

FOLLOW UP OF THE EFFECT OF PORCINE DERMAL SLING (PELVICOL®) IN THE TREATMENT OF STRESS URINARY INCONTINENCE.

Hypothesis / aims of study

Evaluation of the effect of the porcine dermal sling in the treatment of stress urinary incontinence in 33 consecutive patients during 3 years.

Study design, materials and methods

Retrospective analysis of the results of 33 patients with urodynamically proven stress urinary incontinence who underwent Pelvicol® sling implantation.

Technique: Prior to surgery a Pelvicol® sling of 1.5 cm x 10 cm is prepared. On both lateral sides a monofilament synthetic absorbable suture (PDS®) is fixated, using an atraumatic needle. The anterior vaginal wall is incised lengthwise. Thereafter a para-urethral dissection towards the endopelvic fascia is made. A small suprapubic incision towards the level of the fascia anterior is made. The sling is then pulled through using a vertical positioning device. The sling is positioned and fixed midurethrally; the PDS® sutures are knotted on the fascia anterior.

Postoperatively there is a chance that urinary retention or residual volumes develop, so the procedure was only done when patients learned how to perform clean intermittent self-catheterisation, and when they agreed to do so postoperatively if necessary.

Results

We analyzed 33 women, operated between 2003-2006. Mean age was 52 years (range 27-78). 26 (78.9%) of them had stress urinary incontinence, urodynamic. 7 (21.1%) of them had mixed urinary incontinence.

17 Patients were dry after the initial procedure (52%).

3 Patients had an improvement of 70% (reduction of incontinence material and subjective improvement) and were satisfied, requesting no further treatment (9%).

4 Patients developed de novo urge incontinence (12%). 1 Patient had a bladder augmentation for this, the others were treated with anti-muscarinics.

3 Patients developed de novo overactive bladder, dry (9%).

6 Procedures failed to relieve the incontinence (18%): of these 5 patients were treated with a polypropylene retropubic tape, 1 was treated with bulking material.

In the whole group, 13 patients need some degree of clean intermittent self catheterisation (39.4%).

6 Patients experienced a sudden decline in effect 3-6 months after surgery (18%).

Interpretation of results

The indication for Pelvicol® sling procedure is intrinsic sphincter deficiency (ISD) or mixed urinary incontinence (MUI). In the former Pelvicol® is indicated because it increases the MUCP when a "tight bio sling procedure" is performed, in the latter it is used to avoid additional irritative complaints by performing a "tension free procedure".

Four out of 7 patients with MUI did worse after the initial procedure. Mean MUCP in these patients was 68.7 cm H₂O. Although the procedure was performed tension-free, they nevertheless developed more irritative symptoms in a way that it worsened their situation.

MUCP of patients with ISD was 39.8 cm H₂O.

The failures in the group with SUI are due to sudden failures or occur gradually.

A sudden decline in effect can have several causes.

It is most likely due to an acute failure of the sling; the soluble PDS® sutures may have absorbed too quickly or may have been torn out of the sling. This results in a sudden loss of the midurethral support.

An other explanation is provided by literature where autolysis of bio slings has been described [1].

We examined resected bio slings of patients who came for subsequent treatment and found various results. In some patients we found no porcine material at all anymore, in others the sling was intact and surrounded by a granulomatous reactive tissue. In other patients the sling has been replaced by fibro muscular tissue.

Autolysis results in a sudden decline of effect when the sling breaks; when there is not enough fibromuscular tissue formation there will be a gradual worsening of the situation.

Concluding message

Pelvicol® slings are effective in the treatment of urinary incontinence and the indications of SUI and MUI still stand. Patients with MUI do have more chance to be worse afterwards, also after a tension-free procedure.

The postoperative result is partially mechanical-related (strength of suture, of sling), partially patient-related (body's reaction to the sling placement).

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HUMAN SUBJECTS: This study did not need ethical approval because it is a retrospective study about postoperative results but followed the Declaration of Helsinki Informed consent was not obtained from the patients.