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OBSTETRICAL FORCEPS WITH PASSIVE ROTATION AND SENSOR FEEDBACK

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BACKGROUND

An improved tool for operative vaginal delivery can reduce maternal and fetal trauma during the delivery and recovery processes. When a delivery cannot be completed naturally due to maternal exhaustion or fetal distress, physicians must perform an operative vaginal delivery (OVD), with forceps or a vacuum, or a Cesarean section (C-section). Although C-sections are more prevalent in the United States than OVDs, they require longer maternal hospital stays and recovery time and increase risk of maternal infection and fetal breathing problems [1]. In 2015, the American College of Obstetrics and Gynecology pushed to increase the number of OVDs to limit C-section associated delivery risks [2]. However, the current tools for OVD either have steep learning curves, are unable to be used for all fetal head presentations, or have associated maternal and fetal risks [3][4]. There is a need for an easy to use, safe, and reliable tool for operative vaginal delivery.

Current operative delivery devices fall under one of two categories: vacuums and forceps. Vacuums extract the fetus by applying suction to the top of the fetal head, while forceps grip the fetus by the zygomatic arch, the widest dimension of the fetal head. Both OVD devices have associated risks. Vacuums’ localized suction force may lead to internal fetal head trauma, and after multiple breaks in suction (“pop-offs”), delivery must proceed immediately to emergency C-section [6]. Forceps, on the other hand, may be associated with higher order perineal lacerations [5]. Although the forceps’ clamping force may seem dangerous to the fetus, in modern practice, physicians should fully closed and lock forceps, thus not exerting excessive force on the fetus when placed properly [7].

Although forceps have the highest success rate among OVD devices [5], forceps are used less frequently by obstetricians than vacuums, because vacuums are easier to use and can be applied to a wider range of fetal head presentations [6]. The rigidity of traditional forceps, unlike the flexible tube attached to the vacuum, means that they can only be used if the fetus is directly occiput anterior (OA) or occiput posterior (OP), where the fetal head is facing up towards the mother’s abdomen, or down toward the mother’s back. This makes forcep delivery of non-direct OA and OP, as well as occiput transverse (OT), very difficult, if not impossible. This inability to use OVD forceps in all fetal presentations directly reduces forcep usage by physicians despite their better safety record. In order for forceps to be more widely adopted, there is a significant need for forceps that are (1) more physician-friendly to use, and (2) capable of handling more presentations.

To fill this need, we designed forceps with a passively rotating handle to allow delivery of babies in non-direct OA, OP and OT positions, expanding the potential use cases of forceps. In addition to this rotating handle component, we investigated removable sensors to improve the teachability of forceps, reduce forceps misuse, and make physicians feel more comfortable in a high stress environment, mitigating the risk of maternal injury by improving the training and knowledge of best practices.

METHODS

The device was designed to improve the efficacy, ease of use, and safety of operative delivery forceps. The primary functional requirement of the device was to allow passive rotation of the fetal head during vaginal delivery. The device (Fig. 1a) was also designed to be sterilizable, lightweight, easy to use, and easy to learn (with the additional sensing attachment).

The main device can be split into 2 modules: (1) the rotational handle with sterile cover, (2) the blades and their quick-lock connection to the handle (“T”). An optional electronic sensing attachment is also discussed in this paper.
Braun forceps, facilitating two different ergonomic hand positions.

**Forceps Blades and Handle Connection**

The blades and handle-blade connection (“T”) were designed to be as close to existing forceps as possible and allow the obstetrician to easily remove the forceps blades once the OVD is complete. The first goal is accomplished by taking blades from existing standard Simpson-Braun forceps. The second goal is accomplished by using quick-release ball locks. This mechanism allows the blades to be inserted into the vagina one at a time, similar to traditional forceps. Tabs underneath the “T” can be pulled by the physician to quickly detach either blade. This process is shown in Figure 2, with the direction of pull shown by a black arrow. The hexagonal ends of the blades click into the ball locks, and are only released when initiated by the physician.

**Optional Sensing Attachment**

The separate sensing attachment was designed to enhance the physician training process by giving visual real-time feedback during delivery. The sensing attachment is separate from the device, and can be added upon physician’s request during training to provide real-time visual feedback about the force applied to the fetal head, progression of the fetal head (yes, moving/no, stationary), and direction (degrees) that forceps are being used. These feedback parameters were determined by conversations with current obstetricians (ex. inexperienced obstetricians tend to pull straight toward themselves instead of downward, leading to forceps misuse).

There are two modules for the optional sensing attachment: an onboard system directly measuring on the forceps and an offboard system clearly displaying the results to the obstetrician.

