CONTROLLED ENVIRONMENT TREATMENT
FOR LIMB SURGERY AND TRAUMA
(A PRELIMINARY REPORT)\(^a\)

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ABSTRACT

This paper demonstrates a new approach to postsurgical and post-traumatic wound management in the lower limbs. Our own results of 20 below-knee amputations are documented. A less detailed report is then given of experience with an additional 20 amputees: this second group includes experience not only here at Seattle but at five other centers in the United States. The same method for wound management and for control of edema was employed in all cases.

The method, Controlled Environment Treatment (CET), uses filtered air as a dressing medium, with a control console to maintain the pressure, constant or varying, according to a preset program. Temperature and humidity are also controllable, as is gas composition. The limb, together with its controlled environment, is contained within a pliable, transparent, treatment bag, which permits

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inspection and palpation of the wound site without disturbing the bacteriologically sterile air within the chamber. A special seal reduces air leakage yet avoids constriction of the limb.

This CET system was originally developed by the Department of Health and Social Security, Biomechanical Research and Development Unit, Roehampton, England. Subsequent developments are also noted of an improved Mark II CET Unit and of simpler, related, management systems for conditions not requiring sterile environments.

BACKGROUND

Background on Wound Healing

Wound healing has been described as "the foundation of surgery." Every traumatic and incisional injury initiates an orderly sequence of cellular and molecular events which serve to restore structural continuity (11). New operations, new techniques, and new systems of surgical management must all rely on wound healing for success.

The voluminous literature on the subject of wound healing in the past has related to an understanding of the physiological response of injured tissue, as exhibited by the repair process (11, 12, 21, 24). Excluding burn care, little attention has been paid to the physical treatment of the postoperative wound. Conventional postoperative management consists of application of a variety of sterile dressings. The problems associated with these conventional dressings are the lack of adequate control over pressure, humidity, temperature, immobilization, and sterility of the wound site. Investigations have shown that pressure under "pressure support dressings" is variable, unpredictable, often poorly localized, and in limbs can frequently have a proximal tourniquet effect. Moisture, humidity, healing wound-surface environmental temperature, and sterility under conventional dressings, are difficult to monitor and control. The wound is invisible and can only be observed by periodic removal and renewal of dressings. This process removes any blood and serum which have oozed from the wound, but dressing changes may be painful for the patient. Removal of a potential culture medium must be balanced against the risk of new contamination. The pressure of the new dressing again is variable. Edema may increase while the wound is exposed.

Regarding pressure, until recently very little has been added to Blair's classic treatise, "The Influence of Mechanical Pressure on Wound Healing," published in 1924 (3). As we come to understand
more fully the pressure relationships within injured tissue, and the effects of externally applied pressure, one realizes how generally haphazard has been the use of pressure in post-surgical and post-traumatic wound management (1,15,16,17,23).

The argument is advanced that this area of treatment is not so important and that present techniques, though not precise, appear to be adequate. This attitude is not justified by current knowledge of the physiology of wound healing. Cellular repair and regeneration are among the most basic and fascinating aspects of living matter. An increasing understanding of these life processes parallels the rapid accumulation of knowledge in genetics. The clinician is committed to as much practical application of this knowledge as is possible in support of the body and the healing process: a more complete understanding of the biomechanical, electrical, chemical, and genetic forces involved in the repair process accentuates the importance of presenting to the healing tissue the most favorable physical environment.

**Background Leading to Development of Investigation**

Our interest in the clinical investigation of the wound healing environment for the past 13 years has been directed toward amputations (4,5,6). The amputation provides an excellent clinical laboratory for wound healing study. All tissues of the limb are severed in cross section, each must heal in its specific manner under the broad canopy of general principles of tissue repair. The amputation is terminal, and this anatomical fact permits the application of an external environment which need not concern body structure distal to the site of surgery. Thus there is latitude for manipulation of the physical environment not present in segmental or intercalary surgery and trauma.

A majority of amputations are performed for ischemia. Postsurgical circumstances favorable to healing are especially critical when cell viability is less than optimum. Thus, amputations for ischemia present a special challenge in the area of wound healing. Since residual limb function and prosthetic rehabilitation are so closely related to amputation level, the surgeon must measure success against the dual yardsticks of distal amputation level and primary wound healing. This is a particularly critical choice in the case of a lower limb in a geriatric patient.

In 1964 we set out to clinically evaluate wound healing following amputation when using a rigid dressing with pressure interface (8). Early function was obtained, in both the upper and lower limbs, by use of detachable functional terminal units to allow restricted ambulation in lower limb amputations and terminal device
control in upper limb amputations. Our system was modified from reported techniques dating back to World War I: e.g., Wilson (27) (Fig. 1) and more recently by Weiss (26) and Berlemont et al. (2). It has come to be known as Immediate Postsurgical Prosthetic Fitting, or IPPF.


The rigid dressing (IPPF) system, as we use it, is designed to provide an improved postsurgical physical environment for amputation wound healing. It incorporates wound support, immobilization, external pressure both constant and intermittent, non-occlusive dressings to control moisture and humidity, reasonable sterility, and active residual limb use consistent with the dressing. IPPF is now a relatively standard system of postsurgical management in many areas throughout the world (14,18,19,20,25).

