

A Blinded, Prospective, Randomized Controlled Trial of Topical Negative Pressure Wound Closure in India

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Wound closure using topical negative pressure (TNP) has been reported to be effective, but equipment costs can be prohibitive in resource-challenged countries. Because nonhealing wounds are exceedingly common in developing countries such as India, the ability to optimize wound care with limited resources is very important. To investigate the feasibility and efficacy of providing TNP in an Indian medical referral center, a randomized controlled trial comparing a locally constructed TNP device (treatment) to wet-to-dry gauze dressings (control) was conducted. Eligible study participants ($N = 48$) were recruited from the inpatient wards. Wound etiologies included diabetic foot ulcers (15), pressure ulcers (11), cellulitis/fasciitis (11), and "other" (11). Following enrollment, wound size was assessed using computer-aided measurements of digital photographs and block-randomized to the study arms using a concealed allocation table. Wounds in both treatment groups were débrided before dressing application and patients were followed until wound closure or being lost to follow-up for an average of 26.3 days (± 18.5) in the control and 33.1 days (± 37.3) in the treatment group. No statistically significant differences in time to closure between the two treatment groups were observed except in a subset analysis of pressure ulcers (mean 10 ± 7.11 days for treatment and 27 ± 10.6 days in control group, $P = 0.05$). Direct costs to close a pressure ulcer also were lower in the TNP than in the control group. A review of the literature suggests the outcomes obtained using a locally constructed TNP device are similar to those obtained using commercially available devices. As a result of this study, a dedicated tissue viability team has been established to identify wounds suitable for TNP, oversee treatment, monitor the need for surgical débridement, and employ wound healing principles and technology appropriately. These results suggest that inexpensive materials can be utilized for TNP wound closure in a developing country.

KEYWORDS: wounds, topical negative pressure, developing world, randomized controlled trial, South India

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Topical negative pressure (TNP) as a wound treatment utilizes a combination of mechanical force and controlled drainage in a closed environment to promote healing.^{1,2} Dressings for TNP involve packing material, tubing to create negative pressure at the wound site, a suction pump, an airtight drape, and an effluent collector. Changes that have been observed in the wound environment exposed to TNP include reduced bacterial load and edema, improved vascularity, increased granulation tissue through mechanical deformation of tissues, skin stretching, and reduced exposure to shear forces on granulation tissue in the wound bed through frequent removal or disruption of the dressing.^{2,3}

Originally described in the 1980s as a clinical innovation to enhance débridement of infected wounds, the initial TNP prototype was developed into a method of wound closure by several contemporary surgical groups.⁴⁻⁷ Based on these designs, commercial systems were constructed using medical-grade foam and pressure sensors.⁸ Reductions in healing time and wound size of chronic nonhealing wounds and diabetic foot ulcers affected by TNP have been documented in several randomized controlled trials of these systems.⁹⁻¹¹ Currently, TNP is most often used to close surgical and traumatic wounds and chronic ulcers and to bolster skin grafts.^{2,12} Its role in treating enterocutaneous fistulae and other complex wounds also has been described.^{7,13}

Given its utility, TNP may be particularly useful in the developing world where traumatic and chronic nonhealing wounds are a major source of morbidity and financial disability.^{14,15} However, the cost of commercially available systems such as the V.A.C.[®] (Vacuum Assisted Closure) Therapy System (KCI, San Antonio, Tex) limits the use of TNP in resource-poor settings.¹⁶ A prospective, randomized controlled trial was conducted among inpatients at a tertiary-level hospital in Southern India to compare healing and cost of care outcomes of surgically débrided wounds using standard wet-to-dry gauze dressings

(control) to a locally designed and constructed TNP device (treatment).

Methods

Using wound-healing data from a randomized controlled trial in which McCallon et al¹⁰ demonstrated a reduction in healing time by nearly 50% using TNP for a variety of wounds, an *a priori* sample size of 36 wounds treated with conventional and 18 wounds treated with TNP dressings was calculated to obtain a power of 80% and to accept a *P* value of 0.05. Institutional Review Board approval to conduct the study was obtained from the Ethics Committee of the study facility, Christian Medical College (CMC), Vellore, India.

