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**Pressure and traction on a model fetal head and neck associated with the use of forceps, Kiwi™ ventouse and the BD Odon Device™ in operative vaginal birth: a simulation study**

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**Running title:** Pressure exerted on a model fetal head by the BD Odon Device

## **Abstract**

### **Objective**

To determine the pressure and traction forces exerted on a model fetal head by the BD Odon Device, forceps and Kiwi ventouse during simulated births.

### **Design**

Simulation study.

### **Setting**

Simulated operative vaginal birth.

### **Population or Sample**

84 simulated operative vaginal births.

### **Methods**

A bespoke fetal mannequin with pressure sensors around the head and strain gauge across the neck was used to investigate pressure applied over the head, and traction across the neck during 84 simulated births using the BD Odon Device, non-rotational forceps and Kiwi ventouse.

### **Main Outcome Measures**

Peak pressure on the fetal face and lateral aspects of the head during correct use of the BD Odon Device and forceps. Peak pressure on orbits and neck during misplacement of the BD Odon Device and forceps. Peak traction force generated until instrument failure using the BD Odon Device, forceps and Kiwi ventouse.

### **Results**

When correctly sited and using 80kPa inflation pressure on the cuff, the BD Odon Device generated a lower peak pressure on the fetal head than forceps (83kPa vs 146kPa).

When instruments were purposefully misplaced over the orbits the BD Odon Device generated a lower peak pressure on the orbits than forceps (70kPa vs 123kPa). When purposefully misplaced over the neck the BD Odon Device, compared to forceps, generated a greater peak pressure on the antero-lateral aspect of the neck (56kPa vs 17kPa) and a lower peak pressure on the posterior aspect of the neck (76kPa vs 93kPa) than forceps. In cases of true cephalic disproportion the BD Odon Device 'popped-off' at a lower traction force than forceps (208N vs 270N).

### **Conclusions**

In simulated assisted vaginal birth with correctly placed instruments the peak pressure exerted on the fetal head by a BD Odon Device is lower than pressure exerted by non-rotational forceps. In cases in which delivery of the fetal head is not possible due to cephalo-pelvic disproportion lower traction forces could be applied using the BD Odon Device than with forceps before the procedure was abandoned due to device failure.

### **Keywords**

Odon, forceps, Kiwi, pressure, traction

## Introduction

Complications of operative vaginal birth (OVB) are related to pressure exerted by the instrument on the fetal head (forceps exerting a positive pressure, vacuum exerting a negative pressure) and the traction force required to complete the birth. Compared to spontaneous vaginal birth, OVB is associated with higher rates of maternal perineal and anal sphincter trauma and neonatal facial injury (forceps) and neonatal cephalohaematoma, subgaleal and retinal haemorrhage (ventouse) (1,2). Furthermore, injuries are more likely to occur if the use of OVB does not follow guidance concerning its safe use (3), including when an instrument is incorrectly applied (4) or if there is prolonged traction (5).

The BD Odon Device (BD, Franklin Lakes, New Jersey, USA) is a new device being developed for OVB. The BD Odon Device consists of an inflatable circular air cuff attached to a thin circumferential polyethylene sleeve. A plastic applicator places the air cuff and sleeve into the birth canal, past the widest diameter of the fetal head. The air cuff is inflated, and the applicator removed. During maternal contractions the accoucheur applies traction to the sleeve, to expedite the birth.

The use of an air cuff positioned circumferentially around the fetal head as the 'anchor point' for traction has the potential to reduce fetal injury when compared to forceps. Pressure applied to the fetal head during birth may be more evenly distributed than pressure by forceps and therefore a lower risk of facial injury might be expected. Similarly, the wider distribution of pressure may also reduce the risk of adverse outcomes such as subgaleal haemorrhage and cephalohaematoma associated with the use of ventouse.

