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ORIGINAL ARTICLE

Retention of polyurethane foam fragments during VAC therapy: a complication to be considered

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Abstract

Vacuum-assisted closure (VAC) therapy is a closed-loop, non invasive active system, characterised by a controlled and localised negative pressure applied on porous polyurethane absorbent foams. It promotes healing of acute and chronic wounds. Therapeutic effects of VAC therapy have been proved and demonstrated; however, this method can have some disadvantages. Even if it is a quite versatile device, only qualified medical/paramedical personnel should use it in order to avoid possible complications that can occur after an improper application. In this report, 11 cases of foam-fragment retention within the wound are presented. This rare complication did not promote healing, but further hindered it. On the basis of our experience, it is mandatory to define indications, benefits and limitations of the VAC therapy.

Introduction

The majority of acute pressure sores have the capacity to heal rapidly. Nevertheless, wider and chronic sores can require weeks or months to heal, a process that can be further delayed by infections, vascular insufficiency, high local pressure or by other causes (1). Difficult pressure sores are a common problem (2). A wide range of treatments is available to treat chronic ulcers, such as simple or advanced medications, compressive bandage, antimicrobials, surgical revision with grafts or flaps (3) and vacuum-assisted closure (VAC) therapy (4,5).

The practice to expose a wound to a negative atmospheric pressure for a long period of time in order to promote wound healing was first described by Fleischmann *et al*. in 1993; this technique was successful on 15 patients with open fractures (6).

The VAC therapy is a sophisticated system that allows carrying out a medication that keeps a humid, closed, sterile and isolated environment (4–6). Essentially, the technique is simple to be performed: a piece of foam of porous polyurethane with an open-cell structure is cut according to the size of the wound and is set on top of the wound itself. The whole area is then covered with a transparent adhesive membrane that adheres tightly to the healthy skin surrounding the wound. A drainage tube, which is connected to a vacuum source, is then linked in order to suck wound fluids through the foam and these are collected into a tank to be subsequently disposed. The plastic membrane prevents the air penetration and allows creating a partial vacuum in the wound. The foam ensures that the whole surface of the wound is equally exposed to the negative pressure (4–6). This treatment presents standardised indications in acute and chronic sores (5).

In our opinion, the broad diffusion of VAC-therapy devices, the great marketing pressure exerted on medical/paramedical personnel and an improper training could lead to inappropriate use that can be harmful. The focus of this report is on a rare complication of VAC therapy, that is, the retention of foam fragments within the wound that hindered the healing process.

Key Messages

- it is important to consider foam-fragments retention during VAC therapy
- the foam-fragments retention did not promote healing
- instrumental exams evidenced full-thickness wounds to the underling bone structures with wound-bed infection
- it is mandatory to define indication, benefits and limitation of the VAC therapy

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Patients and methods

Since January 2004, among all patients presenting chronic ulcers and followed up in our Department, a total of 345 patients were treated with a VAC therapy. The average time required to achieve complete healing in this patient group was 60 days and this was achieved with different treatment modalities including conservative wound management, surgical debridement, the use of skin grafts and flaps associated to VAC therapy.

The retention within the wound of polyurethane foam fragments was evidenced in 11 paraplegic patients (10 males and 1 female) ageing from 24 to 55 years old (average: 30 years old).

According to medical history, the 11 paraplegic patients presented a medullary trauma that resulted in a condition of paraplegia. Between 6 and 24 months after trauma, the patients developed grade III and IV pressure sores (7) as a consequence of the forced decubitus, the partial immobility and the sensitivity loss.

Therefore, the initial therapeutic modality consisted of a conservative wound management and VAC therapy (KCI Licensing, Inc., San Antonio, TX). Before applying the device, the lesion was disinfected with sodium hypochlorite solution and then irrigated with saline solution. Antibiotics were administered only to patients with clear symptoms and signs of infection according to antibiogram after positive wound swabs. The VAC polyurethane foams were applied on a single layer directly on the wound, avoiding their overlapping. An average of 1·4 foams of 18 × 12·5 × 3·3 cm in dimension was used for a single patient (Table 1). Dressing change was performed every 3–5 days for 4–8 weeks (average 6·3 weeks) for a total dressing changes of 6–28 (average 14·5; Table 1). A crescent negative pressure level from 50 to 125 mmHg in a continuous mode was achieved. This approach allowed an initial temporary wound improvement but without obtaining healing. Subsequently, a progressive wound worsening was noted with symptomatic bad smelling, discharge with positive germ culture and progressive wound enlargement (Figure 1).

