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PROSPECTIVE MULTICENTRE OBSERVATIONAL TRIAL OF COMPOSITE POLYGLACTIN / POLYPROPYLENE MESH (VYPRO* MESH) FOR RECONSTRUCTION OF RECURRENT ANTERIOR VAGINAL WALL PROLAPSE

Hypothesis / aims of study

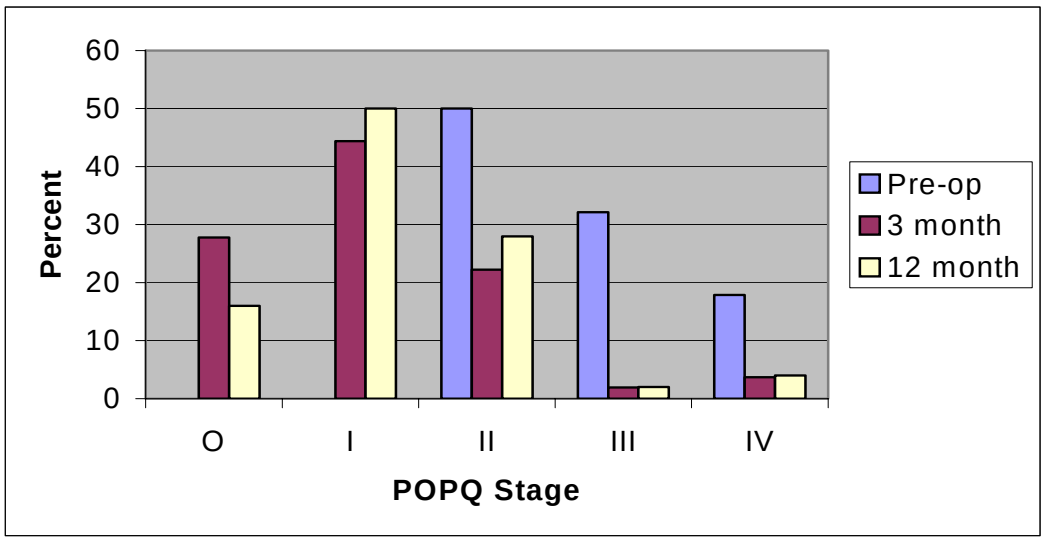
Recurrence rates following traditional reconstructive vaginal surgery are high [1]. This has resulted in the increased use of prosthetic and biological mesh grafts in cases of recurrent prolapse and when the quality of autologous connective tissue is felt to be poor. However there remains a lack of published outcome data relating to the use of such materials, particularly with respect to Quality of Life (QoL), despite their increased uptake in clinical practice. The aim of this study was to establish the safety, handling characteristics, erosion rate and clinical efficacy of a polyglactin / polypropylene mesh (Vypro* mesh™).

