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Pilot Study to Assess Safety and Usability of the Kyron NPWT System

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Background: There is an evident need for Negative Pressure Wound Therapy (NPWT) systems specifically designed for use in resource-constrained settings to aid in the treatment of open wounds.

Methods: Prospective single-arm interventional pilot study of 14 patients with complex wounds was conducted at Kirtipur Hospital in Kathmandu, Nepal. A novel NPWT device, the Kyron Suction Unit, was used by 4 plastic surgeons. Primary outcomes were ease of use (10-point Likert scale) and device safety (adverse events recorded). Pain (Visual Analogue Scale score), quality of life (modified EuroQol Derived Single Index scores), and wound dimensions were recorded.

Results: User ratings on the 10-point Likert scale indicated high confidence and ease of use: median confidence setting up the device of 1.0 [interquartile range (IQR), 1.0; mean 2.3], median confidence maintaining the device of 1.0 (IQR, 1.0; mean, 1.5), and median ease of disassembly of 1.0 (IQR, 1.0; mean, 1.4). Significant improvement in Visual Analogue Scale scores ($P = 0.03$), modified EuroQol Derived Single Index scores ($P < 0.001$), and a reduction in wound volume [median, 47.25–9.75 cm^3 ($P = 0.01$)]. Image analysis of wounds pretreatment and posttreatment demonstrated increase in granulation tissue surface area [median, 7.6–28.7 cm^2 ($P = 0.003$)] and decrease in open wound surface area [median, 48.33–33.6 cm^2 ($P = 0.01$)].

Conclusions: The Kyron Suction Unit was safe and easily managed by plastic surgeons. The device design promoted access to NPWT, a therapy proven to reduce healing time and decrease complications for patients with open wounds, in a resource-constrained setting. *(Plast Reconstr Surg Glob Open 2019;7:e2334; doi: 10.1097/GOX.0000000000002334; Published online 9 August 2019.)*

INTRODUCTION

The global estimate for the annual incidence of severe, open wounds exceeds 100 million, and for traumatic wounds, 50 million.[1] Negative pressure wound therapy (NPWT) accelerates wound healing by applying subatmospheric pressure to a wound bed through an airtight seal, causing tissue macrodeformation, microdeformation, removal of exudate and detritus from the wound bed, and stabilizing the wound environment.[2] NPWT has been deemed effective in treating both acute wounds (burns,[3,4] skin grafts,[5,6] open fractures,[7,8] dehisced sternal wounds,[9–11] and open abdominal wounds[12–15]) and chronic wounds (pressure ulcers,[16–19] diabetic ulcers,[20–24] and leg ulcers[25,26]). It has been validated in numerous clinical studies as a methodology that reduces healing time of open wounds, reduces complications in wound closure, and in turn increases overall patient survival.[12,13,25,26]

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This clinical investigation was an R&D pilot study.

Subject protection was assured within the guidelines of ISO 14155 (2011), The Belmont Report (Ethical Principles and Guidelines for the Protection of Human Subjects of Research, April 18, 1979) and Declaration of Helsinki (The World Medical Association Ethical Principles for Medical Research Involving Human Subjects, June 1964, as amended).

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Despite the advances in the NPWT field, current market technology is limited by high costs and inappropriate designs for ease of use. The conventional, reusable standalone NPWT devices include adjustable settings for customized therapy and are useful in treating larger wounds with higher volumes of exudate. However, these devices require engagement with elaborate on-board software and complex connection mechanisms for consumables. Often, the training required for operating and troubleshooting restricts use to settings with highly skilled personnel. Furthermore, the complex device electronics and components are heavy, costly, and require reliable power sources, limiting patient mobility and access. An emerging sector of single-use, disposable NPWT devices offers benefits in ease of use and mobility during treatment. However, their indications are limited to small, fast-healing wound types with low exudate volume, as they feature smaller canisters and console systems, and a short use-life (eg, 7 days). The limitations of both NPWT device segments and high costs have impeded their widespread use in low-income world settings.

