THE CHANNEL

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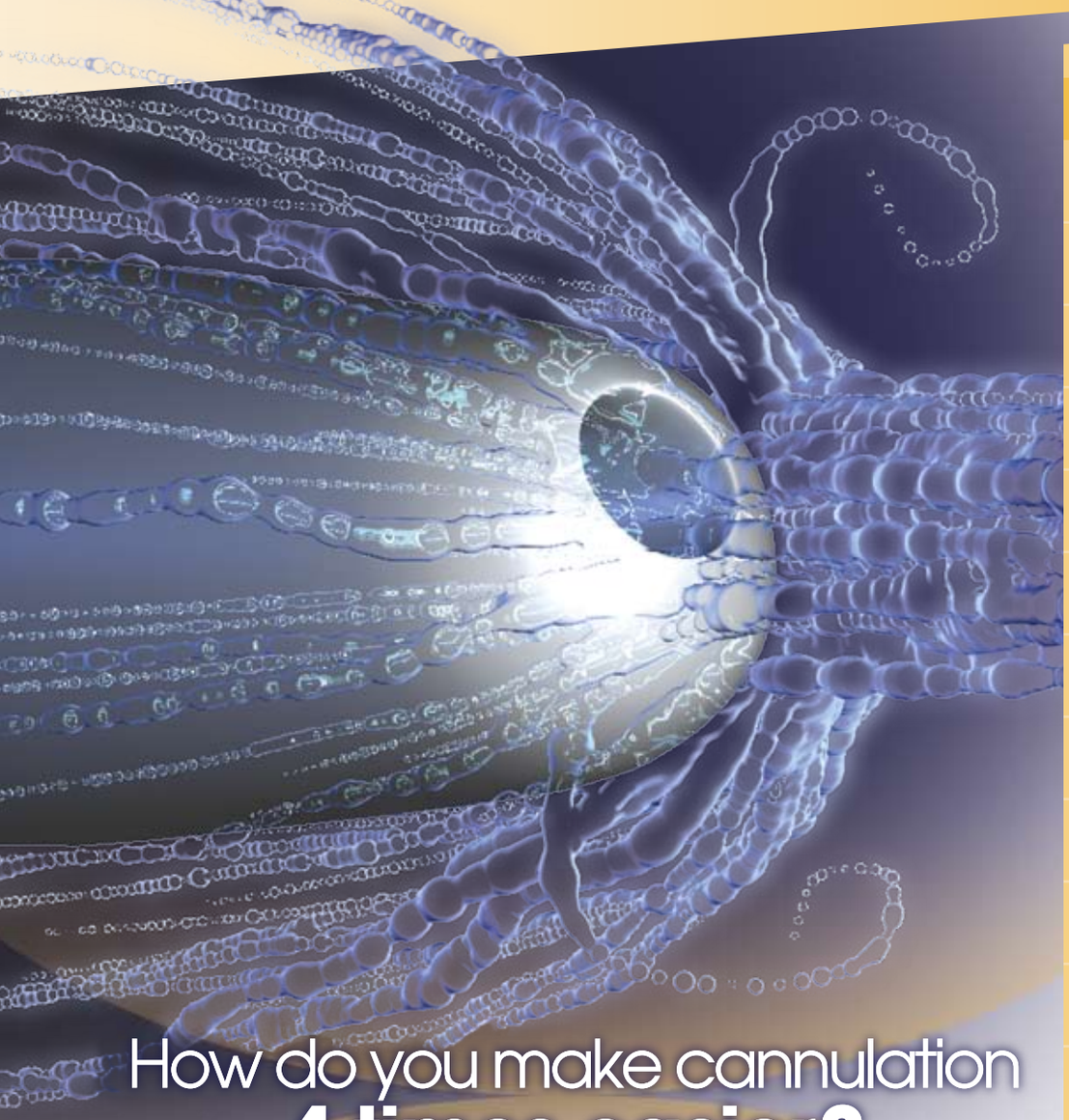
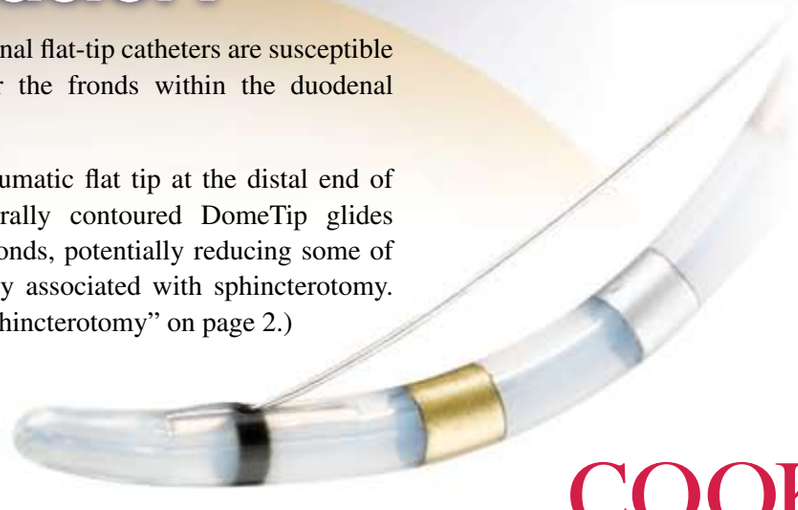


INSIDE THIS ISSUE

How do you make cannulation 4 times easier?

It's a long-standing clinical problem: Traditional flat-tip catheters are susceptible to becoming lodged in the papilla and/or the fronds within the duodenal end of the biliary ductal system.

By completely eliminating the potentially traumatic flat tip at the distal end of conventional cannulating devices, the naturally contoured DomeTip glides more smoothly through the papilla and the fronds, potentially reducing some of the risks – including pancreatitis – commonly associated with sphincterotomy. (See "Complications of Endoscopic Biliary Sphincterotomy" on page 2.)



DOMETIP™

CANNULATION 4 TIMES EASIER *Continued on page 2*

COOK® Endoscopy

Complications of **Endoscopic Biliary Sphincterotomy**

Freeman ML, Nelson DB, Sherman S, Haber GB, Herman ME, Dorsher PJ, Moore JP, Fennerty MB, Ryan ME, Shaw MJ, Lande JD, Pheley AM. Hennepin County Medical Center, Minneapolis, MN 55415, USA.

