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The Landmark Signia™ Stapling System

Faculty

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Innovations in Smart Surgical Stapling

The first powered surgical stapler was introduced a decade ago, creating the potential for more secure and reliable stapling.[1,2] The Signia™ stapling system is a descendant of that first device and was created to bring "smart" features, such as real-time feedback, to powered stapling (Figure 1). According to Amit V. Sastry, MD, a hepatopancreaticobiliary surgeon at the Center for Advanced Surgical Oncology in Hialeah, Florida, the advantages of the Signia™ stapler are relevant to a broad range of procedures—from bariatric surgeries to colorectal resections—and have raised the standard in pancreatic surgery. "One reason the Signia™ stapler works so well in distal pancreatectomy is the real-time feedback," said Dr Sastry, who gained substantial experience with a variety of staplers and closure techniques during his surgical fellowship before fully transitioning to the Signia™ stapler. "I use the Signia™ device for all of my stapling needs," he said.

Adaptive Firing™ Technology and Feedback

The Signia™ stapler is compatible with Endo GIA™ and Tri-Staple™ 2.0 reloads (Figure 2). With audible and visual cues, the Signia™ stapler's handle provides surgeons with real-time feedback from device setup through the completion of firing.[3-6,a-c] Upon clamping, for example, an organic light-emitting diode (OLED) screen easily visible in the stapler handle identifies zones based on clamp force measurement.[7,a] This feedback correlates to the tactile feedback a surgeon would get with a manual stapler.[4,d] The firing speed adapts to these measurements, slowing as higher forces are experienced, while the gauge on the handle climbs from zone 1, the lowest, to zones 2 and 3 (Figure 3).[7,a] This feedback allows surgeons to assess the load selection and monitor forces on tissue before and during firing.[5,6,a] By monitoring the forces in real

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Figure 1. The Signia™ stapler.

time, the Signia™ stapler will adjust its firing speed based on an elevated compression force reading. Although surgeons can adjust to slower speeds with a double click, the device does not permit a faster speed than the one identified as appropriate.[5,6,a]

The tissue-sensing technology enables firing speed adjustments that optimize staple formation,[5,6,a] resulting in a secure closure.[8,9,a,e] Dr Sastry is unsatisfied with the functionality of other smart staplers that use tissue-sensing technology to adjust firing speed. In his experience, these devices read tissue more slowly than the Signia™ stapler, producing delays that can be significant if a change in staple reload cartridge is required. With Signia™, when the surgeon selects the appropriate reload for each case in advance of the procedure, the real-time feedback for adjusted firing speeds allows the case to progress smoothly.[5,6,a] "I have learned to trust the underlying Signia™ technology," Dr Sastry said.

Smart Stapling in Distal Pancreatectomy

Distal pancreatectomy is required for many indications, including malignancies, pseudocysts, trauma, and chronic pancreatitis.[10] In Dr Sastry's experience, the unique features of the Signia™ stapler directly address the challenges of this procedure, and thus have the potential to improve outcomes compared with his previous stapler.

Secure closures are essential to prevent leaks, a potentially catastrophic outcome.[11] In the pancreas, risks include leakage of pancreatic juice, a major risk factor for postoperative

Figure 2. The Signia™ stapler is compatible with Endo GIA™ reloads with Tri-Staple™ technology and the Tri-Staple™ 2.0 reloads.

pancreatic fistula formation.[11] Related complications include intraabdominal fluid collection, abscesses, and hemorrhage.[11] According to Dr Sastry, use of the Signia™ stapler ensures functional closure at the staple line in his procedures.[8,9,a,e]

"The intelligence of the device for addressing tissue variability is important," Dr Sastry said. "A variety of techniques to reduce the risk for pancreatic leak have been proposed, including hand sewing or fibrin glue after pancreatic neck division.[11] However, the linear stapler, which simultaneously cuts and closes the parenchyma and ducts, is both efficient and effective."

