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Case Report

EASEPort NPWT System to Enhance Skin Graft Survival – A Simple Assembly

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Skin graft has been known to be prone to failure. This study was aimed to make a simplification of the negative pressure wound therapy (NPWT), which follows EASEPort (effective, affordable, safe, easily handled, and portable) concept to support the take of skin graft. The design of the EASEPort-NPWT was then made and technically verified. Thereafter, an animal experimental study comparing the EASEPort-NPWT to the classic tie-over technique on skin graft over exudative wound was conducted. The EASEPort-NPWT was verified to be able to yield and sustain the subatmospheric pressure needed. In the animal study, the treatment group showed better skin graft survival rate (97.55 ± 11.18% take) than the control group (54.88 ± 19.73%) on day-7. Histopathology examination showed good quality of the skin structures taken from the treatment group, which was better than the structures of the skin in the control group. In summary, this study has been able to fulfill its objective to create a device following EASEPort concept. Subsequently, the EASEPort-NPWT was able to enhance skin graft survival rate in exudative wound.

Key words: Bandages – Foreign body – Exudate and transudate – Skin transplantation – Wound healing

Skin graft has been known to be prone to failure due to its nature to rely on recipient bed vascularity; thus, several techniques have been proposed to facilitate its survival. One of the techniques to support the success of the skin graft take is negative-pressure wound therapy (NPWT). The NPWT technique was proven to be effective in treating a wide range of wounds ever since. It

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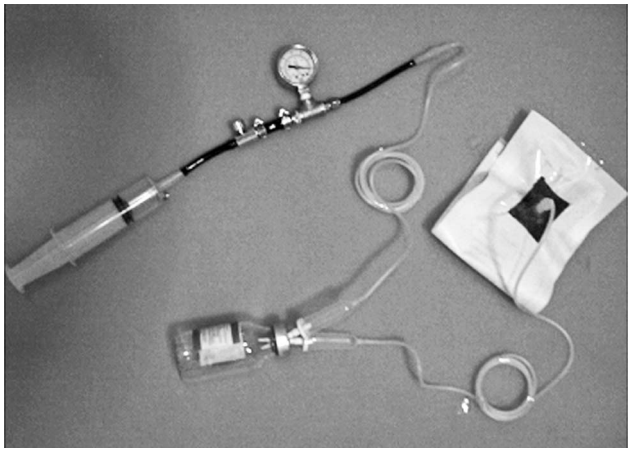

Fig. 1 The assembled EASEPort NPWT. The EASEPort NPWT unit was connected with an infusion set tube towards the canister and the PU sponge via a connector. Over the PU sponge is an occlusive dressing.

promotes wound healing by enhancing the rate of skin graft survival and the granulation tissue formation, while decreasing bacterial counts.[1–3]

The NPWT system mechanism in promoting wound healing is supported by several studies. A meta-analysis on NPWT versus standard wound care concluded that the NPWT is an effective treatment especially for chronic wound.[4] All in all, since 1997, various studies have shown good results using the NPWT procedure to treat a range of wounds.[5]

Despite the great efficacy, several drawbacks of this procedure were noted. The major ones included the cost of the entire procedure that was unaffordable for the lower socio-economic patients and the size of the machine that restrained the patient's mobility.[6] In 2004, the vacuum-assisted closure freedom therapy unit was introduced to solve the problem regarding mobility.[7] Though it was portable, it was costly and battery dependent. These disadvantages were thought to be the main reason of lack of report in the usage of NPWT in many developing countries. Thus, a wound healing treatment that is cost-, time-, and energy-effective would be favorable.

Although many[8–11] have ever reported their efforts, considering the great benefit of NPWT procedure in enhancing wound healing, NPWT modification is still necessary to make it accessible for everyone. An ideal simplification of NPWT should be easy, affordable, safe, effective, and portable (EASEPort). This study reported the development of the EASEPort along with its technical discussion, and the EASEPort NPWT experimental study on animal. The analysis was focused on its benefits in enhancing skin graft survival.

