The Design and Construction of a Medical System to Optimize the Endoscopic Ultrasound Procedure

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ABSTRACT

This project involved the use of rapid prototyping to produce a model of a section of the gastrointestinal (GI) tract which could be used for practice of the Endoscopic Ultrasound (EUS) procedure.

Computed Tomography (CT) scans were obtained from Dr. Donald Jacobsen, Assistant Professor of Radiology at the Medical College of Wisconsin in Milwaukee. Apart from the final testing, the entire project was performed at the Milwaukee School of Engineering's Rapid Prototyping Center. To convert the CT scans into files that are compatible with the rapid prototyping machines, a software developed by Materialise, N.V., was used. The rapid prototype models were used as master patterns for molds so that a polyurethane material with similar properties to human tissue could be used for actual simulation. Finally, these polyurethane models were placed in an enclosure and surrounded by a gelatin to simulate fatty abdominal tissue. The system was tested at Froedtert Memorial Lutheran Hospital under the supervision of Dr. Anthony Bohorfoush in conjunction with the Medical Physics Department of the Medical College of Wisconsin.

INTRODUCTION

The need for accurate models of the human body is greater in this age of rapid medical advancement. As new medical procedures and equipment are developed, few physicians and medical personnel have the knowledge and skills needed to use them effectively. Even the most skilled endoscopists have difficulty navigating the endoscope into the duodenum and targeting a specific organ. In addition, once the images are obtained, it is extremely difficult to interpret them due to the awkward orientation of the ultrasound transducer. Therefore, any system which will accurately simulate the human abdomen and allow physicians to practice EUS, will greatly increase the effectiveness of this relatively new medical procedure.

The purpose of this project was to develop a system that accurately simulated the human abdominal organs when subjected to the endoscopic ultrasound (EUS) procedure. Specifically, a model of the human stomach with the duodenum and an accurate simulation of the fatty tissue that surrounds them were desired to allow physicians and radiologists to practice and teach the EUS procedure.

DISCUSSION

Rapid prototyping is a technique which is used to develop mechanical designs into a functional prototype within a few hours or days for physical or market testing. It can also be used to check the feasibility of new design concepts, to assess the fit of complex mechanisms, to make molds for wax cores in casting, and to use as a master pattern in silicon and epoxy molds.

In medicine, rapid prototyping can be used in a process called reverse engineering, where the structure already exists but does not have regular geometric properties, such as that of the human body. Three-dimensional models can be created using two-dimensional data from imaging devices such as CT or MRI scanners. These three-dimensional models provide the surgeon with tactical visibility and an acute understanding in some complicated cases. A physical model of the patient's anatomy is easier to interpret than a series of two-dimensional images. The models can be used in surgical planning where complex operating procedures can be tried out on the model, greatly reducing the time in the operating room. Physical models can also be used for communication of the patient's condition and expected outcome to members of the surgical team and for the patient's understanding of the treatment plan.

ENDOSCOPIC ULTRASONOGRAPHY

Endoscopic ultrasonography (EUS, sometimes simply called endoscopic ultrasound) is a relatively new technology that combines the features of two existing methods of obtaining structural information about the gastrointestinal tract and the tissues and organs immediately surrounding it. The combination of endoscopy and ultrasonography (ultrasound imaging) allows physicians to obtain information that is not available or is not as accurate by other non-invasive means.

With conventional ultrasound imaging, computed tomography (CT), and magnetic resonance imaging (MRI) already successfully in use, why was an invasive ultrasonography technique needed? CT, MRI, and transcutaneous ultrasonography all have limitations for resolving small structures within and surrounding the gastrointestinal tract. CT uses radiation and MRI is fairly expensive. Conventional ultrasonography may not provide adequate resolution of the structural details of the GI tract due to the low frequencies used to provide deep penetration. Since the EUS probe is actually placed in the GI tract, adjacent to the target area, higher frequencies can be used (little penetration required) resulting in better resolution of the tissues of the GI wall and of adjacent structures.

