

Clinical Evaluation of a novel hydrogel dressing for protection of Caesarean Section Incisions under expected use conditions



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Background

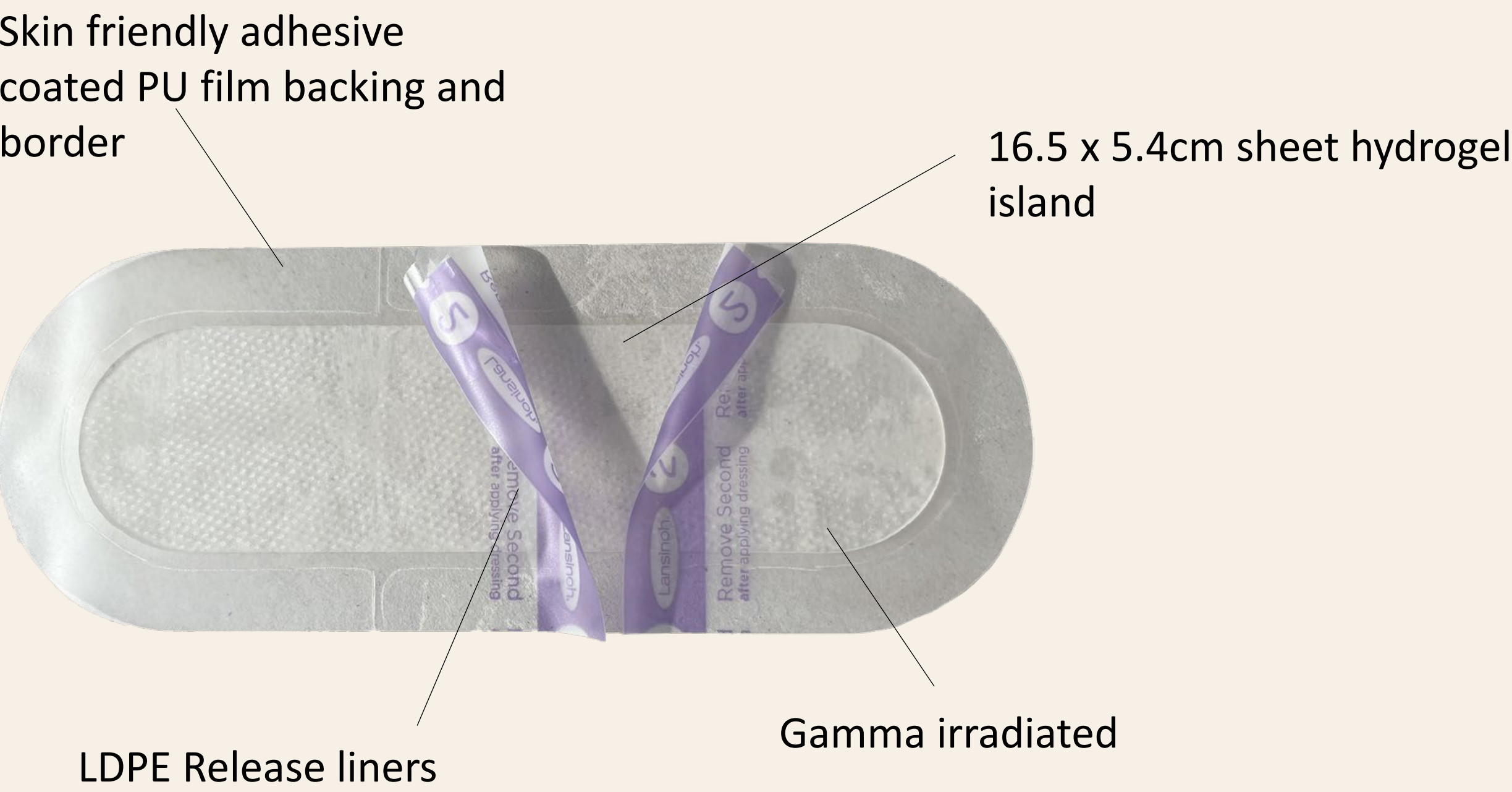
Caesarean section (CS) is associated with an extended recovery period, where the incision is at risk of contamination. Infection following CS is a common issue, with reported rates of 3-15%. The incision location, combined with overexertion when caring for their new baby may contribute to this high level of infection compared to other surgeries. While most incision complications occur soon after surgery, the healing incision remains vulnerable to friction and irritation from clothing and activities for several weeks, which may negatively impact healing. The aim of this study was to evaluate the ability of a novel hydrogel based dressing to protect a newly healed CS incision under expected use conditions.

Methods

Study Design: The dressing was evaluated in a Home Use Trial, allowing data to be captured on dressing performance under normal use conditions. Ethical approval was gained for the study and informed consent was obtained. Only participants who had horizontal CS which had healed with no complications were eligible for study inclusion.

