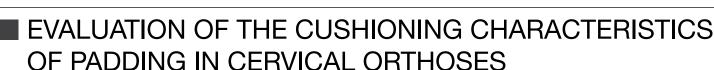
TECHNICAL REPORT



Overview

Clinicians agree that sustained pressure greater than 32 MMHG can cause irreversible skin damage in as little as two hours.¹ Manufacturers of cervical orthoses must consider these parameters in their selection of padding materials, since the effectiveness of the padding can influence pressure at the skin surface. Research suggests that when properly fitted, both the Miami J[®] Cervical Collar and the Aspen[®] Cervical Collar generate a maximum average pressure of less than 25 MMHG.² While this is below the capillary closing pressure of healthy tissue, not all patients have healthy tissue. In this report, the cushioning characteristics of the padding material used in the Aspen[®] Collar and the Miami J[®] Collar are evaluated. The results demonstrate that at pressures of ~25 MMHG the foam used in the Aspen pads provides cushioning that is approximately twice as effective as the pads used in the Miami J[®] Collar.

Materials & Methods

Replacement pads were obtained from currently available Aspen[®] and Miami J[®] Cervical Collars. Analysis showed that the Miami J[®] pads are manufactured from a "non-clickable" foam with a density

of 1.6 LBS. "Non-clickable" foam does not readily spring back after it is die cut, so the edges appear to be sealed. Aspen[®] pads are manufactured from 1.6 LBS. foam that is "clickable." Clickable foam is designed to have superior resiliency so that edges do spring back and do not stay compressed after it is die cut.³

The thickness of each pad was measured. A 1 κ G weight, fitted with a base plate designed to yield a pressure of ~25 MMHG was pressed into both pads and allowed to rebound. After 60 seconds, with the weight in place, the thickness of each pad was again measured (FIGURE 1).

Results

The Miami J[®] pad averaged an initial, uncompressed thickness of 0.4015 inches and showed an average compressed thickness of 0.1860 inches after 60 seconds. The Aspen® pad had an average, uncompressed thickness of 0.4280 inches and rebounded to an average compressed thickness of 0.3180 after 60 seconds (FIGURE 2).

FIGURE 1



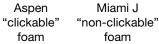
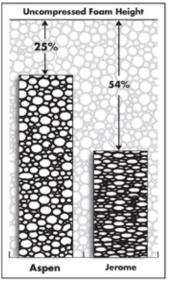


FIGURE 2



Compression at 25 ммHg²

Discussion

While the Aspen[®] padding rebounded to 75% of its original cushioning height, the Miami J[®] padding rebounded to less than half (46%) of its original height. These differences in performance may explain why using Aspen[®] Cervical Collars, in conjunction with comprehensive protocols, can significantly reduce the incidence of skin breakdown commonly seen when other cervical collars are used.^{4,5}

Conclusions

The results of this evaluation demonstrate that there are clear differences in the cushioning ability of the pads used in the Miami $J^{\text{(B)}}$ and Aspen[®] Collars. The clickable foam used in Aspen[®] Cervical Collars offers superior cushioning to the non-clickable foam used in Miami J[®] Collars. The padding material used in Miami J[®] Collars lost more than half of its thickness at pressures that were significantly below capillary closing pressure.

Acknowledgment

This report data was generated by Orange County Materials Test Laboratories, Anaheim, California.

References

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Mr. John Hamilton Aspen Medical Products 1901 Obispo Avenue Long Beach, CA 90804

Dear John,

Per my conversation with August Eltz at Heubach Corporation, here is an explanation of the differences between clickable and non-clickable polyester polyurethane foams. To be sure, when foam is clickable, this means that it will not edge seal or crimp when die-cut.

Traditionally, the differences between clickable and non-clickable polyesters are found in the base chemistry of the foam. A clickable polyester has a different ratio of components prior to foaming which make it cut cleanly compared to a non-clickable polyester. These chemical differences change the other physical properties of the foam. Please note that two properties are considered constant in this comparison – density and pore size. Here are the relative comparisons:

Property	Clickable	non-Clickable	Tousile Steenath Flammation
Tensile Strength	Worse	Better	Tensile Strength, Elongation, and Tear Strength are not appli-
Elongation	Worse	Better	cable when a backing material
Tear Strength	Worse	Better	is laminated to the foam.
Stiffness (CLD or ILD *)	Better	Worse	1
50% Compression Set	Better	Worse	
Ball Rebound	Better	Worse	

* CLD stands for Compression Load Deflection; ILD stands for Indentation Load Deflection. Both measure foam stiffness using different test sizes.

Please note that as density and/or pore size is altered for one of the products, the applicable property comparison may not be valid. As you can see, at constant density and pore size, when foam needs to maintain its shape or configuration under pressure, clickable polyester would be best. However, if the foam needs to stretch or bend, non-clickable polyester would be best.

I hope this information is useful for you. Please let me know if you have any questions.

Sincerely, Hew

Marc J Albero Manufacturing Technical Manager Technical Products Group

CC: August Eltz, Heubach Corporation Gary Jones, Foamex Brian Beranek, Foamex

1500 East Second Street Eddystone, PA 19022 Telephone # (610) 499-7800 Facsimile # (610) 876-2341 e-mail: malbero@eddy.foamex.com

Foamex International, Inc.