

## Perineal outcomes after practicing with a perineal dilator

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Judy Slome Cohain, CNM, MSN writes and reviews research. This research was entirely funded by the author. The author does not now, nor never has had any commercial relationship with the company selling the item tested nor with the product itself. The author has never purchased, owned or used a perineal dilator.

### ABSTRACT

The use of routine episiotomy has been shown to be harmful and should be discontinued. Its continued practice, particularly for first births, has necessitated women to take an active role in avoiding episiotomy and perineal trauma. For the past 4 years, hundreds of women have exercised with a silicon inflatable perineal dilator in an attempt to avoid perineal trauma at birth. The dilator is practiced with at home before labor begins. The device is inserted into the vagina by the pregnant woman herself, pumped up and pushed out, every day in a 10 minute practice session during the 37- 40th week of pregnancy. The intended result is to stretch the perineum before labor in order to prevent perineal trauma during delivery. This descriptive, retrospective study evaluates the pros and cons of the dilator by phone interviewing all women in Israel who bought it before April 2002. The study compares the perineal outcomes of primipara women who practiced with the dilator in Israel with perineal outcomes of comparable primipara women in Israel as reported in the literature. The study showed a lower episiotomy rate. The majority of women reported an increased confidence in their ability to birth, and most women, including the majority of women in the study group who got an episiotomy, felt that it prepared them for the sensations of pushing and birth.

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### INTRODUCTION

The practice of routine episiotomy is grounded on several theories proposing benefits which have been unequivocally refuted by randomized controlled studies (Thacker, 1983; Eason and Labrecque, 2000). Both of the above review articles, as well as Carroli and Belizan (2000) conclude that, contrary to the theories that episiotomy is grounded on, episiotomy actually increases damage to the perineum, takes longer to heal, does not prevent brain damage to the fetus even in the tiniest premature babies, does not prevent either long term stretching of pelvic floor muscles, cystocele, rectocele, urinary stress incontinence or prolapse of the uterus, and/or sexual dissatisfaction for the man or woman after childbirth.

In addition to having no evidence-based support for routine episiotomy, research has revealed additional drawbacks like "more bleeding, more pain, more permanent vaginal deformity, more temporary, and long-lasting difficulty with sexual intercourse" compared with a natural tear (Wagner 1999). Episiotomy is associated with third and fourth degree extensions of the cut into the rectal tissue and muscles. Median episiotomy clearly promotes anal tears (Klein MC etal 1994, Labrecque etal 1997, Shiono etal 1990, Signorello 2000, Sultan etal 1993). Two large randomized controlled trials of liberal versus restricted use of medial lateral episiotomy show no prophylactic effect of the liberal use of medial lateral episiotomy (Sleep J etal 1984, Argentine 1993).



Martin et al (2001) in a retrospective cohort study of 3,769 women found that the risk of tearing on the second birth was higher in women with a previous episiotomy (45%) than in women with a spontaneous second-degree laceration on first birth (36%). The study concludes that avoiding episiotomy, in addition to increasing the rate of intact perineum, reduces the severity of perineal trauma at the next birth.

The infection and abscess rate, mostly a result of episiotomies that extend into rectal tissue, is 0.5 -3.0% of all episiotomies (Thacker SB and Banta HD, 1983).

Episiotomy is indicated in the final minutes of the second stage of labor in certain cases of fetal distress. There is not enough research to say exactly how much faster the delivery occurs when episiotomy is used. In Klein's 1992 randomized controlled study, first-time mothers in the liberal-episiotomy group had an average of nine minute shorter second stage than first-time mothers in the restrictive-episiotomy group. How much an episiotomy shortens second stage on average on a first birth is unclear, but the above evidence would imply, not more than 9 minutes.

The reported episiotomy rate in the US was 39.3% of deliveries in 1998 (Curtin, 2000).

Israel:

The probability of a woman having an episiotomy is common in Israel, although it has decreased over the past 10 years. In 1990, the episiotomy rate at Hadassah Ein Kerem Hospital in Jerusalem was 91% for first births and 51% in general. In 2000, the episiotomy rate at Hadassah Ein Kerem Hospital was 51% for first births and 23% overall (Yoselis, 2001). The sutured tear rate was 18% in 1990, with no data available for 2000. The 1995 Brookdale Institute Nationwide Survey, based on a sample of maternity patients proportionately from all parts of Israel, found a nationwide 81% episiotomy rate for first births and 54% overall episiotomy rate (Zalcborg, 1999).

