

A Novel Treatment for Hemorrhoids: PRECISION Endoscopic Infrared Coagulator.

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Introduction

The purpose of this Registry is to verify and quantify the effectiveness and therapeutic benefit of the use of the PRECISION Endoscopic Infrared Coagulator to treat internal hemorrhoids. The Registry was carried out at five treatment sites in the U.S.A., and to date includes a total of 55 patients who have completed post treatment evaluation. Participating physicians have experience treating internal hemorrhoids by banding and/or infrared coagulation. Collection, analysis and reporting of data from the various sites are being coordinated by Investigative Clinical Research in Annapolis, Maryland.

Background

Hemorrhoids can be found in over 4% of the US population. Common symptoms of hemorrhoidal disease include painless bleeding, itching or burning of the rectum. Hemorrhoids can be caused by vascular congestion from intra-abdominal pressure and prolonged straining or mucosal prolapse. Hemorrhoidal conditions are classified according to their location either internal or external. Internal hemorrhoids are graded based on the degree of the prolapse. Hemorrhoids that are unresponsive to topical and suppository agents may be treated with rubber band ligation or thermotherapy by using infrared beam, electric current, CO2 laser, ultrasonic energy, or cryotherapy. Most non-surgical treatment options for internal hemorrhoids require the use of an anal retractor, adequate lighting, and specialized instruments. These treatments are often performed at a different time and location than the endoscopic procedure, leading to inefficient use of resources.

Materials

The PRECISION device consists of (1) a control unit that houses a source of infrared energy and control circuitry, and (2) a single-use disposable MAXi-guide flexible fiber optic light guide whose proximal end is connected to the control unit by a quick-connect threaded handle, and whose distal tip is inserted into the accessory channel of a colonoscope, flexible sigmoidoscope, or other flexible endoscope. The PRECISION Endoscopic Infrared Coagulator is an effective alternative to the standard infrared coagulator as it can be performed at the same time as a colonoscopy or flexible sigmoidoscopy.



When in use, visible light and infrared energy enter the proximal end of the fiber optic and are passed through its entire length to the distal tip. As the distal tip is placed in contact with tissue, infrared energy is transferred to the tissue, rapidly increasing the temperature and coagulating the tissue.

Methods

Patients selected for treatment with the PRECISION Endoscopic Infrared Coagulator reported chronic persistent hemorrhoid symptoms for an average of 10 years. Each patient underwent detailed history and physical examination, including anoscopy, sigmoidoscopy, or colonoscopy in order to eliminate other sources of bleeding from the colon and rectum. Hemorrhoids were graded on a severity scale of grade I-IV (see figure 1). Patients completed six point visual analog symptom scales (see figure 3) before treatment. After hemorrhoid inspection, treatment was applied by passing the flexible fiber optic light guide through the suction channel of the endoscope, and gently retro flexing the instrument to visualize the hemorrhoids. Thermal therapy was applied in a circumferential manner above the dentate line. The amount of energy transferred to the site of treatment is controlled by setting the number of seconds of activation. Patients were assessed six weeks after all treatments by completing a second series of visual analog scales.

Demographics

Figure 1: Hemorrhoids findings from patient examination

Internal Hemorrhoids	Internal Hemorrhoid Data (Number of patients)			
	Grade I	Grade II	Grade III	Grade IV
Internal Hemorrhoids	6	19	20	3
Location of Hemorrhoids	LLO	RAO	RPO	UNK
	33	22	19	18

