Sonopill Pathfinder: Rapid Prototyping for Ultrasound Capsule Endoscopy

Sonopill Pathfinder:
Rapid Prototyping for Ultrasound Capsule Endoscopy

G. Cummins[1], V. Seetohul[2] , Y. Qiu[2], K. Wlodarczyk[1], W.A. Lewinger[3], H. Lay[2], B. Cox[4], D. Hand[1], C. Démoré[2], M.Y.P. Desmulliez[1], S. Cochran[2]

[1]School of Engineering and Physical Sciences, Heriot-Watt University, Edinburgh, UK
[2]School of Engineering, University of Glasgow, UK
[3]School of Science and Engineering, University of Dundee, UK
[4]School of Medicine, University of Dundee, UK

G.Cummins@hw.ac.uk

INTRODUCTION

Imaging of the gastrointestinal (GI) tract is vital for the diagnosis of conditions such as colon cancer, haemorrhage or inflammatory bowel disease. Endoscopy is by far the most common approach for diagnosis, though it can induce discomfort in patients. Another disadvantage is that significant regions of the small bowel cannot be easily viewed as standard endoscopic imaging is limited to the upper GI tract and colonoscopy is limited to the terminal ileum and below. Imaging of the small bowel can be achieved by video capsule endoscopy (VCE), which has improved patient acceptance because of the small device size. However, imaging with commercially available endoscopic capsules is limited by the nature of optical imaging to only look at the mucosal surface. Despite this video is the sole imaging method of capsules in development.[1].

The integration of ultrasonic imaging into an endoscopic capsule can be seen as the next extension of VCE as it allows safe, non-ionizing imaging of the GI tract sub-surface[2],[3] with ultrasound imaging already common in upper GI endoscopy. However, engineering challenges such as manufacturability, packaging and increased integration need to be addressed to ensure that ultrasound capsule endoscopy (USCE) can be used as viable diagnostic tool. To investigate these concerns, the Sonopill project [4] is utilising rapid prototyping technology to create "Pathfinder" pills to assess different sensing modalities, including ultrasound for clinical diagnosis [4].This paper presents work conducted on the fabrication of an ultrasound imaging Pathfinder pill.

MATERIALS AND METHODS

The dimensions of any CE device are limited to approximately 1 cm in diameter and 3 cm in length for easy swallowing and travelling through the GI tract. The capsule must also allow ultrasonic waves emitted from the transducer to propagate with little or no reflection at the capsule/transducer or capsule/tissue interfaces. To the authors' knowledge, previous attempts at USCE did not consider the impact of the surrounding capsule casing on ultrasonic transmission [2] or its impact on image quality [3]. Removal of acoustically reflective surfaces by using quarter-wavelength thick material, on the order of 10 μm for the 32 MHz frequency polyvinylidene fluoride (PVDF) focused microultrasound (μUS) transducer is not possible because of manufacturing difficulty and fragility. Lowering the frequency would hinder high quality imaging of the gut wall layers. This problem was addressed for the Pathfinder pill by having the transducer fixed along the central axis of the pill, with the emitted ultrasound reflected off a rotating quartz acoustic mirror embedded in a polydimethylsiloxane (PDMS) dome, shown as A in **Fig. 1**, to give the desired 360^{O} view. PDMS is a biocompatible material with acoustic impedance (1 - 1.9 MRayl) [5], close to that of tissue (1.3 - 1.7 MRayl) [6], minimising impedance mismatch. The μUS transducer as shown by component B in **Fig. 1**, is aligned along the central longitudinal axis of the pill and fixed in place. Previous attempts at USCE rotated the transducer, which may cause excessive stress and strain on any cabling.

Mechanical scanning was used rather than electronic scanning to reduce the need for integration of electronic components. In addition, imaging by mechanical scanning can lead to better image quality because of reduced side lobe interference [2]. The quartz mirror is rotated with a commercial micro-motor of diameter 3.2 mm and length 8.1 mm (103-100. Précis on Microdrives, London, UK) in conjunction with a laser machined gear assembly, shown as C and D in **Fig. 1**. The gear assembly shown in Fig. 2 comprises an annular gear connected to the midsection of the capsule and three spur gears within it, one driven by the motor. The gear ratio is approximately 2.8:1. Laser micromachining was used as Polyjet and stereolithography additive manufacturing (AM) processes cannot provide the feature resolution needed for the gears. Friction between the rotating section and the static transducer is minimised through the use of PTFE washers (Bokers Inc., MN, USA).

A combined accelerometer and gyroscope (LSM9DS1, STMicroelectronics, Geneva, Switzerland) was included in the capsule to monitor potential rotation and translation of the capsule caused by torqueing of the lower sections have been designed to incorporate fins to

stabilise the capsule if this is an issue, though clinical impact must be assessed. The motor, transducer and other components are currently powered via a tether, which is also used to connect external electronics to the transducer. The tether consists of a PTFE tube with an inner diameter of 0.9 mm and outer diameter of 1.1mm, shown as E in Fig. 1. It is intended that the tether will eventually be removed as systems are integrated further into the capsule.

