Health Policy Advisory Committee on Technology

Technology Brief: Update

SpyGlass® direct visualization system

November 2012

HealthPACT
emerging health technology
TECHNOLOGY BRIEF UPDATE

Register ID  WP118

Name of Technology  SpyGlass® direct visualization system

Purpose and target group  SpyGlass® provides direct visualisation for diagnostic and therapeutic applications during endoscopic procedures in patients with biliary and pancreatic diseases

Stage of development in Australia

☐ Yet to emerge  ☐ Established
☐ Experimental  ☐ Established but changed indication or modification of technique
☐ Investigational  ☐ Should be taken out of use
☒ Nearly established

Australian Therapeutic Goods Administration approval

☒ Yes  ARTG number 138593 (probe/camera ocular)
☐ No  ARTG number 137089 (SpyBite biopsy forceps)
☐ Not applicable

International utilisation

| Country       | Trials underway or completed | Limited use | Widely diffused |
|---------------|-----------------------------|-------------|-----------------|
| Japan         | ✓                           |             |                 |
| United States | ✓                           | ✓           |                 |
| Spain         | ✓                           |             |                 |
| United Kingdom| ✓                           |             | ✓               |
| Sweden        | ✓                           |             |                 |
| Australia     |                            |             | ✓               |

2012 Safety and effectiveness issues

Two case series (level IV intervention evidence) were eligible for inclusion in this update. In Chen et al, the SpyGlass® device was used for diagnostic and therapeutic procedures in the bile duct. Kalaitzakis et al also used the device for diagnosis and biliary stone therapy, but this was undertaken in a population which was
contraindicated for conventional endoscopic therapy. Together, these studies provide an additional 462 subjects to the current evidence base.

Chen et al\textsuperscript{1}

This study was a prospective, multicentre observational case series of 297 patients across ten centres in the United States and five centres in Europe. Patients 18 years of age or older with an indication for endoscopic retrograde cholangiopancreatography (ERCP) in conjunction with cholangioscopy were included, whether for therapeutic or diagnostic purposes. The mean age of participants was 63 years. The primary endpoint of procedural success was defined as the ability to target lesions and collect a biopsy specimen (if required), or the ability to visualise biliary stones and undertake stone fragmentation and removal. Each procedure was undertaken according to study centre standard practice. It appeared as if SpyGlass\textsuperscript{®} visualisation was undertaken in conjunction with ERCP, although the methods were not explicit on this detail. Patients were usually discharged on the same day if no complications were apparent. Participants were evaluated at baseline, at 2–4 days post-procedure, and at one-month follow-up. A total of 226 patients underwent the procedure for diagnostic purposes and 66 for stone therapy, having failed at least two attempts at stone clearance by conventional methods. Twenty patients were lost to follow-up. Of these, 11 died from issues not related to the procedure, and two withdrew from the study.

The procedure was unsuccessful in five patients, either as a result of failed access or poor visualisation. It is unclear whether these patients were indicated for diagnosis or for stone therapy. In the 30-day follow-up period, 17 patients experienced one serious procedure-related adverse event, each of which required an additional intervention or additional hospital stay. Early cholangitis was experienced in seven patients. Two patients each had bacteraemia, transient hypotension, and abdominal pain and distension. One patient each had pancreatitis, elevated amylase and lipase, nausea and vomiting, abdominal pain, bilious emesis, gas, cramping and radiculopathy. Sixteen of these events resolved without sequelae, while one event of cholangitis required medication and stenting. There were four late episodes of cholangitis beyond the follow-up period (up to 270 days post-procedure). Three resolved with no additional intervention, while one was managed with medication and stenting. In the stone therapy cohort, four of the 66 patients experienced five serious adverse events, all within five days of the procedure. There were two cases of cholangitis and a single case of bile duct perforation. One patient experienced two adverse events: duodenal perforation and transient desaturation secondary to aspiration. The duodenal perforation was treated surgically while the other four events resolved with no additional intervention reported.
Overall success was reported as 88.6 per cent (95% CI [84, 92]). For diagnosis, the success rate without biopsy (i.e. visualisation of the lesion) was 93 per cent (95% CI [85, 97]), and the success rate of adequate biopsy for histological evaluation was 87 per cent (95% CI [80, 92]). Final diagnosis of malignancy was confirmed and presented for 95 patients, 45 of whom were positive. In this subset, SpyGlass® visual sensitivity was 78 per cent; specificity 82 per cent; and accuracy, positive predictive value (PPV) and negative predictive value (NPV) were 80 per cent. Matched diagnostic data (sensitivity, specificity, accuracy, PPV and NPV) for ERCP impression and for single-operator peroral cholangioscopy (SOC)-guided biopsy histology were: 51, 54, 53, 88, 77 and 49, 98, 75, 100, 72 per cent respectively. However, the technique used to establish the diagnosis (gold standard) was not detailed; therefore, it is not clear how these data were calculated. For stone therapy the success rate was 92 per cent (95% CI [83, 97.5]), 50 patients being treated with electrohydraulic lithotripsy and 16 with laser lithotripsy. The quality of stone visualisation was rated as good or excellent in 85 per cent of cases. Complete stone clearance was achieved in 71 per cent of cases (n=47). The nineteen patients with incomplete stone clearance subsequently underwent a total of 29 additional procedures to clear the stones.

