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Reshaping total hip replacements:

Using exponential technologies to improve patient outcomes, drive economic benefits, and create growth opportunities

The future of total hip replacement will likely be very different than today. “Push” factors such as aging populations in the developed world that are increasing demand, shrinking health care budgets, longer life expectancies, and higher patient expectations, when combined with “pull” factors such as the advent of new exponential technologies, promise to change the experience for patients, physicians, providers and medical device manufacturers. As with any major disruption to the status quo, we believe the winners will be the ones who are faster to adopt to the new normal. The first step in successfully navigating change is recognizing the major drivers.

The convergence of exponential technologies – 3D printing, embedded sensors, “smart” materials, and others – combined with a redesigned care delivery model for total hip arthroplasty (THA) – have the potential to improve patient outcomes and drive measurable economic benefits. Potential advantages include earlier and more effective diagnosis, decreased pre-operative and procedure times, lowered post-operative infection rates and treatment costs, and reduced recidivism. When evaluating future care delivery and commercial models, physicians and executives should consider the opportunities and risks associated with such changes.

Two recent US government initiatives may have implications for the future direction of THA reimbursement: Bundle Payment for Care Improvement (BPCI) and Comprehensive Care for Joint Replacement (CCJR). In 2015, the Centers for Medicare and Medicaid Services (CMS) launched CCJR, mandating bundled payments for knee and hip replacements in 75 metropolitan areas starting in 2016.[1] The CCJR program makes hospitals financially accountable for the cost of surgery and subsequent hospital stay, as well as payments to the physician(s) performing the surgery and any and all subsequent medical costs in the 90 days after patient discharge. With an estimated USD $7 Billion in Medicare reimbursement[2] for joint replacements, these initiatives promise to significantly impact the economic future for providers, payers, and medical device suppliers.

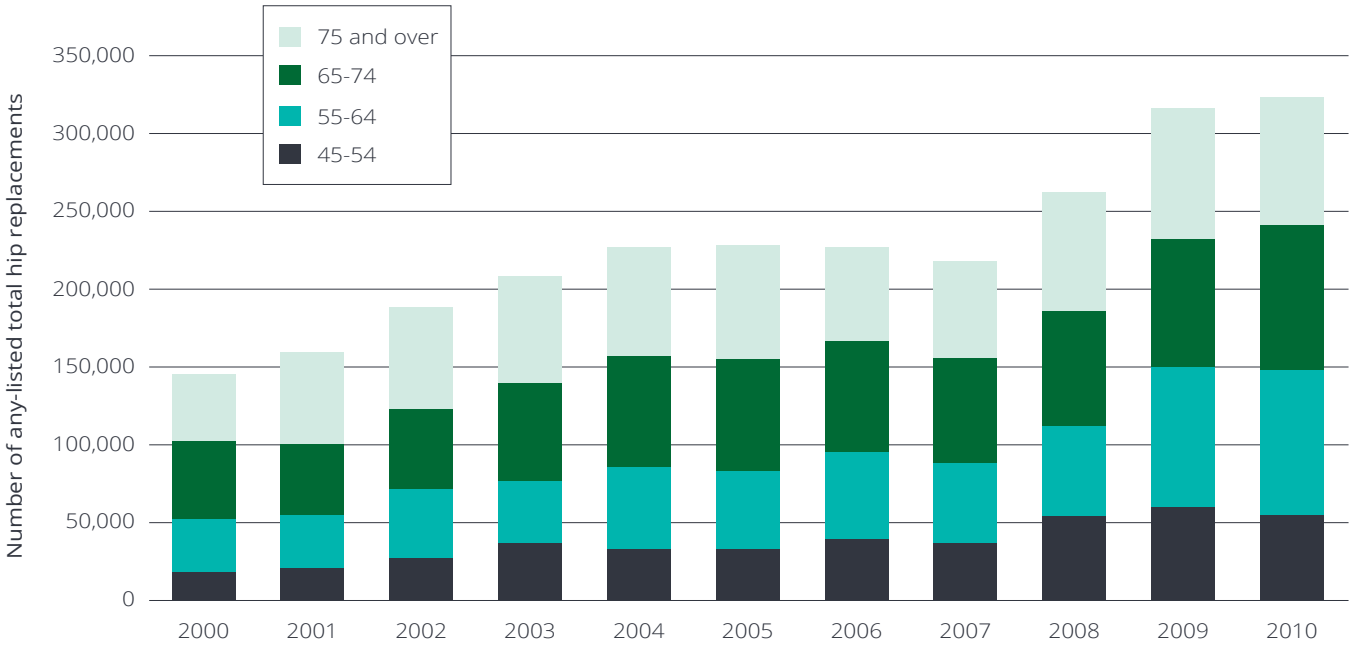
What's at stake

Every year, physicians in the United States perform more than 311,000 total hip replacements in patients aged 45 years and older (Figure 1),[3] with an expected future growth rate of 3.1 percent annually.[4]

