Preclinical characterization of the Spyglass peroral cholangiopancreatoscopy system for direct access, visualization, and biopsy

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Background: Current cholangioscopes are restricted to 2 deflection angles and require more than 1 operator. The newly developed Spyglass peroral cholangiopancreatoscopy system provides 4-way deflected steering by a single operator.

Objective: To evaluate access and biopsy in all simulated biliary-duct quadrants with the Spyglass system, high-level disinfection of the reusable Spyglass optical probe, and feasibility of in vivo biopsy.

Design: Laboratory simulations comparing biliary-duct access and biopsy with the Spyglass versus a conventional system, laboratory determination of high-level disinfection effectiveness, and observational investigation of biopsies in a porcine model.

Setting: Research laboratories.

Main Outcome Measurements: Rate ratios (RR) and 95% confidence intervals (CI) for successful access to all quadrants and simulated biopsy.

Results: Success rates for access in all quadrants were significantly higher with the Spyglass system than with the control system, both without (RR 1.71, 95% CI 1.39-2.29) and with (RR 2.00, 95% CI 1.56-2.78) biopsy forceps loaded. Higher success rates were also attained by using the Spyglass system to access biopsy targets (RR 2.09, 95% CI 1.60-2.91) and to perform simulated biopsies (RR 2.94, 95% CI 2.05-4.52). Microbial species log reductions of 6.0 to 7.0 were achieved by high-level disinfection of Spyglass optical probes. In 31 in vivo porcine biopsies yielding adequate gross specimens, the quality for histologic examination was excellent to adequate for 90% of specimens.

Limitations: Study procedures were performed by a single nonblinded operator. All data were collected ex vivo or in animals, and clinical applicability remains to be determined.

Conclusions: The Spyglass system allows access and biopsy in all quadrants and merits clinical investigation.

Despite refinements in techniques and technologies such as ERCP, MRCP, and EUS, differential diagnosis of biliary strictures and filling defects can prove difficult. Biliary strictures can result from malignant or benign tumors, as well as from various inflammatory diseases, and benign strictures can mimic malignant strictures by manifesting as focal areas of wall thickening. Intraductal tumors may also mimic large stones. Exact evaluation of the potential resectability of such tumors, and thus the appropriate therapeutic intervention, has remained a major diagnostic challenge. Forceps biopsy under direct visualization can aid in diagnosis.

Peroral cholangiopancreatoscopy (CP), a technique of ERCP that uses a fiberoptic cholangioscope passed through a therapeutic duodenoscope directly into the biliary tract, can be enlisted in cases that are hard to diagnose or treat. A distinct advantage of peroral CP is that it provides direct visualization of the stricture or filling defect and allows inspection of the biliary epithelium for subtle abnormalities that may not be detectable by radiography. Peroral CP has been shown to improve the ability to distinguish malignant from benign biliary disease and was found to be especially useful for diagnosing filling defects.
visualization by CP enables more precisely targeted biopsy of suspected sites, which can provide a definite diagnosis.\(^3,4\) CP is also used in treating large difficult stones by electrohydraulic lithotripsy (EHL).\(^4-8\)

Despite these advantages, CP has not been commonly performed, in part, because the cholangioscopes used for CP have been characterized by fragility and by both high initial and repair costs.\(^3\) Also, the approach has been labor intensive. Two endoscopists are required, one to operate the duodenoscope and the other to operate the cholangioscope. Developed as miniaturized endoscopes, cholangioscopes have evolved and are greatly improved from the earlier versions. Nonetheless, several technical limitations remain. Among them are limited tip deflection and suboptimal ability to irrigate the lens and visual field.\(^3,9\)

A newly developed peroral CP system allows single-operator examination and 4-way deflected steering, with separate dedicated irrigation channels. Instead of a single-piece miniaturized endoscope, the system is composed of a reusable optical probe, a disposable access and delivery catheter, and a disposable biopsy forceps. A preclinical characterization of this system is described in this report, including tests conducted with a novel bench simulator designed to furnish standardized reproducible comparative performance data.