Kalaitzakis et al\(^2\)

In this study, 165 consecutive patients referred to four major centres in the United Kingdom for SOC with SpyGlass® were retrospectively included. All patients had to be eligible for ERCP. The SpyGlass® probe was introduced through a duodenoscope. The authors claim that these patients represent more than 95 per cent of all SpyGlass® procedures performed in the UK in the three years following the availability of this device. Thirty-three patients received electrohydraulic lithotripsy therapy for ‘difficult’ biliary stone clearance that had failed at least two attempts at clearance by conventional means. The remaining 132 participants received diagnosis either for biliary lesions or filling defects. Mean patient age was 62 years. The primary endpoint of procedural success was defined as adequate visualisation of the lesion or stone; collection of biopsy specimens from lesions; and/or fragmentation and removal of stones. The gold standard of diagnosis of a malignant or benign lesion was obtained through positive histopathology of a biopsy taken at a procedure separate to the use of SpyGlass®, progression of the disease consistent with malignancy, or no clinical progression at a minimum of six months follow-up. There were a total of 179 SOC procedures: one patient received three procedures; twelve patients had two procedures; and 152 patients received one procedure each. There were sixteen adverse events in total (9%). These were cholangitis (n=9), abdominal pain (n=3), post-sphincterectomy bleeding (n=1), nausea and vomiting.
(n=1), arterial hypertension (n=1) and hypothermia (n=1). The most severe incidences were for cholangitis: there was one death, and two other cases required inpatient treatment for 7 and 10 days. The remaining adverse events were mild, and required hospitalisation for between one and four days.

Overall, procedural success was 80 per cent. Patients who underwent the procedure under general anaesthesia were associated with greater success than those under conscious sedation (75% versus 87%, \( p=0.039 \)). Of the 130 patients receiving SOC for diagnostic purposes, access of the bile duct was successful in 124 cases. The sensitivity, specificity, accuracy, positive predictive value and negative predictive values for SOC (including tissue sampling) were 66, 98, 87, 93 and 86 per cent, respectively. Due to procedural failure, SOC-guided biopsies were not possible in 20 patients. Biopsies were not required in 46 procedures following visualisation of the lesions. In 74 procedures, a mean of three biopsies (range 1–10) were sampled and found to be adequate for histology in 72 per cent of cases. The authors also note that SOC-directed biopsies correctly identified 43 per cent of malignant tumours as such. Two procedures were undertaken to determine biliary involvement in two known conditions. In both cases, SOC findings were confirmed by subsequent intervention.

Of the 33 patients who underwent SOC for stone clearance, electrohydraulic lithotripsy was not possible in three cases (reasons not provided). Complete stone clearance (confirmed by an occlusion cholangiogram) was achieved in 24 patients (73%), and was maintained up to the six-month follow-up. Complete clearance was achieved in the index procedure in 14 cases (42%); one patient received a repeat SOC and the remaining nine patients required additional ERCP-guided procedures. At the end of the study period, partial clearance was achieved in 6 patients (18%). These patients were referred for further treatment.