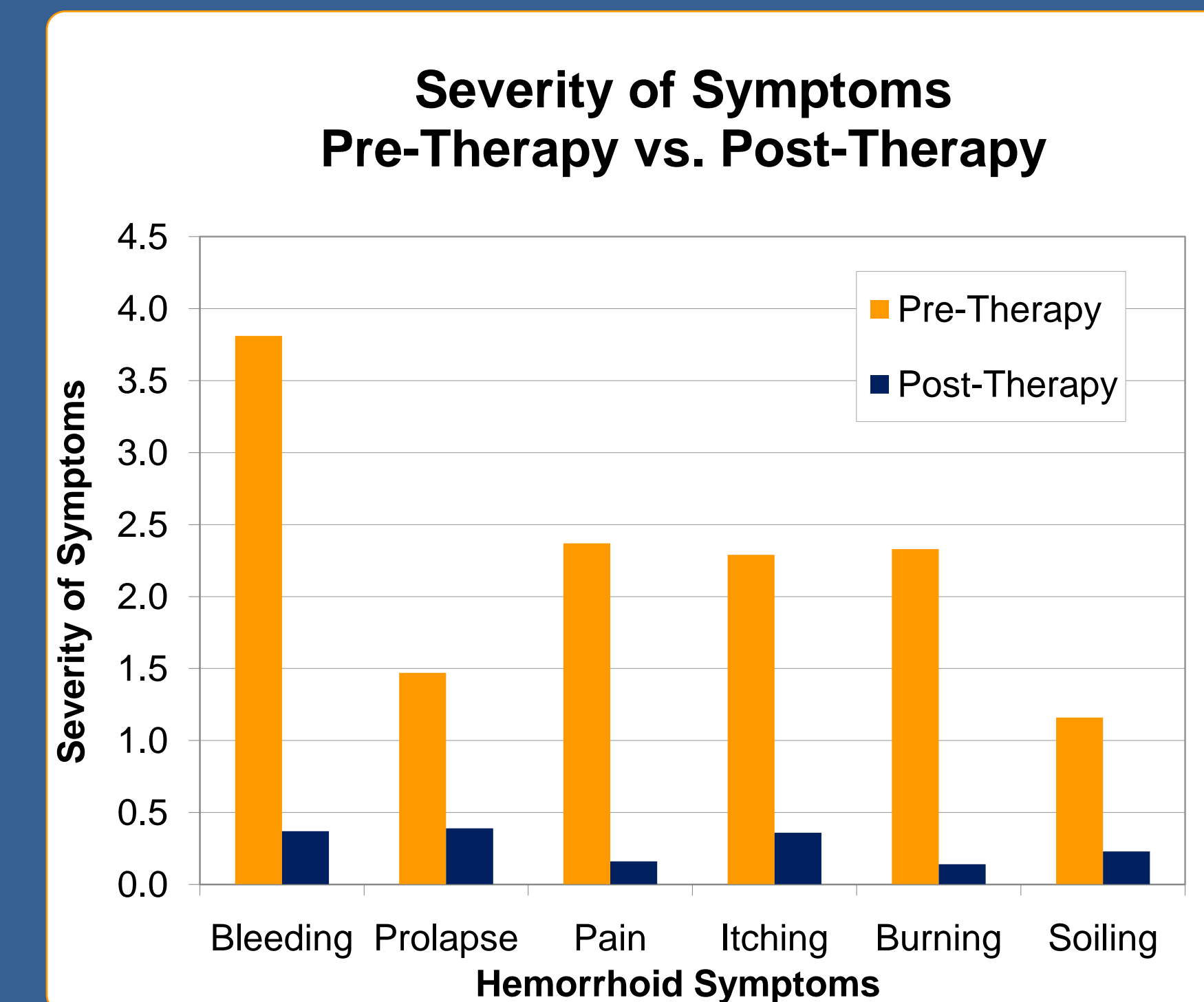
Figure 2: From History and Exam of Subjects