**MATERIALS AND METHODS**

The Spyglass Direct Visualization System (Microvasive Endoscopy, Boston Scientific Corp, Natick, Mass) was evaluated by bench simulation, irrigation-fluid flow-rate measurements, determination of optical resolution, high-level disinfection (HLD), and porcine model experiments. The system is shown in Figure 1. Specifications of the reusable Spyglass optical probe, the SpyScope disposable access and delivery catheter, and the SpyBite biopsy forceps are summarized in Table 1. The disposable SpyBite biopsy forceps is designed to maximize tissue retention through the teeth on the front of the cup and a spike inside the cup body.

**Bench simulation**

The capabilities of the Spyglass system for direct access, visualization, and biopsy in all quadrants were compared with those of a control fiberoptic transendoscopic choledochoscope with 2-way deflection (CHF BP30; Olympus America Inc, Center Valley, Pa). Despite limitation to 2-way deflection (160° up and 130° down), the Olympus choledochoscope may potentially provide access to more than 2 quadrants when torque is applied to the duodenoscope. A novel bench simulator was designed by this author and was constructed specifically for the comparative evaluation of the 2 systems. The simulator was composed of acetal guide blocks and supports, and a glass tube was incorporated to represent the span through the esophagus to the stomach. All simulations involving the Spyglass system were performed by a single operator (Fig. 2), whereas 2 operators carried out control system simulations. The second operator in the control simulations was a GI endoscopy nurse experienced in routinely assisting the investigator with cholangioscopy and cholangioscopy-directed biopsies with the control choledochoscope.

The simulator allowed testing of both short and long duodenoscope positions, approximately 63.5 and 94.0 cm in length, respectively. In the short position (Fig. 3), the potential for transmission of torque was greater and the cholangioscope could be manipulated with the duodenoscope (TJF160; Olympus), although, in the long position, the effect of duodenoscope manipulation was minimal.

Testing was performed both with 5- and 9.5-mm simulated bile-duct diameters corresponding to the average small and large ducts, respectively, likely to be encountered in vivo. The ducts were composed of silicone tubing (Cole-Parmer, Vernon Hills, Ill) arrayed on the simulator with a pattern of curvature similar to that in vivo. The curvature could be adjusted as desired. During testing, physiologic temperature was maintained inside the ducts through circulation of water at 37°C.

Three replicate series of tests that compared the Spyglass and Olympus systems were conducted for each duodenoscope position and simulated bile-duct diameter. The following capabilities of the 2 systems were assessed: accessing quadrants inside the simulated bile duct without and with the SpyBite forceps loaded; opening and closing the forceps; accessing simulated biopsy targets; performing simulated biopsies; and ease of forceps insertion and removal through the working channel. Access tests of the control system were performed without and, if necessary, with application of torque to the duodenoscope.
Serving as biopsy targets were monofilament suture knots with a spherical diameter of 1.2 mm placed in each quadrant approximately 18 cm proximal to the simulated papilla (Fig. 4). A simulated biopsy was scored as successful if the knot could be clasped and withdrawn by the biopsy forceps. A suture was passed from the knot target through the silicone duct wall so that, after a successful biopsy, the knot target could be easily returned to its original position by retracting the suture (Fig. 4). The SpyBite forceps was used in tests of both the Spyglass and control systems.

**Irrigation**

Flow rates of irrigation fluid through the SpyScope were compared with those through 2 control cholangioscopes (CHF BP30, Olympus; and FCP-9P, Pentax Medical Co, Montvale, NJ). Deionized water was pumped through the systems by using an ENDO 100 Lavage Pump (ERBE USA, Inc, Marietta, Ga) at low, medium, or high settings. At each pump setting, single flow rate determinations were carried out during irrigation through a working channel that contained no instrument, a 0.035-inch guidewire (Jagwire; Microvasive), or a SpyBite forceps. It was necessary to compare flow rates through the working channel, because neither control system includes dedicated irrigation channels. For the SpyScope, additional flow-rate measurements were made through the dedicated irrigation channels.

**Optical resolution**

A standardized test target (1951 USAF Glass Slide Resolution Targets; Edmund Optics Inc, Barrington, NJ) was visually evaluated at a distance of 5 mm to determine the optical resolution of the Spyglass optical probe and the Olympus cholangioscope. Resolution was measured as the maximum number of line pairs/mm that could be distinguished on the test target. After reprocessing with HLD, the Spyglass optical probes were reevaluated to detect any deterioration in resolving power.

