Development and Validation of an *In Vitro* Test Method for the Assessment of Superabsorbent Wound Dressings

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Background

ISO, ASTM and BS EN standardised test methods are used to substantiate claims and inform customers of the efficacy of products. They have an essential role in the regulatory process, however, there is often a discrepancy between the results of *in vitro* and clinical tests. It is important to ensure standard test methods are clinically relevant.

Aim

To develop and validate a vertical wound model that mimics how superabsorbent polymer (SAP) wound dressings perform *in situ*.

Methodology

- Synthetic, adult human tissue was fixed onto artificial human legs (Figure 1).
- Simulated wound fluid (SWF) was pumped through the model at 70 mL/24 hr and 100 mL/24 hr.
- SAP wound dressings applied to the model and exudate was recovered over a 24-hour period.
- The method was performed by multiple operators, in triplicate.
- Modified EN 13726-1 test methods were performed concurrently.

Figure 1. Photograph of the vertical wound model.

Results

- SWE recovery rates had low standard deviations and showed a high degree of repeatability across different test days using the vertical wound model (Figure 2 and Figure 3).
- Recovery rates for SAP wound dressings were lower when tested at high exudate rates compared to medium exudate rates.
- The vertical wound model could differentiate between high performing products (P3 and P4), medium performing SAPs (P1) and low performing SAPs (P2) at both medium and high exudate flow rates.
- The recovery of wound exudate was typically lower when tested using the vertical wound model compared to the modified EN 13726-1 test method, with greater differences observed for the high performing SAPs (P3, P4, P5)
- The recovery of wound exudate using the vertical wound model was also lower than the free swell method using the 100 mL/24 hr flow rate, which suggests that it is the vertical orientation that is responsible for the differences (Figure 4).

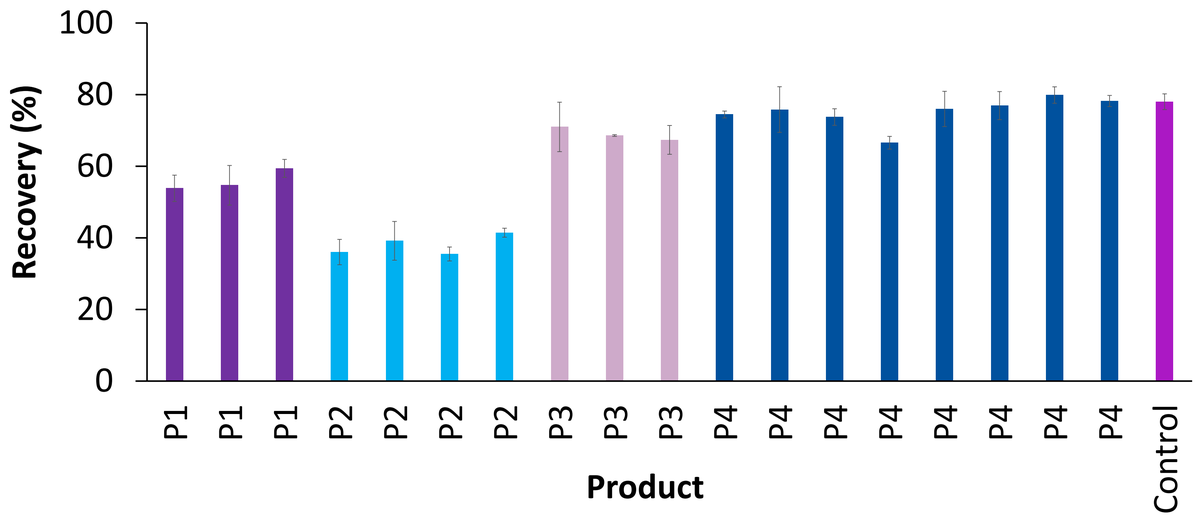

Figure 2. Recovery of wound exudate by superabsorbent polymer dressings using the vertical wound model under a medium flow rate (70 mL/24 hr).