As such, makeshift NPWT devices have been contructed in low-resource settings (environment defined by difficulty covering healthcare costs, limited access to supplies, poor infrastructure, or less-trained personnel[27]). Studies suggest that homemade NPWT devices demonstrate benefits, such as a reduction in reoperation, graft loss, and hospital length of stay,[5,28,29] and reduce costs compared to commercial products ($25.40/day compared to $110.06/day),[30] but homemade devices lack evidence supporting safety, reliability, and ease of use.

Accordingly, there is a need for improved NPWT systems that are durable, reusable, portable, economical, low-power, and have streamlined interfaces for ease-of-use even among less-trained populations. The successful implementation of NPWT in resource-constrained settings requires an innovative design that reduces device maintenance and training requirements.[31] Any design must also meet the safety standards and quality expectations for a commercial NPWT device.[32,33] A redesigned NPWT system has the potential to deliver therapy across multiple healthcare settings, and in turn improve healing and the quality of life for millions of underserved patients afflicted with open wounds.

The primary aim of this single-site pilot study was to assess ease of use and safety of a novel NPWT device specifically designed for resource-constrained environments in a hospital setting in Kathmandu, Nepal. The secondary aim was to explore the trends in wound healing on patients related to use of the device.

METHODS

Ethics

Regulatory approval was obtained through the Nepal Health Research Council in line with the medical device regulations. Written informed consent was obtained from all patients participating in the study. Patient confidentiality and privacy were protected.

Design

A prospective, single-arm interventional pilot study of 14 patients with complex open wounds was undertaken. Patients were treated with the Kyron Suction Unit (Healyx Labs Inc., Fogarty Institute for Innovation, Mountain View, Calif.), at a single site at Kirtipur Hospital in Kathmandu, Nepal, between February and April 2018. A 100-bed resource-constrained hospital, Kirtipur, serves low-income patients with limited practitioners and no current access to commercial NPWT. Four plastic surgeons at Kirtipur Hospital completed training in study conduct and device use, and reported ease of use of the Kyron Suction Unit during treatment. Patients were also briefed on device use and therapeutic goals. Family members were taught to charge the device and recognize an alarm and notify a caregiver if the alarm occurred.

Subjects

Patients were enrolled if they presented with an open wound and were over the age of 18. Baseline medical histories were taken at the time of enrollment. Exclusion criteria included wounds secondary to malignancy, presence of necrotic tissue that had not been debrided, and wounds with active bleeding, exposed blood vessels or organs. Patients were also excluded if they were noncompliant, pregnant, or nursing, if they presented with uncontrolled wound-related comorbidities, such as hyperglycemia, vascular disease, or arthritis, or if their wounds were nonsurvivable. Consented subjects were screened and subjects fitting the inclusion/exclusion criteria outlined above were enrolled in the study.

Device and Procedures

The Kyron Suction Unit is an electrically controlled vacuum pump for the delivery of continuous NPWT, created for medical settings that have infrastructure and training limitations (Fig. 1). The Kyron Suction Unit is simplified for ease-of-use, streamlined for cost-effectiveness, and designed for portability, durability, and reusability.

Pressure is controlled by a novel pneumatic and electronic system. The technology is configured to provide only a single level of negative pressure in a reliable, simple process. The Kyron Suction Unit provides suction at 125 mm Hg ± 10%, the standard vacuum pressure used in commercially available NPWT devices for a majority of wound types, including open fractures,[7,34] posttraumatic wounds,[7] acute burns,[35,36] pressure ulcers,[37] diabetic foot ulcers,[37] chronic leg ulcers,[25] sternal wounds,[9] and skin graft sites.[38] Kyron's novel mechanism controls device system pressure through a combination of simple pressure control circuitry and a passive mechanical valve. This pressure control method is implemented with fewer components than traditional devices (eg, control circuitry does not use a microcontroller). Additionally, the component and material costs are lower than pressure control mechanisms used in currently marketed devices, significantly reducing the production cost of the device. This simplified scheme provides benefits including easier servicing and improved field reliability compared to complex, standalone NPWT devices.

