

WOUND OR MEDICAL DEVICE PROTECTION: BENEFITS OF THE WATERPROOF DRESSING SECUDERM®.

Protection des plaies ou d'un dispositif médical: intérêts du pansement étanche Secuderm®.

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Keywords: Secuderm®, secondary dressing, wound healing, waterproof, army, polyurethane, wound

ABSTRACT

Aim: The wound is the consequence of an acute skin aggression either limited or spreading, sometimes iatrogenic, which may be worsened by a delay in care in peculiar circumstances. The aim of this study is to present the benefits and give potential indications of a waterproof dressing. This dressing guarantees the protection during the healing process and increases the patient's compliance to the treatment of his wounds, even in difficult situations.

Methods: We used various dressings or means (primary adherent dressings, polyurethane film, cling film) to protect wounds in isolated or precarious care situations, but also in a more conventional context.

Results: Secuderm® is the only dressing that is waterproof, reliable for acute and chronic protection for repeated exposures to water: excessive sweating, friction of clothing, projection or complete immersion under water. We report the use of Secuderm® in different exemption situations: in Guyana during French military missions by the Navy divers, in Cameroon for the treatment of Buruli ulcers, after arthroscopy, to protect medical devices (catheters, etc.) on acute wounds, or even during patient exposure to a nuclear, radiological, biological or chemical risk (NRBC).

Discussion: To effectively protect a wound is difficult when the human resources and materials are limited. An efficient protection of the healing wound allows the resumption of professional, social and private activities in a certain comfort. Probably the only solution that is currently available, Secuderm® is a cunning waterproof protection for several days. Its indications are multiple whether in the treatment of acute, chronic or iatrogenic wounds, at the hospital, at home, in degraded situation or even when exposed to nuclear, radiological, biological or chemical risk. Prospective comparative studies are required.

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INTRODUCTION

To take care of broken skin in exceptional situations requires focusing on the healing process. These lesions are the result of acute aggressions, more or less extensive, sometimes aggravated by the delay of care in an “extra ordinary” context. They are disabling for the individual and the group to which the injured belongs [1;2].

To efficiently protect a wound may be difficult in some hostile environments, where human resources and material are limited and delivery time is extended to a clean and quiet facility [3-5]. To efficiently protect a wound while it is healing allows the patient to continue his professional and private activities in comfort. This severely limits jeopardizing the healing process that we must optimize, while participating in patient compliance to his care by surely a “better life”.

These challenges have urged us to seek a medical device (MD) that could be used in such precarious working conditions. The MD must avoid overexposure of the acute wound to external aggressions until seeking medical advice. During the controlled healing phase, this MD should limit attrition of operational capacity of units engaged in hostile conditions: friction, hygiene, humidity, temperature, underwater environment, etc. Still, what is the interest in such a MD in the care of a patient exposed to nuclear, radiological, biological and chemical (NRBC) risk [6]? The aim of this work is to present Secuderm® dressing, its benefits, limitations and disadvantages in the context of indications that we were able to test or were appropriate to experiment.

MATERIAL

Secuderm® is presented as a watertight protection. This allows a customized protection zone, without applying glue, through a film of non-adhesive flexible and breathable polyurethane. The patent of this class I medical device was introduced in 2005 by a frenchman. It can be used in primary dressing by direct application to the affected area, or as a secondary dressing to cover a primary one or even a medical device such as catheter for example.

The kit (**Figure 1**) containing the dressing consists of a cardboard box in which we find a leaflet, the polyurethane film on its support paper and one (size 10 x 20 cm) or two (size 20 x 30 cm) tubes of adhesive gel, hypoallergenic silicone-based, for skin application. This dressing may be held in place for more than five days. Its removal is painless. The dressing is done in several steps whether as primary (**Figure 2**) or secondary (**Figure 3**) dressing without changing the treatment to be performed on the area to be protected:

1. Before applying, clean and dry surrounding skin thoroughly.
2. Using the applicator tube and its pre-assembled cannula, apply a thin continuous gel bead directly to the periphery of the area to be covered within a safety margin of a few millimeters. Each kit contains a sufficient quantity of adhesive gel to provide a frame of respectively 10 x 20 x 20 cm and 30 cm (around 4 x 8 x 8 inch and 12 inch). To avoid excessive tackiness and mainly deposits upon removal of the dressing, one must understand that the amount of gel applied must be proportionally adjusted to the surface to be protected.