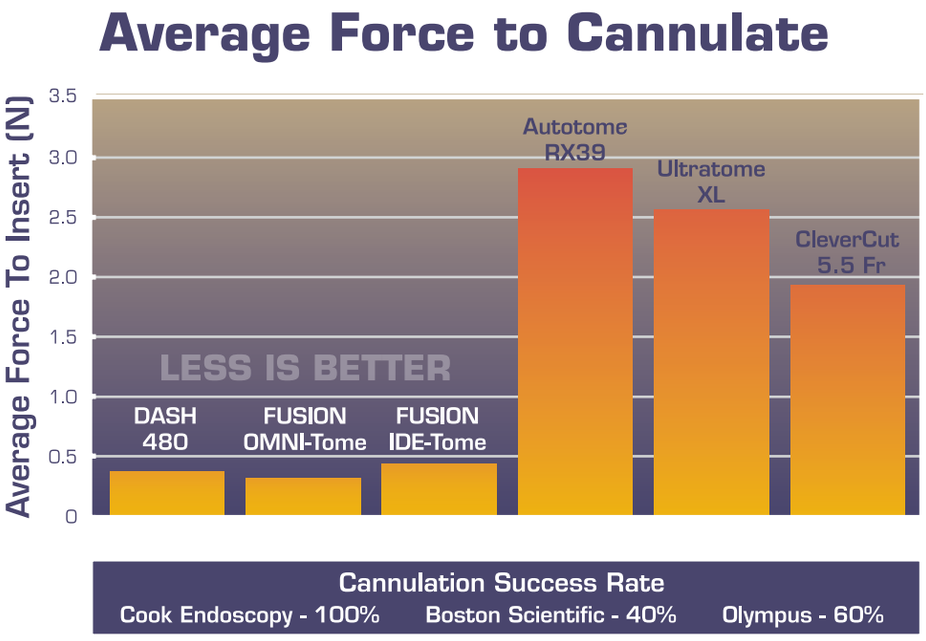
Background: Endoscopic sphincterotomy is commonly used to remove bile-duct stones and to treat other problems. We prospectively investigated risk factors for complications of this procedure and their outcomes. **Methods:** We studied complications that occurred within 30 days of endoscopic biliary sphincterotomy in consecutive patients treated at 17 institutions in the United States and Canada from 1992 through 1994. **Results**: Of 2347 patients, 229 (9.8 percent) had a complication, including pancreatitis in 127 (5.4 percent) and hemorrhage in 48 (2.0 Percent). There were 55 deaths from all causes within 30 days; death was directly or indirectly related to the procedure in 10 cases. Of five significant risk factors for complications identified in a multivariate analysis, two were characteristics of the patients (suspected dysfunction of the sphincter of Oddi as an indication for the procedure and the presence of cirrhosis) and three were related to the endoscopic technique (difficulty in cannulating the bile duct, achievement of access to the bile duct by "precut" sphincterotomy, and use of a combined percutaneous-endoscopic procedure). The overall risk of complications was not related to the patient's age, the number of coexisting illnesses, or the diameter of the bile duct. The rate of complications was highest when the indication for the procedure was suspected dysfunction of the sphincter of Oddi (21.7 percent) and lowest when the indication was removal of bile-duct stones within 30 days of laparoscopic cholecystectomy (4.9 percent). As compared with those who performed fewer procedures, endoscopists who performed more than one sphincterotomy per week had lower rates of all complications (8.4 percent vs. 11.1 percent, P=0.03) and severe complications (0.9 percent vs. 2.3 percent, P=0.01). **Conclusions:** The rate of complications after endoscopic biliary sphincterotomy can vary widely in different circumstances and is primarily related to the indication for the procedure and to endoscopic technique, rather than to the age or general medical condition of the patients.

Complete article available from The New England Journal of Medicine, Volume 335, Number 13, September 26, 1996, pages. 909-918.

CANNULATION 4 TIMES EASIER *Continued from page 1*

In a recent bench-top study comparing Cook Endoscopy's DomeTip devices against blunt tipped devices, the DomeTips required a lower entry force to cannulate (See "Average Force to Cannulate" chart below).

The chart, from that third party, independent lab study, illustrates the insertion force required to cannulate a physiologically relevant papilla model. The catheters were pushed through the soft-material model and the insertion forces were measured in Newtons. At a certain point, the force of the insertion overcame the initial resistance to cannulation and the catheters were advanced.



"The average insertion force for the DomeTip products is significantly lower than the blunt flat tip products. (p< 0.001)"

Averages for peak insertion forces (see chart) indicate that the Cook Endoscopy DomeTip devices required dramatically and significantly lower entry force to cannulate -- four to six times less force than competitive blunt flat tip devices. The higher cannulation force required by blunt flat tips can potentially result in a greater risk of trauma, including pancreatitis.

All DomeTip devices achieved cannulation of the model on the first attempt -- a 100% cannulation success rate. The "Cannulation Success Rate" legend (shown under the graph) indicates the success rate percentage for Cook Endoscopy, Boston Scientific and Olympus devices. One full cannulation attempt using calibrated machinery that resulted in a failure actually damaged the device so there were no second attempts performed using the same device within a group. Despite using a small sample group of each shape, a statistical significance was found. ($p<0.001$) This is the only study comparing sphincterotome cannulation effectiveness at this time. The study data is on file at Cook Endoscopy.

Wake Forest University Baptist Medical Center

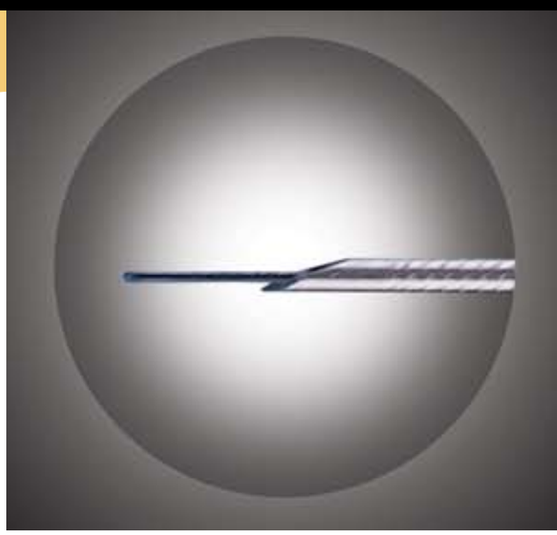
Gastroenterologist Wins Medical Research Award

WINSTON-SALEM, N.C. – Girish Mishra, M.D., M.S., Associate Professor of Internal Medicine, Director of Endoscopic Ultrasound Services, Section of Gastroenterology at Wake Forest University Baptist Medical Center was recently awarded the Research Excellence in Gastroenterology and Liver (REGAL) award, a national honor for gastrointestinal and liver researchers.

Dr. Mishra, director of the gastroenterology fellowship program at Wake Forest Baptist, received the REGAL award for a research project titled, "Determination of Qualitative Telomerase Activity as an Adjunct to the Diagnosis of Pancreatic Adenocarcinoma by Endoscopic Ultrasound Guided Fine Needle Aspiration." His research was recently published in the scholarly journal, *Gastrointestinal Endoscopy*. This study evaluated the incremental benefit of telomerase, a genetic enzyme, in addition to cytology in helping diagnose pancreatic cancer from samples obtained at the time of endoscopic ultrasound guided fine needle aspiration (EUS-FNA). The study found that assaying for telomerase in addition to routine cytology by EUS-FNA increased the sensitivity for detecting pancreatic cancer to 98%.

The REGAL awards program honors junior faculty members or clinical fellows who demonstrate the ability to conduct important research in areas of upper gastroenterology, endoscopy, lower gastroenterology, outcomes or hepatobiliary research. Twenty recipients were selected from medical research centers throughout the country by a national panel of eight senior-level researchers. Each received a cash award plus travel and lodging to attend a symposium in San Francisco, CA, where they presented a summary of their research.

The Digestive Health Center at Wake Forest Baptist offers patients the region's most advanced equipment and procedures to diagnose and treat gastrointestinal diseases. The center has established a Hepatobiliary and Pancreatic Disorders Service to address the particular needs of patients with disease of the pancreas, bile ducts and gall bladder. Gastroenterologists on this team, headed by Professor John Baillie, offer the latest technology in tissue biopsy, gall stone removal, and the use of stents in bile and pancreatic ducts to restore the flow of digestive fluids.



2006 Rocky Mountain Therapeutic Endoscopy Course Update

The Rocky Mountain Therapeutic Endoscopy Course, directed by Dr. Yang Chen and Professor Jacques Devierre took place February 23-26, 2006 in Denver, Colorado. The course, presented by the University of Colorado, is a compilation of didactic and video lectures, live therapeutic cases performed by various course faculty, and a hands-on pig lab. It was attended by over 100 participants from multiple locations around the country.

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A Unique View on Multiple Hemorrhoidal Ligation

David N. Armstrong, M.D., F.R.C.S.

The Saeed Short Shot Hemorrhoidal Multi-Band Ligator, and TriView anoscope.

The ligator has four rubber bands pre-loaded on the tip of the ligator. Each hemorrhoidal complex is individually suctioned into the tip of the ligator, and a rubber band is released by depressing the trigger.

Rubber band ligation of internal hemorrhoids has been a mainstay of surgical practice for over 50 years. A number of published trials have concluded that ligation is more effective than other non-surgical methods of hemorrhoidal obliteration, such as infrared coagulation or injection. Surgery is reserved for patients with significant external hemorrhoidal components. Rubber band ligation is easily performed in the office, is cost effective, requires no anesthetic, and causes little discomfort for the patient.

Two significant innovations have combined to make hemorrhoidal ligation technically simpler, less uncomfortable for the patient, and more convenient for all concerned – the Saeed ShortShot Multi-Band Hemorrhoidal Ligator and the TriView anoscope.

