Taking the opportunity

DIANATAL®
obstetric gel



Dianatal –
Facilitating natural birth
Preventing birth trauma



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Cesarean epidemic !
Vaginal birth is best. WHO 2010

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The steadily raising global rate of cesarean section has become one of the most debating topic obstetrics as its prevalence has increased in last few years . Repeat cesarean section contribute to 30% of all cesarean section. Vaginal birth after one cesarean section is one solution to decrease the rising cesarean section rate.

Qamarunissa, Fkharunissa. Cesarean section; frequency and fetomaternal morbidity. Professional Med J 2013;20(4): 537-541

WHO indicated that a cesarean section rate greater 5 than 10-15% is not justified in any region of the world . In the recent years the rate has increased to a record level of 46% in china, and 25% and above in many 6 Asian countries, Latin American, USA.

C-section rates around globe at epidemic level. The Associated Press; msn Canada news 2010. Available at http//.www.msnbc.msn.com /id/34826186/.

Caesarean section without medical indications is associated with an increased risk of adverse shortterm maternal outcomes: the 2004-2008 WHO Global Survey on Maternal and Perinatal Health.

Souza JP et al. Caesarean section without medical indications is associated with an increased risk of adverse short-term maternal outcomes: the 2004−2008 WHO Global Survey on Maternal and Perinatal Health. *BMC Medicine,* 2010;8(1):71

A number of other concerns have also been expressed about the rising rates of nonmedically indicated caesarean deliveries. A major one is the cost of such operations for public-sector services. Another important concern relates to a rise in antibiotic resistance (as a result of routine use of antibiotics during or after caesarean surgery). For example, a study in the United States of America found that caesarean sections, together with incidence of mastitis, are key factors behind the rising cost of treating methicillin-resistant Staphylococcus aureus (MRSA) infections in American obstetric patients.

Souza JP et al.

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The fears and the unmet needs cause the „cesarean epidemic"

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Patient

Trauma
Safety
&
Pain

Obstetrician

Time
Money
&
Litigation





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Impact of friction on labor outcomes

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Our Parity Adjusted Outcome Study 2004

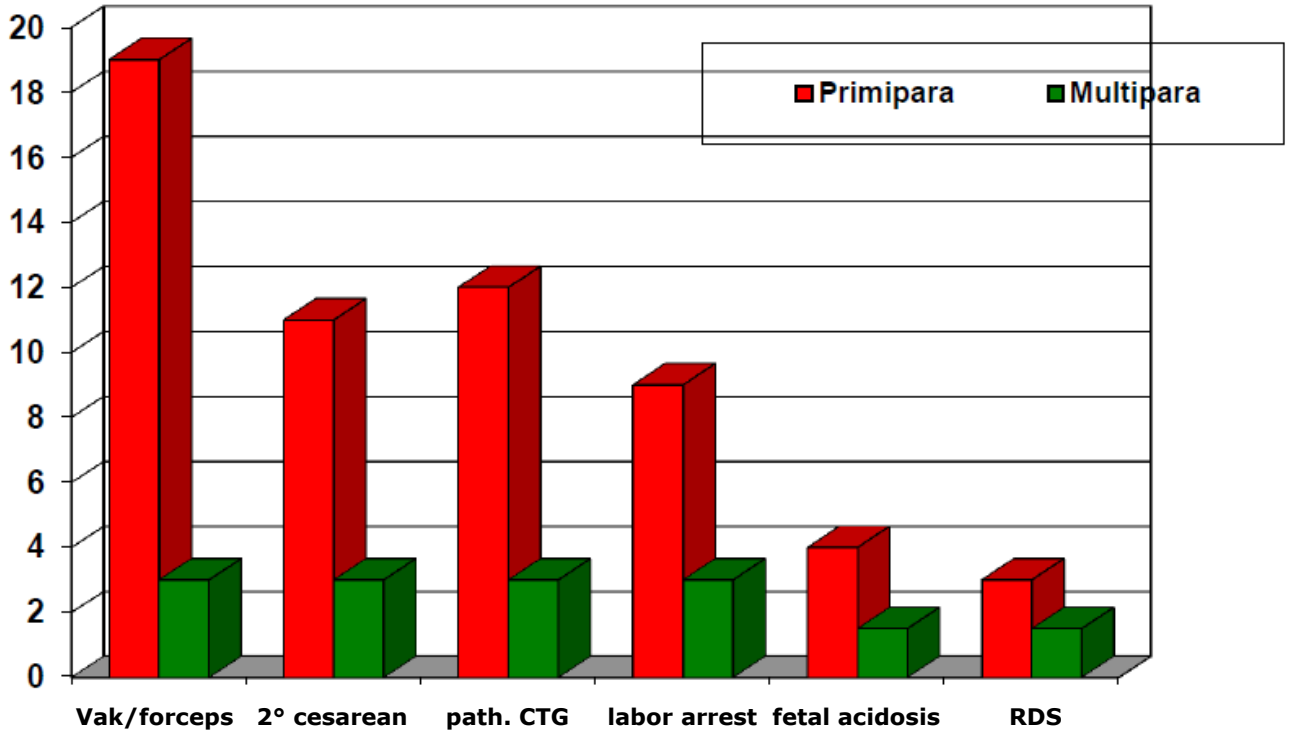
- **period: 1993 until 2003**
- **Switzerland**
- **Source: 352’215 deliveries, ASF nationwide statistics**
- **Discriminating factor: friction [parity & birth weigth (4000 g)]**
- **Included very low risk deliveries: 188’339**
    - **Primipara: 82’003**
    - **Multipara: 103’106 (2 to 4)**
    - **Grandpara: 3‘230 (> 4)**

