

Visibility enhancement of common bile duct for laparoscopic cholecystectomy by vivid fiber-optic indication: a porcine experiment trial

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Abstract: Bile duct injury (BDI) is the most serious iatrogenic complication during laparoscopic cholecystectomy (LC) and occurs easily in inexperienced surgeons since the position of common bile duct (CBD) and its related ductal junctions are hard to precisely identify in the hepatic anatomy during surgery. BDI can be devastating, leading to chronic morbidity, high mortality, and prolonged hospitalization. In addition, it is the most frequent injury resulting in litigation and the most likely injury associated with a successful medical malpractice claim against surgeons. This study introduces a novel method for conveniently and rapidly indicating the anatomical location of CBD during LC by the direct fiber-optic illumination of 532-nm diode-pumped solid state laser through a microstructured plastic optical fiber to avoid the wrong identification of CBD and the injury from mistakenly cutting the CBD that can lead to permanent and even life threatening consequences. Six porcine were used for preliminary intra-CBD illumination experiments via laparotomy and direct duodenal incision to insert the invented CBD illumination laser catheter with nonharmful but satisfactory visual optical density.

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1. Introduction

During the past decade, laparoscopic cholecystectomy (LC) has become the procedure of choice for the treatment of symptomatic cholelithiasis [1,2]. Laparoscopy has several benefits to the patient, including less perioperative pain, improved cosmesis, decreased length of hospitalization, and earlier return to normal activities. Unfortunately, the benefits of laparoscopy do not come without the potential for great harm. Numerous retrospective reports have demonstrated that the incidence of iatrogenic common bile duct (CBD) injury during LC is relatively higher when compared with open cholecystectomy, at least 0.1%–0.2% versus 0.4%–0.7% [2–14]. Despite the broad experience of surgeons with LC after the learning curve, rates of CBD injury have not declined [7–9,15,16]. Though serious complications of CBD injury during cholecystectomy occurs with relative infrequency [17–19], they can be catastrophe, leading to patient morbidity and mortality, impaired quality of life and functional status, and premature death [20–22]. Among Medicare beneficiaries in 1990s, after CBD injury there was approximately 3-fold increase in risk of short-term death compared with uninjured patients [10]. Serious injuries often require at least 1 surgical repair, and these repairs have variable long-term outcomes, e.g. CBD injury may even cause end-stage liver disease and necessitate liver transplantation [23,24].

It is thought that the lack of 3-dimensional vision and problems with perception inherent in laparoscopic surgery result in spatial disorientation and the misidentification of biliary anatomy, and these issues can lead to more complications. When the cystic duct/gallbladder junction is inadequately exposed, or if excess traction is being applied to the cystic duct/CBD junction, the CBD can be mistaken for the cystic duct. If not recognized, this can cause clipping and resection of part of the CBD, distal common hepatic duct, and associated right hepatic arterial injury [25–27]. Even by experienced surgeons, misperception may occur when the CBD adhered closely to the gallbladder after the chronic and fibrotic process with a significant Calot's inflammation [28–30]. The above phenomena are like a latent land mine of LC to injure both the patient and the surgeon. Even open cholecystectomy cannot avoid CBD

injury due to the uncertain anatomy. It has been indicated that about 34%–49% surgeons are expected to cause such an injury during their career [25,29]. Operation error is most likely the cause to result in a claim and the only cause associated with a successful claim. Previous reports have shown that the CBD injury by far ranks the third most common surgical complication leading to medical malpractice claims against surgeons and the most likely injury associated with a successful claim. The average payout for a successful claim was 168,337 USD in England and four times higher of the magnitude of payout in US [16,18,31,32].

