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SURGICAL OUTCOMES WITH A SINGLE MESH KIT FOR FEMALE GENITAL PROLAPSE.

Hypothesis / aims of study

Reports of complications of a single synthetic mesh surgical repair kit for female pelvic organ prolapse is submitted in this abstract. We report experience and clinical management of complications in an initial study group.

Study design, materials and methods

Patients undergoing anterior, posterior, or combined anterior and posterior repair of pelvic organ prolapse by a vaginal approach and with the use of synthetic mesh material were prospectively enrolled into an IRB approved database. This abstract specifically focuses on a single mesh kit which has been in use since June of 2009. Outcomes of surgery are reported, managed, and outcomes followed. Failure was defined as recurrent prolapse of zero or greater POPQ score in any previously repaired vaginal segment.

Results

A total of 66 patients underwent surgical repair of prolapse. 32 underwent anterior repair, 24 posterior repair, and 10 combined anterior and posterior repair. Follow up ranged from 2 to 23 months with a mean follow up of 12 months. Average pre-operative POP-Q points are as stated in table 1. Three patients (4.5%) experienced failure defined as recurrent prolapse with POPQ of zero or greater value. Two patients (3%) experienced mesh exposure which was repaired successfully. All mesh exposures occurred at the posterior fourchette. Average time to exposure was 5.5 months. 24 of 66 (36%) patients were sexually active and 42 of 66 (64%) were not sexually active pre-operatively. Of the sexually active patients three complained of post-operative dyspareunia. Two cases of dyspareunia were secondary to mesh exposure and resolved following excision of the exposed segment. The third patient's dyspareunia persists but she rates her discomfort as mild and remains very pleased with the overall outcome. Overall satisfaction of surgical outcome is reported in table 2. One patient developed new onset posterior prolapse after undergoing anterior repair. There were no kit associated complications, specifically hollow organ, vascular, or nerve injury.

Table 1:
Average pre-operative POP-Q score

Segment Repaired	A	B	C/D
Anterior	+2	+5	-4
Posterior	+1	+4	-5
Both	+2, 0	+5, +2	-2

Table 2:
Patient Self Reported Satisfaction
Post Operative

Very Happy	56
Happy	8
Mixed	2
Unhappy	0

Interpretation of results

We present the prospective outcomes of a single surgical mesh kit which has excellent results with a mean follow up of 12 months. The 3 failures in this series were at the apex. 2 of 3 patients had undergone combined anterior and posterior repair, one patient anterior repair only. All three patients remain pleased with current outcome and have not opted for repeat repair. 2 of 3 failures were by POPQ criteria only and the patients would not have been aware had they not been prospectively followed and examined per protocol. Time to failure was 4, 8, and 9 months (mean 7 months). The mesh exposure rate is lower than most other published series (1,2). Exposure was only seen in those undergoing posterior repair and were category 2 or 3 BcT3S1 of the ICS/IUGA complication classification codes . Modification of technique at perineoplasty will likely eliminate these occurrences.

Concluding message

This mesh product proves clinically effective, safe, and with good patient satisfaction with mean 12 month follow up.

References

1. Neurourol Urodyn. 2011 Mar;30(3):384-9. doi: 10.1002/nau.20956. Epub 2010 Nov 11.
2. Eur J Obstet Gynecol Reprod Biol. 2011 Feb 28

Specify source of funding or grant	**None**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**

Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Unviersity of Florida Institutional Review Board-03**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**