Cleveland Clinic

Outcomes 2006

Digestive Disease Center




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Outcomes | 2006

Quality counts when referring patients to hospitals and physicians, so Cleveland Clinic has created a series of outcomes books similar to this one for its institutes and departments. Designed for a health care provider audience, the outcomes books contain a summary of our surgical and medical trends and approaches; data on patient volume and outcomes; and a review of new technologies and innovations. We hope you find these data valuable. To view all our outcomes books, visit Cleveland Clinic's Quality Web site at clevelandclinic.org/quality/outcomes.



About the Cover

Laparoscopic view of pelvis showing stapled J Pouch being joined to anal canal. This approach allows for small incisions, less trauma and more rapid recovery than open surgery.

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Chairmen's Letter





Cleveland Clinic's Digestive Disease Center is pleased to present the fourth edition of *Outcomes*, highlighting the work of the Departments of Colorectal Surgery and Gastroenterology and Hepatology, as well as the collaboration between the Departments of General Surgery and Thoracic Surgery. It is this collaboration that enables us to provide expert treatment and innovative solutions for patients with all forms of digestive disorders. We created this booklet to share with our colleagues, patients and alumni the scope and volume of medical and surgical procedures performed each year at our center. In addition, we detail some of the many innovative treatments, procedures and techniques developed by our physicians each year. We hope you find this information helpful and informative, and we welcome the opportunity to work with you.

Victor W. Fazio, M.D.,
and Arthur J. McCullough Jr., M.D.
Co-Chairmen, Digestive Disease Center

Department Overview

Total Patient Visits	66,941
Total New Patients	3,460
Admissions	3,718
Patient Days	25,741
Average Length of Stay (Days)	6.92
Total Endoscopic Procedures	22,763
Total MIS Cases	372
Total Inpatient Surgical Cases	2,304
Total Outpatient Surgical Cases	1,279

At the Digestive Disease Center, our goal remains to provide compassionate, innovative and effective care to all patients. Cancer of the colon and rectum, gallbladder disease, diverticulitis, hepatitis, esophageal reflux disease, Crohn's disease, ulcerative colitis, pancreatitis and pancreatic cancer are gastrointestinal diseases that commonly affect the lives of people in the United States and throughout the world. Specialists in the medical and surgical treatments of these and all diseases of the gastrointestinal tract are at work at Cleveland Clinic.

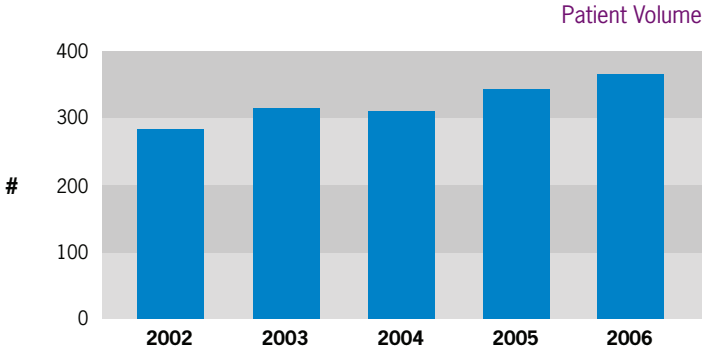
Innovative procedures, including advanced endoscopy and minimally invasive surgery, combined with decades of experience, enable our physicians to achieve success in both the prevention and treatment of the full spectrum of gastrointestinal diseases. The close association between physicians and surgeons in the Digestive Disease Center allows patients to be evaluated by multiple specialists, in a single day, in one location. A state-of-the art endoscopy unit, complete radiology services, enterostomal therapists and nutritional specialists are all available.

Quality & Outcomes Measures

Anorectal Disease

Fistulas

Up-to-date treatments are available for all anal problems, including anal fistulas, hemorrhoids, anorectal abscesses and cancer.



Many patients are treated immediately in the office with minor surgery under local anesthetics.

For most people, an anal fistula only requires unroofing or opening the tract. Complex fistulas may require other treatments if the amount of anal sphincter muscle to be cut in the unroofing would compromise sphincter continence. Advancement rectal flaps are used in this situation. A flap of rectal wall is elevated and sutured down over the opening in the anal area. This allows closure of the fistula, without division of the sphincter, practically assuring continence or control of rectal evacuation.



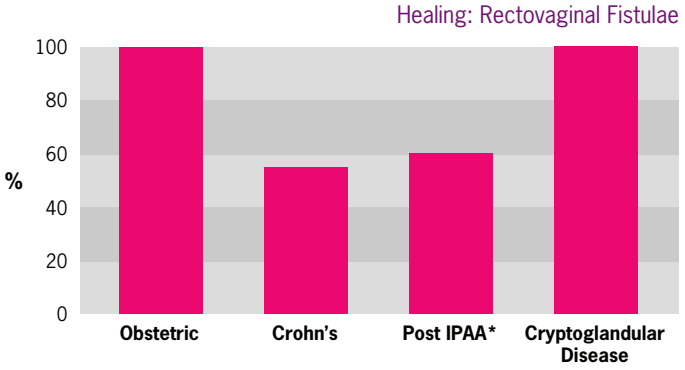
Rectal, flap types

Episioproctotomy

Episioproctotomy is a procedure to repair a rectovaginal fistula in patients who have an anterior defect of the external sphincter. Patients with a cloacal deformity can be similarly treated.

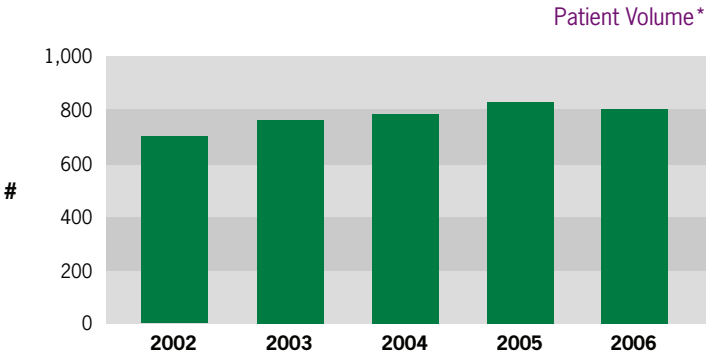
In our series (in press), a 75% success rate was found. Patients who had a cloaca did not experience any recurrence. Of the patients who had recurrences, 72% had a failed previous repair.

Patients who had no recurrence showed improved quality of life and continence scores postoperatively.



*IPAA: Ileal Pouch Anal Anastomosis

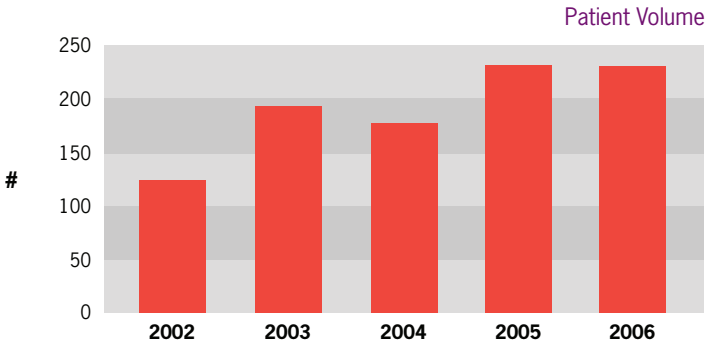
Hemorrhoids



*Patient volume data represent unique patients seen each year.

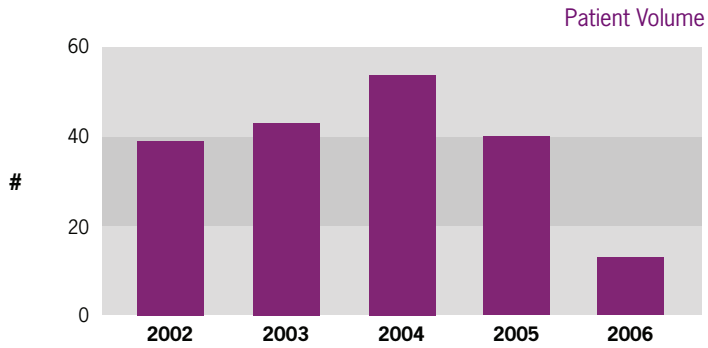
Patients with prolapsing hemorrhoids not suitable for banding may be advised to undergo surgical hemorrhoidectomy, performed as a day procedure in over 95% of cases. Thirty-eight percent of patients had an operative procedure.

Anorectal Abscesses



Perianal abscesses and acute septic complications of the ano-rectum are complex issues that require expert treatment to minimize recurrent symptoms and reduce future complications. Abscesses in this area are commonly treated by surgeons in the department.

Anal Cancer



Anal cancer is treated with a multidisciplinary approach, incorporating Cleveland Clinic's Taussig Cancer Center oncology team for access to the latest radiotherapy and chemotherapy treatments with acceptable morbidity.

Stapled Hemorrhoidectomy

The Department of Colorectal Surgery led a national study investigating the circular stapled technique for hemorrhoids. This technique is a surgical treatment for prolapsing hemorrhoids, but with significantly less pain, less requirement for analgesics and less pain at first bowel movement than the traditional excisional treatment. In addition, it provides similar control of symptoms and need for additional hemorrhoidal treatment at one year.

The technique is performed using a circular purse-string suture positioned above the enlarged internal hemorrhoids. A stapler is placed transanally to perform a circumferential excision of the anorectal prolapsing tissue, restoring the anoderm to its proper location in the anal canal. Positive short-term results using the circular stapler are well-documented. Patients also experience a quicker return to work than patients undergoing a traditional excision. A total of 70 stapled hemorrhoidectomies were performed in 2006.



Staple Hemorrhoid



Anal Hemorrhoids

Turnbull-Cutait Abdomino-anal Pull-through Procedure

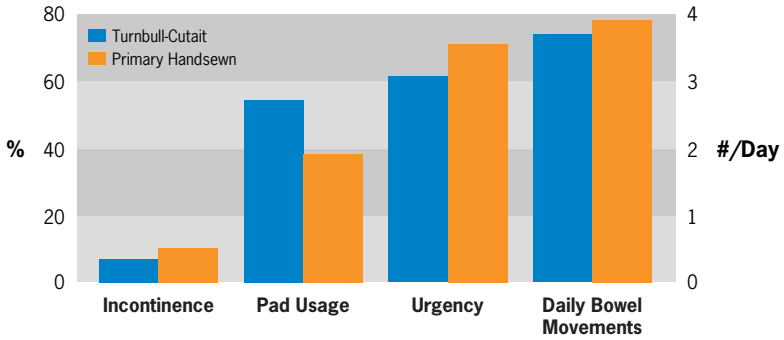
Turnbull-Cutait abdomino-anal pull-through procedure is used to salvage patients with non-malignant problems (such as complications of a low colorectal anastomosis, radiation-induced fistulas or complex anorectal Crohn's disease) who might otherwise require permanent fecal diversion. In this technique, an initial abdomino-anal pull-through operation is followed by a second stage perineal procedure where a handsewn coloanal anastomosis is done five to seven days after the initial procedure.



Turnbull-Cutait Procedure

In a review of all patients undergoing Turnbull-Cutait procedures, 78% were able to avoid permanent stoma. Functional outcome was comparable to the cohort of patients with primary handsewn coloanal anastomosis.

Turnbull-Cutait Procedure Compared with Primary Handsewn Incontinence



Results show Turnbull-Cutait abdomino-anal pull-through procedure safely salvages patients with low anastomotic complications and complex anorectal Crohn's that might otherwise require permanent fecal diversion.

Anal Fistula Plug to Repair a Perianal Fistula

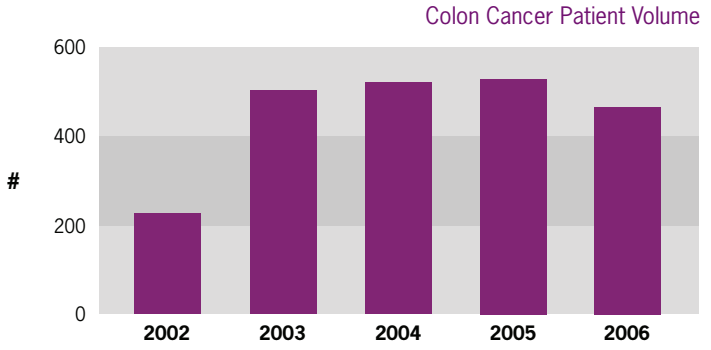
Anal fistula plug technique utilizes the anal fistula plug to close fistulas with long or multiple tracts. The plug is made of a biodegradable material which helps in the healing of the fistulous tract. The procedure is done after a draining seton has been placed to drain any infectious material. This procedure is performed on an outpatient basis.

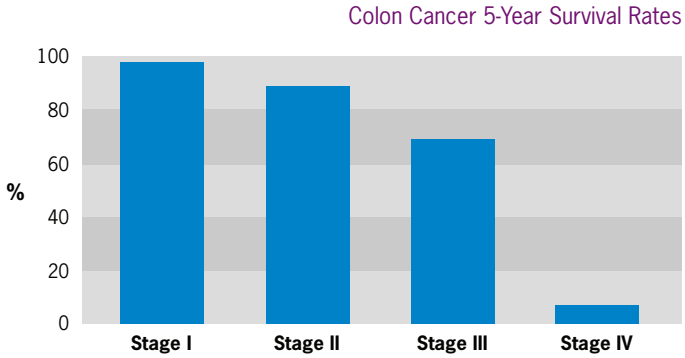
Doppler Guided Hemorrhoid Ligation

The Doppler guided hemorrhoid ligation is a new technique for treating second- and third-degree hemorrhoids. This procedure uses ultrasound to detect the artery supplying the hemorrhoid pedicle which is ligated through a specially designed proctoscope. A Mucopexy fixes the hemorrhoid pedicle, to prevent a prolapse. This procedure has been popular in Europe and received FDA clearance in August 2006.

Colon and Rectal Cancer

The Digestive Disease Center is at the forefront of colon polyp and cancer prevention through patient screening, education, detection and treatment. Prevention of colorectal neoplasms is one major research interest. The Center is a study site for many large national and international trials of a variety of chemopreventive agents for sporadic adenomas and for inherited colorectal cancer syndromes such as familial adenomatous polyposis.

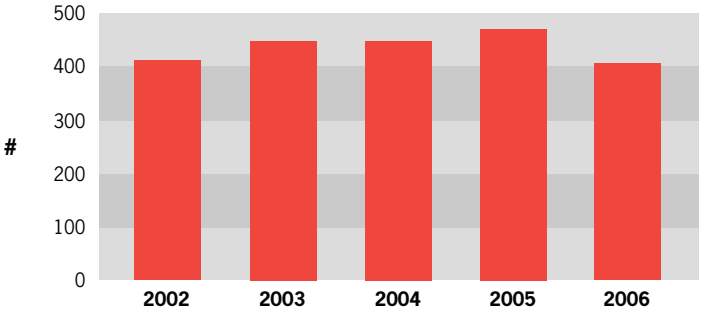




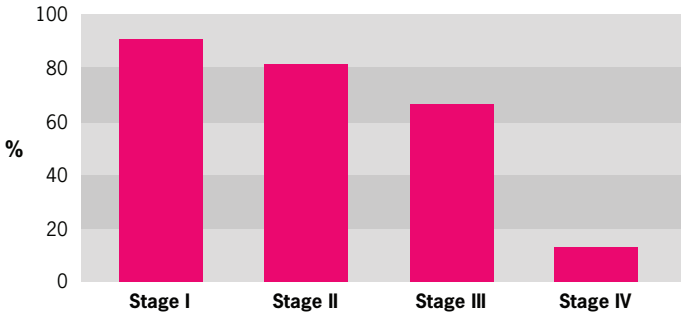
In most cases, patients with colon cancer require a colectomy to remove the segment of bowel in which the tumor lies. In more advanced cases, it may include removal of a contiguous organ to maximize the chance of cure. Clinic surgeons, experienced in the complexities of these major surgeries, collaborate with surgeons in other specialties when necessary. Many referred patients are seen for recurrent cancer after prior treatment elsewhere. These patients are expeditiously assessed by the gastrointestinal imaging staff for strategic planning of complex reoperative surgeries. Intraoperative radiotherapy is given in selected cases after resecting recurrent rectal cancer. Five-year survival data for each stage of colon cancer are among the best published. Recurrence is unlikely for patients who are disease-free for five years or more. Patients who require surgery are frequently recruited into trials to evaluate methods of improving recovery after surgery. This has been an increasing focus of the Center in recent years.

