The Thermal Safety Profile of a New Bipolar Vessel Sealing Device for Thyroid Surgery

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ABSTRACT

Introduction: Bipolar electrocautery devices used to achieve intraoperative hemostasis carry risk of imparting thermal energy to adjacent tissue, leading to postoperative morbidity. The aim of this study was to compare a new vessel sealing device, the CoolSeal™ Reveal (Bolder Surgical, Louisville, Colorado), with an established industry standard device, the LigaSure™ Exact Dissector (Valleylab, Boulder, Colorado), to assess their safety and the extent to which they impart thermal damage to tissue during thyroid surgery.

Materials and Methods: Vascular bundles associated with the thyroid gland in anesthetized sheep were exposed and sealed with a single activation of each device and excised en bloc. Additionally, vascular structures of the sheep were also sealed 0, 1, or 2mm adjacent to the recurrent laryngeal nerve (RLN). Vascular and RLN samples were processed for histopathologic evaluation and assessed for extent of thermal injury, seal width, and coagulative changes.

Results: The mean thermal injury extent across all sample sizes and vessel types was significantly lower for the CoolSeal™ Reveal device (547.2 ± 27.9µm) compared to the LigaSure™ device (802.7± 48.6µm) ($p<0.001$). Seal widths were significantly smaller in samples sealed with the CoolSeal™ Reveal device (899.0 ± 14.9µm) than samples sealed with the LigaSure™ device (1645.3 ± 160.3µm) ($p<0.001$).

Conclusion: The CoolSeal™ Reveal device demonstrates significantly lower thermal spread in vivo compared to the LigaSure™ Exact Dissector. These results indicate that the CoolSeal™ Reveal is an effective tool for sealing blood vessels and minimizing thermal damage to adjacent structures during delicate surgeries or in narrow surgical fields associated with the thyroid gland.

INTRODUCTION

Establishment of intraoperative surgical hemostasis is critical to delicately divide tissue and minimize blood loss during a procedure. Failure to control bleeding from major vessels can lead to significant postoperative morbidity and mortality.[1] Traditionally, hemostasis was accomplished with the clamp and ligation technique wherein hemostatic forceps are clamped on blood vessels, which can then be transected and subsequently clipped, tied off, or ligated.[2] More commonly, however, surgeons rely on newer monopolar, bipolar, or ultrasonic technologies[3-6] to facilitate quicker and more stable hemostasis.

Ultrasonic technologies deliver high-frequency sound waves to coagulate and seal small vessels.[7-9] Bipolar cautery devices utilize a narrowly directed electrical current to denature collagen and elastin within their clips, thereby fusing opposing sides of a vessel.[10] Both of these technologies have been shown to carry a risk of imparting thermal damage to surrounding tissues, leading to potential postoperative sequelae.[10-13] Thus, it is critical that vessel sealing technologies minimize thermal spread to adjacent structures. This is particularly important in procedures with narrow surgical windows such as a thyroidectomy, wherein surgeons must navigate in close proximity to dense vasculature and nerves, including the recurrent laryngeal nerve (RLN).

Bolder Surgical™ recently developed a new bipolar sealing technology, termed the CoolSeal™ Reveal Vessel Sealing device (Bolder Surgical, Louisville, Colorado). The CoolSeal™ Reveal has a shafted design with small jaw widths relative to other devices on the market and, combined with its quick sealing bipolar technology, was designed with the goal of minimizing adjacent thermal damage during delicate procedures while maximizing surgical visibility. Its efficacy and degree of thermal spread compared to industry standards for bipolar technology, however, have not yet been studied or reported in surgical literature. The aim of this study was to assess and compare the efficacy of the CoolSeal™ Reveal device with a predicate device, the Medtronic LigaSure™ Exact Dissector Sealer/Divider (Valleylab, Boulder, Colorado). Evidence of thermal damage adjacent to the edge of a vascular seal during multiple surgeries including thyroidectomy was evaluated.

