Healthcare

A deeper look into the R&D of seating surfaces made to prevent pressure sores reveals high-tech testing methods that examine the effectiveness of initial concepts. By using the data collected, designers can construct these cushion cells to redirect air flow and imitate the buoyancy effects of seawater.

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Patients with paralysis or other disabling diseases are often forced to sit or lie for long periods and can't adjust their posture when they become uncomfortable. On the other hand, able-bodied, sensate patients regularly change their sitting position to help blood flow to areas of discomfort. Maintaining healthy skin tissue at the interface between a disabled patient's body and the supporting surfaces, such as a wheelchair cushi on or mattress, is a major concern of healthcare clinicians.

The *Journal of Enterostomal Therapy* published a strategic planning report in 1989 that labeled the US dermal wound care market as a $2 billion business, covering nearly 26.5 million wounds, ulcers, and burns. It also claimed another $4 billion is spent each year on the treatment of pressure ulcers, while $8 billion goes for skin care products used in nursing homes.

To cut these health costs and make patients more comfortable, the company develops pressure-reducing support surfaces and tissue-interface products. Designers continually try many different techniques to improve these products while ensuring that the new ideas are relevant to their patients' problems.

Clinicians place a lot of credence on interface pressure measurement as a means of evaluating the comfort of seated or lying patients. Although the real value of pressure measurement as an indication of tissue defor-

Medical device designers are taking advantage of advanced materials, components, tools, and manufacturing methods to make home healthcare products measure up to hospital standards.

Home Improvements and Renovations

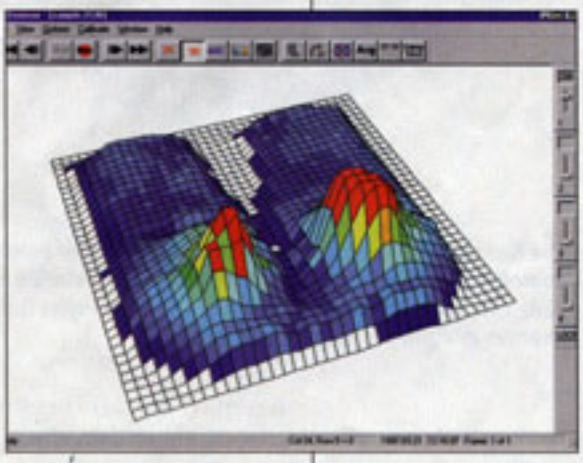
mation is always in question, designers have pressure-mapping systems to evaluate the performance of design concepts and to demonstrate the efficacy of these concepts for clinicians.

Pressure mapping systems use multiple sensor points on a mat that drapes over a support surface and rests between that surface and areas of a human body, such as a seated patient's buttocks. It indicates the distribution of pressure across the surface. Areas of high pressure are displayed as color changes and peaks on a 3D image. When hot spots or high pressure points are observed, it is symptomatic of a poor fit to the buttocks' contour. It does not indicate what the effective shape should be, only that the fit is inappropriate. Nonetheless, pressure mapping is a useful tool in guiding the designers.

Other techniques are being developed that measure the effectiveness of a surface conforming to a body contour without deforming human tissue. This kind of indent instrumentation is designed to represent the behavior of tissues when loaded onto a particular surface. It evaluates the cause of tissue deformation, not the symptom. Designers will be able to evaluate the concepts and produce internal design standards.

Measurements of both pressure and shape matching is carried out after a conceptual model has been produced. To guide the designer before he fires up the solid modeling software or puts the machine shop to work, researchers are collecting buttock contours from several disabled and able-bodied patient groups to look for generic trends. Test subjects sit on shape sensing instrumentation and their body contours, at the point of contact with the instrumentation, are recorded as 3D data points, providing visual and quantitative information.

The challenge for designers becomes the analysis of the data and extracting meaningful information. This will enable them to construct ideas that are more relevant to the best seating solutions before projects reach the concept or prototype testing phases. The ultimate goal is a better understanding of needs and a more effective and efficient product development process.



The Xsensor pressure mapping system is a clinical tool that measures interface pressure between the patient's skin and contact surfaces. As a capacitive sensor system, it is useful in comparing alternative products used in seating and support surfaces.

Design teams are multidisciplined and bring together clinical knowledge, design engineering, marketing, and manufacturing during applied research projects and throughout the subsequent product development process. These teams are better equipped to experiment with the trade-off between shape conformity, stability, and postural positioning. Ultimately, they are better able to develop

support surfaces with performance characteristics that fit a variety of patients' needs.

