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The Mayo Clinic experience (1998-2000)

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Background. **The aim of this retrospective observational study was to review the use of an intermittent pneumatic compression device on nonhealing wounds in patients with critical limb ischemia at Mayo Clinic Rochester.**

Methods. **The setting was a community and referral multidisciplinary wound care clinic. The authors analysed 107 patients, median age 73, with critical limb ischemia and active ulcers started using a compression device between 1998 and 2000; 101 patients had lower extremity ulcers, and 25% had a history of amputation, and 64% had diabetes. Of all the wounds, 64% were multifactorial in etiology, and 60% had associated transcutaneous oxygen tension levels below 20 mmHg. Patients were typically asked to use the device at home on the affected limb(s) for 6 hours daily. The main outcome criterion was complete wound healing with limb preservation.**

Results. **The median follow-up after initiation of treatment was 6 months. Complete wound healing with limb preservation was achieved by 40% of patients with $TcPO_2$ levels below 20 mmHg; by 48% with osteomyelitis or active wound infection; by 46% with diabetes treated with insulin; and by 28% with a previous amputation. Half of all amputations occurred in patients with prior amputations. Seven patients discontinued the device because of pain experienced with its use.**

Conclusions. **Patients with critical limb ischemia and nonhealing wounds at high risk of amputation can achieve complete wound healing and limb preservation by using an intermittent pneumatic compression device.**
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Key words: **Wound healing - Peripheral vascular diseases - Ischemia.**

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Nonhealing ulcers in patients with critical limb ischemia lead to amputation, disability, pain, and death.[1] These patients may not be amenable to revascularization for technical reasons (*e.g.*, the anatomic distribution of vascular disease), frail health status, or patients' rejection of operative interventions. Beyond amputations, few non-operative options are available for patients with critical limb ischemia.[2]

Intermittent pneumatic compression devices may represent an effective and safe limb-salvage therapy for patients with wounds and critical limb ischemia. These devices deliver intermittent pressure to the limb of concern (with or without synchronization to the cardiac cycle) to promote small vessel circulation,[3] reduce edema, oxygenate ischemic tissues, deliver inflammatory cells, and augment other processes that may lead to a more favorable environment for wound healing. Limited reports suggest that these devices may be safe and effective for the treatment of nonhealing wounds in patients with critical limb ischemia.[2, 4]

The Mayo Gonda Vascular Ulcer and Wound Healing Center at the Mayo Clinic Rochester has been using the AIRCAST ArterialFlow™ pump (Aircast Inc, Summit, New Jersey), an intermittent compression device, for the last 10 years as rescue therapy for patients contemplating, but unwilling or unable to undergo, limb amputation. In this study, we report

our experience with patients who started using the device between January 1, 1998 and December 31, 2000.

Materials and methods

Study design and ethical conduct of research

This is a retrospective observational study of patients with limb wounds and severe to critical limb ischemia who used an intermittent pneumatic compression device. The institutional review board approved the research protocol. The Mayo Foundation funded the study. Aircast Inc. did not participate in the design, conduct, analysis, reporting, or funding but they provided the Gonda Vascular Center with some devices for temporary compassionate use. The authors have no financial interest in Aircast Inc. or any other manufacturer of wound healing products or technologies, including intermittent compression devices.

Setting and patient selection

The Vascular Ulcer and Wound Healing Clinic (Ulcer Clinic) of the Gonda Vascular Center at the Mayo Clinic, Rochester, is a multidisciplinary clinic that offers wound care services to Mayo Clinic patients. A team of expert physicians, nurses, and clinical assistants from internal medicine, vascular medicine and surgery, podiatric medicine, dermatology, and physical medicine and rehabilitation provide care at the clinic. In addition to providing primary ulcer care to patients from Olmsted County, MN, the clinic provides ulcer care to regional, national, and international patients. All patients receive standard wound care including biologically active products (such as growth factors) and appropriate off-loading [1] in addition to aggressive medical management to improve general and cardiovascular health and metabolic control.[5]

