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A Multimodality Navigation System for Endoscopic Fetal Surgery: A Phantom Case Study for Congenital Diaphragmatic Hernia

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Abstract

This article presents a multi-modality tracking and navigation system achieved by merging optical tracking and ultrasound imaging into a novel navigation software to help in surgical pre-planning and real-time target setting and guidance. Fetal surgeries require extensive experience in coordination of hand-eye-ultrasound-surgical equipment, knowledge, and precise assessment of relative anatomy. While there are navigation systems available for similar constrained working spaces in arthroscopic and cardiovascular procedures, fetal minimally invasive surgery does not yet have a dedicated navigation platform capable of supporting robotic instruments that can be adapted to the set of unique procedures. This article discusses the testing of the novel multi-modality navigation system in a phantom environment developed for this purpose. The outcomes suggest that the subjects demonstrated an increase in average reaching accuracy by about 60% and an overall reduction in time taken by 33.6%. They also showed higher levels of confidence in reaching the targets, which was visualised from the pattern of trajectory of movements during the procedure. To evaluate the navigation system, a phantom surgical environment was found necessary. Therefore, the article also discusses the details of the development of a fetal phantom environment for congenital diaphragmatic hernia for surgical testing, evaluation, and training. A surgical procedure was conducted on the phantom using the proposed tracking navigation system and using only ultrasound.

Keywords

fetal surgery, fetal endoscopic tracheal occlusion, FETO, congenital diaphragmatic hernia, CDH, ultrasound, USG, degrees of freedom, tracking, navigation

Introduction

Fetal surgeries are performed as a final resort to save the life of a fetus, especially when the postnatal prognosis for the condition is poor. These procedures had been mostly done using open surgical methods, which, with the progression in technology, have been transformed into minimal invasive surgeries.[1] Minimal access fetal surgery is a form of minimally invasive surgery (MIS), where, unlike most other MIS, the procedure is highly restricted in terms of field of view, dexterity, force perception, and orientation, leading to limitations in the number and type of procedure done. Many congenital conditions such as congenital diaphragmatic hernia (CDH), twin to twin transfusion syndrome, spina bifida, and so on, can be treated using minimal access procedures. For example, less invasive fetal procedures such as minimally invasive tracheal balloon occlusion are being developed as effective alternatives to open surgeries. Randomized controlled trials were conducted[1-5] to determine whether fetal endoscopic tracheal occlusion improved survival in cases of CDH.

When compared with open surgeries and regular MIS, minimal access surgery is much more challenging and requires extensive practice and training. Even simple processes such as grasping, suturing, and cauterization can be daunting. Also, the smaller the surgical instrument is, harder the manipulation and positioning become. Fetal surgeries from this perspective raise the bar

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for the challenge. MIS is entirely dependent on spatial positioning and orientation capabilities of the surgeon. Complicated visuospatial perception of the surgeon is an absolute necessity. In fetal surgery, however, there is a requirement of multiperspective viewing: hand to eye to ultrasound—eye-hand and video—eye-hand. After which there is a process of assimilation of images into surgeon's anatomical orientation, making the process more difficult.

Orientation in 3-dimensional (3D) space of surgical tools, tip tracking, and manual navigation can be very difficult in MIS procedures even to the most trained eyes. Therefore, tracking equipment with a virtual 3D software environment called navigation software is used to assist orthopedic, neurological, cardiovascular, and many other procedures.[6-8] However, there can be constraints in the physical movements of the surgical tools due to the presence of anatomical structures and cannot be identified by tracking systems. Therefore, imaging systems such as computed tomography, magnetic resonance imaging (MRI), ultrasound, and so on, have been used to extract real-world structural information from the patient's anatomy and referenced into the navigation environment. This process of registering a real-world target into a virtual environment is known as "registration."

Unlike other procedures that use non–real-time imaging modalities, fetal surgeons utilize ultrasound imaging. Therefore, the surgeon is required to imagine and coordinate the 3D orientation of the ultrasound probe, ultrasound image plane, and the tools used with regard to the anatomy on table. This process of orientation takes a lot of effort and training from the side of the surgeon. Due to the uncertainty of the target position, the tooltip can keep wavering till the specific target is reached. However, when a navigation software combined with the ultrasound imaging and tracking equipment is used, the confidence of the surgeons in terms of 3D orientation and accuracy can be much higher and the wavering can potentially be reduced. However, no such navigation systems have been implemented for use in fetal surgeries. Therefore, this article introduces a navigation environment and evaluates a navigation system that supports tracking equipment, robotics, and visual feedback in real time for use in minimal access surgeries such as fetal surgeries.

Methods

In order to evaluate the effectiveness of a navigation system, in terms of reaching accuracy, time taken to reach the target, and compare the outcomes of using such an interface with plain ultrasound guidance, 2 phantom environments are created.

Fetal Phantom Development

For the evaluation of the navigation system in a virtual surgical environment, a fetal phantom is required to be developed. The manufacturing processes include 3D printing and silicone molding for the fetal phantom development. The phantoms are held in place under water magnetically, as every phantom has inbuilt magnets that attract oppositely polarized magnets inside the water tank.

Werner and his group conducted a virtual bronchoscopy on a virtual 3D model.[9-11] In this section, a similar virtual model of a real fetal structure up to the primary bronchi is made for similar but real phantom testing. The phantom is formed in several stages, as the fetus has internal structures that are required to be formed to simulate a simple procedure such as tracheal balloon occlusion.