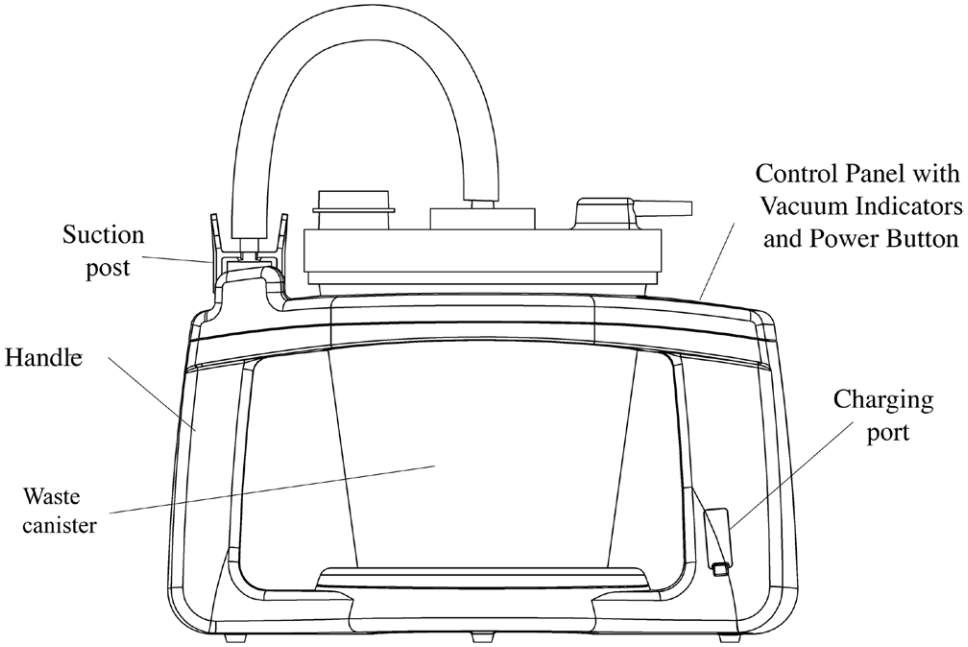

Fig. 1. Kyron Suction Unit technical drawing. The Kyron Suction Unit is an electrically controlled vacuum pump for the delivery of continuous NPWT, created for medical settings that have infrastructure and training limitations.

The system is electrically powered by a lithium-ion battery that is rechargeable by a micro USB cable. The system can be used for 24 hours or more without being plugged into the wall, allowing for use in low-power or off-the-grid environments, and mobility for the patient. The design further reduces device cost and complexity through the use of LEDs instead of a digital output display to indicate essential safety features including system vacuum status, alarms, and battery level.

The device form factor is designed for easy cleaning, transport, and handoffs between caregivers. The system is created to be simple for unskilled operators. The only user input required to initiate, pause, or terminate treatment is an intuitive power button that. Furthermore, the Kyron Suction Unit is paired with a large disposable waste canister and dressing kit, enabling the treatment of both low- and high-level exudate wounds. The Kyron Suction Unit is designed to accept lower priced and even locally available NPWT consumables (eg, dressings, canisters, and chargers) to reduce accessory expenditures and barriers to implementation. In comparison, the majority of market available units only pair with proprietary, brand-specific accessories that increase the treatment cost. The Kyron Suction Unit's cost-effective design enables affordable implementation to expand access to therapy in resource-constrained settings. For this study, the Kyron Suction Unit was paired with a US Food and Drug Administration-cleared, compatible wound dressing kit manufactured by Cork Medical (Cork Medical, Indianapolis, Ind.).

Investigators determined "wound bed readiness" before treatment, based on cleanliness of wound and infection status. Device and dressing were set up for treatment and monitored daily within the normal flow of care. Dressings were changed twice weekly for every patient. Patients were treated for up to 6 weeks. When investigator-determined healing endpoints were reached, the Kyron Suction Unit and dressing were removed following final wound and quality of life assessments. Definitive treatment was planned where necessary. Patients completed follow-up visits in person or over the phone at 4 weeks post study termination.

Primary Outcomes

The primary outcomes measured were device safety and ease of use at each step of NPWT dressing placement, dressing change, and dressing removal.

