

A Hemostatic Scalpel for Burn Debridement

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• We studied excision of burns with a new heated scalpel. The disposable blades resemble conventional scalpel blades, except that their edges can be heated and the temperature controlled within narrow limits. The control mechanism compensates "instantaneously" for varying losses of heat depending on the vascularity of the tissues and rate of cutting. Cutting is done by the blade's sharp edge and hemostasis results from direct transfer of heat; no electric currents are generated in the tissues. The blades can be fashioned in a variety of shapes and sizes, including those suitable for tangential excisions. The heated scalpel allows excision of third-degree burns in pigs and humans with much smaller loss of blood than when the usual cold surgical scalpel is used. Skin grafts applied immediately after excisions with the heated scalpel had excellent rates of success, similar to those of grafts applied immediately after excisions with the cold scalpel.

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Sepsis is still the main cause of death in patients with extensive, deep burns.¹⁻³ The skin irreparably damaged by burns is highly susceptible to infection, and the severely burned patient has lowered "defenses." Although local and systemic chemotherapy has lowered mortality from sepsis, the incidence of severe burn-wound infection is still high and morbidity still too prolonged. We believe, as do some others,⁴⁻⁹ that prompt removal of irrevocably damaged, burned skin followed by immediate grafting with viable, compatible skin diminishes sepsis, lessens functional

abnormalities, lessens disfigurement, speeds recovery, and decreases mortality of patients with extensive third-degree burns. The problem is doing this safely and quickly. Accurate diagnosis of depth of burn is important for surgical escharotomy, but we will not discuss this problem. Totally compatible skin is now limited to autologous or syngeneic skin; how to extend the sources of skin in a way that does not require immunosuppression in the graft recipient⁹ is a problem yet to be solved. The use of artificial skin substitutes has been discussed elsewhere by others.¹⁰

Early surgical excision of the eschar using the conventional cold surgical scalpel is excellent where feasible, but when the deep burn is extensive such excision often is difficult, involving prolonged anesthesia and considerable loss and replacement of blood. Burke, for example, has stated that "you need a big blood bank" to perform such excisions.¹¹ If the operative procedures could be carried out with markedly less loss of blood and without significant local or systemic adverse effects, there would be considerable benefit to patients. The carbon dioxide laser, which we introduced, offers great advantages for excision of large, deep burns in terms of blood loss, as shown by us,¹²⁻¹⁴ by Fidler and his colleagues,^{15,16} and Levine et al.¹⁷ However, excision with current models is relatively slow and awkward.¹⁸ There are drawbacks, also, to the use of radiofrequency current electrosurgical units introduced for burn excision by Lewis and Quimby,¹⁹ that is, blood loss seems to be greater than when the carbon dioxide laser is used¹⁷ and risks are associated with the electrical currents generated in the body by such units.²⁰ We studied excision of burns with a new heated scalpel. We found that we can excise deep burns with a loss of blood considerably less than when comparable areas are excised with the usual cold surgical scalpel. The success of skin grafts applied immediately was excellent with both instruments.

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MATERIALS AND METHODS

The Heated Scalpel System

The heated scalpel blades we used (Shaw Hemostatic Scalpel System, Oximetrix, Inc, Mountain View, Calif) are similar in size, shape, and sharpness to conventional cold steel scalpel blades, except that the steel cutting edge of the blade can be heated. The scalpel may be used either cold (without hemostasis) or heated (with hemostasis).²¹ The degree of heat can be controlled within narrow limits at levels designed to give varying degrees of hemostasis, depending on the surgeon's preference. The control mechanism is sophisticated enough to compensate "instantaneously" for varying losses of heat, depending on the type and vascularity of the tissue being excised or incised, and the rate of cutting.²² No electric currents are generated in the tissues by the heated scalpel; cutting is accomplished by the sharp edge of the blade, just like the conventional surgical scalpel; hemostasis is induced by the direct transmission of heat from the edge of the blade to the tissue. The temperature-control mechanisms in the heated scalpel automatically deliver additional thermal energy to only those regions of the blade losing heat due to tissue contact and only that amount of thermal energy needed to maintain the blade edge close to the preselected temperature (Fig 1). The heated scalpel system consists of three principal components.

Controller.—An electronic power supply and controller energizes the blade, provides various automatic calibration, sensing, and control functions, and has visual and audible indications of instrument status and user controls. The controller operates on standard 115-V/60-Hz hospital electrical power, using a conventional electric cord.

Handle.—A reusable scalpel handle is connected to the controller with a light, flexible electric cable. The disposable scalpel blades are inserted into it.