Rectal Cancer

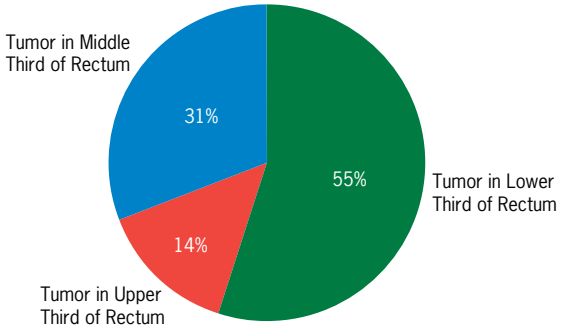
Patient Volume



Rectal Cancer 5-Year Survival Rates



*Low Rectal Cancer vs. All Rectal Cancers



*Mean distance of tumor from anal verge: 7.79 cm

Average Percentage Distribution of Surgery

Procedure Type	2002	2003	2004	2005	2006
Local excision/treatment	9.9	11.2	10.6	8.8	7.6
Low anterior resection	64.9	66.8	65.9	56.2	68.3
Radical resection with stoma	24.0	19.4	22.7	31.2	22.8
Unresectable	1.2	2.6	0.8	3.8	1.3

Our extensive experience treating rectal cancer comes from having one of the highest volumes of patients in the world with this condition. One factor that sets us apart is the number of treatment options available to save the sphincter and avoid colostomy. These options include transanal excision and radical surgery with anastomosis of the colon to the anus, incorporating a J-pouch or coloplasty. (For more information, see page 22.) Colorectal surgeons avoid a permanent colostomy in approximately 80% of cases and achieve some of the lowest recurrence rates in the world. Detailed assessments of tumors required to make these decisions involves a comprehensive array of tests. Endoanal ultrasound and anal manometry

are immediately available at the office visit, avoiding a prolonged wait and subsequent visits for treatment decisions. On average, 27 patients each year with early tumors can have them removed through the anal canal, eliminating the need for abdominal surgery.

Complications are carefully monitored. Surgeons may use temporary defunctioning ileostomies for patients with low rectal cancer, particularly those with preoperative radiation. Immediate consultation with the enterostomal nurses can be obtained at the time of the initial office visit so patients are fully aware of the outcomes and treatment plans.

Operative Morbidity and Mortality in Colorectal Cancer

N = 5,034

Operative mortality was 2.3%, with no significant variability between surgeons or through time.

Multivariate Analysis

Primary End Point = 30-Day Operative Mortality

Risk Factors for Increased Morbidity and Mortality

- Increased age
- Increased grade (American Society of Anesthesiologists)
- TNM staging
- Urgent surgery
- Anemia

This model has important implications in everyday practice, as it can be used in the process of informed consent and for monitoring surgical performance.

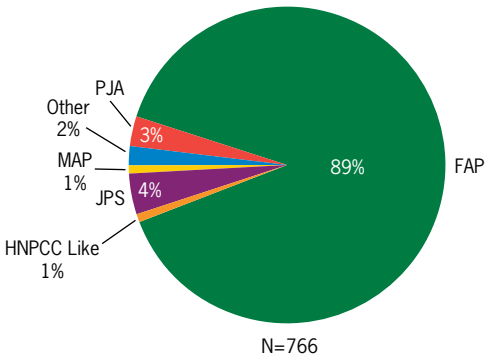
Jagelman Registries

Cleveland Clinic is home to the largest single-institutional registries in the United States and the second largest in the world. Individuals with multiple cases of colorectal cancer in their families or with an inherited colorectal cancer syndrome are eligible to participate in the registry and its associated High-Risk Hereditary Colon Cancer Clinic.

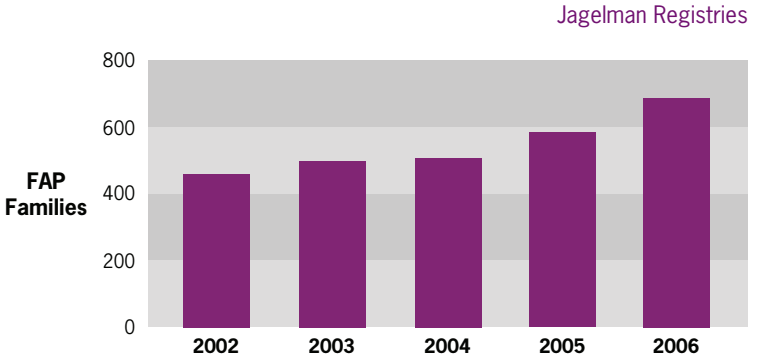
Members of the Jagelman Registries who have Hereditary Non-Polyposis Colorectal Cancer (HNPCC) also may participate in the Collaborative Family Registry (CFR). The CFR is part of an international effort to study both the genetic and lifestyle causes of colorectal cancer. The CFR is sponsored by a National Cancer Institute (NCI) grant and is managed by Cleveland Clinic's Department of Medical Genetics and the Digestive Disease Center. This collaboration between departments led to the recent five-year, $2 million grant renewal from the NCI for the registry.

In the Phase 3 study, 120 families will receive active and passive follow-ups. More than 400 participants will be interviewed. In addition, 60 colorectal cancer surgery patients without a family history will be recruited, as well as 20 new high-risk families. About 120 family members will be recruited to participate in the collection of epidemiological and biospecimen data.

David G. Jagelman Inherited Colorectal Cancer Registries



HNPCC – Hereditary Non-Polyposis Colorectal Cancer, HNPCC Like, FAP – Familial Adenomatous Polyposis, PJA – Peutz-Jeghers, JPS – Juvenile Polyposis Syndrome, MAP – MYH-Associated Polyposis



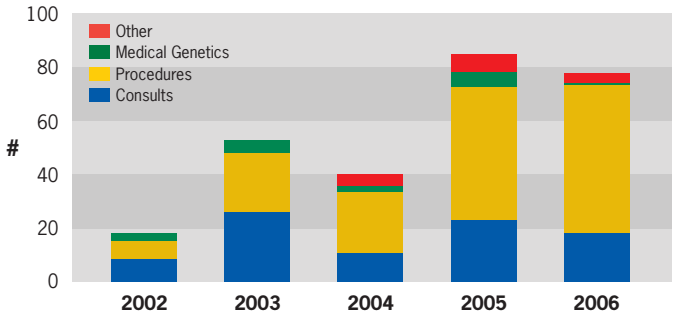
Center for Colon Polyp and Cancer Prevention

Many trials are underway to study the effectiveness of different strategies to prevent colorectal neoplasia, including precancerous polyps and cancer. Many studies are co-sponsored by the National Cancer Institute and include studying the safety of Celecoxib in children with FAP, the effectiveness of Celecoxib and DFMO in adults with FAP, the effectiveness of the use of black raspberries to prevent rectal polyps in adults with FAP, and a colorectal adenoma chemoprevention study with calcium and vitamin D. The Center completed a study assessing the proper intervals for post-polypectomy colonoscopy. In collaboration with the Departments of Colorectal Surgery and Radiology, the accuracy of CT colonography versus endoscopic colonoscopy for the detection of colorectal neoplasia is being studied.

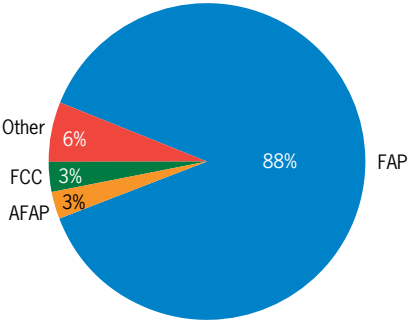
High-Risk Hereditary Colon Cancer Clinic

A multidisciplinary inherited colon cancer high-risk clinic was established in 2001. Patients with a dominantly inherited colon cancer syndrome who require multispecialty care are encouraged to participate. The clinic is held once a month on Tuesday morning in the Digestive Disease Center. Patients have the opportunity to consult with physicians, genetic counselors and the Jagelman Registries registrar. Additionally, they may undergo any necessary procedures or genetic testing on the day of their consultation.

High Risk Clinic Visits



High Risk Visits by Diagnosis



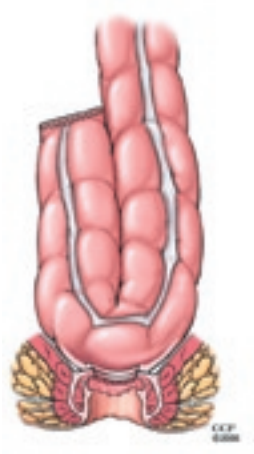
FCC – Familial Colon Cancer, FAP – Familial Adenomatous Polyposis, AFAP – Attenuated Familial Adenomatous Polyposis

Referral to our high risk clinic provides multidisciplinary evaluation, counseling and prospective procedures in the hope that early diagnosis will increase a patient's chance of cure.

While cancer treatment remains paramount, a number of techniques developed over the years were aimed at preserving anal sphincter function through the construction of a coloanal anastomosis. Variations of the straight coloanal anastomosis to further improve anal function are the creation of a colonic J-pouch and, more recently, a coloplasty.

Colonic J-pouch

Clinic surgeons have extensive experience with colonic J-pouch for reanastomosis of the colon to the anus in patients with the lowest rectal cancers. The technique permits improved function for patients and may reduce the risk of complications, such as anastomotic leak.



Colonic J-Pouch

Coloplasty

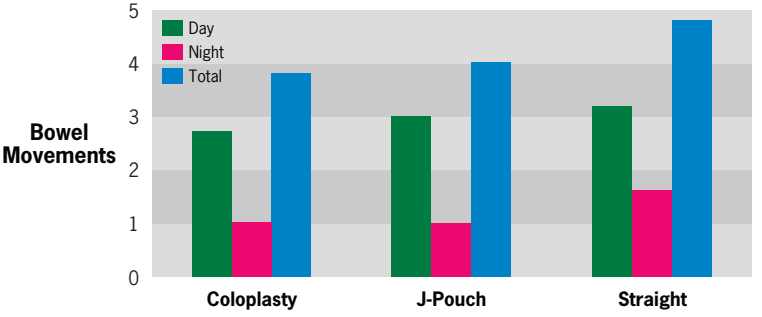
The coloplasty pouch is a new technique extensively pioneered and studied by Clinic surgeons. It is a new option following reconstruction of an ultra-low rectal anastomosis, which improves the function of patients who might otherwise have undergone a straight colorectal anastomosis due to an anatomically narrow pelvis. This is frequently seen in male patients.



Coloplasty

In 2005, the Department of Colorectal Surgery published the results of 162 patients with coloanal or low colorectal anastomosis. Patients underwent straight coloanal anastomosis (50 cases), colonic J-pouch construction (43 cases) or coloplasty (69 cases). Patients with colonic J-pouch or coloplasty had significantly fewer bowel movements both during the day and at night, used less antidiarrheal medications and, ultimately, had a better quality of life.

Functional Outcome Comparison



Contact Radiotherapy

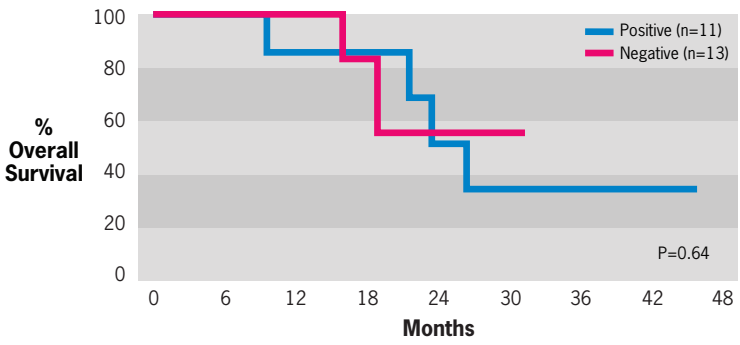
Cleveland Clinic is one of only five centers in the world that offers contact radiotherapy. It can be very effective for patients who are infirmed or have other major medical co-morbidities. It is administered through the anal canal without requiring surgery.

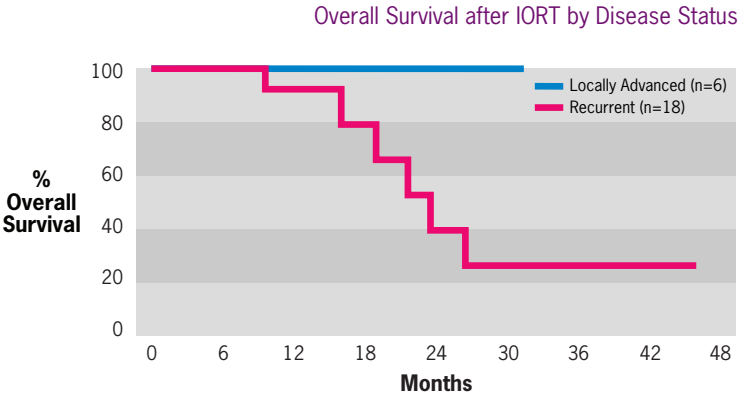
Intraoperative Radiotherapy

Intraoperative radiation therapy (IORT) has the advantage of irradiating the tumor bed while protecting surrounding normal organs from radiation. This approach is especially useful when the required radiation dose exceeds the tolerance dose of surrounding normal tissues. The technique, only available in selected institutions, is delivered in conjunction with radiotherapists who come to the Clinic's operating rooms to deliver the radiation.

A review was conducted of recurrent and locally advanced rectal cancer patients treated with IORT after tumor resection. Twenty-four patients with recurrent (18) or locally advanced (6) rectal cancer received IORT. One-year overall survival rate was 94%. Better survival outcomes were seen in patients with negative resection margins and primary locally advanced cancer compared to recurrent cancer. IORT appears to be a safe technique for improving local control in this very complex and difficult patient management group.

Overall Survival after IORT by Tumor Fixation





Transanal Endoscopic Microsurgery (TEM)

This year, our institution introduced a new procedure called transanal endoscopic microsurgery. This involves the use of stereoscopic endoscopes to fully resect lesions of the rectum and distal colon without making any abdominal incisions or splitting the sphincter. It is used for treatment of benign lesions up to 20 cm level and early rectal cancers. Cleveland Clinic is one of the few centers in the Midwest that has this technology.



TEM Device

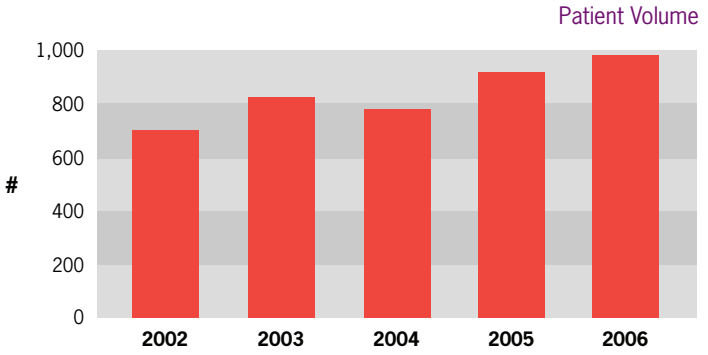
TEM is the least invasive method to remove all polyps and select cancers of the rectum and distal colon.