A laboratory accredited by the Intersocietal Commission for the Accreditation of Vascular Laboratories conducts noninvasive vascular studies, including measurement of transcutaneous oxygen tension ($TcPO_2$). We measure $TcPO_2$ levels using an electrode (that warms the skin to 45°C to overcome vasoconstriction) attached for 20 min to the skin of interest and to the skin of the chest as a control. $TcPO_2$ levels reflect the degree of mismatch between oxygen delivery (low in critical arterial and arteriolar insufficiency) and oxygen consumption (a reflection of the local metabolic rate which increases with trauma or infection) at the site of interest.[6] Thus, $TcPO_2$ levels quantify the degree of cutaneous ischemia and predict the chances of healing clean ischemic wounds. Bacharach *et al.* demonstrated no healing at clean surgical amputation sites with $TcPO_2$ of less than 20 mmHg and essentially universal healing at sites with $TcPO_2$ of greater than 40 mmHg.[7]

Patients prescribed the device rented or purchased it through the Mayo Store, a local medical appliance vendor. Other patients received it free of charge through the manufacturer's temporary compassionate use program. The Ulcer Clinic staff flagged the charts of patients who received a device through this program. Thus, we compiled a complete list of patients by consulting the records of the Mayo Store and the Ulcer Clinic.

To be included in this study, patients should have started using a device between January 1, 1998 and December 31, 2000, should have used it to assist healing of wound or ulcer, and should have returned for at least 1 follow-up visit. The only exclusion criterion was lack of patient authorization to review the medical record.

The intermittent pneumatic compression device

The Aircast ArterialFlow™ system is an intermittent pneumatic compression device intended to augment arterial flow and microcirculation with pulsatile compression of the limb. In the lower extremity, it is usually applied to the calf. Compression is rapid, graduated and sequential. The distal compartment inflates rapidly to 95 mmHg, the proximal compartment then following in 0.3 sec to 85 mmHg. After 2 sec of compression, the cuff deflates. This cycle repeats every 20 sec.

In our practice, we encourage patients to use this device for a minimum of 6 hours per day. To accomplish this goal, we suggest 3 2-hour

sessions in the morning, afternoon and evening. We also encourage patients to use it for extended periods at night (some patients sleep while wearing it), when ambulatory requirements are minimal.

Data collection and outcome definition

For each patient, we reviewed the complete medical record (paper and electronic), which includes all outpatient and inpatient care, the vascular laboratory non-invasive testing record, and the general laboratory electronic record.

Data collected included: 1) history of diabetes, hypertension, renal impairment, dyslipidemia, previous cardiovascular disease, previous revascularization or amputation; 2) present health status; 3) wound etiology, complications, $TcPO_2$ levels before initiating pump use, and plans for revascularization and amputation; 4) use of the device, including total period of use, pattern of use (hours of use per day and days used per week) and complications. In patients with more than 1 ulcerated region (6 patients in this cohort), we randomly selected and included 1 before conducting data analyses.

Patients with a favorable outcome had complete wound healing with limb preservation. Patients with unfavorable outcomes had either amputation of the limb bearing the wound or a persisting wound at the last follow-up visit.

Statistical analyses

Exploratory univariate analyses tested whether patient or wound characteristics modified the chance of wound healing with limb preservation. We used Fisher's exact test and χ^2 tests for count data and proportions, Wilcoxon rank sum test for comparing continuous variables that did not follow a normal distribution, and "t"-tests for normally distributed variables. Because of the exploratory nature of these analyses we did not adjust the level of significance to keep the study-wide α at 0.05. To determine time to amputation, we conducted univariate failure analysis (akin to survival analysis) limited to patients suffering amputations with comparisons between $TcPO_2$ categories (less than 20 mmHg *vs* greater than 40 mmHg) and history of amputation. We used Microsoft Access 97 (Microsoft Corporation, Redmond, WA) to handle the database and JMP 4.0 (SAS Institute Inc, Cary, NC) to perform all the statistical analyses.

