Table 1. Baseline characteristics

Variable	FP Group N = 120	NFP Group N = 120
Maternal age, y (range)	22.1 +/-2.6 (18-28)	22.8+/- 2.0 (18-33)
Maternal weight, kg	55.6 +/-4.6	54.8 +/-4.9
Parity: n		
0	82 [68.3%]	84 [70%]
1	33 [27.5%]	27 [22.5%]
2	5 [4.2%]	7 [5.8%]
3	0	2 [1.7%]
1st Stage of Labour, hrs[a]	7.8 +/-0.7	7.6 +/-0.6
Augmentation of Labour	79 [65.8%]	80 [66.7%]
2nd Stage of Labour, hrs[a]	1.9 +/-0.3	1.9 +/-0.3
Pregnancy duration, wk	38.9 +/-1	39.0 +/-1
Indication for CS		
Failed progress	88 [73.3%]	82 [68.3%]
Failed instrumental	20 [16.7%]	21 [17.5%]
Fetal distress	12 [10.0%]	17 [14.2%]
Station of head		
0	2 [1.7%]	2 [1.7%]
1	46 [38.3%]	50 [41.7%]
2	72 [60.0%]	68 [56.7%]
Position of head		
Occipito Anterior	48 [40%]	60 [50%]
Occipito Transverse	33 [27.5%]	27 [22.5%]
Occipito Posterior	39 [32.5%]	33 [27.5%]
Birth weight, kg	2.85 +/-0.26	2.87 +/-0.31

There were no differences in characteristics between the two groups.

[a] Data available for 89 patients in FP group and 92 in NFP group because some were transferred from other hospitals already in labor.

[b] Data available for 90 patients in FP group and 95 in NFP group because some were transferred from other hospitals already in labor.

Table 2. Maternal outcomes

Variable	Fetal Pillow Group N = 120	Non-Pillow Group N = 120
Uterine extensions*	12 [10%]	43 [35.8%]
Grade of uterine extensions		
I	6 [50%]	4 [9.3%]
II	3 [25%]	12 [27.9%]
III	3 [25%]	27 [62.7%]
Major uterine extensions (Grade 2-3)**	6 [5%]	39 [32.5%]
Total Time taken for LSCS, min	32.7 +/-4.3	53.9 +/-10.3
Incision to delivery interval, sec	176.5 +/-14.0	297.2 +/-27.1
Difficulty with delivery of fetal head		
Very difficult	2 [1.7%]	26 [21.7%]
Difficult	5 [4.2%]	21 [17.5%]
Moderately easy	11 [9.2%]	3 [2.5%]
Easy	57 [47.5%]	31 [25.8%]
Very easy	45 [37.5%]	39 [32.5%]
Pre-operation Hb, g/dL	10.3 +/-6	10.3 +/-5
Post-operation Hb, g/dL	9.6 +/-5	9.0 +/-8
Blood loss > 1000 mls: n [%]	5 [4.2%]	26 [21.7%]
Blood transfusions: n [%]	4 [3.3%]	22 [18.3%]
Hospital stay in days: mean [s.d.]	3.9 +/-0.80	5.0 +/-1.2
Re-laparotomy: n [%]	0	4 [3.3%]

*RR 0.37 (0.22 to 0.63), **RR 0.23 (0.11 to 0.48)

Table 3. Neonatal outcomes

Variable	Fetal Pillow Group N = 120	Non-Pillow Group N = 120
5 minutes APGAR score = 3	1 [0.8%]	8 [6.7%]
Admission to NICU	13 [10.8%]	21 [17.5%]
Duration of NICU stay >24 hours	3 [23.1%]	12 [57.1%]
Neonatal sepsis	0	4 [3.3%]
Neonatal death	0	3 [2.5%]

*RR 0.37 (0.22 to 0.63), **RR 0.23 (0.11 to 0.48)

Reanalysis of the randomized controlled trial data[1]

Objectives

This reanalysis of existing Randomized Control Trial data was carried out to study the maternal and fetal outcomes in the Hand Push group (one of three methods of delivery) from the Non Fetal Pillow arm compared to the Fetal Pillow arm.

The outcomes in the Hand push group were compared with the outcomes in the FP group as this is the most commonly used method in a second stage CS when difficulty is encountered during delivery.