In avoiding bile duct injury, intraoperative cholangiogram (IOC) during LC, a radiologic contrast-based examination of the bile duct, is commonly used as a system-level approach to reduce the incidence [33–38]. By using IOC as a road map of the biliary system, the surgeon can theoretically confirm the adequacy of the operative dissection, clarify assumptions made about the anatomy, and identify the location of the CBD before division of any biliary structures that could potentially help avoid major injury. However, when the cystic duct partially or completely hidden from the view by the infundibulum (hidden cystic duct), ultra-shorten and barely or completely disappeared cystic duct had been encountered, in such situations IOC examination itself could be the cause of CBD injury. Suzuki et al. had reported 11.1% of 244 consecutive LC cases having no cystic artery in Calot's triangle [39]. In our data, absent cystic artery was about 20% and 50% in overall and Calot fibrosis groups, respectively, which rendered the critical view of safety checking impossible [6,40–42]. Transcystic cholangiography and intraoperative fluorescence cholangiography are currently implemented in LC [43–46]; however, our findings indicates that a transcystic or transpapilla CBD illuminating device can be a much better alternative approach to prevent the tragedy of iatrogenic CBD injury.

2. Materials and methods

The illumination unit consists of a 50-mW, 532-nm diode-pumped solid state laser (TWC Opto, Taiwan) and a 1-m length plastic optical fiber (TWC Opto, Taiwan). The diameter of core and cladding is 0.8 and 1.0 mm, respectively. The cladding is made of biocompatible material. The front-end 10-cm length of illuminating optical fiber was featured of periodic microstructures on the cladding portion by picosecond laser micromachining (1064 nm, 22 mJ/pulse, mode-locked Nd:YAG laser) and adhered inside a conventional endoscopic nasobiliary drainage (ENBD, Wilson-Cook Medical) tube. The end face of optical fiber was sintered to weaken the light loss. The laser fabricated microstructures on the cladding portion of optical fiber were used to achieve the high uniformity of light emission out from the fiber core through the wall of hollow cannula, so that the CBD can be directly illuminated and rapidly identified by the visual judgment of surgeons during surgery. The length, width, depth, and pitch of fabricated light emission window is 20, 10, 20, and 20 μm , respectively. Figure 1(a) shows the corresponding schematic diagram of the developed choledochoilluminating drainage device. Microscopic image of the laser fabricated periodic microstructures is exhibited in Fig. 1(b). The optical configuration for choledochoilluminating drainage device is exhibited in Fig. 1(c). The laser was coupled into the fiber core through the light collimator, which was a combination component of a 20 \times microscope objective (Thorlabs) and a fiber clamp (Thorlabs). The measured optical intensity of the developed CBD illumination laser catheter is 10.8 W/cm². The picture of current illumination unit is given in Fig. 1(d). Six porcine experiments were performed for this preliminary study under direct insertion through the papilla of Vater via laparotomy and duodenal incision.