We developed a simulation model to study the pressure and force applied across the fetal head and neck during OVB. The model head was used to compare pressures on the fetal

head in births using (i) non-rotational forceps, (ii) Kiwi ventouse (Clinical Innovations, Salt Lake City, Utah, USA) and (iii) the BD Odon Device. Aware that the risk of neonatal injury is increased with incorrect use of a device, we also sought to simulate attempted OVB in true cephalopelvic disproportion to measure the traction force that could be applied to a non-deliverable fetus before the device failed ('popped-off') and to compare the pressure exerted on vulnerable structures (fetal orbit and neck) when a BD Odon Device or forceps were incorrectly applied.

## **Methods**

### **Development of a fetal mannequin to measure dynamic pressure changes during simulated operative vaginal birth**

A bespoke fetal mannequin was designed and manufactured by a multi-professional team of obstetricians, midwives, engineers and model makers. A PROMPT Flex® fetal mannequin (Limbs & Things Ltd, Bristol, UK) was adapted. Pressure sensors (Tekscan®, Boston, Massachusetts, USA) were mounted against a bespoke modelled fetal skull and neck. Three pressure sensors (Tekscan Pressure Mapping Sensor 5101: sensor pad dimensions = 111.8mm x 111.8mm, thickness 0.102mm; 1,936 sensels; sensel density = 15.5 sensels/cm<sup>2</sup>) covered the majority of the fetal skull including the entirety of the face and the lateral aspects of the head. These locations are shown in Figure 1.

An additional pressure sensor (Tekscan Pressure Mapping Sensor 6300: sensor pad dimensions = 33.5mm x 264.2mm, thickness 0.102mm; 2,288 sensels; sensel density = 25.8 sensels/cm<sup>2</sup>) was placed around the fetal neck. The fetal neck was modified with the addition of a silicone 'collar' to an antero-posterior diameter of 58mm, equivalent to the 50<sup>th</sup> centile of fetal neck diameters at 40 weeks gestation (6). Moulded silicone

representing features of the fetal face (nose, mouth, orbits and ears) and scalp skin (5mm thick) was positioned over the pressure sensors to simulate a fetal head. The fetal mannequin had a bi-parietal diameter (BPD) of 96mm, to simulate an average-sized term baby (BPD on 50<sup>th</sup> centile of 97mm) (7). A calibration device (Tekscan PB15C) was used to equilibrate, calibrate and zero all pressure sensors prior to each use.

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

The bespoke pressure monitoring fetal mannequin was used with a standard PROMPT Flex<sup>®</sup> maternal mannequin (Limbs & Things Ltd, Bristol, UK) to enable the simulation of operative vaginal births. The traction across the fetal neck was measured using the PROMPT Flex Force Monitoring fetal mannequin and associated software (Limbs and Things Ltd, Bristol, UK).

A series of simulated OVBs using the BD Odon Device, Kiwi ventouse and non-rotational forceps were performed by a single operator (SO'B). The air cuff of the BD Odon Device was inflated to 60kPa and 80kPa. This is the expected pressure range that will be used in-vivo. The peak pressure over the face (right orbit, left orbit, nose and chin) and lateral aspects of head were measured in 40 simulated births (cephalic presentation, direct occipito-anterior, vertex 2cm below the ischial spines) in which either a BD Odon Device (cuff inflation pressure 60kPa n = 10 or 80kPa n =10), non-rotational forceps (n=10) or Kiwi ventouse (vacuum pressure 70N) (n=10) were correctly applied and used to complete the birth of the fetal model in the standard manner.

Peak pressure exerted on sensitive fetal structures (orbits and neck) were measured throughout birth in an OA position at station 2cm below the ischial spines in 19 non-standard scenarios: (i) with the BD Odon Device cuff placed purposefully over the orbit and

inflated to 60kPa (n = 3) (ii) with the BD Odon Device cuff placed purposefully over the orbit and inflated to 80kPa (n = 3) (iii) with non-rotational forceps placed purposefully over the orbit (n = 3) (iv) with the BD Odon Device cuff placed purposefully around the neck and inflated to 60kPa (n = 5) (v) with the BD Odon Device cuff placed purposefully around the neck and inflated to 80kPa (n = 5) and with non-rotational forceps placed correctly on the fetal head (n = 5). Pressure data was initially captured and analysed using the proprietary iScan<sup>®</sup> program (Tekscan, Boston, Massachusetts, USA). The location of pressure sensors on the model fetal face and neck is shown in Figure 1.

