feedback, using ISO 9241 (ergonomics of human-system interaction) as guidance			■	ISO 9241 (ergonomics of human-system interaction)		■	■		analysis against standard practices along with user trials
M7		feedback for end states	the physician should easily know if rupture or reduction has occurred	■				■				will notify radiologist if an end state (reduction or perforation) has occurred				(Grattan-Smith, 2015; Mahaffey, 2015)	■				compare ability of device to predict end states to actual presence of end states
M8		instructions for use (IFU)	easily understood IFU			■	■	■				conforms to ISO 37 (IFUs), is easy for new users to use			■	ISO 37 (IFUs)		■	■		compatibility with specifications and user trial
N1	Regulatory	biocompatibility	general medical stuff			■			■		■	ensure materials are biocompatible over device lifespan			■	ISO 10993 (biological evaluation of medical Devices), USP VI (implantable materials)	■	■			analysis of known material properties and accelerated aging
N3		unique device identification (UDI) compliance	plan for upcoming UDI guidance implementation			■					■	every device uniquely identified per FDA guidance			■	FDA guidance on UDI		■		■	design in UDI and inspect
O1	Research	data storage capability	ability to plug in a USB drive and extract a csv file with pressure, duration, date and other relevant data	■			■			■	■	ability to plug in a USB drive and extract a csv file with pressure, duration, date and other relevant data			■	IEC 62680 (USB)			■		successfully place patient information less data onto standard USB storage device

VI. Design Concepts

The design concepts generated for this device surrounded around the four key issues with the current device and procedure: air leakage at the child-device interface, fluid backflow into the tubing, unstable pressure, and user fatigue. A total of over 80 concepts were generated to address these four key issues with additional concepts generated during development. Of the initial 80 a small number were chosen based on their potential to meet the design input criteria.

Child-device interface:

An improved child-device interface is a necessary step in providing an improved intussusception reduction system. The interface must be non-intimidating, easily-insertable and retrievable, and provide a dynamic seal that accommodates different child anatomies at the specified pressure range. Below are the primary design concepts evaluated for the child-device interface:

The Wedge:

The first design concept was a wedge design wherein two low durometer medical-grade silicone wedges would be places around the enema tip and held into place, creating a secure seal (Figure 4).

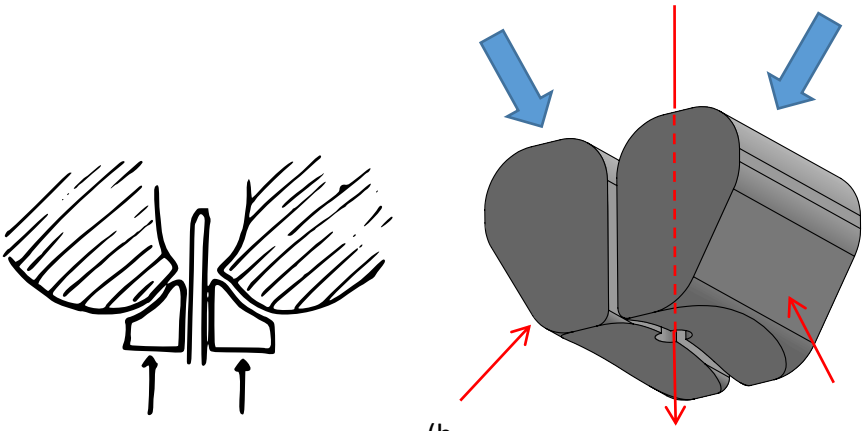


Figure 4: The Wedge enema tip design. The cross-sectional view (a) shows the interface between the wedge, the enema tip, and the buttocks such that the enema tip is positioned inside the rectum. The 3-dimensional view (b) shows the direction of the enema tip (red dotted line) and the 4 main forces on the wedge. The two red arrows indicate the force on the wedge caused by the buttocks while the two blue arrows indicate the force on the wedge caused by the nurse or technician holding the wedge in place.

Umbrella Tip:

The umbrella enema tip would provide a dynamic seal for all children within the specified pressure range, a medical-grade silicone umbrella will be attached 1" from the distal end of a small diameter catheter (Figure 5). To deliver this system, the silicone umbrella will be crimped inside of a sheath. The sheath will be smaller in outer diameter than currently used enema tips, both reducing insertion difficulty and the level of intimidation parents would feel during the procedure. Once placed in the anal canal, the sheath can be removed. When pressure is introduced via the catheter, this silicone umbrella will conform to the native anatomy of the anal canal, creating an air-tight seal. Removal would only require reinserting the sheath over the silicone umbrella and pulling the entire system out.

