

# Clinical evaluation of the Hegenberger Retractor for perineal repair: an evaluation of clinicians' experience

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## ORIGINAL

### Introduction

Around 85 per cent of women who have a vaginal birth will sustain some degree of birth-related perineal trauma and, of these, around 70 per cent will need repair using a technique called perineal suturing, usually within an hour of the birth (Ismail et al 2013).

Between 2019–2020 there were 399,509 vaginal deliveries in England, suggesting approximately 237,707 women per year (651 per day) underwent perineal suturing across NHS trusts (NHS Digital 2020). This very common procedure has lifelong consequences for women's physical, sexual and psychological health and, if performed incorrectly or inadequately, carries substantial financial burden to the NHS (Anderson 2013).

### Poor implementation of evidence-based perineal suturing in the UK

Until recent years, standard perineal suturing was not systematically incorporated into clinical practice; resulting in a wide range of techniques practised across the country.

Early evidence demonstrated that minor perineal lacerations (grades I–II) can be left to heal spontaneously, citing benefits for women in terms of bonding, breastfeeding and avoiding the discomfort of analgesia and suturing (Lundquist et al 2000). The SUNS randomised controlled trial (RCT) (Fleming et al 2003) showed that perineal suturing resulted in improved wound approximation and healing at six weeks compared to women who were not sutured. Subsequent Cochrane systematic reviews have consistently shown that continuous suturing using absorbable synthetic sutures leads to less perineal pain, requirement for analgesia and the need to remove sutures postnatally (Kettle et al 2012).

This evidence is now incorporated in routine clinical care in the UK, in national clinical guidelines (National Institute for Health and Clinical Excellence (NICE) 2014, Royal College of Obstetricians and Gynaecologists (RCOG) 2015) and training (Royal College of Midwives (RCM) 2018).

In the UK, trained midwives are responsible for undertaking perineal assessments and repairs as part of the normal childbirth process. Obstetricians repair complex tears, such as those arising as part of operative delivery (for example, episiotomies) and

obstetric anal sphincter injuries (OASI), classed as grades III–IV.

Conducting a proper perineal repair is dependent on the skill of the clinician and repair technique. Despite national guidelines, some studies have shown considerable gaps in the application of relevant evidence to guide the management of perineal suturing, leading to disparities in methods used by clinicians (Bick et al 2012).

A UK-based study of qualified midwives (n=592) found that only 38.5 per cent felt their training on perineal suturing was adequate, with only 62.8 per cent receiving hands-on training prior to undertaking their first repair on a patient (Selo-Ojeme et al 2015). Furthermore, while 87.2 per cent felt that midwives should be the primary clinicians to assess and repair episiotomies and grade I–II tears, only 37.6 per cent were of the opinion that midwives received enough training.

The lived experiences of early-career midwives (those with less than five years post-qualification experience) highlight that this unmet need stems from pre-registration teaching, where perineal suturing is now a high priority on the curriculum yet becomes a stark reality in clinical practice (Hunter & Bick 2019). Another UK study (n=405), examining the extent to which perineal suturing practice reflected evidence-based guidelines, found that only six per cent of midwives used evidence-based suturing methods to repair all layers of the perineal trauma while only 17.3 per cent routinely performed rectal examination

as part of their routine trauma assessment prior to suturing (Bick et al 2012). This highlights a considerable gap of implementation of evidence into the practice of perineal suturing by midwives.

In order to address this, the Perineal Assessment and Repair Longitudinal Study (PEARLS) formed the main part of a national clinical quality improvement (QI) project to improve maternal clinical postpartum outcomes through a focus on multi-disciplinary training of perineal suturing (Ismail et al 2013).

This interactive educational package aimed to provide a systematic evidence-based approach to perineal assessment, suturing and aftercare. Results showed that PEARLS training significantly improved overall use of evidence-based practice in clinical practice. Despite this, almost 10 years later there is still no nationally accredited standard of competency in the UK, and no international equivalents. This means that, although perineal suturing is systematically incorporated into clinical practice for grades II–IV using a continuous technique, a considerable variation in competency and practice remains in NHS hospitals across the UK.

### Incidence of clinical negligence claims due to inadequate perineal repair

It is well known that obstetrics and gynaecology has the second highest number of clinical negligence claims as a specialty, with the highest, by far, pay out among all medical specialties (NHS Litigation Authority 2012). Data shows that perineal trauma following childbirth resulted in 441 claims (8.55 per cent of all obstetric claims) over a 10-year period in the NHS. This resulted in a total pay-out of £31,202,863 in claims, which surpassed CTG misinterpretation, postpartum haemorrhage, stillbirth and shoulder dystocia (NHS Litigation Authority 2012). In fact, perineal trauma was the fourth most common claim prior to mismanagement of labour, caesarean section and cerebral palsy, respectively (NHS Litigation Authority 2012).

