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Microbiologic Assessment of Disposable Sterile Endoscopic Sheaths: Prospective Clinical Trial


In this article, Alvarado et al described a clinical trial that included a microbiologic assessment of the ability of the Slide-On® EndoSheath® Technology (Medtronic ENT, Jacksonville, FL) to provide protection against bacterial contamination of flexible nasopharyngoscopes. Three 30-mm Olympus nasopharyngoscopes (ENF Type P4, Olympus America, Melville, NY) were used while covered with an EndoSheath® barrier to examine the nasopharynx and larynx of 100 different, randomly selected patients. The surface of the head and shaft of each nasopharyngoscope was wiped to obtain two samples for culture at each of the following times: before application of the EndoSheath® Technology and the endoscopic examination, immediately after the examination and removal of the EndoSheath® disposable, and after a disinfection procedure consisting of the following steps: vigorous wiping of the endoscope with an enzymatic detergent, rinsing with running tap water, drying with gauze, wiping with gauze soaked in 70% ethanol, and air drying in a vertical position. All samples were plated on 5% sheep blood agar and incubated for 72 hours at 37°C. Bacterial colony types were enumerated and identified by using standard methods. The study also included leak testing of the 100 used disposable sheaths removed from the nasopharyngoscopes and of 20 unused sheaths taken from the clinic inventory. The barrier integrity of the EndoSheath® Technology was assessed by using a pressure decay system (138 ± 2 inches of water [5 lb per square inch]).

Bacteria grew in cultures of 16 head and 6 shaft samples obtained before the endoscopic procedure, 13 head samples and 1 shaft sample taken immediately afterward, and no samples obtained after the disinfection procedure. The contamination found was low level (2 to 100 colony-forming units) and due primarily to skin commensals, mainly coagulase-negative *Staphylococcus* and *Bacillus* species. One sample was positive for *Staphylococcus aureus*; none showed gram-negative bacilli or fungi. None of the 120 used or new sheaths lost barrier integrity on leak testing. Alvarado et al noted that not a single leak or tear had been detected in the total of 755 sheaths in their study and all previously reported clinical trials in which the EndoSheath® Technology was used.

In light of their findings, the researchers concluded that use of the EndoSheath® Technology followed by proper cleaning and intermediate disinfection with 70% ethanol can provide a safe, patient-ready nasopharyngoscope, with reliable protection against contamination by virulent bacteria pathogens such as methicillin-resistant *Staphylococcus aureus*, *Pseudomonas aeruginosa*, and mycobacteria species and by viruses likely to be present in the respiratory tract. Alvarado et al also suggested that the acquisition costs of disposable sheaths would be offset by avoidance of high-level reprocessing of flexible endoscopes, which is expensive and may expose health care workers to toxic disinfectants; by reductions in endoscope downtime; and, possibly, by a decrease in costs associated with inadequate high-level reprocessing practices.
**Endoscope Sheaths as Viral Barriers: Laboratory FDA Study**


The aim of this bench study conducted by scientists at the Center for Devices and Radiological Health of the US Food and Drug Administration (FDA) was to characterize virus transmission through otolaryngologic endoscope sheaths in which a hole or tear had been made with an excimer laser or acupuncture needle. EndoSheath® Technology (n = 22) with a hole or tear ranging from 2 to 84 μm were applied to an endoscope, which was then submerged in a high-titer virus suspension (108 viruses/mL). The inside of each EndoSheath® barrier and the endoscope on which it had been placed were then rinsed separately to determine the amount of any virus that had penetrated through the hole.

A sequential test was also conducted. In this experiment, a virus challenge was first performed outside an EndoSheath® disposable in which a 30-μm hole was created before it was applied to an endoscope. The EndoSheath® Technology was then removed from the possibly contaminated endoscope, and a second EndoSheath® barrier, in which a 20-μm hole had been made in the same location as the 30-μm hole in the first EndoSheath® disposable, was placed on the endoscope. Another virus challenge was conducted to determine whether any virus would pass outward through the second sheath.

The first experiment found that small volumes of virus-containing fluid penetrated through the holes or tears in the EndoSheath® Technology and that up to 45% of passed virus particles could be recovered from the endoscope after removal of the EndoSheath® Technology. In the sequential test, virus was found on the second disposable barrier in only one case. Most important, according to the researchers, no virus was found outside the second sheath.

The FDA researchers recommended that an endoscope reprocessing step be combined with use of disposable sheaths. They also said, however, that their data indicated that the step need not be high-level disinfection. Instead, they concluded that meticulous cleaning of an endoscope followed by intermediate-level disinfection should provide a safe instrument for otolaryngologic endoscopy.

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**Immersion Disinfection for Flexible Fiberoptic Laryngoscopes**


The purpose of the prospective clinical study described in this article by Bhattacharyya and Kepnes was to determine whether high-level disinfection renders flexible fiberoptic laryngoscopes free of nonviral infectious microorganisms. The investigation was conducted in an outpatient otolaryngology clinic staffed by five general otolaryngologists 5 days a week. The high-level disinfection protocol used routinely in the clinic to reprocess laryngoscopes consisted of the following steps: rinsing with tap water and wiping with gauze, soaking in
enzymatic detergent for 5 minutes and rinsing with tap water, soaking in glutaraldehyde for 20 minutes and rinsing with tap water, and storage in an upright holder. The EndoSheath® Technology was not used in any of the endoscopic procedures.

For the clinical study, samples for culture were obtained from six laryngoscopes after high-level disinfection at the beginning, middle, and end of a work day. Control samples were obtained by directly contaminating the endoscopes with saliva.

Of the 48 samples obtained from “in use” but disinfected endoscopes, 1 yielded positive culture results (for a mold species). All control samples were positive for oral flora. The difference between the in-use and control samples with respect to the positive culture rate for all microorganisms was significant ($P < 0.001$). The confidence interval for the chance of a laryngoscope harboring any microorganism after the disinfection procedure was 0.11% to 11.6%.

Bhattacharyya and Kepnes concluded that their findings indicate that high-level disinfection provides reasonably effective decontamination of laryngoscopes but cannot remove all contaminants. They also noted that high-level disinfection is time consuming, potentially damaging to endoscopes, often hazardous to health care personnel performing the procedure, and only as effective as the personnel managing it. Thus, according to the researchers, other options for managing the cleaning of flexible fiberoptic endoscopes should be considered, including covering the instruments with a sheath (EndoSheath® Technology, Vision Sciences, Natick, MA) during use. Bhattacharyya and Kepnes commented that the disposable sheaths are expensive (per use) and increase endoscope diameter (which may make passage difficult in certain patients) but that the use of EndoSheath® Technology avoids the need for immersion-type disinfection and reduces the wear on endoscopes that results from repeated exposure to chemical solvents.

