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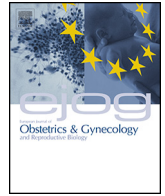
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## A perineal protection device designed to protect the perineum during labor: a multicenter randomized controlled trial



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### ABSTRACT

**Objective:** The objective of this study was to evaluate the protective effects of a new device for reducing perineal tears during vaginal childbirth.

**Study design:** A multicenter open randomized controlled trial (RCT) was performed in Helsingborg, Lund and Malmö, Sweden consisting of 1148 women. Women anticipating a vaginal delivery were either randomized to the intervention group ( $n = 574$  in which the perineal protection device was used, or a control group ( $n = 574$ ), in which the perineal protection device was not used. The main outcome measurements were incidence of vaginal and perineal tears (1st to 4th degree tears) and adverse effects on the parturient and newborn.

**Results:** The incidences of first- and second-degree tears of the vagina ( $p = 0.018$ ) and perineum ( $p = 0.005$ ) were significantly reduced in the intervention group compared with the controls. In the intervention- and control group, 184 women (34.9%) and 142 (26.6%) showed no perineal tearing, respectively ( $p = 0.034$ ). Numbers needed to treat to avoid any perineal tearing was 12. The incidence of anal sphincter rupture (ASR) was the same in both groups ( $n = 19$ ; 3.4%). No negative effects on mother or child from using the device were observed.

**Conclusions:** The perineal protective device significantly reduced the incidence of first- and second-degree tears in the vagina and perineum during vaginal birth and also significantly increased the number of parturients with a fully intact posterior commissure. No significant reduction of ASR and no negative effects of the device were observed.

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### Introduction

Perineal lacerations in conjunction with labor may cause considerable discomfort for the parturient, including short term complications such as pain, infections and hemorrhage [1]. Long-term complications include urinary and anal incontinence and dyspareunia [1]. The associated morbidities may have further impact on the woman's recovery, health and psychological wellbeing. However, with a clinical intervention program focusing on a manually protecting the perineum the incidence of anal sphincter ruptures (ASR) has been successfully reduced from 4.1%

to 2.3% [2]. The incidence of extensive tears has increased in the last decades [3,4], and recently even reports describing short- and long-term complaints caused by minor tears has been published [5–7]. Given this, the challenge is not only to reduce the incidence of ASR, but also to reduce the incidence of minor tears (first- and second-degree tears).

We have performed a multicenter open randomized controlled trial in which a new device designed to protect the perineum during delivery was used. The aim of the study was to estimate the device's protective effect in reducing the incidence of tears in the perineum during vaginal childbirth.

### Material and methods

The study enrolled 1148 women and was performed at three hospitals in Helsingborg ( $n = 644$ ), Lund ( $n = 370$ ) and Malmö

Abbreviation: ASR, anal sphincter rupture.

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**Table 1**  
Obstetric and fetal characteristics of controls and women randomized to deliver with the perineal protection device (PPD).

	Controls (n=552)	PPD (n=546)	p
Age of parturient (years)	30.1 (18–47)	29.8 (18–45)	n.s.
Primiparous (%)	342 (62)	351 (64)	n.s.
Gestational weeks (median)	39.6 (34–42)	39.6 (33–42)	n.s.
Second stage of labor (min)	64 (5–360)	60 (5–360)	n.s.
Episiotomies (%)	28 (5.1)	25 (4.6)	n.s.
Instrumental deliveries (%)	55 (10)	50 (9.9)	n.s.
Birth weight (g)	3622 (2320–5170)	3630 (2300–5700)	n.s.
Umbilical artery pH (range)	7.24 (6.97–7.44)	7.24 (6.97–7.5)	n.s.
Labial tears/women <sup>a</sup>	169/111	199/135	n.s.

Data given are the median (range) or n (%).

A p-value  $\geq 0.05$  was considered not significant = n.s.

<sup>a</sup> The total number of labial tears is expressed/number of women (more than one can be present at each women).

(n = 134) in Sweden. The patients were included between June 2010 and December 2111. Obstetric and fetal characteristics are presented in Table 1. Medical journals for 14 women were inadequately completed, and were therefore, excluded along with the 36 women who underwent emergency caesarean section. The two groups were comparable in respect to obstetric and fetal variables, as shown in Table 1.