Initially, the 3D model is obtained from an open source MRI image and converted to STL (stereolithography) image of a 26-week-old fetus.[11] Skull of the fetus was redesigned as per the dimensions obtained from segmented MRI similar to the process used by Werner and his team.[9] Trachea, esophagus, and tongue were 3D modelled based on the information gathered from segmented MRI of the fetal anatomy.[12,13] The sections of external and internal anatomy were 3D printed separately and plastic welded together. The hollow structures like the trachea were dip coated with platinum-cured RTV (room temperature vulcanizing) silicone multiple times to obtain a thickness of at least 1 to 2 mm. Later, the 3D printed skull is glued using silicone to the silicone-molded structures. The soft structures are bonded with the 3D printed skull using GP310 RTV silicone as gluing material as seen in Figure 1b. The neck of the phantom was made with very low shore hardness 10A silicone so that it can be flexed and manipulated.

Navigation and Tracking: Demonstration of Navigation System in a Surgical Phantom Environment

The navigation environment is composed of multiple elements such as ultrasound and optical tracking systems, which exist in different local coordinate systems. For merging the different systems, both should be integrated into a world coordinate system with a common reference origin. The merging of the different coordinate systems is done by using a common plane of operation, formed by the table, and the instruments used for surgical simulation are mounted with 5 optical markers forming rigid bodies. Once placed in the respective holders, the ultrasound probe and the fetoscope can be conveniently declared as separate 6 degrees of freedom objects.[14]

Using a tracking system for tracking surgical tool handles is possible outside the body. Since optical tracking is a

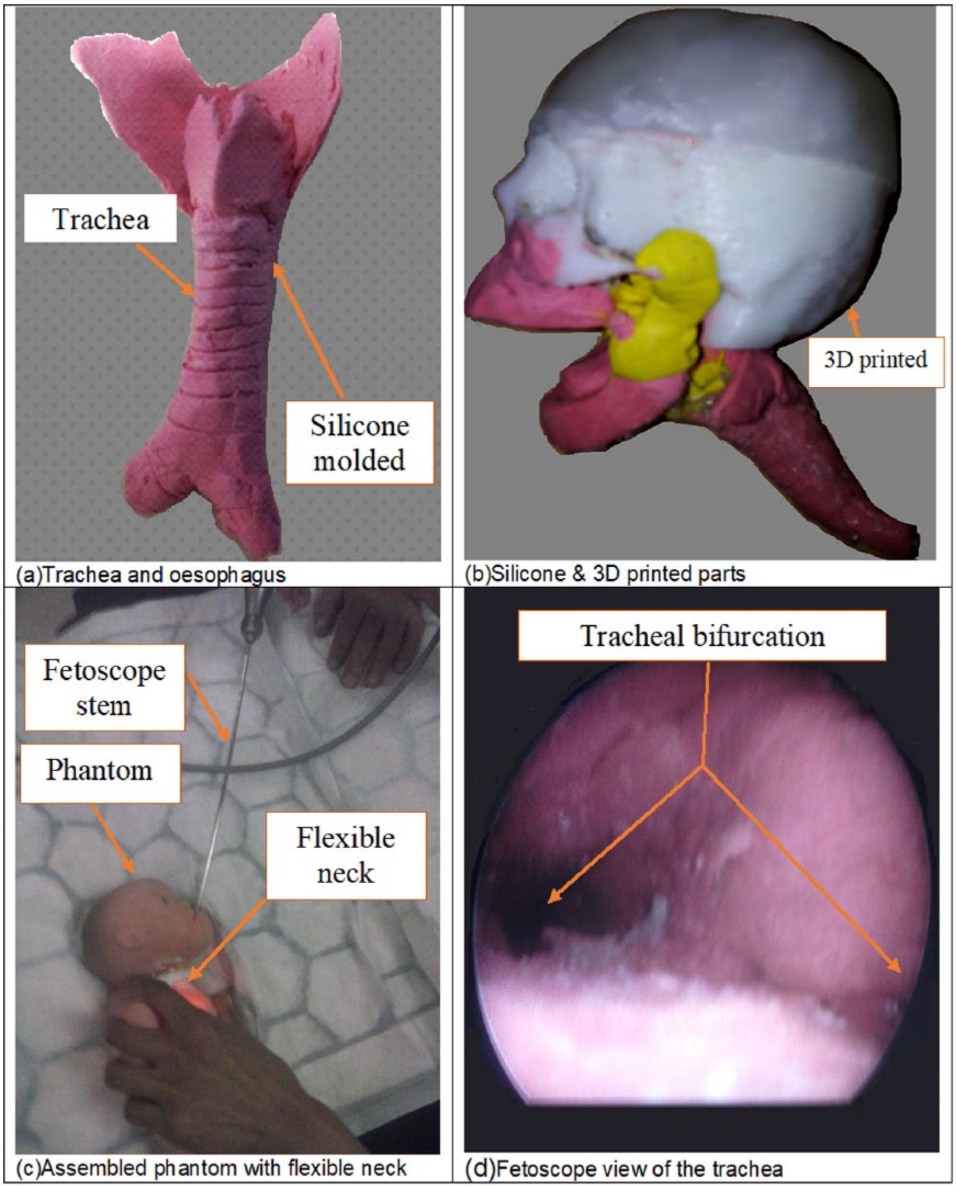


Figure 1. Fetal phantom for balloon inflation of congenital diaphragmatic hernia.

