Concept Proposal.

Title : **Vacuum Regulator Adapter Device For Wound Management System.**

Principle Researcher : Prof Ahmad Sukari Halim

Co-Researcher: Dr Arman Zaharil Mat Saad
armanzaharil@gmail.com

Department of Reconstructive Science, PPSP, HUSM.

Other Team: School of Engineering – Mechanical & Electronic

Main Objective:
To develop a cheap, versatile, user friendly and effective wound management system based on the principle of negative pressure treatment utilising centralised hospital suction system.

Other objectives:
- To develop device with accurate vacuum pressure regulator for multipurpose usage.
- To incorporate electronic or mechanical components to the centralised hospital suction system for negative pressure regulator and cyclical vacuum therapy.

Features of Negative Pressure Regulator Required.

1. Cheap
2. Small/light
3. Silent operation
4. Plug into the wall type (into the available wall suction socket)
5. Has automated pressure regulator (mechanical/electronic) with digital/analogue pressure indicator
6. Has self timer for intermittent therapy (on and off mode eg. 10 minutes on and 2 minutes off therapy for 5 days)
7. Alarm system to indicate required pressure not achieved/leaked/malfunction and alarm off mode/silent

The benefit of this project.

1. To produce a new easy to use and multipurpose wall suction pressure adaptor and regulator.
2. New product invention by the university.
3. The product will be highly value in hospital set up and has potential for world wide marketing
4. Can be used safely for Negative Pressure Wound Therapy

Vacuum Regulator Adapter Device For Wound Management System.

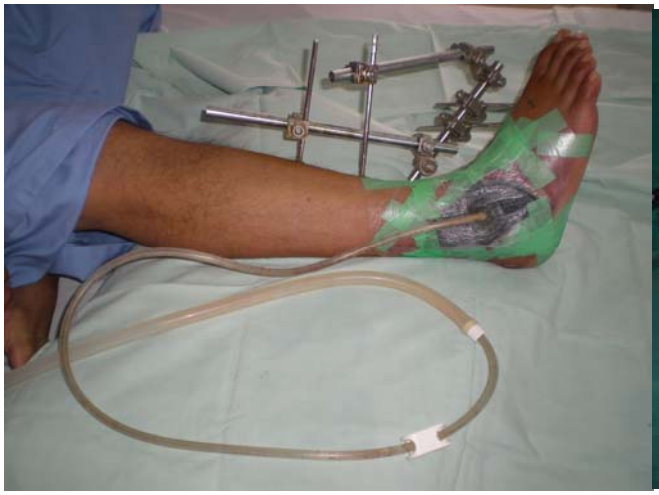
Introduction

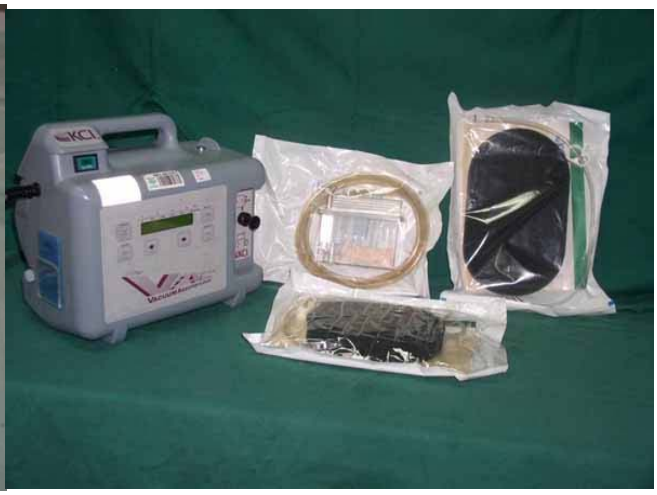
Since its introduction in early 1990's negative pressure wound therapy has gained massive popularity for management of wide range of wound across the entire surgical and medical fields. The concept was based on the mechanics of physics. The application of controlled subatmospheric pressure causes mechanical stress to tissues. Mitosis is stimulated, new vessels are formed, and the wound is drawn closed.[1] The degree of pressure to the wounded tissue is small, but when all areas of the wound work together in an effort to close toward the center point, the effect of negative pressure becomes impressive and results in quicker healing and resolution.

