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A new approach to the management of wounds of the extremities Controlled environment treatment and its derivatives

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Abstract

Controlled Environment Treatment is a new approach to wound management—for the first time it provides the surgeon with the means of controlling and optimizing the wound environment for the duration of the healing period.

Equipment is commercially available and the technique is now being applied internationally; the technique has been established for the treatment of limbs—application to the trunk requires further investigation and development.

Spin-offs have already occurred, one being the control of certain types of lymphoedema by the patient in their own home; the other concerns the application of plaster of Paris to produce casts having significantly superior physiological characteristics using minimal manipulative skills. The former is known as Pressure Environment Treatment, the latter is known as Controlled Pressure Casting; equipment is commercially available internationally.

The treatment and healing of wounds on the limbs

General philosophy

The rate at which a wound heals is governed by the metabolic processes in the adjacent tissues; in ideal conditions the healing time becomes a minimum, but external conditions can impair the local metabolic processes which in turn will result in delayed healing. A wound management system should therefore endeavour to provide a wound environment which does not impair the natural processes.

Ideally, a wound management system should permit an adequate tissue response to the stimulus of injury and actively prevent any over-response such as excessive oedema. The system should not interfere with the normal vascular and lymphatic circulation; indeed it is advantageous if these circulations are positively assisted. The system should prevent bacterial cross-infection and should control the proliferation of the skin-borne bacteria. It should prevent the occurrence of complications such as the formation of a haematoma. Visual observation of the wound and palpation of the tissues without disturbing the environment, would permit the early detection of complications and the implementation of relevant remedial action. When healing is complete, the system of treatment should not retard the resolution of the side effects of the mechanisms of tissue repair; this is of special importance in relation to the persistence of residual oedema which may cause considerable delay in the final rehabilitation of the patient.

Present methods of wound management usually entail the application of a clinical dressing held in place by a soft bandage, a pressure bandage, or a rigid plaster cast. The effect of these dressings on the wound and on the adjacent tissues, and also on the conditions of the environment surrounding the wound, is very dependent upon the skill and experience of the person applying the dressings; furthermore, these conditions can be radically changed—for instance by a change in tissue volume. Once applied, the conventional dressings are passive; any attempt to readjust the influence of the dressing requires removal and re-application with consequent mechanical disturbance and exposure to cross-infection. Bleeding and wound exudate establish moist warm conditions which favour bacterial proliferation. The inability to observe the wound until the dressing is removed may result in complications remaining hidden until other symptoms indicate that all is not well at the wound site; remedial measures are consequently delayed.

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The concept of the gaseous dressing

The Biomechanical Research and Development Unit at Roehampton has developed a wound management system which is unique; it is known as Controlled Environment Treatment (CET) and it complies with most of the requirements of what should constitute an ideal system of wound management. By containing the bare limb within a transparent plastic film bag, and by using a pressurized gaseous environment in direct contact with the limb, a form of wound management has been devised which has the following clinical advantages:

a. The wound is maintained in an environment which is protected from bacterial contamination.

b. The low relative humidity of the environment militates against the proliferation of the indigenous skin-borne bacteria. Additionally, the low relative humidity maintains the wound and adjacent tissues in a dry state.

c. By varying the air pressure in the "dressing" in a predetermined cyclic fashion, the circulation of blood and lymph can be modified with beneficial results.

d. The pressures imposed on the tissues are uniform within the "dressing" and can be set to predetermined levels and will be maintained at these levels, regardless of change of size or shape of the traumatized limb. A tourniquet effect is impossible.

e. The temperature within the "dressing" can be set to a predetermined level.

f. Direct contact between the skin/tissues and the gaseous environment permits the normal gaseous and water exchange mechanisms of the skin to remain viable and functioning.

g. Clinical assessment of the wound can be made both visually and by palpation at any time and without disturbing the environment.

h. There is no interference with the normal nursing and rehabilitation procedures.

i. The treatment is simple to set up and maintain.

