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**Fetal head position and perineal distension associated with the use of the BD Odon Device<sup>(TM)</sup> in operative vaginal birth: a simulation study**

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**Running title:** Positioning of the BD Odon Device on the fetal head

## **Abstract**

### **Objective**

To investigate (i) the placement of the BD Odon Device on the model fetal head, and (ii) perineal distention during simulated operative vaginal births conducted with the BD Odon Device

### **Design**

Observational simulation study

### **Setting**

North Bristol NHS Trust, UK

### **Population or Sample**

440 simulated operative vaginal births

### **Methods**

Three bespoke fetal mannequins were developed to represent (i) bi-parietal diameter of the 50<sup>th</sup> centile at term (ii) bi-parietal diameter at the 5<sup>th</sup> centile at term and (iii) 50<sup>th</sup> centile head with 2 cm of caput. Siting of the BD Odon Device on model heads was determined before and after 400 simulated operative vaginal births. Variables were analysed to determine their effect on device siting and movement during birth.

The fetal mannequins were placed inside a maternal mannequin (PROMPT Flex, Limbs & Things, Bristol, UK) and the BD Odon Device was placed around the fetal head as per the instructions for use. The location of the air cuff was determined before and after the head was delivered. Perineal distension was determined by recording maximum perineal distention during a simulated operative vaginal birth using the same procedure, as well as scenarios employing an inappropriately non-deflated air cuff (for the BD Odon Device), the Kiwi ventouse and non-rotational forceps.

## **Main Outcome Measures**

Site and displacement during birth of the BD Odon Device on a model head. Maximal perineal distension during birth.

## **Results**

The BD Odon Device was reliably sited in a standard over the fetal head position (approximately 40mm above the fetal chin) for all stations, head sizes and positions with no significant displacement. In occipito-posterior births, compared to occipito-anterior or transverse, the BD Odon Device routinely sited further down the fetal head (toward the chin).

The BD Odon Device was not associated with more perineal distension than forceps or Kiwi ventouse (21mm vs 26mm vs 21mm at posterior fourchette).

## **Conclusions**

The BD Odon Device reliably sited over a safe area of the fetal head in 400 simulated births representative of clinical practice. The BD Odon Device generates similar levels of perineal distension compared to Kiwi ventouse when used correctly.

## **Keywords**

BD Odon Device, placement, positioning, movement, perineal

## Introduction

The first reported use of obstetric forceps was in the 16<sup>th</sup> Century (1), the ventouse was introduced in the 1950s as an alternative (2). Both obstetric forceps and ventouse are independently associated with increased maternal and neonatal morbidity, including; maternal trauma, neonatal facial injury (forceps), cephalohaematoma, subgaleal haemorrhage, and retinal detachment (ventouse) (3). However, despite this and in an era with rising Caesarean birth rates, there have been few innovations to assist vaginal birth. Any potential new instrument for operative vaginal birth must be carefully evaluated for safety and efficacy. An ideal instrument should be associated with minimal risks to the mother and her baby, have a low failure rate, be simple to use and finally, be acceptable to both women and medical practitioners.

The BD Odon Device (BD, Franklin Lakes, New Jersey, USA) is presently in development and offers a potential alternative to obstetric forceps and ventouse. The BD Odon Device consists of an inflatable circular air cuff attached to a thin circumferential polyethylene sleeve. A semi-rigid plastic applicator is used to place the air cuff and sleeve into the birth canal, past the widest diameter of the fetal head. The air cuff is inflated around the fetal head, and the applicator is removed. During maternal contractions the accoucheur applies traction to the polyethylene sleeve, to assist birth of the baby.

An earlier prototype of the BD Odon Device has been employed in a series of 48 normal vaginal births in Argentina. This demonstrated a 75% success rate. Various design modifications were proposed following this testing in 48 healthy volunteers. Simulation testing was then employed to investigate the reliability and safety of device placement in a variety of situations prior to the resumption of clinical studies.

The air cuff provides the traction anchor point of the BD Odon Device. We sought to determine where the cuff sits in relation to sensitive fetal anatomy (neck, nose and eyes) in simulated births. In particular, this study investigated the effect on the position of the air cuff in relation to: (i) fetal position, (ii) fetal station, (iii) fetal head size, (iv) presence of caput succedaneum, and (v) the inflation pressure of the air cuff.