Pancreatic tissue is generally soft and amenable to resection, but, as Dr Sastry explained, chronically inflamed pancreatic tissue can be hard and thick, which may compromise good staple formation.[10] Equipped with Tri-Staple™ reloads that communicate with microprocessors in the handheld device, the Signia™ stapler provides visual and audible cues, indicating when it is ready to fire. "By adjusting the speed, the staple line is optimized to achieve functional closure[12] and adequate blood supply," Dr Sastry said.[13,f] This outcome is relevant to any surgical resection, but given the potential for leakage of pancreatic juice, the quality of the seal in distal pancreatectomy is particularly important.[11]

Some leakage of pancreatic juice is inevitable, but Dr Sastry considers leakage with amylase content greater than 3 times the expected level on or after postoperative day 3 a metric for a suboptimal outcome, which he closely monitors.[14,15] Dr Sastry has not specifically compared complication rates across closure devices. "However," he said, "it's safe to say that I have had more leaks from the pancreatic remnant with other devices than the Signia™ stapler."

Figure 3. An indicator shows forces on tissue before firing to assess load selection (left). Visual cues show that firing speeds are adjusting to optimize staple formation in variable tissue thicknesses (right).[a]

Based on reference 7.

Dr Sastry pointed to the Tri-Staple™ 2.0 reloads as another feature that may contribute to the reduced risk for leaks.[12,16,17,c,g] Each of the 3 color-coded sizes provides 3 rows of varied-height staples. The staple line closest to the closure line has the lowest height for the most secure seal. The second row is an intermediate height and contributes to the strength of the staple line.[16,17,c,g] The farthest row is the highest, allowing for greater perfusion into the staple line.[13,f]

These advantages are coupled with fully powered features, including articulation, rotation, clamping, and firing.[3,b] The fully powered device reduces the potential for staple movement, according to Dr Sastry. Unlike older manual staplers that required pressure on the trigger, "the Signia™ stapler is fired with precision and improved maneuverability," he said.[18,h] The stapler does not need to be moved or lifted once in place and is well balanced to permit single-handed operation.[19,c] Dr Sastry cites the ability to maneuver and fire the device with a single hand as a distinct advantage.[3,b] With a free hand, he frequently moves obstacles out of his line of sight. Even with assistants in the operating room, he indicated that most surgeons agree on the need for an extra hand. "The more hands you have free, the better," he said.

Similarly, Dr Sastry suggested that other staplers contribute to counterproductive involuntary movements, and he appreciates the precision provided by the Signia™ stapler[18,h] and the resulting consistent quality of the staple lines.[5,6,8,a,e] "The Signia™ device is very user-friendly and well designed," Dr Sastry said. "Many of the individual features are valuable, but the sum of the features is also important."

Smart Stapling in the Whipple Procedure

In a pancreaticoduodenectomy (ie, Whipple procedure), a complex process of resecting or mobilizing multiple adjacent organs for the treatment of benign and malignant diseases,[20] Dr Sastry typically uses the stapler for division of the duodenum or for the occasional gastrojejunostomy. Whether performed with an open or minimally invasive approach, in Dr Sastry's experience, the efficiency of the Whipple procedure can be improved with the Signia™ stapler. "For example," he said, "dissecting the uncinate process comes toward the end of the Whipple. The uncinate process is close to the portal vein and superior mesenteric artery, so it is a very vascular area. Dividing the uncinate process with a stapler is not always feasible, but it can be a huge time-saver when it is." The placement of sutures is time-consuming, but according to Dr Sastry, a linear stapler can rapidly resect and repair the tissue.