Benefits include:

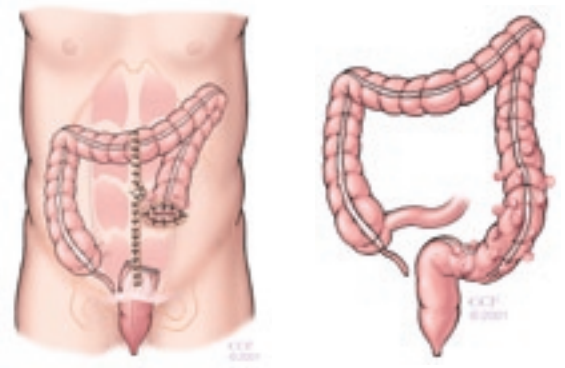
- No abdominal incision
- No stoma
- Uses a closed airtight system that provides constant rectal distension, improved visibility and longer reach than conventional instrumentation
- Virtually any rectal adenoma and select rectal cancers can be removed
- Safe; associated with minimal complications
- Outpatient or single-night hospital stay
- Lower recurrence rates than with conventional methods
- All polyps
- Select T1 cancers
- Select T2 cancers with neoadjuvant therapy
- T3 cancers in medically compromised patients
- Superior exposure of tumors higher in the rectum
- Greater precision of excision
- Allows for “total excisional biopsy”
- Short operative time
- Negligible blood loss
- Relatively pain-free procedure

Diverticular Disease

Diverticulitis



Most patients are referred for elective management of recurrent diverticulitis. Surgery is recommended based on American Society of Colorectal Surgery guidelines. Some patients present with an acute complication and require emergency surgery. A further cohort is referred for reconstructive surgery, having had an emergency procedure performed elsewhere. Hartmann's procedure is still one of the more common types of emergency resections done universally. It is associated with significant morbidity.



Diverticulits/Hartmann's Resection for Urgent Presentation

We recently published our results comparing surgical outcomes between primary resection and anastomosis versus Hartmann's reversal procedure. Our results showed Hartmann's reversal was associated with a higher prevalence of surgical or medical complications compared with primary resection and anastomosis. Patients who underwent Hartmann's reversal were 2.1 times more likely to have adverse surgical events during their postoperative period.

Primary Resection and Anastomosis (PRA) vs. Hartmann's Reversal (HR) Procedure

	PRA (n=731)	HR (n=121)	*P* value
All complications	212 (29%)	59 (48.5%)	<0.001
Surgical complications	190 (26%)	53 (43.8%)	<0.001
Postoperative ileus	72 (9.8%)	28 (23.1%)	<0.001
Medical complications	35 (4.8%)	11 (9.1%)	0.052
Respiratory failure	6 (0.8%)	5 (4.1%)	0.012
Renal failure	6 (0.8%)	5 (4.1%)	0.012
Reoperation rate	79 (10.8%)	23 (19%)	0.001



Colorectal rectal anast



Colorectal rectal anast with stoma



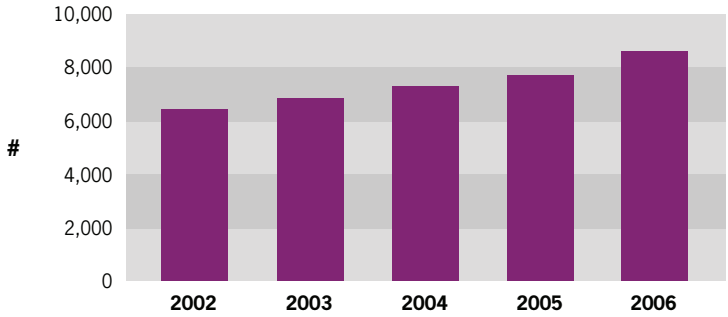
Diverticulitis

Every effort is made to re-establish the anastomosis, even in urgent conditions, to avoid further associated morbidity with Hartmann's procedure. Cleveland Clinic surgeons are proficient at selecting appropriate candidates for primary anastomosis, with or without defunctioning ileostomy. Elective surgery for diverticulitis is increasingly performed using minimally invasive laparoscopic techniques. This results in less postoperative pain, shorter length of stay and earlier return to work and other activities than similar resections using the laparotomy technique. Almost all patients requiring surgery for diverticulitis are candidates for the laparoscopic technique.

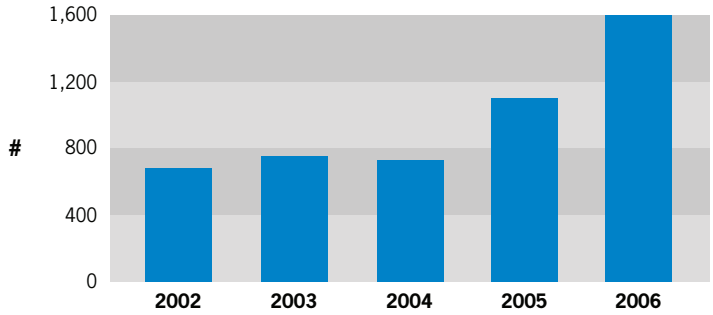
Endoscopy and Pancreatic-Biliary Disorders

A high volume of standard gastroenterologic procedures are performed: EGD, colonoscopy, sigmoidoscopy as well as advanced procedures such as ERCP, EUS and PEG. In most cases, these procedures may be performed on an outpatient basis. With the experience of our physicians and nurses, these procedures are performed efficiently and safely, with complication rates at or below national averages.

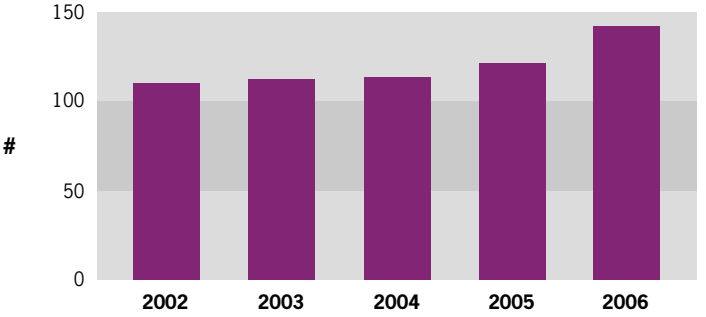
EGD Volume



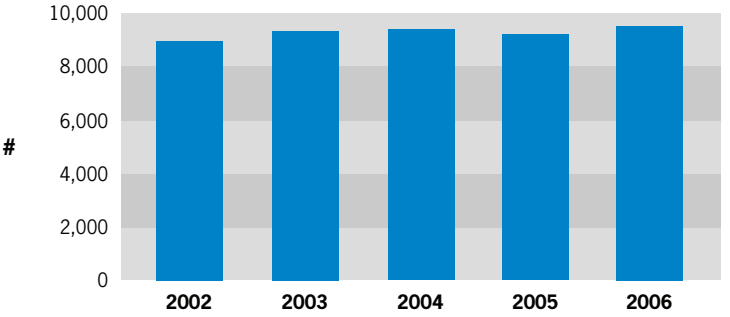
ERCP Volume



PEG Volume



Colonoscopy Volume



In a recent study from the Colorectal Surgery Endoscopy Section, our outcomes on colonoscopy completion rates and adenoma detection rates for different indications were reviewed. Results showed greater than 90% completion rate and comparable excellent adenoma detection rates within the staff.

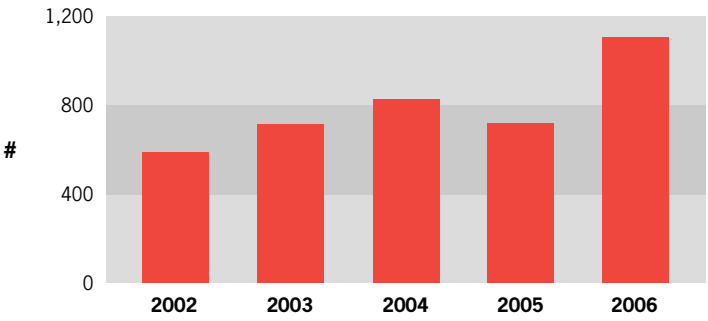
ADR Detection Rates

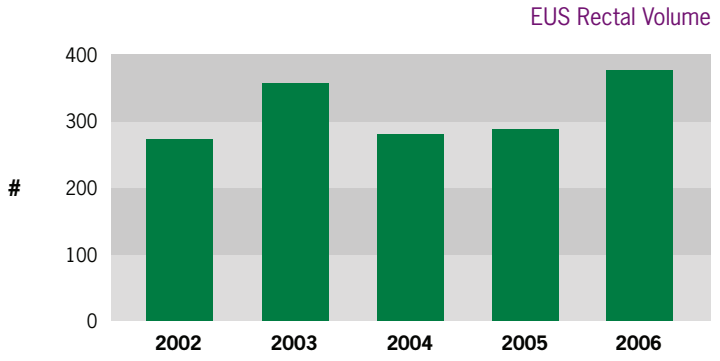
Staff	# of Exams	% Completed	ADR Polyp Surveillance	ADR Cancer Surveillance	ADR Rectal Bleeding	ADR Screening
1	359	98%	49%	43%	39%	22%
2	221	98%	29%	13%	21%	13%
3	335	98%	41%	24%	18%	18%
4	175	98%	39%	39%	21%	31%
5	193	95%	24%	22%	24%	11%

Endoscopic Ultrasound (EUS)

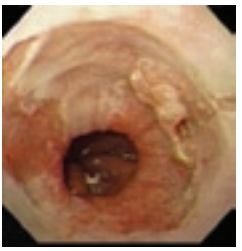
Endoscopic ultrasound is one of the most important breakthroughs in digestive diseases over the past few years. Passage of an ultrasound probe on the tip of an endoscope allows a more efficient staging of esophageal, gastric, pancreatic and rectal cancers. Fine-needle aspiration of benign and malignant tumors can be performed safely.

EUS Upper Tract Volume





Small or early growths are being found in the gastrointestinal tract through the widespread use of endoscopy. Some lesions are significant and occasionally found in patients unable to withstand a traditional surgery to remove them due to other medical problems. Options for these patients include endoscopic mucosal resection (EMR), or ablation techniques that cause the tissue to blister and slough off over time. When surgery is not an option, a new protocol is testing cryotherapy which uses super cooled liquid nitrogen spray in patients with Barrett's esophagus with high-grade dysplasia or intramucosal cancer.



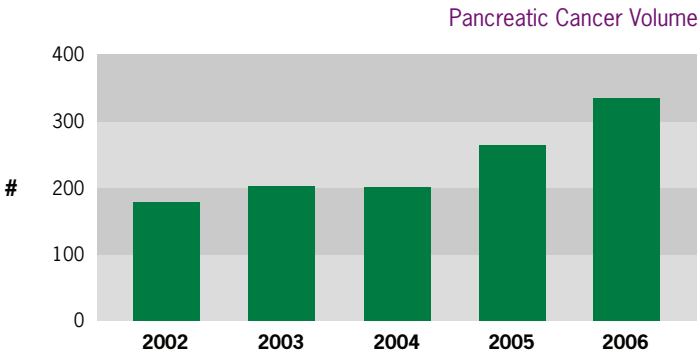
Small Adenocarcinoma and
5-year remission surveillance examination

Pancreatic Cancer

The Pancreas Clinic and the Departments of Gastroenterology and Hepatology and General Surgery see a high volume of patients with pancreatic cancer. Endoscopic ultrasound offers close-up images of the mass and adjacent vascular structures to help the gastroenterologist and surgeon determine resectability. Furthermore, fine needle aspiration can be performed to confirm the diagnosis. Endoscopic ultrasound can also be used to treat the debilitating pain in selected patients with chronic pancreatitis or pancreatic cancer through a procedure known as celiac plexus neurolysis.



Fine Needle Aspiration of a pancreatic mass



Esophageal Cancer

Accurate staging of esophageal cancer is critical for optimal treatment. Endoscopic ultrasound provides staging information more accurately than other current staging modalities, because it allows assessment of the depth of the invasion of the tumor in the esophageal wall and allows the examination of surrounding lymph nodes. (For more information, see page 79.)



Fine Needle Aspiration of a malignant lymph node

Rectal Cancer

Accurate staging of rectal cancer is critical to optimizing patient survival. A high volume of rectal cancer patients are seen. Surgical expertise combined with a multidisciplinary approach offers patients excellent outcomes. (For more information, see page 13.)

Pancreatic-biliary Disorders

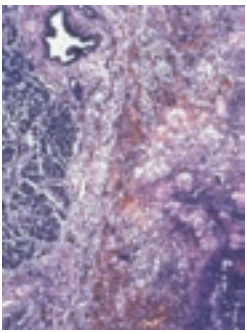
The Department of Gastroenterology and Hepatology treats patients with a wide variety of disorders of the biliary tree, including bile duct injuries after surgery, complications of liver transplantation, choledocholithiasis and sclerosing cholangitis.

Pancreas Clinic

There are more than 1.2 million cases of pancreatic disease in the United States annually, contributing to $2.1 billion of health care expenditures. Our Pancreas Clinic is one of a few designated clinics in the nation for the study of pancreatic disease. Pancreatic specialists see patients with complicated acute recurrent pancreatitis and chronic pancreatitis, as well as a multitude of other diseases, including pancreatic cancer. Gastroenterologists, surgeons, radiologists, anesthesiologists and psychologists continue to develop new protocols for managing pancreatitis that may decrease morbidity. Patients with all forms of pancreatic disease are offered the latest cutting-edge techniques and treatments. Our staff is equipped with the latest technologies and provides patients with the most appropriate evaluation and treatment options.

Acute Pancreatitis

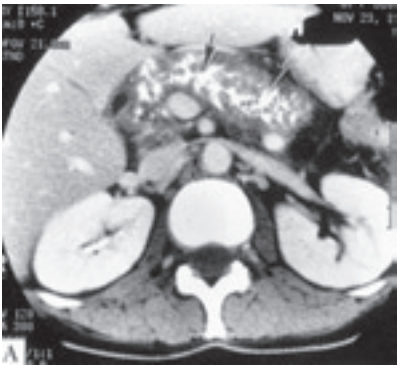
Acute pancreatitis occurs when the pancreas becomes inflamed by a variety of reasons; most commonly alcohol consumption or gallstone disease. Ten to 15 percent of cases are idiopathic in nature. Our center offers the latest in endoscopic, minimally invasive and radiographic imaging to diagnose and treat acute pancreatic inflammation.



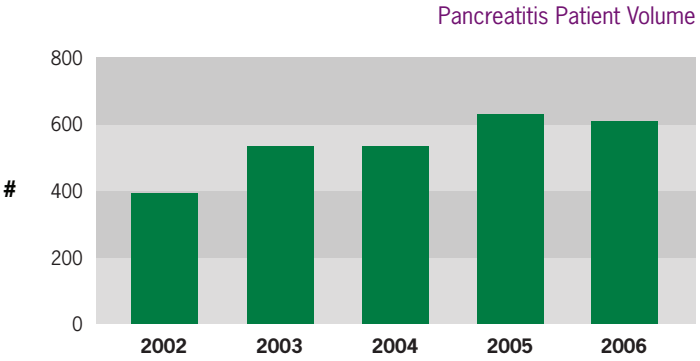
Acute pancreatitis histology

Chronic Pancreatitis

Chronic pancreatitis is caused by continued insult to the pancreas from alcohol or metabolic/genetic disorders, resulting in scar formation, which causes chronic abdominal pain, steatorrhea and weight loss. The Pancreas Clinic, in collaboration with our Pain Management Center, offers a multidisciplinary approach to chronic pancreatic pain management. Medical management of chronic pancreatitis may include pancreatic enzymes, narcotic maintenance, antidepressants, antioxidants and subcutaneous injections of octreotide.



