Although present on the market for about 20 years, the popularity of negative-pressure wound therapy (NPWT) has not decreased [The Vacuum-Assisted Closure (VAC); KCI, San Antonio, Tex.]. NPWT system is known internationally and has revolutionized the way we manage wounds.

NPWT has many indications, both acute and chronic, and has brought great comfort to patients, caregivers, doctors, and nurses. The only real obstacle to this useful procedure is the cost, which slightly decreased, but remains expensive for prolonged indications, making it unaffordable in underdeveloped countries where these dressings are needed.

Therefore, we designed a low-cost NPWT connected to a wall vacuum, which we call PROVACUM (Z-Biotech, Saint-Avertin, France).

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METHODS

First, we designed an inexpensive NPWT device made of polyurethane foam, transparent adhesive film, tubing, and a 3-way valve, which we had manufactured by Z-Biotech. The constraints imposed on the manufacturer were an equipment quality similar to that of commercial NPWT devices and an average treatment cost of $15/d (Fig. 1).

Then, we conducted a prospective study of patients with indications for NPWT from September 2013 to January 2015. The negative pressure was set at 125 mm Hg with a manometer. The exudates were collected in conventional vacuum bottles (See Video 1, Supplemental Digital Content 1, which displays ischial pressure ulcer management with PROVACUUM (Z-Biotech). This video is available in the “Related Videos” section of the full-text article at http://www.PRSGlobalOpen.com or available at http://links.lww.com/PRSGO/A106). The dressings were changed every 3–4 days. Data collected included ease of use, quality of materials, and occurrence of complications during treatment. Pain was evaluated at each stage using a visual analogue scale.

To monitor bleeding and infection, blood count and C-reactive protein were measured twice weekly. All of the patients consented to participate in this study, which had institutional review board approval.

RESULTS

We enrolled 23 patients [20 male, 3 female; mean age, 50.8 years (range, 22–79 years)] in the study from September 2013 to January 2015. The patients had acute or chronic diseases (Table 1). The dressings were changed every 3.3 days (range, 2–4 days). The average treatment lasted 8.5 days (range, 3–21 days). The pain associated with the implementation of NPWT was rated 2 of 10 (range, 0–4 of 10), whereas the pain with dressing changes averaged 3 of 10 (range, 0–6 of 10).

Two serious complications occurred in the first patients; namely, 2 hematomas developed after large pressure ulcer debridement, which required surgical revision and the transfusion of 2 units (Fig. 2). No other adverse events occurred, and no infections were reported. The surgeons who used our device found it as easy to use as commercial NPWT devices, except for the adhesive film (Fig. 3). Indeed, the initial attempts used inadequate adhesive film. We have subsequently improved the quality of the film.

DISCUSSION

Negative-pressure therapy is not new, and the VAC system has been marketed internationally by Kinetic Concepts since 1997.1,2 The omnipresence of conflicts of interest in the medical literature dealing with NPWT is harmful because the results of many studies have been minimized because of this problem. There are many innovations in the field of NPWT, including miniaturization,3,4 the development of a fully mechanical system,5,6 and recent indications.7

The marketing of new commercial devices, such as RENASYS (Smith & Nephew, London, United Kingdom) and VivanoTec (Hartmann, Amtsgericht Ulm, Germany), should have led to a significant drop in costs, but this did not happen. Consequently, the cost has limited the accessibility of VAC systems in various institutions. Other low-cost systems have been described that use a suction drain8 or Pleur-Evac (Teleflex Medical, Morrisville, N.C.) system,9 but their low suction power is insufficient for large or complex wounds.

Currently, the French health authorities consider the safety and reliability of equipment using wall vacuum uncertain,10 which is why we performed this preliminary study to assess the feasibility and safety.
of PROVACUUM (Z-Biotech). NPWT is not risk-free, so any new material must be evaluated and validated. Between 2007 and 2011, the Food and Drug Administration reported 12 deaths and 174 injuries linked to NPWT. Most deaths occurred at home or in long-term care establishments.\(^{11,12}\)

Two patients in our study developed bleeding within the first 48 hours, and this seems to be the main complication and requires monitoring. In subsequent patients, after these 2 complications, we waited at least 24 hours before setting the negative pressure to 125 mm Hg. Nonetheless, this problem can occur with all NPWT devices on the market. In general, for NPWT, it seems safer not to start the aspiration the first day following a hemorrhagic debridement. No bleeding occurred in subsequent cases.