With a 95 percent success rate,[6] THA surgery has improved quality of life for millions of people and provided a growing base of business for providers, payors, and medtech companies. Still, THAs can be costly. From 1998 to 2011, total hip implant prices increased nearly 300 percent.3 Surgery may cost $40,000-$65,000 with a device list price of $13,000, compared with a manufacturer cost of goods of roughly $350 for the device and hospital list price of $4,500-$7,500.[7] Rationale for this pricing is largely due to the traditional fee-for-service reimbursement model where surgeon preference was a major factor in device choice and hospitals were able to increase prices charged for procedures.[8] Surgical complications can be costly, as well; periprosthetic joint infection, for example, is estimated to become a $1.6 billion burden by 2020.[9]

An uptake in health care's use of exponential technologies such as advanced digital imaging, robotic surgery, embedded sensors, and other innovations (see sidebar) may boost THA growth beyond its anticipated 3.1 percent CAGR. When used in concert with a redesigned THA delivery model, exponential technologies can increase efficiency, decrease costs, shorten post-operative recovery, and improve the patient's pre-, peri- and post-operative journey. In addition, increased uptake of exponential technologies in THA creates growth opportunities for medtech companies; however, it is important that commercial, R&D, innovation, and finance executives consider how these technologies may impact current and future-state operations and plan accordingly.

Figure 1: Total US hip replacements among inpatients aged 45+, 2000-2010[5] (latest date for which data is available)



Exponential technologies can provide clinical and financial advantages

The application of exponential technologies in hip replacement surgery has the potential to provide substantial clinical and financial advantages. Defined as technologies in which every year the power and/or speed are doubling and/or the cost is halved,[10] the following are examples of exponential technologies and selected medical applications:

- **Advanced digital imaging** creates visual representations of internal human anatomy, usually in the form of three-dimensional images. Compared to existing imaging techniques, pre-, peri-, and post-operative digital images can be used to obtain a more accurate picture of internal patient anatomy, thus often enabling improved patient outcomes throughout the continuum of care. Advanced imaging also includes remote viewing/reading of images and artificial intelligence (AI)-assisted analysis.
- **Additive manufacturing (3D printing)** adds layer-upon-layer of material to produce a three-dimensional object. Polymers and metals are among the current materials used in 3D printing, and the process is expanding to bioprinting, the printing of human tissue.[11]
- **Robotic surgery** uses robots to help surgeons perform procedures with improved accuracy and often with less invasiveness than manual procedures.
- **Embedded sensors/smart materials** use sensors placed peri- or post-operatively to monitor patient outcomes. Smart materials have the ability to change in a controlled and predetermined way based upon external stimuli such as pH, temperature, electric fields, and bacteria.
- **Telemedicine** uses remote methods to connect patients with caregivers throughout the patient journey.

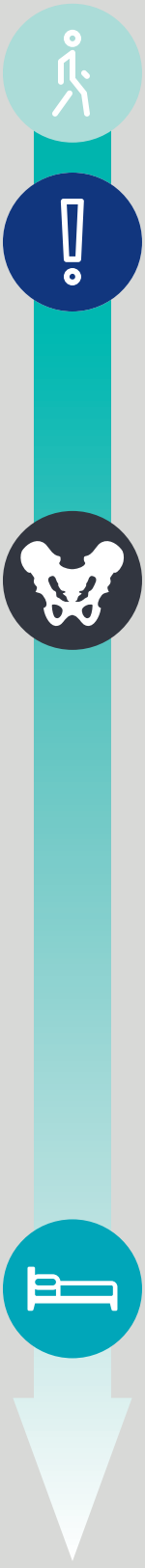
While exponential technologies may provide clinical advantages in patient care and outcomes, stakeholders likely will need to overcome hurdles in several key areas:

- **Care providers/physicians**: Adapting physician practices and conducting clinical end-user training to spur adoption
- **Manufacturing**: Funding incremental R&D costs for enabling compatibility between existing products, virtual imaging, additive manufacturing, and robotics.
- **Regulatory**: Overcoming regulatory restrictions for additional indications for use (IFU), if needed, to apply the technologies as intended during patient journey.

As evidenced by previous innovations in orthopedics, these hurdles are not insurmountable and should not preclude an organization's efforts to pursue a reimagined THA.