Conventional abdominal ultrasonography, CT, and MRI will continue to be an important part of the diagnostic procedures for patients with various gastrointestinal problems. However for several specific applications, EUS has proven itself superior to the other imaging methods. Diagnostic imaging with EUS is particularly valuable for examining endocrine tumors of the pancreas. EUS has also been used to evaluate other pancreatic tumors, pancreatitis, and to find gall stones lodged in the common bile duct. In addition to pancreas abnormalities, EUS has allowed physicians to find and stage early gastrointestinal cancers more accurately, often preventing unnecessary surgery (to obtain biopsies). On occasions, when surgery is necessary, EUS can help to better prepare surgeons and patients for surgery. Ultimately, detection of cancers that are small and at an early stage will increase the chances of cure.

In the short number of years that the EUS procedure has been used, it has proven to be a valuable complement to conventional ultrasonography, CT, and MRI in the examination of the gastrointestinal tract and the surrounding organs.

DESIGN SPECIFICATIONS

The specification for the system was to accurately simulate the behavior of human abdominal organs during the EUS procedure. This requirement applied to the stomach, duodenum, and the fatty tissue that surrounds the internal organs. They had to be of similar size and shape of human organs and possess ultrasonic properties exhibited by human tissue.

The stomach and duodenum were required to be made of a soft, flexible material with nearly the same density as water. The human stomach is very flexible and is normally in a collapsed state, unless food or drink has just been consumed. It was also necessary that the stomach be watertight, as it is inflated with water during the EUS procedure. It was important for the stomach wall to have a uniform density in applications involving ultrasonic waves. Therefore, it was necessary to either utilize a molding technique that produced a casting as one complete part, or if cast in halves, develop a way to attach them without altering the density. The material selected for the stomach and duodenum from over twenty possibilities was a flexible polyurethane called *SKINFLEX* from BJB Enterprises. With this material, it was necessary to use platinum-based silicone as the molding material, since *SKINFLEX* will not cure correctly against tin-based silicones. After much deliberation, it was determined that the most effective method of producing the stomach was to cast it in halves and then glue the halves with the casting material.

In addition to the stomach and duodenum, it was also necessary to accurately simulate fatty tissue in the abdomen. The first requirement was that the material be extremely soft and flexible. Also, the tissue must accurately simulate the ultrasonic properties of human soft tissue. This again involved near water density, and material that simulated the attenuation effect of the cells and cell walls. It was determined that an organic gelatin could best provide the density and texture required. Also, mixing tiny graphite particles into the material would provide the ultrasonic attenuation due to cells. A gelatin-water mixture of approximately 7.5% gelatin to 100% distilled water provided the texture and hardness (firmness) closest to that of abdominal tissue.

The enclosure needed for the project was not one of the primary design focuses of the project. The only requirement of the enclosure was that it be approximately the size of an average human's abdomen and that it be able to hold the gelatin without deforming. A small valve and tube were attached to the end of the duodenum to allow these organs to be filled with water and drained when needed. Four small plastic balls were placed in the gelatin to act as targets during ultrasound imaging. These balls were measured prior to placing them into the enclosure so they could be compared to measurements taken from the ultrasound images. Fishing line and washers were used to weight the balls down, and keep them in place until the gelatin solidified. Finally, a wire mesh screen was also placed in the enclosure to act as another target.

MATERIALS SELECTION

This project required the selection of two materials: (1) a material to simulate the stomach and the duodenum, and (2) a material to simulate the fatty tissue that surrounds the stomach and other internal abdominal organs. It was necessary that both materials be flexible and posses similar ultrasonic properties to the actual human organs.

The ultrasonic properties that were of primary importance were the attenuation and the speed of sound in these materials. The speed of sound is usually related directly to the density of the material. Therefore, materials with densities close to that of water (approximately 1.0 g/cm^3) were selected. Because the ultrasound transducer on the endoscope is placed in almost direct contact with the stomach wall, the attenuation and other ultrasonic properties of the stomach were important. The main requirement for the stomach was that it be of a uniform density. However for the fatty material that surrounds the stomach, acoustic impedence was of great importance. Therefore, in future models, very fine powdered graphite will be added to the gelatin to simulate the attenuation of human fatty tissue caused by cells,.

