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BETTER CLINICAL OUTCOME BY MODIFYING THE TREATMENT WITH TILOOP TIFOUR TITANIUM COATED EXTRALIGHT MESH FOR VAGINAL VAULT PROLAPSE

Hypothesis / aims of study

To assess the clinical efficacy of TiLOOP TiFour titanium coated extralight mesh in the treatment of vaginal vault prolapse in two operation techniques of fixation of posterior mesh arms. The posterior mesh arms are fixed in one group with helical needles near os ischii and the other group placed with an reusable suture device (RSD-Ney) through the sacrospinal ligamanet. The modifying treatment by the RSD that allow for safe, simple and precise mesh placement in the sacrospinous ligament through a single vaginal incision

Study design, materials and methods

The study group consisted of 76 women (mean age 82 years) who underwent vaginal cuff prolapse surgery with TiLOOP TiFour titanized extralight meshes (helical needle treatment - n=30; RSD treatment - n=36) between January 2009 and February 2010. 76 patients had vaginal cuff prolapse POP-Q stage IV and 34 patients--POP-Q stage III with a subjective feeling of prolapse. 63 patients were diagnosed with stress urinary incontinence and 27 with mixed incontinence. Bladder emptying difficultis were present in 61 cases and chronic infection in 61 patients as well.

Results

All patients which accounted for 100% of the total study group were available for follow up visits after 6 and 9 months. Only 4 patients had recurrence of cystocoele but to a much lesser extent than POP-Q stage II. This gives an efficacy of 94% in terms of anatomical restoration of the prolapse. Most patients were completely satisfied with the surgical outcome.
However, the following complications were encountered among our study group:
5 x Post operative stress incontinence or de-novo urge syndrome
1 x Severe pelvic pain causing difficulty with walking and moving (helical treatment)
3 x Dyspareunia (helical treatment)
1 x Dyspareunia (RSD treatment)
2 x Vaginal Erosion of the material (helical treatment)

Concluding message

We can conclude from this study that titanium coated extralight meshes (TiLOOP - TiFour) offer superior outcomes for reconstructive treatment of vaginal vault prolapse. We reduce typical complications like dyspareunia and chronic pelvic pain by modifying treatment of precise mesh placement in the sacrospinous ligament through a single vaginal incision.

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**ethic commitee catholic church thuine - 34/2009**
Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**ethic commitee catholic church thuine - 34/2009**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**