Use of the Shaw Scalpel in Podiatric Surgery

The Shaw[4] scalpel is an electric device that produces instantaneous hemostasis through the direct transfer of heat in order to seal severed blood vessels. It offers an improved method of surgical hemostasis without the muscle stimulation and tissue damage of conventional electrosurgical units. In this presentation, the authors introduce this new hemostatic scalpel, illustrate its use in podiatric surgery, and review results of investigational trial efficacy.

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The achievement of hemostasis is of clinical importance to both patient and surgeon. The bleeding that occurs when blood vessels are severed not only reduces visability and precision, but also contributes to potential infection and can be a contributing factor in the increased morbidity of postoperative patients (1). Surgeons have been concerned with the control of hemmorhage since ancient times. It has not been until the twentieth century, however, that modern methods of hemostasis have been developed. Conventional electrosurgical units (ESU) have been employed with acceptable results, but tissue damage has been reported with their use (2). Therefore, a new thermally activated scalpel, the Shaw scalpel, has been developed by the Oximetrix Corporation that seals blood vessels with heat conducted from the blade, and maintained at a steady temperature from a control panel. This permits the surgeon to maintain careful control over the degree of tissue injury and avoid unnecessary muscle stimulation. Since an electric current is not passed through the patient, there is no need for patient grounding and no risk of grounding pad burns.

In this presentation, the Shaw scalpel system is introduced as a new modality of surgical hemostasis and its product design, technical application, and clinical efficacy are reviewed.

Review of the Literature

In the past several years, investigators have reported on the use of the Shaw scalpel in various surgical specialties. For example, Tromovitch and his associates (3) used the scalpel in 150 dermatologic cases that involved incisions performed around the eyes, ears, nose, cheek, and forehead. They reported excellent cosmetic and functional results. Similarly, in the management of severe burns, Fidler *et al.* (4) stated that the thermal scalpel was an excellent instrument for debridement of necrotic tissue. In 1981, Fee (5) performed 58 head and neck operations on fifty patients with an age range of 1 to 97 years. He concluded that the Shaw scalpel was a very "worthwhile tool" in 70% of the cases, with absolutely no increase in the incidence of complications, when compared to traditional techniques. Since then, several hundred cases involving a variety of procedures in pediatric, vascular, plastic, ophthalmic, and orthopedic surgery, have been performed with equally gratifying results.

Product Design

The Shaw scalpel system used scalpel blades and handles that are similar in handling characteristics to conventional cold steel instruments. However, it is designed so that the cutting edge of the blade may be elevated to a selected temperature that instantaneously seals blood vessels as they are cut. The degree of heat can be controlled to give varying degrees of hemostasis, depending on the type of tissue being incised or excised. No electric current is generated in the tissue by the scalpel itself and hemostasis is induced by direct transfer of heat from the edge of the blade. The temperature control mechanism on the scalpel automatically delivers additional thermal energy to only those regions of the blade losing heat to tissue contact. The scalpel may be used cold (without hemostasis) or hot (with hemostasis), and the entire system consists of the following three physical components.

Blades. Scalpel blades are constructed of surgical grade components and are coated with copper and

