

# Performance of 2-port open fetoscopy for fetal spina bifida repair in a newly established program



## OBJECTIVE

Open fetal myelomeningocele (MMC) repair has proven postnatal benefits with the disadvantage of premature birth and obstetric complications related to hysterotomy as demonstrated in the Management of Myelomeningocele Study (MOMS). Performing the neurosurgical closure fetoscopically aims to avoid the uterine legacy created by hysterotomy but must produce comparable postnatal outcomes to be considered an equivalent alternative. We report the obstetric and early neonatal outcomes of fetoscopic MMC repair for our initial cases related to the MOMS benchmarks.

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## BACKGROUND

Open fetal surgery for myelomeningocele (MMC) reduces the need for postnatal shunt placement for hydrocephalus and improves motor function compared to surgery performed after birth.<sup>1</sup> However, uterine access by second trimester hysterotomy produces substantial maternal risks in index and all future pregnancies. Increased rate of preterm birth and scar complications including uterine dehiscence or rupture occur in up to 11% of all pregnancies.<sup>2</sup>

Reducing such maternal risks has been the primary motivation for development of less invasive fetoscopic techniques. Of these, the open fetoscopic approach allows membrane and port fixation in the uterus. This may decrease the risk of preterm birth and membrane rupture compared to the percutaneous 2-4 port techniques.

## METHODS

Patients with isolated fetal MMC and preserved lower extremity movement in addition to MOMS inclusion criteria were offered open fetoscopic closure under an FDA monitored protocol (clinical trials: NCT03090633). After maternal laparotomy two 12 French ports, secured by uterine stay sutures, were used for uterine access. After partial CO<sub>2</sub> insufflation, which was humidified after the first five cases, the placode was dissected and the lesion repaired with vertical mattress sutures. Follow-up management was by standard obstetric care. Procedure details, obstetric, neurosurgical and neonatal outcomes matching the MOMS trial end points were collected.

## RESULTS

Of 27 screened patients, 15 were excluded for high BMI, additional anomalies, or other reasons. Three chose pregnancy termination and 2 declined intervention, leaving 12 eligible participants.

<sup>1</sup> Adzick NS, et al. A randomized trial of prenatal versus postnatal repair of myelomeningocele. *NEJM* 2011;364:993-1004.

<sup>2</sup> Johnson MP, et al. MOMS: Obstetrical outcomes and risk factors for obstetrical complications following prenatal surgery. *Am J Obstet Gynecol* 2016;215:778.e1-778.e9.

One procedure was converted to open fetal surgery and one baby was delivered for fetal bradycardia prior to fetoscopy (Figure 1).

Characteristics of 10 cases completing fetoscopic MMC repair are shown in Table 1. Total laparotomy time was 299 minutes (range 263-458) and the fetoscopy time was 201 minutes (range 157-324). Pre-fetoscopy fetal venous pH was 7.39 (range 7.33-7.46), and 7.36 (range 7.28-7.39) after insufflation.

Fetal MRI and ultrasound demonstrated improved hindbrain herniation in 9/10 cases (Figure 2). Two participants had preterm premature rupture of membranes. Vaginal delivery rate was 50% (n=5) and cesarean delivery was performed for standard obstetric indications. All newborn surgical sites were well healed at birth. Only one infant required shunt placement for hydrocephalus at 2 months of age thus far (1-20 months) (Figure 3).

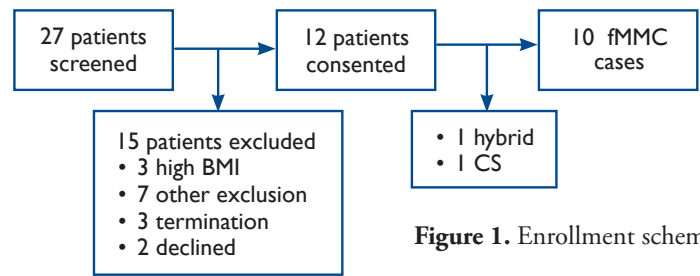


Figure 1. Enrollment scheme.