At present, more than 99% of births in Israel are public births in hospital. Israel is a country of 6,000,000 people which has universal health care coverage including prenatal care and labor and delivery services. The health care in a small country like Israel, is fairly uniform particularly since the majority of doctors graduate from only 3 different medical schools. The 1984 National Perinatal census reported that 99.7% of all women received some form of prenatal care (Mor-Yosef, 1989)

The dilator:

The idea for using an inflatable intravaginal perineal dilator was adapted from a similar practice in Uganda. In Mbarara, Uganda the midwives instruct mothers-to-be to practice with a series of gourds, called calabashes, with increasing diameters, to stretch the pelvic floor as a preparation for the oncoming birth to prevent perineal injuries. In Uganda, especially in rural areas, a tear in the perineum is considered a severe injury since doctors or midwives are either not available or not equipped to treat them. After using the wood-like gourds, the gourds are sterilized in boiling water and hung up again on the wall to dry.

A silicon version of the wood-like gourds is available in Israel for \$100(US). This perineal dilator is an inflatable sausage-shaped silicone balloon, 6 in. long by 2 in.wide, with middle slightly indented. The user inserts it half way, up to the indentation, so that when it is inflated, the largest diameter will be at the entroitus. The balloon is attached to a rubber pumping bulb and pressure manometer exactly like the pump and meter on the device that is used to manually measure blood pressure. After the user inserts the silicone balloon into the vagina, she pumps the rubber bulb and the balloon slowly inflates. She attempts to increase the size that she inflates the balloon



to in each practice session. The balloon can be inflated to 10 centimeter diameter which imitates the diameter of the fetal head at birth. At the end of the 10 minute practice session, she pushes the balloon out of her vagina. After the balloon is removed, the user is instructed to measure the diameter in order to know up to what size her perineum has been stretched.

Perineal dilators are currently sold primarily as a device to stretch the perineum before birth in order to avoid perineal trauma. They are also marketed as a device to strengthen the "Kegel" muscles in order to improve urinary incontinence in non-pregnant women. This study is designed to test whether practice with a perineal dilator affects perineal trauma during birth. This study also examines the women's assessment of the device.

Research into use of the perineal dilator

## METHODS

For this study, all the women who bought an intravaginal perineal dilator in Israel from October 2000 - April 11, 2002 and gave a legible, working phone number upon purchasing it were interviewed by phone. There is only one distributor of the device in Israel. The distributor is required by law, to give every buyer a receipt for the purchase. That receipt is required to have a phone number on it. The distributor, gave the author copies of all 269 receipts for all purchases between Oct 2000 and April 2002. On 36 of the receipts, the phone number was either too illegible to read or was a non working number. On 233 receipts, the phone number was correct. Upon calling the women, I gave my name and said that I was a nurse-midwife researching the outcomes after use of the dilator. I said that I was not affiliated with any institution or organization, but rather wanted women in the future to have some objective data about the outcomes of using the device. I asked the woman if, for the sake of research, I could ask her 10 questions about the device and her birth. I told her that her name would not be included in the results and that the interview could be completed in one minute. No one refused to be interviewed. I asked the following questions:

1. Did you use it more than 3 times? (Inclusion criteria of previous study (Hillebrenner, 2000)).
2. Was it your first, second, third birth?
3. In which hospital did you deliver?
4. Was it a spontaneous birth, instrumental or cesarean section?
5. Did you have an epidural?
6. Gestation age in weeks at delivery ?
7. Birth weight of the baby ?
8. Did you have an episiotomy? / tear? /stitches?
9. Did you have a vaginal infection around the time of the birth?
10. Do you have anything to add about your experience using the device?

Four women were excluded because they practiced less than 3 times, 1 woman was excluded because she had twins, and 1 was postmenopausal, but is using it to strengthen her urethral sphincter muscles, leaving a study group of 227. Eighteen women delivered at home with a private midwife, and they are eliminated from the outcomes which compare the study group to the Israeli population delivering in hospital.

## RESULTS

Since a healthy human body is wired for pain avoidance, the study group and the control group, both consist of women, who, like all women, would prefer to avoid unnecessary perineal trauma. All pregnant women in Israel are guaranteed the same free and easily accessible prenatal care, and free hospitalization due to socialized medicine. The study group was motivated to



spend \$100 on a device that is marketed to prevent perineal trauma. No sociodemographic or socioeconomic data was collected about the women since there is no established association between episiotomy and sociodemographic or socioeconomic status. They may or may not differ from the general population in terms of motivation. It is not known how many women in the general population used techniques such as massaging the perineum with hot packs or plain oil or rosemary oil, meditation, herbs, prayer and/or other techniques to avoid perineal trauma.

92% (209) of the women delivered at 15 different hospitals located all over Israel as public patients. 8% (18) delivered with a private midwife at home.

After practicing with a dilator, the primiparous women and VBAC secondiparous women (who had a previous cesarean delivery), who had a full term spontaneous vaginal birth in hospital experienced an episiotomy rate of 23% (38/163 women). None of the 15 primips who delivered at home had an episiotomy, 3 had sutured tears.