The major materials that were examined for these applications were epoxy, gelatin, latex, polyurethane, and silicone. Latex and epoxy were dropped from consideration early, because they break down in water, and material suppliers were difficult to locate. Numerous companies were contacted, and a great deal of information was gathered to allow the best decision between the remaining materials to be made. The following table summarizes the most appropriate offerings of companies contacted:

Table 1: Summary of Material Offerings of Companies Contacted.

Company	Materials Available	Application	Hardness
Air Products	Polyurethane	Stomach	45+ Shore A
BJB Enterprises	Polyurethane Polyurethane Gel	Stomach Fatty Surrounding	5+ Shore A Gelatin-Like
Ciba-Geigy	Polyurethane	Stomach	35+ Shore A
Eager Plastics	Polyurethane	Stomach	70+ Shore D
GE Silicones	Silicone	Stomach/Mold	14+ Shore A
Hapco	Polyurethane	Stomach	20+ Shore A
Vyse Gelatin	Gelatin	Fatty Surrounding	Gelatin-Like

After analyzing the literature and samples received, polyurethane emerged as the best material for the stomach and duodenum. Because of the wide range of physical properties available in polyurethanes, it was the material of choice. Polyurethane has a hardness that varies from "Shore A" to "Shore D". Also, polyurethane has a density close to the density of water. An extremely flexible polyurethane called *SKINFLEX* (BJB Ent.) was selected for the simulation of the stomach and the duodenum.

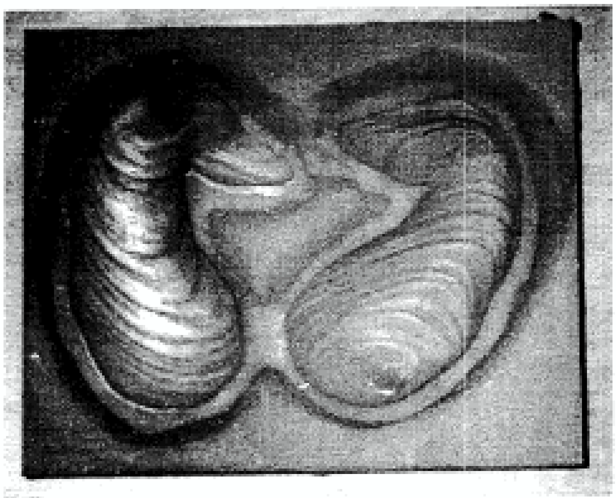

Figure 1: Silicone Rubber Mold of Two Stomach Halves

In addition to the polyurethane, gelatin was explored as a possible material to simulate the surrounding fatty tissue. With gelatin from the *Vyse Gelatin Company*, several samples were made. This gelatin produced a material with suitable hardness and density, but it was found to decompose when it was exposed to air. After several days in an open container, the gelatin samples grew fungus and dried up, becoming very brittle. However, after contacting the material vendor, it became clear that the addition of a preservative would increase the life of the system.

ASSEMBLY OF THE ENTIRE SYSTEM

After successfully producing the stomach model with the duodenum, the components had to be brought together to make a complete, usable system. The enclosure used was a simple plastic waste basket with a small valve fastened on the back side, near the bottom of the container. A small rubber tube was attached to the end of the duodenum and to the valve to allow the stomach and duodenum to be drained periodically. On the other end of the system, a larger rubber tube (1.0" I.D.) was attached. The stomach, duodenum and esophagus were positioned in the enclosure, and four small plastic balls were placed near the stomach and duodenum to act as targets during testing. A course wire mesh was also placed inside the enclosure to act as an additional target. The system prior to the addition of gelatin is shown in **Figure 2**.

