White Paper

Shortcomings of Monopolar Electrosurgery & An Alternative Solution

The Challenge

Monopolar electrosurgery is a widely used surgical technique that creates serious potential risks by using an electrical current to generate the heat necessary to achieve surgical outcomes.Monopolar electrosurgery (MES) conducts an electrical current through a thin electrode at the surgical site to a larger electrode on the patient's body and is used to dissect soft tissues, promote hemostasis, and destroy malignant tissues.[1]

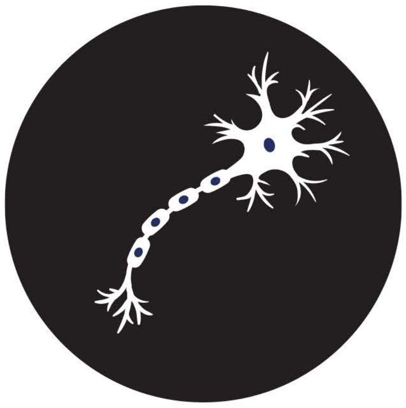
Although MES rapidly provides division and cauterization to the surgical site, the unintended consequences of using electrosurgery can be: **severe collateral tissue damage, nerve damage, tissue edema, seroma/fluid accumulation from tissue liquefaction, surgical smoke, as well as fire ignition hazard.**

Collateral Thermal Spread

MES collateral tissue damage is a significant surgical shortcoming that continues to be evaluated by physicians and researchers to seek a safer method of achieving hemostasis and surgical precision.[2] The electrical current used to achieve hemostasis and incise tissue causes substantial heat dissemination that readily spreads to surrounding tissues.[3]

A 2020 study concerning MES in rabbit appendectomies found that intestinal perforation was strongly correlated with the length of exposure to the electrode, as **thermal spread led to tissue damage in approximately 1.5 seconds.**[4]

The damage caused by this thermal spread can significantly diminish the viability of adjacent healthy tissue, and in specimen resection, monopolar alters the tissue sample artifact and surgical margins for pathology. Scorched tissues may swell, creating patient pain and leading to increased incidence of seroma. Potential for unintended tissue injury is intensified by the conductivity of surgical instruments and patient jewelry.



Nerve Damage

Nerve damage is a concern when MES is used because central nervous tissue does not regenerate.[5] Although peripheral nervous tissue has functional regenerative capacity, there is evidence of myelin and axon damage as a result of electrocautery.[6] A study examining injury to the sciatic nerve following three types of dissection techniques concluded that MES was responsible for a reduction in electromyographic potential far more frequently than alternative techniques.[7]

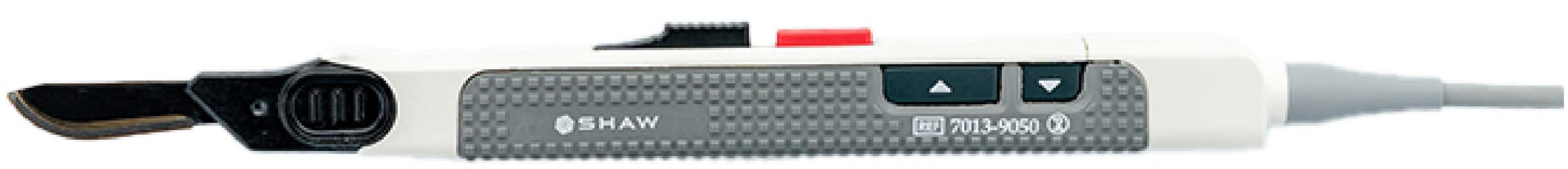
Safety Concerns

The use of MES during surgery for patients with implanted electronic devices can lead to malfunctions in how these devices interact with their target tissues. The electromagnetic interference created by MES can be mistaken for cardiac signals, thereby preventing pacemakers from responding appropriately.[8] Electrosurgery is also contraindicated for patients with cochlear implants, cardioverter-defibrillators, nerve stimulators, deep brain stimulators, and spinal cord stimulators.[9] Surgeons must be aware of the brand and specifications of each implanted device in patients undergoing an operation in order to ensure surgical and patient safety.

Surgical use of MES requires a separate instrument for hemostasis following incision. The lack of immediate coagulation leads to the accumulation of blood in the surgical site. As a result, the patient experiences greater blood loss and the surgeon must operate at a slower pace due to reduced visibility. This surgical challenge creates a greater risk for the patient, as procedural complexity increases and more tissue is dissected.[10]

The Shaw Scalpel is the only surgical instrument that uses controlled thermal energy (heat) to seal blood vessels as they are incised.