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Labor outcomes depend significant on friction (parity/weight)

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all = P < 0.001



labor outcomes are significantly dependent on friction

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Dianatal Birth Gel:
a new option based on old principles

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New in Humans –

A Gold Standard in Veterinary Medicine



Vets have been first again !

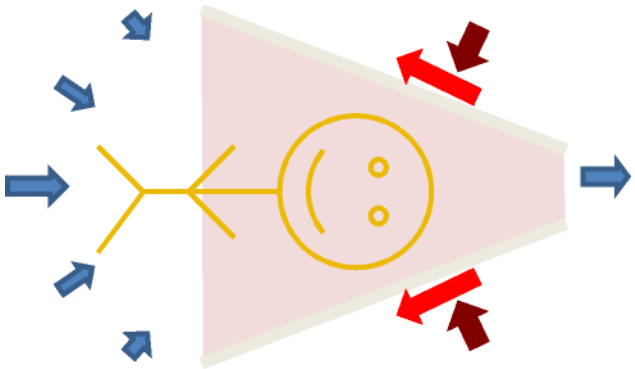
such as in IVF, in ultrasound,

- **~ 400 BC: Chiron: Olive Oil in horses for facilitation**
- **~ 80 AC: Soranus: Olive Oil in humans for facilitation**
- **Oils are used in Israel (Almond, ...)**
- **2008: First Birth Gel: Dianatal**

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Birth formula:
Friction is no fiction

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Newborn expulsion

= uterine contractions (& gravitational force)

***minus* elastic forces (parity, newborn weight)**

***minus* friction force**

(delta friction coefficient)



Dianatal



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A new procedure need a new product

Not every Gel is a Birth Gel !

DIANATAL® obstetric gel

A new procedure

Starting the application at early active stage I to induce an adhesive gliding film on the vaginal birth canal to reduce friction between the birth canal and the fetus.



A new product

- **Dianatal birth gel is**
  - **Sterile gel and sterile packaging**
  - **Adhesive**
  - **Bacterizide in vitro (B Strept, A-Strept., Gardn., E.coli)**
  - **Electroconductive**
  - **Latex-free**
  - **Free of preservatives**
  - **Non-allergenic, non pyrogenic**
  - **Kind on mucous tissue and eyes**

- **and fully biocompatible**

Agar diffusion test, Buehler sensitization test, Embryotoxicity test, Human blood hemolysis test, Intracutaneous injection test, Oral irritation test, Primary ocular irritation test, Primary skin irritation test, Primary vaginal exposure test, Rabbit pyrogen test, Systemic injection test

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Dianatal Set: purely physics

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- **Mode of action: pure physical, no pharmacological action**