CT Chronic



Endoscopic Pancreatic Function Test

When compared with the traditional Dreiling tube method, the endoscopic pancreatic function test eliminates the need for fluoroscopy, is shorter in duration (30 minutes versus 80 minutes) and costs 30% less. It is safe, highly accurate and eliminates radiation exposure. The patient is sedated during the procedure; the physician passes the endoscope down to the duodenum to aspirate the pancreatic fluid.



Pancreatic Function Test

Aspirating Cystic Neoplasm

Conventional imaging of cysts in the pancreas with CT scan does not always provide a definitive answer. Endoscopists perform fine-needle aspiration of these cysts under endoscopic ultrasound guidance. This allows fluid to be taken from the cyst and cancer cells sought. Patients with precancerous or cancerous conditions can undergo timely surgery in the hopes of cure, while patients with non-threatening conditions will avoid unnecessary surgery.

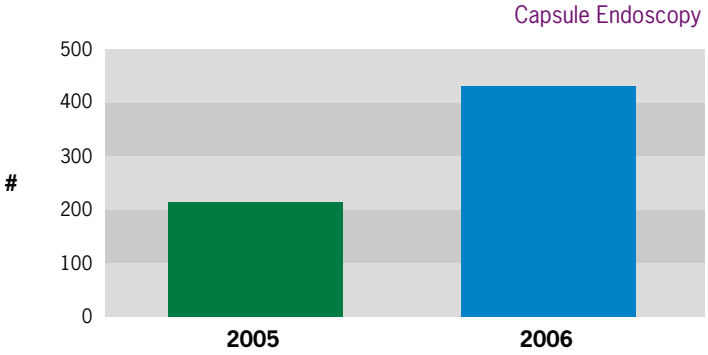
Capsule Endoscopy and Enteroscopy

The Clinic's endoscopists are among the most active in the country in utilizing capsule endoscopy. A special GI bleeding clinic allows patients to be evaluated by experienced capsule endoscopists. This technique has proven invaluable in the evaluation of patients with occult gastrointestinal bleeding, polyps of the small intestine, tumors of the small intestine and inflammatory bowel disease. A capsule specially designed to examine the esosphagus for conditions such as Barrett's esophagus and esophageal varices is also available. In specialized situations, where narrowing of the small intestine is a concern for a patient who is otherwise a candidate for capsule endoscopy, a specialized Patency Capsule can be used to determine if a narrowing is present that would make the placement of a conventional capsule problematic. The Patency Capsule essentially dissolves in the GI tract after a certain time period to remove any risk of causing an obstruction at a site of narrowing.

Balloon-Assisted Enteroscopy (BAE) is also available. BAE involves the use of an ultra-long endoscope coupled to a balloon-tipped overtube to achieve a more comprehensive examination of the small intestine. BAE complements capsule endoscopy by allowing the examination and treatment of segments of the small bowel previously out of reach of traditional endoscopy.



Capsule

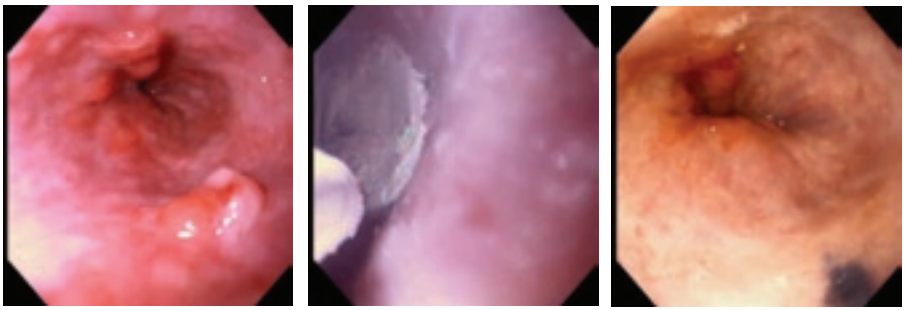


Treatment Protocol for Chronic Pain Management

Pain associated with chronic pancreatitis is difficult to manage. We believe a multidisciplinary approach is best for evaluating this complex syndrome. The Department of Gastroenterology and Hepatology has been developing a chronic pancreatic pain protocol in collaboration with the Departments of General Surgery, Pain Management and Psychiatry and Psychology.

Cryotherapy

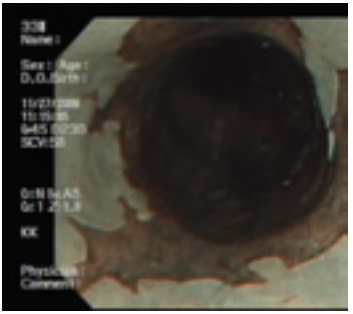
Cryotherapy involves the application of liquid nitrogen through an endoscope for the treatment of precancerous lesions of the esophagus as well as superficial cancers in selected patients. The Digestive Disease Center is one of only a few institutions in the country to offer this therapy.

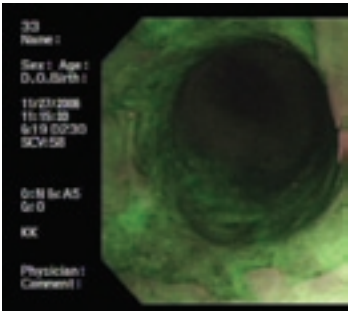


Esophageal cancer in the lower esophagus pre- and post-cryotherapy treatment

Optical Biopsy and other Imaging Modalities

Detection of cancer in the digestive tract may not occur until there is visible growth in the intestine and related symptoms. Unfortunately, it is often too late at this point to cure the patient. Optical biopsy techniques utilize special computers and technology to allow a close-up image of the intestinal tract. Ongoing research at Cleveland Clinic is establishing the role of optical biopsy techniques for such conditions as Barrett's esophagus, polyps and inflammatory bowel disease.



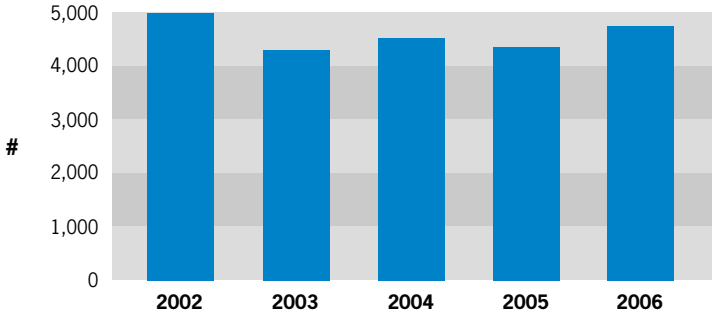


Examples of Narrow Band Imaging and Autofluorescence Spectroscopy

Other imaging modalities being studied, including narrow band imaging (NBI) and autofluorescence spectroscopy (AFI), use different types of light to identify small precancerous and early cancerous lesions that may go undetected by conventional endoscopy.

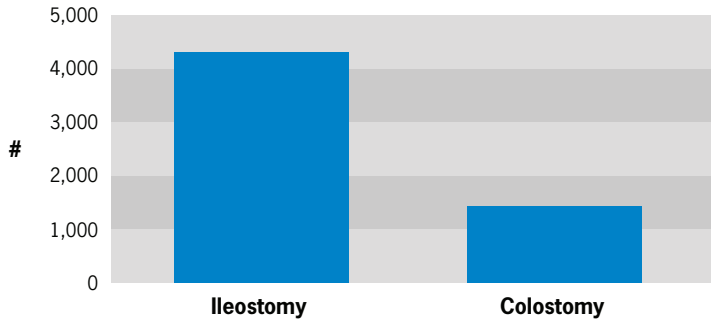
Enterostomal Therapy

Stoma and Fistula Volume



Enterostomal therapy, commonly known as wound, ostomy and continence nursing, was founded at Cleveland Clinic in 1958. Pioneering colorectal surgeons Rupert B. Turnbull and Norma Gill, an ostomate herself, began a specialty now practiced around the world. Cleveland Clinic's School of Enterostomal Therapy, which bears Dr. Turnbull's name, opened in 1961 and was the first of its kind in the world. This specialty program has educated nearly 1,500 nurses around the United States and world, and continues to teach nurses the theoretical and clinical care of people with ostomies, fistulae, wounds and incontinence. Cleveland Clinic boasts one of the largest, most experienced and highly skilled staff of Board-certified ET/WOC nurses in the world who care for people with these very special needs.

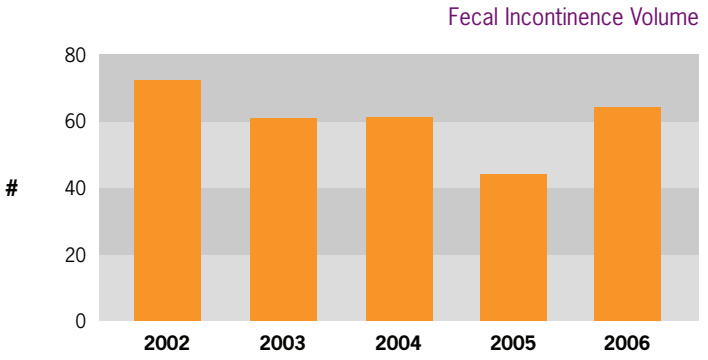
Most Common Ostomies 1998-2006



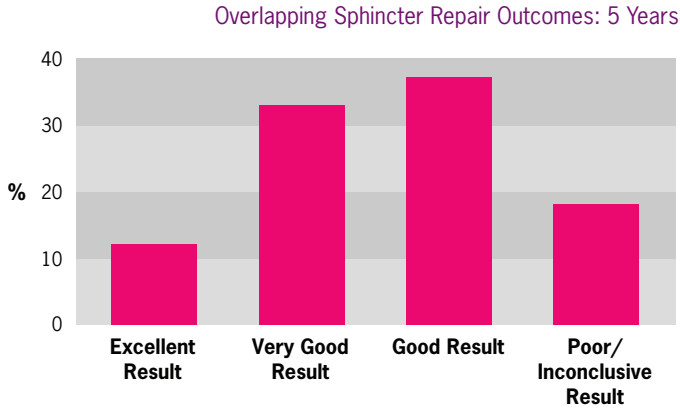
Fecal Incontinence and Pelvic Floor Dysfunction

The Fecal Incontinence and Pelvic Floor Dysfunction Section works closely with the Women's Center for Pelvic Disorders to offer women comprehensive evaluation of pelvic problems. Our specialists work as a team and are constantly investigating new treatment alternatives for these patients. This highly specialized center offers diagnostic aids, new and innovative treatments, and protocols to men and women with fecal incontinence and pelvic floor problems. A team of specialists is committed to integrating newer techniques to help patients cope with these debilitating conditions.

Fecal Incontinence Surgery



Treatment is centered on the severity of symptoms. Treatment plans are individualized to patients after considering medical and quality-of-life objectives. These could range from simple, conservative management and biofeedback, to new techniques like injecting bulk forming agents (such as Durashere's carbon coated beads or Q-Med's NASHA products*), to the SECCA (meaning "dry" in Italian) procedure, and to surgical options like sphincter repair, artificial bowel sphincter and sacral nerve stimulation. When a surgical approach is required for sphincter repair, it is usually performed with an overlapping sphincteroplasty.



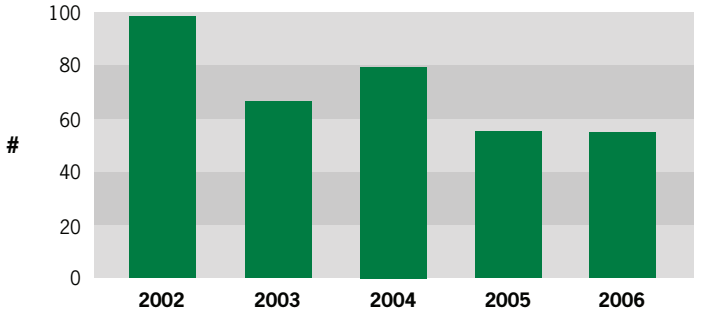
Overlapping Sphincter Repair: 10-Year Results

Unpublished results show a decrease in quality of life scores with only one-third of the women reporting good quality of life. On an average, however, the quality of life was not changed from that at five years. Patients who had two or more children particularly had lesser control of their bowels.

Rectal Prolapse

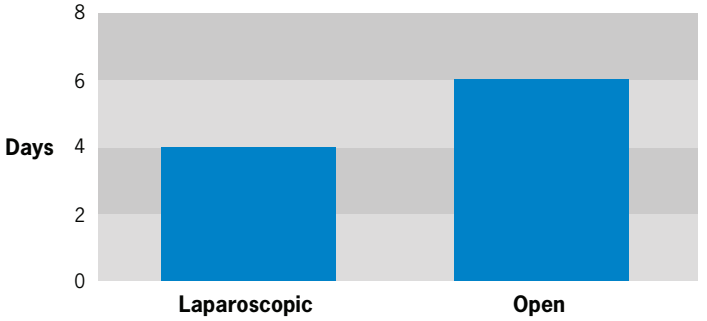
Surgical repair for rectal prolapse is usually advised. This repair can be undertaken via an abdominal operation or anal operation with the exact approach being tailored to each particular patient. When possible, these procedures are performed laparoscopically.

Rectal Prolapse Volume

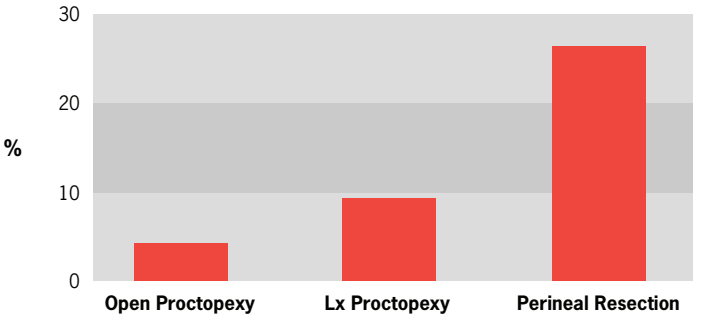


Laparoscopic patients have a shorter hospital stay.

Average Length of Stay



Recurrence Rate in Treatment of Rectal Prolapse



Bulking Agents

Several companies are working toward an ideal bulking agent, a treatment of mild to moderate fecal soiling. This minimally invasive procedure requires injecting the bulking agent into the intra-sphincteric plane. This product is available under a research protocol.

Artificial Bowel Sphincter

The artificial sphincter is a prosthesis that is completely implanted within the body. A fluid-filled cuff fits around the anal canal and is gently inflated like a balloon to prevent the passage of stool. When the patient wishes to have a bowel movement, the cuff is deflated and stool can pass. The cuff automatically closes after several minutes, restoring continence. Patients who have sustained injury to their anal muscles from prior anal surgery, trauma (such as an accident), birth defects or developmental problems, may benefit from an artificial sphincter. Women suffer from fecal incontinence more often than men, and, almost always, because of childbirth. For some patients, an artificial sphincter is an alternative to a colostomy.



Artificial Bowel Sphincter

Sacral Nerve Stimulator

The sacral nerve stimulator is an exciting technique recently developed to improve continence. Under general anesthesia, electrodes are placed close to branches of the sacral nerves. After tests confirm improvement in continence for each individual patient, the temporary electrodes are replaced with permanent electrodes and an implanted power supply. Newer uses of this technique suggest it may also be useful for those with disorders of impaired evacuation. This procedure is awaiting FDA approval.

Outlet Dysfunction Syndrome

Outlet dysfunction syndrome is a disorder in which patients find it exceedingly difficult to evacuate without the aid of digital pressures in various parts of the pelvis and the help of laxatives.

The STARR procedure is a new technique shown to benefit these patients. A Phase II study started in February 2004 at our institution followed 10 patients until its conclusion in 2006. In that study, eight patients showed a marked-to-average improvement in their symptoms. A new study concluded in 2006; we are waiting for the instrument to be available for commercial use.