Results

Patient selection

We identified 101 patients in the Mayo Store records and 47 in the Ulcer Clinic records. Of these 148 patients, 3 did not authorize medical record review, 8 were listed twice, 4 received a prescription for the device or the device itself but did not return for follow-up, 18 did not use the device during the study period, and 8 did not have ulcers or wounds (but were using the device for pain control or other reasons). Thus, we included 107 patients in this study (Table I). Of these, 6 had wounds in their upper extremities and 101 had a wound in 1 of their lower extremities. The rest of this report will focus on the latter group.

The average patient was a man in his mid 70s referred from outside Olmsted County. His vascular risk factors included a history of smoking, type 2 diabetes treated with insulin, dyslipidemia, hypertension, and coronary disease. He had not undergone peripheral revascularization procedures or amputation. His wound was multifactorial with an arterial insufficiency component and had $TcPO_2$ below 20 mmHg (Table I).

About half the patients in this cohort (47%) achieved complete wound healing and maintained limb integrity (Table II). The rest suffered an amputation or experienced null or partial wound healing or wound deterioration. The length of follow-up in the latter group was 12 weeks, significantly briefer (after excluding patients suffering amputations) than the 35 weeks in the group experiencing a favorable outcome (p=0.003).

Characteristics associated with wound healing and limb preservation

Most patient and wound characteristics did not appear to modify the risk of an unfavor-

TABLE I. *-Baseline characteristics of included patients*

Patient characteristics	Values
No. of included patients	107
Age, years (median, IQR)	73 (63-79)
Women, no. (%)	43 (40)
Local patients (Olmsted Co.), no. (%)	49 (46)
History of coronary artery disease, no. (%)	69 (64)
History of previous limb revascularization, no. (%)	34 (32)
History of amputation, no. (%)	27 (25)
Smoking, no. (%)	
Current	6 (6)
Former	53 (50)
Never	45 (42)
Diabetes, no. (%)	69 (64)
No. (%) with type 2 diabetes	62 (90)
No. (%) treated with insulin	39 (63)
Glycosylated hemoglobin (mean, SD)*	7.8 (2.2)
Glycosylated hemoglobin ≤8%, no. (%)	46 (79)
Dyslipidemia, no. (%)	56 (52)
No. (%) treated with statins	37 (66)
Hypertension, no. (%)	91 (85)
Systolic blood pressure at initial visit, mmHg (mean, SD)	140 (22)
Diastolic blood pressure at initial visit, mmHg (mean, SD)	76 (10)
Albuminuria, no. (%) (n=85)	39 (46)
On ACE inhibitors	31 (79)
Serum creatinine (median, IQR)	1.0 (1.0-2.0)
Connective tissue or autoimmune disorder or transplant recipient	18 (17)
No. (%) treated with immunosuppression or steroids	10 (56)
Length of follow-up weeks (median, IQR)	29 (13-67)
Wound or ulcer characteristics	
No. (%) of ulcers on lower extremities	101 (94)
Predominant etiology, no. (%)	
Multifactorial†	56 (52)
Arterial	38 (36)
Small vessel disease	7 (7)
Other (purely neuropathic, venous insufficiency, trauma)	6 (6)
$TcPO_2$, mmHg (median, IQR) (n=102)	16 (5-30)
No. (%) ≤20 mmHg	61 (60)
Any circulator boot use during clinical course	34 (32)
Time from wound onset to pump treatment, weeks (median, IQR)	11 (3-32)

IQR: interquartile range (range of values between the 25th and 75th percentile); SD: standard deviation; $TcPO_2$: transcutaneous oxygen tension; *: normal values for glycosylated hemoglobin are 4-7%; †: most wounds in this group are associated with vascular insufficiency and neuropathy.

able outcome (Table II). Of the 58 patients with $TcPO_2$ ≤20 mmHg, 40% were able to achieve complete wound healing and maintain limb integrity. This result compares favorably with patients with $TcPO_2$ levels above 20 mmHg, of whom 47% achieved wound healing and maintained limb integrity. Patients with type 2 diabetes mellitus with $TcPO_2$ ≤20 mmHg appear to have a similar prognosis as patients without diabetes, with 42% achieving complete wound healing and maintaining limb integrity (Table III).

