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SPECIAL ARTICLE

Generating the clinical evidence for an innovation in maternal and newborn health: The OdonAssist™ inflatable device for assisted vaginal birth

Generando evidencia clínica para una innovación en salud materna y neonatal: el dispositivo inflable OdonAssist™ para parto vaginal asistido

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ABSTRACT

The OdonAssist™ inflatable device for assisted vaginal birth is an investigational device which underwent premarket clinical testing. The clinical evidence generation plan includes preclinical and clinical studies to support development, regulatory approval and post market surveillance of the device.

RESUMEN

El dispositivo inflable OdonAssist™ para parto vaginal asistido es un dispositivo de investigación que se sometió a pruebas clínicas previas a la comercialización. El plan de generación de evidencia clínica incluye estudios preclínicos y clínicos para respaldar el desarrollo, la aprobación regulatoria y la vigilancia posterior a la comercialización del dispositivo.

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INTRODUCTION

Management of the second stage of labor is an area of obstetrics for which there is still no consensus[1]. The current scientific debate on the maximum length of the second stage is inherently conditioned by safety concerns associated with the available options for interventions to expedite birth: emergency cesarean section and assisted vaginal birth with forceps or *ventouse*. In the absence of technological developments that could address those concerns, the debate has been informed by consensus statements based on experts' opinion and by the progressively expanding evidence on pregnancy outcomes associated with variations in the duration of the second stage[1].

The OdonAssist™, an investigational device for assisted vaginal birth (AVB), could bring a new viewpoint to this debate, as premarket clinical trials indicate a positive fetal safety profile, relative ease of use, limited training requirements and high women's acceptability[2,3]. These features could increase obstetricians' confidence in performing assisted vaginal birth, broadening the scope of this intervention in the context of the clinical management of the second stage of labor.

The OdonAssist™ is the first assisted vaginal birth device invented since forceps (16th century) and the *ventouse* (1950s). The mechanism of the OdonAssist™ is based on inflating an air chamber around the fetal head to act as an anchor point, allowing the practitioner to apply traction. The use of a soft traction point represents a potentially advantageous innovation relative to forceps, which utilize rigid metal parts to apply traction and are therefore associated with relatively high levels of injuries to sensitive fetal facial structures. Moreover, the absence of negative pressure (used during a birth assisted by *ventouse*) could potentially eliminate the risk of serious negative-pressure adverse events such as subgaleal and intracranial hemorrhage.

Unlike what occurred at the time of introduction in clinical practice of the forceps and *ventouse*, the development, testing and introduction into clinical practice of the OdonAssist™ is based on a published and methodologically sound clinical evidence generation plan, built around a sequential approach, with milestones to be achieved before a decision is made to proceed to the next stage[4]. Therefore, the clinical evidence generation plan of the OdonAssist™ is envisaged as a series of sequential and coordinated preclinical and clinical studies to progressively generate the evidence to addresses three major needs in the medical device industry (Table 1):

- define the target product profile and inform product development
- obtain evidence on safety, effectiveness, usability and acceptability to comply with requirements for regulatory approvals
- support marketing and adoption and comply with regulatory requirements for post market surveillance

During product development of a new device, evidence is needed to retire or mitigate any foreseeable risk that could be associated with the use in clinical practice and to validate the design of the device. To achieve these objectives in the development of the OdonAssist™, simulation studies were conducted on a validated birth simulator (PROMPT Flex, Limbs & Things, Bristol, UK) to mitigate the probability of risks related to the positioning of the device on the fetal head, the pressure applied on fetal and maternal anatomical structures and the level of traction force that could be applied when delivering a fetus[5,6].

These studies relied on the course manual and simulator used in the context of the Royal College of Obstetricians and Gynaecologists Operative Birth Simulation Training (ROBuST) and were based on previously validated and published methodology[7]. The studies