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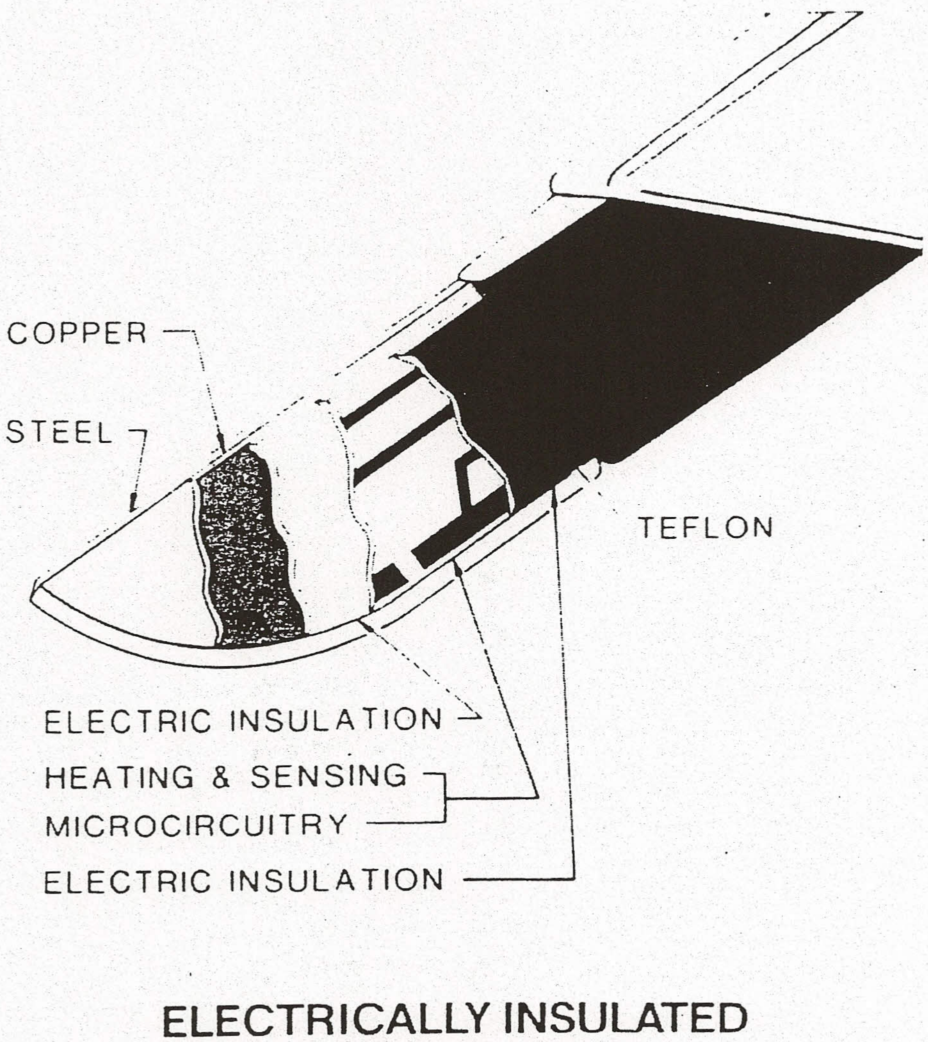


Teflon on their cutting edges. There are three individual sensing units along the belly of each blade (Fig. 1). The blades are supplied in standard no. 10 and no. 15 sizes, and can be fashioned into a variety of shapes.

Handle. A reusable handle, which can be sterilized with ethylene oxide, connects to the control panel with a lightweight and flexible cable. The scalpel blades are inserted into the handle and the temperature can be controlled in increments of 10°C, ranging from 110°C to 270°C. Recommended temperatures are 110°C for epidermal incisions; 240 to 260°C for subcutaneous tissue, muscle, and fat dissection; and 270°C for ligation of blood vessels larger than 0.5 mm. in diameter (Fig. 2). Upon activation of the circuit, the blade reaches the programmed temperature in seconds, and upon deactivation cools quickly so there is little chance of having the blade inadvertently hot.

Control Panel. An electric control panel and power supply source provides various automatic calibrations, sensing and control functions, and has visible and audible indications of instruments and control status. The control panel operates on standard hospital 115-V/60 Hz electrical power, using a conventional electric cord (Fig. 3).

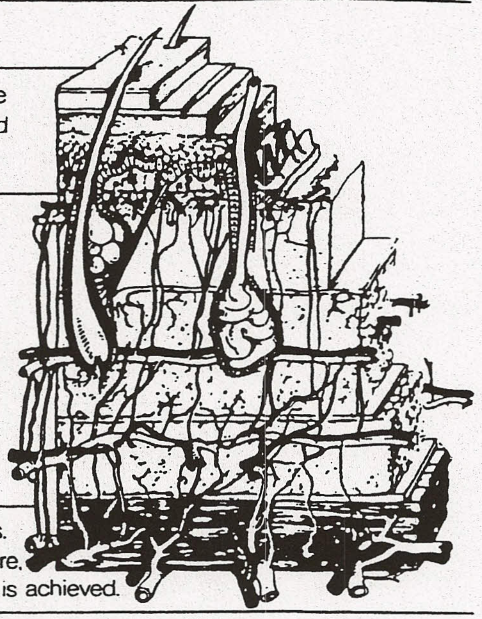
Materials and Methods

A variety of surgical procedures were performed among 128 patients at Atlanta Hospital and Medical Center in order to evaluate the efficacy of the Shaw scalpel. Procedures were divided into three categories for classification: 1) forefoot surgery, 2) rearfoot surgery, and 3) leg surgery. Forefoot procedures included all types of digital, metatarsal, and hallux valgus repair, including implant arthroplasties. Rearfoot procedures included flatfoot and cavus foot reconstruction, midtarsal osteotomies, and major tarsal fusions incorporating bone-grafting techniques. The last category, leg surgery, encompassed the harvesting of full thickness