Methods

The EASEPort NPWT

The NPWT system and its component were studied, and the suitable replacement for each part of the component was searched. The modified device was then verified for its suitability at the Centre of Research and Development of Applied Physics.

Disposable unit components consisted of a canister (100-mL, closed rubber-sealed vacuum bottle) and a nonadhesive dressing (Melolin; Smith & Nephew, London, UK) as wound layer contact. As wound filler, 3 sponges were used as subjects to be tested. The 3 color-typed sponges included polyurethane (PU) black and yellow sponges, and polyvinyl alcohol (PVA) white sponge. Lastly, the components included a tube for plastic connector and two infusions set from Terumo (Terumo; Shibuya, Tokyo, Japan). The sponges were examined in the Polymer Examination Laboratorium for its structure, strut, and pore size at the Physics Research Centre.

The tools were all verified and then applied on the wounds made on the experimental animals. The black polyurethane sponge was used as wound filler. It was placed on the graft, which was layered with a nonadherent dressing (Smith & Nephew) as a dressing material interfacing the wound bed. A drainage tube was connected and fixated to each sponge and it was then covered with an occlusive dressing (Tegaderm; 3M Company, St. Paul, MN, USA), while the other side of the tube was connected to the canister. Another tube was connected into the EASEPort negative pressure unit (Fig. 1).

The procedure

Three 6-month-old Yorkshire swine weighing between 15 to 22 kg and full-length of 75 cm were recruited in the study. The swine were allowed to acclimate for 7 days prior to surgery. The protocols and procedures in this study have obtained ethical approval from the department of agriculture, and all the animals were cared based on the regulations set forth by the same department.

Based on the Farderer formula, as many as 18 samples were needed and 6 second-degree burn wounds were made on the back of each swine. The wounds were randomlydivided into 2 groups: group A consists of wounds with EASEPort NPWT

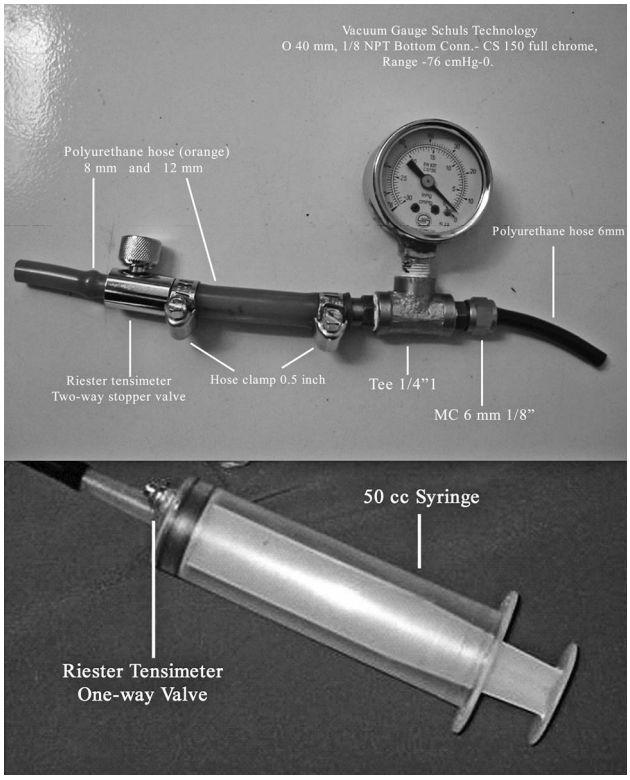

Fig. 2 The components of EASEPort NPWT. The components of the EASEPort NPWT consists of a vacuum Gauge Schuls technology with a diameter of 40 mm, 1/8 NPT Bottom Conn. CS 150 full chrome with range –76 cm HG-0, polyurethane hose size 6, 8, and 12 mm, a tensimeter two-way stopper valve, a tensimeter one-way valve, a hose clamp 0.5″ inch, a tee 0.25 inch, MC 6 mm × 1/8 inch, and a 50-mL syringe.

(treatment group) and group B was wounds with conventional tie-over dressing (control group).

