

# Performance Of Kiwi Omnicup. Does Training Improve Outcome?

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## Abstract

The objective of this study was to evaluate the performance of Kiwi OmniCup to achieve vaginal delivery by trained clinicians. A prospective study of all ventouse deliveries by Kiwi OmniCup was undertaken between January and March 2006 at Northwick Park hospital, a large DGH in London. During this 3 month period, 1045 deliveries took place. OmniCup deliveries were attempted in 116 cases (11%). Successful vaginal delivery was achieved in 104 (90%) cases. This outcome was comparable to that reported in other studies of rigid cup vacuum delivery. 31% of successful deliveries had incorrect placement of the cup. Third and fourth degree perineal tears were reported in 10 cases (9.8%). One infant developed subdural haematoma requiring blood transfusion. Shoulder dystocia was encountered in 5 cases of which one developed Erb's palsy. This study demonstrated that Kiwi OmniCup is an efficient device for assisted vaginal delivery and training in its correct use consistently improves outcome.

## INTRODUCTION

The Royal college of Obstetricians and Gynaecologists advocates that the operator should choose the instrument most appropriate to the clinical circumstances and their level of skill as forceps and vacuum are associated with their own benefits and risks (RCOG, 2005). Randomised control trials and meta-analysis have shown less maternal trauma from ventouse as compared to forceps (Chalmers & Chalmers, 1989) hence it has been advocated as the instrument of first choice for operative vaginal delivery. This is despite increased neonatal morbidity and failure to achieve delivery with this instrument (Johanson & Menon, 2004).

The Kiwi OmniCup (Clinical innovations, Murray, UT) is a single use disposable vacuum device. Its small size makes it less cumbersome and portable and its hand held vacuum pump makes it easy to operate. It has a rigid cup with a central connection to the suction catheter. The small size makes it easy to manoeuvre the cup within the vagina and correct placement on the fetal head is aided by the recess on the cup into which the traction wire can be accommodated. Hence it can be used both as an anterior and a posterior cup. Its single use gives it an additional safety profile in terms of reducing transmission of infections.

Recently two randomized control trials (Attikalos et al., 2005; Groom et al., 2006) comparing the Kiwi OmniCup

with the conventional ventouse cups concluded that OmniCup was not as successful in achieving vaginal delivery. One of these studies stated that training with Kiwi OmniCup was given to staff prior to the study (Groom et al., 2006). According to them training did not decrease the failure rate of Kiwi OmniCup. The second study stated that most deliveries were performed by the trainees (Attikalos et al., 2005) but that this is a more accurate representation of the 'real life situation' in most UK hospitals (Drife, 2005).

## MATERIAL AND METHODS

A prospective study was performed between January and March 2006 to assess the performance of Kiwi OmniCup. All deliveries during normal working hours (9am to 5pm) were supervised by consultants. Training on the mannequin was also provided simultaneously both to trainees (Registrars, Years 1-5 and SHOs n=15) and consultants (n=7). Both training on mannequins and direct supervision consisted of identifying the fifths of head palpable abdominally, determining exact position of the head, verifying correct placement of the cup, and ensuring correct direction of traction.

A proforma was designed which incorporated demographic profile, gestational age, indications for assisted vaginal delivery, duration of active second stage, position and station of fetal head, presence of caput and moulding and analgesia

used. Status of the operator (SHO/Registrar or consultant) was noted. After the delivery, all the relevant details were collected by the team involved in the delivery. Details with respect to number of pulls and detachments (if any), the placement of the cup with respect to the flexion point (confirmed by checking baby’s head after delivery) and any maternal and fetal complication were also recorded on the proforma.

All women for whom operative vaginal delivery was decided by the on call doctor were included into the study. Verbal consent was obtained from the women.

**RESULT**

Between the period January to March 2006, 1045 deliveries took place at Northwick Park hospital. Of these, operative vaginal delivery was attempted in 136 women (13%). Complete data was available only in 122 women although 131 were successfully delivered vaginally (131/136 = 96%).

Kiwi OmniCup was the vacuum cup used in all cases where ventouse was used. In 116/122 cases it was the instrument of first choice. Successful delivery by Kiwi OmniCup was achieved in 104/116 (90%). In 7 cases forceps were used to complete the delivery whereas in 5 cases the delivery was completed by caesarean section. Forceps were used as the primary instrument in 6 cases.

Demographic data in relation to the 122 operative vaginal deliveries is depicted in Table 1.