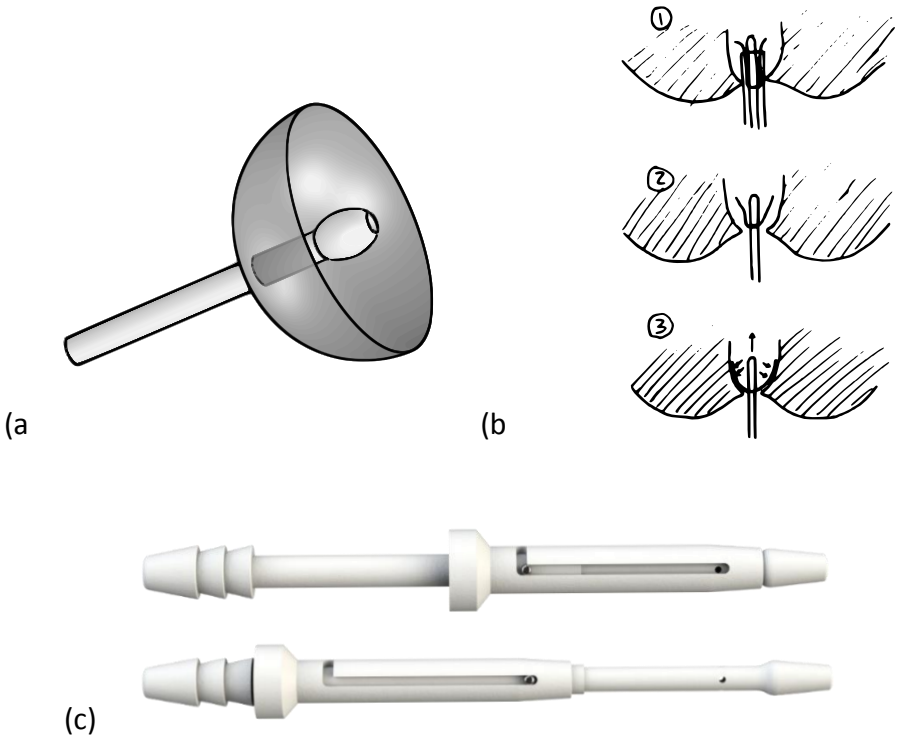


Figure 5: The umbrella enema tip design. (a) 3-dimensional drawing of the silicone umbrella enema tip in its open state; (b) cross-sectional view of the insertion and deployment of the umbrella enema tip; (c) CAD rendering of the deployment mechanism where the sheath is pulled backwards down the tip exposing the umbrella tip (not shown in rendering).

Fecal management

Introducing a fecal management system into a future reduction system is necessary if pressures are to be more closely controlled. The system would need to create an uninterrupted

air path from the pressure source to the enema tip throughout the procedure and also need to store any fecal matter leaving the child. A concept was envisioned using a series of check valves and air-permeable filters to meet these criteria (Figure 6). As seen below, forward flow is encouraged through one tube and reverse flow is encourage through an adjacent tube with the help of two check valves. This design would hypothetically trap fecal matter in the adjacent tube with the help of an air permeable filter.

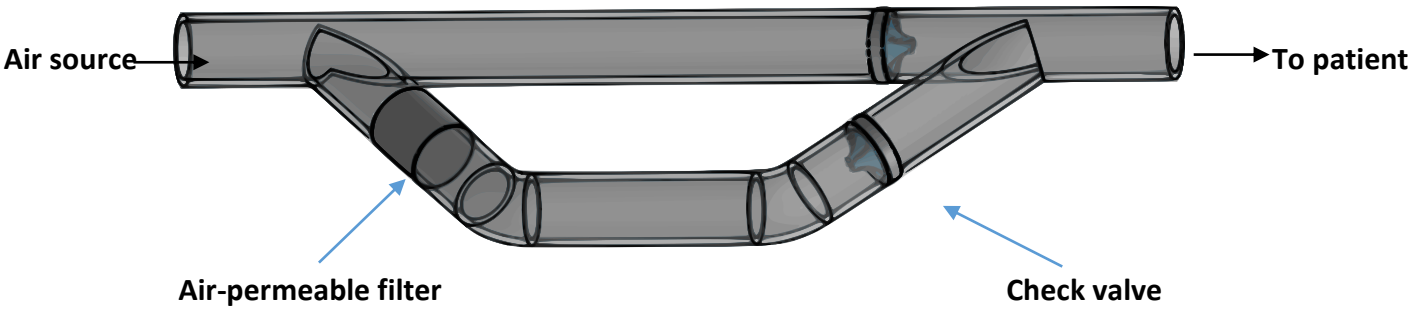


Figure 6: The fecal filtration system encompassing a one-way valve for air to flow in the forward direction with a second one-way valve (check valve) for fluid backflow with a filter only permeable to air to stop the filtration.

