Refer to: Fee WE Jr, Use of the Shaw scalpel in head and neck surgery. Otolaryngol Head Neck Surg 89:515-519 (July-Aug) 1981.

USE OF THE SHAW SCALPEL IN HEAD AND NECK SURGERY

WILLARD E. FEE, JR, MD, Stanford, California

Fifty patients undergoing a variety of head and neck surgical procedures were used to study a new thermally activated scalpel. No electric current passes through the patient and, thus, no ground pad is needed. Subjective equipment evaluation resulted in mean scores of 3.8 (1 = worthless and 5 = excellent) for effectiveness of hemostasis and 4.1 for blade sharpness. The Shaw scalpel system is a worthwhile surgical tool 70% of the time. It is excellent for raising flaps and for use in precise surgery where small capillary bleeding typically obscures visibility (ie, parotid surgery).

OPERATIVE hemostasis is the control of bleeding that occurs when living tissues are cut and conventionally occupies a significant portion of surgical operating time. Producing hemostasis is a necessary requisite to prevention of the most common surgical complication (hematoma) but it also represents drudgery to the surgeon and increases operating time. Dessication of bleeding vessels using conventional electrosurgical units (ESU), commonly the Bovie, while effective, creates significant tissue damage; some surgeons choose to tie off troublesome bleeders rather than produce the additional tissue damage that is associated with the ESU. This report presents a new scalpel that energizes the cutting edge of conventionally sharpened scalpel blades in such a fashion that heat is used to seal small blood vessels, with minimal tissue damage, as they are cut.

METHODOLOGY

The new scalpel, invented by Robert Shaw, MD, is manufactured by Oximetrix, Inc, Mountain View, Calif, and is shown in Fig 1. The controller unit operates using standard hospital power supply (115 V, 50 to 60 Hz) to provide a pulsed-DC current used to heat the scalpel to a user-selected, elevated temperature in the range of 110 C to 280 C. The blades may also be used cold, as with a conventional scalpel. The controller senses and powers microelectronic circuitry in the scalpel blade to maintain the blade at the desired temperature within extremely narrow limits.

The patient is insulated from the electronics of the Shaw scalpel; as a result there are no patient electrical currents nor ground pad needed to use the system.

The Shaw blade used in most of this study had a profile similar to the Bard Parker No. 15 blade and schematic diagrams are shown in Fig 2 and 3. Currently, profiles similar to Bard Parker blades No. 10, No. 15, and No. 20 are available and additional shapes and sizes will be available in the near future. The blade-temperature-regulating electronics in the system are sophisticated enough to compensate for varying heat losses depending on the type of tissue being incised and the rate in which cutting is carried out. During the current investigation, two prototype controllers were used with several modifications made until the final unit, as shown in Fig 1, was developed. Modifications in the blade design were also made by the manufacturer during the course of investigation, particularly with regard to improving blade sharpness.

Submitted for publication April 14, 1981.

From the Division of Otolaryngology, Head and Neck Surgery, Stanford University Medical Center, Stanford, Calif.

Presented as a *New Instrument* at the 1980 Annual Meeting of the American Academy of Otolaryngology, Anaheim, Calif, Sept 28-Oct 2.

Reprint requests to Division of Otolaryngology, Head and Neck Surgery, Stanford University Medical Center, Stanford, CA 94305.

