


Validation of a novel birth simulator for impacted fetal head at cesarean section: An observational simulation study

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Abstract

Introduction: Impacted fetal head (IFH) is a challenging complication of cesarean section (CS) associated with significant morbidity. Training opportunities for IFH have been reported as inconsistent and inadequate. This study assessed the validity of a novel birth simulator for IFH at cesarean section.

Material and methods: Obstetricians and midwives collaborated with model-making company, Limbs & Things (UK), to modify the original PROMPT Flex® simulator and develop a new “Enhanced CS Module” for IFH at cesarean section. Changes included addition of a retractable uterus and restricted pelvic inlet, and the fetal mannequin was modified to allow accurate limb articulation and flexion at the waist. Obstetricians and midwives from three maternity units in Southwest England were individually recorded, each undertaking three simulated scenarios of IFH at cesarean section. Obstetricians were asked to deliver the fetal head and midwives, to perform a vaginal push-up. Participants completed a questionnaire on realism (face validity) and usefulness for training (content validity) with five-point Likert scale responses. Construct validity was assessed by testing an a priori hypothesis that “experts” (consultant obstetricians with >7 years' experience) would be more likely to achieve delivery than “novices” (registrars with <7 years' experience). Performance variables were compared between groups using Chi-square and Mann-Whitney *U*-tests.

Results: In all, 105 simulated scenarios were undertaken by 35 obstetricians and midwives. A range of techniques were employed to deliver the IFH including change of hand, vaginal disimpaction and reverse breech extraction. Overall, 86% (30/35) described the model as fairly (4)/very realistic (5) (median = 4, interquartile range [IQR] = 4–5). The model was considered fairly (4)/very useful (5) for training by 97% (34/35; median = 5; IQR = 5–5). Experts delivered the fetal head in all simulations (36/36) and novices delivered the head in 76.9% (30/39) ($p = 0.002$). Experts delivered the fetal head 58% quicker than novices (median = 66.8 s, IQR = 53–86 vs median = 104 s, IQR = 67.7–137).

Abbreviations: CS, cesarean section; IFH, impacted fetal head.

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Conclusions: This novel birth trainer realistically simulates IFH at cesarean section and allows rehearsal of all disimpaction techniques. It was reported to be very useful for training and distinguishes between novice and expert obstetricians. Techniques for IFH are difficult to learn experientially. Simulation is likely to provide an effective and safe form of training.

KEYWORDS

cesarean section, impacted fetal head, simulation, training

1 | INTRODUCTION

Impacted fetal head (IFH) at cesarean section (CS) is a critical and complex obstetric emergency, increasingly encountered by maternity staff in the UK and internationally.^{1,2} Difficulties disimpacting the fetal head can result in serious complications for mothers and babies.^{3,4} Maternal complications include uterine extensions, postpartum hemorrhage and long-term consequences for future pregnancies.^{1,3,4} Incorrectly performed techniques can cause birth injuries such as skull fractures and intracranial hemorrhage.⁴⁻⁶ Problems disimpacting the head may also delay the birth of an already compromised fetus, leading to hypoxic ischemic encephalopathy and perinatal death.^{5,7,8} Nearly 10% of potentially the most expensive UK maternity claims from 2018 involved an IFH,⁶ and coronial enquiries have called for urgent multi-professional simulation training.⁹

A range of strategies can be employed to manage an IFH, including tocolysis,¹⁰ vaginal push-up¹¹ and reverse breech extraction.^{12,13} Obstetricians and midwives need to be familiar with these disimpaction techniques to reduce the potentially devastating complications.^{6,9} However, IFH is unpredictable, consultant presence is variable and techniques are difficult to learn experientially.¹⁴ Over one-quarter of UK registrars do not feel confident managing cases of IFH and only four in 10 would feel confident performing a reverse breech extraction if the need arose.¹⁴ This is likely a reflection of inadequate training in IFH at cesarean section (CS), which has been identified as both inconsistent and inadequate by junior and senior obstetricians, and midwives.^{14,15}

Scarce training and lack of evidence-based guidance has resulted in widespread variation in practice^{14,16} and avoidably harmful care in some circumstances.^{5,6,8,9} Disimpaction techniques require skill, knowledge and manual dexterity, and incorrectly performed techniques may contribute to adverse outcomes.^{5,6,8,9} Available training has focused solely on the obstetrician, with minimal attention afforded to the wider maternity team.^{2,16,17} Although it is the obstetrician who manages the operative birth, midwives may be requested, as part of the maternity team, to “push up” vaginally if an IFH is encountered.^{14,15}

Multi-professional simulation is likely to provide an effective and safe form of training for IFH, as with shoulder dystocia.¹⁸ Training should include opportunities for maternity staff to learn and practice disimpaction techniques such as vaginal disimpaction (push method) and reverse breech extraction (pull method).