Device Safety

Patients were assessed for adverse events at every dressing change and at treatment termination. If an adverse event was noted, the event start date, resolution date, date of sponsor notification, description of the event, severity, relatedness to the device, procedure, and/or preexisting condition, treatment, and outcome were recorded. Sponsor was notified of adverse events within 24 hours.

Ease of Use Scores

Ease of use was assessed by 4 plastic surgeons for each component of NPWT device assembly, maintenance, and removal using a ten-point Likert scale (1, very easy; 10, very difficult).[39] At initiation, ease of use was assessed for the following categories: foam dressing application, drape application and tightness, connecting tube to vacuum, powering suction on, and ability of system to reach appropriate pressure. During treatment, the ease of completing the following therapy tasks was assessed:

removal of dressing material, disposal of dressing material, disposal of canister content, sizing and placement of new foam in wound bed, checking drape application and tightness, securing tubing connectors, powering on suction, achieving appropriate pressure in the system. At the time of treatment termination, the ease of completing the following therapy steps was assessed: removal of dressing material, disposal of dressing material, disposal of canister content, and preparation of standard gauze dressing.

Pain and Quality of Life Assessment

Pain levels were reported using the validated Visual Analogue Scale (VAS)[40] during and at the end of treatment. Additional quality of life questionnaires based on a modified EuroQol Derived Single Index (EQ-DSI)[41] were completed at the start of treatment and weekly, after the first dressing change of the week. This questionnaire asked patients to rate quality of life on a 3-point scale based on 5 items: mobility, self-care, usual activities, sleep (in place of pain/discomfort on the EQ-DSI; scale: a. I have no problems with sleep, b. I have moderate problems with sleep, c. I am unable to sleep), and hospital care (in place of anxiety/depression on the EQ-DSI; scale: a. I have no problems receiving daily care, b. I have moderate problems receiving daily care, c. I am unable to receive daily care). Numerical scoring translated the responses into a single index of quality of life with a high score indicating a high quality of life.

Wound Assessment

Before treatment, wound type, location, and dimensions were recorded. During the first weekly dressing change, investigators measured the length, width, and depth of the wound. To assess changes in wound volume, data from the initial measurement and at study termination were used. Patient data were excluded from wound volume analysis if investigators failed to collect measurements. A digital photograph of the wound was taken at each weekly assessment. During image capture, the camera lens axis was oriented normal to the wound surface at its center, and a ruler was placed next to the wound on the surface of the skin.

Following study closure, a procedure for analysis of wound healing that was adopted for this analysis defined by Murphy et al.[42] A plastic surgeon directed the image analysis of the digital photographs to assess the surface area of the open wound and granulation tissue. As consistent with Houghton et al,[43] open wound surface area was defined as granulated and nonhealed tissue. Granulation tissue was defined as new vascular tissue filling the open wound, appearing bright, beefy red, and granular.[43] Wound edges and granulation tissue location were manually marked using Adobe Photoshop (CC 2019). Image analysis was performed to quantify pixels in the selected area as defined by the method by Papazoglou et al.[44] Pixel size was estimated using the ruler in the imaging plane of each wound, which was then applied to derive the pixels per square centimeter. Photographic data for 3 patients was uninterpretable and therefore was not included in the statistical analysis of granulation tissue and surface area. All image analysis results were validated by the designated plastic surgeon.

Statistics

Continuous variables were tested for normality using the Shapiro–Wilk test. Based on this testing, the appropriate measures of central tendency and variation as appropriate to the study variable and distribution were used. Categorical data were summarized with frequency and percentage. A paired *t*-test was used to compare pre- and post-NPWT VAS, modified EQ-DSI, wound volume, wound granulation tissue area, and wound open surface area. A P value of 0.05 was considered statistically significant.

RESULTS

Of the 14 patients (median age 39; SD, 15.3), 5 presented with traumatic wounds, 4 with pressure sores, 3 with electric burns, 1 with a flame burn, and 1 with a lower extremity wound (Table 1). The median treatment duration was 11.5 days [interquartile range (IQR), 6.5]. At study termination, 11 patients reached a healing endpoint allowing closure with definitive treatment, including split-thickness skin grafts (n = 8) and free flaps (n = 3). One wound was progressing to closure with secondary intention. Two patients withdrew from the study before study termination, leaving the hospital against medical advice and were excluded from analysis. One patient's exposed calvarium was reported as static due to failure of granulation tissue growth over the bone.