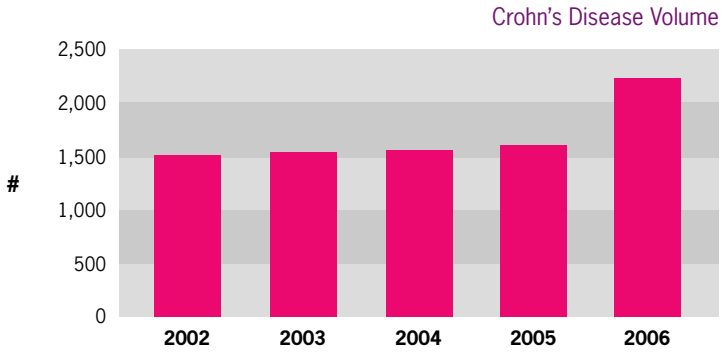


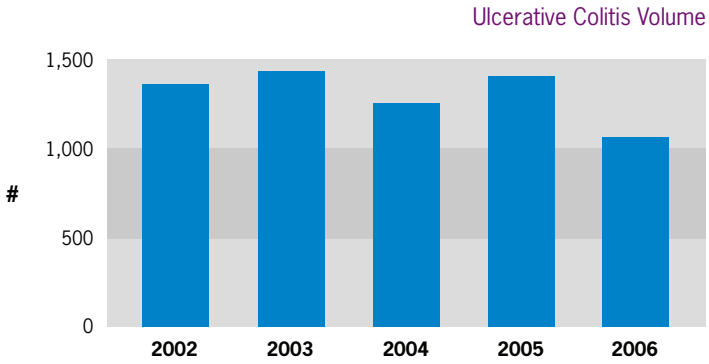
Sutures in Wall

Inflammatory Bowel Disease

Crohn's Disease and Ulcerative Colitis

Crohn's disease and ulcerative colitis are chronic inflammatory bowel diseases that can present with a myriad of manifestations. The Digestive Disease Center's gastroenterologists and colorectal surgeons work collaboratively to identify the optimal approach to managing Crohn's disease and ulcerative colitis.





Innovative therapies, many pioneered at Cleveland Clinic, allow patients with inflammatory bowel disease (IBD) to lead higher quality lives. Due to our participation in clinical trials and the excellent outcome of surgical cases, we have increased worldwide referrals, particularly for complex and severely affected patients.

Proper treatment often hinges upon close cooperation between the patient, gastroenterologist and colorectal surgeon. The Digestive Disease Center is ideally suited for such consultation, since gastroenterologists and colorectal surgeons share space in a common IBD Center. Patients are commonly seen by consultants from each department on the same day. Immediate consultation offers patients two expert opinions, depending on the clinical situation.

Medical Therapy

Gastroenterologists in the IBD Center have extensive experience with immunosuppressive agents and biological therapies and can offer patients the most effective medications for their conditions. In 2006, 827 infliximab infusions were given in the IBD Center.

IBD gastroenterologists participate in most national trials of experimental agents developed by pharmaceutical companies. Not everyone is eligible or able to participate, but many patients are grateful for the opportunity to try something new after approved agents have failed. A complete list of open trials can be found at our Web site: www.clevelandclinic.org/digestivedisease.

A database of all patients with Crohn's disease seen in the Departments of Gastroenterology and Colorectal Surgery who consent to participate has also been compiled. This allows regular studies on disease complications, functional outcome following surgery, and quality of life and complications associated with different treatments so quality of care offered patients can continually improve. Currently, our Crohn's disease DNA bank is linked to this database.

Surgical Procedures for Crohn's Disease

Surgical management of Crohn's disease is an area of special interest to the Department of Colorectal Surgery. Our comprehensive and prospective database, research in basic and clinical science, therapeutic trials and outcomes analyses help maintain our position at the forefront in the management of Crohn's disease. An average of 260 operations are performed each year for Crohn's disease. A broad-based and multidisciplinary team approach to the care of these patients enables us to maintain a considerable level of success in treating patients with Crohn's disease.

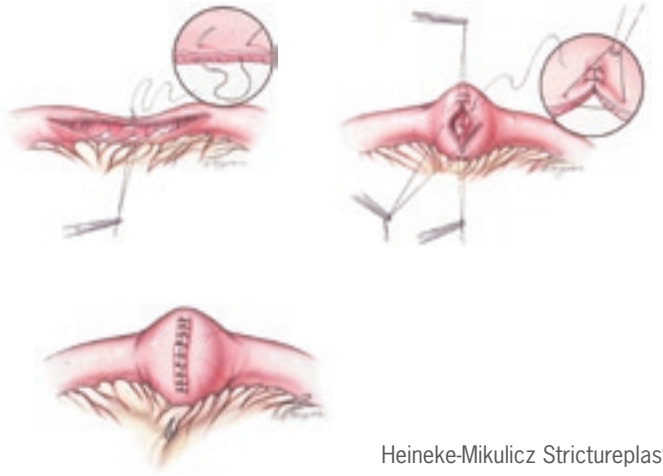
Year	Total	30-Day Mortality (%)	30-Day Readmission (%)	Wound Infection	Abdominal Abscess (%)	Obstruction or Ileus (%)	Anast. Leak (%)	Bleed (%)	Gen. Peritonitis (%)	Total Morbidity (%)
2001	275	1 (.4)	25 (9)	14 (5)	8 (3)	4 (1.4)	6 (3)	7 (3)	3 (1)	49 (20.1)
2002	291	2 (.6)	27 (9.3)	26 (9)	9 (3)	6 (2)	3 (1)	6 (2)	1 (.3)	20 (10.7)
2003	314	1(.4)	33 (10.5)	20 (6)	3 (1)	3 (1)	5 (2)	6 (1.9)	4 (1.3)	42 (15)
2004	233	2 (.9)	33 (14)	17 (7)	8 (3)	5 (2)	4 (2)	3 (1.3)	2 (.9)	51 (17)
2005	243	0(0)	35 (14.4)	21 (8.6)	7 (2.8)	7 (2.8)	4 (1.6)	7 (2.8)	3 (1.2)	52 (17)
2006	186	1(0.5)	15 (8.06)	12 (6.45)	1 (0.5)	2 (1.07)	0 (0)	5 (2.68)	0 (0)	46 (20)

A more recent study focused on the impact of surgery for Crohn's disease on quality of life in the early postoperative period.

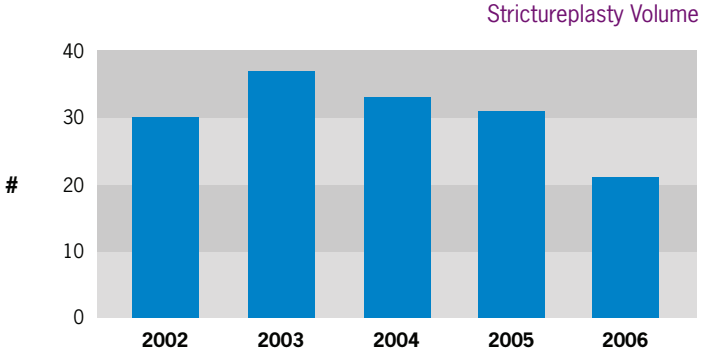
Patients	Abdominal Operations	Postoperative Complications Rate	Hospital Readmission Rate	Quality of Life 30-Days Postop
82	63 (77%)	23%	9%	Significant Improvement

Strictureplasty

Preservation of bowel length is critical for patients with Crohn's disease as multiple operations for recurrent disease are often required. Strictureplasty is a technique used to treat Crohn's-related small bowel obstruction without resection of the diseased segment. We are pleased to report highly favorable results with this bowel-sparing surgical technique.



Heineke-Mikulicz Strictureplasty



Surgical Outcomes for Strictureplasty Procedure in Patients with Crohn's Disease

Two recent Clinic studies included over 300 patients with Crohn's disease who underwent strictureplasty. There were no postoperative deaths. An interesting finding, reported in a prior study, revealed nearly 80% of operative recurrences were actually new areas of disease, distant from the strictureplasty site.

Study	Patients	Stricture Pattern	Strictureplasties Per Patient	Complications	Septic Complications	Follow-up Year	Operative Recurrence
Study 1	123	Diffuse	5	20%	6%	6.7	29%
Study 2	219	Limited	2	18%	5%	7.8	34%

Surgical Procedures for Ulcerative Colitis

Ileoanal Pouch Surgery

One of the many techniques perfected at Cleveland Clinic is the pelvic pouch or the ileal pouch-anal anastomosis (IPAA). The Department of Colorectal Surgery is an established referral destination of any patient with mucosal ulcerative colitis who requires surgical treatment and wishes to avoid a permanent stoma. Colorectal surgeons have a very high success rate with this specialized surgery.

Approximately 170 IPAA surgeries are performed each year. Data accumulated on these patients show quality of life and health ratings are very high from one to 15 years after surgery, with no decline in the vast majority of patients. Most patients do so well after this surgery, they rarely require regular medical treatment for disorders associated with their pouch.



Ileal Pouch Anal
Anastomosis = J Pouch

Ileal Pouch Failure Model

During the last year, Clinic surgeons developed a model for quantification of risk for pouch failure after IPAA surgery. This model accurately predicts risk by examining preoperative, intraoperative and postoperative risk factors. The following risk factors were found to be independent predictors of pouch survival:

- Diagnosis of Crohn's disease
- Presence of anorectal pathology such as fistula prior to pouch surgery
- Abnormal anal manometric pressures, which are a predictor of poor anal sphincter function
- Associated patient co-morbidity
- Postoperative development of pouch-perineal or pouch-vaginal fistulae, pelvic sepsis, and anastomotic stricture or separation

Clinic surgeons reported one of the lowest pouch failure rates of 4.4%, with over 95% retention rate. The ileal pouch failure model is a simple, accurate way of predicting the risk of ileal pouch failure in clinical practice. It plays an important role in providing risk estimates for patients wishing to make informed choices on their treatment. This model has international recognition and is being used worldwide in patients undergoing IPAA surgery. Pouch failure is a concern for patients and their surgeons. The Department of Colorectal Surgery is a major referral center for patients who had a failed IPAA surgery. Our recent study on repeat IPAA showed high retention rates (90% for ulcerative colitis).

Experience of Patients Undergoing Laparotomy, Ileoanal Disconnection and Repeat IPAA

Total Patients	% from Other Institutions	Have Functioning Pouch	Never Described Urgency	Fecal Seepage (Day)	Fecal Seepage (Night)	Would Undergo Repeat IPAA Again	Would Recommend to Others
101	80%	82%	35%	50%	69%	97%	99%

IPAA with Omission Diverting Stoma

Clinic surgeons reported the outcomes in selected patients with no diverting ileostomy and compared these results to patients who had diverting stoma. A recent study indicated no differences between the two groups in pouchitis rates and septic complications, such as pelvic abscess, anastomotic leak, and fistula. These were one of the lowest reported complication rates in IPAA surgery in the world.

Complications Compared between the Ileostomy and No-ileostomy Groups

	Ileostomy (n=1,725) (%)	No-ileostomy (n=277) (%)	P-value
Pouchitis	513 (30)	93 (33)	0.7
Pelvic sepsis	113 (6.5)	15 (5.4)	0.51
Anastomotic leak	94 (5.5)	12 (4.3)	0.57
Fistula	139 (8.1)	18 (6.5)	0.36
Pouch vaginal fistula	52/712 (7.3)	4/154 (2.6)	0.049
Postoperative ileus	195 (11.3)	56 (20.2)	<0.001
Small bowel obstruction	324 (18.8)	28 (10.1)	0.012
Operation for SBO	127 (39)	8 (29)	
Perioperative fever (>38° C)	194 (11.3)	56 (20.3)	<0.001
Hemorrhage	63 (3.7)	3 (1.1)	<0.001
Anastomotic stricture*	352 (20.4)	26 (9.4)	<0.001
Pouch failure	77 (4.5)	5 (1.8)	0.022

*Includes symptomatic and asymptomatic strictures

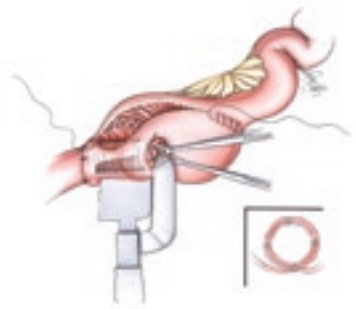


IPAA with Ileostomy and one-stage pouch with no diverting ileostomy

There were no differences between the groups in quality of life assessed by Cleveland Clinic's quality of life questionnaire at intervals of three months and one, three, five and 10 years. Functional outcome results were also similar between the groups at the same follow-up intervals after adjusting for age in the patients with the same anastomosis type. Clinic surgeons believe omitting temporary diverting ileostomy is a safe procedure in carefully selected patients undergoing IPAA surgery.

Continent Ileostomy

Continent ileostomy is an option in patients where an ileal pouch surgery is not possible or the initial and subsequent repeat ileoanal pouch surgery failed and the patient is reluctant to accept a permanent ileostomy. Continent ileostomy, or Kock pouch, is constructed by three loops of small bowel and a one-way valve, which allows patients to avoid wearing an outer appliance. One has to cannulate the Kock pouch three to four times a day to empty itself. Clinic surgeons are very experienced in this technique. We are one of a few centers where this procedure is done.



Kock Pouch

Surgical outcomes in 330 patients undergoing a continent ileostomy procedure were recently reported. Intraoperative and postoperative patient-related factors were evaluated as predictor variables of long-term pouch survival. Quality of life was also evaluated.

Total	Median Revision-free Pouch Interval	10-Year Pouch Survival	20-Year Pouch Survival	Average Number of Complications	Average Number of Revisions
330	14 Months	87%	77%	3.7 (Range: 1-28)	2.9 (Range:1-27)

Independent predictors of pouch failure, using multivariate analysis, include:

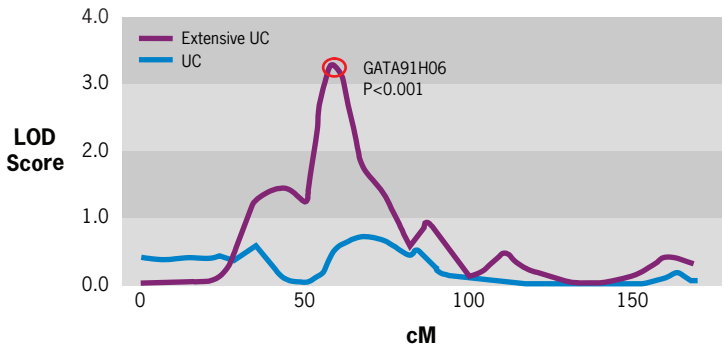
- Crohn's disease
- Female gender
- Fistula development
- Higher body mass index

Quality-of-life measurements for patients with a continent ileostomy were higher on all scales in comparison with patients who had the Kock reservoir and then reverted to a Brooke ileostomy. Clinic surgeons believe that despite the associated morbidity with continent ileostomy surgery, long-term results and quality of life were encouraging. Continent ileostomy can be offered as an attractive long-term option to select patients whose only alternative is an end ileostomy. Many new and innovating clinical research projects aimed at better understanding the causes and treatment of inflammatory bowel disease are under way.

