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Latest Trends in Personalized Medical Devices

INTRODUCTION

The past decade has brought sweeping changes to the medical device industry, and the pace of development won't be slowing anytime soon. New regulations, smarter data capture, and rapidly emerging technologies such as 3D printing and robotics have introduced new complexities and challenges that healthcare providers will likely need help navigating.

Many new technologies are now entering the market in the absence of data quantifying their value. Of particular concern are medical devices marketed as "personalized" (aka "customized")—and at a premium price without evidence that they improve patient outcomes or lower care costs. There is little, if anything, to go on in making the buy-or-forego decision.

This executive briefing reviews some of the currently trending personalized medical devices used during orthopedic, spine or cranial surgery. It also provides guidance on making informed purchasing decisions about these expensive medical technologies.

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PROS AND CONS OF PERSONALIZATION

Personalized medicine is often defined as "prescribing the right patient the right drug at the right time." However, in the surgical field, it generally pertains to tailoring treatment to individual patient needs, preferences and characteristics across all stages of care—including when making a diagnosis, creating a treatment plan, doing preoperative preparations, giving postoperative care and preventing complications.

When it comes to orthopedic, spine and cranial surgery, the introduction of personalized medical devices is a relatively recent occurrence. While many of the newly available products can help surgeons conduct better preoperative planning, and potentially shorten operating times, there is little evidence to suggest they contribute to better clinical outcomes. The data deficit can make it difficult to separate positive medical advancements from clever marketing.

"I think some of the new personalized technology could lead to significantly better outcomes," says Chris Stewart, AVP, inSight Advisory – Medical Device Management. "However, hospitals need to weigh whether the added expense actually benefits patients. In some cases, companies are charging a premium for a customized product that may not be adding any real value."

Not only do personalized medical devices typically cost more than non-personalized ones, Stewart adds. They also tend to require more extensive preoperative planning, including expensive imaging tests. That means their use may cause procedural costs to rise without any discernable value-add for patients.

ORTHOPEDIC MEDICAL DEVICES

Orthopedic surgeons have access to some of the only truly personalized medical devices on the market, notably the ConforMIS knee implant.

The device uses preoperative scans to model patients' knee and make an implant unique to their anatomy. Using ConforMIS involves more legwork before surgery, since patients get a CT scan and X-rays to make exact measurements of their arthritic knee. Computer software transforms the CT image into a 3D model and then virtually rectifies any deformity in order to restore the knee to its pre-arthritic condition. Once the synthetic implant is ready for implanting, patients must undergo surgery within six months to ensure the personalization remains true to their anatomy.

The ConforMIS knee implant is so new to market that there is little data to suggest it improves patient outcomes. Some surgeons favor the device because it minimizes invasive techniques and blood loss, and promotes a

shorter operative time. The precision fit and alignment may lead to less postoperative pain and a quicker return to normal activities; however, the impact on patient-reported outcomes has yet to be demonstrated.

Custom cutting blocks, another advancement in orthopedics, also involve taking patient scans prior to surgery—in this case, to create patient-specific instrumentation to improve the alignment and outcome of total knee replacements. Custom cutting blocks may simplify surgery by reducing the number of steps the physician needs to take and the number of surgical instruments used. Surgeries can be completed more quickly because they know they are sawing in precisely the right place. However, the additive cost of custom cutting blocks can be hundreds of dollars more than the traditional variety—and without real evidence of any kind that their use helps surgeons deliver better patient outcomes.

Unlike custom cutting blocks and the ConforMIS knee implant, the advertised custom features of some medical devices have less-than-impressive practical use. For example, gender-specific knee implants are customized based on typical sizes—not necessarily the frame of an individual woman. A 2012 study[1] found that women who had a gender-specific implant in one knee and a traditional one in their other knee reported no differences in surgical outcomes.

CRANIAL AND SPINAL PERSONALIZATION

3D mapping and printing technologies have facilitated customization of medical devices and procedures in the cranial and spine surgery fields. One example is 3D mapping that helps surgeons make more precise preoperative calculations, says Brent Ford, clinical director of inSight Advisory – Medical Device Management. However, he adds, the implants used in patients aren't actually personalized to their specific measurements.

Spine surgeons might also use 3D mapping to recreate patients' bone structure, to minimize the guesswork they would otherwise have to do. For patients who are diagnosed with scoliosis and opt for surgery, for example, a physician could use 3D mapping to replicate bone structure and determine the best way to approach the procedure. In contrast, traditional scans force surgeons to make countless quick decisions once a patient is on the operating table.

The preoperative work of 3D mapping is more costly than X-rays or other scans. But it can shorten surgical times and lead to more effective procedures.

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Other examples of customization would include:

3D-printed interbody spacers. 3D printing technology can be leveraged to create a spacer customized to patients' measurements and surgical needs. Since these spacers are made from a material that promotes faster and easier bone fusions, the added benefit is that it sets up patients for better long-term outcomes. It's possible that the added upfront expense of the enhanced material could be offset by the fact that expensive osteobiologics may no longer be required (as with traditional spacers) to promote bone growth.

