Prosthetics and Orthotics International, 1980, 4, 15–28

Controlled environment treatment (CET)

The use of a new concept of wound environment in amputation surgery and other conditions of the extremities.

I. M. TROUP

Limb Fitting Centre, Dundee.

Abstract

The use of a new method of improving certain physical aspects of the environment imposed on the extremity is discussed. This follows the use of Controlled Environment Treatment in amputation surgery and other specific conditions within a controlled trial in several Centres in the United Kingdom and United States of America.

The protocol did not attempt to establish any system of controls, the results being based on observation and clinical impression. In other words it is an extension of CET use in an attempt to obtain a wider experience of its application.

One hundred cases involving 128 treatments are listed over a wide variety of clinical presentations. Recordings were made of the presence or absence of oedema, infection, ischaemia and pain, amongst other relevant data. Certain conclusions proved possible and staff acceptance of the system was obtained.

The evidence suggests that the continued use of CET is justified in certain carefully selected clinical conditions. Further, it appears necessary to set up controlled scientific assessments of the system particularly within vascular laboratories where many relevant investigative procedures are carried out on a routine basis.

Introduction

Normally a clinical trial is expected to present a control element against which comparisons are made. Further, the control is expected to bear comparison in certain respects with the trial case. Both trial and control cases should have a potential for objective description allowing accurate data input thus producing a valid statistical result.

CET is such that there is much to hamper a survey based on statistical analysis. The type of case presented, the degree of pre-surgical investigation directed at level determination with its relative uncertainty in amputation surgery, the desirability in terms of rehabilitation of retaining the knee joint and the type of surgical technique used, all introduce variables likely to make comparison impossible. Further, post-operative management varies from the specialised unit to those primarily concerned with general surgery. Finally, the relative limitation in numbers presents a randomisation problem and all of those factors dictate against any statistically significant feedback. Thus, it seems clear that the quality and quantity of evidence must weigh heavily in favour of other methods of clinical evaluation.

A report on a new method of treatment such as CET can, it is submitted, be presented using the basis of a clinical impression. This implies a freedom of clinical judgement and selection of cases, far from being randomised, is made on personal assessment within a relatively narrow field in which experience has been gained of other more conventional methods of management. It is on these cases that the report is presented, with, if required, one further justification, namely a wider experience than most in the application of CET.

Wound healing has generated much thought for many years and basically it depends on well known physiological principles. This applies to wounds following trauma, disease and surgery. Optimum criteria have been recognised and much effort has been expended in attempting to apply these criteria. A great variety of dressings for wounds has been used and much care, particularly by nursing staff, has been directed at the application of these dressings using sterile techniques. However, all these efforts fail to recognise the physical environment imposed on the wound by the method of treatment used. For over half a century it has been known that pressure on tissues can, and does, have a

All correspondence to be addressed to Dr. I. M. Troup, Dundee Limb Fitting Centre, 133 Queen Street, Broughty Ferry, Dundee, Scotland.

significant effect on healing potential. Further, it is known that the degree of pressure, and its variation in level and time, is equally significant.

The temperature of the environment imposed by a conventional dressing is, to say the least, variably harmful. The snug, comfortable bandage must present bacteria with an ideal opportunity to thrive. Equally the moistness imposed by a bandage adds to this unsatisfactory environment. Finally, the absolute sterility of a dressing can never be assured since it must be applied and in so doing contamination is possible.

CET (Fig. 1) is entirely associated with these problems. It imposes certain, quite precise physical factors on the environment, each being variable as the occasion demands.

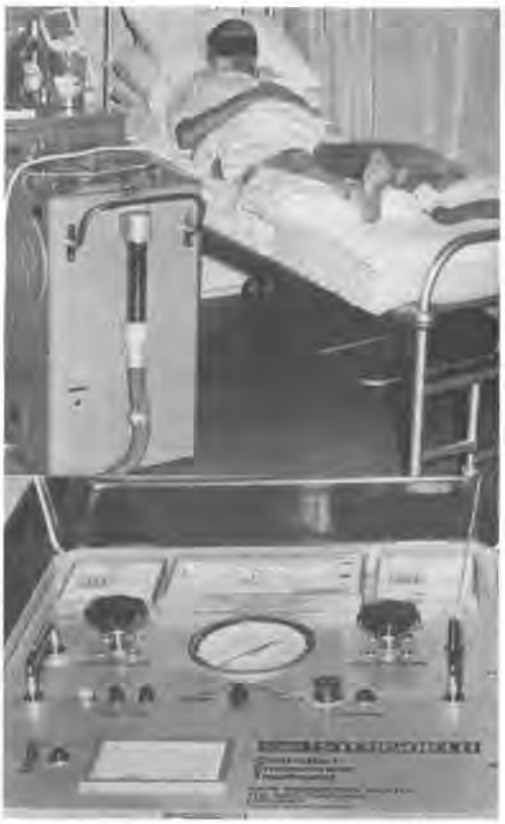

Fig. 1. Top, Controlled Environment Treatment (CET) applied to an amputee patient. Bottom, control console.