Genetics of IBD

IBD runs in families, suggesting a genetic component to the cause of these diseases. Researchers from our IBD Center were involved with studies that led to discovery of the first gene associated with Crohn's disease, NOD2/CARD15. The second IBD gene was discovered this year as the interleukin-23 receptor (IL-23R) gene. Currently, an NIH-funded study is allowing us to create a DNA bank of our IBD patients. To date, over 700 Crohn's disease patients and controls have contributed to this effort. In 2006, Jean-Paul Achkar was the first author of a study in which 904 IBD patients from a multicenter collaboration were stratified by phenotypic information (Achkar JP, et al). Phenotype-stratified genetic linkage study demonstrates that IBD2 is an extensive ulcerative colitis locus. (Am J Gastroenterol 2006;101:572-80). While there was no genetic linkage signal when all ulcerative colitis patients were studied (blue line), there was a strong linkage signal when only patients with extensive ulcerative colitis were studied (purple line). This finding has potential implications for better localizing a gene for ulcerative colitis on chromosome 12.

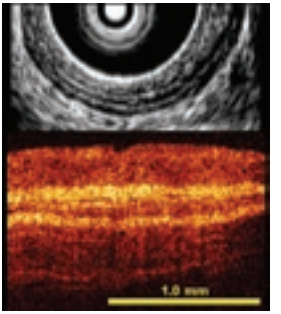
IBD2 is an Extensive Ulcerative Colitis Locus



Optical Coherence Tomography (OCT)

OCT is a new imaging technique for evaluation of the various layers of the intestinal wall. Investigators at the IBD Center are the first in the world to apply the use of OCT to IBD. Major grants have been received from the American College of Gastroenterology to study how OCT can be used in the management of IBD patients. As the resolution of this technique improves, we will be able to better identify which areas of intestinal mucosa are likely to have lesions on biopsy. In coming years, OCT will be considered an “optical biopsy” technique.

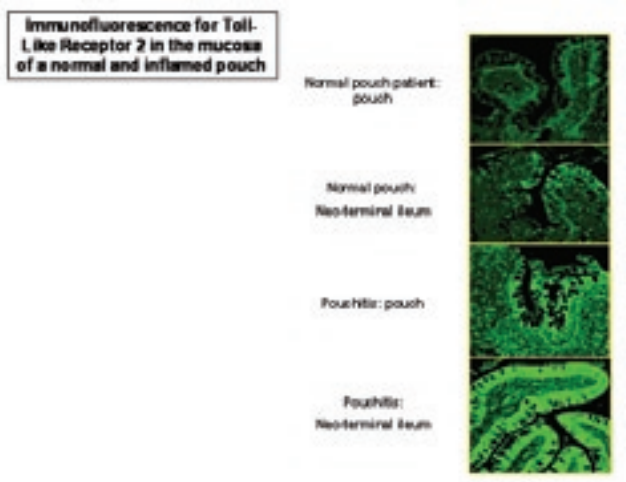




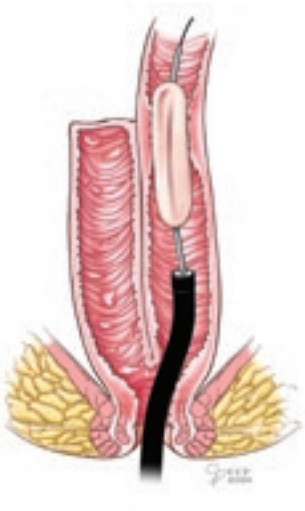
Optical Coherence Tomography

Pouchitis

Patients with ulcerative colitis can be treated by surgery to remove the colon and create an ileal pouch. While some patients have an excellent long-term outcome, some develop complications like acute pouchitis, chronic pouchitis, cuffitis, irritable pouch syndrome and even Crohn's disease. Recent research in the IBD Center concentrates on risk factors for the development of complications of the ileal pouch, accurate diagnostic criteria, cost-effective evaluation of a symptomatic patient, and physiology of the pouch with barostat measurements. Treatment options studied included balloon dilation of inlet and outlet strictures, 5-aminosalicylic acid suppositories for cuffitis, innovative antibiotic regiments for pouchitis, and in a NIH-funded study of amitriptyline for irritable pouch syndrome. More recently, investigators showed toll-like receptor-2 (TLR-2) is involved with the earliest pathogenetic events of acute pouchitis, chronic pouchitis, and Crohn's disease of the pouch (Figure courtesy of Revital Kariv, M.D., and Bo Shen, M.D.).



Immunofluorescence for Toll-Like 2 Receptor in the mucosa of a normal and inflamed pouch





Balloon Dilation

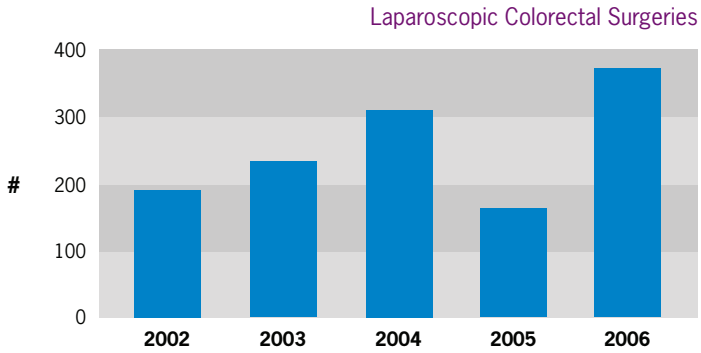
Cancer Biology

Patients with IBD are at increased risk of developing cancer. Current methods of cancer surveillance lack sufficient sensitivity to reassure patients with a negative test that cancer will not develop. Research in the IBD Center is looking at ways to improve sensitivity of testing with chromoendoscopy. Also, in a NIH-funded study, research is under way to find biomarkers that may predict which patients are more likely to develop dysplasia and which patients are more likely to progress to advanced neoplasia. Promising results have been obtained. Using genomic hybridization (Figure), patients who progress to dysplasia or cancer have been shown to have marked genetic instability with multiple gene mutations (green and red dots on the left panel) while patients who do not progress have very few gene mutations (right panel).



Laparoscopy

Traditional surgical treatment for many intestinal disorders required a long midline abdominal incision and a lengthy recovery period, between four and eight weeks. Today, colorectal surgeons are highly experienced in minimally invasive laparoscopic techniques for intestinal surgery.



Benefits of laparoscopic surgery include less pain, shorter hospitalization, quicker return to full health and less scarring. Experience with more than 1,500 laparoscopic intestinal resections, and an average of eight laparoscopic cases each week, shows the approach can be at least as safe as traditional surgical methods when performed by a surgical team with special training and extensive experience.

	Laparoscopic Colectomy LOS (days)	Conventional Colectomy LOS (days)	Cost Reduction with Laparoscopy
Rectal prolapse	3.9	6.0	N/A
Diverticulitis	3.1	6.8	20.0%
Crohn's disease	3.0	5.0	14.7%
Overall	3.0	5.5	N/A

A registry of all patients undergoing laparoscopic colorectal surgery is maintained prospectively. Recent publications continue to suggest laparoscopic cancer surgery offers an equally good outcome to open surgery, when performed by experienced surgeons.

Laparoscopic approach is now offered to nearly 95% of all patients requiring an elective index resective procedure, while conversion rates and a need for a larger incision is needed in less than 10% of patients.



Laparoscopy Colectomy Incision and
Conventional Colectomy Incision

Suitable conditions for laparoscopic colectomy include:

- Diverticular disease
- Crohn's disease
- Ileoanal pouch procedure for mucosal ulcerative colitis
- Familial polyposis
- Rectal prolapse
- Cancers of the colon and rectum

While oncologic ramifications of a laparoscopic approach are proven at least equal to open operation, the possibility a laparoscopic approach may actually help protect colorectal cancer patients against recurrence is now being evaluated.

Liver Disease

With an expertise in treating a wide range of common and uncommon hepatobiliary diseases, the liver specialists treat patients from around the world. The Hepatology Section offers a full range of diagnostic testing and treatment of patients with liver diseases including viral hepatitis, non-alcoholic fatty liver disease, cholestatic liver disease and other less common liver disorders. A comprehensive approach is utilized for patients with liver failure including management of ascites, variceal bleeding and hepatocellular carcinoma. Hepatologists are an integral part of the liver transplant program. In 2006, hepatologists had over 1,700 new patient visits and over 5,500 total clinic visits.

Clinic surgeons have extensive experience with relatively uncommon hepatobiliary procedures, including resection of benign and malignant liver tumors, laparoscopic radiofrequency ablation for inoperable liver tumors and portal hypertension surgery. Our liver transplant program is an essential component of a broad medical and surgical strategy to manage all patients with liver disease with the therapy most appropriate to that patient. Experts in all areas of liver disease participate in the evaluation, management, treatment and follow-up of these patients.

Liver Transplant Program

In 2006, 125 transplants were performed with ever-improving outcomes.

Patient Activity	2005	2006
Transplants	122	125
Adult living donor transplants	3	3
Pediatric living donor transplants	2	1
Size of waiting list	150	183
Number of patients in follow-up	585	792

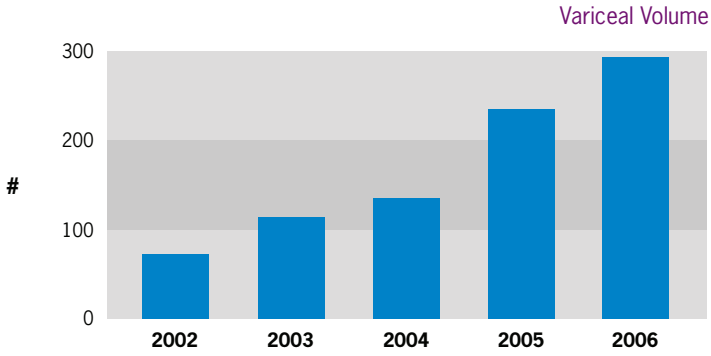
In addition to adult transplantation, the Transplant Center offers pediatric liver transplantation. The living donor transplant program, for both children and adults, was restarted in the second half of 2005. Our commitment to clinical and basic science research in liver transplantation is growing. Clinical trials on induction immune suppression in the hope of reducing the need for immunosuppressive drugs are ongoing. Additional research studies include examining the role of novel immune suppressive medications to protect renal function after transplant and exploring the role of liver transplant in patients with stable HIV infection.

Variceal Bleeding

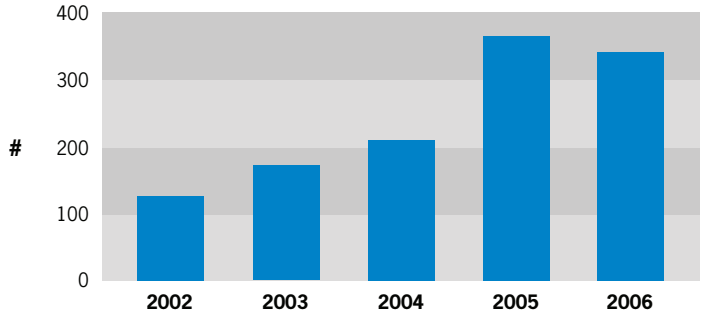
Variceal bleeding is a common life-threatening complication of cirrhosis. The preferred treatment method is variceal banding.



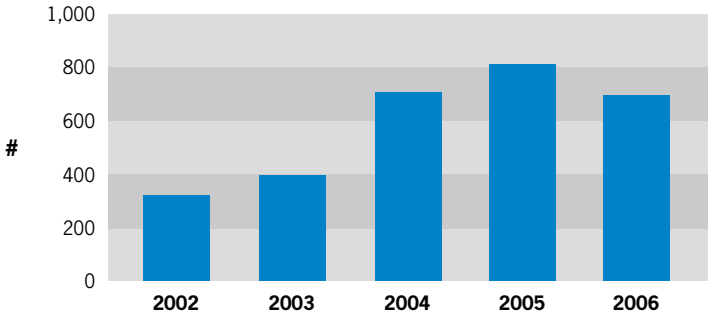
Endoscopic photo of a band placed on an esophageal varix



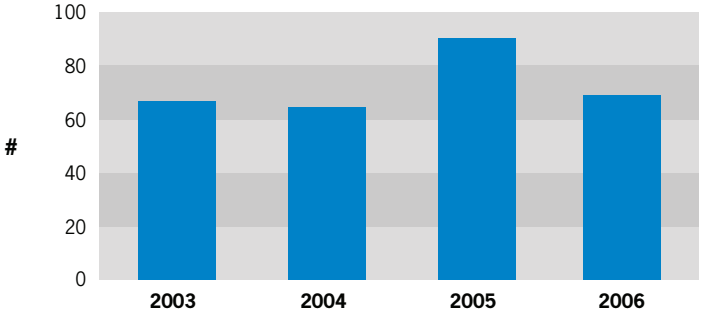
Esophageal Variceal Banding Volume



Paracentesis Volume



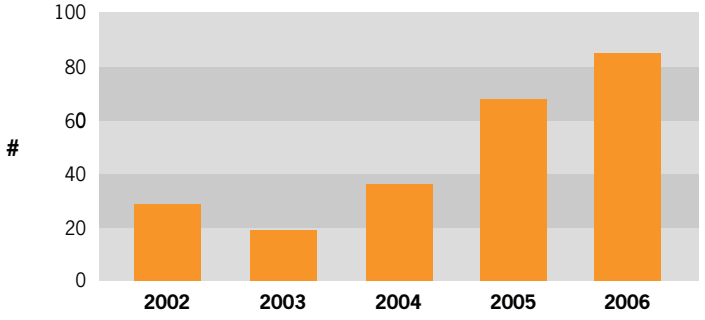
Transvenous Intrahepatic Portosystemic Shunts



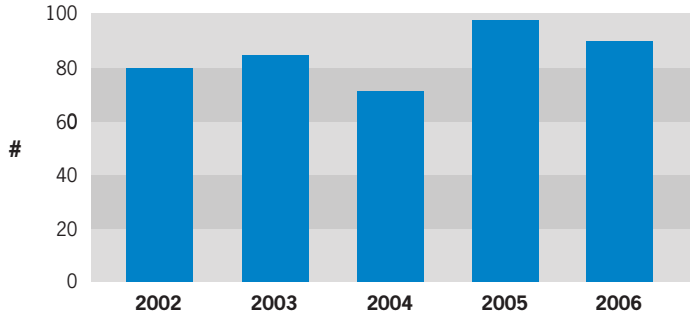
Treatment of Liver Tumors

A multidisciplinary approach is used to treat liver tumors, including surgical resection, tumor ablation, chemoembolism and liver transplant. Combined modalities, such as liver ablation followed by transplant, are often used.

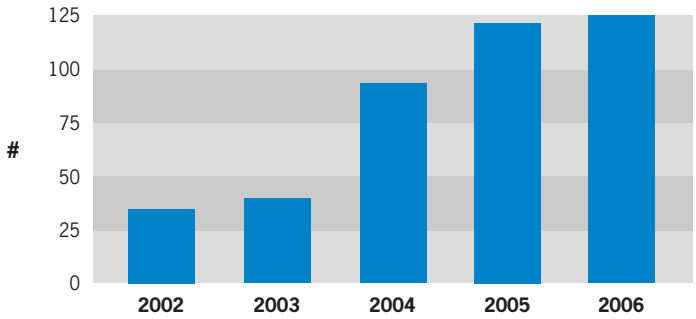
Liver Tumor Resection

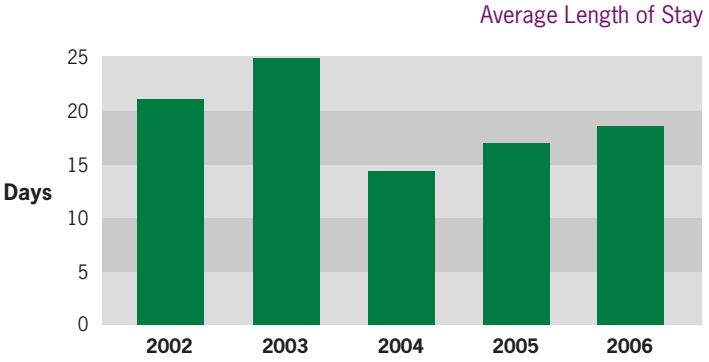


Liver Tumor Ablation



Liver Transplant Volume




Average Length of Stay
Days
25
20
15
10
5
0
2002
2003
2004
2005
2006

Ongoing, New Drugs for Hepatitis C

Since the early 1990s, Clinic hepatologists have been engaged in a series of multi-centered clinical trials of anti-viral therapy. Results from these trials are evident in the success rate of therapy, rising from about 10% to more than 85% in certain subgroups of infected individuals. Additionally, a major effort was initiated to understand the mechanism of failure in therapy in obese patients with hepatitis and in those with insulin resistance. Novel therapies are being tested as adjuncts to care for these specific populations.