In 2002, Cook Endoscopy (Winston-Salem, NC) released the Saeed ShortShot Multi-Band Hemorrhoidal Ligator, which is a disposable multiple-fire suction ligator. The ShortShot contains four pre-mounted rubber bands that are individually released. This technique avoids the need to reload the conventional McGiveney ligator between each firing, which saves time and avoids frustration. It also avoids the need for an assistant to reload the ligator.

At the same time as the ShortShot ligator was released, I designed and developed a unique anoscope, allowing all three internal hemorrhoids to be ligated at the same time. The new anoscope avoids the need to remove and reinsert the instrument multiple times, as in a conventional single-slot anoscope. The TriView anoscope contains three lateral apertures in the left lateral, right anterior, and right posterior quadrants, the normal anatomic location of internal hemorrhoids. Once the anoscope is inserted, each of the three internal hemorrhoidal complexes is exposed in its normal anatomic location, making "synchronous" ligation of all three complexes quicker, easier and more accurate.

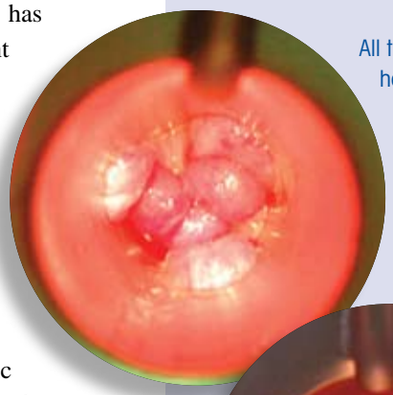
In a prospective randomized trial, I demonstrated that "synchronous ligation" using the new anoscope resulted in less discomfort for the patient and decreased narcotic requirements, compared to multiple conventional ligation. The improved outcomes are a result of avoiding repeated anoscope insertions, and by permitting optimal placement of the rubber bands, away from the sensitive anoderm. Symptomatic relief using the new technique was similar to conventional three-quadrant hemorrhoidal ligation, resulting in complete symptomatic resolution in over 85% of patients.

Optimally, multiple hemorrhoidal ligation is performed immediately after a colonoscopy, when more serious pathology in the proximal colon and rectum has been excluded. With the patient already sedated, lying in the left lateral position and with a full bowel prep, this is the ideal time to ligate symptomatic internal hemorrhoids. This technique is very popular with patients, who appreciate the convenience of combining colonoscopy with a therapeutic "mini-hemorrhoidectomy," at the same visit. By avoiding surgery and minimizing discomfort and time off work, the technique is simple, safe and cost-effective.

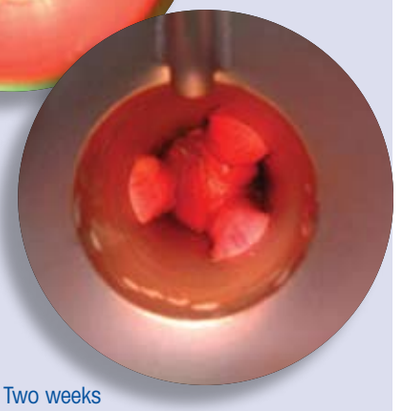
Pending 510(k), not available for sale within the United States.

View down the barrel of the TriView anoscope, with apertures in the left lateral, right anterior and right posterior quadrants, the normal anatomic location of internal hemorrhoids.

All three internal hemorrhoids are optimally exposed, without the need for multiple anoscope insertions.



All three internal hemorrhoids, after synchronous hemorrhoidal ligation.



Two weeks later, the internal hemorrhoids have been largely obliterated.

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How To Reduce the Risk for Work-Related Injuries

By Steve Frandzel

Experts suggest a few simple measures that endoscopists can take to reduce their risk for injury and make their time in the endoscopy suite far more comfortable.

Watch Your Posture Most everyone remembers this advice from childhood—"stop slouching!"—but it turns out to be a very effective prescription. During the many hours that endoscopists and their staff spend on their feet, it's easy to fall into the bad habits of hunching and slouching—as well as craning the neck when viewing video monitors, all of which can upset the neck, shoulders and back. Most endoscopists do not maintain good posture throughout procedures, according to Ray Keate, MD, a gastroenterologist with Richmond Gastroenterology Associates in Virginia, and former Chair of the Division of Gastroenterology and Hepatology at the Mayo Clinic in Scottsdale, Ariz. A good start is to gain an ongoing awareness of a neutral body position that is both comfortable and biomechanically friendly, he recommended.

When one stands with proper posture, an imaginary plumb line begins at the ear lobe, then falls through the bodies of the cervical vertebrae, along the femur, and slightly anterior to the axes of the knee joint and ankle. The head is erect and tilted slightly forward. The pelvis is pitched forward (as if to form a bowl), and the back is in slight lordosis. The hip is slightly flexed, and the abdominal muscles are slightly contracted for support. (That's where a regimen of exercises for strengthening the abs and lower back play an important role.) Some endoscopists use a small block on which to prop one foot, which helps them to find a comfortable position while standing.

When moving about during procedures, try to keep awkward motions to a minimum; if it doesn't feel right, it's probably not. Instead, position yourself properly before you begin to make any major maneuvers with your upper body. Avoid movements in which you bend and twist together, and maintain the symmetry of stress on your lower back, advised Ralph Buschbacher, MD, Professor and Chairman of Physical Medicine and Rehabilitation at Indiana University School of Medicine, Indianapolis.

Get Fit "Physical therapists have told me that much of what we suffer could be alleviated by a combination of stretching combined with aerobic fitness and resistance training," said Dr. Keate, although he acknowledged that endoscopists' schedules often preclude anything but rudimentary training regimens. "I think we're all too busy to do aerobic workouts for 30 to 45 minutes six days a week, but if you can do something at least a few days a week, that's far better than nothing." According to Dr. Keate, it also seems that gastrointestinal endoscopists are not, generally speaking, as fit as colleagues in other specialties. His own research found that more than 80% of endoscopists do fewer than two hours of either aerobic or resistance training each week.

Specifically, Dr. Keate recommended that his colleagues engage in aerobic activities at least three times a week. Even a brisk walk several times a week would be, almost literally, steps in the right direction. Stretches should focus on the hamstrings, piriformis, back and neck. Moderate resistance training (with machines or free weights) should concentrate on the upper body, particularly the triceps, biceps, rotator cuff, deltoids and rhomboids. Dr. Keate also advocated exercises to strengthen the medial, lower and oblique abdominal muscles, such as crunches. A personal trainer, he added, can design a program that fits your schedule and needs, and will ensure that you execute stretches and exercises properly and to the greatest effect.

Modify Your Endoscopy Suite Make it ergonomically friendly for all staff members. One easy and inexpensive improvement is to use rubberized pads to stand on. Position monitors for all personnel so they can be viewed at a level gaze. If possible, enlist an ergonomics expert to assess the suite and critique the positions and movements of each staff member. Spreading out procedures over several days instead of concentrating them in one or two days is also worth considering. Take breaks between procedures when time allows (a good time to do some quick stretches). During endoscopic retrograde cholangiopancreatography (ERCP), use lighter-weight lead aprons that have a hip belt to transfer some of the weight to the legs. Some endoscopists have switched to two-piece aprons, but they may be hard to find for larger individuals.

"The Perils of Endoscopy: Patients Are Not The Only Ones To Suffer Adverse Events" by Steve Frandzel. Reprinted from Gastroenterology & Endoscopy News, September 2005, 56:1, 16 – 17.

Fusing Education and Product Training

An Interview with Dr. Douglas Thorburn

The Liver Unit
Nuffield House
Queen Elizabeth Hospital
Edgbaston
Birmingham, B15 2TH
UK

The Liver Team of Dr. Douglas Thorburn, Dr. Shri Pathmakhanthan, Dr. Geoffrey Haydon and Dr. Stephen Deal.

On Nov. 30th and Dec.1st 2005 Cook Endoscopy sponsored the first Live Endoscopy Course at the Queen Elizabeth Hospital, Birmingham. The workshop incorporated live demonstrations and hands-on training for the 25 physicians and 24 nurses who attended from the UK, Germany and Finland. Dr. Douglas Thorburn gives us some insight into the experience……

What benefits did the Fusion system offer during the live cases shown for all involved over the two days: physician, nurse, time etc.?

