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Clinical Experience Using Multifunctional LigaSure™ Small Jaw Instrument in Vessel Sealing Procedures

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Introduction

What do endocrine and head and neck surgeons want in an energy-based vessel sealing device? "Something that is easy and safe to use, won't harm any neighboring structures, effectively seals lymphatic vessels and minimizes bleeding, is easy to set up and use by the nursing staff, and is relatively inexpensive," said John L. Crawford, MD, surgeon at Texas Health Harris Methodist Hospital in Fort Worth.

According to Paolo Miccoli, MD, Italian director of surgery at Azienda Ospedaliero-Universitaria Pisana in Pisa, Italy, a well-designed vessel sealing device can offer several advantages. "We could obtain optimal coagulation and cutting, and separate the vessels with the same instrument. This way we do not need to clamp and tie, which could reduce the length of the operation by at least 30%," he said. "Another advantage would be to make operating more precise and accurate, with a reduction in blood loss."

Taking into consideration such input from surgeons, Covidien introduced a new member to the LigaSure™ family of cutting and sealing devices—the new LigaSure small jaw instrument—designed to increase ease of use and enhance safety in the operating room. The LigaSure small jaw instrument features an integrated blade that can be activated independent of sealing. The new device is multifunctional, capable of blunt dissection and grasping, and has a low thermal profile, thus reducing the risk for inadvertent burns (Figure 1).

Multifunctionality and Need-Based Approaches

Prior to adopting LigaSure technology, Ellie Maghami, MD, associate professor of surgery and chief of otolaryngology at City of Hope National Medical Center in Duarte, California, used the clamp-and-tie approach for neck dissection. "I would clamp the lymphatic bundles, divide the tissue, and tie off each individual bundle one by one," she said. "That obviously takes some time."

She finds the LigaSure small jaw instrument ideally suited to speed up this task. "I like it for neck dissections quite a bit. A lot of the neck dissections I do are for very advanced bulky disease in the neck where I come across a lot of lymphatics. This [instrument] allows you to quickly sweep through the lymphatics and save some time, especially when operating with a single assisting resident surgeon-in-training."

Dr. Maghami also finds the LigaSure small jaw instrument helpful when operating on patients who have previously undergone treatment for cancer. "I do a lot of post-chemoradiation neck dissections for recurring cancer," she said. "The anatomy in the reoperative cases often is distorted by tumor or dense scar tissue, so it helps to have an instrument that allows you to navigate through soft tissue in a fast and reliable way. That is how I use LigaSure in my practice, in my hands, most efficiently."

Dr. Crawford has used LigaSure technology to seal and cut blood and lymph vessels, divide mesentery in bowel surgery,

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and perform splenectomies and thyroidectomies. Prior to adopting the LigaSure™ small jaw instrument, Dr. Crawford and his team found other ultrasonic devices to be problematic. "We were frustrated because [other ultrasonic devices] took us longer to set up. I had a lot of trouble with the device[s] not working or the energy unit breaking intraoperatively, and I was concerned about energy getting too far out from the probe. The tissue seemed to be coagulated further out from the jaws of the instrument and we were concerned about using it too close to nerves," he said.

"We don't use cautery next to the recurrent laryngeal nerve or the external branch of the superior laryngeal nerve during thyroid or parathyroid surgery, so the [LigaSure small jaw instrument] had a nice niche. We started using it and liked it immediately," Dr. Crawford said. Additionally Dr. Crawford prefers the way the LigaSure small jaw instrument cuts as compared with [other ultrasonic devices]. He noted, "The smooth cutting device built into the LigaSure small jaw instrument allows me to moblize the upper pole of the thyroid gland during a thyroid lobectomy much more quickly than with [other ultrasonic devices]. With [other ultrasonic devices], I often have to switch to scissors to cut the tissue, then go back to the [device] to continue the dissection."

Neil Tolley, MD, a consultant ear, nose, and throat, and thyroid surgeon at St. Mary's Hospital in London, who performs 5 to 10 thyroid/parathyroid surgeries per week, tried LigaSure technology 5 or 6 years ago, but did not find it compatible with the energy platform he was using at the time. When the ForceTriad™ energy platform became available he tried again with the LigaSure technology. "Although we still had to go through the second maneuver—picking up the scissors and cutting the part that was sealed—I gave up [other ultrasonic devices] and went to the LigaSure [small jaw]," he said. "I found the LigaSure [small jaw instrument] ergonomically easier to use and more suited to the confined environment associated with head and neck surgery and, in particular, thyroid surgery through a small incision."