Blades.—Sterile blades have sharp steel edges and incorporate heater and temperature-sensing microcircuitry. The scalpel blades are disposable and can be fashioned in a variety of shapes and sizes. Blades can be made that allow the scalpel to be used for tangential excision of burns.

Experimental Burns and Excision

Controlled, reproducible, third-degree contact burns were produced on the backs and sides of Hampshire-Landrace pigs in a fashion previously standardized in our laboratory. We heated a rectangular copper block to 80 °C, and kept it on the skin for 40 s for 23- to 25-kg pigs and for 60 s for 45- to 55-kg pigs. For burning, the pigs were immobilized with ketamine hydrochloride (Ketaset) and anesthetized with halothane (Fluothane).

The burns were excised to the muscle-investing fascia and muscle 24 hours after burning, using (1) a conventional cold surgical scalpel or (2) the heated scalpel at various temperatures. Blood loss was estimated in each experiment. Split-thickness skin autografting was carried out immediately after excision; the skin was cut with a dermatome. In some cases, the donor and grafted sites were covered with fine mesh gauze impregnated with a bland ointment and a circumferential dressing was applied; the dressings were removed five days later and no further dressing was applied. In other cases, no dressings were applied postoperatively. The pigs were followed up for four to five weeks postoperatively and the success of the grafts assessed. Serial photographs were taken during the experiments. All pigs ate a standard pig ration and drank tap water, both ad libitum. They were housed in individual steel cages in an outside room at a temperature of 25 ± 2 °C and a relative humidity of about 40%.^{20,21}

Tangential excisions of unburned skin of the backs of pigs were carried out with the heated scalpel using a flat blade about 0.6 cm

wide and 7.5 cm long. The blade was heated to 114 °C. Similar tangential excisions were carried out using a cold surgical blade. In each case, immediate split-thickness skin autografting was performed using the dermatome. No dressings were applied. The pigs were followed up for four to six weeks.

Patients

Patients with third-degree burns who were scheduled for excision of their burns gave informed consent to participate in our study. The study was approved by the Albert Einstein College of Medicine-Bronx (NY) Municipal Hospital Center Clinical Investigation Committee. The excised areas were autografted or allografted immediately in most cases, or occasionally after a delay of one or two days.

RESULTS

Temperature Required for Hemostasis (Pigs)

When the scalpel blade was heated to 120 °C, excision of unburned skin (150 sq cm) to the muscle-investing fascia and muscle was accomplished with considerable reduction of bleeding (a factor of seven) compared with similar excisions carried out with the conventional cold scalpel. As the blade temperature was increased, the degree of hemostasis also increased progressively; thus, at a temperature of 180 °C, bleeding was reduced by a factor of ten compared with that seen when the cold scalpel was used (Fig 2). At a temperature of 260 °C, the bleeding was reduced still further, by a factor of 16. When burned eschars were excised with the scalpel heated to 180 °C, blood loss was about 10% of that seen when the cold scalpel was used. Because we believe that the level of hemostasis desired for excision of deep burns and immediate skin grafting should be substantial but not total (since this might be "overkill"), we used a temperature of 180 °C in our subsequent experiments in pigs.

Excision of Unburned Skin and Immediate Autografting (Pigs)

In four pigs, comparable areas of unburned skin were excised down to the muscle-investing fascia and muscle and immediately autografted with split-thickness skin. Blood loss was minimal in the areas excised with the heated scalpel (180 °C), much less (again, by a factor of ten) than in comparable areas excised with the conventional cold scalpel. The success of the skin grafts was excellent, 90% to 100% (Fig 3).

Excision of Third-degree Burns and Immediate Autografting (Pigs)

In ten pigs, third-degree burns were excised down to the muscle-investing fascia and muscle using either the heated scalpel at 180 °C or the conventional cold surgical scalpel. The excisions were accomplished easily with the heated scalpel, with blood loss only 10% of that seen when comparable excisions were carried out with the cold surgical scalpel. There was little damage to the underlying tissue, as indicated by the excellent rate of success (90% to 100%) of the immediately placed skin autografts, whether the excisions were carried out with the heated scalpel or with the cold surgical scalpel (Fig 4).