"Those without experience with a smart stapler might find it difficult to envision how the Signia™ device saves time while minimizing risks," Dr Sastry said. He explained that staplers are not an appropriate substitute for hand suturing in each of the multiple steps of the Whipple procedure, but both the real-time feedback[3-6,a,b,c] and powered features[3,b] of the Signia™ stapler can contribute to successful cases. For steps that can be performed with stapling, the tissue-sensing technology of the Signia™ stapler contributes to the quality of the staple line.[5,6,a] Dr Sastry noted the "seamless" flow of information on tissue depth and appropriate firing speed.[5,6,a]

According to Dr Sastry, passive resistance was the traditional method for navigating instruments into position. Although he does not have the data to show an advantage for powered articulation and rotation, he emphasized that "a risk for injury when applying force against organs is a logical assumption. Some have made the argument that surgeons need the tactile experience, but we know the anatomy. We don't have tactile feedback when we perform robotic surgeries. Certainly, avoiding unnecessary pressure on adjacent organs when navigating to the tail of the pancreas has at least a theoretical advantage." During Whipple procedures, surgeons require a stapler that enables maneuverability to navigate in tight spaces. "The Signa™ stapler's powered features make it more versatile,[18,h] which is particularly useful for those with limited experience."

A Short Learning Curve

Dr Sastry suggested that the Signa™ stapling system is an appropriate device for developing stapling skills and noted the short learning curve for the power functions. "I transitioned to the Signa™ device after experience with other staplers, but it does not require advanced skills. It is an excellent training tool," Dr Sastry said. "For those who understand the anatomy, the features of the Signia™ stapler provide advantages at essentially every step in a resection where stapling makes sense."

The Signia™ stapler can help trainees avoid errors. Lights on the handle quickly signal stapler status,[3,b] and an OLED screen provides additional information on tissue characteristics.[5,6,a] If the initial alignment of the stapler proves to be suboptimal, the powered articulation and rotation often mean that it may not need to be repositioned.[18,h] In addition, the Signia™ device will not fire if the tissue is not amenable to stapling. When tissue properties vary, the stapler automatically adjusts to ensure proper staple formation.[8,9,a,e]

Good Staple Formation

Bench comparisons have revealed evidence for superior staple formation. A manufacturer study found that malformed staples occurred at a rate nearly 7 times lower with the Signia™ device (2.8%) than an alternative system in current use (19.7%).[21,c,i] When compared with a competing powered stapler, the Signia™ stapler produced 3 times fewer malformed staples.[22,a,j] In fact, studies show that the staple lines of the Signia™ stapler were up to 50% stronger.[9,a,j]

Beyond the Pancreas

Across the spectrum of procedures he performs, Dr Sastry trusts the real-time feedback the Signia™ stapler provides (Figures 4 and 5). The visual and audible cues give him the confidence to proceed after he has properly prepared for the procedure and selected the appropriate reload.[4-6,a,c]

Although the adaptive firing speed is common to all reloads, an appropriate match between reload size and tissue thickness is relevant to the integrity of the staple line.[4-6,a,c] Dr Sastry uses the medium-height purple reload for the vast majority of distal pancreatectomies and reserves the tan reload, which has the lowest staple heights, for vascular dissections and closures. The black reload is for extra-thick tissue. "The black load accommodates highly inflamed hard and thick tissue," Dr Sastry said. "It is typically obvious when thick tissue, such as the stomach or colon, warrants a black reload."

Dr Sastry often performs splenectomies to treat immune thrombocytopenic purpura. Due to the high degree of vascularization, the integrity of the staple line in the spleen is critical to minimize bleeding, particularly from the risk imposed by disruption of the splenic hilum.[23] For this reason, he uses the Signia™ stapler for its effectiveness in delivering a secure staple line.[8,9,a,e] "In addition," he said, "a good staple line at the hilum can help prevent a pancreatic tail leak, which is often in close proximity to the splenic hilum."

The powered navigation of the Signia™ device improves the precision of positioning,[18,h] and its smooth delivery is critical when dividing intrahepatic pedicles in liver resections, according to Dr Sastry. "The powered features are helpful in general, but they represent a huge advantage in these

Figure 4. Dr Sastry using the Signia™ stapler with a purple load to divide the intestine.

