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"Gravity" - A New Simple Negative Pressure Wound Therapy Self-Build Design for Low Income Countries

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Abstract

Negative Pressure Wound Therapy (NPWT) is prohibitively expensive at the moment and therefore not easily accessible in low-income countries. An additional problem is the requirement of consistent reliable electricity to power the devices. A new low-cost NPWT device was designed from low cost and simple materials and it can be built and operated following a simple set of instructions. The so-called Gravity device was made from parts costing just under £6 GBP (May 2016) and it creates a constant pressure of 125mmHg. Gravity operated from 4 hours and 40 minutes up to 5 hours and 18 minutes before needing to be reset. This reset can be achieved without patient involvement. Gravity was taken to Kenya by a Doctor on 5 May 2016 to be evaluated. A NPWT device prototype was successfully made and positive feedback was received from Kenya.

1 Introduction and Background

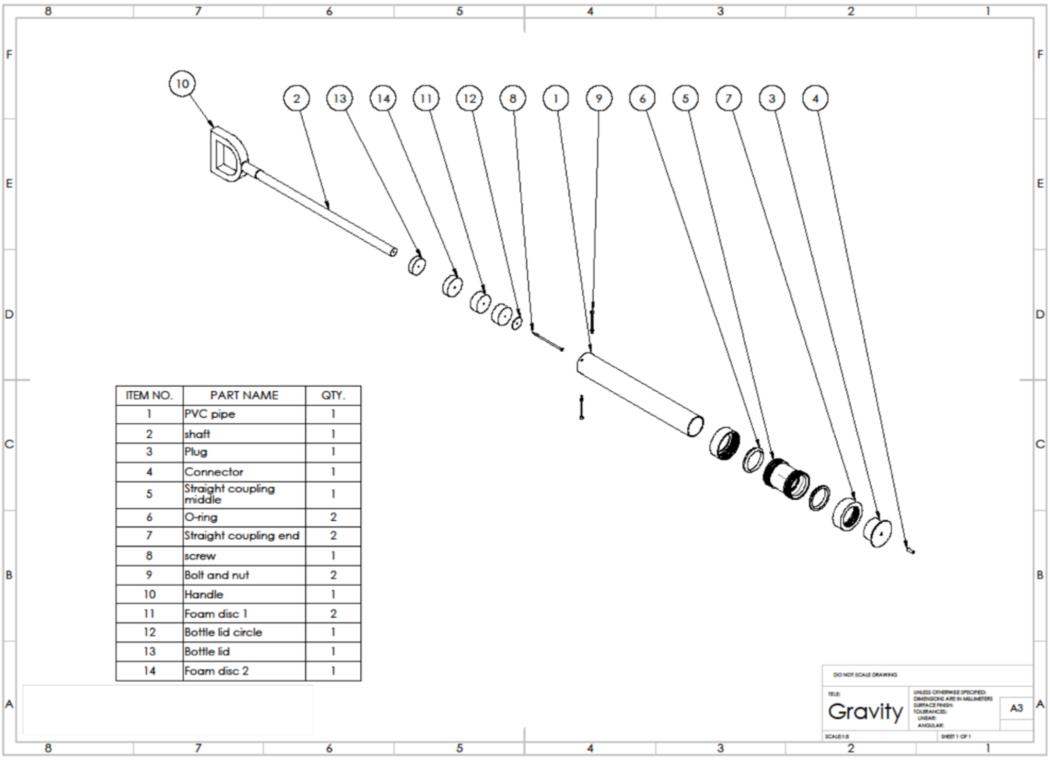
Preston [1] states that the use of topical negative pressure (TNP) in wound management is not a new concept, as it has been documented in the literature for at least 50 years. In early Chinese medicine heating of glass spheres were used to create hyperaemia, alternatively, Western medicine used a similar technique with suction bells to create a therapeutic hyperaemia [1]. Although the early application of TNP is not used for healing wounds, this is clearly the start of the use of TNP in medicine. Mouës et al. [2] add that since the early 1950s when suction drainage was introduced, drainage of wounds after surgery became an established surgical practice. Kostiuchenok et al. [3], Iusupov and Epifanov [4], Davydov et al. [5], Davydov et al. [6], Davydov et al. [7], published five key Russian publications in the 1980s on TNP, which use suction drainage and the research indicates that TNP reduces bacterial infections in wounds and the healing rate is increased. Mouës et al. [2] show what the author believes to be the first use of TNP in wound management and Preston [1] further supports this as his claims detail the benefits of the use of TNP. Chariker et al. [8] used an existing vacuum line as the source of TNP, the method is known as Chariker-Jeter technique. Since then there have been many applications of TNP based on this technique. The author would like to highlight that Chariker et al., appears to be one of the first to use a powered source to produce TNP. The author believes this is a significant development as the suction drainage TNP was primarily used to drain fluid away from the wound. The fact that a powered source is used displays that the primary use of the device was not only to drain the wound but is also to apply TNP to the wound. Huang et al. [9], writes Negative Pressure Wound Therapy (NPWT) has commonly been used to treat pressure sores, open abdominal wounds, sterile wounds, traumatic wounds, diabetic foot infections, second-degree burns and skin graft recipient sites, as it helps healing wounds more efficiently. Ruke [10] claims however, it is still not easily accessible for everybody. Low-income countries have a demand for NPWT devices but the