Photo 1: Secuderm®: bag, leaflet, applicator tube and its pre-assembled cannula with the transparent polyurethane film on its support paper (here in the version 20 x 30 cm). SSA\HLeFort®

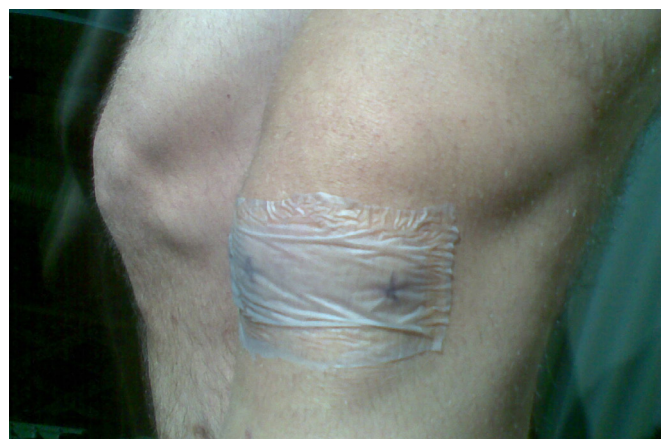


Photo 2: After applying adhesive gel, place the polyurethane film in a way to form a tight unit around the primary dressing, leave it in place for nine days. SSA\HLeFort®



Photo 3: Applying Secuderm® after refection of an abscess dressing. Harpy 2009. Maripasoula, Guiana, France. SSA\HLeFort®

3. Ideally, wait for one or two minutes to let the solvent in the gel evaporates. Use this waiting time to cut the film on its white paper support to the size of the area to be protected while following a margin beyond the line drawn by the glue.
4. Apply the polyurethane film without pressure, using the paper as a guide that is progressively removed.
5. Apply continuous pressure of the film to the glue forming a sticky seal to ensure optimum tightness of formed «cell».

6. If needed trim unnecessary areas of the film outside the silicone seal but in accordance with it.

Film removal is performed painlessly, in the same way as other silicone interface dressings [7], by pulling the film after 45 minutes of exposure time to avoid leaving any residue. This dressing is described as having high adhesiveness over time (over five days) with a strong protective film. It can be used one month after opening the protective pouch according to the manufacturer's recommendations.

PATIENTS & RESULTS

Legacy of the "spectacular revolution" [8] carried out by the French Military Health Service during the First World War, military doctors provide medical support [4;9-11] of armed forces closer to their activities (**Figure 4**). In our precarious fiscal conditions, the maintenance of human resource is crucial while carrying care material is often limited [3-5]. Similarly, the military doctor may need to take charge of the civilian population encountered within the constraints of its main mission of supporting the military forces. When looking for a watertight resistant protection solution, the cling film and various medical devices were tested such as hydrocellular dressings with silicone adhesive interface, adherent polyurethane films of type Tegaderm® and Secuderm®.

We were able to see the 2008 report written by the medical team of "Human Diving and Underwater Intervention cell" (Cephismer - Toulon, France) of the National Marine [12] on Secuderm®. This dressing was not yet available in pharmacies. It has been satisfactorily tested on fourteen students taking Clearance Diver and on board Diver courses and then at the institute of Naval Medicine for the French Health Services of Armed Forces (Imnssa).

On the occasion of the operation Harpie in 2009 [4;5], fighting against illegal gold washing in the Guyanese forest, we have tested it six times during a period of two months while in the equatorial forest. The dressings were installed by a doctor or nurse on wounds in complete detersive phase. Patients went on patrol for a period of few hours to maximum three days. Secuderm® covered most often a primary dressing of Vaseline-Jelonet® type, tulle-compress fixed by a self-adhesive tape of Hypafix® type (specialty staffing in the Army).



