# Validation of an Instrument Prototype for Fetoscopic Surgery of Gastroschisis in an Amniotic Infusion Model – Preliminary Results

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## Background

Gastroschisis is a congenital abdominal wall defect characterized by protrusion of intestinal loops with simple and complex forms, the latter associated with higher morbidity and mortality. Animal studies suggest fetoscopic covering of the exposed bowel may improve neonatal outcomes, particularly in complex cases. However, securing the covering bag remains technically challenging.

This study evaluated a new prototype, designed to improve bag fixation, in an avital uterine model with simulated amniotic fluid.

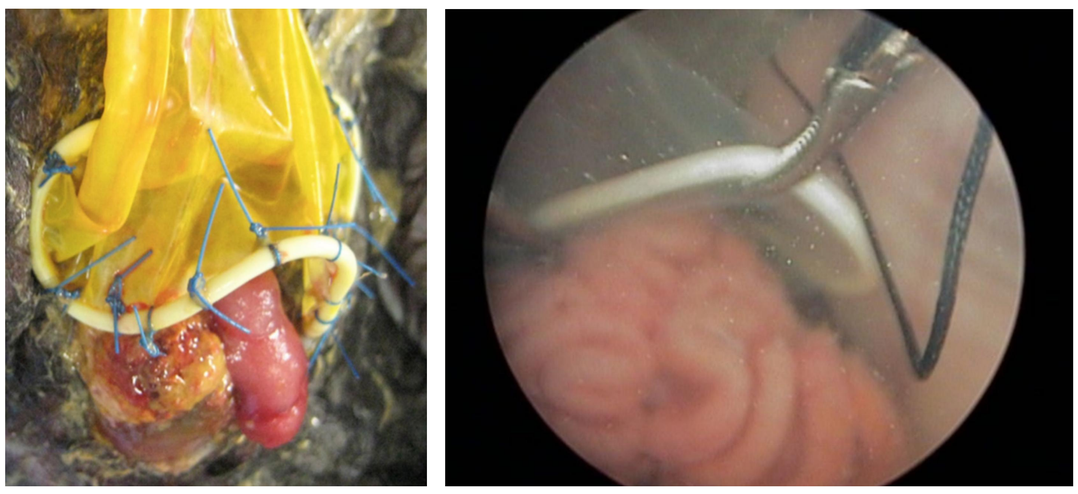

Figure 1. After fetoscopic bag fixation the intestine shows a less swelling and peel formation, even if the bag was partially dislocated until birth. (Bergholt et al., 2020)

## Methods

A prototype instrument for fetoscopic coverage was developed and tested in a self-designed, avital uterine model containing simulated amniotic fluid and a 25-week gastroschisis fetal model. The bag was fetoscopically sutured to the simulated defect: Each participant performed two fetoscopic suture rows; each including two fixations—one using the prototype and one without. A fixation consisted of four knots securing the bag to the simulated defect. Total and per-knot fixation times were recorded.