Key message

There is an urgent need to train maternity staff managing impacted fetal head at cesarean section. This new validated simulator is realistic, allows maternity staff to practice all disimpaction techniques and is very useful for training.

A suitable birth trainer should realistically simulate IFH and facilitate such training. However, current models lack the required realism and/or functionality.^{19,20} It is critical that training tools are appropriately validated prior to wider dissemination to ensure effective learning.²¹ The aim of this study is to assess the face, content and construct validity of a new birth simulator for IFH at CS using established methodology.^{16,22} Face validity refers to how realistic the simulator is; content validity is how appropriate it is as a training tool; and construct validity refers to the extent to which the simulator can distinguish between “experts” and “novices”.^{16,21,22}

2 | MATERIAL AND METHODS

2.1 | Development of novel simulator

Obstetricians and midwives worked in collaboration with model-making company, Limbs & Things Ltd, to develop a novel simulator for IFH at CS. The original CS module, which is inserted into the PROMPT Flex® maternal mannequin, was modified to develop a new “Enhanced CS Module” that better simulates impaction of the fetal head. Changes to the CS module included improvements to the pre-incised skin, addition of a pre-incised, retractable uterus, with an adjustable opening, and a modified pelvis, mimicking the restricted space at the pelvic inlet. The existing PROMPT Flex® fetal mannequin was also modified to allow accurate limb articulation and flexion at the waist.

2.2 | Setting

Simulations took place at three maternity units in Southwest England with birth rates ranging from 4500 to over 6000 per year.

FIGURE 1 Prototype impacted fetal head birth simulator, complete with lower legs, in simulated theater environment.



2.3 | Participants

Obstetricians and midwives were invited to participate in the study, since both may be involved in managing an IFH at CS.

2.3.1 | Obstetricians

For the purpose of this study, obstetricians were categorized as “novices” or “experts”. “Novice” obstetricians were defined as specialty trainee year 3 (ST3) obstetricians and above, with <7years' experience in obstetrics. ST3 obstetric registrars are expected to be competent performing CS without direct supervision and 7years is the minimum time-period in which specialty training can be completed in the UK. “Expert” obstetricians were defined as obstetric consultants who: actively and regularly practice on the labor ward, have >7years' experience in obstetrics and were respected by their peers for their expertise in CS.

2.3.2 | Midwives

Only senior midwives who coordinate the labor ward (core band 6 or 7), have extensive expertise and experience on the labor ward, and who might be expected to perform vaginal disimpaction, were recruited.

2.4 | Sampling and recruitment

Recruitment took place between September and December 2019. An equivalent number of “novice” and “expert” obstetricians were recruited from each participating site. “Novice” obstetricians were identified through the Post Graduate Medical Education School that coordinates specialty training across the participating units. All “novice” obstetricians meeting the inclusion criteria were invited to participate. We elected to recruit experts based on reputation rather than number of CS performed or morbidity data to provide a better representation of expertise. Experts may perform fewer CS

than more junior colleagues but these are likely to be the more high-risk cases. Therefore, consultant labor ward leads nominated three to five obstetricians in their unit whom they considered to have expertise in complex CS. A similar sampling approach has been used in simulation studies of operative vaginal birth.^{23,24} Matrons and labor ward leads identified three to four midwives in their unit who have expertise in coordinating labor ward.^{23,24}

Potential participants were invited to participate by email, with the Post Graduate Medical Education school, labor ward leads and matrons acting as gatekeepers, circulating recruitment material to potential participants on behalf of the research team. Participants were provided with information about the study and made aware that they were free to decline participation.

2.5 | Sample size

There are no clear recommendations regarding the sample size required for validation studies. However, previous studies using similar methodology have had sample sizes in the region of 30 participants.^{16,22,25}

2.6 | Simulated scenarios

Participants were observed and audiovisually recorded undertaking three standardized simulated scenarios. To improve fidelity, PROMPT Flex® lower legs were attached to the maternal mannequin and a theater environment was simulated with theater drapes and equipment (Figure 1). At the start of the scenario, the maternal mannequin's legs were extended and secured with an operating table leg strap. Participants were able to request that the leg strap be released so the legs could be flexed and abducted if desired.

