Orthotics is a field concerned with design, manufacture, and implementation of orthopedic devices called orthoses. An orthosis can be as simple as a splint, band, helmet, or a brace that is more complex in nature. These devices are used with body segments such as joints, extremities, even the skull, for a variety of reasons—assisting, restricting, or stopping movement, reducing forces exerted, and helping promote tissue healing.

Main applications of orthoses also include remolding of the body segment for correcting deformities, its function, or serving as an attachment for assistive devices. There are many different orthotic devices available for human use. A variety of upper-limb orthoses such as clavic-
ular, shoulder, arm, elbow, hand, combinations of forearm-wrist, forearm-wrist-hand, forearm-wrist-thumb as well as lower-limb orthoses for knee, ankle-foot, knee-ankle-foot are commonly used. Sport rehabilitations require an array of orthoses in the form of braces. Prophylactic, functional and knee rehabilitation, and unloader braces are mainly used in sports applications. Other important implementations of orthotics are in spinal and dental medicine.

We’ll look closely at the design and manufacturing of cranial remolding orthoses—head bands and helmets—as well as at body shields for protection of organs after surgeries or transplants. Both groups of orthoses are simple in terms of their design and manufacturing, but have to conform to a certain anatomic form and material requirements.

Cranial Remolding Orthosis

Cranial remolding orthosis are employed when an infant or baby’s head have deformational or positional anomaly. Deformational plagiocephaly is a condition where a baby’s head has a flattening appearance on one side of the head resulting in facial asymmetry. Sometimes this large area of flattening distorts the skull greatly, making it parallelogram-shaped.

Other similar disorders include: brachycephaly, a symmetrical flattening of the occiput where infants or babies have little or no rounding on the back of their head and appear to have a disproportionate and wide head; and scaphocephaly—an elongated (long and narrow) head shape with compensatory growth in the front and back of the skull as well as asymmetric brachycephaly, a complex disorder of combined brachycephaly and plagiocephaly.

Craniosynostosis can cause a deformational head shape due to premature joining of a skull’s sutures and may require surgery. Non-synostotic or positional plagiocephaly does not require surgery and mild cases may correct themselves within the first six weeks after birth without any interference. However, more serious cases can be treated with a custom-made head band or helmet by redirecting the skull growth to achieve symmetry. A few weeks after starting to wear the orthosis the babies exhibit improvement. However, the patients should continue to wear the device until full symmetry is achieved. As the baby’s head grows, the head band or helmet needs to be adjusted by a qualified practitioner for proper fit and function.

Since the 1970s, several remolding helmets and associated protocols for treatment have become available. In 1998, the FDA categorized cranial orthosis as a Class II medical device, imposing strict regulations and requiring 510(k) clearance. To avoid this expensive and labor-intensive process, many orthotists stopped providing this important device.

Different Companies and Different Cranial Remolding Orthoses

There are different types of cranial remolding orthoses for different anomalies mentioned above. Remolding orthoses are most effective within 4–12 months of the birth. Variation also exists in terms of plastic materials used, presence or absence of soft lining materials, straps, and ventilation holes.

Companies such as Ballert Orthopedic (Chicago, IL) focus on the complete coverage of the cranium with a helmet design. According to the company, many orthotists focus primarily on the upper cranial vault with their remolding bands. However, infants and babies have sutures over and around their ears as well as on the top of their head. The remolding helmet designs restrict skull growth in the direction of the bulge while encouraging its growth in the direction of the flattening making them effective. In this company’s view,
remolding bands do not have adequate coverage over and around the ears and therefore allow growth in the bulging area, adding to its deformation. In contrast, we point to Orthomerica (Orlando, FL), which offers a wide variety of solutions, including:

- **STARband**: This design is for all cases except scaphocephaly, where the head has a long, narrow shape. The band is made of a plastic shell and a 1/2" (12.7-mm) foam liner. The orthotist sees the baby every two weeks and possibly more often during periods of rapid growth and may shave additional material out of the band to allow more space in the areas of flatness. The side and top openings make it a lightweight and easy to apply orthosis.