The 441 claims were split between: grades I–II and episiotomies (205); grades III–IV/OASIs (200); not classified (36). Clinical details are available for 83 claims, which reveal a total cost of £17.5 million, or £210,000 on average per claim. An even split of deliveries were managed by midwives (39) compared to obstetricians (44). In 23 (59%) of midwife-managed claims and 29 (66%) of obstetrician-managed claims, allegations were made that the grade of tear was misdiagnosed and therefore negligent. Eighty-seven per cent of midwife-managed claims involved misdiagnosing first- or second-degree tears when they were actually third- or fourth-degree tears. This also applied to 86 per cent of obstetric-managed tears (NHS Litigation Authority 2012).

**Table 1. Grade of tear diagnosed compared to true grade (NHS Litigation Authority 2012)**

Midwife-managed claims		
Grade of tear	Correct grade of tearing	Number of claims
First degree	Third/fourth degree	10
Second degree	Third degree	5
Second degree	Fourth degree	5
Third degree	Fourth degree	3
Doctor-managed claims		
Grade of tear	Correct grade of tearing	Number of claims
First degree	Third degree	9
First degree	Fourth degree	2
Second degree	Third degree	10
Second degree	Fourth degree	4
Third degree	Fourth degree	4

Table 1 shows that clinician experience does not necessarily mitigate against the risk of misdiagnosis. In fact, in the four claims made when a fourth-degree tear was misdiagnosed as a second-degree tear, the grading was carried out by consultant obstetricians. The emerging theme of claims identified criticisms of failure to diagnose the true extent and grade of injury, including failure to perform an adequate repair. The consequences of such failure include incontinence of faeces and/or flatus, vaginal discharge, rectovaginal fistula, irritable bowel syndrome, colostomy and psychiatric damage.

The key message is that training remains a crucial issue for diagnosing the existence, extent and severity of perineal trauma following delivery.

### Need for improved visualisation of perineal trauma

The above literature highlights an urgent unmet need for improved visualisation of the birth canal and perineum to facilitate assessing the extent and grade of trauma in order for the clinician to carry out an adequate repair. Current clinical practice is limited to the suturing clinician digitally locating and retracting the vaginal tissue in order to diagnose the extent of repair. Digital retraction continues throughout the suturing procedure, leaving the clinician handicapped either to suture with one hand only or needing the assistance of another clinician to retract while they perform the repair. This is not compatible with the implementation of evidence-based practice, for example, PEARLS training, and limits the quality of repair while increasing the risk of inadequate repair.

In 2019, a Danish midwife, Malene Hegenberger, invented the Hegenberger Retractor for perineal repair following childbirth. This self-retaining device is inserted into the birth canal prior to perineal suturing in order to visualise the grade and extent of trauma, allowing the suturing clinician to perform repair according to evidence-based practice, using both hands for the duration of the procedure.

Figure 1. The Hegenberger Retractor



This study is the first published evaluation of the Hegenberger Retractor for postpartum perineal repair.

### Research aims

To investigate the clinician's experience of using the Hegenberger Retractor for perineal repair compared to standard care.

### Hypotheses

- Null hypothesis: the Hegenberger Retractor does not improve the clinicians' experience of perineal suturing.
- Alternative hypothesis: the Hegenberger Retractor does improve the clinicians' experience of perineal suturing.

### Primary outcomes

- Visualisation of extent of tear
- Ability to practise evidence-based suturing technique

### Secondary outcomes

- Ergonomics of use
- Autonomous practice
- Teaching aide

## Methods

### Design

#### Site and sampling

Site selection was made according to where perineal repair was routinely undertaken for tear grades II–IV and episiotomies. Consequently, university teaching hospitals with a focus on perineal repair teaching were selected. These were based in the capital cities

of Sweden, Norway and Denmark. Site selection was therefore purposive to ensure highly trained clinicians who were competent in perineal repair formed the target population and sample population, respectively. All three sites were consultant-led maternity departments.

#### Target population

The target population was obstetricians and midwives working on duty in the labour ward/high-risk unit/consultant-led department within the site on a randomly selected day. This ensured that the participants forming the study sample were those performing perineal suturing as part of their routine duties on a regular basis.

The study sample was comprised of clinicians who were going to perform perineal repair of a grade II–IV tear during the given day. All clinicians were informed of the study aims, objectives and methods at the beginning of their shift.

None of the target population had prior knowledge or training on the Hegenberger Retractor. Training was provided by the researcher on how to prepare the woman for suturing, how to place and remove the Hegenberger Retractor. Clinicians who formed the study sample were then approached by the researcher and consented to participate in the study. The researcher then provided hands-on supervision during the suturing procedure undertaken by the clinician.