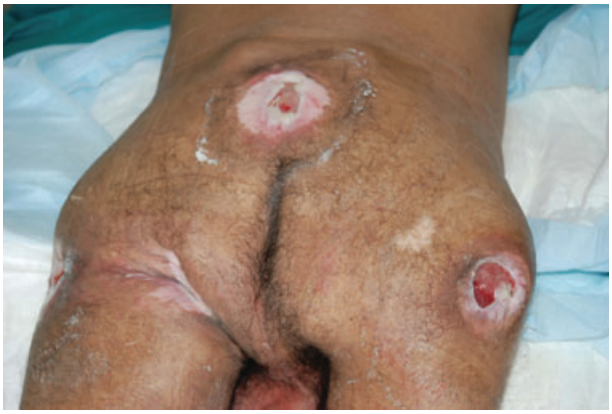

Figure 1 Pre-operative view of pressure sores in the trochanteric, left ischiatic and sacralis regions.

Table 1 Patients' casistic evidencing wound characteristics, treatment frequency and lasting with foams used, and germ involved with targeted therapy required

Case study	Lesion site	Lesion dimension	Treatment lasting (weeks)	Foams used (18 × 12·5 × 3·3 cm)	Dressing changes	Germ infection	Antibiotic therapy
1	Sacral Trochanteric	12 × 10 cm 8 × 9 cm	7	1	16	*Staphylococcus aureus*	Levoxacin (500 mg twice a day iv for 2 weeks)
2	Sacral	8 × 9 cm	7	1	9	*Proteus mirabilis*	Amoxicilin + clavulanic acid (2·2 g twice a day iv for 2 weeks)
3	Ischiatic	9 × 6 cm	4	1	6	*Staphylococcus aureus*	Levoxacin (500 mg twice a day iv for 10 days)
4	Sacral Trochanteric	12 × 12 cm 10 × 11 cm	8	2	22	*Enterococcus faecalis*	Levoxacin (500 mg twice a day iv for 2 weeks)
5	Trochanteric	9 × 7 cm	4	1	7	*Staphylococcus aureus*	Minocycline (100 mg twice a day iv for 10 days)
6	Ischiatic Trochanteric	2 × 12 cm 5 × 11 cm	5	1	9	*Staphylococcus aureus*	Levoxacin (500 mg twice a day iv for 12 days)
7	Sacral	9 × 11·5 cm	5	1	9	*Enterococcus faecalis*	Levoxacin (500 mg twice a day iv for 12 days)
8	Sacral Ischiatic Trochanteric	12 × 11 cm 9 × 6 cm 8 × 9 cm	8	2	28	*Pseudomonas aeruginosa*	Levoxacin (500 mg twice a day iv for 12 days)
9	Sacral Trochanteric Trochanteric	10 × 9 cm 9 × 11 cm 7 × 8 cm	7	2	20	*Enterococcus faecalis*	Amoxicilin + clavulanic acid (2·2 g twice a day iv for 2 weeks)
10	Ischiatic Sacral Trochanteric	8 × 12 cm 12 × 12 cm 12 × 9 cm	8	2	22	*Enterococcus faecalis*	Levoxacin (500 mg twice a day iv for 2 weeks)
11	Sacral Ischiatic	11·5 × 9 cm 10 × 7 cm	6	1	11	*Staphylococcus aureus*	Amoxicilin + clavulanic acid (2·2 g twice a day iv for 2 weeks)

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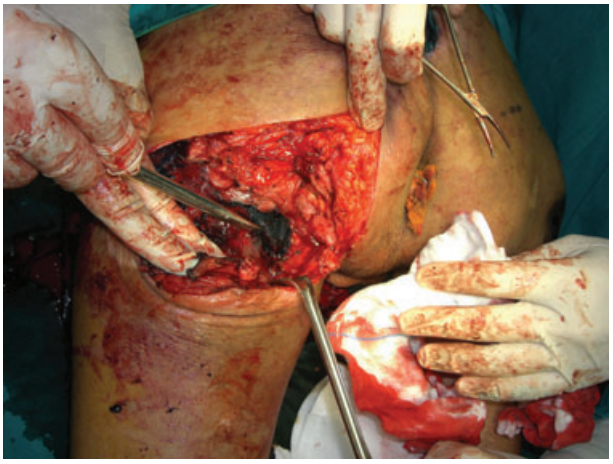

Figure 2 Intra-operative view in which it is evident a VAC-therapy foam fragment in the left trochanteric pressure sore.