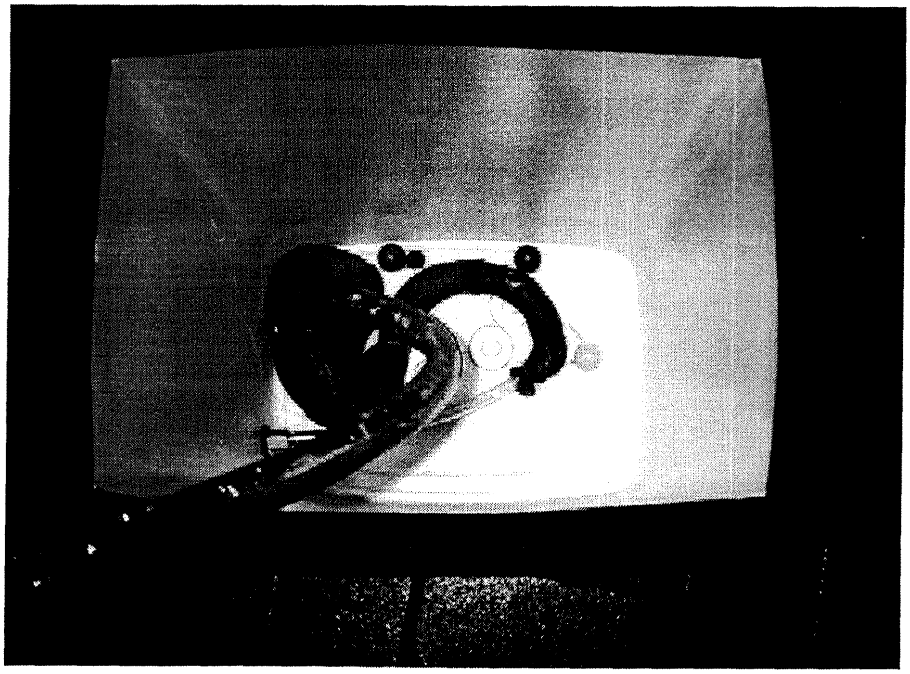

Figure 2: System prior to addition of gelatin.

Finally, the gelatin powder was mixed with six gallons of water at a 7.5% to 100% ratio and poured into the enclosure, around the internal organs. After several hours, the gelatin solidified.

TESTING THE SYSTEM

The final step of the project involved testing of the system with Dr. Anthony Bohorfoush at Froedtert Hospital. The probe was inserted into the stomach and the first portion of the duodenum ultrasound and video images were obtained.

The ultrasound images can be frozen, and printed at any time. **Figure 3** shows an image from one of the initial tests of the stomach. The main purpose of this initial test was to determine how well the material simulated the wall of a human stomach. The black half-ellipse on the top of the image is the ultrasound transducer, itself. In this case, the transducer is inside of the stomach, sending waves out. The top bright white line is where the ultrasound waves hit the inside of the stomach wall, while the lower white line shows the interface between the outside of the wall and the water (gelatin was not used in the initial test). After looking at the images, Dr. Bohorfoush admitted that this material looked very much like a human stomach wall.