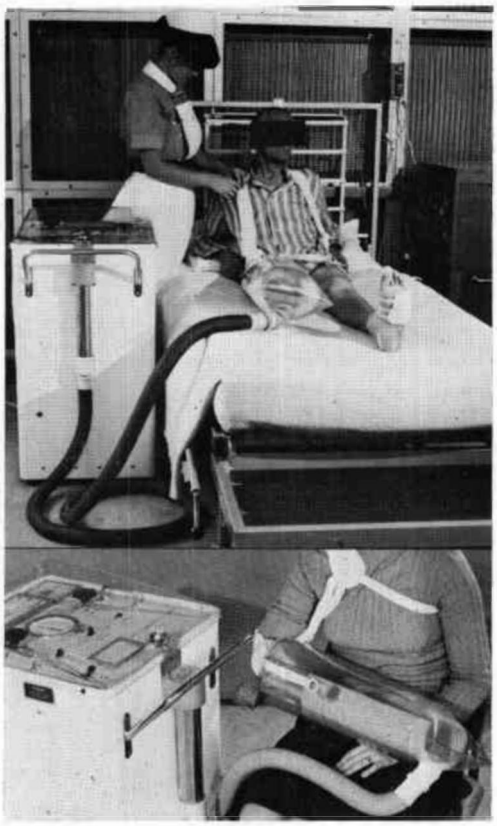

Fig. 1. Controlled Environment Treatment (CET). Top, application to surgical case. Bottom, sterile treatment bag enclosing the limb.

The apparatus for this treatment (Fig. 1) consists of a control console containing an air compressor, feeding bacterially free air via pressure, timing, and temperature control devices and a lightweight flexible hose to the sterile treatment bag which encloses the limb. The pneumatic circuit system is shown in Figure 2. Figure 3 shows the console with its controls. The treatment bag, Figure 4, is a flexible transparent "open bag" with the air hose connected to the closed distal end. The open proximal end incorporates a self-adapting pleated type of air seal used within the hovercraft industry. Following surgery, the limb is inserted into the sterile bag by passing it through the pleated seal. No dressings are applied to the wound which is therefore clearly visible through the transparent wall of the bag; the limb rests on a soft open-cell plastic foam pad attached to the inner wall of the bag. The

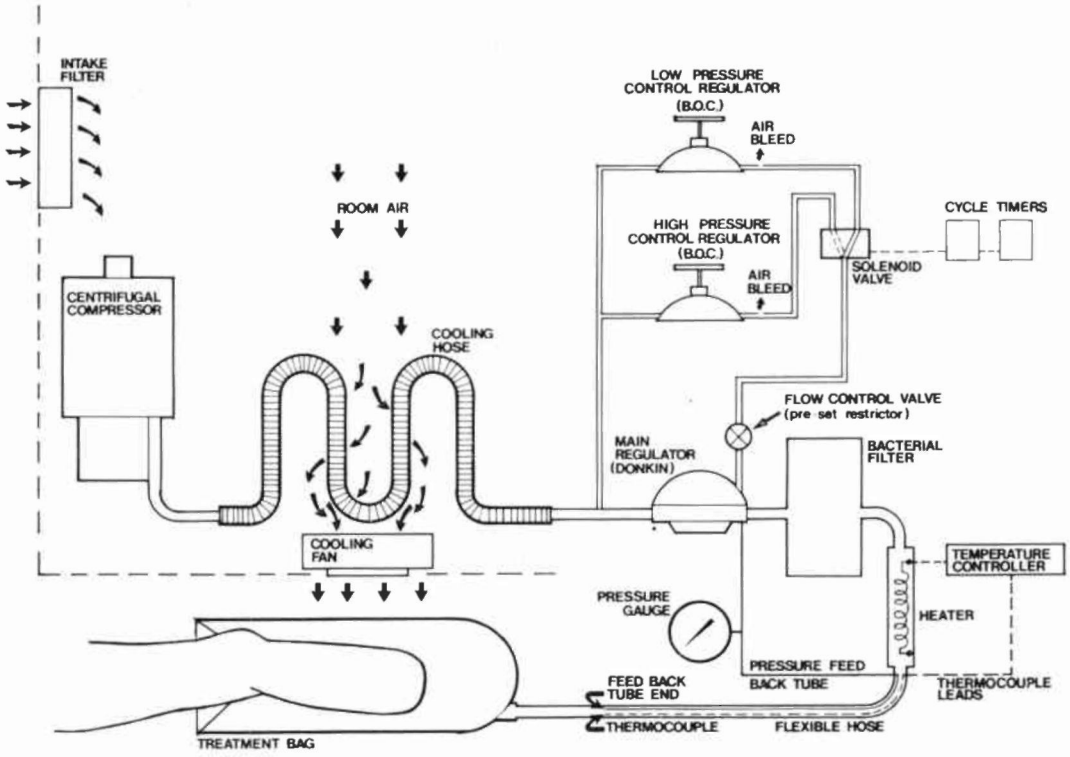

Fig. 2. Block diagram of pneumatic circuit system.

