

Micheletti T¹, Cabral L¹, SL Yong¹, Febas G² , Borrós S², Eduard Gratacos¹, Eixarch E¹

1.BCNatal | Fetal Medicine Research Center (Hospital Clínic and Hospital Sant Joan de Déu, University of Barcelona), Barcelona, Spain; Institut d’Investigacions Biomèdiques August Pi i Sunyer (IDIBAPS), Barcelona, Spain; 2. Grup Grup d’Enginyeria de Materials (GEMAT), Institut Químic de Sarrià, Universitat Ramon Llull, Barcelona, Spain

Objective

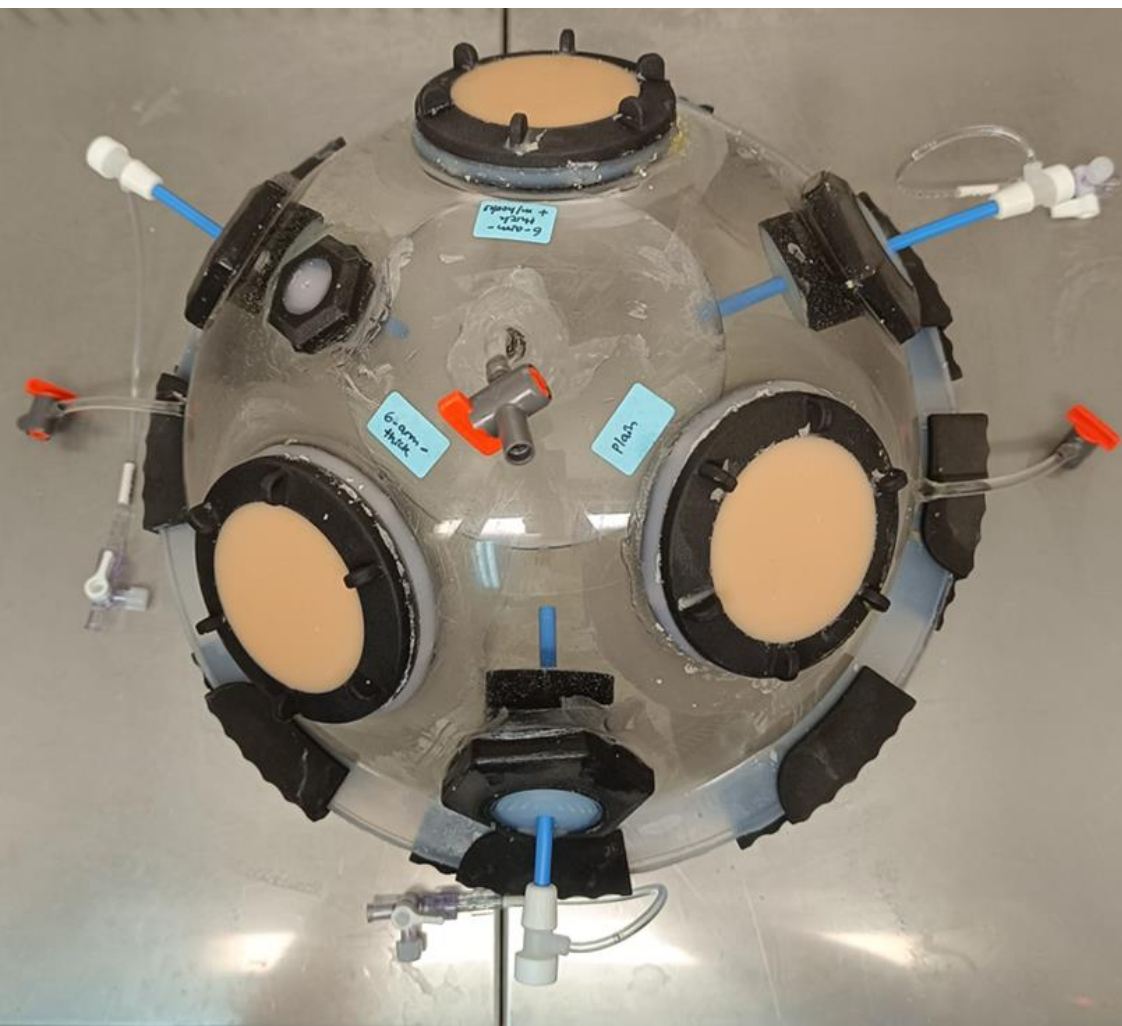
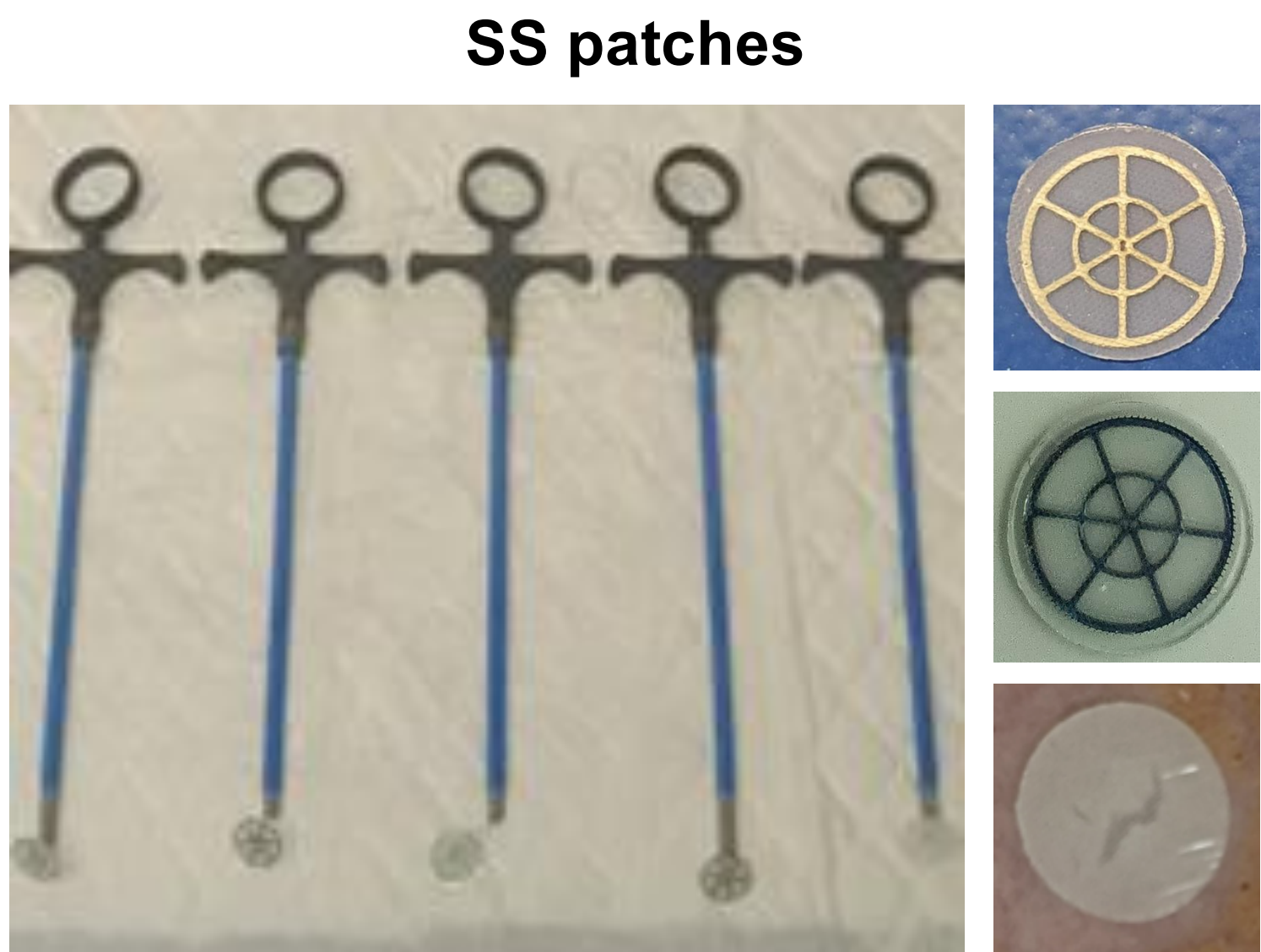
To evaluate the feasibility of insertion and 15-day adhesion of sealing system patches (SSp) combining Nitinol-integrated silicone (NiS) and a cyanoacrylate-based bioadhesive (CbB) for fetal membrane defects post-fetoscopy in a custom-made simulated uterine environment.

