FREE PAPER 8

Engineering and Clinical Research in New Product Development for Intelli-Gel® Pressure Care

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Summary

An overview of several discrete studies using various lab based and clinical methods to evaluate seat cushions within the context of new product development is given. Investigations using pressure mapping, instrumented buttock indenters, visual inspection of skin quality, ultrasound measurements, and one case study are reported.

Aims and Objectives

To first evaluate existing and potentially new static seat cushion materials that could be used to reduce the risk of tissue damage and to identify which has the greatest potential.

To develop a range of seat cushions that enhances the characteristics of the selected material(s) for various applications.

To provide case studies that contribute a broader understanding of various research methods and data interpretation.

Background

The Kirton Healthcare Group Ltd design and manufacture specialist seating for people with, or at risk of developing, pressure ulcers. Among other factors, the interface materials are very important for the health of those clients. The present research addresses the need for a greater understanding of interface materials within the context of new product development.

During the first stage of the research, pressure distributions of 32 cushions containing a wide variety of materials were compared. Results show a trend where the lowest Peak Pressure Index values corresponds to cushions incorporating various arrays of deep gel columns, collectively known as Intelli-Gel®. These results were followed up independently at the Georgia Institute of Technology where an instrumented buttocks model was used to compare the Intelli-Gel® against various cushions including a multi-cell air cushion. These data corroborate the in-house findings showing the lowest ischial tuberosity pressures for the Intelli-Gel® cushion at loads equal to or below 70 kg.

The Wound Healing Centres UK Ltd and an independent Skin Science Consultant were subsequently commissioned to carry out a small clinical study. Five residents in a nursing home, all with pressure ulcers up to Grade II, participated. The only intervention to their care was the exchange of their existing pressure relieving cushion with the Intelli-Gel®. Both visual inspections of skin quality and ultrasound measurements showed signs of healing by week 2, with a total return of skin quality to normal by week 4.

The Intelli-Gel® material was given to a young girl with Lichen Sclerosis to use at school where she found sitting painful, and followed up in a case study. Lichen Schlerosis is a chronic inflammatory dermatosis which affects the skin of the anogenital region and is aggravated by heat. Use of Intelli-Gel® was found highly effective for the girl and she is now largely asymptomatic. Pressure reduction is believed to have improved comfort; however the reduction in symptoms is attributed to the ability of the cushion to reduce heat build up in the skin. The open structure of Intelli-Gel® may have also helped to keep

the skin dry.

New versions of Intelli-Gel® have been developed for wheelchair use, armchair drop-in cushions and toppers for existing cushioning. These were benchmarked against several CE marked cushions using pressure mapping and two subjects. The pressure distributions were analysed using Peak Pressure Index, Average Pressure, Dispersion Index, Seat Pressure Index-SD, and Total Force. In general, the Intelli-Gel® outperformed all cushions except for the multi-cell air cushion, where no significant differences were observed.

Hysteresis curves of Intelli-Gel® and standard PU foam were measured at the Furniture Industries Research Association and compared to elaborate the in-house findings. The hysteresis curves show that for foam, the increase in reaction force from the cushion is approximately linear to the distance the indenter travels into the cushion, whereas for the Intelli-Gel® the curve levels off, which is indicative of the cushion's pressure redistributing characteristic.

Discussion

The Kirton Healthcare Group Ltd has disclosed, in detail, the research behind the Intelli-Gel® cushions so that people are able to make their own decisions on whether to support the medical claims. The strength of the research is in the number of different methods used in both lab and clinical settings, and in the 'triangulation' of those findings. Each individual evaluation taken in isolation has obvious limitations of scale. Larger randomised control trials, for example, would provide more conclusive evidence, but this is not reflective of the context of this research. Research carried out as part of the new product development process happens at different stages of the product's evolution and with different research questions. The choice of research methods and the funding available corresponds to those stages.

Some of the observations from the pressure mapping work may be of interest to clinicians, as well as the protocols used. The Intelli-Gel® cushions and the inflatable air cushions can both be characterised as having heterogeneous pressure distributions. Some of the pressure sensors overlay the gel columns or air bladders (reading high pressures) whilst others overlay the interspaces (reading low pressures). When measuring Total Force, the pressure mats underestimate the applied load for these cushions but not for foam and others with more homogenous distributions. The interesting question though is how well the measured pressure distributions predict the health of the skin. Variability of data and resolution of the pressure mat are two factors that are considered.

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