Table 1. Patient and Wound Characteristics of 14 Patients Treated with Negative Pressure Wound Therapy

Metric	
Patient	
Age (median, IQR)	39 (21–74)
Male	12 (86%)*
Female	2 (14%)
BMI (median, IQR)	21 (15–25)
Wound-related comorbidities	
Hypertension	1 (7%)
Diabetes	1 (7%)
Smoking	5 (36%)
Other	
Paralysis	3 (21%)
Epilepsy	2 (14%)
Transverse myelitis	1 (7%)
Tuberculosis	1 (7%)
Wound type	
Traumatic wound	5 (36%)
Pressure ulcer	4 (29%)
Electric burn	3 (21%)
Flame burn	1 (7%)
Low extremity ulcer	1 (7%)
Wound location	
Ankle/foot	4 (29%)
Hips/buttocks	4 (29%)
Lower leg (including knee)	2 (14%)
Hand/wrist	2 (14%)
Lower arm (including elbow)	1 (7%)
Scalp	1 (7%)
Wound dimensions	
Length (cm) (median, IQR)	9.5 (7.4–10.5)
Width (cm) (median, IQR)	6.5 (5.8–8.5)
Depth (cm) (median, IQR)	1 (0.4–1)
Wound existence in days (median, IQR)	70 (15–365)

*n (%) unless otherwise noted.
BMI, basal metabolic index.

Table 2. Wound Assessment Pretreatment and Posttreatment with the Kyron Suction Unit

Patient	Metric	Before Treatment	End of Treatment	Change
1	Volume (cm^3)	91	29.9	−61.1
	Surface area (cm^2)	65.4	54.3	−11.1
	Granulation tissue (cm^2)	7.4	50.2	42.8
2	Volume (cm^3)			
	Surface area (cm^2)	58.9	57.6	−1.3
	Granulation tissue (cm^2)	43.5	56	12.5
3	Volume (cm^3)	47.3	7.2	−40.1
	Surface area (cm^2)	18.3	14.6	−3.7
	Granulation tissue (cm^2)	7.9	11.1	3.2
4	Volume (cm^3)	60	4.7	−55.3
	Surface area (cm^2)	55.3	53.4	−1.9
	Granulation tissue (cm^2)	47.5	53.4	5.9
5	Volume (cm^3)	36.4	1.1	−35.3
	Surface area (cm^2)	26.5	13.1	−13.4
	Granulation tissue (cm^2)	0.8	13.1	12.3
6	Volume (cm^3)	4.3	0	−4.3
	Surface area (cm^2)	24.9	20.7	−4.2
	Granulation tissue (cm^2)	7	20.6	13.6
7	Volume (cm^3)	80.8	9.8	−71
	Surface area (cm^2)	63.9	30.3	−33.6
	Granulation tissue (cm^2)	2.2	30.3	28.1
8	Volume (cm^3)	23.1	14.5	−8.6
	Surface area (cm^2)	41.4	31.6	−9.8
	Granulation tissue (cm^2)	22.2	20.6	−1.6
9	Volume (cm^3)	25.7	15.1	−10.6
	Surface area (cm^2)	58.8	39.6	−19.2
	Granulation tissue (cm^2)	7.9	36	28.1
12	Volume (cm^3)	304.6	144.5	−160.1
	Surface area (cm^2)			
	Granulation tissue (cm^2)			
14	Volume (cm^3)			
	Surface area (cm^2)	35.8	35.6	−0.2
	Granulation tissue (cm^2)	1.1	27.1	26
Median	Volume (cm^3)	47.25	9.75	
	Surface area (cm^2)	48.33	33.60	
	Granulation tissue (cm^2)	7.63	28.73	
Paired *t*-test	Volume		*P* value = 0.01	
	Surface area		*P* value = 0.01	
	Granulation tissue		*P* value = 0.003	

A statistically significant reduction in wound volume, increase in granulation tissue, and decrease in open wound size is observed.
*Select patients were excluded from analysis due to early termination from the study, investigator failure to collect data, or distortion of digital photographs.

