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EXPLORING THE APPLICATION OF 3D PRINTING IN HEALTHCARE

JANUARY 16, - JANUARY 21, 2018

203 POSTS | 25 PARTICIPANTS

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FOCUS OF THE PROJECT

A leading medical devices company is wanting to enter the 3D printing market for their manufacturing of joint replacements (hip, knee, shoulder, etc.).

While they have established relationships with hospitals and providers, who are happy with the current joints, the company does not currently utilize 3D printing for joints, specifically, but are actively pursuing the capabilities. They do have capabilities to 3D print for less complex items, such as surgical guides and tools, but are in the process of rolling out more advanced capabilities.

Operating on an ambitious timeline, Deloitte sought a more dynamic way to develop product concepts and platforms that address white space opportunities at the intersection of 3D printing and healthcare.

Deloitte Pixel identified Convex.it as the best crowd-based capability to quickly convene target stakeholders in the market and ultimately accomplish this goal. This engagement came together quickly and was executed over a 4-day virtual 'Design Sprint' with 21 external experts.

OBJECTIVES

- 1 Test current 5 hypotheses and understand gaps & alternatives
- 2 Understand the different motivations of various stakeholders and their preferences
- 3 Deep dive into specifics around costs, outcomes, and quality to stakeholders
- 4 Prioritize viable approaches for building a business case with a special focus on 3 of the 5 options

AGENDA

- | | |
|-------|---|
| DAY 1 | Hypothesis Testing & Strategic Options |
| DAY 2 | Stakeholder Motivations |
| DAY 3 | Deeper Dive into Specifics around Cost, Quality, & Outcomes |
| DAY 4 | Viable Approaches for Building a Business Case |

BACKGROUND CONTEXT: 5 BUSINESS MODEL HYPOTHESES

Experts were provided relevant (and anonymous) details of Deloitte's current understanding and their 5 business model hypotheses -- with the goal of providing a common starting point. The 5 models considered were:

Strategic Option 1 **Supply Chain Efficiency:**

Bringing manufacturing closer to time and place of use through 3DP, lowering operating and working capital costs across the value chain.

Strategic Option 2 **Customization of the Product:**

Drive better patient outcomes by creating tailored, fit for patient products through 3DP.

Strategic Option 3 **Own the Operating Room:**

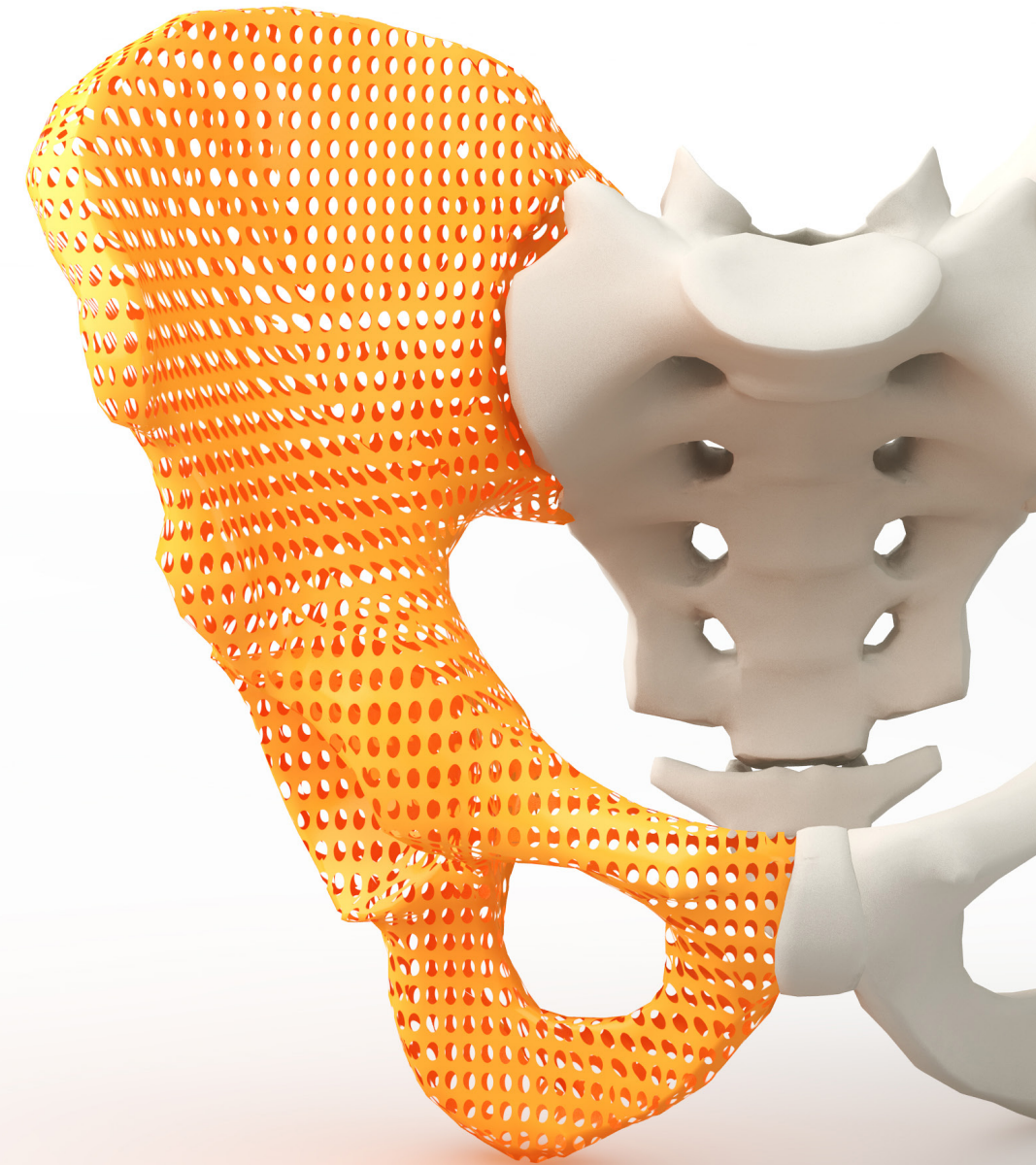
Manage the surgical suite: digital equipment, product training, and scheduling and operations.

Strategic Option 4 **Own the Patient Journey:**

Collect data to improve outcomes and provide advanced analytics to improve decision support throughout the patient journey (e.g. timing of surgical intervention, pre-, peri-, and post-op support, and monitoring and adjustment of recovery).



























Strategic Option 5 **Become the iTunes of 3DP:**

Establish the physical and digital infrastructure and the design platform to enable the ecosystem of medical device designers, manufacturers, and support services.



PARTICIPANTS

Convett.it rapidly identified 21 relevant external stakeholders that were approved by Deloitte. Diverse perspectives included: 3D printing experts, hospital executives, healthcare payers, and orthopedic surgeons.