Symptom	Percentage of Patients (Number of Patients)		
	0-10 years	>10 years	Unknown
Number of years Hemorrhoids Present	62% (34)	22% (12)	16% (9)
Blood in Stool	Frequently 24% (13)	Occasionally 58% (32)	Never 18% (10)
Hemorrhoids Protrude	31% (17)	29% (16)	34% (19)
Straining with BM	29% (16)	49% (27)	22% (12)
Constipation	18% (10)	60% (33)	22% (12)
Hard and Firm Stools	30% (17)	56% (31)	12% (7)
Feel lump in rectum	18% (10)	24% (13)	55% (30)
Pain with BM	18% (10)	30% (17)	51% (28)
Drainage around rectum	3% (2)	24% (13)	73% (40)
Soil Underwear	5% (3)	27% (15)	65% (36)
Laxative Use	7% (4)	29% (16)	68% (34)
Fiber Supplement Use	22% (12)	34% (19)	38% (21)
Female patients (40% (22))	With Children		With Episiotomy
	32% (18)	16% (9)	
Blood Thinner use	Yes		No
	13% (7)	87% (48)	
Hernia in Groin	3% (2) (repaired)		96% (53)
Anal Fissure	25% (14) (11% currently active)		93% (51)
Anal Fistula	2% (1)		98% (54)
Family History Colon Cancer	16% (9)		84% (46)
Colonoscopy	78% (43)		22% (12)
Colonoscopy Findings	1 - Diverticulosis, 5 - Polyp, 4 - hemorrhoids		
Personal Medical History	1/hysterectomy; 1/bowel surgery; 1/bladder surgery; 1/prostate cancer & radiation		

Results and Statistical Analysis

Fifty three patients received a single treatment, and two patients underwent a second treatment session. Patients graded their symptoms pre- and post therapy. These results were analyzed to determine the improvement in each symptom. Post therapy results indicated an average 87.62% decrease of global symptoms. There have been no adverse events reported to date, neither serious adverse events nor non-serious adverse events.

Figure 3: Symptom Analysis



A one-sided p-value of the null of no difference was calculated between pre and post symptom scores vs. the alternative that the post symptom scores were less than the pre symptom scores. The non-parametric Wilcoxon signed rank test via the R function wilcox.exact was used. In some cases an exact p-value could not be computed. In that case, an "asymptotic" p-value is reported.