As evaluated by Dorafshar et al.,\(^{13}\) this system uses a wall vacuum and must be restricted to hospital use to ensure regular monitoring and good functioning. In practice, we require monitoring every 4 hours to confirm good depression of the dressing and to ensure that the exudate in the bottle is not bloody, which could indicate bleeding or discharge, suggestive of infection. We included a 3-way valve that allows manual instillation, similar to the VAC Ulta (KCI, San Antonio, Tex.). Instillation with NPWT has led to interesting results in acutely infected wounds,\(^{14}\) but the real role of this procedure in the treatment algorithm is not fully defined.

| Patients | Gender | Age | Indication | Localization | NPWT Duration | Evolution | Complications | Management Post-NPWT |
|----------|--------|-----|------------|--------------|---------------|-----------|---------------|---------------------|
| Acute wounds |        |     |            |              |               |           |               |                     |
| 1        | Female | 52  | Wound dehiscence with steatonecrosis | Breast | 7 days | Good | No | Dressings |
| 2        | Male   | 62  | Bone exposure following skin cancer excision | Fibula | 8 days | Good | No | Skin graft |
| 3        | Male   | 47  | Bone exposure after trauma | External malleolus | 7 days | Good | No | Propeller flap |
| 4        | Female | 44  | Wound dehiscence | Latissimus dorsi donor site | 6 days | Good | No | Dressings |
| 5        | Male   | 55  | Bone exposure after trauma | Calcaneus | 14 days | Good | No | Sural neurocutaneous flap |
| 6        | Male   | 57  | Cellulitis | Abdominal | 4 days | Good | No | Skin graft antibiotic therapy |
| 7        | Male   | 65  | Skin necrosis (trauma) | Lower limb | 4 days | Good | No | Split-thickness skin graft |
| 8        | Male   | 45  | Infected implant | Shoulder | 4 days | Good | No | Antibiotic therapy |
| 9        | Male   | 79  | Electrical burn | Foot | 21 days | Good | No | Split-thickness skin graft |

Chronic wounds |

| Patients | Gender | Age | Indication | Localization | NPWT Duration | Evolution | Complications | Management Post-NPWT |
|----------|--------|-----|------------|--------------|---------------|-----------|---------------|---------------------|
| 15       | Male   | 29  | Pressure ulcer | Ischial | 14 days | Good | No | Bleeding requiring surgical revision |
| 16       | Male   | 54  | Pressure ulcer | Ischial | 16 days | Good | No | Coverage by flap |
| 17       | Male   | 22  | Pressure ulcer | Ischial | 16 days | Good | Bleeding requiring surgical revision | Coverage by flap |

| Patients | Gender | Age | Indication | Localization | NPWT Duration | Evolution | Complications | Management Post-NPWT |
|----------|--------|-----|------------|--------------|---------------|-----------|---------------|---------------------|
| 18       | Female | 50  | Implant removal | Calf | 3 days | Good | No | Direct closure |
| 19       | Male   | 51  | Pressure ulcer | Ischial | 4 days | Good | No | Coverage by flap |
| 20       | Male   | 40  | Wound dehiscence following flap | Ischial | 7 days | Good | No | Wound healing |
| 21       | Male   | 45  | Pressure ulcer | Ischial | 4 days | Good | No | Coverage by perforator flap |
| 22       | Male   | 39  | Pressure ulcer | Ischial | 10 days | Good | No | Coverage by flap |
| 23       | Male   | 74  | Pressure ulcer | Sacral | 9 days | Good | No | Wound healing |
Ultimately, the low cost of PROVACUUM (Z-Biotech) makes this procedure available in less wealthy institutions and countries, with similar safety and comfort of use as the NPWT systems marketed for hospital use.

**CONCLUSIONS**

NPWT has completely changed our management of wounds, even in the most complex or desperate situations. The development of a NPWT dressing kit accessible to all, costing an average of $15/d, is a step in the democratization of NPWT. This process is not intended to replace miniature or autonomous devices with batteries, but rather offers a less expensive alternative, especially during the first weeks of hospitalization, and makes NPWT accessible in the most precarious regions.
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