**HLD**

The ability of the Spyglass optical probe to undergo effective standard HLD was evaluated by using 3 lots each of Cidex (Advanced Sterilization Products, Irvine, Calif) activated dialdehyde and Cidex OPA orthophthalaldehyde solutions. The criterion of effective HLD was a

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**TABLE 1. Spyglass system specifications**

<table>
<thead>
<tr>
<th>Component</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spyglass optical probe</td>
<td></td>
</tr>
<tr>
<td>Working length</td>
<td>300 cm</td>
</tr>
<tr>
<td>Outer diameter</td>
<td>0.77 mm</td>
</tr>
<tr>
<td>Field of view</td>
<td>70°</td>
</tr>
<tr>
<td>Focal length</td>
<td>2.7 mm</td>
</tr>
<tr>
<td>SpyScope access and delivery catheter</td>
<td></td>
</tr>
<tr>
<td>Working length</td>
<td>220 cm</td>
</tr>
<tr>
<td>Outer diameter</td>
<td>10F</td>
</tr>
<tr>
<td>Working channel diameter</td>
<td>1.2 mm</td>
</tr>
<tr>
<td>Irrigation channel diameter</td>
<td>0.6 mm*</td>
</tr>
<tr>
<td>Optic channel diameter</td>
<td>0.9 mm</td>
</tr>
<tr>
<td>Four-way tip deflection</td>
<td>≥ 30°</td>
</tr>
<tr>
<td>SpyBite biopsy forceps</td>
<td></td>
</tr>
<tr>
<td>Working length</td>
<td>270 cm</td>
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<tr>
<td>Outer diameter</td>
<td>3F</td>
</tr>
<tr>
<td>Cable diameter</td>
<td>0.039 inches</td>
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<tr>
<td>Jaw outer diameter</td>
<td>1.0 mm</td>
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<tr>
<td>Required working channel</td>
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</tr>
<tr>
<td>Approximate jaw opening</td>
<td></td>
</tr>
<tr>
<td>Linear</td>
<td>4.1 mm</td>
</tr>
<tr>
<td>Angular</td>
<td>55°</td>
</tr>
<tr>
<td>Composition</td>
<td>Stainless steel</td>
</tr>
</tbody>
</table>

*Specified diameter for each of the 2 irrigation channels.

*With Spyglass optical probe loaded and therapeutic device in working channel.
≥6 log reduction in populations of 3 microbial species (Staphylococcus aureus [S aureus], Mycobacterium smegmatis [M smegmatis], and Candida albicans [C albicans]). Additional testing was conducted by using Steris 20 Sterilant (STERIS Corp, Mentor, Ohio). For simulation of routine repeated reuse, 8 Spyglass units each were subjected to 20 complete reprocessing cycles with enzymatic cleaner and disinfectant solution before testing with each microbial species. A 0.1-mL inoculum that contained ≥10⁶ viable organisms was deposited in 0.01-mL aliquots along the length of the probe. After air-drying for ≥30 minutes, 3 units each were soaked in Cidex solution for 45 minutes at 25°C and Cidex OPA solution for 12 minutes at 20°C. Two nondisinfected units served as positive controls. The probes were then submerged, wiped, and gently agitated in peptone buffer, and the buffer was filtered through 0.45-μm membranes. The membranes were placed on tryptic soy agar plates and incubated at 30°C to 35°C for ≥7 days for test units and 24 to 72 hours for positive controls, and colonies were enumerated.

After reprocessing with HLD, the Spyglass optical probes were inspected under magnification levels that ranged from ×50 to ×100 by using an OMIS MINI Optical Measurement Inspection System (RAM Optical Instrumentation Inc, Rochester, NY). Inspection under magnification was also performed during flexing of the probes to expose any gaps or material degradation. Optical resolution was also assessed after reprocessing with HLD.

**Porcine model**

The Spyglass system was advanced into the biliary and hepatic ducts of 5 anesthetized pigs. Spyglass-directed biopsies were attempted above and below the hepatic bifurcation, and specimens were subjected to pathologic examination. Each specimen obtained from each biopsy attempt was recorded and deposited in a separate specimen bottle. The adequacy of the gross specimen was based on specimen size (adequate, inadequate, no sample) as assessed by visual inspection. The adequacy of the histologic sample was graded under microscopic examination on a scale of excellent, adequate, inadequate, no sample. Gross specimen adequacy and quality for histologic examination were rated by an independent consulting GI pathologist with extensive prior experience in evaluating clinical specimens from cholangioscopy-directed biopsies. The pathologist was blinded to the source and the site of the specimens. All animal procedures were carried out in conformity with the Guide for Care and Use of Laboratory Animals of the National Research Council, Guidelines of the U.S. Department of Agriculture Animal and Plant Health Inspection Service, the Animal Welfare Act, and Standard Operating Procedures of the University of Colorado.