The dressing (Fig. 2, top) is simply sterile air or gas delivered from, and controlled by, a console to a treatment bag, fabricated in polyvinyl chloride.

The bag, or sterishield to use the commercial term, (Fig. 2, bottom) has an internal proximal apron which forms a partial seal allowing pressures to be generated within the bag, this being suspended by an appropriate shoulder harness and hemipelvic band.

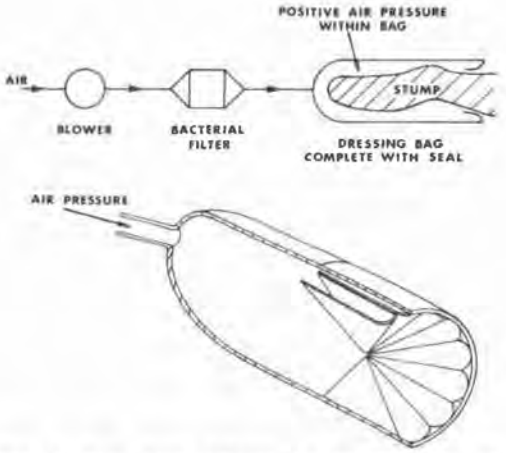

Fig. 2. Top, basic scheme for pressurisation of amputation stump. Bottom, dressing bag showing formation of pleated seal.

The pressures can be varied in level and time, automatic cycling imposing what might be seen as a vascular pump effect on the extremity, promoting lymphatic and venous return. Significantly, every part of the extremity enclosed within the sterishield has imposed upon it equal and consistent pressures, there being no high loading or tourniquet effect. Finally, the temperature of the air or gas, and thereby to some extent the humidity, can be controlled.

This method of treatment was used within an international trial with a very precise protocol from May 1976. This followed its development by the Biomechanical Research and Development Unit, Department of Health and Social Security, Roehampton, England (Redhead 1973; Redhead et. al. 1974, 1977). During this phase all the treatment at the Dundee Centre was devoted to the amputee in the immediate post-operative period. A system of controls was devised and recordings were made of such things as oedema, pain and status of wound healing at specific periods during the post-operative phase. Very early it became apparent that there were great difficulties in making these assessments and in

particular the assessment of pain proved an insuperable hurdle. Even if one assesses the amount of analgesic drugs administered this is by no means an accurate index of the degree of pain. Oedema, of course, is difficult to assess with accuracy and clinical judgement was the only means of arriving at the necessary data. Other recordings were involved in the trial, such as the degree of infection of the wound and bacteriological control was widely used. During this phase only one machine was available.

The number of cases treated with CET was nineteen and the controls totalled fifty-one.

It would appear in retrospect that this international programme must be regarded mainly as a learning process which terminated in November 1976 and may be the subject of an independent report. At this time two further machines, Mark II's became available, and the entire nature of the trial was changed. It was no longer necessary to follow the previous trial protocol because of its termination and thought was therefore given to the means of assessment for future application.

So far, preliminary reports have been published by Burgess and Pedegana, Seattle (1977) on the use of CET for limb surgery and trauma and Redhead and Snowdon, Roehampton (1978) on CET and its derivatives, PET (Pressure Environment Treatment) and CPC (Controlled Pressure Casting). It was considered that the widest application of CET in clinical practice required further evaluation and this paper gives an experience in Dundee of 100 such cases:

Total number of cases treated 100, of which:
17 required 2 periods of CET
2 required 3 periods of CET
1 required 4 periods of CET
1 required 5 periods of CET
In all there was a total of 128 events.

Consideration at this stage was given to the recording of results and a very simple form was devised which graded such things as general clinical status, oedema, infection, ischaemia, pain, the administration of drugs and the status of healing, along with patient activity and the settings determined for CET during the period of treatment (Table 1). The grading of oedema, infection, ischaemia and pain is basic, making no attempt to show anything other than the clinical presentation as seen on a day to day basis. It could be argued that the recordings are such that no statistical proof could be available finally, but the intention is to establish a clinical feeling or impression following the trial of the machine in a variety of situations. This trial of CET is set against the normal management of the amputee, that is, rigid dressings or pressure bandaging and in non-amputee cases it is obviously a new experience. Criteria had to be established for the necessary coding (Table 2) and these were divided into three specific areas:

1 The type of event
2 The status of healing
3 The general clinical impression

It should be said that the general clinical impression is in itself ambiguous. It is patently obvious that a person subjected to amputation for a gangrenous foot has "improved" if he exhibits a healing stump and for this reason the word "improved" is open to question. It might seem more appropriate to call it "satisfactory" but this, in effect, would not cover other situations. In any event no results were looked at in any way whatsoever until the end of the period in question, and the figures presented are a truthful clinical impression of the results following the use of CET. For the sake of clarity each type of event will be described and the individual results pertaining will be given. Certain specific conclusions or deductions within each group of events may be given but general conclusions regarding CET are presented later.

