

# A randomised controlled trial comparing Drawtex with standard dressings for exuding wounds

- **Objective:** This randomised controlled clinical trial compared a capillary dressing (Drawtex, now rebranded as Vibriant RCD [Vibriant Technology Services]) with routine practice for exuding wounds greater than 2.5 x 2.5cm.
- **Method:** The target population was 300 control and 300 test subjects across three sites in the UK, but recruitment difficulties resulted in only 125 patients being evaluable. Wound progress was recorded by nurses' perception of the progress of wound healing and by objective digital imaging. In the final analysis digital images were randomised (in time order) and a panel of nurses who were not otherwise involved in the research project graded the wound's progress.
- **Results:** After deconvolution of the data, the subjective (nurse perception) method of evaluation determined that the new dressing resulted in wound improvement in 12.7% more patients than did routine practice, but the blinded assessment method (based on the digital images) showed that routine practice was better by 6.6%.
- **Conclusion:** Evaluation of wound progress is clearly difficult. Human nature makes us favour novelty if we believe it is going to be better. Making interpretation more objective removed that bias and did not demonstrate a significant advantage for the test dressing. The findings suggest that unblinded assessment by trial nurses is unacceptable on its own. Blinded assessments may miss finer nuances of wound progression, but are likely to be more accurate. The authors suggest that the true result lies somewhere in the middle, with the trial dressing likely to be as effective as, but not more effective than, a standard dressing.
- **Declaration of interest:** This trial was funded by Vibriant Technology Services.

exuding wounds; capillary action dressing; unblinded and blinded assessment

The demand for wound-care products is growing rapidly due to demographic and technological changes.<sup>1</sup> Additionally, there has been an exponential rise in demand for evidence to support clinical nursing practices. Bradley et al.,<sup>2</sup> in a health technology assessment review, identified that:

- For surgical wound treatment, only five randomised controlled studies were available, all of which were of poor quality
- For pressure ulcer treatment, there were 28 trials of poor quality, and a meta-analysis was required to demonstrate statistically significant results
- For leg ulcers, there were 60 trials of multiple agents, but no clear conclusion.

Overall, there was little evidence to indicate which dressings or topical treatments are effective.

Similarly, O'Meara et al. found that studies of treatments for diabetic foot ulcers and chronic wounds were of poor quality and offered little useful evidence.<sup>3</sup>

Finally, the National Institute for Clinical Excellence (NICE) found only 12 randomised controlled trials investigating wound debridement using objective measures of wound healing.<sup>4</sup>

The overall implication is that good quality studies need to be commissioned with:

- *A priori* sample size calculation
- Objective wound-healing measures — such as changes in wound area — rather than subjective opinions
- Randomisation of experimental groups in head-to-head trials of dressings that are designed for similar tissue damage.<sup>2</sup>

Unfortunately, none of the above reports indicates just how this should be achieved.

This paper reports details of a multicentre randomised controlled trial in which the effect of Drawtex (Vibriant Technology Services), a capillary action wound dressing, is compared with a standard protocol for the treatment of any loss of continuity of the epidermis and any exuding wounds. Drawtex has since been rebranded Vibriant RCD.

## Method

Relevant local research ethics committees granted ethical approval (South Staffordshire LREC, Leicester LREC and Central Birmingham LREC). All patients were aware that they were in a clinical trial and gave signed informed consent.

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**Table I. Recruitment into the study**

	Birmingham*	Burton	Leicester	Total
Screened for trial entry	200	280	298	778
Recruited	18	72	52	142
Withdrawn/ died with only one record	0	10	8	18
At least two paper records available	15	61	45	121
At least two images collected	18	53	19	90
Total evaluable patients	18	62	45	125

\*Recruitment proved more difficult due to the inconvenient timing of the clinics attended by patients who were suitable for inclusion into the trial

**Recruitment and power calculation**

Patients were recruited at three sites: Queen’s Hospital, Burton-on-Trent; Glenfield Hospital, Leicester; Queen Elizabeth Hospital, Birmingham. We planned to assess/recruit 200 patients per site (100 trial product, 100 control) in order to give the trial 80% power to detect a 20% absolute difference within site, and a 60% power to detect a 10% absolute difference in the whole group.

