An interim analysis of device functionality and usability of

RENASYS® TOUCH - a new portable Negative Pressure Wound Therapy (NPWT) system

Martin Forlee (Kingsbury Hospital, Cape Town); Jeanne Nel (Tiervie Trial Centre, Cape Town); Judith Richardson, Alan Rossington, John Cockwill, Jennifer Smith (Smith & Nephew, UK)

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 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, namely, an 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

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Overall (n=23)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Mean [Range] years)</td>
<td>63.3 (24 – 83)</td>
</tr>
<tr>
<td>Gender [Males, N (%)]</td>
<td>16 (69.6%)</td>
</tr>
<tr>
<td>Body Mass Index (kg/m²)</td>
<td>29.3 (9.8 – 40.1)</td>
</tr>
<tr>
<td>Median wound duration (Median [Range] weeks)</td>
<td>3 weeks (range 0.3–26)</td>
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The clinical results of the study are described in more detail elsewhere 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%) dressing 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 (figure 2).

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.

<table>
<thead>
<tr>
<th>Compression Rate</th>
<th>Any pain on application number of patients (%)</th>
<th>Level of pain on initiation of therapy according to Adjustable Compression Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low (-120, 2.8%)</td>
<td>5 (83.3%)</td>
<td>Low (-120, 2.8%)</td>
</tr>
<tr>
<td>Medium (-80, 37.9%)</td>
<td>29 (35.8%)</td>
<td>Medium (-80, 37.9%)</td>
</tr>
<tr>
<td>High (-40, 99.3%)</td>
<td>8 (48.2%)</td>
<td>High (-40, 99.3%)</td>
</tr>
</tbody>
</table>

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 (2.6%) 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.

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 Trauma. Vol. 69 (3) G1
2. Forlee et al. (2011) Evidence-based recommendations for the use of Negative Pressure Wound Therapy in patients with wounds and infectious surgery. steps towards an international consensus. Veto 69 (3) G1
4. Smith & Nephew Medical Ltd

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