Docket #: S23-250

Ultrasound Heat Therapy Device for Preventing Perineal Tears During Labor and Delivery

Of the 1.4 million first time mothers giving vaginal birth in the United States, approximately 75% will experience tearing of their vagina or perineum. During labor, the pelvic floor stretches to accommodate fetal passage, and overstretching of this relatively inelastic tissue can result in tearing and permanent injury. Up to 7% of mothers will experience the most severe form of tears, where the laceration extends from the vaginal opening all the way to the anus and rectum, damaging the underlying tissues. These severe injuries require comprehensive repair, and put patients at increased risk of post-partum complications such as infections, wound dehiscence, and pain. Patients with severe tears are also more likely to experience long term sequelae of their injuries including incontinence, prolapse, and dyspareunia. These result in ongoing follow-up visits, out of pocket costs, and in some cases additional surgical procedures. The prevention of perineal trauma during childbirth remains a significant concern for maternal health.

Evidence suggests that applying heat to the perineal area can potentially reduce the risk of trauma by increasing tissue elasticity and blood flow. However, current methods for delivering this heat, such as conductive heating pads or compresses, present challenges in achieving safe and effective temperatures. Conductive heat can easily lead to burns, especially in the sensitive perineal region of patients that are often under anesthesia. Most available equipment is not designed to provide the consistent, controlled heat necessary to induce beneficial changes at the tissue level. The development of an ultrasound-based heating device specifically for the perineum offers a promising solution to these challenges. By using ultrasound technology, heat can be applied more precisely and safely, reducing the risk of burns while delivering the optimal temperature needed to increase tissue elasticity and potentially lower the risk of perineal tears. This approach combines both safety

and effectiveness, addressing the usability gaps in current heating methods and providing a novel intervention for childbirth-related perineal trauma prevention.

Inventors at Stanford have developed a handheld therapeutic device that uses ultrasound energy to heat the tissues of the perineum. The device consists of a reusable ultrasound unit with a single use disposable gel pad which will be exchanged between patients and can be easily replaced if soiled. The energy from the device improves pelvic floor elasticity by 1) changing the viscoelastic properties of the underlying tissue at a precisely controlled depth, 2) stimulating blood flow to improve tissue's resistance to tearing, and 3) inhibiting neural pathways that lead to over-contraction of the pelvic muscles during the delivery. The device provides a low-cost therapeutic solution that ensures sterility, patient comfort, and ease of use at the bedside.

Stage of Development
Proof of Concept - The device is at the proof-of-concept stage. Existing literature supports the efficacy of heat in reducing perineal trauma, and we have successfully demonstrated that our ultrasound technology can safely heat tissues at the required depth without causing burns. This establishes a strong foundation for the device's potential in preventing perineal tears during childbirth. Further development is focused on optimizing the device for clinical use.

Applications

- Perineal trauma
- Maternal health
- OB/GYN
- Labor and Delivery
- Medical device
- Therapeutic ultrasound

Advantages

- No existing commercial solutions aimed at reducing perineal tears during delivery

- Precise control of heat delivery: precision targeting and controlled temperature that ensures an optimal temperature at deeper tissues without overheating the skin
- Non-invasive and safe
- Portable and user-friendly design

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