OBSTETRIC ANAL SPHINCTER INJURIES

THD ProctoMobile

THD® ProctoMobile: the ultimate diagnostic tool for the assessment of obstetric anal sphincters injuries (OASIS) and prevention of faecal incontinence

Document intended for Health Care Professionals only.

OBSTETRIC ANAL SPHINCTER INJURIES (OASIS)

OASIS are caused by perineal trauma during vaginal delivery. Also known as perineal lacerations, these injuries involve the anal sphincter complex and, in more severe cases, anal mucosa. Obstetric anal sphincter injury is the most important risk factor for female **Anal Incontinence** (AI).

Anal incontinence incorporates a range of **symptoms** including: **flatal incontinence**, **soiling**, **incontinence of liquid or solid stool**, **faecal urgency**.

Despite surgical sphincter repair performed immediately after delivery, many women have residual defects and AI symptoms.

The true prevalence of AI related to OASIS may be **underestimated**. The reported rates of AI following the primary repair of OASIS range between 15% and 61%, with a **mean of 39%**[1].

The onset of symptoms of AI may occur immediately or several years after delivery; AI may only appear in old age, when the aging process adds to the delivery insult.

OASIS is a **leading risk factor** for subsequent **loss of bowel control** in women.

RISK FACTORS:

The principal factors associated with OASIS are **nulliparity** and instrumental (midline **episiotomy**) **delivery**; other factors are advanced maternal age, previous history of OASIS, fetus much larger and heavier than average, posterior cephalic positions, and long labour.

The prevalence of **OASIS in primiparous** women is **between 1.4 and 16%**.

RECOMMENDATIONS:

Any vaginal delivery can lead to OASIS, and there is a **significant percentage of occult anal sphincter lesions** that could only be found by performing functional (**Anorectal Manometry**) and structural (**Ultrasound**) exams after the labour. In some cases a subsequent surgical sphincter repair could be indicated to avoid the onset of AI symptoms[2].

Women who have had a **previous OASIS**, especially a **third degree tear** and have persistent symptoms of faecal incontinence or significantly abnormal ultrasound or manometry results are **best delivered by prelabour caesarean section**, as are those who have undergone previous incontinence surgery[3].

GUIDELINES:

American College of Obstetrics and Gynaecology - Practice Bulletin Number 198. Prevention and management of obstetric lacerations at vaginal delivery	**US**	2018
Royal College of Obstetrics and Gynaecology - Green-top Guideline No 29 Management of third- and fourth-degree perineal tears	**UK**	2015
Sphincterruptur: Diagnostik, behandling og opfolgning (OASI: Diagnosis, treatment and follow-up)	**DK**	2019
Government of South Australia - South Australian Perinatal Practice guideline.Third and fourth-degree tear management	**AU**	2018
Society of Obstetrics and Gynaecology of Canada- Clinical Practice Guideline, Number 330. OASIS: prevention, recognition and repair	**CA**	2015
German Society of Gynaecology and Obstetrics - Management of 3rd- and 4th-degree tears after vaginal birth	**DE**	2014
Austria Urogynaecology Working Group - Guidelines for the management of third- and fourth-degree tears after vaginal birth	**AT**	2013
Dutch Society of Obstetrics and Gynaecology: Risk factors for and interventions that reduce the risk of a total rupture during childbirth	**NL**	2013

1. *Diagnosis of perineal trauma* - Sultan AH, Kettle C. - 2009 - Perineal and anal sphincter trauma
2. *Obstetrical Anal Sphincter Injuries (OASIS): Prevention, Recognition, and Repair* - 2015 - J Obstet Gynaecol Can.
3. *Clinical Practice Guideline - Management of Obstetric Anal Sphincter Injury* - 2012 - Institute of Obstetricians and Gynaecologists - Royal College of Physitians of Ireland

THD ProctoMobile

All-in-one portable diagnostic instrument which allows performing anal manometry and 360° EAUS

BENEFITS

ERGONOMIC

THD® ProctoMobile offers the best ergonomic position for the provider. Its size allows comfortable exams even in smaller rooms. THD® ProctoMobile is a lightweight and portable option between outpatient, OR and home visits.

FAST

Each exam can be done in under 10 minutes. THD® ProctoMobile is ready for use and doesn't require previous calibration of the manometry or EAUS probes. Current services and pathways can require the patient to make 2 or more visits to the hospital to complete the diagnostic procedures and subsequent interpretations. THD® ProctoMobile allows the clinician to offer first contact diagnostics and interpretation.

EASY

Procedures can be performed easily in the lateral decubitus, prone, or dorsal lithotomy position. The entire exam is user-friendly both for the clinician and the patient.