"During the Course the ERCPs were performed using short wire technology with the Fusion system. This gave us the opportunity to demonstrate the technique of short wire exchanges in a range of clinical situations, namely choledocholithiasis, malignant biliary strictures, primary sclerosing cholangitis and biliary complications after liver transplant. We were able to demonstrate the increased independence for the medical practitioner using the Fusion technology which reduces the complexity of the procedure and the experience required from the Endoscopic Nursing Staff."

How did you find the new DomeTip feature on the Fusion sphincterotome?

"The course gave us an opportunity to further evaluate the DomeTip feature on the Fusion sphincterotome which performed very satisfactorily. We felt that it was a better way of getting a wire across distal bile duct strictures and there was less separation between the wire and catheter compared to the older Fusion sphincterotome."

Please comment on the use of the Fusion Wire Locking Device.

"Ease of the Wire Locking Device with the additional hole to allow the proximal end of the wire to be safely locked in position is a further advance in the evolution of Fusion. The new sphincterotome DomeTip improved ease of cannulation."

Did you find the training models during breaks were beneficial teaching aids for both Physicians and Nurses?

"Due to the timings in running the Course it was very difficult for the Faculty to spend much time on the models. They did appear to offer good opportunity to view the basic principles of short wire technology and hence offered a useful additional opportunity to delegates at the course."

Please comment on the input from Dr. Deal both for hands-on training and clinical discussion.

"Dr. Deal provided excellent input throughout the duration of the course. He was always willing to discuss the cases and the options for management and to provide excellent insights into the evolution of the technology that led to Fusion as we know it. He struck up a good rapport with delegates and we felt that he made an excellent contribution over the duration of the Course."

Please comment on the overall feedback from the GI Teams and the panel.

"The feedback we received from the evaluation forms was very enthusiastic both in terms of the content and the value of the Course. A few useful suggestions have been made for future Courses and we are already making plans to undertake another Workshop in 2006."

What were the highlights of the Fusion Workshop?

"The venue for the Course was excellent and there was ample space and opportunity for delegates to practice on models. The standard of discussion from the invited Faculty was excellent and we hope we created a pleasant, informal atmosphere that welcomed discussion from both Medical and Nursing Staff in the audience. For the Course Organizers the most pleasing aspect was the successful completion of all four cases, the encouraging feedback we received from the Delegates and the strengthening of bonds within the ERCP Team (both medical and nursing) from successfully undertaking our first live endoscopy Course."

What is your daily experience of Fusion?

"We are now largely using Fusion for most of our cases which include complex tertiary referral biliary cases. We are extremely happy with its use for managing choledocholithiasis and think that in time its role in more complex cases will be established. The main benefit of the new equipment in our day to day experience is that more control of the procedure is with the Endoscopist and hence less reliance is placed on the experience of the Nursing support in ERCP. This is particularly important as we have an inexperienced group of nursing staff in endoscopy and staff turns over frequently. Access to Fusion prevented this having a more detrimental impact on the ERCP service at UHB."

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New Needle for an Old Pain

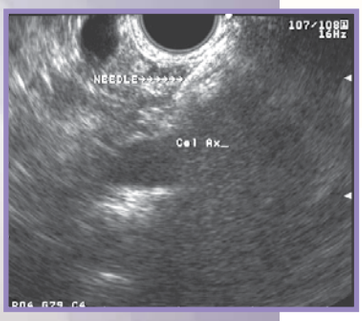


Figure 1. Insertion of the 20G Cook Endoscopy Celiac Plexus Neurolysis Needle

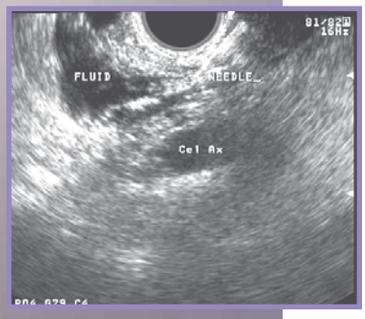
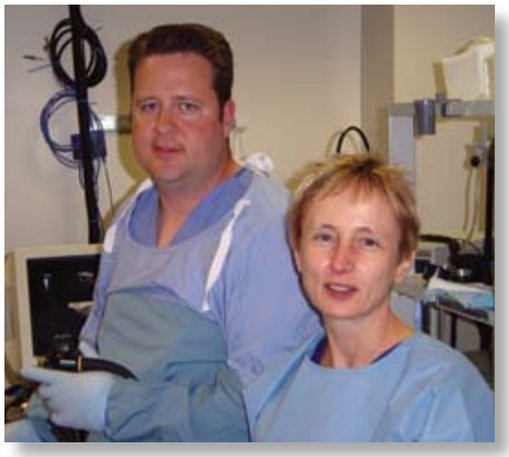


Figure 2. Post injection.

Patients with pancreatic cancer and chronic pancreatitis frequently have pain that can be difficult to manage. Commonly, narcotics are required to control the pain, although the side effects may decrease quality of life. In many of these patients, celiac plexus block or neurolysis may alleviate pain and dependency on narcotics.

The close proximity of the celiac plexus to the stomach makes EUS guided block or neurolysis very safe and easy to perform. Linear EUS guidance is used to puncture the stomach and guide the needle into the space just anterior to the celiac artery takeoff where the celiac plexus resides. After placement of the needle, it is aspirated, flushed with 2-3 cc of sterile normal saline, and reaspirated to ensure the tip of the needle is not in a vascular structure. After the procedure patients are monitored closely for at least 2 hours for signs of hypotension while being hydrated with at least 1 liter of normal saline. Patients should be warned about potential complications including hypotension, diarrhea, and increase in pain – all of which are typically transient.

Celiac plexus block is typically reserved for patients with pain due to chronic pancreatitis requiring daily narcotics. We use 80 mg of triamcinilone (2 ml of 40 mg/ml solution) mixed with 20 ml of 0.25% bupivicaine. In patients with pancreatic cancer neurolysis is achieved by first injecting 6 ml of 0.25% bupivicaine. Two minutes later, 20 ml of 100% dehydrated alcohol is injected.



Jason D. Conway, MD, MPH
Advanced Endoscopy Fellow in Endoscopic Ultrasound
Medical University of South Carolina
Charleston, SC

Brenda Hoffman, MD
Professor of Medicine
Medical University of South Carolina
Charleston, SC

The 20 gauge Cook Endoscopy EUS celiac plexus neurolysis needle (EUSN-20-CPN) has been available and widely used in Europe for some time. Recently, the needle has been approved for use in the US. The needle features a solid tip and four small sideholes just proximal to the tip to allow easy injection and subsequent diffusion of the injectate into the surrounding tissues. We found the needle to readily puncture the stomach wall. The needle is very echogenic and easy to visualize with the linear echoendoscope scanning at 7.5 MHz. (see Figure 1). Injection of the solution used for the block was very fluid with little resistance and quickly generated the desired hypoechoic cloud in the area of the celiac plexus (see Figure 2).

EUS guided celiac plexus block and neurolysis is safe and well tolerated by patients. The new Cook Endoscopy Celiac Plexus Neurolysis Needle makes this procedure easy to perform.

A State-of-the-Art Idea for Treating Fistulas

David N. Armstrong, M.D. FRCS FACS FASCRS
Program Director, Georgia Colon and Rectal Surgical Clinic, Atlanta GA

A "fistula" is defined as an abnormal channel between any two epithelial-lined tracts of the body. The most common fistulas occur in the anorectal region as a result of infection in "anal glands" (the same glands your dog has!). The resulting abscesses drain via the skin in the perianal region and result in fistulas. Fistulas cause pain, constant drainage, and the risk of repeat abscess formation. These so-called "crypto glandular fistulas" are very common, and approximately 100,000 fistula surgeries are performed per year in the US. Similarly, rectovaginal fistulas may develop from complications of childbirth, or GYN surgery. Worldwide, rectovaginal fistulas are the most common fistula in humans. The cause is often a result of inadequate healthcare in third world countries which can result in unmanaged pregnancies and unsupervised delivery, subsequently leading to childbirth trauma.