The study reported here relates to a refinement and greater degree of control of the modalities just outlined. The method to be described, i.e., Controlled Environment Treatment (CET), uses equipment developed by the Biomechanical Research and Development Unit, Department of Health and Social Security, Roehampton, England. Clinical investigation of CET in the United States
began in March 1974, at the VA Hospital, Seattle, Washington, under the supervision of the Prosthetics Research Study, and this report records our specific experience in the treatment of 20 below-knee amputations between March 1974 and December 1975, using Mark I equipment.

Then, during the summer of 1975, additional CET units were provided to the San Francisco VA Hospital (Vascular-Surgical Service), San Francisco, California, the Castle Point VA Hospital (Surgical Service), Castle Point, New York; the Duke University Medical Center (Departments of Orthopaedic and Hand Surgery), Durham, North Carolina; the Rancho Los Amigos Hospital (Rehabilitation Engineering Center), Downey, California; and to the University of Washington School of Medicine (Departments of Orthopedics and Surgery), Seattle, Washington. Some of the preliminary results of these efforts will also be presented in this report, though separate publications are anticipated when more extensive series are completed.

At Seattle and elsewhere, the method also has been used in a variety of limb surgical procedures and trauma including burns, hand surgery, fractures, sprains and dislocations, crush syndromes, and for the relief of edema. Some results are presented in these areas.

**DESCRIPTION OF METHOD AND EQUIPMENT**

CET uses filtered air as a dressing medium. Equipment in a control console maintains air pressure, constant or varying, on the enclosed part of the limb. The gas composition, duration and magnitude of pressure phases, temperature, and humidity can all be controlled. The limb, together with its controlled gaseous environment, is contained within a polyvinyl chloride (PVC) treatment bag. Pliability and transparency of this dressing allow inspection and palpation of the wound site without disturbing the bacteriologically sterile gas within the chamber. A special seal where the limb enters the bag avoids constriction that could impede circulation within the limb.

The Controlled Environment Treatment Unit consists of three basic parts: an air-control console, an interconnecting flexible hose, and a dressing bag (9,10,22). Filtered air is used as a dressing medium and timed cycles of alternating high and low air pressure are used according to a preset program under the operator’s control. The amputation wound, together with its controlled environment, is housed within the transparent polyvinyl chloride (PVC) bag. Bag position is maintained with a lightweight webbed harness anchored about the waist.
Equipment in the air control console (Fig. 2) includes several stages of centrifugal air compression, several stages of air filtration, provision for temperature and humidity control, and the valves and timing mechanisms needed to regulate the magnitude and duration of pressure phases (9,10,22). The controls allow the operator to preset a cycle with alternating high and low pressure phases: pressures available are anywhere from 10 to 50 mm Hg, and phase durations from 0 to 5 minutes are available.

Following final compression, air is cooled and blown through a high-efficiency filter capable of 99.998 percent retention of particles of 0.6 \( \mu \) or greater, thus providing sterility. The filtered air is then passed over a heating element and raised to a preset temperature. Temperature may be varied in a range from approximately 4 deg Celsius above ambient room temperature to 40 deg Celsius (3 deg above body temperature). Three separate thermal cutouts are incorporated to switch off the heater in the event that air temperature rises too high. This fail-safe feature is automatic and will reset after the temperature returns to normal limits. Since air is cooled and re-warmed before delivery to the amputation site (Fig. 2), relative humidity is reduced, providing dry conditions within the dressing bag.
Once heated to the desired temperature, the processed air travels through a length of flexible hose to a presterilized, pliable, transparent treatment bag enclosing the residual limb or other part to be treated (Fig. 3). The hose allows convenient placement of the machinery near the patient's bed, and permits the patient to sit, or to stand beside the bed, or even to walk a few steps on the remaining foot with the aid of crutches or a walker.

FIGURE 3.—CET polyvinyl chloride treatment bag illustrating cross sectional and full view of proximal “flutter” seal.
Construction of this transparent, flexible yet tough dressing allows visual inspection and palpation of the wound through the bag. A thin pad supports the limb, but there is no rigid support for contouring.

A flexible, pleated seal at the proximal end of the bag maintains the preset pressure within the chamber regardless of limb volume changes and without the risk of a tourniquet effect, i.e., pressure from the seal around the thigh is generated only by the air pressure inflating the pleats, so seal pressure never exceeds that within the bag (22). (The seal is a modification of the Hovercraft® principle.) In addition, the seal’s “flutter” system provides a continuous but slow escape of air, which serves to cool and to ventilate the wound environment. Because of the positive pressure within the treatment bag, and the gradient through the seal about the thigh to the atmosphere, only the warm, sterile air introduced is present. Unsterile air cannot gain entry against the pressure gradient and low flow rate through the nominally open proximal end (23). Consequently, risk of environmentally induced infection is minimal.

Bag design has been patented by the British Medical Research Council. Variations in types and sizes of treatment bags, including a body surface or trunk “barnacle” dressing, are being studied at Roehampton and will be made available as needed.

APPLICATION OF CET

The CET unit used in the initial study is designated Mk I. It was a large, heavy, moderately noisy, yet easily constructed device which allowed convenient access to its internal machinery for repair and modification. As an evaluation prototype it has served its purpose well. An improved, more compact device, CET Mk II (Fig. 4), is currently being used, and other variants are described below.