**Statistical analysis**

Comparisons of bench performance results between Spyglass and control systems with respect to binary study end points were performed by calculation of rate ratios (RR) and exact 95% confidence intervals (CI). The RR was defined as the proportion of successes from attempts with the Spyglass system divided by successes with the

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**Figure 2.** Spyglass system procedure conducted by a single operator.

**Figure 3.** Bench simulator in short scope position.

**Figure 4.** Illustration of monofilament suture knot biopsy targets with a suture used to return target to its original position after simulated biopsy.
control system. The absence of 1 from the CI implies a statistically significant difference ($P < .05$). StatXact 7.0 (Cytel Software Corp, Cambridge, Mass) statistical software was used for the analysis.

RESULTS

Quadrant access

In 12 bench simulations each with the Spyglass and control systems, access was attempted to 48 quadrants by using each system. Access with the Spyglass system was successful in 48 of 48 (100%) quadrants, both without and with the biopsy forceps loaded (Fig. 5). Forceps opening and closing were also successfully accomplished during access to all 48 quadrants.

Quadrant access success rates without and with forceps loaded were significantly higher with the Spyglass than with the control system, as indicated by RRs of 1.71 and 2.00, respectively (Fig. 5). Without and with forceps loaded, 28 of 48 (58%) and 24 of 48 (50%) quadrants, respectively, could be accessed with the control system. Four control system quadrant access attempts (8.3%) without forceps required torquing the duodenoscope for success, as did 3 attempts (6.3%) with forceps. Opening and closing the forceps were attempted 23 times each with the control system, and all attempts were successful.

With the Spyglass system, 100% quadrant access success rates were achieved in both scope positions and duct sizes tested. With the control system, quadrant access success rates were generally similar between duodenoscope positions and duct sizes. Thus, in the short scope position, control system quadrant access success rates without and with forceps loaded were both 56%. Control system success rates in the long position were 50% without and 38% with forceps loaded. In 5-mm ducts, success rates with the control system were 54% without and 58% with forceps loaded. Corresponding rates in 9.5-mm ducts were 62% and 42%.

Simulated biopsy

The Spyglass system permitted access to 48 of 48 biopsy targets (100%). In a median of 1 attempt per target with an interquartile range (IQR) of 1 to 2, simulated biopsy with the Spyglass system succeeded at 47 of 48 targets (98%) (Fig. 5). After the biopsy, ease of forceps withdrawal was rated excellent in 46 of 47 attempts (98%) and adequate in 1. Withdrawal was not evaluated in 1 case. Of 31 attempted forceps reinsertions with the Spyglass system, 28 (90%) were rated excellent, and 3 (9.7%) were adequate.

Rates of successful biopsy target access and simulated biopsy with the Spyglass system were 2.09 and 2.94 times, respectively, those with the control system (Fig. 5). The control system could be successfully maneuvered to 23 of 48 biopsy targets (48%), with torquing of the duodenoscope required in 2 instances (4.3%). Simulated biopsy with the control system succeeded at 16 of 48 targets (33%) after a median of 3 attempts per target (IQR, 1-3). Ease of forceps withdrawal from the control system after biopsy attempts was judged excellent at all 48 of 48 targets (100%), whereas 34 of 38 reinsertions (89%) were rated excellent and 4 of 38 were adequate (11%).