ones that are commercially available are designed specifically for the needs of developed countries and their infrastructure. Especially, in terms of the power supply requirements and product costs. Therefore, NPWT devices are being made from readily available materials in low-income countries [11]. However, most of these devices still rely on electricity, for which low-income countries do not necessarily have a reliable supply of [12]. This explains the need for a device to be developed that can meet the needs of low-income countries, in terms of product cost, power supply requirements and the possibility of being made from simple materials and components directly where it is needed. For a NPWT device to work properly it is important that it produces the right level of negative pressure (suction pressure). Birke-Sorensen et al. [13] remind us of the reason why 125mmHg became the standard commercial pressure setting, despite the original clinical recommendations suggesting the use of lower pressures for some types of wounds. The original foundation for the pressure setting of 125mmHg was based on observations of optimal blood flow during a porcine excisional wound study [14]. Furthermore, there was a significant increase in granulation tissue formation at 125mmHg in comparison with no pressure [15]. Additionally, a pressure setting of 25mmHg yielded no difference in granulation tissue formation compared to no pressure, and the pressure setting of 500mmHg presented detrimental effects on granulation tissue. As 125mmHg was the only pressure setting which gave desired results, it was decided that this was the optimal setting, thus resulting in 125mmHg being used as the setting for early clinical protocol [16]. An overall scientific conclusion of a study by Birke-Sorensen et al. [13], would be that the optimal pressure setting is somewhere between a pressure of 25mmHg and 125 mmHg. This review agrees with Birke-Sorensen et al. [13], that the optimum pressure setting is somewhere between 25mmHg and 125 mmHg. Especially as recent commercial devices use lower pressure settings than 125 mmHg. The optimal pressure range for the following attributes wound contraction, blood flow, micro-deformation, fluid removal and granulation tissue associated with NPWT is 40mmHg to 150mmHg [13].

2 Topical negative pressure wound therapy versus advanced moist wound therapy

A randomised controlled trial with 278 patients was carried out to compare the ability of negative pressure wound therapy and advanced moist wound therapy (AMWT) to treat diabetic foot ulcers. During the trial, 50% of patients received AMWT where moist dressings were used and changed daily. The other 50% of patients received NPWT where dressings were changed every 48–72 hours and a pressure of 125mmHg was administered using vacuum suction. At the start of the trial, the wound size of patients being treated with AMWT was15.07 ± 2.92 cm^2. The patients being treated with NPWT started with a wound size of 15.09 ± 2.81 cm^2, the size difference is not significant. After two weeks the size of wounds treated by AMWT was 13.70 ± 2.92 cm^2 and wounds treated by NPWT was 11.53 ± 2.78 cm^2. Therefore the significant difference in the reduction of the wound shows that NPWT was more effective in treating foot ulcers compared to AMWT [17].