The onboard system, shown as a block diagram in Figure 3 consists of a microcontroller connected to an accelerometer and load cell. The load cell directly measures the tension force, while the angle of pitch can be calculated directly from accelerometer readings. In order to measure progression, double integration is performed on filtered accelerometer readings to get an estimate of distance. Although double integration usually results in a quadratic error by time, a very short time window is considered in this case, and a very low accuracy is required. Double integration is only performed from the beginning of a pull to end of pull (as measured by force on the load cell). Once this processing is complete, the microcontroller sends the sensor data via a Bluetooth radio. The offboard system serves as a display. It is comprised of a microcontroller with a Bluetooth radio connected to a 5” screen with an appropriate driver. Both systems are powered by a lithium-ion battery to maintain portability.

**Rotational Handle and Cover**

The rotational handle was designed to naturally rotate as the fetal head moves during vaginal delivery. This is a passive rotation; the forceps are not being used to actively spin or turn the fetus, which would lead to fetal trauma. The handle (Fig. 1b) includes a brass outer housing and steel shoulder bolt. The shoulder bolt connects to the “T” middle section, and turns when the blades turn, as initiated by the fetus. The interface between the bolt and brass housing is low-friction to permit rotation when the forceps are pulled axially during delivery.

The cover provides an ergonomic handle and in future iterations, would provide a watertight seal for sterility. The handle cover was designed to be similar to the grip on Simpson-Braun forceps, facilitating two different ergonomic hand positions.
**RESULTS**

It was critical to limit the torque needed to turn the forceps blades relative to the handle. The following analytical model, Eq. (1a) and (1b), was developed to relate the torque resulting from friction ($\tau_f$) around the major axis of the handle, to the applied force. $r_1$ and $r_2$ are the inner and outer diameters of a concentric ring, respectively, $F$ is the axial load on the forceps, $F_f$ is the resulting friction force, $\mu$ is the dynamic coefficient of friction.

\[
d\tau_f = dF_f L = \mu \frac{F}{4} dA L \quad (1a)
\]

\[
\tau_f = dF_f L = \frac{2\mu F (r_2^4 - r_1^4)}{3(r_2^5 - r_1^5)} \quad (1b)
\]

The worst expected coefficient of friction between brass and steel is 0.35 [8]. The expected torque required to overcome static friction for a 25 lb (111 N) pull on the forceps is 1.38 in-lb (0.156 N-m). Experimental evaluation showed that with a pull of 25 lb (111 N), 0.31 in-lb (0.035 N-m) were required to turn the handle, lower than the projected torque by a factor of 5. This difference can be attributed to uneven distribution of normal force, which lowers the expected value to 1.09 in-lb (0.119 N-m), and the polished surface at the rotational interface, resulting in a lower coefficient of friction.

We determined current delivery simulators were inadequate to assess the usability of the device. In the simulators, models of the fetal head and the vagina are constructed out of rigid plastic, making conventional forceps nearly impossible to use. We constructed a model using an anatomically accurate pelvis, lined with deformable material. Insertion of the forceps and removal of the model fetus was successful with this configuration. Although this testing demonstrated feasibility of the device, it also exposes the necessity for better simulators and training tools in OVD.

Similarly, the optional sensing attachment was found to be sufficiently accurate using constructed models such as a model fetus attached to a spring scale. However, without a more mechanically accurate delivery simulator, further validation of the sensing attachment’s accuracy remains challenging.

**CONCLUSIONS**

The novel forceps were created to deliver non-direct OA/OP and OT presentations, increase safety to the mother, and increase ease of use and learning for physicians, while also maintaining current forceps designs’ high rate of OVD success and safety to the fetus. Preliminary tests have shown that the rotational handle is a low-friction interface which is promising for its success in future OT deliveries. In addition, increased ease of use and learning is addressed with a sensing module. Paired with an appropriate simulator, the sensing module can serve as a valuable teaching tool, as well as provide important information about the best practices of OVD in actual deliveries. Our forceps build on the success of existing forceps designs through the unchanged Simpsons-Braun blade configuration. The modularity of our design allows for the potential of future blade design iterations.

The improved forceps provide an exciting opportunity for safer deliveries for fetuses in OT and non-direct OA and OP presentations. The sensing module has the potential to revolutionize the forcep learning process for residents, while also providing data to analyze best practices for OVD in new ways. By lowering the learning curve for obstetricians and increasing efficacy of forceps, the device can reduce the risks presented to both mother and fetus during the delivery process.

Future work should concentrate on the development of better labor simulators to allow for testing and innovation in OVD devices. Additionally, we believe a sensing attachment for existing forceps could provide a valuable teaching tool as well as information on best practices for delivery, without the testing barriers of a new OVD device. A simulator and sensing device could provide all of the information needed for informed innovation in operative vaginal delivery devices, creating an intermediate step between device design and clinical trials.

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**REFERENCES**


Oct. 2015.