The Shaw Scalpel is a hybrid device that provides the best traits of a traditional scalpel and what IS desired from electrosurgery - WITHOUT the consequences of radiofrequency monopolar electrosurgery.



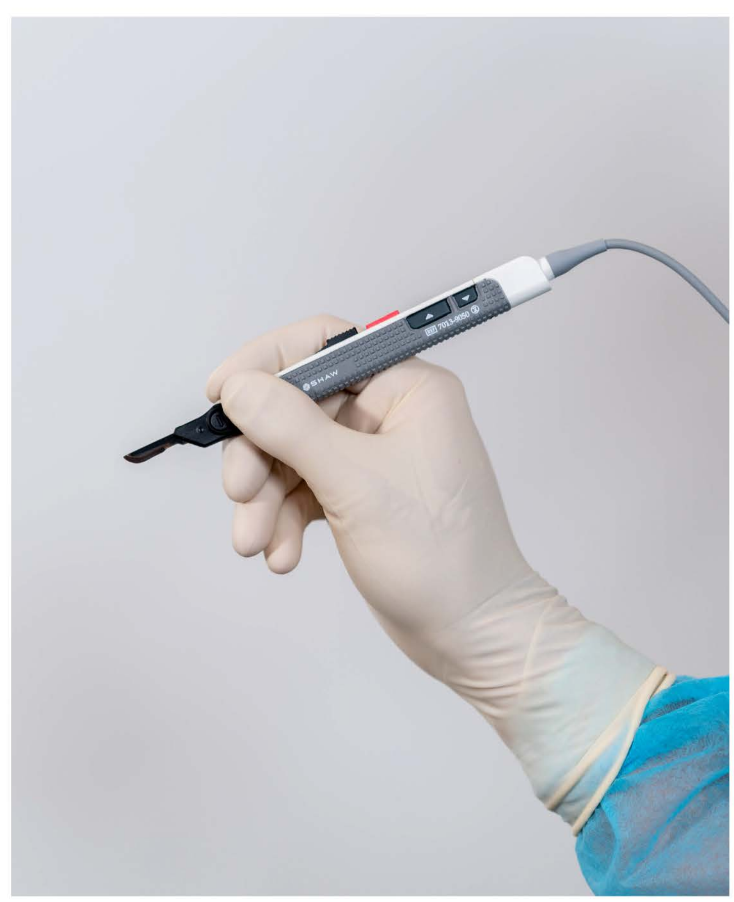
The Blades

The Shaw Scalpel blades are engineered for performance. The 5-layer laminated copper and stainless steel blade with a micro-printed circuit allows for precise, sharp, non-stick dissection with instantaneous heat transfer to bleeding surfaces. Surgeons can control and maintain desired blade temperatures (between 70-300°C) via a continual feedback loop. The blade can be used seamlessly with or without the application of heat, mitigating switching from a traditional steel scalpel to a monopolar.

When energized, the Shaw Scalpel completely insulates the patient from electrical currents and traditional grounding techniques are not required. The lack of muscle excitation creates a stable surgical field and tissue planes, enhancing operative efficiency. Small vessel bleeding and collateral tissue damage are minimized, promoting visibility during surgical procedures.

The Handle

The Shaw Scalpel handle provides the same, trusted feel from the traditional steel scalpel. The intuitive, built-in handle controls allow for intra-operative blade temperature adjustments while you control the speed and rate of cut depending on tissue type, density, and vascularity.



The Proof

The re-engineered Shaw Scalpel has been used in over 1 million procedures over the last 40 years. Historically used in head and neck procedures, the surgically sharp blade and the ability for immediate hemostasis enable physicians to achieve exceptional visualization with a dry, clean surgical field. One study noted a 39% reduction in blood loss compared to the cold steel scalpel during radical neck dissection.[11]