- **Dianatal Set:**
- **6 sterile single-use 5 ml tubes with high effective obsteric gel**

- **CE marked: Medical Device Class II a:**
- **Carbomer, Cellulose, Propylenglycol**
- **No ingredients of animal origin**

- **Swiss innovation & invention**
- **Manufactured in Switzerland**

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Dianatal:
two ways to unlock the benefits of physics

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The preventative way (at least 5):

- application start: early active stage 1 (~ 5 cm dilatation)

The therapeutic way (at least 2):

- application start: late stage 1 (~ 8 cm dilatation)

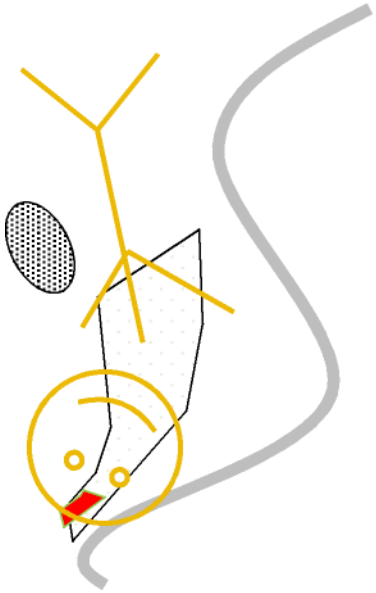
Prevention is better than treatment!

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What is the difference of Dianatal to perineum massage?

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Perineal massage:
Starting at the end -
Only head area is lubricated, body area not lubricated

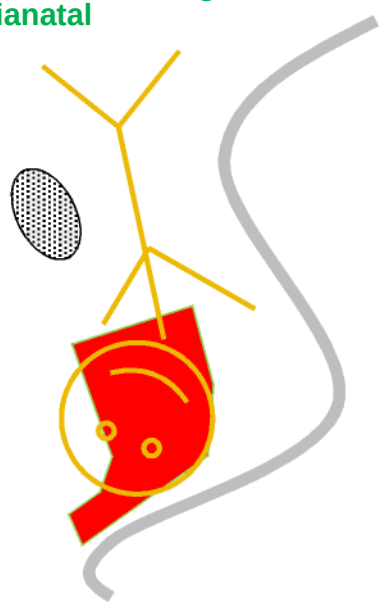


Lubricated area: ~ 30 cm^2

Oil is greasy & sticky with amniotic fluid
Oil can irritate the newborn eyes and can complicate perineum healing

Dianatal +/- perineal massage
Starting at the beginning -
All the baby surface is lubricated

Perineal massage can be best performed with Dianatal



Lubricated area: ~ 525 cm^2

Dianatal is adhesive slippery with amniotic fluid
Dianatal does not irritate the newborn eyes and supports perineum healing

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ETH Zurich: Birth model results

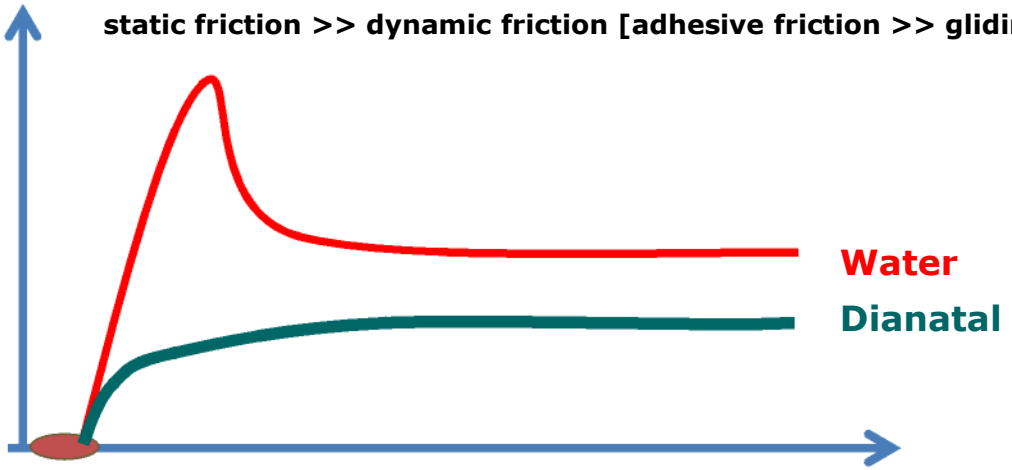
Published: Quantification of friction force reduction induced by obstetric gels. Med Biol Eng Comput. 2009 Jun;47(6):617-23