Incidence of device-related adverse events (AEs) was low. The 2 reported AEs were expected sequalae during wound healing and recorded as mild severity. The first event involved the adherence of the dressing foam to the patient's wound, resulting in the removal of a $1.5 \times 1\,cm^2$ portion of granulation tissue. The second event involved pus collection at the wound bed. The wound was treated with thorough irrigation followed by reapplication of a new NPWT dressing. Both events were resolved and required no further medical attention, allowing treatment with the Kyron Suction Unit to continue.

The median reported ease of use across all components of device use was 1.0 (very easy) out of 10.0 (IQR, 1.0; mean, 1.7). Median rankings within subcategories ranged from 1.0 to 4.0, with initial drape application reported as most difficult (median, 4.0; IQR, 4.5). Subcategories involved in device assembly also included foam dressing application (median, 2.0; IQR, 1.8), connecting tube to vacuum (median, 1.0; IQR, 0.0), powering on suction (median, 1.0; IQR, 0.0), and ability to reach appropriate pressure (median, 1.0; IQR, 1.0). The median ranking across all subcategories for device assembly

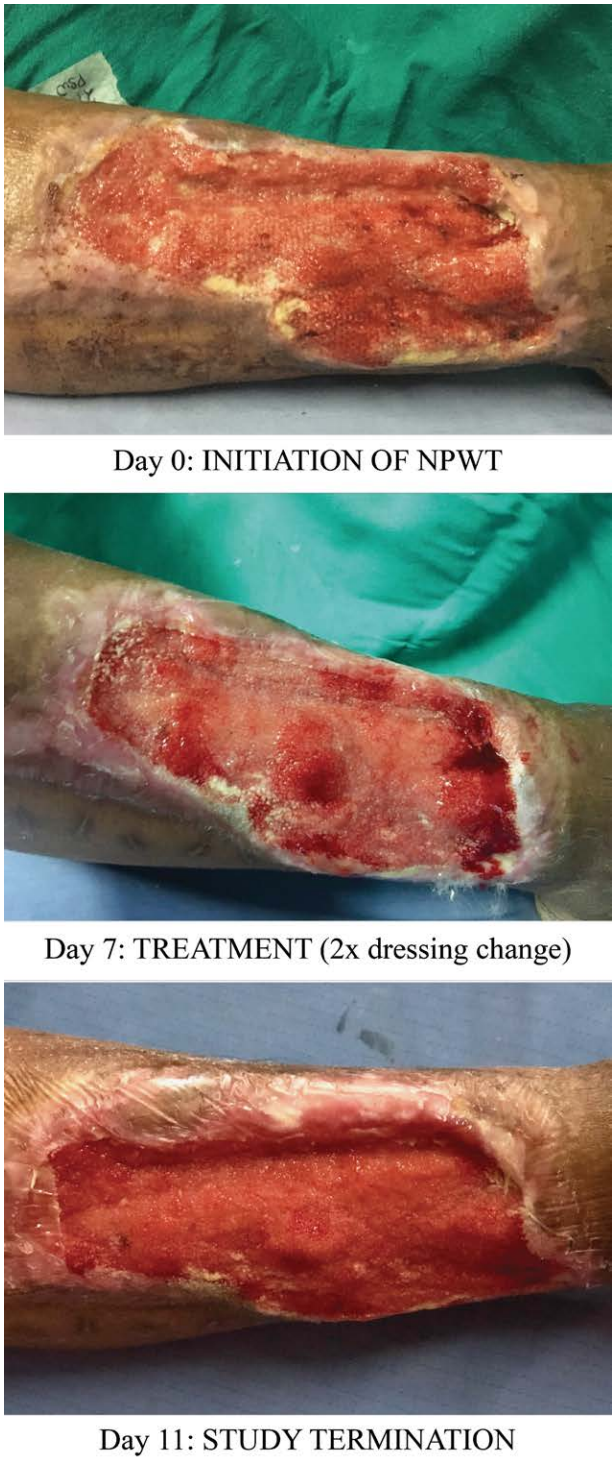

Fig. 2. Healing progression, case report 1. A 59-year-old woman status postemergency fasciotomy for acute limb ischemia complicated by compartment syndrome, resulting in a lower extremity post-surgical wound, was treated with NPWT delivered by the Kyron Suction Unit and compatible accessories. After 11 days of treatment, including 2 dressing changes, the wound bed showed complete coverage with granulation tissue. This allowed for the placement of a split-thickness skin graft and discharge home. At follow-up, the patient reported no complications and had returned to her normal daily activities.

was 1.0 (IQR, 1.0; mean, 2.4), for maintenance was 1.0 (IQR, 1.0; mean, 1.5), and for disassembly was 1.0 (IQR, 1.0; mean, 1.4). Drape application and tightness check was again the most difficult step during device maintenance (median, 2.5; IQR, 1.8), whereas dressing removal was the most difficult step during device disassembly (median, 2.0; IQR, 1.0).