Methods

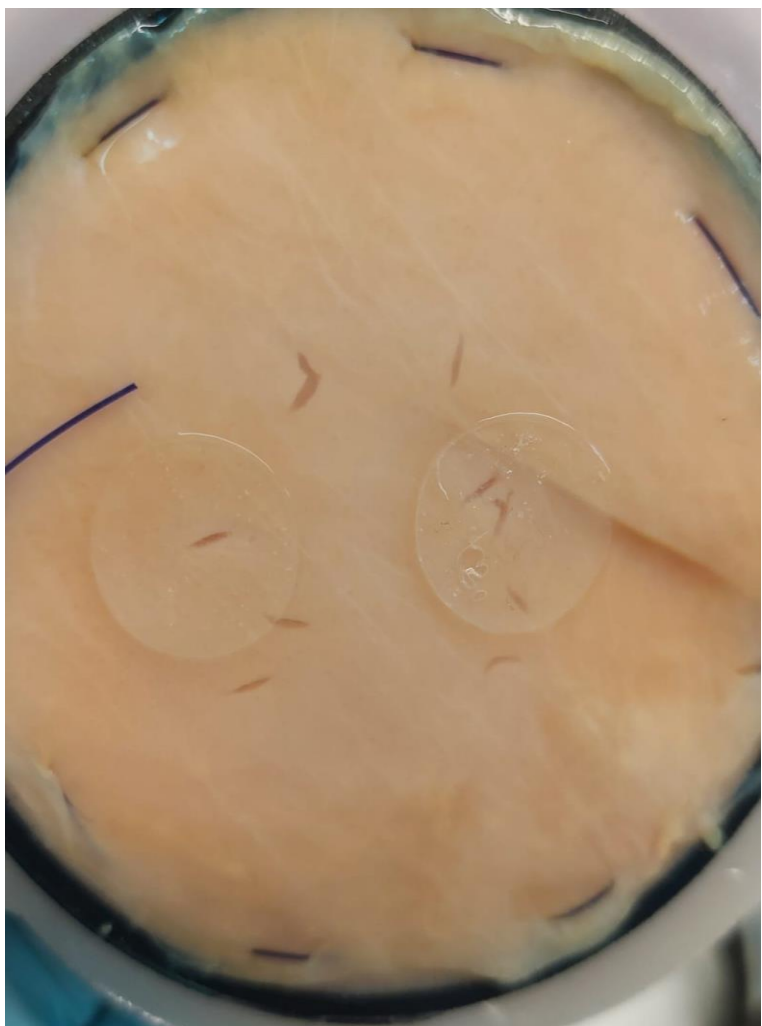
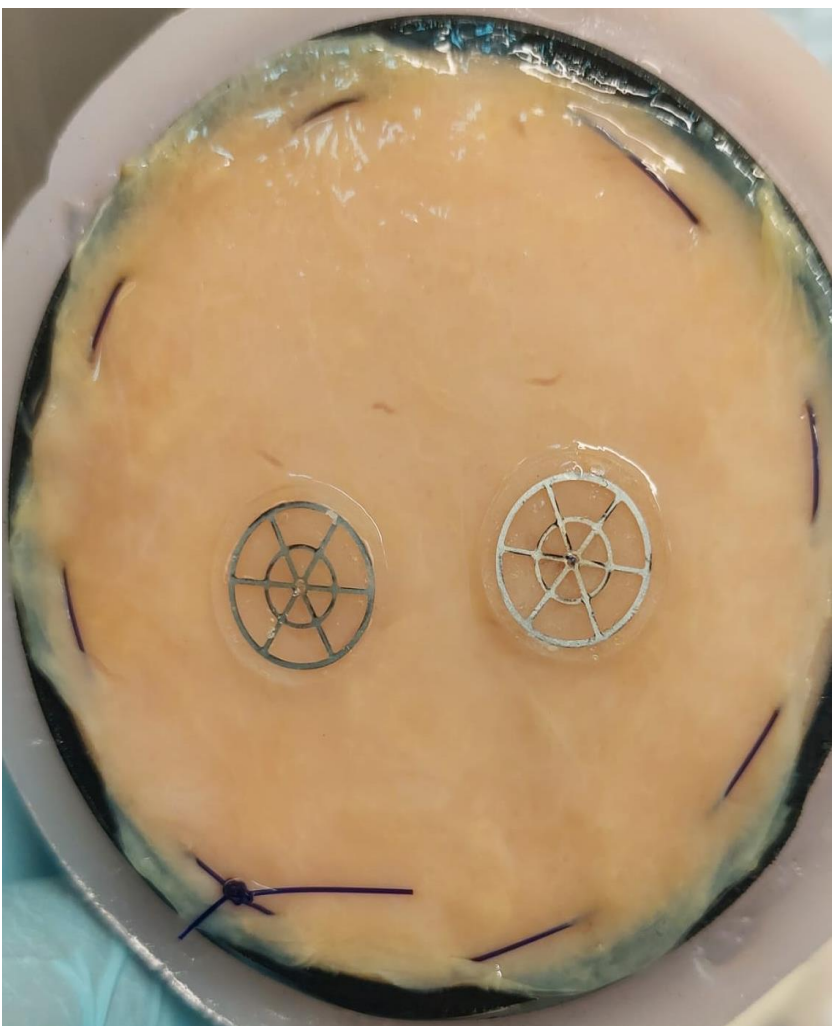
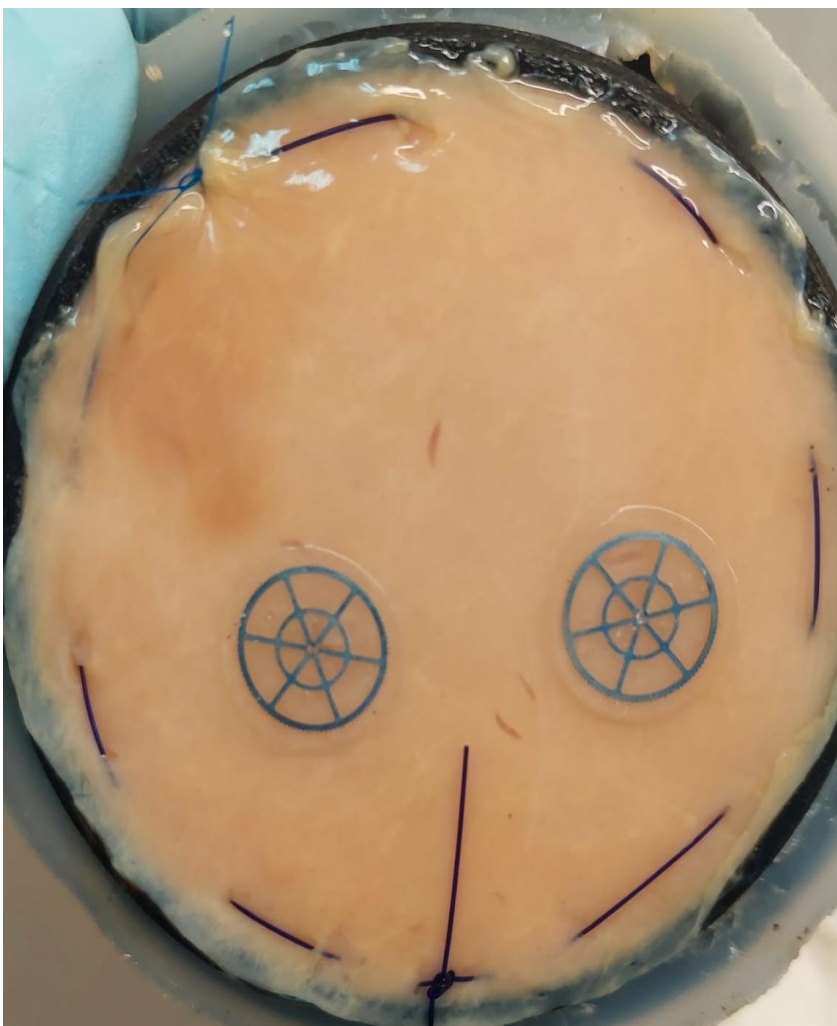
Preparation of the ex-vivo experiment
Amniotic membranes affixed with silicone phantoms
CbB applied to NiS and preloading them into the introducers
Fluid medium (NaCl 0.9%, human amniotic fluid, amikacin & fluconazole) at 37°C

