1241

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ANATOMOPATHOLOGICAL CLINICAL RESULTS IN PATIENTS WITH SURGERY WITH PROLENE-MONOCRYL HYBRID MESH (ULTRAPRO ETHICON) FOR TOTAL PROLAPSE

Hypothesis / aims of study

Results obtained using pure polypropylene meshes (Prolene) for vaginal prolapse surgery had shown an important percentage (more than 60% in our series) of patients with vaginal functional and anatomic disorders by abnormal healing of the tissue where the mesh was included. As this was thought to be related with a "healing reaction excess" due to "graft excess", we thought to place a material containing lower graft load and thus a lower and more physiological tissular reaction. Ultrapro Ethicon is a mesh formed by two strands, being Prolene the first and Monocryl the other one. The last one is reabsorbed in an estimated timeframe of 90 – 120 days and the graft remains with very lower final weight and total surface with a spongy surface 50% higher to those left by Prolene but preserving a permanent definitive structure because a lower amount of polypropylene included. The Ultrapro Ethicon mesh is softer and more elastic when handled than Prolene mesh simply by visual and mechanical comparison and this is related with the Monocryl strand. This lead us to define as work hypothesis that placing this mesh would cause a better "healing result"; therefore we decided to perform an histological clinical trial on patients operated with this mesh and to compare them with a group of patients operated with J&J's total Prolift mesh.

Study design, materials and methods

Applied research, comparative, prospective, observational, longitudinal, controlled trial performed on four patients with surgery for total prolapse (grade III and IV) with prolapse correction using TVM technique (Total Prolift System type) but including ULTRAPRO ETHICON mesh. Patients underwent surgery between February 3rd and December 1st 2009 and they were carefully clinically monitored and later a biopsy was performed in the mesh inclusion area to perform the histopathological study of the healing tissue. These results were compared with a group with similar pre-surgical features who underwent surgery with a pure polypropylene mesh. This was a head-to-head analysis on these two groups of patients and was performed by the same gynecologist and the same pathologist. (Biopsies and the last observational analysis were performed in the last week of March 2010). The same surgeon performed the surgery on all patients. H-E was the histological technique used. At this stage of the trial we did not perform IHC which is starting to be assessed on a new group.

Results

This four patients undergoing surgery with Ultrapro mesh showed an appropriate resolution of their prolapse in their progression and at the completion of the observational period with a very good uterine suspension. Subjectively the patients were considered as cured. At the progression and at the completion of the analysis they did not show: referred healing stiffness in their vagina or dyspareunia or any pelvic pain. We did not see any erosion. The physical exam of the patients showed a very appropriate uterine suspension (point C: mean -4 -5); in two cases we have asymptomatic residual cystocele POP-Q grade II. Paradoxically, in these two patients point D was larger (-6). IN NO PATIENT IS PALPATED THE CORD which is normally palpated in most patients operated with pure polypropylene and which is located in the pre-cervical zone of the anterior vaginal wall (posterior edge of the body of the mesh). The subjective interpretation about vaginal elasticity (by vaginal examination) is very much higher in the group who underwent surgery with Ultrapro and it is consistent with the subjective references from patients. Histological studies (AP) of biopsies from this group in relation with those who underwent surgery with polypropylene clearly show: a significant lower local inflammatory reaction; lower foreign body reaction; lower granuloma; and "better arranged and physiological" healing reaction. These AP evidences are consistent with obtained clinical results.

Interpretation of results

Analysis of the results of this small group of patients seem to show that the new Prolene and Monocryl hybrid mesh will allow better functional and more anatomical results, and will give us a significant solution to the pain issue. The waited report of the trial in 11 sites which was presented at launching by Michael Cosson in IUGA 2009 (Como-Italy) in patients undergoing surgery with this mesh will finally enlighten about it and we think it will open a new way in this surgeries in relation with materials, remaining to be assessed and discussed the better methodology for anchoring the ideal material.

Concluding message

In this task-force we think that the new Prolene Monocryl hybrid mesh is the one we should use without any doubt and until industry progress give us a superior material. We still think as we previously reported that an internal local anchorage without needle use will be very superior, safer and it will allow us to have more control over other issues that nowadays this technique has, such as vascular-neural injuries and their sequelae components on the sacrospinous ligament area and the fascia of the obturator internus in the sciatic spine area. We do not leave the analysis of the possibility to place the mesh without fixation such as in the first stages of surgeries which trigger the TVM technique; however, although a very novel proposal (Gynecare Prosima de J&J) the possibility of a fold in the material if it has no fixation in clear remark points does not allow us to be satisfied with this idea up to day.

References

1. Dr. Enrique Ubbertazi. Hospital Italiano Buenos Aires

Specify source of funding or grant	**Private. Personal**
Is this a clinical trial?	**Yes**

Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**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	**common usage of the product**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**