Time/Temperature Relationship

Adequate hemostasis will result if the time/temperature combination is correct. To improve hemostasis, increase temp and/or prolong contact.

Tissue	Suggested Temperature*	Time
Epidermis, Superficial Dermis	110°C	Make a shallow dermal incision—Use the same cutting pressure and speed as with a regular scalpel.
Deep Dermis Subcutaneous Tissue, Fat, Muscle, Fascia, Small Blood Vessels	240–260°C	Use the same cutting pressure as with a regular scalpel—use a longer, more deliberate cutting stroke.
Large Blood Vessels, Bleeders	270°C	The entire blade provides hemostasis. Seal blood vessels with lateral pressure, maintaining contact until hemostasis is achieved.



*Suggested temperatures only: Use cold on skin for MOHS surgery, lower temperatures may provide adequate hemostasis in pediatric procedures, use at 180°C on mucosa.

Figure 2. Recommended time/temperature relationships of various tissue planes.

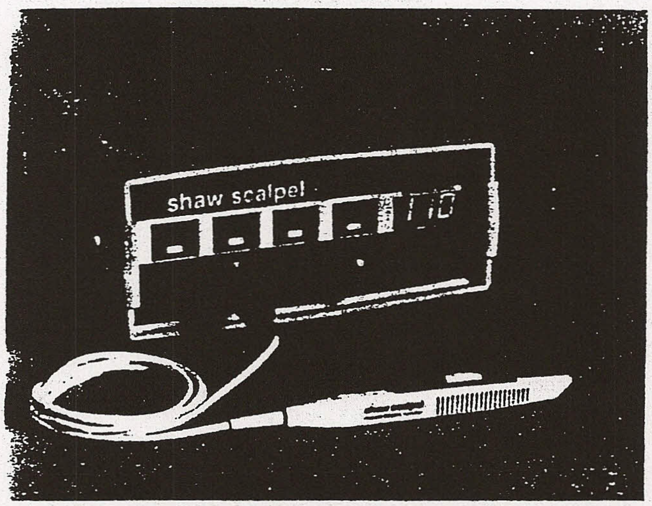


Figure 3. Shaw scalpel system control panel with reusable handle.

skin grafts, Achilles tendon surgery, major tendon transfers, and ankle joint fusions. Virtually no podiatric procedure was left untested and a total of 300 individual procedures were evaluated.

The scalpel system was then subjectively judged by surgeons of Atlanta Hospital according to a numerical scale based on a point system: 1 = worthless, 2 = poor,

Results

The results of the evaluation are shown in Table 1. The effectiveness of thermal hemostasis received mean

TABLE 1. **Results of subjective evaluation**

Type of Surgery	Mean Score		
	Hemostasis	Blade Sharpness	Average (Combined)
Forefoot	3.1	3.7	3.4
Rearfoot	3.9	3.3	3.6
Leg	4.2	4.4	4.3

scores of 3.1, 3.9, and 4.2 in forefoot surgery, rearfoot surgery, and leg surgery, respectively. This progressive acceptance in larger surgical procedures was believed to result from inceasing size and importance of blood vessel hemostasis.

Blade sharpness received mean scores of 3.7, 3.3, and 4.1 as one progressed from forefoot to leg surgery. The slight decrease in approval for rearfoot surgery was a direct consequence of the increasing difficulty encountered in the dissection of periosteal tissue off larger tarsal bones. Increased blade flexibility was encountered with mixed opinions as to its effectiveness. Most surgeons agreed however, that the efficacy of the thermal scalpel system seemed to increase as one moved proximally up the extremity.