VAS scores improved significantly with the Kyron Suction Unit treatment (from median 5.0 to 2.0, $P = 0.03$). Nine patients experienced less pain at the end of treatment, 4 of whom reported no pain at study termination. Additionally, modified EQ-DSI scores improved significantly with the Kyron Suction Unit treatment from median 0.6 to median 0.2 ($P < 0.001$).

Comparison of wounds pretreatment and posttreatment showed a reduction in wound volume from median 47.25 to 9.75 cm^3 ($P = 0.01$). Granulation tissue surface area increased from median 7.63 to 28.73 cm^2 ($P = 0.003$) and open wound surface area decreased from median 48.33 to 33.6 cm^2 ($P = 0.01$) (Table 2).

Case reports of 3 patients who underwent NPWT treatment with Kyron Suction Unit and compatible accessories are shown in Figures 2–4.

DISCUSSION

Healyx Labs developed the Kyron Suction Unit by working with plastic surgeons and patients in target resource-constrained clinical settings to understand the needs of these end users and to engineer solutions collaboratively. The product's design has been iteratively improved through a process of user feedback and testing. The pilot study results validated that the Kyron Suction Unit, paired with wound dressing kit and waste canister, met functional and safety expectations. The 14 cases presented illustrate the Kyron Suction Unit's versatility across a range of different wound locations and eti-

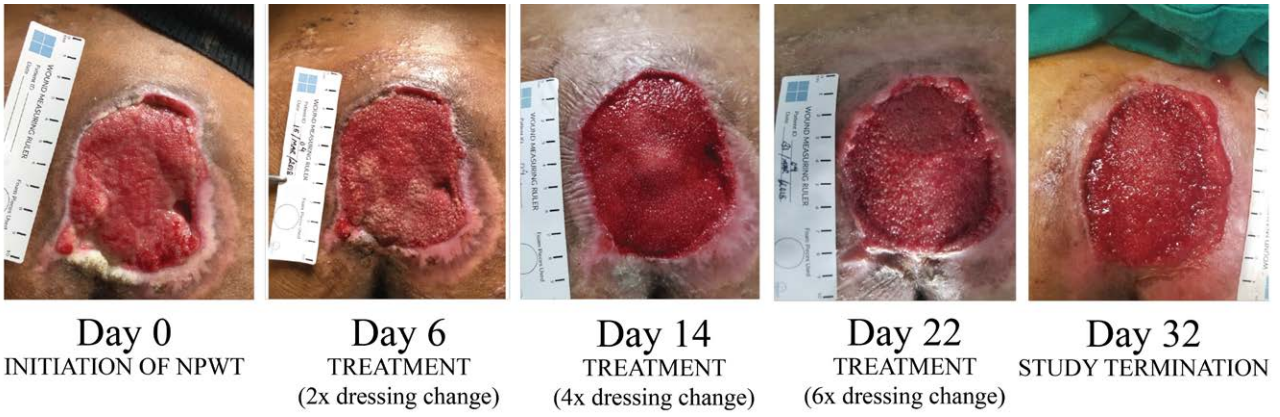

Fig. 3. Healing progression, case report 2. A 25-year-old man with a history of transverse myelitis resulting in paraplegia presented with a sacral pressure ulcer present for 2 months, measuring 10 × 6 × 1 cm. Patient completed 32 days of treatment with the Kyron Suction Unit, at which time the wound was covered with granulation tissue, allowing for closure by split-thickness skin graft.