Patient groups

Methods of delivery used in the Non Fetal Pillow arm (n=120)

1. 40 women were delivered using the head push method
2. 12 women were delivered using a reverse breech extraction method
3. 68 women were delivered using the normal abdominal delivery method

RCT reanalysis: Fetal Pillow Group vs Hand Push Method for Maternal outcomes

	Fetal Pillow Group N = 120	Hand Push Method Group N = 40
Extensions of uterine incision *		
Yes	10 (8.3%)	23 (57.5%)
No	110 (91.7%)	17 (42.5%)
Mean Incision to Delivery time (sec)	176.5	278.0
Total Time taken for Caesarean Section, (min)	32.7	55.3
Blood loss >1000 mls	1 (0.8%)	15 (37.5%)
Mean Length of stay in Hospital, (days)	3.93	5.30

*Chi-squared Test p-value P< 0.0001

Results

Extensions of uterine incisions* were significantly less common in the FP group. Incision to delivery interval, total time for CS, intra-operative blood loss and length of hospital stay were all lower in the FP group when compared with the hand push method of delivery.

Comparison of maternal and neonatal outcomes from full-dilatation caesarean deliveries using the Fetal Pillow or hand-push method (Brisbane study).[2]

Objectives

To compare maternal and neonatal outcomes of full-dilatation Caesarean Deliveries using the Fetal Pillow or Hand-Push method.

Methods

A retrospective cohort study included data from all women who underwent full-dilatation Caesarean Deliveries at term that involved the use of the Fetal Pillow or the hand-push method at Mater Mothers' Hospital, Brisbane, Australia between May 1, 2013 and March 31, 2015. Maternal (estimated blood loss, need for blood transfusion, uterine angle extension, and duration of stay in hospital following delivery) and neonatal outcomes (5-minute Apgar score below 7, cord arterial pH, admission to neonatal intensive care unit, and need for endotracheal intubation) were compared between the two treatment methods.

Inclusion criteria

- Singleton pregnancies
- Caesarean section at full dilation
- Pregnancy >37 weeks

Exclusion criteria

- Multiple pregnancies
- Intrauterine fetal death
- Major congenital abnormalities

Results

Of 361 Caesarean Deliveries performed at full dilation during the study period, clinicians documented the use of a Fetal Pillow in 91 deliveries and use of the hand-push method in 69. Lower mean intra-operative blood loss (P =0.026), a shorter duration of postpartum hospital admission (P =0.002), and higher mean cord arterial pH (P =0.003) were observed in the Fetal Pillow group (Table 2).

Table 1. Patient characteristics

Baseline characteristics	Fetal Pillow method (n=91)	Hand-push method (n=69)
Maternal age, y	29.94+/- 4.5	31.0+/- 4.9
Duration of pregnancy at delivery, wk	39.7+/-1.1	39.8+/-1.1
Nulliparous	75 (82%)	45 (65%)
BMI	24.7+/-6.1	24.0+/-4.5
Previous failed instrumental delivery	6 (7%)	3 (4%)
Category I caesarean section	45 (49%)	36 (52%)

*Chi-squared Test p-value P< 0.0001

Table 2. Maternal and neonatal outcomes

Outcome	Fetal Pillow method (n=91)	Hand-push method (n=69)
5-min Apgar score <7	3 (3%) 7-10	4 (6%) 6-10
Neonate required intubation	0	2 (3%)
Neonatal ICU admission	14 (15%)	17 (25%)
Cord arterial pH	7.24 +/- 0.06	7.19 +/-0.09
Estimated blood loss, ml	273 +/-145	403 +/-199
Blood transfusion required	3 (3%)	2 (3%)
Uterine angle extension	18 (20%)	24 (35%)
Duration of hospital stay, hours	77.9 +/- 19.6	97.8 +/-27.6

Retrospective audit of Fetal Pillow use in 75 patients in a UK hospital (Wishaw Hospital).

The existing dataset was reanalyzed to see the effect of high BMI, fetal weight and epidural use on the outcomes[3].

Inclusion criteria

All patients having CS at full dilation or after a failed instrumental delivery where Fetal Pillow was used.

Maternal outcomes studied

- Mean incision to delivery time.
- Extension of uterine incision.
- Blood loss >1000mls.
- Need for blood transfusion.
- Length of post-operative hospital stay.

Results

There was no difference observed in the outcomes studied from Fetal Pillow use in this analysis when maternal BMI, Fetal weight and use of epidural in labor were taken in to account.