In the 11 paraplegic patients, chronic ulcers were lasting from 2 to 4 years; this was the reason to request specialist consultation that required hospitalisation. The therapeutic indication was surgical debridement and eventual wound coverage with skin flaps.

Clinical, laboratory, haemato-chemical and instrumental exams evidenced full-thickness wounds extending to the underling bone structures, measuring from 2 to 12 cm in diameter, in the ischiatic, sacralis and trochanteric regions. Wound swabs evidenced multiple germ infection (*Proteus mirabilis*, *Enterococcus faecalis*, *Staphylococcus aureus*, etc.) with increased inflammatory parameters, without hyperpyrexia and probable osteomyelitis. Surgical debridement of wounds was performed, taking tissue and bone biopsies for histological and cultural examination. During surgery, fragments of VAC foam, up to 5×6 cm size, were identified deeply into the wounds within tissue tunnels and removed. These fragments were also sent for cultural examination (Figure 2). We noticed that the foam-fragments retention occurred at a negative pressure level between 100 and 125 mmHg. A targeted antibiotic therapy based on previous antibiograms was started, a copious irrigation of wound bed executed and reconstruction with skin and fasciocutaneous flaps performed. Confirmation of germ growth was found at the third postoperative day both in tissue samples and in VAC foam fragments, but not in bone biopsies. The antibiotic therapy was then adjusted and continued as required (Table 1). The histological exams showed tissue fragments with intense inflammatory response and a pseudo-epitheliomatous reaction with no sign of neoplasm degeneration. The postoperative course was uneventful. The flaps remained vital and the patients were discharged between 2 and 3 weeks after surgery. Patients were followed up from 1 to 3 years after surgery without recurrence evidence.

Discussion

Pressure sores represent a frightful complication in critical patients, particularly in traumatised ones with spinal cord injury, in virtue of possible opportunistic infections difficult to be eradicated. Such complex wounds set numerous problems in terms of the treatment modality. Although well-standardised protocols on pressure sore treatment do exist, the same cannot be said about the existence of management protocols to help setting indications, timing and clinical priorities (8–11). VAC therapy is indicated to treat these wounds and has gained a very important role in clinical management (6,12,13). Originally, this system was used for extremely debilitated patients, showing extensive loss of infected and chronic substances and regarded as non treatable (12).

The VAC therapy is a closed-loop system that, by applying negative pressure (from 25 to 250 mmHg, either as continuous or intermittent cycle), allows exudates and oedema removal, the reduction of bacterial load and the stimulation of the wound healing (9). By using the foam dressing, the negative pressure allows the retention of interstitial fluids that are subsequently collected in a tank and disposed of. The evacuation of these fluids does not allow the formation of purulent surface that can be a fertile ground for a subsequent colonisation by anaerobic germs. Furthermore, some studies have proved that the negative pressure application allows a dilation of the arterioles with a consequential rise in the blood flow, thus favouring the formation of the granulation tissue in the wound (12,14). It also exerts a real mechanical traction that allows the wound margins to close, reducing its size. This accelerates the healing process with numerous and proved advantages both in a clinical and economic level. The VAC therapy is applied in many fields, from chronic to post-traumatic ulcers, from post-surgical wound dehiscence to post-oncological loss of substance. Furthermore, the slow therapeutic action of VAC therapy has proved to be very useful for the preparation of the area receiving skin graft, improving the percentage of graft take (15–18). Nowadays, there are different negative therapy pressure (NTP) systems available beside the KCI system, such as VISTA and EZCARE by Smith and Nephew (London, UK), SVEDMAN and SVED by Innovative Therapy, Inc. (Gaithersburg, MD) and other [Table 2 (19)]. The most important differences between these systems are the filler materials used such as foam or non adherent antimicrobial gauze, the connecting suction catheter as a flat drain or an integrated tubing with pressure sensor and the intensity of the negative pressure (20). Recently, KCI Licensing Inc. developed NTP pumps called ActiVAC and InfoVAC (19). These devices improved highly the technology and introduced a silver-impregnated granular foam, which is an optimal source to treat infection (21).