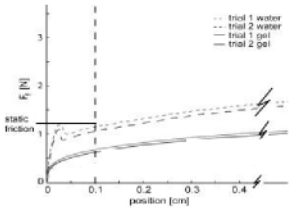
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1. **Dianatal reduces static friction significantly by 50 % / eliminates static friction**
2. **Dianatal reduces dynamic friction significantly by 50 %**
3. **Not every Gel is a Birth Gel**

Control: water



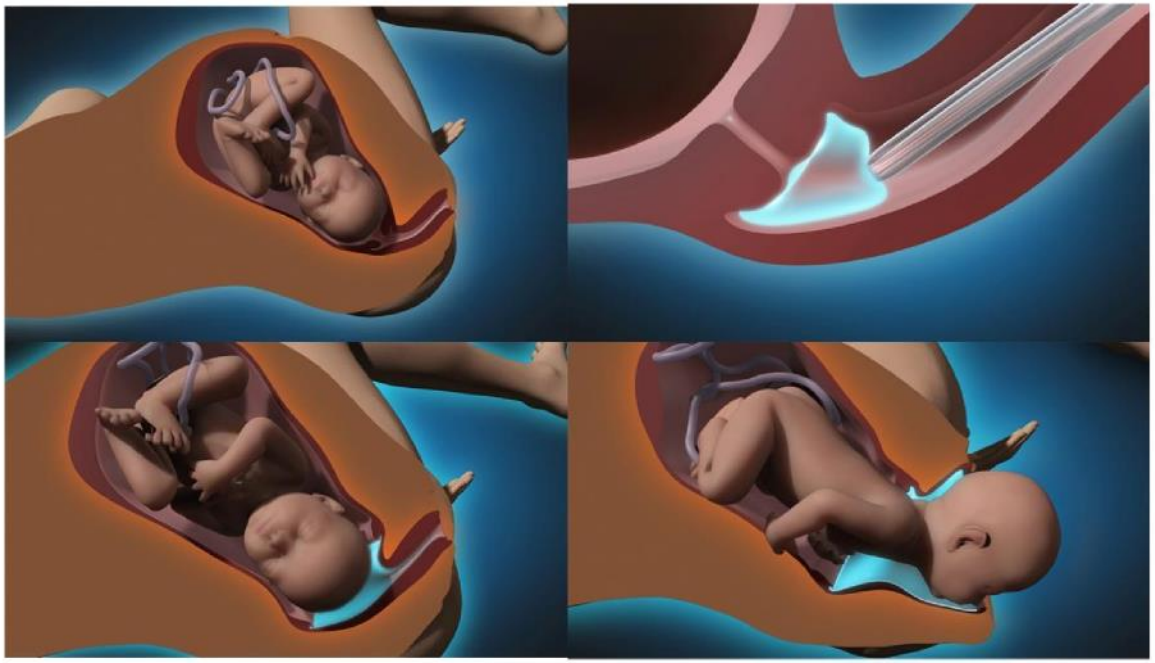




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Dianatal Birth:
to help mother & child

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- Dianatal® is administered in a two hours interval to the presenting part after vaginal examinations

- Do use up to 6 of Dianatal® obstetric gel applicators in total to ensure optimal child birth facilitation. Ad fluid in dry vaginal conditions

- Do use a dry towel during delivery to prevent slipping

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Preventative use: Swiss results

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Our Swiss Study 2005 to 2007:

- randomized prospective trial with active control at three Swiss Obstetrics Dept.
- active control (KY Jelly), blinding not possible, placebo not possible

347 primiparous women randomized into (low risk for vaginal delivery)

  - Group A: standard of care without Dianatal Obstetric Gel
  - Group B: standard of care with Dianatal Obstetric Gel

- Intervention: Dianatal application onto the birth canal starting at early labor stage 1 (before 4 cm dilatation) End points: Labor duration, perineal outcomes, intervention rates

