BILATERAL ILIOCOCCYGEUS FIXATION FOR VAGINAL VAULT PROLAPSE USING THE DIGITAL NEEDLE DRIVER (DND) DEVICE

Aims of study
To evaluate the feasibility, efficacy, and safety of a new suturing device; the Digital Needle Driver, during iliococcygeus fixation (ICF) for vaginal vault prolapse repair.

Methods
Sixteen patients underwent bilateral iliococcygeus fixation using the Digital Needle Driver device. This device was designed to facilitate suture placement during vaginal surgery. It has a “thimble” containing a surgical needle and a cartridge preloaded with suture material (polydioxanone no. 0) connected by a flexible cable to an operating mechanism. Preoperatively, all patients underwent a standardized urogynecologic review, prolapse quality of life questionnaire, complete physical and site-specific vaginal examinations in the left lateral position using a Sim’s speculum during a Valsalva manoeuvre. All patients had symptomatic vault prolapse or enterocele more than grade 1. The prolapse was graded using the standardized International Continence Society (ICS) scoring system for pelvic organ prolapse. All patients underwent preoperative urodynamic evaluation with prolapse reduction to identify incontinence or voiding difficulty. The outcome measures were the feasibility of the procedure, the time needed, intraoperative and postoperative complications, the improvement in prolapse-associated symptoms and vaginal examination results.

Results
The mean age of the patients was 64.6 ± 5.2 years (range 53-72), the median parity was 2 (range 1-6) and the mean body mass index (kg/m2) was 23.9 ± 2.7 (range 20.4-30.4). All the patients were postmenopausal, and seven patients, (43.7%) used hormone replacement therapy. Thirteen patients (81.2%) had previous hysterectomy (six vaginal hysterectomy and seven abdominal hysterectomy), nine (56.2%) had previous prolapse surgery and 7 (43.7%) had a previous Burch colposuspension. In the first two cases, the suture placement was satisfactory in only one pelvic sidewall. After modification of the device, all the other cases were successful. Relocation of the suture was required in four cases when there was a doubt of the position or anchorage of the sutures. The mean time for ICF using the DND device was 18.8 ± 11.2 minutes (range 7-45). In ten patients the procedure was accomplished in less than 15 minutes. In addition to ICF three patients underwent vaginal hysterectomy, fourteen posterior repairs, seven anterior repairs and five TVT. In nine cases a prolene mesh was used to support the vault. The mean blood loss per surgical procedure was 264 ± 225 ml (range 80-1000) except for one patient who bled more than 1000 cc. The mean hospitalization was 4.6 ± 1.2 days. Postoperatively, one patient had mesh erosion, one had a vaginal infection and three patients had temporary voiding difficulty. At 2-months postoperative evaluation none of the patient had prolapse symptoms (p<0.001). There was a statistically significant improvement in all prolapse POP-Q measurements (p<0.001). None of the patients had vault prolapse or enterocele greater than grade 1. The mean total vaginal length was shorter postoperatively (7.8 ± 1.0 cm vs. 6.6 ± 1.4 cm, p<0.001) although the vaginal hiatus width and perineal body length were not significantly different.

Conclusions
The use of DND device significantly facilitates the vaginal approach for vaginal vault prolapse repair with good short-term results.