Treatment of the first 20 amputee patients was initiated immediately following below-knee surgery and was continued for an average of 10 postoperative days. During that time wound healing progress, incidence of infection and hematoma, degree of any limb edema, requirements for pain medication, and patient activity were clinically observed. The drain, when used, was removed with a sterile forceps through the proximal opening and seal of the dressing bag, normally within 72 hours following surgery. Upon completion of Controlled Environment Treatment, the residual limb was routinely fitted with an Immediate Postsurgical Prosthesis and carried on through the routine rigid dressing technique to definitive limb fitting.
Pressures, Cycle Times, and Temperature Settings

Pressures, cycle times, and temperature were set within ranges recommended by the Biomechanical Research and Development Unit, Roehampton, England (9,10). The initial 12 cases managed with CET were on a regimen with high pressure ranging from 45 to 50 mm Hg for 30 s, and low pressure set at 10 mm Hg for 60 to 90 s. In several instances, the high pressure setting was reduced on or about the 7th postoperative day. The last eight cases in this study were managed with a somewhat reduced high pressure phase: in those cases, the high pressure phase was applied at 30 mm Hg for 30 s, and low pressure was set at 10 mm Hg for 60 to 90 s. Temperature was set at 38 deg Celsius for the first 12 cases, and reduced to 32 deg Celsius for the last 8 cases. Patients appeared to be more comfortable at the lower temperature.

The relatively arbitrary pressure, time, and temperature parameters were based on clinical and experimental observations relative to dynamic limb blood flow. Ischemic limbs coming to amputation have only one common and absolute characteristic, i.e., the need to amputate. Individual variations in limb blood flow and limb hemo-
dynamics vary from patient to patient in different pathological states. The treatment protocol was designed with sufficient latitude of safety neither to harm nor to delay the wound healing process.

Adjustments to pressures and cycle times were in many instances made partially on the basis of patient comfort. For example, the trial use of cycle with a 10-s low pressure phase produced noticeable discomfort in cases with both normal and impaired vascularity. We currently use a program of approximately 30 mm Hg for 30 s on high pressure, and 10 mm Hg for 30 to 90 s on low pressure. Basic research on cycle pressure/time relationships is currently a subject of investigation at our center (13,17). It is possible that more flexible treatment regimens will result from these studies.

EXPERIENCE ON FIRST 20 CASES

The 20 below-knee amputation surgeries here reported were all treated by the Prosthetics Research Study staff at the Veterans Administration Hospital, Seattle, Washington. Consecutive below-knee amputations, regardless of etiology, were placed in the machine whenever it was available. Cases were not randomized nor was a control group used, although the patient population could be compared with an experience of several hundred below-knee amputations at this single hospital for similar pathologies.

Patient population consisted of all males, ranging in age from 25 to 85 years (Table 1). Nine patients, or 45 percent, had peripheral vascular disease with diabetes; another 7 (35 percent) underwent amputation for peripheral vascular disease without diabetes; and in the remaining 4 cases (20 percent) posttraumatic complications was the primary reason for amputation (Fig. 5).

Eighteen patients in this study were unilateral amputees, two were bilateral. Both bilateral patients were amputated for peripheral vascular disease, one with diabetes and one without. All 20 cases involved primary wound closure with or without drainage. The standard long posterior myocutaneous flap was utilized in all instances except one in which the flap was irregularly fashioned due to skin loss from the original trauma.

Wound Healing Progress

Eighteen patients (90 percent) healed promptly and without incident at the below-knee level. The two cases which required revision to the above-knee level failed to heal due to ischemic skin and muscle necrosis. This diagnosis was confirmed in both cases by tissue examination and culture. No infection was present in either patient.
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a Bilateral below-knee amputees.
In addition to the two patients who required revision to the above-knee level, there was one instance of mild wound separation at the suture line with delay in healing. This individual, a 59-year-old male with peripheral vascular disease and diabetes, had previously been treated by bilateral aortofemoral and femoral-popliteal Dacron grafts. The below-knee amputation was healing uneventfully at the time of the patient’s removal from the CET unit and application of the first cast, which was on the 12th postoperative day. At the time of the second cast application, the 26th postoperative day, it was noted that the skin was overlapped and that a small area of skin necrosis had occurred at the suture line. No additional surgery was necessary, and the patient proceeded to uneventful wound healing without infection. He was fitted with a definitive prosthesis on the 70th postoperative day with subsequent completion of his rehabilitation.
Infection

There were no instances of postoperative wound infection among the 20 patients.

Hematoma

Wounds were drained by Penrose drain in 55 percent of the cases. There were two instances of postoperative hematoma. One occurred during the first postoperative week subsequent to drain removal, in a case of amputation for chronic, gangrenous foot ulcers with peripheral vascular disease and diabetes. Occurrence of the small hematoma was, in our opinion, due to improper drain placement. The drain was removed and wound healing progressed uneventfully.

The second hematoma occurred in a wound which was not drained. This patient presented with a severely infected crushed right foot. An emergency open guillotine amputation was performed just proximal to the ankle and was managed postoperatively with CET. A closed below-knee amputation revision was carried out 10 days later, also followed with CET. A hematoma occurred on the second day after definitive amputation; two sutures were removed, the hematoma evacuated, and a new bag was put in place. The wound subsequently healed promptly and without further difficulty, and the patient progressed rapidly to full rehabilitation.