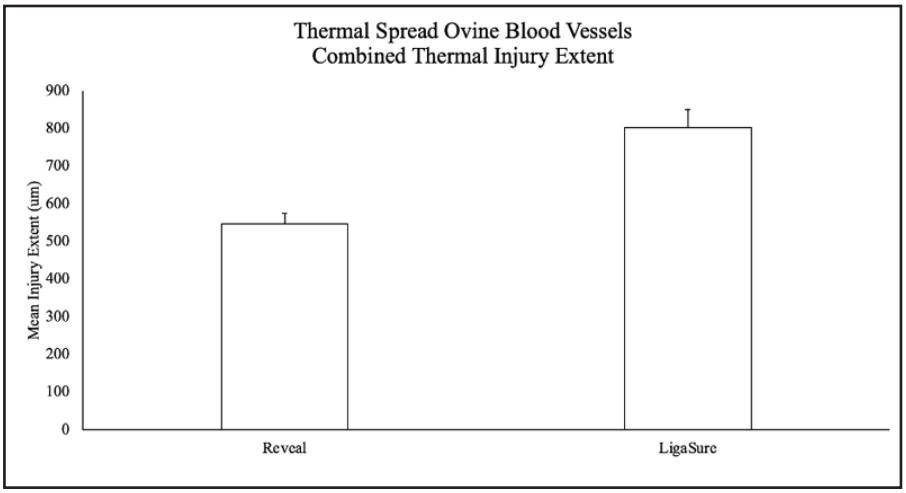

Figure 1. Thermal spread ovine blood vessels; mean combined thermal injury extent. Sheep blood vessels sealed with the CoolSeal™ Reveal device had smaller injury measurements compared to those sealed with the LigaSure™ device.

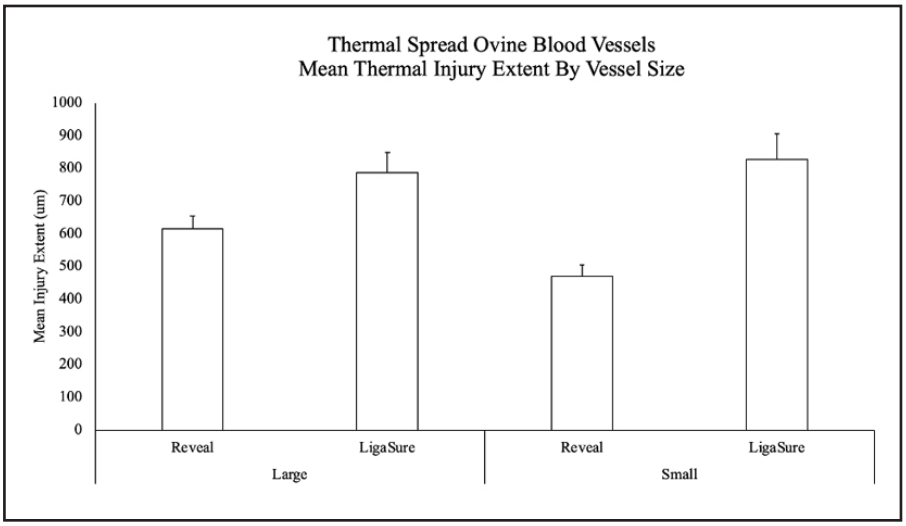

Figure 2. Thermal spread ovine blood vessels; mean thermal injury extent by vessel size. As seen for all vessels combined, both large and small vessels exhibited less extensive injury when sealed by the CoolSeal™ Reveal device compared to the LigaSure™ device.