Patient selection. Patients admitted to the general surgery, physical medicine, and rehabilitation wards of CMC and referred by the surgical consultants for care of an acute or chronic extremity, sacral, or abdominal wound that could not be treated with primary closure were eligible for study participation. Exclusion criteria included wounds in anatomical locations where an adequate seal around the wound site could not be obtained, ischemic wounds, wounds with exposed bowel or blood vessels, wounds with necrotic tissue that could not be débrided, wounds with communicating fistulae, osteomyelitis, or wounds with malignancy — ie,

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KEY POINTS

- The challenge of managing chronic wounds is compounded when resources and materials are limited.
- The authors of this randomized controlled clinical study compared the use of a negative pressure therapy (NPT) device, developed using locally available materials, to their standard regimen of wet-to-dry gauze dressings in 48 patients.
- Although overall closure rates did not differ significantly, NPT-managed pressure ulcers in patients who remained hospitalized were closed significantly faster than gauze-dressed ulcers and these outcomes were similar to those reported using commercially available NPT devices.
- Studies to ascertain most favorable NPT treatment time and a comparison of these devices to nongauze dressings are needed to optimize care in both developed and developing countries.



Figure 1a. Sterilized packing material (right), suction catheter, and wound cleaning supplies.



Figure 1b. Suction catheter tunneled into a small piece of packing material cut to fit wound cavity.

wounds contraindicated by the commercial manufacturers of TNP devices. Recently grafted wounds were not included because healing rates may differ from wounds that have not been grafted. Although therapeutic anticoagulation is not a contraindication for TNP, patients receiving this treatment were excluded because close monitoring for increased bleeding risk was not available in all wards. Ambulatory status was not a criterion for exclusion. Wounds that met inclusion and exclusion criteria were assessed for size (in a manner that allowed blinding) and then block-randomized using a concealed computer-generated table in a 1-to-2 ratio of TNP closure versus conventional wound dressing. Written informed consent was obtained from all study patients before randomization. Patient age and gender were recorded.

Wound assessment and classification. Wounds were assessed on the day of enrollment (before randomization), at random intervals throughout the treatment, and on the day when the wound was determined to be healed by secondary intention or ready for delayed primary closure. Admitting surgeons classified wounds by type and diagnosis according to their etiology. Diabetic foot ulcers were defined as wounds with an underlying etiology of peripheral neuropathy and vascular disease in patients with a clinical diagnosis of diabetes and included wounds débrided superficially (grade 1) through minor (tarsal and transmetatarsal) amputations (grade 3). Above- and below-knee amputations were analyzed separately from this group (in the

“other” category) due to the inherent larger size of these wounds. Pressure ulcers were defined as wounds caused by sustained pressure. Wounds with an underlying soft tissue infection were categorized as cellulitis or fasciitis. The remaining wounds were classified as “other” and were analyzed separately due to heterogeneity in size and etiology.

Wound location and duration were recorded — the duration of the wound was defined as number of days since surgical débridement or surgical creation of the wound before enrollment. Size was determined using computer-aided measurements of digital photographs — ie, a photograph was taken of the wound and an adjacent centimeter ruler and uploaded in JPEG format. The Scion Imaging Program (Scion Corporation, Frederick, MD) was calibrated by measuring 1 cm in length on the ruler. Three sequential measurements of the photographed wound were taken by tracing the edges of the wound with the “lasso” tool. The three surface area measurements were averaged. Wounds with measurable depth were assessed using a centimeter ruler at the maximum dimension for depth (anterior-posterior projection).

TNP dressing protocol. Wounds were débrided, hemostasis achieved, and sterilized porous packing material obtained from a local source was cut to fit the wound. A 14-French suction catheter was tunneled into the packing material (see Figure 1a,b), which then was placed into the wound cavity. A sterile adhesive plastic drape (Dermincise, Vygon, UK) was cut to overlap the surrounding skin and applied over the



Figure 2. TNP timer and wall suction apparatus.

packing material, forming an airtight seal. Tubing was used to attach the free end of the suction catheter to a wall suction canister. The TNP timer was placed in circuit between the wall suction apparatus and the wall suction canister (see Figure 2).