Twenty further scenarios were performed to evaluate the force at which a device would detach or 'pop-off' the fetal head when the head was not deliverable. A bespoke 'pelvic shelf' was produced to prevent descent and birth of the fetus in order to simulate cephalo-pelvic disproportion. The traction force (N) exerted during attempted non-rotational forceps (n=5), kiwi ventouse (n=5) and BD Odon Device with cuff inflated to 60kPa (n = 5) and BD Odon Device with cuff inflated to 80kPa birth (n=5) on a cephalic presentation, direct OA position with the vertex at the ischial spines was measured using the integrated force monitoring device within the PROMPT Flex fetal mannequin.

Traction force data was captured by the PROMPT Flex<sup>®</sup> birthing simulator software (Limbs & Things, Bristol, UK) at 20Hz and subsequently exported for analysis.

Results are presented using descriptive statistical data due to the limited number of repetitions within each scenario. Data are reported as mean values for each dataset with full ranges of all values.

## **Results**

Eighty-four simulated operative vaginal births were performed (Table 1).



### **Pressure over fetal face, lateral aspects of head, orbits, nose and mentum**

Mean peak pressures over fetal face and lateral aspects of the head are shown in Table 2.

The mean peak pressure over the lateral aspects of the fetal head was greater using non-rotational forceps (146kPa) compared to the BD Odon Device (109kPa at 60kPa air cuff pressure and 83kPa at 80kPa air cuff pressure) and Kiwi ventouse (79kPa). The difference in magnitude of these applied pressures over the lateral aspects of the head is illustrated in Figure 2.

Mean peak pressures over the fetal face was comparable between the simulated births performed with non-rotational forceps (108kPa), Kiwi ventouse (96kPa) and BD Odon Device with cuff inflation pressure of 60kPa (99kPa) and 80kPa (106kPa).

Mean peak pressures over the orbits were greater using the BD Odon Device at both 60kPa and 80kPa cuff inflation pressures (47kPa and 67kPa respectively) than non-rotational forceps and Kiwi ventouse (24kPa and 19kPa respectively).

Mean peak pressures over the nose were lower using the BD Odon Device at 80kPa compared to all other scenarios, where the mean peak pressures were broadly comparable (Table 2).

Mean peak pressures over the mentum were comparable using the BD Odon Device at 80kPa inflation pressure (30kPa), non-rotational forceps (38kPa) and Kiwi ventouse (44kPa) and higher in scenarios using the BD Odon Device at 60kPa inflation pressure (60kPa).

### **Pressures exerted when devices are incorrectly sited**

Three simulated births were performed with the BD Odon Device air cuff purposefully incorrectly sited over the left orbit and inflated to 60kPa, and a further three simulated births with the air cuff inflated to 80kPa. Peak pressures over the left fetal orbit were

compared to three simulated births in which the non-rotational forceps were also incorrectly sited to lie over the left fetal orbit. It was only possible to perform three births for each scenario due to sensor degradation during these tests, so robust statistical comparison is not possible. However, the measurements suggest that incorrectly placed forceps generate substantially greater mean peak pressure over the fetal orbit (123kPa) than an incorrectly positioned BD Odon Device inflated to 60kPa or 80kPa (60kPa and 70kPa respectively) (Table 3).

The air cuff of the BD Odon Device was purposefully placed around the fetal neck (50mm below the fetal chin) and inflated to 60kPa and 80kPa. Five OVBs were performed with the fetus in a direct OA position at each inflation pressure. A comparison of applied peak pressure was made with five non-rotational forceps births (Table 4). Forceps tended to exert a higher median peak pressure on the posterior aspect of the fetal neck (94kPa) when compared to BD Odon Device with the cuff inflated to 60kPa (87kPa) and 80kPa (76kPa). However, the median peak pressure applied to the antero-lateral aspects of the fetal neck (the likely location of the fetal carotid arteries) by an BD Odon Device at 60kPa (59kPa) and 80kPa (56kPa) inflation was greater than that generated with non-rotational forceps (17kPa).