- Study report/surveillance: Prof. Dr. J. Drewe, Dept. for Clinical Pharmacology, University Hospital Basel:

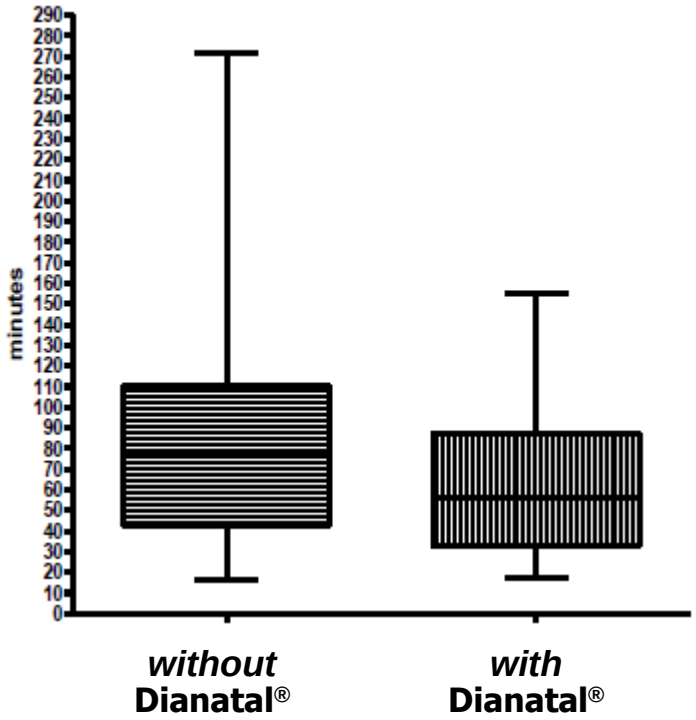
- Centers: Prof. W. Holzgreve, Prof. M. Litschgi, PD V. Geissbühler
  University Hospital Basel, Cantonal Hospital Frauenfeld,
  Cantonal Hospital Schaffhausen

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Results of the three study centers:

Published: Human Study Report 2009, Prof. J. Drewe

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Dianatal:
Reduces labor stage 2 significant by 22 min

N = 106, delta 22 min, $p < 0.05$ (p= 0.016)

Stage 2 without Dianatal:	**81 min**
Stage 2 with Dianatal:	**59 min**

Delta: 27 %

group +/- EDA +/- AMN

No center effect

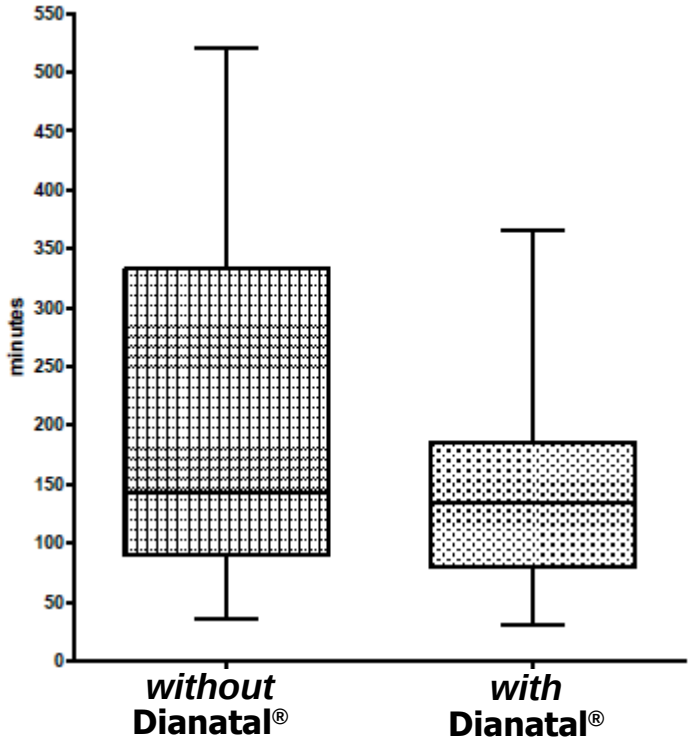
dose - effect relationship: ave use 20 ml

