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Clinical application of a novel high-selectivity steerable-tip catheter for endoscopic retrograde cholangiopancreatography in patients with altered surgical anatomy

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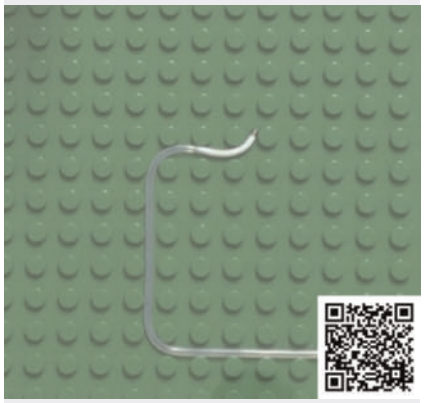
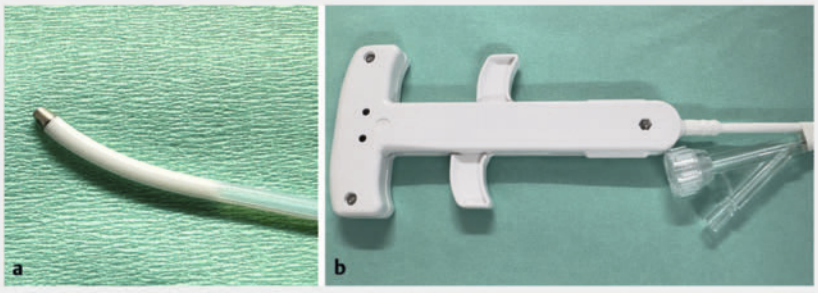


Video 1 This video demonstrates tip-steerable catheters' trackability in bile duct-seeking during endoscopic retrograde cholangiopancreatography procedures performed with a balloon enteroscope alongside a comparative experiment on the bending performance.



▶ **Fig. 1** Image of the novel tip-steerable catheter. This catheter measures 2200 mm in length with an outer diameter of 2.1 mm. The tip can bend bidirectionally up to 90°, controlled by pulling two wires via a controller attached at the base. The insertion port is designed for 0.035-inch guidewires and is the injection site for contrast agents.

Endoscopic retrograde cholangiopancreatography (ERCP) for the selective treatment of the biliary branch is frequently challenging in patients with surgically altered intestinal tracts [1–3]. We have developed and commercialized a novel steerable catheter for ERCP (KC226; Zeon Medical, Tokyo, Japan) capable of balanced bidirectional tip-bending at steep angles by using a seamless tube with a distal part made of an artificial blood vessel material and a wire-driven antagonistic mechanism [4] (▶ **Fig. 1**). This study evaluates the efficacy and safety of this catheter inserted into balloon enteroscopes for accessing the biliary tract in patients with surgically altered anatomy.

We compared its endoscopic bending performance with a conventional steerable-tip catheter (PR-233Q; Olympus Medical Systems, Tokyo, Japan) through desktop experiments using a balloon enteroscope. Results demonstrated that the novel catheter could achieve bidirectional tip bend angles of ± 90° within a 10-mm radius, significantly enhancing maneuverability (▶ **Video 1**).

Clinically, we evaluated four consecutive patients (mean age 74 years) who had undergone Roux-en-Y cholangiojejunostomy, presenting symptoms such as acute cholangitis and recurrent abdominal pain. With the conventional steerable-tip catheter, guidewire (GW) insertions in all cases were limited to the bile duct of a single lobe, and it was impossible to perform cholangiography across bilateral lobes. However, switching to the newly developed catheter in all cases could complete bilateral bile duct cannulation, GW insertions (▶ **Video 1**, ▶ **Fig. 2**), and cholangiography successfully and swiftly under single- or double-balloon enteroscopy in 2.8 minutes on average. No catheter-related complications were observed.

The catheter-tip steerability proved particularly beneficial in navigating the complex biliary anatomy post-cholangiojejunostomy, effectively overcoming the typical challenges posed by altered anastomotic angles between the bile duct and jejunum. Thus, this novel catheter may be valuable for challenging bile duct access in patients with surgically reconstructed intestinal tracts.

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Conflict of Interest

The authors declare that they have no conflict of interest.

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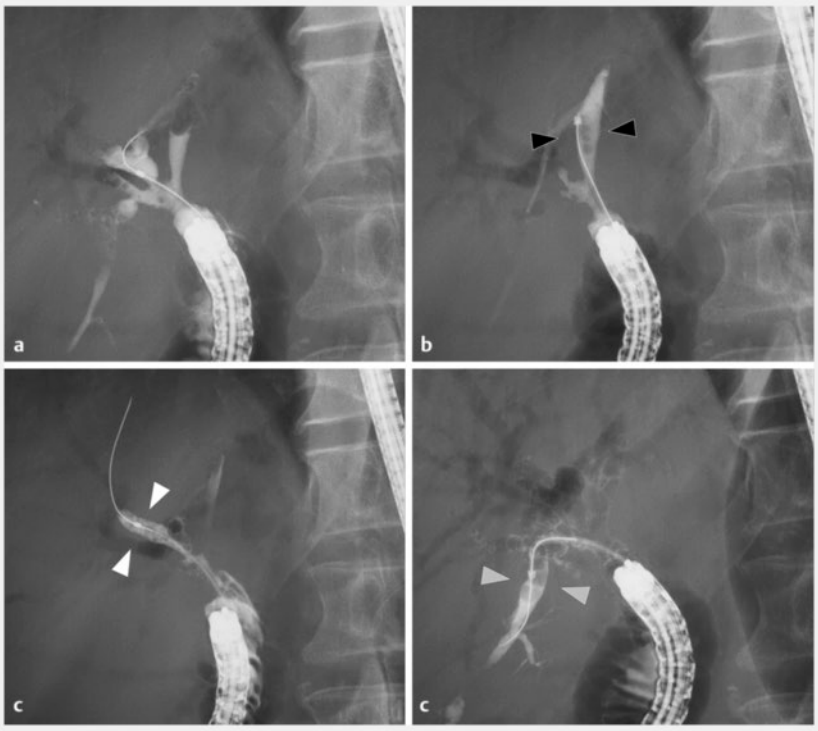

▶ **Fig. 2** Cholangiography image from a clinical case. A 70-year-old man with surgically altered intestinal tracts due to pancreaticoduodenectomy experienced repeated episodes of acute cholangitis. **a** Cholangiography revealed multiple stenoses in the right bile duct, attributed to recurrent inflammation. **b** The tip-steerable catheter efficiently completed guidewire insertion into the left bile duct. **c** Insertion into the anterior branches. **d** Insertion into the right bile duct.

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