FACILITATOR	CO-FACILITATOR	CO-FACILITATOR	CO-FACILITATOR	CO-FACILITATOR
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Gaps and Market Needs

Reimbursement Models: There was a great deal of discussion on the importance of understanding the reimbursement mechanics, either insurance, government, or individual payer and justification of premium payment. The main observations are (for the US):

1. Shifting reimbursement models among risk-bearing entities
2. Consolidation of US healthcare industry and resulting consolidation of demand
3. Demand variables in regards to the age of the individuals (and underlying reasons whether acute or chronic) for the 3DP joint
4. The need for outcome studies to support the points of differentiation and cost premium to justify reimbursement: e.g., cost, increased speed of recovery, decrease in pain levels during recovery, increase in quality of life and performance of activities of daily living, decrease in complications, increase in useful life) through the eye of the stakeholder (e.g., payer, patient, provider).
5. It is difficult to get third-party payers to cover the cost of these implants thus posing a potentially significant financial burden on the patient or loss for the hospital. Until more high-quality evidence is published, cost will continue to be the main limiting factor to adoption of this technology.
6. Since we are talking about joints, we are probably going to see the demand weighted heavily in the senior population, which means by definition the support of MA plans and CMS is crucial to the widespread use and success of the technology.

Quality Control and Validation: Related to above, the participants discussed the need for robust, standardized and applied quality control and performance validation which is complicated by the localized, just-in-time nature of 3DP manufacturing.

1. Identifying the level of confidence that the implant will work as designed.
2. Validating the quality/appropriateness of the design and the process used to create it.
3. Lack of evidence to show that either a) implant design, fit, etc. is better or b) patient outcomes are better with specific instrumentation or implants.
4. In order to be considered an essential tool for the healthcare specialists, it needs to be shown that custom implants and the possible additional time in producing them, show obvious real world benefits (less pain, longer lasting etc.).
5. Hospitals need to validate the costs and time they spend. Pre-op planning MIGHT save surgical time and shorten patient recovery time (therefore saving money and time). What if it does not save time for an operation.
6. Customization of implantable joints by definition may not come quickly enough for patients who have need of immediate intervention as current technology would likely require use of CT scan and time for planning/modeling the device.
7. My biggest concern is with supply and demand. It's great that it reduces production time to minutes, but will the manufacturer be prepared for the demand.

Opportunities to Fill Market Gaps

Weighing strategic options: Looking at the 5 options, the participants discussed how these options filled the market gaps and needs in 3DP market. The general approach is that while each are novel and seem out of a text book, none of them are fully satisfactory. Elements of each can develop a hybrid model that fill gaps as this is a diverse market with many different customers.

1. **Strategic Option 1:** Supply Chain Efficiency. Coupled with strategic options 2 & 4, the success of the business model for 3DP joints is required for optimal efficiency and use. Unless the timing of identified need to surgical deployment is superior to off the shelf options, surgeons would likely not use this approach in the general population.
2. **Strategic Option 2:** Customization of the Product. As stated by others in previous posts, the value in customization is potentially better outcomes which can be tailored for the complex population that requires it. But what percent of the population falls into this category? There needs to be a critical mass to warrant the cost.
3. **Strategic Option 3:** Owning the Operating Room. Owning the OR would likely be an expensive proposition for most community-based hospitals, but academic centers or orthopedic-specific hospitals might find value in this approach due to volume
4. **Strategic Option 4:** Own the Patient Journey. Some patients will pay for the advanced therapeutic benefit that customized joints may offer. Payers may even consider reimbursement if it can be proven that length of stay is reduced, readmission rates remain low, cost is decreased [including OR cost], and patient outcomes, e.g., reduced loss of time away from school/work is improved. The journey is the entire experience and both patients and some payers will support 3DP joint replacement once clinical trials and outcomes are favorable and published.
5. **Strategic Option 5:** iTunes of 3D Printing. Measuring quality provides data to drive proper decisions and direction with the device. It's something that's absolutely necessary before resources are utilized, expended or wasted. Yet on the other hand, faster production could mean higher demand and lower prices. The market landscape may become so incredibly massive because the innovation is needed in so many other specialty areas of medicine.

Alternative Solutions

The participants looked at alternative to above solutions as a way to address some of the gaps and needs in the market place.

1. **The fully integrated operating room:** Having a fully integrated platform that allows surgeons to evaluate the patients potential for a custom device, handles the scans, modeling, manufacturing, post processing, etc. will be a market that we will see emerge as the custom devices become validated and more affordable.
2. **Private manufacturing custom devices:** Private companies will start by manufacturing custom devices, the same way ProtoLabs manufactures custom engineering prototypes. This will be big business for a little while, until the tech becomes even more affordable and hospitals can afford to manufacture devices in-house, (the same way many engineering firms are switching to now).
3. **Security measurements:** Security in the 3D printing industry is going to be critical when files are being sold, shared, and printed around the world. When these files include private patient information, it will be a tough problem to solve.

“Spotify” Model Alternative

1. Spare parts for medical equipment
2. Display models (for communication with the patient prior to surgery etc)
3. Training models (that can be sawn and manipulated, colored etc)
4. Anatomical models for students or experimental procedures and innovative thinking (tiny parts can be blown up and we could lose the expensive and poisonous cadavers)
5. Formulas for medicament and 3D printers' pills
6. Instruments, both basics and innovative iterations/new parts

Orthopedic Surgeons

1. Orthopedic surgeons practice how they have been trained and find difficulty accepting new technology.
2. They need to significant improvement in outcome and show demonstrated outcomes, in order to adapt.
3. There are also some concerns that some surgeons would not appreciate changes and/or disruptions to their workflow.
4. The technology needs to offer unique properties for broader acceptance.
5. 3DP could provide competitive advantages, such as marketing, availability of cutting edge technology, and enhanced performance.
6. Surgeons want to have more input into the design process.

Hospital Administrators

1. Hospital admins share similar concerns as orthopedic surgeons, in terms its impact to workflow and need to see improvement in patient outcome before adopting.
2. Similarly, 3DP provides hospitals with unique marketing opportunities, particularly for specific segments of the patient population. Hospital admins also felt that in certain high demand areas, the ability to incur more revenue through higher usage of the technology would be a significant advantage.
3. Hospitals could attract higher quality surgeons if they adapt to this technology.
4. Cost of implementation of technology and/or delivering the service could deter hospitals from adopting the technology.
5. The initial disruption to the hospitals' procurement process could be frustrating if there are changes to the vendor mix and technology services.

Policy and Regulatory Administrators

1. There was a lot of positive acknowledgement of FDA's guidance on the use of 3DP technology, which will spur utilization, innovation and growth in its adoption.
2. There needs to be more evidence on the efficacy of the technology and its impact on outcome.
3. Evidence on efficacy and impact on outcomes were particularly important for CMS, which is the oversight agency for the two biggest government run insurance programs, Medicare and Medicaid. Specifically, because CMS' decisions on payment models and accepted procedures impact almost 100 million patients, it also impacts private insurance decisions on reimbursement rates. And the main considerations for CMS are patient safety, quality of care, and cost of delivery.