Edema Control

The CET was noticeably effective in controlling postoperative residual limb edema. In all 20 cases, edema was felt to be absent or significantly reduced from the preoperative state. A number of photographic methods were used to measure edema, and we are currently in the process of refining a technique to quantitate residual limb volume changes during Controlled Environment Treatment. This technique, which makes use of a small strain gage sutured adjacent to the operative site, was used in conjunction with CET in 4 of the 20 cases. This system of instrumentation is based upon the hypothesis that skin tension adjacent to the suture line is related to limb volume (7). With the feasibility phase of this method now completed, it is expected that CET

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*See paper entitled, “A Proposed Technique for the Postoperative Monitoring of Skin Tension in Below-Knee Amputees,” by E. M. Burgess, M.D., Craig A. Spolek, M.S., and A. James Moore, as presented elsewhere in this issue of the BPR. (Three of the four cases are described in detail. Data on the fourth, and on four others, were invalidated by various mechanical difficulties).*

30
efficacy in edema control can be quantitatively demonstrated with more accuracy in the future.

Pain

In general, patients were remarkably comfortable during CET. The amount of pain medication was monitored (Fig. 6). It is interesting to note that one patient required only aspirin following amputation. The majority of patients did not require injectable pain medication after the first postoperative day and took no oral narcotics after the fourth postoperative day. More frequent and extended use of injectable or oral narcotics was required in a few cases where there had been a previous history of drug abuse or excessive preoperative pain medication. One patient who developed a hematoma required larger amounts of pain medication until the hematoma was evacuated. Diabetic patients appeared to experience less postoperative discomfort than others in this series.

The number of patients requiring injectable narcotics is shown in Figure 6. Two patients did not require injectable narcotics.

**Figure 6.** Injectable narcotics required for the first five postoperative days. Two patients did not require injectable narcotics.
Time from Surgery to Definitive Prosthetic Prescription

Sixteen of the patients were successfully cast and measured for a definitive below-knee prosthesis. The average time from surgery to cast and measurements for a definitive prosthesis was 43 days; of the 16 patients fitted, 12 averaged 37 postoperative days. Average time was relatively the same in all three etiological groups.

Of the four additional patients, one was discharged to a nursing home on a non-ambulatory basis with the below-knee amputation well healed (this patient had been non-ambulatory for more than 1 year prior to admission and had a severe left hemiparesis). Another patient expired from myocardial infarction before completion of his rehabilitation; a third patient (a bilateral amputee) was, because of associated disabilities, not included in the routine postoperative rehabilitation protocol; and the fourth patient was successfully fitted following revision to the above-knee level.

Case Studies

*Case No. 1:* 58-year-old male with severe arteriosclerosis without diabetes. Associated diagnoses included hypertension, cardiac hypertrophy, glaucoma, arrested pulmonary tuberculosis, chronic rheumatoid arthritis, and carcinoma of the larynx (postsurgical). In 1972 a cross-pubic (femoral-femoral) vascular vein graft was placed in an attempt to relieve left lower limb ischemia. Pain was decreased, but chronic ischemic ulcers developed over the lateral aspect of the distal left foot, and the lateral three toes were amputated. Superficial ischemic ulcers also developed over the distal dorsum of the right foot. The patient had not walked for 1 year prior to admission on March 13, 1974 for amputation of the left leg (Fig. 7).

A long-posterior-flap, closed, left below-knee amputation was performed on March 15, 1974, and the residual limb was placed immediately in the Controlled Environment Treatment chamber. The high pressure reading was initially set at 50 mm Hg for a 30 s interval, and the low pressure at 11 mm Hg for 120 s interval, with the pressure states alternating. The patient was comfortable postoperatively, requiring nothing but salicylates for relief of pain. The low pressure state was gradually reduced over a 3-day period from 120 s time duration to a 60 s time duration, and on the seventh postoperative day the high pressure was reduced to 37 mm Hg continuing at a 30 s duration (Fig. 8). Temperature remained at 30 deg Celsius.

Healing progressed uneventfully; the patient remained afebrile, comfortable, and without demonstrable evidence of residual limb.
FIGURE 7: Case No. 1: Preoperative view of failed vascular reconstructed patient.
edema. On the 14th postoperative day the limb was removed from the CET unit and placed in a plaster of Paris rigid Immediate Postoperative type of prosthetic dressing. Assisted ambulation with touchdown was then initiated, and weightbearing was gradually increased according to tolerance. Sutures were removed on the 27th postoperative day with firm primary healing of the operative wound (Fig. 9).

The patient was measured and cast for a definitive prosthesis on the 39th postoperative day. After it was delivered, he was discharged from the hospital (Fig. 10), walking independently with his prosthesis and walkerette. At this time, the superficial ulcers on the right foot had healed.

Two years following amputation, he continues wearing his prosthesis daily, ambulatory with external aids, and living at home. No other surgical treatment has been required for ischemia of his lower limbs.

**Case No. 2** (Case No. 5 on Table 1): 53-year-old male who had sustained severe compound fractures of the right distal tibia and fibula, secondary to missile wounds incurred in 1945. Chronic osteomyelitis of the distal tibia developed, requiring 2½ years of hospitalization and approximately 15 open surgical procedures. Fracture union was achieved but there was a 3 in leg length discrepancy, with a spontaneous arthrodesis of the ankle and limited motion throughout the tarsal and toe joints. The foot was fixed.
FIGURE 9. — Case No. 1: Four weeks following surgery.
FIGURE 10. Case No. 1: Patient in definitive prosthesis after completion of rehabilitative care.
in varus, and moderate hypesthesia and motor dysfunction secondary to scarring were present (Fig. 11). An orthopedic shoe and brace had been required for many years, and the patient experienced pain on weightbearing.

