Background
World-wide, 10–20% of deliveries require some form of intervention, and this intervention is frequently a caesarean section. (1) Instrumental vaginal deliveries (forceps and vacuum extraction) account for 2–23% of deliveries. (2-3) Obstetric history of assisted vaginal delivery started with the invention of instruments designed 400 years ago. However, it is only in the last 20 years of different intervening methods that scientific evaluation of risks and benefits have been discussed. (4) Operative vaginal delivery rates in Latin American countries are low compared with those in most developed countries. Data from hospital deliveries in 18 countries show that rates do not exceed 6% and are below 2% for half of them (Latin American Center for Perinatology, 1985–1995). It is a region with low operative vaginal delivery rates and high caesarean section rates. (5) The forceps is the standard instrument used in our countries.

This profile makes particularly relevant the introduction of a new device which would prioritize maternal safety, would be easy to use, disposable and would not require a highly skilled attendant. In this sense, people from all over the world could have access to it and the most vulnerable populations would benefit to a higher extent.

The new device provides an extractive mechanism as well as a mechanism to facilitate the physiological expulsion of the cephalic pole, and neither instruments nor devices for the extraction of the fetal head have been developed over the last 160 years. It also provides a mechanical mechanism of action different from the forceps or the vacuum extractor, or Thierry spaltus.

Device physical mechanism of action

This instrument has been designed on the basis of a double physical phenomenon consisting of a conveyor belt and an air clamp. The device consists of a polyethylene sleeve with a cuff-like fold on the fetal insertion edge, which fits the fetal head diameter. This sleeve is introduced using two flexible plastic spaltus 3-mm thick. One of them is straight and is used to crown the fetal head, and the other one follows the fetal cephalic curvature and allows placing the device in the adequate final position.

After applying the device, a small amount of air may, or not, be insufflated at zero pressure. The atmospheric air entering during the device application with the spaltus is generally enough to produce the air clamp around the fetal head. However, the air clamp effect may be enhanced by insufflating a small amount of air at zero pressure through an insufflation cannula, which runs along the device until reaching the chamber in the distal edge of the fold. Thus, an air clamp is obtained, which holds the fetal head at 360°. This adds to the conveyor belt or sliding effect occurring between the inner parts of the fold upon force exertion. Such force may be either external, i.e., through traction from outside the device, or internal, i.e., arising from the natural forces that bring about uterine contractions and maternal pushing. The optional traction handle would allow maintaining the polyethylene sleeve diameter, thus facilitating maternal soft tissues distension during the extraction of the cephalic pole.

In order to test the physical phenomenon, a real size pregnant uterus was designed. This was a 1-inch glass uterus at full cervical dilation (10 cm). Through its transparent walls can be seen both physical phenomena: the air clamp (figure 1) and the belt conveyor phenomenon (figure 2).

Simulation Laboratory

To perform a preclinical study, an obstetric simulator was considered. Superior primates (chimpanzees, gorillas, and orangutans) would be the best choice for testing the device. However, this option is not feasible, since any experimental maneuver would require general anesthesia and would interfere in the physiological mechanisms of labor. Previous studies have demonstrated the effectiveness of childbirth simulator for the teaching of forceps placement, and the extraction manipulation. (6-8)

According to the above mentioned, the research was performed in a childbirth simulator (simulator S 575 ~ “Nooite”) at the Obstetric Simulation Laboratory in Des Moines University (DMU), Iowa, USA, October 21–23, 2008. Multiple trials were successful. Action physical mechanisms (A- the air clamp and B- conveyor belt) generated upon device placement were objectively proved in the simulator obtaining feasible, since any experimental maneuver would require general anesthesia and would interfere in the physiological mechanisms of labor. Previous studies have demonstrated the effectiveness of childbirth simulator for the teaching of forceps placement, and the extraction manipulation.

We believe that the use of the device in humans will be technically easier because of the elasticity of tissues and the biological fluids lubrication compared with the rigidity and lack of lubrication of the simulators. On the other hand, uterine contractions and the strength of maternal pushes represent another advantage compared with the simulators.

Potential comparative advantages over other devices: forceps or vacuum

Medical advantages:
• It could decrease the risk of fetal-maternal injury
• It could decrease the risk of uterine inertia
• It could help to contraction forces and maternal pushing efforts
• It could reduce the risk of uterine rupture
• It could reduce postpartum hemorrhage (uterine atony) through a reduction in the second stage of labor
• It would decrease operative delivery
• It would reduce perineal damage (low incidence of episiotomy)
• It would result in less maternal discomfort
• It would decrease perinatal infections acquired through the birth canal (HIV and Streplococcus B haemolitics)

Technical advantages:
• It does not require expertise and individual training
• Easy-to-learn technique
• Very low production cost

FEASIBILITY AND SAFETY STUDY OF THE ODÓN DEVICE FOR ASSISTED VAGINAL DELIVERY

Main Objective: The main objective is to evaluate the safety and feasibility in terms of ease of application and successful delivery, of the new device in assisting vaginal delivery in singleton term pregnancies during the second stage of labor.

Safety will be assessed by examining potential short and long-term maternal and infant outcomes. Feasibility will be evaluated by observing successful expulsion of the fetal head after one-time application of the device under standardized conditions (full cervical dilation, anterior presentation, +2 station, normal fetal heart rate) in singleton uncomplicated pregnancies.

Study design and Population: A prospective study enrolling 100 pregnant women at the Centro de Educación Médica e Investigaciones Clínicas "Norberto Quimio" (CEMIC) University Hospital in Buenos Aires, Argentina over a period of 12 months. Only women with singleton uncomplicated pregnancies will be enrolled in the study.

Ethical Considerations: This project has been approved by CEMIC and the World Health Organization Ethics Committees.

Selected innovative technologies category 2: non-commercialized/isable stage

Call for innovative technologies that address global health concerns

2.2 SINGLE USE ASSISTIVE VAGINAL DELIVERY SYSTEM

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