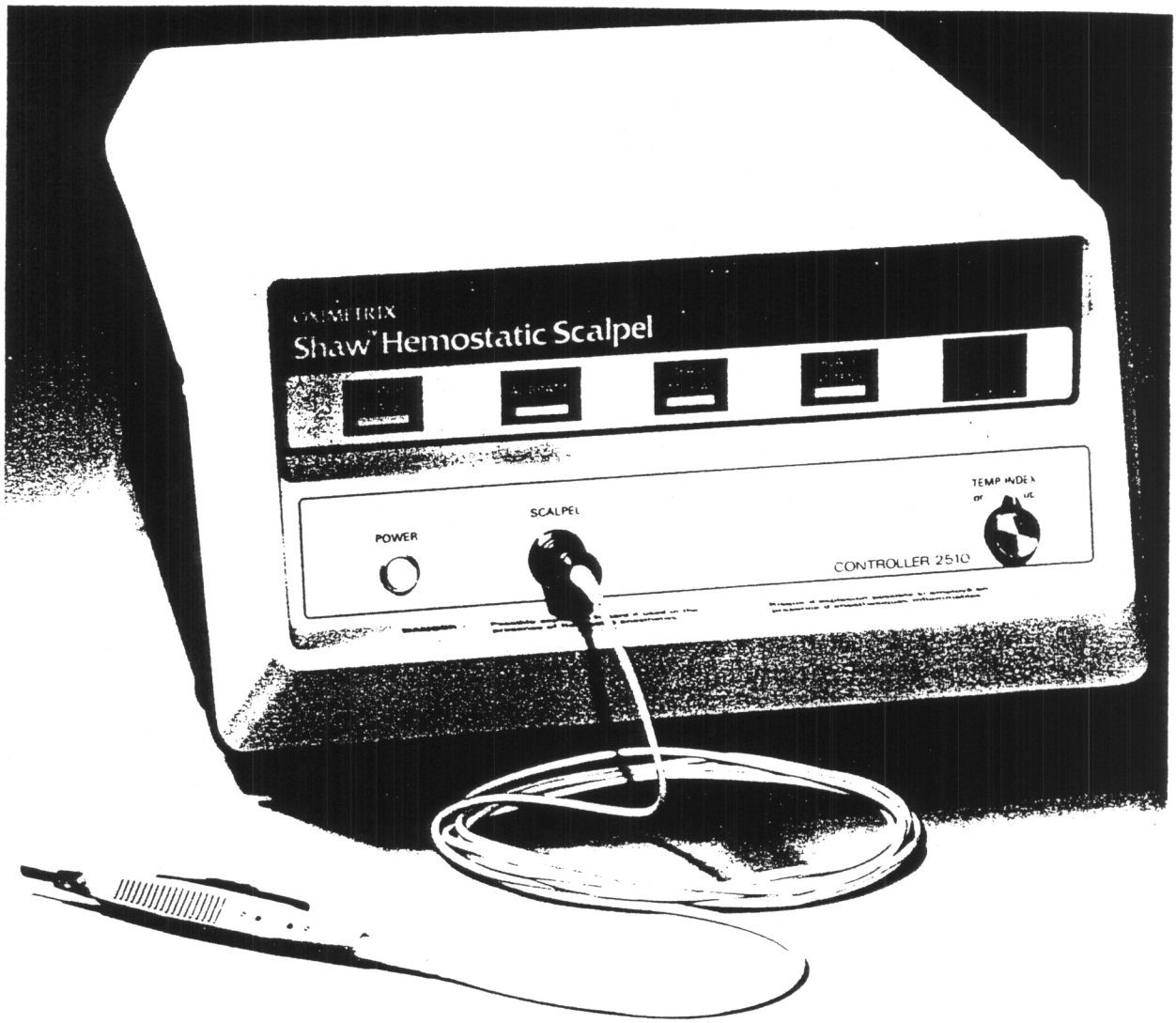

Fig 1.—Shaw hemostatic scalpel controller, handle, and No 15 blade.

Fifty patients were studied between July 1979 and June 1980. All patients signed an informed consent approved by the Stanford University Human Investigation Committee. The patients were monitored closely for a minimum of three months for complications operatively or postoperatively or both.

Equipment evaluation was subjectively evaluated by the investigator and his operating assistant independently on a numerical scale based on 1 = worthless, 2 = poor, 3 = fair, 4 = good, and 5 = excellent. If the two were in disagreement, then an average of the two scores was used.