New Approach to HCV Treatment with a TNF Inhibitor

A Clinic hepatologist showed viral eradication may be enhanced significantly by adding an inhibitor of tumor necrosis factor alpha to standard therapy. This modification is thought to enhance specific aspects of the immune response leading to successful viral eradiction. The concept was tested through a randomized, placebo-controlled study that included patients with chronic hepatitis C. Our hepatologists are leading a large multicenter trial in 10 sites throughout the United States to validate the potential of this novel therapy (*Journal of Hepatology* 2005; 42:315-322).

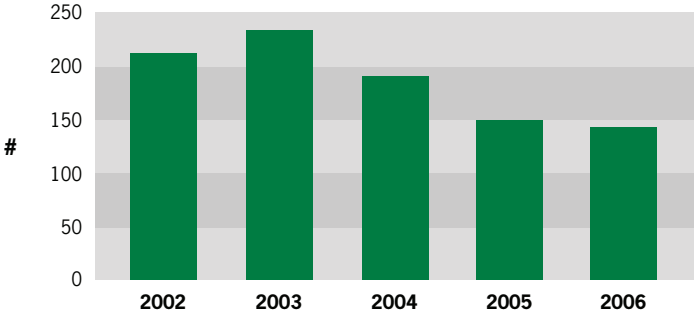
Novel Diagnostic Tools for Non-alcoholic Fatty Liver Disease

Potential novel markers to distinguish steaotosis from non-alcoholic steatohepatitis are being explored. In addition, noninvasive methods of assessing degree of liver injury in non-alcoholic fatty liver disease are being tested on a national level. This test may prevent the need for biopsy in patients with non-alcoholic fatty liver disease (*Hepatology* 2006; 44:27-33).

Motility Disorders

Diagnostic procedures required for assessment of motility disorders outside the esophagus, including gastroduodenal manometry, anorectal manometry and anal ultrasound, are provided. Radiologic and nuclear medicine tests are performed by appropriate departments.

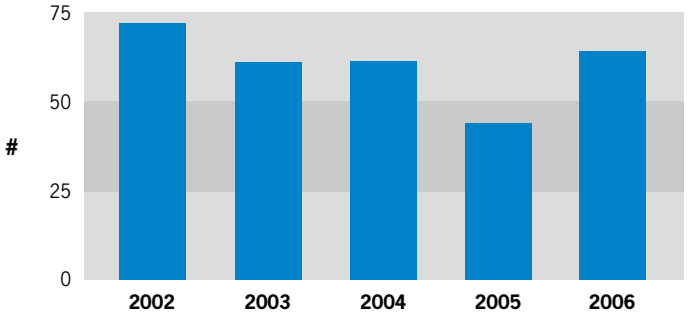
Gastroparesis Patient Volume



Fecal Incontinence

Following anatomic and physiologic evaluation, patients are offered therapy directed at changing bowel habits and/or biofeedback. Those who can benefit from surgery are referred to our colorectal surgery specialists. (For more information, see page 43).

Fecal Incontinence Procedure Volume



Constipation and Evacuatory Disorders

Patients are usually managed initially by a gastroenterologist to laparoscopically perform a subtotal colectomy with ileo-rectal anastomosis.

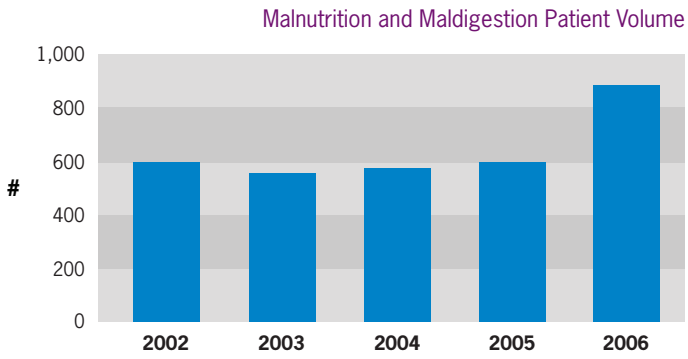
Endosonography

Endosonography is also known as rectal ultrasound endoscopy. This is a new diagnostic tool making it possible to visualize the sphincter muscles by using sound waves to produce images and precisely identify abnormalities.

Clinical Nutrition

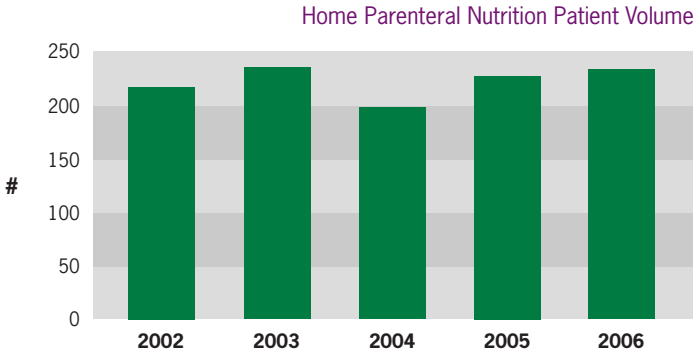
Malnutrition and Maldigestion

More than 500 patients with maldigestion and malabsorption are seen each year. Some patients have unusual conditions such as refractory celiac disease, intestinal lymphangiectasia and Whipple's disease, while others have radiation enteritis or intestinal failure often leading to weight loss, dehydration, electrolyte abnormalities and anemia. The Center can also provide specialized treatment to patients with severe malnutrition through the Nutrition Support Team and the Intestinal Rehabilitation Program.



Home Parenteral Nutrition

The Nutrition Support Team provides comprehensive care for one of the largest cohorts of home parenteral nutrition patients in the nation. The team, in existence for more than 25 years, provides expertise for management of these complex patients while avoiding many of the associated complications of parenteral nutrition. A careful assessment of patient outcomes shows that tunneled central venous catheters, compared to peripherally inserted catheters, are less likely associated with complications of this therapy (*Am J Gastroenterol* 2006; 101:S401).



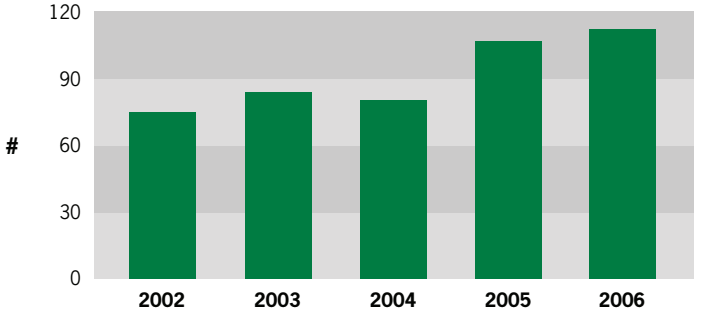
Enteral Feeding Tubes

Dysphagia is one of the leading indicators for percutaneous endoscopic gastrostomy (PEG). Patients with malabsorption may also benefit from these devices. Endoscopic jejunal tube placement for patients with gastroparesis or gastric outlet obstruction that leads to malnutrition or tube feeding-associated aspiration pneumonia can also be performed. Options include placement of a jejunal extension tube through a gastrostomy tube (PEG-JET) or direct percutaneous endoscopic jejunostomy (direct PEJ).

Intestinal Rehabilitation Program

The Intestinal Rehabilitation Program (IRP) was established in 2001 to optimally manage patients with intestinal failure. This ambulatory-based program seeks to restore nutritional status and maximize the patient's quality of life through the safest and most cost-effective techniques. An initial diagnostic evaluation of the patient's nutrition, vitamin, and trace element status as well as gastrointestinal anatomy is followed by intensive preliminary and follow-up dietary counseling, including the possible use of vitamins, minerals, trace elements, oral rehydration solutions and soluble fiber. Preliminary research suggests a predigested liquid supplement with a prebiotic may promote transition from parenteral to enteral nutrition (*Am J Gastroenterol* 2006;101:S313). Medical management modalities may include the use of antidiarrheal and antisecretory agents, pancreatic enzyme replacement therapy and non-absorbable oral antibiotics. In addition, evaluation for restorative surgical procedures can lead to enhanced intestinal absorption by increasing intestinal absorptive capability. Recombinant human growth hormone was recently approved for use in parenteral nutrition-dependent short bowel syndrome patients to promote intestinal adaptation and enhance function of the residual bowel for possible reduction or elimination of parenteral nutrition. The IRP provides comprehensive evaluation, education, and monitoring of patients undergoing therapy with this and other trophic substances to safely and effectively transition patients from intravenous nutrition to oral or enteral feedings.

IRP New Patient Volume



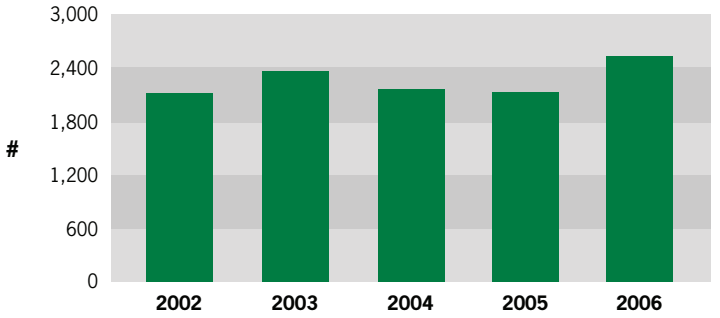
Swallowing and Esophageal Disorders

The Center for Swallowing and Esophageal Disorders is one of only a few such academic centers in the United States. The Center's multidisciplinary team includes gastroenterologists, radiologists, general and thoracic surgeons, neurologists, lung specialists, swallowing therapists, and ear, nose and throat specialists.

Gastroesophageal Reflux Disease (GERD)

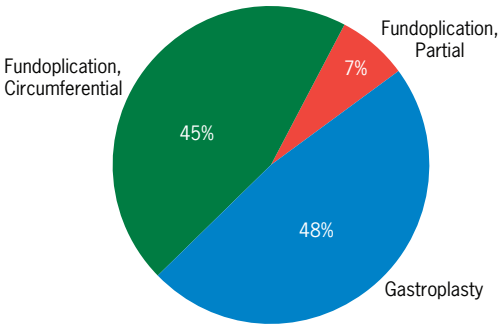
Broad treatment modalities are offered for all forms of GERD, from typical heartburn and regurgitation to atypical presentations including acid-induced asthma, chest pain, and cough, hoarseness and sore throat.

Gastroesophageal Reflux Disease Patient Volume



Anti-reflux surgery can be done through one of a variety of approaches best suited to the patient. For the initial surgery, a minimally invasive laparoscopic approach is preferred. Our surgeons now have the largest referral practice in the region for complicated GERD and redo operations. Seventy percent of procedures for complicated reflux disease involve a technically more complex Collis-Belsey or Collis-Nissen procedure to lengthen the esophagus to prevent reoccurrence. There have been no operative deaths since 1998.

GERD Case Distribution



Barrett's Esophagus

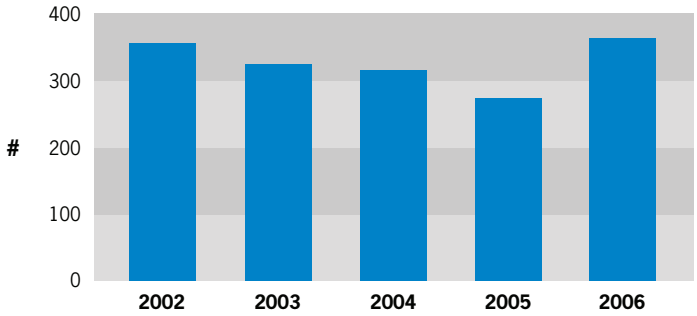
Barrett's esophagus is a complication of chronic GERD that may increase the risk of esophageal cancer in a small subset of patients. Current strategies for improved survival in patients with esophageal adenocarcinoma focus on cancer detection at an early and potentially curable stage. This can be accomplished by screening for Barrett's esophagus with endoscopic surveillance of patients with known Barrett's esophagus. Expert pathology evaluation is key to the diagnosis.



Barrett's Esophagus

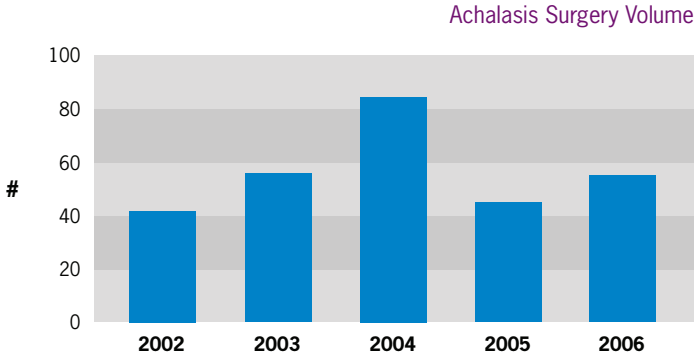
Acid suppression with proton pump inhibitors is the cornerstone of medical therapy for Barrett's esophagus because it provides consistent symptom relief. The result is either no regression of the Barrett's segment or modest clinically insignificant regression.

Barrett's Esophagus Volume



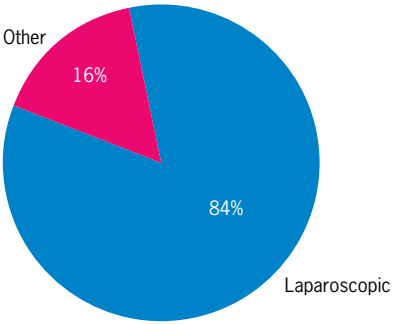
Achalasia

Cleveland Clinic has a long history of treating patients with achalasia. Available treatments include endoscopic botulinum toxin injection into the esophagus (especially for elderly patients), surgical Heller myotomy, and pneumatic (balloon) dilation. Nearly 100 pneumatic dilations a year were performed with an overall success rate of 85% and a very low perforation rate (< 2 %). Cleveland Clinic is also one of the only centers in the world researching the cause of achalasia.



Surgical myotomy as a treatment for achalasia continues to increase due, in part, to recent advances in endoscopic surgery. There have been no operative deaths for the past four years in this group of patients.

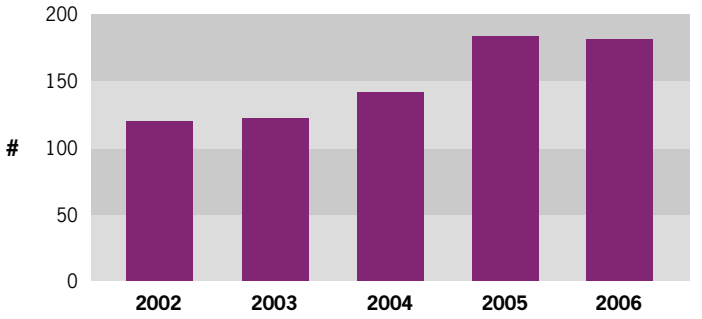
Achalasia Procedure Volume



Esophageal Cancer

Surgery offers the best chance for long-term survival for esophageal cancer. Radiation therapy offers tumor control; however, it is most effective on small tumors. Sometimes chemotherapy is added to radiation therapy. If a tumor blocks the esophagus, laser therapy, photodynamic therapy or stenting may be used to create an opening so swallowing is easier. Nutritional support with all of these procedures is necessary. Recent studies combining radiation and chemotherapy prior to surgery demonstrate longer survival for patients diagnosed with esophageal cancer.

