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RESEARCH NOTE

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Development of a simulator for training of fetoscopic myelomeningocele surgery

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Abstract

Objective: To develop a realistic simulation model for laparotomy-assisted fetoscopic spina bifida aperta (SBa) surgery, to be used for training purposes and preoperative planning.

Methods: The predefined general requirement was a realistic model of an exteriorized uterus, allowing all neurosurgical steps of the intervention. The uterus was modelled using ultrasound and MRI images of a 25 weeks' gravid uterus, consisting of flexible polyurethane foam coated with pigmented silicone. The fetal model, contained an opening on the dorsal side for a customizable spinal insert with all the aspects of a SBa, including a cele, placode, and myofascial and skin layer. The model was assessed in a series of validation experiments.

Results: Production costs are low, uterus and fetus are reusable. Placental localization and the level and size of the spinal defect are adjustable, enabling case-specific adaptations. All aspects of the simulator were scored close to realistic or higher for both appearance and functional capacities.

Conclusions: This innovative model provides an excellent training opportunity for centers that are starting a fetoscopic SBa repair program. It is the first simulation model with adjustable spinal defect and placental localisation. Further objective validation is required, but the potential for using this model in preoperative planning is promising.

Key points

What is already known about this topic?

- Fetal surgery is a well-known option for the treatment of myelomeningocele (MMC), yet the downside of the open procedure is its invasiveness. Fetoscopic surgery may be an option to overcome at least part of these complications but comes with a long learning curve.
- Simulation models may prove themselves effective in shortening these learning curves; however, for MMC, the current models are either expensive, animal based, or low fidelity.

What are the novel findings?

- This is the first model for fetoscopic MMC repair that has the option to adjust both the characteristics of uterus and spinal defect. Furthermore, the spinal defect is developed to provide the opportunity to train all essential components of the neurosurgical part of this intervention.
- This low-cost, yet high-fidelity, simulation model could be useful in shortening learning curves, and after further refinement for preoperative planning.

Spina bifida aperta (SBa) is a severe condition, with significant neurological impairment due to local neural damage in combination with central brain abnormalities (Arnold-Chiari II malformation and hydrocephalus amongst others). Fetal surgery can ameliorate postnatal outcomes, but the current gold standard of an 'open' (*i.e.*, requiring maternal laparo- and hysterotomy) procedure comes with substantial maternal risks.[1] The latter has prompted multiple centers to develop a fetoscopic approach. However, these are complex procedures and require a substantial learning curve.[2] Simulation training provides an excellent opportunity to gather sufficient exposure, and thus has become an essential part of training programs for junior surgeons.

Ideally, a simulation model combines both purposes of training and surgical preparation and is realistic, case-specific, low cost, reusable, and of nonanimal origin. This study aimed to create such a training simulator, based on the laparotomy-assisted fetoscopic technique described by Belfort et al.[3]

The steps for surgical repair of the SBa defect are: (1) dissection of the placode with release into the spinal canal; (2) closure of the myofascial layer, and (3) closure of the skin to create a watertight closure of the defect, for which the designed defect needed to have all of the relevant anatomical structures. For realistic simulation of the fluid-filled sac, fluid spill, a reduction in tension of the arachnoid, and retraction of the placode into the spinal canal should be visible after incision. To allow future correlation with the defect's characteristics on ultrasound imaging, the defect had to be incorporated into a model part that could be inserted into a fetal model.

The fetus needed to have the appearance and size of a 25 weeks' fetus, with adequate flexibility to allow external version.

The uterine model (Figure 1) was designed to have the following properties: a realistic appearance of a uterus of 25 weeks' gestation, the ability to stretch with insufflation, the possibility to train port placement using the Seldinger technique, and provide an accurate representation of the intrauterine space during fetoscopic surgery. Additionally, *external visualisation* and a case-specific location of the placenta should be possible to plan the position of the port insertion sites.

All components and casting molds for silicon parts were designed in Fusion 360 (version 11.5.6, Autodesk, San Rafael, CA, USA). Molds for silicone casting were printed using a thermoplastic polymer (Tough PLA, Ultimaker B.V., Utrecht, The Netherlands) on a 3D printer (Ultimaker S5, Ultimaker B.V.). For specific components, different materials were chosen based on their specific properties.

