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BEYOND THE COMPLICATIONS: MEDIUM TERM ANATOMICAL, SEXUAL AND FUNCTIONAL OUTCOMES FOLLOWING REMOVAL OF PROLIFT.

Hypothesis / aims of study
The transobturator mesh kit procedures, including the Prolift, Perigee and Avaulta, have become an established option for prolapse surgery with many surgeon choosing to use these devices for both primary and secondary prolapse surgery. The use of these devices is unfortunately associated with well described complications. The problems of post-operative dyspareunia, vaginal pain and erosion are now well described but there remains very little literature on the outcomes following intervention for these complications. The aims of this study were to assess the anatomical, sexual and functional outcomes of women undergoing repeat surgical intervention for complications associated with the insertion of the Prolift mesh kit.

Study design, materials and methods
We recruited women undergoing a re-intervention following the Prolift total vaginal mesh procedure. The indications for re-intervention included dyspareunia, mesh erosion, urinary retention, mesh contraction and prolapse recurrence. As part of the pre-operative work up we recorded the patients symptoms including a history of prolapse, stress incontinence, urgency, defaecatory difficulty and digitation. We also recorded whether the women were sexually active and if they had any symptoms of dyspareunia. We also recorded the pre-operative POP-Q score. A number of surgical interventions of variable combinations were performed on the cohort depending on the indication and the anatomical findings. Since most of the problems were related to the anterior prolift device, this was removed in the majority of cases. Following removal of the mesh, we felt these women were at an increased risk for a recurrence and various procedures were performed to address this including re-attachment of the vaginal apex to the top of the posterior prolift, insertion of a porcine subintestinal submucosal graft (surgisisSIS) and vaginal hysterectomy. Subjects were followed up at 6 weeks, 6 and 12 months for resolution or persistence of pre-operative symptoms, any new prolapse, stress incontinence, urgency and sexual symptoms. The examination and POP-Q were repeated at each visit.

Results
Nineteen women were recruited to our study and underwent re-intervention following insertion of a Prolift. The mean interval between the primary and repeat surgery was 129 weeks (Range 34-247, SD +/-61). The primary surgery included Anterior Prolift in all 19 cases, Posterior Prolift in 14 (73%), TVT-O in 1(5%), and vaginal hysterectomy in 2 (10.5%). Indications for repeat surgery included dyspareunia in 13 women (68%), mesh erosion in 5 (26%), urinary retention in 1 (5%) and mesh contraction in 5 (26%). There was significant overlap between the cases regarding the indications for re-intervention. The surgical re-intervention procedure included removal of the anterior prolift in 17 (90%) of the 19 women. Re-attachment of the vaginal apex to the top of the posterior prolift was done in 6 (31%) and in 16 (84%) a SurgiSIS graft was used to bolster the anterior compartment. women. Five (26%) of the women had a vaginal hysterectomy. There were no intra-operative bladder or bowel injuries. Mean intra-operative blood loss was 127ml (range 50-200, SD+/- 60). Sixteen women were seen at 6 week follow up and none of these had a complaint of prolapse. There were no additional cases of erosion. None of the women had commenced sexual activity. To date, only 12 women have reached the six month follow up but of none of these patients had a complaint of prolapse. Seven of the 12 women are sexually active and in 6 cases the dyspareunia has resolved completely with one women retaining an element of pain at intercourse. Only 7 women have been seen for a 12 month assessment and again none of these have any symptoms of prolapse and all four of the sexually active women are completely free of dyspareunia.

Parameter	**Pre-op (n=19)**	**6 weeks (N=16)**	**6 months (N=12)**	**12 months (n=7)**
Prolapse symptoms	9 (47%)	0	0	0
Stress Incontinence	1 (5.3%)	1 (5%)	2(10%)	0
Urgency	1(5.3%)	0	0	0
Sexually active	14	0	7	4
Dyspareunia	13	0	1	0
Aa >-1	5 (26%)	0	0	0
Ba>-1	5 (26%)	0	1 (5%)	2(10%)
Ap>-1	2 (10%)	1(5%)	2 (10%)	1 (5%)
Bp>-1	4 (21%)	1 (5%)	2 (10%)	0
C>-1	6(32%)	0	1 (5%)	0

*p<0.05, **p<0.001

Interpretation of results
Re-operation following prolapse surgery is always a challenging operation. The surgeon has to contend with the increased adhesions and unclear tissue planes. In addition, the long term outcomes of the surgery on the prolapse also needs to be

considered and addressed. In our small cohort of 19 women undergoing repeat surgery following a complicated Prolift operation, we have demonstrated good anatomical and functional outcomes. Dyspareunia following mesh kit surgery is a distressing symptom which we feel can and should be addressed surgically. Although there is no data to guide us on the use of prophylactic xenograft insertion at the time of Prolift removal, we have demonstrated excellent outcomes using this technique in this very small cohort.

Concluding message

We have demonstrated good anatomical, sexual and functional outcomes in our small cohort of women presenting with a complication of a Prolift total vaginal mesh kit. Since large numbers of these operations are being performed worldwide, further studies should focus on developing guidelines as to the management of the complications. Furthermore, we are in urgent need of data regarding the risk of prolapse recurrence following removal of the Prolift and need for additional prophylactic interventions.

References

1. . Hurtado EA, Appell RA.. Int Urogynecol J Pelvic Floor Dysfunct. 2009 Jan;20(1):11-7. Epub 2008 Sep 20.

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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	**Stichting Zorgsaam Board**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**