**2012 Cost impact**

The price of the SpyGlass® system is approximately $110,000. Other costs include equipment for lithotripsy ($26,400 for the generator, $635 for cables) and approximately $600 for a single-use trans-oral biliary probe (personal communication, HealthPACT Committee). A recent editorial has suggested a cost of $2,500 in addition to the cost of ERCP for SpyGlass® visualisation procedures, and an additional $3,500 for SpyGlass® biopsy.\(^3\)

**2012 Ethical, cultural or religious considerations**

No issues were identified from the retrieved material.
**2012 Other issues**
There are currently a number of centres across Australia and New Zealand that utilise the SpyGlass® technology. These are located at the Royal Brisbane Hospital (QLD), Liverpool Hospital, Royal Prince Alfred Hospital, Westmead Hospital (NSW), Monash Medical Centre, St Vincent’s Hospital (VIC), the Royal Adelaide Hospital (SA), Sir Charles Gairdner Hospital (WA), and at Auckland City Hospital, Christchurch Hospital and Waikato Hospital (NZ) (personal communication, K. Hegarty).

A search of clinical trials registries identified three clinical trials assessing the SpyGlass® device, one of which has been completed (NCT01556555) and two others which are recruiting (NCT01414400, NCT01447238). All are observational case series of between 30–50 participants, so may not add significantly to the current evidence base. No trials were identified in Australia or New Zealand. Two publications have been identified which report the successful use of SpyGlass® via ERCP cannulas (rather than the SpyScope) for visualisation purposes.4,5

There was significant industry support in the two studies. Of the sixteen authors of Chen et al, ten disclosed that they were consultants to Boston Scientific. The study was sponsored by Boston Scientific. In Kalaitzakis et al, four of the eleven authors were members of Boston Scientific advisory boards, and another had received support from the company to attend a medical meeting. No other conflicts were reported.

**2012 Summary of findings**
SpyGlass® provides a functional option for therapeutic and diagnostic interventions for biliary and pancreatic conditions in a select group of patients. Based on the data provided within these two studies, the procedural success of SpyGlass® is 80–88.6 per cent. In terms of procedural complications there was one case of duodenal perforation that required surgery. The most common complication following the procedure was cholangitis, which also accounted for the most severe events. It is unclear whether any of these events may have been due to existing comorbidities, or by any concurrent ERCP procedure. The device appears to be successful in visualising biliary stones, and in facilitating stone clearance. Sensitivity of SpyGlass® appears higher for visualised impression than for SOC-guided biopsy histology. It may be that improved sampling technique or increased number of samples may improve the diagnostic ability of the device. SpyGlass biopsies and subsequent diagnostic results may be limited by the small size (1 mm) of the SpyBite biopsy forcep sample.
2012 HealthPACT assessment
Members agreed that the technology is useful but due to the limited number of patients it should be provided throughout Australia and New Zealand in a rationed manner, ideally limited to a single site per state. Due to the expected limited diffusion of SpyGlass® it is recommended that this technology brief be archived.

2012 Included studies
All evidence included for assessment in this Technology Brief has been assessed according to the revised NHMRC levels of evidence. A document summarising these levels may be accessed via the following link on the HealthPACT web site.

Total number of included studies 2
Total number of level IV intervention evidence studies 2

2012 References
1. Chen, Y.K., Parsi, M.A. et al. (2011). ‘Single-operator cholangioscopy in patients requiring evaluation of bile duct disease or therapy of biliary stones (with videos)’. *Gastrointest Endosc*, 74 (4), 805-814.

2. Kalaitzakis, E., Webster, G.J., Oppong, K.W. (2012). ‘Diagnostic and therapeutic utility of single-operator peroral cholangioscopy for indeterminate biliary lesion and bile duct stones’. *Eur J Gastroenterol Hepatol*, 24, 656-664.

3. Nguyen, N.G. (2012). ‘Getting the most out of SpyGlass cholangiopancreatoscopy: How and When?’ *J Gastroenterol Hepatol*, 27, 1263-1265.

4. Kawakubo, K., Isayama, H. et al (2012). ‘Clinical utility of a single-operator cholangiopancreatoscopy using a SpyGlass probe through an endoscopic retrograde cholangiopancreatography catheter’. *J Gastroenterol Hepatol*, 27, 1371-1376.