For example, the design brief behind the first cushion called for a support surface capable of conforming to the contours of any individual's seated or lying position with minimum disruption to the soft tissues that cover the human body. In addition, the cushion should conform, irrespective of posture or frequent changes in posture.

When the natural contours of the body are deformed by poorly fitting surfaces, localized areas of contact pressure increase and transfer to the underlying tissues. These incidences often appear where bony prominences reside beneath the skin, such as heels and parts of the pelvis. If these increased pressures occlude the supply of oxygen-rich blood to the tissue for long periods, the tissue eventually dies and falls away. The developing wound is commonly referred to as a pressure sore or ulcer.

During ongoing research, a surface was developed to package the buoyancy and conforming characteristics of a fluid. After studying sea mammals and their ability to withstand high pressures in the ocean, the designer of the original ROHO cushion developed what they call Synthesis of Floatation Technology (SOFT). By containing an adjustable volume of air in a matrix of interconnected air cells, the flow of air within the surface forces it to behave the way seawater envelops and supports a sea mammal. Since pressure equals force over area, the greater area leads to lower pressure for a given force. The envelopment of water distributes forces over the greatest possible area, producing a perfect fit that doesn't deform the tissues and doesn't occlude blood flow.

The Nexus Spirit cushion is a modular system that combines a contoured polyurethane foam base with a dry flotation support pad. The foam base comes with built-in leg troughs that improve midline positioning of the femurs.

The volume of air within the cushion is adjusted to immerse the patient to an optimum depth and expose a maximum load-bearing contact area. The design of the surface structure ensures that the cells synthesize the behavior of a fluid. As the load on the cell increases, the volume of air within the cell is forced into adjoining cells until the air pressure across the matrix equalizes. The resolution of cells at the surface was selected to best describe the curve of the buttocks. To increase the surface contact area, the elastic properties of the material and the geometric shape of the cells expand under compression and bridge the spacing between the cells. Then, in contrast, the tops of the cells crinkle as they deform and subtly break up the contact surface, providing ventilation between the skin and cushion.

Although the cells offer minimal resistance to changes in the seated position and dynamically conform to patients, two major factors also contribute to effective seating. For instance, cells that move and flow offer limited positioning and stability.Designers are challenged to develop surfaces that provide a balanced program for conformity and stability.

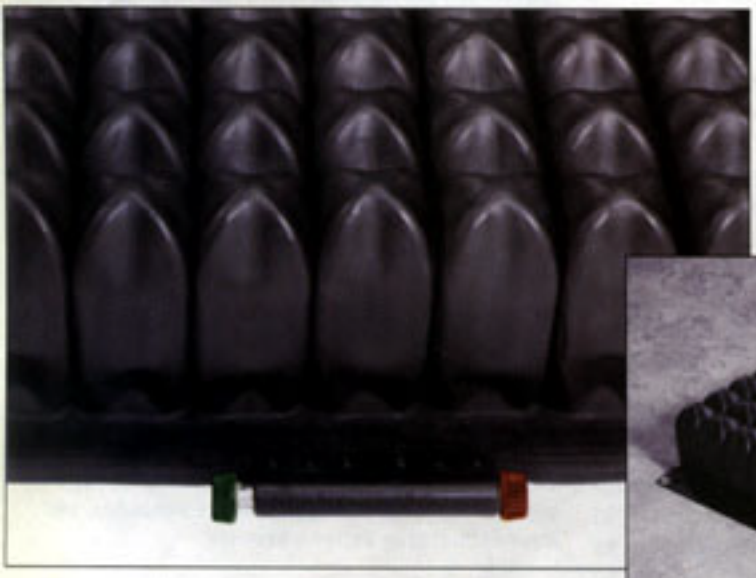
Building on the foundation

Although a stable sitting position begins with a firm foundation under the seated area, back support is also a contributing factor. Most commercial back supports take the form of single planar surfaces. Supports, providing an intimate fit, usually are custom molded to a patient's shape.

Molding a seated position is a snapshot in time. A clinician poses an individual in an optimal seated position while a technician begins the shaping and measuring operation. Almost artistic in nature, the technician must do it right the first time. Modifying the solution is difficult and the molded body shapes are often complex.

Disabled patients requiring postural support often have spinal deformities caused by poor posture or severe imbalance in the muscles that support and control the trunk and hips. These patients need support that maintains or corrects their posture. Since weight bearing is greater through the buttocks and thighs than the backrest, tissue integrity is not the overriding factor when prescribing or developing a solution.