Reprocessing Techniques for Flexible Nasopharyngoscopes


This article by Collins is a review of the English-language medical literature on reprocessing flexible nasopharyngoscopes. The aim of the review was to identify the steps critical to effective reprocessing.

In summarizing the reviewed literature, Collins noted that high-level disinfection has been determined to be the minimum level of disinfection required for reprocessing of flexible nasopharyngoscopes, but that traditional high-level reprocessing requires strict adherence to recommended procedures and that the risks of human error and device failure must be recognized. According to Collins, all effective reprocessing techniques include manual cleaning, leak testing, cleaning with an enzymatic agent, high-level disinfection, and drying with vertical storage. The author commented, however, that three methods for achieving high-level disinfection are available: manual disinfection with a liquid disinfectant or sterilant, use of
an automated reprocessor, and use of a disposable sheath during the endoscopic procedure.

With respect to EndoSheath® Technology (Vision Sciences, Medtronic, Jacksonville, FL), Collins said that his otolaryngology literature review found that no defects in these devices have been reported; that flexible nasopharyngoscopes used with disposable sheaths still require mechanical cleaning, application of an enzymatic agent, and wiping with 70% ethanol; and that the barrier provided by EndoSheath® Technology has been tested down to 27 nm, the same size as the smallest infective human virus (poliovirus).

**Flexible Bronchoscope and Disposable-Sheath Endoscope System: Technological Evaluation**


The goal of this prospective, multicenter, clinical study by Colt et al was to assess the image clarity, ease of use, and handling performance of an early-generation flexible fiberoptic bronchoscope (B-F 100, Vision Sciences, Natick, MA) with a sterile, single-use, disposable sheath containing a working channel (BS-F21 EndoSheath® Technology, Vision Sciences). The investigation was conducted in three tertiary care referral centers and enrolled 24 patients who underwent bronchoscopy using either a transnasal or transoral approach.

After each examination, the endoscopist used a 5-point scale (with 5 indicating excellent and 1 poor) to evaluate the following 12 aspects of the performance of the bronchoscope system: image clarity, fiberoptic-to-video conversion clarity, illumination, fogging, handling comfort, distal tip angulation, insertion tube handling, ease of passage and patient tolerance, suction valve performance, suction volume, accessory passage, and fluid injection and removal.

For each of the 12 variables assessed, the mean score was at least 3.5. The highest scores were for image clarity and illumination (mean values, 4.5 and 4.63, respectively). Handling comfort was average, a finding that the researchers considered due to the unfamiliar feel of the B-F 100 bronchoscope compared with other bronchoscopes.

Colt et al noted that their study was a preliminary technological evaluation of a new system that requires more fine tuning. They concluded, however, that their results convincingly demonstrated the effectiveness of the system and cited several possible specific advantages of the single-use EndoSheath® Technology. These benefits are faster endoscope turnaround times; the opportunity to use one endoscope more often and perhaps avoid the need to purchase additional instruments; and an increase in the availability of bronchoscopy in settings in which sophisticated disinfection or sterilization equipment is not readily available, such as primary care clinics, mobile screening programs, and intensive care units.
Flexible Cystoscopy with a Disposable Slide-On® EndoSheath® System in Outpatients


In their introduction to this article, Kimuli and Lloyd observed that waiting times for urgent flexible cystoscopy in their day-surgery unit in England had reached 9 months, but that purchase of the large number of cystoscopes that would be required to reduce waiting times was considered too costly. They therefore investigated the feasibility of moving cystoscopy to the outpatient setting by using a Vision Sciences CST-2000 flexible cystoscope with Slide-On® EndoSheath® Technology containing a working channel.

Twenty-seven patients were randomly chosen from the day-surgery cystoscopy waiting list to undergo an outpatient procedure. The cystoscope operators evaluated the ease of use, flexibility, and images provided by the Vision Sciences device. The patients were asked to give their opinion of the outpatient cystoscopy service.

The endoscope operators and their assistants found the process of sheathing and resheathing the cystoscope to be smooth and efficient (requiring about 2 minutes), though somewhat more complicated than standard procedures. There were no breaks in the integrity of the EndoSheath® Technology or instances of damage to the cystoscope. The operators found that the cystoscope handled identically to conventional instruments, with no restriction of movement, and that use of the EndoSheath® Technology had no noticeable effect on the quality of the image. All patients provided positive feedback on the outpatient cystoscopy service and preferred it to the day-surgery setting.

Kimuli and Lloyd commented that flexible cystoscopy using a disposable sheath avoids the need to support outpatient cystoscopy with sterilization units or several prepacked cystoscopes. They noted that high-level disinfection of flexible cystoscopes with either glutaraldehyde or peracetic acid is time consuming, labor intensive, and costly and that it may not always be effective in preventing iatrogenic infection. The researchers also found that the cost of cystoscopy using the Vision Sciences system was lower than that of cystoscopy with standard instruments. Kimuli and Lloyd recommended that outpatient flexible cystoscopy be considered for both diagnostic and surveillance procedures and that Vision Sciences® cystoscopes and EndoSheath® Technology be included in the planning of this service.

Practice Efficiency with a Sheathed Flexible Cystoscope: Randomized Controlled Trial


This article describes a randomized controlled trial by Krebs et al in which 100 patients were assigned to undergo flexible cystoscopy using either an unsheathed cystoscope (Karl Storz Endoscopy, Culver City, CA) that had been disinfected with high-level reprocessing employing ortho-phthalaldehyde or glutaraldehyde or a cystoscope covered with the EndoSheath® Technology containing irrigation and working channels (CST-2000 Flexible
Cystoscope with Slide-On® EndoSheath® System, Vision Sciences, Natick, MA). Three patients were subsequently excluded from the study after a review of consent forms; therefore, the final analysis included data from 49 patients in the disposable sheath group and 48 in the control group.

Cystoscope preparation times in the EndoSheath® Technology and unsheathed groups were recorded. The physicians assigned scores on a 10-point scale (with 1 being the worst and 10 the best possible score) for ease of cystoscope insertion, optical quality, cystoscope handling, irrigation setup/handling, ease of instrument passage, and patient comfort. The patients used the same scale to rate their comfort during the cystoscopy procedure, comfort during postcystoscopy voiding, and overall satisfaction with the procedure. The researchers conducted a cost-analysis comparison of sheathed and unsheathed cystoscopy that considered the following expenses: initial purchase price of the cystoscope, cystoscopy repair/replacement cost, cost of disposables (EndoSheath® Technology versus disinfecting agents), and hours of work by the nursing staff.