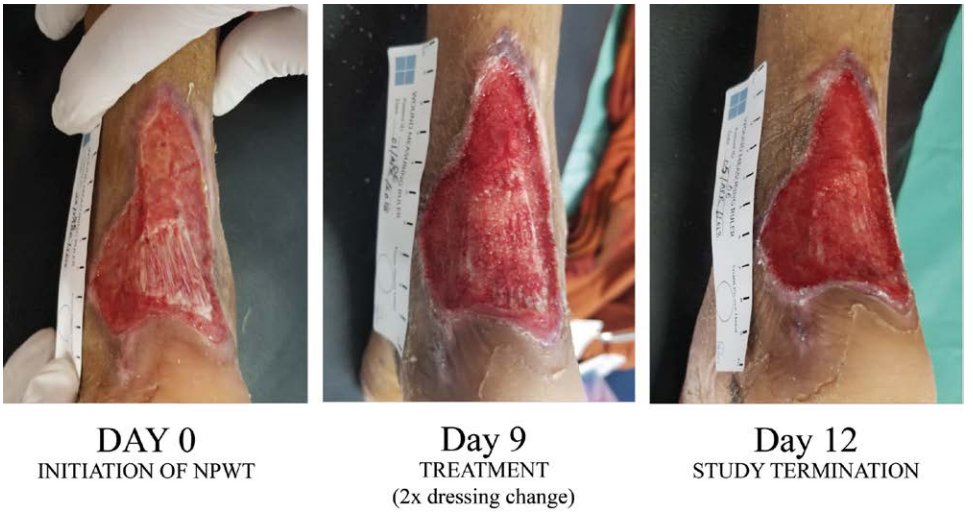

Fig. 4. Healing progression, case report 3. A 22-year-old woman suffering from a traumatic wound on the posterior ankle with exposed achilles tendon following a bike accident 46 days prior presented to the hospital for treatment. Patient completed 12 days of treatment with the Kyron Suction Unit after which granulation tissue covered her exposed tendons allowing placement of a split-thickness skin graft.

ologies. This study supports the successful integration of the Healyx Labs device in its target low-resource setting.

The majority of users in our study reported ease of use rankings at either 1 or 2, where a score of 1 indicates highest amount of ease. These scores indicate that users felt confident in using the device, including its setup, maintenance, and removal. Two AEs were reported: adherence of the foam to the wound bed and pus collection. These events are comparable to those reported in other NPWT studies.[34] Complications from these events can be mitigated by diligent attention to the timing interval between dressing changes, and ensuring a wound is thoroughly cleaned before application of the NPWT dressing.

Importantly, the majority of users in the study presented with improvements in wound healing trends after treatment with the Kyron Suction Unit including, a reduction in wound volume, an increase in granulation tissue, and decrease in open wound surface area.

Limitations of this study include the small sample size and single-arm design. Convenience sampling was employed to select patients, limiting generalizability of results. A larger randomized prospective clinical trial is needed to compare clinical effectiveness of the Kyron Suction Unit to existing vacuum-assisted closure systems. Such a study will allow for the determination of equivalence to alternative NPWT devices in the healing rate and quality of open wounds. Further studies are also needed to explore individual and system cost savings associated with use of the Kyron Suction Unit as compared to alternative NPWT devices and conventional wound dressings.

CONCLUSIONS

This pilot study provides initial evidence that the Kyron Suction Unit is safe and easy to use in a low-resource setting. The NPWT device design makes therapy easy to implement and maintain. The Kyron Suction Unit has the potential to increase access to advanced wound treatment across resource-constrained settings around the world. Further research is needed to elucidate its potential for improving wound care in low-resource settings.

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