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The Development of a Neonatal abdomen Ultrasound Imaging Probe for Assessment Purposes

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Abstract

Application of ultrahigh frequency (UHF) ultrasound to the outer wall of the intestinal wall has been shown to be able to delineate detailed histoanatomical layers and distinguish between normal bowel and agangliosis. This may reduce or alleviate the need for biopsy, which is now mandatory for diagnosis of Hirschsprung's disease. However, to our knowledge, there are no Abdomen probes on the market suitable for such applications. The aim was to define specifications for a transAbdomen UHF (50 MHz center frequency) ultrasound probe suitable for use in infants. Probe requirements according to patient anatomy, clinician requirements, and UHF requirements for biomedical engineering were collected within an expert panel. Appropriate probes in commercial and clinical use were reviewed. The requirements were translated into sketches of potential UHF ultrasound transAbdomen probes using subsequent 3D prototype printing. Two prototypes were built and tested by five pediatric surgeons. A larger, straight 8 mm head and shaft probe is preferred because it facilitates stability, ease of anal insertion, and the potential of UHF technology with his 128 piezoelectric elements in a linear array. I was born. Here, we present the processes and considerations underlying the development of a proposed novel transAbdomen UHF probe for pediatric use. Such devices may open up new possibilities for diagnosing anoAbdomen disease in children.

Keywords: Abdomen conditions, Diagnosis; Hirschsprung's disease; Pediatrics; Probe

Introduction

Hirschsprung's disease (HD) is a congenital disorder with an incidence. It is characterized by the absence of ganglion cells in the intestinal wall (agangliosis), requiring surgical removal of the affected intestine. Ganglion cells are normally found in the submucosa and intestinal layers of the intestinal wall. A rectal to abdominal biopsy is performed to diagnose Huntington's disease, but biopsy-associated physical and psychological problems have been reported with insufficient accuracy in up to 50% of cases [1]. There are about 10 times more children than children who have HD only. B. Children with bowel motility disorders should be examined by abdominal biopsy. Finding a rapid and safe HD diagnostic technique to replace abdominal biopsy could have enormous benefits for this patient population [2].

Ultrahigh-frequency ultrasound (UHF) is currently being investigated as an alternative to biopsy diagnosis. Histoanatomical morphometry has been shown to distinguish between aganglionic and ganglionic bowel walls. In addition, UHF (center frequency 50 MHz) ultrasound imaging of intestinal samples was shown to replicate the difference [3]. These studies were conducted with the aim of differentiating between aganglionic and ganglionic bowels in children already diagnosed with HD. Primary diagnosis intended to replace the need for abdominal biopsy requires transanal and mucosal ultrasound imaging. Currently, the only UHF ultrasound probes on the market (UHF 48 with a bandwidth of 20-46 MHz and UHF 70 with a bandwidth of 29-71 MHz, FUJIFILM VisualSonics, and Toronto, Canada) are very sensitive to the anus and rectum of children. The pediatric abdominal UHF probe enables studies of large pediatric cohorts. In addition, collecting images of reference intestinal walls from healthy children facilitates verification of UHF ultrasound [3]. In other clinical indications, the pediatric transabdominal UHF probe facilitates detailed diagnosis of anorabdominal fistulas, internal and external sphincter injuries, pelvic floor malformations, and may also aid in the differentiation of anorabdominal tumors. Our overriding goal was to enable diagnosis by UHF ultrasound, but also to open up new possibilities for high-resolution ultrasound imaging of other abdominal and pelvic floor diseases. The specific aim of this study was to develop a requirement specification and propose a prototype abdominal UHF ultrasound probe suitable for use in infants [4]. Here, we present the process and reasoning behind the development of a proposed new pediatric UHF transabdominal probe.

Materials and Methods

The study was conducted in 2018 at the National Center for Huntington's disease and Abdominal Malformations, named Pediatric Surgery. Geographically it covers an area of 5 million inhabitants [5]. The process underlying the development of the pediatric UHF probe followed a specific structure and involved an expert panel of pediatric surgeons (n=5) and biomedical engineers (n=4). Pediatric Surgeon He has 8-13 years of professional experience and specialized in the field of pediatric gastrointestinal surgery. All biomedical engineers and researchers specialized in medical ultrasound imaging and had extensive experience with UHF ultrasound. One of them also had experience in life sciences development of abdominal ultrasound probes for adults [6].