He was admitted to the Seattle Veterans Administration Hospital on May 8, 1974, for the treatment of an acute flareup of the osteomyelitis, demonstrated by drainage, fever, chills, regional lymph adenopathy, and elevated white count and sedimentation rate.
It was decided, after control of the systemic aspects of the infection, to proceed with amputation.

On May 10, 1974, a closed below-knee amputation was performed above the site of the draining osteomyelitis. The patient was placed immediately after surgery in the CET unit (Fig. 12).
Pressures were set at 50 mm Hg for 30 s and 10 mm Hg for 50 s, alternating with the temperature set at 30 deg Celsius (Fig. 13). The drain placed at surgery was removed on the first postoperative day, and the patient was allowed up in a chair.

Preoperatively, 50 mg of Demerol and 25 mg of Phenergan by intramuscular injection had been required for pain control. The patient was kept on this medication for one postoperative day, but at the end of the second postoperative day, only an occasional oral analgesic was needed. No edema developed; the patient was allowed in a walkerette with the CET chamber in place, and no local or systemic evidence of infection followed the amputation.

Six days following amputation, because of the patient’s rapid and excellent progress, his leg was removed from the CET chamber and placed in an immediate postsurgical prosthetic cast. He was discharged from the hospital, ambulatory on crutches, the following day.

Healing progressed uneventfully (Fig. 14), the definitive prosthesis was delivered and fitted on the 39th postoperative day, and he has become a successful, fully rehabilitated amputee, requiring no external aids and carrying out essentially a normal social and work life.
Case No. 3 (Case No. 15 on Table 1): 33-year-old male, who on July 15, 1975, sustained a crushing injury with partial amputation of his right foot in a railroad accident. He was taken to a community hospital, where a debridement was carried out on the day of injury and the amputation site closed at a transmetatarsal level.
FIGURE 16. - Case No. 3. Gullodine amputation for severe sepsis, prior to definitive below-knee amputation.
Severe infection with septicemia developed; the patient was transferred to the Seattle Veterans Administration Hospital, and on July 20, 1975, an emergency open amputation was performed just above the ankle joint to control infection (Fig. 15). Soft dressings were applied. Two days following amputation, the limb was placed in the CET bag with pressure readings at 30 mm Hg for 30 s on high and 10 mm Hg for 60 s on low, with the temperature set at 32 deg Celsius (Fig. 16). Local and systemic signs of infection were promptly controlled; pain moderated rapidly.

Ten days following the guillotine amputation, a closed below-knee amputation 18 cm in length was performed, using a long posterior flap. No drain was placed because the wound was dry after hemostasis and release of the tourniquet. The residual limb was again placed in the CET chamber, with pressure gradients set at the same levels as previously. On the second postoperative day, a hematoma developed. The limb was removed from the chamber, two sutures were removed, the hematoma evacuated, and the limb replaced in the CET. The patient then continued to heal uneventfully with rapid elimination of the edema present at the time of surgery and with a comfortable postoperative course. A strain gage had been applied at the suture line at the time of closure. This was not disturbed, and continuous readings, indicating tissue tension, were taken.

Nine days following amputation, the leg was removed from the CET chamber. Healing was progressing well without infection,
edema, or evidence of necrosis or wound disruption (Fig. 17).
Further rehabilitation progressed uneventfully with the rigid
dressing technique.
A cast and measurement were taken for a definitive prosthesis 41 days following amputation. Amputee rehabilitation proceeded uneventfully to an excellent functional result.

Case No. 4: 85-year-old male, admitted to Seattle Veterans Administration Hospital on March 25, 1974, with severe peripheral vascular disease, ischemia of the lower limbs, and gross edema (Fig. 18). Associated diagnoses were generalized arteriosclerotic cardiovascular disease, congestive heart failure, and severe anemia.

The chief complaint involving the lower limbs was severe rest pain in the right foot, increasing over a 3-year period. The patient required daily nitroglycerin for control of angina. Four weeks of medical supervision were necessary after admittance to prepare the patient sufficiently to withstand a below-knee amputation. This surgery was performed on April 23, 1974, using the classical long posterior flap technique. The wound was not drained; CET

**Figure 18.** — Case No. 4: Preoperative appearance of patient with severe peripheral vascular disease.
**FIGURE 19.** — Case No. 4: Residual limb in CET immediately following surgery.

**PRESSURE CYCLE**

**CASE NO. 4**

![Pressure Cycle Graph]

**FIGURE 20.** — Case No. 4: Pressure cycle during CET.
was initiated immediately (Fig. 19) with a high pressure reading at 50 mm Hg for 30 s, and low pressure at 10 mm Hg for 50 s, alternating, and with the temperature at 38 deg Celsius (Fig. 20).

Pain was minimal; the patient moved the leg comfortably within the chamber, but on the second postoperative day, he experienced increasing substernal chest pain and shortness of breath, and developed a recurrence of congestive heart failure. His cardiovascular status, including chest pain, was improved by further active medical treatment, but the below-knee amputation site did not heal (Fig. 21); marginal skin necrosis developed, and it was necessary to revise the amputation to the above-knee level 17 days following the initial surgery.