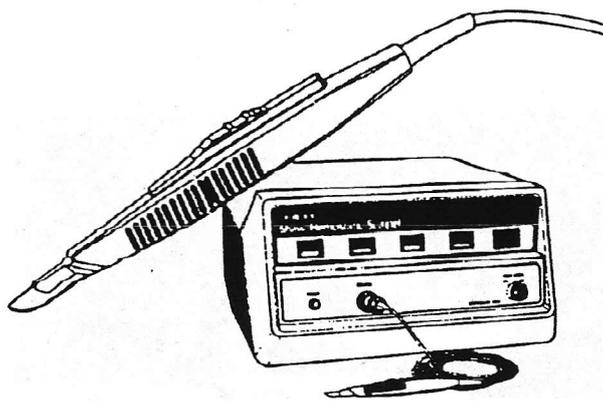
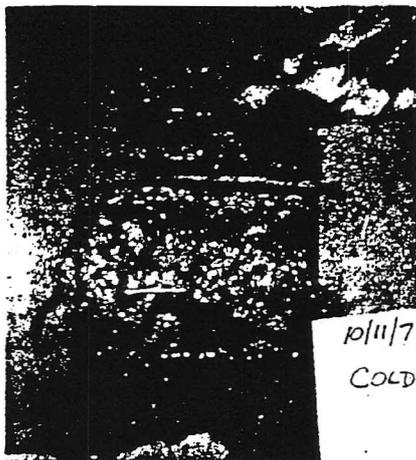
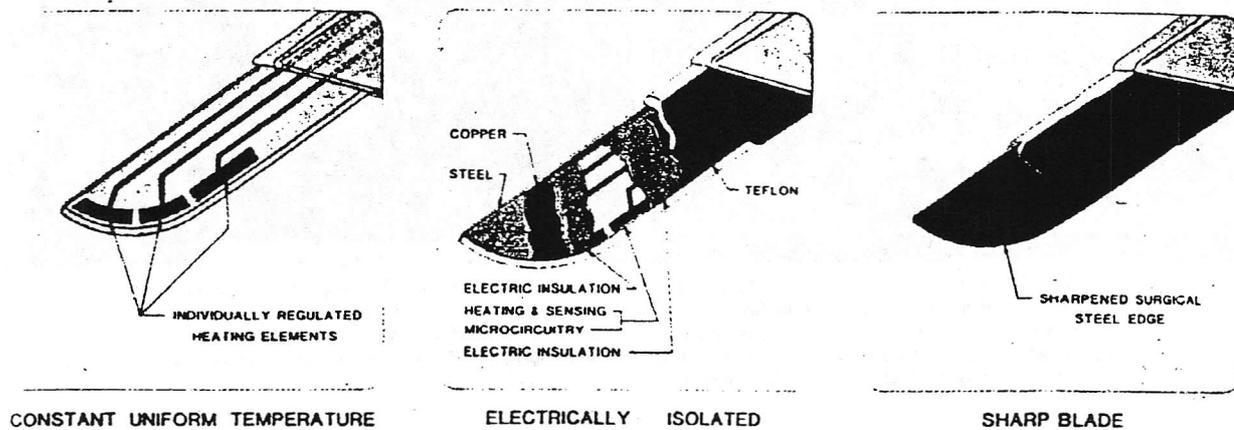


Fig 1.—Heated scalpel system. Top, Overall unit. Bottom, Picture and diagram of blade.



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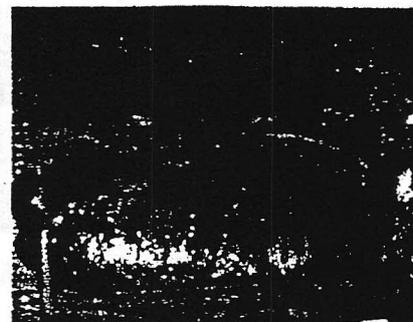


Fig 2.—Excision of unburned skin of pig to muscle-investing fascia and muscle using cold or heated scalpel. Left, Using cold scalpel. Center and right, Using heated scalpel. Note marked difference in blood loss and healthy appearance of tissue bed in each case.

Tangential Excision of Unburned Skin of Pigs With Immediate Autografts

Tangential excision to the dermis of unburned skin of a single pig carried out with the heated scalpel (115 °C) resulted in much less bleeding than when similar excisions were carried out in comparable areas with a conventional cold knife (ratio of blood loss, 1:20). The rate of success of immediately applied split-thickness skin autografts was 90% to 100% in each case (Fig 5). Only a few blades machined for tangential excision were available; this pre-

cluded use of these special blades in additional pigs or patients.

Excision of Third-degree Burns of Humans

During our first cases, we attempted to determine the "optimal" temperature at which to set the heated scalpel. We quickly saw that, as anticipated, the vascularity of the subcutaneous layer in humans is considerably greater than in pigs; when excisions are carried out at the level of the muscle-investing fascia, eg, on the chest wall, there are a