Table 1. Clinical Evidence Generation Plan

Product Development	Registration	Postmarket Clinical Follow Up Studies
Bench tests **Animal study** **Simulation studies** **Human Factors studies** **Feasibility study (ASSIST study)**	**Safety and efficacy studies:** ASSIST II study United Kingdom (N=104) ASSIST Besançon study France (N=104)	**Randomized clinical trial:** France (N=740) Funded by French Ministry of Health **Safety and efficacy study:** ASSIST Etiopía (N=104)
Funded by: Saving Lives at Birth BJOG 2017 AJOG 2020	Funded by Gates Foundation Results presented at the *"7th Birth Congress"*, Dec 2022 BMJ Open 2021 AJOG, in press	**Monitored introductions** Clinical audits (N=104) Italy

were conducted at the University of Bristol, Bristol, UK from August to December 2015. The results showed that: 1) the inflatable air cuff sit reliably at the level of the fetal chin and in no cases the cuff was observed to reach and exert pressure on the fetal neck; 2) when used correctly, the OdonAssist™ generated levels of perineal distention during birth comparable to the *ventouse*; 3) the OdonAssist™ generated lower average pressures on a model fetal head during simulated birth than forceps[5,6]. Overall, these tests did not provide any evidence that the contact and pressure of the OdonAssist™ with vulnerable maternal and fetal anatomy was likely to be unsafe. In addition, tests on the birth simulator provided preliminary indications on the feasibility and safety of the OdonAssist™ when a standardized protocol for insertion, inflation and traction was applied[5,6].

In addition to mitigating or retiring foreseeable risks, another major objective of device development is to ensure that the design of the device is reliably safe and effective when used by the intended user population (in this case, obstetricians and midwives), and to validate the instructions for use. Therefore, a series of human factors studies were undertaken to evaluate the usability of the device and the acceptability of the instructions for use. These human factors studies were conducted at multiple locations from March 2016 to March 2017[8] aiming to include doctors and midwives of different geographical and clinical backgrounds. The results of these studies showed that with training and written instructions for use, 100% of doctors and midwives could successfully perform a simulated AVB with the OdonAssist™ [8].

On the basis of the evidence generated by the preclinical and animal studies, the Medicine and Healthcare products Regulatory Agency of the UK (MHRA) granted a non-objection certificate for use of the device in a feasibility trial conducted in Bristol, UK from October 2018 to February 2019[2]. The trial, sponsored by the UK National Health System (NHS), had the objective of validating the design and instructions for use of the OdonAssist™ when used in the intended human population. The study demonstrated that the OdonAssist™ could be successfully used with and without regional anaesthesia, in all occipito-anterior, occipito-transverse & occipito-posterior positions and that it is safe for mothers and infants. Because of its innovative mechanism of action, the OdonAssist™ does not cause typical bruising patterns on the fetal head, as is the case with forceps and *ventouse*. Additionally, satisfaction of both mothers and health professionals with the use of the device has been very high[2,3].

Following the successful completion of the feasibility study, two additional efficacy and safety studies were conducted from August 2019 to June 2021 in Bristol, UK and in Besançon, France. Preliminary results presented at the 7th BIRTH Congress held in Milan, Italy in December 2022, appear to support the previous observations of a very positive newborn safety profile, reduced training requirements, ease of use and high acceptability among women.

The post market phase of the clinical evidence generation plan will be implemented contingent upon regulatory approval of the device for its placement on the market. The main objectives of this phase of the plan are to identify rare side-effects that might not have been observed in premarketing studies and to monitor the occurrence of known side effects as well as to document possible misuses of the device and continually assess its benefit-risk ratio. Currently planned post-marketing studies include a randomized clinical trial comparing the OdonAssist™ to vacuum assisted delivery to be conducted in four hospitals in France and a safety and efficacy study to be implemented in two hospitals in Ethiopia to confirm the performance of the device in a low-resource environment. In addition, several clinical audits will monitor the introduction of the device into obstetric practice in hospitals in Italy and the United Kingdom by collecting safety and efficacy data on each assisted vaginal birth performed with the OdonAssist™ over predefined periods.

Developing and scaling up a health innovation requires several elements to succeed, including generating data to demonstrate safety, clinical utility and acceptability by patients and health providers. The evidence generation plan developed for OdonAssist™ aims at proving solid scientific support to ensure adoption of the device worldwide in compliance with current regulatory, research ethics and health care standards.

Conflict of interest
Mario Merialdi is cofounder, investor and Chief Medical Officer at Maternal Newborn Health Innovations, Public Benefit Corporation (PBC), which holds the rights to the OdonAssist™
Disclaimer: The OdonAssist™ is a product under development by Maternal Newborn Health Innovations, PBC and may not be placed on the market until it has been CE-marked.Disclaimer: The OdonAssist™ is a product under development by Maternal Newborn Health Innovations, PBC and is not currently available for sale.

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