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Atraumatic Cervical Canal Access: Preclinical Evaluation of CerAMvix Self-Expanding Nitinol Stent and Integrated Optical Navigation System

Abstract:

Statement of the Problem: Every gynecological procedure requiring uterine access begins with cervical dilatation, yet current methods remain outdated and traumatic. Globally, approximately 100 million women annually undergo painful cervical dilatation, with risks of perforation (1.7%), hemorrhage (6.9%), and cervical laceration (11%). Pain is the leading cause of failure in office hysteroscopy, accounting for up to 84% of failures. Cervical stenosis affects 33% of women, further increasing the risk of procedural failure.

Study Objective: To evaluate the safety, deployment characteristics, and visualization capabilities of CerAMvix, a self-expanding nitinol cervical stent/os-finder, and CerAMvix Smart, an integrated optical dilator, using ex vivo human tissue and high-fidelity 3D models.

Design: A preclinical validation study utilizing ex vivo human uterine tissue and 3D-reconstructed human cervical models (GyneSim™) designed to replicate human cervical geometry and tissue elasticity.

Setting: A multi-center preclinical evaluation involving ten independent hospitals and private surgical centers.

Interventions: Surgeons performed cervical access and dilation procedures using the CerAMvix system. Performance was measured against standard surgical endpoints.

Measurements and Main Results: CerAMvix achieved successful cervical canal dilation to 210 mm in 100% of cases (95% CI: 72–100%). Atraumatic traversal of the cervical external os was consistently achieved without the need for traditional mechanical force. The system provided an unobstructed passageway for hysteroscopes in all trials. The average procedure time was 7.8 minutes (95% CI: 6.9–8.7 minutes), encompassing deployment, visualization, dilation, and retrieval. Notably, there were zero device-related complications, including tissue tearing or cervical obstruction.

Conclusion & Significance: The CerAMvix system offers a reproducible, atraumatic, and visually guided alternative to traditional mechanical dilation. By providing reliable access to the uterine cavity, this system demonstrates strong potential for reducing procedural trauma while improving procedural efficiency.

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Biography: Dr. Roxana Belciu-Kerns has over 25 years of clinical expertise as a surgeon and anesthesiologist, including more than 15 years of experience in women's health and gynecology. She is a lead innovator with 12 patents filed and 3 granted through the USPTO, EPO, and CN.

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