**Inclusion criteria**

- Patients with any exuding wounds that may/may not be clinically infected. This criterion was deliberately broad in order to maximise the range of patients who would potentially benefit from inclusion into the trial
- Wound size greater than 2.5 x 2.5cm — an arbitrary choice to ensure that wounds were not so trivial as to heal rapidly regardless of therapy
- Patients aged 18 and over
- Patients expected to remain in hospital for at least eight days following entry into the trial.

**Exclusion criteria**

- Patients who had been recruited into this trial
- Patients involved in another research study that may influence wound management
- Patient sensitivity to Drawtex or the standard protocol post-entry into the trial
- Changes in the patient’s condition that would compromise normal treatment
- Arterial leg ulceration and fungating cancerous wounds
- Moribund patients (those likely to die before wound healing could occur).

**Randomisation**

Each site had 400 opaque envelopes, within which were sealed a trial number and treatment allocation. The excess of numbers available over numbers required was to reduce the variation in probability of selection bias — it is necessary to ensure that the probability of allocation to the trial dressing was the same as that to the standard dressing. Allocation would vary nearer the end of the research trial, as each allocation was made, if there were exactly the number of envelopes required for each site.

**Dressing protocols**

- Drawtex: dressing to be applied daily for one week, then as required. Extra layers may be applied on heavily exuding wounds.
- Standard dressing: protocols used at the three centres were compared and a standard was defined. An alginate or hydrogel dressing could be used as a primary dressing, but required a secondary dressing. Hydrocellular foam, hydrophilic foam or hydrocolloid could be used as a primary or secondary dressing. Antibacterial or antiseptic dressings could be used as a primary dressing if an infection was present. Patients would be prescribed systemic antibiotics if deemed clinically necessary. Films, tapes, bandages and non-adherent dressings were used as a securing layer as appropriate.

The protocol was deliberately broad, despite the potential effect on the clinical results of the different dressings’ ability to cope with wound exudate. This is because the three trial centres had widely differing standard wound-product formularies, which it would be politically impossible to change. The plan was for this variation to be evaluated by the sub-group analysis.

**Monitoring**

- All patients were assessed and wounds photographed according to a standardised protocol on days 1, 8, 15, 22 and 29
- Assessment of wound size, site, depth, severity, type and causation was undertaken by research nurses in each centre. Comparability of the assessments was achieved by regular meetings to design the study, ensure comparable methods for wound-size assessment and grading, and to allow nurses to work together during pre-study training to ensure cross-calibration. Size was estimated by measuring length and width. Depth was estimated by probing
- Demographic factors, mental status, primary and associated medical history, weight, height and ethnic origin were recorded
- All wounds were digitally photographed by medical photographers using a standard protocol defining lens size and flash settings. The photographers ensured that the distance and patient position ►

remained consistent so that all the ensuing images would be comparable. To achieve this, a copy of the first image taken was brought to each photography session, enabling patients to assume the same position in subsequent shots as in the first one.

### Statistical analysis

Demographic data for each group were evaluated by non-parametric methods. Numeric results — age, body mass index (BMI) — were compared by rank sum test, and distribution data — gender, mental state, urinary incontinence, faecal incontinence, mobility and steroid use — were tested by chi-square test.

Acknowledging the difficulties of blinding nurses to the dressing applied, we originally planned to assess wound progress through nurse assessment, but using a blinded statistician. However, two other studies have demonstrated that this leads to a significant over-statement of the benefit of the trial dressing.<sup>5,6</sup>

To reduce this confounding influence, two wound images — the first and last digital image of each wound — were printed on a single page using a high-quality photographic printer in random order — that is, the image in the first column may have been either the first or last image.

Nine nurses unconnected with the research project were asked to evaluate each pair of images and to determine whether the image in the right-hand column had improved, was worse than or the same as the image in the left column. This constituted the blinded assessment.