The study found that the mean total times required to prepare the cystoscope for use were 11, 15, and 42 minutes, respectively, in the EndoSheath® Technology group, glutaraldehyde group, and orthophthalaldehyde group (P < 0.01 for the EndoSheath® Technology group compared with each of the other two groups). This represented a 27% reduction in preparation time with the use of disposable sheaths. Optical quality, ease of instrument passage through the working channel, and patient comfort assessed by the physician were equivalent in the disposable sheath and unsheathed group; cystoscope insertion and handling and irrigation setup/handling were significantly easier in the unsheathed group. There were no differences between the two groups in patients’ assessments of comfort. The cost analysis found that using sheathed cystoscopes was less expensive than using unsheathed cystoscopes and orthophthalaldehyde disinfection.

Krebs et al commented that even though the urologists in the study found the sheathed cystoscope slightly more difficult to operate than the standard instrument, the fact that optical quality with the two endoscopes was determined to be equivalent suggests that diagnostic accuracy would not be affected by use of the EndoSheath® Technology. The researchers concluded that the increase in productivity associated with EndoSheath® Technology could provide a cost advantage over standard cystoscopy by obviating the need for backup cystoscopes in busy urologic practices.

**Sterile Disposable Sheath System for Flexible Cystoscopes: Experience in 200 Patients**


This article by Lawrentschuk and Chamberlain describes an initial use of a flexible cystoscope (CST-2000, Vision Sciences, Natick, MA) with a disposable sheath (EndoSheath® Technology, Vision Sciences) in a urologic office setting. In a series of 200 patients, no breaches of the
EndoSheath® Technology, instances of contamination of the cystoscope, or cases of infection occurred. Within the first 100 procedures, nine sheaths were damaged because the physician had difficulty placing the sheath over the cystoscope. In all nine cases, a second EndoSheath® barrier was obtained and used successfully. All patients who were surveyed were satisfied with their procedure, and many commented on the reassurance with respect to sterility that was provided by witnessing the application and disposal of the EndoSheath® Technology. An analysis that considered the purchase price of flexible cystoscopes and EndoSheath® Technology, cystoscope repair costs, and sterilization expenses (staff salaries and equipment) found that the cost per use of a cystoscope with EndoSheath® Technology was about $3 less than that of a standard cystoscope.

Lawrentschuk and Chamberlain commented that the strength of the sheathed endoscope system is that the endoscope itself does not contact bodily fluids or environmental contaminants. They also noted that intermediate-level disinfection between uses of an endoscope covered with EndoSheath® Technology is recommended, whereas unsheathed instruments require high-level disinfection. The authors concluded that the EndoSheath® System has several possible advantages, including simplicity, a reduction in exposure to sterilizing agents, time savings, and the opportunity to own only one cystoscope. Moreover, according to the authors, improvements such as video camera attachments will likely enhance the ergonomics of the system and expand its use in surgery.

**Bronchoscopy with the Vision Sciences BF100 Disposable-Sheath Device: 328 Procedures in France**


This article describes a retrospective study by Margery et al in which a flexible endoscope (BF100, Vision Sciences, Natick, MA) with channeled EndoSheath® Technology (BS-F21, Vision-Sciences) was used in 328 elective and emergency bronchoscopic procedures in France. Ninety-two of the patients in the series had a known or suspected infection (with multiresistant bacteria, tuberculosis, hepatitis B or C virus, or human immunodeficiency virus) or were immunocompromised. The bronchoscope was introduced either nasally, orally, or through a tracheostomy or intubation probe. No data on post-procedure infections were collected because the endoscope and EndoSheath® Technology had already been approved by the US Food and Drug Administration.

Margery et al reported that maneuverability of the bronchoscopy system was initially problematic but that any difficulty had resolved by the time the operator had performed about 10 procedures. No adverse events occurred in the series other than poor visibility due to faulty assembly of the system in five early cases. The authors commented that it was noteworthy that no sheaths tore when inserted through a tracheostomy or intubation probe after lubrication with paraffin oil. They also noted that, in 1998, the cost of the sheaths was nearly twice that of disinfection (84 versus 46 euros), although they acknowledged that their
study did not assess the cost of using EndoSheath® Technology in routine conditions.

Margery et al concluded that the bronchoscope/EndoSheath® Technology offers several advantages that can reduce its direct costs: the time otherwise required for disinfection and sterilization procedures is saved; the nursing team’s activity is optimized because the disinfection interval is obviated and training is limited to assembly and removal of the sheath; the nursing team is no longer exposed to noxious disinfectants; and the operating life of the endoscopic equipment is increased because of a reduction in the wear that results from repeated disinfection.

**Disposable-Sheath, Flexible Gastroscope System Compared with Standard Gastroscopes: Randomized Trial**


This article describes an early randomized German trial by Mayinger et al of a prototype disposable sheath (reusable endoscope and EndoSheath® Technology, Vision Sciences, Orangeburg, NY) in upper gastrointestinal gastroscopy. The EndoSheath® system was compared with a standard endoscope (GIF Q30, Olympus, Hamburg, Germany) with respect to setup and reprocessing times, procedure duration, downtime, number of biopsies, instances of contamination, problems during handling, and several specific aspects of handling and use. One hundred patients with various indications for gastroscopy (primarily upper abdominal pain, anemia, suspected reflux disease, and tumor evaluation) were enrolled in the study, and 50 were randomly assigned to each endoscope group.

The two physicians, four endoscopy nurses, and patients who participated in the study used a 10-point scale to rate each endoscope system, with 10 representing a perfect score and 0 the worst possible score. After each gastroscopic procedure, the standard endoscope was reprocessed in accordance with the protocol in place at the authors’ institution and the EndoSheath® Technology endoscope in accordance with the manufacturer’s recommendations. Samples for microbiologic analysis were taken from three sites on the sheathed endoscope after each procedure (and removal of the EndoSheath® Technology). Samples were obtained from the standard endoscope after regular disinfection, but before use, by rinsing the accessory and water channels with 0.9% saline. All used sheaths were examined for leakage by inflating them with air (0.3 kg/cm2) for 2 minutes.

The mean duration of the gastroscopy procedure was slightly longer with the EndoSheath® system than with the standard endoscope, but the difference was not significant. The mean setup time was about 6 minutes for the EndoSheath® system and 0.5 minutes for the standard system (P < 0.05). The reprocessing time and total instrument turnaround time were significantly shorter with the EndoSheath® system (about 3 versus 48 minutes and 19 versus 56 minutes, respectively; P < 0.05). The standard endoscope was preferred by the endoscopists for each item rated, whereas the EndoSheath® system was preferred by the nurses for its ease of reprocessing and staff safety. However, both the physicians’ and the nurses’ scores for the
EndoSheath® system improved with the number of procedures and approached those for the standard instrument by the end of the study. There were no differences between the two endoscope groups in patients' scores.

