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# First Australian trial of the birth-training device Epi-No: A highly significantly increased chance of an intact perineum

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## Abstract

**Background:** A German report suggested significantly better outcomes in terms of perineal care, second stage length and neonatal outcome for users of Epi-No.

**Objective:** To carry out a pilot study of the first use of the Epi-No birth training device in Australia for women having their first baby.

**Study population and methods:** Forty-eight primigravidae having their confinement at Birralee Birthing Unit who used the device compared to all other primigravida who delivered during the same period.

**Results:** The study shows a highly significant improved outcome for the perineum when users are compared to primigravid non-user controls. We could not demonstrate decreased instrumental delivery rates nor a better outcome in terms of Apgar scores.

**Discussion:** The Epi-No device should be offered as an option to all primigravidae to use during the late third trimester.

**Key words:** episiotomy, perineum, primigravida, vaginal tears.

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## Introduction

With the return of conservative obstetrics in the 21<sup>st</sup> century, and the appeal of minimal intervention, one of the wish list items for vaginal delivery is to have an intact perineum. While women receive extensive antenatal education including exercises for breathing and general muscle tone, preparing the perineum has had little scientific attention. The Epi-No Birth Trainer was developed with the specific aims of gradually stretching the vagina and perineum with gentle dilatation with volumes similar to the fetal head.

A previous study in Germany<sup>3</sup> suggested that using the Epi-No device significantly shortened the second stage of labour and significantly decreased the incidence of episiotomies. Consequently it also suggested that 1 and 5 min Apgar scores were superior in babies delivered by women who had previously used the Epi-No device. It was decided to undertake a prospective controlled study to assess the effects of Epi\_no on Australian women. The Epi-No devices used in the present study were donated by Tecvana.

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## **Method**

The purpose of the project was to assess whether the Epi-No Birth Trainer improved birth outcomes with regards to lower requirement for instrumental delivery, the episiotomy rate, the incidence of vaginal tears, the duration of the second stage of labour, and the comparison of Apgar scores at 1 and 5 mins.

The perineum was considered 'intact' if no suturing was required.

Forty-eight primigravid women delivering at Birralee birthing unit were enrolled prospectively to use the Epi-No Birth Trainer and the other 248 primigravid women who delivered in the Birralee Unit during the same period were used as controls.

The subjects were asked to undertake preparation with the birth trainer for 15 min a day for 14 days consecutively between 37 weeks and term. The women were asked to insert the Epi-No Birth Training device into their vagina, pump up the balloon until at least it became firm and then until it produced a distended feeling. Once the balloon was inflated the woman was asked to use her vaginal muscles to glide the device out of her vagina in a controlled fashion, in order to stimulate childbirth. This could be assisted in the beginning by gently guiding the balloon out by hand. After several attempts, this should be restarted with the balloon deflated and then pumped up again with the exercise repeated as described above.

After use, the balloon was washed with soap and water and then used again the following day. The project was approved by the Research and Ethics Committee of Box Hill Hospital, Eastern Health and all women gave written consent.

The birthweight of babies in the subjects was compared to the control group, to ensure that the groups were comparable.

## **Results**

Of the 48 women who used the Epi-No, nine underwent a Caesarean delivery and therefore the effect of the Epi-No device on the perineum could not be evaluated.

For the remaining 39 women the average birthweight for the subjects was 3477g (standard deviation (SD)  $\pm$  484g) and for the 248 controls the average birthweight for the subject was 3324g (SD  $\pm$  423g).

Tables 1-4 show the mode of delivery, state of the perineum, 1 and 5 min Apgar scores, and the duration of the second stage of labour.

**Table 1** Mode of delivery

Mode of delivery	Subjects	Percent	Controls	Percent	<i>P</i> -value
Normal vaginal	27	69	194	78	0.215 (not signif.)
Vacuum	8	21	27	11	
Forceps	4	10	27	11	

**Table 2** Effect on the perineum

	Subjects	Percent	Controls	Percent	<i>P</i> -value
Intact	18	46	41	17	0.00002
Episiotomy	10	26	85	34	0.286
Tear	11	28	122	49	0.0146

**Table 3** Apgar scores

	Apgar score 1min Subjects	Apgar score 5 min Controls	Subjects	Controls
Mean	7.6	7.9	9.2	9.1
Standard deviation	1.5	1.3	1.7	0.8

**Table 4** Duration of second stage (mins)

	Subjects	Controls
Mean	61	81
Standard deviation	52	58

## Discussion

The significant finding from this pilot study is that women who used the Epi-No device did have a beneficial effect on their perineum. The women had a highly significant increased chance of an intact perineum ( $P < 0.0001$ ) after normal vaginal delivery, and a significantly lower rate ( $P < 0.05$ ) of perineal tears, and a lower but not statistically significant rate ( $P = 0.286$ ) of episiotomy.

The other aspect which many users commented upon, although it was not formally evaluated, was that having practiced with the Epi-No device, the women had more confidence in their ability to cope with the passage of the fetal head during the second stage.

We conclude that this first Australian trial of Epi-No suggests that the use of the device is beneficial in decreasing damage to the perineum during vaginal birth.

We were not able to show a shortened second stage, a decreased incidence of instrumental delivery, nor an improvement in Apgar scores in this pilot study with small numbers.

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## **Reference**

<sup>3</sup> Hillebrenner J, Wagenpfeil S, Schuchardt R, Schelling M, Schneider KTM. First clinical experiences with the new birth trainer Epi-No in primiparous women. *Zeitschrift für Geburtshilfe & Neonatologie*. 2001; **205** : 12-19.

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