line of sight dependent system, it cannot be used for tracking inside the body. However, for rigid instruments, the tip position in relation to the handle remains constant and therefore can be mapped on to a 3D model of the instrument along with its coordinate positions, resulting in a virtual surgical tool being manipulated when the real tool is moved. It should be noted that this system requires a direct line of sight for its functionality. For the same reason, we would have to use hybrid tracking—the combination of optical tracking technology with ultrasound tracking—to get the position. This is the experiment that involves coordination and usage of most of the above-mentioned components. For this procedure to be performed, the user needs to orient the fetoscope in a specific way to achieve a complete insertion in a trachea of 7-cm length, though in the actual surgical procedure, complete insertion is not required. The phantom is placed underwater, and the subjects are requested to perform an ultrasound scan and then requested to simulate balloon inflation at different levels of the trachea. Initially, the experiment is done under ultrasound guidance and the subject sets the target. Later, the experiment is repeated with guidance using the navigation system (Figure 2).

The computer display shows the amount of *X, Y*, and *Z* translation required and indicates any 3D errors and boundaries to the marked target, provided the target has

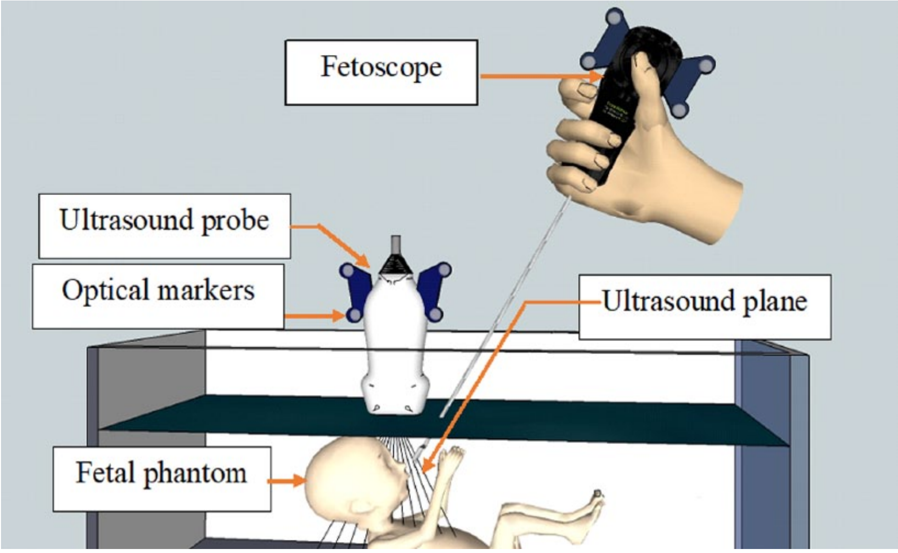


Figure 2. Fetal phantom underwater setup for fetal balloon inflation experiment simulation to assess the confidence of the surgeon and compare it with the conventional ultrasound-guided method.

been registered correctly. The position and orientation data of the tip with regard to the corresponding targets assigned are measured. Once a target is reached, the subjects are informed on the interface that they had reached the specific target and can move to the next target or repeat the experiment. The rate of movement is tracked during the entire process, and the 3D trajectory is also recorded.

Every robotics guidance system requires feedback for improvisation and effectiveness of control. Since this is entirely subjective, the subjects were requested to briefly report their perception in the surgical environment with every variation in tests and toward the end of the experiment about how the surgical guidance can be improved.

Evaluation of Accuracy When Using the Navigation System

The general flowchart used for hardware and software training of the subjects for doing the evaluation experiments is shown in Figure 3. In general, all the subjects are given a 15-minute training for hardware use and 25-minute training for the software use.

After this training process, the subjects should be able to do the following functions independently:

1. Use of ultrasound to view targets
2. Registration of targets using the fetoscope and the navigation software

Figure 4a shows the fetal surgery simulation setup. Both the fetoscope and the ultrasound probe are optically tracked. Figure 4b shows the calibration setup for the fetoscope, which also acts as the calibration plane for the table. The subject is oriented in such a way that the ultrasound, navigation interface, and the phantom are within their reach and visibility. The fetoscope has duplex wireless communication capabilities that helps communicate sensor parameters, video, and also has buttons to register targets with a single click in real time.

The navigation interface is also capable of informing the subject about the target status and if it has been reached. Trajectory data collection post registration can be enabled from the navigation interface control panel or by directly double clicking the fetoscope joystick button. The collected data are displayed on the navigation interface and saved as an Excel file with time and image reference at the point of registration. The navigation interface capabilities are not limited to line of sight or straight-line trajectory guidance. However, since optical tracking is used and the tools used are rigid, only direct guidance of fetoscope is demonstrated.