The scores of all nine nurses were collated and a consensus decision identified. This was then evaluated against the randomisation list to identify whether any individual wound had in fact worsened, improved or remained the same.

The agreement between the assessors was generally good. In more than 60% of image pairs, there was a majority of 7:2 or more in favour of one decision and in 72% of cases the agreement was 6:3 or more.

A computer analysis program was not used because, although this could have reproducibly calculated wound size or average colour, it would not have indicated wound progression.

### Results

Details of the recruitment into the study and the final sample size are given in Table 1. Although a total of 125 patients had evaluable records (either two paper records with details of the unblinded assessment, two sets of images with details of the blinded assessment, or both), some did not have both paper records and images. Therefore, there were 121 patients in the paper-record analysis and 90 in the image-based analysis.

**Table 2. Unblinded assessment\***

	Drawtex No (%)	Standard No (%)	Total
Improved	43 (71.7)	36 (59)	79
No improvement	17 (28.3)	25 (41)	42
<b>Total</b>	<b>60</b>	<b>61</b>	<b>121</b>

Difference between improvement rate of the two dressings was +12.7% (in favour of Drawtex); chi-square=6.41; p=0.01 (statistically significant difference)

\*Based on the impressions, made by nurses who cared for the patients, of wound appearance, including healing, infection progress and changes in exudate rate

**Table 3. Blinded assessment\***

	Drawtex No (%)	Standard No (%)	Total
Improved	25 (55.6)	28 (62.2)	53
No improvement	20 (44.4)	17 (37.8)	37
<b>Total</b>	<b>45</b>	<b>45</b>	<b>90</b>

Treatment duration mean (SD) (days)

Difference between the improvement rate of the two dressings was -6.6% (in favour of the standard dressing); chi-square=0.41; p=0.52 (no significant difference)

\*Based purely on the assessment made by nine independent nurses of digital images of the wounds

### Demographic and clinical factors

Sixty patients recruited into the Drawtex arm and 61 into the standard protocol arm of the trial had paper records available for analysis.

There were no statistically significant differences for the two groups in terms of age (Drawtex 75.5 ±12.5 years; standard 76.3 ±11.1) or BMI (Drawtex 28.6 ±9.1; standard 27.6 ±9.6) when tested by the rank sum test.

Gender distribution (20 male:40 female, Drawtex; 21:40, standard), mental state (assessed by minimal state score), mobility (self-mobile, requires mechanical aid, immobile), incontinence (urine or faeces) and steroid use (nine steroid users, Drawtex; 10 steroid users, standard) were not significantly different, according to a chi-square test. Exudate production was recorded subjectively and was not statistically significant.

### Wound progress

Tables 2 and 3 show the differences between the blinded and non-blinded assessments. A significant difference in favour of Drawtex was found for the unblinded assessment (p=0.01), whereas the

blinded assessment indicated that the standard protocol was more effective, although this was not statistically significant ( $p=0.52$ ).

Rank sum testing for treatment duration was only calculated for image-based analysis because of the known potential for bias in the unblinded assessment. This gave rank sums of 1852 for Drawtex ( $n=44$ ) and 1974 for the standard dressing ( $n=43$ ). The 95% and 99% cut-offs for interpretation for this statistic were 2087 and 2195 respectively. Therefore, there was no statistically significant difference in treatment times for either group.

### Discussion and limitations

The NICE guidelines identify the difficulties of undertaking rigorous scientific trials, highlighting the limited ability to blind products or complete detailed economic evaluations.<sup>4</sup>

The strength of the present study lies in its true randomisation and blinding. Its major limitations centre around the inability to blind product application and to achieve rigorous standardisation of a comparator dressing. We originally thought that these effects could be evaluated in the centre-specific sub-group analyses, but recruitment was insufficient to do this.

Furthermore, although the subjectivity of wound assessment was reduced by using the blinded image-based assessment, the interpretation of the paper records and the changes recorded in them could not have been entirely objective as they were based on the nurses' non-blinded interpretation of the wounds' progress.

