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A Smart Surgical Stapler: Advantages of Full-Powered Functionality

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Intelligent Surgical Stapling

Surgical staplers continue to evolve, and the more sophisticated devices are notable for their consistency in delivering well-formed and reliable staple lines.[1,2] Powered devices were introduced a decade ago to reduce variability in surgical stapling.[2,a,b] For the last 3 years, Andrew Wheeler, MD, a bariatric surgeon at the University of Missouri Health Care in Columbia, Missouri, has used the landmark Signia™ stapling system because of its advanced features (Figure 1). Dr Wheeler credits the single-handed operation,[3,c] powered functions,[3,c] and tissue-sensing technology before and during staple firing.[4,5,a]

Fewer Malformed Staples

Before switching to the Signia™ stapler, Dr Wheeler had a low complication rate in his laparoscopic bariatric surgery practice, but nonetheless encountered intraoperative staple-line bleeding, particularly in sleeve gastrectomies. He was thus drawn by the potential value of the Signia™ system tissue-sensing technology.[4,5,a] "The hope was that with more consistent staple lines, a level of complete hemostasis would be achieved more reliably," Dr Wheeler said. He credits the Signia™ stapler with optimizing staple formation.[4,5,a] "If the tissue is thick, for example, staples are not reliably driven through to the anvil. When this happens, the staples tend to malform, which is a common concern for surgeons."

Although malformed staples can occur across tissue thicknesses, manufacturer studies reveal consistently lower staple malformation rates in thick tissue with the Signia™ stapler. In one such preclinical experiment, Signia™ yielded a 2.8% malformed staple rate compared with 19.7% with an alternative contemporary system.[6,d,e] Another study found that Signia™ produced 3 times fewer malformed staples than a competing powered stapler.[7,a,f]

Adaptive Firing Speed and Feedback

The Signia™ device measures forces on tissue in real time and provides audible and visual feedback when used with any reload with Tri-Staple™ technology.[4,5,8,a,d] This tissue-sensing technology optimizes staple formation by adjusting the firing speed when stapling in tissue of variable thickness.[4,5,a] "Force and tissue thickness are correlated," Dr Wheeler said. "The Signia™ device measures the firing force which is an indirect measure of tissue thickness."

An OLED screen readily visible in the handle of the stapler identifies zones based on clamp force measurement.[4,5,a] The firing speed adapts to these measurements, slowing

Figure 1. The Signia™ stapler.

as tissue thickness climbs from zone 1, the lowest, to zones 2 and 3. The clamp force is measured continuously, providing surgeons with guidance before and during stapling and tissue division (Figure 2).[4,5,a] "If the measurement moves to zone 3, I have a chance to consider the reason," Dr Wheeler said. "If unexpected, it could mean I have closed on another staple line or a clip, or the tissue is too thick for that particular staple load. In some cases, I might wait for a few seconds for the edema to decrease at the staple line. Sometimes that's enough, but this information prevents me from forcing the firing, which threatens the quality of the staple formation." According to Dr Wheeler, it is this technology that achieves "the shape needed for a secure line."[5,9,10,a,g]

The value of the smart technology lies in the guidance it provides for achieving the appropriate force and speed of stapling and enabling the surgeon to make informed decisions about staple load selection during a procedure.[4,5,8,a,d] If the tissue at the staple line is thicker than expected, for example, Dr Wheeler might size up to a more appropriate reload. Although Dr Wheeler had been comfortable with manual stapling devices, he believes the tissue-sensing technology is an unbiased measure and reduces the risk for misinterpreting the feel of the tissue. "With the Signia™ stapler, the resistance that comes with manual clamping is not felt. Instead, the 3-zone dial gives you a relative indication for tissue thickness," he said.[4,5,8,a,d,h] The Signia™ stapler will reduce the firing speed when it reaches thicker or variable tissue,[4,5,a] but Dr Wheeler nonetheless pays close attention to the feedback before firing and as the staple line advances. As the device encounters differences in the varying forces necessary to fire staples, the real-time feedback alerts him to the need for adjustments.[4,5,8,a,d] He might change his next reload selection, for example, with an elevated compression force reading from the screen. Dr Wheeler emphasized that smart technology helps surgeons make informed choices for each patient and recognizes the benefits it brings to his practice.[8,d]

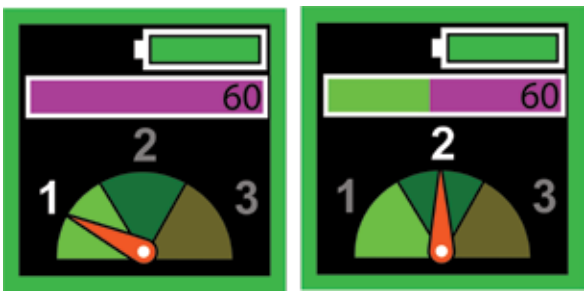

Figure 2. An indicator shows forces on tissue before firing to help assess load selection (left). Visual cues show that firing speeds are adjusting to optimize staple formation in variable tissue thicknesses (right).[a]

Based on references 4 and 5.

Fully Powered Features

Dr Wheeler said the feedback from the Signia™ stapler helps establish the relatedness of tissue thickness, firing force, and optimal staple formation[4,5,a] and is therefore useful for training fellows. An appreciation of this relationship, he said, can play a role in preventing potential complications, such as malformed staples and bleeding.[2,4,5,a,b]

In addition, he considers the Signia™ stapler a good training tool because of its single-handed operation.[3,c] "It is well balanced and has a good feel in the hand, including for surgeons with small hands," Dr Wheeler said.[11,d] Whether for trainees or experienced surgeons, the single-handed operation frees the other hand for other tasks.[3,c] "If you need to maneuver the device, the free hand is available to hold or pull away tissue, which is more complicated if both hands are occupied," Dr Wheeler said. "If you are using your left hand when maneuvering tissue to avoid an adjacent organ or for appropriate tissue retraction, you don't have to let go of that tissue because you can still fire with the hand holding the device."