One of the most debilitating forms of fistula is caused by Crohns disease. Crohns disease is an inflammatory disease which can occur anywhere in the intestine, and the resulting fistulas may invade any organ in the body – bladder, uterus, another segment of the gut – or drain onto the body's skin surface. Depending on where these fistulas erode, Crohns fistulas are one of the most difficult challenges in modern medicine, and may cause a multitude of life-threatening complications.

Conventional surgery for anorectal fistulas consists of surgically "laying open" the fistula tract (fistulotomy), but this often results in sphincter damage and resulting incontinence. Alternatively, a surgical drain "seton" may be inserted through the tract, to prevent abscess formation. Unfortunately these setons are usually required lifelong, and the patient experiences continued drainage from the tract as well as discomfort.

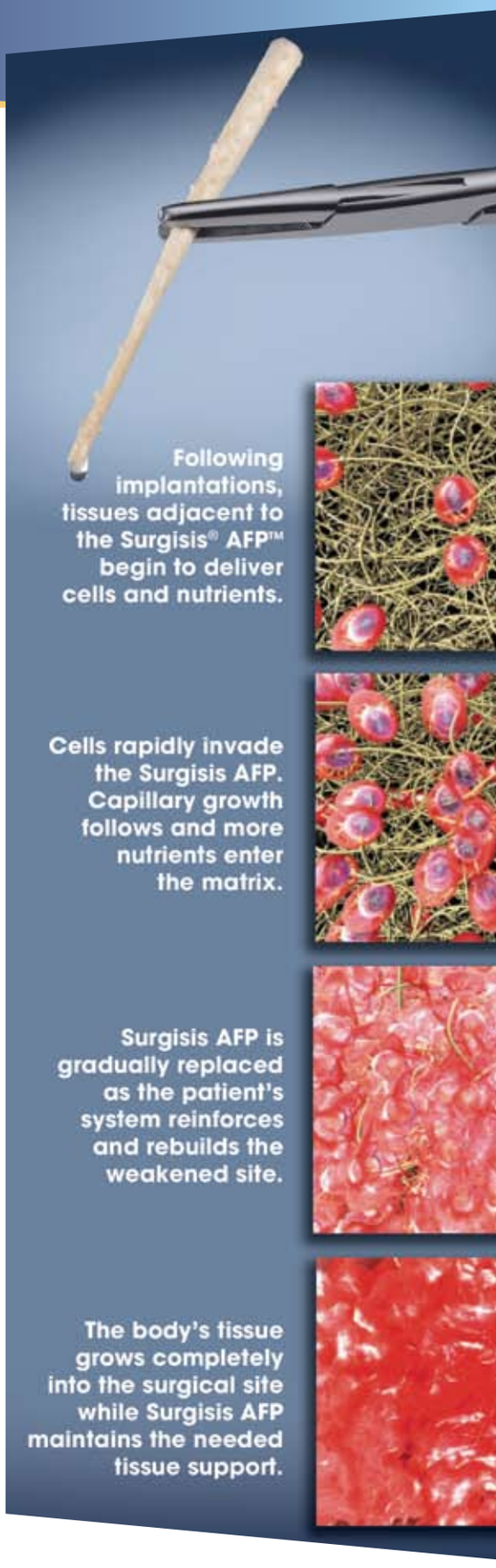
In 2003, I began making small plugs out of 2x3 cm sheets of Surgisis® ES™ Soft Tissue Grafts, to close anorectal fistulas and rectovaginal fistulas. The simple premise was to develop a "biological" plug, which could be inserted into the entrance to the fistula, and close the tract in exactly the same manner as putting a plug in a hole, or a cork in a bottle. Surgisis, derived from a layer (submucosa) of pig small intestine, is composed of an "extracellular matrix" that is gradually repopulated by the host's cells.

Preliminary studies were published in March 2006 reporting successful closure of 87% of anorectal fistulas using the new plug. Most exciting was the discovery that, in our early experience, the Surgisis plug was successful in closing 80% of Crohns fistulas, so seriously impacting one of the most serious challenges facing Crohn's patients.

The new plug also offers the additional benefits of little or no discomfort after surgery (the plug is simply sutured in the fistula tract), and most important, the plug avoids the need to divide or cut any tissue whatsoever. This therefore avoids the risk of sphincter damage, and eliminates the potential of incontinence – a dramatic leap forward in surgery of fistulas.

It is early days and exciting times for the Surgisis plug. Engineers at Cook are collaborating with surgeons in many specialties – Urology, Plastics, Bariatrics, and Gynecology, to develop innovative and imaginative ways of using Surgisis plugs to close the many kinds of fistula which afflict mankind. Unique delivery systems are under development to allow surgeons to deploy the plugs into abdominal fistulas, such as entercutaneous fistulas, to make an otherwise dangerous and complex abdominal surgery as simple as corking a bottle.

Available from Cook Surgical - our sister company.



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Cleveland Clinic Digestive Disease Center:

A collaborative approach to world-class patient care, research, and education

Victor Fazio, M.D.

Arthur McCullough, M.D.

James Church, M.D.

Gregory Zuccaro Jr., M.D.

In talking with physicians about the Cleveland Clinic Digestive Disease Center, two words immediately enter into the conversation: pride and collaboration.

In an organization that is internationally renowned for patient care, research and education, the Digestive Disease Center stands at the pinnacle of virtually all such centers in U.S. hospitals. Ranked second nationally (among 6000 U.S. hospitals) by *US News* and *World Report*, the Center's dedicated staff takes pride that its specialists help patients with highly complex digestive and other diseases. They also speak of the pride they have in the collaboration with their surgical colleagues and how their patients benefit from it.

"Many of our patients have been turned away by other institutions and physicians," explains Arthur McCullough, M.D., Chairman of the Department of Gastroenterology and Hepatology, and co-chair of the Center. "Our high volume of patients results from the reputations of our medical staff and the advanced procedures they offer. For example, we perform more than 2000 advanced endoscopy procedures per year, and we have one of the largest capsule endoscopy experiences in the country."

"Research and education are as much a priority as clinical care," adds Victor Fazio, M.D., Chairman of Colorectal Surgery, and Center co-chair. "The volume and diversity of clinical problems provides excellent data for research as well as the opportunity to teach others. *(The Center's physicians have participated in more than 600 important publications in the last four years alone.)* Our focus is on translational research – the 'bench to bedside' approach. The physicians who see patients are the same physicians leading research. This enables them to bring the most up-to-date concepts to the patient's individual case."

Collaborative Disciplines

With the opening of the Digestive Disease Center in Spring 2001, Cleveland Clinic became the largest digestive disease center in the region. Today, it is the only U.S. medical center to fully integrate its departments of Colorectal Surgery and Gastroenterology & Hepatology. Combining these disciplines in one location facilitates clinical work, multidisciplinary education and collaborative research, and offers patients unprecedented convenience.

One notable collaboration occurs in the Pouchitis Clinic, which is staffed by inflammatory bowel specialist Bo Shen, MD, FACG; and colorectal surgeons Victor Fazio, MD, FACS; and Feza Remzi, MD, FACS. "On average we see 10 patients per week

from around the U.S. or other countries," notes Dr. Shen. "The clinic is unique, and enables us to advance our research in the pathogenesis, risk stratification, diagnosis and treatment of pouch disease."

Another notable collaboration appears in The Center for Swallowing and Esophageal Disorders. Here, gastroenterologists, thoracic and general surgeons, otolaryngologists, speech pathologists, radiologists, and pathologists focus on the clinical management of patients with esophageal disorders such as GERD, Barrett's esophagus and other structural abnormalities of the esophagus. Research in the section centers on Barrett's esophagus, eosinophilic esophagitis and evaluation of impedance technology.

Also, once each month, Gastroenterologist Carol Burke, MD and Colorectal Surgeon James Church run a High Risk Clinic in which patients and families receive genetic counseling, genetic testing, diagnostic and screening endoscopies and plans of care.