bag is held on the limb by means of a simple retention harness made from flexible webbing. The pressure and temperature conditions in the treatment bag can be preset via the controls on the console; the air pressure will be cycled automatically, typically 50 mm Hg for 30 seconds followed by 10 mm Hg for 10 seconds. The temperature control is normally set to supply air to the bag at about normal skin temperature (33 ± 3°C). The fit of the seal around the limb cannot exert a pressure on the underlying tissues which is greater than the air pressure in the bag, and thus there is no risk of a tourniquet effect. The seal is not air tight, and is organized to permit a specific leakage of air from the bag to atmosphere at all times; this

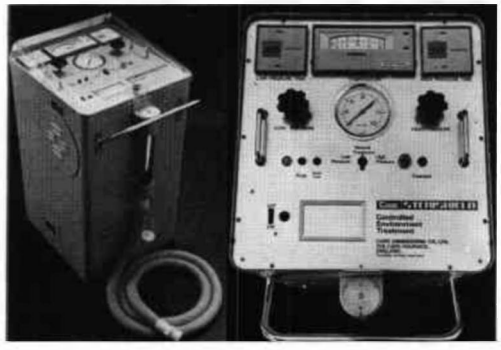

Fig. 3. Air control console.

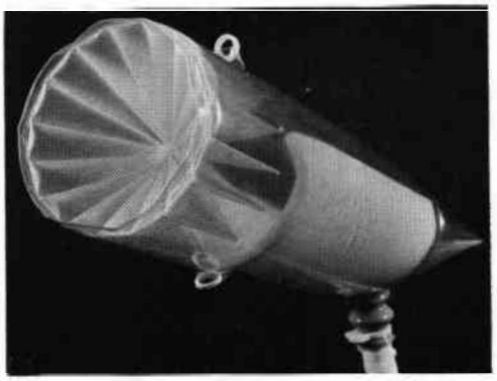

Fig. 4. The treatment bag showing pleated self-adapting seal.

air leak allows a continuous passage of air through the bag enabling both temperature and humidity to be controlled. This controlled air leak is provided by a single layer of knitted stockinette which is placed over the limb in the region of the bag seal; it is important that this stockinette is in place. Additionally this prevents the seal vibrating and emitting an undesirable raucous noise. The positive pressure gradient that is maintained at all times between the inside of the bag and the outside atmosphere, prevents the re-entry of any non-sterile air past the pleated seal. The control console does not incorporate a preset relative humidity control, but raising the temperature of the ambient atmosphere to bag temperature produces a relative humidity within the bag of about 20%—which has a significant drying effect.

The treatment is maintained for 24 hours a day for the duration of the healing period.

By the early part of 1974, sufficient clinical experience had been accumulated in the U.K. at Queen Mary's Hospital, Roehampton, and by the Prosthetic Research Study at Seattle, U.S.A., to indicate that the Controlled Environment Treatment offered significant clinical advantages over the current/classical wound management technique in the fields of amputation and hand surgery.

The use of the equipment was extended, and by 1975 5 Centres in the U.K. and 5 Centres in the U.S.A. were using it in the fields of:

a. Amputations of the leg for
   i. Vascular disease including diabetic gangrene
   ii. Non-vascular causes

b. Hand surgery for
   i. Dupuytren's contracture
   ii. Re-implantation surgery
   iii. Syndactyly
   iv. Arthroplasty

c. Burns of the extremities

d. Post-traumatic oedema of the extremities
   i. Acute } Closed
   ii. Chronic } trauma

e. Chronic obstructive lymphoedema

f. Ulceration of the lower limb
   i. Gravitational (varicose)
   ii. Diabetic

In order to compare the performance of this form of treatment over conventional forms of wound management several independent colleagues were involved in the conduct of a formal trial. After attempting to collect information for a twelve month period, experience clearly indicated that the combined effects of (i) limited equipment availability, (ii) small sample population, (iii) inability to stabilize the surgical, the nursing and the range of physiological conditions, and (iv) the problems of attempting to quantify such qualitative parameters as pain and oedema, have made rigorous statistical analysis difficult and of debatable value.