Dr. Tolley found the LigaSure technology to be more reliable and consistent than instruments he had used in the past. "[Other ultrasonic devices have] a learning curve; you have to learn about its limitations in vessel sealing. The LigaSure [small jaw] is superior for sealing thin-walled vessels such as veins. I found [other ultrasonic devices] less reliable for sealing larger caliber veins," Dr. Tolley said.

Dr. Tolley also preferred the cooler temperature profile of the LigaSure technology. "You have to be careful with the active blades [when working with other instruments]—if you just touch the skin you will get a burn," he said. "Of course, what we really wanted was the LigaSure technology with an integrated blade. That came on the market in January in the United Kingdom. I haven't looked back since."

Table 1. Comparison Between the Clamp-and-Tie Method and LigaSure™ Small Jaw Instrument

Operating Time	Conventional Group	LigaSure Group	*P*-Value
Lobectomy (min)	67.25±4.49	37.65±4.68	<0.0001
Subtotal thyroidectomy (min)	101.20±7.51	66.80±4.56	<0.0001
Total thyroidectomy (min)	132.13±7.50	93.16±5.68	<0.0001
Length of incision (cm)	9.11±1.38	9.02±1.50	0.505
Intraoperative blood loss (mL)	132.72±28.38	65.60±14.79	<0.0001

Based on references 1-5.

Figure 1. LigaSure™ Small Jaw Instrument with ForceTriad™ Energy Platform.

Reduced Operating Time

Studies have shown that the use of LigaSure technology in head and neck surgery results in reduced blood loss, less postoperative pain, and reduced hospital length of stay compared with conventional techniques.[1] In a study of 110 patients with thyroid disease, Youssef and colleagues found that postoperative blood loss was reduced by approximately 67 mL in the LigaSure group ($P<0.0001$) and that operating time was reduced by roughly 30 minutes ($P<0.0001$). There was a significant reduction in reported pain and analgesic use with LigaSure. Additionally, patients in the LigaSure group were able to return to activity and work without pain sooner than patients in the conventional group. The most consistently noted benefit, however, has been reduction in operating times (Table 1).[1-5] Surgeons using the LigaSure small jaw instrument are finding that its multifunctionality and integrated blade might contribute to the reduced operating time, eliminating the need to reach for separate instruments.

Dr. Maghami was quite pleased with the first-generation LigaSure Precise™ instrument. "I liked that instrument because it somewhat mimicked the tonsil dissector we use in head and neck surgery. But it did not have cutting integrated, and in surgery that often translates into additional time spent for instrument exchanges," she said. "By integrating [a] cutting function into the new device, efficiency is enhanced."

Noting the well-documented coagulating capacity of radiofrequency technology, Dr. Miccoli considers the ability to cut and coagulate with one instrument an important advance.[6] "The main advantage acquired with the new LigaSure small jaw instrument is the ability to cut with great precision the vessels that have been coagulated," said Dr. Miccoli, who has been using LigaSure technology for the past decade; nearly 3,000 thyroidectomies per year are performed at his center.

"Using this instrument allows you full control over the surgical procedure, which is not only time saving, but also makes you more comfortable with the procedure; that is the most important thing."

Temperature Profile

The design of the LigaSure small jaw instrument, with a relatively cool temperature profile and insulated tip, is meant to confine effects to the target tissue and minimize the risk

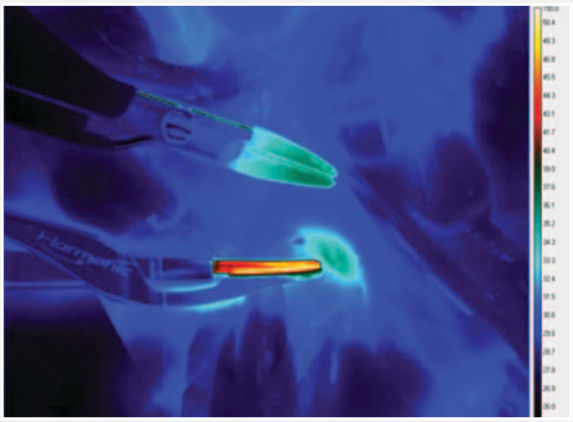

Figure 2. Thermal imprint comparison of the Ligasure™ Small Jaw Instrument and the Harmonic FOCUS™*.

for thermal spread to surrounding tissues. "One of the reasons nerve damage occurs is transmission of heat, so the capacity of controlling better heat transmission means less [risk for] heat injuries to the nerve," Dr. Miccoli said.