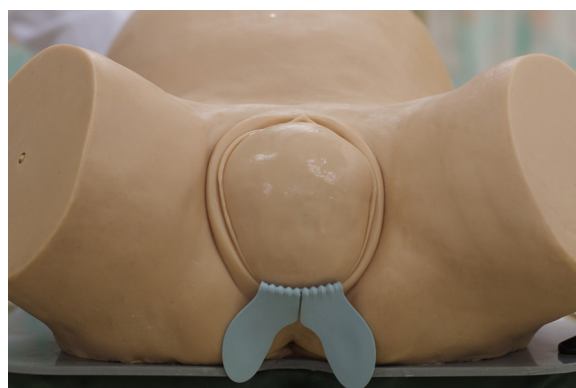
In the study the participating women were recruited from the antenatal maternity clinic and the delivery department (see CONSORT flow diagram Fig. 3). Inclusion criteria for the participants were as follows: delivery with cephalic presentation, age of more than 18 years and an understanding of both oral and written information in Swedish. All participants signed an informed consent form and received a copy wherein the study was described in detail. The women were randomly allocated to an intervention or a control group, i.e., the midwife drew an opaque sealed envelope in which the randomization was revealed. The envelopes were numbered, and the randomization was computerized ([www.randomizer.org/form.htm](http://www.randomizer.org/form.htm)). Women undergoing emergency caesarean section were excluded.

The risk of ASR has been approximately 4% at the hospitals involved. Given an ASR incidence of 2% statistical power calculations (SPSS version 19, SPSS Inc., Chicago, IL, USA) estimated a study size of 1000 women. The estimated exclusion rate was 10–20%; therefore, the total number required was 1100–1200 women to find a risk reduction of 50% for ASR.

The device was produced by Calle Gejde AB, Lomma, Sweden, provided by Vernix Pharma A/S, Oslo, Norway, who owns all the related intellectual property. The product is not commercially available. The material used in the device is Santoprene; a medical grade vulcanized thermoplastic approved by the Food and Drug Administration (FDA) for clinical use. The device and instructions are shown in Figs. 1–2. The maximal thickness of the device placed in the posterior wall is 0.75 mm, and the width covering the posterior commissure is 47 mm. The tongue has a length of 76 mm. One part of it, “the tongue”, was inserted between the fetal head and the posterior vaginal wall during crowning as described in Figs. 1 and 2. If an episiotomy was required, it was performed in both group groups with a lateral incision. The characteristics were not described further (length, angle etc.).

The women allocated to the control group delivered following the procedures of the labor ward, which includes perineal support with the fingers or the palm of the hand.

The midwife filled in a report postpartum with delivery data as shown in Table 1. The midwife measured the tears with a ruler, both in the vagina and in the perineum, and the results are shown in Table 2. In the case of multiple tears, the sums of the lengths of all tears were calculated. If an episiotomy was performed, only tears beyond the cut were recorded. The depths of first- and



**Fig. 1.** Instruction for use of the perineal protection device. (1) When 5–6 cm of the head is visible in the introitus during crowning, the device should be inserted. The device is held so that the tongue and wings are kept apart with a finger. The waved tongue is inserted as indicated above the posterior commissure. The device should be inserted without resistance. Gel can be used if needed. The vaginal opening at this stage of the delivery is oval, and the wings are, therefore, spread apart. Fix the wings against the perineum with the thumb and index finger of the right hand to support the perineum and with the left hand control the speed of crowning and push the device back during contraction when it will be squeezed out. If it falls out, put it back.



**Fig. 2.** As the crowning progresses, the vaginal opening becomes circular. This change results in the movement of the wings together. The posterior commissure is effectively locked between the tongue and the wings, and the device prevents the initiation of tearing when the head is maximally crowned. The device should be kept in place by the assistant during delivery of the shoulders. If an episiotomy is required, it can be performed laterally of the device. In the case of an instrumental delivery, the device can be used as described earlier. The assistant then holds the device in place to reduce the risk of tears, while the obstetrician performs the instrumental delivery by steering the head gently through the introitus. The device is preferably kept in place during the delivery of the shoulders.