MATERIALS AND METHODS

In vivo experiments

In an anesthetized male sheep, a region of the neck was exposed through a ventral midline approach to access small (3.0mm or less) or large (>3.0–6.0mm) arteries, veins, and vascular bundles associated with the thyroid gland (cranial and caudal thyroid vessels, carotid artery branches). Equivalent sites were selected for sealing with each device. Vessels were measured *in situ* with a calibrated ruler and sealed with a single activation of each device but not transected. Following sealing, and upon return to baseline temperature, blood vessels were excised *en bloc*. Additionally, vascular structures of the sheep were also sealed 0, 1, or 2mm adjacent to the RLN, and each region of the nerve corresponding with these sites of device application were excised *en bloc*. The seals were created with the seam of the jaw facing the RLN. Steam escapes through the seam of the jaws during device activation, making this area the hottest part of the device. The animals were euthanized following the completion of the procedure. All samples were fixed in 10% neutral buffered formalin. Institutional approval was obtained for this study and all appropriate animal use standards were followed in accordance with ARRIVE guidelines and the National Institutes of Health guide for the care and use of laboratory animals.

Histopathology

Twenty small and large formalin-fixed

blood vessels (individual arteries, individual veins, and vascular bundles [multiple arteries and/or veins together]) were sealed and excised from the thyroid region and 20 formalin-fixed samples of the right and left RLN were submitted to HistoTox Labs. Blood vessels were embedded longitudinally in paraffin, perpendicular to the seal site, either intact or following longitudinal bisection; paraffin blocks were sectioned at approximately 4µm at several (3-5) levels (spaced 100 to 800µm apart) through the vascular portion of the tissue. RLN samples were either bisected or embedded in paraffin intact in the transverse plane to create cross sections. Paraffin blocks were sectioned at 4µm, and five levels separated by 500µm were generated for each sample. All samples were stained with hematoxylin and eosin (H&E) or Picrosirius red (PSR).

Glass slides were evaluated using light microscopy by an ACVP board-certified veterinary pathologist blinded to the device. PSR-stained blood vessel slides were examined under polarized light to obtain measurements (cellSens software and an Olympus SC180 digital camera coupled to an Olympus BX51 microscope fitted with polarizing filters; 2x objective [Olympus Life Science, Waltham, Massachusetts]) of thermal seals and the extent of thermal injury beyond the seal. The thermal seal was defined as the compressed region of vessel and/or perivascular soft tissue exhibiting morphological changes to the collagen. Thermal injury adjacent to the seal was characterized by complete to partial loss of birefringence observed with polarized light and coagulative changes to the collagen and/or smooth muscle seen under non-polarized light.[14] When possible, three measurements were performed per side (upper, central, lower).

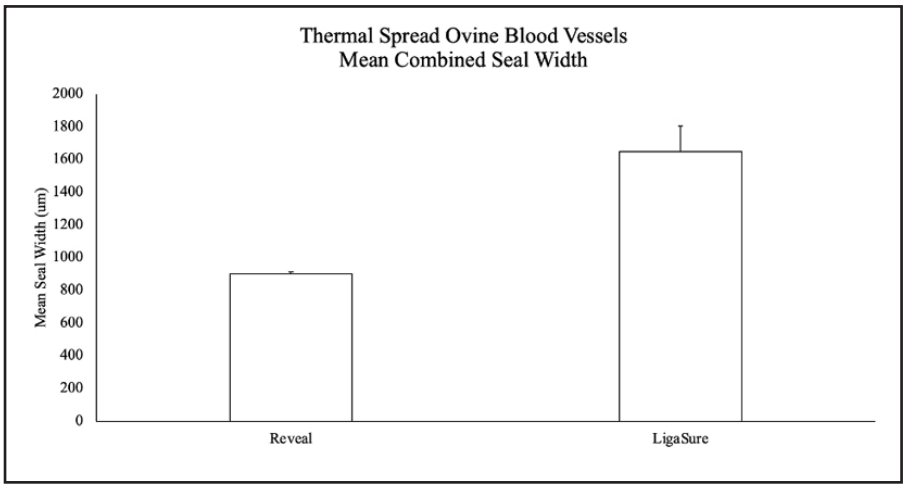

Figure 3. Thermal spread ovine blood vessels; mean combined seal width. In samples from sheep, seals created with the LigaSure™ device were wider than those created with the CoolSeal™ Reveal device.