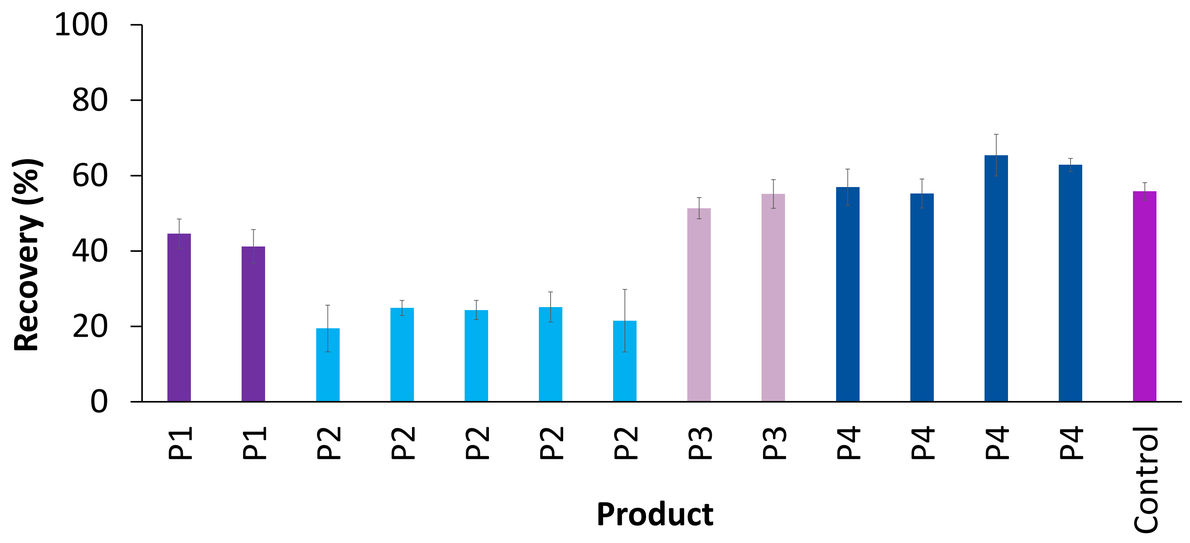

Figure 3. Recovery of wound exudate by superabsorbent polymer dressings using the vertical wound model under a high exudate rate (100 mL/24 hr).

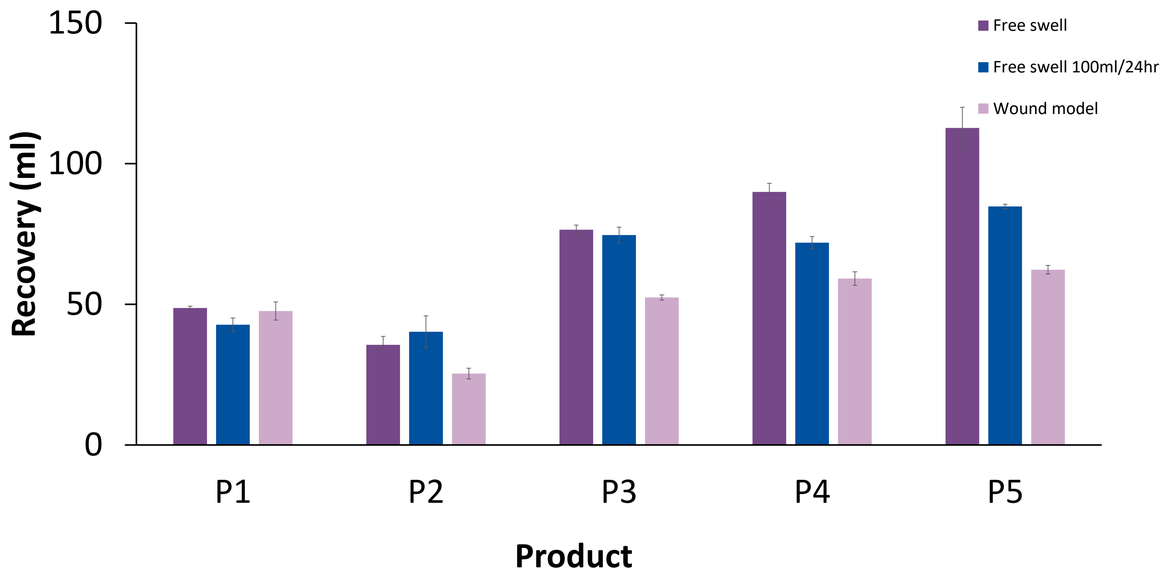

Figure 4. Recovery of wound exudate by superabsorbent polymer dressings using the a modified EN 13726 method, a modified EN 13726 at 100 mL/24 hr exudate rate, and the vertical wound model.

Conclusions

Clinicians are required to make daily decisions relating to fluid handling of exuding wounds, with the aim of supporting moist wound healing whilst reducing the development of peri-wound maceration. Physical product support data is typically limited to horizontal fluid absorption and retention studies. This work developed a repeatable vertical leg wound model which can used to assess and differentiate the absorption efficacy of SAP dressings at intermediate and high flow rates. This method aims to better inform clinicians about SAP dressing performance, resulting in improved patient care.

References

1. Malmsjö *et al* (2014). Biological effects of a disposable canisterless negative pressure wound therapy system. *ePlasty*, **14**, 113-127

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