Furthermore, we investigated the perineal distension during simulated births with the BD Odon Device, using an appropriately deflated cuff, non-rotational forceps and Kiwi ventouse. Misuse of the BD Odon Device, where the air cuff remains inflated during crowning contrary to instructions for use, was also simulated using a modified procedure, to evaluate the degree of perineal distention provided by the inflated air cuff if the practitioner inadvertently failed to deflate the air cuff prior to crowning of the fetal head.

## **Methods**

### **Development of fetal mannequins**

The PROMPT birthing simulator (Limbs & Things, Bristol, UK) fetal mannequin was used. This mannequin has, an average size head for a term fetus with a bi-parietal diameter (BPD) of 96mm, comparable to the 50<sup>th</sup> centile of 97mm at 39 to 40 weeks gestation (12) (Figure 1).

Two additional fetal mannequins were developed for use in this study. A new fetal model was manufactured with a BPD of 89mm, equivalent to a fetal head on the 5<sup>th</sup> centile (12) (Figure 2) to assess the risk of the device slipping onto and constricting the fetal neck in cases of a small head size. A second fetal mannequin was developed to simulate a 50<sup>th</sup> centile term fetus with a 2cm depth of caput succedaneum (situated in the midline between the anterior fontanelle and 2cm posterior of the posterior fontanelle) (Figure 3) to assess if

the presence of caput succedaneum could interfere with the application and use of the BD Odon Device.

### **Simulation of operative vaginal births**

The pre-existing PROMPT birthing simulator fetal mannequin together with the two bespoke fetal mannequins were used with a PROMPT Flex maternal mannequin birthing simulator (Limbs & Things Ltd, Bristol, UK) for the simulated operative vaginal births. All simulated OVBs were conducted by a single operator (SO'B).

Four hundred simulated OVBs were performed to investigate the placement of the BD Odon Device and the effect of key variables on the position and movement of the BD Odon Device air cuff during simulated birth, namely:

- (i) fetal head size: 50<sup>th</sup> centile, 5<sup>th</sup> centile
- (ii) presence of caput succedaneum
- (iii) fetal position (occipito-anterior (OA), occipito-posterior (OP), right occipito-transverse (ROT), face presentation)
- (iv) fetal station: vertex at the ischial spines, vertex 1cm below the ischial spines, vertex 2cm below the ischial spines
- (v) BD Odon device air cuff inflation pressure: 40kPa, 60kPa, 80kPa.

The number of births for each combination of variables is provided in the Supplementary Material S1.

The range of BD Odon Device cuff inflation pressures tested (40 to 80kPa) is the range envisaged to be used in vivo. The behavior of the device at pressures over 80kPa were not

investigated. The device incorporates a pressure limiter which prevents the generation of inflation pressures greater than 80kPa.

During each simulated OVB, a modified procedure for using the BD Odon Device was employed. The air cuff was inflated and the applicator was removed. The distance of the inferior edge of the air cuff from four reference points on the fetal head ((i) mental protuberance (ii) right angle of mandible (iii) left angle of mandible and (iv) C7 posteriorly) was then measured in mm (see Figure 4). Routine traction was applied in the standard manner to the BD Odon device sleeve to assist the birth of the fetal head. After crowning of the head, the air cuff should be deflated. However, in our modified procedure to ensure the position of the air cuff after traction had been applied to deliver the fetal head, the air cuff was left inflated and measurement of the distance between the air cuff from the fixed reference points on the fetal head was repeated.

Device placement data were collected: site of the device on a model head before birth, distance moved by the device over the model head during the simulated birth (mm), and site of the device on the fetal head post birth. All positions were determined relative to four reference points: the fetal mental protuberance, right angle of mandible (RAoM), left angle of mandible (LAoM) and C7 posteriorly. The data measuring distance from the mental protuberance and C7 were analysed as separate outcomes, whilst data from RAoM and LAoM were pooled to give a composite measure of device movement around the lateral aspects of the fetal head. Distances and displacement are reported as positive if the air cuff was sited or moved cephalad relative to the reference point (i.e. closer to the fetal vertex), and negative if the air cuff was sited or moved caudal relative to the reference point (i.e. closer to the fetal chin).



Results are provided for the location of the device on the model fetal head relative to fetal mental protuberance (Table 1) and relative to C7 (Table 2) before and after birth in scenarios where only one variable has changed (i.e. inflation pressure or head size or position or station).