Our take

Using exponential technologies as part of a redesigned THA delivery model may drive beneficial changes for patients, providers, payors, and medtech companies during each stage of the diagnosis and treatment path.



Pre-diagnosis

Prior to being diagnosed with a condition such as osteoarthritis or osteonecrosis, a patient will likely report having joint pain, stiffness, and swelling. Sometimes it may be difficult to schedule a timely in-person appointment with primary and specialty physicians.

Potential impact of exponential technology

The patient may choose to see a triaging physician via a telemedicine appointment or at a walk-in clinic with advanced virtual imaging. This approach could result in a prompt, shorter interaction in which the physician determines if that the patient should see a specialist for consideration of a THA surgery or seek alternative treatment, such as physical therapy.

Diagnosis and implant preparation/production

Following an initial diagnosis and potential indication for hip replacement, a patient may visit a specialist for an anterior-posterior pelvic x-ray, where osteoarthritis and narrowed joint space might lead to the decision to undergo a THA.

The surgeon may record the various dimensions of the patient's hip including acetabulum size and rotation, femoral neck-shaft angle, and limb lines to determine the range of appropriate implant sizes. Typically, the surgeon records these measurements by hand directly on the x-rays or via digital imaging software.

Potential impact of exponential technology

Alternatively, advanced digital imaging may provide more accurate measurements to aid implant size selection, and additive manufacturing/3D printing capabilities may facilitate design and engineering of a customized implant. For example, some patients need higher-density polyethylene in regions of the femoral neck and less highly cross-linked polyethylene in the femoral shaft

Producing customized implants based on highly accurate digital imaging (examples of which are already evident in the market[12]) could reduce complications from dislocation, loosening, instability, wear (osteolysis), leg length discrepancy, fracture, and periprosthetic joint infection. In addition, an increase in customized implant production could encourage companies to invest in distributed, smaller-scale manufacturing facilities in areas of high-density procedure locations, potentially reducing surgery lead times and logistics costs. These benefits may be further strengthened as the future of implants shifts from complete removal of patient bone and replacement with foreign implants to partial/no removal and replacement enhanced with cartilage regeneration in the patient's native hip.

Peri-operation

On the day of surgery, a patient will arrive at the hospital several hours in advance and the surgeon will prep him/her. An orthopedic company representative often joins the surgeon to help specify and assemble the required implant.

Despite pre-op measurements, the surgeon may require multiple attempts to find the appropriate acetabular cup size and femoral shaft angle. This lack of proper pre-op implant sizing can lead to excessive or insufficient bone reaming as well as prolonged operating time.

Once the surgeon has placed the implant, he/she may use existing surgical navigation tools to ensure proper alignment and implant positioning. However, these tools may provide only limited evidence of appropriate fit due to their two-dimensional perspective and/or lack of real-time imaging.

Potential impact of exponential technology

Using additive manufacturing and advanced digital imaging during a THA procedure can mitigate complications by providing more accurate measurements and customized implants. A surgeon may be able to generate the closest approximation possible to what the patient's hip actually was prior to degenerative changes. In addition, using robotic surgery may improve implant placement accuracy and precision, reduce patient morbidity, and decrease operating time.[13] Other technologies, such as embedded sensors, can be placed during the procedure and leveraged post-operatively for early detection of misalignment and infection.[14]

Post-op

Post-surgical periprosthetic joint infection (PJI) is a serious adverse event which, if not detected early, significantly increases the potential for patient morbidity, disability and, sometimes, mortality. The incidence of PJI after a THA can range from 0.3 – 2.2 percent, and result in an estimated financial cost to the health care system of more than $96,000 per patient including the costs of surgical revision.[15] Current methods of detecting infection consist of traditional imaging techniques such as x-ray, CT, and MRI, as well as blood tests.

Potential impact of exponential technology

Nanodevices and embedded sensors at the implant site have the potential to play an impactful role in early PJI detection as well as other unwanted outcomes from a THA, including dislocation, loosening/instability, wear (osteolysis), leg length discrepancy, and fracture. These sensors could detect bacterial DNA and then transmit warning signals and information around which bacterium are present, such as staph species, pseudomonas, and anaerobes, thus allowing treatment to be tailored without the need for a joint aspiration or bone biopsy. This can improve short- and long-term outcomes for patients as well as provide data and predictive analytics feedback on patient type and implant success.

The embedded sensors may also play a role in post-operative patient adherence, especially during rehabilitation. The sensors may help health care providers monitor compliance as well as correct movements, thus potentially predicting the need for coaching and/or physical therapy and rehabilitation interventions to make certain that the patient continues to successfully recover from the THA procedure.

