Breaking Barriers

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The trend toward minimally invasive surgical technique moves forward with the success of a transvaginal NOTES® partial gastrectomy, and the instrumentation that made it possible.

Advancements in minimally invasive surgery have made the far-reaching benefits of these techniques quite clear. In addition to less pain, a shorter hospital stay and improved recovery experiences for patients, these procedures can cut operating room (OR) times for surgeons, and the related costs for hospitals. Recently, surgeons in Japan moved the trend even further, successfully completing a transvaginal NOTES® (Natural Orifice Transluminal Endoscopic Surgery) partial gastrectomy. NOTES, a new minimally invasive surgical approach, involves passing surgical instruments through the body's natural orifices, such as the mouth, vagina or rectum, to remove a diseased organ or tissue.

Using the iNOLC Intelligent Natural Orifice Linear Cutter from Power Medical Interventions (PMI), Kiyokazu Nakajima, M.D., and Toshiru Nishida, M.D., of Osaku University removed a gastric submucosal tumor (SMT) through a patient's vagina with two minor abdominal incisions. The procedure is the fourth ever of its kind, all performed by Dr. Nakajima and Dr. Nishida using PMI instrumentation—either the iNOLC or the i60XXL Articulating Endoscopic Linear Cutter. The iNOLC has since been cleared for clinical use by the FDA, however, the iNOLC and cutting and stapling cartridges used in the procedure have not been cleared by Japanese regulatory authorities. Each was used pursuant to one-time compassionate use waivers under the surgeon's license and the University's relevant committee approval.

As a result of the NOTES operation, all four patients' tumors were successfully removed with minimal postoperative pain. The patients required no medication and were able to walk the day following surgery. "We have confirmed the feasibility and safety of a hybrid NOTES gastrectomy via a transvaginal route. The use of two small transabdominal ports is a reasonable compromise to make this procedure oncologically acceptable," Dr. Nakajima says. "It is too early to conclude anything

from only four cases, but at least we can say that transvaginal NOTES may become one attractive choice for females with gastric SMT and is a very good ‘bridge' to other NOTES approaches, such as transgastric and transrectal."

Progressive Instrumentation

With advancement in surgical methodology comes the necessary instrumentation to match. According to Michael Whitman, CEO of PMI, instrumentation had not progressed enough for large organ procedures, such as gastrectromy, colectomy and thorocotomy, to transition from open to laparoscopic surgery. In 1999, together with cardiologist Dr. Gerald Dorros, Whitman founded PMI and began to develop instruments to facilitate this transition.

As Whitman explains, "We set out to develop instrumentation that uses computer intelligence and power to transfer the types of force required to do advanced surgery—either minimally invasive or NOTES procedures, in a remote way."

The instruments employed by Dr. Nakajima and Dr. Nishida can be used in NOTES, as well as laparoscopic and open procedures. According to Whitman, the instruments contain titanium-grade surgical staples and utilize the same reloads. The i60XXL is a 60-mm long linear cutter that comes on a rigid shaft with a 90-degree articulating angle.

Meanwhile, the iNOLC is a 45-mm linear stapling device with a flexible shaft. "The gastrectomy is actually performed by the stapling device," Whitman says. "It compresses the stomach and cuts and staples simultaneously, so it's like scissors across the stomach that are used to transect a portion of the stomach in removing the cancerous section." PMI's Intelligent Surgical Instruments™ use proprietary software with two buttons and two toggle switches.

"For instance," Whitman explains, "if you're using the iNOLC, one toggle generates the angulations in the instrument and the other toggle controls the rotation, so there are three degrees of freedom in the instrument. "The two buttons operate the compressive force," Whitman continues. "There are jaws on the instruments, so you take the open jaws, angle it on the proper orientation of the stomach, press the top button and it would compress on the stomach. Then, another press of the button deploys the staples and the surgical knife that cuts and transects the stomach. The software and the computer control the compressive force and proper steps of the procedure, so the staples can't prematurely fire or be fired if they're not in proper orientation or range."

With a flexible shaft, the iNOLC is particularly effective in smaller patients with a small pelvis, Dr. Nakajima says. Further, the longer length of the instruments' shafts enables access from deep in the pelvic floor to the upper abdominal organs. The articulating/rotating function of the iNOLC tip makes gastric stapling effective in NOTES, where tissue manipulation is limited compared to standard laparoscopic cases. "It is true that NOTES is not an easy technology," Dr. Nakajima says. "We, however, have to continue R&D efforts since NOTES and its related technologies will immediately contribute to ultra less invasive, ‘purely endoluminal' treatment without any abdominal wall destruction. From this viewpoint, PMI's staplers seem to be on the right track."

A Major Shift

With the development of these surgical tools, larger organ surgeries have progressed into laparoscopic and NOTES methodologies. "The most striking benefit is the ability to avoid or minimize abdominal wall destruction," Dr. Nakajima says. "As a result, we can expect not only acute merits such as less pain, rapid recovery, short hospital stay and better cosmesis, but also late merits such as a lower risk of incisional hernia and adhesional ileus."

Whitman concurs. "We believe that natural orifice procedures will, in fact, as they become standard, reduce hospital stays," he says. "Just 10 years ago the gastrectomy was a seven-day stay at the hospital. And here we are 10 years later with the first transvaginal approach where patients are able to walk and eat the next day."

Not only does the success of NOTES benefit patients, but surgeons, staff and OR processes are prospering as well. According to Dr. Nakajima, NOTES advancements represent a major paradigm shift in the OR in several ways:

- Making surgeons reconsider the reasonability of “abdominal wall destruction.”
- Changing surgeons' and gastrointestinal (GI) physicians’ minds to no longer consider contraindication to cut the visceral wall intentionally.
- Changing the OR crew’s recognition of the flexible endoscope and its related tools that are now part of the OR armament.

Overall, Dr. Nakajima says through the transvaginal NOTES procedures, surgeons have started collaborating with GI physicians in the OR and more GI physicians are entering into the OR with flexible tools. "The OR should be aware of this change. They should appreciate their valuable input and feedback, which would not be obtained without the NOTES evolution. NOTES was new because it really broke the ‘barrier' between surgeons and GI physicians for the first time, by breaking the visceral wall," states Nakajima. "We should not lose this opportunity."

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