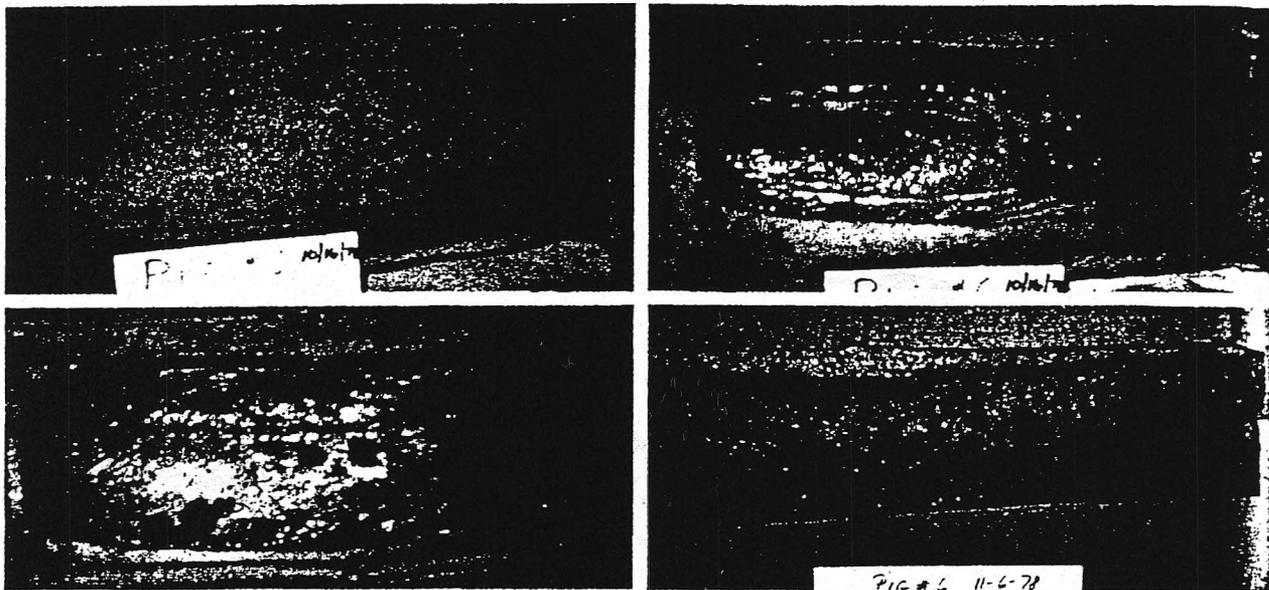


Fig 3.—Excision of unburned skin of pig to muscle-investing fascia and muscle using heated scalpel and immediate autografting. Top left, Area to be excised. Top right, Healthy appearance of tissue base after excision, with almost no bleeding during excision. Bottom, Appearance of skin autografts applied immediately after excision (left) and 21 days after grafting (right). Graft took completely. Dark areas are natural pigmented spots in transplanted skin.

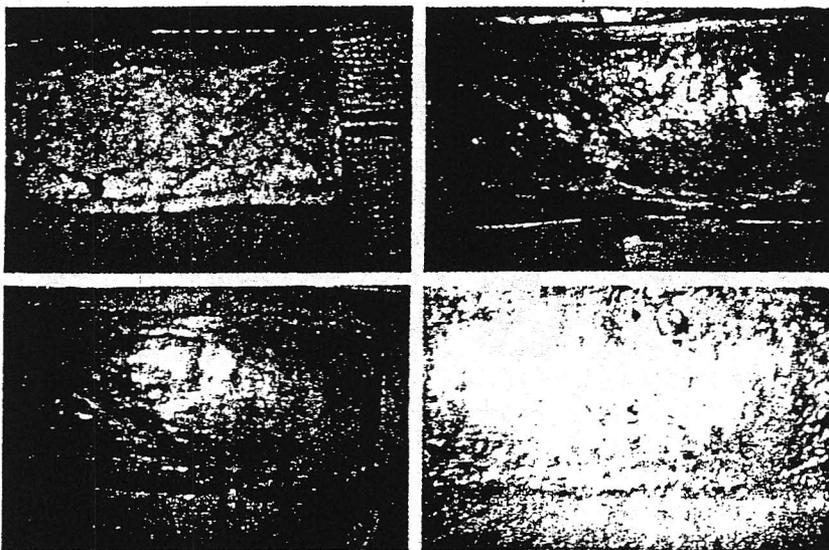
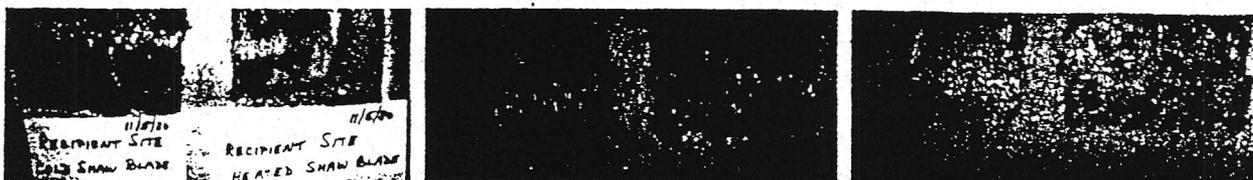


Fig 4.—Excision of third-degree burn of pig to muscle-investing fascia and muscle using heated scalpel and immediate autografting. Top left, Note dead white appearance characteristic of third-degree burn. Top right, Note healthy appearance of tissue base after excision; almost no bleeding occurred during excision. Bottom, Appearance of skin autograft applied immediately after excision (left) and 26 days after grafting (right). Graft took completely.