Scenarios were adapted for each professional group such that clinicians were only asked to perform tasks that might be expected of them in real-life. Obstetricians were advised that CS had commenced and uterine incision performed, and were asked to proceed to deliver the baby as they would in real-life. Midwives were advised that the obstetrician was experiencing difficulty delivering the head

and had requested a vaginal “push-up” from the midwife. Actions that could not be simulated were verbally confirmed.

The same researcher performed the role of the operating obstetrician during midwifery scenarios, and undertook any requests for vaginal disimpaction during obstetrician-led scenarios.

Three simultaneous scenarios were undertaken, differing only by fetal position. The fetal position most commonly associated with IFH (occipito-posterior) was simulated first, followed by occipito-transverse and then occipito-anterior.¹ The order of simulations was kept consistent for all participants. Scenarios were timed and continued until the fetal mannequin was delivered or the participant felt it would be unsafe to continue.

Immediately after all three simulated scenarios, participants were asked to complete a written questionnaire. Questions were answered confidentially and data were anonymized.

2.7 | Outcomes

Five-point Likert scales were used to assess face and content validity.²¹ To assess face validity, participants were asked whether they considered the model realistic overall, and in occipito-posterior, occipito-transverse and occipito-anterior positions. To assess content validity, participants were asked whether they thought the model would be useful for training in IFH at CS.

Construct validity was assessed by testing an a priori hypothesis that “experts” would be more likely to achieve successful delivery than “novices” within 5 minutes. A pragmatic decision was made to select an endpoint of 5 minutes for successful delivery, based on the relation between the head-to-body delivery interval in shoulder dystocia and the risk of fetal acidosis and hypoxic ischemic encephalopathy (HIE).²⁶ There is no equivalent research regarding CS and uterine incision to delivery interval and HIE. Furthermore, in the absence of extraneous factors influencing the progress of the clinical scenario, all required maneuvers could easily be completed within 5 minutes. Time taken to deliver the head, number and type of techniques employed were also recorded.

2.8 | Statistical analyses

Demographics are presented as frequencies and proportions. Descriptive statistics were used to analyze Likert scale responses. Construct validity was assessed by comparing successful delivery and median time to delivery between “experts” and “novices”, using Chi-square test and Mann-Whitney *U*-tests, respectively. The number of techniques used was compared using the Kruskal-Wallis test. Analyses were performed using STATA version 17.0.

2.9 | Ethics statement

This is a study of healthcare practitioners only. The study was sponsored by North Bristol NHS Trust and ethically approved by the University

TABLE 1 Participant demographics

	n (%)
Role	
Expert obstetrician ^a	12 (34.3)
Novice obstetrician ^b	13 (37.1)
Midwife ^c	10 (28.6)
Years of experience	
<5 years	11 (31.4)
5–20 years	9 (25.7)
>20 years	15 (42.9)
Maternity unit	
A	9 (25.7)
B	14 (40.0)
C	12 (34.3)
Overseas experience	
Yes	16 (45.7)
No	19 (54.3)
Previous simulation training for IFH	
Yes	5 (14.3)
No	30 (85.7)
Gender	
Female	30 (85.7)
Male	5 (14.3)

Abbreviation: IFH, impacted fetal head.

^aExpert obstetrician = actively practicing obstetric consultant with >7 years' experience and expertise in CS.

^bNovice obstetrician = specialty trainee year 3 obstetrician and above (registrar) with <7 years' obstetric experience.

^cMidwife = senior, coordinating midwife with labor ward expertise.

of Bristol Faculty of Health Sciences Research Ethics Committee (ref. 87364; July 8, 2019). All participants provided signed, written consent.

3 | RESULTS

3.1 | Demographics

A total of 105 simulated scenarios were undertaken by 35 participants (three scenarios per participant). Participants included 12 “expert” obstetricians, 13 “novice” obstetricians and 10 senior midwives, from three maternity units (Table 1). Two-thirds (8/12) of the “expert” obstetricians had >20 years' experience, and 92% had >10 years' experience. Seven of 10 participating midwives had >20 years' experience.

3.2 | Face validity

Overall, 30/35 (86%) participants reported that the model fairly or very realistically simulated IFH at CS (Table 2). Of the five remaining participants, four considered the model somewhat realistic and one, slightly realistic.

3.3 | Content validity

The model was considered fairly or very useful for training by 97% of participants (Table 2). The one remaining participant considered the model somewhat useful for training.