Medical Device Manufacturers (MDM)

1. MDMs have an important role to play in this space. In general, the fact that MDMs can become more entrenched in the hospital vendor landscape by offering this technology is a huge plus for their bottom lines.
2. Given MDMs breadth of expertise and technology they could significantly advance the technology and showcase the efficacy and improved outcomes that other stakeholders are looking for.
3. Cannibalism of 3DP devices on existing products and technologies similar to the hearing aid market could cause revenue loss.

Survey Results

Cost:

1. The cost can be higher because the cost of material and level of touch involved.
2. Custom can be more expensive because it is designed to exact specs and the unique make up of the individual - take into account the patients' anatomy, bone condition, life, style, and other factors.
3. Barrier to entry: Perception of cost.

Speed

1. Faster is better because of productivity gains if printer is at the hospital
2. But faster can also be more expensive and may be lower quality; the need for speed however is really dependent on the use. If it is a chronic condition, then the need for speed is much less than for acute trauma.

Outcomes:

1. Not a big difference between 3DP and conventional. Problem with surface finishing and friction pairs still needs to be resolved before any claims for less readmission/revision rates could be made. For custom cosmetic 3DP implants, medical value is very clear

However, there are many ways to showcase improved outcomes

1. Enhanced mobility through personalized designs - (i.e. amputees with particular design needs or desires)
2. Improved wound care (3D skin grafting)
3. Enhanced bone and cell regrowth (ink based)
4. Increased innovation (advanced modeling and planning, nimbleness of design, cheaper faster trial and error for complicated/expensive procedures)
5. Lower costs (dental, hearing, other wearables, made from lighter/cheaper material, decrease middlemen/transportation & delivery of devices)
6. Fewer post-surgical/visit complications (due to personalization/customization, advanced modeling and planning)
7. Increase patient cost share (due to interests in personalization/customization)
8. Improved patient satisfaction (personalization/customization, assumed decrease in post-visit complications)
9. Increase patient endorsement (personalization/customization, fewer complications)
10. Improved capabilities (prosthetics, wearables, organs/skin/human tissue)
11. Lower re-admission rates because of the above
12. Faster operating time, less wastage, better patient satisfaction, reduced surgeon stress.

Faster is better:

1. Decrease variable costs of the OR (staff hours, some materials/supplies)
2. Lower risk of infection due to exposure of open wound
3. Less time patients are under anesthesia (lowers risk, can improve recovery)
4. Increased throughput of other surgeries (not necessarily just joints)
5. Faster can also be better from the eyes of the patient

Business Case:

If there is going to be a business or businesses operating in these areas, they need to consider following:

1. ISO certification
2. Integration with hospital medical databases
3. Hospital, health service and insurance scheme compliance
4. Training schemes for surgeons plus their technical and data management staff.
5. An understanding of the financial and treatment benefits
6. The business case should center on “value”. The 3 strategic options are what differentiate this innovation from others. In sales, the focus of price and differentiation of your product or service provides growth. The 3 strategic options give the innovation's stakeholders sustainability, momentum and value.

Stakeholder Roles:

1. There needs to be willing partnerships between scientists, surgeons and software developers in collaboration with the 3DP manufacturers.
2. We should consider “regionalization” of orthopedic joint implant services where healthcare organizations and physicians choose to collaborate in a joint-venture type of partnership in order to drive both volume and value to patients who are initially willing to pay for the service.
3. Third, there will still need to be studies published to establish the evidence that 3 DP joints offer better outcomes or the money will not follow.
4. To make it work would involve ensuring that a small team (with representation from the 7 stakeholders) work together to drive it at pace. Slow/ineffective communication will result in inertia and nothing being introduced.

Premortem:

1. **Inertia as the largest impediment:** The largest impediment to these strategies becoming successful are those associated with inertia in the industry and the fact that there are many large businesses wishing to protect the status quo.
2. **FDA approval:** Failure to acquire a blanket approval from FDA for custom 3DP joints in quantities larger than 5 is an existential risk. This should be the very first step in market validation strategy for 3DP vendor before company even starts thinking about anything else.
3. **Payer support:** Failure to gain support from payers (for public assistance as well as for private health insurance plans) is vital as the number of self-pay patients is quite limited in any given moment.
4. **Low risk contracting:** Greatest chance of succeeding as a business is to contract 3DP services to industry. In such a case medical device manufacturer (customer) must account for all remaining risks. This is not the most profitable, but safest strategy, at least for initial operations.
5. **Importance of surgeons:** The surgeon plays the greatest role of whether or not this product will succeed. Since the surgeon is ultimately the one performing the procedure she needs to be a part of each relevant phase in product design and development.
6. **Adoption:** In this scenario, it is the surgeons and the manufacturers who are responsible for the failure of the adoption of this technology.



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DAY 1

HYPOTHESIS TESTING AND STRATEGIC OPTIONS

Gaps and Market Needs:

There is a strong consensus that the industry needs to continue to evolve.
It needs to get faster, cheaper and more collaborative.

“Collaborative delivery could create opportunities across Strategic Options to lower costs (e.g., scale of a specialized manufacturer). This is more an additive opportunity to e each scenario.”



Kevin Kujawski
Associate and Focus Area Leader

“Without good evidence showing that we can reliably change clinical outcomes, not just laboratory measurements, it will become increasingly difficult to get third party payers to cover such **expenses.**”



Tyler Keller
Orthopaedic Surgeon

“In today’s business **“customized”** means there’s an additional value coming with a premium. This is great for medical provider. **This is great for implant manufacturer.** This is **not so great for a patient.**”



Alex Kosik
Serial Entrepreneur, Mentor, Angel

“We should also consider how the **process could be speeded up**, as today we don’t have fast enough printers to make a good business case for the time patients spend at the hospital.”



Camilla Nymann
Owner of 3D Business -
creating society of the future

Opportunities to fill market gaps:

Standardization and certification will be crucial for both acceptance of the technology and for effective collaboration.

“Certification and qualification are absolutely the big issues here. Rightfully the process is lengthy, and the larger 3DP healthcare specialises are now beginning to reap the benefits from having gone through the regulatory hurdles.”