Statistical analyses of the significance of degree of change in position of the device before and after birth relative to the mentum between all variable groups relative to a baseline group (BD Odon Device, 40kPa inflation pressure, OA, station +2, 50<sup>th</sup> centile head size, no caput) are presented in Supplementary Material S2.

The evaluation of the perineal distension was investigated using forty simulated OVBs. The 50th centile head diameter fetal mannequin was used to measure the perineal distension during birth in four separate clinical scenarios (10 births per scenario):

- (i) BD Odon Device, OA position, vertex 2cm below the ischial spines (station +2cm), air cuff inflation pressure of 40kPa, cuff appropriately deflated at crowning of the fetal head
- (ii) BD Odon Device, OA position, vertex 2cm below the ischial spines (station +2cm), air cuff inflation pressure of 40kPa, cuff inappropriately not deflated at crowning of the fetal head
- (iii) Kiwi ventouse, OA position, station +2cm
- (iv) Non-rotational forceps, OA position, station +2cm

Perineal distension with the vertex at 2 cm below the ischial spines (the baseline) was measured for each simulation prior to the application of an instrument (BD Odon Device, Kiwi or non-rotational forceps). Measurements were taken from three fixed points on the

maternal mannequin; (i) posterior fourchette (PF), (ii) left mid-vestibular edge (LMVE) and (iii) right mid-vestibular edge (RMVE) (Figure 5). Measurements were repeated at the point of maximum perineal distension (either laterally for LMVE and RMVE or directly inferiorly for PF) during the simulated birth (Figure 6). The difference between the baseline and maximum distension measurements were calculated to determine the maximum perineal distension in each of the five scenarios described above. The scenario where the BD Odon Device cuff was left intentionally inflated during crowning (contrary to instructions for use) was included to simulate a worst-case scenario where the operator neglects to deflate the cuff.

Data from the posterior fourchette were analysed as a single outcome, while data from LMVE and RMVEs were pooled to give a composite measure of lateral perineal distension. Results are presented using descriptive statistics for distention data in each scenario.

Data describing differences in degree of movement of the device over the model fetal face from before to after birth between variable groups (in Supplementary Material S2) were analysed using a Kruskal-Wallis test. Bonferroni corrected p-values were derived to account for test-multiplicity. A p-value  $\leq 0.05$  was considered as evidence of group difference.

Analyses were conducted using Stata software, version 13 (StataCorp, College Station, Texas, USA).

## **Results**

### **Position of BD Odon Device air cuff before and after simulated birth of the fetal head**

#### **Location of air cuff in relation of the fetal chin:**

Prior to the application of traction, the inferior edge of the BD Odon Device air cuff was positioned on, or above, the fetal mental protuberance (i.e. between the fetal chin and nose) in all simulations. In all 400 simulations performed prior to the application of traction to the BD Odon Device the median distance between the inferior edge of the BD Odon Device air cuff and the fetal mental protuberance was 40mm (1<sup>st</sup> and 3<sup>rd</sup> quartiles [Q1, Q3], 21mm & 45mm).

The inflation pressure within the air cuff had little effect on the initial position of the device from the fetal chin: 43mm [40 to 44.5], 46mm [43.5 to 46.5] and 44.5mm [41 to 46] for inflation pressures of 40, 60 and 80kPa respectively.

The ROT position, presence of caput, 5<sup>th</sup> centile head size and vertex at station +1cm below ischial spines had little effect on the position of the device relative to the fetal chin: 44mm [41.7 to 48], 44.5mm [42 to 50.5], 37mm [33 to 38.5] and 44mm [42 to 44.5] respectively.

On average the air cuff moved less than 10mm in either direction during birth.

However, the air cuff was located lower on the fetal face (nearer the chin) when the fetus was in the OP position (median distance to chin 31mm [25 to 36.5] before birth, and was noted to be beneath the fetal chin after birth in the majority of cases (median distance to chin -10mm [-12 to -6]). The air cuff moved by a greater margin in these OP simulations, on average moving down the fetal face (toward the chin) by 36mm during birth [-47.5 to 30.5].

In births where the model fetus was at the level of the ischial spines, the air cuff moved by 9.5mm during birth. This is due to the air cuff being placed higher (toward the vertex) on the fetal head before birth than in any other scenario, 49.5mm [45.7 to 74] above the fetal chin.