The TNP timer, constructed from local electronics, was designed to intermittently cycle wall suction using a simple timed switch and a system of valves. For the study protocol, the timer was set to cycle 2 minutes on, followed by 5 minutes off. Wall suction pressure was set at 125 mm Hg. In sensitive wounds, suction was reduced to a tolerable level (usually 50 mm Hg to 100 mm Hg) until it could be comfortably increased. For edematous wounds, the suction was kept on a continuous setting until edema had been reduced and an intermittent regimen could be followed. The dressing was changed every 2 days unless otherwise scheduled by the treating physician. Wounds were débrided as needed to keep the wound bed free of necrotic tissue. Patients receiving TNP who no longer required hospitalization for their primary diagnosis or could not afford to remain in the hospital remained in the study with conventional wound dressings in the outpatient setting but outcomes were analyzed in the original treatment groups. Surgical nurses and interns were trained in equipment use, dressing application, and TNP set-up monitoring. Average initial set-up time was estimated at 23 minutes and average dressing change time at 17 minutes.

Conventional dressings. Following débridement of the wound, saline-soaked gauze and dry pads were used to cover the wound. Dressing changes

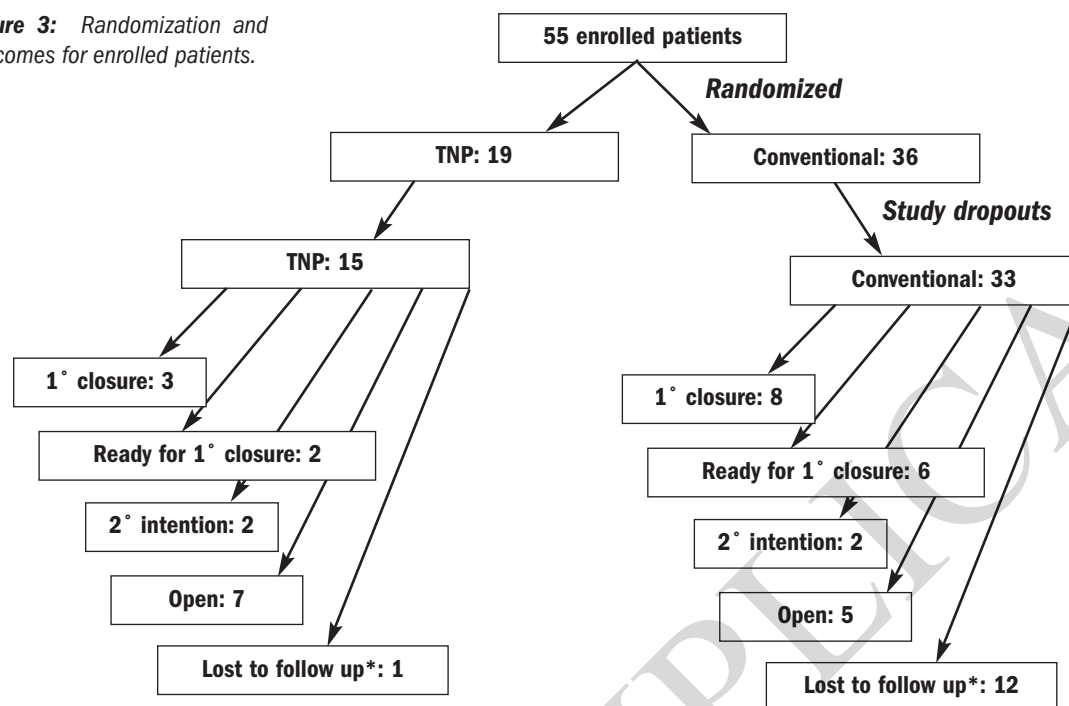
were typically performed twice daily; the frequency was adjusted per the judgment of the treating physician. Adjunctive treatment included chemical débridement (one patient) and use of ceramic-based dressing (one patient). Ceramic-based dressings comprise pre-manufactured sachets of ceramic beads that are used to pack edematous wound beds. Patients treated with conventional dressings were followed as outpatients after discharge.

Wound outcomes and costs of care. The primary outcome was the number of days to satisfactory healing, defined as complete wound closure by secondary intention or wound readiness for delayed primary closure as determined by the study investigator and treating surgeon.

The actual amount and cost of all materials required for the initial TNP and conventional dressing were obtained and tabulated for two representative pressure ulcers of similar size (106.8 cm³ for the TNP dressing and 79.2 cm³ for the conventional dressing). Although the TNP-treated pressure ulcer was larger than the conventional dressing, this difference was accepted as an accurate representation of patients enrolled in the study. Costs were obtained from the hospital's central supply department but did not include sterilization of materials, dressing forceps, or scissors because these were required for both treatment groups. All dressing materials were considered to be single-use. Total material costs for one treatment and one control dressing application were summed and total daily cost calculated based on twice-daily changes of the control and once-every-two-day change of the treatment dressing. Overall TNP and conventional treatment cost of one representative pressure ulcer was determined by multiplying the daily cost by the average number of days required to achieve satisfactory healing.