COST EFFECTIVE

By combining EAUS and THD® Anopress in one portable diagnostic tool, THD® ProctoMobile may be useful for setting up one-stop specialist perineal clinics, reducing hospital attendances.

ANORECTAL MANOMETRY

Anorectal Manometry performed with THD® Anopress in OASIS

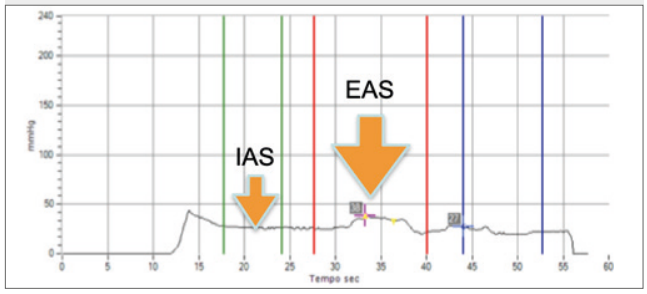
Anorectal Manometry is the principal exam to assess the functional activity of the anal sphincter complex, providing precise numeric values of muscular contraction, relaxation, rectal sensitivity and reflexes. Manometry **is a mandatory test** in any case of clinically evident or possible AI condition.

Anorectal Manometry can:

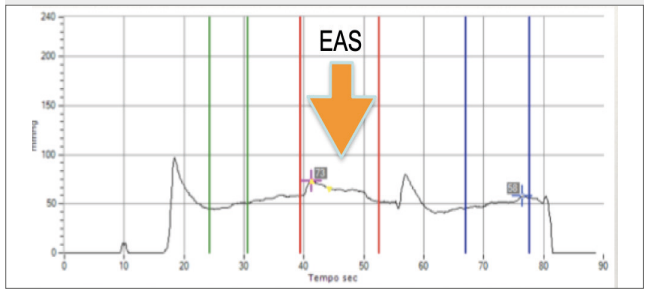
- determine functional deficits of sphincter complex
- identify damages of the IAS and EAS
- monitor biofeedback results
- provide evidence of the absence of contractile reflexes
- plan management after OASIS

Anorectal Manometry should be performed 1 month to 6 months after delivery.

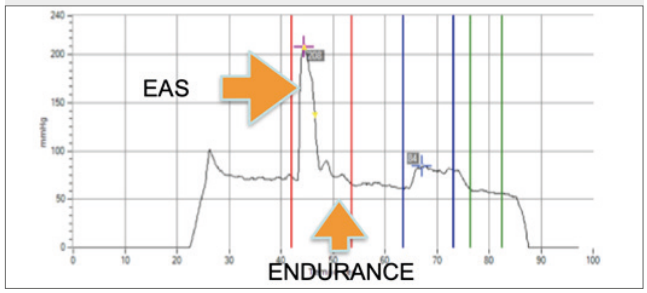
Severe reduction in rest and squeeze pressure, injury of IAS and EAS following IV degree OASIS



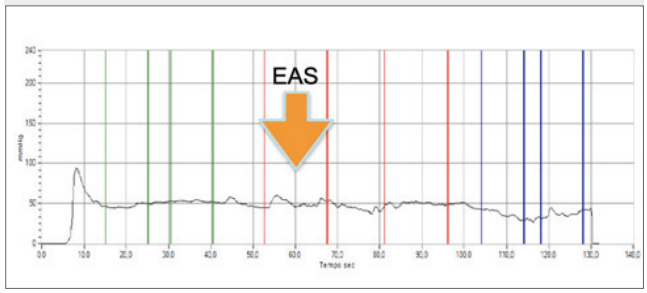
Reduction in EAS activity following III degree OASIS



Urgency with significant reduction in contractile endurance of EAS due to obstetric injury



Anterior EAS lesion causing a severe reduction of EAS squeeze pressure



- *Evaluation of the Anopress® device in assessment of obstetric anal sphincter injuries in a specialist urogynaecology service* - L. Godbole, C. Godbole, S. Bulchandani - 2020 - European Journal of Obstetrics and Gynecology
- *Early secondary repair of obstetric anal sphincter injuries (OASIs): experience and review of the literature* - N. A. Okeahialam, R.Thakar, A. H. Sultan - 2021 - International Urogynecology Journal
- *Effect of a subsequent pregnancy on anal sphincter integrity and function after obstetric anal sphincter injury (OASI)* - N. A. Okeahialam, R. Thakar, A. H. Sultan - 2020 - International Urogynecology Journal
- *Outcome of anal symptoms and anorectal function following two obstetric anal sphincter injuries (OASIS)-a nested case-controlled study* - Okeahialam et al. - 2020 - International Urogynecology Journal

ENDO ANAL ULTRASOUND (EAUS)

Early EAUS diagnosis of sphincter lesions in OASIS

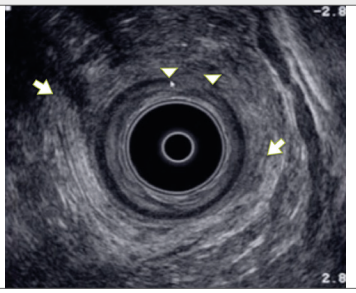
EAUS examination **is the gold standard imaging modality for the morphological assessment of the anal sphincters**. This is used in combination with anorectal manometry, clinical history and examination to assess anal sphincter function and anatomy.