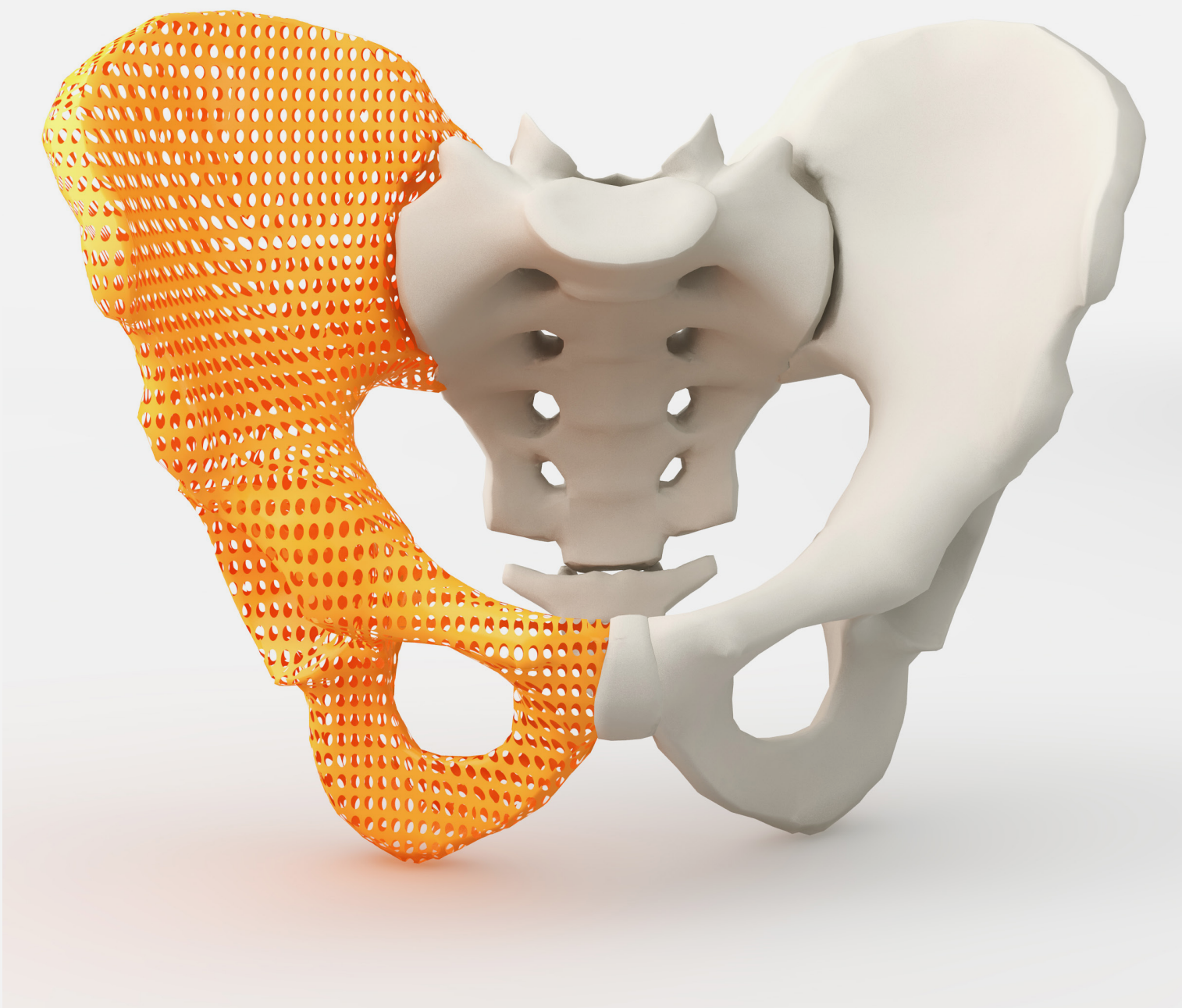


Michael Petch
Editor-in-chief at 3D
Printing Industry

“A printing service business with the **newest equipment** at all times is the better choice. Though we’ll have to make sure that they live up to all standards in order to make medical devised.”



Camilla Nymann
Owner of 3D Business -
creating society of the future



Alternative Solutions:

Open source collaborative platforms could open up new market areas, such as the military.

"Strategic Option 6: An Open Source Innovation model (as mentioned in another comment to a post – could be **Government/Military, University, open collaborative, or hybrid model**)."



Kevin Kujawski
Associate and Focus Area Leader

"A **spotify for 3D printing** was mentioned. It would be valuable for hospitals to log in to a global database with tested and proven generic files."