Pressure regulation user interface

An improved pressure-regulation component is critical if the proposed reduction system is to outperform the predicate in both improved reduction rates and decreased user fatigue. The predicate device utilizes a hand aneroid pump that requires rapid and extended force exertion by the user to provide adequate pressure to the intestine. Besides the user fatigue that can come from this mechanism, the pressure delivered to the intestine fluctuates (observed to be greater than +-80 mmHg) and a consistent pressure cannot be maintained. After speaking to several pediatric radiologists, the lack of user control when pressurizing became apparent. The proposed pressure regulation component would utilize a series of valves, pressure sensors, and pressure switches working in unison with a control architecture to convert wall air into an adjustable, maintainable pressure going to the enema tip. The proposed design would minimize user fatigue and allow for a more controlled pressure delivery through automation. This automation would also allow the pediatric radiologist to focus his attention on the

fluoroscopy images, by being able to view all relevant parameters on a table top box (Figure 7) and on a handheld remote (Figure 8).

Figure 7: The pressure regulation system

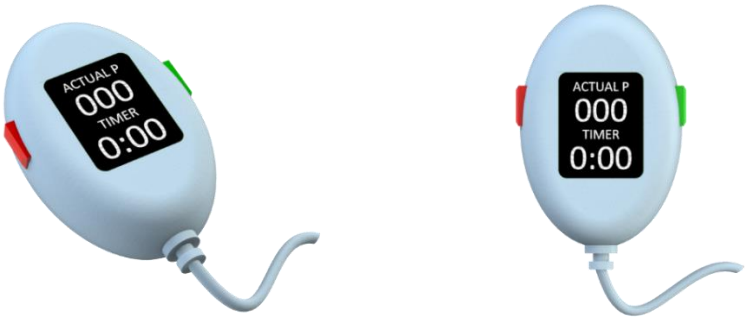


Figure 8: The handheld device

VII. Proposed Design & Prototypes

The proposed design solution is composed of several components placed together to form a complete reduction system for intussusception. To form this system, lessons from the existing prior art along with a number of internal design revisions were used to better address all major design inputs for the child-device interface, fecal filtration system, and pressure regulation system.

Child-device interface

Prototypes for the enema tip began with design iterations and improvements in CAD, with the primary motivation being to create a tip that would be easily insertable and retrievable, yet while inside the anus, could form a better seal with the child. Prototypes were then printed followed by more design changes. After iterating a number of times, the design in

Figure 9 was chosen to be moved forward. A high quality prototype was machined from ABS, with the silicone portion molded using an RTV silicone.

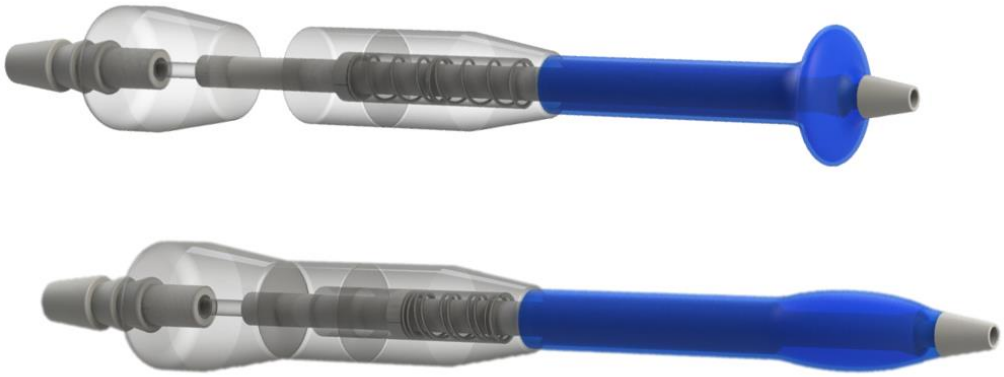


Figure 9: Enema tip

Fecal management

The final fecal management system presented less of a creative challenge and more of a technical one, thus it is similar to the original concept, with check valves and filters attempting to divert the fecal matter into an adjacent tube. However, a more optimal system was envisioned that kept fecal matter from potentially compromising the check valves. To do this, the check valve open during reverse air flow was placed behind the filter and would no longer have contact with fecal matter.