Problems with handling were more commonly reported in the EndoSheath® Technology group, primarily during the first half of the study, thereby indicating the presence of what the researchers termed a “marked learning-curve effect.” The leakage tests never showed any breach in the disposable sheaths. Microbial contamination (with apathogenic common environmental and human-flora bacteria only) was found after 10% of standard gastroscopy procedures and 16% of EndoSheath® Technology procedures. Because no EndoSheath® barriers were found to have a leak, Mayinger et al assumed that contamination of the sheathed endoscope was the result of improper handling (for example, pushing the endoscope out of the sheath onto a contaminated surface or grasping the endoscope with contaminated gloves).

The researchers noted that the most striking advantage of the EndoSheath® Technology revealed by their study was the shortening of reprocessing time, which permitted a potential tripling of the number of gastroscopy procedures. They also commented that the use of EndoSheath® Technology might allow endoscopy in settings in which the number of endoscopes and the resources for cleaning them are limited (for example, primary care clinics, mobile screening programs, and intensive care units). Mayinger et al concluded that the EndoSheath® Technology offers a new standard for endoscope reprocessing that has important advantages in terms of decreased instrument turnaround time and a possible increase in safety for both health care staff and patients.

Out-of-Hours ENT Facilities in England


This article describes a survey conducted by Moorthy et al on out-of-hours (emergency, outpatient) ear, nose, and throat (ENT) services in England. The purpose of the survey was to determine whether out-of-hours ENT units had a dedicated ENT treatment room, appropriately maintained ENT equipment, and adequate staffing. The mechanism used in each unit to disinfect flexible nasal endoscopes to prevent cross-infection was also documented. Data were gathered by means of telephone calls to the first on-call ENT physician in the 106 units providing out-of-hours ENT services in England.

Moorthy et al found that 101 of the 106 units surveyed (95%) had a separate ENT treatment room, and 74 of those rooms were well stocked and maintained. Sixty-two units (58%) had assistance available. The most common endoscope disinfection mechanism was use of the EndoSheath® Technology (26% of 86 units that provided disinfection data). Alcohol wipes were employed in 23% of units and glutaraldehyde in 21%.

The researchers concluded that not all ENT units in England have appropriately equipped
out-of-hours facilities and that national guidelines on the minimum equipment and staff required to provide a safe and adequate out-of-hours ENT service are needed. Moorthy et al also noted that the use of EndoSheath® Technology is considered an alternative to high-level disinfection of nasal endoscopes but that such usage must be combined with intermediate-level disinfection of the instruments. The authors recommended that all out-of-hours ENT units have a formal disinfection protocol for flexible nasal endoscopes and Hopkins rods that includes training of nursing and medical staff.

**Removal of Impacted Fish Bones with a Sheathed Nasopharyngoscope**


This article is a report by Robertson and Bowyer on three clinical cases in which EndoSheath® Technology with a 2.1-mm working channel (Vision Sciences, Orangeburg, NY) were used with a rhinolaryngofiberscope (ENF Type P3, Olympus, Tokyo, Japan) to remove fish bones impacted in the tongue base, vallecula, and pyriform fossa, respectively. In each case, the patient’s oral cavity and oropharynx were anesthetized and an endoscopic examination of the larynx and hypopharynx was performed to determine the location of the fish bone. Once the bone was visualized, biopsy forceps were introduced through the channel in the sheath to grasp one end of the bone. The bone was then removed through the nose while the endoscope was simultaneously withdrawn. There were no complications in any of the three cases.

Robertson and Bowyer noted that two methods by which a flexible endoscope could be used to remove fish bones from the laryngopharynx had previously been described. One employed an endoscope with an integral instrument channel for foreign-body forceps; the other used a flexible nasopharyngoscope to guide orally introduced forceps. However, according to the authors, these methods have the following disadvantages: many clinicians do not have access to a nasopharyngoscope with a biopsy channel; the presence of an integral instrument channel complicates endoscope decontamination; and manipulating a flexible endoscope and orally inserted forceps is technically demanding, often requires an assistant, and may not permit easy removal of more distally lodged bones. Robertson and Bowyer concluded that use of the channelled EndoSheath® Technology provides an inexpensive alternative to other methods of removing fish bones from the laryngopharynx.

**Disposable, Sheathed, Flexible Sigmoidoscopy: Multicenter Randomized Trial**


This article describes a 15-center, randomized control trial by Rothstein et al in which the function and reprocessing of a first-generation sheathed flexible sigmoidoscope (Vision System, Vision Sciences, Natick, MA) were compared with those of standard endoscopes (Fujinon, Wayne, NJ; Olympus, Lake Success, NY; or Pentax, Orangeburg, NY). The study include 143 flexible sigmoidoscopy procedures, 73 of which were done with the sheathed endoscope.
and 70 with a standard device. Twenty-four endoscopists and 30 reprocessing staff members (nurses and assistants) participated in the study.

The following data were recorded for each procedure: endoscope setup time, reprocessing time (cleaning and disinfecting), total instrument downtime (setup time plus reprocessing time), depth of endoscope insertion, and duration of procedure. The endoscopists and reprocessing personnel evaluated numerous handling, design, and reprocessing characteristics of the sheathed and standard endoscopes by using a 100-point visual analog scale (VAS), with 100 indicating a perfect score (an imagined “ideal” endoscope) and 0 the worst possible score. The standard endoscopes were reprocessed in accordance with the usual protocol at each center. Reprocessing of the sheathed endoscope system was done in accordance with the manufacturer’s recommendations.

The study found that procedures using the sheathed sigmoidoscope system took a mean of about 1 minute longer than those done with a standard endoscope. The mean reprocessing time and total downtime were significantly shorter with the sheathed endoscope (31 versus 3 minutes and 33 versus 8 minutes, respectively; P < 0.00005 for both comparisons). The endoscopists preferred the standard sigmoidoscopes over the sheathed device with respect to each handling characteristic assessed, as well as overall (mean, 82 versus 68 points on the VAS), although not all differences were statistically significant. In contrast, reprocessing personnel favored the sheathed system for every characteristic and overall (79 versus 62 points; P < 0.00005).

Rothstein et al commented that the downtime for reprocessing of standard sigmoidoscopes is a major factor in delay between procedures and that a sizable supply of endoscopes is required in order to have an instrument ready for the next patient; therefore, the markedly decreased turnaround time is an important advantage of the sheathed sigmoidoscope system. Moreover, according to the authors, the high-level disinfection required for standard endoscopes places patients and staff at risk of reactions to disinfection solutions. In addition, reprocessing errors that resulted in contaminated “patient-ready” endoscopes have been reported. Rothstein et al concluded that use of an EndoSheath® barrier may reduce the risk of endoscopically transmitted infections and increase patient and staff safety. They also noted that future refinements in the sheathed system will likely improve the features about which the endoscopists in their study expressed concern.