3 Technical Solution

The challenge was to design a simple and inexpensive
NPWT device for the low-income world. The chosen and final design is shown in an exploded 3D-CAD (Computer Aided Design) view of the assembly drawing of the so-called "Gravity" NPWT device, including the corresponding parts list, is shown in Figure 1. The assembly drawing displays clearly all necessary parts and indicates their position in the assembly. Furthermore, it shows that Gravity is a very simple design which can be easily build and assembled in a hospital where it is needed.



ITEM NO.	PART NAME	QTY.
1	PVC pipe	1
2	shaft	1
3	Plug	1
4	Connector	1
5	Straight coupling middle	1
6	O-ring	2
7	Straight coupling end	2
8	screw	1
9	Bolt and nut	2
10	Handle	1
11	Foam disc 1	2
12	Bottle lid circle	1
13	Bottle lid	1
14	Foam disc 2	1

Figure 1 Exploded view of assembly drawing of the Gravity, including parts list.

The following calculation was carried out to find the required mass to achieve a pressure of 125mmHg.

Calculation of the necessary circle area:

$A = \pi \times r^2 = \pi \times (0.020m)^2 = 0.001257m^2$ (1)

Calculation of the necessary Force:

P = 125mmHg conversion to Pa

$P = 125mmHg \times (101325/ 760)\ Pa/mmHg = 16665Pa$ (2)

$F = P \times A = 16665Pa \times 0.001257m^2 = 20.9479N$ (3)

Calculation of the required Mass:

$m = F/ g = 20.9479N/ 9.81m/s^2 = 2.1354kg$ (4)

Should no scales be available then 2 bags of sugar/flour etc. (usually bought in 1kg bags) could be used.

Friction:

In order to find out the mass required to overcome friction, mass was gradually added to a bag which was attached to the handle until the plunger started to move. The mass needed was 2.1 kg (2 bags of sugar) to achieve a pressure of 125 mmHg. The pressure the device delivers is dependent on the mass. The above calculation can be used to find the mass required for any pressure. In this case, the pressure range is 40mmHg–125mmHg as the literature suggests the optimum pressure for healing wounds is somewhere between 40mmHg and 125 mmHg. The masses required for pressures of 40 mmHg, 80mmHg and 125mmHg are 0.68 kg, 1.37 kg and 2.14 kg, respectively plus the mass required to overcome friction. Alternatively, if a different pressure between the stated values is required 5mmHg=85 g, plus the mass required to overcome friction.

4 Dynamic Regulation

Gravity was initially set up and ran for a full cycle at a pressure of 125 mmHg without being disturbed. Therefore ensuring Gravity was functioning correctly before carrying out dynamic testing. Gravity was picked up from its original hanging position on a door and carried by its hanging string. Simply carrying it around did not change the pressure. Then gravity was swung vigorously side to side which did not affect the pressure. Gravity was then shucked up and down vigorously from its hanging string. One vigorous shake changed the pressure from 125 mmHg to 250 mmHg. Once gravity had stopped being shaken and walked around within an orderly manner, the pressure resets back to 125 mmHg within 5 minutes. The reason the pressure changed was due to the mass in the bag dropping back down onto the handle. In conclusion, the patient would be able to move around in a general manner without changing the pressure delivered.

5 Construction Methodology

Basic tools and simple materials were used to produce a NPWT device prototype Gravity. Gravity can be assembled and operated by following a simple set of instructions (see attached manual) so that Gravity is easily accessible. Testing of Gravity was carried out using a pressure of 125mmHg without patient involvement.

Materials:
PVC pipe (diameter 40 mm, length: 300 mm), compression waste straight coupler (diameter 40 mm), plastic bottle lid (diameter 35 mm), spade handle (diameter 17 mm), screw (4x75 mm), garden string (2400 mm), connector (diameter: 4 mm), petroleum jelly (small amount to lubricate plunger), epoxy, foam flip flop (adult size), plug (diameter 40 mm), elastic band, marker pens 3 different colours and PTFE tape.