The generation of clinical opinion based on clinical experience was however much more positive and generally convinced most colleagues that this form of treatment was beneficial. Since 1976 a much wider and more extensive background has been accumulated and may have regularized its use. Success is not universal and there is a minority of cases where enthusiasm is either lacking or is muted; nevertheless—to the best of our knowledge—there is no instance of the treatment adversely affecting the progress of the patient.

A summary of clinical opinion could be stated as:—

(i) In all applications CET is effective in the reduction of pain and oedema;

(ii) in hand surgery, it presents no obstacle to the early mobilization of the joints and consequently appears to result in a more rapid restoration of function;

(iii) in amputation surgery, the stump at the end of the healing period is more mature and dimensionally stable;

(iv) both (ii) and (iii) above have implications in the cost of subsequent rehabilitation;

(v) provides the additional aid to circulation/healing processes thereby promoting healing of "marginal" cases which, having healed, do possess adequate circulation to maintain tissue viability (Fig. 5).

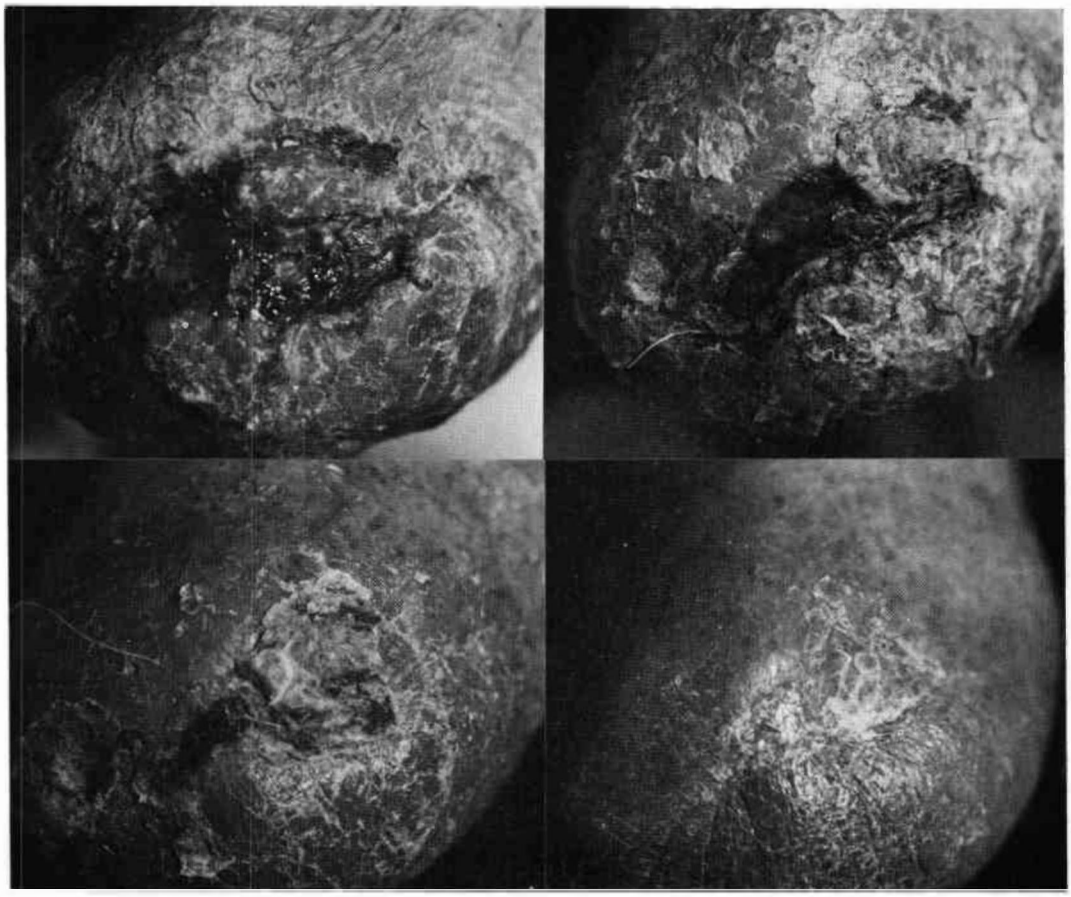

Fig. 5. Response from a chronic ulcer remaining after amputation 14 months earlier. Top left, stump at start of treatment. Top right, stump after 2 weeks. Bottom left, after 4 weeks. Bottom right, after 6 weeks.

