

## 1-3 YEARS FOLLOW UP WITH ENDOFAST RELIANT™ SYSTEM – SINGLE INCISION ATTACHMENT OF VAGINAL MESH FOR PELVIC ORGAN PROLAPSE REPAIR

### Hypothesis / aims of study

The use of mesh reinforcement in repair of pelvic organ prolapse (POP) with various surgical kits has become popular in the last few years, and its efficacy has been mainly proven to reduce recurrent cytocele (1). The first used kits, based on trocar assisted mesh positioning. Those steps with potential injury to nearby structures led to development of new concept - direct fixation of the mesh without the need of blind trocar passage. Very few studies are available for one year followup of this new concept (2,3). Endofast Reliant system was developed for mesh attachment into soft tissue, using four soft- tissue stainless steel fasteners, as previously described (3). The aim of this study was to evaluate prospectively more than one year follow up of patients who underwent prolapse repair with EndoFast Reliant™ system in one center.

### Study design, materials and methods

From March 2009 an ongoing prospective audit is carried out in 80 women with anterior and/or posterior POP, who underwent vaginal mesh reinforcement with Endofast Reliant System. All patients had preoperative evaluation including physical examination (Baden Walker system) and urogynecological evaluation based on local German questionnaires. At follow-up the patients were examined at the clinic yearly and underwent physical examination and the same urogynecological evaluation. For the purpose of this audit the medical and surgical history were collected and also any further intervention needed since surgery. For statistical analysis we used SPSS software.

### Results

At the last followup 80 patients reached 1 -3 years since surgery (mean: 17 months, range: 12-36 month). 65 (81%) patients had anterior mesh implant, 16 (19%) patients had posterior mesh implant. 28 (35%) had previous prolapse surgery and 10 (12.5%) had previous incontinence surgery. There were no intra-operative complications, and up to discharge no major complications were observed. During follow up period 3 cases (3.8%) of mesh erosion were noted, that were removed at the office. Six fasteners could be felt in the vagina at 3 months and later disappeared, apart from one case of a fastener that was felt in the rectum and was removed surgically. Eleven cases of de – novo SUI occurred (13.8%), of whom one was treated with Bulkamid and 10 had mid urethral sling.

Three patients needed recurrent surgery for recurrent prolapse (3.8%) during follow up period – one case in the contra-lateral compartment and two cases in the same compartment. Prolapse signs improved significantly (anatomical failure defined as  $\geq$  Grade 2) for cystocele (87.6% to 3.8%), rectocele (15.1% to 0%) and uterine / vault prolapse (34.2% to 6.2%). Over active bladder symptoms (as frequency and nocturia) improved significantly, and pad use was also reduced. No chronic pains were induced by the procedure.

### Interpretation of results

EndoFast Reliant™ system was found to be safe and efficacious procedure for up to 3 years. We suggest that the high incidence of de novo stress incontinence (13.8%) should be discussed with the patients for possible prophylactic surgery.

### References

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2. Moore RD, Mitchell GK, Miklos JR Single-incision vaginal approach to treat cystocele and vault prolapse with an anterior wall mesh anchored apically to the sacrospinous ligaments. Int Urogynecol J. 2012 Jan;23(1):85-91.
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### Disclosures

**Funding:** No funding **Clinical Trial:** No **Subjects:** HUMAN **Ethics not Req'd:** It was an audit of a surgical procedure that is performed routinely for the last 3 years in this center. **Helsinki:** No **Helsinki not Req'd:** This was a summary of an audit without the need to get permission of the local Helsinki committee. **Informed Consent:** No