Tools:
Drill, holesaw (38mm diameter and 44mm diameter), drill bits, hacksaw, Tenon saw file, tape measure, screwdriver, clip and Stanley knife

The center of the plug was drilled out to 4mm and the connector was cut down to size, which was then inserted into the hole and secured into place using epoxy (Figure 2).

Figure 2 Photo of plug with connector

The center of a bottle lid was drilled out to 4mm and a circle was then cut out of the lid using a Stanley knife. The plastic circle was secured to a screw using epoxy. One 44mm and two 38mm discs were cut out of a flip flop using a hole saw. Once the epoxy had dried on the screw and plastic circle the two 38mm discs were placed on to the screw followed by the 44mm disc. Then a bottle lid with a 4mm hole was placed onto the screw, this is now the plunger (Figure 3).

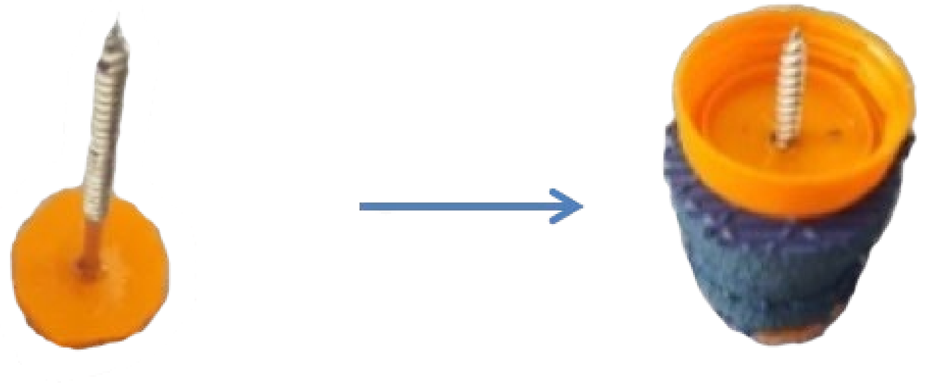


Figure 3 Photo of assembly of plunger

The spade was removed from the shaft and the shaft cut down using a Tenon saw so the total length of the shaft was 430mm including the handle. The centre of the spade was also drilled out to 4mm where the plunger would be screwed into the shaft. Three different coloured lines were drawn on the plunger shaft as a gauge to how far the shaft has travelled (Table 1 and Figure 4).

Table 1 Colour indicator descriptions

Line Colour	Description
Green	Plunger at top
Orange	Plunger half way down
Red	Plunger very near bottom (Reset of Gravity necessary)

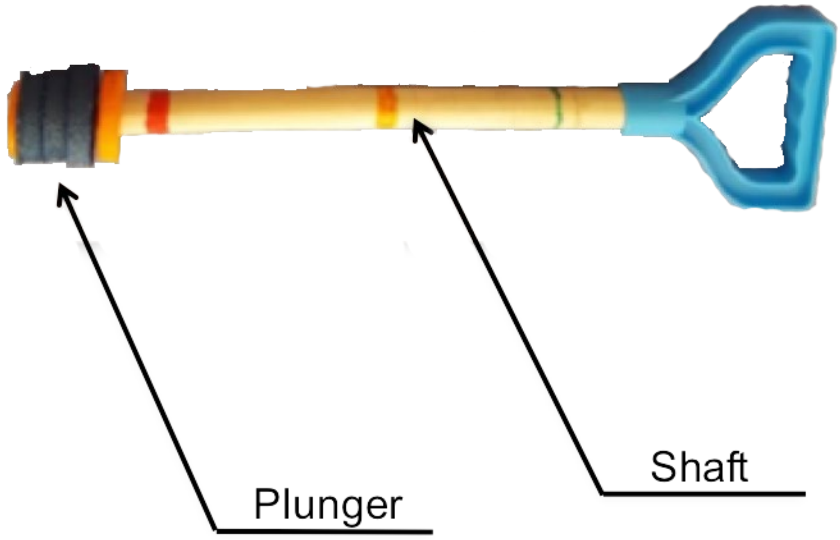


Figure 4 **Photo of coloured indication markers on plunger shaft**

Four holes were additionally drilled near the bottom of the PVC pipe. A file was used to remove material (Figure 5). PTFE tape was used around the threads of the coupler which was then connected to the PVC pipe and plug.