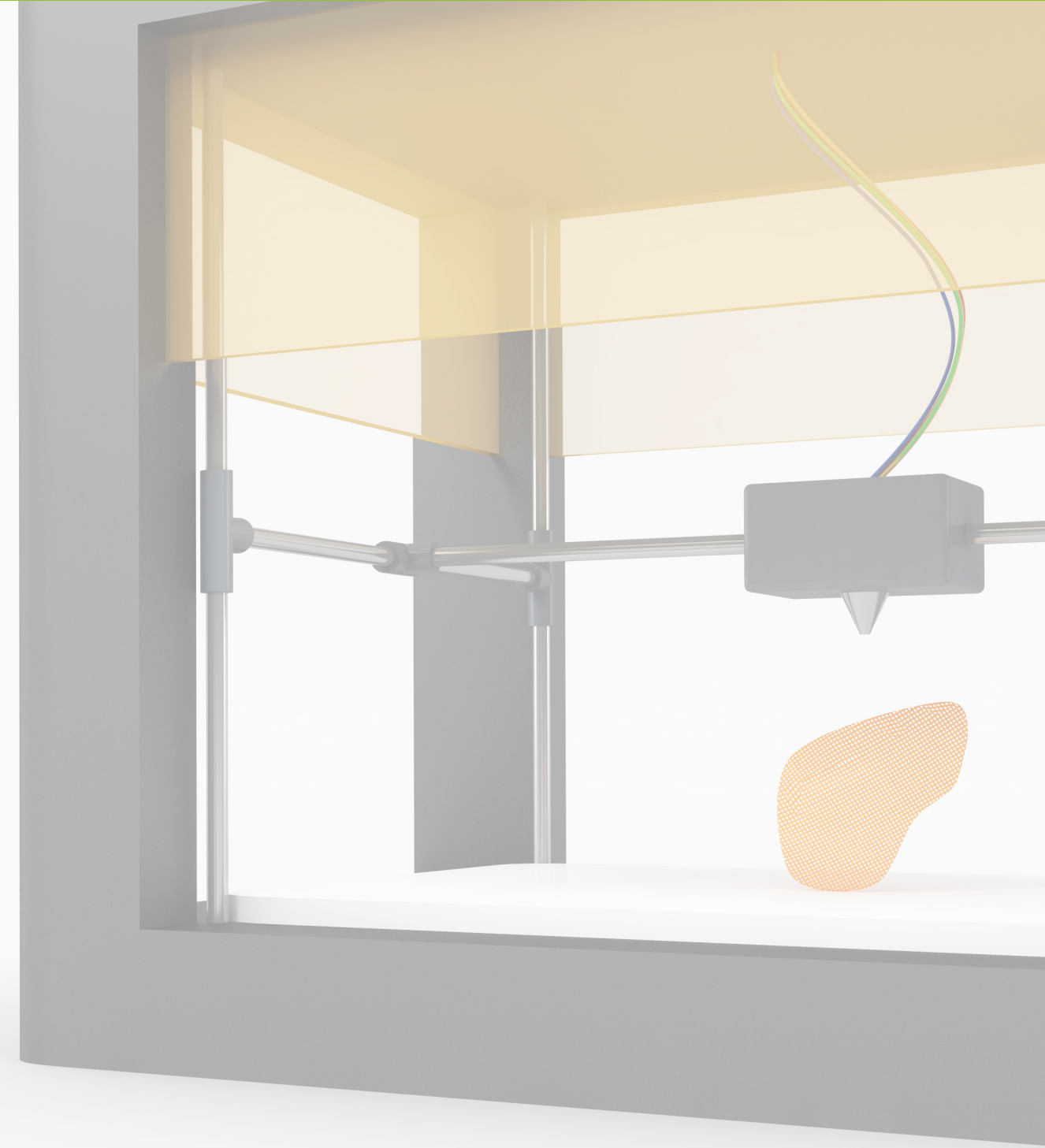
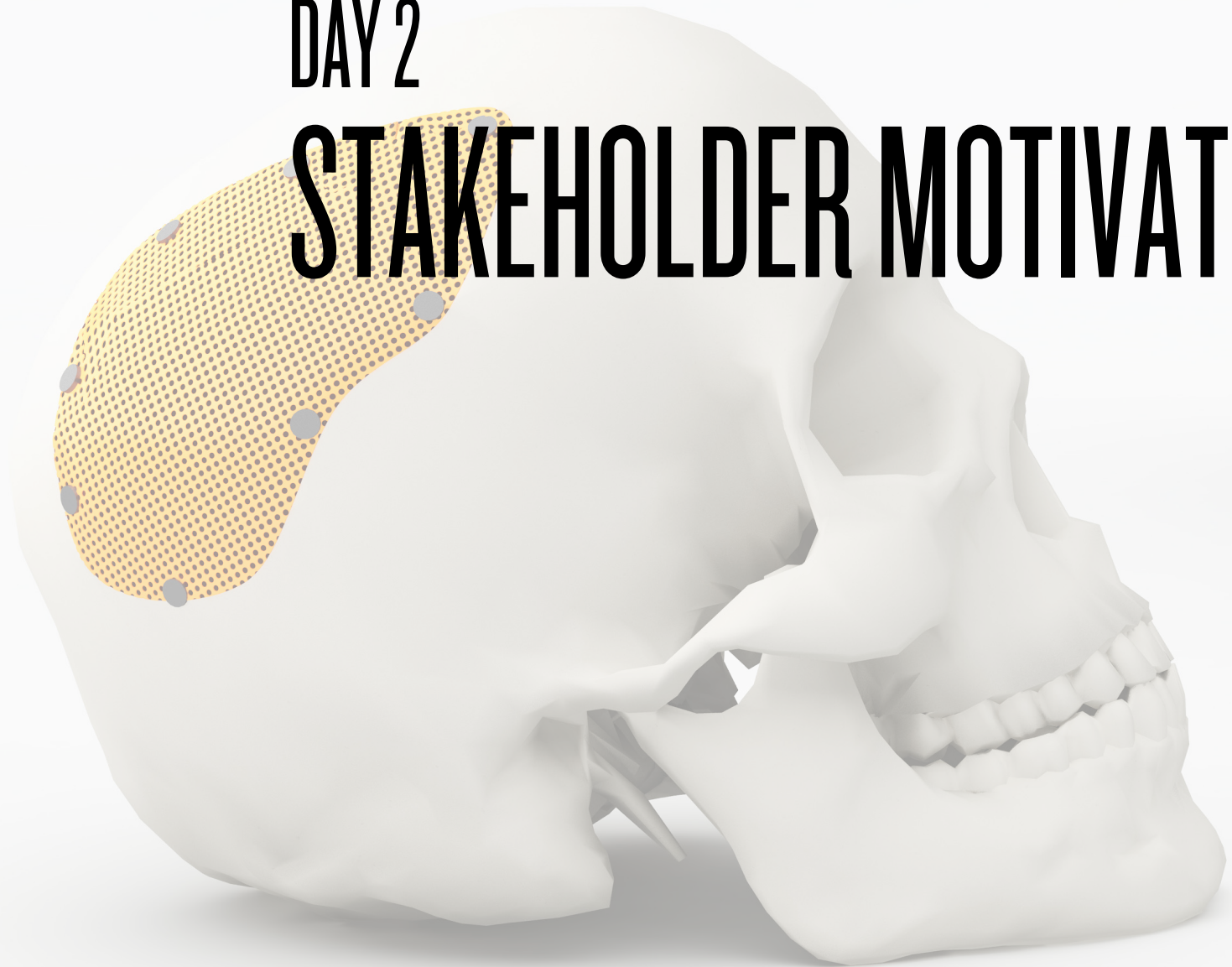
Camilla Nymann
Owner of 3D Business -
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DAY 2

STAKEHOLDER MOTIVATIONS



Summary Stakeholder Motivations:

Patient engagement and buy-in is critical for all stakeholders to come on board. And key to patient engagement is showing value and patient education.

“A key to marketing a 3DP product will be **targeted messaging** to each of the customers. This is challenging for many med device manufacturers. Physician, hospital admin, and patient each have deferring motives. All three need to be onboard an elective device for product to move forward.”



Steven Castle
COO

“Option 4: The low hanging fruit for the patient journey is to provide effective **pre operative counselling** and post **operative explanation** of findings.”



Iain Hennessey
Clinical Director of Innovation at Alder Hey Children's Hospital

“From a patient's perspective, every new treatment should be well **tested, proven, and better** than the previous treatment.”



Camilla Nymann
Owner of 3D Business - creating society of the future

“Medical device manufacturers - must realise that their business model must **change**. They can no longer develop an implant design and sell to the market over a 10 year ROI period, absorbing new patents to prevent competition for their products.”



Ian Gibson
Professor at Deakin University

Summary Stakeholder Motivations (Cont'd):

Unless the cost of the service and the investment associated with the procedures align with existing procedures, 3DP will continue to be a niche technology for rare and difficult to treat issues.

“Such a niche and business model around it, is **contract manufacturing** of 3DP implants as a service business that serves the needs of existing implant vendors and suppliers. Product as a service.”



Alex Kosik
Serial Entrepreneur, Mentor, Angel

“The only thing that matters to admin is the **bottom line**. If custom devices remain more expensive than current products, 3D printed devices will remain only for the patients with rare and difficult-to-treat issues.”



Jerry Ennett
CEO at Taurus 3D

“The question is whether smaller manufacturers can justify the **capital investment** and whether this means (counter to some commentary) that centralisation, rather than decentralisation will occur.”



Michael Petch
Editor-in-chief at 3D Printing Industry

“**Payers** - cost will be the biggest concern for them. Also, changes in disease management allowing for different treatment options that have not been offered in the past will be a struggle for the insurance companies, as they decide to cover services or not.”



Selene G. Parekh, MD, MBA
Co-Chief Foot and Ankle Service at Duke University

Summary Stakeholder Motivations (Cont'd):

Ease of use of the new technology and practices will have a significant impact on the extent of adoption by surgeons.

“As for **medical state manufacturing**, there must be a huge entry barrier due to patient safety requirements, so this would be for the big players which have the ability to invest and move agilely as the tech changes.”