**Efficiency of a Sheathed Fiberoptic Sigmoidoscope Compared with a Conventional Sigmoidoscope**


This 1997 study by Sardinha et al compared the productivity of a sheathed flexible sigmoidoscope (EndoSheath® Technology, Vision Sciences, Natick, MA) with that of a conventional sigmoidoscope (Pentax, Orangeburg, NY). All the sheaths used in the trial
had air, water, and biopsy/suction channels. The specific goal of the study was to measure sigmoidoscope preparation time (that is, mean total reprocessing time between clinical procedures) with the two instruments. The per-procedure cost associated with each sigmoidoscope was also calculated.

The study took place during a 2-day period, and all sigmoidoscope procedures were performed by the same physician. Ten patients were randomly assigned to undergo examination with the sheathed sigmoidoscope and nine with the conventional device. Reprocessing of the sheathed instrument consisted of removal and replacement of the EndoSheath® Technology and cleaning and disinfection of the control knobs. Reprocessing of the conventional sigmoidoscope included meticulous manual cleaning and use of an automatic washer to achieve high-level disinfection.

The mean reprocessing time for the conventional sigmoidoscope was about 47 minutes (range, 46-50), whereas that for the sheathed sigmoidoscope was 5 minutes (range, 2-6; P < 0.0001), a difference of nearly tenfold. In 1993 dollars, the per-procedure cost at the researchers’ facility was higher with the sheathed sigmoidoscope ($47 versus $33). However, Sardinha et al estimated that a daily increase in revenue of about $1000 would be possible with the sheathed device because of the 42 minutes a day of additional time its use made available.

The authors commented that effective reprocessing of standard flexible sigmoidoscopes is costly and time consuming and that an ideal sterilizing agent has not yet been found. Moreover, the complex design of conventional devices does not permit visualization or confirmation of efficient cleaning of all channels, and this may result in improper or incomplete disinfection. Sardinha et al also noted that exposure to germicides used in high-level disinfection can increase the risk of physical damage to standard endoscopes and of glutaraldehyde-induced colitis in patients. The researchers concluded that the sheathed sigmoidoscope offers an improved safety profile compared with standard instruments and appears to be a viable, cost-effective alternative for facilities performing flexible sigmoidoscopy.

Endoscopy-Related Infections, Pseudo-Infections, and Toxic Reactions in the United States


The purpose of this extensive literature review by Seoane-Vazquez et al was to analyze the characteristics of endoscopy-related adverse events reported in the United States in 1974 to 2004. The reviewers attempted to collect the following data on each identified report of an exogenous endoscopy-related infection, pseudo-infection, or toxic reaction to an agent used to disinfect endoscopes: the type of endoscope (arthroscope, bronchoscope, etc.), report date, type of contamination, number of patients exposed and contaminated, and health outcomes of the contamination. An analysis was conducted to determine whether the outbreaks of
Seventy outbreaks, reported in 64 scientific articles, were included in the data analysis. Bronchoscopy accounted for 61% of all exogenous endoscopy-related infections; upper gastrointestinal endoscopy accounted for 91% of toxic reactions (primarily to glutaraldehyde [73% of reactions]). About two-thirds of outbreaks (60%) were primarily linked to inadequate decontamination practices. Seoane-Vazquez et al determined that health care providers could have prevented the endoscopy-related cause of contamination in 91% of outbreaks for which a cause was reported.

A total of 10,989 patients were exposed to contamination agents during the 29 outbreaks for which the reports included data on patient exposure. A total of 740 patients were contaminated during the 69 outbreaks for which the number of contaminated patients was provided. Fourteen endoscopy-related deaths were described in nine reports (1.9% of contaminated patients). In 41 outbreaks, clinical symptoms developed in 59% of patients.

Seoane-Vazquez et al noted that the available literature contains insufficient information to allow estimation of the true risk and incidence of endoscopy-related infections and toxic reactions and virtually no data on the economic consequences of these events. Therefore, according to the authors, the reporting of endoscopy-related occurrences must be improved. Seoane-Vazquez et al also commented that their review demonstrates the importance of improving endoscope decontamination practices and indicates the need both for provider surveillance systems that would detect adverse events earlier and for international surveillance systems that would allow timely identification of deficiencies in endoscope design and manufacturing.

Seoane-Vazquez et al drew the following conclusions pertaining to the disposable sheath: EndoSheath® Technology represent an improvement in endoscope design aimed at reducing the risk of exposure to contaminating agents; the use of disposable sheaths decreases the need for high-level sterilization and expedites endoscope reuse; sheathed endoscopes are safe and as effective as nonsheathed endoscopes; and EndoSheath® Technology use could reduce the number of endoscopy-related adverse events.

**Sterile Sheath for Flexible Nasopharyngolaryngoscopes**


This article is a report by Silberman on his initial experience with a disposable, single-use EndoSheath® Technology (EndoSheath® Technology with ENT Scope, Vision-Sciences, Natick,
MA) to provide sterility during flexible nasopharyngolaryngoscopy. For 50 procedures, the author recorded one of five ratings (poor, below average, average, above average, or excellent) for nine variables associated with use of the system (image clarity, illumination, uniformity of illumination, lack of fogging, ease of passage and feel of the endoscope, flexibility of endoscope during procedure, ease of distal tip angulation, ease of sheath placement and removal, and overall impression).

The most common rating in the series was excellent, which was assigned for one or more of the nine evaluated characteristics in 29 to 40 of the 50 procedures, including 36 procedures in which overall impression received an excellent rating. The second most common rating was above average. A poor or below-average rating was assigned only eight times, primarily for difficulty in removing the EndoSheath® Technology, which the author noted was caused by his mishandling of the device. The two instances of difficulty in passing the endoscope occurred in patients who had extremely dry mucosa because of systemic disease or radiation therapy. There were no ruptures of any disposable sheaths in the series.

Silberman commented that the EndoSheath® system has excellent optical qualities, with no degradation of the image, and avoids the need for high-level disinfection or sterilization of a nasopharyngolaryngoscope between uses. According to the author, the disadvantages of high-level disinfection or sterilization include damage to the endoscope over time; the risk of contamination because of inadequate disinfection practices; the potential for allergic reactions in health care personnel exposed to glutaraldehyde during endoscope reprocessing; and the considerable time required, which may necessitate the purchase of several nasopharyngolaryngoscopes in order to provide continuous service.

Silberman concluded that the EndoSheath® Technology worked extremely well in his patients, with no adverse effects on diagnostic variables. He recommended the system as the simplest method of obtaining true sterilization of nasopharyngolaryngoscopes.