Numerous studies have been conducted to determine the effects of negative pressure on wound healing.[2, 3] These studies have shown that controlled negative pressure assists in wound healing by:
providing a moist, protected environment
reducing peripheral edema around the wound
stimulating circulation to the wound bed
decreasing bacterial colonization
increasing the rate of granulation tissue formation and epithelialization.

How is the Negative Pressure Therapy (NPT) applied?

Basically the system has 3 main components. (1)The semi-occlusive dressing materials that consist of polyurethane foam and see through semi-permeable plastic adhesive/drapes. This is the connected by semi-rigid tubing to a (2) machine, which generate and regulate negative pressure; with a (3) reservoir to collect the effluent from the wound. This dressing can last from five to seven days. (Figure 1)





What is the cost implication for this NPT system?

Currently the system is provided by KCI Company with a patent product called Vacuum Assisted Closure ® dressing (VAC). In most country the main units (Figure 2) are not available for purchase, and they are supplied to the patients on a rental basis which may cost around USD$20-30 per day. However in Malaysia, it is available for purchase that cost about RM70 000 per unit. There are new company emerging which offer competition for NPT system in the market of which may reduce the price of the products.

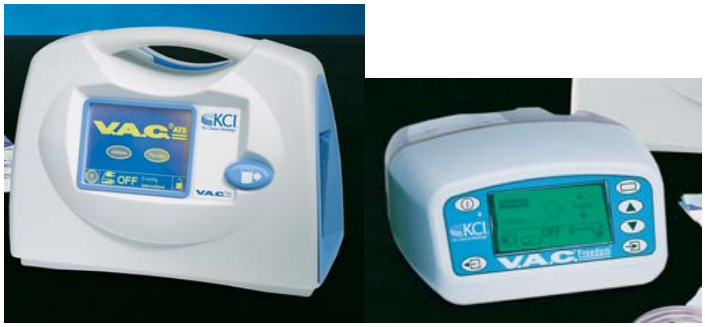


Figure 2 (Left –Standard unit , Right – Portable unit)

The reservoir or the canister had a capacity of around 280ml – 1000ml (Figure 3) will cost around RM500- RM 750 depending on the capacity.

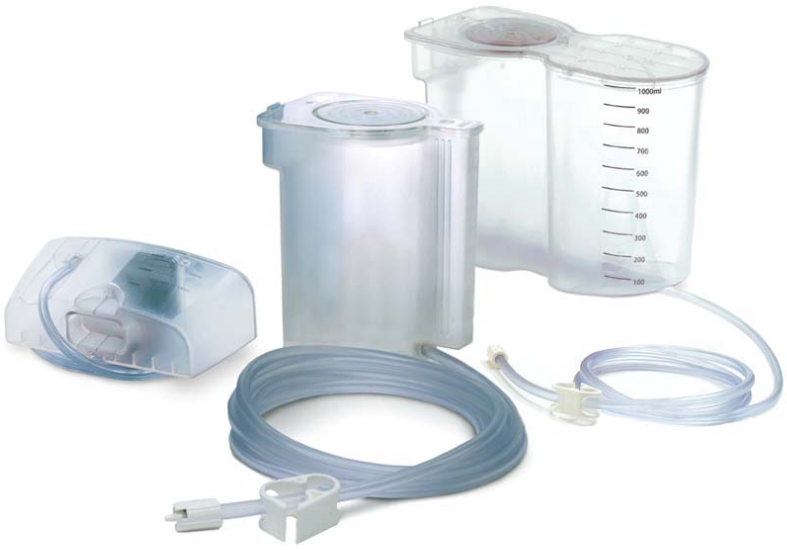


Figure 3

Meanwhile the cost for polyurethane foam that come with tubing and transparent semi-permeable occlusive dressing will range from RM180-RM350 (according to size S-M-L) (Figure 4)