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Results of Frauenfeld und Schaffhausen:

Published: Human Study Report 2007, Prof. J. Drewe
Annual Conference of the Swiss Society of OBGYN, 2008

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Dianatal:
Reduces labor stage 1 significant by 65 min

N = 47, delta 65 min, p < 0.05 (p= 0.049)

Stage 1 without Dianatal: 203 min
Stage 1 with Dianatal: 138 min

Delta: 32 %

Group without EDA +/- AMN

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Risk reduction for perineal tears:

Published: J. Perinat. Med. 36 (2008) 129-135

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Significant reduction of perineal tears: risk twofold reduced.

N = 95, odds ratio 2.7, p < 0.05

	N	Intact perineum diff.	Odds Ratio	p value
Spontanous	95	15%	2.7	0.024

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Soft tissue protection vaginal birth canal

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Ukraine study 2009: randomized active control, 130 primiparous

Significant reduction of episiotomy rate by Dianatal:

3 % vs 28 %

Significant reduction of vaginal/urethral burn feeling by Dianatal:

6 % vs 39 %

Minsk study 2011: prospective active control, n = 116

Significant reduction of soft issue lacerations by Dianatal:

8 % vs 20 %

Significant reduction of cervical lesions by Dianatal:

5 % vs 22 %

S. Zhuk, N. Pekhnyo. Advanced Technologies in Vaginal Labour Management. !! Healthcare in Ukraine, 2009

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Preventative use: Central Europe results 2011

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University Medical Center Lubljana, Dept. of Perinatology

Births in 2010: 6715

prospective investigation in primiparous women, singleton pregnancy, vertex presentation, group with Dianatal (n = 118) compared with control group without Dianatal (n = 1427), 2010

- **Emergency cesarean rate halved by Dianatal (5,9 versus 11,8 %)**
- **Intact perineum rate doubled by Dianatal (22 versus 11,4 %)**
- **No side effects, newborn outcome unchanged**
- **Episiotomy rate decrease by Dianatal (44,9 versus 50,7 %)**
- **Vaginal operative procedure rate decrease with Dianatal (4,2 versus 4,8 %)**

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Therapeutic use: Marburg results

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2011: University Marburg, Prof. Dr. M. Kühnert:

- randomized prospective intervention study in the therapeutic use of Dianatal (n = 200), singleton vertex presentation
- Indications:
  - Prolonged delivery /Labor arrest
    - Stage I: Dilatation < 1 cm/h
    - Stage II: descent of head < 1 cm/h
- Intervention: Dianatal application versus control

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Therapeutic use:
2011 Marburg results

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200 investigated cases with prolonged delivery

<u>Outcome:</u>

operative deliveries reduced by 22 % with Dianatal

Mode of delivery	Dianatal group (n = 100)	Control group (n = 100)
Vaginal delivery:	43 (+ 63%)	27
Vaginal operative delivery:	12 (- 34%)	18
Forceps:	0	1
Vacuum extraction:	12	17
Cesarean section	45 (- 19%)	55