All attempts at biopsy target access and all simulated biopsies but one were successful with the Spyglass system, and, hence, no differences were detected between the short and long duodenoscope positions and between 5 and 9.5 mm ducts. With the control system, such differences were relatively minor. In the short and long scope positions, control system biopsy target access success rates were 56% and 42%, respectively. Corresponding rates in 5- and 9.5-mm ducts were 58% and 38%, respectively. Control system simulated biopsy success rates were 38% and 29% in the short and long scope positions and 38% and 29% in 5- and 9.5-mm ducts, respectively.
Irrigant flow rates
The results of single irrigation-fluid flow-rate determinations with the Spyglass and 2 control systems are presented in Table 2. With a SpyBite biopsy forceps loaded in the working channel, irrigation-fluid flow rates through the working channel of the Spyglass system ranged from 0.44 mL/s at a low pump setting to 0.59 mL/s at a high setting, whereas, rates with the 2 control systems were lower (0.15-0.30 mL/s). Use of the Spyglass dedicated irrigation channels increased flow rates to 0.74 to 1.33 mL/s with the forceps loaded in the working channel.

Comparative resolution
The optical resolution of the Spyglass optical probe was 7.13 line pairs/mm. This resolution was approximately twice that determined for the Olympus choledochoscope (3.56 line pairs/mm). After 20 complete cycles of reprocessing with HDL, there was no demonstrable deterioration in optical resolution of the Spyglass optical probes.

HLD effectiveness
After 20 prior reprocessing cycles of Spyglass optical probes, HLD effectiveness was assessed in 7 determinations for S aureus and 6 each for M smegmatis, and C albicans. The minimum log reduction in S aureus was 6.0 to 7.1, M smegmatis was 6.1 for all determinations, and C albicans was 6.9 to 7.0. In additional testing when using Steris 20 Sterilant and the Steris System 1 processor after inoculation with 1.07 \times 10^8 CFU/mL Geobacillus stearothermophilus endospores, the absence of microbial growth was demonstrated over 5 consecutive sterile reprocessing half cycles. During this repeated reprocessing, the probes did not develop gaps or other surface irregularities resistant to disinfection.

Porcine biopsy
In the porcine model, 14 Spyglass system–directed biopsies were performed above and 20 below the hepatic bifurcation. Adequate gross specimen was secured in 31 of 34 bites (91%). For purposes of histologic examination, the quality of 28 of 31 specimens (90%) was rated excellent to adequate.

DISCUSSION
Although direct visualization of the pancreaticobiliary system for diagnosis and therapy offers decided theoretical advantages, this approach has not been widely applied in clinical practice because of both technical and technological limitations. Further refinements in instrumentation have been needed to fulfill the potential of CP. The newly developed Spyglass system was designed to address some of the limitations of existing cholangioscopes. Direct visualization can aid in distinguishing between tumors and choledocholithiasis and in identifying mucosal irregularity and villous tumors of the biliary epithelium. The appearance of the vasculature within biliary strictures may be helpful in differentiating benign from malignant lesions, and, by means of CP, the vascular pattern within strictures can be compared with the normal bile duct. Irregularity in vascular contour is suggestive of a malignant stricture. The extent of mucosal involvement by primary ductal tumors may be more accurately defined by CP than by conventional fluoroscopic imaging. Pancreatoscopy can allow visualization of chronic scarring and stenosis of the duct, pancreatic-duct stones, and intraductal pancreatic mucinous tumors.

Early CP instruments were not steerable, and it was recognized that this limitation greatly reduced their clinical value. Currently, commercially available cholangioscopes have evolved and are now capable of 2-way deflection (up-down) of the tip. Four-way deflection, as is standard in GI endoscopes, would significantly increase the utility of these instruments. As demonstrated in this study by bench simulation, 4-way deflection can allow access to all 4 quadrants of the biliary tract without or with forceps loaded, access to biopsy targets, and simulated biopsy. As could be predicted, the control system endowed with only 2-way deflection permitted access to only approximately half the quadrants and biopsy targets, and its success