Event 1 Pre-surgical-amputation

Ten cases were treated, the average age being 62.5 years. The main indication, if not the only one, was the presence of pre-operative oedema, but in some cases the degree of oedema was such that level determination was difficult, if not impossible.

Treatment was continued for varying periods (three to nine days) and oedema was completely eradicated in eight cases and diminished in two cases. The subsequent surgical treatment was undoubtedly eased by an oedema free operating field and, if amputation level was in doubt, there was clinical clarification rather more rapidly than one would normally expect. Infection and pain were relatively unchanged.

TABLE 1

CONTROLLED ENVIRONMENT TREATMENT **DLFC Trial No.**

Name _____ Hospital _____ Hospital _____

Age _____ Unit No. _____ Unit No. _____

Diagnosis _____

_____

Type of event:

Dates:

General clinical status: 1—Good; 2—Average; 3—Poor
Oedema: 1—None; 2—Mild; 3—Moderate; 4—Severe
Infection: 1—None; 2—Cellulitus; 3—Serous; 4—Purulent
Ischaemia: 1—None; 2—Possible; 3—Clinically evident
Pain: 1—None; 2—Mild; 3—Moderate; 4-Severe
Drugs: 1—None; 2—Antibiotics; 3—Vasodilators

Status of healing:

1—Wound complete
2—Wound satisfactory
3—Wound ¼ incomplete
4—Wound ½ incomplete
5—Wound ¾ incomplete
6—Wound total breakdown
7—N.A.—non surgical

Patient activity: 1—Bed; 2—Seated; 3—Standing; 4—Ambulant
(maximum to be recorded)

CET Programme:

HP _____ mm Hg Time _____ sec

LP _____ mm Hg Time _____ sec

HP (seated) _____ mm Hg

HP (standing) _____ mm Hg

Temperature _____ °C

Change in pressures/timing/temperature:

Date _____

Date _____

Clinical assessment of result of CET:

_____ 1—Much improved

_____ 2—Improved

_____ 3—ISQ

_____ 4—Deteriorated

_____ 5—Clinical clarification

TABLE 2

Coding

Type of event:

1—Pre-surgical, amputation
2—Routine post-surgical, amputation
3—Non routine post-surgical, amputation
4—Unhealed stump
5—Post operative—general
6—Extremity—trauma, diabetic
7—Extremity—trauma, non diabetic
8—Extremity—oedema
9—Extremity—ulceration
10—Extremity—diabetic
11—Extremity—infected, non-diabetic

Status of Healing:

1—Wound—complete
2—Wound—satisfactory
3—Wound—¼ incomplete
4—Wound—½ incomplete
5—Wound—¾ incomplete
6—Wound—total breakdown
7—N.A.—non surgical

General Clinical Impression: (G.C.I.)

1—Much improved
2—Improved
3—ISQ
4—Deteriorated
5—Clinical clarification

Event 2 Routine post-operative—amputation

Forty-seven cases were treated and it is entirely significant that most were vascular in origin. Constantly, in a desire to maximise rehabilitation, retention of the knee joint was a desirable feature in level determination. Further, the relevance of pre-surgical clinical assessment of level must be considered and in particular its nature and accuracy.

Ages ranged from thirty-seven to eighty-seven, the average being 65.3 years.

Oedema

There is little doubt that post-operative stump oedema is controlled by CET. In ony two cases oedema was noted as persisting following treatment. The first was a clinically doubtful below-knee level which apparently exhibited free bleeding at operation. There was early clinical clarification of non-viability and the oedema was very likely due to the degree of ischaemia. The second case presenting with persisitng oedema was a through-knee level complicated by a deep intra-condylar haematoma.

Infection

Infection is difficult to assess since it is frequently associated with ischaemia and the dominance of one or other is a matter of clinical judgement. Many pre-operative assessments revealed infection (68%) and of these 28% presented with post-operative stump infections. Bacteriological control proved impossible since it was common to have no growth of pathogens reported despite what appeared to be obvious infection. Of the cases (32%) presenting with no evidence of pre-operative infection, nine (60%) had some evidence of stump infection later. It is of interest to note that of these nine cases, three

proceeded to complete stump breakdown and five to quarter incomplete wound healing. A number of these failures had an acceptable clinical explanation and perhaps were a reflection of level assessment.