Figure 5a shows a tracked and navigated ultrasound plane in relation to the surgical tool. The tool can be seen to intersect with the ultrasound plane. In Figure 5b, the stem of the fetoscope is aligned to that of the ultrasound plane and the target point is registered using the interface control panel. Once registration is complete, a red sphere appears at the point of registration and a trajectory planning virtual cylinder appears, as seen in Figure 5c and d. Post target setting, the direction of entry of the fetoscope needs to be planned. Figure 5c and d shows screenshots of the navigation interface post registration of the target point, seen as a red sphere. Figure 5c shows an orange transparent cylinder, which

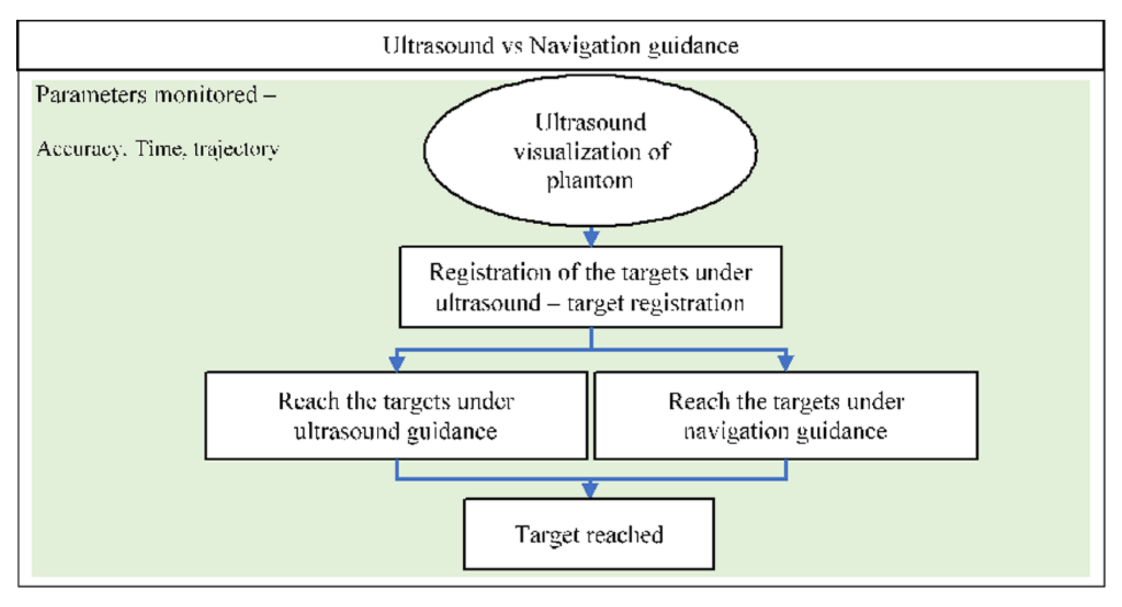
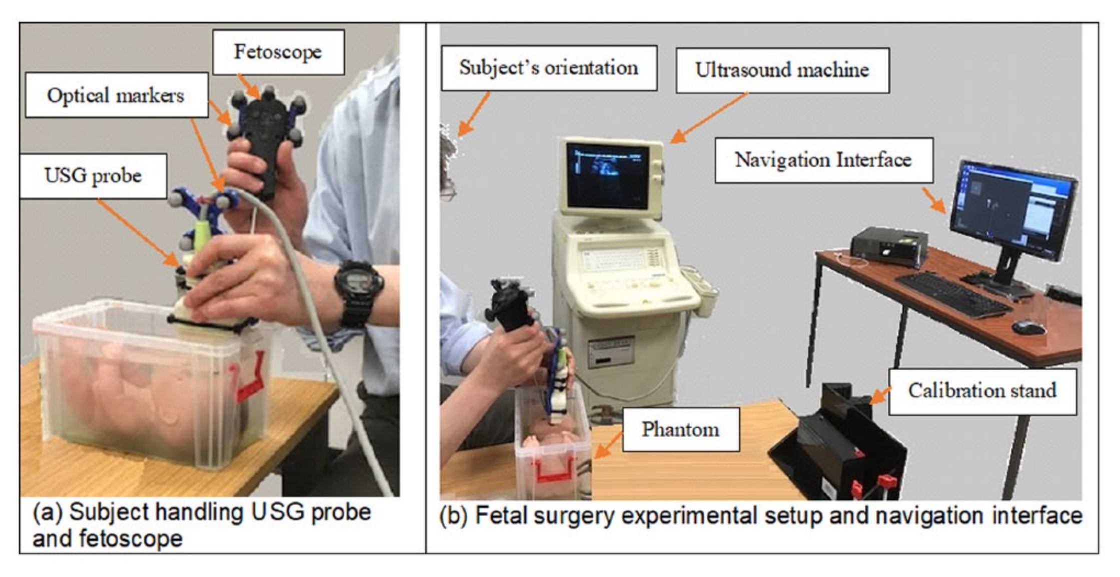


Figure 3. Flowchart for comparing the effectiveness of the navigation system versus using plain ultrasound imaging. Reaching accuracy is evaluated and time taken and trajectory are monitored and compared.



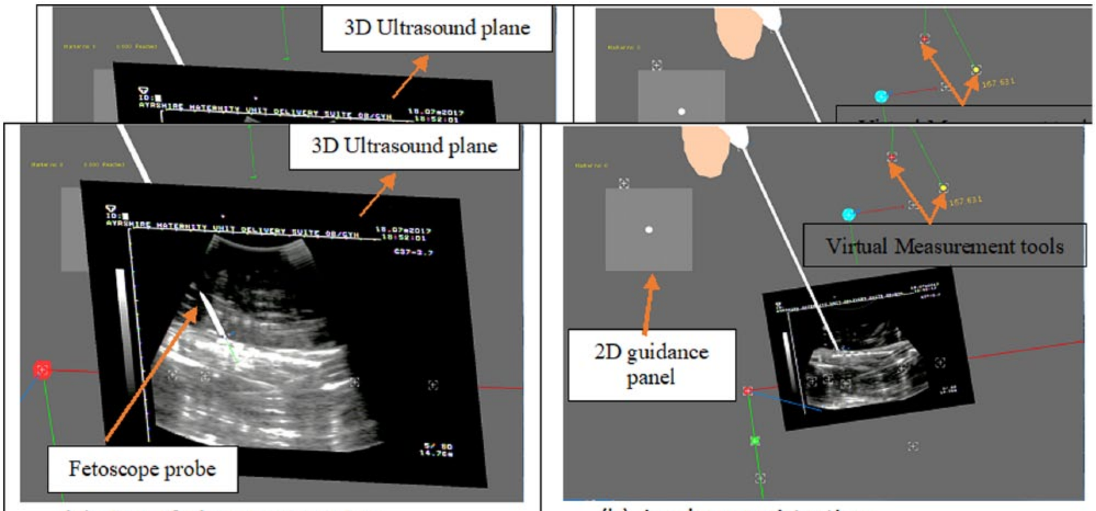
(a) Subject handling USG probe and fetoscope

