MEDTRONIC REVIEW
CLINICAL SUMMARY

Medtronic provides the following synopsis of a clinical publication involving Parietene ProGrip™ Self-Gripping Polypropylene Mesh.

TITLE: "Self-fixating mesh for the Lichtenstein procedure – a prestudy"

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JOURNAL: Langenbecks Arch. Surg.

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TYPE OF STUDY

Double blinded, prospective, randomized, controlled clinical trial.

PURPOSE OF THE STUDY

The aim of this study was to test Parietene Progrip™ versus traditional Lichtenstein repair in a double-blinded randomized study evaluating postoperative pain and the use of analgesics with 6 months of follow up. Patients were evaluated by blinded surgeons who did not participate in the actual surgical procedure.

METHODS

- Number of patients enrolled: 50 patients
- 6 surgeons experienced in Lichtenstein technique
- Two groups:
  - Group A: Parietene Progrip™ mesh (11 x 9 cm) without fixation sutures
  - Group B: Polypropylene mesh (Optilene™*) (12 x 10 cm) fixed with 2/0 polypropylene suture (Surgipro™)
  The two groups were comparable in number, age and defect size
- Postoperative course was observed by blinded surgeons who were not involved in the surgery
- Primary endpoint: pain on the first postoperative day (VAS: Visual Analog Scale)
- Secondary endpoint: chronic pain, analgesic (metamizole) consumption during hospital stay, amount of analgesics taken at home up to 6 months after surgery, and the operative time
- Follow-up: 6 months (follow-up was conducted by phone since attempts to contact by mail showed poor response rate)

	Group A	Group B	P Value
Operative time (min)	51	63.2	0.0078[1]
VAS post operative score on first postoperative day before analgesics (mm)	17.9	32.3	0.031[1]
Cumulative doses of analgesics during hospital stay (mg)	2 938	4 356	0.043[1]
Cumulative doses of analgesics during the period after hospital stay (mg)	5 298	7 500	0.003[1]
Mean pain score after 6 month follow-up (mm)	3.8	12.6	0.07

[1] *statistically significant*

- Pain after surgery was significantly reduced in the Parietene ProGrip™ group versus the Lichtenstein group
- This was supported by significant reductions in analgesic consumption before and after discharge from the hospital
- At 6-month phone follow-up, patients experienced more pain with Lichtenstein repair compared to Parietene ProGrip™ mesh. This trend was very strong though not statistically significant (P = 0.07)
- There were no significant differences in procedural complications between groups
- The few complications consisted mostly of small hematomas that were unrelated to the mesh

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DISCUSSION

- The differences in chronic pain were marked and trended strongly in favor of Parietene ProGrip™ though it did not achieve significance (p = 0.07). This is probably due to the small sample size and the fact that most patients (61%) reported no pain after 6 month follow-up
- The self-fixating mesh costs 2.5 times more than the comparable mesh of pure polypropylene. From an economical point of view, these increased costs are compensated by the reduced utilization of the operating room

CONCLUSION

- This is the first randomized study which demonstrates a beneficial effect of Parietene ProGrip™ mesh on pain score
- The operative time is reduced, and this is a considerable factor in economical aspects as well as beneficial aspects for the patients

This concludes the clinical synopsis of this publication

INDEPENDENCE

This is an independent study.

REFERENCES

None

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