Photo 4: Minor surgery in an exceptional situation in camp Dorlin. Harpie 2009. Guiana, France. SSA\HLefort®

The medical device managed to resist extreme conditions of temperature, humidity and hygiene (**Figure 5**). Thirty "operational" days [4] have been saved in this way.

Since 2010, Doctors Without Borders (MSF) are testing this dressing under the Buruli ulcer management program in Cameroon. This disease, transmitted by *Mycobacterium ulcerans* [13;14], mainly affects children. The results are very encouraging; the dressing provides comfort in healing experience for the patient and his family and lower costs of care (labor, financial costs, and time). Indeed dressing renewal is performed when necessary and during the logical healing process. The social cost of parents' duty to accompany the child during care is thus reduced; they can pursue their professional activities between care. It has been tested within debridement phase, in direct contact of a hydrogel tulle gras dressing and without compress.

One of the authors, who have undergone bilateral arthroscopic meniscectomy on the knees, placed Secuderm® on the first dressing renewal until the tenth day, the date of removal of the stitches. No other treatment has been carried out for nine days. The transparency of the film allowed supervising the possible appearance of signs of local inflammation (**Figure 2**). Condensation after the shower was almost always observed, disappearing quickly (in less than half an hour) without maceration or pruritus.

Wishing to experience the practicality of using these dressings in NRBC situation, five samples of this device were placed during a large-scale exercise, called NRBC 11 in June 2011. Coordinated by the Fire Brigade of Paris, the scenario anticipated four simultaneous attacks (involving a neurotoxic, a vasicator and a dirty bomb with radiological elements) in different places of the French capital city [6;15]. Two mobile decontamination units occurred at the place of testing Secuderm®. We wanted to experience the practical feasibility of placing Secuderm® dressings. Where radiological attack occurred, the dressing has been placed despite the gloves and has resisted to jets of decontamination shower [16].

DISCUSSION

Principles of modern wound healing

Modern wound healing allows a faster improvement of the wound

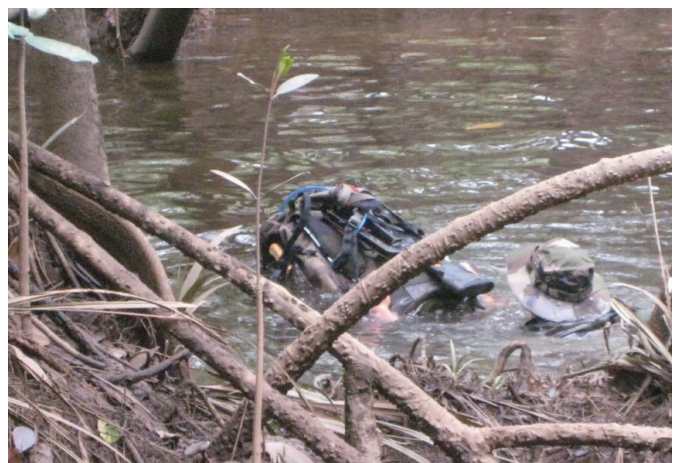


Photo 5: River crossing in a rain forest by a military, reflecting extreme conditions for the use of the dressing. SSA\HLefort®

especially if the injured has no preexisting comorbidities [17;18]. It is based primarily on preserving a controlled moist environment, an active debridement, the respect of local microbial ecology and the rational use of dressings [19]: hydro-cellular dressings, alginates, tulle and interfaces, creams, etc. This approach can enforce and maintain the natural healing effort passing through the vascular inflammatory phase followed by granulomatous phase and prepares the granulation before the epidermization phase.

These principles are fundamental and applicable more than ever on the practice of medicine in an exceptional situation, with many benefits if it is enabled by a waterproof and breathable cover. The initial management of acute wounds in isolated post or even in deteriorated conditions [20] is greatly simplified [4;5;21]: increased healing rate, faster care, easy monitoring, cost-effective in terms of technical and human resources, decreased operational failure, improvement of physical and psychological comfort of the wounded, etc.