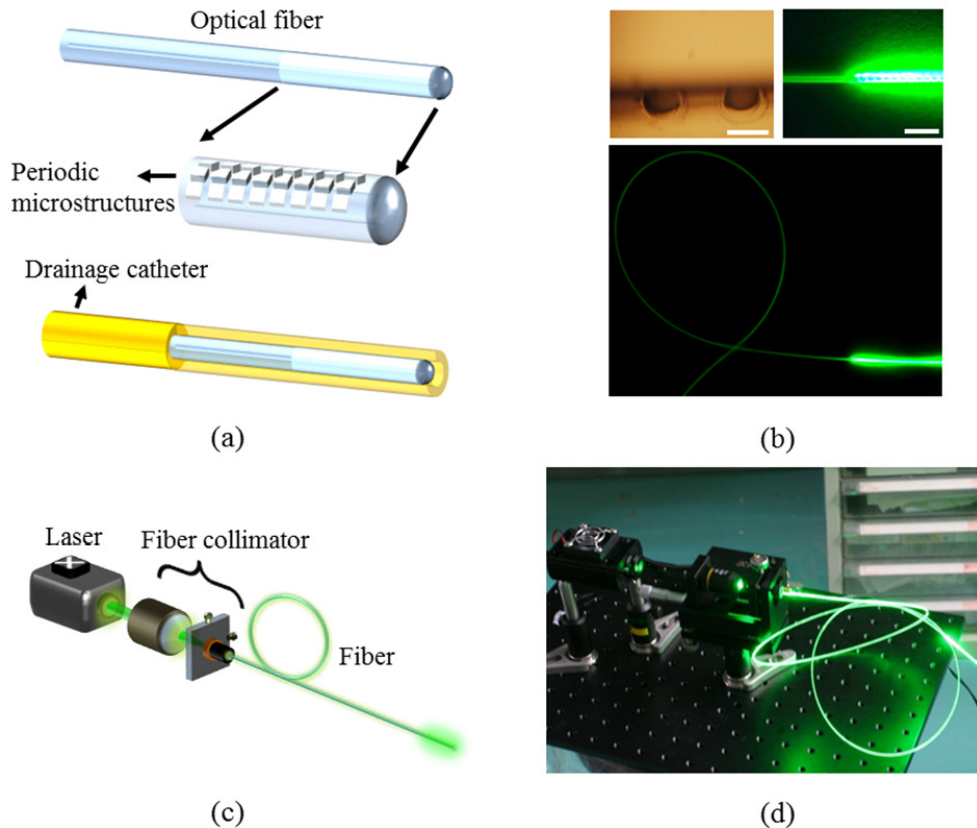


Fig. 1. (a) The schematic diagram of a common plastic optical fiber fabricated into a choledochoilluminating drainage device. (b) Upper left: microscopic image of the laser fabricated periodic microstructures. Scale bar: 20 μm . Upper right: picture of light illumination from laser-fabricated microstructure windows. Scale bar: 50 mm. Lower: picture of green laser light emission from the front-end 10-cm length of optical fiber which was featured of periodic microstructures on the cladding portion by picosecond laser micromachining. (c) The optical configuration of illumination unit. Fiber collimator is the combination of a 20 \times microscope objective and a fiber clamp. (d) The picture of current illumination unit.

3. Results and discussion

In these six porcine experimental trials, the CBDs were successfully illuminated and thus can be clearly visualized and differentiated from surrounding anatomy through the developed choledochoilluminating device. The time required for the experimental trial ranged from 15 to 50 min with a median time of 30 min. No complications occurred in our cases. Initially, a plastic optical fiber without picosecond laser-fabricated light emission windows and not encapsulated inside an ENBD tube was introduced into the duodenal papilla and entering the CBD, as shown in Fig. 2(a). Cautious introduction of optical fiber is necessary. The movement of fiber must be slow and soft, otherwise the tissue and duct wall will be injured by the fiber. The illumination mechanism is achieved by the optical fiber microstructures fabricated on the plastic optical fiber where the guided laser light can scatter from the fiber core and transmit through the ductal and surrounding tissue of CBD making the whole segment of buried CBD visible to human eyes. The length, width, depth, and pitch of fabricated light emission windows on the optical fiber have been optimized to achieve the maximum light flux can scatter out from the fiber core but not breaking the optical fiber as it is inserted into the ENBD catheter. The measured illumination optical intensity was about 6.9 W/cm^2 . It's seen that the CBD was indicated and visualized by the assistance of green optical