Also, physicians in the Center for Colon Polyp and Cancer Prevention collaborate in their clinical and research work to develop strategies for the early detection and prevention of colorectal neoplasia. Among the current studies are chemoprevention trials to reduce risk of recurrent, sporadic colorectal neoplasia as well as the study of novel agents on the regression of aberrant crypt foci and adenomas in individuals with FAP.

The Digestive Disease Center also houses one of the world's leading collections of medical data: the David G. Jagelman Inherited Colorectal Cancer Registries. The is the largest registry for inherited forms of colorectal cancer in the U.S. and the second largest in the world. The Center is also a strategic new location for such services as laparoscopic surgery, enterostomal therapy and the gastrointestinal motility laboratory.

The Endoscopy and Pancreatic-Biliary Disorders Section

The Digestive Disease Center boasts a dozen centers of excellence. (See list on this page). One of these, the Endoscopy and Pancreatic-Biliary Disorders section, embraces seven key areas by itself: capsule endoscopy, endosonography, esophageal cancer, GI bleeding, gallstones, pancreatic cancer, and pancreatic neoplasms.

"Our section employs a multidisciplinary approach to the care of patients with pancreatic disease," notes Gregory Zuccaro, Jr., M.D., Section Head of Endoscopy. "Specialists from many different departments work together to plan patient care. As an example, gastroenterology specialists collaborate with their colleagues in surgery, anesthesiology and radiology."

John Dumot, D.O., cites an example: "The endoscopy section is collaborating with the esophageal and thoracic surgery sections to evaluate the efficacy and safety of a new ablation technique involving the spray of liquid nitrogen through a catheter."

Endoscopic Innovations

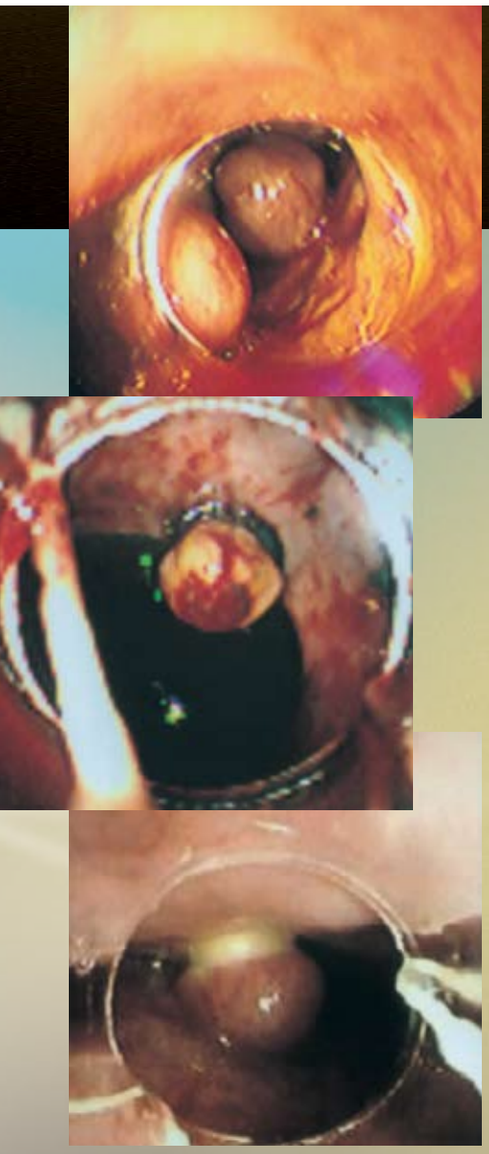
The Endoscopy and Pancreatic-Biliary Disorders section, like the other centers of excellence in the Center, continually innovates. Three recent endoscopy examples illustrate the breadth and depth of the work:

Endoscopic Pancreatic Function Test When compared with the traditional Dreiling tube method, this endoscopic method eliminates the need for fluoroscopy, takes less time (30 minutes vs. 80 minutes), and costs 30 percent less. It is safe, highly accurate and eliminates radiation exposure. The patient is sedated during the procedure and the physician places the endoscope down to the duodenum to aspirate the pancreatic fluid. This test was developed by Darwin Conwell, M.D.

Aspirating Cystic Neoplasm Endoscopists at the Center perform fine-needle aspiration of pancreatic cysts under endoscopic ultrasound guidance. This allows fluid to be taken from the cyst and cancer cells sought.

Capsule Endoscopy Endoscopists at the Center are among the most active in the country in using capsule endoscopy. They offer a special GI bleeding clinic that allows patients to be evaluated by experienced capsule endoscopists. This technique has proven valuable in the evaluation of patients with occult gastrointestinal bleeding, polyps of the small intestine, tumors of the small intestine, and inflammatory bowel disease.

"In all our centers of excellence, Cleveland Clinic Digestive Disease Center will continue to set the standard of excellence in patient care, well into the 21st century," concludes Dr. McCullough.



Professor Mostafa's ANSWER TO MULTIBAND LIGATION

About 10 years ago, Professor Ibrahim Mostafa performed his first ligation in Egypt. Before, variceal treatments were done by injection and, with the arrival of the Saeed Six-Shooter Multi Band Ligator, Professor Mostafa quickly realized an improvement for his patients and his comfort. Safety is the key when he uses the Six Shooter.

According to Professor Mostafa, the Six Shooter has highly decreased the rate of post treatment complications and it also increased the number of physicians dealing with endoscopic treatment of varices in Egypt.

Today, the Six Shooter is a part of the endoscopists' education plan in Egypt. Two big single topic courses have been organized in Cairo for physicians coming from Africa. Each course is a hands-on training for 20 African physicians from Morocco, Tunisia, Libya, Algeria, Sudan, Kenya, Ethiopia, Chad and South Africa. In parallel, Professor Mostafa has, as of today, already trained 20 African doctors through short visits (1 to 3 months) in his hospital, the Theodor Bilharz Research Institute of Cairo. He has also participated to the organization of live courses for teaching and training in band ligation in Cairo, Libya and Sudan. Next July, he will share the first band ligation course in Kenya. Hence, each trained physician could begin treating patients with variceal bleeding safely in Africa.

What is MBL for you?

"MBL means for me: Safety."

What do you like the most in the Six-Shooter?

"No bleeding."

Is MBL important for you?

"Mandatory."

What are the major advantages of MBL against other endoscopic techniques?

"Easy to teach."

Why is MBL so important / successful for Egypt?

"Many patients with varices need better, safer treatment."

What has MBL changed for you in Egypt?

"It decreases post treatment complications. It increases the number of physicians dealing with endoscopy and banding."

How was it before MBL?

"Each physician had his own approach in dealing with variceal bleeding."

Do you remember the first time you used the Six-Shooter?

"It has been so long ago, from about 10 years; I did first band ligation of oesophageal varices in Egypt."

Is MBL a part of your education plan in Egypt / in Africa?

"Yes, it is a part of our education plan in Egypt."

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Putting Orientation To The Test

"The essence of successful sphincterotomy is the control of the position and orientation of the cutting wire."

Jerome H. Siegel, MD, Seth A. Cohen, MD, Franklin E. Kasmin, MD
Sphincterotome Techniques, Vol 1,
Professional Communications Inc., 1997

"The wire should be oriented to the 12 o'clock position of the papillary orifice to avoid injury to the duodenal wall or pancreatic duct."

Joseph E. Geenen, MD, David E. Fleischer, MD, Jerome D. Waye, MD
Techniques in Therapeutic Endoscopy,
2nd Edition, Gower Medical Publishing, 1992

In the middle of an ERCP and/or sphincterotomy, the last thing you want to be is "disoriented." Stable and consistent orientation of the device tip is critical when performing these procedures. Documentation is abundant as to the dangers of ERCP and sphincterotomy. Many of the predominant complications associated with the procedures – including pancreatitis, bleeding, perforation, and cholangitis – can be caused by substandard orientation of the sphincterotome during cannulation.

A well-oriented sphincterotome begins with superior design, but that superior design must be maintained from the time it leaves the manufacturer to the time of the actual procedure in which it is being used. That's why, by thinking "outside the box," Cook Endoscopy discovered that delivering a well-oriented sphincterotome to its customers begins *inside* the box.