Fig 5.—Tangential excision of unburned skin of pig to dermis, and immediate autografting. Left, Using cold scalpel and heated scalpel. Note difference in amount of bleeding. Center and right, Appearance of immediately applied skin autografts three days (center) and 14 days (right) after grafting. Note essentially complete take of grafts in both cases.



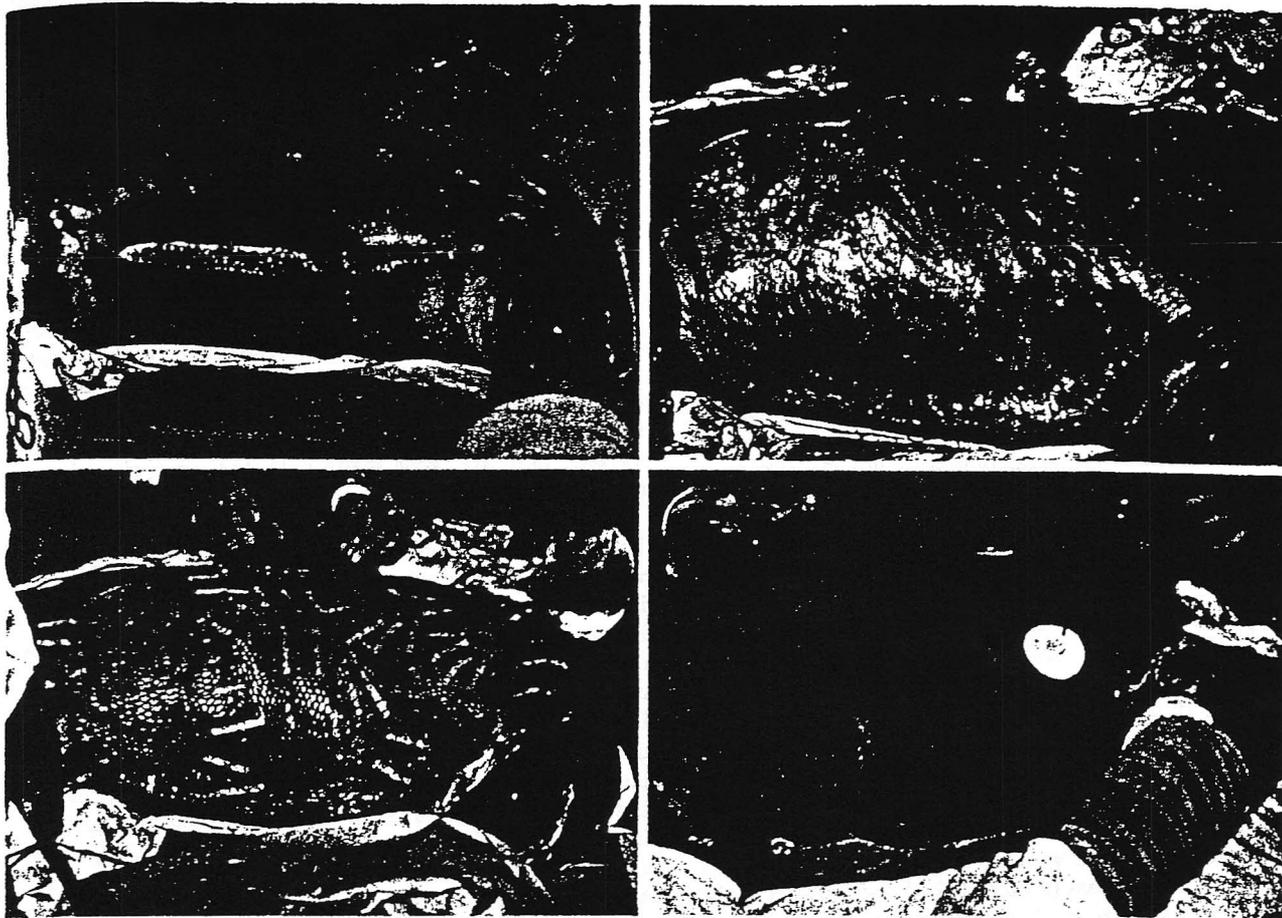


Fig 6.—Excision of third-degree burn of human to muscle-investing fascia using heated scalpel and current electrosurgical unit with immediate autografting. Top left, Appearance of third-degree burn of chest wall three days after burning, just prior to excision. Note charring. Longitudinal incision was purposeful escharotomy shortly after burning. Top right, Note healthy appearance of tissue base after excision of half with heated scalpel and other half with current radiofrequency unit in the cutting mode. Little bleeding is seen in each case; larger perforations were coagulated with radiofrequency electrosurgery unit in coagulation mode in each case. Bottom, Appearance of immediately applied skin autografts just after application (left) and several weeks later (right). Grafts took completely over all areas.

large number of perforator vessels. Also, it was immediately evident that there was a great temptation to cut quickly, since the heated scalpel blade edge is as sharp as the conventional cold scalpel—in fact, when the blade is heated, the sharpness seems increased. However, if one cuts too rapidly, hemostasis is inadequate. *The surgeon has to learn the appropriate combination of cutting speed and blade-edge temperature.* This combination varied with the vascularity of the tissue; the surgeon must determine at the operating table the appropriate combination for each major site for each patient. Commonly, blade temperatures of 160 to 180 °C were used, though in some instances temperatures of 115 to 120 °C were suitable. Perforator vessels at these temperatures (115 to 180 °C) bled if cut through fairly quickly, so these were generally coagulated with a radiofrequency current electrosurgical unit. As a result of this experience, the heated scalpel system now includes in the handle a button that, when depressed, immediately raises the blade edge temperature to 260 °C

momentarily, to help secure hemostasis when such vessels are cut (these vessels can be seen before cutting). We have not had much experience with this feature.

When excisions of deep burns of patients were carried out down to muscle-investing fascia with the heated scalpel, blood loss was considerably less than when comparable areas were excised with the conventional cold surgical scalpel. As before, no attempt was made to achieve complete hemostasis.

REPORT OF A CASE

A 50-year-old man (Fig 6) suffered a flame burn that involved 35% of his body (almost all third degree: left side of chest and back, left arm, left leg, buttocks, and perineum). There was no serious respiratory tract injury. His resuscitation (intravenous lactated Ringer's solution) proceeded well. The burns were treated locally with silver sulfadiazine ointment.

On the third day after the burn, the deep burn of the chest was excised to the muscle-investing fascia using the heated scalpel for one half of the area and a radiofrequency current electrosurgical