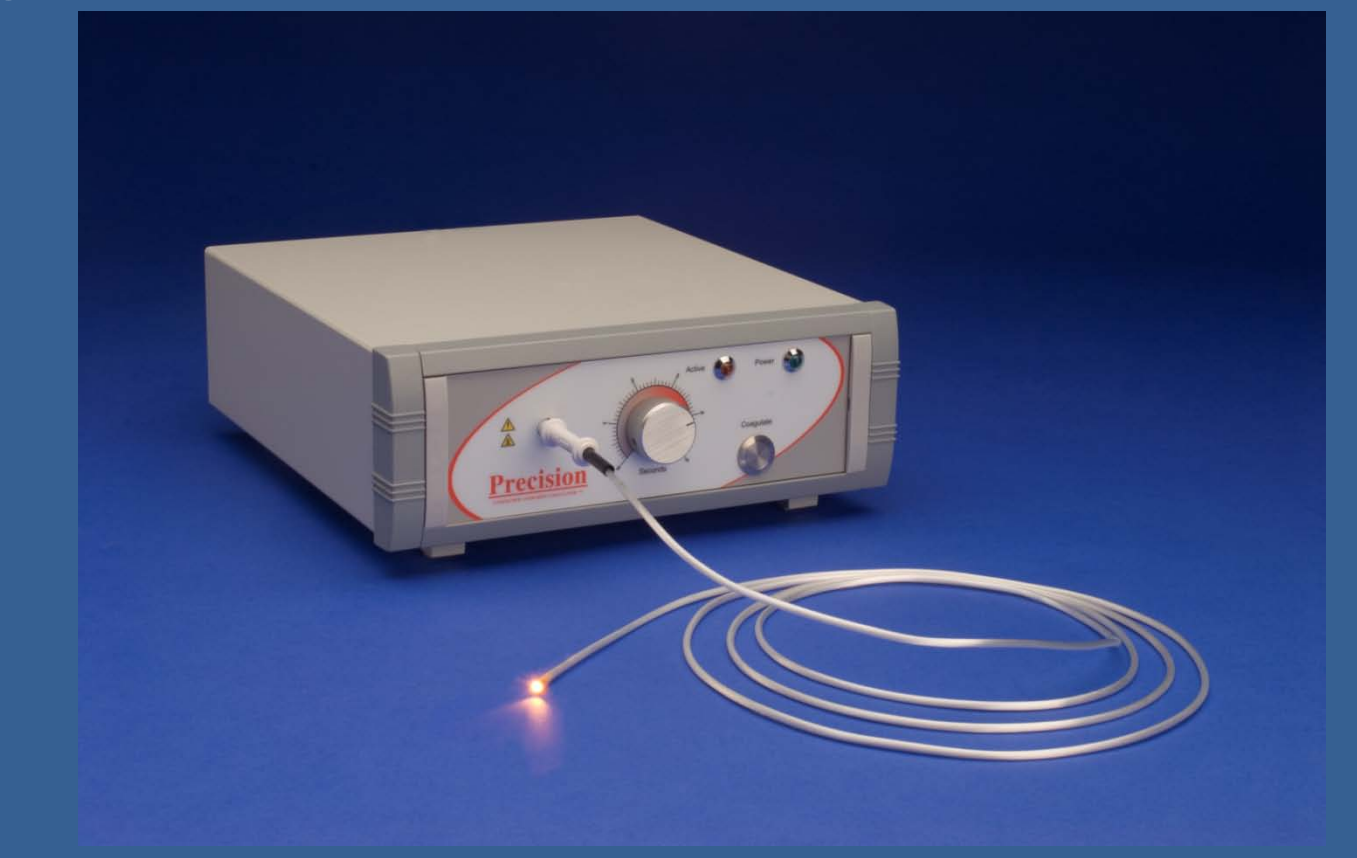
Symptom	Pre-Treatment Average Score	Post-Treatment Average Score	P-Value *	Worsened Post-Symptom Score**
Bleeding	3.81	0.37	<0.0001 (A)	0
Prolapse	1.47	0.39	<0.001 (E)	2
Pain	2.37	0.16	<0.0001 (E)	1
Itching	2.29	0.36	<0.0001 (E)	1
Burning	2.33	0.14	<0.0001 (E)	0
Soiling	1.16	0.23	<0.0001 (E)	1
Total	13.44	1.66	<0.0001 (A)	na

*Based on one-sided (post < pre) non-parametric signed rank test. (E) Exact p-value; (A) Asymptotic p-value
**3 patients had a increased post-score in one or more symptoms by .02 or more

Conclusion

PRECISION Endoscopic Infrared Coagulator appears to be safe and effective therapy for internal hemorrhoids. The data collected suggests that this treatment method does not present significant safety issues or unexpected risks for patients or clinicians. The data on the fifty five subjects who have completed therapy in this Registry suggest a dramatic improvement in the severity of symptoms.

Future clinical trials are planned to further evaluate the effectiveness of the device for hemorrhoid treatments, radiation proctitis, and Barrett's esophagus.



Resources

Registry Sites

This Registry is being carried out at multiple sites, with one physician at each site providing hemorrhoid therapy to patients in accordance with the established protocol.
Site 001: Michael S. Epstein, M.D., F.A.C.G., A.G.A.F. – Annapolis, MD
Site 002: Junaid Siddiqui, M.D. – Round Rock, TX
Site 004: Rudy Rai, M.D., MBA, F.A.C.G – Columbia, MD
Site 005: P. Patrick Basu, M.D., P.C. – Forest Hills, NY
Site 006: Mousab Tabbaa, M.D. – Westlake, OH

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Financial Disclosures: Dr. Michael Epstein is a board member and shareholder of Max Endoscopy.