In 1998, applying its extensive knowledge of production processes and receiving valuable input from leading physicians, the company patented the 3-D Forming Wire (shown magnified below). This innovative device effectively maintains the predetermined, three-dimensional shape of the distal tip of a catheter or sphincterotome during sterilization, storage and, most importantly, after removal from the package.

Many device manufacturers package their devices relatively loosely in trays, or by placing them in groove-formed, flat trays. Some even attempted to insert a two-dimensional metal wire into the distal tip. The problem with these forms of packaging is that they do not account for the three-dimensional nature of the shape of an accurately oriented device tip and often result in poorly oriented sphincterotomes.

To get devices into the proper shape, some manufacturers suggest rotating the handle of the device, twisting the shaft to create tension on the cutting wire in an attempt to torque the tip into a suitable shape. However, this method creates new variables, such as the possibility of under-rotating or over-rotating the tip and the potential to break the cutting wire, producing a possibly dangerous situation (at the very least, a new device will have to be used).

A key factor in assuring that Cook Endoscopy sphincterotomes are created with and maintain optimum shape is the company's Quality Control System. Each

and every sphincterotome must be verified and validated to orient in a target zone between 11 and one o'clock. If the device fails this test, the company will not release it to the market.

As a result of these efforts, Cook Endoscopy consistently receives positive feedback from leading endoscopists around the world regarding the optimal orientation capabilities of its sphincterotomes. Recently the company decided to take that positive feedback a step further by commissioning an independent bench-top orientation test of the primary competitive sphincterotomes currently on the market.

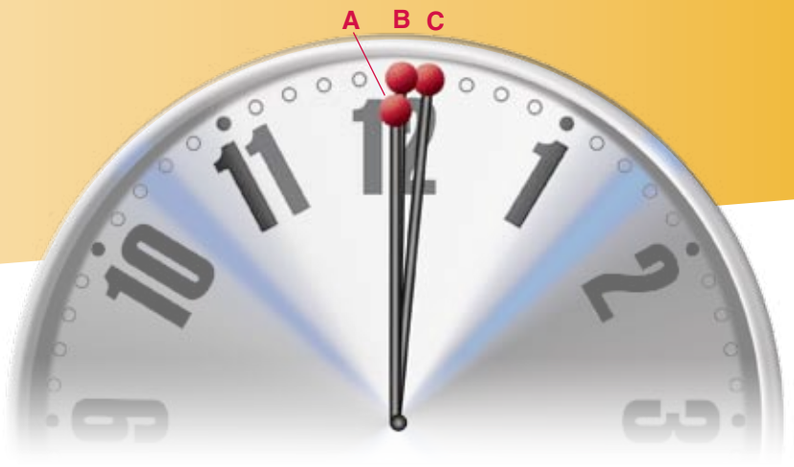
The test included simulation of physiologically correct positions for the endoscope, an anatomically relevant model of a papilla, and an accurate measurement system capable of reproducible results for each group of sphincterotomes. The monitor was overlaid with a target zone representing the 11-, 12- and one-o'clock positions. By test definition, any orientation outside of the target zone would be unacceptable.

The results are reflected in the charts to the right. Each line represents the average of the orientation results for each sphincterotome group. Each dot represents multiple sphincterotomes average score.

In the middle graph, the five Boston Scientific sphincterotomes align their orientation positions outside of the target zones. The bottom graph shows that the Olympus CleverCut (KD-V431M-0730) had an average orientation score outside of the target zone. The average position of all three Cook Endoscopy sphincterotomes was at or near 12 o'clock (represented by 90 degrees on the graph). They split the 12 o'clock mark, lying virtually one on top of another.

The results confirmed the positive results that physicians had been reporting about their on-the-job experiences regarding Cook Endoscopy sphincterotome orientation. From the production facility to the procedure room, the company's sphincterotomes deliver accurate and consistent orientation.

(Complete results of the sphincterotome orientation testing are on file at Cook Endoscopy.)



Cook

Ⓐ Fusion™ IDE-Tome FS-25M-35

Ⓑ Dash™ 480 DASH-25-480

Ⓒ Fusion™ Omni-Tome FS-OMNI

Boston Scientific

Ⓐ Ultratome™ M00545060

Ⓑ Autotome™ Rx 39 M00545200

Ⓒ Autotome™ Rx 44 M00545180

Ⓓ Tapertome™ M00532820

Ⓔ Ultratome™ XL M00535920

Olympus®

Ⓐ Endotherapy CleverCut™ KD-V431M-0730

A minimum quantity of 7 were tested of each type.

COOK® Endoscopy

the Revolution has begun

Left to right: Dr. Srinivas Seela, Dr. Draganov (University of Florida), Dr. Forsmark (University of Florida), Dr. Jason Klapman and Christopher M. Taylor

Dr. Forsmark and Katherine O'Meara, R.N.

February 1st was a revolutionary day for both Cook Endoscopy and Shands University of Florida Teaching Hospital, the day the first Fusion Revolution event took place.

Fusion Revolution events are hands-on teaching opportunities, in which Fusion experts demonstrate and teach the unique advantages of Ultra Short Wire ERCP technology at various sites around the USA.

The first Fusion Revolution was such a success that all involved expressed interest in making Shands/UF a permanent regional training center for the innovative Fusion system.

"As new equipment is developed for ERCP, physicians need to be able to incorporate these new developments into their practice to maximize the outcome of ERCP," said Christopher E. Forsmark, MD, Professor, UF College of Medicine. "Regional training centers allow physicians to receive training and thereby benefit patients. Shands/UF is committed to this important mission."

The day began with a discussion on therapeutic ERCP by Dr. Forsmark, after which he and Dr. Peter V. Draganov, MD, Clinical Assistant Professor, UF College of Medicine, answered questions by attendees.

The focus of the inaugural event was mainly Fusion Omni devices, with an assortment of cases performed, including stone extraction, multiple stent placement, as well as placement of a Fusion Zilver Biliary Stent.

"The system has been easy for the nurses to learn and incorporate," Dr. Forsmark said. "Like many tertiary institutions, we use equipment from many manufacturers depending on the particular clinical situation and the Fusion system has been easy to incorporate into this type of complex system."

At the beginning of each case, Dr. Forsmark delivered a brief case history and a procedural overview, pointing out various techniques as well as potential Fusion benefits related to each case. Dr. Forsmark explained each procedure while two monitors allowed a fluoroscopic view and a view of his hands as he worked.

Between the Fusion cases, Dr. Draganov demonstrated the uses of the Quick-Core Endoscopic Ultrasound Needle and the new Duette Multi-Band Mucosectomy device.

After the demonstrations came the hands-on Fusion practice, allowing participants to get a good feel for the Fusion devices. These hands-on sessions were well received, a welcomed opportunity for learning first-hand what Fusion is all about. The attendees were impressed with the wire control possibilities of Fusion, as well as with the ease of use of the Wire Guide Locking Device.

Since the inaugural event, Fusion Revolution events have taken place in Cincinnati, Chicago, Dallas, Denver and Seattle. Future events are planned all across the country, including Houston; New York City; Washington, DC; Indianapolis; Nashville; and Atlanta.

For more information about Fusion Revolution events, contact your Cook Endoscopy territory manager.

Columbia University Medical Center and the ECHOBRUSH™

Unlocking Information from Pancreatic Cysts

For years, endoscopic digestive and liver disease specialists have used endoscopic needles guided by ultrasonography to draw fluid from pancreatic cysts for cytologists to examine. The procedure, however, has mixed results. Under the best circumstances, the fluid drawn may contain CEA markers, or possibly cells. Often, however, needed cells escape the endoscopic needle; they slide off, or simply do not appear in the fluid.

This ongoing dilemma inspired Charles J. Lightdale, MD, to envision a special echocytology brush that scrapes the inside of a cyst wall to gather cyst cells. Professor of Clinical Medicine at Columbia University Medical Center, Division of Digestive and Liver Disease, Dr. Lightdale designed the brush several years ago, and worked with Cook Endoscopy engineers in Ireland to develop the working instrument. Introduced in Europe, the brush is now FDA cleared. Dr. Lightdale was the first U.S. physician to utilize the instrument, and the brush is now in use at Columbia and several other medical centers.