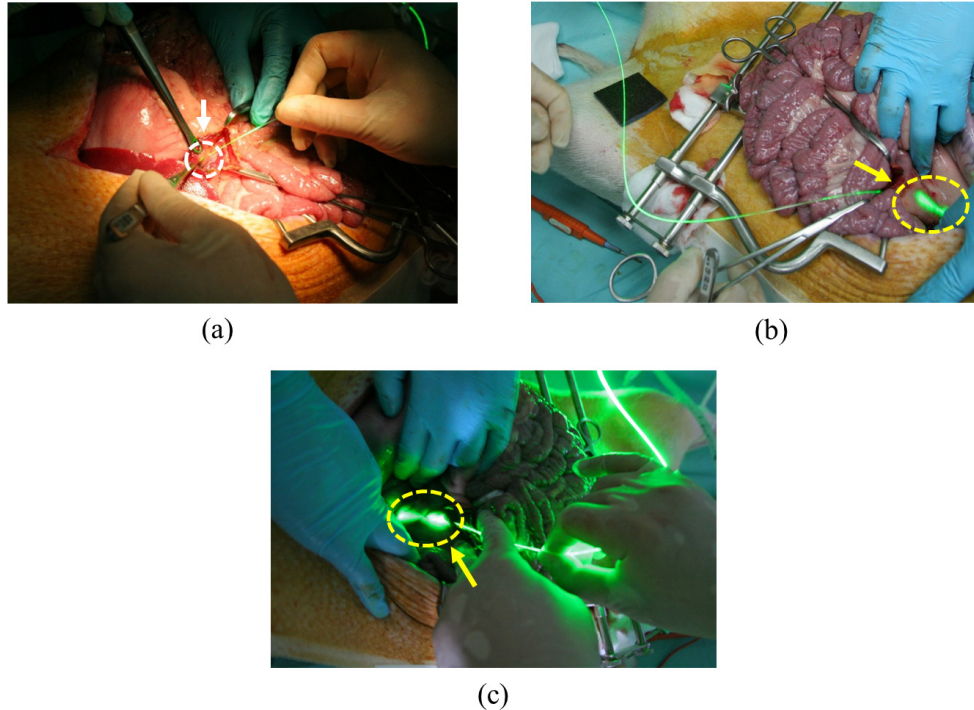


Fig. 2. (a) A common plastic optical fiber without laser-fabricated microstructures and not encapsulated inside an ENBD tube was inserted into the papilla. The measured optical power was 6.9 W/cm^2 . (b) A plastic optical fiber with laser-fabricated microstructure of light-emission windows but not encapsulated inside an ENBD catheter was passing through the duodenal papilla and entering the CBD. The green emission from microstructure windows of optical fiber clearly illuminates the entire section of CBD under room light. The measured optical power was 42.1 W/cm^2 . (c) The same optical fiber and optical power in (b) brightened the CBD in the dark.

fiber (as the indication by white arrow). Here, the introduction of 532-nm laser illumination was adopted instead of infrared (IR) lasers since human eyes are much more sensitive to green light and the sensitivity peak is at 555 nm [47]. Thus, surgeons can instantly identify the anatomical position of CBD during surgery to avoid the mistakenly cutting. Infrared light has deeper penetration depth, but it is almost invisible to human eyes. Surgeons must use IR viewer, IR camera, or IR photodetector to observe it. In this study, we hope the surgeons can directly see the indication light without the help of any excess instruments. Like the pilot, the green light guides surgeons not to do the misjudged cutting of CBD. For the safety issue of introduction, the optical fiber incorporated with ENBD tube was considered. The ENBD tube also enables the possibility of combining multiple functions inside a single tube due to three separate channels of its drainage catheter, e.g. biliary drainage is considered. However, with the cooperation of ENBD tube, the light illumination from optical fiber should be enhanced because the illuminating light has to pass through the wall of hollow cannula. The increased optical path will weaken the transmitted optical intensity and make fiber itself dim in visibility. Hence, the optical fiber with laser-fabricated microstructure windows on the cladding portion was used to illuminate the CBD. Figures 2(b) and 2(c) exhibit the corresponding pictures of CBD illumination. The CBD can be easily visualized and indicated no matter under room light or in the dark condition by the green laser light from fiber (as the indication by yellow arrow). The measured optical intensity was 42.1 W/cm^2 .

Figures 3(a)–3(d) show the images of introducing a plastic optical fiber with laser-fabricated microstructure of light-emission windows but not encapsulated inside an ENBD catheter through the papilla into the CBD with the laser power of 3, 13.7, 27.5, and