H&E- and PSR-stained RLN slides were examined for evidence of collagen thermal change and/or nerve injury.

Statistical analysis

Data are presented as mean ± standard error of the mean (SEM). Thermal injury extent measurements were analyzed by a two-tailed Student's T-test. Significance was set at $p \leq 0.05$.

RESULTS

Thermal spread in blood vessel seals

The mean thermal injury extent across all sample sizes and vessel types was significantly lower for the CoolSeal™ Reveal device (547.2 ± 27.9µm) compared to the LigaSure™ device (802.7± 48.6µm) ($p<0.001$; Fig. 1). Similar between-group trends were seen with small (CoolSeal™ Reveal: 470 ± 34.5µm; LigaSure™: 826.1 ± 79.8µm) and large (CoolSeal™ Reveal: 615 ± 38.7µm; LigaSure™: 786.9 ± 61.3µm) size blood vessels and were separated (Fig. 2). Seal widths were significantly smaller in samples sealed with the CoolSeal™ Reveal device (899.0 ± 14.9µm) than samples sealed with the LigaSure™ device (1645.3 ± 160.3µm; $p<0.001$; Fig. 3). Representative histopathological images of a sealed ovine artery and vein are shown in Figure 4a and b.

Thermal spread in adjacent recurrent laryngeal nerves

Coagulative changes to the soft tissue collagen (swelling, degeneration, and

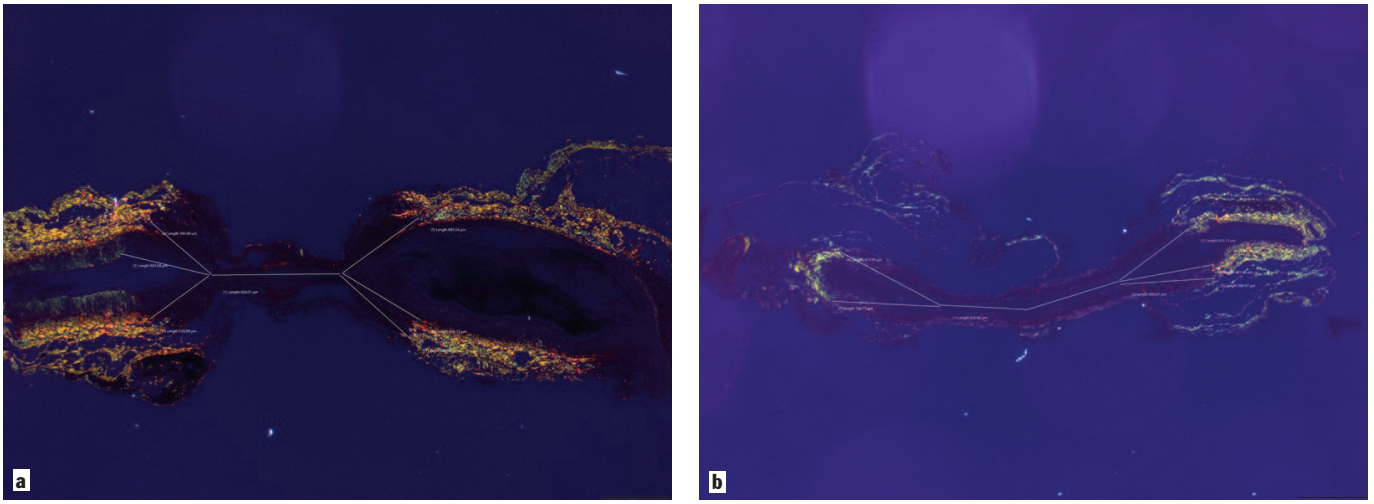

Figure 4. Representative PSR-stained histopathological slides of an artery (a) and vein (b) demonstrating vessel seal width and thermal spread with the CoolSeal™ Reveal device. White lines represent measurements, with central line indicating the seal zone and peripheral measurements indicating thermal spread. Images shown at 20x magnification.