Patients who had undergone previous amputation had a 3-fold increase in the risk of an unfavorable outcome (odds ratio 3, 95% confidence interval 1-9). Half of all amputations in this study occurred in patients with a previous amputation. In this group, 81% of amputations were at the transmetatarsal, below-the-knee, or above-the-knee level. Of the 4 above-the-knee amputations, 3 occurred in patients with previous amputations (Table IV).

The median time to amputation (measured from the date the patient began using the device to the amputation date) in the 23 patients who suffered this outcome was 26 weeks (95% confidence interval 18-49). The median time to amputation was 25 weeks in patients with $TcPO_2$ ≤20 mmHg and 46 weeks in those with greater $TcPO_2$ levels (p=0.7). There were no differences in time to amputation between patients with and without prior amputation. The 16 patients with type 2 diabetes mellitus who suffered amputations exhibited the same median time-to-amputation as the rest of the cohort.

A third of the cohort received treatment with a circulator boot,[8] a device used under medical supervision at the Ulcer Clinic that synchronizes the intermittent lower limb compressions to the cardiac cycle. Patients typically received 1 or 2 45-min sessions each day for 1 to 2 months. There were no differences in patient and wound characteristics between patients receiving and patients not receiving circulator boot therapy (data not shown). There was a nonsignificant decrease in the risk of an unfavorable outcome with the concurrent use of circulator boot and compression device (odds ratio 0.6, 95% confidence interval 0.3-1.5), (Table IV).

Patterns of pump use and complications

The medical record contained limited information about the patterns of use of the devices in terms of time of day, length of sessions,

TABLE II. -*Characteristics of patients with lower extremity wounds by outcome.*

Patient characteristics	Outcomes	
	Open wound or amputation (n=54)	Healed wound, intact limb (n=47)
Age, years (median, IQR)	75 (62.75-80.25)	73 (63-79)
Women, no. (%)	19 (49)	20 (51)
Local patients (Olmsted Co.), no. (%)	26 (53)	23 (47)
History of coronary artery disease, no. (%)	35 (52)	32 (48)
History of previous limb revascularization	17 (50)	17 (50)
History of amputation	18 (72)	7 (28)
Smoking, no. (%)		
Current	5 (83)	1 (17)
Former	28 (56)	22 (44)
Never	20 (48)	22 (52)
Diabetes, no. (%)	34 (49)	35 (51)
No. (%) with type 2 diabetes	30 (48)	32 (52)
No. (%) treated with insulin	21 (54)	18 (46)
Glycosylated hemoglobin (mean, SD)*	8.1 (2.7)	7.5 (1.6)
Glycosylated hemoglobin ≤8%, no. (%)	22 (48)	24 (52)
Dyslipidemia, no. (%)	30 (57)	23 (43)
No. (%) treated with statins	22 (61)	14 (49)
Hypertension, no. (%)	47 (54)	40 (46)
Albuminuria, no. (%) (n=79)	(n=44) 21 (55)	(n=35) 17 (45)
On ACE inhibitors	17 (57)	13 (43)
Serum creatinine (median, IQR)	1 (1-2)	1 (1-2)
Length of follow-up in weeks (median, IQR)	24 (8-49.25)	35 (21-68)
Excluding amputations (median, IQR)	12 (4-38)	35 (21-68)
Ulcer characteristics		
Predominant etiology, no. (%)		
Multifactorial†	30 (54)	26 (46)
Arterial	19 (54)	16 (46)
Small vessel disease	1 (25)	3 (75)
Other (neuropathic, venous stasis, trauma)	4 (67)	2 (33)
Infection or osteomyelitis, no. (%)	11 (52)	10 (48)
$TcPO_2$, mmHg (median, IQR) (n=99)	13 (5-27)	21 (10-35.75)
No. (%) ≤20 mmHg	35 (60)	23 (40)
No. (%) 21-40 mmHg	10 (42)	14 (58)
No. (%) >40 mmHg	8 (47)	9 (47)
Any circulator boot use during clinical course	16 (47)	18 (53)
Time to initiation of boot in weeks (median, IQR)	10 (3.75-33.5)	14 (3-32)