Insertion of SS patches
14-Fr trocar insertion to perforate membrane
Metallic punch removal
12-Fr introducer insertion to release SS patch
Withdrawal of the introducer
SSp adhered to the membrane

Fluid medium change every 48 hours
Daily inspection for 15 days



Simulated uterine environment



SSp adhesion to human fetal membranes

Results

Most of the patches inserted maintained their adhesion till 15 days, without significant differences among the different designs

Table 1- Insertion and adhesion rates of the SSp in the ex vivo phantom model

Variables	NiS	NiS with microhooks	Plain silicone	P-value
Successful insertion*	9 (90)	9 (90)	9 (90)	-
Complete adhesion+				
Day 0	9 (100.0)	8 (88.9)	9 (100.0)	1.000
Day 1	9 (100.0)	8 (88.9)	9 (100.0)	1.000
Day 2	9 (100.0)	8 (88.9)	9 (100.0)	1.000
Day 3	9 (100.0)	8 (88.9)	9 (100.0)	1.000
Day 4	9 (100.0)	8 (88.9)	9 (100.0)	1.000
Day 5	9 (100.0)	8 (88.9)	9 (100.0)	1.000
Day 6	9 (100.0)	8 (88.9)	9 (100.0)	1.000
Day 7	9 (100.0)	8 (88.9)	9 (100.0)	1.000
Day 8	9 (100.0)	8 (88.9)	9 (100.0)	1.000
Day 9	9 (100.0)	8 (88.9)	9 (100.0)	1.000
Day 10	9 (100.0)	8 (88.9)	9 (100.0)	1.000
Day 11	9 (100.0)	8 (88.9)	9 (100.0)	1.000
Day 12	8 (88.9)	8 (88.9)	9 (100.0)	0.751
Day 13	8 (88.9)	8 (88.9)	9 (100.0)	0.751
Day 14	8 (88.9)	8 (88.9)	9 (100.0)	0.751
Day 15	8 (88.9)	8 (88.9)	9 (100.0)	0.751

*n=10; +n=9 (excluded one unsuccessfully inserted patch)

Values are n(%)

P-value defined with fisher’s exact test

Conclusions

- Ex-vivo fetoscopic insertion of bioadhesive silicone patches was feasible in a simulated uterine environment.
- All types of sealing system patches achieved high adhesion rates up to 15 days.
- NiS patches exhibited similar performance with and without microhooks.