5. Nguyen, N.G., Shah, J.N., Binmoeller, KF (2010). ‘Diagnostic cholangioscopy with SpyGlass probe through an endoscopic retrograde cholangiopancreatography cannula’. *Endoscopy*, 42, E288-289.
PRIORITISING SUMMARY 2010

Register ID: S000119

Name of Technology: SpyGlass® Direct Visualization System

Purpose and target group: SpyGlass® provides direct visualisation for diagnostic and therapeutic applications during endoscopic procedures in patients with biliary and pancreatic diseases.

Stage of development (in Australia):
- ☑ Experimental
- © Established but changed indication or modification of technique
- × Investigational
- © Nearly established

Australian Therapeutic Goods Administration approval:
- ☑ Yes
- × No
- × Not applicable

International utilisation:

| Country | Trials Underway or Completed | Limited Use | Widely Diffused |
|---------|-----------------------------|-------------|-----------------|
| Japan   | ✓                           |             |                 |
| USA     |                             | ✓           |                 |
| Spain   | ✓                           |             |                 |

2010 Impact summary:
SpyGlass® offers direct visualisation for diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system, including the hepatic ducts, in patients with biliary and pancreatic diseases.

2010 Background:
Until recently, direct visualisation of the pancreatobiliary system for the diagnosis and treatment of lesions in the biliary and pancreatic ducts has been limited by the technical challenges associated with developing a scope capable of allowing direct
visualisation of these ducts. A number of limitations of traditional cholangioscopy systems have been identified, including (Chathadi and Chen 2009):

- Suboptimal functionality and lack of user-friendliness. For example, there is a need for two trained operators, one physician to handle the ‘mother’ duodenoscope, and another to manoeuvre the ‘daughter’ cholangioscope.
- A limited field of view due to the fact the scope is only capable of two-way steering.
- Damage to the scope was common after just a few uses, due to thin steering cables and a fragile fiberoptic bundle which increase the susceptibility to rupture of the scope’s outer sheath, particularly at the bending section.
- Costly repairs, ranging from 35% to 50% of the original cost of the scope.
- Sharp angulations, which often prevent access into intrahepatic ducts, the cystic duct, and the pancreatic duct.

In the past, conventional endoscopic retrograde cholangiopancreatography (ERCP), an indirect radiographic imaging technique, has been used for guidance; however, this procedure can lead to an inaccurate or inconclusive clinical diagnosis, which in turn necessitates additional testing (Reavis and Melvin 2008). More recently, the SpyGlass direct visualization system (Boston Scientific, Natick, MA, USA) has been developed to provide direct visualisation for diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system. This system is a mother–daughter scope system and consists of a monitor, light source, camera, and cart; a 10 French single-use access and delivery catheter (SpyScope) with a 1.2 mm working channel; a reusable 0.77 mm-diameter fibre optic visualisation probe attached to the camera head; and disposable biopsy forceps (Reavis and Melvin 2008). The visualisation probe is inserted through the single-use access and delivery catheter via the 1.2-mm working channel, which allows for four-directional steering to access and examine all parts of the area under investigation (Paul 2006).

The SpyGlass direct visualization system has a number of advantages over traditional cholangioscopy systems. Firstly, procedures can be performed by a single operator, as the endoscopist can operate the controls of both the duodenoscope and the SpyScope with one hand, therefore eliminating the need for two operators (Judah et al 2008). In addition, this system utilises 4-way tip deflection, which enables improved access of the tertiary ducts.

Intraductal endoscopy using the SpyGlass direct visualization system can be used for a variety of diagnostic and therapeutic indications. Diagnostic indications include the detection of occult stones, evaluation of equivocal fluoroscopy findings, and
characterisation and directed tissue sampling of strictures (including determination of morphologic features and extent of cholangiocarcinoma) (Chathadi and Chen 2009). Therapeutic indications include treatment of biliary stones, palliative therapy of biliary malignancies, and facilitation of selective guide wire access to the gallbladder or intrahepatic ducts (Chathadi and Chen 2009).

