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THE SAFETY AN EFFICACY OF BIOLOGICAL MESH KITS FOR PELVIC ORGAN PROLAPSE REPAIR.

Hypothesis / aims of study

A prospective study to evaluate the short term safety and efficacy of the Apogee with Intexen and Perigee with InteXen biological mesh kits for the repair of pelvic organ prolapse.

Study design, materials and methods

All women implanted with Apogee with Intexen or Perigee with InteXen between September 2007 and February 2009 were included. Women with either recurrent prolapse POPQ stage 2 or more or with primary prolapse POPQ stage 3 or more were offered vaginal mesh repair. Data on demograhics, intra operative and post operative complications was collected. Intra operative haemorrhage was defined as blood loss >500ml. Women were reviewed at 6 to 12 weeks postoperatively and examined following ICS POPQ examination guidelines. Surgical success was defined as a POPQ stage of 0 or 1. Ongoing follow up at 6 monthly intervals is continuing.

Results

Mean age was 57.8(31-84), mean parity was 2.66(1-7) and mean BMI was 25.5(18.26-38.1). 27 Perigee and 25 Apogee with InteXen meshes were implanted in 40 patients. Concomitant surgery included, sacrospinous fixation 11/40(27.5%), sub urethral sling procedure 9/40(22.5%), vaginal hysterectomy 5/40(12.5%), anterior or posterior colporrhaphy 11/40(27.5%) and Perigee with IntePro Lite 12/40(30%). 1 patient had an intra operative haemorrhage, 1 patient developed an intra operative retropubic haematoma and required a blood transfusion. There were no bladder, bowel or neurological complications and no patients returned to theatre postoperatively. At 3 month follow up there were no cases of groin or buttock pain or denovo dyspareunia. 1/40(2.5%) patient developed denovo stress urinary incontinence, 1/40 (2.5%) patient developed a small mesh extrusion which was managed conservatively and healed without complication.

At 6 to 12 week follow up, 26/27 (96%) patients with Perigee with Intexen had a POPQ stage of 0 or 1 in the anterior compartment, 1/27 (4.0%) had a POPQ stage of 2 and was asymptomatic. 24/25 (96%) of patients implanted with Apogee with InteXen had a POPQ stage of 0 or 1in the apical and posterior compartments, whilst 1/25(4%) had a POPQ stage of 2. 12/12(100%) of patients implanted with Perigee with Intepro had a POPQ stage of 0 or 1.

Interpretation of results

Mesh extrusion rates of between 7 and 13% have been reported with type 1 polypropylene mesh implants, the mesh extrusion rate of 2.5% in our study is low and the short term anatomical success rates in line with success rates of permanent polypropylene meshes. InteXen is a non cross linked porcine dermis which is reabsorbed slowly over a period of 6 months; this may be an advantage particularly in younger sexually active women where implantation of a permanent mesh would be inappropriate in the light of very limited long term data.

Concluding message

Initial short term results suggest that biological mesh kits are safe and efficacious with fewer complications than polypropylene meshes. Follow up of patients is ongoing.

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What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
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Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**