Finally, most surgeons initially reported that the cutting technique required for effective use of the Shaw scalpel was unfamiliar to them. A slower cutting speed with longer strokes was required to maintain meticulous hemostasis at every step. Such technique obviated the need to return to the same area to coagulate bleeding vessels. Familiarity with the instrument indicated that once experience was obtained, the result was a more precise and satisfactory overall procedure, with a net reduction of operating room time and blood loss.

Discussion

Controlled animal studies using the Shaw scalpel were conducted in 1978 (6). The postoperative wound healing was measured in paramedian incisions made in Sprague-Dawley rats, with an ordinary scalpel, a conventional electrosurgical unit, and the Shaw scalpel. Breaking strengths were then measured at 7 to 42 days and were highest in the incisions made with a conventional scalpel and the Shaw scalpel. The only difference was noted at 21 days, in favor of the conventional scalpel (Fig. 4). In contrast, both the conventional scalpel and the Shaw scalpel produced stronger wounds than incisions made with the Bovie in either of its "coagulation" or "cutting" modes, at most testing levels.

In similar studies, the comparative infection rate of incisions made with the Shaw scalpel and conventional scalpel were determined. Rat incisions were inoculated with 10^8 viable *Pseudomonas aeruginosa* organisms. No wound infection developed in either group; however, incisions made with standard Bovie units did become infected (7). *In vivo* and *in vitro* toxicologic studies have shown Shaw scalpel blade materials to be both nontoxic and nonhemolytic (8).

Summary

One hundred patients undergoing a variety of foot and leg surgical procedures were used in clinical trials to study a new thermally activated scalpel system. Subjective equipment evaluation resulted in mean scores of 3.7 (1 = worthless and 5 = excellent) for effectiveness of hemostasis, and 3.8 for blade sharpness. The system offers a unique method of hemostasis without the tissue damage and muscle stimulation of conventional electrosurgical units. Therefore, the Shaw scalpel system is being introduced to the profession and deemed a valuable tool in podiatric reconstructive surgery.

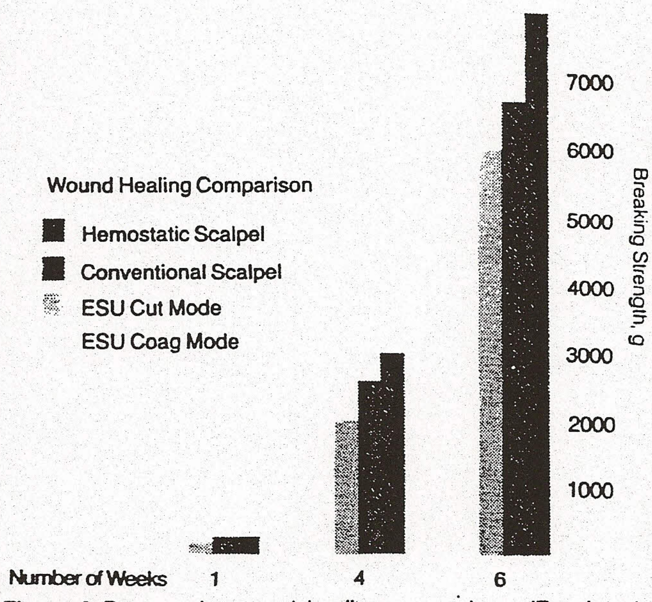


Figure 4. Bar graph wound healing comparison. (Reprinted with permission of Stanley Levenson, M.D., Albert Einstein College of Medicine, New York, N. Y. and Oximetrix Corporation.)

Acknowledgments

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Comment: It has been well documented that precise hemostasis prevents complications such as hematoma formation and residual bleeding after podiatric surgical techniques. Complications with the traditional coagulaton methods have been burning of the dermis and epidermis when coagulation takes place too near the skin surface, and excessive burning of soft tissues around the surgical site. The Shaw scalpel is an excellent concept concerning coagulation at both the epidermal/dermal and subcutaneous levels. The variable heating elements are an added advantage because of the ability to control precisely the amount of coagulation that is necessary in foot and ankle surgery with varying levels of subcutaneous tissue. The concept has been well thought out and developed by Dr. Shaw. The principle is very applicable to forefoot, rearfoot, and ankle reconstructive procedures. The statistics indicate that the device becomes more acceptable with continued use. The Shaw scalpel is an interesting addition to the podiatric surgeon's armamentation of precise and sophisticated surgical instruments.

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