One company that is beginning to transform total knee arthroplasty (TKA) procedures through sensor-assisted technology is OrthoSensor.[16] Its Verasense[17] sensor-assisted TKA replacement can improve soft tissue and ligament balance as well as implant positioning by using sensors to provide real-time, evidence-based date during primary and revision TKA surgeries. OrthoSensor's product is disposable and used intra-operatively to verify that the surgeon has appropriately positioned the joint replacement to achieve optimal patient outcomes. While the product is used only during the procedure and not left in the patient's body, it is a step forward in longer-term joint replacement monitoring.

Long-term monitoring

A hip replacement lasts between 15-20 years, with an average annual failure rate of 0.5-1 percent.[18] During that time, patients typically recover their strength and endurance within three months and are encouraged to visit their orthopedic surgeon every three-to-five years. Some patients, however, may not be able to easily visit their surgeon even if they are experiencing warning signs of side effects, such as pain, swelling, and redness.

Potential impact of exponential technology

Telemedicine can provide easier physician access from almost any location. It also can play a supporting role in physical therapy, where two-way communication between patient-sensored implant and therapy provider could improve results. During physical therapy, patients may be able to go to any gym and use existing equipment to track their recovery progress, such as through range of motion, stability, and strength exercises guided by a smartphone app. Their progress may be captured in the form of data input by the patient and/or video, then sent for interpretation by the healthcare provider.

Improved economics and value

Using exponential technologies in hip replacement surgery has the potential to improve THA economics at patient, health care stakeholder, and population health levels. For individual patients, exponential technologies may shorten the pre-, peri-, and post-surgical journey and help their care team more easily design and make the best hip implant. Also, patients and care providers leveraging telemedicine and embedded sensors may form a more significant and engaging pre- and post-operative relationship.

For industry stakeholders, exponential technologies may alter and improve THA economics and value by reducing the cost of care for payors and increasing revenue and improving margins for providers and implant manufacturers. It is also likely that more patients will be able to receive a THA at an earlier age or more severe disease state, resulting in a larger eligible patient population and increased market size.

At the population health level, exponential technologies may improve clinical outcomes by enabling earlier detection of pre-operative disease states, facilitating more accurate surgical planning, providing a more comprehensive understanding of patient-specific implant sizing, and detecting infection and/or implant rejection earlier.

As the health care market shifts from volume- to value-based patient care and reimbursement, a redesigned THA patient journey can drive improved economics via:

1) Earlier and more effective pre-diagnosis (triage)
2) Faster and more efficient diagnosis
3) Reduced surgical time and/or reduced need for surgery altogether
4) Reduced post-operative infection rates and costs
5) Reduced (or increased time between) recidivism.

The path forward

It is conceivable that one or more consortia[19] within a given health care market could pilot and eventually scale a redesigned THA model targeted toward improved outcomes, economics, and population management. Combining efforts to redesign the THA patient journey, reduce the overall cost and time associated with an aggregated number of THA procedures, and improve economic benefits for each participant may result in lower overall health care costs (via reduced readmission rates and decreased episodic costs) for providers and payors, as well as improved revenue and margin for device manufacturers.[20]
If a manufacturer can gain a competitive advantage through the combined use of some of the emerging technologies and/or provide additional care throughout the patient continuum of care, even if a patient does not ultimately receive a THA procedure, the company may be able to increase its revenues.

Medtech companies assessing business-building opportunities arising from the use of exponential technologies in the THA treatment model should consider the following:

- New technologies and their application cannot happen without appropriate clinical research to validate efficacy, safety, and related considerations, as well as supportive policy and regulatory changes. Companies may want to increase their collaboration with regulators to help advance the new technologies and maintain compliance with changing regulations.
- Medtech R&D organizations will likely require new capabilities – produced organically or acquired – as they expand traditional clinical, materials, and manufacturing process R&D into areas such as additive manufacturing, translating higher-resolution images to production-ready machine instructions, tooling, packing, kitting, etc.
- Quality systems and processes will likely need to incorporate the addition of new technologies into the THA product lifecycle.
- Sales and marketing functions will likely need to adapt traditional commercialization models to reflect the impact of exponential technologies on clinician training and patient education.

Bottom line

The convergence of exponential technologies and a redesigned THA care delivery model are expected to provide numerous benefits to health care stakeholders, including:

- Easier and more efficient patient implantation
- Increased implant-patient specificity and customization, likely enabling longer implant viability
- Earlier detection of infection and implant rejection
- Improved patient satisfaction, clinical outcomes, and health care economic value.

Using exponential technologies in THA also creates revenue and market growth opportunities for medtech companies. However, when assessing future business models, executives should carefully consider how various technologies may impact their current and future-state operations and plan their steps forward accordingly.

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