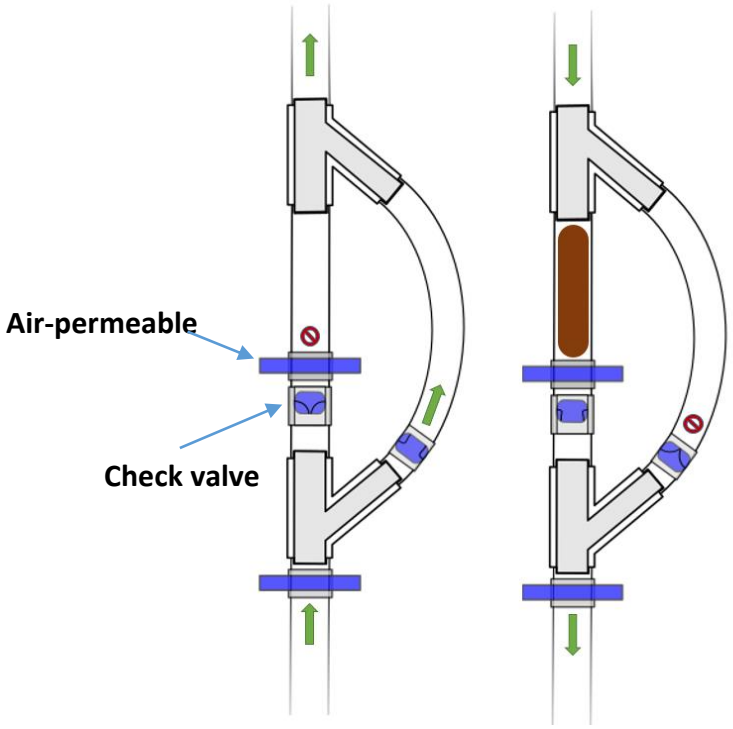


Figure 10: Final fecal management system design

Pressure regulation user interface

The final pressure regulation system is intended to convert wall air into air with a pressure controlled by the pediatric radiologist. This control is maintained on the back-end using a series of solenoids that trap and release wall air in small volumes into tubing that goes to the enema tip. This methodology ensures that in a failure, the high pressure delivered by the wall air source never reaches the child. By measuring the pressure in the enema tubing with a pressure transducer, the onboard controller can toggle the opening and closing of the solenoids to maintain pressure in the tubing. On the front-end, the pediatric radiologist can designate the pressure with a hand held controller or on the pressure control box itself. This system makes it easy for the physician to ensure that the child receives the correct amount of pressure to attempt reduction, while incorporating features that a radiologist might appreciate in the fluoroscopy room for ease of use.

Figure 11: Pressure regulation system

Figure 12: Handheld pressure controller

IX. Future Work

In order to continue developing this device from prototype to market release, there are additional steps required including prototype modification, engineering analysis, testing, clinical evaluations, regulatory proceedings, intellectual property proceedings, and manufacturing.

The pressure regulation system, requires additional prototype iterations to mature the technology. It also requires an engineering analysis which considers all of the constraints which

are generate. At current the electronics have too much noise present to perform within the specifications designated by the relevant engineering design metrics and thus further development is needed. Finally, the system would need to be miniaturized and made visually appealing.

For the fecal management system, a more in depth analysis of the volume of fluid backflow in the reduction procedure will allow assessment of the size of the fecal management system and length of tubing. Additionally, testing with various densities of fluid as well as mixtures of solids and fluids can verify the function of the system. Finally the system would need to be made more ergonomic and visually appealing.

The enema tip requires further design iterations, including careful final material selection in order to ensure the conformational change occurs properly. The enema tip would then require testing in an inorganic intestine model followed by testing in a porcine or bovine intestine model to perform an engineering analysis of containment of pressure in a system and the ease of use by trained professionals.

The handheld controller is the most developed of the 4 features of the IntussAssist device. Some design modifications would need to be made to utilize cheap mass produced parts and move the device to a manufacturable configuration. Verification of the size, shape, and position of the buttons would be done by user testing and interviews.

Iterations of user studies and benchtop tests against the engineering design metrics along with manufacturability considerations would be used to inform design changes. Once a viable product was prepared, FDA regulatory proceedings would be undertaken. Finally the device could be manufactured and distributed.

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