**Figure 1**

Table 1. Demographic features

<b>Age</b>	
<20y	7 (5.7%)
21 -30y	85 (69.6%)
31-40y	30 (24.5%)
<b>Parity</b>	
Primi	101 (82.7%)
Multi	21 (17.2%)
<b>BMI</b>	
< 25	71 (58.1%)
26-30	16 (13.1%)
> 30	11 (9%)
ND	24 (19.6%)
<b>Ethnicity</b>	
Asian	71 (58.1 %)
Caucasian	21 (17.2%)
Afro Caribbean	14 (11.4%)
Others	16 (13.1 %)

**ND - Not documented**

Primigravidas comprised 82.7% of the group. 58% were of Asian ethnicity and 9% had a BMI of >30 (although in 19.7% the BMI was not documented).

In 86% of women the gestational age was >37 weeks. In 2 women it was <37 but >34 weeks. The primary indication for attempted operative delivery was presumed fetal compromise (55%). Delay in second stage was noted in 36%, deep transverse arrest in 1%, maternal exhaustion in 4%. (Table 2)

Figure 2

Table 2. Labour Characteristics

<b>Gestational Age (122)</b>	
<37 weeks	2 (1.6%)
>37 weeks	105 (86%)
ND	15 (12.2%)
<b>Indication (122)</b>	
Presumed fetal compromise	67 (55%)
Delay in 2 <sup>nd</sup> stage	44 (36%)
Maternal Exhaustion	5 (4%)
DTA	1 (1%)
ND	5 (4%)
<b>Position of fetal head (122)</b>	
OA	80 (65.5%)
OP/OT	38 (31.1%)
ND	4 (3.2%)
<b>Station (122)</b>	
Spines	
+1	21 } 55.7%
+2	47 } 44.3%
+3	7 }
<b>Application (116)</b>	
Flexing median	74 (63.8%)
Flexing paramedian	28 (24.1%)
Deflexing median	10 (8.6%)
ND	4 (3.4%)

OA – Occipito anterior; OP – Occipito posterior; OT – Occipito transverse;  
ND – Not documented; DTA – Deep transverse arrest

The position of fetal head was occipito-anterior in 65.5% women and occipito-posterior or transverse in 31.1%. The station was midcavity (ischial spine to +1cm below) in 55.7% case and low (+2 to +3 cm below ischial spine) in 44.3% women. 64 women had epidural anesthesia on board whereas 57 had perineal block.

The position of the cup was noted to be flexing median in 63.8%. Incorrect application was noted in 75% women where OmniCup failed to deliver the baby. In women where successful delivery was achieved by OmniCup, it was noted that in 31% (flexing paramedian = 27, deflexing median = 5) the cup was placed incorrectly. 96.9% of deliveries occurred in <= 4 pulls and 91.2% were delivered in <= 15 minutes. Cup detachment occurred in 11 cases.

46% deliveries were conducted between 9am to 5pm and directly supervised by or conducted by the consultants. 54% deliveries occurred between 5 pm to 9am hours. Out of these a consultant was present in 5 cases. Therefore in total 50% of the deliveries were supervised or conducted by consultants. Of the 5 cases which ended up with caesarean section 3 were out of hours (consultant present in 1 case) whereas 2 were during normal working hours. Majority of the deliveries (68.8%) were conducted by registrars in

various years of training. Consultants conducted delivery in 23 women whereas 5 deliveries were conducted by SHOs under supervision.

Maternal complications encountered were 3<sup>rd</sup>/4<sup>th</sup> degree tears in 10 cases of Kiwi OmniCup delivery. 5 babies suffered shoulder dystocia and one of them ended with Erb's palsy. Subgaleal haemorrhage occurred in 1 case where sequential instruments were used. In this case fetus was in occipito-posterior position at +1 station. After 3 pulls and cup detachment twice the delivery was completed by forceps. In another case, the fetus was in occipito-anterior position at +2 station. The baby was delivered with OmniCup with 3 pulls over 7 minutes. There was no detachment. The baby weighed 4700gm. Shoulder dystocia was encountered and 3<sup>rd</sup> degree tear occurred. The baby developed Erb's palsy and subdural haematoma. This delivery took place out of hours. The registrar was trained in OmniCup use but was not supervised by consultant.