#### Data collection

A total of 23 participants were approached between May–June 2019 and all consented to be included in the study. Once the suturing procedure was completed the clinician completed the questionnaire in a private

room away from the researcher and other colleagues and sealed it in an envelope. The sealed envelopes were collected by the researcher at the end of the study.

The questionnaire consisted of closed questions in a printed format. Questions directly assessed the primary and secondary outcomes of the study to ensure validity. To gauge the clinical experience of the participants, they were asked to select the number of perineal repairs they had previously completed. Answers were less than or equal to 100, between 101–500 or more than 501 procedures. Students were excluded from the study as they do not routinely perform perineal repair. The type of tear was not routinely recorded.

**Data analysis**

Once data collection was completed an independent researcher input the answers from the paper questionnaires into an Excel database. An Excel spreadsheet was used for data analysis to tabulate the number of ‘yes’, ‘no’ and ‘uncertain’ results for all questions. Tables and graphics were created using Microsoft Office and Visio software. Findings were checked for accuracy by an independent researcher.

**Ethical considerations**

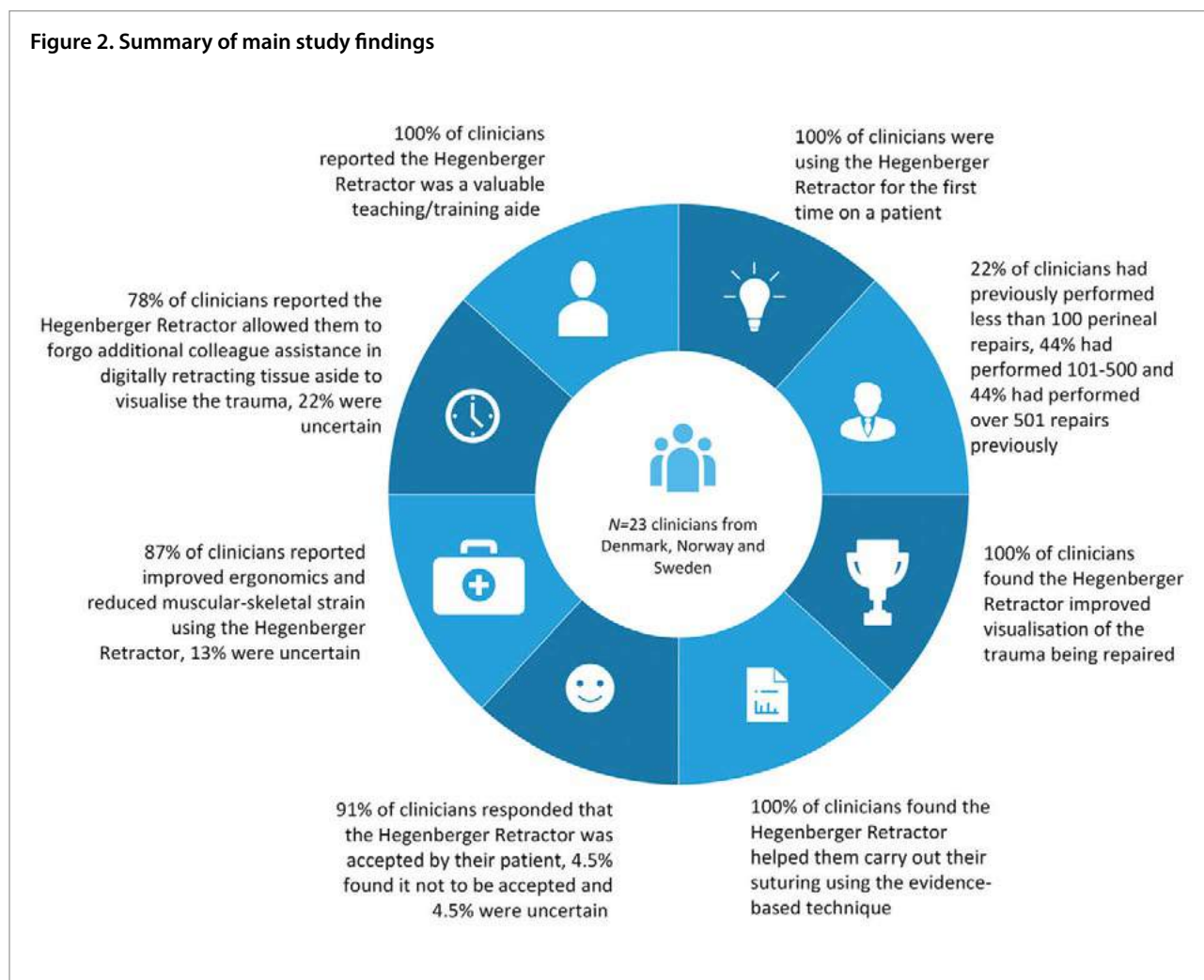
Permission was sought from the Danish government to undertake this research. Permission was also obtained from the individual study sites, but no formal ethical approval was required for this type of study due to its clinical evaluation/quality improvement nature. Verbal consent of participants was obtained. The device has a CE mark and can be implemented into clinical practice on this basis. This study was funded by the inventor, Malene Hegenberger of Hegenberger Speculum ApS.