A rigid dressing was applied, tilt table positioning was gradually instituted, and the patient was discharged from the hospital 15 days following the above-knee amputation. Healing progressed uneventfully (Fig. 22) and 30 days later, the patient was cast and measured for a definitive prosthesis. He continues to use the prosthesis at home with a walker and has had no further hospital admissions. He is ambulant for short distances with the prosthesis and walker, lives with his family, and requires no special nursing care.

Figure 21. — Case No. 4: Residual limb 17 days following amputation. Dry ischemia and gangrene present, with no evidence of edema, cellulitis or infection.
At the time of the above-knee amputation, the below-knee site was studied. There was no infection present; the failure in healing was due to ischemia. This elderly patient was considered a failure in pre-operative level determination. He would normally have had an above-knee amputation initially; however, an attempt was made to salvage the knee since he had been ambulatory prior to hospitalization. Judgment as to rehabilitation potential was, however, verified by the fact that 1 yr following the amputation, he was walking with an above-knee prosthesis and living at home. This case represented one of two healing failures, neither of which can be attributed to the CET physical environment.

**CET Mk II UNIT**

Following initial clinical trials at Roehampton and Seattle, a smaller, lighter-weight, and quieter version of the CET was constructed. This unit, designated Mk II (Fig. 4), provides easier operation and control. Of paramount importance is the replacement of the deadweight pressure regulator system with a gas-regulated
method. Simple adjustments in pressure, temperature, and cycle times can be made with controls conveniently located in the front panel. The Mk II unit is now standardized equipment, available commercially (through the Cape Engineering Company Limited, Warwick, England) as the Cape Sterishield Controlled Environment Treatment System®.

Capabilities of Equipment

1. Pressure — 0—50 mm Hg, constant pressure or alternating cycles of high and low pressure.
2. Cycle Time — constant pressure, or a cycle made up of two alternating periods, each of which may be set at 0—300 s (Mk I) or 0—999 (Mk II).
3. Temperature — from approximately 4 deg Celsius above ambient room temperature to 40 deg Celsius (3 deg above body temperature).
4. Sterility — HEPA bacterial filter (99.998 percent efficiency on 0.6 μm particles).
5. Humidity — provides reduced relative humidity (air is cooled and rewarmed prior to entering the treatment bag).
6. Gas Composition — room air is routinely used; however gas composition may be altered by introduction of other gas; e.g., O₂.

DEVELOPMENT OF RELATED MANAGEMENT SYSTEMS

The clinical application of CET has provided impetus for the development of related management systems. These units supply elevated air pressure for control of edema states which do not require a sterile environment. Compared with CET, they cost and weigh less and are more compact.

First to design a related system was the Biomechanical Research and Development Unit (BRADU), Roehampton, England. Their Pressure Environment Treatment (PET), incorporates all features of the CET, with the exception of sterility and temperature controls. The PRS system, Modulated Air Controlled Environment (MACE), has basically the same capabilities as the PET, with slightly different treatment ranges and methods of adjustment. Both the PET and the MACE employ the CET dressing bag.

A third unit, the Rancho Edema Control System, developed at the Rancho Los Amigos Hospital, employs a doughnut-shaped seal in its treatment bag. This seal, inflated to only three-quarters of the pressure in the bag, is intended to avoid constriction but to
<table>
<thead>
<tr>
<th></th>
<th>Mk II CET</th>
<th>PET</th>
<th>Mk II MACE</th>
<th>Rancho Edema Control System</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cost (approx.)</strong></td>
<td>$5,000-$6,000</td>
<td>$2,500-$3,500</td>
<td>$1,200</td>
<td>$1,500</td>
</tr>
<tr>
<td><strong>Size</strong></td>
<td>18 x 26 x 35 in. (9.5 ft³)</td>
<td>18 x 26 x 20 in. (5.4 ft³)</td>
<td>10 x 16 x 13 in. (1.2 ft³)</td>
<td>10 x 17 x 11 in. (1.1 ft³)</td>
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<tr>
<td><strong>Weight</strong></td>
<td>154 lb</td>
<td>100 lb (approx.)</td>
<td>25-35 lb</td>
<td>15 lb</td>
</tr>
<tr>
<td><strong>Pressure</strong></td>
<td>0-50 mm Hg Externally adjustable</td>
<td>0-50 mm Hg Internally adjustable</td>
<td>High pressure externally selected for 20, 30, 40 mm Hg or higher; low pressure 10 mm Hg internally adjustable</td>
<td>0-30 mm Hg Externally adjustable (no pressure feedback)</td>
</tr>
<tr>
<td><strong>Cycle time</strong></td>
<td>Continuous or alternating; 0-999 s high and low pressure</td>
<td>Alternating high and low pressure 0-300 s</td>
<td>Continuous or alternating high and/or low pressure 30, 60, 90 s</td>
<td>Continuous</td>
</tr>
<tr>
<td><strong>Temperature control</strong></td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td><strong>Sterility</strong></td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td><strong>Seal</strong></td>
<td>CET</td>
<td>CET</td>
<td>CET</td>
<td>“Doughnut” type; seal pressure 75% of bag (set) pressure</td>
</tr>
</tbody>
</table>
allow slow leakage from the bag. Unlike the CET, PET, and MACE, the Rancho System provides constant pressure only. A comparative summary of these treatment systems is seen in Table 2.