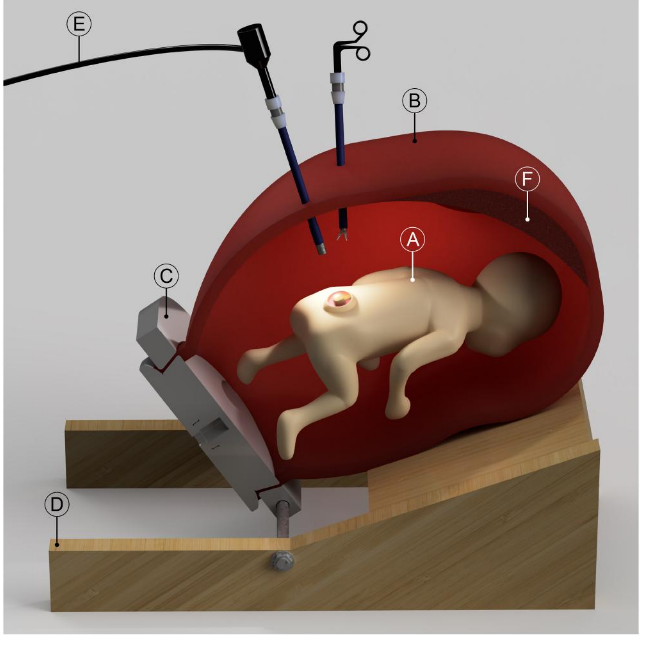

FIGURE 1 Graphic representation of the fetoscopy simulator. The fetal model (A) is placed inside the uterus (B) to recreate the surgical environment during fetoscopy. The uterus is closed off using a connector (C) that forms a hinge together with the wooden support structure (D). The ports with the fetoscope and trocars (E) can be inserted anywhere on the uterus at least 5 cm from the placenta (F) [Colour figure can be viewed at wileyonlinelibrary.com]

Silicone pigments were used to dye silicone casts (Silc Pig® Smooth-On Inc., Macungie, PA, USA).

The defect was incorporated in a reusable flexible insert containing rigid vertebrae (red TPU 95A and white ABS, Ultimaker B.V). The placode with the spinal cord, arachnoid, and myofascial and skin layers were made of silicone rubber (Dragonskin™ FX-Pro™, Smooth-On Inc). To allow suturing and to create homogeneous stretch properties of the skin layer, two layers of stretch mesh were incorporated in perpendicular directions. For a watertight connection to the polyurethane insert, the tissue layers were connected using cyanoacrylate glue (Super Glue Gel, Bison). The defect was represented by a cavity at the SBa site, which was connected by a channel to a Luer lock connector. The channel holds the spinal cord and allows infusion of water using a two-way Luer lock valve.

To provide an appropriate reflection of the weight and flexibility, the reusable fetus was made of silicone rubber (Ecoflex 00-30, Smooth-On Inc.). On the posterior side of the fetus, there is an opening for the insert.

The uterus was made from pourable flexible polyurethane foam (FlexFoam-iT! V, Smooth-On Inc.) and the placenta was made of silicone foam (Soma Foama 15, Smooth-On Inc.). The design was based on MRI images. Insertion and removal of the fetal model, placenta, and amniotic fluid is possible through a 75 mm diameter opening at the cervical end. Both the uterus and placenta were covered in pigmented silicone (Dragonskin Fx-Pro, Smooth-On Inc.). For training purposes, the placenta can be placed at any location on the uterine wall. After inserting the fetus and adding the amniotic fluid, the opening at the cervical end is closed. A plastic hinge connector (Tough PLA, Ultimaker B.V.) allows watertight closure of the uterus and connects it to a wooden support frame. The hinge mimics the exteriorized position and allows positioning of the uterus for port placement.

For evaluation, we used a simulator of which the fetus had a lumbar SBa and an anterior position of the placenta. Four obstetricians with experience with fetoscopic port placement evaluated this part of the procedure. The uterus was partially filled with saline to substitute amniotic fluid. The material of the uterus allows the external visualization of the placenta with a light source. This feature avoids the need for an ultrasound device at each training session. A 12 French cannula (Performer Introducer, RCFW-12.0-38-J, Cook Medical, Bloomington, IN, USA) was inserted into the uterus, followed by insufflation. The correct position of the port with respect to the fetus was visually confirmed using a 0° 4 mm rod lens scope (27015A, Karl Storz, Tuttlingen, Germany) connected to a TELE PACK + monitor (Karl Storz).

The neurological part of the surgery was evaluated by three pediatric neurosurgeons experienced in postnatal SBa repair; this was done directly on the fetus to allow for tactile feedback of the tissue layers. The insert containing the SBa defect was filled with water to simulate spinal fluid. The myofascial layer can be dissected and sutured, followed by interrupted sutures to close the skin layer. Sutures were performed using 5-0 Monocryl™ (Ethicon Inc., Raritan, NJ, USA). Once finished, the water tightness of the operated SBa was tested using the incorporated valve system.

After completion of the procedure, realism of appearance and handling were separately evaluated using a 4-point scale. For each component, appearance was scored, while handling was assessed per procedural task. For all items, the following score was applied: (1) unrealistic, (2) a bit realistic, (3) close to realistic, and (4) realistic. Additionally, three yes–no questions evaluated the expert opinion on the usefulness of the simulator for training and for case-specific preparation.

