Original article

The role of standardised product terminology in product development and clinical practice

ABSTRACT

Convexity products for ostomy care have been available many years. However, there still remains confusion regarding both nomenclature regarding convexity products and their clinical application. This gap creates a non-scientific approach to patient care as the clinician often relies on personal experiences creating more of an 'art-based' approach rather than care delivered from evidence.

Recent publications are helping to improve the base knowledge of the clinician with new evidence that supports such clinical decision making in clinical practice. Ultimately, this evidence-based approach can improve patient outcomes by facilitating quality care while assisting product developers to create products that are more humanistic and patient-centered.

This article explores some of this recent evidence, some clinical applications substantiated by evidence, and the potential for future product developments and ostomy product standardisation.

Keywords standardised product terminology, convexity, ostomy product development, clinical practice, patient-centred.

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INTRODUCTION

In the evolving landscape of ostomy care, clinicians face a challenge arising from the inconsistent use of terminology associated with ostomy products, specifically soft convex, firm convex, or deep convex. These commonly used terms, though familiar to clinicians, lack standardised definitions, resulting in variations in product attributes across manufacturers. For instance, a convex product from one manufacturer will have differences in fit and performance compared to a convex product from another manufacturer. This lack of uniformity poses a challenge to clinicians when prescribing products. While product performance uniformity across manufacturers isn't the goal, uniformity of terminology used to describe these products would be of great benefit to clinicians. That way, the clinician can make a more informed decision when prescribing products, using the terminology as guidance. Recognising this challenge, the Hollister research and development team aims to continue down the path of a trailblazing journal article published in 2021,[1] which initiated a shift in clinical practice by introducing a standardised framework defining ostomy products based on certain characteristics—specifically flexibility, compressibility, depth, slope, and tension location.

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FIVE CHARACTERISTICS OF CONVEXITY AND CLINICAL APPLICATION STATEMENTS

Published in 2021, the five characteristics of convexity and clinical application statements (Table 1) have been instrumental in how clinicians and manufacturers frame discussions about convexity products.[1]

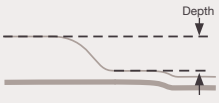
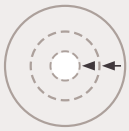
Twelve nurse panelists from eleven countries convened to define and establish consistency in convex skin barrier characteristics and associated clinical application of the products based on these defined characteristics.[1] Setting common nomenclature will be influential for both research opportunities and novice nurse education, as clinicians can now describe specific convexity attributes and the clinical decision making for correct product selection.[1] Adopting new nomenclature and incorporating it earlier into clinical practice seems a fundamental shift in ostomy care, however if stoma care is to advance, it should become the norm.[2]

INCORPORATING STANDARDISED CHARACTERISTICS INTO OSTOMY PRODUCT DEVELOPMENT

The goal for research and development is to incorporate these characteristics into new products. Moving away from conventional labels of firm, soft, and deep convex, our emphasis is on continuing to explore these five product characteristics as we continue to innovate in the world of convexity. Before we can incorporate the characteristics into designs, we must standardise how we measure them and how we think about their impact to the end user.

Having standardised measurements creates a foundational structure for product development. Furthermore, it guides new convexity designs, anchoring innovative concepts in these five principal characteristics that govern fit performance.

Table 1. Definitions and clinical application statements for the five characteristics of convexity[1]

Flexibility 	**Flexibility** is how easily the convex skin barrier can bend. • A more flexible convex skin barrier should be considered when convexity is needed and the barrier needs to conform securely to abdominal contours.	
Compressibility 	**Compressibility** is the capacity of the convex dome to be displaced or flattened. • An easily compressible convex barrier should be considered when there is post-operative edema and convexity is required to achieve a good seal. • An easily compressible convex barrier should be considered when convexity is required in patients with a firm abdomen. • An easily compressible convex barrier is indicated when the barrier needs to conform securely to the abdominal contours. • A less compressible convex barrier is indicated when the barrier needs to flatten the abdomen and/or assist with stoma protrusion. • A less compressible skin barrier should be considered when convexity is required in patients with a soft abdomen. • Peristomal skin health should be considered when selecting the compressibility of the convex barrier when convexity is indicated. • When using convexity, the most compressible skin barrier should be considered to avoid potential peristomal skin complications.	 
Depth 	**The Depth** of the convex skin barrier is defined as the measurement from the apex of the dome to the base. • The depth of creases and folds around the stoma should be considered when determining the depth of the convex barrier. • The use of a belt augments the efficiency of the convex barrier. • The depth of the convex barrier should be limited to the least amount needed to obtain a seal. • The compressibility of the convex dome influences the depth of convexity.	
Tension location 	**Tension location** is the position in which the convex dome exerts downward and outward forces on the peristomal topography. • A convex barrier in which the greatest tension is located as close as possible to the stoma should be considered if protrusion of the stoma is needed. • A convex barrier in which the greatest tension is located away from the stoma should be considered if the peristomal skin needs to be flattened. • Select the most appropriate tension location, taking into consideration the location of the opening of the opening of the stoma and/or pH, volume, and consistency of the output.	 
Slope 	**The slope** is the angle from the base of the convex skin barrier to the apex of the dome. • Consider a convex skin barrier with a less steep slope and wider plateau to flatten the peristomal skin.	