**Nasal and Sinus Endoscopy for Management of Resistant Rhinosinusitis**


This article is a review by Tichenor et al of the history of nasal and sinus endoscopy in evaluating and treating chronic rhinosinusitis (CRS); the equipment and techniques used by allergists to perform endoscopy; and common endoscopic findings in patients with CRS, including those who have undergone sinus surgery. The authors noted that nasal and sinus endoscopy is employed for a variety of CRS-related disorders because it allows visualization of or access to the septum, middle meatus, uncinate process and hiatus semilunaris, accessory ostia, and sphenoethmoidal recess and choana. In patients who have undergone sinus surgery, endoscopy can be used to detect or treat several conditions, including perforated septum, retained secretions, non-patency of the surgical ostium, recirculation of mucus, hyperplastic nasal disease, synechiae, empty nose syndrome, frontal sinus disease, dental and related disease, and atrophic rhinitis.
Tichenor et al commented that sinus examinations are easier to perform with flexible endoscopes than with rigid endoscopes, although rigid endoscopy provides better optics and visualization and can be done without an assistant. According to the authors, concerns about adverse events (other than vasovagal reactions) during nasal endoscopic evaluations of allergic disease are minimal; in particular, there is little risk of bleeding.

The reviewers noted that EndoSheath® Technology with a channel external to the endoscope but within the sheath (Vision Sciences/Medtronic Xomed, Jacksonville, FL) represent a valuable addition to otolaryngologic endoscopy for two primary reasons: they substantially shorten the time between endoscopic procedures because the necessity of sterilizing endoscopes after use is avoided, and the channel allows brushings or procedures such as removal of foreign bodies or fungus balls to be performed with an endoscope not originally designed for surgical procedures. Tichenor et al concluded that nasal endoscopy is a critical component of the management of CRS.

**Optical Quality of Nasendoscope with and without EndoSheath® Technology**


This article describes a laboratory study by Vaz et al that assessed images from a nasal endoscope (Olympus P4, Tokyo, Japan) with and without EndoSheath® Technology. The endoscope was secured to an optical bench, and a target was placed 20 mm from its tip, in the mid-range of the depth of field. The target was designed to fill the field of view when viewed with the endoscope at a distance of 20 mm. The researchers first used a spectrophotometer to measure the spectral distribution of the endoscope's visible output with and without EndoSheath® Technology. They then asked nine experienced endoscopists blinded to whether the endoscope was sheathed to guess whether the EndoSheath® Technology was present. The endoscopists were initially shown the image with and without EndoSheath® Technology. Subsequently, on 10 separate occasions, they viewed the target while blinded to the presence or absence of a disposable sheath and used a score sheet to record whether they thought an EndoSheath® barrier was in place. The sheathing and unsheathing were done by an independent observer in accordance with a previously determined random sequence.

The spectral analysis found that application of EndoSheath® Technology had no effect on the spectrum of light emitted by the endoscope. Therefore, according to Vaz et al, any apparent difference in images from the sheathed and unsheathed instrument should not have been due to any chromatic effect. The score sheets completed by the endoscopists were reviewed to determine how many times the physicians correctly guessed that the endoscope was sheathed (or not). This analysis found that the endoscopists provided significantly more correct answers than would be expected by chance (P = 0.00052; mean, 6.8 correct answers per endoscopist; range, 4-9).

Vaz et al mentioned two principal benefits of using EndoSheath® Technology: the ability to quickly reuse nasal endoscopes in the clinic that results from the decrease in downtime necessitated by sterilization; and the prevention of contamination, especially in situations in
which an endoscope must be employed outside an otolaryngology unit (for instance, in the intensive care unit or emergency room). The authors also noted the importance of following the manufacturer's guidelines to ensure safe fitting of the disposable barrier to, and removal from, an endoscope. Vaz et al concluded that their findings suggest that EndoSheath® Technology use is associated with an optical change but that the magnitude of the change and its possible effect on clinical practice require further investigation.

**Flexible Nasendoscope with Disposable-Sheath System Compared with Standard Nasendoscopy: Randomized Trial**


This article by Winter et al describes a randomized trial in which flexible nasal endoscopy using EndoSheath® Technology was compared with standard flexible nasal endoscopy in 100 patients (50 in each group). The study assessed setup times, ease of setup, patient comfort during the endoscopic procedure, and image quality with and without a disposable sheath. The same nasal endoscope (3-mm Olympus, Tokyo, Japan) was used for all procedures. If no disposable sheath had been applied to the endoscope during a procedure, reprocessing of the instrument before use in another patient included immersion in glutaraldehyde for 10 minutes, in accordance with departmental protocol. When EndoSheath® Technology was used, the endoscope was reprocessed by removing the disposable sheath and cleaning the instrument with alcohol wipes. Setup times (which did not include the 10 minutes of glutaraldehyde immersion for the unsheathed endoscope) were measured by an independent timekeeper. For each clinical procedure, the assisting nurse rated the ease of setup and cleaning according to a 10-point visual analog scale, with 0 indicating bad and 10 good. Patients used the same scale to record their comfort during endoscopy. The one endoscopist in the study rated the ease of passage of the endoscope and the quality of the image (nonblinded evaluation). Several images were recorded with a video system and subsequently rated for quality by an otolaryngologist blinded to whether the EndoSheath® Technology had been used during the endoscopic procedure.

Winter et al found no significant differences (with 99% confidence intervals [CIs]) between the sheathed and unsheathed nasal endoscope in setup time, patients' perception of the comfort of their procedure, or the physician's perception of the ease of passage or image quality. There were also no significant differences (99% CI) between the image-quality ratings of the nonblinded endoscopist and those of the blinded otolaryngologist.

Winter et al concluded that the use of disposable sheaths allows more nasal endoscopic procedures to be performed with each instrument because the 10-minute glutaraldehyde immersion is avoided. The authors also noted that they advocate the use of EndoSheath® Technology as a physical barrier that provides protection against the risk of cross-contamination between patients. Winter et al explained that although the risk of such contamination is not high in otolaryngologic endoscopy, it still exists, particularly because of the association between prion diseases and lymphoid tissue of the head and neck.
Preventing Cross-Contamination with Flexible Fiberoptic Endoscopy in Otolaryngology: a Comparison of Two Methods


The goal of this prospective controlled trial was to assess the efficacy of sterile disposable sheath usage to prevent cross-contamination during endoscopic procedures with a fiberoptic nasopharyngolaryngoscope (FNPL), as compared to immersion of the instrument in a germicidal liquid. Many otolaryngologists who use FNPLs to evaluate patients use a liquid germicide for disinfection; this requires multiple steps, including preparation, cleansing, immersion for specified length of time, and drying. In order for this disinfection method to be highly effective, clinical staff must strictly adhere to protocols. Elackattu et al note that not all medical assistants have extensive experience performing this disinfection procedure, and some may object to exposure to potentially toxic chemicals during the immersion process. As an alternative, disposable sterile sheaths were developed to fit over the FNPL and are marketed as a means of preventing cross-contamination between patients. The investigators in this study evaluated microbial presence on endoscopes after use with a sterile sheath, and comparatively analyzed microbes cultured from endoscopes that were used in a procedure without a sheath, and were then disinfected with a liquid germicide. Patients were examined in an otolaryngology clinic and assigned to one of two groups: the liquid germicidal disinfection group, and the sterile sheath group. The endoscopes used in the sterile sheath procedures were cleaned between patients as per manufacturer recommendations; immersion in enzymatic detergent after sheath removal, friction rub with water rinse, intermediate level disinfection with 70% alcohol-soaked gauze, and air dry. The endoscopes in the liquid germicide group went through high-level disinfection as a required additional step beyond intermediate-level disinfection.