Study design, materials and methods

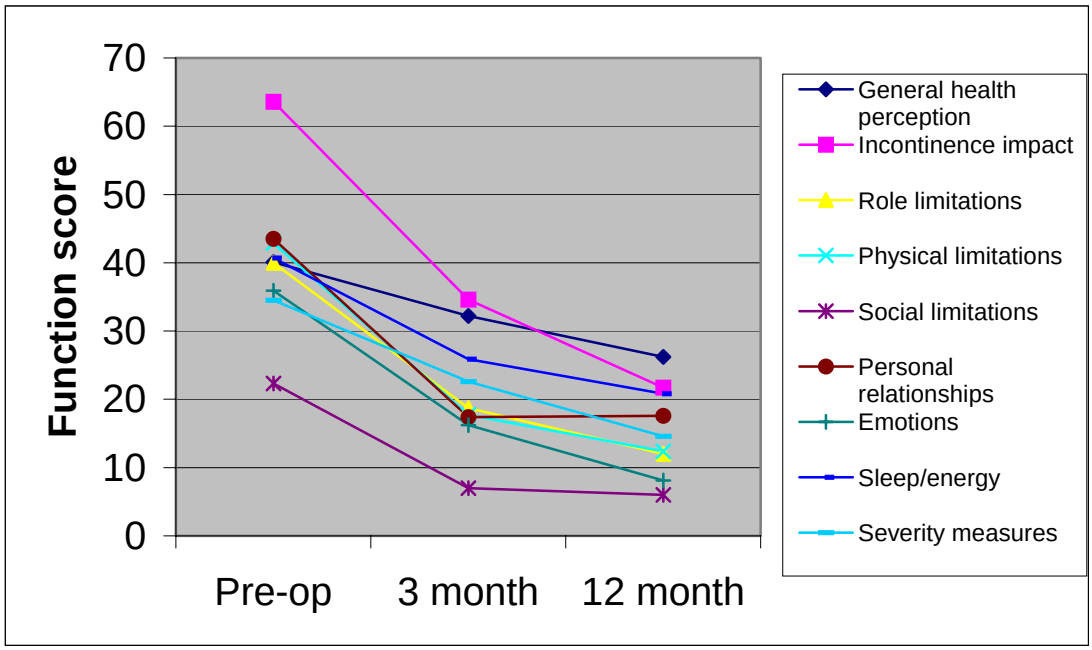
57 women (mean age=64.6years) awaiting surgery for a recurrent, isolated anterior vaginal prolapse were recruited from seven European tertiary referral centres, and followed up at 3 and 12 months. Pre-operative assessment included supine and erect subjective prolapse grading, POP-Q measurement, and a comprehensive Quality of Life evaluation using the King's Health Questionnaire (KHQ), Prolapse QoL Questionnaire (P-QoL) and a standardised interview related to sexual activity. Surgery was performed using a vaginal approach. The anterior vaginal wall defect was identified and reduced using fascial plication sutures. The polyglactin/polypropylene mesh was inserted and fixed without tension at the site of the defect. Surgeons were asked to score the mesh for various 'desirable' handling characteristics on a 5-point Likert scale. Subjective assessment, POP-Q, QoL assessment, and an examination for mesh erosion were repeated at 3 and 12 months.

Results

55/57 women were available for 3 month follow-up and 52 women completed the study (91%). An overall assessment of mesh handling at the time of surgery was rated as 'good' or better in 77.2% (44/57, 95% CI 64.8%-86.2%) of cases, with the highest score for 'mesh visibility' and lowest for 'mesh moulding'. There was a significant reduction in the positions of points Aa and Ba found at 3 months, which was still present at 12 months. There was no significant difference in any of the other POP-Q parameters, indicating no adverse changes in vaginal length or posterior wall support as a result of surgery. Using POPQ ordinal stages (0 – IV): Pre-operatively all patients were staged as II or greater. At 3 months 72.2% women were staged as 0-I, falling to 66.0% at 12 months. Of the 17 patients stage II or greater at 12 months, 7/10 had a recurrence of prolapse symptoms, while 10/17 were asymptomatic.



All QoL domains of the KHQ showed an improvement at 3 months and a further improvement at 12 months. Pre-operation, 38.6% of patients were sexually active. This fell to 27.3% at 3 months, rising to 47.1% at 12 months. Women reported that the original prolapse detracted from the enjoyment of sexual activity in 59.1% of cases, whilst the subsequent surgical repair detracted in 26.7% of cases at 3 months and 16.7% at 12 months.



Mesh erosion was observed in 7.3% of women at 3 months and there were no further erosions detected up to 12 months. All erosions observed were into the vagina and were resolved by mesh trimming and over-suturing. There were no bowel or bladder erosions and no serious adverse functional impairment at 12 months.

Interpretation of results

Vypro* mesh performs well when assessed against 'ideal' mesh handling properties. Improvements in POPQ stage as a result of reconstructive surgery are well maintained up to 12 months and this is associated with a universal enhancement of QoL domain scores. The rate of mesh erosion and recurrence of symptomatic and anatomical anterior vaginal wall prolapse is comparable to other published series describing prosthetic mesh repairs [2,3]. A significant improvement in sexual activity rates 12 months after surgery (38.6% vs 47.1%) and a universal improvement in QoL domain scores, even amongst patients with mesh erosions (7.3%) was observed. Longer-term follow-up is necessary to assess the ongoing rate of prolapse recurrence.

Concluding message

Vypro* mesh™ demonstrates good handling properties, satisfactory medium term efficacy and an erosion rate comparable with other prosthetic materials for use in reconstructive surgery. The improvement in patient-centred outcome measures is encouraging.

1. Obstet Gynecol 1997; 89: 501
2. J Reprod Med. 2005; 50(2):75-80.
3. BJOG. 2005; 112(1):107-11.

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