Long term safety and efficacy assessment of the polypropylene mesh Sacromesh®

in the treatment of pelvic organ prolapse by sacrocolpopexy

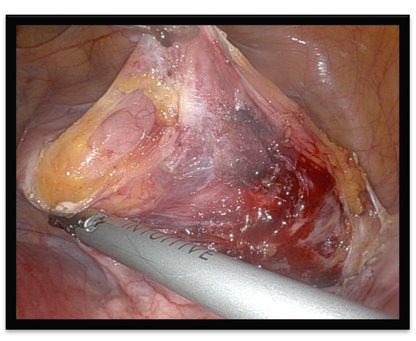
M. Schaller[1], S. Benelmir[1], M. Homa[2], R. Ramanah[1]

[1]Besancon University Medical Centre, Besancon, France

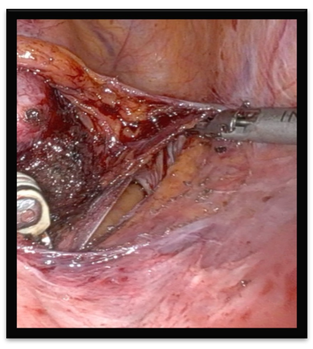
[2]Cousin Biotech, France

Objective of the study

- Sacrocolpopexy has become the treatment of choice for pelvic organ prolapse
- Purpose of this study is to assess the **safety** and **efficacy** of propylene mesh (Sacromesh®) in the long term follow-up



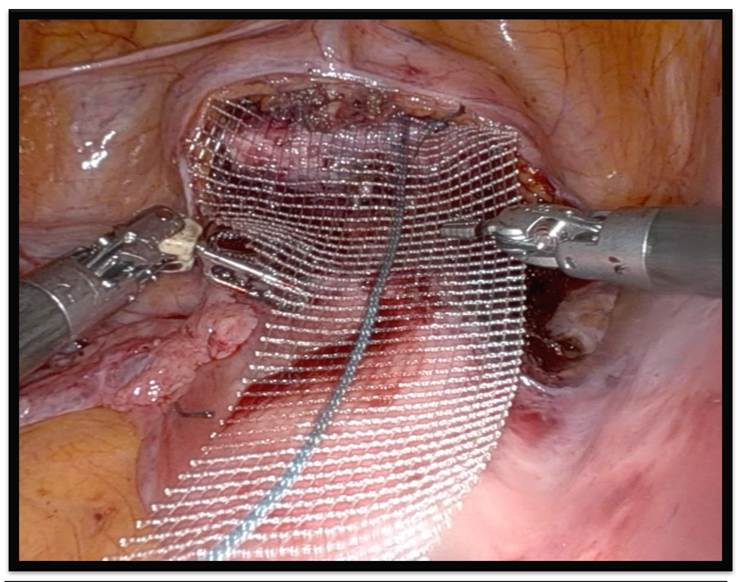
Pic. 1 *– Dissection of the space between the bladder and the vagina*



Pic. 2 *– Fenestration of the broad ligament in order to allow the mesh to stretch to the sacrum*

Materiel & methods

Between 2009 and 2023, an **open-label multi-centered observational study** was conducted to investigate patients' treatment and functional outcome, to collect any complications following the placement of Sacromesh®, and to assess real-life use of the mesh. Pre-operative, operative and short term post-operative data was collected retrospectively from patients' medical files while long term post-operative efficacy and quality of life data were collected prospectively. The primary endpoint for evaluating efficacy was the rate of re-intervention and safety was assessed by the rate of complications.



Pic. 3 *– Positioning the mesh on the anterior part of the vagina and fixing it on the top.*

Results

A total of 290 women were enrolled in the study with a mean follow-up of 5.9 ± 2.7 years, a mean age of 62.0 ± 9.5 years, a mean Body Mass Index (BMI) of 25.0 ± 3.7. Most patients (95.8%) had sacrocolpopexy for a cystocele-predominant prolapse.