EAUS allows the clinician to view the pelvic floor and the sphincter muscles and to accurately identify obstetric injuries:

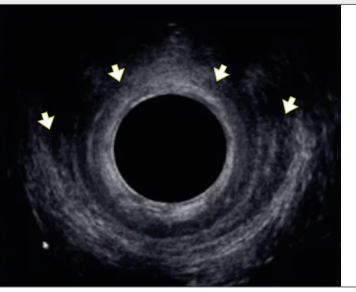
- EAS tear (length and depth of muscle involved)
- IAS tear (length and depth of muscle involved)

EAUS should be performed 1 month to 6 months after delivery.

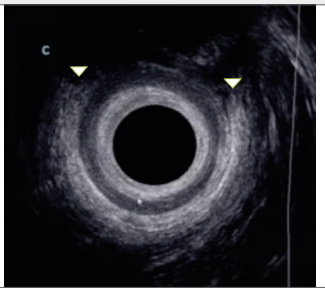
Small IAS and major EAS lesion in the anterior aspect of the anal canal



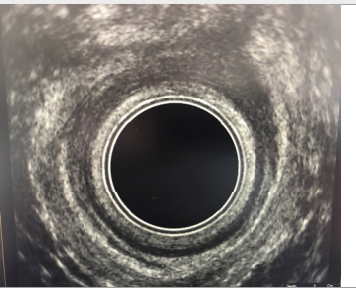
180 degrees lesion of EAS and minor IAS injury in OASIS



Anterior injury of EAS with intact IAS in grade III OASIS



EAS injury following an instrumental vaginal delivery



- *Anal-Sphincter Disruption during Vaginal Delivery* - Sultan et al. 1993 - N Engl J Med
- *The Management of Third- and Fourth-Degree Perineal Tears* - 2015 - Royal College Of Obstetricians and Gynecologists Guidelines
- *Obstetrical Anal Sphincter Injuries (OASIS): Prevention, Recognition, and Repair* - Society of Obstetricians and Gynaecologists of Canada - 2015 - J Obstet Gynaecol Can
- *Effect of a subsequent pregnancy on anal sphincter integrity and function after obstetric anal sphincter injury (OASI)* - N. A. Okeahialam, R. Thakar, A. H. Sultan - 2020 - International Urogynecology Journal
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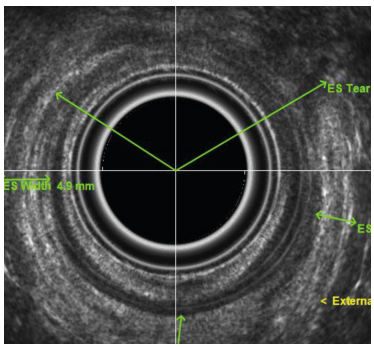
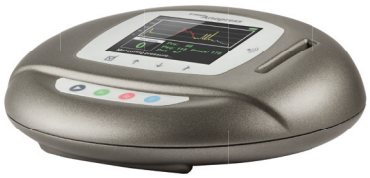
THD ProctoMobile

THD EAUS PROBE 12MHZ



- Two dimensional 360 degrees rotating array of ultrasonic crystals
- Frequency average of 12 MHz, tuning from 10 to 15 MHz
- Full control of brightness, contrast, depth, frequency, gain
- Linear, angle and volume measurement
- Intra-operative use
- USB connection

THD® Anopress + THD® PressProbe & THD® SensyProbe



THD PressProbe THD SensyProbe

- The portable solution for Clinical Anorectal Manometry
- THD® PressProbe has an ergonomic grip and a completely atraumatic profile to ensure minimum discomfort for the patient
- THD® SensyProbe offers the same features of THD® PressProbe with the additional capability to perform RAIR and rectal sensation investigation
- Quick and accurate
- Wireless Bluetooth connection

THD Procto Software

CE 1936

The THD® Procto Software allows a **rapid execution and interpretation** of the diagnostic tests which are integrated and comparable both in real time or during the follow-up visits.
The results of Manometry and EAUS are easily exportable in digital form and **automatically integrated into the clinical report**.
The software is a medical device certified by the certifying body TUV Rheinland Italia (CE 1936).

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