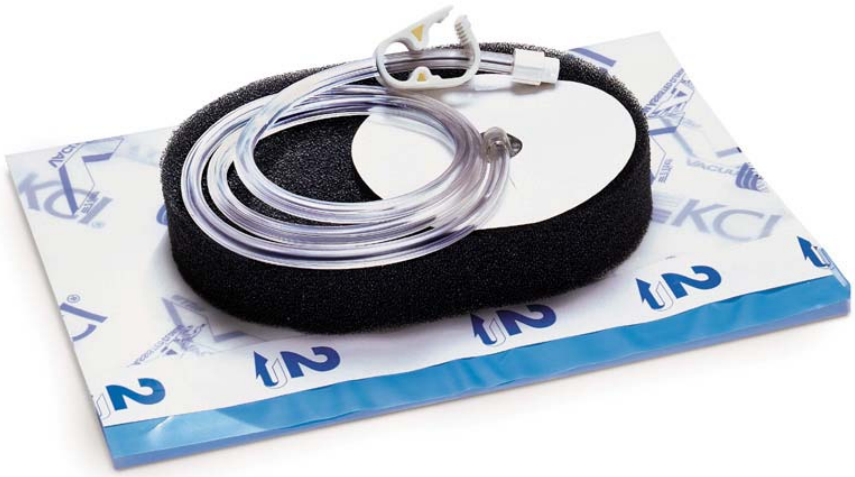
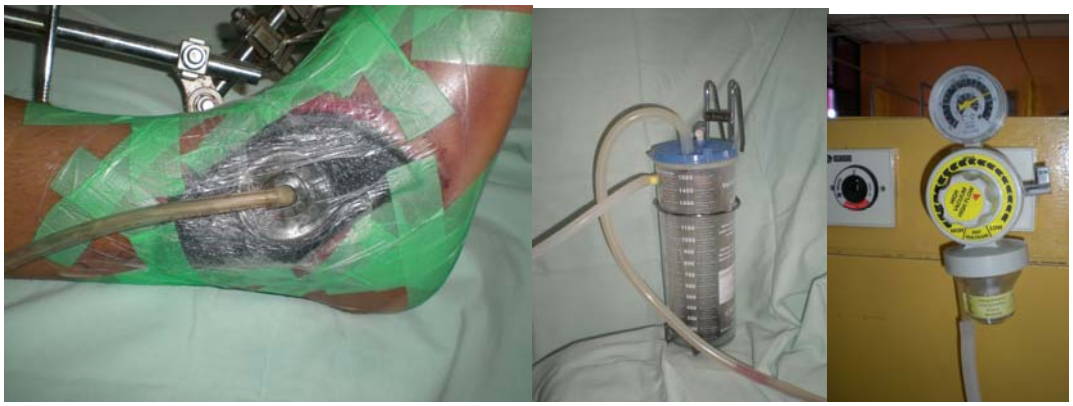


Figure 4

Due to high cost and increasing demand for this NPT system which is being monopolised by a single company, many centres have modified and come out with their on innovation to apply the similar principle for complex wounds management. [4-7]

We have used the centralised wall suction apparatus with a portable canister with the original polyurethane Granufoam ® supplied by KCI. This has reduced the cost by more than 75% as the original canister and the machine are not used. (Figure 5)This modification has allowed us to provide the treatment to many patients without much limitation. (previously limited by the number of machines available).



What are the potential flaws and disadvantages of these modifications?

1. Unlicensed used of the product or therapy

2. Wall suction in which negative pressure is delivered is lacked off the control mechanisms needed to provide safe negative pressure and has no regulator mechanism to control and provide constant negative pressure, precise amount of subatmospheric pressure, which is important in providing the maximum benefits of NPT.

3. Loss the advantage of having intermittent therapy, which is available on the KCI-VAC system that can further enhance wound healing. Controlled intermittent suction that stimulates replication of cells via mechanical stretch. Intermittent negative pressure is also an essential component for accelerated cell proliferation.

4. The is no alarm system to indicate loss of pressure or malfunction.

5. Contamination concerns
    a. There is a high risk of cross-contamination from the backflow seen in low-volume suction lines.[8, 9]
    b. The collection canisters on most wall devices are not designed to provide a closed system. If wound fluid is allowed to stagnate, microorganisms are likely to thrive. Collected body fluids represent an infectious disease component that provides an opportunity for cross-contamination between patients and clinicians.
    c. A standard wall suction collection canister does not have regulated safety devices to reduce the risk of backflow or spillage.

6. The NPWT canister has a limited capacity; it will hold 280 mL of wound fluid. It also is designed to alert the clinician when 280 mL of fluid has been evacuated from the wound. Wall suction devices lack a similar alarm system, and anecdotal reports from clinicians using wall suction and a standard collection canister (which may hold up to 1500 mL of liquid) include descriptions of exsanguination resulting in serious patient injury and death.

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