2010 Clinical need and burden of disease
Gallstones are a major cause of morbidity in Western countries. In the USA, the estimated incidence of symptomatic cholelithiasis is 2.2 per 1000 individuals, with more than 500,000 cholecystectomies being performed each year (Keus et al 2009). Common bile duct stones (CBDS) may occur in up to 3%-14.7% of all patients for whom cholecystectomy is performed (Shojaiefard et al 2009). Patients presenting with CBDS have symptoms including biliary colic, jaundice, cholangitis, pancreatitis or may be asymptomatic, and CBDS can be caused either by primary bile duct stones that originate in the bile duct or by secondary bile duct stones that have descended from the gallbladder (Shojaiefard et al 2009). In addition, cholecystectomy at a young age leads to common bile duct dilatation and is another acquired risk factor for CBDS. Based on AIHW National Hospital Morbidity Database data, there were 88,529 hospital separations attributed to disorders of the gallbladder, biliary tract and pancreas in 2007-2008 in Australian hospitals (AIHW 2008). In Australia, cholecystectomy is one of the most common hospital procedures, with 47,331 hospital separations for cholecystectomy occurring in 2006–2007; 52% of these were public hospital patients (AIHW 2008).

2010 Diffusion
The SpyGlass Direct Visualization Probe received US Food and Drug Administration (FDA) 510(K) approval on 24 August 2005 (510(K) number: K052194) (FDA 2005). The SpyGlass Direct Visualization Probe was approved by the FDA to be used through the SpyScope Access and Delivery Catheter (510(K) approval date: 16 June 2005; 510(K) number: KO51504) which provides stability for steering the device. SpyScope is inserted into the working channel of a duodenoscope for entry into the duodenum for access to the indicated site. The intended use of the SpyGlass Direct Visualization Probe is to provide direct visualisation for diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts (FDA 2005).

2010 Comparators
Two procedures that enable the optical examination of the ductal systems have been identified as comparators for the SpyGlass direct visualisation system:
• Percutaneous choledochoscopy
• Laparoscopic choledochoscopy

Percutaneous choledochoscopy can be used for a number of the diagnostic and therapeutic interventions that the SpyGlass direct visualisation system is used for, including management of stones with lithotripsy and targeted biopsy (Judah et al 2008). This procedure is generally used if the SpyGlass direct visualisation system has failed or is unavailable, rather than as a first line treatment option, due to its more invasive nature.

Laparoscopic choledochoscopy has been shown to be one of the safest and most effective procedures for exploring the common bile duct, and has been frequently used during laparoscopic cholecystectomy when retained stones have been indicated on the intraoperative cholangiogram (Judah et al 2008).

2010 Safety and effectiveness Issues

Two case series studies were retrieved for inclusion in this summary. One of these studies evaluated SpyGlass for its performance, feasibility and safety in the management of pancreaticobiliary disease (Fishman et al 2009) and the other evaluated the clinical utility and safety of the SpyGlass system for diagnostic and therapeutic endoscopic procedures in bile ducts specifically (Chen and Pleskow 2007).

Fishman et al (2009) conducted a multicentre retrospective analysis of 128 patients with various pancreaticobiliary disorders. Seventy-one patients were male and 57 were female, with a mean age of 57.6 years. Forty-four percent (n=56) of SpyGlass procedures were undertaken for diagnostic purposes, for indications including abnormal serum liver tests (n=15), abnormal imaging studies (n=38) and cholangiocarcinoma staging (n=3), and 56% (n=72) were for therapeutic indications including choledocholithiasis (n=41), pancreaticolithiasis (n=6) and biliary strictures (n=25). The majority of SpyGlass procedures were performed per-orally (n=121) and the remaining procedures were performed percutaneously (n=7).

The second included case series study by Chen and Pleskow (2007) was a multicentre prospective observational clinical study where 35 consecutive patients underwent (per-oral) SpyGlass evaluation. Of these patients, 13 were male and 22 female, with a mean age of 63 years (standard deviation, 16 years). Study inclusion criteria were either the need to answer biliary diagnostic questions unresolved by previous cholangiopancreatography or to perform biliary therapeutic interventions that were failed during previous cholangiopancreatography. Specific indications for SpyGlass examination included indeterminate stricture (n=22), indeterminate filling defect (n=5), stone therapy (n=5), cystic lesion (n=2) or gallbladder stent placement to treat
symptomatic gallstone disease in patient with pretransplant cirrhosis (n=1). Procedural success rate was defined as the proportion of SpyGlass procedures in which the diagnostic/therapeutic objectives of the procedure was achieved. Where evaluation of indeterminate strictures or filling defects, with the intent of ruling out malignancy, was the objective success was judged by the ability to visualise the stricture and obtain adequate biopsy tissue from the target lesion. The success of stone therapy was measured by the visualisation and clearance of the stones.