Advantages, limitations, disadvantages

The idea for a non-adherent interface between the skin or a primary and the outer dressing, sealed with a silicone joint is original but old [22]. We did not find any description of similar medical devices in the literature or in pharmacy. It is therefore difficult to compare it to competing devices. Devices that may relate to it are usually fully adherent and more waterproof than actually watertight (allow taking a shower) such as hydrocellular dressings with silicone interface or polyurethane adhesive Tegaderm® films [21;23]. Only Tegaderm® HP has a good waterproof action if a margin of sufficient adherent safety is observed, but within less than 24 hours and with less resistance to tearing and stretching.

Secuderm® tightness is well established within the standard conditions of use. This is its purpose. We have tested out its qualities in more delicate situations. Initially intended for the general public, an explanatory leaflet is present in each kit. Directions for use are easy to understand without requiring prior training. It easily adapts to the size and shape desired to cover the elevation of a primary dressing, a joint, moving areas or ones that are difficult to access. The polyurethane film is thick enough to prevent natural distention with time or because of external friction (clothing, skinfolds, etc.).

Finally it can withstand a few days of multiple aggressions imposed by situations of exceptional care. Its maintenance is easy in time without the need to use other means of restraint, despite the ambient humidity, perspiration and aggressions [4;12]. The transparency of the film is a definite advantage that allows simple monitoring of primary dressing and local skin condition (if Secuderm® is used as a primary dressing such as in-use experience in Cameroon on Buruli ulcer) or locoregional in patient or caregiver [21]. The holding time of the waterproof dressing is then linked to the imperative necessity of monitoring the underlying primary wound dressing. This is also the need to change an absorbent dressing (hydrocellular, hydrocolloid ...) [4;23-25] at saturation point or when in situ debridement must be followed, etc.

This dressing must cover an acute or healing wound but also shall enable the protection of an intrusive medical device whether of catheter, arterial or dialysis type. Even if it is tested in this particularly problematic indication [26], sterile version must be created. Currently, fifty dialysis centers in France use it on a daily basis. The necessary dressing change requires being vigilant to limit any eventual gel deposits at withdrawal. Initially absent, the laboratory has recently added an applicator nozzle,

premounted on the tubes allowing a proper application, accurate and a sufficient gel quantity.

Throughout its protective and retention qualities over several days, this dressing spares time spent on care and therefore material used, days of field exemptions, improves the real-live patient healing experience [4;21;23]. Our patients have less difficulty to find it in pharmacies. Secuderm® is not on the list of medical devices reimbursed by French social security fund. Also, some of our patients are seeking alternatives that may be less effective or prefer to limit their activities to avoid compromising healing.

Benefit of a sealed cover in a NRBC context

National doctrine [27;28] for the use of the emergency facilities and care facing an NRBC terrorist action highlights in recent years the need for medicalization as close to the event in a controlled area. This medicalization preserves a maximum of human lives and optimally supports victims awaiting further decontamination when necessary [6]. Providing care for victims in this context includes the management of poisoning and contamination such as the case of Tokyo Sarin attack [29-31], but should also take into account the triad “wounded, burned, blasts” in scenarios or mode of dispersal of RBC agents also cause physical damage (dirty bomb, explosive, etc.). Finally, panic and its attendant injuries, skin break-ins must be taken into account in addition to poisoning and contamination.

This highly deleterious context to the individual poses several problems for the management of traumatic or medical skin injuries. Under the management of injured in RBC atmosphere, waterproof dressings potentially have two major advantages:

1. Covering radiological contaminated wounds, which unlike chemical contaminated wounds must be covered after the local administration of diethylene triamine penta-acetic acid (DTPA 25%) [32] drug acting by osmotic effect. They prevent contaminating again radiological wound previously decontaminated at the victims gathering point [15] in a thorough decontamination while limiting the induced pain.
2. Solid and tight fixation of medical devices (intra-osseous catheters, intravenous infusion) before passage of victims by thorough decontamination cycle.

Currently, and in case of contamination by chemical agent, it is indeed not recommended to cover a wound after completion of dry decontamination at the victims gathering point. The occlusion could encourage systemic absorption of residual contamination. It is better to leave the lesion exposed to open air.