<table>
<thead>
<tr>
<th>Instrument in working channel</th>
<th>Channel type used to irrigate</th>
<th>Flow rate (mL/s) at pump setting</th>
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</thead>
<tbody>
<tr>
<td>Spyglass</td>
<td>Working</td>
<td>Low</td>
</tr>
<tr>
<td>None</td>
<td>Working</td>
<td>3.11</td>
</tr>
<tr>
<td>Guidewire</td>
<td>Working</td>
<td>1.18</td>
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<tr>
<td>SpyBite biopsy forceps</td>
<td>Working</td>
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<td>SpyBite biopsy forceps</td>
<td>Irrigation</td>
<td>0.44</td>
</tr>
<tr>
<td>None</td>
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<td>0.74</td>
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<td>Olympus</td>
<td>Working</td>
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<td>Guidewire</td>
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<td>SpyBite biopsy forceps</td>
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<td>Pentax</td>
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<td>SpyBite biopsy forceps</td>
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</table>
rate for simulated biopsy was only approximately a third that of the Spyglass system. To increase access when using cholangioscopes with only 2-way deflection capabilities, torque is routinely applied to the duodenoscope through which the cholangioscope is passed. But torquing provides only limited additional access to the biliary tree, and this access is further reduced when accessories such as forceps or probes are loaded in the cholangioscope. Torquing the duodenoscope may also increase the chance of damaging the cholangioscope. In the present study, the application of torque to the duodenoscope during the use of the control system had minimal impact in improving success rates for access and simulated biopsy.

Direct visualization of the biliary system facilitates more accurate tissue sampling. Obtaining adequate tissue samples in malignant biliary strictures can be difficult, but it is often essential for a definitive diagnosis. Decisions regarding the total management plan can be made with more certainty when tissue confirmation of the tumor has been obtained. CP is essential for mapping biopsies to establish how far longitudinally the cancer has extended along the bile duct. Cholangiocarcinoma often extends along the bile duct, and cholangiography cannot adequately determine the extent of local invasion.

Brush cytology, endobiliary forceps biopsy, and FNA are the approaches used in ERCP tissue sampling, but sensitivity and specificity remain suboptimal. Even when the 3 sampling methods were used in combination, the cumulative sensitivity in cancer patients was only 52% if atypia was considered benign and 77% if considered malignant. Tissue sampling during ERCP is usually performed under fluoroscopic guidance, and sometimes it can be difficult to target and sample the tumor with accuracy. The location of the tumor in the medial rather than the lateral wall of the bile duct may influence the results of sampling techniques. Despite these challenges, ERCP remains a well-established and widely used method for obtaining tissue samples from the bile ducts.

Percutaneous choledochoscopy has proven more effective than fluoroscopic guidance alone for obtaining a cytologic diagnosis in biliary strictures. When technically feasible, however, the peroral approach is the preferred route of accessing the biliary tree, because percutaneous choledochoscopy requires either a hepatic puncture with formation of a bilocutaneous fistula or entry via a surgical T-tube tract. The Spyglass system enables, for the first time, peroral direct observation combined with 4-way tip deflection, which can allow precisely targeted access to suspicious sites in a less invasive procedure than percutaneous choledochoscopy.

The optimal number of biopsy specimens needed from biliary strictures or other biliary abnormalities has not been determined. Brushing is the most frequently used tissue-sampling method but, often, inadequate samples are obtained. Although forceps biopsy can secure a sample deeper to the epithelium than brushing, forceps biopsy specimens are often small and may be superficial and fragmented. When the quality of individual specimens is relatively low, a greater number of specimens may improve yield. With ERCP, the diagnostic yield was shown to increase with the number of interpretable biopsy specimens. With regard to percutaneous CP, it has been shown that the numbers and the locations of the biopsies required to make a diagnosis depend on the origin and endoscopic findings of the tumor. The combination of direct visualization with greater tip flexibility afforded by the Spyglass system can allow the endoscopist to sample the most appropriate sites. In the present study, high success rates in obtaining biopsy specimens were achieved both ex vivo and in vivo. In the porcine model, 90% of specimens were excellent to adequate in quality for histologic examination. Even so, only limited evidence is currently available on CP-directed biopsies and their potential to improve diagnostic sensitivity and specificity, and the favorable experimental results of the present study will require clinical confirmation.

Another major advantage of the Spyglass system is the elimination of the need for a second endoscopist to operate the duodenoscope. The system uses a silastic belt that permits the endoscopist to strap the SpyScope catheter just below the operating channel of the duodenoscope and, therefore, to control both the ratchets or wheels of the duodenoscope and the knobs of the cholangioscope with the same hand. This capability not only eliminates a significant clinical staff requirement of the procedure but also may improve the efficiency of the procedure, because the single operator may be able, with greater ease, to synchronize the movements of the duodenoscope and the cholangioscope through a range of positions. This method of operation differs from that in another recent report that described duodenoscope-assisted cholangioscopy performed by a single operator. That approach involved wearing a breastplate that secures the cholangioscope in a socket holder so that the duodenoscope can be operated by using the left hand while the cholangioscope is operated by using the right hand.

