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Assisted vaginal birth with the Odon Device™

Nicolas Mottet^a, Joanna F. Crofts^b, Emily J. Hotton^{b,c}, Astrid Eckman-Lacroix^a and Didier Riethmuller^{a,d}

^aDepartment of Obstetrics and Gynecology, Jean Minjot Hospital, Besançon University Medical Center, Besançon, France; ^bDepartment of Women and Children's Health, Southmead Hospital, Bristol, UK; ^cUniversity of Bristol, Bristol, UK; ^dDepartment of Obstetrics and Gynecology, University Hospital Grenoble Alpes, Grenoble, France

ABSTRACT

The Odon Device™ is an innovative investigational device for assisted vaginal birth (AVB) and has not yet been granted regulatory approval for sale in any country. It is the first innovation in AVB since the introduction of the vacuum extractor in the 1950's and the device is designed for use by different level of trained health care providers. Efficacy studies are presently in progress in two centers: The ASSIST II Study, Bristol, England, and The BESANCON ASSIST Study, Besançon, France. The device consists of an applicator, sleeve and cuff. This original paper illustrates the operating process in real conditions.

ARTICLE HISTORY

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KEYWORDS

Assisted delivery; Odon device; feasibility study

The Odon Device™ is an investigational device and has not yet been granted regulatory approval for sale in any country. It was invented by automotive mechanic Jorge Odon and further developed by a multi-disciplinary group of midwives, obstetricians, engineers and designers [1].

The device consists of an applicator, sleeve and cuff (Figure 1). The applicator (Figure 2(A)) enables to pos-

ition the air cuff over the fetal head, beyond the widest point - to the level of the fetal mouth anteriorly and the nape of the fetal neck posteriorly. The operator then inflates the air cuff to the target pressure (70 kPa) using the hand pump (Figure 2(B)). Once the sleeve is situated over the fetal head, and the air cuff inflated, the applicator is removed (Figure 3). The operator then grasps the handles of the sleeve and



Figure 1. Technical description of the device.

CONTACT Nicolas Mottet  n1mottet@chu-besancon.fr  Service de Gynécologie-Obstétrique, C.H.R.U. de Besançon, Boulevard Alexandre Fleming, Besançon, 25000, France

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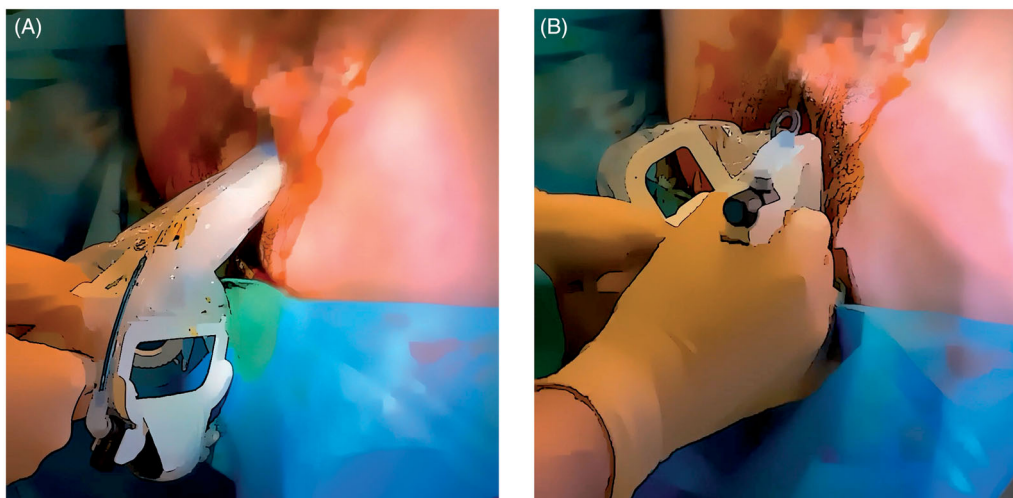


Figure 2. (A) Insertion of the applicator during a contraction. (B) Inflation of the air cuff using the hand pump.