Thirty-one patients (10.9%) required reinterventions (Fig. 1) : 4.9% for de novo Stress Urinary Incontinence (SUI), 1.8% for prolapse recurrence, 1% for pain, 0.7% for vaginal erosion, 0.3% for bowel obstruction, 0.3% for sigmoid fistula and 0.3% for mesh infection. Of these complications, **only 3 surgical reinterventions were directly related to the mesh** and led to total mesh removal. Post-operative mean PFIQ-7 score was found to be 14.03 ± 24.7 (scale from 0 to 100), mean PFDI-20 score was e 53.53 ± 50.17 (scale from 0 to 300). Postoperative pain was assessed through a Visual Analogy Scale (VAS) with a mean score of 1.86 ± 7.39. No deaths or device deficiencies or Unanticipated Serious Device Effects (USADEs) were reported in the course of study follow-up.

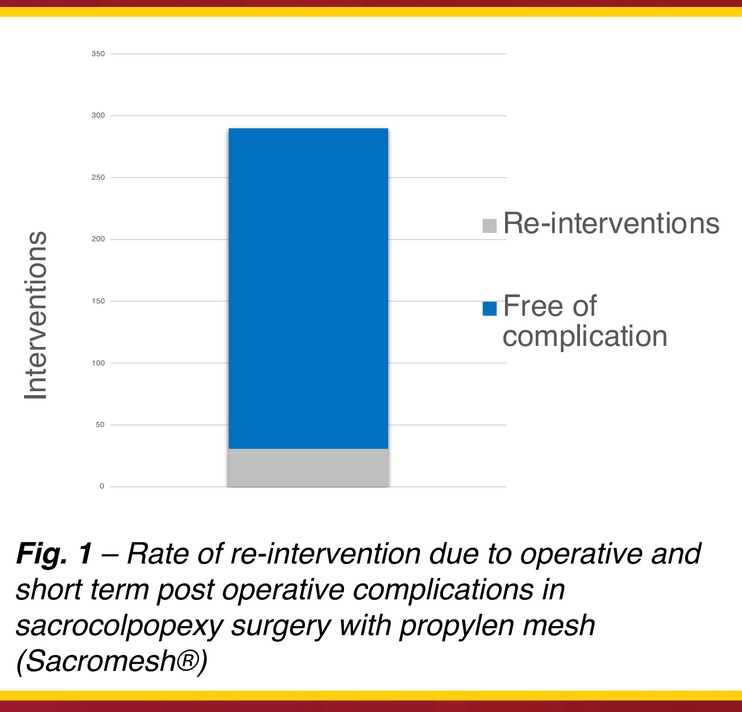


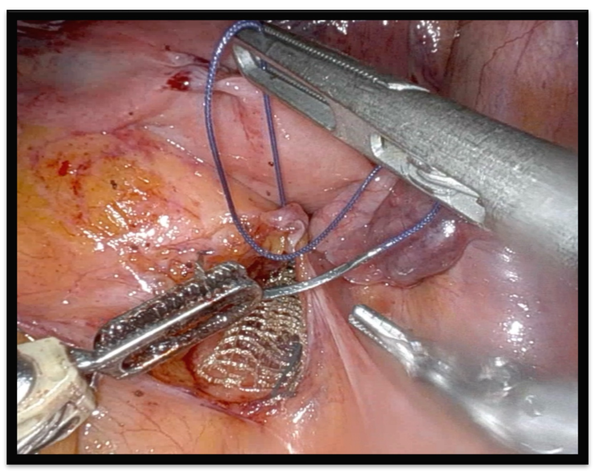
Fig. 1 *– Rate of re-intervention due to operative and short term post operative complications in sacrocolpopexy surgery with propylen mesh (Sacromesh®)*

290 women enrolled

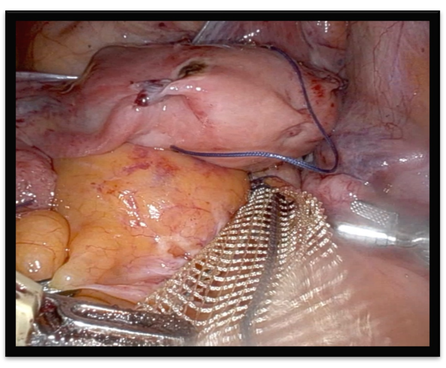
Conclusion

This study confirms the beneficial outcome of the treatment of prolapse by sacrocolpopexy with the Sacromesh® in terms of :

- Reinforcement and support of tissues
- Effectiveness of prolapse repair
- Reduction of POP recurrence
- Optimized patient confort
- Benefit/risk balance



Pic. 4 *– Covering it with peritoneum*



Pic. 5 *– Pulling the mesh and fixing it to the sacrum*