RESULTS

Twenty-eight males and 22 females with a mean age of 43 years and an age range from 1 to 97 years underwent 58 head and neck operations as shown in Table 1. Surgical complications are shown in Table 2. Noteworthy is that in 2 of 13 parotidectomies (15%) postoperative seventh nerve paresis developed; one patient had a 30% paresis and another had 80% paresis; both resolved spontaneously without synkinesis within two months. Small pneumatoceles that developed in two tracheal reconstruction patients postoperatively resolved with aspiration and pressure dressings within a week. A delayed hematoma developed in one parotidectomy patient at five days and the patient required rehospitalization and a return to the operating room for control. A small seroma developed in one patient in the inferior aspect of a radical neck dissection. The seroma required no treatment. Cellulitis developed in another patient on the second postoperative day and it resolved with antibiotic

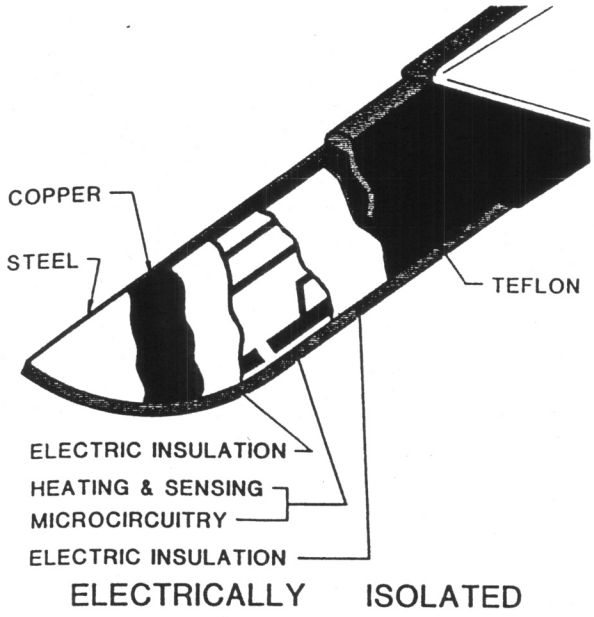

Fig 2.—Cut away drawing showing electrically isolated microcircuitry.

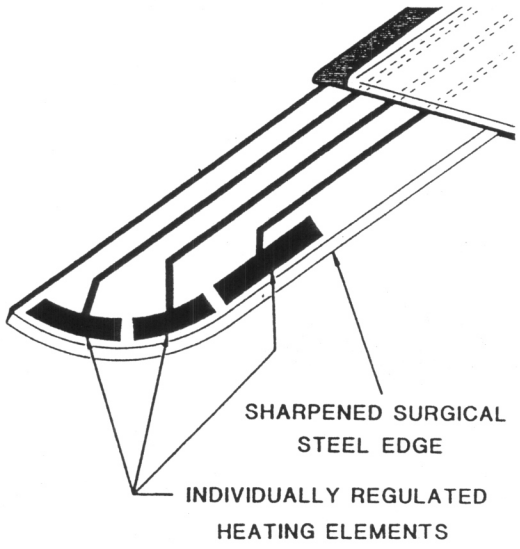

Fig 3.—Diagrammatic representation of No. 10 blade showing heating elements.

therapy. One patient who underwent a radical neck dissection for recurrence following 7,000 rads to his neck was judged to have slow wound healing, which was most likely secondary to his prior unplanned radiation. The above complication rate (16%) is not dissimilar to our complication rate prior to usage of the Shaw scalpel system. A third degree skin burn directly attributable to the Shaw scalpel system developed in a patient; this complication was a preventable technical

TABLE 1

TYPES OF OPERATIONS

Supraneural parotidectomy	7
Total parotidectomy	6
Composite resection	4
Radical neck dissection	4
Modified neck dissection	4
Resection neck mass	4
Laryngeal or tracheal reconstruction or both	5
Skin flap reconstruction	4
Total laryngectomy	2
Partial laryngectomy	4
Tonsillectomy	3
Miscellaneous (thyroidectomy, face lift, tracheotomy, sinus surgery)	11
Total	58

error when the scalpel was used at a temperature of 230 C to raise a dermal flap to facilitate wound closure. The temperature setting should have been adjusted to a lower level (110 C) to prevent this complication.