Photo courtesy of Amit V. Sastry, MD

cases.[18,h] The stapler has very good articulation and can be inserted in tight windows with minimal shaking," he said.[3,b] In addition to the liver, Dr Sastry has used the Signia™ system in procedures involving adjacent organs, such as division of the neck of the gallbladder during a difficult cholecystectomy.

Dr Sastry also appreciates the benefits of the Signia™ stapler in gastrectomies and appendectomies. He noted that for the thicker tissue of the stomach, reinforced staple lines provide an added defense against leaks of gastric contents, and the powered articulation facilitates device positioning to remove the part of the cecum along with the appendix.[18,h] "Compared with other staplers, I have noticed less arterial bleeding from the staple lines for these procedures. I like the Signia™ stapler for gastrectomies because it minimizes the bleeding, and it ensures a well-formed staple line for a gastrojejunal anastomosis," he said.

Dr Sastry does not perform bariatric surgery, but he finds the feedback from the Signia™ stapler helpful for other bulky tissue, such as the colon and rectum. He singled out the diverticular colon as an example of when adaptive firing can contribute to a consistent staple line.[5,6,a] "Inflamed colons tend to be very thick, so the advantage of a secure and well-formed staple line is important to attaining a reliable anastomosis. Smart technology helps with that," Dr Sastry said. He inspects the staple lines after the completion of a procedure and said leaking and other complications are uncommon. "If I have some oozing from a staple line, I won't touch it," he said. "Oozing doesn't worry me. I want to see some evidence

