

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

James R. DeBord MD, FACS – Peoria, IL Carl Doerhoff MD, FACS – Jefferson City, MO Danuta I. Dynda MD – Peoria, IL
 Karl A. LeBlanc MD, MBA, FACS – Baton Rouge, LA Richard C. Montgomery MD, FACS – Lexington, KY William Walton MD, FACS – Lexington, KY
 Brent D. Matthews MD, FACS – St. Louis, MO Salvador Morales-Mendez MD – Sevilla, SPAIN Salvador Morales-Conde MD – Sevilla, SPAIN

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 scarring⁶. 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 plugs.

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 previously⁷.

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 hernias 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.

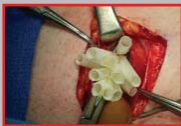
No pain was reported by 80% of patients at one month; 84% at three months; 96% at 12 months; and 97% at 24 months.

CONCLUSION:

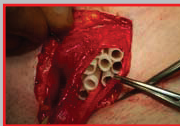
Results show the GORE Bioabsorbable Hernia Plug with onlay mesh is effective with minimal short-term complications (3.6%) and minimal long-term pain (3% incidence of pain at two years).



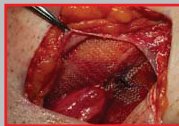
Grasp the tubes with a Pean or other suitable clamp.



The device is inserted disk first through the internal ring. The disk is positioned in the pre-peritoneal space.



Fixate the tubes to the sides of the defect with absorbable suture.



Fixate the overlay patch with absorbable suture.

DISCUSSION:

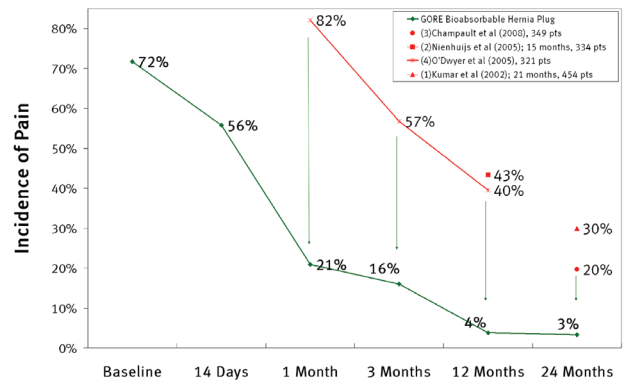
In this single arm evaluation study the GORE Bioabsorbable Hernia Plug with permanent onlay patch has been shown to be effective at reducing the incidence of chronic pain. Compared to what is generally reported in the literature, the BHP results in decreased levels of pain in a shorter period of time^{1,2,3,4}. 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.

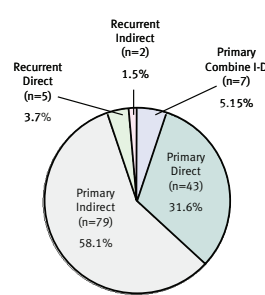
REFERENCES:

- Kumar S, Wilson RG, Nixon SJ, Macintyre IMC. Chronic pain after laparoscopic and open mesh repair of groin hernia. *British Journal of Surgery* 2002;89:1476-1479.
- Nienhuijs SW, van Oort I, Keemers-Gels ME, Strobbe U, Rosman C. Randomized trial comparing the Prolene Hernia System, mesh plug repair and Lichtenstein method for open inguinal hernia repair. *British Journal of Surgery* 2005;92(1):33-38.
- Champault G, Bernard C, Rizk N, Polland C. Inguinal hernia repair: the choice of prosthesis outweighs that of technique. *Hernia* 2007; 11:125-128.
- O'Dwyer PJ, Kingsnorth AN, Molloy RG, Small PK, Lammers B, Horeysek G. Randomized clinical trial assessing impact of a lightweight or heavyweight mesh on chronic pain after inguinal hernia repair. *British Journal of Surgery* 2005; 92:166-170.
- LeBlanc KA. Complications associated with the plug-and-patch method of inguinal herniorrhaphy. *Hernia*. 2001;5:135-8/
- Scott NW, McCormack K, Graham P, Go PM, Ross SJ, Grant AM. Open mesh versus non-mesh for repair of femoral and inguinal hernia. *Cochrane Database of Systematic Reviews* 2002;(4):CD002197.
- DeBord JR, Doerhoff C, LeBlanc KA, et al. Preliminary results utilizing a bioabsorbable hernia plug and permanent polypropylene patch in inguinal herniorrhaphy. Poster presented at the Hernia Repair 2005 - American Hernia Society Meeting; February 9-12, 2005; San Diego, CA.

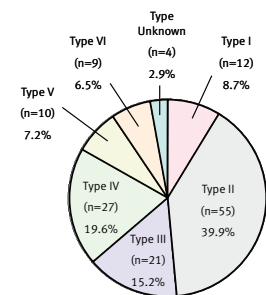
Incidence of Chronic Pain Utilizing GORE Bioabsorbable Hernia Plug & Mesh Compared to Literature for Open Inguinal Herniorrhaphy



HERNIA TYPE



HERNIA CLASSIFICATION



OPERATIVE FINDINGS

Inguinal Hernia	138
Right	83
Left	55
Bilateral	5
Mean Operative Time (min) n=132	39
Range	(18, 130)
Mean Defect Size (cm²) n=138	6.4
Range	(1, 20)

PATIENT DEMOGRAPHICS

Gender n=133	
Male	125 (94%)
Female	8 (6%)
Mean Age (years) Range (21, 84)	n=133 55
Mean BMI Range (15.1, 36.8)	n=131 26.1
Mean ASA n=132	Level 2
(level 1 = 31, level 2 = 76, level 3 = 24, level 4 = 1)	

COMPLICATIONS

Hematoma (no sequelae) (without intervention/draining)	2
Ileus (no sequelae) (patient has previous ileus postop history)	1
Neuralgia – additional surgery	2
One - schwannoma/neuroma of ilioinguinal nerve - resolved by resection of the neuroma (not BHP related).	
One - left genitofemoral nerve (related to original dissection and mesh onlay) - resolved with triple neurectomy (not BHP related).	
Recurrence	9 (6.5%)
Mean time to recurrence (mos)	14
Range (8, 20) All recurrences related to onlay mesh, not related to BHP	

PATIENT RECOVERY

Length of Hospital Stay (days) n=132	
0 day	121 (92%)
1 day	5 (4%)
2 days	5 (4%)
3 days	1 (1%)
Convalescence (days) n=128	Mean
Range (1, 35)	8.6
Return to Work (days) n=110	Mean
Range (1, 75)	13



W. L. GORE & ASSOCIATES, INC.

Flagstaff, AZ 86004

+65.67332882 (Asia Pacific) 800.437.8181 (United States)

00800.6334.4673 (Europe) 928.779.2771 (United States)

goremmedical.com

Products listed may not be available in all markets pending regulatory clearance. GORE, and designs are trademarks of W. L. Gore & Associates. © 2008 W. L. Gore & Associates, Inc. AM3018-EM1 NOVEMBER 2008

Poster Presented at the Miscellaneous Session, American College of Surgeons' 94th Annual Clinical Congress Reprinted with Permission by Department of Surgery, University of Illinois College of Medicine at Peoria