In a previous small dressing trial ( $n=29$ ), unblinded assessment of wound progress demonstrated a statistically significant 40.8% superiority for the trial dressing, which decreased to a non-significant 20.6% superiority when blinded images were used.<sup>5,6</sup> A numerical data-only assessment arm in the same study, which ignored the finer nuances of wound healing, demonstrated only a 11.2% superiority of the trial dressing. This was felt to be an unfair judgment as some wounds that had clearly improved visually were graded as 'no improvement'.<sup>6</sup> Therefore, in the trial reported here only unblinded and blinded visual assessments were analysed.

### Trial power

At the outset of the trial it was planned to have a total of 300 patients in each trial arm, giving a 100:100 split in each site. Unfortunately, despite screening a very large number of patients, it was impossible to recruit them into the trial.

In comparison, we have carried out several trials of pressure-relieving mattresses, with very few refusals to participate. The difference appeared to be that patients regard mattresses as 'just something

you lie on', whereas when a wound was present they had to decide between a product that was 'known to work' (standard dressing) and one that had not yet been 'proven' (Drawtex). This might explain why recruitment to the present trial was so much lower than expected.

The resultant size of the study means there would be approximately a 60% power to detect a 20% difference. Consequently, the identification of a statistically significant +12.7% difference in performance may be a statistical anomaly.

The precise implications of the results are difficult to assess. Does it mean that the trial dressing is superior, inferior or just as good as standard dressing products? Or is it more likely that the truth lies somewhere in between — that is, human optimism means that unblinded assessment overestimates the benefits of the trial dressing but blinded assessment hides the finer nuances of wound healing, thereby underestimating the benefit? It appears from this trial that Drawtex was as effective at promoting wound healing as the standard dressings.

### Conclusion and recommendations

The unblinded assessment gave a very positive view of the effectiveness of Drawtex when compared with standard dressings. But blinding the image assessment reversed the apparent effectiveness of the Drawtex dressing.

The truth probably lies between the two extremes: Drawtex is as effective as standard dressings. This is a very important paradox because it indicates that research findings should not be taken on blind faith.

Appropriate interpretation of data is essential and just because one method appears to show a desired result does not mean this is true. Just as with financial services, one should always remember that something that appears too good to be true often is.

### Lessons for future trial design

Unblinded assessment of wound progression by trial nurses is not acceptable on its own. Blinded assessments give similar assessments of wound progress but miss the finer nuances of wound progression. The truth probably lies half way between the two. But again, there may be such an element of researcher bias that unblinded interpretation would skew the results heavily. It may therefore be that the blinded assessment is more accurate. ■

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**More information on Drawtex (now rebranded as Vibrant RCD) can be obtained from their website (in development at the time of going to press): [www.vibrant.co.uk](http://www.vibrant.co.uk)**

### References

- 1 Roberts, C.D. Wound management products: the evidence we need and the difficulties in obtaining it. *J Tissue Viability* 1998; 8: 2, 12-15.
- 2 Bradley, M., Cullum, N., Nelson, E.A. et al. Systematic reviews of wound care management: (2) Dressings and topical agents used in the healing of chronic wounds. *Health Technol Assess* 1999; 3: 17 (pt 2), 1-35.
- 3 O'Meara, S., Cullum, N., Majid, M., Sheldon, T. Systematic reviews of wound care management: (3) antimicrobial agents for chronic wounds; (4) diabetic foot ulceration. *Health Technol Assess* 2000; 4: 21, 1-237.
- 4 National Institute for Clinical Excellence. Guidance on the Use of Debriding Agents and Specialist Wound Clinics for Difficult to Heal Surgical Wounds. NICE, 2001.
- 5 Russell, L., Deeth, M., Jones, H.M., Reynolds, T. VACUTEX capillary action dressing: a multicentre, randomized trial. *Br J Nurs* 2001; 10: (Suppl. 11), s60-s65.
- 6 Reynolds, T.M., Russell, L. Evaluation of a wound dressing trial by different methodologies demonstrates current wound care evidence is unreliable. *Br J Nurs*, in press.