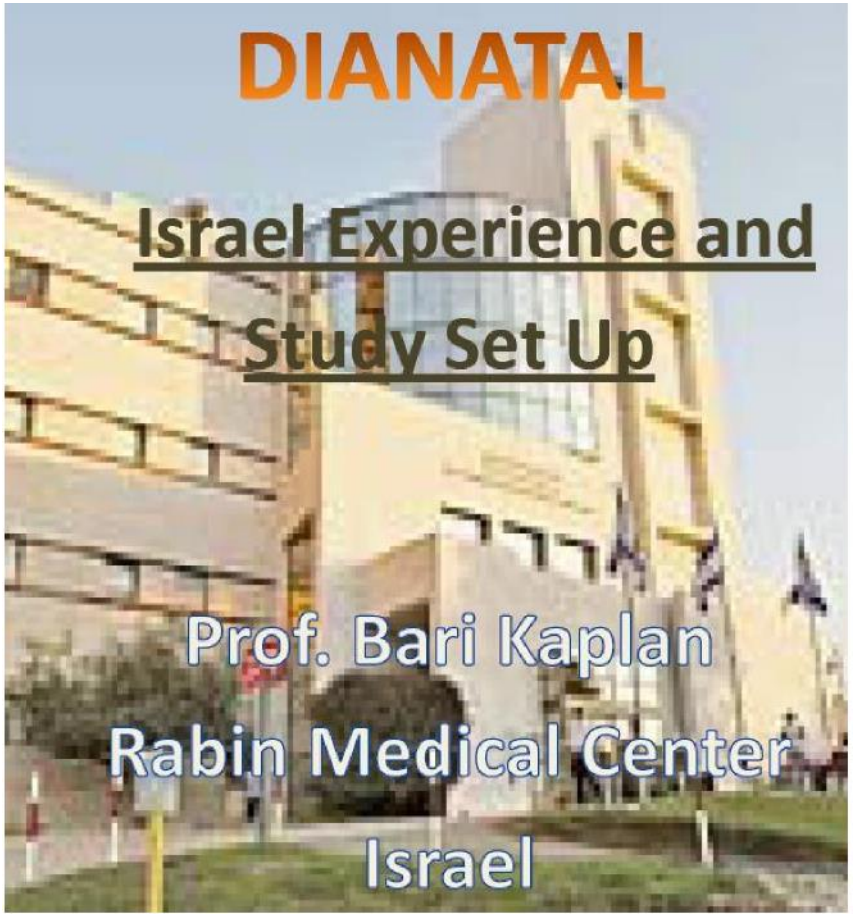
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Dianatal & vacuum ?

Great ! Prof. B. Kaplan, Tel Aviv, 2011

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Vacuum does not slip.

Smooth extraction.

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Dianatal quick facts

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- **so far approx. 35‘000 Dianatal deliveries have been performed**
- **Dianatal is safe and shows no side effects**
- **Dianatal facilitates vaginal delivery and significantly protects the pelvic floor, the vagina and the perineum and reduces the need for episiotomies**
  - **Dianatal reduces labor duration significant by 20 to 30 % in primiparous women**
    - **Stage 1: up to 65 min, Stage 2: up to 33 min**
  - **Dianatal significantly protects pelvic floor, vagina and perineum (twofold risk reduction for laceration). Dianatal further reduces the need for episiotomies.**
- **Dianatal can be combined with all obstetric procedures (water deliveries, vacuum/forceps extraction, ….)**

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Dianatal quick facts

DIANATAL® obstetric gel

- **Dianatal has proven to be used in a preventative approach as well as in a therapeutic approach:**
  - **Preventative:**
    - **Primiparous**
    - **Multiparous with complicated history**
    - **Women who want to facilitate their vaginal delivery and to protect their „love channel" and their baby**
  - **Therapeutic:**
    - **Obstructed delivery, Labor arrest**
    - **labor facilitation in patients with preterm labour, a history of previous c-section, big baby or borderline pelvis size**
- **Contraindications ? Contraindications for vaginal delivery**

Remember: Dianatal is no guarantee for an easy delivery but for sure Dianatal makes the delivery easier !

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Marketing messages / claims

DIANATAL® obstetric gel

Indication and uses of Dianatal obstetric gel

Dianatal obstetric gel has been developed specifically to facilitate vaginal delivery. Dianatal is bioadhesive and has a high water binding capacity. Dianatal is used during vaginal delivery to make birth easier for both mother and child and to reduce perineal trauma. Dianatal forms a low-friction bioadhesive film on the vaginal birth canal, reducing the friction forces between the child and the vaginal birth canal to facilitate vaginal delivery.

Dianatal obstetric gel is sterile, non-allergenic, electroconductive, slightly acidic and does not cause irritation to mucosal membranes or eyes.

Dianatal obstetric gel can be used in first-time mothers (randomized control trial (RCT) results) as well as in multiparas and in women with a history of cesarean section (clinical experience, investigator trial results).

Dianatal obstetric gel eases and shortens both the first and second stages of labour and offers protection to mother and child; in particular protecting the vagina, the pelvic floor and the perineum.

