Two Year Results: Reducing Chronic Pain Utilizing GORE Bioabsorbable Hernia Plug in Inguinal Herniorrhaphy

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INTRODUCTION
The incidence of pain in chronic open inguinal herniorrhaphy is prevalent and is reported to be as high as 20 to 43%1,2,3,4. In many patients, pain and other serious complications of plug-and-patch hernia repairs have been specifically associated with the polypropylene plug (PP)5. PPs are known to provoke an intense, continuous fibroblastic response and scarring5. A bioabsorbable hernia plug (BHP) could provide short-term benefits of a plug, such as ease of use and mechanical reduction of the hernia sac, while the onlay mesh becomes incorporated without long-term pain and pain related complications associated with polypropylene pluses.

The purpose of this study was to evaluate the FDA-approved GORE Bioabsorbable Hernia Plug with a lightweight polypropylene patch in open inguinal herniorrhaphy. Evaluation of BHP implantation techniques and handling characteristics were reported previously5. Primary endpoints were evaluation of BHP implantation techniques, handling characteristics and short- and long-term outcome and pain assessments.

METHODS
An observational, prospective, multicenter, IRB-approved study of patients with primary or recurrent inguinal hernia without previous mesh repair. Patients underwent examination and completion of McGill Pain Questionnaire (MPQ). Surgeons recorded defect type/size, suture type/amount, and discharge conditions. Handling characteristics of the BHP were rated by the surgeon. At 14 days, one, three, 12-, and 24-months post-operative, patients completed the MPQ and underwent physical examination.

RESULTS:
One-hundred and thirty-three patients (138 implants), with 88 indirect, 37 direct, nine combined, and four unclassified hernias were studied. Complications occurred in 3.6% and consisted of two hematomas, one ileus and two neuralgias. Nine recurrences (6.5%) were noted. Mean time to recurrence was 14 months (range 8-22 months) and were all attributed to the onlay mesh, none were related to the BHP. Patient convalescence averaged 8.6 days; average work return was 13 days. No pain was reported by 80% of patients at one month; 84% at three months; 96% at 12 months; and 97% at 24 months.

CONCLUSION:
Results show the GORE Bioabsorbable Hernia Plug with onlay mesh is effective with minimal short-term complications (3.6%) and minimal long-term pain (3% incidence of pain at two years).

DISCUSSION:
In this single arm evaluation study the GORE Bioabsorbable Hernia Plug with permanent onlay patch has been shown to be effective at reducing the incidence of chronic pain. Compared to what is generally reported in the literature, the BHP results in decreased levels of pain in a shorter period of time1,2,3,4. The incidence of pain utilizing BHP at one month is comparable to that of similar techniques at 24 months, and at two years is over six times lower (refer to graph at right).

Comparative study of the GORE Bioabsorbable Hernia Plug will likely be needed to confirm improved performance over standard techniques and devices.

REFERENCES:
5Leblanc KA. Complications associated with the plug-and-patch method of inguinal hernia repair: Hexon 2001:5:15-16/1

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