Camilla Nymann
Owner of 3D Business - creating society of the future

“Primary concerns when choosing what technology to adopt are a combination of simplicity of use, and reduction of **post-surgical complications**. He is not as concerned about cost.”

“**Innovation** can sometimes be the enemy for payers, so it is important in very early stages to get them on board.”



Jennifer Dunphy, MBA, MPH
Chief Population Health Officer || Doctor of Public Health Candidate

“**Orthopedic surgeons**- what I have found is that most surgeons tend to practice the way that they were trained and may have difficulty accepting new technology that they are not well familiar with.”



Brandon Barrett
DPM

Summary Stakeholder Motivations (Cont'd):

There is an opportunity to differentiate and market the use of 3DP technology by stakeholder influencers.

“Over time it is reasonable to expect that **payers** would also negotiate printing costs as well as recommend/require use of specific 3DP printing facilities (if not held in house) to physicians and/or patients.”



Melina Davis-Martin
Chief Operating Executive
& EVP | Turnaround Expert |
Executive | CEO | Strategist

“From the hospital administrators and policy segment there might be hidden a **branding opportunity**, being a first mover on implementing cutting edge technologies to significantly improve treatment. Especially the private clinics who are ‘competing’ for patients in a different way that the public hospitals.”



Camilla Nymann
Owner of 3D Business - creating
society of the future

“3DP manufacturers are looking for **new use cases** to prove out the benefit of their machines in a healthcare setting.”

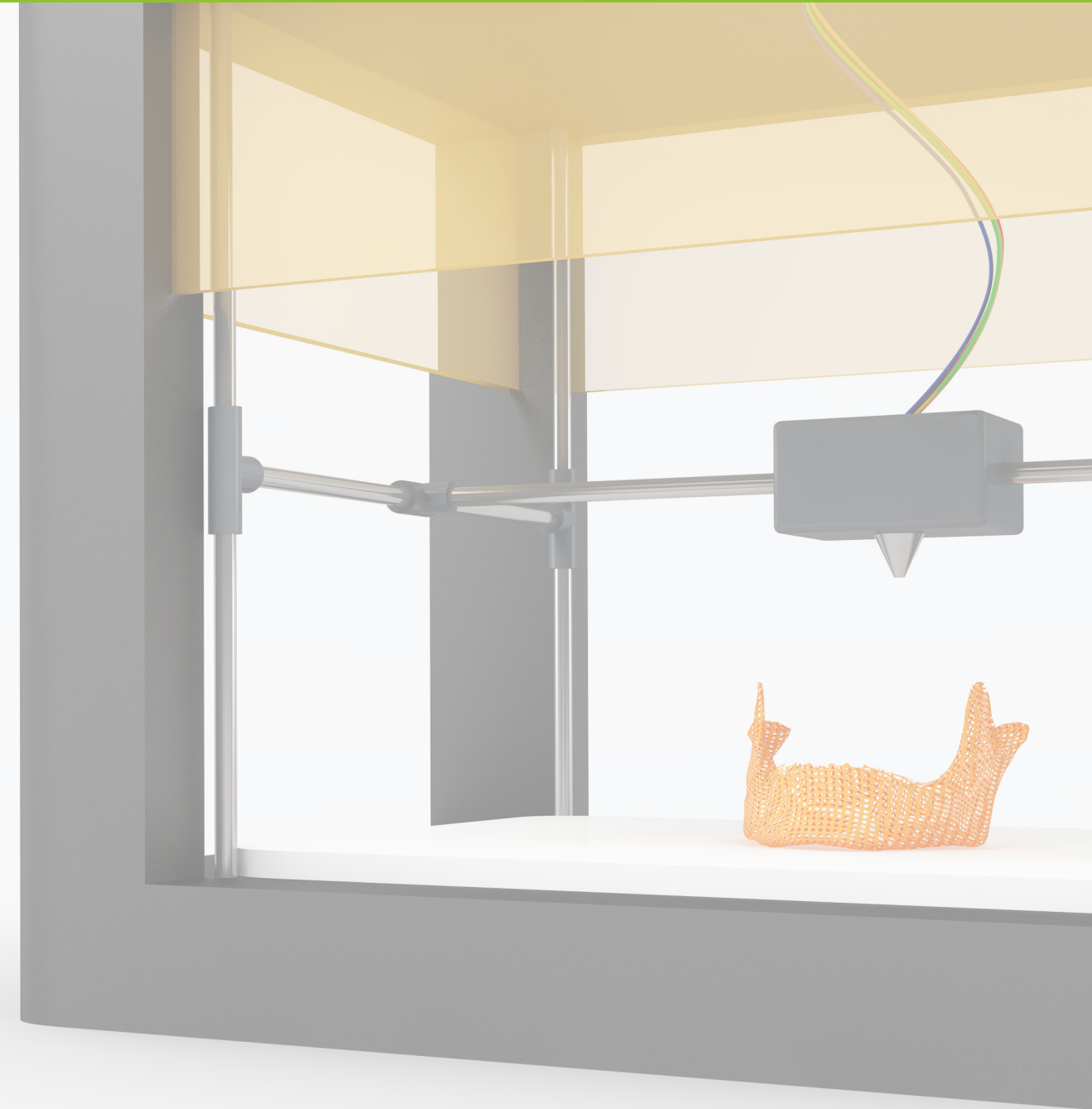


Kevin Goldston
Director, Venture Operations
at Northwell Health

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DAY 3

DEEPER DIVE INTO SPECIFICS



Specific Values

The key to better acceptance is proven improved outcome of the technology.

“**Customisation** could initially best serve special case joint replacements where standard inserts don't fare so well.”



Peter Gordon PhD
Research Associate at King's College London

“What outcomes would 3DP really drive? **Key outcomes:** Faster operating time, less wastage, better patient satisfaction, reduced surgeon stress.”



Iain Hennessey
Clinical Director of Innovation at Alder Hey Children's Hospital

“Most **returns** to the hospital are related to failure, infection or rejection. If the outcomes over a longer term period point to decreases in these areas, probably any of them, there's more likelihood that payers and regulators will be more inclined to favor 3DP.”



Melina Davis-Martin
Chief Operating Executive & EVP | Turnaround Expert | Executive | CEO | Strategist

“Most customized products are more expensive. I don't think that's the case here. I think that **3-D printing may reduce the cost**. The fact that it takes less time to produce, could mean an **increase in supply**.”



Pamela Dotson, M.S., MHL
Quality Improvement

Specific Values (Cont'd):

A key value driver for adoption of the technology is the promotion of customized medicine to fit the exact needs of the patient.

“Medical device company can promote a custom made implant made as a **one-in-kind joint replacement** printed to exact specs for this very patient, taking into account their anatomy, bone condition, lifestyle and other factors. This is a great marketing tool.”

“Smaller 3DP joint/non load bearing implants would be a **clear choice**. Vertebraes would be my first selection. Ankles, carpal and wrist, maxilla/mandibula would be my 2nd selection. Major hinge, saddle, and ball and socket joints would be me third selection until the surface quality problems are resolved.”



