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A new obstetrical polyurethane versus stainless steel forceps: a comparison of forces generated to the base of the fetal skull during simulated deliveries*

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Abstract

Background: Decreasing the maximum force applied during traction to the base of the fetal skull using a less rigid polyurethane forceps is the basis of this study. Our hypothesis was that less force would be generated with polyurethane forceps than with steel forceps.
Objective: To test a new soft polyurethane obstetrical forceps for maximal force generated to the base of the skull during simulated occiput anterior deliveries and to compare this to a similar shaped steel forceps.
Methods: After designing a prototype polyurethane forceps, we used a pelvic manikin model and a fetal manikin model. Force and load sensors were attached at the inner tips of the distal forceps blade. A Tekscan 201 (accurate for measuring 0–25 pounds of force) 0.0008 inches flexible printed circuit was used that measured contact forces. Forceps with an attached calibrated sensor were applied to the fetal head while inside the pelvic model.
Results: The median maximum traction force at the base of the fetal skull was 4.60 pounds (range 4.3–4.62) for polyurethane forceps vs. 9.52 pounds (range 9.22–9.52) for steel forceps ($P=0.027$).
Conclusion: The polyurethane forceps applied 50% less overall mechanical force than the steel forceps at the tip of the forceps and base of the skull during simulated occiput anterior outlet deliveries.

Keywords: Forceps; polyurethane forceps; vacuum forceps.

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Introduction

Fetal and neonatal injury attributed to forceps delivery can occur, can produce severe morbidity [11], and puts obstetricians and healthcare institutions at medico-legal risk. Injury may be in part due to the combination of rigidity of the forceps and the amount of traction able to be generated by obstetricians. The greatest force on the fetus appears to be at the base of the fetal skull. Although vacuum delivery is more common, there is a risk of severe sub-galeal hemorrhage that can be life threatening [6, 10, 15]. We desired to create a new forceps design that focused on decreasing the likelihood of injury by using less rigid materials and providing a shorter handle so that only one hand may be used, limiting the amount of force possible. We chose polyurethane for the creation of a new forceps because medical grade polyurethane materials are more flexible than steel. Decreasing the pressure to the fetal skull was an important consideration. The comparative flexibility of polyurethane compared to metal allows polyurethane to work like a spring and become more linear (straighten) when the traction on the forceps is increased. The intracranial force able to be generated should thus be limited. Our objective for this study was to compare the forces generated between steel and polyurethane forceps during a simulated delivery using pelvic and fetal manikins.

Materials and methods

Several types of polyurethane were initially tested in the form of bars with different degrees of hardness, flexural (spring) strength, breaking point and loss of geometry (shape). The highest duro-meter designation of hardness was too brittle and was not chosen. Test bar samples of Tecoplast OP-770-000 and Tecothane TT-1075D-M, DuPont Zytel and glass filled Polyamide PA 3200 GF were molded into forceps (Figure 1). The glass filled Polymide PA 3200 GF was chosen and used in the testing in this study.

Flexi force sensors were used to determine the amount of force generated. Flexi-force sensors are ultra-thin and have a flexible printed circuit. The active sensing area is 0.375 inches (9.53 mm) diameter at the end of the sensor. The sensors are constructed of two layers of substrate composed of polyester film. On each layer a conductive material (silver) is applied followed by a layer of pressure sensitive ink. The linearity is defined as the sensor's response (digital output) to the applied load over

Figure 1 The new polyurethane forceps.

the range of the sensor. Error is ±3% and drift was <5%. Sensors were conditioned before calibration and testing, which helps lessen the drift.

After designing the prototype polyurethane forceps [1, 3, 4, 5], force and load sensors were attached at the inner tips of the distal forceps blade. A Tekscan 201 (accurate for measuring 0–25 pounds of force) 0.0008 inches flexible printed circuit was used that measured contact forces. Resistance is measured in piezo-resistance, which is inversely proportional to applied forces. When the force sensors are unloaded the resistance is high. Calibration was done by applying 5 lbs, 10 lbs, and 15 lbs to the sensor and equating this resistance output to the force. We then plotted force vs. conductance (I/R). A linear interpolation was then done between zero and the known calibration loads to determine the actual force range that matched the sensor.

First, we tested the maximum force able to be applied by applying 18–115 pounds of force to the distal tip of the forceps blades manually using a rigid, immovable surface (table-top) while the forceps were outside the pelvic manikin and not on the head of the fetal manikin. We observed the effect on the shape of the forceps blades.