In these scenarios the air cuff was located in a similar site on the fetal head to procedures in OA or OT positions after birth, 42mm [39 to 44.5] above the fetal chin.

These results are shown in Table 1.

Ten attempts were made to apply the BD Odon Device in a mento-anterior face presentation, although this would be an unlikely circumstance in clinical practice. The BD Odon Device spontaneously slipped off the face during inflation in three (30%) of these attempts. These findings confirm that it is inappropriate to use the BD Odon Device for face presentations.

### **Positioning of BD Odon Device air cuff before and after simulated birth of the fetal head**

#### **Location of air cuff in relation to the fetal 7<sup>th</sup> cervical vertebrae (C7):**

All variables, except the OP position, had little effect on the position of the BD Odon Device air cuff relative to the 7<sup>th</sup> cervical vertebrae (C7): for all variables except OP position, the air cuff was located within 15mm of C7, and moved less than 10mm from before to after birth. In the OP positions, the air cuff was consistently sited higher up the fetal head, towards the vertex (26mm, [15 to 29]). During birth it moved down the fetal head by 23mm [-29.5 to -17.5] so that it was located just below C7, with a median distance from C7 of -2mm [-2.5 to 0.5]

These results are presented in Table 2.

#### **Perineal distension**

During birth, when used correctly, there was no difference between the means of posterior fourchette distension using the BD Odon Device and Kiwi ventouse. When the BD Odon Device was used with the air cuff purposefully left inflated at crowning (simulating a user error) to investigate perineal distension in a worst-case scenario, greater perineal distension was observed at the posterior fourchette than with obstetric forceps or Kiwi ventouse (Table 3).

## **Discussion**

### **Main Findings**

Using the standard operating procedure for placement, the BD Odon Device was consistently sited over the same area of the fetal head for all fetal head sizes, stations and positions, except OP and when the vertex was at the level of the ischial spines. For all other scenarios tested, the BD Odon Device was sited around the fetal head within 15mm of the level of C7 posteriorly, and between 37mm and 46mm above the fetal chin anteriorly (Figure 7). This is the same level as the tips of correctly applied forceps blades. Furthermore, the device was stable with minimal movement of the device (<10 mm) during simulated birth.

In OP positions, the placement of the air cuff of the BD Odon Device was further down the fetal head, typically sited more cephalad (toward the vertex) over the posterior aspect of the neck, and more caudal (toward the chin) over the chin anteriorly when compared with births in an OA position. This may be a desirable feature, as deflexion of the fetal head is frequently associated with OP positions, and during inflation the BD Odon Device air cuff generated flexion of the fetal head. Increased flexion of the fetal head was observed in all positions, which may partially explain the mechanism of action of the device.

A significant hypothetical risk of the BD Odon Device was the possibility of the device slipping onto, and subsequently constricting the fetal neck. However, we observed that even when the device appeared to slip below the fetal chin, the downward traction on the device caused the cuff to only exert pressure on the inferior aspect of the mandibles, rather than on the anterior aspect of the fetal neck.

The location of the BD Odon Device was different in births performed with the vertex at the level of the ischial spines. In these births, the device was initially sited further cephalad (toward the vertex) than usual (49.5mm from the mental protubence, Table 1). After traction, the device was sited at the same level as other procedures, (42mm above the fetal chin). After the application of traction the BD Odon Device moves to the same site irrespective of the initial fetal station.

The BD Odon Device consists of an air cuff which, once inflated, is relatively incompressible. If the air cuff is further compressed (by an external force or by an increase in the intrinsic air pressure using the hand pump), the cuff will move to an area of lower external pressure. Because the fetal head progressively narrows between the widest point at the parietal ridge and the chin, an increase in pressure will result in the cuff to moving caudally (toward the chin). However, the anterior surface of the face between the nose and the chin is relatively flat, meaning that the cuff is likely to come to rest here rather than continue to travel caudally down the face. This observation was most pronounced in the births conducted with the vertex at the level of the ischial spines. The cuff initially is located higher towards the vertex. However, as traction force is applied, the air cuff moves caudally down the fetal head, coming to rest on the relatively flat portion of the face between the nose and chin. The BD Odon Device was reliably sited in a “safe area” between the fetal chin and nose, for all the investigated fetal positions and stations.

