

Case Series: Ultrasound Follow-up of Complete Levator Ani Muscle (LAM) Avulsions in EASE Study Phase 2

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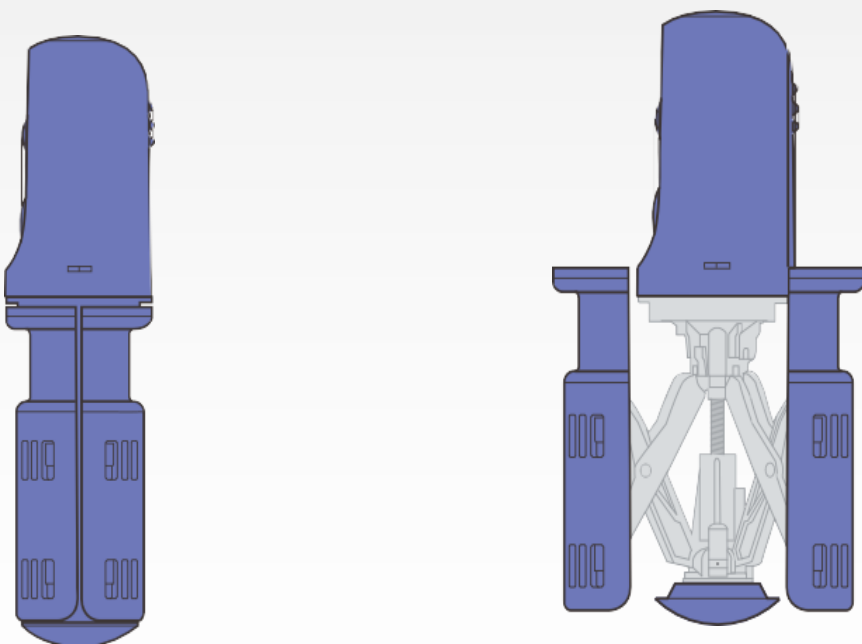
Background

Vaginal delivery carries risk of injury to the pelvic floor anatomical structures. Damage to pelvic floor structural integrity increases the likelihood of developing serious sequelae, including pelvic organ prolapse (POP). Crowning of the fetal head during delivery considerably stretches the LAM and can lead to detachment, or avulsion, of the puborectalis component from its origin at the inferior pubic ramus. Partial or complete LAM avulsion can be quantifiably diagnosed using tomographic ultrasound imaging. Complete and severe partial avulsions have shown an increased risk of pelvic trauma, such as prolapse. Currently, there are no proven preventive approaches documented in the literature for reducing these injuries to the pelvic floor muscles during vaginal birth.

Ellora Dilator (profile view)

Starting Size: 3.4 cm

Full Expansion Size: 8 cm



The Ellora Obstetrical System is an investigational device under FDA review through the De Novo classification process.

Hesham-UltrasoundFollow-upCompleteLevatorAniMuscleAvulsionsEASEStudyPhase2

Case Series Description

A multicenter, randomized controlled trial enrolled nulliparous participants planning vaginal delivery. During the first stage of labor, participants were randomized to receive the intravaginal device or standard-of-care labor management. The primary effectiveness endpoint was the presence of partial or complete LAM avulsion on transperineal pelvic-floor ultrasound observed at 3 months (average of 3.3 months with a range of 2.4 to 4.5 months) postpartum. A follow-up ultrasound was performed a minimum of 18 months after delivery to assess healing. The final interpretation of all ultrasounds was the consensus result of image evaluation by a panel of three urogynecologists blinded to the treatment administered, the results of any previous imaging, and the follow-up time point when the scans were performed. This case series reports the results from follow-up ultrasounds of the documented complete avulsions (average of 27.7 months with a range of 18.3 to 40.2 months).

Results

At 3 months (average of 3.3 months with a range of 2.4 to 4.5 months), 110 participants in the Per Protocol analysis--46 Device subjects who received full device treatment, and 64 Controls--underwent ultrasound. No complete LAM avulsions (0.0%) were diagnosed for the Device group versus 7 out of 64 (10.9%) in the Control group (p = 0.040; two-tailed Fisher’s test). For the 7 subjects diagnosed with a complete avulsion at 3-month follow-up, ultrasounds were collected in an average of 27.7 months (range 18 to 40 months) after delivery to note the type of injury present and determine change over time. Six of the 7 subjects were again diagnosed with a full avulsion by the blinded panel, with one subject being diagnosed with a severe partial avulsion (defects noted on multiple slices of the ultrasound image).* This reinforces prior published literature demonstrating that LAM avulsions do not heal over time. See Table 1.

	Table 1: Ultrasound Follow-up of Complete Levator Ani Muscle (LAM) Avulsions						
Avulsion	1	2	3	4	5	6	7
Age at enrollment	27	29	27	34	29	27	21
Gestational age (weeks, days)	39, 4	38, 6	39, 6	39, 2	39, 6	40, 6	38, 6
Instruments used	None	None	None	None	None	None	Forceps
infant weight, length, head circ	6lb 3oz, 18.5in, 32cm	7lb 15oz, 21in, 36cm	6lb 15oz, 21in, 34cm	6lb 9oz, 19in, 34cm	9lb 15oz, 22in, 34cm	8lb 11oz, 20in, 34cm	8lb 1oz, 20in, 34cm
Time to scan 1 (months)	3.0	2.4	3.8	4.1	2.7	4.4	3.0
Time to scan 2 (months)	18.3	21.3	22.4	23.7	29.8	38.1 Partial*	40.2

Conclusions

The literature suggests that injury to the LAM complex during vaginal delivery occurs in 13–36% of individuals after vaginal birth and is strongly associated with subsequent POP. Over half of women with complete LAM avulsions subsequently develop POP beyond the hymen within the first 6–17 years from first vaginal delivery. The follow-up ultrasound evaluations revealed LAM injuries persisted up to 40 months postpartum. One of the control subjects in this case series (Table 1, Avulsion #7), who was diagnosed with a bilateral complete avulsion three months after forceps-assisted delivery and again when re-imaged over three years later, reported symptoms of POP that were having a profound negative impact on her quality of life.

*While one (1) participant (Avulsion #6) was diagnosed with a complete avulsion at her 3-month follow-up visit and a severe partial avulsion at 38 months, the referenced data on the strong association between LAM injury and subsequent symptomatic POP is based on an initial occurrence of a complete avulsion, regardless of subsequent diagnosis.

References

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Acknowledgements

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