Pain

Pain is impossible to assess with accuracy and the recording simply indicated whether or not the pain was a marked feature of post-operative management. In eighteen cases (38%) patient reaction appeared to indicate the presence of a relevant pain level. It is significant that of these eighteen cases, eight proceeded to healing, three to quarter incomplete wound healing, one to half incomplete wound healing and four to complete breakdown.

Of the forty-seven cases, thirty (64%) showed either complete healing or a satisfactory wound at the termination of CET. Twelve cases (25.5%) showed quarter incomplete healing, one case showed half incomplete healing and four cases showed total wound breakdown. It is of interest to note the remarks recorded in these cases where breakdown occurred, i.e.

1. Pre-operative oedema (untreated by CET)
2. Clinically doubtful below-knee level, bleeding at operation seemed to indicate below-knee level
3. Wrong clinical assessment
4. Multiple pathology—rheumatoid arthritis, systemic lupus erythematosis, vasculitis and steroid administration.

The 25.5% of cases showing quarter incomplete healing were nearly all infected but ischaemia may have been playing a significant role.

Number of days under treatment

Less than five days—3
Five to ten days—11
Ten to fifteen days—15
Fifteen to twenty days—12
Twenty to twenty-five days—6

Three cases where treatment ceased early were—a sudden death on the fourth post-operative day, a confusional state and one most appropriately called a machine phobia.

Of the eleven cases treated for five to ten days three were terminated early because of machine phobia, one died on the sixth post-operative day, one was of multiple pathology including colostomy management and one was discontinued for technical reasons (unsuitable sterishield size). To some degree the length of treatment was dictated by the varying numbers of cases presenting and limited equipment. However, patient need was always considered and priorities decided.

General Clinical Impression

Of the forty-seven cases, forty-three (91.5%) were judged to be either improved or much improved and in this context must be interpreted as satisfactory. This group included a percentage of cases which did not show primary healing but generally the stumps were viable, allowing local wound revision. Only four cases broke down completely (mentioned above under status of healing) and one of these was interpreted as clinical clarification since the level was very doubtful.

Conclusion

The conclusion is based on a comparison with the normal type of stump management at these levels, practised over many years. This was by rigid dressings, mostly without mobility but some with mobility, that is, the application of an immediate or delayed post-operative fitting (IPOF). There is little doubt that CET controls the oedema of surgical trauma better than a rigid dressing which, of course, is entirely passive, simply containing a specific stump volume. The control of pain perhaps favours rigid dressings but it is submitted, since the assessment is open to question, that the value of any opinion is equally suspect. The status of healing is encouraging but again it must be set against other factors, e.g. the desire to save the knee, the adequacy of pre-operative assessment of level and the surgery. In the absence of any acceptable control system, largely due to the complexity of the problem, and the difficulty with randomisation, it is believed that the results are better than those achieved by the use of rigid dressings. It should be said that rigid dressings in this context are applied by the author with utmost care, in the knowledge that the stump environment problems are quite as relevant as the preceding surgery.

Event 3 Non-routine post-surgical—amputation

Twenty-two cases fell within this category (Table 3). Almost half (nine cases) were being treated with other types of post-operative

Event 3

TABLE 3

Age	Oedema after treatment		Pain after treatment:			Treatment No. of days	G. C. I.	Remarks
	Present	Absent	Similiar	Absent	Reduced			
57		✓	✓			10	5	Initial below-knee in doubt, CET used for viability. Finally achieved local below-knee revision.
44		✓		✓		8	5	Initial clinical assessment below-knee level. Finally transmetatarsal level achieved.
76		✓	✓			5	5	First rigid dressing change at 8 days post-operatively. Ischaemic stump. CET resulted in rapid clarification non-viability.
34		✓		✓		9	1	Delayed below-knee healing. IPOF with oedema. Healed.
74		✓		✓		6	1	Post-rigid dressing oedema.
19		✓		✓		5	2	Pre-fitting oedema.
57	✓		Pain increased			1	3	Discontinued because of pain.
68		✓		✓		6	5	Clarification—non viable below-knee level.
68		✓			✓	7	2	Revision after 9 days. CET to optimise environment. Healed.
68	None before			✓		9	2	Local wedge revision.
67		✓	✓			5	5	Post rigid dressing 15th post-operative day. Doubtful viability.
47	Reduced		✓			16	2	Trauma leading to below-knee. Gross oedema when first seen. CET followed by local below-knee revision. Healed.
47		✓		✓		7	2	Below-knee revision treated by delayed rigid dressing. Marked oedema necessitated CET.
58		✓	✓			8	5	Clarification prior to local below-knee revision.
32	None before			✓		12	1	Below-knee revision treated with routine CET.
66	None before		✓			7	3	Below-knee revision—treated CET—early cessation of treatment—wrong choice of patient.
64	None before		✓			10	5	Previous amputation toes—failed—below knee level treated CET.
62		✓			✓	8	5	Delayed CET post below-knee amputation —clarification.
69		✓			✓	10	2	Post below-knee rigid dressing (9 days)—oedema— treated CET.
48		✓			✓	4	2	Oedema 14th post-operative day—treated CET.
58	✓			✓		5	2	Diabetic foot.
52		✓			✓	8	2	Frostbite—late post-operative amputation toes with grafting—oedema.