**Results**

The first three questions addressed the clinician’s background and experience. Twenty-one (91%) were midwives and two (9%) were obstetricians. Five (22%) had previously performed less than 100 repairs, nine (44%) had performed between 101-500 and nine (44%) had performed more than 501 repairs.

The results of the study are summarised in Figure 2. 100% of participants were using the device for the first time on a patient following training.

**Figure 2. Summary of main study findings**



## Discussion

This study is the first published work evaluating the Hegenberger Retractor for perineal repair following childbirth. The results of this study provide the foundation for future research incorporating the device into routine perineal repairs with the aim of implementing evidence-based suturing for all clinicians and patients.

This study included sites in three Scandinavian countries in order to improve the generalisability of results across those territories. No significant variation in responses was noted between the three sites. University teaching hospitals were chosen to ensure a high level of experience and standard of perineal repair. Results showed that the vast majority (88%) of participants had previously completed at least 100 perineal repairs, showing sufficient experience to ensure competence. This means the findings of this study may not be generalisable to clinicians who are at an earlier stage in their careers, newly qualified or who work in rural, smaller maternity units.

The participants were heavily skewed towards midwives (91%) compared to obstetricians (9%). This was due to national perineal repair practice in Scandinavia, which regards midwives as specialists of normality whose role includes routine perineal repair of tear grades II and episiotomies. Obstetricians would routinely suture more complex tears, for example OASIs. Therefore, the achieved sample was mostly comprised of midwives as this is reflective of clinical practice.

A limitation of our study was that the grade of tear was not recorded, which prevents cross-analysis of clinician experience based on type of repair required. This gap in knowledge is scope for future work.

Our sample size of n=23 participants was relatively low due to the short study period. However, on submission of these findings to the Danish Regulatory Board, these were found to be sufficient to launch the Hegenberger Retractor onto the European market. Since launch, clinician feedback has continued to endorse the benefits noted in this research, which will form part of future work. Also, a sample of 23 participants does not allow accommodation for minor inconsistencies in response; any will be clearly visible in our findings.

To ensure reliability of results, it was crucial that all participants had not previously been exposed to the device or its training. This allowed us to capture an accurate measure of the experience of a first-time user. This is important as it shows that one hands-on training session is sufficient for clinicians to competently use the product in clinical practice.

To ensure validity of results we used a self-administered questionnaire undertaken in a private room in the maternity unit in order to remove the

influence of the researchers and other colleagues taking part in the study on participants' responses. A limitation of this method is a restriction for participants to ask for clarifications if they did not fully understand the questions, which could threaten the validity of answers given. This design also prevented the researcher from asking for elaborations when participants responded 'uncertain' — this would have been beneficial to understand and will form part of future work. Also, the dichotomous nature of the closed questions provides little room to understand the context of the respondent experience, leading to perhaps an over-representation of the final results. The degree of satisfaction was therefore not taken into account, which is a limitation of this study.

A small number of questions (nine) were asked in direct relation to the primary and secondary research aims and to avoid respondent burden/question fatigue. To that effect, we believe the questions were valid in addressing the research question and adequately represented different attributes which compile the clinician's experience; visibility, suturing technique, ergonomics, additional assistance and teaching/collaborative working. The closed question design allowed clear and unambiguous questions to be put to all respondents and to be understood in the same way. To control for memory distortion/gaps and selective memory, participants were asked to complete the questionnaires immediately after leaving the suturing room.

Future work is needed to investigate the degree of benefit to visualisation of the perineal trauma, grading and repair compared to standard practice. Further work is also needed to measure the clinician benefits of reducing suturing time, needlestick injury and muscular-skeletal strain with use of the device. Research on the patient experience and outcomes is also required to show the benefit of using the device.

## Conclusion

This study into use of the Hegenberger Retractor shows a positive improvement in clinicians' visualisation of trauma and aids the implementation of evidence-based perineal repair and the teaching of suturing. It is largely beneficial in improving ergonomics and reducing the need for additional support from colleagues to digitally retract vaginal tissue for the duration of repair.

Further research is needed to quantify the degree of user benefit and explore the clinical need for the retractor to be implemented into clinical practice.

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