IQR: interquartile range (range of values between the 25th and 75th percentile); SD: standard deviation; $TcPO_2$: transcutaneous oxygen tension; *: normal values for glycosylated hemoglobin are 4-7%.

number of sessions per day, and number of days per week of treatment.

Ten patients reported pain associated with compression use. Three patients were able to continue using the device after reviewing technique, reassurance, or recommendations to decrease compression time to 30-60 min or to use analgesics prior to its use. The other 7 patients discontinued its use because of pain. Other local complications included increased lower extremity edema (1 patient), development of a new ischemic toe ulcer (1 patient), deep venous thrombosis (1 patient), calf hematoma (1 patient, also being treated with warfarin at the time of use of the device), and contact skin rash (1 patient). There were no reports of new wounds arising on the skin receiving intermittent compression.

TABLE III.—*Comparison of lower extremity wounds in type 2 diabetes by $TcPO_2$ levels.*

$TcPO_2$ (mmHg)	Open wound or amputation No. (%)	Healed wound, intact limb No. (%)
≤20	19 (58)	14 (42)
>20	11 (38)	18 (62)

$TcPO_2$: transcutaneous oxygen tension.

TABLE IV.—*Lower extremity wounds and outcomes.*

Parameters	All No. (%)	$TcPO^2$ ≤20 mmHg No. (%)	Patients with prior amputation No. (%)	Circulator boot use No. (%)	No circulator boot use No. (%)
No. patients with a lower extremity ulcer	101 (100)	58 (57)	28 (28)	33 (33)	67 (66)
Wound healed	57 (56)	29 (50)	11 (39)	21 (64)	36 (54)
Limb intact*	47 (83)	23 (79)	8 (73)	18 (86)	29 (81)
Amputation	9 (16)	5 (17)	3 (27)	2 (9)	7 (19)
— Toe(s)	4 (44)	3 (60)	1 (33)	1 (50)	3 (43)
— Ray	1 (11)	0 (0)	0 (0)	1 (50)	0 (0)
— Transmetatarsal	1 (11)	0 (0)	1 (33)	0 (0)	1 (14)
— Below-the-knee	1 (11)	1 (20)	0 (0)	0 (0)	1 (14)
— Above-the-knee	2 (22)	1 (20)	1 (33)	0 (0)	2 (29)
Amputation recommended	1 (1)	1 (3)	0 (0)	1 (5)	0 (0)
Wound not healed	44 (44)	29 (50)	17 (61)	13 (36)	31 (46)
Limb intact*	26 (59)	18 (62)	4 (23)	9 (69)	17 (55)
Amputation	14 (32)	7 (24)	11 (65)	3 (23)	11 (35)
— Toe(s)	7 (50)	5 (71)	4 (36)	2 (67)	5 (45)
— Ray	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
— Transmetatarsal	4 (29)	0 (0)	5 (45)	1 (33)	3 (27)
— Below-the-knee	1 (7)	0 (0)	0 (0)	0 (0)	1 (9)
— Above-the-knee	2 (14)	2 (29)	2 (36)	0 (0)	2 (18)
Amputation recommended	4 (9)	4 (14)	2 (12)	1 (8)	3 (10)

*) May have had amputation before onset of index wound. $TcPO_2$: transcutaneous oxygen tension.