**Safety**

Fishman et al (2009) reported that there was no morbidity or mortality associated with the use of SpyGlass SpyScope for the diagnosis of malignant/benign biliary stricture or for the treatment of stone disease.

Chen and Pleskow (2007) reported procedure-related complications in only 6% (2/35) of patients. One patient experienced ascending cholangitis, marked by jaundice without fever, white blood cell elevation and positive blood cultures, which developed 3 weeks after SpyGlass examination, during which the patient was diagnosed with intraductal papillary mucinous neoplasm. A biliary stent was not placed at the time of the original procedure which may have allowed ductal occlusion by viscous mucin, contributing to the occurrence of cholangitis. Repeat cholangiopancreatography revealed purulent material coming from the biliary orifice and treatment consisted of placement of a plastic stent and intravenous antibiotics. This patient was hospitalised for 4 days and recovered uneventfully. The second complication (ascending cholangitis and right lobe intrahepatic abscess) occurred in another patient with pre-existing cholangitis 11 days after the SpyGlass examination. This patient was treated with CT-guided percutaneous drainage of the infected fluid, was hospitalised for 7 days and recovered without further sequelae.

**Effectiveness**

In the study by Fishman et al (2009), 29 patients underwent SpyGlass procedures to determine the behaviour of their bile duct strictures (for diagnostic purposes). Of these patients, 20 had their diagnosis modified postoperatively as a result of SpyGlass findings. Of the 23 patients with preoperative diagnoses of malignant strictures, only 10 were confirmed to be malignant by SpyGlass, and of the 17 patients with unknown biliary stricture diagnoses preoperatively, 9 were found to have malignant strictures and 8 were found to have benign strictures, according to SpyGlass.

Fishman et al (2009) also reported the use of SpyGlass to facilitate the treatment of biliary stone disease (for therapeutic purposes) by electrohydraulic lithotripsy (EHL) or holmium laser fragmentation of the stone, in 41 patients. Lithotripsy was
successful in 37 out of 41 patients. The manoeuvrability of the SpyGlass device was superior if the guide wire was removed from the working channel. Intrahepatic peroral advancement occurred without difficulty in 80% (8/10) of cases, percutaneous advancement occurred in 100% (6/6) of cases and holmium laser usage was achievable in 100% (3/3) of cases. Poor targeting of the lesion with EHL occurred in 10% (4/41) of patients and EHL was unable to be advanced in 7% (3/41) of patients. Visualisation was considered to be good in 31 cases, fair in six cases and poor in four cases; however, the criteria on which visualisation was measured was not reported.

Overall, SpyGlass modified the preoperative diagnosis of 66% of patients, prevented unnecessary surgery in two patients with cholangiocarcinoma, changed the diagnosis of malignant to benign disease in 45% of patients with biliary stricture and provided successful therapy in 87% of patients with stone disease.

Chen and Pleskow (2007) carried out the following procedures at the time of SpyGlass examination: biopsy (n=20), stent placement (n=13), balloon dilation (n=9), stone removal (n=9), sphincterotomy (n=8), brushing cytology (n=7), EHL (n=5) or sphincterotomy extension (n=1). No additional procedures were carried out in 4 patients. The diagnostic and therapeutic objectives of the SpyGlass procedure were achieved in 32 patients; therefore, the procedural success rate of SpyGlass was 91% (95% confidence interval, 77-98%). In the three patients where objectives were not met, access to the area of interest was precluded by small intrahepatic duct size (n=2) and suboptimal visualisation of a short presphincteric stricture was apparent (n=1). Technical difficulties were encountered in 12.5% (4/32) of successful SpyGlass procedures, and included trouble advancing the SpyBite Biopsy Forceps (n=1), clearing stone fragments during EHL (n=1), orienting the forceps within the left hepatic duct (n=1), and maintaining the desired position of the SpyScope for biopsies (n=1).