unit in the cutting mode for the other half. Control of bleeding was excellent in each case; the larger perforator vessels were coagulated with the radiofrequency unit in the coagulation mode in each case. Packed RBCs, 400 mL, were transfused during the operation; the hemoglobin level 12 hours postoperatively was 10.3 g/dL (the preoperative hemoglobin level had been 9.7 g/dL). Split-thickness skin autografts took almost completely (95% to 100%) over the entire excised area.

The patient's subsequent course was complicated first by pneumococcal pneumonia treated successfully with penicillin, and then by an episode of acute respiratory distress syndrome that required endotracheal intubation and ventilatory support; this gradually cleared. The patient underwent several more excisions of his deep burns to the muscle-investing fascia using the heated scalpel and a current electro-surgical unit, with similar control of bleeding, followed by allografting and autografting. The patient was discharged from the hospital four months after his injury.

COMMENT

In operative surgery, the attendant blood loss often poses a major problem and, in fact, is a serious threat to the patient. A notable example is the excision of extensive, deep burns. If the operative procedures could be carried out with markedly less blood loss and without significant local or systemic adverse effects, the patient would benefit considerably. Our use of the heated scalpel allows prompt excision of third-degree burns of pigs in a nearly bloodless fashion, after which skin autografts applied immediately showed excellent success (90% to 100%), comparable to the rate of success of skin grafts applied to other burned areas that were excised with the conventional cold surgical scalpel with considerably greater blood loss.

After our burn excision and grafting experiments in pigs and before our first clinical trial with the heated scalpel, we performed experiments²² to determine how the heated scalpel affects the healing of dorsal skin incisions of male Sprague-Dawley rats.^{24,25} The incisions were made either with a conventional cold surgical scalpel or the heated scalpel. The rats were anesthetized with pentobarbital. In an initial series of experiments, we found that the breaking strengths of incisions made with the heated scalpel at 114, 120, 140, 160, and 180 °C were similar after seven days. The lowest of these temperatures is sufficient to control bleeding considerably. We used the highest of these temperatures in a series of wound-healing experiments to secure essentially complete hemostasis while making the incisions rapidly, with a single stroke. The incisions were closed with interrupted, fine, stainless-steel sutures. Breaking strengths of the incisions were tested in both the fresh state and after formaldehyde fixation 7, 14, 21, 28, 35, and 42 days postoperatively, the period during which such wounds gain strength most quickly.²⁵ The only statistically significant difference ($P < .05$) between the breaking strengths of the incisions made with the conventional cold surgical scalpel and with the heated scalpel was noted after 21 days, modestly in favor of the conventional scalpel. There was no evidence of adverse systemic effects in any rats.