Next, we used a pelvic manikin model and a fetal manikin model [2] for simulated deliveries. Forceps with an attached calibrated sensor were applied to the fetal head while inside the pelvic model. Five real-time recordings were made of simulated deliveries and were recorded on a digital movie program. An 8-bit application was used that was compatible with Microsoft Windows (Techscan ELF) and that was capable of storing force data.

Results

The polyurethane forceps were seen to begin to straighten during the application of maximal force over 18 lbs of torque against a rigid surface and became completely linear at 36 pounds of force outside the pelvis. The steel forceps began to straighten at 64 pounds of force and became completely linear at 115 pounds of force. The forceps we made of Dupont Zytel began to straighten at 42 pounds of force and became completely linear at 78 pounds of force.

The results of force testing are shown in Table 1. The polyurethane forceps median maximum traction force at the base of the fetal skull within the pelvis (distal tip of the forceps) was 4.60 pounds (range 4.3–4.62). The steel forceps median maximum traction force was 9.52 pounds (range 9.22–9.52). This difference was significant by Kruskal-Wallis testing ($P=0.0266$). We were not able to observe straightening of the forceps within the pelvis even with maximum traction.

Table 1 Results of comparative forces generated for polyurethane and steel forceps.

Polyurethane forceps, lbs	Steel forceps, lbs
4.50	9.22
4.61	9.51
4.58	9.52
4.62	9.22
4.30	9.52
4.61	9.52

Discussion

We designed polyurethane forceps that look like any other forceps. The differences are a shorter handle, a larger pivot-locking device, larger shanks and blades that mold more closely to the fetal skull. The polyurethane handle is much shorter and limited to one-hand use, which was designed to limit the applied force. The larger polyurethane pivot-locking device keeps the forceps in better alignment during use. The polyurethane forceps maintained their shape and rigidity during traction with one hand while exerting maximum force in a simulated forceps delivery. Pressure from the maternal pelvis helped maintain the integrity of the shape of the forceps.

The polyurethane blades applied decreased traction force to the unprotected base of the fetal skull during maximum traction compared to steel forceps. This was confirmed by placing calibrated weights on the end of the forceps while outside the pelvic manikin and not on the head of the fetal manikin. During this process, the polyurethane forceps began to straighten at 18 pounds of force, while the steel forceps began to straighten at 64 pounds of force. The forceps made out of Dupont Zytel began to straighten at 42 pounds of force. Even with maximum traction by the obstetrician with the fetus in the manikin pelvis, straightening of the polyurethane forceps did not occur. The steel forceps did not begin to straighten until 64 lbs of pressure and may be overly rigid since no more than 10 pounds of force could be generated to the fetal skull within the maternal pelvis with one-handed traction.

Neonatal and maternal complications associated with assisted vaginal delivery vary according to the instrument used. Steel forceps are associated with facial nerve injury, brachial plexus injury, and intra-ventricular hemorrhage in infants. Steel forceps deliveries can also be associated with massive neonatal cerebellar hemorrhage [6, 10], as well as maternal soft tissue injuries, such as pelvic hematomas, vaginal lacerations, cervical lacerations, vulvar hematomas, third- and fourth-degree perineal tears, anal sphincter damage, urinary retention and postpartum hemorrhage [11]. Although vacuum extraction is less likely to cause maternal injury, it is associated with significant neonatal morbidity, such as sub-galeal hemorrhage [6, 10, 15], cephalohematoma [7, 9], scalp injury [14], jaundice, retinal hemorrhage and intracranial hemorrhage [12]. What might be optimal is a material less hard than steel forceps but still adequate to perform the necessary functions. Decreasing the pressure applied to the fetal skull, the base of the fetal skull, the orbits and the facial nerves and muscles are important considerations [8]. Polyurethane forceps have the potential to address the problems of fetal/neonatal injury and maternal soft tissue injury. We believe the design of these polyurethane forceps should prevent the use of excessive force during delivery, In addition, these forceps provide the potential for less maternal soft tissue trauma due to the relative thinness and better molding of the blades to the fetus we observed compared to steel forceps.

In summary, we have designed and tested a new polyurethane forceps and demonstrated that the force generated at the base of the fetal skull in a manikin model is less than that of steel forceps, suggesting that this new material may have the potential to decrease fetal and maternal injury.

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