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SURGICAL RE-INTERVENTION AFTER PROLIFT ® MESH REPAIR FOR PELVIC ORGAN PROLAPSE: A 4 YEAR RETROSPECTIVE COHORT STUDY.

Hypothesis / aims of study Mesh kits are increasingly being used in surgery for pelvic organ prolapse (1). As new procedures, they require monitoring of outcome to assess their safety and effectiveness (2). A number of studies reported low operative morbidity and short term results (3) little work has been carried out on operative re-intervention. One study described repeat surgery in a series of 13 patients but this was restricted to mesh complications after Apogee ® and/or Perigee ® mesh repair (1). No similar work has been carried out in relation to Prolift ®.
The aim of this study was to explore the nature and rate of surgical re-intervention after Prolift ® mesh repair for pelvic organ prolapse.
Study design, materials and methods This was a retrospective cohort study that included all the patients who had Prolift ® mesh repair for pelvic organ prolapse at a tertiary unit between 2005 and 2008. Patient data were obtained from hospital notes and patients were telephoned to check if they had surgery in other hospitals. Operative re-interventions for complications, recurrence of prolapse, both direct and indirect, as well as continence were included.
Results A total of 589 cases were identified and all notes were available. Attempts were made to contact patients by phone to check if they had surgery in other units and 481 (81.7%) were contacted, of whom only 3 (0.6%) had surgery in other hospitals. Background and operative features of all patients, alongside the P value for any difference between those who were available for telephone interview and those who were not, are shown in table 1. Significantly more patients had previous prolapse surgery as well as concomitant prolapse surgery at the time of having Prolift® mesh repair and longer duration of follow up in the group that was not possible to contact. The nature and distribution of subsequent operative re-intervention are shown in table 2. A comparison of those who had surgical re-intervention and those who did not is shown in table 3.

Feature / description test	**Result**	**P value (comparative test)**
Age (years) / Median [interquartile range]	63 [57-72]	P > 0.05 (Mann Whitney test)
Parity / Median [interquartile range]	2 [2-3]	P > 0.05 (Mann Whitney test)
Follow up duration (months) / Median [interquartile range]	34 [22-45]	**P < 0.01** (Mann Whitney test)
Previous hysterectomy / No. (%)	130 (22.1%)	P > 0.05 (X^2)
Previous prolapse surgery / No. (%)	115 (19.5%)	**P 0.01** (X^2)
Previous continence surgery / No. (%)	83 (14.1%)	P > 0.05 (X^2)
Type of prolift ® mesh used / No. (%) - Anterior - Posterior - Anterior and posterior - Total	 - 55 (9.3%) - 114 (19.4%) - 347 (58.91%) - 73 (12.4%)	P > 0.05 (X^2)
Concomitant surgery / No. (%) - Prolapse - Continence - Hysterectomy	281 (47.7%) - 84 (14.3%) - 212 (36%) - 52 (8.8%)	**P < 0.05** (X^2) **- P < 0.05** - P > 0.05 - P > 0.05
Complications / No. (%) - Visceral injuries - Bleeding / haematoma - Mesh erosion - Vaginal adhesions	 - 4 (0.7%) - 5 (0.8%) - 20 (3.4%) - 2 (0.3%)	P > 0.05 (X^2)

Table 1: Background features of the cohort and comparison of those who were available for telephone interview and those who were not.

Indication and type of re-intervention	**First operation**	**Second operation**	**Third operation**	**Total**
Prolift® complication - Excision of mesh exposure / erosion - Division of vaginal adhesions - Haematoma - Colostomy / closure - Mesh retraction	20* (3.4%) - 15** (2.5%) - 2 (0.3%) - 2 (0.3%) - 1 (0.2%) - 0 (0%)	5 (0.8%) - 3 (0.5%) - 0 (0%) - 0 (0%) - 1 (0.2%) - 0 (0%)	1 (0.2%) - 0 (0%) - 0 (0%) - 0 (0%) - 0 (0%) - 1 (0.2%)	26 (4.4%) - 16 (2.7%) - 2 (0.3%) - 2 (0.3%) - 1 (0.2%) - 1 (0.2%)
Prolapse surgery - Direct recurrence - Indirect recurrence + SCP + SSF + Prolift® mesh + VH / trachelectomy	17 (2.9%) - 0 (0%) - 17 (2.9%) + 4 (0.7%) + 3 (0.5%) + 6 (1%) + 7 (1.2%)	2 (0.3%) - 1 (0.2%) - 1 (0.2%) + 1 (0.2%) + 0 (0%) + 1 (0.2%) + 0 (0%)	0 (0%) - 0 (0%) - 0 (0%) + (0%) + (0%) + (0%) + (0%)	19 (3.2%) - 1 (0.2%) - 18 (3.1%) + 5 (0.8%) + 3 (0.5%) + 7 (1.2%) + 7 (1.2%)

Continence (Tape) complication	9 (1.5%)	2 (0.3%)	0 (0%)	11 (1.9%)
Continence operation	29 (4.9%)	5 (0.8%)	0 (0%)	34 (5.8%)
Total	71 (12.1%)	14 (2.4%)	1 (0.2%)	71 (12.1%)

*1 urethrolysis & ** 1 intravesical erosion required laparotomy.
SCP: sacrocolpopexy, SSF, sacropsinous fixation, VH: vaginal hysterectomy.
Table 2: Type, rate and order of subsequent surgical re-intervention.

Feature	**P value (Mann Whitney Test)**
Age (years)	P > 0.05
Parity	P > 0.05
Previous hysterectomy	P > 0.05
Previous prolapse surgery	P > 0.05
Previous continence surgery	P > 0.05
Type of prolift ® mesh used	P > 0.05
Concomitant surgery - Prolapse - Continence - Hysterectomy	 - P > 0.05 - P > 0.05 - P > 0.05
Complications	**P < 0.01**
Follow up duration	P > 0.05
Recurrence	**P < 0.05**

Table 3: Association between surgical re-intervention and background, operative and post-operative features.

Interpretation of results One in 8 patients having Prolift® mesh repair may end up having one further surgical intervention, 1 in 40 may have 2 operations and 1 in 500 hundred may require a third surgical intervention. However, not all of these re-interventions are due to Prolift® mesh repair, as some of them cane to deal with de novo stress incontinence or a complication of a continence procedure carried out at the time of Prolift® mesh repair. Nonetheless, mesh related complications remain the largest single indication for repeat surgery after Prolift® mesh repair. Likewise, surgery for indirect prolapse recurrence is far more frequently needed than surgery for direct pelvic organ prolapse, which calls for addressing all pelvic floor defects at the time of primary surgery. The only 2 factors that were significantly associated with surgical re-intervention were recurrence and more so complications. These findings should be considered within the limitations of this retrospective unselected cohort from a large tertiary unit with a heavy work load.
Concluding message Prolift® mesh repair is associated with a relatively low re-intervention rate, which is significantly related to complications and recurrence.

References

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Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require ethics committee approval because	**A retrospective study looking into the outcome of surgery actually carried out as part of routine day to day practice.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**