To examine wound resistance to infection, just before closure we inoculated skin incisions made in rats with the heated scalpel and with a conventional cold steel scalpel

with up to 10^8 viable *Pseudomonas aeruginosa* or *Staphylococcus aureus* organisms.²⁵ No wound infection developed in either group; in fact, in each case (heated or cold scalpel) there was a striking increase in breaking strength when the incisions were contaminated with the *S aureus* ($P < .001$) (but no effect on breaking strength was seen when the incisions were contaminated with *P aeruginosa*). Previous work by others has indicated that incisions made with the carbon dioxide laser or a radiofrequency current electro-surgical unit are significantly less resistant to infection when purposefully contaminated with bacteria (*S aureus*) than are those made with the conventional cold stainless-steel scalpel.²⁷

We then began to use the heated scalpel to excise deep burns of patients. Blood loss was demonstrably less than when the cold scalpel was used and the success rate of immediately applied skin grafts was similar. One must learn the art of using the heated scalpel; it is tempting to cut very quickly because the blade is as sharp as an ordinary cold surgical scalpel, but hemostasis would be inadequate. The speed at which one can cut using radiofrequency current electro-surgical units or the carbon dioxide laser is regulated by the instruments themselves; that is, the surgeon can go no faster than the speed at which the laser beam²⁸ or the electrical currents^{29,30} respectively vaporize or dissect tissue. In contrast, the heated scalpel passes no electrical current, and there is no sparking or electrical arcing to the tissue. The heated scalpel cuts with a sharp steel edge, like a cold scalpel, and seals blood vessels using heat thermally transferred to the tissue from the heated blade edge. *The degree of hemostasis obtained with the heated scalpel depends on blade temperature, the time the blade is in contact with the tissue, the contact area, and the type of tissue—especially its vascularity.* The surgeon obtains the desired degree of hemostasis by manipulating these variables. As mentioned, we did not attempt to achieve complete hemostasis because this might cause unnecessary tissue damage. Also, since this was the first clinical use of this new instrument for the excision of burns, we were conservative and in most cases did not attempt to achieve the degree of hemostasis previously achieved with the carbon dioxide laser or with a radiofrequency current electro-surgical unit turned up high.

There are a number of advantages of the heated scalpel.

1. In shape and sharpness it resembles the usual surgical scalpel.

2. The scalpel blades are disposable, and can be made in a variety of shapes and sizes. An advantage of this type of instrument is that blades can be designed to permit its use for tangential excision, which is not possible with the carbon dioxide laser or current electro-surgical units.

3. The scalpel may be used heated or cold, depending on the surgical step required.

4. The control mechanism compensates for varying heat losses depending on the type of tissue incised and the rate of cutting. We think that a small amount of bleeding is desirable to avoid tissue damage caused by excessive heat. Larger perforators were generally controlled using a

radiofrequency electrosurgical unit in the coagulation mode. By depressing a switch in the handle in the present model, the blade temperature immediately rises momentarily to 260 °C for "sealing" larger vessels.

5. The heated scalpel is easier to manipulate and use than the carbon dioxide laser, and excisions with it can proceed faster than with the laser.

6. The scalpel thermally transfers heat directly to the tissue and is electrically insulated from the patient. No electric current passes through the patient. As a consequence, a grounding pad is not needed and the risk of accidental radiofrequency electrical current burns at grounding sites can be eliminated. Also, the muscle stimulation associated with the passage of radiofrequency elec-

trical current through the body is eliminated.

7. Blood loss is lessened considerably when excision of burned skin is carried out with the heated scalpel, with little damage to the underlying tissue as indicated by the excellent success rate of immediately applied skin grafts.

8. The heated scalpel is useful in other surgical operative procedures for the control of blood loss²⁰ (F. Steichen, MD, H. Kessler, MD, personal communication).

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Discussion

JAMES P. FIDLER, MD, Cincinnati: Both Dr Levenson and Dr Shaw, the inventor of the heated scalpel, are pioneers in the use of thermal knives. Dr Levenson excised clinical burns with the carbon dioxide laser as early as 1972. Dr Shaw was also the inventor of the plasma scalpel. I am sure that these early experiences have helped them develop and evaluate this heated scalpel. My comments depend on earlier controlled animal and clinical studies with the carbon dioxide laser, the electrosurgical unit, and the plasma scalpel, and do not come from any first-hand use of the heated scalpel.