Statistical analysis. Statistical analysis was performed using Stata statistical software (Stata Corporation, College Station, TX). Wound volume was calculated by multiplying surface area measurement by measured depth. Average post-débridement (ie, initial) wound sizes and standard deviations were determined. For patients with multiple wounds, only the largest wound that achieved closure was included in the analysis.

Figure 3: Randomization and outcomes for enrolled patients.



* lost to follow up prior to reaching closure

Mean days to closure and standard deviations for wounds achieving satisfactory healing were calculated according to wound etiology. Means and standard deviations were compared using a one-sided Student's *t*-test. Kaplan-Meier estimates of time to wound closure by treatment were calculated.

Results

Wound characteristics. Of the 55 patients initially assessed, seven (four in the treatment and three in the control group) were dropped from the study for refusing to participate or inability to complete the course of treatment (see Figure 3). The average age of all patients was 53.5 years and 72% were men (see Table 1.) One wound in the cellulitis group had tissue involvement beyond the superficial subcutaneous level and diagnosed /described as necrotizing fasciitis. Five wounds in the cellulitis/fasciitis group were débrided superficially (grade 1) and six wounds required débridement to tendon or capsule (grade 2). All pressure ulcers were débrided to either grade 1 or grade 2. "Other" wounds included major amputations (due to vascular disease and/or diabetes), abscesses requiring superficial débridement ($n = 2$),

and surgical abdominal wounds ($n = 2$). The majority of wounds were acute (<30 days in duration) and while most wounds were large, they ranged widely in size (1.66 cm^3 to $1,329.0 \text{ cm}^3$) (see Table 2).

Length of study participation. Patients were seen by treating personnel and followed by the study investigator an average of 26.3 ± 18.5 days ($n = 27$) in the control and 33.1 ± 37.3 days ($n = 14$) in the treatment group before achieving closure or being lost to follow up. In the study group, wounds were treated with TNP an average of 11.3 ± 9.2 days before changing to the control dressing group, achieving closure, or being lost to follow up. Eight wounds started in the treatment group and were followed after changing to conventional dressings. Patients with pressure ulcers were the only participants to remain on TNP for the duration of the study (until satisfactory closure).

Healing outcomes. In the conventional dressing group, one diabetic foot ulcer and one cellulitis wound closed by secondary intention and three diabetic foot ulcers, four pressure ulcers, and one cellulitis wound underwent delayed primary closure. Six wounds (one diabetic foot ulcer, four pressure ulcers, one "other") were ready for delayed primary closure but were not

actually closed and/or grafted during the study period. In the TNP group, one diabetic foot ulcer and one other wound closed by secondary intention, one pressure ulcer and two cellulitis wounds were closed primarily, and one pressure ulcer and one other wound were ready for closure. Seven (47.6%) wounds in the treatment group and 16 (48.4%) in the control group achieved satisfactory healing (see Figure 3). Kaplan-Meier analysis found that a similar proportion of wounds remained open in both study arms by the end of the study (total of 214 days) (see Figure 4). For pressure ulcers that reached satisfactory healing, the average number of days to healing was 10 ± 7 days for TNP and 27.4 ± 10.6 days for control treatment ($P = 0.05$) (see Table 3). When adjusted for initial volume, days to closure were (marginally) significantly fewer for TNP and when adjusted for initial surface remained significantly fewer. For the other wound etiologies, no statistical differences in the days to closure for wounds that healed were observed.

Cost analysis (US dollars). The material cost of one TNP dressing change was approximately \$2.27 (packing material \$0.11, catheter \$0.30, and film drape \$1.86), 5.7 times more expensive than the materials used for one conventional dressing change (gauze \$0.40). Total material costs for reaching satisfactory closure of the two representative pressure ulcers were \$11.35 for the treatment and \$22 for the control dressings.

Complications. The complications reported for patients on TNP included two minor wound revisions (bedside débridement) and one revision of transmetatarsal amputation in the operating room. Two patients reported leg pain or cramps at night (which resolved off treatment) and treatment was discontinued because of reported pain in one patient with cellulites. In the control dressing group, two complications requiring minor revisions (bedside débridement) occurred.