Subjective evaluation of the equipment is shown in Table 3. The effectiveness of hemostasis received a mean score of 3.8 and a range of from 1 to 5. In general, as experience developed with the system, its efficacy improved as I was not sure what was the best temperature setting for each clinical situation in the early phases of the study. Blade sharpness received a mean score of 4.1 with a range of from 2 to 5. Blade sharpness steadily improved as the study progressed, but the consistency of sharpness relative to Bard Parker scalpels was not uniform. Some blades were as sharp or sharper than Bard Parker blades and maintained their sharpness for a prolonged period of time (15 to 20 minutes of cutting) while others were as sharp as Bard Parker's, but appeared to dull more quickly and still others were not as sharp initially.

Although an attempt was made to determine if any savings in operating time ensued as a result of using the Shaw scalpel system, it was impossible to do so because of the fact that no adequate control existed in view of the lack of identical tumor sizes and positions, age, and clinical conditions of patients, etc. To optimize the effectiveness of the unit, a modification of surgical technique is required: the actual cutting should proceed at a slower than ordinary rate. The slower cutting is more than compensated for by the reduced time required to achieve hemostasis. Certainly, there was no apparent increase in operative time as a result of using the unit.

TABLE 2

SURGICAL COMPLICATIONS

NO.	TYPE	RESULT
2	Temporary seventh nerve paresis	One 30%, one 80% resolved spontaneously
2	Pneumatocele	Resolved spontaneously
1	Delayed hematoma	Required return to OR
1	Seroma	Required no treatment
1	Cellulitis	Resolved with antibiotics
1	Slow wound healing	Post 7,000 rads
1	Skin burn	Technical error, resolved with wound care

TABLE 3

	MEAN SCORE	RANGE
Hemostasis	3.8	1 to 5
Blade sharpness	4.1	2 to 5

While difficult to quantify with precision, there was a distinct impression that a fewer number of transfusions were required for major head and neck operations. For example, one total parotidectomy with upper chain cervical node resection procedure was performed with a less than 25 cc total blood loss and one tonsillectomy was performed with a less than 5 cc loss and did not require packing or ESU coagulation. Overall, the reliability of the unit was judged to be good. One note of caution—if the ESU is used in conjunction with the Shaw scalpel, great care must be exercised not to touch the blade with the activated ESU as this will result in internal damage to the electronics in the Shaw controller unit.

Skin incisions were made initially with a blade in a cold mode and as experience developed temperature settings in the 120 to 150 C range were used. At 150 C, 1 mm of skin erythema representing heat damage was seen in some patients, but did not result in any untoward wound healing; the cosmetic results were judged to be excellent. Nonetheless, I now routinely use the blade heated to a temperature in the 110 to 120 C range and sacrifice some of the hemostatic advantages of higher temperatures. After cutting through the dermis, the blade temperature is raised to the 180 to 250 C range, with a setting at 220 C being the most common temperature. At higher temperatures, cutting through muscle, thyroid, and parotid resulted in a whitish discoloration of these tissues akin to the coagulative protein that occurs when an egg is poached. There appeared to be a wide subject variation in response to the temperature selected: in some patients 180 C was sufficient to achieve excellent hemostasis while in others 250 C was not. In those patients who had diabetes, moderate to severe atherosclerosis, or old age, hemostasis results were not as good as in young, healthy individuals.