(b) Fetal surgery experimental setup and navigation interface

Figure 4. Fetal surgery simulation experiment. (a) Subjects position and orientation to the phantom. (b) Screen visualization of the subject during the experiment.

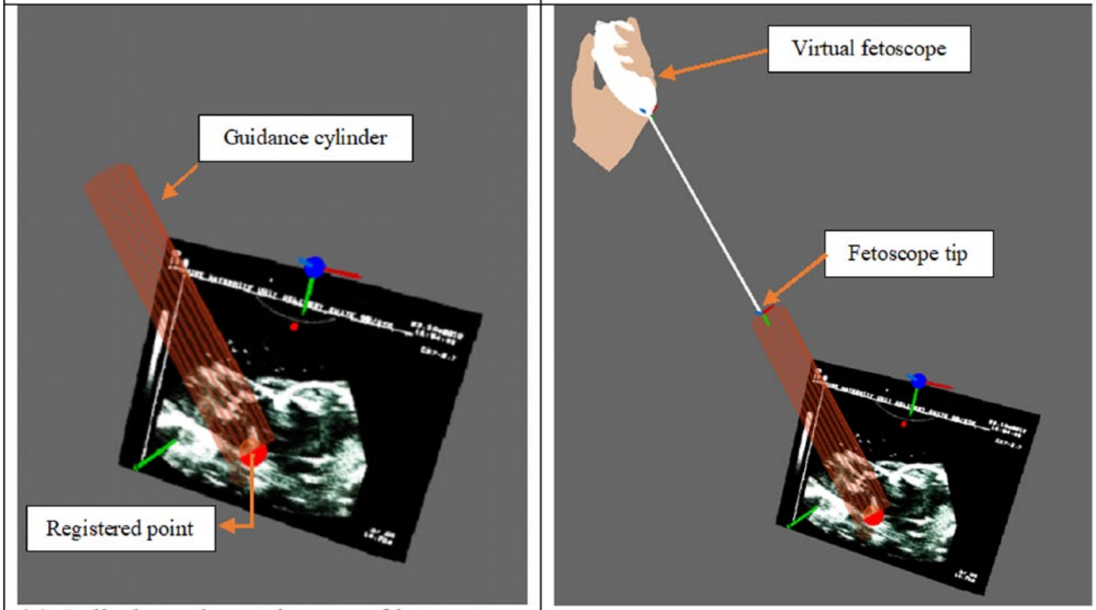
can be directed according to the direction of entry and the required angle on the interactive marker can be set. This hollow cylinder serves as the virtual guidance tube within which the fetoscope is to be always maintained in order to reach the trachea directly. Any movement outside this volume results in an error indication on the screen, which the user can easily notice and correct immediately.

Figure 6 displays a virtual 3D navigation environment and a 2D top section view. The 2D view shows the tip of the fetoscope as a red dot. The diameter of the green circle seen in the 2D view is representative of the distance between the tip and the target. Furthermore, the 3D navigation environment shows the ultrasound plane in relation to the virtual fetoscope being tracked and moved in real time. This provides a real-time orientation of the



(a) Out of plane registration

(b) In-plane registration



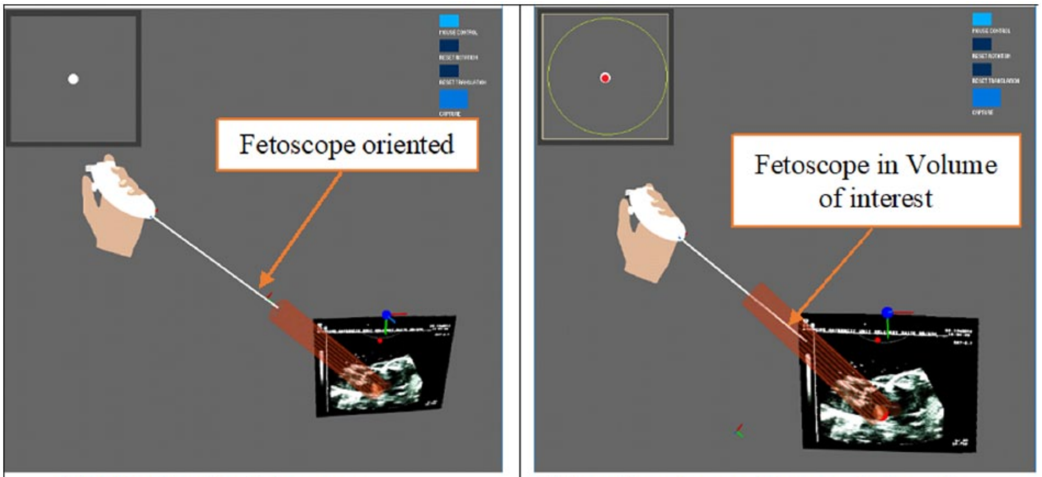
(c) Cylinder volumetric area of interest