Alex Kosik
Serial Entrepreneur, Mentor, Angel

MVP

“3DP adds in to the current trend of customised medicine, whether that be stratification methods or like the recent “living” cancer therapy whereby the patient’s own cells are re-targeted for the cancerous cells.”



Peter Gordon PhD
Research Associate at King’s College London

“I think that you make a good point when you talk about 3D printing **not always meaning customization.**”



Brandon Barrett
DPM

Alternative Models

There are opportunities for unique enhancements (e.g. drug coated 3DP joints) that will improve its value proposition.

“I believe an Open Innovation Model is an alternative where there are opportunities for **value-added support, “add-on’s” and integrations**. This can actually be additive to any of the strategic options.”

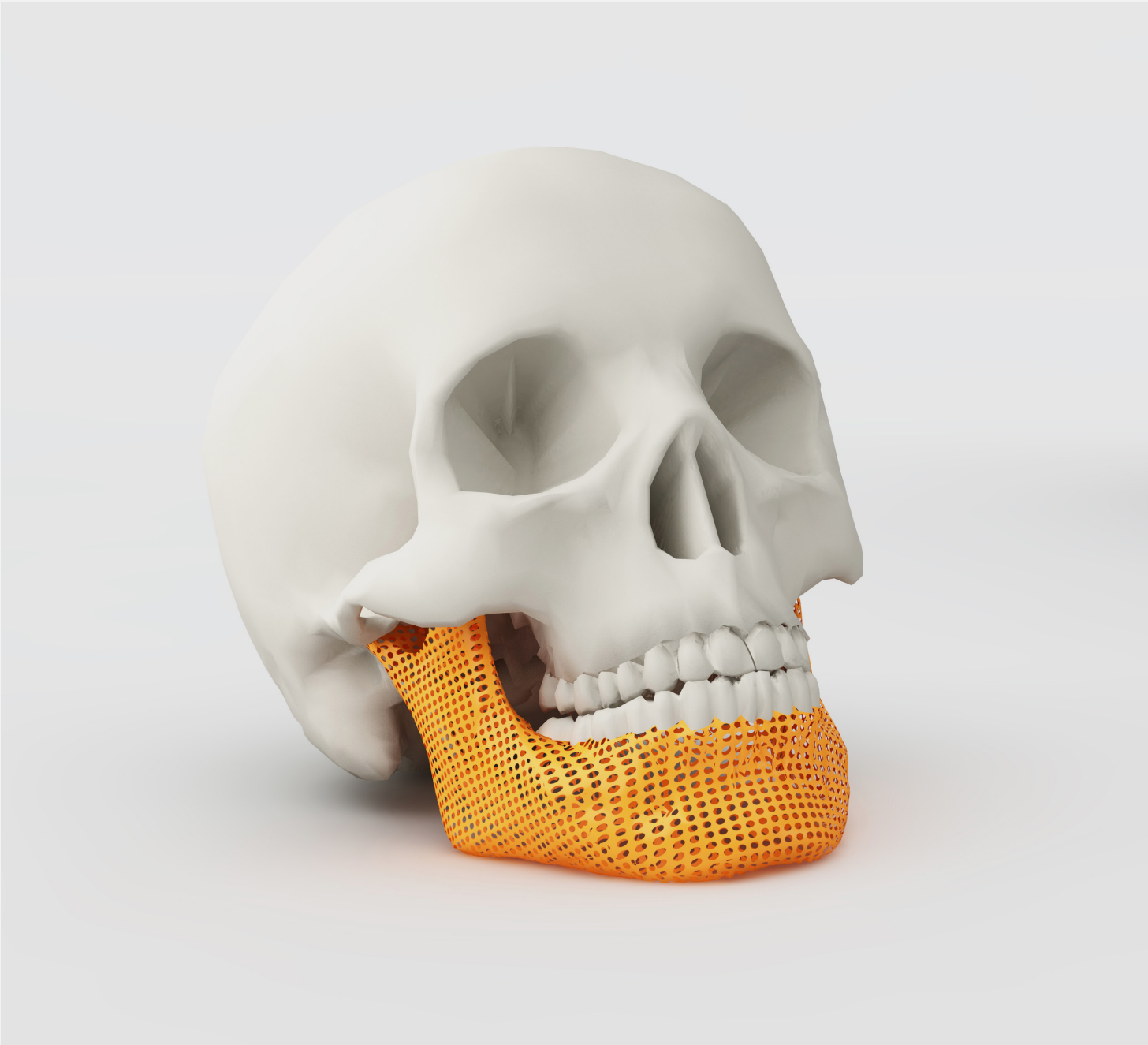


Kevin Kujawski
Associate and Focus Area Leader

“To think outside of the box a little bit, this is effectively a device that is inserted into patients, so to refer back my previous point about coating them in a drug/biologic, could this also offer a **delivery route for drugs treating other chronic pathologies** not linked to the hip replacement.”



Peter Gordon PhD
Research Associate at King’s College London



Specific Barriers

The industry needs to continue to justify and explain the cost differential for widespread adoption.

“Is custom more expensive? Why? What are the drivers? Can we test this as an orthodoxy? Like everything, this depends. Factors include the **material** (metals or polymers) one example is failed prints in more costly materials eat into margin.”



Michael Petch
Editor-in-chief at 3D Printing Industry

“From medical standpoint **I don’t see a huge outcome difference** in joint **3DP implants VS conventional.**”

“In my opinion most patients who would be willing to pay for 3DP joints would **be self-pay patients.**”