All the current thermal knives decrease blood loss by heat closure of vessels. Following Dr Levenson's initial studies—and these are initial studies—I see four important differences between the heated knife Dr Levenson and co-workers used and the other thermal knives. One is the ability to perform a tangential excision of pig skin. If this can be repeated in a clinical series with

immediate grafting and tangentially excised burns, it will be a first for a thermal knife.

Second, wound healing with the heated knife is the same as with the conventional knife, as estimated by breaking strengths of incisions (except at the 21st day). In our experience, all the thermal knives showed a difference for as long as 40 days in controlled animal experiments.

Third, the use of the heated knife did not increase the incidence of infection. This, again, is in contrast to studies by Madden, which showed that all the thermal knives—namely, the carbon dioxide laser and the electrosurgical knife that he studied—created an environment favoring infection.

Fourth, the heated knife is only a coagulator. There is no need to achieve tissue temperatures of 100 °C or more to make the incision, as in other thermal knives that use either a radiofrequency electric current, a light, or plasma. Tissue heat of approximate-

ly 70 and 75 °C for 1 s must be achieved to close a small vein or a small artery. The number of vessels controlled depends on these two factors: (1) the tissue heat, and (2) the time the heat is applied. A 6,000-°C plasma scalpel will do no more heat damage than a 114-°C heated scalpel, if the rate is sufficient to avoid tissue heating. Since there is an exponential function between the heat and the power required to produce permanent necrosis, a very hot blade is required to permit the surgeon to incise at normal rates of movement.

My questions to Dr Levenson are as follows. Would you expect the same amount of tissue damage and the same results in wound healing and infection studies if the rate of the heated knife is slowed down, or if the temperature elevated to produce the same degree of hemostasis as that seen with the electrosurgical knife, the carbon dioxide laser, or the plasma scalpel?

ROGER W. YURT, MD, San Antonio, Tex: I interpreted your figures as suggesting that most of these excisions were performed down to fascia. I personally have more problems with blood loss during the tangential type of excision. Is there any application for the heated scalpel under those circumstances?

DR LEVENSON: The degree of hemostasis achieved using the heated scalpel in animal experiments was almost total; it was comparable with what one achieves with a carbon dioxide laser or with a current electrosurgical unit.

Referring to our statement that we did not attempt to achieve complete hemostasis in our patients, I do not think it is necessary to achieve complete hemostasis. We like a major but not total reduction in bleeding; we want to avoid the possibility of overkill. Also, as this was our initial experience and we were cautious, we did not attempt to achieve the degree of hemostasis possible with the carbon dioxide laser or electrosurgical units. That does not mean that one cannot get excellent control of hemostasis with the heated scalpel. As Dr Fidler pointed out, the degree of hemostasis depends on the amount of heat delivered, that is, the total caloric input. The caloric input is a function of the temperature of the blade edge, the time of contact, area of contact, and the vascular-

ity of the area. As with any instrument, if used improperly harm can result; if one delivers excess heat by any instrument, tissue damage results, the degree of damage being proportional to the amount of excess heat. The surgeon must learn the art of using the heated scalpel system. This is not difficult.

When the surgeon uses the carbon dioxide laser, the rate of cutting is governed by the equipment, not by the surgeon; that is, the surgeon must wait for the laser beam to vaporize the tissue. With the heated scalpel system the surgeon cuts the tissue with the sharp edge of the blade (and it is as sharp as the usual cold surgical scalpel) and the initial tendency of the surgeon is to cut rapidly; however, if the surgeon goes too quickly, hemostasis will be inadequate. The surgeon must learn the appropriate temperature and speed (that is, the time of contact), necessary to achieve the degree of hemostasis desired. This will vary from area to area in the body and from tissue to tissue; when an area is extremely vascular, either a higher temperature is required or the surgeon must go slower.

The heated scalpel has potential for tangential excision, something that cannot be done with the carbon dioxide laser or electrosurgical units. Our experience is limited, because we have had only a few of the specially made blades suitable for tangential excisions. We used them in pigs for the tangential excision of unburned skin followed by immediate autografting. One needs only relatively low temperatures for such tangential excisions with excellent control of hemostasis, as low as 114 °C, the lowest setting the equipment has. Similar tangential excisions and autografting were carried out with a cold surgical scalpel. Control of hemostasis using the heated blade was excellent and the take of the grafts was complete with both instruments. There is no question in my mind that, in principle, the heated scalpel system is suitable for tangential excisions in burned patients.

In addition, the heated scalpel is useful in other areas of operative surgery in which the control of blood loss is important.