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EVALUATION OF THE SAFETY AND EFFICACY OF PELVIC ORGAN PROLAPSE REPAIR USING SURELIFT® SYSTEM – PRELIMINARY RESULTS

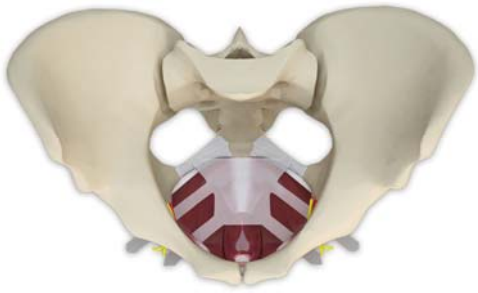
Kaplan, E., Center for Advanced Gynecology Sgy. Walnut Creek, CA.

Hypothesis / aims of the study

Pelvic organ prolapse (POP) is a disorder that may have significant impact on pelvic organ function and quality of life. Though various surgical techniques and modifications have been proposed, surgical treatment of POP has yet been exposed to failure and re-operations. The use of synthetic implant materials in pelvic reconstructive surgery has increased considerably in recent years. Two new concepts: 6 points of fixation and special tissue anchors to attach the mesh to the sacrospinous ligament are presumed to decrease surgical failure. However, clinical efficacy and safety remain uncertain. The objective of the study is to evaluate the efficacy and safety of POP repair using the SURELIFT system.

Study design, materials and methods

A prospective study was conducted between January and November 2009, a total of 76 women with symptoms attributed to POP and the condition-specific POP quantification stage (POP-Q)≥II, underwent surgical repair using SURELIFT(Neomedic International, Spain) . Primary endpoint was objective cure rate after 12 months of operation based on POP-Q system. Other outcome measures were urodynamic parameters, symptom questionnaire of Pelvic Floor Distress Inventory (PFDI) (2), and patients' satisfaction. An objective cure was defined as POP-Q stage 0, improvement as stage I. Failure was defined as stage II or greater. Adverse events during follow-up were also evaluated.



Results

Median age was 66.4 (range 49-75), median parity 2.6 (range 1-5), mean body mass index 26.3±2,9. I present preliminary results at median follow-up of 7 months (2-13). Both anterior and posterior meshes were used in 52 patients (68.4%), an isolated anterior mesh in 18 patients (23.7%) and an isolated posterior mesh in 6 patients (7.9%). Concomitant procedures were Readjustable Sling (TRT) in 53 women (69.7%), posterior colporrhaphy in 5 (6.6%), and hysterectomy in 6 (7.9%). 92.8% of the anterior vaginal wall prolapses, 84.5% of the posterior vaginal wall prolapses, and 78% of the apical prolapses were cured. No patient is considered failure.

Pre- and post-operative maximum flow rate and post-void residual were not different. 76 (100%) of the women were satisfied with the operation. There was no bladder or rectal perforation during the procedure.

During the follow up period, two patients (2.6%) suffered from mesh exposure of less than 1 sq. cm. Both cases were excised on an ambulatory basis.

Concluding message

The POP repair using the SURELIFT® system seems to be effective in terms of objective and subjective assessments with no significant complications.