On the day of surgery, the animals were sedated with intramuscular injection of ketamine/xylazine (10 g: 1 mg per kilogram body weight). Induction of sulphas atrophine 0.05 mg and diazepam 0.5 mg per kilogram body weight was also given for the anesthesia maintenance. Six circular 2.5 cm second-degree burn wounds were created on their backs using a hot iron.

Thereafter, 10^8 *Staphylococcus aureus* bacteria were injected into each of the wound beds. The wounds were then dressed with sterile gauze and micropore tape (3M Company) for 5 days to create exudative wounds. Skin graft taken from the outer thigh area was then applied subsequently after proper irrigation. Group A received treatment with the EASEPort NPWT system, which was applied to the skin grafted area with negative pressure at approximately –125 mm Hg. On the other hand, the skin grafts were covered with conventional tie-over dressing for the treatment of group B.

The swines were placed in a special body-fit cage to limit their movement. Both treatment groups were given amoxicillin 500 mg and paracetamol 500 mg three times a day, which were blended into their food. All skin-grafted sites were assessed for wound contraction at days 2, 5, and 7. Tissue biopsy was taken from each grafted wound on day 7, which was then set for histopathological examination with hematoxilin and eosin staining.

The analysis

To quantify the incorporation of the skin grafts; both area of skin graft take and lysis were drawn on a transparent plastic, which was then scanned and transferred into the computer with 100% scale. Analysis was performed using a mapping program (AutoCAD Map; Autodesk, Inc., Mill San Rafael, CA, USA). Statistical analysis was performed with parametric two-way ANOVAs and the difference were considered to be significant if $P < 0.05$. Histopathological examination was also conducted to assess the outcome of the treatment in both groups

Results

The EASEPort NPWT

Negative-pressure unit components consisted of a 50-mL disposable syringe, a one-way valve (Riester pump; Rudolf Riester GmbH, Jungingen, Germany) which is placed at the end of the syringe, a two-way valve, a manometer from vacuum gauge Schuls Technology with diameter of 40 mm, 1/8 NPT (National Pipe Thread) Bottom Conn. CS 150 full chrome with range of –76 cm Hg-0, a tee ¼ inch, a Male Connector (MC) 6 mm x 1/8 inch, a hose clamp ½ inch, and a polyurethane hose with size of 12 mm, 8 mm, and 6 mm (Fig. 2).

A series of tests on the components were conducted to evaluate the vacuum gauge calibration and to detect any air leakage. After several corrections, it was concluded that the negative pressure produced by the assembly of these components was able to yield and sustain a subatmospheric pressure that was measurable through the vacuum gauge.

The pore size of the yellow sponge was 45.4% with farthest pore distance of 378–465 μm and strut thickness of 80–114 μm. It had a rough structure and

Table 1 Percentage of skin graft take by day of assessment

Treatment	Skin graft take area, %			
	Day 2	Day 5	Day 7	Mean intake area ± SD
EASEPort NPWT	99.79 ± 8.68	98.05 ± 10. 51	97.55 ± 11.18	98.79 ± 10.03
TIE-OVER	68.15 ± 23.81	56.83 ± 20.35	54.88 ± 19.73	59.94 ± 21.38

also a lot of membranes covering the pore surface. The strut was thick and its continuity was not homogeny. Meanwhile, the pore size of the orange and black sponge pore size was 38.7 and 49%,' respectively. Both sponges were PU and the farthest pore distance was 430–578 μm and the strut thickness was 40–86 μm. The PU sponge had a smooth structure without any membrane covering its surface while the strut continuity was homogeny.

Figure 1 showed the assembly of the apparatus. Nonadhesive dressing (Smith & Nephew, London, UK) was placed on the wound beneath the sterilized sponge. Preferably, the size of the sponge is 1 cm wider than the wound area as to accommodate shrinkage when the vacuum is applied. A connector was placed over the sponge and an occlusive dressing sealed the area. The infusion set tube was then connected with the connector, which appeared out of the occlusive dressing. Finally, the other end of the infusion set was connected into the canister.