Table 1. Maternal BMI & Distribution of maternal outcomes in Women treated with the Fetal Pillow

	Maternal BMI >=30 N = 38	Maternal BMI < 30 N = 37
Mean Incision to Delivery time (mins)	4.63	5.43
Extension of uterine incision		
Yes	13 (34.2%)	11 (29.7%)
No	25 (65.8%)	26 (70.3%)
Blood loss >1000 ml	4 (10.5%)	5 (13.5%)
Blood transfusion		
Yes	1 (50%)	1 (50%)
No	37 (50.7%)	36 (49.3%)
Mean Length of stay in Hospital (days)	3.18	3.02

Table 2. Fetal Weight and Distribution of maternal outcomes in Women treated with the Fetal Pillow

	Fetal weight >= 3500g N = 53	Fetal weight <3500g N = 22
Mean Incision to Delivery time (mins)	5.11	4.81
Extension of uterine incision		
Yes	17 (32.1%)	7 (31.8%)
No	36 (67.9%)	15 (68.2%)
Blood loss >1000 ml	8 (15.1%)	1 (0.5%)
Blood transfusion		
Yes	2 (3.8%)	0
Mean Length of stay in Hospital (days)	3.15	3.00

Table 3. Epidural use and Distribution of maternal outcomes in Women treated with the Fetal Pillow

	Epidural used N = 54	No Epidural used N = 21
Mean Incision to Delivery time (mins)	5.22	4.52
Extension of uterine incision		
Yes	14 (25.9%)	10 (47.6%)
No	40 (74.1%)	11 (52.4%)
lood loss >1000 ml	5 (9.3%)	4 (19.0%)
Blood transfusion		
Yes	0	2 (9.5%)
Mean Length of stay in Hospital (days)	3.11	3.10

References

1. Seal SL, Dey A, Barman SC, Kamilya G, Mukherji J, Onwude JL. Randomized control trial of elevation of fetal head with a fetal pillowduring caesarean delivery at full cervical dilation. Int J Gynaecol Obstet 2016; 133(2): 178-82.
2. Safa H, Beckmann M. Comparison of maternal and neonatal outcomes from full-dilation caesarean deliveries using the Fetal Pillow or hand push method. Int J Gynaecol Obstet 2016; 133(2): 178-82.
3. Mufti N, Beaton L. Re-Audit of the Fetal Pillow (FP): A novel intervention to reduce maternal and fetal complications at caesarean section at full dilation. BJOG: An international journal of Obstetrics and Gynaecology, 122:48. Dec 2015

Single Use Only

Do not resterilize

Store at room temperature.
Avoid excessive heat< 50°C.
Protect from direct sunlight.

Consult Instructions For Use.

30°C Max
5°C Min

Rx only

Date of expiry:
00 / 00 / 00

Date of manufacture:
00 / 00 / 00

LOT SN
STERILE EO
CE 0120

Ref:- FP-010

SOS SAFE OBSTETRIC SYSTEMS

www.safeob.com

Manufactured by:
SAFE OBSTETRIC SYSTEMS Ltd
Linden Lea, Hillwood Grove Shenfield
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Ref:- FP-010

US patent numbers
US 9,055,973 B2, US 8,556,913 B2

Fetal Pillow®

Instructions For Use

SOS SAFE OBSTETRIC SYSTEMS

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Shenfield Essex, UK
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Indications for use

Fetal Pillow is intended to elevate the fetal head and facilitate delivery of the fetus in women requiring a Caesarean Section at full dilation or those requiring a Caesarean Section after a failed instrumental vaginal delivery. Fetal Pillow is indicated for use in gestational age >37 weeks.

Caution

Federal (U.S.A) Law restricts the use of this device by or on order of a physician.

Warnings

The safety and effectiveness of Fetal Pillow has not been established in the following:

1. In women who have had a previous caesarean section
2. In women with a pregnancy less than 37weeks
3. Non vertex presentation
4. Pregnancy with Intra-uterine Fetal Death
5. Pregnancy induced hypertension 6. Intra-uterine Growth Retardation
7. Diabetes in pregnancy
8. Major congenital abnormalities
9. Presence of chorioamnionitis
10. Multiple gestations

Contraindications

Fetal Pillow should not be used in the presence of active genital infection, as it could increase the risk of ascending infection.

Precautions

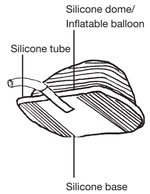
1. DO NOT use air to inflate the device
2. Maximum inflation should not be more than 180cc
3. The device will fail to inflate if the dome/balloon surface of device is not in contact with fetal head when inserted
4. Make sure that the package is intact before use
5. Inflate the device with 60 cc saline prior to use to check the integrity of the device

Please read all information carefully

Failure to properly follow instructions may result in improper functioning of the device.

Device description

Fetal Pillow is a sterile single use device consisting of a base plate and a dome (inflatable balloon) made of silicone. A 100cm long tubing is attached to this for inflation. The tubing has a two-way tap at the distal end for inflation and deflation. A sterile 60cc syringe is provided with the device for inflation using sterile saline. The dome inflates only in upward direction when placed correctly.