An increasing number of patients presenting for pancreatic studies also spurred Dr. Lightdale's inventive nature. "Advances in imaging through CT and MRI scans now enable us to see images of pancreatic cysts in the one-to-two centimeter range," he says. "In the past, those cysts were frequently overlooked."

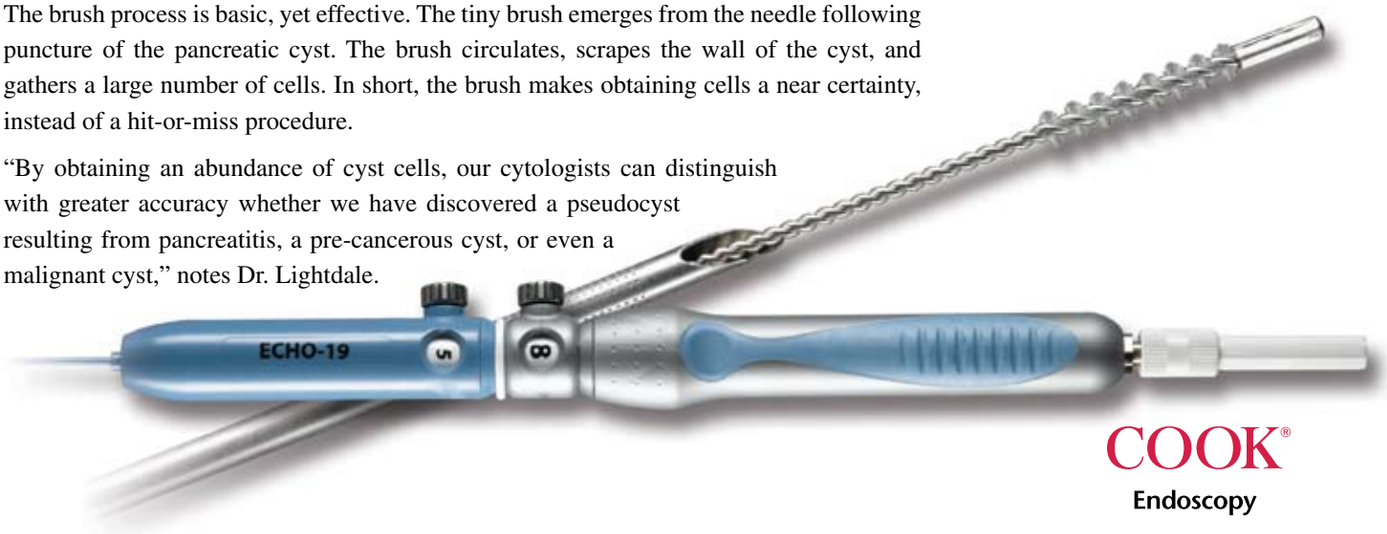
"Further, we know that cysts in that size range may be pre-malignant, or malignant. And at that stage many are curable. Thus, we are performing a much greater number of endoscopic ultrasonography procedures."

The basic needle procedure – with a twist

"When I had the idea for the EchoBrush (as Dr. Lightdale refers to the new instrument), "my first thought was to call the engineers at Cook Endoscopy. They are very talented in this field and I have had a long relationship with them. For example, we collaborated on an esophageal stent, and on the needle that is used in conjunction with the brush."

The brush process is basic, yet effective. The tiny brush emerges from the needle following puncture of the pancreatic cyst. The brush circulates, scrapes the wall of the cyst, and gathers a large number of cells. In short, the brush makes obtaining cells a near certainty, instead of a hit-or-miss procedure.

"By obtaining an abundance of cyst cells, our cytologists can distinguish with greater accuracy whether we have discovered a pseudocyst resulting from pancreatitis, a pre-cancerous cyst, or even a malignant cyst," notes Dr. Lightdale.



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If you would like to submit material for The Channel, please email us at thechannel@wilsoncook.com. We welcome your comments and suggestions.

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UPCOMING 2006 EVENTS

XII Workshop *Prof. Guido Costamagna*	*Rome, Italy*	***May 11-12***
DDW	*Los Angeles, CA*	***May 21-24***
SGNA	*San Antonio, TX*	***May 21-23***
Medical University of South Carolina Advanced Endoscopy Update *Drs. Peter Cotton & Rob Hawes*	*Kiawah Island, SC*	***May 26-28***
XVth Videoendoscopy Course *Sire-Libanes Hospital*	*Sao Paulo, Brazil*	***June 15-16***
XXIVth Gastroenterology & Endotherapy European Workshop, ERASME *Prof. Jacques Devière*	*Brussels, Belgium*	***June 19-21***
XVth International Course on Therapeutic Endoscopy *Sao Paulo Medical School*	*Sao Paulo, Brazil*	***July 3-4***
Mayo EUS Course	*Rochester, MN*	***Aug 3-5***
Argentinian Congress of Gastro-enterology & Digestive Endoscopy	*Buenos Aires, Argentina*	***Sept 2-5***
Boston Live Endoscopy	*Boston, MA*	***Sept 28-Oct 1***
UCI Interventional Endoscopy	*Orange, CA*	***Sept 28-Oct 1***
XIXth Therapeutic Endoscopy Course *Dr. Norman Marcon*	*Toronto, Ontario Canada*	***Oct 11-14***
DDW-Japan 2006	*Sapporo, Japan*	***Oct 11-14***
ACG	*Las Vegas, NV*	***Oct 20-25***
XIVth UEGW	*Berlin, Germany*	***Oct 21-25***
AASLD	*Boston, MA*	***Oct 27-31***

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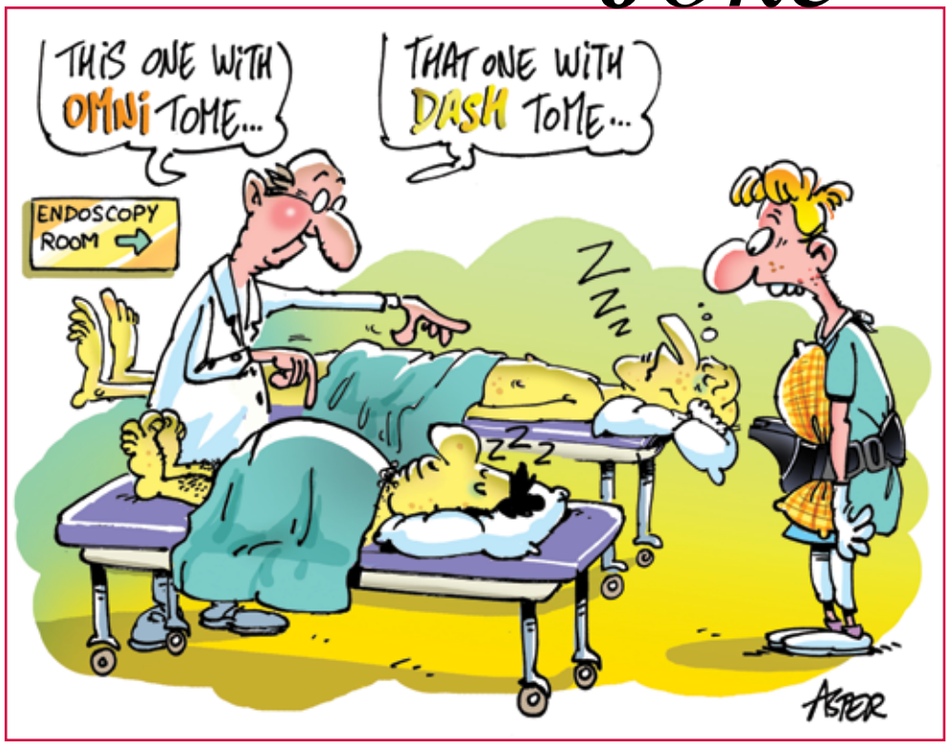
INSIDE *Joke*



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