environment and were exhibiting some clinical indication of doubtful level viability. Of the remaining cases eight presented with post-operative oedema, perhaps due to the initial pathology of trauma, perhaps in association with the rigid dressing or for varying other reasons.

Thus, non-routine post-surgical amputation cases consist of a number of varied conditions. They probably reflect the wide use of CET and offer little of statistical interest. The number of days CET was applied tends to be less.

Less than five days—2
Five to ten days—16
Ten to fifteen days—3
Fifteen to twenty days—1

This would seem rational in as much as it was being applied for a fairly specific purpose.

General clinical impression was favourable, twelve cases being improved, two cases unchanged and eight exhibiting evidence of rapid clinical clarification.

Event 4 Unhealed stump

Five cases were treated in this category. CET was used for a variety of reasons:

1. Following trauma to a healing below-knee stump. Oedema was reduced but infection and non-viability necessitated higher revision, the latter probably preceding the trauma.
2. Sloughing, unhealed, below-knee suture line, eight weeks post-operative. Both oedema and infection subsided and the stump healed.
3. Post-rigid dressing—unhealed, oedematous stump which healed following CET.
4. Unhealed stump with oedema—pre-IPOF. Later required revision.
5. Post-IPOF—granulating clean wound with oedema. Finally healed following nine days CET.

Event 5 Post-operative—general

Five cases were treated including one double treatment (six events). (Table 4).

Event 6 Extremity—trauma—diabetic

Only one case was treated in this group—a man aged 61 years with a history of diabetes who presented following an injury to his forefoot. Clinically either a Syme's or a below-knee amputation seemed necessary but following CET for ten days with reduction of oedema and pain he required only amputation of the hallux. Primary healing was achieved. CET was used pre- and post-operatively. The potential of CET in this type of case warrants full evaluation.

TABLE 4

Event 5

Age	Oedema after treatment: Present	Oedema after treatment: Absent	No. of days	G. C. I.	Remarks
67		✓	7	4	Infected foot—non-diabetic. Debridement—CET on 5th post-operative day. Technical failure of machine—below-knee amputation.
18	✓		8	2	Fracture bases 2,3, 4 metacarpals—open reduction with wiring—delayed CET—improved hand function but only partial reduction of oedema.
62	None before		15	2	Infection following excision of head of 1st metatarsal and base of proximal phalanx. Infection much reduced.
58		✓	8	2	Tuberculous ankle involving tendon sheaths with contra lateral below-knee amputation—post operative and pre-plaster immobilisation—oedema much reduced—finally settled and mobilised.
58		✓	7	2	Paronychia hallux in diabetic—surgery followed by CET.
58		✓	10	2	Recurrence infection and oedema in last case—below-knee amputation following reduction of oedema.

Event 7 Extremity—trauma—non-diabetic (Table 5).

Conclusion

The elimination or reduction of post-traumatic oedema has undoubted benefits not only with regard to healing but also in achieving improved function. Failure to eliminate the oedema in three of the severe cases is ascribed to delay in CET application. The use of CET in this type of case, as in event 6, requires evaluation.

Fig. 3. Left, elephantiasis with "cauliflower" foot. Right, considerable reduction of oedema following CET. The excessive skin fold is clearly shown (see Table 6).

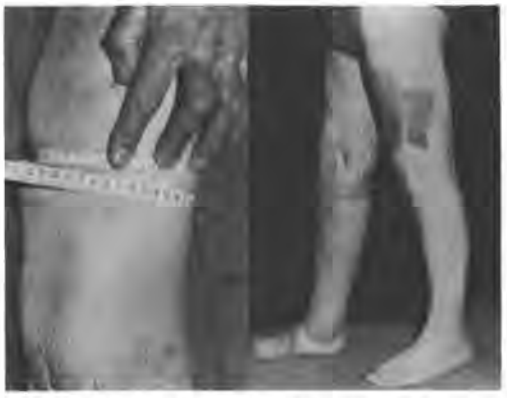

Fig. 4. Left, reduction of calf oedema from 73 to 44cm. Right, following plastic surgery—removal of skin fold, reduction of cauliflower foot with grafting and amputation of toes. Calf circumference now 33cm (see Table 6).