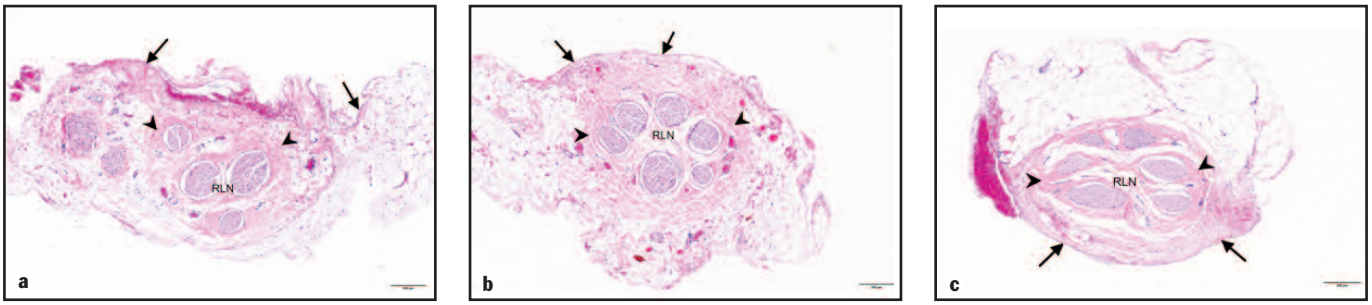

Figure 5. H&E-stained slides of transverse cross sections of the RLN following sealing of vascular structures 0mm (a), 1mm (b), and 2mm (c) adjacent to the nerve. There is no evidence of RLN injury or epi-/perineurial collagen (black arrowheads). Thermal change to the soft tissue (black arrows) is visible as slightly swollen collagen bundles with tinctorial change from pink to purple.

tinctorial change: H&E; loss or distorted birefringence: PSR) were seen in the adipose and soft tissue at the periphery of RLN samples in which the LigaSure™ and CoolSeal™ Reveal devices were utilized 0, 1, or 2mm away from the nerve. However, no samples exhibited histologic evidence of epi-, peri-, or endoneurial collagen coagulation, or RLN injury associated with either the CoolSeal™ Reveal or LigaSure™ device usage at any distance from the nerve. Representative histopathological images are shown in Figure 5a–c.

DISCUSSION

Electrosurgical technology has become widespread in a variety of settings and operations. In particular, feedback-responsive bipolar technology is especially useful in surgeries of heavily vascularized areas to achieve hemostasis and delicately dissect tissue from surrounding structures. However, such devices carry risk of imparting thermal spread to adjacent tissue which can cause localized necrosis, delayed wound healing, and damage to other critical structures.[15] The CoolSeal™ Reveal device was designed with smaller, 12mm jaw widths to allow for more precise movement, increased surgical visibility, and reduced collateral damage when dissecting tissue and achieving hemostasis in areas of dense vasculature. Additionally, the generator in the CoolSeal™ Reveal device is purported to utilize a novel energy delivery algorithm which reduces seal time and power needed to achieve adequate hemostasis. Our data showed that mean thermal injury extent was significantly lower in ovine blood vessels sealed with the CoolSeal™ Reveal device compared to those sealed with the LigaSure™ device. Furthermore, injury to the RLN was not seen in association with either device when their seams, which are the hottest part of the devices during sealing, were in direct contact to the nerve (distance of 0mm).