The single-handed functionality is made possible by the powered features, including articulation, rotation, clamping, and firing.[3,c] In Dr Wheeler's experience, nonpowered devices permit only limited movement in either direction from the midline. The powered movement provides greater precision and maneuverability,[12,i] which means less movement of the stapler itself. By positioning the stapler with greater precision, there is an opportunity for better closure with less risk for iatrogenic adverse events.[1,12,i] "When I am using the stapler where placement is challenging, such as behind the stomach, the power functions are helpful for

Figure 3. Tri-Staple™ 2.0 reinforced reloads with the smart Signia™ stapler.

maneuvering to deliver staples more precisely," Dr Wheeler said.[12,i] "For the trainee, the powered articulation and rotation means that there is more forgiveness if the stapler needs to be realigned. You don't need to pull it away from the tissue but are better able to make the adjustments without repositioning."[12,i]

Tri-Staple™ Technology

The Signia™ stapler is compatible with the Endo GIA™ reloads with Tri-Staple™ technology and Tri-Staple™ 2.0 reloads (Figure 3). In addition, cartridges with preloaded buttress material are available, which Dr Wheeler uses for most, but not all, transections.

Tri-Staple™ technology provides 3 rows of varied-height staples in each of the reload cartridge types instead of the 2 rows of uniform-height staples of the predecessor to Tri-Staple™ technology. The lower staple height in the row closest to the closure line means a more secure seal where hemostasis is more important.[13-15,d,j] Staple heights are incrementally higher in the second and third rows. As the tissue is clamped, the stepped cartridge face delivers graduated compression, reducing stress on the tissue.[16,17,k,l] The greater height of the 2 adjacent staple rows preserves perfusion.[18,k] In addition, cartridges are color-coded for tissue thickness indications. For sleeve gastrectomies, Dr Wheeler commonly starts with black reload cartridges, which are designed for extra-thick tissue, but he individualizes the cartridge size for each case. Dr Wheeler thinks Tri-Staple™ technology contributes to the good hemostasis and leak resistance he associates with the Signia™ stapler.[13-15,d,j]

Conclusion

According to Dr Wheeler, the feedback provided by the tissue-sensing technology,[4,5,a] powered functions, and single-handed operation[3,c] represent meaningful technological advances and are valuable for ensuring the quality of the staple line."[9,10,a,g] Staple-line integrity[13,14,d,j] and increased perfusion[18,k] are further ensured by the Tri-Staple™ technology with graduated compression and varied-height staples. "Even oozing along the staple line has become an uncommon event with the Signia™ stapler in my procedures," Dr Wheeler said. "The results I have seen have been reassuringly consistent."

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

[b] Ethicon™ powered stapler versus manual stapler.

[c] Thirty-eight out of 38 surgeons surveyed agreed.

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

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

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

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

[h] $P<0.001$

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

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

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

[l] Compared with Echelon Flex™ green reload analysis comparing different stapler designs, performance, and impact on tissues under compression using 2D finite element analysis.

References

1. Chekan E, Whelan RL. Surgical stapling device—tissue interactions: what surgeons need to know to improve patient outcomes. *Med Devices* (Auckl). 2014;7:305-318.

2. Kimura M, Terashita Y. Superior staple formation with powered stapling devices. *Surg Obes Relat Dis*. 2016;12(3):668-672.

3. Data on file. Signia™ stapling system summative usability report. Internal test report #RE00024826 rev D. Medtronic; September 2016.

4. Data on file. ASA verification testing with slow speed force limit evaluation. Internal test report #R2146-173-0. Medtronic; 2015.

5. Data on file. Powered stapling firing speed DOE analysis and ASA parameters. Internal test report #R2146-151-0. Medtronic; 2015.
6. Data on file. Internal test report #PCG-029. Intuitive Surgical™ stapling competitive analysis. Medtronic; June 2017.
7. Data on file. Signia™ stapling system competitive claims. Internal test report #PCG-028. Medtronic; March 27, 2017.
8. Data on file. Surgeon evaluation testing Signia™ stapling system sensing technology and real-time feedback. Internal test report #RE00055515. Medtronic; August 4, 2016.
9. Data on file. Signia™ stapling adaptive firing technology data calculations and references. Internal report #RE00218740. Medtronic; August 7, 2019.
10. Data on file. 4.5 mm round staple pull-apart analysis report. Internal test report #RE00147607. Medtronic; 2018.
11. Data on file. Signia™ power stapler center of mass. Based on internal report #RE00027558. Medtronic; 2015.
12. Data on file. iDrive™ Ultra stapler PCR summary report. Internal report #R0033554. Medtronic; November 2012.
13. Data on file. Tyvek pull-apart test comparing Echelon™ and Tri-Staple™ technology. Internal test report #PCG-001. Medtronic; March 2011.
14. Data on file. In-vitro leak comparison. Internal test report #PCG-002. Medtronic; March 8, 2011.
15. Contini E, Whiffen J, Bronson D. Comparison of endostapler performance in challenging tissue applications. *Surg Obes Relat Dis*. 2013;9(3):417-421.
16. Data on file. Perfusion into clamped media. Internal test report #PCG-007 rev 1. Medtronic; September 2, 2011.
17. Data on file. 2-D FEA of linear staplers. Internal test report #PCG-018. Medtronic; November 2012.
18. Data on file. Final analysis of staple-line vascularity using MicroCT. Internal test report #2128-002-2. Medtronic; July 2015.

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