DISCUSSION

Controlled animal studies using the Shaw scalpel system have been conducted by Stanley M. Levenson, MD, during 1978 and 1979.[1] Postoperative wound breaking strength was measured in paramedian incisions made in male Sprague-Dawley rats with an ordinary scalpel, the Shaw scalpel, an ESU in the coagulation mode, and an ESU in the cutting mode. Wound healing and breaking strength were tested at 7 to 42 days and were highest in the incisions made with a conventional scalpel and the Shaw scalpel system. The only statistically significant difference between the Shaw scalpel and the conventional scalpel was noted at 21 days in favor of the conventional scalpel. In contrast, both the conventional scalpel and the Shaw scalpel produced statistically stronger wounds than incisions made with the ESU in either of its "coagulation" and "cutting" modes at most testing intervals. Dr Levenson reported that there was no instance of wound infection and no evidence of adverse systemic effects in any rats.

Prior work has reported that wounds made with an ESU device show less resistance to infection than wounds made with the cold scalpel. In the animal studies referenced previously, Dr Levenson also examined the comparative wound resistance to infection of the Shaw scalpel and the conventional scalpel by purposely inoculating skin incisions made in rats with

the Shaw scalpel at various elevated temperatures, and with a conventional cold steel scalpel just before closure with up to 10^8 viable *Pseudomonas aeruginosa* or *Staphylococcus aureus*. No wound infection developed in either group.

In vivo and in vitro toxicologic studies have been performed by Huntingdon Research Center in Baltimore, and in Biotechnics Laboratories, Inc, in Los Angeles. The tests performed have shown the blade materials to be both nontoxic and nonhemolytic.[2]

Glover et al[3] have an excellent technical review on the surgical use of ESU, lasers, and plasma scalpels. They report that temperatures as high as 500 to 600 C were measured on the surface of carbonized tissue. Key to the understanding of tissue effects of using thermally activated scalpels is the understanding of the influence of blood perfusion on thermal damage and the time-temperature relationship in producing tissue injury. Irreversible cell damage begins to occur at 44 C after an exposure of seven hours but requires only a one-second exposure at 70 C. While this poses certain theoretic questions with regard to the temperatures used with this instrument (120 to 250 C), it was not clinically significant. However, no tissue thermal probes were used in this study and, thus, actual tissue temperatures are unknown.

Advantages of the Shaw scalpel system include less drudgery in achieving hemostasis, a probable reduction in the number of transfusions, better visibility at the incision site, and, when raising flaps, less apparent tissue damage than ESU, no ground plate necessary, and no electric current through the patient, ability to cut muscle without excitation, and the presence of tactile sensation when cutting as opposed to the cutting mode of the Bovie. Disadvantages include an approximately five-second waiting time between blade changes, an additional expense to the patient (this may be offset by a reduction in operative time or reduction in transfusions or both), and regulation of the blade temperature by the circulating nurse (a new scalpel handle is now available where the surgeon can regulate the temperature).

This instrument is a worthwhile surgical tool for the head and neck surgeon 70% of the time. No adverse effects occurred the other 30%, but there was no advantage either. In many cases, the Bovie was not used during operative procedures in which the Shaw scalpel was used. (However, in general, with the prototype Shaw scalpel equipment used in this study the ESU was able to coagulate the larger vessels that the Shaw scalpel could not.) The Shaw instrument is excellent for raising flaps and in precise surgery where small capillary bleeding typically obscures the visibility as in parotid surgery. It requires minor modifications in technique to achieve maximal benefit.

REFERENCES

1. Levenson SM: Progress report: Studies with a new scalpel for "bloodless" surgery, April 1979. Data on file at Oximetrix, Inc, Mountain View, CA 94043.

2. Huntingdon Research Center, Baltimore, File No. 791732, May 1, 1971, and Bio Technics Laboratories, Inc, Los Angeles Report No. 1-2-20456-1 Jan 17, 1979.

3. Glover JL, Bendick PJ, Link WJ: The use of thermal knives in surgery: Electrosurgery, lasers, plasma scalpel. *Curr Probl Surg* 15:1978.