TABLE 1
PARTICIPANT DEMOGRAPHICS AND WOUND DIAGNOSIS BY TREATMENT GROUP OF ALL ELIGIBLE ENROLLED PATIENTS

	Topical negative pressure (n = 15)			Conventional (n = 33)		
	n	Age (years)	% male	n	Age (years)	% male
Diabetic foot ulcers	6	53.2±15.1	67%	9	59.6±8.5	67%
Pressure ulcers	2	46.5±12.0	100%	9	41.5±17.9	89%
Cellulitis/fasciitis	3	55.3± 3.1	67%	8	64.3±6.3	75%
Other	4	58.0±14.0	50%	7	47.6±10.2	67%

Discussion

Topical negative pressure therapy was originally utilized to speed bedside débridement of wounds. Since its inception, TNP has become a popular wound closure option but few well-designed randomized controlled trials have been conducted.² Morykwas and Argenta⁸ compared the commercial V.A.C.[®] device to standard wet-to-dry dressings on acute wounds in animal models and reported that negative pressure (125 mm Hg) improved wound blood flow, particularly after intermittent cessation of pressure. These results guide current recommendations for commercial TNP device settings, although data comparing healing rates on different regimens are lacking.

Many case studies describe the effects of TNP on patients with a specific type of wound, including infected sternotomy wounds (average 9 days to close),¹⁷ leg ulcers,^{18,19} and enterocutaneous and incisional fistulae⁷ (average 16 days to close). Mullner et al²⁰ demonstrated an 80% reduction in the size of pressure ulcers treated with TNP, similar to the 77% pressure ulcer size reduction observed in the current study.

Joseph et al⁹ randomized 24 patients with multiple wounds due to pressure, dehiscence, trauma, venous stasis, or radiation to TNP or wet-to-moist dressings changed three times daily. At 6 weeks, reported wound volume reduction was 78% in the TNP and 30% in the conventional gauze dressing group. These results are similar to current study data. A randomized controlled trial¹⁰ of 10 nonhealing postoperative diabetic foot ulcers randomized to TNP or moist gauze dressings changed twice daily demonstrated an approximately two-fold reduction in healing time, similar to current results for pressure ulcers, as well as reduction in surface area of 28% with TNP (versus 9.5% with conventional dressings).

TABLE 2
AVERAGE WOUND DURATION AND SIZE AT TIME OF ENROLLMENT

	Topical negative pressure (n = 15)		Conventional (n = 33)	
	Duration (days)	Size (cm ²)	Duration (days)	Size (cm ²)
Diabetic foot ulcers	8.5±8.3	25.7±9.7	5.2±2.3	48.1±53.4
Pressure ulcers	17.5±4.9	157.8±72.2	19.8±15.1	59.6±57.5
Cellulitis/fasciitis	6.7±1.5	151.4±163.3	6.4±7.8	286.6±456.3
Other	9.7±6.7	20.9±10.7	7.7±4.6	103.1±82.0

TABLE 3
DAYS TO SATISFACTORY HEALING* BY WOUND ETIOLOGY

	Topical negative pressure (n = 7)	Conventional (n = 16)	P value
Diabetic foot	107 (n = 1)	25.6±21.9	n/a
Pressure sore	10±7.1	27.4±10.6	0.05
Cellulitis/fasciitis	51±60.8	42±46.7	0.56
Other	11±4.2	23 (n = 1)	n/a
Average	35.9±44.5	28.4±18.9	0.66

* Satisfactory healing: wound closure by secondary intention or ready for delayed primary closure.

Armstrong et al¹¹ conducted a randomized trial comparing gauze dressings to TNP in 162 patients after partial foot amputation due to nonhealing ulcers caused by diabetes and reported that more wounds in the TNP than in the gauze group healed; however, 40% of the wounds remained open after 4 months of treatment and at least 3 weeks of TNP were needed before improvement was noted in the rate of healing compared to conventional dressings. The wounds enrolled in their study were similarly sized (20.7 cm²) to the diabetic foot wounds randomized in the current trial (average size 37.2 cm²).

The results of the current study suggest that wound healing outcomes using TNP dressings made from locally available resources are similar to those reported using commercially available TNP dressings. Of the variety of wounds randomized, only pressure ulcers could be followed until the majority achieved complete healing. The disparity in follow-up rates by wound type was likely due to prolonged hospitalization for rehabilitation of nonambulatory patients with pressure ulcers and the major socioeconomic limitations of providing inpatient wound care and long-term follow up for ambulatory patients. Pressure ulcers that healed during the study did so in fewer days

with TNP than when gauze dressings were used. Based on the sample cost calculation, the TNP dressing used in this study was also cost-effective. In addition, TNP treatment requires less time spent on dressing changes and simpler management of large, difficult-to-dress, or edematous wounds. These results suggest that inexpensive materials can be utilized for TNP wound closure in a developing country.