Figure 5 **Coupler before and after material removal**

Petroleum jelly was applied to the foam discs and then the plunger was put into the bottom end of the PVC pipe. The bolts were then placed through the holes at the bottom of the PVC pipe to stop the plunger from falling out. Garden string was then tied at each end of the bolts and tied together at the top so it could hang safely. An elastic band was placed over the top of the string passing over the coupler to offer extra support to the device (Figure 6).

Figure 6 **Photo of completely assembled prototype Gravity**

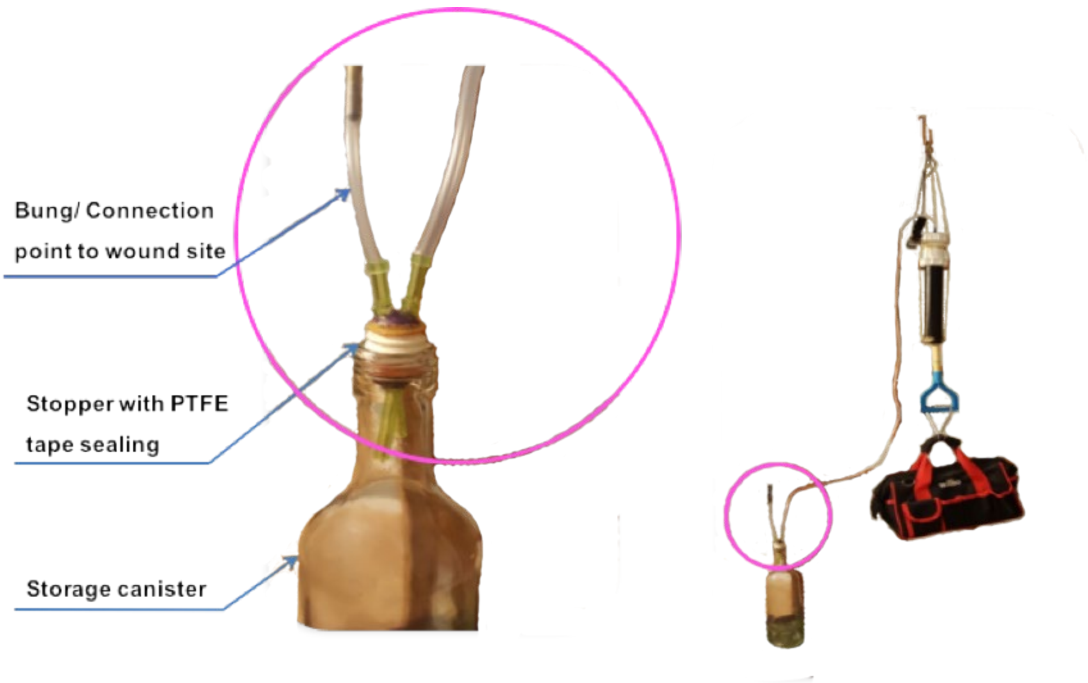


Figure 7 **Photo and description of the Gravity device with overall test set up and detail close-up.**

The device was hung up and the plunger pushed up to the top. Tubing was used to connect Gravity to the canister and a bung was used to create an air tight seal (where the wound site would be if a patient was involved) (Figure 7). Then the mass was applied to the handle, the device needed to be reset one time as the first set up removed the excess air from the system. A clip was used to clamp the tubing so that Gravity could be reset and the pressure maintained in the canister / at wound site. The mass was removed and then the tube was disconnected from Gravity and the plunger reset. Then the mass was reapplied and the clip removed and the plunger then stayed stationary confirming there were no major leaks or excess air within the system.