(d) Fetoscope entering volume of Interest

Figure 5. Navigation interface showing real-time 6 degrees of freedom tracking merged with processed ultrasound image. (a) Virtual fetoscope tip in relation to the ultrasound image—out of plane positions of the ultrasound image and the surgical tool. (b) Fetoscope aligned along the ultrasound plane and specific target is registered virtually. (c) Volume of interest positioned as a cylinder arising from the point of the target. (d) Fetoscope entering the volume of interest.

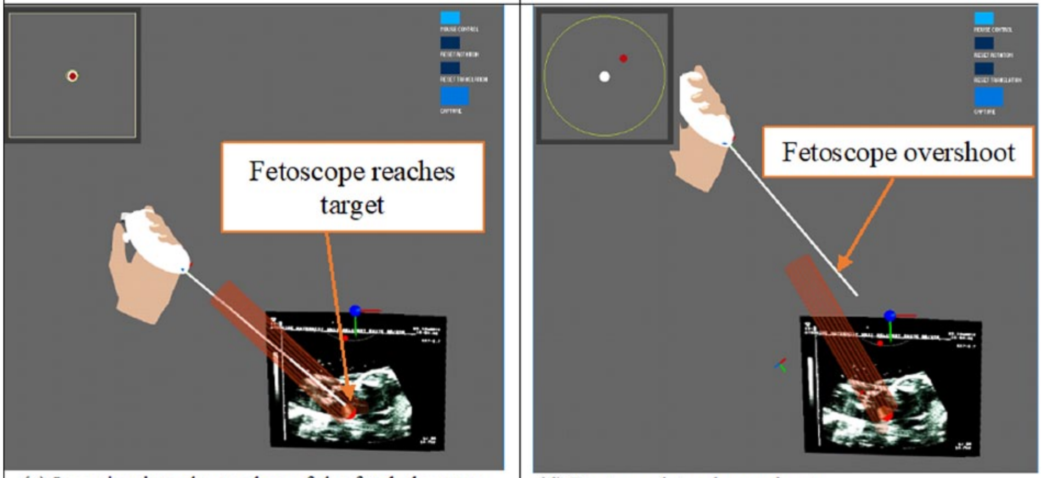
fetoscope to the target and helps move it in the preplanned trajectory along the axis of the orange guidance cylinder. Figure 6a to c illustrates the process of achieving the target. Figure 6d shows how self-intuitive and simple it is for the untrained eye to identify and correct the errors in navigation. Hence, in ultrasound-guided (USG) fetal surgeries like CDH, intrauterine myelomeningocele, and so on, and conventional USG biopsies, catheterization, and fluid aspiration techniques, this system can be employed.

The fetoscope insertion into the trachea of the fetal phantom and fetal balloon inflation simulation were done with and without the tracking system guidance. The subjects reported that they had a better 3D orientation with the proposed guidance system. Graph time required using



(a) Orienting the Fetoscope

(b) Insertion along guidance cylinder axis



(c) Insertion into the trachea of the fetal phantom

(d) Postero - lateral overshoot

Figure 6. Process of guidance from the user navigation interface. (a) Orienting the fetoscope. (b) Insertion along the axis of the guidance cylinder. (c) Insertion into the trachea of the fetal phantom. (d) Posterolateral overshoot.

only ultrasound versus time required to do the procedure using the proposed tracking system.

Results and Discussion

The experiment focuses on simulating a simple fetal surgical procedure involving the method of reach and ideal angle of the approach. The trajectory of movement adopted for reaching and the time taken for the process can indicate the confidence of the subject. The fetoscope insertion into the trachea of the fetal phantom and fetal balloon inflation simulation were done with and without the tracking system guidance. Figure 3 shows the setup used for this experiment and the subject's orientation to the fetal phantom, ultrasound machine, and the navigation guidance in the computer. The subjects were assisted in one-click registration within the ultrasound image interface on the computer. Once the required points are registered under ultrasound, the tracheal insertion process under ultrasound guidance is compared with the same procedure assisted by the proposed navigation interface.

Figure 7 shows the corresponding error distance and time taken to reach the registered target. The results of Figure 7 suggest that ultrasound guidance resulted in an average reaching inaccuracy of 6.8 mm and the maximum error was as high as 9.8 mm. Whereas, when the subjects used the proposed navigation system, it resulted in finer strokes. The subjects could concentrate more on getting the position of tip correct, and the average inaccuracy was 2.7 mm and the maximum error was lower than 4.5 mm.