Event 8 Extremity oedema

Fourteen cases were treated in this group, including one double and one triple treatment (Table 6).

There is little doubt that the extremity oedema can be reduced or diminished with resulting increased function and improved cosmesis. As a pre-fitting measure CET is most successful and pre-surgical benefit can also be recognised.

TABLE 5

Event 7

Age	Oedema after treatment: Absent	Oedema after treatment: Reduced	No. of days	G. C. I.	Remarks
18		✓	7	2	Fracture bases 2, 3, 4 metacarpals—gross oedema leading to circulatory deficit—marked benefit.
53		✓	9	2	Degloving injury forearm—delayed treatment but still resulting in improved function of the hand.
30		✓	9	2	Injury forearm and hand—delayed CET—incomplete resolution of oedema.
68	✓		7	2	Fracture medial malleolus—late treatment on 18th day—gross oedema much improved.
59	✓		11	2	Fracture tibia and fibula treated with internal fixation—reduction of oedema achieved.
47		✓	4	1	Fracture humerus, radius and ulna—severe oedema markedly reduced.
32	✓		13	1	Injury of arm with amputation distal phalanx thumb—grafting—oedema completely resolved.

TABLE 6

Event 8

Age	Oedema after treatment: Absent	Oedema after treatment: Reduced	No. of days	G. C. I.	Remarks
47		✓	5	2	Lymphoedema arm—unknown aetiology—fibrosis tissues—limited improvement.
67		✓	15	1	Elephantoid limb of unknown aetiology. Reduction circumference calf from 74 to 42 cm. **(see Figures 3 & 4).**
67	✓		13	2	Post-operative recurrence oedema—plastic surgery to remove excessive skin folds—inadequate support from normal compression bandaging.
67	✓		5	1	Recurrence mild oedema at fitting stage of calf boots—CET reduced calf by 5 cm.
17	✓		13	2	Lymphoedema leg for 10 years—unknown aetiology—reduction mid calf by 6 cm and above ankle circumference by 5½ cm.
21	✓		6	2	Lymphoedema calf of unknown aetiology—oedema eliminated.
84	✓		5	2	Bilateral lower limb lymphoedema—probably postural. Completely eliminated
84	✓		6	2	**(see Figure 5).**
67		✓	7	2	Post-radiation oedema—tissues indurated—oedema is completely eliminated.
80		✓	3	2	Post-radiation oedema arm—pathological fracture humerus—abandoned due to pain caused by impaction of fracture with opposing sterishield and suspension pressures.
72		✓	7	2	Elephantiasis nostras—much improved.
73	✓		7	2	CVA and hemiplegia—using conventional apparatus with much oedema—oedema eliminated prior to contemporary orthotic fitting.
70	✓		2	2	Pre-orthotic fitting.
59		✓	5	2	Pre-tendo-Achilles tenotomy.
57		✓	4	1	Brachial plexus lesion leading to oedema of hand with reduced function—much improved following reduction of oedema.
41		✓	1	2	Friedreichs ataxia with oedema lower limbs—pre-orthotic fitting—CET not tolerated.
59	✓		6	1	Post-mastectomy oedema arm—delayed treatment—upper arm reduced by 6 cm and forearm by 4 cm.

TABLE 7

Event 9

Age	Oedema after treatment: Absent	Oedema after treatment: Reduced	Infection	No. of days	G. C. I.	Remarks
77	✓		Unchanged	13	1	Varicose ulceration much improved by CET—early termination due to technical failure.
68	✓		Unchanged	9	2	Varicose ulceration vastly improved—CET combined with plastic surgery.
84		✓	Unchanged	6	2	Varicose ulceration-treatment abandoned due to general status.

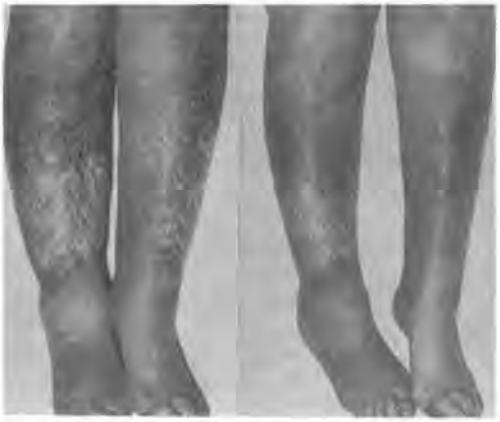

Fig. 5. Bilateral lymphoedema. Left, before treatment. Right, after treatment (see Table 6).

Event 9 Extremity ulceration

Three cases in this group (Table 7) form a very small experience of the use of CET in varicose ulceration but it clearly indicates the necessity to expand application in this type of condition to allow adequate evaluation. Initial impressions are favourable as might be expected where an environmental situation favours healing by encouraging venous and lymphatic return and reducing distal stasis.