3.4 | Construct validity

“Expert” obstetricians delivered the fetal head in all simulations, whereas “novice” obstetricians were successful in 76.9% ($p = 0.002$). Expert obstetricians were more likely to achieve delivery of an occipito-anterior fetal mannequin than novices (Table 3).

3.5 | Management of simulated impacted fetal head

In simulated scenarios where the fetal head was successfully delivered, “expert” obstetricians delivered the fetal head a third quicker than novices (“expert” median time to delivery = 66.8 seconds [IQR = 53–86] vs “novice” median time to delivery = 99 s [IQR = 74.7–134]; $p = 0.06$) (Figure 2).

TABLE 2 Face and content validity of simulator

	Median (IQR)
Face validity (realism)	
Overall	4 (4, 5)
Fetal head position	
Occipito-posterior (OP)	4 (4, 5)
Occipito-transverse (OT)	4 (4, 5)
Occipito-anterior (OA)	5 (4, 5)
Content validity (usefulness for training)	
Overall	5 (5)

Note: 1 = not realistic/useful at all; 2 = slightly realistic/useful; 3 = somewhat realistic/useful; 4 = fairly realistic/useful; 5 = very realistic/useful.

Abbreviation: IQR, interquartile range.

A range of techniques were employed to disimpact the fetal head during simulated scenarios, including change of hand, tocolysis, head-down tilt, vaginal disimpaction, reverse breech extraction and the Patwardhan method (Table 3). Obstetricians most commonly changed their hand or asked an assistant to perform vaginal disimpaction (push method) to assist delivery. “Expert” obstetricians were less likely to change their hand or use head-down tilt compared with “novices”. Only one obstetrician attempted the Patwardhan method, where the baby's arms are delivered first.

Across all simulated scenarios, obstetricians used an average of two disimpaction techniques to deliver the fetal head (IQR = 1–2) (“expert” vs “novice” obstetrician, $p = 0.06$). “Novice” obstetricians used more disimpaction techniques for the simulated scenario with an occipito-posterior fetal mannequin compared with “expert” obstetricians (two techniques [IQR = 1–3] vs one technique [IQR = 0–2]; $p = 0.02$) (Table 4).

Midwives were able to elevate the fetal head vaginally in 60% of simulated scenarios (Table 5). On average, it took midwives 16 seconds successfully to disimpact the fetal head and 39 seconds to stop if unable to elevate the fetal head. In nearly half the simulated scenarios, midwives inserted two or three fingers to perform the vaginal push-up and did not re-position the woman's legs. Most midwives did not modify their approach according to fetal position (Table 5).

4 | DISCUSSION

This novel birth simulator has been validated by obstetricians and midwives performing over 100 simulated scenarios. The simulator is realistic, very useful for training and allows hands-on practical training of all recognized disimpaction techniques. It distinguishes between “novice” and “expert” obstetricians: using the simulator, “experts” were more successful delivering the fetal head, quicker in doing so and used fewer techniques. This study also highlights the variable and potentially unsafe approaches used to manage an IFH and urgent need for training.

We used a rigorous, established approach to assess the face, content and construct validity of the simulator.²¹ We assessed face and content validity using objective, Likert-scale measures, and compared two separate performance variables (success and time to

TABLE 3 Techniques employed to deliver the fetal head in simulated scenarios

	All scenarios ($n = 75$) n (%)	“Expert” scenarios ($n = 36$) n (%)	“Novice” scenarios ($n = 39$) n (%)	p -value
No additional technique	13 (17.3)	8 (22.2)	5 (12.8)	0.28
Change of hand	48 (64.0)	18 (50.0)	30 (76.9)	0.02
Tocolysis	35 (46.7)	14 (38.9)	21 (53.9)	0.20
Head-down tilt	8 (10.7)	0 (0.0)	8 (20.5)	0.004
Vaginal push method	37 (49.3)	16 (44.4)	21 (53.9)	0.42
Reverse breech extraction	17 (22.7)	6 (16.7)	11 (28.2)	0.23
Patwardhan technique	1 (1.3)	0 (0.0)	1 (2.6)	0.33

Note: p -values were calculated using Pearson's Chi-square test or Fisher's exact test where numbers were small.