The subjects with ultrasound training and experience found the interface and the guidance self-intuitive and relatively straightforward. Inexperienced subjects,

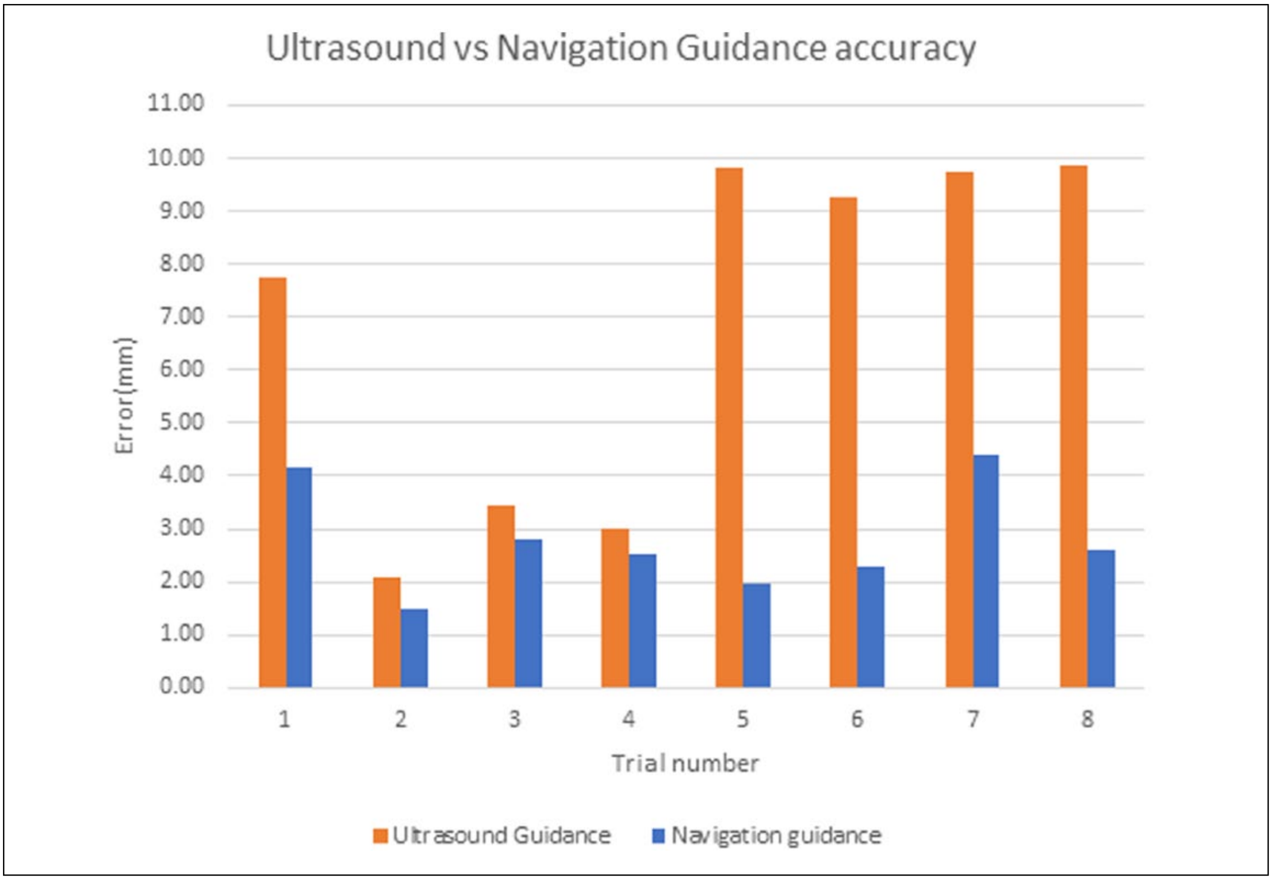


Figure 7. Graph distance to target using ultrasound versus distance to target using fetal surgery assistance system.

nevertheless, had orientation problems because of less hand-eye coordination and understanding of mirrored kinematics in terms of endoscopic surgery. But, overall, the subjects reported that they had a better 3D orientation with the proposed system.

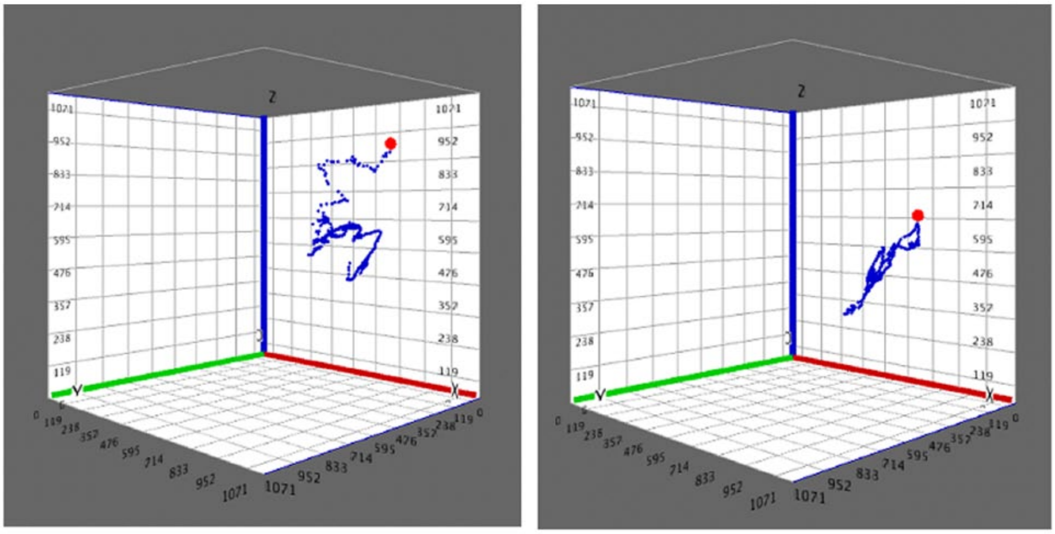
The motion trajectories accumulated during the best case of ultrasound guidance–assisted simulated surgical procedure and multimodality assistance are compared Figure 8a and b, respectively. In Figure 8a and b, the blue dots represent the trajectory, and the red dot indicates the point of entry in Figure 6a showing the top face of the orange virtual cylinder and the target point seen as a red sphere on the other face of the cylinder seen in Figure 6b. From the comparison, accumulated trajectory points using only the ultrasound can be seen to have wavering, whereas the proposed system reduced the number of wavering movements of the surgical instrument.