Event 10 Extremity diabetic

The results of treatment of the diabetic foot deserve consideration (Table 8). CET is clearly one of the measures likely to offer benefit in the future. There is little doubt, that correctly applied to the appropriate case, CET is a valuable form of treatment.

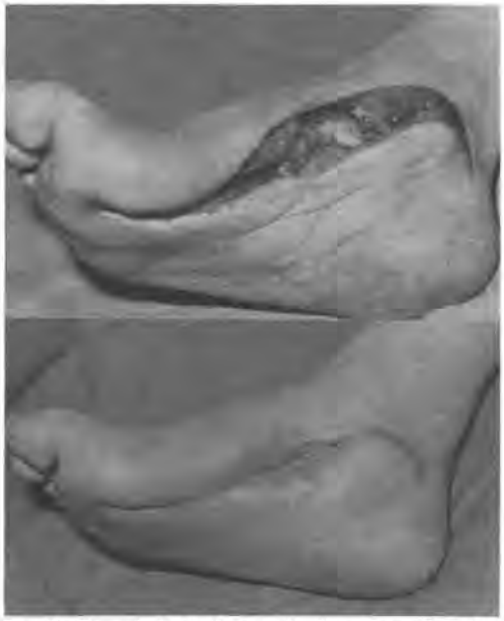

Fig. 6. Top, diabetic foot with ulceration related to first metatarsal head—wide surgical drainage. Bottom, foot healed after treatment (see Table 8).

Event 10

TABLE 8

Age	Oedema after treatment:		Infection:		Pain after treatment:			No. of days	G. C. I.	Remarks
	Absent	Reduced	Reduced	Unchanged	Reduced	Absent	Unchanged			
37	✓			✓		✓		9	1	Ulceration related to first metatarsal head—treatment repeated after six months—finally wide surgical drainage —foot healed **(see Figure 6).**
37	✓			✓		✓		7	2	
37	✓		✓			✓		52	1	
62	✓			✓		✓		22	2	Improved but infection remained due to underlying bony involvement.
57	None before			✓		✓		11	2	Infection hallux—deslough-ing and removal infected bone—healing failure but no initial oedema.
58	✓			✓	✓			11	2	Paronychia hallux—improved.
65	✓		✓			✓		15	2	Infection related to first metatarsal head which was excised—wound healed.

Event 11 Extremity infected non-diabetic (Table 9).

Pressures/temperatures used

Generally speaking, the console settings for pressure, cycling times and temperature were those originally suggested within the international protocol. It is believed that pressures tended to be higher in the later stages of trials in other Centres in the United Kingdom. The whole question of pressures requires further thought. The majority of amputation cases are vascular in origin and the pressures require to be related to such things as skin blood pressure and blood flow. Other cases simply presenting with oedema appeared to respond to the pressures used in the Dundee trial and this evidence would support the use of lower pressures. In effect, if one believes that the elimination of oedema is mandatory in all cases on the assumption that peripheral circulation becomes less embarrassed, the use of lower pressures would appear to be adequate.

Temperature is related to two factors;

(a) comfort

(b) a level which would limit bacterial growth and resulting infection

This appears to be achieved within the range of 28°C to 31°C the variation being entirely due to the element of patient comfort. Patients were specifically asked whether the limb appeared to be uncomfortably hot or cold and the temperature was adjusted accordingly.

Conclusions

It could be argued this paper simply lists observations over a wide selection of cases. There is no intention to do otherwise and it is simply a necessary preamble offering impressions on the use of CET. Ideally comparisons would allow an indication of performance and how it differed from more conventional treatments. However this was not the stated approach and rigid control systems, even if possible, are not an essential element of this type of evaluation. Perhaps the data presented at length in the paper will allow the reader to draw his own conclusions.

Before considering the clinical evidence there are several areas of major interest if CET application is to be efficiently managed.

1 Staff acceptance

a) Medical

There are three major ways in which the doctor is involved. Firstly, in the assessment of case suitability, and this is critical. Secondly, in day to day treatment observation, to allow personal evaluation and perhaps criticism of selection. Thirdly, in the instruction of paramedical staffing in the use and application of CET.

b) Nursing

Nursing staff familiarise rapidly given the essential initial instruction. Management of the

TABLE 9

Event 11

Age	Oedema after treatment		Infection		Pain:			No. of days	G. C. I.	Remarks
	Absent	Reduced	Reduced	Unchanged	Reduced	Absent	Unchanged			
58		✓		✓	✓			8	2	Tuberculous disease involving tendon sheath, ankle with abscess formation—pre-operative measure.
24		✓	✓			✓		19	2	Abscess ankle in chronic myeloid leukaemia—grafting thought necessary but healed.
77		✓		✓		✓		8	2	Sinus associated with fourth metatarso-phalangeal joint which was dislocated. CET after curettage.

patient is found to be fairly easy although the necessity of moving patient and machine within a unit in the course of any rehabilitation programme causes some inconvenience. In this respect it is staff dependent.

c) Physiotherapy

Essentially CET demands a fresh approach by the physiotherapist. Mobilisation is still possible in the amputee, but within a limited area. An advantage recognised by the physiotherapist is the facility of early joint mobilisation within the sterishield. Any stated disadvantage tends to be negated through time, and with the recognition of the advantages of CET.