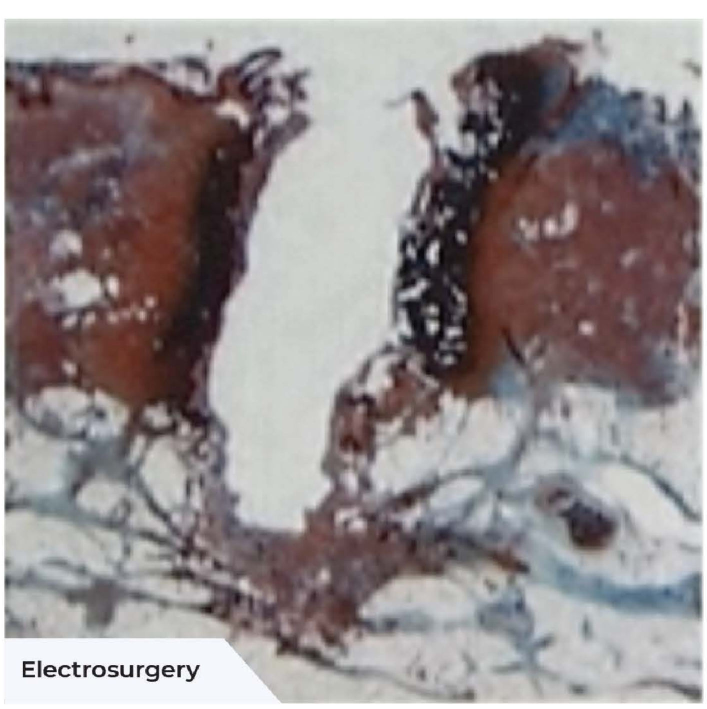
The Shaw Scalpel is an advantageous and effective surgical tool for all surgeons, particularly those who work around nerves, critical anatomy, and those focused on surgical oncology.

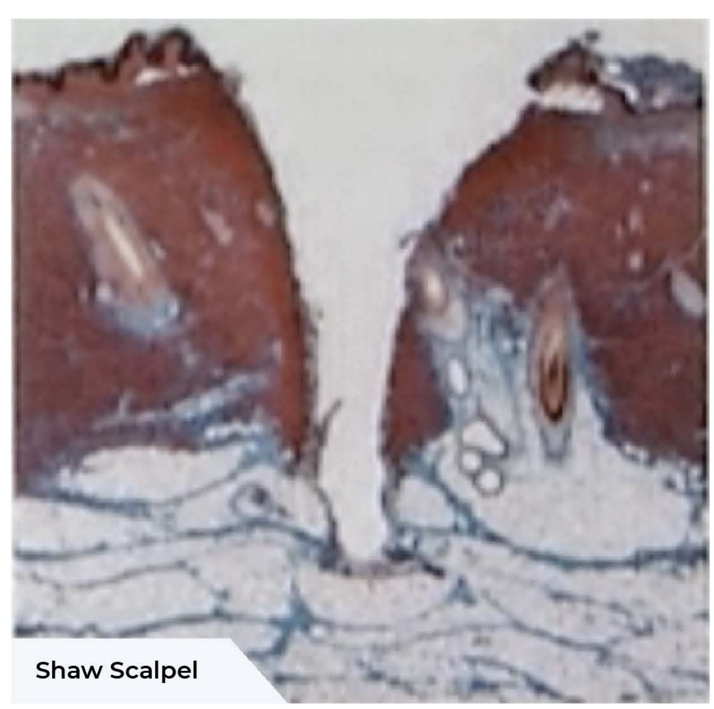
Gentle on Tissue

The Shaw Scalpel preserves tissue as it dissects. Heat from the blade is transferred to incised tissue within a narrow margin and with no undesirable spread.

A study analyzing wound healing with the thermal scalpel compared to the cold steel scalpel found no statistically significant difference in healing, from both a histologic and tensile strength perspective, at the 8-week post-operative time.[12] Moreover, another study concluded a reduced incidence of nerve weakening and recovery time compared to traditional methods.[13] When comparing traditional hemostatic methods, such as MES and Raney Clips, Raney Clips resulted in the greatest alopecia width.[14]

Dissected Tissue Comparison





No Nerve Damage

A study evaluating parotid gland surgeries found that only 31% of patients who underwent a superficial parotidectomy via Shaw Scalpel experienced temporary partial facial nerve paralysis, versus 43% of patients who were operated on with electrocautery.[13]

> **The Shaw Scalpel has become an indispensable part of my surgical technique. It minimizes blood loss for the patient, maximizes my surgical efficiency, and nicely preserves visibility during my dissection. It has a limited radius of energy dispersion which is essential for working in the crowded anatomy of the neck where many important nerves and other structures are in close proximity."**
>
> **Donald B. Kamerer Jr., MD**

Safety and Control

The Shaw Scalpel is a safe dissection instrument for patients with CIEDs. A patient with breast cancer was scheduled for a mastectomy 2 cm away from her pacemaker, and the Shaw Scalpel System ensured successful tissue removal while protecting the electrical function of the pacemaker.[15]

While electrosurgery is contraindicated for cochlear implant surgery due to the electrical current, the Shaw Scalpel can be used to safely implant and replace such devices without compromising their internal components.[16]

About C2Dx

C2Dx is a medical device company that acquires and invests in underserved products to propel their impact worldwide.

