An interim analysis of device functionality and usability of RENASYS◇ TOUCH - a new portable Negative Pressure Wound Therapy (NPWT) system

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Background

Negative pressure wound therapy (NPWT) in its modern form has been shown to be effective in the management of chronic and surgical wounds[1-2]. NPWT devices have evolved continuously since its first inception. Early pumps were very simple in terms of the functionality they could provide and as time has progressed the sophistication, capability and usability of the devices has continued to improve.

RENASYS TOUCH is the latest advancement in NPWT device evolution. This new NPWT device has enhanced usability, as exemplified by a touch screen graphical user interface (GUI) and enhanced functionality, such as, improved troubleshooting capability and an adjustable compression rate feature. This trial is the first to assess performance, functionality and usability of this new NPWT device.

Methods

A prospective, randomized, open-label, multi-centre study was carried out to assess the clinical efficacy, functionality and device performance of the RENASYS TOUCH portable NPWT system in the management of acute, sub-acute and chronic wounds.

All patients enrolled into the study received therapy with the RENASYS TOUCH device but were randomised into treatment with continuous NPWT (-120mmHg) or adjustable intermittent pressure where the negative pressure oscillated between a high set point of -120mmHg for 10 minutes and a low set point of -25mmHg for 2 or 3 minutes. Patients were treated with NPWT for a maximum of 28 days.

Clinicians could choose whether to apply foam or gauze wound fillers with or without a wound contact layer as deemed clinically necessary.

An interim analysis was carried out on the first twenty-three subjects. Device usability and functionality aspects were assessed at each dressing application and throughout the treatment period.

Results

23 patients were included in the interim analysis with a mean age of 63.3 and BMI of 29.3. Patients had a variety of wound types suitable for treatment with NPWT (see Table 1).

Table 1: Patient demographics

	Overall (n=23)
Age [Mean (Range)] (years)	63.3 (24 – 83)
Gender [Males, N (%)]	16 (69.6%)
Body Mass Index (kg/m^2) [Mean (Range)]	29.3 (19.8 – 40.1)
Median wound duration [Median (Range)] (weeks)	3 weeks (range 0.3-26)

The clinical results of the study are described in more detail elsewhere[3] but in summary there was an overall significant reduction in wound area (42.6%, $p<0.001$) and volume (65.2%, $p<0.001$) following treatment with RENASYS TOUCH. This equated to a 17.3% and 26.9% reduction per week in area and volume respectively.

In the safety evaluation there were three non-serious adverse events possibly relating to the medical device. These reported an increase in wound pain making therapy painful.

Usability and functionality

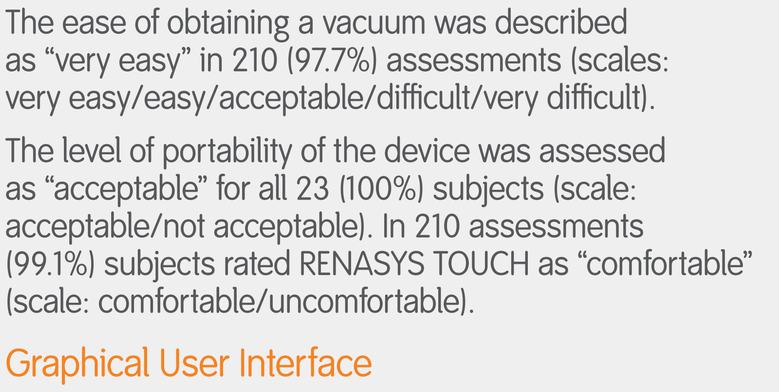
The ease of obtaining a vacuum was described as “very easy” in 210 (97.7%) assessments (scales: very easy/easy/acceptable/difficult/very difficult).

The level of portability of the device was assessed as “acceptable” for all 23 (100%) subjects (scale: acceptable/not acceptable). In 210 assessments (99.1%) subjects rated RENASYS TOUCH as “comfortable” (scale: comfortable/uncomfortable).

Graphical User Interface

Using the Graphical User Interface (GUI) (Figure 1) clinicians found the set-up of the device to be “very easy” for all 23 (100%) subjects and the Graphical User Interface (GUI) “very easy” to navigate for 208 (96.7%) assessments, whilst at the remaining 7 (3.3%) applications an ‘easy’ rating was recorded. No instances of Acceptable, Difficult or Very Difficult were recorded.

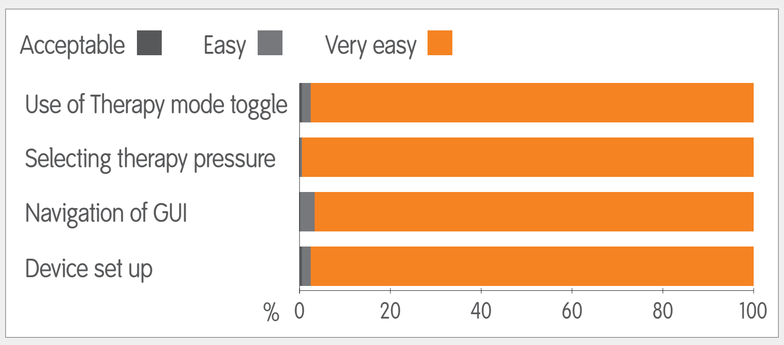
Figure 1: Graphical user interface



Selecting the correct therapy pressure set point was found by clinicians to be ‘very easy’ in 214 (99.5%) applications and easy in the remaining 1 (0.5%) application.