Issues for India. The time and costs associated with wound care are a considerable problem in India. Evidence relevant to wound care in Southern India has been published. Population surveys indicate that up to 21% of adults >40 years of age have diabetes mellitus.²¹ Diabetic foot infections account for 10% of Indian hospital admissions.¹⁴ An Indian patient with diabetes and a foot ulcer requiring surgical intervention will spend up to 32.3% of his/her income on medical care.²² The amputation rate in India for complications of diabetes is approximately 8% to 9%, above that in developed nations.²³ Given the large and increasing burden of diabetic and other wounds, the Indian patient will greatly benefit from advances in wound care.

Cost. In the UK, cost for care of chronic wounds is estimated to be 1 billion pounds per year.¹ Although TNP use requires purchase of equipment and appropriately trained personnel, comparisons of case studies on the cost of wound treatments has shown that the cost of TNP is lower than that of conventional

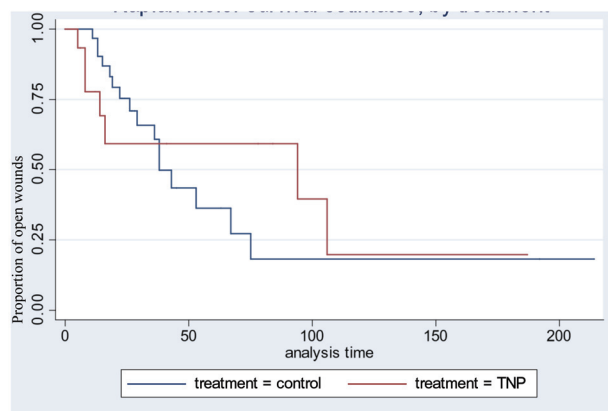


Figure 4. Kaplan-Meier survival estimates for time to wound closure by treatment (TNP versus conventional dressings [control]). Analysis time is in days.

treatment. This difference in cost has been attributed to reduced treatment times and fewer dressing changes, requiring fewer personnel hours. Philbeck et al²⁴ retrospectively reviewed 1,032 patient records and showed that treatment with commercial vacuum-assisted devices required an average of 97 days and \$14,546; whereas, treatment with conventional wound dressings required 247 days and \$23,465. However, the cost of the commercially available vacuum-assisted therapy device prohibits its use in the authors' setting. Clinicians have demonstrated in case studies⁷ that TNP systems developed at the bedside are also cost effective, with a lower weekly cost to treat enterocutaneous fistulae with TNP compared to conventional dressings (\$205 versus \$1,400).

The current study confirms these observations. Direct dressing costs were calculated because all study patients were enrolled while hospitalized for wound débridement or medical care. Although nursing time and hospital resources utilized (ie, the suction system) differed between the two groups, their use is part of the hospital cost subsidized for all patients. Further, the negative pressure regulators are reusable. TNP was discontinued when patients no longer needed or could no longer afford continued inpatient care. Therefore, despite the requirement that patients be hospitalized to receive TNP with the authors' current system, these costs were not considered an additional expense of providing TNP.

Complications. The complication rates of TNP and conventional wound dressings have been shown

to be similar.¹¹ In the current study, one patient on TNP reported pain, leading to discontinuation of treatment, and one patient with a diabetic foot wound, treated for 40 days on TNP, developed a tendon-tracking infection beneath granulation tissue. As a result, some surgeons at the study facility were concerned about TNP monitoring when treating infected wounds. Due to the closed dressing, extended intervals between dressing changes, and faster granulation tissue formation, infection may remain undetected. Infection and colonization are not contraindications — TNP treatment of infected wounds has been reported in many case series. A recent case series²⁵ involving culture-positive wounds with evidence of abscess formation showed that TNP-treated infected wounds decreased in size. However, suppurative tissue should be débrided and consideration should be given to placing patients on appropriate antibiotics.² Revisions or continued intermittent sharp débridement of the wound are necessary and should not be a contraindication to continuing TNP therapy once hemostasis has been reestablished.