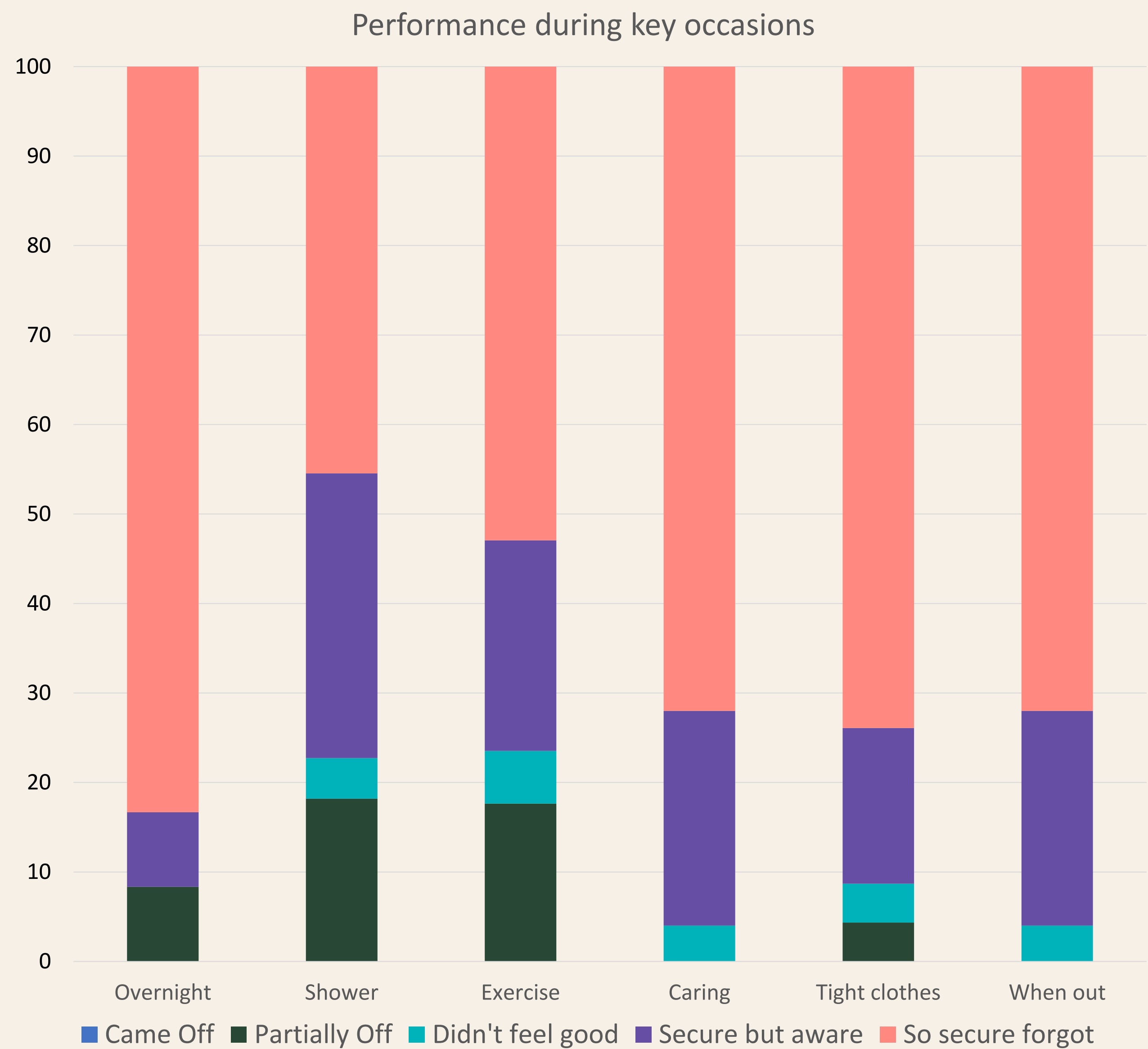
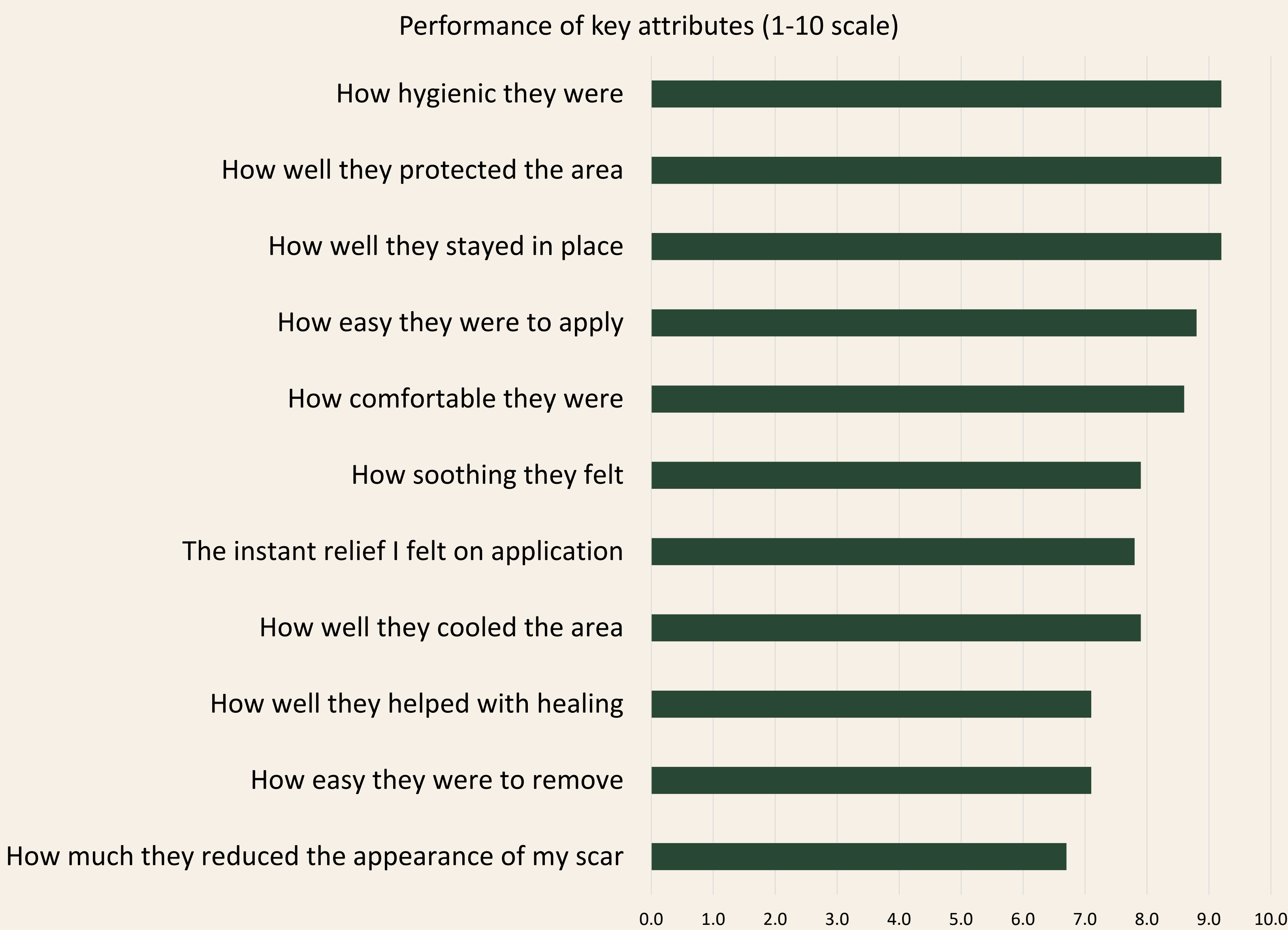
Method: Twenty-six USA based mothers, who had undergone CS delivery in the past 6-24 weeks trialled a novel C-section hydrogel dressing* designed to protect a healing CS incision, while cooling and soothing the area. The dressing is designed to be used from 10 days post CS, when the sutures have been removed or have dissolved and the incision has closed. Participants were asked to use the dressing for 3 days and provide feedback on their experiences of the dressing via online survey, with focus on dressing performance in a variety of situations including overnight, when showering and when caring for baby.