Custom cranial implants. Many cranial implants come from established companies, such as Biomet, Stryker and DePuy Synthes. However, in 2015, a boutique firm called Kelyniam started offering custom implants made from polyether ether keytone (PEEK) OPTIMA, a durable, colorless polymer used to replace portions of the skull after a head trauma. While most custom PEEK cranial implants take several days to make, Kelyniam offers a rapid turnaround times of 24 to 72 hours. However, experts say there's no need to rush a custom cranial implant. In general, implants can't be attached until the swelling goes down after a trauma, which can take several days or longer. Custom PEEK cranial implants are expensive, costing up to $15,000, although a 2016 study[2] found that they result in satisfactory outcomes.

External fixation. When it comes to craniofacial and spine surgeries, external fixation allows for a greater degree of customization. This is the case with the Magnetic Expansion Control Rod, or MAGEC Rod, a spinal growing rod for children with scoliosis. After an initial procedure to implant the device, doctors lengthen the magnetically-controlled rod as children grow. This non-invasive procedure can be done in a surgeon's office and scheduled according to children's growth patterns.

Traditional spinal rods are used in children whose scoliosis is too severe to be controlled with bracing or casting. These rods are surgically attached to the spine above and below the curve, and are lengthened during follow-up surgical procedures as children grow. This allows the spine to continue growing while managing the curve until children are old enough for spinal fusion surgery. However, traditional rods require several invasive, painful procedures. Using external fixation, MAGEC rods make this lengthening process faster and less invasive.

The vertical expandable prosthetic titanium rib (VEPTR) is another example of personalization through external fixation. This spinal implant is often used in children who suffer from thoracic insufficiency syndrome, a rare condition characterized by the inability of the chest to support normal breathing or lung growth. The VEPTR is a metal rod that is curved to fit the spine and placed in an up and down position on the ribcage. It can be made longer as children grow, helping the spine to straighten and allowing the lungs to develop and fill with enough air to breathe. The device effectively rebuilds the chest over time by making it larger, longer or more normal in shape and size.

In these cases, personalization through external fixation leads to greater patient satisfaction via fewer invasive procedures and by minimizing pain.

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TOWARD MORE INFORMED DECISION-MAKING

Suppliers often market their personalized medical devices with the promise, but not the proof, that their products make surgeries faster and easier, and improve patient outcomes. Here are a few tips for making informed budgetary decisions:

Have a system in place to vet new technology. Given skyrocketing supply costs, it's no longer feasible to purchase medical devices based purely on physician preferences. Although many hospitals have value analysis committees, it is still surprisingly common for purchasing decisions to be made based on marketing brochures and physician requests. A more rational approach is to create a rigorous, formal process for evaluating new technology that is focused on identifying clinically significant devices that are potentially worth a higher price than predecessor products.

Seek out the data. The FDA's application process for most medical devices does not require clinical data, leaving little incentive for manufacturers to conduct relevant studies. However, hospital committees seeking to reduce costs and provide additional value could demand proof that newer, more expensive devices are effective, efficient and better for patients. Before making the purchasing decision, ask medical device sales reps for clinical data or seek the advice of a consultancy that can help comb the literature for such proof.

Prioritize patient benefits over physician preferences. Although hospitals bear the cost for cutting-edge medical devices, they often (and understandably) leave utilization decisions up to physicians. Unfortunately, their decisions are often based on factors unrelated to either cost or patient outcomes—such as personal experience with a product, trust in a manufacturer or greater comfort during procedures. Before catering to physician preferences, initiate a conversation with them about the impact their choices have on patient satisfaction and clinical outcomes.

HOW HEALTHTRUST CAN HELP

HealthTrust's inSight Advisory – Medical Device Management team can assist providers in making informed decisions and answer the demands of value-based payment models, lower fee-for-service reimbursement and rising healthcare consumerism. This includes reviews of new technology and sourcing strategies for physician-preference items that are cost-effective—as well as supported by clinical evidence, best practices and guidelines for appropriate use.

Our team draws on the expertise of more than 150 physician advisors across 25 medical specialties. These advisors help us evaluate cutting-edge technology by reviewing and grading clinical studies, gathering data and providing an unbiased analysis of product advantages and disadvantages. We share our insights with

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The Future of Personalization

Device makers are working on implants that can provide feedback to physicians about infection or failure, or deliver important drugs such as antibiotics. Here's a sampling:

- Sensortech's Bluetooth-enabled knee replacement was developed in 2013 to give doctors real-time data, reducing the duration of surgery. Sensortech believes this technology could be used to give wireless updates on the wear and tear of an artificial joint.
- At Renssalaer Polytechnic Institute, researchers are developing sensors to tell doctors what's going on in patients' body, including knee pain following joint replacement surgery and the start of an infection at a surgical site.
- NeuroPace developed the responsive neurostimulator system (RNS) system, an implant that scans electrical activity under the skull to identify early signs of seizures in people with epilepsy. When the RNS system recognizes early seizure symptoms, it releases a targeted pulse to cut it off.

physicians and decision-makers at the hospital level, enabling them to reduce unwarranted clinical variation while making the best-value technology available in their operating rooms and physicians' offices.

The size and purchasing power of our collective ensure our partners good pricing on both national and custom contracts for personalized medical devices that have value in shortening surgical procedures, assessing patients' needs and potentially improving their clinical outcomes.

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