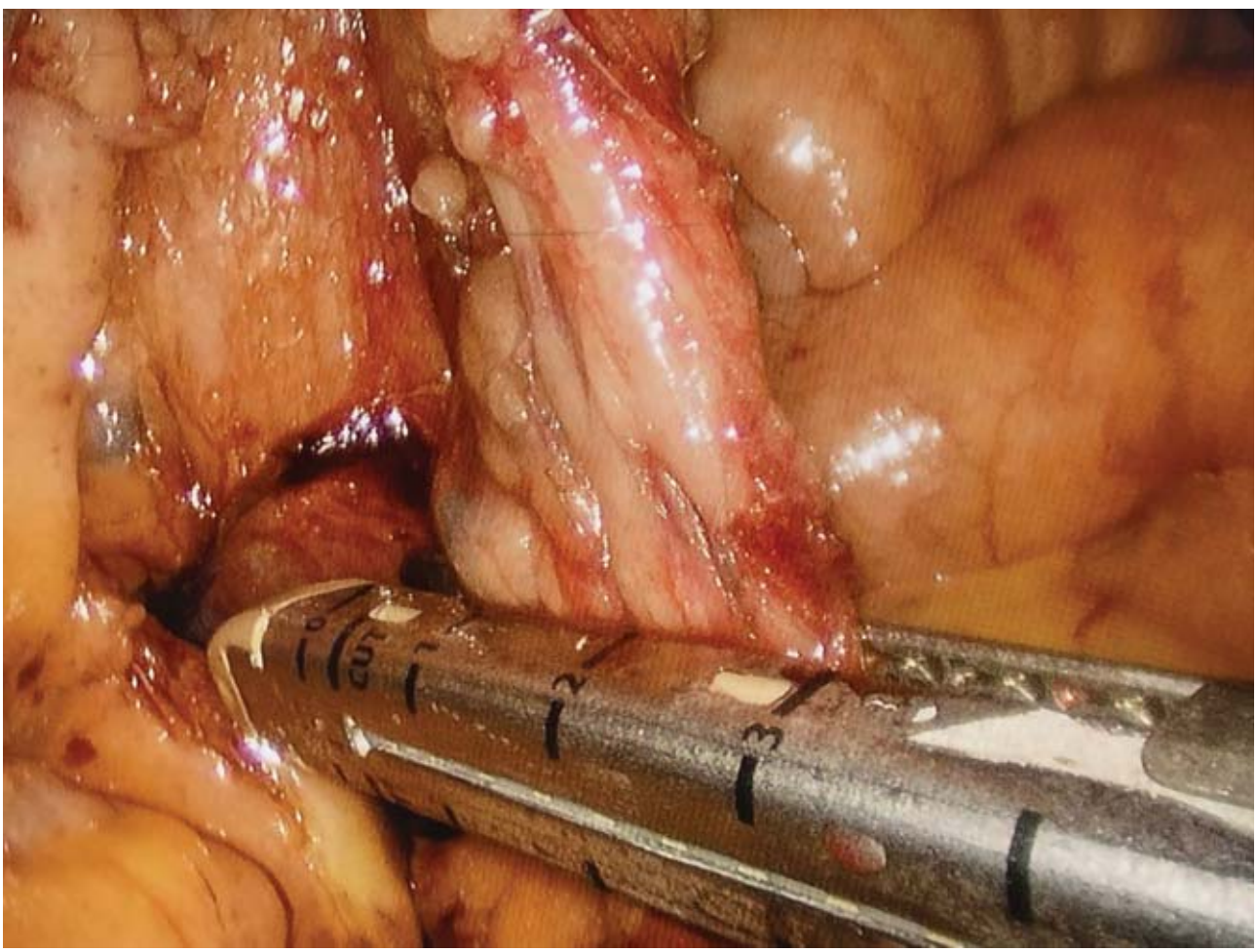

Figure 5. Dr Sastry using the Signia™ stapler with a tan reload to divide the ileocolic pedicle during a right hemicolectomy.

Photo courtesy of Amit V. Sastry, MD

of blood flow. If there is some oozing, it means the tissue has some room for perfusion."

For many resections in the abdomen, Dr Sastry acknowledged the difficulty of demonstrating a difference in outcomes (eg, leak rates) between closure devices with data from a single practice. Nonetheless, he believes the Signia™ stapling system represents a significant advance, and that the powered, easy-to-use system contributes to his low rates of complications while also improving efficiency.

Staple Reload Selection

Dr Sastry credited the tissue-sensing feature of the Signia™ device for a more predictable result compared with devices not similarly equipped and emphasized that despite its clear benefits,[5,6,a] surgeons should understand that the Signia™ stapler provides valuable information that helps surgeons make informed decisions about their staple reload selection.[4,c] The intelligence of the device, that is, translates to a potential reduction in unforced errors and adverse outcomes, but is not a substitute for thorough preoperative planning. "The basics cannot be ignored," Dr Sastry said. "When initiating a case, I am familiar with the challenges and have formulated a clear strategy. The Signia™ stapler is valuable because it reinforces and challenges my decisions, reducing the risk for unexpected problems. Unbiased feedback about tissue properties and conditions allows me to immediately adapt. The information is available before you lay down the staple line, so you avoid problems before they arise."

Conclusion

Dr Sastry finds the Signia™ stapling system advantageous not just for distal pancreatectomies and Whipple procedures but for the full range of procedures he performs and challenges he encounters, including differences in tissue quality. The Signia™ stapler has a number of powered features that facilitate access into tight anatomy,[18,h] and the tissue-sensing capability and adaptive firing optimize staple formation for consistent staple lines.[5,6,a]

In addition to the powered features,[3,18,b,h] he credits the tissue-sensing and Adaptive Firing™ technology of the Signia™ system for improving his confidence in the performance of complex procedures. "By knowing when to slow the process, the stapler optimizes the compression to achieve a good seal," Dr Sastry said. "For skilled surgeons, the difference in staple line formation is not going to be very different with current devices. But the Signia™ stapling system reduces the risk for poor staple formation, which is an important factor for achieving a good seal on challenging tissue."