Therapy mode was switched between continuous and adjustable intermittent mode using a Therapy Mode Toggle and was found to be ‘very easy’ by the clinician in 210 (97.7%) dressing applications, ‘easy’ in 4 (1.9%) applications with the remaining 1 (0.5%) rated as acceptable (Fgure 2).

Figure 2



Adjustable compression rate

The compression rate is the time it takes to reach the set negative pressure level. Selecting the high compression rate resulted in the most rapid dressing draw down (illustrated in Figure 3). It is understood that in some cases a low setting (resulting in the vacuum being created in a slower fashion) may result in less pain or discomfort for subjects with particularly elevated pain sensitivity.

The choice of compression rate was left solely to clinical judgement accounting for the needs of the subject as required. The High compression rate setting was engaged at a majority of dressing applications, 127 (59.3%), with the remaining 81 (37.9%) applications using the Medium compression rate setting. The Low setting was rarely used however, at only 6 (2.8%) dressing applications.

Medium draw down was typically selected in patients with more painful wounds. A higher level of pain recorded in cases where the medium compression rate was utilized ($p<0.001$). This is likely an association rather than causation as the clinicians selected a lower compression rate for subjects with a pre-existing sensitivity to pain (Table 2). There were too few instances of using low compression rate for statistical analysis.

Figure 3

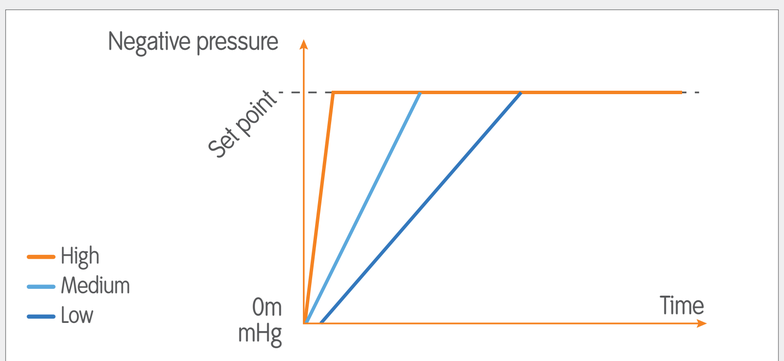


Figure 3: High, medium and low compression rates. Selection of compression rate allows the device to reach the set point at varying speeds depending on the pain and other factors experienced by the patient.

Level of pain during initiation of therapy according to Adjustable Compression Rate

Adjustable Compression Rate	Any pain on application *number of patients (%)*	Level of pain on application/initiation (0 – 9) *Mean (range)*
Low (n=6, 2.8%)	5 (83.3%)	4.8 (0 – 9)
Medium (n=81, 37.9%)	29 (35.8%)	1.8 (0 – 8.0)
High (n=127, 59.3%)	7 (5.5%)	0.3 (0 – 8.0)

Table 2: The medium or low compression rate feature was more likely to be used on application of pressure in patients with pre-existing sensitivity to pain. High compression rates were more likely to be used in patients with no or low pain according to clinical judgement.

Alarms are an important safeguard during use of NPWT. Where alarm conditions were observed, the alarm audibility was rated as “acceptable” for 53/54 (98.1%) interventions and the visibility of the error message on the GUI was rated as “acceptable” in all 54 (100%) interventions (scales: acceptable/not acceptable).

Troubleshooting Guide

Clinical usage of the majority of NPWT devices, typically needs some degree of device intervention for example to change canisters when full. To support troubleshooting and aid efficient device interventions, RENASYS TOUCH includes an integral Help section which provides guidance on device functions and operation, via a quick reference guide and a trouble shooting guide.

Throughout the study, some degree of device intervention classed as ‘trouble shooting’ was required in 14 cases. Troubleshooting relating to resolving an alarm was required in 13 (22.0%), with 1 (1.7%) relating to resolution of a leak. Where trouble shooting was used, the problem was resolved in 13 (92.9%) instances; in most cases 9 (64.3%) the quick reference guide was consulted.

Discussion

The new RENASYS TOUCH device was found to be functional and easy to use via a combination of therapy settings available on the device. New features of the device such as the Graphical User Interface were easily understood and managed. Features such as the adjustable compression rate allowed for patient specific changes to therapy.

References

1. Vig *et al.* 2011 Evidence-based recommendations for the use of negative pressure wound therapy in chronic wounds: steps towards an international consensus. J. Tissue. Viability 20:S1-S18
2. Krug *et al.* 2011. Evidence-based recommendations for the use of Negative Pressure Wound Therapy in traumatic wounds and reconstructive surgery: steps towards an international consensus. Injury 42:S1-S12
3. Forlee M, Nel, J, Richardson J, Rossington A, Cockwill J, Smith J. Wound management with variable intermittent or continuous negative pressure wound therapy (NPWT): Interim results from a randomised controlled trial. Presented at WUWHS Florence 2016.

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