

A Prospective, Multicenter Study to Evaluate the Performance of the GORE Bioabsorbable Hernia Plug and Permanent Overlay Patch in Inguinal Herniorrhaphy

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GORE Bioabsorbable Hernia Plug

Introduction

The use of a polypropylene hernia plug (HP) with an onlay patch of polypropylene is a popular method of inguinal herniorrhaphy. A bioabsorbable HP could provide short-term benefits of a plug without long-term complications associated with polypropylene plugs. The onlay patch should provide the additional assurance of a secure repair. The purpose of this study is to evaluate a FDA-cleared bioabsorbable HP (GORE Bioabsorbable Hernia Plug) with a permanent polypropylene patch in open, tension-free inguinal herniorrhaphy. Primary endpoints are establishment of optimal HP implantation techniques/handling characteristics and short- and long-term outcome data.

Methods

This is an observational, prospective, multicenter, IRB-approved study. Planned enrollment was 120 patients with primary or recurrent inguinal hernias without previous mesh repair. Patients underwent examination and completion of the McGill Pain Questionnaire (MPQ) preoperatively. Intraoperatively, surgeons recorded defect type/size, suture type/amount, operative time, and discharge condition among other observations. Handling characteristics of the HP and polypropylene patch are also rated. At 14 days, one-, three-, 12-, and 24-months post-operative, patients completed the MPQ and underwent physical examination.

Results

Current results are based on an enrollment of 134 patients and 139 implants, with 91 indirect, 37 direct, and nine combined direct/indirect defects treated. Two defects were not specified. Immediate post-operative complications included two instances of hematoma and one ileus which were all treated without sequelae. The average convalescence was 8.6 days, and 120 patients reached 14-day follow-up with minimal or no discomfort. Ninety-three patients reached 12 months follow-up with only two reporting occasional 2/5 pain (McGill Present Pain Intensity scale). [On a scale of 1 to 5, 5 being the best] Surgeon satisfaction is 4.5/5 and handling is rated 4.4/5.

Conclusions

Preliminary results show the bioabsorbable HP (GORE Bioabsorbable Hernia Plug) is effective with minimal short-term complications. Longer term results will be updated for the European Hernia Congress in 2007*.

*Note: At the time of presentation the data had been updated: 104 patients reached twelve months follow-up with only four reporting occasional 2/5 pain (McGill Present Pain Intensity scale) for an incidence of 3.8%.



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Dr. Karl A. LeBlanc, MD, MBA, FACS
29th International Congress of the
European Hernia Society
Athens, Greece, 2007

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