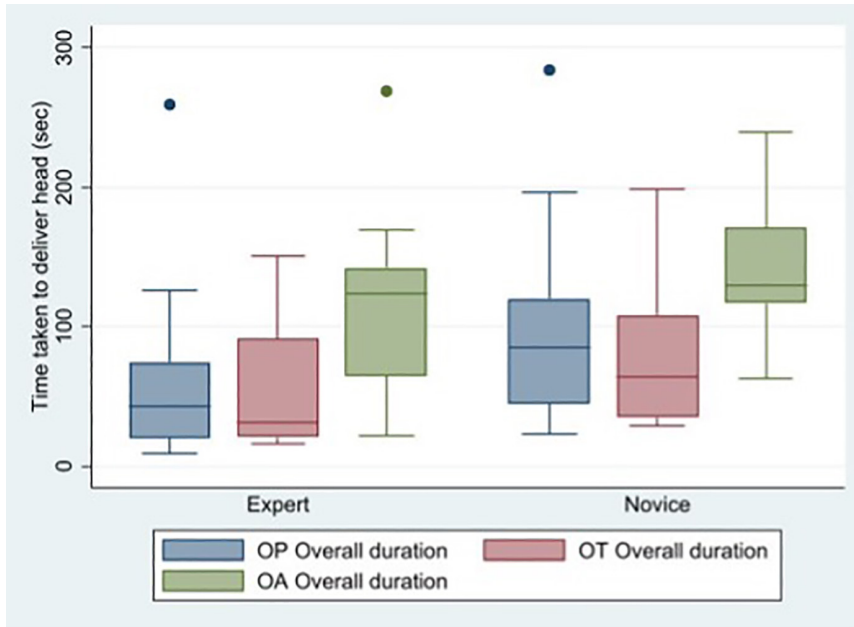


FIGURE 2 Comparisons of time taken to deliver the fetal head according to head position and expertise (OA, occipito-anterior position; OP, occipito-posterior position; OT, occipito-transverse position).

TABLE 4 Obstetric scenario features according to fetal position and expertise

	"Experts" (n = 12)	"Novices" (n = 13)	p-value
Successful delivery, n (%) ^a			
OP	12 (100)	10 (77)	0.22
OT	12 (100)	13 (100)	1.0
OA	12 (100)	7 (54)	0.02
Median time to delivery, s (IQR) ^b			
OP	43 (20-75)	85 (45-120)	0.08
OT	31 (21-91)	64 (35-108)	0.07
OA	124 (65-142)	130 (117-171)	0.23
Median number of additional techniques (IQR) ^c			
OP	1 (0-2)	2 (1-3)	0.02
OT	1 (0-2)	1 (0-3)	0.26
OA	3 (1-4)	3 (2-4)	0.18

Abbreviations: OA, occipito-anterior; OP, occipito-posterior; OT, occipito-transverse; Techniques, change of hand, tocolysis, head-down tilt, vaginal disimpaction, reverse breech extraction, Patwardhan method.

^aFisher's exact test.

^bMann-Whitney U-test.

^cKruskal-Wallis test.

deliver) to establish construct validity. To minimize bias, participants completed the questionnaire on face and content validity in private.

We ensured that maternity staff were appropriately and fairly represented. We included midwives, recognizing the importance of their role in assisting in the management of this emergency and in response to their lack of inclusion in training and IFH research to date. Only speciality trainees who would be expected to be competent performing CS independently were included in the "novice" group.

TABLE 5 Midwifery scenario features

	Midwife scenarios (n = 30)
Successful elevation of the fetal head, n (%)	18 (60)
Median time, seconds (IQR)	
To successfully elevate the head	16 (13, 21)
Before stopping if unable to elevate the head	39 (30, 57)
Re-positioning of woman's legs, n (%)	17 (57)
Uses a whole hand to perform vaginal disimpaction	17 (57)
Attempt to flex the fetal head	13 (43)

"Experts" and midwives were identified and recruited on the basis of their expertise in intrapartum care, using robust and recognized processes.²³ We simulated a theater environment to improve fidelity and better assess more realistic practices. To standardize external factors and minimize confounding, any requests to disimpact the head vaginally in obstetrician-led scenarios were undertaken by the same researcher.

The primary limitation of this study is that it was undertaken in a single region of the UK. However, participants were recruited from three different maternity units, and nearly half had experience of working overseas, thereby minimizing institutional bias towards certain practices and improving generalizability. Fetal Pillow®, a soft silicone balloon inserted vaginally to elevate the fetal head if an IFH is anticipated,²⁷ was not in use at any of the participating maternity units. However, use of the device can be demonstrated using this simulator. We did not include a patient-actor as that was outside the scope of this study. However, hybrid simulation incorporating a patient-actor can easily be achieved using this simulator.