(vi) improvements have been noted in the orthopaedic field, but these are too limited in number to be detailed;

(vii) in relatively clean wards it is difficult to make any statement about the avoidance of cross-infection (a single case at Roehampton involving both legs clearly demonstrated this protection);

(viii) very little work has been done in the field of burns, what has been done was disappointing, but there is every reason to continue to investigate revised techniques;

(ix) the technique and equipment presented no major difficulties to the nursing and physiotherapy staff; the fitting and adjustment of the harness proved troublesome to the uninitiated —new and simpler forms of harness are available.

The equipment for this form of treatment is now commercially available throughout the world and is now in use in the U.S.A., Canada, Russia, Japan, Australia.

The control of limb volume

Oedema is a natural consequence of damage to the tissue; the damage may be direct as in the case of surgery or accident, or it may be physiological such as interference with the tissue fluid

transfer mechanisms. Whatever the cause, the presence of oedema can interfere with the fluid exchanges which maintain the tissues in a normal state.

The oedema resulting from closed trauma can result in surgery being delayed until the oedema has significantly subsided. Oedema resulting from damage to the lymphatic mechanism can produce a chronic state which may result in serious restriction of joint movement and loss of muscle power coupled with the encumbrance of an overweight and oversize limb.

Whilst the Controlled Environment Treatment can be used for the treatment of these cases, it was realised that this equipment was unnecessarily complex for this category of patient, and a simplified version (and hence cheaper) was designed. This equipment provides the pressure cycling facility and is known as Pressure Environment Treatment (PET); limited adjustment of the cycle is possible but only after access to controls locked away inside the equipment. There is no temperature control, but the air is warmed to a comfortable temperature; there is no bacterial filter. The equipment was designed for use in the patient's home; safety and simplicity of operation were of paramount importance. Figure 6 shows the equipment which is commercially available; the treatment uses the same bags and harnesses as the CET equipment.

Fig. 6. Demonstration of Pressure Environment Treatment (PET) air control equipment.

From a clinical point of view it is relatively easy to demonstrate the effectiveness of this form of treatment since the non-existence of a wound enables the volume of the affected limb segment(s) to be measured by direct water displacement methods. Such a case is depicted in Figure 7. This patient had chronic lymphoedema of her dominant arm rendering the hand almost immobile together with an oversize and overweight arm. A phlebogram produced normal results, but a lymphangiogram showed no functional lymphatic channels. This was the first patient to be fully documented and to whom this form of treatment was offered as a serious alternative to the possibilities of the grossly disfiguring and somewhat unsatisfactory process of the excision of skin and subcutaneous tissue with subsequent grafting (the Charles operation), or amputation. Treatment by elevation, massage, exercises, or compression treatment using a commercially available pneumatic double walled splint-type treatment bag inflated by a small air pump, all failed to produce any significant response. Figure 7 shows the normal and abnormal arms immediately before treatment. Alternating pressure treatment using the PET type of equipment resulted in a dramatic response after 24 hours of continuous treatment. Continuous treatment was applied for several days before an attempt was made to restrict treatment to a limited daily

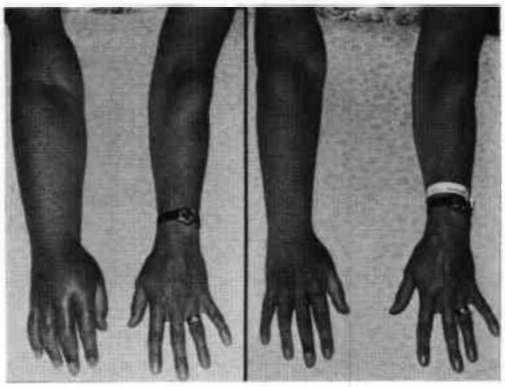

Fig. 7. Patient with lymphoedema. Left, immediately before treatment. Right, following 24 hours continuous treatment. See text and Figure 8.