TABLE 1:

Perineal outcomes for primip spontaneous & instrumental births in public hospitals:

No perineal dilator use:	51%, 81% (Yoselis, Zalcborg)
Used perineal dilator:	29% episiotomy rate (54/185)
	15% (27) reported sutured tears.
	14% (25) reported a minor tear repaired with "one stitch" or "one or two stitches".
	43% (79) reported absolutely no tears at all.

Birth weights ranged from 2400 gms to 4650 gms. The average birth weight of the primiparas was 3320 grams. The reported average birth weight for primiparas in one hospital is 3180 grams (Yoselis, 2001)

The vacuum rate was 11.7% (23 women). The reported national vacuum rate in Israel is 11%(Zalcborg, 1999). The perineal outcomes for women with vacuum births after perineal dilator use were: 68%(16 women) had episiotomies, 27% (6 women) had second degree tears (no episiotomy) and 5% (1 woman) had a vacuum performed over an intact perineum.

The cesarean section rate was 6% (11/196).

All of the multiparous women (15 women) who used it for second or third births delivered over an intact perineum. They all chose to use it because of "traumatic" experiences from episiotomies from either their previous or both previous births.

Epidural anaesthesia was used by 44% (72/163) of the women having first births in hospital. The National reported epidural rate is 54% (Zalcborg, 1999)

One women reported a yeast infections at the time of practicing with the inflatable intravaginal perineal dilator, treated the infection and stopped using the device but she had already practiced more than 3 times.

Several primips reported a 15 minute pushing time. Many talked about 1 1/2 hours of pushing.

98% of the women recommend the use of an inflatable intravaginal perineal dilator after their experience. Five women were negative about it. They said that it hurt alot to use it and it didn't help and they didn't recommend it. The rest, including women who had episiotomies, said things like:



"It gave me confidence."  
 "It taught me how to push".  
 "You see progress, you learn to exercise the muscles"  
 "Wonderful, I am sure it helped me alot"  
 "Worth all the effort"  
 "Sorry I didnt use it enough!"  
 "Helped the recovery after birth."  
 "I had bad stitches twice and on this birth -none!"  
 "I had a VBAC with no episiotomy! I am very happy!"

Several women who had episiotomies said, "I know it helped. I didn't really need the episiotomy. The midwife did not know any other way." or "It was the end of the shift and the midwives just wanted the baby out" (In Israel, midwives do not do the perineal repairs.) or "The doctor cut an episiotomy but he said it was a smaller episiotomy than it would have been if I hadn't used it. One woman, who had twins used it and was excluded, believed it helped her. She said they cut a very small episiotomy.

Several first birth users said their midwives commented that "their perineum seemed to be like a woman who has already delivered a baby vaginally." One primiparous woman delivered a 3100 gram breech baby over an intact perineum despite vaginal breech birth protocol which calls for a routine episiotomy for first births on the theory that there is no head to slowly stretch the perineum and breech maneuvers are done very fast. This woman was very assertive and insisted that the doctor write in her chart that she refused episiotomy. She is convinced that this is why he didn't cut her. Several woman said it was hard to keep in in place while practicing. One woman had the following advice: Do not lubricate it very much and lay on your side with your legs together to help hold it in before you pump it up.

## DISCUSSION

The parturient factor in episiotomy rates has barely been explored. No study has yet looked whether assertiveness or compliance and both in what combination works best to assure getting evidence-based medicine at birth. Studies examining perineal self-massage during pregnancy have differed in their conclusions as to the influence on perineal outcomes(Shipman 1997, Labrecque 1999). No one has scientifically examined what happens when a woman directly asks the practitioner not to cut an episiotomy. The dilator in this study had a positive influence on perineal outcomes. Possibly the device gave the woman the confidence to ask in such a way that sometimes she succeeded in not being cut. Some primiparous women mentioned very short second stages. Perhaps the pre-labor practice shortened second stage. Episiotomy rate has been shown to increase directly proportionally to the length of second stage (deLeeuw etal 2001). Shortening second stage by 15 minutes incrementally decreased chances of episiotomy by a proportionate percent. Second stage could be shortened either because the tissue stretched more easily or the woman pushed more effectively, or both or neither. The birth weights were slightly above average reported primiparous birth weights, so it was not because of smaller babies. Several women reported posterior babies, one weighing 3700, delivered over intact perineums. A third hypothesis is that practice actually stretches the perineum, perhaps the way a multipara is stretched, in such a way as to stretch more easily at birth. This is a very difficult device to study objectively since there is no way to study this device without selection bias. There is no way to randomly assign use of a device that requires a woman to insert a 2 inch wide silicon balloon into her vagina and blow it up to 10 centimeters wide and push it out on more than 3 occasions. The minute she actually carries out this assignment, she is no longer a random woman, but a highly motivated, select woman. You cannot pay most women to do this, particularly most women who are 9 months pregnant.