The preliminary sensitivity and specificity of SpyGlass visual diagnosis were 100% (7/7) and 77% (10/13), respectively. Three false-positive visual findings occurred in patients with primary sclerosing cholangitis (PSC). The preliminary sensitivity and specificity of SpyGlass biopsy diagnosis were 71% (5/7) and 100% (13/13), respectively. One false-negative result was obtained due to difficulties maintaining the desired SpyScope position for biopsy of the presphincteric target lesion in the distal common bile duct. A second false-negative occurred in a patient with confirmed unresectable pancreatic adenocarcinoma. True-negative biopsy results were obtained in the three patients with PSC; hence the concordance between SpyGlass visual examination and SpyGlass-directed biopsy was 75% (15/20).
SpyGlass-directed EHL was successful in all of the five patients who underwent stone therapy. Complete stone clearance was achieved without the need for further intervention in two patients, and following repeat SpyGlass-directed EHL (n=2) or cholangiopancreatography (n=1). Four additional patients underwent SpyGlass-directed stone removal without EHL. Cystic dilation was successfully evaluated by SpyGlass examination in two patients and SpyGlass-directed stent placement was performed in a patient with pretransplant cirrhosis and symptomatic cholelithiasis resulting in relief from gallbladder disease symptoms.

2010 Cost impact
There were no cost analysis studies identified from the retrieved material. Contact with the manufacturer of the SpyGlass system was made in regards to the current cost of the device (awaiting response).

The SpyGlass Direct Visualization System is designed to accelerate diagnostic accuracy during cholangiopancreatography. The SpyGlass System is a single-operator system developed to overcome the hurdles of traditional cholangioscopy systems and reduce the need for exploratory surgery. The proposed benefits of SpyGlass over conventional visualisation may translate into cost reductions as a result of reduced time in the operating theatre, the need for only one trained endoscopist to use the device, and the elimination of unnecessary exploratory surgeries. Further research evaluating the effects of SpyGlass on cost are required to support these assumptions.

The current equipment cost (in an Australian clinical setting) of Spyglass is likely to range from $120,000 to $125,000. Similarly the cost of procedural consumables is likely to be in the range of $3,000 to $3,500.

2010 Ethical, cultural or religious considerations
There were no issues identified from the retrieved literature.

2010 Other issues
Both authors of the included case series study published in 2007 (Chen and Pleskow) were reported to be consultants to the Boston Scientific Corporation (the manufacturer of the SpyGlass system) and grant support was provided by Microvasive Endoscopy, Boston Scientific Corporation.

In addition to this, it is important to note that the SpyGlass direct Visualization system is likely to undergo design refinements to improve its capabilities in the near future, with particular emphasis on improvements in image quality (Chathadi and Chen 2009). Currently, SpyGlass produces fiberoptic images which are inferior in
quality to digital images (acquired in the gastrointestinal tract with standard video endoscopes) (Chathadi and Chen 2009). At this point in time fiberoptic images are acceptable for recognising and delivering therapy to target sites within pancreatic/biliary ducts; however, in order to differentiate between benign and malignant lesions higher-quality images are required (Chathadi and Chen 2009).

2010 Summary of findings
SpyGlass appears to be clinically feasible and safe. In general, the SpyGlass device was not associated with significant complications. As well as this, the procedural success rate of SpyGlass was reported as 91% in one of the included case series studies. Narrow ducts impeded the advancement of the SpyGlass device in a small proportion of patients and suboptimal visualisation occurred at times; these technical difficulties resulted in failed SpyGlass interventions in some patients. The most recently published included study noted that improvements in the optical quality, catheter size and manoeuvrability of SpyGlass were anticipated.

2010 HealthPACT assessment
Based on the unlikeliness of additional high-quality comparative studies reporting the use of SpyGlass being published in the near future, it is recommended that no further assessment of this technology be undertaken at this time.