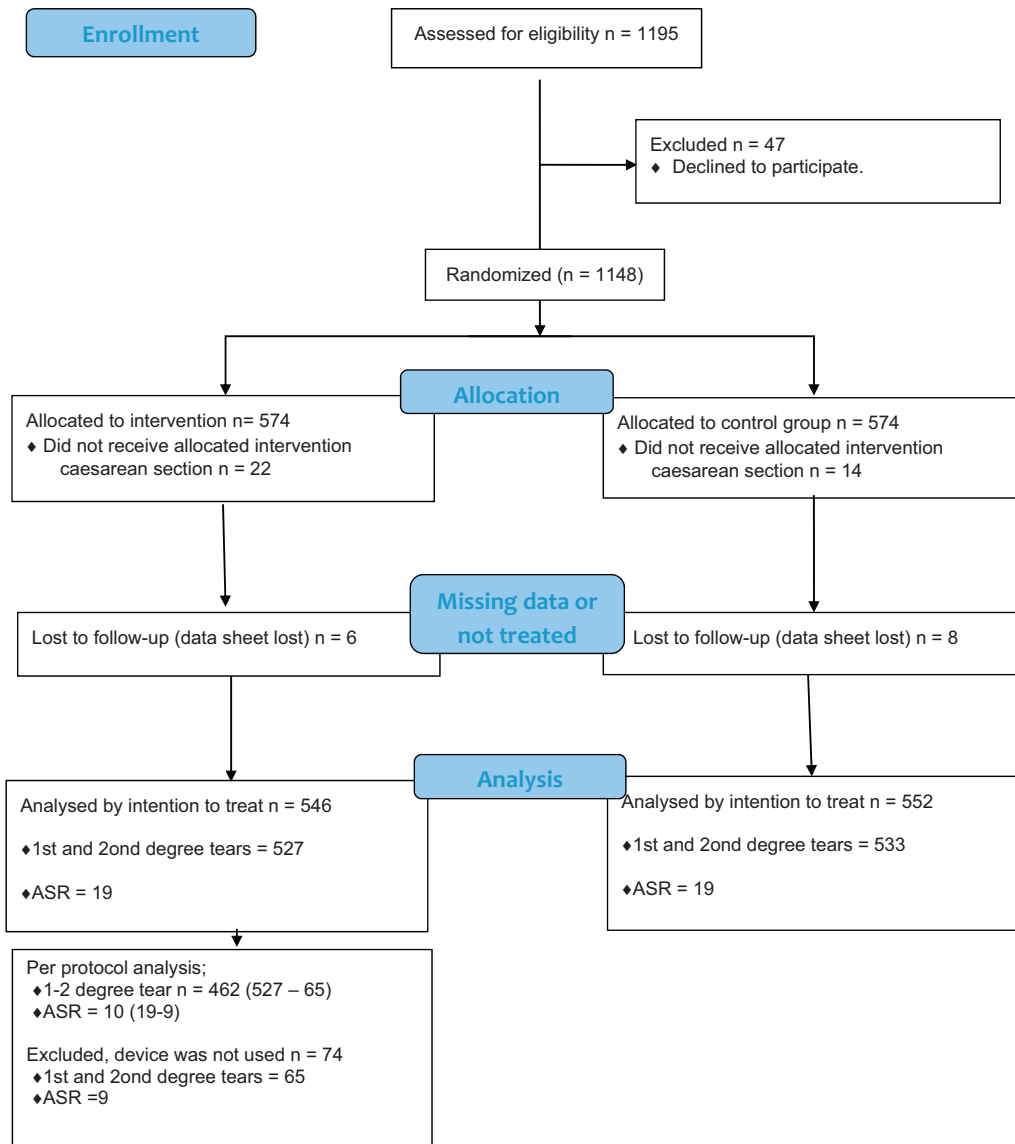


Fig. 3. CONSORT 2010 flow diagram.

**Table 2**  
Length of first- and second-degree tears in cm. shown by group of randomization.

	Controls	n	Intervention group ITT, all included	n	p	Intervention group PPA	n	p
Vaginal tears (cm)	1.3 (0–7.5)	533	1.1 (0–10)	527	0.018	1.1 (0–10)	462	0.006
Nulliparous	1.6 (0–10)	317	1.5 (0–10)	314	0.11	1.4 (0–10)	270	0.05
Multiparous	0.9 (0–6)	216	0.7 (0–4)	213	0.049	0.7 (0–4)	192	0.048
Perineal tears (cm)	1.1 (0–5)	533	0.9 (0–5)	527	0.005	0.9 (0–5)	462	0.002
Nulliparous	1.1 (0–5)	317	0.9 (0–5)	314	0.003	0.8 (0–5)	270	0.001
Multiparous	0.9 (0–5)	216	0.9 (0–5)	213	0.45	0.9 (0–5)	192	0.56

Ruptures are expressed as median (range). *P*-values are comparing controls with ITT- and PPA-groups.

Intention to treat analysis (ITT) was performed comparing women allocated to the intervention and control group. Per protocol analysis (PPA) compared women allocated to the group where the device actually was used (excluded *n*=65 were the device was not used) with the controls.

second-degree tears were not recorded, assuming that it was the same for both groups.