Other possible selection biases: Perhaps the study group women was motivated to use the device because they were at higher risk than the general



population to get an episiotomy (for example, family history, previous episiotomy). Also, it is not known what methods the control group used to avoid episiotomy and this is a limitation of the study.

This study used the same practitioners for both study and control groups, namely randomly assigned midwives working at almost all the hospitals in Israel. The large percent of women who used an epidural (44%) and the vacuum rate of 11%, identical to the national average, supports the hypothesis that this sample is comparable to the Israeli population as a whole. The low cesarean section rate of 6% compared to a national cesarean section rate of 20% for primips, may be explained by the fact that women only buy the device at the end of pregnancy, which eliminates some of the women who turn high risk during pregnancy, or may again reflect selection bias.

However, without any research based evidence, doctors at Assafe Rofe Hospital in Israel have already told their patients that the intravaginal perineal dilator is very dangerous because it causes "dangerous bleeding and premature rupture of membranes". No such problems were found in this or in the previous Hillebrenner study. Since this study was completed, the distributor informed me that another 552 devices were sold in Israel between April 12, 2002 and Jan 12, 2003 bringing the total to 821 sales to date. Six months after the study was completed, one and only one woman who had recently bought a device came to the distributor for a refund reporting that the practice with the device caused her a vaginal laceration which she went to the emergency room for, but did not require any suturing.

Although the device demanded significant expenditure, time and discomfort, 98% of the users were very enthusiastic about the device during the phone interview and recommend that women use it. Since protocol in all Israeli hospitals calls for episiotomy with instrumental births, the perineal outcomes after perineal dilator use, were an improvement over the current protocol.

The use of the intravaginal perineal dilator showed a 29% primiparous episiotomy rate. The episiotomy rate is an improvement over the current National statistics in Israel but are more than double The World Health Organization's recommendation for an episiotomy rate of 10% based on the 1984 Sleep article (WHO 1996). Exceptional episiotomy rates of 0.5% (homebirths) / 1%(hospital births)(Slome 2002), 1.4 % (Aikins Murphy1998), 3.8% (Janssen 2002), and 4 %(Wagner 1994) have been documented by motivated one-to-one care midwife practices and might be a goal to aspire to. The national episiotomy rate for the Netherlands is 8%(Wagner, 1999).

Although the last 10 years have shown a general trend towards a lowering in the episiotomy rate, this may or may not continue. In Rosario, Argentina in the hospital where the randomized controlled trial of routine episiotomy was done and showed clearly that "routine episiotomy should be abandoned" (Argentine 1993), the episiotomy rate for primiparous women rose from 40% during the trial to 82% the year after the trial and in 1995 was still 71% (Belizan and Carroli 1998). Non-evidence based protocols can vascillate unpredictably.

In their phone interviews, the womens' words implied that they derived much empowerment from taking part in the preparation for birth. Goldberg (2002) suggests 3 reasons for the lowering of the episiotomy rate in his facility: one being improved patient education and participation in decision making (the other 2: the body of research against routine episiotomy and decreased use of forceps). In this study, both the controls and the study group had the same prenatal care. Future studies should control for and



compare how women in each group educated themselves before birth and participated in decision making at birth.

Hillebrenner (1999) suggests that the device lowers the need for medical pain relief since the 45 women using the device, in his study, used less medical pain relief than the control group. Epidural anesthesia was used by 44% of the women having first births, which is lower than the reported national average epidural rate of 54% for first births (Zalcborg, 1999), but not dramatically so. Since there are no reported statistics on other pain relief methods used in Israel in the literature and the study group is not a random sample, no conclusions can be drawn about the device lowering the need for pain relief.

## SUMMARY

In this preliminary study, 233 women who used an inflatable intravaginal perineal dilator to prepare for birth were interviewed on the phone. The rate of intact perineums reported for spontaneous vaginal births to primiparous and secondiparous births after a cesarean for their first births was 43% with another 29% having tears, half of those minor. The episiotomy rate was 29%. This is a higher percentage of episiotomy than would be expected if evidence-based protocols were in place, but a 50% reduction in the episiotomy rate for first births in non-users in Israel. Although the users were aiming to avoid episiotomy, 86% of the women who practiced with the device and had an episiotomy, felt positive about their experience since it taught them how to push and gave them confidence and they believe it helped. Three possible theories are suggested. The perineal dilator may increase intact perineal outcomes in primiparous women by 1. shortening second stage by teaching the woman how to push and/or 2. by stretching the perineum before birth and/or 3. may empower women to participate in the decision not to perform episiotomy.

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