Esophageal Cancer Volume



Esophagectomy

Esophagectomy remains one of the most challenging of general thoracic operations. In 2004, half the resections performed were for locally advanced malignancies. These procedures were performed as part of a trimodality approach to the disease, with surgery following an intensive course of concurrent chemoradiotherapy. Keys to success are experience from a high surgical volume, careful patient selection and excellent postoperative care. Overall surgical mortality rate is only 2%.

Eosinophilic Esophagitis

Eosinophilic esophagitis is an increasingly recognized cause of many esophageal symptoms. Cleveland Clinic investigators are involved in novel translational research examining the link between eosinophilic inflammation and clinical symptoms in subjects with eosinophilic esophagitis.

Barrett's Esophagus Registry

Cleveland Clinic has the largest non-VA hospital registry in the United States, following more than 800 patients; nearly 25% are women. Swallowing Center doctors are using the registry in studies to assess the possible inheritance pattern for Barrett's esophagus, the role of new biomarkers to better risk-stratify these patients, and new treatments, including high dose acid suppression with/without aspirin or NSAIDs, radiofrequency ablation and cryotherapy to promote regression of metaplasia and decrease the risk of cancer.



Bravo Ph Probe

Intraluminal Impedance Monitor

We are one of five centers in the world studying the utility of impedance in assessing bolus movement and non-acid reflux. When combined with traditional esophageal manometry, impedence allows for simultaneous correlation of motility with the movement of liquid and solid bolus. This test may be particularly useful prior to anti-reflux surgery in patients with dysphagia after fundoplication and in patients with motility disorders.

High Resolution Manometry

High resolution manometry allows more accurate assessment of esophageal motor function. Cleveland Clinic is a pioneer in the development of combined impedance / high resolution manometry for optimal esophageal testing.

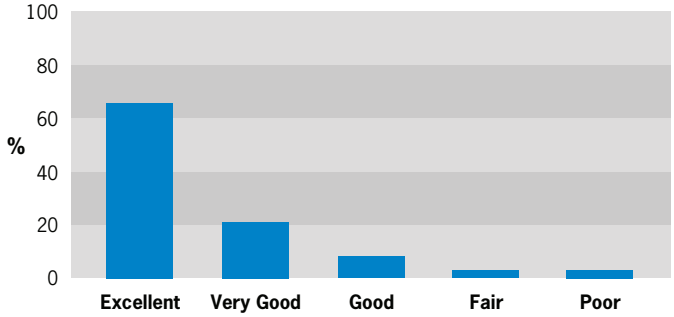
Alternative Imaging in Barrett's Esophagus

Investigators are examining the role of novel imaging technologies including narrow band imaging and autofluorescence endoscopy in an effort to facilitate the detection of precancerous changes in Barrett's esophagus.

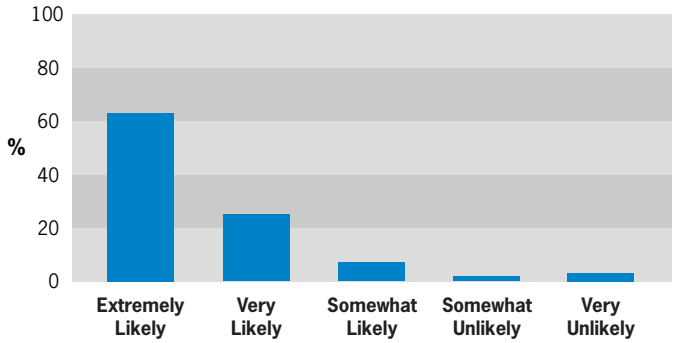
Patient Experience

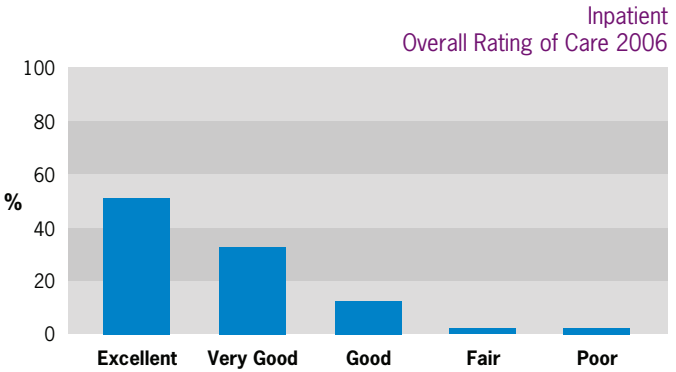
We ask our patients about their experiences and satisfaction with the services provided by our staff. Although our patients are already indicating we provide excellent care, we are committed to continuous improvement.

Outpatient
Overall Rating of Care 2006



Outpatient
Would Recommend Provider 2006





A Note Regarding H-CAHPS, the New National Standard for Reporting Hospital In-Patient Experience of Care:

The service excellence data displayed above shows results from an external patient experience survey administered for Cleveland Clinic.

A new national standard patient experience survey instrument called H-CAHPS was instituted across the country on October 1, 2006. Public reporting of initial results on CMS's Hospital Compare website is anticipated in late 2007. Accordingly, Cleveland Clinic outcomes booklets will transition to reporting H-CAHPS inpatient service excellence results in 2007.

Innovations

Colonoscopy Access Program

The Digestive Disease Center implemented a Colonoscopy Access Program designed to standardize practices that increase access, simplify the patient experience and reduce cancellations.

The program includes:

1. A standard colonoscopy preparation that reduces patient confusion (reduced the number of prep instructions from seven to two).
2. Open access, using an enterprise-wide, cross-site scheduling tool allows choice of sites. It also reduces the number of calls, times placed on hold and hand-offs/transfers.
3. Scheduling options allow patients the procedure to be performed with an endoscopist of their choice or with one of the endoscopists in the main campus afternoon pool.
4. A call-ahead reminder (and education) process reduces no-shows and same day cancellations, the occurrence of poor preps and/or lack of driver, and allows more time to identify and backfill a cancellation.
5. Empowers Cleveland Clinic Nurse-on-Call group to immediately reschedule patients canceling “after hours.” Patient can be easily rescheduled using the open access scheduling tool and the standard preps.

Outcomes

Process	Before	After
Scheduling processes	4 Processes	1 Process
Prep instructions	7 Documents	2 Documents
1st non-urgent available	9-140 Days	5 Days
No-show rate	13%	8.7%

New Knowledge

Selected Publication Highlights

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Staff Listing | Chairman



Victor W. Fazio, M.D.
Chairman, Department of Colorectal Surgery

Appointed: 1974

Medical School: University of Sydney-Faculty of Medicine Sydney, Australia

Specialty Training: Fellowship - Cleveland Clinic, Cleveland, OH Internship - Saint Vincent's Hospital, Sydney, Sydney NSW Australia; Residency - Cleveland Clinic, Cleveland, OH; Residency - Lahey Clinic Hospital, Burlington, MA; Residency - Saint Vincent's Hospital, Sydney, Sydney NSW Australia

Specialty Interests: Crohn's disease and ulcerative colitis; carcinoma of the colon, rectum and anus; diverticulitis and intestinal stomas; continent ileostomy; intestinal fistulae; rectal-sparing operations for carcinoma of the rectum; pelvic pouch procedures for ulcerative colitis and familial polyposis

Staff Listing | Chairman



Arthur J. McCullough Jr., M.D.
Chairman, Department of Gastroenterology and Hepatology

Appointed: 2006

Medical School: SUNY Health Science Upstate Medical Center, Syracuse, NY

Specialty Training: Fellowship - Mayo Clinic, Rochester, MN
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Residency - Cleveland Clinic, Cleveland, OH

Other Education: B.S. - Fordham University Bronx, NY

Specialty Interests: Liver disease emphasizing fatty liver, the metabolic sydrome, nutrition, viral hepatitis, and metabolic diseases

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Brooke Gurland, M.D.
Tracy L. Hull, M.D.
Matthew Kalady, M.D.
Ian C. Lavery, M.D.
Luca Stocchi, M.D.
Scott A. Strong, M.D.
Ursula Szmulowicz, M.D.
Jon D. Vogel, M.D.
Ryan Williams, M.D.
James S. Wu, M.D.
Massarat Zutshi, M.D.
Elena Manilich, M.S.

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Colon Cancer
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Endoscopy
Gregory Zuccaro Jr., M.D.,
Quality Review Officer
John A. Dumot, D.O.
John J. Vargo II, M.D.
Mansour Parsi, M.D.
Madhusudhan Sanaka, M.D.
Milan Dodig, M.D.
Tyler Stevens, M.D.
Srinivasan Dasarathy, M.D.

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William D. Carey, M.D.
Kyrsten Fairbanks, M.D.
Arthur J. McCullough Jr., M.D.
Robert O'Shea, M.D.
Anthony Tavill, M.D.
Jamile Wakim-Fleming, M.D.
Nizar Zein, M.D.

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Aaron Brzezinski, M.D.
Bret A. Lashner, M.D.
Douglas L. Seidner, M.D.
Bo Shen, M.D.
Le Chu Su, M.D.

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Gary W. Falk, M.D.
Gurjit Kaur, D.O.
Steven S. Shay, M.D.

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Talal Adhami, M.D.
Michelle Inkster, M.D.
David Lever, M.D.
Seema Maroo, M.D.
Joseph Moses, M.D.
James Murphy, M.D.
Le-Chu Su, M.D.
Prashanthi Thota, M.D.
Bennie Upchurch, M.D.

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John J. Fung, M.D., Ph.D.
J. Michael Henderson, M.D.
Charles Miller, M.D.
Allan Siperstein, M.D.
Ezra Steiger, M.D.
David P. Vogt, M.D.
Matthew Walsh, M.D.
Charles Winans, M.D.

Thoracic Surgery
Thomas Rice, M.D.

Department Contacts | How to Refer Patients

Direct to a Physician
800.223.2273

This is a Cleveland Clinic operator-assisted number. State the surgeon's name and you will be connected directly to the office.

Hospital Transfer
800.553.5056

The Access plus line for physicians is available 24 hours a day, seven days a week.

For more details about Digestive Disease Center, visit www.clevelandclinic.org/digestivedisease

For more details about maps and locations, visit www.clevelandclinic.org/maps

Colorectal Surgeons Available on Google Maps

Colorectal surgeons and software engineers at the Digestive Disease Center at Cleveland Clinic have developed a web site that makes it easy to locate colon and rectal surgeons on popular Google Maps. The Web site is an excellent resource and free service for patients, referring physicians, and colorectal surgeons. The Web-based software generates distinctive maps with virtual pushpins marking hospitals and medical offices of colorectal surgeons. On-line users can search the database of colorectal surgeons practicing in the United States and other countries by surgeon's last name, geographic location, or hospital. Please visit us at www.colorectal.ccf.org for more information.



Locations



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9500 Euclid Avenue/A30
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Colorectal Surgery:
216.444.5404
Gastroenterology & Hepatology:
216.444.6536

Beachwood Family Health and Surgery Center
26900 Cedar Road
Beachwood, OH 44122
Colorectal Surgery:
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Gastroenterology:
216.839.3850

Independence Family Health Center
5001 Rockside Road
Independence, OH 44131
Colorectal Surgery &
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216.986.4000

Strongsville Family Health and Surgery Center
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Strongsville, OH 44136
Colorectal Surgery &
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Westlake Family Health Center
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Colorectal Surgery &
Gastroenterology:
440.899.5555

Solon Family Health Center
29800 Bainbridge Road
Solon, Ohio 44139
440.519.6800

Cleveland Clinic Overview

Cleveland Clinic, founded in 1921, is a not-for-profit academic medical center that integrates clinical and hospital care with research and education. Today, 1,700 Cleveland Clinic physicians and scientists practice in 120 medical specialties and subspecialties.

Cleveland Clinic's main campus, with 41 buildings on 130 acres in Cleveland, Ohio, includes a 1,000-bed hospital, outpatient clinic, subspecialty centers and supporting labs and facilities. Cleveland Clinic also operates 13 family health centers, eight community hospitals, two affiliate hospitals, and a medical facility in Weston, Florida.

At the Cleveland Clinic Lerner Research Institute, hundreds of principal investigators, project scientists, research associates and postdoctoral fellows are involved in laboratory-based research. Total annual research expenditures exceed $150 million from federal agencies, non-federal societies and associations, and endowment funds. In an effort to bring research from bench to bedside, Cleveland Clinic physicians are involved in more than 2,400 clinical studies at any given time.

In September 2004, Cleveland Clinic Lerner College of Medicine of Case Western Reserve University opened and will graduate its first 32 students as physician-scientists in 2009.

For more details about Cleveland Clinic, visit clevelandclinic.org

Online Services

eCleveland Clinic

eCleveland Clinic uses state-of-the-art digital information systems to offer several services, including remote second opinions through a secure Web site to patients around the world; personalized medical record access for patients; patient treatment progress access for referring physicians (see below); and imaging interpretations by the Department of eRadiology's subspecialty trained academic radiologists. For more information, please visit eclevelandclinic.org.

DrConnect

Online Access to Your Patient's Treatment Progress

Whether you are referring from near or far, our new eCleveland Clinic service, Dr**Connect**, can streamline communication from Cleveland Clinic physicians to your office. This new online tool offers you secure access to your patient's treatment progress at Cleveland Clinic. With one-click convenience, you can track your patient's care using the secure Dr**Connect** Web site. To establish a Dr**Connect** account, visit eclevelandclinic.org or e-mail drconnect@ccf.org.

MyConsult

My**Consult** Remote Second Medical Opinion is a secure, online service providing specialist consultations and remote second medical opinions for more than 600 life-threatening and life-altering diagnoses. My**Consult** remote second medical opinion service allows you to gather information from nationally recognized specialists without the time and expense of travel. For more information, visit eclevelandclinic.org/myconsult, e-mail eclevelandclinic@ccf.org or call 800.223.2273, ext 43223.

Cleveland Clinic Contact Numbers

How to Refer Patients
24/7 Hospital Transfers or Physician Consults
800.553.5056

General Information
216.444.2200

Hospital Patient Information
216.444.2000

Patient Appointments
216.444.2273 or 800.223.2273

Medical Concierge
Complimentary assistance for out-of-state patients and families
800.223.2273, ext. 55580, or email: medicalconcierge@ccf.org

International Center
Complimentary assistance for international patients and families
216.444.6404 or visit www.clevelandclinic.org/ic

Cleveland Clinic in Florida
866.293.7866

www.clevelandclinic.org

Cleveland Clinic is determined to exceed the expectations of patients, families and referring physicians. In light of this goal, we are committed to providing accurate and timely information about our patient care. Through participation in national initiatives, we support transparent public reporting of healthcare quality data and participate in the following public reporting initiatives:

- Joint Commission Performance Measurement Initiative (www.qualitycheck.org)
- Centers for Medicare and Medicaid (CMS) Hospital Compare (www.hospitalcompare.hhs.gov)
- Leapfrog Group (www.leapfroggroup.org)
- Ohio Department of Health Service Reporting (www.odh.state.oh.us)

In addition, this publication was produced to assist patients and referring physicians in making informed decisions. To that end, information about care and services is provided, with a focus on outcomes of care. For more information, please visit the Cleveland Clinic Quality Web site at clevelandclinic.org/quality.



Cleveland Clinic

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Cleveland Clinic is a not-for-profit multispecialty academic medical center. Founded in 1921, it is dedicated to providing quality specialized care and includes an outpatient clinic, a hospital with more than 1,000 staffed beds, an education division and a research institute.

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Cover photograph by Stephen Travarca
Laparoscopic view of pelvis showing stapled J pouch being joined to anal canal