The mean maximum external jaw temperature ranges of the LigaSure™ small jaw instrument during a procedure are lower than those of other ultrasonic devices. During a single activation for sealing an isolated vessel, the LigaSure small jaw instrument achieves temperatures of 60˚C to 95˚C, compared with 178˚C to more than 250˚C for similar ultrasonic devices. On average, the external jaw temperature of the LigaSure small jaw instrument was at most 155˚C cooler than similar ultrasonic devices (Figure 2).[7] "I think that what has been considered low temperatures, less than 100˚ [Celsius], can be very harmful to critical structures," Dr. Miccoli said. "So we should not exceed 40˚ or 50˚ [Celsius] when close to critical structures. Since radiofrequency generally does not exceed 60˚ to 70˚ [Celsius], I think we are [getting] close to the ideal instruments."[8]

The LigaSure small jaw instrument takes just up to 5.4 seconds to cool down to less than 60˚C after a single activation on isolated vessels, whereas other ultrasonic devices may require at least 10 to as many as 60 seconds to cool down to 60˚C. The LigaSure small jaw instrument seals effectively at cooler temperatures compared with other ultrasonic devices (Table 2).[7] The cooler temperature profile is an attractive feature to head and neck surgeons for a variety of reasons. For one, there is less risk for personal injury or for inadvertent burns to the patient. More importantly, this lowers the risk for injury to the critical and sometimes delicate structures in the head and neck.[7,9]

"You can help avoid thermal injury to very important structures like the recurrent laryngeal nerve, the very delicate parathyroid glands, the trachea, the esophagus, and the skin, as well as the drapes." Dr. Crawford said. The lateral heat spread of previous instruments was of concern to Dr. Tolley, as it may have been larger than the expected 2 mm, he said. "[Other ultrasonic devices] get very hot, and you really appreciate how significant this is, in my opinion, when you're assisting someone else."

Dr. Tolley found that instruments he used in the past were prone to cause small burns to the patient's skin. "When you take the instrument out of the wound, you may get a little burn on the skin," he said. Although the burns were not third degree, they could still scar. "When you're operating, sometimes you're 'micro-focusing.' You're really looking very carefully at a structure and you may not be aware of what is happening in the more generic use of the instrument," Dr. Tolley said. "You're cutting with the tip, but you may be touching the skin or other structures with the part of the instrument you are not focused on."

Dr. Maghami appreciates the confidence she has that the instrument in her hand will allow her to focus without the concern of another area being at risk. "Both tips of the [LigaSure] instrument are guarded, and it functions like a bipolar instrument in the sense that you have thermal energy between the tips and nowhere else," she said.

"With [other ultrasonic devices], one end of the blade is uncovered and it gets very hot. Throughout the application, you have to be very mindful of where you're putting that end of the instrument, and in proximity to what structure you are engaging it," Dr. Maghami said. "[With the application of the jaws], you must be careful not to place the hot tine near critical neurovascular structures during thyroid surgery. With the LigaSure device you really don't have that [concern] to the same degree. It's much safer, especially in a training program where you're educating relatively novice surgeons [about the] application of these technologies. One must constantly remind young residents of the heat polarity of the tines in the application of [other ultrasonic devices]. This is not necessary with the LigaSure."

Vessel Sealing and Sutureless Surgery

Used with the ForceTriad energy platform, LigaSure technology provides a continuous output of energy, making 3,333 adjustments per second to seal vessel walls (Figure 1). The LigaSure small jaw instrument can seal vessels up to 7 mm. Lamberton and colleagues studied the burst pressure of several vessel sealing devices. As compared with similar ultrasonic devices, LigaSure was observed to have a higher burst pressure, indicating better vessel sealing (Figure 3).[10] Dr. Tolley is confident that the LigaSure small jaw instrument can seal any vessel he encounters in head and neck surgery.