Study and treatment limitations. This study has several limitations, including the high attrition rate, small sample size, difficulty in obtaining interval wound assessments, and reliance on gauze as the comparison dressing. Each limitation highlights the need for investigating wound-healing technology appropriate for the developing world. The most challenging aspect of studying wounds in India is the ability to continue treatment and follow-up until wound closure. No difference was observed in healing outcomes between TNP and conventional dressings for all wounds. A subset analysis of similar wounds (pressure ulcers) that were followed until healing found a difference between treatment groups but interpretation of these results is limited per the small number of wounds in this group (two in the TNP and eight in the conventional dressing group). However, author observations and the success of a wide range of TNP systems documented in the literature suggest that TNP closure in this population warrants further study. Complete wound closure would require long-term hospitalization or the development of an affordable portable device. Alternatively, TNP could be used to speed débridement and initial granulation tissue

formation, although the efficacy of short-term treatment has not been studied.

The other major limitation was timing of interval assessments, largely due to irregular follow-up in the outpatient clinic. Further studies in this institution will require a mechanism to capture wound-healing data from nonhospitalized patients.

Current and previous TNP studies have used wet-to-dry or moist gauze dressings as a control treatment. Although both may accomplish mechanical débridement or, if kept moist, a moist wound healing environment, some evidence supports use of advanced materials (including hydrocolloids and silver alginate) in chronic and acute wound healing.^{26,27} Future studies on TNP will be improved by including non-gauze dressing control treatments. However, the current standard of care in India is wet-to-dry dressings and most advanced dressings are not widely available in the authors' institution. Further, their use in low-resource settings is significantly limited by the need to obtain stock from abroad or to initiate local production. Conversely, locally available materials and suction systems already in place were easily assembled to deliver TNP at the study site. By using the conventional dressings as the control dressing, the current study more accurately reflects how TNP will affect the current state of wound care in India. In addition, the use of gauze dressings in this study made it easier to compare results to published TNP clinical studies.

Challenges. There are barriers to providing TNP in the current study setting — eg, reliance on electricity, patient acceptance of the new therapy, and occasional pain or discomfort. While the features of commercial systems continue to advance, the availability of resources limits their use worldwide. Notably, the initial applications of TNP were the result of clinical innovation using available resources. Research should be directed at developing inexpensive, small, portable designs that could be constructed from locally available materials. A recent report²⁸ from Switzerland on the use of weight-loaded syringes to simulate negative pressure conditions demonstrates the innovative use of inexpensive and portable materials that can be used in a variety of settings. Innovative use of low-cost and readily available materials such as the authors' locally designed TNP device will be critical to initiating

advancements in wound healing worldwide.^{16,25} Further research also should clarify which types of wounds benefit most from TNP and whether short-term treatment is effective and cost effective.

Applying study outcomes. The authors estimate that more than 150 wounds per year could be treated with TNP in their institution, including traumatic wounds,²⁹ chronic ulcers, infected wounds,²⁵ and complex wounds involving enterocutaneous fistula.¹³ The burden of difficult-to-heal wounds will continue to increase even as the developing world rapidly becomes modernized. While advances are occurring in dressing materials, débridement devices, antibiotic therapy, and wound healing protocols, technology must be appropriately translated to meet developing world needs.

As a result of this study, a dedicated tissue viability team has been approved at the study institution. Its role is to identify wounds suitable for TNP, oversee treatment, monitor the need for surgical débridement, employ the principles of wound treatment including proper offloading, and apply new wound healing technology appropriately. The role of the tissue viability team will evolve as TNP is more widely utilized and further innovated.

Conclusion

Results of a randomized, controlled trial comparing a TNP treatment using locally available materials to wet-to-dry dressings suggest that outcomes of care are similar to those reported using commercially available TNP. Although no overall healing differences were observed, subset analysis of wounds (pressure ulcers) that were followed until satisfactory healing indicate that healing occurred in less time in the treatment than in the control group. Material costs to achieve satisfactory healing were lower in the TNP than in the gauze dressing group. In addition to the encouraging healing results achieved, management with the locally developed TNP was found to offer other advantages compared to traditional gauze dressings, such as fewer dressing changes and automated delivery of wound treatment. These results suggest it is possible to provide TNP treatment to wound patients in a resource-poor environment. In addition, TNP may

be useful in the management of large, difficult-to-dress, or edematous wounds, both for patient comfort and to improve the efficiency of the treating team. - OWM

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