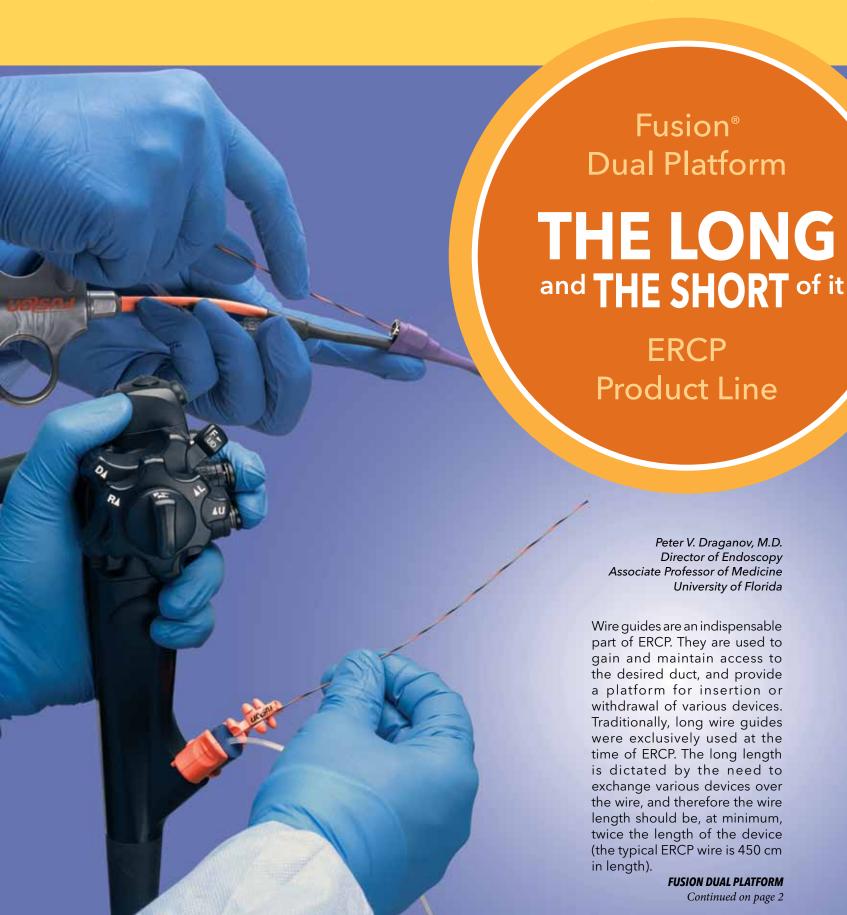


The Channel

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If you would like to submit material for The Channel, please email us at thechannel@cookmedical.com.

We welcome your comments and suggestions.

Performance of Long Wire

FUSION

Efficiency of Short Wire

A number of problems are attributed to the use of long wires:

Longer exchange time, which can lead to increase of procedure and fluoroscopy time, and sedation requirements

Need for excellent communication between physician and assistant

Contamination from the long wire touching the floor

Success of the ERCP is dependent on the availability of a highly trained assistant

To overcome the disadvantages of the long-wire system, three short-wire systems have been introduced. They share three essential elements: 1) shorter wire length ranging from 205 to 270 cm, 2) the ability to lock the wire in position during the device exchange and 3) the ability of the endoscopist to independently manage and manipulate the wire. The short-wire systems have some perceived advantages.

Reduced device exchange, stent insertion, total procedure, and fluoroscopy times

Maintaining stable ductile access

Physician control of the wire may facilitate cannulation and reduce ampullary trauma, and decrease rate of post-ERCP pancreatitis

Unfortunately, the use of a short-wire system may impose insurmountable challenges in some situations:

More complex cases where multiple exchanges are needed

Advanced techniques are required, such as double wiring for hilar stricture

When the ERCP devices are not used in typical order

When non-ERCP devices are used at the time of ERCP, such as over the wire upper endoscopy dilation balloons



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Fusion was created with the intent to overcome the shortcomings associated with the use of a short wire. Fusion is the only dual-platform ERCP product line that allows use of ERCP devices with a short wire or in an over-the-wire, longwire manner.

ERCP remains the most complex endoscopic procedure and provides a particular challenge even for very skillful physicians. Therefore, a device system with a full range of capability combining the benefits of short-wire and long-wire platforms will be of great value.

I recently did a case at the University of Florida of a hilar stricture. Once the endoscope was positioned in the second portion of the duodenum, the papilla was found located deep on the side wall of a large duodenal diverticulum. That created a challenge with obtaining cannulation with standard devices. I selected to use the Fusion Omni sphincterotome. That gave me two distinct advantages: the ability to rotate the sphincterotome to accommodate the altered anatomy, and to take control over wire manipulation for precise cannulation.

After I achieved successful bile duct cannulation, the hilar structure was visualized; then deep-wire access was obtained to the right biliary system. I was able to access the right biliary system and then immediately inserted a second wire through the same sphincterotome and gained access to the opposite left side of the liver. To complete the procedure, I sequentially deployed two plastic stents, one in the right and the other in the left biliary branches.

I noted that Fusion carries some distinct advantages, including reduced device exchange, stent insertion and fluoroscopy times. It also provides for physician to control of the wire, which may lead to improved cannulation rate, decreased trauma to the ampulla and decreased risk of post-ERCP pancreatitis. In addition, physician wire control makes the success of ERCP less dependent on the availability of a highly trained assistant.

Finally, I concluded that Fusion provides trainees the opportunity to experience both the use of short wires and long wires as appropriate and ultimately prepare them for both options when moving into practice of their own.

Fusion Dual Platform: A Prospective, Randomized, Controlled Trial

A recently completed randomized control study, performed at the University of Florida, formally evaluated the performance characteristics of Cook Medical's Fusion Dual Platform ERCP product line. A total of 71 patients (38 male, 33 female), mean age of 60.3 years, were enrolled. The indications for the ERCP were biliary stones (N=38), obstructive jaundice (N=14), post-liver transplantation (N= 11) and chronic pancreatitis (N=7).

Fusion provided for a significantly faster mean device exchange time (125 seconds), compared with the long-wire system (177 seconds) (p=0.05). The mean stent insertion time (135 seconds) was significantly shorter with Fusion versus the long-wire system (254 seconds) (p>0.001). A trend toward shorter procedure time, fluoroscopy time and cannulation time was also noted with Fusion. One incident of post-ERCP pancreatitis occurred in the Fusion group and two cases in the long-wire groups.

This first study evaluating Fusion has a number of strengths: 1) it is a prospective randomized controlled trial; 2) potential for bias was minimized by blinding the endoscopist to the study hypothesis and measured outcomes, and the person measuring the outcomes to the study hypothesis; 3) all procedures were done by the same physician, reducing confounding from variation in technical skills; 4) patients with various indications for ERCP were enrolled; and 5) the difference in device exchange and stent insertion times were not only statistically significant but also clinically significant (device exchange and stent insertion were faster on average by 52 and 119 seconds, respectively, for Fusion compared with the long-wire device). This latter point is particularly obvious in patients undergoing more complex ERCP procedures requiring multiple device exchanges or placement of multiple stents, in whom these efficiency advantages are magnified.

In conclusion, the study demonstrates that Fusion provides for significantly shorter device exchange and stent insertion times compared with traditional long-wire ERCP devices.