These waterproof dressings must meet the constraints (**Figure 6**) induced by the interventions required to NRBC protection [33-35]: Gripping and handling, reduced field of vision, thorough decontamination, etc. It is possible to recommend a waterproof dressing to complement NRBC means of intervention. It might be wise to add these devices to NRBC batches currently allocated in the various departments of French and international relief services and specify their indications and procedures for specific use in RBC atmosphere.

Benefit of a medical device in other indications

This original sealed cell-restoring dressing incredibly conformable, allows for other indications already validated or being validated by also visualizing other perspectives of use where appropriate to test:



Photo 6: Using high fidelity simulation (SimMan 3G®) by the Paris Fire brigade to practice management of victims of neurotoxic projection in the subway. SSA/BSPP/MBignand®

- The absorbent dressings placed on exuding wounds (hydrocellular, hydrocolloids, alginates, etc.) may be finally brought to saturation, in a hospital setting or in homecare. Interventions on a wound are reduced, improving patient comfort for an optimized healing and cost management.

- The qualities of such sealed cell provide assurance to care givers for protection and maintaining the quality of primary dressing before the next treatment. This is particularly exemplary during the use of dressings in Guyana and Cameroon.

- The maintenance of primary dressings in particularly exposed areas is effective: sweating, friction, excrement and urination. The risk of contamination between care is limited (perineal region, folds, joints, back, abdomen, chest, neck, etc.) [24]. In complex wounds [36] such as those of Fournier's gangrene [37], the waterproof dressing could come as waterproof and protective overcoat therapies in negative pressure in difficult areas (anal region, scrotum, etc.) in patients with constant sweating and increased inflammatory metabolism.

- Protection of postoperative surgery scars set to ten days [24;38]. Secuderm® is being tested in various hospitals and French clinics in prosthetic breast surgery, hand surgery, neurosurgery and in the management of bedsores.

- Antibacterial protection of medical devices of peripheral or central catheters type in intensive care in burn victims or in spa centers or dialysis [26].

- In isolation, before or after medical advice, benefit of a sealed cell for the protection of an acute wound, an open fracture potentially hemorrhagic, after having it drowned in a

colorless antiseptic [2;39]. After retrieving the wounded from risk and fast hemostasis act (manual compression, compression dressing), a temporary tourniquet can be placed upstream of the injured member by the time to place the waterproof dressing then overlay compression dressing before releasing the tourniquet (left while waiting). This avoids the use of an hemostatic dressing (ChitoFlex®, Celox®, QuikClot® [40;41]), allows the monitoring of the wound for thirty minutes and avoids the definite sanction of vascular shutdown downstream the placement of a tourniquet. Resistance of silicone seal must be tested in case of hemorrhagic recovery. Failing to make the externalization hemostasis of bleeding is in any case delayed, leaving time to replace a compression dressing that does not need to be changed.

- In exceptional medical practice [2;10;39], non-adhesive waterproof dressing provides coverage of an abdominal wound prior to discharge to the surgical unit, closing of a chest wound before exsufflation or distance drainage, achieving an effective three sided dressing, etc.

CONCLUSION

Wound protection with Secuderm® is a simple and effective solution in many care situations, especially those performed in an exceptional situation. When the carrying capacity of equipment is poor, when the mobilization of potentially blasted patients, patients with shrapnel injuries even shocked in NRBC context should be limited when the patient must be transported in a degraded conditions, Secuderm® severely limits consumption of other medical devices. Training on its use is simple. This transparent dressing allows monitoring of the wound or the underlying primary dressing for a reduced cost in terms of technical and financial act while greatly improving patient comfort and care givers. An algorithm for use in RBC atmospheres at different times of management/care as per agent identified since each has its intrinsic specificities should be considered.

The establishment of a non-adherent waterproof cell with a silicone seal is an original solution for protecting an acute or chronic wound authorizing the pursuit of physical activity or normal social life. Feedback from multiple experiments experiences of Secuderm® in an emergency allow a more conventional use, very reassuring for a better patient care and a healing optimized and at a reduced cost. Further studies are needed to arouse the interest of such a dressing in situation of common or more exceptional care.

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