HSLU Hochschule Luzern

Technik & Architektur

Master of Science in Engineering with Specialization in Medical Engineering

Development and Validation of a Simulated-Use Model

of the Abdominal and Uterine Wall for a Transuterine Trans-Amniotic Suturing Device

Fig.1. Simulated-use model design.

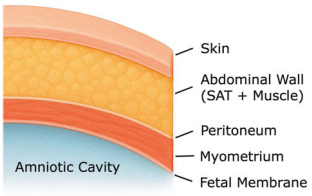

Fig.2. Tissue layer structure.

Fig.3. Intra-amniotic view while suturing.

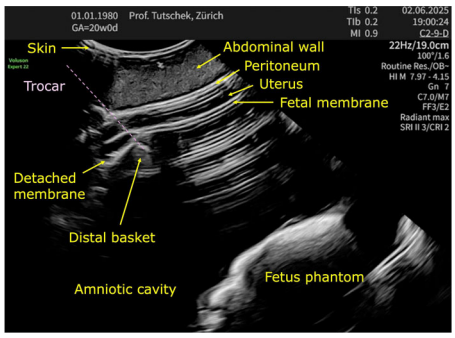

Fig.4. SUM ultrasound image obtained during clinical validation with Prof. Tutschek.

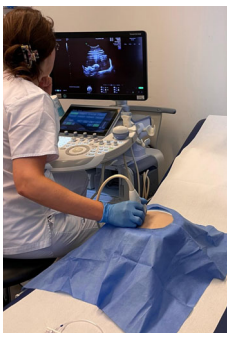

Fig.5. Validation setup at Kantonsspital Luzern.

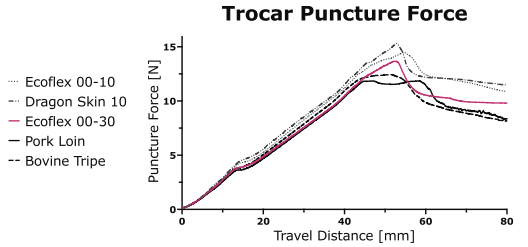

Fig.6. Puncture force of different uterine tissue mimics.

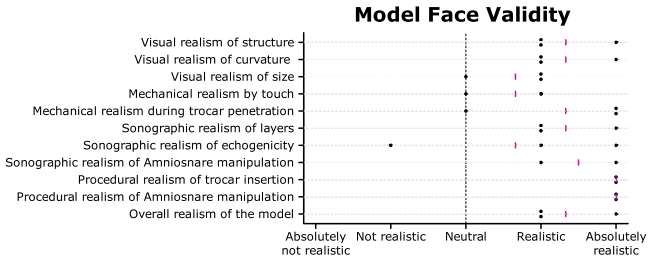

Fig.7. Results of clinical face validity assessment.
• = individual rating by a specialist, | = mean.

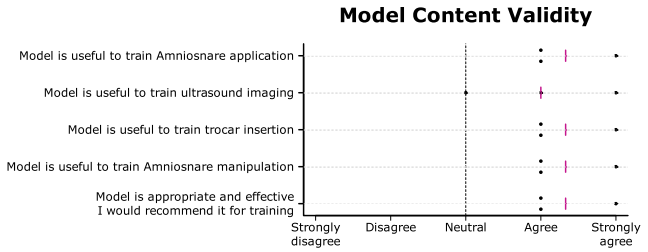

Fig.8. Results of clinical content validity assessment.
• = individual rating by a specialist, | = mean.

Problem Statement

KOVE Medical is in the final phase of developing the Amniosnare intended to place a transuterine trans-amniotic suture for approximation of fetoscopic port site punctures. The fixation of the fetal membranes to the uterus aims to reduce preterm birth and other post-operative complications following fetoscopic interventions.

In order to obtain market clearance for the Amniosnare device, KOVE Medical must first conduct design and usability validations. However, due to the novelty of the device, an appropriate simulated-use model (SUM) for validation testing does currently not exist. Therefore, KOVE Medical requires a newly developed and validated SUM replicating the mid-gestational pregnant abdomen, including the uterine wall and the fetal membranes. This model should subsequently enable KOVE Medical to perform preclinical device validation, usability studies, and surgical training with the Amniosnare device.

Design Approach

Model requirements were defined based on literature, FDA guidelines, and clinical input. An iterative development process was used to implement and test these requirements. Mechanical and sonographic verification, theoretical comparisons with literature data, and evaluations by clinical experts were conducted to support appropriate material selection and model design.

Functional and critical user tasks validation was conducted with experts from KOVE Medical. The validation of the model's clinical relevance and realism was evaluated by clinical specialists from three institutions in Germany and Switzerland.

Results

The developed SUM fulfils the pre-defined requirements and provides a modular, reproducible, and transportable simulation tool. It enables the simulation of all clinically relevant steps and critical user tasks during Amniosnare application under realistic ultrasound imaging conditions.

Clinical specialists assessed the SUM to realistically mimic the anatomy of the pregnant female abdomen at 20 weeks of gestation (Fig. 7) and to be appropriate for surgical training with Amniosnare (Fig. 8).

In conclusion, the SUM offers KOVE Medical a valuable tool for preclinical evaluation of the Amniosnare device in simulated use settings.

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KOVE