Building a backrest system has been a special learning experience for the company. The system had many potential failure modes that engineers and designers evaluated while concepts and prototypes were tried. The torsion and bending forces an individual can inflict upon various areas of the back were investigated and incorporated into a formal process of failure-mode effects analysis and system effectiveness. The complex development



The Quadtro Select cushion with Isoflo control is a progressive positioning system that eases stability and positioning adjustments for users and clinicians. It uses air to lock into position and can be adjusted over time. The cushion corrects or counteracts seating and stability problems associated with a variety of deformities or disabilities.

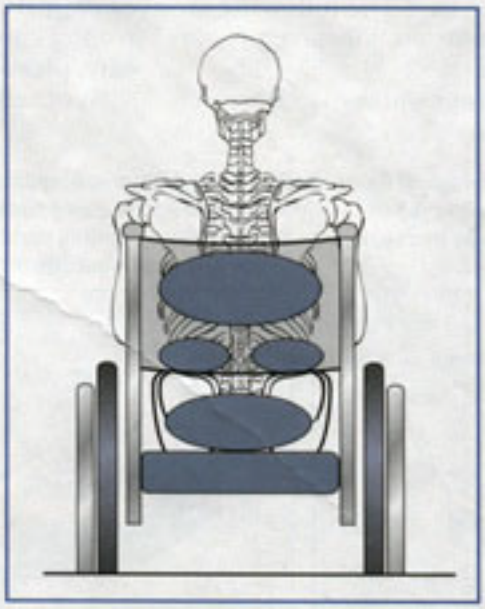
process of this product was a research tool, providing engineers and designers with knowledge beneficial to future development projects.

Traditionally, backrest systems supported the human spine as though it were a uniform, homogenous rod. Some of the spine's behavior can be described as an elastic rod, but it is an oversimplification of this nonuniform structure. The concept of the Symmetrix back began with an examination of the underlying biochemical nature of the spine and postural stability. This physical reasoning lead to an approach using independent support pads at crucial levels of the spine, reinforcing maximum support at these points. The design team concluded that in its simplest form, a backrest system needs to offer three points of contact to the spine. By accurately positioning and orienting the supports at appropriate locations along the spine, its surface can be shaped to fit a person without any additional resources or complex forming techniques. Therefore, an intimate fit is done with a one-step process that can be modified or easily changed at any time.

The most flexible areas of the spine are described in terms of appropriate mechanical joints. The lower thoracic area of the spine, between vertebral discs T10 to T13, has a relatively high degree of flexion and rotation. A ball and socket joint with three degrees of freedom represent this area. Ribs stiffen the thoracic region and limit rotation but allow some flexion and extension. As a result, a single hinge with one degree of freedom represents this region. Above vertebral disc T1, the cervical spine provides considerable flexibility. It is represented by a ball and socket joint providing three degrees of freedom. After the essential movements of the spine are identified, the nature and position of the support pads became apparent.

Positioning the support points

The first level of support provided is the sacral pad. This pad moves with six degrees of freedom and is positioned to support extreme sitting asymmetry. The sacral pad controls the pelvic tilt in an anterior-posterior direction. It allows the pelvis to be stabilized be-



The standard 3-tier Symmetrix back system will accommodate growth and changes in posture, eliminating the need for purchasing multiple back systems. It has mounting attachments for a wide variety of manual and power chairs, as well as laterals and a headrest option for additional postural support. Changes in trunk width, sitting height, recline requirements of 30° forward and backward, and seat depth up to 10 in. can be done while the patient is in the chair.

fore the rest of the spine is addressed.

The lower trunk pad fits over the lower ribs and thoracic spine to provide the initial stabilization of the trunk. This pad sets the angle of the spine with respect to the pelvis. If the spine is flexible, the relationship between the anterior pelvic tilt (set by the sacral pad) and the lower thoracic spine will also initiate lordosis of the lumbar spine.

A third tier of dual pads is located between the sacral pad and the lower trunk pad. The clinician's hands move these pads into place. They coax the lumbar curve of the spine into a position of stability and provide limited lateral positioning. The pads are particularly effective when positioning and stabilizing mild spinal deformities. A fourth and fifth tier as well as peripheral supports can be added to the system when the seating problems are more complex. Various hinge and locking mechanisms let the pads move through six degrees of freedom. ■