6 Testing Results

Gravity costs £5.83 GBP for parts, in May 2016, and the pressure used for produced testing was 125mmHg as this is widely accepted as the clinical standard [18]. The device was connected to a tube using a bung to make a seal (Figure 7). During testing Gravity operated for 4 hours and 40minutes up to 5 hours 18 minutes, before needing to be reset (Table 2). At the end of each test, Gravity was inspected to ensure the foam discs maintained a seal. The coupler was inspected for tightness and a pressure gauge was used to check the required pressure was being achieved. If the pressure reading was too low due to friction then additional petroleum jelly was added in-between the tests.

Table 2 Gravity test results

Test number	Time (hours . minutes)
1	5.18
2	4.40
3	4.47
4	4.55
5	5.09

7 Cleaning gravity

As gravity could come into contact with body fluids in order for it to be reused it would need to be sterilised to prevent infection [19]. There are various methods of sterilisation which can be categorised into the following categories heat, chemical and radiation [20]. The use of heat is the most common method of sterilisation used in low-income countries. The equipment used is dry heat sterilisers and autoclaves [21]. Dry heat sterilisation is achieved by the items being heated to temperatures greater than 140 °C for a certain amount of time depending on the temperature. If a gravity displacement autoclave is used the temperature required is 121 °C for 30minutes [20]. However, even if this equipment is available it may not be functional and there may not be any electricity available to power the devices. Where there are no dry heat sterilisers or autoclaves it has been found that pressure cookers are being used as an alternative and powered using gas, electricity, charcoal or kerosene [21]. The main component of gravity is made out of a plastic solvent weld waste pipe which is commonly made from Acrylonitrile butadiene styrene (ABS) or Polyvinyl chloride (PVC) which can only withstand being heated to a maximum of 82 °C and 65 °C, respectively [22]. Therefore it would be difficult to sterilise the device as the coupler and plug are also made out of ABS and these three components make up the majority of Gravity.

8 Discussion

The Gravity device parts costs were £5.83 (May 2016) and still met the functional requirements as it is capable of removing air and fluid from around the wound which is collected in a separate container. Furthermore, Gravity is activated and deactivated in order to maintain the constant pressure required. Gravity is activated when there is a leak in the system and the mass causes the plunger to fall and the required pressure is maintained. Gravity can also deliver a range of constant pressures as the applied pressure is dependent on the mass applied. Gravity was constructed using basic hand tools and simple, easy assessable materials. The materials used cannot be reused as they cannot be sterilised. However, the components are relatively low cost; therefore the components can be disposable. However, the canister that collects the fluid can be sterilised as it is glass but the stopper would need to be disposed of and replaced. Gravity meets the user requirements as a simple operating manual can be followed to operate Gravity. Furthermore, a simple construction manual can be followed to construct Gravity. The size of Gravity means that it can be easily transported and it can be hung anywhere at a height of at least 74.5 cm plus the length of the container which contains the mass. The mass of Gravity is 360 g plus the mass required to apply the pressure and to overcome friction. Therefore the total mass for a pressure of 125mmHg is 3.25 kg, which can be moved by one person. Furthermore, testing of Gravity showed that it can operate for 4 hours 40 minutes and up to 5 hours and 18 minutes, when connected to a canister and sealed using a bung before needing to be reset. Also, a range of constant pressures can be achieved, as depending on what mass is applied determines the pressure produced. The construction and operating manuals shown in the Supplementary Appendix, cost details and prototype for Gravity were given to a doctor who took everything out to Kenya on the 5 May 2016 to be evaluated.

9 Conclusion

Gravity has shown that, it is possible to make a prototype NPWT device using basic tools and simple materials which resulted in Gravity costing £5.83 GBP (May 2016). During testing Gravity operated for 4 hours and 40 minutes up to 5 hours 18 minutes, before needing to be reset. Gravity was evaluated in Kenya and positive feedback was received.

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