2 Management of equipment and reliability

The CET apparatus has been found through experience to be self managing, as indeed the designers intended. Servicing is minimal, involving the change of an air filter after one month's use and the bacterial filter after one year. As with any machine faults can develop but they have been infrequent and relatively simple. Temperature control depends to some degree on the ambient conditions and unless recognised this can be a difficulty. Related to the management of the equipment is the harness used for upper limb treatment. The design of this harness is open to considerable criticism and this is mainly due to the inability of the design features to accommodate the very varied, desired range of function at the shoulder joint, as opposed to the hip.

There are certain conclusions regarding the advantages and disadvantages of CET which can be stated unequivocally.

CET advantages

1. No skill of application is required
2. Adequate control of pressures
3. Adequate control of temperature
4. Sterility
5. Observation of stump or extremity under treatment

Specific staff defined advantages/disadvantages

Nursing—

Stump visible
Management of device easy
Saving of nurse/hours—dressings, bandaging

but

Unwieldy environmental hazard

Physiotherapist—

Knee can be exercised,

but

Limited assisted function by physiotherapist
Patient less mobile
Frustration of seeing others more mobile using other methods of stump environment
Walking bars mobility—excessively staff dependent

CET conclusions

Oedema controlled
Improved venous/lymphatic return
Peripheral stasis reduced
Pain controlled adequately
Early joint mobilisation
No high loading or tourniquet effect

Observation of wound

Sterility

Advantages and disadvantages must be set against conventional dressings of whatever type are normally favoured. CET after all is simply an air dressing which is not only sterile but exerts the influence of cycling evenly distributed pressure on the extremity as a whole and, if applicable, the wound in particular. The effect of cycling pressure is to reduce or, more often, to eliminate oedema and this can only come about by increasing the vascular and lymphatic return from the limb. If this is correct there must be an elimination or reduction of peripheral vascular stasis, an element well known to be detrimental to wound healing.

The elimination or reduction of oedema is seen repeatedly in the use of CET and evidence of improved healing is noted in many cases. Improved function can also result and there are clear applications in the orthotic field.

Two specific conditions deserve much wider exposure to CET, the diabetic foot and chronic varicose ulceration. Both these conditions present frequently seen clinical problems often treated too lightly by those responsible for their care. It is believed that CET forms the ideal environment to encourage healing but it must be said, particularly in the diabetic foot, that surgery should be radical, since without this facility CET will fail.

Finally it is believed that the evidence presented in this series is sufficient to justify the continued application of this form of treatment even to a degree excluding other more commonly used forms of wound environment management. Evaluation of CET must proceed and this, it is believed, must be based and quantified against known methods of assessment and investigation in vascular disease. CET is a valuable addition to the equipment available to the clinician in the treatment of certain disease categories.

Acknowledgement

The assistance of clinical and para-medical colleagues at Dundee Limb Fitting Centre and Kings Cross Hospital, Dundee is gratefully acknowledged, as is the assistance of Miss Marilyn Anderson, Dundee Limb Fitting Centre.

REFERENCES

BURGESS, E. M. and PEDEGANA, L. R. (1977). CET for limb surgery and trauma. (A preliminary report). *Bull. Pros. Res.* **10:28,** 16–57.

REDHEAD, R. G. (1973). The problems of the post-operative and stump/environment interface. Ist International Congress on Prosthetic Techniques and Functional Rehabilitation, 65–73, Egermann, Vienna.

REDHEAD, R. G., SNOWDON, C., BURGESS, E. M. and VITALI, M. (1974). Controlled environment treatment for the post-operative management of wounds of the upper and lower limbs including amputation stump. 1st World Congress, ISPO, Montreux.

REDHEAD, R. G. and SNOWDON, C. (1977). A new approach to the management of wounds of the extremities; controlled environment treatment and its derivatives. Scientific Symposium, British Trade Fair, Tokyo. Copies from BRADU Library, Roehampton, London.

REDHEAD, R. G. and SNOWDON, C. (1978). A new approach to the management of wounds of the extremities. CET and its derivatives. *Pros. & Orth. Int.* **2:3,** 148–156.