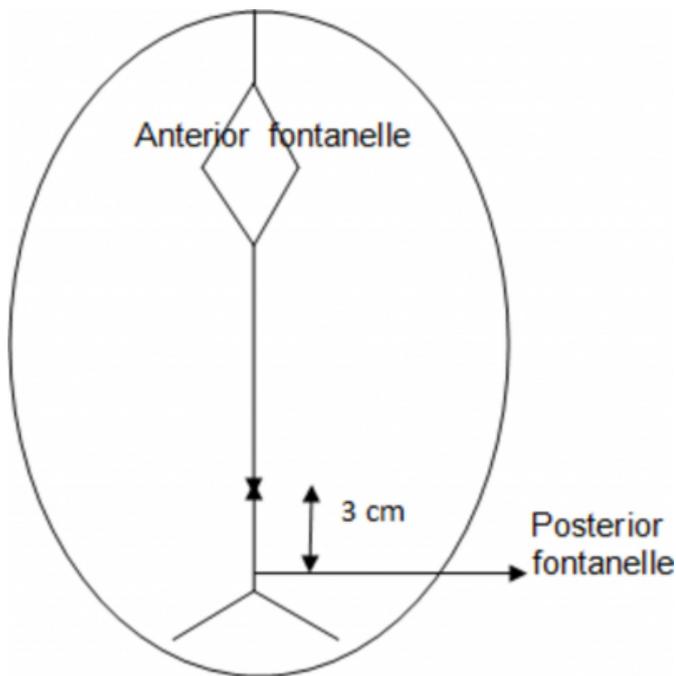
## DISCUSSION

Our study demonstrates that OmniCup is an effective delivery system when used for appropriately selected cases by appropriately trained clinicians. In the UK setting, majority of the operative vaginal deliveries are carried out by trainees (Drife, 2005). Like other instruments, the success to deliver with OmniCup is directly related to the training in its use (22 doctors trained). This kind of hands on study therefore helps identify training issues and minimize failure rate. This can be seen by the success in achieving delivery with OmniCup in 90% cases in our study (only 50% supervised) which is similar to another observational study (Hayman, 2002) as against 98% quoted by a study (Vacca, 2001) where most deliveries were conducted by consultants or registrars under supervision.

Studies have shown that in order to achieve a delivery by ventouse it is vitally important that the cup is placed over the flexion point (Bird, 1976; Bird 1982; Vacca, 2001) (Fig 1). The compact nature of the OmniCup and the flexibility of the traction axis improves manoeuvrability of device within the vagina. This ensures correct placement over the flexion point. In our study flexing application was seen in 88% cases although in 27% of these it was paramedian.

**Figure 3**

Fig. 1 Flexion point in relation to posterior fontanelle



Not only the application, but also the direction of traction and the traction force applied are equally important in achieving delivery, preventing detachment and fetal scalp injury. The direction of traction was monitored in all cases supervised by consultants. The traction force could not be measured as the Kiwi Omnicup used in our study did not incorporate the Traction Force indicator TM (Clinical Innovations Inc., Murray, UT, USA) which accurately measures the traction force exerted on the fetal scalp (Whitlow et al., 2005).

In our study 96.9% of deliveries occurred in  $\leq 4$  pulls and 91.2% were delivered in  $\leq 15$  minutes which are similar to those quoted in another study (Vacca, 2001). Cup detachment occurred in 11 cases (9.4%) out of which only in 2 cases the application was deflexing. This is higher than quoted in other studies (Vacca, 2001; Hayman et al., 2002). 10 of these were unsupervised and hence the possible explanation could be wrong direction of traction. However with training it was noted that the detachments decreased (January – 7, February – 3, March – 1). (Table 3)

**Figure 4**

Table 3. Outcome

Total 116	Supervised (58)	Unsupervised (58)
Successful (104)	54 (93.1%)	50 (86.2%)
Unsuccessful (12)	4 (6.9%)	8 (13.8%)
Detachment (11)	1	10
3 <sup>rd</sup> /4 <sup>th</sup> degree tear ( 10)	3	7

3<sup>rd</sup>/4<sup>th</sup> degree tears were encountered in 9.8% cases which is similar to that in a recent RCT (Attikalos et al., 2005) but higher than quoted in other studies (Vacca, 2001; Hayman et al., 2002). Shoulder dystocia was encountered in 1 of these cases. We are unable to comment if this higher rate was by chance or poor technique. This needs further study.

With European working time directive resulting in restraints on the number of working hours for trainees, it is important that appropriate and perhaps intense hands-on clinical training in procedures such as Kiwi Omnicup ventouse delivery takes place. This will have to be continued to be combined with other teaching aids such as training on mannequins, visual aids and computer guided training.

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