	Pressure	Time	Pressure	Time	Duration
A	50mm	10sec	10mm	10sec	24 Hrs/day
B	50	10	10	10	12 Hrs/night
C	30	10	10	10	12 "
D	55	10	10	10	24 Hrs/day
E	55	30	10	10	12 Hrs/night
F	30	30	20	10	12 "
G	55	30	10	10	12 "
H	55	22	10	8	12 "
I	55	18	10	12	12 "
J	55	20	10	10	10 "
K	Treatment discontinued				
L	55	20	10	10	8 Hrs/night
M	55	10	10	20	8 "

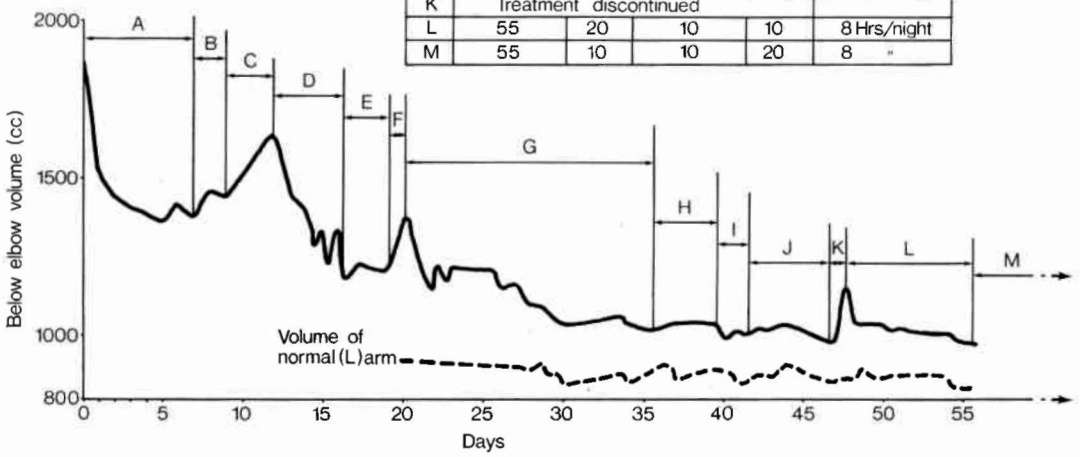

Fig. 8. Response to PET of patient shown in Fig. 7.

period; being very early in the experimental phase, progress was not uniform—as the graph depicts (Fig. 8). Furthermore, the patient was detained in hospital for other reasons and hence became a "long stay" captive subject. As will be seen from the graph, the arm volume became virtually normal, and with the aid of physiotherapy, the muscle and joint functions were completely restored. The patient continued the treatment on a nightly basis in her home; although it could only be offered as a palliative treatment, it was found two years later that treatment was no longer necessary and the arm remained normal in all respects.

This is not a unique case—as Figure 9 shows. This is not a fully documented case but the before and after photographs show clearly the dramatic response. Treatment continues in the patient's home.

Several patients suffering from arm lymphoedema subsequent to mastectomy have been treated—with varying degrees of success. The effectiveness of the treatment is governed by the extent of the lymphatic damage and also by the way and extent to which the patient judges and values the response.

Many other applications have been and are still being explored by colleagues; it is being seriously used for the immediate treatment of injuries to the limbs on the sports field thereby preventing the build-up of oedema before detailed examination and other remedial treatment can be undertaken. (There is serious interest in the athletic world in its use to assist in the removal of metabolic products from tissues subsequent to prolonged physical exertion.)

As indicated earlier, there are a number of pneumatic compression devices available on the market, and unlike the CET and PET, use double walled splint-type treatment bags; it should not be assumed that comparable results can be obtained using these less sophisticated and cheaper forms of treatment.

Controlled pressure plaster casts

Where the preferred treatment is the mechanical support of the whole of the limb (or limb segment) or the immobilization of the muscle groups, the conventional way of obtaining such states is either by the application of pressure/support bandages or by plaster casts. The