Pancreatectomy and Splenectomy in an 80-Year-Old Woman Using the Signia™ Stapler and a 60-mm Tan Tri-Staple™ Reload

Amit V. Sastry, MD

An 80-year-old woman with a history of hypertension, diabetes mellitus, and asthma presented with complaints of left upper quadrant discomfort. She had no surgical history. Her performance status was fairly strong, as she was able to carry out activities of daily living.

Preoperative cross-sectional imaging revealed a lesion in the distal body of the pancreas that was solid, irregular, and hypoenhancing. There were no signs of distant disease, and the pancreatic duct was not visible, indicating it was nondilated. I assessed the lesion to represent a malignant process. The patient's cancer antigen 19-9 level was normal. After informing the patient of the risks of the operation (eg, pancreatic stump leak, abscess, bleeding) and obtaining perioperative medical clearance, we proceeded with a robotic distal pancreatectomy and splenectomy.

Intraoperatively, I began with the standard method of suspending the stomach anteriorly to expose the pancreas. I dissected out the inferior border of the pancreas and was able to see the splenic vein entering into the portal vein–superior mesenteric vein junction. I then encircled the neck of the pancreas with umbilical tape. Next, I divided the splenic artery and vein using 3-0 silk ties and clips.

The most critical part of the operation was the division of the neck of the pancreas. First, I assessed the caliber and size of the pancreas itself. The pancreas was thick but soft, with a moderate amount of peripancreatic fat. I specifically chose the Signia™ stapler with Tri-Staple™ technology 60-mm tan reload because I needed a stapler that could conform to a variety of textures within the pancreas. The peripancreatic fat is softer while the pancreas parenchyma is slightly denser. In addition, the pancreatic duct was miniscule in diameter, so it was important to ligate and seal it to prevent pancreatic duct leak from the stump.

I scrubbed into the patient's bedside and introduced the stapler under the window of the pancreatic neck. The fully powered articulation and rotation of the Signia™ stapler from any 12-mm port facilitated this step. I could see the tip of the stapler on the superior border of the pancreas. As I compressed, the tissue felt thick but adequate, and I saw a zone 2 reading from the display screen dial. The tissue-sensing technology

corroborated my tactile sensation that I was stapling in tissue of variable thickness that would require a slower firing speed to achieve a good staple formation. I was able to fire without issue. After division of the pancreas, the remainder of the pancreas, spleen, and retroperitoneal lymph nodes were successfully resected and removed. I then mobilized the round ligament of the liver and secured it to the stump of the pancreas, securing it with a 3-0 silk suture to the pancreatic capsule as an additional method of security to cover the pancreatic stump.

The patient's hospital length of stay was 3 days, and she recovered well postoperatively. An amylase level checked from the drain revealed 80 units/L, which I interpreted as normal and not indicative of a leak. Therefore, the drain was removed in the office. Pathology revealed a mixed adenocarcinoma and neuroendocrine tumor. She received adjuvant chemotherapy. On her 9-month postoperative visit, the cross-sectional imaging did not show any signs of recurrent or residual disease.[k]

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[a] Preclinical results may not correlate with clinical performance in humans.

[b] Thirty-eight of 38 surgeons surveyed agreed.

[c] Bench test results may not necessarily be indicative of clinical performance.

[d] Bench test results may not necessarily be indicative of clinical performance ($P<0.001$).

[e] Compared with manual and fixed-speed powered staplers.

[f] Compared with flat-faced cartridges with single-height staples.

[g] Staple-line strength: Endo GIA™ tan reload versus Echelon Flex™ white reload and Endo GIA™ purple reload versus Echelon™ green, gold, and blue reloads. In vitro synthetic leak resistance comparison: Endo GIA™ purple reload versus Echelon™ blue and gold reloads.

[h] Compared with manual staplers or EES Echelon Flex™ during placement.

[i] Compared Medtronic Endo GIA™ purple reload with Tri-Staple™ technology with Intuitive™ Surgical's green staple cartridge.

[j] Compared with Ethicon™ powered stapler with GST technology.

[k] Results may vary.

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