The experimental study

At day 5 after wound creation and bacterial injection, all wounds became exudative which represented chronic wounds. Randomly, 9 wounds were allocated in EASEPort NPWT and 9 others were in control group.

It was found that there was no significant effect between the treatment and the time in which the skin graft was taken ($P = 0.142$). There was no interaction between the type of treatment given and the day of assessment as well ($P = 0.848$).

The skin grafts take and its lyses area that were measured by a mapping program (Autotext, Inc.) showed that EASEPort NPWT was favorable compared with conventional tie-over treatment. The skin graft treated with EASEPort NPWT showed better skin graft survival rate (97.55 ± 11.18% take) on day 7 than the control group (54.88 ± 19.73%; Table 1).

Histopathological examination showed that the negative pressure produced a dome-like structure on the tissues, which correlated to the pore structure of the sponge. Moreover, the increased in blood capillary amount and fibroblast proliferation in vertical direction were also noticed and the tissues appeared to be dense and neat, with less vacuoles within the area. On the other hand, the biopsies taken from the conventional treatment group showed more necrotic area, capillary congestions, red blood cells, less fibroblast proliferation, and less neutrophil (Fig. 3).

Discussion

The objective of this study was to simplify the NPWT system with available resources that are easily obtained, less costly, safe, portable, and feasible for mass production. The identification of the components of NPWT system has enabled the medical practitioner to modify the variables composing the NPWT using inexpensive materials.

Previously, three studies have attempted to simplify the NPWT system.[12–14] One study used bellow reservoir, while the other two studies employed drainage pouch to maintain the negative pressure. Compared with the drainage pouch, bellow reservoir was still quite expensive and

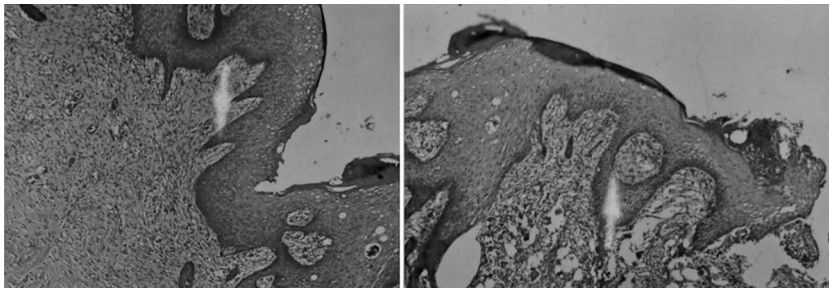

Fig. 3 Histopathological examination result comparing the EASEPort NPWT treatment with Tie-Over treatment. The histopathological examination which was conducted on day 7 showed that the treatment group (left) had good undulation on the skin surface, more blood capillaries, better cell proliferation than the control group (right).

limited the patient mobility. Thus, a drainage pouch of 100-mL closed rubber-sealed vacuum bottle was chosen for the EASEPort NPWT.

Apparently, the black PU sponge is the best material among the 3 sponges for its large pores, and homogenous struts, without any membranes, which allows the subatmospheric pressure to be evenly distributed.[2] Furthermore, the placement of nonadhesive dressing (Smith & Nephew) beneath the wound as wound contact layer showed benefit in reducing the pain.[2]

All items used to assemble the EASEPort NPWT can be found easily. For instance, the air pressure meter, hose, tee, tube, and sponge can be found in a construction material shop. Meanwhile, the syringe, the tensimeter, the canister, and the infusion set can be obtained in a medical shop. Additionally, the size of the EASEPort NPWT would not restrain patient's mobility because it is compact and light enough to be carried around; and also it is not electrically dependent.