Techniques for IFH are difficult to learn experientially. Simulation using this validated simulator is likely to provide an effective and

safe form of training. Introduction of the European Working Time Directive and associated reduction in junior doctor working hours has resulted in issues with trainees achieving required surgical competencies.^{28,29} This is likely to have compounded the problem of managing IFH at CS, with junior obstetricians having less experience of complex cesarean birth.²⁸ Furthermore, hands-on clinical training may not always be feasible, since difficulties delivering an IFH are not always possible to predict.¹ Obstetric trainees may therefore face this emergency while working out of hours and without consultant supervision.

Courses such as ROBuST (RCOG Operative Birth Simulation Training) and the full dilation cesarean delivery simulator, Desperate Debra®, have provided more training opportunities for IFH.^{2,16,17} However, any available training has centered exclusively on the obstetrician, neglecting the importance of the wider multi-professional team and especially the role of midwives in performing vaginal disimpaction.^{2,16,17}

This study reveals inconsistent and potentially harmful approaches to vaginal disimpaction, even among senior midwives. This likely reflects an absence of training in the push method, despite evidence indicating that it is the most commonly employed technique used by UK practitioners.^{14,30} To perform vaginal disimpaction safely and effectively, the accoucheur should use their whole hand to cup and flex the fetal head.^{11,29,31} To achieve adequate vaginal access for disimpaction, the woman's legs should be re-positioned in a semi-lithotomy position.^{11,29} However, nearly half of midwives participating in this study neither re-positioned the legs nor used a whole hand. This emphasizes that any accoucheurs performing vaginal disimpaction should be trained in how to do so.

Lack of training in vaginal disimpaction may be explained by limitations with existing models. The Desperate Debra® simulator does not easily accommodate a whole hand, allowing digital disimpaction only.^{16,32} The simulator described in this study allows practitioners to introduce their whole hand to flex and elevate the fetal head vaginally. Addition of lower legs to the maternal mannequin also allows the maternity team to learn and practice altering the position of the woman's legs to facilitate vaginal disimpaction.

Furthermore, the Desperate Debra® simulator does not include a complete fetal mannequin but rather uses a fetal head attached to a spring mechanism.¹⁶ It is therefore not possible to practice reverse breech extraction. However, there is increasing evidence that reverse breech methods may be safer for women undergoing CS when an IFH occurs.^{3,4,33} Despite this, many UK obstetric trainees are not confident performing it.¹⁴ Participants in this study performed reverse breech extraction in nearly one-quarter of simulated scenarios. This demonstrates that this technique is utilized by UK obstetricians and that this new simulator allows rehearsal of this method.

This study suggests that more experienced obstetricians may have greater underlying skills in abdominal cephalic disimpaction, ie delivering the fetal head with their hand, since they used fewer

techniques to achieve delivery. This may explain why, in a recent observational study of emergency CS, junior operators were more likely to diagnose an IFH, as most obstetricians define IFH as a cesarean birth requiring additional techniques.¹ Our study also emphasizes that several disimpaction techniques may be required to deliver an IFH, echoing other research.¹ This stresses the need to train maternity staff in a range of evidence-based disimpaction techniques, so maneuvers can be employed sequentially if required.

Our findings mirror recent surveys indicating that junior obstetricians may favor less technical strategies, such as tilting the operating table head down.^{14,30} This study also shows a lack of familiarity with the Patwardhan technique, since only one trainee attempted to use it.¹⁴ Both "expert" and "novice" obstetricians experienced the most difficulty disimpacting the fetal mannequin in an occipito-anterior position. This likely reflects real-life, since an occipito-anterior position not compatible with vaginal birth, may represent true cephalopelvic disproportion and present greater challenges for the obstetrician in getting below the fetal head to flex it.

5 | CONCLUSION

Multi-professional training is urgently required for the management of impacted fetal head at CS. Simulation training would allow maternity staff to learn skills in a safe environment before techniques are employed in clinical practice. This study has validated this new simulator, which was reported as realistic, useful for training and distinguishes between experienced and less experienced obstetricians. Moreover, this new model can be used for training in all disimpaction techniques. This study reveals expert practices and potentially unsafe actions employed by maternity staff managing IFH. Further qualitative assessment of these behaviors is under review to develop lessons for training.

AUTHOR CONTRIBUTIONS

KC conceived the idea, designed the study, conducted the data collection, carried out the analysis and wrote the manuscript, supervised by EL, TD, CW and RB. All authors edited and approved the manuscript.

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CONFLICT OF INTEREST

The authors have stated explicitly that there are no conflicts of interest in connection with this article.

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