Abstract

Devices currently in practice for assisting vaginal childbirths may cause irreversible injury to mother and child, such as hemorrhaging or physical deformation. Traditional methods include use of obstetric forceps or vacuum extraction, which apply concentrated loads to the neonatal head. To improve this, a cylindrical, helically woven extraction device with applicator was fabricated. SolidWorks FEA simulations were performed on a neonatal head for loading conditions corresponding to implementation of the extractor, forceps, and vacuum. The simulations concluded the increased contact area of the extractor reduces the conditions corresponding to implementation of the extractor, forceps, and vacuum.

Introduction

Client Description
Dr. Jay C. Lick, D.O.
• Obstetrician and Gynecologist at Meriter Hospital

Motivation
• 13.4 million assisted vaginal deliveries every year,¹
• a technique used to expedite and achieve vaginal childbirth
• Risks of prolonged labor include neonatal brain trauma, injury, and death to mother and infant²
• Current methods are associated with bruising, laceration, hemorrhaging, and death³

Background
• Infant skull diameter ranges from 9.5 to 13.5 cm⁴
• Indications for assisted vaginal delivery include maternal exhaustion, fetal distress, and preeclampsia
• Current devices apply concentrated loads to neonatal head
• Need a device that uses distributed forces to minimize trauma

Current Methods

Design

Design Specifications
• Decrease radially when lengthened
• No trauma
• Minimal training
• One-time use
• Operate within birth canal⁵
• Less than 2 min application⁶
• 100% successful application
• 75% successful infant delivery

Final Design
• 6.5-9 cm diameter extractor
• Polyurethane-coated nylon and HDPE strips
• Eyelleted or heat-bonded in pairs
• Handle for tightening
• Interior pockets for applicator
• Polypropylene & biocompatible stainless steel applicator

Useability Testing
• 8 test subjects, 4 trials each
• Attempted to remove doll from model birth canal using device
• 5 min training and practice
• Recorded percent of successful attempts and trial time
• Average success rate: 87.5%; Average application time: 17.4 s

Results & Discussion

Usability testing: device meets PDS requirements
• Physical testing: extrapolated to approximate average pressure at 200 N load
• Simulation: smaller principal stresses and deformation for woven extractor
• Does not consider shear forces and idealizes skull as rigid body
• No significant stress concentrations over skull for woven extractor

Testing & Results

Usability Testing
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Physical Testing
• Skull approximated as sphere
• Hanging weights simulate applied pull forces
• Resultant pressures recorded via FSRs
• Pressures vary linearly with applied force (see Graph 1)
• 17% of applied force is transmitted as pressure to head

Simulated Finite Element Analysis
• Assumptions: linearly elastic, homogeneous, and isotropic materials
• Segmented infant CT scans with 3D Slicer
• Skull geometry smoothed and decimated with Geomagic®
• Imported into SolidWorks, thickness ~ 0.029 mm⁷
• Performed SolidWorks FEA Static Simulation:
  • Woven extractor: 34 kPa pressure⁸
  • Forceps: 200 N force⁹
  • Vacuum extractor: 80 kPa suction¹⁰
• FEA Results:

<table>
<thead>
<tr>
<th></th>
<th>Woven</th>
<th>Forceps</th>
<th>Vacuum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Highest Principal Stress (MPa)</td>
<td>0.53</td>
<td>1.11</td>
<td>3.84</td>
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<tr>
<td>Largest Displacement (mm)</td>
<td>0.45</td>
<td>1.00</td>
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</tbody>
</table>

Figure 1. (Left) Forceps, (Center) Vacuum extraction, (Right) Odin Device – in development

Figure 2. Extractor with handle on operator end

Figure 3. (Left) Applicator inside extractor; (Right) Interior pocket

Figure 4. Physical testing set-up

Figure 5. SolidWorks FEA deformation results: (Top) Woven extractor, (Center) Vacuum, (Bottom) Forceps

Conclusions

Through SolidWorks FEA simulation, it was determined that the woven extractor causes less stress and displacement to the fetal skull than current devices. Additionally, the woven extractor did not cause any considerable stress concentrations in the facial region. Usability testing verified that the design meets the product design specifications.

Future Work

• Characterize geometric variability of woven extractor (strip number, width, diameter) and effect on force distribution
• Modify design for manufacturability
• Submit journal manuscript for publication
• Complete clinical trials for design validation, and assess safety and effectiveness

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References