The participants were able to perform all tasks on the simulator and all aspects of the simulator were rated between “close to realistic” and “realistic”. The content validity was rated through the realism of the performed tasks, which were also rated between “close to realistic” and “realistic”. The surgeons all agreed that the simulator is suitable for use as a training model for fetoscopic repair of SBa as well as for case-specific surgical preparation based on the tissues and tissue handlings. They agreed that the simulator can improve cooperation between obstetrician and neurosurgeon.

In this paper, we describe the development and evaluation of a training simulator for fetoscopic SBa surgery. It is the first training model containing a realistic and modifiable representation of the uterus, placenta, and fetus. The developed model provides an excellent opportunity for both training and case-specific surgical preparation. Moreover, the materials used are widely available and thus, provided the availability of a 3D printer; the model can be easily reproduced with minimal investment costs.

Most parts of the design are reusable, including the fetus and plastic base of the insert. The uterus can be used several times, depending on the leakage caused by trocar placement. The silicone components of the defect are single-use. The set-up time for training purposes using non-case-specific pre-produced components is 30 min. The production costs for a set of silicone components are around 60 euros. For case-specific training, the insert containing the defect needs to be printed and the silicone components of the insert have to be cast, requiring approximately 2 days of production time.

There are several training models available for fetoscopic SBa surgery. In one model, the fetus consists of a doll on which a piece of raw chicken is attached to its back and is then placed in a kickball forming the uterus.[4] This model does represent the fetus within a restricted surgical space; however, it does not account for the different tissue layers of the SBa and watertight suturing cannot be assessed. Likewise, the kickball does not provide the limitations with port placement that the anatomy of the uterus and location of the placenta impose. A more refined version of the fetus in this model was recently published.[5] Using 3D images of the fetal spine, a case-specific fetal defect can be generated that has proven to be very useful in the rehearsal of the surgical procedure. The uterus was still represented by a kickball.

Another simulation model that is commercially available has a realistic appearance of the maternal abdomen and uterine wall; however, the fetal model is basic and has no SBa.[6] Another important consideration is that this simulation model is relatively expensive, especially when compared to the model that we developed.

At the moment, there are two different animal models for fetoscopic SBa surgery. One was created to evaluate a running single suture technique using two-port access. This surgical model consisted of lambs with surgically created SBa defects.[7] The other was developed specifically for the purpose of training the fetoscopic approach. In this leporine model, the abdominal cavity mimics the amniotic cavity and defect repair is practiced on the gastric fundus.[8] While both models are high in fidelity, these uterine analogues are either thinner (sheep) or of a different structure (rabbit abdominal wall) than a gravid uterus and thus less realistic. In addition, animal models are logistically difficult to use repeatedly, are expensive, and come with ethical constraints. Our model can be used repeatedly without the logistical and ethical constraints associated with animal models.

There are several possible applications of our simulator in dedicated fetal surgery centers apart from it is possible role in shortening extensive learning curves.[2] For instance, as it is a desktop model with limited preparation time, this simulator provides an easily accessible opportunity for more experienced surgeons to maintain certain surgical skills, and also to rehearse or recreate unusual operative complications. In addition, because the simulator contains a uterus and a fetus, it also provides an opportunity for multidisciplinary practice. The simulator may also provide a standardized environment in which technical improvements and alterations can be evaluated. For example, a 2-port technique can be compared with a 3-port technique in identical settings. But also, adaptations such as the use of a dural patch, as well as instrument or entry port modifications, could be tested using this simulation model. One could also recreate other neural tube defects on the insert, such as myeloschisis, but adaptations of the fetal model for other fetoscopic interventions, such as gastroschisis, are also relatively easy.

Case-specific modifications require processing of ultrasound imaging or MRI, and this can thus far not be done automatically. The materials used in this model negatively influenced the spatial resolution of the ultrasound imaging, and thus, it is currently not possible to fully practice the ultrasound guided parts of the procedure (*i.e.*, determination of fetal position, trocar placement, and fixation). Regarding the limitations of this study, the evaluation experiment was based on subjective feedback from a small group of participants. However, we feel that this was sufficient to demonstrate the realistic appearance of the model.

In summary, we describe the development of a low-cost, realistic training simulator for fetal surgery of SBa for which the fetal and maternal anatomy, the intended surgical procedure, design, and production requirements were investigated. Future developments should focus on continuing the refinement of its components, validation as a training device, and evaluation of its role in surgical planning.

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CONFLICT OF INTEREST

Authors declare to have no conflicts of interest.

DATA AVAILABILITY STATEMENT

Data is available upon reasonable request.

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