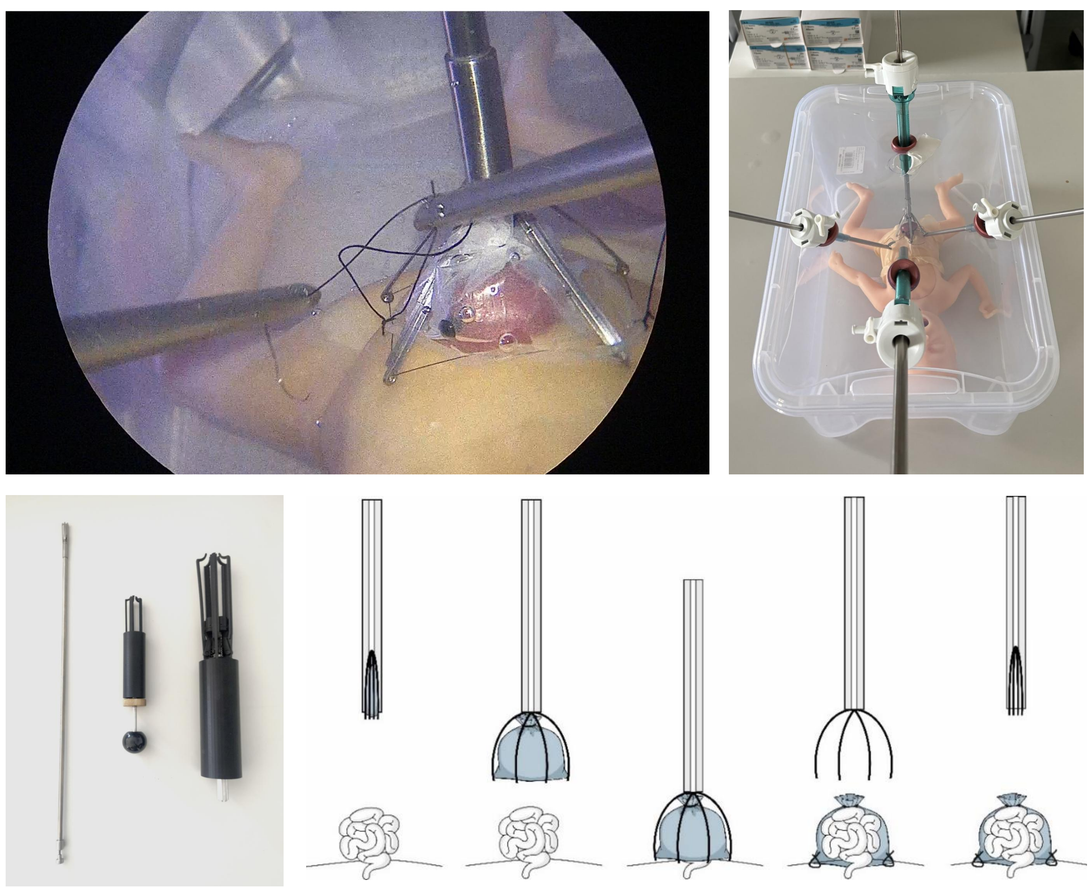

Figure 2. To address this problem and optimize bag fixation, we collaborated with the Faculty of Engineering in Kiel to develop a prototype instrument, with a final diameter of less than 0.7 cm and designed like an umbrella.

## Results

Five participants completed the experimental protocol. Median knotting time was significantly shorter when using the prototype compared with manual fixation (1,194 s [IQR 251.8] vs. 1,953 s [IQR 553.1]; $p = 0.031$). The first suture row showed a marked reduction in time ($p = 0.031$), whereas the second row demonstrated a non-significant trend toward improvement ($p = 0.219$), suggesting a potential learning effect.

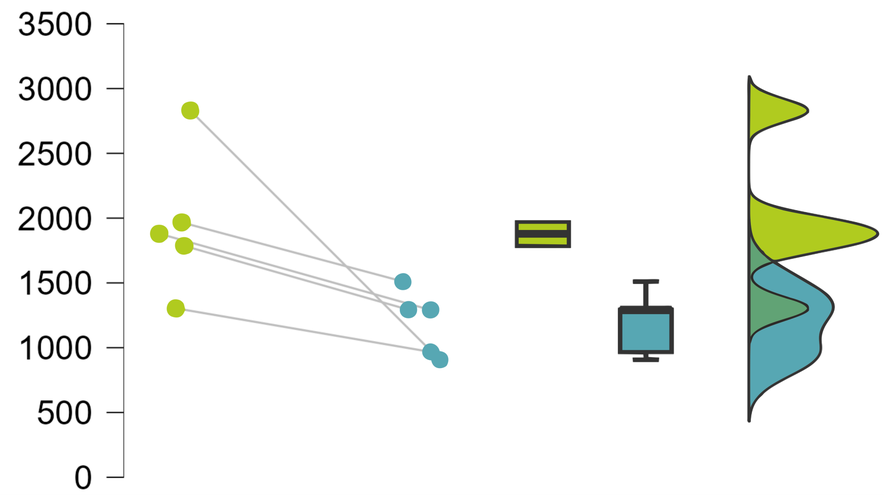


Figure 3. Box and raincloud plots of paired times without (green) and with the prototype (blue), showing a significant reduction of knotting time in seconds with prototype use.

## Conclusion

The prototype significantly reduced procedure time under amniotic infusion conditions, outperforming previous results under PACI (partial amniotic carbon dioxide insufflation). The most pronounced benefit was seen during the first suture row, suggesting a potential learning effect. Further evaluation with a larger sample is ongoing to confirm these findings and compare performance between infusion and PACI conditions.