Despite the appeal of a single operator, mastery of the Spyglass system use entails a learning curve. The operator uses the same hand sequentially to control both the duodenoscope and the cholangioscope, as well as load the biopsy forceps or EHL probe. These maneuvers obviously place demands upon the dexterity of the operator, and the system is most suitable for use by endoscopists with advanced skills.

Separate dedicated irrigation channels are another design advance in the Spyglass system. Continuous irrigation of the bile duct is frequently required because blood, stone debris, sludge, or pus may obscure the cholangioscopic view. Adequate irrigation is critical to maintain a clear field during biopsy and a water-filled medium in the duct during EHL. When irrigation fluid must be
directed through a working channel during use of a biopsy forceps or EHL probe, flow rate is restricted and may be suboptimal. For instance, the laboratory measurements provided in this report indicate that, with a biopsy forceps loaded, the dedicated irrigation channels of the Spyglass system can produce irrigant flow rates 4- to 5-fold those attained through the working channel of conventional systems.

The Spyglass system is designed as a modular cholangioscope with a relatively small turning radius more suitable for maneuvering through small ducts compared with other miniaturized endoscopes. The system can routinely access tertiary ducts. However, because the SpyScope and the Spyglass optical probe are not fused, the probe may retract slightly during SpyScope turning, necessitating readjustment during the procedure. Other limitations of a fiberoptic probe such as the Spyglass are poorer image quality than that afforded by a video chip and susceptibility to partial breakage during steering, with consequent image degradation. Video cholangioscopes currently clinically available in prototype form are not subject to such limitations. Nonetheless, the measured optical resolution of the Spyglass optical probe was twice that of the conventional control cholangioscope.

The novel bench simulator developed for use in this study was designed to mimic as faithfully as possible the operating environment for CP, including physiologic temperature. A major advantage of the simulator was the availability of standardized and spatially well-demarcated simulated bile-duct quadrants and biopsy targets, which allowed reproducible quantification of access and biopsy success rates. By comparison, accurate identification of 3-dimensional position within bile ducts in vivo is problematic. Another advantage of the simulator is the ability to adjust the contours of the simulated ducts as desired. The present report is the first to describe the design and use of the bench simulator, and formal validation studies have not thus far been performed. It was not feasible to blind the single operator in this study.

The applicability of the simulator to clinical CP needs further investigation. For instance, the distensibility of the silicone simulated-duct material may differ importantly from that of actual bile-duct tissue. Also, the difficulties posed in securing certain biopsy tissues in vivo may be notably greater than those of acquiring a simulated biopsy target composed of suture material. Because the focus of investigation was on performance of the cholangioscopes, the simulator was configured to limit the mobility of the duodenoscope. In the clinical setting, the duodenoscope would be readily manipulated during the procedure. The SpyBite biopsy forceps was used in all parts of the study involving forceps use. This approach avoided differences between forceps as a source of variability; however, it is possible that forceps specifically designed for the control systems might have altered their relative performance in those tests involving forceps usage.

In this preliminary study, rigorous testing of technical performance when using the simulator was supplemented by evaluation in an in vivo porcine model as an additional approach to proof of concept. Although the porcine results were encouraging, there was a subjective element in the scoring of gross specimen adequacy and suitability for histologic evaluation. Also, the in vivo data were derived from sampling of normal porcine bile ducts rather than human bile-duct tissue, which may be diseased, further highlighting the importance of confirmation in clinical studies.

HLD is required for reprocessing of GI endoscopes, and, with adherence to current reprocessing guidelines, there have been no published reports describing transmission of infection. Reprocessing that used HLD has been shown capable of effecting a mean 6 log reduction in the number of test organisms. A 6 log or greater reduction after HLD of Spyglass optical probes was attained in the present study. These results were secured after 20 prior reprocessing cycles, thus indicating the durability of the probes. Furthermore, surface integrity and optical resolution were maintained during reprocessing. These data affirm the suitability of Spyglass optical probes for repeated reuse.

In the present model studies, the Spyglass system proved highly effective for direct biliary access, visualization, and biopsy. A clinical study of the system is currently underway.

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DISCLOSURE

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