- **STARlight Bivalve**: This design was originally created to treat infants with scaphocephaly. The mold to make this orthosis is usually altered to allow more space along the sides of the infant's head for additional growth, but it can also be altered to handle other head shapes. It is made from clear plastic with a front and back shell held in place at the top. It also has a Velcro strap that fastens at the back of the orthosis. The clear material enables visualization of the areas of total contact and space, and can be modified with a heat gun to accommodate growth in specific areas.

- **STARlight Band**: This orthosis is made of clear plastic, and has side and top openings similar to the STARband. It is an extremely lightweight band, and is beneficial for very young babies, or for an infant who may need another orthosis for a short period of time until he or she is rolling or sitting up independently. This band can be heat-molded to accommodate growth.
Clarren Helmet: This design was originated by Sterling Clarren, MD, in 1979 to treat infants with deformational plagiocephaly. It is made from a plastic shell with a thin liner for comfort. All the modifications are built into the helmet from the start, so follow up appointments are less frequent than with other types of orthoses. This design comes with a chin strap to help suspend the orthosis on the infant or baby’s head.

Design and Manufacturing Process

There are two alternative paths in making custom-fitted remolding bands and helmets, the traditional way and the modern method based on modern tools.

In the traditional way, the orthotist place a nylon stockinette on the baby’s head. A cast (negative) impression of the head is taken using plaster or plaster bandages (splints). The plaster material sets in between 15–30 min. As the cast is removed the orthotist will make marks where the eyes, nose,

Dow Corning’s Deflexion, S-Range. There are six products in the Deflexion range: Two S-Range products and four TP-Range products. Products vary in terms of their weight, thickness, feel, degree of breathability and impact performance levels. The S-Range Deflexion technology is based on spacer textiles impregnated with specially formulated energy absorbing silicone polymers.
ears and the centerline are located. The negative impression is then filled with liquid plaster to obtain a positive impression which is the 3-D model of the baby's head.

Accuracy of the negative impression may be in question due to the thin wall of it and the removal process. An orthosis is then fit to the positive impression after making changes to accommodate specific areas of directional growth of the skull. Hard plastic shells are used with soft foam liners as band or helmet materials.

Modern methods of fabrication are based on laser scanning of babies’ heads. Orthomerica’s STARscanner is the first system to receive FDA clearance. It has two side walls with two eye-safe Class I laser sources on each side and a total of eight cameras. The orthotist places a stockinette cap embedded with sensors on the baby’s head. The cap helps with the scanning process and allows specific measurements. The digitization process takes less than two seconds and is accurate up to 0.5 mm, making it far superior to the previous method.

Protective Materials for Possible Medical Applications

Today there are many uses for modern protective materials ranging from military to athletic. However, use of protective materials in the medical field is relatively new and there is great potential for growth. Many companies and researchers at universities are finding ways to develop better and better protective materials to be used in orthoses. Doctors are now prescribing protective braces and pads for patients with transplanted organs, most notably, transplanted kidneys. Below is a summary of different companies and their products that can potentially be used alone or in combination with other materials for such medical applications.

Dow Corning (Midland, MI), a materials company, has developed a product called Deflexion. Deflexion is based on textiles, as its scaffold with silicon impregnated into the textile material, allows for flexibility as well as toughness. Thus far, Deflexion comes in a variety of
shapes and sizes and its energy absorption ranges from 0.7 to 28 kN. All are washable and can perform at 18° C. In terms of form fitting for parts of the body, it can be custom-molded for any anatomical position.

Another company on the rise in protective materials is Zoombang Protective Gear (Irwin, PA). Zoombang has developed a special shear-thickening polymer, Zoombang. A shear-thickening liquid is one that hardens upon sudden impact while absorbing the energy of the impact. Shear-thickening has become a very useful property in protection of the human body. The pads containing Zoombang at rest are filled with the liquid. Therefore, it is very comfortable and formfitting for wearing on the body as well as lightweight and not a noticeable piece of equipment. It can be used to protect transplanted organs, such as kidneys, or insulin pumps.

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Gor-Tex by W. L. Gore and Associates (Newark, DE) has also been in the field of protective materials, not protection from blunt force, but rather protection from extreme elements such as wind and cold temperatures. After surgery it is important to keep the transplanted organ away from the elements. Gor-Tex provides some of the best protection from the cold and wind and has been used by a range of people from outdoorsmen trying to stay warm on camping trips to Navy SEALs trying to keep out the wet and cold in the most extreme environments. ME