Founded in early 2019 by industry experts, C2Dx is committed to providing leading medical products and superior customer service while continually evolving to ensure that healthcare providers have the devices and technology they need.

Contact C2Dx to learn how the Shaw Scalpel can maximize your surgical technique and optimize outcomes

(888) 902-2239 c2dx@c2dx.com www.c2dx.com

Sources

1. Cordero, I. (2015). Electrosurgical units – how they work and how to use them safely. Community Eye Health 28(89), 15-16.
2. Brill, A.I., Feste, J.R., Hamilton, T.L., Tsarouhas, A.P., Berglund, S.R., Petelin, J.B., Perantinides, P.G. (1998). Patient Safety During Laparoscopic Monopolar Electrosurgery – Principles and Guidelines. Journal of the Society of Laparoscopic & Robotic Surgeons 2(3), 221-225.
3. Dodde, R., Gee, J.S., Geiger, J., Shih, A. (2022). Monopolar Electrosurgical Thermal Management for Minimizing Tissue Damage. IEEE Transactions on Biomedical Engineering 59(1), 167-173.
4. Nechay, T.V., Titkova, S.M., Anurov, M.V., Mikhalchik, E.V., Melnikov-Makarchyk, K.Y., Ivanova, E.A., Tyagunov, A.E., Fingerhut, A., Sazhin, A.V.(2020). Thermal effects of monopolar electrosurgery detected by real-time infrared thermography: an experimental appendectomy study. BMC Surgery 20(116).
5. Huebner, E.A. & Strittmatter, S.M. (2009). Axon Regeneration in the Peripheral and Central Nervous Systems. Results and Problems in Cell Differentiation 48, 339-351.
6. Dagtekin, A., Comelekoglu, U., Bagdatoglu, O.T., Yilmaz, S.N. (2011). Comparison of the effects of different electrocautery applications to peripheral nerves: An experimental study. Acta Neurochirurgica 153(10), 2031-2039.
7. Carlander, J., Johansson, K., Lindstrom, S., Velin, A.K., Jiang, C.H., Nordborg, C. (2005). Comparison of experimental nerve injury caused by ultrasonically activated scalpel and electrosurgery. British Journal of Surgery 92(6), 772-777.
8. Madigan, J.D., Choudhri, A.F., Chen, J., Spotnitz, H.M., Oz, M.C., Edwards, N. (1999). Surgical Management of the Patient with an Implanted Cardiac Device. Annals of Surgery 230(5), 639.
9. Morris, C.R. & Hurst, E.A. (2019). Electrosurgery and Implantable Electronic Devices: A Survey of Current Practices among Cutaneous Surgeons. The National Society for Cutaneous Medicine 3(5), 326-334.
10. James Gallo, W., Moss, M., & Gaul, J. V. (1986). The Shaw scalpel: Thermal control of surgical bleeding. International Journal of Oral and Maxillofacial Surgery, 15(5), 588–591. https://doi.org/10.1016/s0300-9785(86)80064-3
11. Takagi, R., Ohashi, Y., & Abe, M. (1985). Blood loss with use of the Shaw Scalpel® for the treatment of oral cancer. Journal of Oral and Maxillofacial Surgery, 43(8), 580–584.
12. Millay, D.J., Cook, T.A., Brummett, R.E., Nelson, E.L., O'Neill, P.L. (1987). Wound Healing and the Shaw Scalpel. Archives of Otolaryngology –Head & Neck Surgery 113, 282-285.
13. Fee, W.E., Jr. & Handen, C. (1984). Parotid Gland Surgery Using the Shaw Hemostatic Scalpel. Archives of Otolaryngology 110, 739-741.
14. Kadakia, S., Badhey, A., Ashai, S., Lee, T.S., Ducic, Y. (2017). Alopecia Following Bicoronal Incisions. JAMA Facial Plastic Surgery 19(3), 220-224.
15. Tokumine, J., Sugahara, K., Matsuyama, T., Nitta, K., Fuchigami, T., Miyaguni, T. (2005). Shaw Scalpel for Breast Mastectomy in a Pacemaker Implanted Patient. Journal of Anesthesia 19, 345.
16. Roland, J.T., Jr., Fishman, A.J., Waltzman, S.B., Cohen, N.L. (2000). Shaw scalpel in revision cochlear implant surgery. Annals of Otology, Rhinology & Laryngology 185, 23-25.