Case characteristics and obstetric outcomes							
Case	GA Repair	Upper border	PPROM	fMMC to delivery (d)	GA Birth	BW (g)	Delivery mode
1	25	L2	No	81	36+4	3400	SVD
2	24+4	L5	Yes	69	34+3	2030	SVD
3	25+1	L4	Yes	40	30+6	1350	SVD
4	22+6	L4	No	101	37+1	2720	CS - repeat
5	25+1	L3	No	100	39+2	2600	SVD
6	25+3	S1	No	100	39+6	3010	SVD
7	24	L4	No	36	29+6	1360	CS - abruption
8	25+5	L3	No	88	38+2	2960	CS - breech
9	24+5	L4	No	93	38	2490	CS - breech
10	25+6	L5	No	92	39	3840	CS - elective
Median	25.1	--	--	84.5	37.6	2660	--

Humidified CO<sub>2</sub>

Table 1. Characteristics of the initial cases completed fetoscopically.

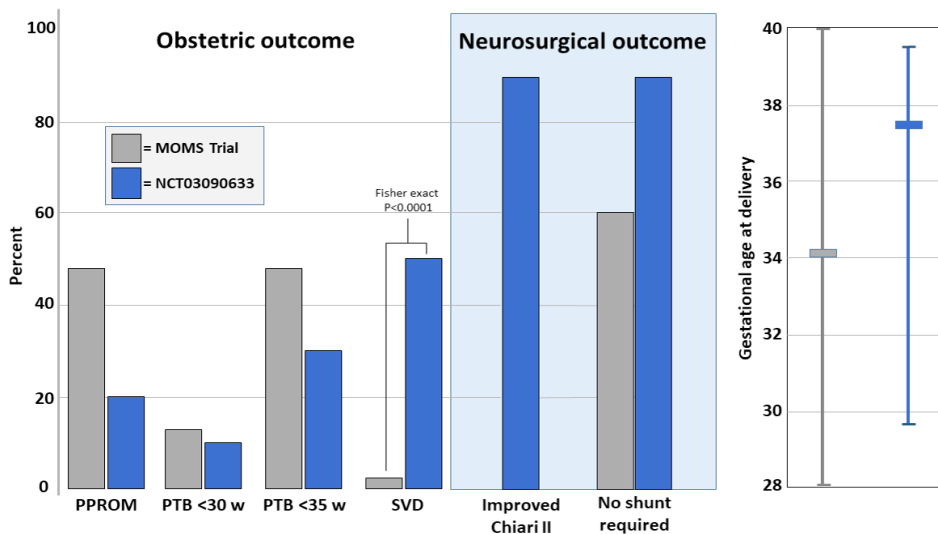


Figure 3. 2-port open fetoscopic fetal MMC repair compared to MOMS trial benchmarks.

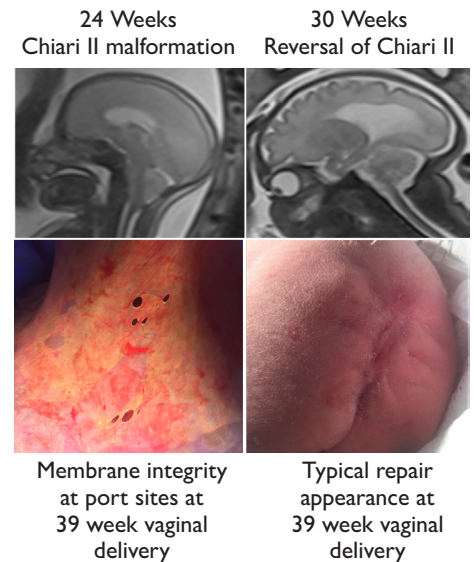


Figure 2. Preoperative and 6 week postoperative fetal MRI shows improved Chiari II (top). Amniotic membrane port and stay suture site appearance and healed surgical site at term delivery (bottom).

## CONCLUSIONS

Open two-port fetoscopic fetal MMC repair appears surgically equivalent to open fetal surgery with favorable obstetric outcomes despite long operative times. Our early outcomes meet the perinatal benchmarks that have demonstrated benefit for prenatal repair established by the MOMS trial with the encouraging benefit of subsequent vaginal delivery.

For more information about the Center for Fetal Therapy at Johns Hopkins, visit [hopkinsmedicine.org/fetaltherapy](http://hopkinsmedicine.org/fetaltherapy) or call 410-502-6561