**CET TRIAL CENTER REPORTS**

*San Francisco VA Hospital; Wesley S. Moore, M.D.*

As of February 25, 1977, 8 patients had been managed with CET. Five of these cases were part of a controlled and randomized study of lower-limb amputations in which CET is being compared with the Immediate Postsurgical Prosthetic Fitting Technique. Three additional cases of venous stasis ulcers were treated with the device, and results were encouraging.

Dr. Moore will report his findings in a separate publication upon completion of a larger number of cases. At this time, he remains enthusiastic about CET; however he is not yet in a position to measure the advantages or disadvantages in wound healing with either method of postoperative management. His program using CET is ongoing, carefully ordered in a scientific statistical manner, and requires more time before additional conclusions can be drawn.

Dr. Moore was appointed Professor and Head, Section of Vascular Surgery, The University of Arizona Health Sciences Center, College of Medicine, Department of Surgery, Tucson, Arizona, and will serve as a consultant to the VAH, Tucson, Arizona.

*Rancho Los Amigos Hospital; Downey, California, F. William Wagner, Jr., M.D.*

Between March 1, 1975 and March 31, 1976, CET was used in the postsurgical management of the first stage of 13 two-stage Syme’s amputations, performed for diabetic and dysvascular infection and gangrene. A control group, comprising 41 patients, used a bias-cut stocking as the method of postoperative treatment. Average age of combined cases completed during this time period was 60.4 years.

Dr. Wagner reported a 62 percent wound healing success in the trial (CET) group and a 73 percent success in the control group. He feels that at this time it is not possible to determine the advantages or disadvantages of CET, as it relates to wound healing progress, compared to conventional wound management systems.

Dr. Wagner is, however, interested in the use of CET as a therapeutic tool, he has suggested monitoring tissue levels of antibiotics to determine the efficacy of the equipment in management of infection prior to proposed amputation. Rancho Los Amigos Hospital has submitted a grant request for a wound healing study using CET.
Additional cases involving the use of CET at this facility have included treatment of edema states of the lower limbs, vascular ulcers, and well-draining infections (primarily in the ischemic limb). At this time, the Rancho Edema Control System, developed under Veterans Administration financing and sponsorship, is being used as well in treatment of edema states which do not necessarily require a sterile environment.

*Castle Point, New York, VA Hospital: Bok Y. Lee, M.D., Frieda S. Trainor, Ph.D., and David Kanner, Ph.D.*

During a 15 month trial period, which began in December 1974, CET was used in below-knee and distal amputations (3 cases) and in the management of ischemic ulcers (3 cases). Overall experience has been positive, and CET has been incorporated into the treatment armamentarium of the Vascular-Surgical Service at Castle Point.

This facility continues to use the equipment and is satisfied with the technique, particularly in control of edema and in the treatment of circulatory and static ulcers of the lower limb. A major interest of this project is prevention of amputation in dysvascular patients. Because of the low amputation rate at Castle Point VA Hospital (3 to 5 yearly), CET is primarily being used in the management of ischemic ulcers, with emphasis on studying the effect of CET on compartmental fluid distribution, venous pumping, and skin blood flow.

*Duke University Medical Center, Durham, North Carolina: James R. Urbaniak, M.D., and Frank W. Clippinger, Jr., M.D.*

CET has been used at this facility for the treatment of upper and lower limb edema states and for the postsurgical management of hand trauma and hand reconstructive surgery. Between January 1975 and January 1976, 9 cases were managed with CET, including 8 hand pathologies (of which 4 were replantation procedures) and 1 case of posttraumatic edema of the lower limb. Because it was not possible to include suitable controls in their study, the clinical trials at Duke University Medical Center were essentially a field study, consisting of carefully documented case reports.

Their results to date have been encouraging in the areas of application. The staff at Duke have found the equipment to be a most valuable clinical asset in the treatment of acute and chronic edema states, and they have suggested further long range use of the device to determine the efficacy of CET in wound healing. Following initial clinical trials, longer treatment bags to provide elbow support were requested and supplied to this facility; additional suggested modifications included a banana-shaped dressing bag to accommo-
date a flexed elbow.

This facility plans to continue incorporation of CET into the care of postsurgical and posttraumatic hand problems and, at present, is investigating use of the equipment for edema states which do not necessitate a sterile environment. Hence, the simpler management systems (PET, MACE, and Rancho Edema Control System) would be helpful in these situations.

**Prosthetics Research Study, Seattle, Washington: Ernest M. Burgess, M.D.**

The CET Technique was used by the Prosthetics Research Study for a period of approximately 3 years, treating lower-limb amputations immediately postsurgically.

The original upper-limb dressing bags were too short. Modified bags have since been constructed to accommodate the entire arm up to the axilla, however there is still a need for a banana-shaped bag to provide for elbow flexion.

Twenty below-knee amputations were managed with CET between March 1974 and December 1975. The result of that clinical study is incorporated in the first part of this paper.

Since December 1975, 20 additional below-knee amputations have been treated with the equipment in Seattle. Use of the device during the past 12 months has also included treatment of upper and lower limb edema states (5 cases) in which amputation was not involved. Application of CET concepts has been extended in modified form, with the development of the MACE at Prosthetics Research Study, for control of limb edema conditions and for the immediate management of closed limb trauma, primarily about the knee and ankle.

At the present time, four CET units are available to this investigator. Two are stationed at the Seattle VA Hospital, principally for the postsurgical care of lower-limb amputations, and a third is located at Providence Hospital in Seattle for similar use. A fourth unit is situated at the Harborview Medical Center, Seattle (a University of Washington affiliate) where a wide variety of fresh trauma, including compartmental syndromes, closed fractures, and joint injuries, are available for study.