SOURCE: McNichol L, Cobb T, Depaifve Y, et al. Characteristics of convex skin barriers and clinical application: Results of an international consensus panel. JWOCN. 2021;48(6):524–532.

In measuring the characteristics, two styles of measurement become apparent. On one hand, we have slope, depth, and tension location. These three characteristics are more self-apparent or clearly visible when a clinician is handling a convex product. These three characteristics can be defined through readily available metrological techniques, like using a 3D light scanner to understand the exact depth, slope, or tension location of the product. On the other hand, we have flexibility and compressibility. These two characteristics are less self-apparent and not easily defined by merely looking at a product. They are dynamic, as opposed to static, in that the properties of flexibility and compressibility are better defined using time as an element. For example, these two characteristics become more apparent as the clinician handles the product and applies force to it by either flexing the product or compressing it with their hands. Another example is the end user who will wear a convex product for an extended period of time. Over time, they will feel the flexibility and compressibility of the product differently as they create different motions with their bodies. Therefore, these two characteristics are best measured in a laboratory using force and time as inputs.

INNOVATIVE SOLUTIONS FOR FUTURE PRODUCT DEVELOPMENT

In current products on the market today, slope, depth, and tension location are all geometrically focused and relatively static, with product shape and size playing a key role in defining the three characteristics. Conversely, flexibility and compressibility are more dynamic in that they both incorporate the element of time. While product shape and size are still important, how the product behaves while in contact with the patient is highlighted by these two dynamic characteristics.

Flexibility refers to the product's ability to adapt and conform to the abdominal contours of the body. Clinicians recognise its importance to ensure a good fit that supports a patient's abdominal topography and abdominal tone. For example, a soft convex barrier will provide a better fit than a firm convex barrier on an abdomen with deep creases, where the barrier needs to flex into those contours.[3] Therefore, selection of the right convex skin barrier hinges on this dynamic barrier characteristic.

Another dynamic component is compressibility. This refers to how the product responds to pressure and deformation during wear. Clinicians evaluate compressibility of the ostomy barrier to ensure a good fit around the stoma and for the barrier to adapt to the abdominal contour changes. For instance, an easily compressible barrier should be considered when the patient presents with a firm abdomen so less pressure is exerted on the abdomen.[1] A less compressible barrier should be considered when the abdomen is soft or if the stoma needs additional support to protrude.[1]

While the dynamic characteristics of flexibility and compressibility significantly influence how a convex product behaves while in contact with the patient, it's crucial to recognise that all five characteristics are interrelated and collectively contribute to getting an optimal fit. For instance, consider the clinical application of a convex skin barrier. Here, compressibility directly affects the depth of convexity provided.[1] An easily compressible convex skin barrier will provide less depth when compared to a less compressible convex skin barrier. This can be seen when comparing a soft convex barrier to a firm convex barrier. Understanding how these two characteristics impact the convex barrier's ability to provide the right amount of depth is essential for achieving an effective seal around the stoma using the right barrier.

CONCLUSION

In new product development, the focus extends beyond terminology and measuring the characteristics. The five characteristics will play a pivotal role in identifying potential gaps in current convex products, guiding strategies to address challenges posed by diverse end user topographies encountered by clinicians daily. Tailoring products to meet the specific needs of individual users, with a particular emphasis on achieving a better fit, is a key focus. This approach is called human-centered design, focusing on true unmet needs, and designing products to meet those needs.[4] Continued research of avenues to enhance the adaptability of products will potentially allow adjustments to these five characteristics of convexity during wear. While representing an exploratory direction, this solution may offer a more personalised and comfortable experience.[5] This research remains grounded in the principles of measurement precision, nomenclature standardisation, and user-centered designs, ensuring that future products meet and exceed the expectations of clinicians and patients alike.

CONFLICT OF INTEREST

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