The first to four degree ruptures were defined according to Sultan [8]. The number of women suffering from ASR was given, but the injuries were not described in cm as the operation report did not usually include that information. Anal sphincter tears were all sutured in the operation theater by physicians. The presence of any labial tears was noted and the number of labial tears was

registered, but not the length. Complications or comments regarding the use of the device were noted as well.

At the end of the investigation, during a two days period, a questionnaire was distributed to all involved doctors and midwives, in total 18, about their experience using the device.

The study was approved by the ethics committee of the University of Lund (D.nr 148/2008). The Swedish Product Agency accepted the study using a new medical device.

## Data analysis

Statistical analyses were performed with SPSS version 19 (SPSS Inc., Chicago, IL, USA). The tests used were the Mann–Whitney *U*-Test (variables that were not normally distributed) and the Pearson Chi-square test. A level of  $p < 0.05$  was considered to be statistically significant. Number needed to treat (NNT) is calculated with  $NNT = 1/\text{incidence}$ .

## Results

Vaginal and perineal tears in the intervention group were significantly shorter compared with those in the control group (see Table 2). The protective effect was most pronounced in the perineum of the nulliparous parturients, however even multiparous had some benefit of using the device. The number of women without tears in the perineal area, intact perineum (vaginal and perineal) was significantly higher ( $p = 0.034$ ) in the intervention group ( $n = 184, 34.9\%$ ) compared with the controls ( $n = 142, 26.6\%$ ). Number needed to treat (NNT) was 12; i.e. the device has to be used 12 times to avoid one parturient with perineal tears. Vaginal and perineal tears were described in length in cm, but not depth because that was impossible to determine for practical reasons.

No significant side-effects were reported in the mother or child using the device with regard to injury or obstruction of the birth canal, however three (17%) of the birth attendants reported trouble inserting the device, and one parturient experienced some discomfort when the device was put in place.

There was no difference in the number of women suffering from ASR between the two groups (19 in the intervention group and 19 in the control group).

The labial tears (first-degree tears) are expressed in quantity (more than one can occasionally be present) as the length of the tears were imprecisely recorded. In the intervention group 199 tears were recorded in 135 women. The corresponding numbers in the control group were 169 tears among 111 women ( $p = 0.07$ ).

After exclusion of women who did not use the device in the intervention group, the difference between the two groups was statistically significant as it was in the intention to treat analysis; however an insignificant extra effect was seen for the nulliparous with vaginal- and perineal tears. Among women in the study group with ASR, in nine (47%) cases the device was not used as intended. After exclusion of women in the study group not actually using the device, the incidence of ASR was 2.1%. The difference in incidence was not statistically significant ( $p = 0.095$ ) compared to the incidence of ASR in the control group (3.4%). Fourth-degree tears occurred in 5 women, two in the intervention group and three in the control group.

The device was not used in 74 deliveries in the intervention group, and there were three reasons for not using it: in one-third of the cases, a lack of time was stated because of a vacuum delivery and asphyxia; in one-third of the cases, the device was not used for technical reasons, e.g., it was pushed out, there were difficulties in getting it into place or due to special delivery positions, etc.; and in one-third of the cases, the device was not used because of medical personnel-related decisions, e.g., the midwife or the attending doctor forgot or were reluctant to use it. The explanations were often contradictory.

An episiotomy was performed in 25 (4.6%) cases in the intervention and 28 (5.1%) cases in the control group (n.s.) as described in Table 1. Eleven women had no further tears in the posterior fourchette after having an episiotomy. After exclusion of these 11 women a total of 173 women in the intervention group and 131 in the control group had no vaginal or perineal tears ( $p = 0.031$ ).

ASR was more common after instrumental deliveries, three in the intervention group and five in the control group. An episiotomy was also performed more often in the women with instrumental deliveries: seven in the intervention group and six in the control group. ASR occurred in 29 women who were primiparous and nine who were multiparous.

