

**PROSPECTIVE RANDOMIZED EVALUATION OF A NEW COMPOSITE MESH (4DDOME®) AS COMPARED TO A CONVENTIONAL MESH (PERFIXPLUG®) :
A ONE YEAR CLINICAL EVALUATION**

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Objectives :

Conventional inguinal hernia repair necessitates the use of mesh implants that guarantee low recurrence rates but may be involved in postoperative pain and discomfort, hence altering quality of life. Low density and partially absorbable biomaterials are intended to limit adverse healing reactions partially at the origin of some undesirable effects. Combination of light polypropylene (10%) with PLLA (90%) was used to obtain a dome-shaped and partially absorbable prosthesis (4DDome®); Cousin Biotech, France) which was compared to a 100% polypropylene standard inguinal prosthesis (Perfixplug®, Bard).

Patients and methods :

80 male patients (mean age 60, extremes 25 to 91) presenting with a non-recurrent inguinal hernia were prospectively and randomly included. The surgical techniques performed were identical in both groups of patients. The patients were followed-up for a period of 1 year. Complications, recurrence, chronic pain, inguinal discomfort (VAS-visual analog scale) and return to personal activities were assessed. P considered as significant if <0.05.

Results :

Inguinal hernia repair was performed using the Dome mesh in 41 patients and using the Plug prosthesis in 39 patients. Preoperative pain evaluation, length of surgery, and postoperative in-hospital stay (2 days; extremes 0-2) were similar in both groups. Postoperative pain and discomfort were similar (p=ns) at postoperative day 1, 8, and 30. Half of the patients had a one-year follow-up (19 vs.26). Pain was lower at 6 and 12 months in the Dome group but the result was not significant (at 6 months : 0.22 vs. 0.46; and at 12 months : 0.18 vs 0.27). Discomfort was lower in the Dome group at 6 months (0.18 vs. 0.80, p=0.047) and at 12 months (0.05 vs. 0.30 ;p=0.6). Minor complications were observed in the Plug group (1 hematoma, 4 edema vs. none in the Dome group (p=0.015). At 1 month, one inflammatory testis was noted in the Plug group. Return to personal or professional activities was comparable in both groups. One recurrence was noted in the Plug group (p=ns).

Conclusions :

The use of a composite and partially absorbable prosthesis (4DDome®) offers comparable or slightly better results than with a conventional polypropylene prosthesis. Late pain and discomfort seems lower with the composite mesh. This may be explained by the low rate of initial and remaining biomaterial (10%) combined with the original initial shape of the prosthesis that counterbalances abdominal pressure during the initial healing period. The 4DDome® mesh is at the cutting edge of the potential recommendation for an inguinal parietal reinforcement mesh, i.e. high resistance, partially absorbable and a shape enhancing the resistance of the product during the initial healing phase.