Step 1:

Before Inserting

Insertion and inflation of the device should be carried out just before performing the Caesarean Section.

Inflate the device with 60 cc saline prior to use to check the integrity of the

device. Empty the device using the syringe provided before insertion.

Hold the base plate of Fetal Pillow between fingers and thumb as shown and fold to squeeze the Dome (balloon) between the base-plate.

The tube attachment should be at the superior end during insertion as shown. If the tube attachment is facing downwards the tube is likely to block due to twisting, making it difficult or impossible to inflate the device.

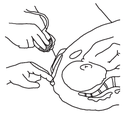
Step 2:

Insertion

Insert the device using a sterile lubricating cream or gel. The process is similar to inserting a soft vacuum (ventouse) cup.

Make sure that the dome/balloon surface of the device is in contact with the fetal head and the base plate in contact with the pelvic floor.

The device will not inflate or function effectively if placed incorrectly.



Step 3:

Device Position

Once inserted the device should be pushed posteriorly until it is touching the coccyx.

The position is similar to the insertion of a vacuum (ventouse) cup for an occipito posterior position.

Step 4:

Inflation

Patient's legs must be placed flat before inflation is carried out using sterile saline with the 60cc syringe provided.

If the legs are not placed flat before inflating, the device can be expelled or could move during inflation and fail to produce the desired elevation.

A total of 180cc of saline is required to produce the desired elevation (3 syringes of fluid). Close the tap after filling to stop the fluid from leaking.

Inflation volume should not exceed 180cc.

Step 5:

Caesarean Section

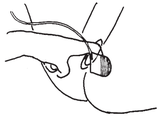
Once the inflation is complete, the Caesarean Section is performed using the standard technique.

Step 6:

Device Removal

After delivery of the baby, the two-way tap is opened to release the fluid.

The device is removed by the assistant at the end of procedure by pulling on the tubing or hooking a finger on the plate and pulling the device out of the vagina. If the two-way tap fails, the tube can be cut to release the fluid for removal.



Storage

Store above 5ºC and below 30ºC. Do not use if package is damaged.

Device Disposal

The device should be discarded according to the hospital regulations.

Clinical studies of fetal pillow use

Randomized control trial of elevation of fetal head with a fetal pillow during caesarean delivery at full cervical dilation[1]

This prospective randomized controlled trial was carried out in two teaching hospitals in India and compared the use of Fetal Pillow with other methods of delivery in a second stage Caesarean Section (CS). A total of 240 patients who required a CS in second stage of labor were enrolled into the study. Thirteen patients were excluded from the study, due to lack of informed consent (n=4), previous caesarean (n=2), breech presentation (n=2) and suspected chorioamnionitis (n=5).

Primary Outcome Measure

- Major uterine incision extensions (Grade II and III)

Grade I extensions were defined as those that did not increase operating time and blood loss.

Grade II extensions were defined as those that increased operating time and blood loss.

Grade III extensions were defined as those that involved uterine blood vessels, cervix, vagina or urinary tract.

Secondary Outcome Measures

- Total time taken for CS
- Incision to delivery interval
- Difficulty with delivery of fetal head
- Duration of hospital stay
- Blood loss >1000cc
- Need for blood transfusion
- 5 minute APGAR <3
- NICU stay >24 hours
- Neonatal sepsis
- Neonatal death

Inclusion Criteria

- Ability to give informed consent
- CS at full dilation
- CS after failed instrumental delivery

Exclusion Criteria

- Presence of active genital infection
- Chorioamnionitis
- Breech presentation
- Previous Caesarean Section
- Pregnancy less than 36 weeks
- Inability to give informed consent

Study Methodology

All patients were informed about the trial when admitted to the labor ward. Patients who were able to give informed consent if requiring a CS at full dilation were included in the study. Participants were randomized 1:1 into two parallel groups, the Fetal Pillow group (FP group) and the non-Fetal Pillow group (NFP group).

The delivery methods used in the NFP group were:

- Hand push method
- Reverse breech method
- Abdominal delivery method

CS was carried out using the standard technique and Fetal Pillow was inserted and inflated prior to performing the procedure.

Results

The two groups were similar in terms of their baseline characteristics (Table 1).

Major extensions of uterine incisions were less common in the FP group (Table 2). Incision to delivery interval, total time for CS, need for blood transfusions and length of hospital stay were all significantly lower in the FP group. The intra-operative blood loss >1000mls was more common in the NFP group (Table 2). With regards to fetal outcomes, newborns in the FP group were less likely to have a 5minute Apgar of 3 or less, be admitted to the NICU, or stay in NICU for more than 24 hours than were the newborns in the NFP group (Table 3).