NTP devices can have some disadvantages. In fact, even if it is a quite versatile tool, only qualified medical/paramedical personnel should handle it in order to avoid possible complications due to improper use (22).

After the approval of Food and Drug Administration for the treatment of non healing chronic wounds (23), VAC-therapy indications have been subsequently extended [acute wounds, diabetic ulcers, pressure sores and partial- and full-thickness burns (6)]. Such guidelines have been accurately described by Mendez-Eastman in 2001 (13).

VAC therapy is contraindicated when there is a wound with a necrotic tissue at the bottom or when there is an ongoing osteomyelitis process underneath the wound, when arteries or

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Table 2 Manufacturer and trade or brand names of TNP devices

Smith & Nephew (London, UK)	Boehringer Wound Systems/ Convatec (Rome, Lazio, Italy)	Innovative Therapies, Inc. (Gaithersburg, MD)	Medela AG Medical Equipment (McHenry, IL)	Talley Group, Ltd (Romsey, Hampshire, UK)
V1STA negative wound therapy (home care), EZCARE negative wound therapy (stationary unit), RENASYS EZ, RENASYS GO	Engenex Advanced NPWT System	SVEDMAN and SVED Wound Treatment Systems both portable units	Invia Liberty wound therapy (portable), Invia Vario 18AC/DC c/l wound therapy (stationary, mobile with battery)	Venturi Avanti en Venturi compact
Premco Medical Systems, Inc. (New Rochelle, NY)	**Prospera Technologies (Fort Worth, TX)**	**Kalypto Medical (Petersburg, FL)**	**The Medical Wound Care Company (Montfoort, Nederland)**	**KCI, United States Inc. (San Antonio, TX)**
Prodigy NPWT System (PMS-800 and PMS-800V) (last update website 2007)	PRO-II (portable), PRO-III (stationary and portable)	NPD 1000 Negative Pressure Wound Therapy System (pocket size, portable)	Exusdex wound drainage pump (portable unit)	InfoVAC Therapy Unit (stationary unit), ActiVAC Therapy Unit (portable unit), VAC Freedom, VAC ATS, VAC Instill System (delivery of topical solutions)

blood vessel are exposed when a neoplasm process causes loss of substance or in cases in which there is a non enteric and unexplored fistula. Furthermore, this method is not indicated when there are not enough margins of healthy skin surrounding the wound that can adhere to the medication or when the wound is near a functional orifice. Finally, a special attention must be paid with metabolic or coagulation alterations.

Possible VAC-therapy complications are toxic shock syndrome (24), bleeding complication (25), arterial erosion and haemorrhage (26), empyema (27), uncontrolled sepsis (28,29) and major bleeding complication due to cardiac rupture (30). We also include cases of skin lesions that can occur if the foam is not perfectly applied on top of the wound margins, covering also the healthy skin surrounding the wound.

On the basis of our experience, a rare and more harmful complication is the retention within the wound of foam fragments. Such occurrence does not promote the healing process and creates a condition of chronic morbidity difficult to be managed. Indeed, the presence of a foreign body that, having collected the entire previous VAC cycle secretions, becomes a fertile field for the bacterial colonisation, preventing the wound from healing.

Furthermore, it can become troublesome the differential diagnosis with more severe conditions, such as osteomyelitis, if the retention of the foam fragment is not detected.

According to our experience, we believe that defining indications, benefits and limits of the NPT as well as user guidelines is necessary in order to avoid the above described complications. The retention of foam fragment should be considered in cases of prolonged VAC therapy not bringing any benefit or even a possible worsening of the pathological condition.

In conclusion, we believe that NPT is a useful and efficient device to manage difficult wounds, but at the same time, the patients undergoing such treatment must be carefully selected and, above all, qualified personnel must be involved.

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