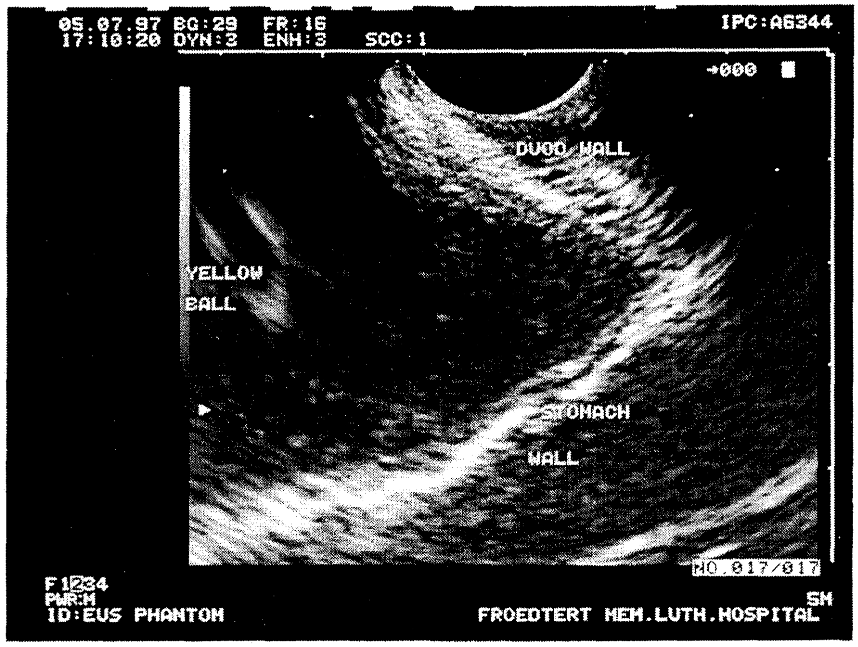

Figure 3: Ultrasound image of ball next to duodenum wall.

Figure 3 also shows one of the small balls placed under the stomach. The diameter of the ball and the distance from the transducer and the ball were measured and were within 5% of the actual values.

Another portion of the procedure involves real-time visual images. The images are displayed on a color video monitor and can help the endoscopist navigate through the organs, as well as see any deformities on the inner walls of the gastrointestinal tract. Like the ultrasound images, the visual images can be printed at any time, and the entire session can be recorded for review at a later date. **Figure 4**, on the following page, shows visual images obtained from inside of the stomach. The yellow ball can be clearly seen floating in the gelatin. The bright light of the scope makes it possible to see right through the stomach and gelatin.

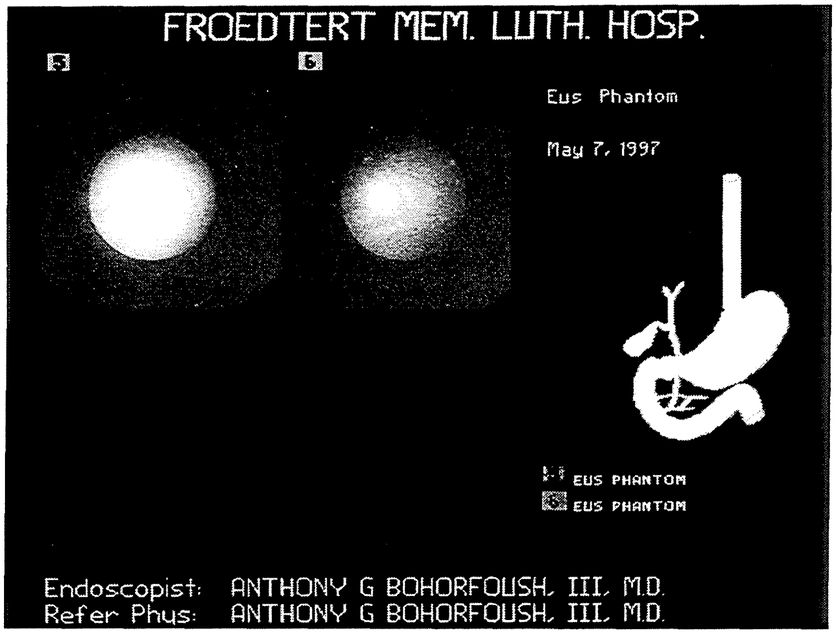

Figure 4: Images of yellow ball and duodenum entrance from inside stomach.

CONCLUSION

The medical system, developed in this project to allow physicians to practice and teach the endoscopic ultrasound procedure, was a great success. Rapid prototyping has proven to be a useful tool in surgical planning, as exemplified in this case. The doctors who tested the system were extremely pleased with the project, and commented numerous times on how similar the images obtained were to the images obtained from an actual patient. This system has exciting possibilities for training both new as well as experienced users in the performance of the procedure, and in the identification of abdominal anatomy as imaged with the EUS. The doctors, radiologists, and students at the medical colleges now have an invaluable tool at their disposal for practicing the EUS procedure.

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