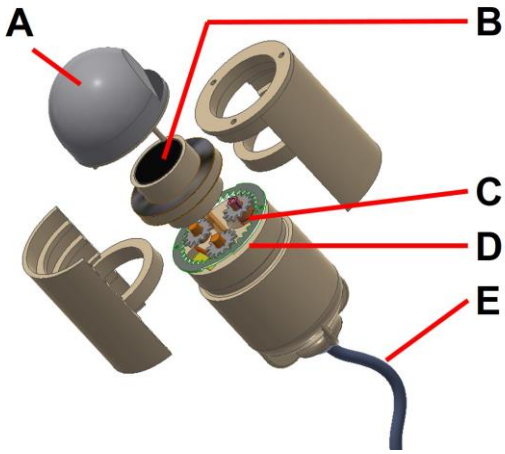

Fig. 1 Exploded schematic of the Pathfinder pill

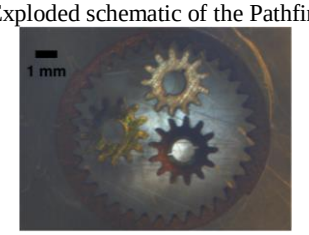

Fig. 2 Magnified view of laser machined gear assembly components

The majority of the capsule is produced with VeroWhite, a rigid polymer deposited using the Objet Connex 500 AM tool (Stratasys Inc., Rehovot, Israel), shown in beige in Fig. 1. These sections are manually assembled and fixed together using a biocompatible adhesive (4161, Loctite, London, UK) before the entire USCE is coated with a thin film of Parylene C.

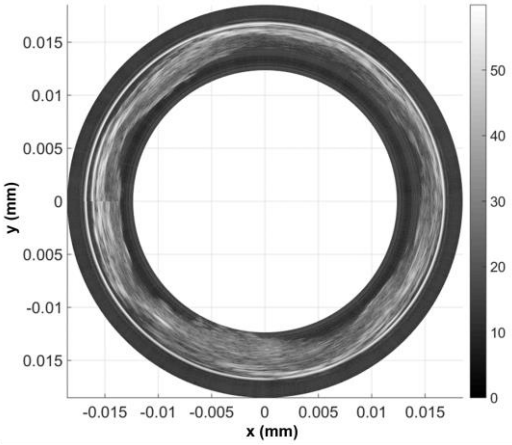

Fig. 3 Reconstructed grey-scale ultrasound image of the full width of dissected pig bowel, digitally processed into a cylinder for use as a virtual phantom. The linear image was stitched together at 9 o'clock to form a continuous loop.

RESULTS

Despite the flexibility and ease of production, the design and manufacturing of USCEs with rapid prototyping technologies is complex. As well as the inability to produce the gears with AM processes, the production of the thin rotating outer sections attached to the PDMS dome was problematic due to shell deformation upon removal of the support material. Multiple solutions were implemented to overcome this, such as the interlocking structure shown in Fig. 1 to provide rigidity and increasing the shell thickness, giving the capsule a 10.4 mm outer radius, with the length remaining at 30 mm. These dimensions are closer to those required for clinical use than previous USCEs [2].

Assessment of the diagnostic ability of μUS transducers in the target frequency range was performed using *ex vivo* ethically-sourced, defrosted and rehydrated porcine GI tissue dissected along the long axis and mounted on an agar substrate for mechanically scanning along the short axis. The single-element transducer used for these trials had a 48 MHz centre frequency. The layer distinction within the resultant scans was found to be comparable to histological sections and this distinction was maintained in images, e.g. Fig. 3, simulated at a 25 MHz centre frequency using these scans.

DISCUSSION

Rapid manufacturing techniques such as laser machining and additive manufacturing enable Pathfinder pills to be built quickly to assess different modalities, such as ultrasound imaging and determine solutions to various technical issues. Such devices also provide valuable information that will help to develop USCE as a clinical tool in the future.

REFERENCES

[1] J. L. Toennies, G. Tortora, M. Simi, P. Valdastri, and R. J. Webster, "Swallowable medical devices for diagnosis and surgery: the state of the art," *Proc. Inst. Mech. Eng. Part C J. Mech. Eng. Sci.*, vol. 224, no. 7, pp. 1397–1414, Jan. 2010.

[2] J. H. Lee, G. Traverso, C. M. Schoellhammer, D. Blankschtein, R. Langer, K. E. Thomenius, D. S. Boning, and B. W. Anthony, "Towards wireless capsule endoscopic ultrasound (WCEU)," in *2014 IEEE International Ultrasonics Symposium*, 2014, pp. 734–737.

[3] J. Correia, "Final Report Summary - TROY (Endoscope Capsule using Ultrasound Technology)," 2009.

[4] "Sonopill Website." [Online]. Available: http://sonopill.dundee.ac.uk/.

[5] "Onda Corporation." [Online]. Available: http://www.ondacorp.com/images/Rubbers.pdf. [Accessed: 31-Mar-2016].

[6] T. R. Gururaja, "Piezoelectric transducers for medical ultrasonic imaging," in *ISAF '92: Proceedings of the Eighth IEEE International Symposium on Applications of Ferroelectrics*, 1992, pp. 259–265.