#### **Evaluation of the force at which a device detaches from the model fetal head when the head is not deliverable**

The maximum traction force applied before the device detached from the fetal head during an obstructed OVB (in which it was not possible for the fetal head to be delivered) was greater in non-rotational forceps (270N) compared to attempts using the BD Odon Device at

80kPa inflation pressure (208N), 60kPa inflation pressure (167N) and Kiwi ventouse (70N) (Table 5).

## **Discussion**

### **Main Findings**

The BD Odon Device, when correctly sited, generates less peak pressure on a model fetal face than correctly sited forceps, but higher peak pressure than Kiwi ventouse. The mechanism of action of the Kiwi ventouse, whereby there is no instrument in contact with the face or lateral aspect of the head, clearly explains the lower pressures for this instrument. When incorrectly sited, the BD Odon Device generates less pressure on vulnerable facial structures (the orbit) than forceps.

When the BD Odon Device was purposefully placed around the neck (previous simulation work has demonstrated that this is unlikely to occur), it generates more pressure over the anterior, but less pressure over the posterior aspect of the neck than forceps.

When used inappropriately in an obstructed birth and used forcefully until device failure, the BD Odon Device generates substantially less traction than forceps but more than Kiwi ventouse. However, as our simulator was unable to generate a chignon, the true pop-off/failure force for a Kiwi ventouse is likely to be higher in clinical practice – previous studies have demonstrated pop-off forces of between 110N to 130N (5).

### **Interpretation**

The BD Odon Device generated lower levels of peak pressure over the lateral aspects of the fetal head than forceps, but higher levels than Kiwi ventouse. This is biologically plausible.

Forceps have a much lower instrument surface area in contact with the fetal head (the blades) than the BD Odon Device (the circumferential air cuff) hence identical traction forces will result in lower pressure peak pressure exerted by the Odon Device when compared to forceps. It is therefore plausible that the risk of neonatal injuries specifically associated with high peak pressures, such as facial nerve palsy, scalp injury, skull fracture and bruising (2) are likely to be lower in OVBs using the BD Odon Device than those conducted using forceps. The low pressure detected on the lateral aspects of the head during a Kiwi ventouse birth is in-keeping with the birthing mechanism and lack of contact of the instrument with the lateral aspects of the fetal head.

Direct pressure to the orbit during birth can result in serious and permanent ophthalmic injuries (8). The peak pressure generated by the BD Odon Device, at both inflation pressures of 60kPa and 80kPa, when placed directly over the orbit was substantially lower than that generated by forceps – this is likely to correlate to lower rates of trauma to the face during birth if the BD Odon Device is incorrectly sited compared to incorrectly sited forceps.

The BD Odon Device generated lower peak pressure over the posterior aspect of the neck compared to forceps. This may reflect the mechanism in which a baby in the OA position extends its neck as it negotiates the pelvic curve. Pressure is exerted on the posterior aspect of the neck as the fetus lies directly beneath the pubic symphysis, acting as a locus around which the fetal head extends. However, when a baby is delivered with the assistance of a BD Odon Device that has been purposefully misplaced around the fetal neck the air cuff rests between the posterior aspect of the neck and the pubic symphysis and appears to act as a cushion, redistributing pressure around the circumference of the neck.

We acknowledge that the simulated pressure readings can not be a true reflection of the exact pressures exerted in clinical practice. However the relative degree and distribution of pressures in vivo are likely to be similar to those we have observed in simulation. This simulation study suggests that the BD Odon Device generates approximately half the peak pressure generated by the forceps, with pressure distributed across a wider area i.e. there is less point pressure.