Anatomic, clinical and technological considerations

Patient comfort and safety are paramount, as abdominal ultrasound must be performed without the use of anesthesia or sedation. Therefore, indices of pediatric anatomy for anal orifice size, abdominal diameter, and rectal length were compiled from the literature. These were also collected from the medical records of her last 10 patients treated in

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pediatric surgery with an arteriographic diagnosis of Huntington's disease [7]. The anatomical design of the proposed probe considered close contact between the probe head and the intestinal wall to avoid shadow effects in the images. Clinical considerations: Information on physician requirements for Tran's abdominal probes was collected within an expert panel, as well as from discussions and clinical observations. In developing the design, various aspects of patient safety regarding movement, environmental conditions during anal examination, and examiner ergonomics were considered. Prior knowledge-based technical considerations and technical specifications for UHF ultrasound of the intestinal wall were collected within an expert group [8]. Small pediatric anal probes have not yet met the technical requirements for using UHF ultrasound technology. The center frequency of the probe, the number of piezoelectric elements and the image view were considered. Contact between the probe head and the intestinal wall was also considered as a technical solution. The electronics requirements have been noted for later evaluation [9].

Review of available and feasible probes

A market analysis was conducted to identify currently available probes that fit our goal of introducing UHF technology in the form of pediatric anal-abdominal probes. The overview should include the physical dimensions, frequency range, number of elements, and field of view of the various probes. Clinical visits were conducted in departments using several miniature ultrasound alternatives for diagnosis to gain detailed clinical insight into their practical use [10].

Results

Anatomic, clinical and technological considerations

Anatomical considerations the literature reports an anal orifice size of 12–15 mm in newborns by 1 year of age, with or without malformations and ganglogenesis. Anal openings in children with Huntington's disease who underwent washout (n = 10) or children with anorabdominal malformations with perineal fistulas who underwent calibration and enema (n = 10) according to the Pediatric Surgery Medical Table used to diagnose HD in children weighing 2.5–7.1 kg with a 6–10 mm abdominal suction device (rbi2®) had a diameter of 7 mm and was inserted into the anus and rectum without resistance.

Clinical considerations

When designing the proposed probe, the clinician's needs for patient comfort, safety, and ergonomics were focused on the size and shape of the probe her head, shaft, and handle. The probe head should be large enough to enter the anus without discomfort to the patient. The length and size of the shaft should allow flexible orientation of the probe elements so that the probe head can reach the mucosa from the posterior, anterior, and lateral surfaces. The handle should allow the examiner's hand to rest on the pad to avoid movement during image acquisition. Additionally, it should fit most surgeons' hands, regardless of size. The handle and shaft should allow the examiner to easily perform the test while standing both in front of and to the side of the child. The handle size and grip were tested by surgeons, resulting in a handle length of 9-11 cm and a circumference of 4-7 cm.

Discussion

The purpose of this study was to develop a geometrically designed requirements profile for a pediatric UHF abdominal ultrasound probe that enables high-frequency abdominal sonography. Sketches and 3D printed prototypes were created and tested using information gathered regarding abdominal measurements and technical requirements. The selected prototype turned out to be satisfactory in terms of design and ergonomics. However, some features were missing, such as handles and neck markings to help the examiner align the probe. Certain technical uncertainties were revealed during the development process, especially regarding the nature of the elements used in the small diameter probes and their highest center frequencies. The main challenge was to come up with a probe design that was small and tidy, yet met all the technical specification requirements. Having achieved this and also considering the electronic requirements, this is the first step in the development of a pediatric UHF abdominal probe. This product is a much needed product for children.

Conclusion

This is the first step in developing a pediatric abdominal UHF ultrasound probe, a new non-invasive diagnostic method for examining the intestinal wall in children. We believe that such devices may open new possibilities for the diagnosis of pediatric abdominal diseases.

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