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Librata™ - A Fully Hand-Held Endometrial Ablation Device: Proof Of Concept Using Extirpated Human Uteri

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Study Objective: Evaluate a new endometrial ablation device using the extirpated uterine model. This study evaluated: 1) the feasibility of using a completely hand-held endometrial ablation device, 2) the intrauterine cavity ablation profile and characteristics (predictors of efficacy) and 3) the proximity of the ablation to the uterine serosa (safety parameter).
Design: Clinical feasibility study.
Setting: International gynecology practice.
Patients: Thirty women previously scheduled for a benign hysterectomy were consented for study.
Intervention: The extirpated uteri were treated with a single endometrial ablation procedure that utilizes four sequential 33 second 150°C glycerin cycles (treatment time 132 seconds) inside an endometrial balloon deployed from a 5.4 mm outer diameter device. The resultant endomyometrial ablations were evaluated using macroscopic TTC viability staining.
Measurements and Main Results: The uteri were efficiently treated with no treatment-associated myometrial perforations or serosal thermal injury. The corpus, bilateral cornua, and lower uterine segment endometrial cavity surfaces and underlying myometrium were thermally ablated (TTC-negative staining, non-viable). No TTC-negative lower endocervical or exocervical thermal injury was identified.
Conclusion: The Librata is a fully hand-held device that 1) replicates the historically optimized ablation profile of hyperthermic devices; 2) has excellent cavity coverage with contoured full thickness endometrial ablation; 3) provides thermal ablation in a clinically appropriate time frame; and 4) has an acceptable safety profile for future *in vivo* clinical studies.

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Microablative Fractional CO_2 Laser for Vulvovaginal Atrophy in Women With a History of Breast Cancer

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Study Objective: To assess the efficacy and safety of microablative fractional CO_2 laser in the treatment of women with a history of breast cancer (BC) reporting vulvo-vaginal atrophy (VVA)-related symptoms.
Design: Prospective cohort study.
Setting: University teaching hospital.
Patients: Patients with a history of BC reporting symptoms of VVA (vaginal dryness, vaginal burning, vaginal itching, dyspareunia and dysuria).
Intervention: All patients included in the study were treated intravaginally with the fractional microablative CO_2 laser system (SmartXide2 V2LR, Monalisa Touch, DEKA, Florence, Italy). A treatment cycle included 5 laser applications (every 4 weeks). The procedure was per- formed in the outpatient clinic and did not require any specific preparation (e.g. analgesia/anesthesia).
Measurements and Main Results: The primary outcome of the study was to assess the rate of satisfied patients at 20-week follow up. Secondary outcomes were: 1) effects of the laser treatment on VVA symptoms; 2) changes in vaginal health index (VHI); 3) changes in overall quality of life (QoL) assessed using the Short Form 12 (SF-12); 4) changes in overall sexual function assessed using the Female Sexual Function Index (FSFI).
Forty women with a history of BC were prospectively enrolled in this cohort study. All patients completed the 20-week follow-up. Satisfaction with the laser procedure was reported by 31 women (77.5%). At 20- week follow-up, CO_2 laser treatment was effective to improve VVA symptoms ($p<0.001$), VHI score ($p<0.001$), QoL scores ($p<0.001$), as well as FSFI scores ($p<0.001$). No adverse events were recorded during the study period.
Conclusion: A 20-week treatment with the fractional CO_2 laser was efficacious and safe in inducing a significant improvement of VVA symptoms by ameliorating vaginal health in women with a history of breast cancer. In addition, it was associated with a significant improvement of sexual function and satisfaction with sexual life.

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The Use of a Closable Polyurethane Bag for Power Morcellation

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Study Objective: The aim of the study was to establish a new way of in-bag power morcellation with reduced risk of tissue and fluid loss into the abdominal cavity during the process of morcellation and the bag extraction.
Design: Case series
Setting: Community Hospital Dormagen, Germany
Patients: Nine patients presented in our hospital for a laparoscopic supracervical hysterectomy (SCH). Eight patients complained of abnormal uterine bleeding, one patient was scheduled for a combined prolapse correction procedure including SCH.
Intervention: We carried out nine laparoscopic supracervical hysterectomies. After the uterine body was cut from the cervix, it was placed into a modified polyurethane extraction bag. Additionally to the already existing opening of the bag, two other incisions were integrated into its upper side to allow the insertion of a morcellator and a grasper. Additional strings were integrated into these two openings to allow a tight closure to prevent tissue and fluid loss during the morcellation and bag extraction. All surgeries were carried out via three abdominal incisions, we used both a 12 mm and a 15 mm morcellator.
Measurements and Main Results: No intraoperative complications and no bag ruptures occurred. The mean time requirement to insert the bag into the abdomen, place the specimen into the bag and adjust the trocars was 14 min (range, 8-19 min). The mean specimen weight was 196.6 g (range, 32-710 g). Mean morcellation time was 10 min (range, 3-28 min), mean weight of remaining tissue and fluid in the bag after the morcellation was 12.3 g (range, 7-19 g).
Conclusion: We describe the first morcellation bag which allows a tight closure during the morcellation as well as bag extraction. Since some fluid and small tissue particles still remain in the bag after the morcellation, this measure may reduce the risk of parasitic myomas and malignancy spread. This promising method should be evaluated in further studies.

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Review and Outcomes of Power Morcellation Using an Innovative Contained Bag System

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Study Objective: To assess feasibility of an innovative method of power morcellation within a specimen bag.
Design: Retrospective Chart Review.
Setting: Data was collected from a specialty practice in suburban Chicago.
Patients: The study included patients who underwent power morcellation during a laparoscopic or robotic-assisted hysterectomy or myomectomy from May 2014 through March 2015. Exclusion criteria were known uterine malignancy or successful specimen removal without morcellation.
Intervention: The procedure was performed using the Espiner EcoSac 230. The bag was inserted through the umbilical port and the specimen placed inside. The cinched bag edge was pulled out through a 15mm umbilical