Discussion and conclusions

In patients with nonhealing multifactorial wounds and limb ischemia treated with an intermittent compression device, we observed complete wound healing and limb preservation in 40% of patients with $TcPO_2$ levels below 20 mmHg; 48% with osteomyelitis or active wound infection; 46% with diabetes treated with insulin; and 28% with any previous amputation. These unexpectedly high rates suggest that the device may have affected the clinical course of nonhealing wounds in patients at high risk of limb loss.

Inferences from this large retrospective case series are weakened by the lack of a prospectively defined cohort (including a control group), randomized allocation of patients to compression or standard care, complete and standardized follow-up, and standardized assessment of outcomes blind to treatment allocation. Furthermore, while corresponding to a consecutive series of patients, the sample is likely to be affected by referral and selection bias. These sources of bias may overestimate the efficacy of the device if clinicians were able to decide which patients were more likely to respond to the device and preferentially offered this treatment to them. On the other hand, these same sources of bias may lead to underestimation of the efficacy of the device, if only those in line for amputation (or declining this operation) received it as a measure of last resort. The briefer follow-up of those suffering unfavorable outcomes could also underestimate the efficacy of the device, with some of these patients potentially going on to complete healing and limb preservation after they were lost to follow-up. Our strict and explicit definition of a favorable outcome (complete wound healing with limb preservation) was easily verifiable in the medical record. However, its strict character left out many more patients experiencing "favorable" outcomes including partial wound healing with limb preservation and improvement of ischemic limb pain.

Differences in patient population, outcome definition, and secular progress in wound and medical care limit comparison of our results with other published series. These limitations also apply to comparisons with previously published series from our center (Table V).[4, 7] For instance, in the study by Vella *et al.* that reported our experience with circulator boots, patients had a mean $TcPO_2$ of 30 mmHg (double the $TcPO_2$ level of patients from the present

TABLE V.—*Comparison with historical controls (Bacharach* et al.[7] *and Vella* et al.[4]).

$TcPO_2$ (mmHg)	Favorable outcome				Unfavorable outcome			
	Present study		Vella*	Bacharach†	Present study		Vella*	Bacharach†
	Total	Circulator boot			Total	Circulator boot		
≤20	23 (40)	8 (50)	13 (45)	0 (0)	35 (60)	8 (50)	16 (55)	20 (100)
>20	23 (56)	10 (59)	29 (47)	40 (67)	18 (44)	7 (41)	33 (53)	20 (33)

series) and did not have osteomyelitis. All patients received circulator boot therapy with 38% of them receiving both circulator boot and the compression device. Although more patients in the present series had severe and critical limb ischemia, our results confirm the findings of Vella *et al.*[4] of benefit with circulator boot therapy and extend these findings to a portable technology that patients can use at home minimizing the need for repeated visits to the Ulcer Clinic. Our study also confirms the adverse prognostic implication that having suffered a prior amputation has on the risk of suffering new (*i.e.* more proximal) amputations.[1]

Health technology assessment standards call for unbiased evaluations of technologies such as the intermittent compression devices. A multicenter, randomized, controlled clinical trial should be conducted to determine whether these devices truly modify the clinical course of critical limb ischemia and nonhealing wounds, to determine the best sequence of use in relation to peripheral vessel revascularization and amputation, and to determine its role in the management of patients with painful ischemic limbs. The only randomized trial of an intermittent compression device to assist wound healing applied the real device or a sham device to the foot to reduce edema. This trial showed that use of the real device in diabetic foot ulcers achieved a significant improvement in wound healing (odds ratio 3, 95% confidence interval 1-7).[9] Further investigation should clarify the best way to use the device given that we base our current recommendations on unsystematic clinical observations. Moreover, published reports suggest low patient adherence to these recommendations.[2, 9]

In summary, this study suggests that patients with limb ischemia and nonhealing wounds at high risk of amputation can achieve complete wound healing and limb preservation by using an intermittent pneumatic compression device.

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