Figure 9 shows the results for the time taken to attain the target excluding the duration spent for registration when conventional ultrasound techniques and multimodality navigation guidance are used. The comparison between the 2 modalities reveals that the subjects on an average were 33.6% faster when multimodality tracking was used when compared with the USG procedure.

Conclusion

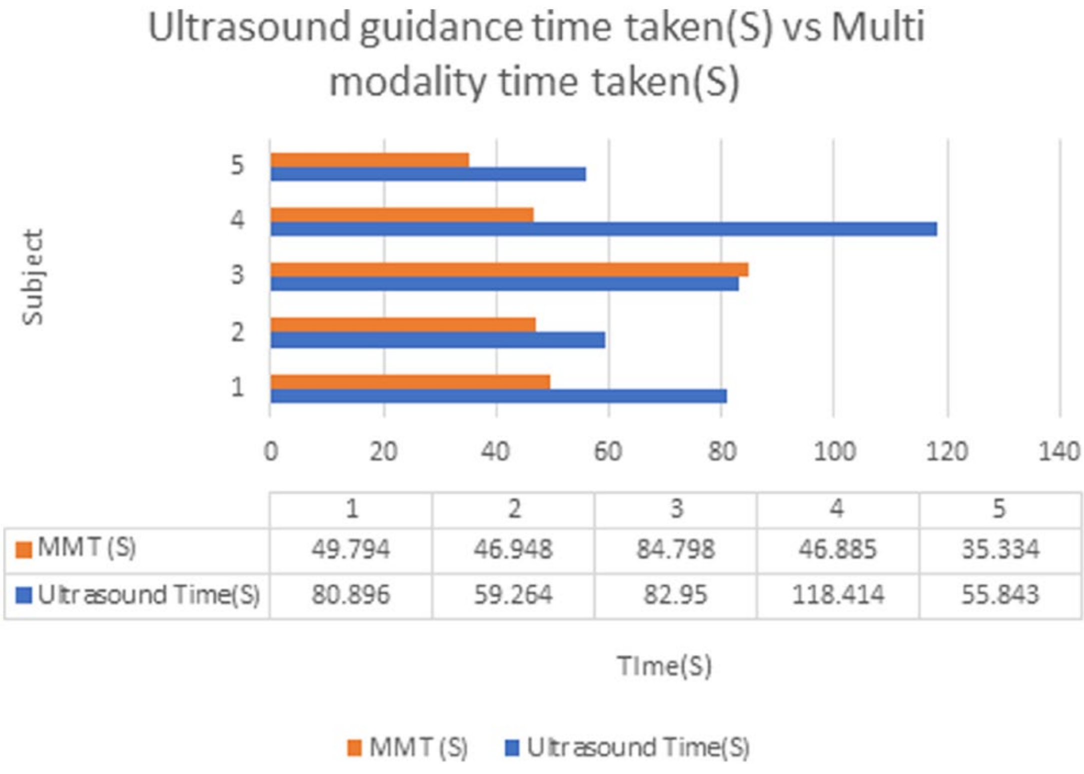
A simple surgical procedure has been simulated on a fetal surgery phantom under ultrasound and multimodality guidance. While all other subjects were given half an hour of training, one of them who did not receive the complete training took more time than the others, and this explains the impact of training when using the navigation assistance setup. The accuracy, the trajectory of movements adopted by the subjects, and the duration taken to reach set targets have been compared in both cases.

The pattern of the trajectory of the movement of instruments is usually an indication of the confidence of the subjects. Results showed that the subjects tended to waver due to target position uncertainty and an inability for preplanning under plain ultrasound guidance. Whereas, with the proposed navigation system, the users did not fluctuate much and reached the goal with relative ease and stability. The observations also indicate that subjects had a more profound sense of orientation and had a



(a) (b)

Figure 8. Trajectory of tip movement during the experiment of a comparison between the 2 methods. (a) Ultrasound guidance trajectory of tip movement (best case). (b) Multimodality navigation guidance trajectory of tip movement.



	1	2	3	4	5
MMT (S)	49.794	46.948	84.798	46.885	35.334
Ultrasound Time(S)	80.896	59.264	82.95	118.414	55.843

Figure 9. Comparison of time taken to reach the target under the ultrasound guidance and multimodality tracking guidance.

better perception of the relationship between the tooltip and the target in 3D space. Use of multimodality tracking resulted in a shorter and clearer trajectory, reduced the average duration taken to reach targets, and greater overall accuracy. Therefore, the proposed navigation system could potentially help increase accuracy, increase the confidence of the surgeons, while also reducing the time taken for the procedure.

Author Contributions

Study concept: Wei Yao
Design, analysis, and interpretation: Hariprashanth Elangovan
Study supervision: Kypros Nicolaides
Study concept and design: Wei Yao
Acquisition of data: Hariprashanth Elangovan
Analysis and interpretation: Wei Yao
Study supervision: Kypros Nicolaides

Declaration of Conflicting Interests

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