We chose to compare the efficacy of the two devices using vascular bundles associated with the thyroid gland because of the rich blood supply of that area and its anatomic proximity to other vital organs. For these exact reasons, feedback-responsive bipolar devices, such as the LigaSure™, are widely used in thyroid surgery. In such devices, sensors in the jaws of the device are able to detect the density of tissue and impart a corresponding amount of energy to seal and fuse opposing vessel walls. The device is additionally able to sense when sealing is complete to terminate the pulse to minimize thermal spread. Previous studies have shown that the LigaSure™ device reduces total operative time and has intraoperative complication rates comparable to those of conventional hemostasis techniques in thyroid surgery.[16,17] Additionally, use of bipolar technology has been shown to decrease hospital stay and reduce postoperative pain in this setting.[18,19] The data presented herein indicate that the CoolSeal™ Reveal device may further improve upon these advantages and reduce risk of thermal injury. Our data show that the extent of thermal injury for the CoolSeal™ Reveal device was approximately 255µm less than that of the LigaSure™. Additionally, the CoolSeal™ Reveal had reduced thermal spread compared to the LigaSure™ even when stratified by vessel size. Thus, our data indicate that surgeons may be better equipped with the CoolSeal™ Reveal device when operating in areas with such small vasculature. However, it should be noted that the smaller seal widths found with the CoolSeal™ Reveal may, in theory, predispose such seals to increased rates of rebleeding or seal failure. Additional in vivo studies are likely required to definitively compare the rates of adequate long-term hemostasis between the two devices.

As stated previously, damage to adjacent nonvascular structures is an important consideration when assessing the safety of vessel sealing devices. In the case of thyroid surgery, RLN injury is a common and well-documented source of morbidity.[20,21] Previous data has shown that rates of RLN injury in thyroidectomy with use of LigaSure™ was comparable to rates of injury with conventional hemostasis techniques.[22,23] A study by Dionigi et al. examined the safety of the LigaSure™ Small Jaw in RLN dissection and reported that activation of the device should occur a minimum of 2mm away from the nerve bundle.[24] By contrast, we found that neither of the instruments we tested imparted thermal injury to the RLN even when the device was placed in direct contact with the nerve sheath. It is important to note that Dionigi et al. studied the LigaSure™ Small Jaw, while we conducted experiments with the LigaSure™ Exact Dissector, the latter of which may allow for tighter surgical maneuvering with less thermal spread. Our histopathologic data of nerve samples following use of both the CoolSeal™ Reveal and LigaSure™ instruments did not show evidence of any overt thermal damage, focal myelin swelling, multifocal myelin dilation, perineural mucinous material, or collagen degeneration of the endoneurium. Thus, both devices are likely to be safe when used in proximity to critical nerve bundles.

Although we utilized a standardized protocol with animal models to closely replicate in vivo surgical settings as a proof-of-concept model, our study still has certain limitations which are important to consider. Firstly, these experiments were not survival surgeries intended to assess postoperative outcomes or milestones such as additional bleeding, RLN palsy, or wound healing. Additionally, given the very recent development of the CoolSeal™ Reveal device, we sought to examine only its safety with

regard to thermal spread and damage to local tissue in one setting. As a result, we did not study operative time or thermal effects in vascular beds to other organs. Similarly, we only conducted experiments on blood vessels up to 6mm in diameter. Thus, we cannot draw any conclusions regarding the safety and efficacy of the CoolSeal™ Reveal device in larger vessels. Lastly, seal width and injury extent measurements were performed on fixed, processed tissue which exhibits shrinkage during its preparation. Thus, the measurements presented herein represent a lower bound of potential injury for both devices but may be larger in vivo. Nevertheless, data presented herein serve as a proof of concept for the safety of the CoolSeal™ Reveal device as a vessel sealing technology. Further prospective data in in vivo models is required for definitive comparison to current industry standards in clinical settings.

CONCLUSION

In this study, we examined the amount of adjacent thermal damage of a new vessel sealing instrument, the CoolSeal™ Reveal Vessel Sealing device, in comparison to an industry standard device, the LigaSure™ Exact Dissector. Overall, thermal injury extended less than 1000μm (1mm) from the electrothermal seal borders for both the CoolSeal™ Reveal and LigaSure™ devices, although extent of thermal injury with the CoolSeal™ Reveal device was significantly lower than that of the LigaSure™. Neither device imparted thermal damage to the recurrent laryngeal nerve. Thus, the CoolSeal™ Reveal device is a promising instrument that has been shown to be effective in sealing blood vessels while minimizing damage to adjacent tissue. STI

AUTHORS' DISCLOSURES

The authors have no conflicts of interest to disclose.

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