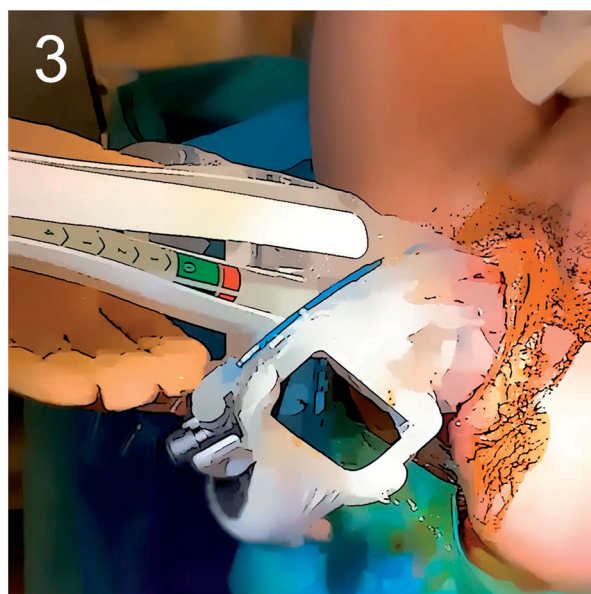


Figure 3. Removal of the applicator.

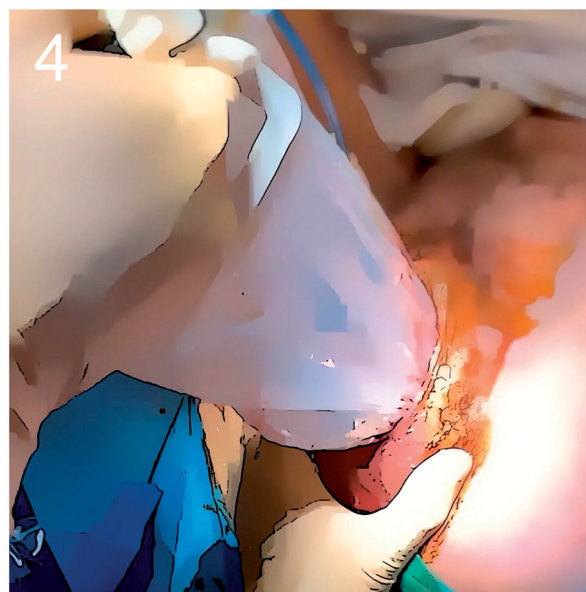


Figure 4. The operator grasps the handles of the sleeve and applies traction during maternal contractions.

applies traction during maternal contractions (Figure 4). Just prior to the crowning of the fetal head, the operator deflates the cuff which spontaneously detaches allowing the operator to continue to assist the birth of the baby (Figure 5). Performances of the device are currently being studied in two studies: The ASSIST II Study, Bristol, England, and The BESANCON ASSIST Study, Besançon, France [2,3].

Disclosure statement

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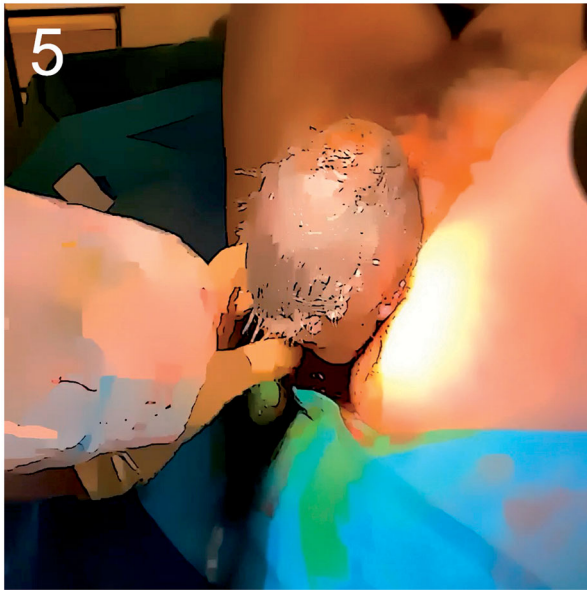


Figure 5. Delivery of the fetal head after deflation of the cuff.

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