1-Year Preliminary Results: A Randomized, Multicentric & Open Study Evaluating the Clinical Efficacy of the GORE BIO-A® Hernia Plug versus Bard® PerFix® Plug in Tension-Free Inguinal Hernia Repair

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INTRODUCTION

Inguinal hernia repair is the second most common digestive surgery procedure in the world. Annually, it represents roughly 130,000 cases in France, 220,000 in Germany and 700,000 in the United States. In many patients, pain and other serious complications of flat-mesh and plug-and-patch hernia repairs have been specifically associated with use of a non-absorbable prosthesis made of polypropylene. The aim of this study is to compare GORE BIO-A® Hernia Plug versus Bard® PerFix® Plug in tension-free inguinal hernia repair. The GORE BIO-A® Hernia Plug is composed of a microporous synthetic bioabsorbable copolymer (67% polyglycolide – 33% trimethylene carbonate). The device reinforces soft tissue during the phases of wound healing by filling or bridging void spaces or defects in the tissue.

METHODS

- **Type of Study –** Randomized, Multicentric & Open
- **Product Evaluated –** GORE BIO-A® Hernia Plug
- **Comparator –** Bard® PerFix® Plug
- **Sample Size –** 200 patients, split evenly between GORE BIO-A® Hernia Plug and Bard® PerFix® Plug
- **Number of Sites –** 10
- **Total Study Duration –** Three years comprised of one year recruitment and two years follow up
- **Subject Population –** Subjects diagnosed for curative treatment of groin hernia
- **Primary Objective –** Assess the clinical efficacy of the GORE BIO-A® Hernia Plug in the surgical treatment of inguinal hernia, defined by the absence of migration of the prosthetic material or hernia recurrence
- **Secondary Objective –** Assess the pain decrease by means of the McGill questionnaire and the resumption of activities

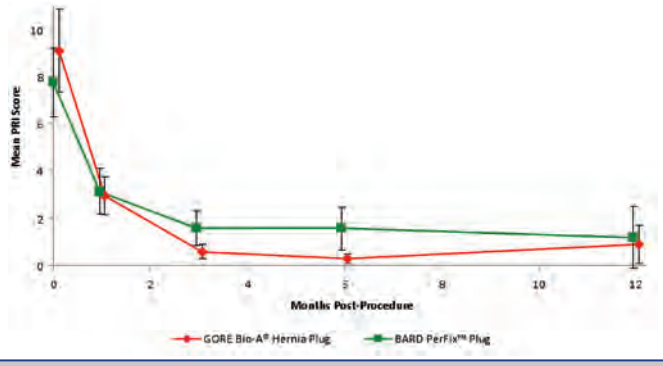
PRIMARY OBJECTIVE

Prosthetic Material Migration or Hernia Recurrence

		GORE BIO-A® Hernia Plug	Bard® PerFix® Plug
	N	92	89
Recurrence / Re-intervention		0	1 (Day 3)

SECONDARY OBJECTIVE

McGill Questionnaire – Pain Rating Index Scores



PATIENT DEMOGRAPHY

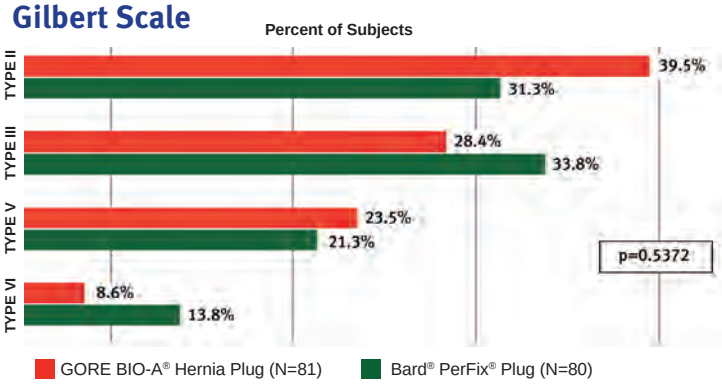
		GORE BIO-A® Hernia Plug	Bard® PerFix® Plug
Gender (M/F)	N	88/4	88/1
Age (years)	Mean	58.2 (19 - 80)	56.1 (25 - 79)
BMI (kg/m²)	Mean	25.1 (17 - 32)	24.4 (18 - 33)
ASA Factor	ASA 1	84.6%	83.7%
	ASA 2	15.4%	16.3%

OPERATIVE FINDINGS

	GORE BIO-A® Hernia Plug	Bard® PerFix® Plug
Defect Location		
Right	60.9%	52.8%
Left	39.1%	47.2%
Type of Anesthesia		
Local	48.1%	52.5%
Epidural	4.9%	12.5%
General	46.9%	35.0%

	GORE BIO-A® Hernia Plug	Bard® PerFix® Plug
Number of Sutures Used for Plugs	*Absorbable Sutures*	*Non Absorbable Sutures*
Mean	2.6 (1 - 6)	2.5 (1 - 5)
Number of Sutures Used for Patches	*Non Absorbable Sutures*	*Non Absorbable Sutures*
Mean	5.3 (2 - 10)	5.5 (2 - 10)

HERNIA TYPE Gilbert Scale



CONCLUSION

As primary objective, preliminary results show one recurrence in the Bard® PerFix® Plug group.

As secondary objective, preliminary results show a significant pain assessment difference (Pain Rating Index Scores) at three and six months in favor of the GORE BIO-A® Hernia Plug group.

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Refer to the Instructions for Use for a complete description of all warnings, precautions, and contraindications. $R_{x\ Only}$

Products listed may not be available in all markets.