Test Dressing:



Results:

Participants wore the dressing for an average of 25 hours before changing the dressing. Most found the instructions clear (72%) and easy to follow (80%) with 32% saying they would not have needed the instructions at all to apply the dressing. Removal of the dressing was considered to be similarly straightforward. When rating a variety of performance attributes on a 10 point scale, the hydrogel dressing rated positively on all key metrics, including protection (9.2/10), ease of application (8.8/10), comfort during wear (8.6/10) instant relief (7.8/10) and cooling (7.9/10). The dressing performed well when used in the shower, overnight, when exercising, caring for baby or wearing tight clothing. Qualitative feedback was positive about the cooling and soothing effect, particularly when used after refrigeration. 92% of participants said they would use this type of protective dressing if they were to have another CS and would recommend it to others.



100% would use the test dressing if they had another C-section

92% would recommend the test dressing to others

CONCLUSIONS

Women who undergo CS do not always get the same rest and recovery period seen after similar surgeries, as they focus on caring for their new baby. Wounds which have closed successfully are still vulnerable to complications should irritation or friction occur. Hydrogels have extensive use in wound healing and are known for their cooling protective properties. The dressing* evaluated in this clinical study applies these benefits to support newly healed skin; protecting the incision area as the wearer resumes normal levels of activity. The use of such dressings may aid women recovering from CS to manage their self care needs.

*Soothies C section Recovery Pads, Lansinoh Laboratories