☐ Horizon Scanning Report  ☐ Full Health Technology Assessment
☐ Monitor  ☑ Archive

2010 HealthPACT action

2010 Number of studies included
Total number of studies 2
Level IV evidence 2

2010 References
Australian Institute of Health and Welfare (AIHW). Australian hospital statistics 2006–07. Health services series no. 31. Cat. no. HSE 55. Canberra: AIHW 2008. http://www.aihw.gov.au/publications/hse/ahs06-07/ahs06-07.pdf [Accessed July 2009]
Chan YK, Pleskow DK. SpyGlass single-operator peroral cholangiopancreatoscopy system for the diagnosis and therapy of bile-duct disorders: a clinical feasibility study. Gastrointestinal Endoscopy 2007; 65(6): 832-841.
Chathadi KV, Chen YK. New kid on the block: development of a partially disposable system for cholangioscopy. Gastrointestinal Endoscopy Clinics of North America 2009; 19(4): 545-555.

Fishman DS, Tarnasky PR, Patel SN, Raijman I. Management of pancreaticobiliary disease using a new intra-ductal endoscope: the Texas experience. World Journal of Gastroenterology 2009; 15(11):1353-1358.

Judah JR, Draganov PV. Intraductal biliary and pancreatic endoscopy: An expanding scope of possibility. World Journal of Gastroenterology 2008; 14(20): 3129-3136.

Keus F, Gooszen HG, Van Laarhoven CJHM. Systematic review: open, small-incision or laparoscopic cholecystectomy for symptomatic cholecystolithiasis. Aliment Pharmacol Ther 2009; 29(4):359-378.

Paul D. Cholangioscopy procedure with SpyGlass™ system description. Last Updated 1 November 2006. http://www.bostonscientific.com [Accessed July 2010].

Reavis KM, Melvin WS. Advanced endoscopic technologies. Surgical Endoscopy 2008; 22: 1533-1546.

Shojaiefard A, Esmaeilzadeh M, Ghafoori A, Mehrabi A. Various techniques for the surgical treatment of common bile duct stones: a meta review. Gastroenterol Res Pract Epub 2009 Aug 6.

US Food and Drug Administration (FDA). Section 11 510(K) Summary: SpyGlass Direct Visualization Probe. Last Updated 24 August 2005. http://www.accessdata.fda.gov/cdrh_docs/pdf5/K052194.pdf [Accessed July 2010].

2010 Sources of further information

Antillon MR, Tiwari P, Bartalos CR, Marshall JB. Taking SpyGlass outside the GI tract lumen in conjunction with EUS to assist in the diagnosis of a pancreatic cystic lesion. Gastrointestinal Endoscopy 2009; 69(3 Part 1): 591-593.

Barkay O, Bucksot L, Sherman S. Endoscopic transpapillary gallbladder drainage with the SpyGlass cholangiopancreatoscopy system. Gastrointestinal Endoscopy 2009; 70(5): 1039-1040.

Baron TH, Saleem A. Intraductal electrohydraulic lithotripsy by using SpyGlass cholangioscopy through a colonoscope in a patient with Roux-en-Y hepaticojejunostomy. Gastrointestinal Endoscopy 2010; 71(3): 650-651.

Bhat YM, Kochman ML. Novel management of complex hilar biliary strictures with the SpyGlass Direct Visualization System. Gastrointestinal Endoscopy 2009; 69(6): 1182-1184.

Kantsevoy SV, Frolova EA, Thuluvath PJ. Successful removal of the proximally migrated pancreatic winged stent using the SpyGlass visualization system. Gastrointestinal Endoscopy 2010; March 12 [Epub ahead of print].

Mou S, Waxman I, Chennat J. Peroral cholangioscopy in Roux-en-Y hepaticojejunostomy anatomy by using the SpyGlass Direct Visualization System. Gastrointestinal endoscopy 2010; March 10 [Epub ahead of print].

Ransibrahmanakul K, Hasyagar C, Prindiville T. Removal of bile duct foreign body by using SpyGlass and SpyBite. Clinical Gastroenterology and Hepatology 2010; 8(1): e9.
Wright H, Sharma S, Gurakar A, Sebastian A, Kohli V, Jabbour N. Management of biliary stricture guided by the SpyGlass Direct Visualization System in a liver transplant recipient: an innovative approach. Gastrointestinal Endoscopy 2008; 67(7): 1201-1203.

Search criteria to be used
SpyGlass OR SpyGlass Direct Visualization

Health PACT decision
☐ Horizon Scanning Report ☐ Full Health Technology Assessment
☐ Monitor ☐ Archive
☐ Refer ☐ Decision pending

Priority rating
☐ High ☐ Medium ☐ Low