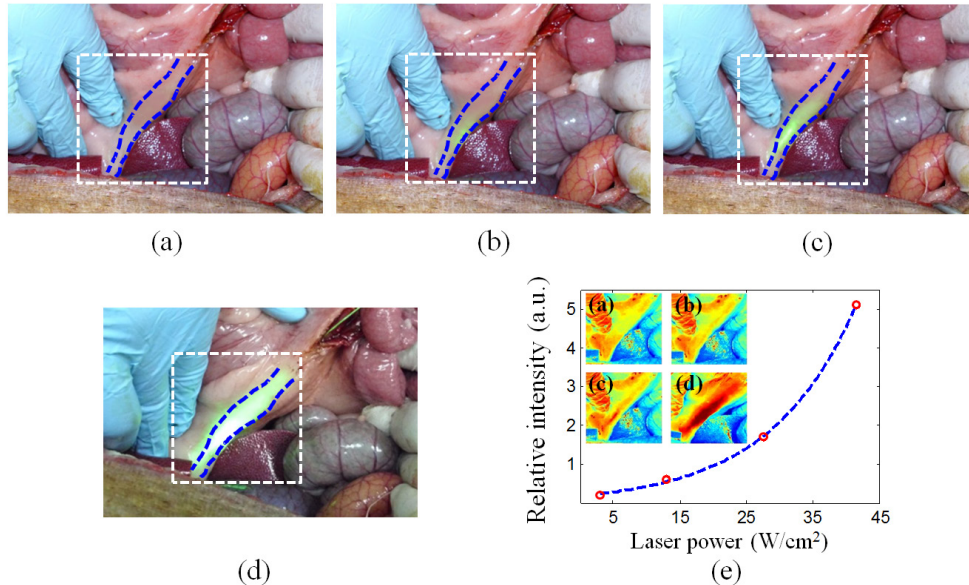


Fig. 3. Relative intensity analysis by the image processing. The plastic optical fiber with laser-fabricated microstructure of light-emission windows but not encapsulated inside an ENBD catheter was passing through the duodenal papilla and entering the CBD. The laser power was (a) 3, (b) 13.7, (c) 27.5, and (d) 41.1 W/cm², respectively. (e) shows the quantitative comparison results of the relative intensity of visible green light with respect to different introduced laser power. Insets show the transformed light intensity distribution images as the white dot-line square regions marked in (a)(d).

41.1 W/cm², respectively. The regional visible green light intensity of CBD images is quantitatively analyzed by individually normalizing the light intensity of CBD region (blue dot-line region) of Figs. 3(b), 3(c), and 3(d) to that of Fig. 3(a). The transformed light intensity distribution images are exhibited in the insets of Fig. 3(e). The resultant relative intensity displays an exponential increase with respect to the increment of laser power as shown in Fig. 3(e). Since the introduced laser power of 41.1 W/cm² can light the whole CBD segment (Fig. 3(d)), we choose this laser power for the subsequent light scattering illumination of CBD by using the fiber-optic ENBD catheter.

Figure 4(a) shows the image of introducing a fiber-encapsulated ENBD catheter through the papilla into the CBD. The image of direct CBD illumination by using the compact choledochoilluminating catheter is exhibited in Fig. 4(b). It's obvious that the CBD was easily identified and indicated. The measured optical intensity was 10.8 W/cm². To test the optical damage of CBD tissue induced by long-time illumination, the choledochoilluminating device was placed inside CBD up to 4 hours. After sustained 4-hour 10.8 W/cm² irradiance, the tissue was taken out for pathologic section examination. Examination results show no abnormal influence from 4-hour illumination via the introduced green laser light as compared with nonirradiated tissue. Moreover, these swine have survived until now.

The illumination of CBD is not absolutely necessary. However, during LC, when difficult identification of the CBD is encountered or dangerously CBD is recognized by the surgeon before injuring the CBD, an intraoperative insertion of this illuminating unit into the CBD can be performed either by endoscopic retrograde insertion through the papilla of Vater or direct insertion through inner opening of the cystic duct by opening the infundibulum of gallbladder. The advantage of current approach is much safer and more convenient for the identification of CBD during surgery than the fluorescence cholangiography and conventional intraoperative cholangiography without the risk of injecting potential toxic photon sensitive reagents and the radiation exposure of tissue. In addition, the incident laser power of the device is adjustable to satisfy the visibility to surgeon eyes to rapidly locate the precise position of buried CBD.



Fig. 4. (a) A compact cholechoilluminating catheter was passing through the papilla (as the indication of white arrow) entering the CBD. (b) An optical fiber with laser-fabricated microstructure of light-emission windows encapsulated inside an ENBD catheter was placed in the CBD. The green illumination clearly indicates the CBD under room light (as the indication of yellow arrow). The measured optical power was 10.8 W/cm^2 .

4. Conclusion

The CBD was successfully identified using the cholechoilluminating device during laparotomy. To the best of our knowledge, the CBD illumination laser catheter is the first report to be applied on LC in an effort to prevent CBD injury. The controlled optical intensity is sufficiently bright to identify the CBD easily by human eyes. This technique is a simple, effective, and safe adjunct method to strengthen the correct identification of CBD during LC. Therefore, it can play a useful role in lowering and preventing the occurrence of iatrogenic CBD injury, especially for clarifying uncertain anatomy in selected cases.

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