Culture samples were collected prior to use on the patient and after high-level disinfection on the immersion group of endoscopes; for the sterile sheath group, samples were taken three times: prior to use on the patient, after sheath removal, and after intermediate level disinfection.

The results of the microbial study revealed that the sterile sheath system is as effective as using a liquid germicidal system for preventing cross-contamination when using FNPL’s sequentially in a series of patients. The investigators noted that baseline contamination can be a concern: in this study, about 8% of the insertion tubes in either group and a small percentage of control handles in either group had organisms on them at baseline, after having undergone high-level disinfection (a requirement of the study design). This may have been the result of improper storage or other contamination during transport. Overall, the results of the study suggest that using an individually-packaged disposable sterile sheath on an FNPL does prevent microbes from adhering to the insertion tube of the scope, thus providing a method to avoid the transmission of infection from one patient to another.

The authors commented that while the immersion method is known to be effective for
disinfecting endoscopes, it is not a perfect method, in that a sterilization process is required
to destroy all living micro-organisms (bacterial spores and viruses) which may still be present
after high level disinfection. The article also discusses the many adverse reactions which have
been reported by clinical staff (e.g., asthma, skin disorders) after exposure to noxious liquid
germicides; and points out that other methods of disinfection which involve dry heat, steam,
hydrogen peroxide, or peracetic acid have not been widely adopted for a variety of reasons.

In their conclusion, Elackattu et al mentioned the issue of patient perception as a
significant consideration. They found that typical patients derive a sense of security about
sterility when they see a sterile sheath being removed from its one-time-use packaging and
placed over the endoscope immediately prior to insertion of the scope into his/her nose.

**Disposable Sheath System for Flexible Sigmoidoscopy in Decentralized
Colorectal Cancer Screening**

Bretthauer M, Hoff G, Thiis-Evensen E, Grotmol T, Larsen IK, Kjellervold O, Skovlund E. Use of a
disposable sheath system for flexible sigmoidoscopy in decentralized colorectal cancer screening.
*Endoscopy* 2002;34:814.

This study by Bretthauer et al, conducted during an ongoing population-based screening
trial (total of 21,000 men and women ages 50–64), was designed to assess the feasibility of
using a disposable sheath system for flexible sigmoidoscopy in decentralized colorectal
cancer screening. In many countries there is an increasing demand for colorectal cancer
screening by endoscopy. Decentralized screening is difficult because the design of endoscopy
equipment towers and cleaning apparatus does not favor mobility. Flexible sigmoidoscopy is
recommended for the average-risk population; reusable endoscopes are commonly used for
this purpose. The authors point out that cleaning and disinfection of these devices have been
a subject of concern, as transmission of infectious material cannot be completely excluded
from the working channel; in addition, reprocessing of endoscopes is time-consuming and
expensive. An endoscope with disposable sheaths (EndoSheath® Technology) which does
not require conventional reprocessing and which is possibly transportable was introduced
and selected for use in the study. Bretthauer et al note that according to the colorectal
cancer screening committee of OMED (Organisation Mondiale d’Endoscopie Digestive), use
of a disposable sheath is generally desirable. Emphasis on the prevention of transmission of
infectious agents and reduction of instrument reprocessing time has resulted in promoting
the use of disposable sheath systems as opposed to conventionally reprocessed endoscopes
for flexible sigmoidoscopy.

For this screening trial, participants were randomly allocated to have flexible sigmoidoscopy
performed with either a 60 cm fiberoptic sigmoidoscope (SS-F32/S-F100 EndoSheath®
Technology, Vision-Sciences, Natick, MA) covered with a disposable sheath (EndoSheath®
Technology group) or a 140 cm conventional video colonoscope (Olympus 140/VI, Hamburg,
Germany) (standard colonoscope group). All examinations were performed at a temporary
screening center; three screening centers were used, one of which was located in a remote,
rural area. With the exception of the control knobs attached to the control handle, the
reusable core of the sheathed endoscope was covered by a disposable barrier to protect
working surfaces from contamination. Air, water and biopsy channels are incorporated in the sheath, not the endoscope. The sheath was discarded after each examination to provide every patient with a sterile endoscope. Three experienced endoscopists performed all examinations. No sedation was used. To adjust for the different lengths of the endoscopes, patients in the standard colonoscope group with examinations beyond 60 cm were excluded from analysis. According to the protocol, tissue samples for histological evaluation were taken from all detected polyps, using a disposable biopsy forceps.

Results from examinations of 113 patients in the EndoSheath® Technology group and 87 patients in the standard colonoscope group were analyzed. The patients’ experience was documented using a questionnaire relating to overall satisfaction with the procedure and discomfort during the examination, and the feasibility of running temporary screening units was evaluated. Among the respondents who completed the questionnaire after the examination, 94% were generally satisfied, and 98% would recommend the procedure to others, with no differences between the groups. The vast majority of all patients reported no discomfort: 76% in the EndoSheath® Technology group, and 75% in the standard colonoscope group. Only slight discomfort was reported by 17% in the EndoSheath® Technology group and 18% in the standard group. Seven patients in the EndoSheath® Technology group reported moderate discomfort, compared with six patients in the standard group. None of the individuals examined reported severe discomfort during the examination. No differences were observed between the groups regarding age and gender; mean age was 58.5 years in both groups and the proportions of women were 53% (EndoSheath® Technology group) and 56% (standard colonoscope group).

The researchers found that when the sheathed system was used, all the devices needed could be satisfactorily transported. A screening center could be set up within a few hours. The EndoSheath® system worked adequately during the trial; the investigators noted that for passage and subsequent withdrawal of the forceps, the tip of the endoscope had to be straightened. They also determined an advantage of the EndoSheath® Technology is its stronger suction pump, allowing greater improvement on any suboptimal bowel cleansing, when compared with the standard system.