The total cost for the items to build EASEPort NPWT is lesser than the NPWT system currently available in the market. A literature review published in 2004 in Canada made an economic analysis regarding the use of NPWT, which manufactured by certain company, and compared it with traditional wound care therapy.[15] This study reported that the costs of the NPWT pump was CDN $11,500–20,000 when purchased and CDN $63–85 when rented. Moreover, the disposable dressings cost CDN $380–640; while the disposable canisters and tubes, which sold in 10 pieces, cost CDN $360–400.[15] In this literature review, they also include a study by The Weindberg Group in 1999, which was funded by certain manufacturer, to analyze their NPWT system cost-effectiveness and compared it with standard care.[15] It was reported that the NPWT system costs more (US $53,073) than the standard care (US $47,070) with the same duration of treatment of 7–26 weeks.[15]

By personal communication with a certain NPWT distributor available in Indonesia, we found that the pump costs up to USD $7000 and the sponge costs up to $124. Taken into account that the sponge itself needs to be changed periodically, thus the costs for a 1-week treatment may reach up to $372. Meanwhile, the cost of EASEPort NPWT for a week treatment is less than $60 and $30 for the negative pressure unit and the disposable, unit respectively. Compared with those commercial NPWT exists nowadays, it can be safely concluded that the EASEPort NPWT cost is more affordable for patients in any economic level.

Ideally, the pressure delivered by EASEPort system is kept at –125 mm Hg. As the device is controlled manually, it was difficult to keep the desired subatmospheric pressure stable. In this experiment, the subatmospheric pressure was initially applied at 200 mm Hg with tolerable pressure deterioration as much as 100 mm Hg. Within a good vacuum environment, the subatmospheric pressure may be preserved up to 7 hours. Such circumstances made the pressure became intermittent. In accordance to such condition, a study in 2001 found that by giving the negative pressure intermittently, it would keep the cells sensitive to the pressure force thus enhancing the healing process.[13,16,17]

The role of EASEPort system in wound healing process can be seen in details under the microscope. Levelled pressure produced by the NPWT device was assumed to affect the anatomy changes of dermal, subdermal, and its surrounding layer.[17,18]

Wounds treated with EASEPort system showed no pathological process with good healing process. The negative pressure triggered the fibroblast proliferation, blood capillary formation, and good neutrophil infiltration with all processes growing in vertical direction. Given such environment, the growth of the skin surface was more extensive and has good density. In comparison, the wounds treated with conventional tie-over technique showed many necrotic tissues and red blood cells accumulation, and less blood capillaries, fibroblast proliferation, and neutrophil infiltration.

A study in microdeformation of wound and cell proliferation found that the mechanical force plays an important role in facilitating the chemical process in new cell formation.[17] Thus, stretched cells due to the subatmospheric pressure will trigger cell proliferation, angiogenesis, and finally wound healing.

The wound healing process in both treatment groups were observed on days 2, 5, and finally, day 7. The observation on day 2 documented better healing process in the EASEPort NPWT group, with skin graft take almost reaching 100%. There were no significant differences in the skin graft take on day 5 versus 7. The force given by the EASEPort NPWT allows the skin graft to be closely connected with the wound base, thus enabling the graft to be kept on the same position even though the animals were actively moving. The mechanical effect produced by the sponge and NPWT system allows the skin graft to be fixated evenly and consistently to the wound bed.[3]

A Cochrane study published in 2012 has concluded that the NPWT treatment has no effect on the healing process of the wounds, which expected to heal with primary intention. Moreover, they also highlighted that the noncommercial systems that are used to create the negative pressure showed clear cost benefits with no apparent reduction in clinical outcome.[19] This study also suggested to conduct a trial study that is suitable and high-quality to analyze the latest NPWT products and focusing more into the difficult-to-heal wounds.[19] As the EASEPort NPWT experimental study was conducted on a chronic wound, thus it can be considered that the NPWT is still valuable in treating difficult to heal wounds.

Conclusion and Suggestion

This study has managed to create the simplified version of NPWT system and reliable science institution has verified its function. The EASEPort NPWT system was able to enhance the skin graft survival rate in exudative wound. No complication was found. Thus, it can be concluded that the treatment given is both effective and safe.

The negative pressure produced by EASEPort NPWT that was performed intermittently, depicted better results compared with the tie-over technique. This finding was supported by the histopathology analysis. Furthermore, owing to the origin and the size of the tools assembling the EASEPort NPWT, this device is both affordable and portable. It is also effective, with additional advantages that include easily handled and safe. Further study to improve the presentation and to measure the patient's satisfaction level may be necessary.

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