The clinical significance of the observed pressure on the anterior portion of the neck when the BD Odon Device is purposefully misplaced is unclear. Animal studies and clinical observation of 48 births in healthy volunteers in Argentina suggest the BD Odon Device is extremely unlikely to be placed around the fetal neck. Reported mean systolic blood pressure of term neonates is 72.6 (SD 9.0) mmHg (9) therefore even if a pressure of 59kPa was exerted on the fetal neck by a misplaced Odon Device the systolic circulation through the carotid arteries should not be occluded. In addition, the BD Odon Device is unlikely to exert this peak pressure at any point other than during traction by the operator during a contraction.

Greater traction forces used in OVBs correlate with higher rates of neonatal injury and maternal anal sphincter damage (5). The BD Odon Device generates less traction force before device failure than forceps. The incidence of adverse outcomes related to inappropriate traction force applied using an BD Odon Device is therefore likely to be less than those associated with forceps. Previous research has demonstrated that traction forces of 110 to 130N are routine using Kiwi (5), suggesting that rates of adverse outcomes due to high traction may be comparable between the BD Odon Device and the Kiwi ventouse. The

BD Odon Device does not generate negative pressure on the fetal head, reducing the likelihood of adverse outcomes such as subgaleal or retinal haemorrhage and cephalohaematoma being associated with the use of a BD Odon Device when compared to vacuum assisted births.

### **Strengths and Limitations**

This is the first study to attempt to quantify the pressures exerted on a baby's head and face during OVB and the methodology is necessarily pragmatic. However, our group has extensive experience using simulation models to identify intrapartum forces (10) which have previously enabled the development of validated and effective training tools (11,12).

We used a modified version of the PROMPT Flex® Force Monitoring birthing simulator (Limbs & Things®, Bristol, UK) with bespoke fetal heads incorporating pressure sensors. The pressure sensors have previously been employed to quantify pressures generated using forceps made from novel materials (13). We acknowledge that given the complexities of the birthing process, and the inherent limitations of any simulation based modeling, our results are unlikely to be quantifiably reproducible in-vivo. However, the results are likely to be internally consistent and reflect the location and broad relationships in the pressures exerted by the BD Odon Device, forceps and Kiwi ventouse.

We have not been able to quantify negative pressures, or replicate the chignon associated with ventouse births. However, due to its mechanism of action we are confident that the BD Odon Device not generate any negative pressure on the fetal head and therefore will not cause a chignon. It is therefore unlikely that the most serious outcomes generated by negative pressure (subgaleal or retinal haemorrhage and cephalohaematoma), or those

associated with movement of the cup over an established chignon (scalp abrasion/avulsion) will occur following births conducted using the BD Odon Device.

## **Conclusion**

The BD Odon Device generates lower peak pressure than non-rotational forceps during simulated birth and does not exert a negative pressure required to perform a vacuum assisted birth. It is therefore likely that the BD Odon Device will be associated with lower adverse outcomes related to both peak pressure (bruising, facial nerve palsy, skull fracture) and negative pressure (subgaleal or retinal haemorrhage and cephalohaematoma, scalp abrasion/avulsion) compared to currently available instruments (forceps and ventouse).

This study has generated sufficient data to suggest that the BD Odon Device is likely to be as safe, if not safer, than forceps and ventouse. Clinical studies are now required to evaluate the efficacy of the BD Odon Device.

## **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.

S O'B has no conflict of interest.

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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### **Table/Figures caption list**

Table 1: Summary of simulations performed

Table 2: Median peak pressure generated during correct placement of instruments

Table 3: Median peak pressure generated during incorrect placement over orbit

Table 3: Median peak pressure generated during incorrect placement of instruments over neck

Table 4: Traction force generated across fetal neck at pop-off of instrument

Figure 1: Location of pressure sensors on model fetal head and neck – gridlines demarcate where pressure sensor was present

Figure 2: Example of peak pressures generated on right lateral aspect of a model fetal head during an OA position OVB using the BD Odon Device with 60kPa pressure and forceps