Bretthauer et al noted that the safety of the procedure, high examination quality, and acceptable cost-effectiveness are important requirements in population-based flexible sigmoidoscopy colorectal cancer screening. Despite meticulous cleaning, following recommended guidelines, the transmission of infectious material cannot be completely excluded when conventional endoscopes are used. The authors found that the use of disposable sheath systems minimizes the risk of cross-contamination. Additionally, the time- and cost-intensive high level reprocessing, which is mandatory when using conventional reusable endoscopes, is not necessarily needed with a disposable sheath system. Mid-level reprocessing is recommended with the EndoSheath® Technology which includes removal and disposal of the sheath, a wash of the endoscope with an enzymatic detergent, rinse, and a wipe down with a 70% alcohol wipe. Several trials have reported a significant decrease in reprocessing time, favoring the EndoSheath® Technology.
Perhaps the most important advantage of the disposable sheath system in this study was its transportability. The researchers were able to easily establish a temporary satellite screening unit, since the system does not require any large cleaning facilities and all the equipment needed could be easily transported in a medium-sized car. By using the EndoSheath® Technology, it was possible to move a completely self supported flexible sigmoidoscopy screening unit by car from one location to another, with two employees, and be operational the same day. The authors noted it would have been more than a 2 hour drive for people living in the remote parts of the screening area to get to the nearest main screening center. By establishing the satellite unit, they were able to maintain a high compliance rate in those areas as well. The investigators suggest the use of easily transportable disposable sheath systems, set up in temporary screening centers, may contribute to high attendance rates for colorectal cancer screening in outlying areas. In rural countries in particular where endoscopy facilities are very distant, the use of the disposable sheath system may be crucial for the success of future colorectal cancer screening programs.

High-Volume Screening Sigmoidoscopy with a Flexible Fiberoptic Endoscope and Disposable Sheath System: an Assessment


The investigators' primary objective in this study was to assess the feasibility of high-volume single-day screening sigmoidoscopy as a means of addressing a prevailing concern among physicians regarding inefficient use of time and resources. The authors note that colorectal cancer continues to be a leading cause of cancer-related death in the U.S. and although compelling evidence exists to demonstrate that screening sigmoidoscopy can significantly reduce colorectal cancer mortality, this type of screening has yet to achieve national impact on colorectal cancer incidence or mortality. Consensus among medical professionals indicates this is largely due to poor patient acceptance and inadequate promotion and utilization by physicians, even by gastroenterologists. The secondary objective of the investigators in this study was to assess the performance and functional status of an innovative fiberoptic sigmoidoscope (Vision Sciences® S-F100) with a single-use disposable sheath system (Vision Sciences® EndoSheath® Technology) for use in high-volume screening.

All municipal employees of a northeast city over the age of 50 yrs. (n=6137) were invited to undergo screening sigmoidoscopy free of charge, and were advised the sessions would be conducted on the weekend, at a prominent local hospital. A total of 227 individuals were scheduled, and pre-registration was efficiently handled the week before each session, to maximize potential for rapid patient turnaround time during the screening sessions. Patients were scheduled consecutively into 15 min. slots during 6 half-day (3 hr.) weekend sessions. Of the 227 scheduled, 86% (n=198) patients presented for the screening sessions. For this study, all screening procedures were performed with the Vision Sciences® S-F100 and disposable EndoSheath® Technology. The authors noted that the reusable components of this endoscopic system are similar to conventional fiberoptic sigmoidoscopes except...
that the scope itself does not contain air, water, or biopsy/suction channels. These channels are incorporated into the disposable sheath, which can be quickly removed and replaced between procedures; all parts that come into contact with the patient and/or the patient’s bodily fluids are disposed of after each use.

Study staff included an observer who recorded depth of sigmoidoscope insertion, procedure time, instrument set up time, and patient turnaround time. To reduce the potential for observation bias, the endoscopy nurse also documented patient turnaround time, which in turn provided a means for monitoring accuracy of procedure and instrument set up times. Total number of procedures per physician and per room were also recorded. Schroy et al reported that only 15% of the patients had undergone a previous sigmoidoscopy or colonoscopy, yet 32% acknowledged a positive family history of colorectal cancer or polyps.

Physicians performed a mean of 3.5 procedures per room per hour, or 4.7 procedures per hour overall; and the mean procedure time was 4.7 ± 3.3 mins. Equipment set up time and patient turnaround time averaged 4.6 ± 1.7 min. and 11.0 ± 6.0 min. respectively. There were no equipment malfunctions or technical difficulties. These results led the investigators to conclude that the use of the flexible fiberoptic sigmoidoscope and disposable sheath system was a highly expeditious and efficient approach. They found that as many as seven to eight procedures could be performed per hour by a single physician rotating between two endoscopy rooms. Schroy et al cited a previous study by Rothstein et al (1), which directly compared the performance status of the sheathed system versus a conventional system. In that study of 143 procedures, the authors found that procedure time was slightly longer with the sheathed system (5.6 min. vs. 6.7 min.), however, down time was considerably shorter with the sheathed system (32.8 vs. 8.1 min.). In the Schroy et al study, the authors noted that the sheathed sigmoidoscopy system minimized down time by eliminating elaborate and time-consuming high-level disinfection/sterilization routines between each procedure. In this study, a mean of only 4.6 min. was needed to unload and reload the S-F100 EndoSheath® Technology sigmoidoscope between procedures, compared with the >45 minutes currently recommended for conventional sigmoidoscopes by leading chemical germicide manufacturers to achieve high level disinfection. Minimized down time enabled the physicians to perform 3.7 procedures per room per hour with the S-F100 system vs. only a single procedure per room per hour had a conventional endoscopic system been used. The authors commented that this benefit could only be offset by the availability of an arsenal of conventional sigmoidoscopes, which is impractical in most settings, and extremely costly. The investigators also noted that in addition to its positive impact on efficient use of time and resources, the sheathed system offers a potential strategy for reducing the risk of endoscopically transmitted infectious complications and patient or staff reactions to harsh disinfectant solutions. It was suggested that although this study evaluated the performance of the sheath system for the purpose of high-volume screening, this system may well have distinct advantages in lower volume settings, such as private offices.
In conclusion, the authors discussed the validity of the study from a cost-effectiveness standpoint; and while it is understood that the issue of cost-effectiveness is extremely complex, they approached this by addressing comparable costs between the disposable sheathed system and a conventional endoscopic system. The capital equipment costs of the two systems were found to be comparable; the major differential costs to be considered were those of the sheaths and costs associated with reprocessing. It was noted that at face value the cost of the sheath was about $45 and the associated reprocessing cost was minimal; in contrast, the costs associated with reprocessing conventional sigmoidoscopes include costs for prolonged labor, specialized equipment (fume hoods, disinfection chambers, etc.), space, protective gear, chemical disinfectants, and cleaning supplies. The investigators commented that to obtain a meaningful cost comparison between the two systems, it is necessary to factor in procedural routines involved in using an un-sheathed conventional endoscopic system, which result in physician and nurse "idle time." A previous study by Trowers et al (2) was cited to support the finding that increased patient turnaround and maximized efficiency of time and resources provide a strong incentive for office-based sigmoidoscopy.

References