"You need to have the best and most reliable means of sealing the vessels. If you have a bleed, the patient will have to go back to surgery. They may end up with long-term brain damage, which has huge consequences to the patient and

Table 2. Temperature Comparison of LigaSure™ Small Jaw and Harmonic FOCUS™*

Mean Maximum External Jaw Temperature Ranges During Operation	LigaSure Small Jaw	Harmonic FOCUS
Single activation for sealing isolated vessels	60-95˚C 1-7 mm diameter	178->250˚C 1-5 mm diameter
Single activation for mesentery dissection	55-61˚C	194->250˚C
Minimum time to achieve device cool down (temperature <60˚C) after single activation on isolated vessels	0-5.4 sec	10.2-60 sec
Multiple activations (10) for mesentery dissection	78-82˚C	>250˚C
Minimum time to achieve device cool down (temperature <60˚C) after multiple activations (10) on mesentery	17-33 sec	53-83 sec

the hospital in terms of litigation," Dr. Tolley said. "For all the vessels that you encounter [in head and neck surgery], the LigaSure small jaw is fit for the purpose," he continued.

Dr. Crawford has the utmost confidence in the LigaSure™ small jaw instrument. "I think it's been [very] consistent. Just last week for the first time I did a total thyroidectomy on a gentleman who is HIV- and hepatitis B–positive and I didn't use any sutures," he said.

Ergonomically, the LigaSure small jaw instrument may offer some advantages to head and neck surgeons, particularly those who use the clamp and tie approach for neck dissection. "Before energy devices, we used to clamp and tie," Dr. Miccoli said. "Reaching a more limited space was ergonomically unfriendly. This changed the economy of the surgical gesture."

Dr. Maghami clamped, divided, and tied her way through residency and fellowship. "But as an attending and going through cases with a single surgical resident assisting, it became a bit cumbersome," Dr. Maghami said. "So I started experimenting with the [LigaSure] small jaw instrument, and it seemed to be an efficient and reliable device."

Dr. Tolley appreciates the shorter length of the LigaSure small jaw instrument for working in confined areas. "For example, [some devices are] not designed for head and neck work, whereas the LigaSure has been specifically designed for use in the head and neck."

Ergonomically, the LigaSure small jaw instrument has an edge over other available ultrasonic devices, according to Dr. Crawford. "It's smaller, it's lightweight, and it's nice because it has that cutting device [incorporated]."

Conclusion

Although surgeons might be inclined to quickly adopt an instrument that offers clear advantages in terms of patient outcomes and their own satisfaction, hospital directors and materials managers, too, need to be convinced of the benefits of a new technology before the instrument can debut in the operating room. Increased efficiency with LigaSure technology could offset the cost of its use.[5]

"A high-volume hospital should acquire new technologies because it is in the position of offering the best quality, both to the surgeons and their patients," Dr. Miccoli said. "I think it could be beneficial for hospitals to acquire this instrument, which is an objective improvement over the previous instruments."

For Dr. Tolley, adoption of the LigaSure small jaw instrument makes sense clinically and economically. "There are factors limiting the number of cases you can do, but if you can operate faster, there will be more patient turnover, which economically benefits both the hospital and the surgeon. Furthermore, and more to the point, increased vessel sealing reliability will enhance patient safety."

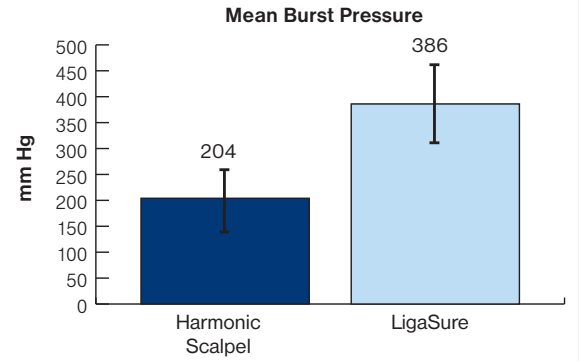

Figure 3. Comparative mean burst pressure between Harmonic™* and LigaSure™ products.
Adapted from reference 10.

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