When correctly used, the BD Odon Device did not generate greater perineal distention than Kiwi ventouse. However, in ‘worst case’ simulations in which the air cuff was not deflated, the BD Odon Device did generate greater distention at the posterior fourchette than either forceps or Kiwi. Previous studies have not demonstrated a link between perineal distention

in labour and anal sphincter injury (4). However these findings suggest that incorrect use of the BD Odon Device, by not deflating the air cuff prior to crowning, may generate similar or higher rates of perineal tears than forceps and Kiwi ventouse. Whereas correct use of the BD Odon Device produced similar perineal distention to the Kiwi. This finding highlights the importance of training accouchers to use the BD Odon Device correctly.

### **Strengths and Limitations**

This is the first study to prospectively investigate the performance of a novel device for operative vaginal birth using simulation. We employed a simulation methodology previously used to investigate and improve management of other areas of intra-partum care (5-8).

All simulations were performed by a single operator, which assisted internal consistency of measurement and eliminated inter-operator variability. However, we recognise the inherent limitations of this strategy, in particular the possibility of repeated systematic error.

A further potential criticism of this study is the uncertainty whether our findings are generalisable to actual use of the device in clinical practice. We also acknowledge that there are no anatomical measurements with sufficient predictive validity to accurately assess the risk of perineal tears. However, our comparison of perineal distension during Kiwi ventouse, forceps and the BD Odon Device is a pragmatic proxy for prediction of perineal tears.

### **Interpretation (in light of other evidence)**

Studies of ventouse and forceps have demonstrated that poor device positioning increases the risk of adverse outcomes (9,10). While correct positioning can be successfully taught (11), an instrument that can be reliably sited is an important safety feature. Our study

demonstrates a high degree of concordance in the siting of the BD Odon Device across a wide range of fetal positions and stations.

## **Conclusions**

In 440 simulations, using a robust and validated model, the BD Odon Device is consistently and reliably sited over the fetal head, the location of the air cuff on the fetal head is likely to be safe in clinical practice. The device does not appear to slip or move significantly during simulated births, and generates a degree of head flexion.

Inflation of the air chamber results in flexion of the fetal head which may be associated with an increase in efficacy of the device when compared to ventouse.

The device did not constrict the fetal neck during use.

The perineal distension associated with the use of the BD Odon Device was similar to the Kiwi ventouse when the air cuff was deflated appropriately just prior to birth of the fetal head.

The BD Odon Device is predictably and reliably sited over a safe area of the fetal head in a representative sample of simulated head positions and sizes. The BD Odon Device appears to be safe in simulations and should now be evaluated in a clinical trial.

## **Disclosure of interests**

All authors (SO'B, CW, CB, MB, TD & JC) are members of the BD Odon Device Scientific Advisory Board. Members of the Board receive no honoraria, and solely received reimbursement of travel and accommodation expenses to attend meetings of the Board.



JC, TJD, and CW are members of the PROMPT Maternity Foundation (a registered charity in England and Wales).

CW and TD have been seconded to work with the PROMPT Maternity Foundation from North Bristol NHS Trust.

TD has acted as an independent advisor to Limbs and Things. TD has received payment for travel to meetings from Laerdal and has received payments for educational initiatives by Ferring pharmaceuticals.

### **Contribution to Authorship**

All authors (SO'B, CW, CB, MB, TD & JC) contributed to conception and design of the study. SO'B conducted all data gathering and analysis and prepared the first draft of the manuscript. All authors (SO'B, CW, CB, MB, TD & JC) revised and approved the final version of the manuscript.

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### **List of Tables/Figures**

Figure 1. Fetal head with a normal BPD

Figure 2. Fetal head with a small BPD

Figure 3. Fetal head with 2cm of caput succedaneum

Figure 4. Measurement reference points on model fetal head

Figure 5. Measurement reference points on model perineum at rest

Figure 6. Measurement points on model perineum at maximal distention

Figure 7. Location of BD Odon device on model fetal head in OA

Table 1. Placement of BD Odon Device in relation to the mental protuberance

Table 2. Placement of the BD Odon Device in relation to C7

Table 3. Perineal distension associated with the use of BD Odon Device, non-rotational

forceps and Kiwi in OA, 2cm below the ischial spines

Supplementary Material 1. Numbers of births for each combination of variables

Supplementary Material 2. Degree of movement of BD Odon Device in relation to mentum

from before to after birth between single variable groups across all births