Dianatal obstetric gel is used specifically:

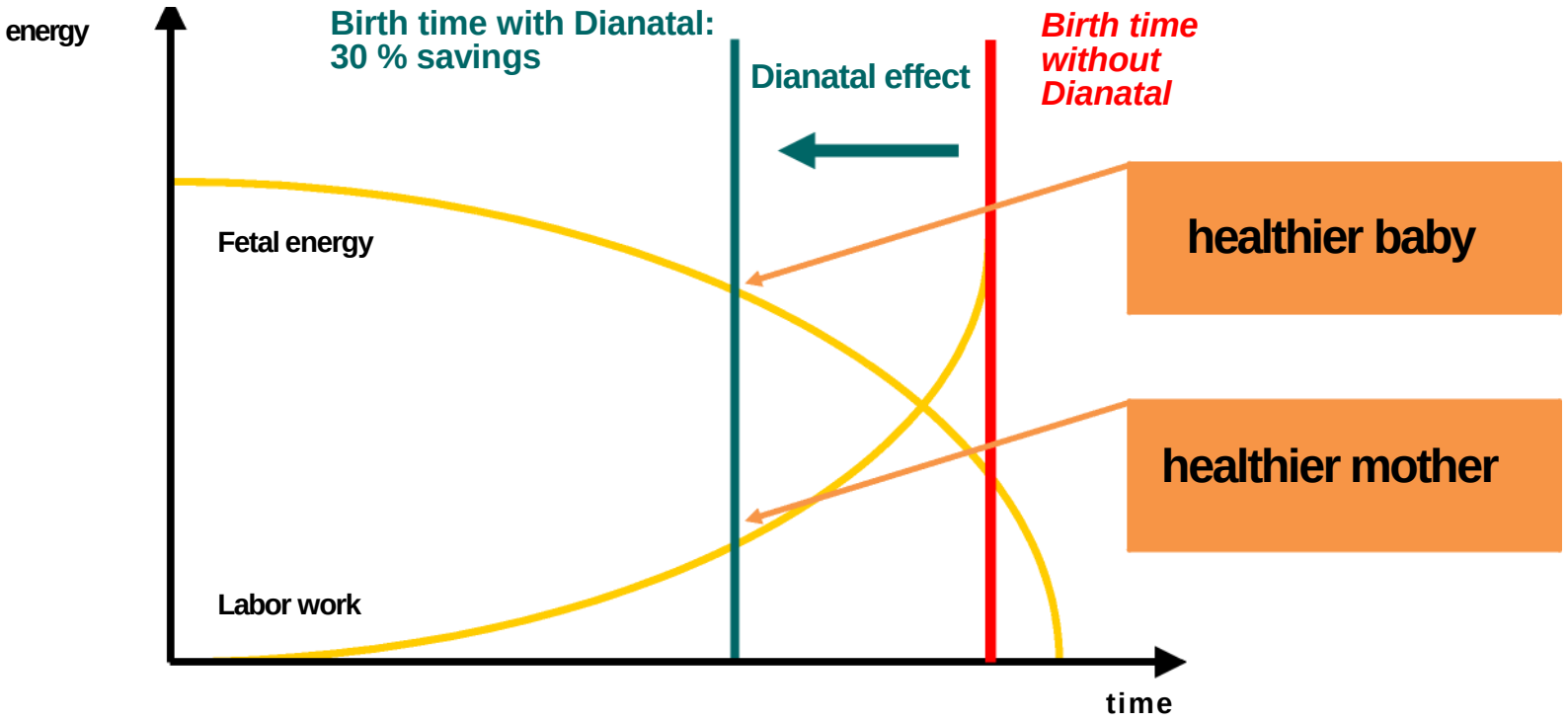
- to facilitate vaginal delivery and to protect both mother and child by reducing the opposing friction force in first-time mothers (RCT results)
- to facilitate vaginal delivery and to protect both mother and child by reducing the opposing friction force in multiparas, water deliveries and women with history of cesarean (clinical experience, investigator trial results)
- to prevent or treat prolonged or obstructed delivery (clinical experience, investigator trial results)
- to facilitate vaginal operative procedures (vacuumlforceps) (clinical experience)
- to protect the perineum and the Vagina during vaginal delivery **(RCT** results)
- to reduce the vaginal-urethral burn feeling post partum (clinical experience)

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Delivery time shift – a big difference

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Shift towards left means time and energy savings



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