The simplified MACE unit has been loaned directly to the Department of Biomedical Engineering and Orthopaedics at the University of Washington, where basic research is underway to study the effects of external pressure. Here, the device is being used (in conjunction with supplementary electronic equipment) to measure surface and muscle blood flow in the limbs of a rabbit animal model. Data derived from these studies will be translated to clinical
application of the CET and related management systems.

Conclusions Reported from Investigating Centers

Advantages of CET:
1. CET is easy to apply and to operate.
2. CET provides uniform pressure, regardless of limb volume changes, there is no danger of a tourniquet effect or localized pressure areas.
3. CET provides a dry wound surface and sterile environment, conducive to wound healing.
4. CET allows visual inspection and palpation of the wound site without disturbing the sterile environment.
5. CET provides edema control.
6. In the absence of postsurgical complications, patients report minimal discomfort using CET.
7. Patient acceptance of CET is positive.
8. CET permits freedom to carry out knee flexion exercises.

Disadvantages of CET:
1. Originally the noise disturbed patients. This problem is now essentially eliminated with the quieter Mk II CET.
2. Weightbearing is delayed with CET.
3. Mobility is somewhat limited with CET; some patients become restless if treatment is extended for a long period of time.
4. Careful nursing is required to prevent decubiti in debilitated patients.
5. CET does not provide residual limb contouring.
6. Syme's amputees have difficulty ambulating because the dressing bag hose connection contacts the floor. (Redesigned treatment bags have helped to alleviate this problem.)

Summary of CET Equipment Malfunctions

Mechanical problems encountered during use of the equipment were corrected through a joint effort on the part of the PRS engineering staff, BRADU, and appropriate personnel at the various trial centers. The most common equipment malfunction was cooling fan failure, which occurred at the Duke University Medical Center, the Castle Point VA Hospital, and in three of the four units at the Prosthetics Research Study. In addition, it was necessary to rewind the main compressor motor at Castle Point and to replace a burned-out main blower bearing at the San Francisco VA Hospital. Current Mk II CET units employ an improved cooling fan model, which provides increased durability.
Recommendations from Investigating Centers

Overall experience with CET at the participating trial centers has been positive. All investigators view this system of management as a viable technique and are enthusiastic about its continued use and extension into other areas of treatment. The following recommendations were suggested at an evaluation workshop held in Seattle in May 1976:

1. At this time, CET offers an alternative to conventional systems of wound management. A long-range controlled and randomized study is needed to ascertain the effectiveness of CET on wound healing progress, i.e., to determine where CET stands in relation to conventional techniques for managing ischemic ulcers, amputations, and hand pathology.

2. There is a need to extend the use of CET into several areas of treatment in order to define where CET can be most effectively used.

3. A jointly controlled study involving all investigating centers, will provide comparative results in a short period of time.

4. Further basic research should be carried out to determine the effects of CET on tissue physiology. Particular emphasis should be placed upon the nature of the CET cycle times and pressure phases as they relate to the status of peripheral circulation, tissue compartment pressure changes, and tissue gas concentrations.

5. Immobilization of the limb within the treatment bag is an important area to explore, e.g., the possibility of splints to support fractures or the long posterior flap in below-knee amputation surgery.

6. Protocols should be prepared for the above phases of CET investigation.

DISCUSSION AND CONCLUSIONS

Wound healing, a process of tissue regeneration and repair, relates directly to restoration of function. The external physical environment in which tissues heal and the influence of these environmental forces on clinical wound healing are the bases of this study.

Thermal injury, i.e., burn and frostbite, has attracted the most interest in external healing environment. There is need for improvement in understanding and treating all types of tissue trauma in an optimum physical environment during healing.

This study outlines our observations using a controlled system of environmental management following the surgery of amputation. Amputations were selected as a pilot clinical study because
this operation without distal tissue to support constitutes an excellent, controllable wound healing model. Our experience in the first 20 below-knee amputations using this specific Controlled Environment Treatment technique has encouraged us to extend this management system to a wide variety of types of trauma and disease of the limbs. Contraindications to this management system would be those circumstances in which the application of external pressures could be harmful. Posttraumatic compartmental syndromes unrelieved by fasciotomy, infections (particularly closed space infections), undrained hematomas, and thromboembolic states exemplify situations in which CET could possibly produce harm.

A major drawback of the CET device in the management of amputees is the inability to ambulate these patients, except with difficulty and with no terminal wound support. We are strongly committed to postsurgical immobilization, i.e., a rigid dressing. It is of considerable advantage to be able to visually inspect the healing amputation with CET, but we favor a rigid dressing for support. With these factors in mind, we are currently exploring methods to immobilize the residual limb within the treatment bag in order to obtain the advantages of external wound support and tissue rest, as well as the modalities provided by the CET equipment.

Good experience using this specific system of Controlled Environment Treatment has encouraged the cooperating centers not only to continue it for amputations but to extend this management technique to a wide variety of trauma and disease of the limbs.

Prosthetics Research Study anticipates extended use of the CET. We believe it fills a need in many areas of limb and, in fact, trunk trauma disease. We continue to document case results and plan to record our experience with further publication.

ACKNOWLEDGMENT

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REFERENCES