## Comment

A study aimed at reducing the incidence of first- and second-degree perineal tears by the use of a new perineal protection device has not, to our knowledge, been previously published. In our analysis (Table 2), we found a significant difference in the incidence of both vaginal and perineal tears between those that used the perineal protection device compared with those in the control group, indicating that the device had a positive protective effect. The ruptures are more extensive in the nulliparous women as shown in other studies [9]. Discomfort related to first- and second-degree tears can be disputed as being of minor clinical significance; however, reports by Signorello et al. [5], Røkner [6] and Ejegård [7] indicate that short- and long-term complaints exist such as dyspareunia and vaginal dryness at intercourse, showing importance minimizing all perineal damage incurring during childbirth. The results as described in Table 2, in terms of mm, may seem minor; however, studies have shown that length of episiotomy correlates with sexual problems in women without ASR, indicating that length of tears matters [10]. More importantly, an increased frequency of women experiencing no tears at all in the posterior fourchette was significantly reduced compared to the control group. Not surprisingly, parturients with no tears at all have the least long- and short term morbidities [5–7] compared to those with tears, a finding we believe has clinical significance. As few as 12 women need to use the device in order to avoid 1 case of perineal tearing. After exclusion of cases, in the intervention group, not actually using the device, according to the per protocol analysis, an insignificant protect effect was observed, but criticism can be raised in this context because no one was excluded in the control group.

The theory behind the device and its function is that it supports and protects the edge of the perineum, which is locked between the tongue and the wings of the device, preventing the initiation of tearing. The device ensures that the fingers/hand remain fixed against the perineum; otherwise, the device will fall out indicating that manual support has not been practiced. The technique of protecting the perineum with the hand has recently been reported by Hals et al. [2], Laine et al. [4], Stedenfeldt et al. [11] and who were able to significantly reduce the incidence ASR. Usage of this device ensures correct manual support of the perineum during delivery, and in addition the putative effect of the device is the locking by the two parts of the device of the perineum in the posterior commissure. As the midwives measured the tears themselves, the objectivity of the results can be questioned. In this study, the attitude was restrained toward using the device, based on a notice that manual support is sufficient without using any new technical device and subsequently, any bias may be both disadvantageous and favorable. However, blinded measurements by another person would have been preferable.

It was not possible to reduce the number of ASR in this study, and the incidence was higher than observed in other studies where manual perineal protection has been used [2,4,11]. The idea with the device, as with manual support, is the same, and subsequently, suspicion of insufficient handling by the users, supported by the relatively high number of women excluded ( $n = 74$ ) further indicates that the device was not always properly used. The incidence of ASR was reduced to 2.1% after exclusion of women in the study group not using the device (per protocol analysis), and this incidence of ASR is in the same range as earlier reports [2,4,11]



in which manual support was used. There is most likely room for improvement of the results via training with the device on a pelvic model, contrary to what we believed when we started the study.

The number of episiotomies in our study material was low compared with other studies [1–4,9–12] and the relationship between episiotomies, dyspareunia and perineal pain has been demonstrated in earlier studies [5–7,10]. Therefore, we believe that it is important to keep the frequency of episiotomies low even when intervening to reduce the number of ASR. However, the optimal number of episiotomies in relation to the risk of ASR remains to be clarified. The protective effect and characteristics of episiotomy related to ASR has been discussed, as whether it should be medial, mediolateral or lateral and the results are contradictory [13–18]. This can partly be explained by the fact that standardization of episiotomies has not been performed as described by Kalis et al. [19].

The difference in labial ruptures between the two groups was not significant. We speculated initially if the head of the baby might change the crowning passage caused by the device, initiating ruptures elsewhere, for example the labia. That was not the case.

The soft device showed no signs of obstructing the vaginal opening, and no injury was experienced by the parturient or baby. Three (17%) delivery attendants claimed difficulties inserting the device, and this issue can be minimized with training on a pelvic model. One of the midwives described some discomfort for the women when inserting the device. It is not clear however, if it was the device per se that caused discomfort or the mere fact that a vaginal examination was performed during crowning of the fetal head.

Signorello et al. [5] have shown that infants delivered over an intact perineum report the best outcome overall, whereas perineal trauma and the use of obstetric instrumentation were factors related to the frequency or severity of postpartum dyspareunia, indicating that it is important to minimize the extent of perineal damage incurred during childbirth. Future studies should be performed, preferably consisting of nulliparous women who are most likely to tears [1].

### Competing interests

The authors declare that they have no competing interests except for KH who is shareholder in Vernix Caseosa. No payment has been done to any of the authors.

### Authors' contribution

TL conducted the trial and drafted the manuscript. IDG, AS, ASK, HN and MS made substantial contributions in planning and realising the trial at their respective units. KH initiated and planned the study. All authors read and approved the manuscript.

**Trial registration number:** ClinicalTrials.gov.ID:NCT01533467

### Condensation

A new perineal protection device is described, showing a reduction on first- and second-degree tears and no adverse effects on the parturient and baby.

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