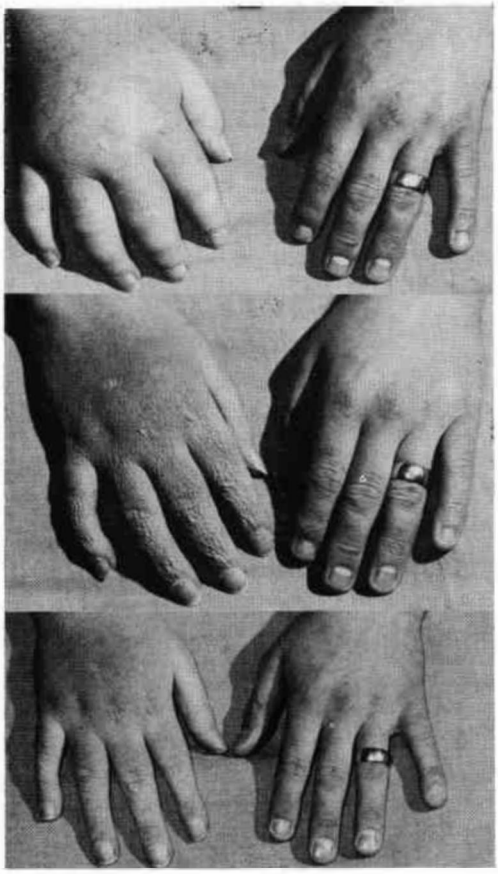

Fig. 9. Patient with lymphoedema. Top, condition at start of PET. Centre, after 2 days. Bottom, treatment maintained at night only in patient's home.

hazards of bandaging have been mentioned earlier; plaster casts can also introduce hazards because the fit of the cast is dependent primarily upon the skill of the operator whose task varies widely because of the variable mobility and distortion characteristics of the tissue/bone structure of the limb segment. As is well known in practice, regions of excessive pressure over bony prominences and zero pressure in re-entrant areas are not uncommon. Non-uniform pressure distribution around the circumference of the limb can invoke a variety of responses including the generation of pressure areas; non-uniform pressure distribution along the axis of the limb can constitute a tourniquet and invoke general oedema.

The concept of pressure air "dressings" has been extended to the application of a uniform

Fig. 10. Controlled Pressure Casting (CPC) equipment.

pressure fluid plaster dressing which subsequently solidifies in that precise form. This technique is known as Controlled Pressure Casting (CPC); the equipment shown in Figure 10 is commercially available.

The technique can be readily understood by reference to Figure 11. A length of tubular knitted stockinette is placed over the segment to be encased in plaster. Strips of wet plaster bandage are placed longitudinally on the surface of the stockinette using enough strips to cover the limb to a depth of two or three layers. Placing the plaster strips longitudinally ensures that they cannot apply any pressure to the tissues—as would be inevitable if the plaster bandage was wrapped on in the conventional

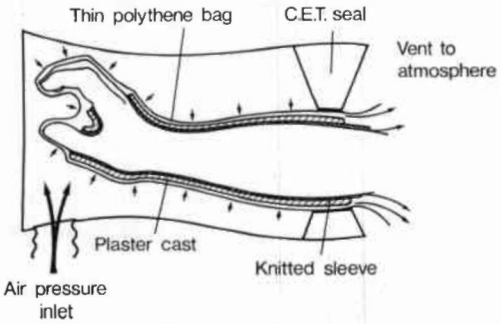

Fig. 11. Principles involved in CPC.

way. The wet, unset assembly is now placed inside a thin walled plastic film bag and the whole pushed into a CET treatment bag; it is imperative that the open proximal end of the plastic film bag and the stockinette must extend through the fluted seal of the CET bag and be free to atmosphere. Inflation of the CET bag with air to the desired pressure will result in air being expelled to atmosphere from the wet plaster/stockinette assembly, and because the plaster is still fluid, the plaster strips and plaster will be held against the tissues at a pressure equal to that of the air in the CET bag. This state is maintained until the plaster has set, whereupon the limb with its shell cast can be removed from the inner plastic film bag. This shell is strong, but it is advisable to reinforce it with plaster bandage wound on in the conventional way until an acceptable thickness is achieved.

This process involves transfer of pressure from one medium to another and it is absolutely essential that the plaster is quite fluid and has not started to set before air pressure is applied. It is also essential that the inner plastic film bag is free from leaks and pinholes.

The fit of the plaster to the tissues is entirely governed by the air pressure applied to the CET treatment bag; a pressure of 50 mm Hg will correspond to a tight fit, 10 mm Hg will correspond to a snug but light fit.

Experience has indicated that the use of cold water to soak the plaster bandage is advantageous and leaves adequate time to complete each stage without the need for unseemly haste.

Patients who have had experience of both conventional casts and CPC casts have commented on the firm and unique fit of the CPC cast. This controllable and superior fit has been employed to stabilize a tibial fracture sufficiently to enable the knee and ankle joints to remain free. The finer details of the technique are still being established, but the clinical experience to date is demonstrating a successful technique with obvious clinical advantages.

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