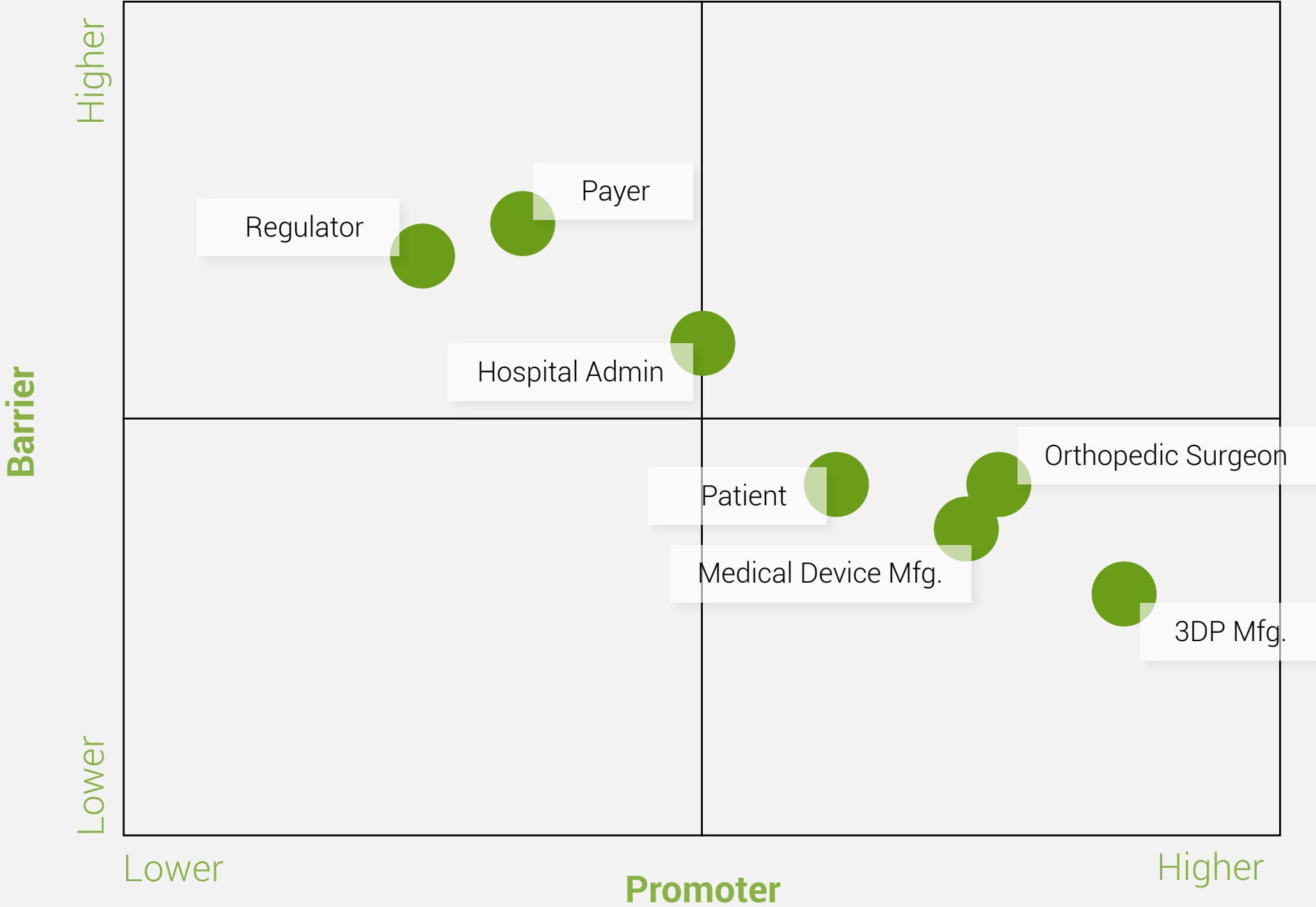
Alex Kosik
Serial Entrepreneur, Mentor, Angel

“From my experience, the bottle neck of the system is not due to a lack of joints, but a **surplus of people needing surgery** and **not a surplus of surgeons available.**”



Jerry Ennett
CEO at Taurus 3D

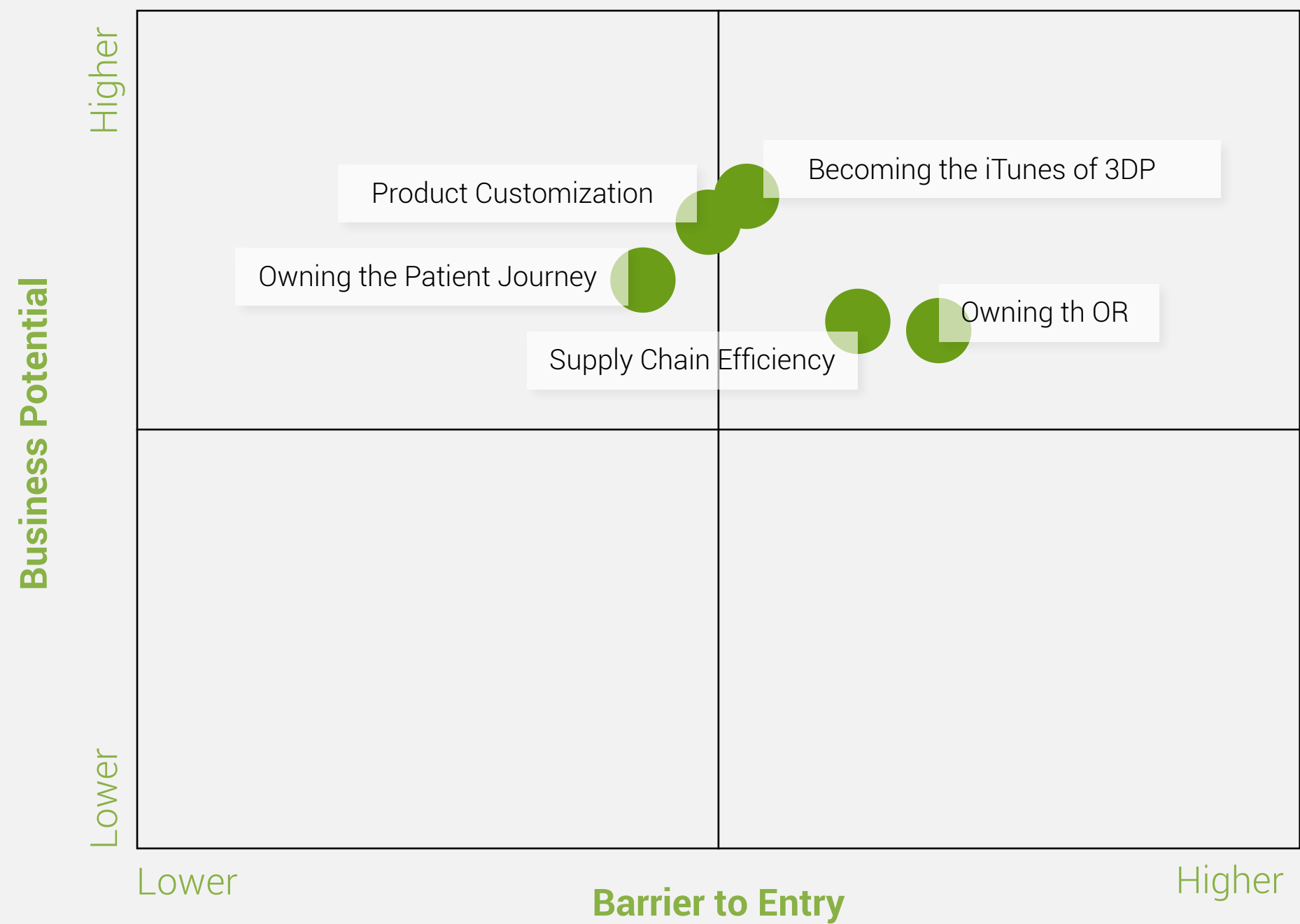
Promoter vs. Barrier: Key Stakeholders Role in the 3DP Marketplace.



Key Takeaways:

- 1. There is key split between Promoters and Barriers. A stakeholder cannot be both a high promoter and barrier.
- 2. The greatest promoters of the technology are those that have a stake in the success of the industry, (e.g. growth for 3DP manufacturers, better outcomes, and differentiation for patients and surgeons).
- 3. The biggest barriers are those that may have to pay more for the success of the promoters (e.g. payers, admins and regulators).

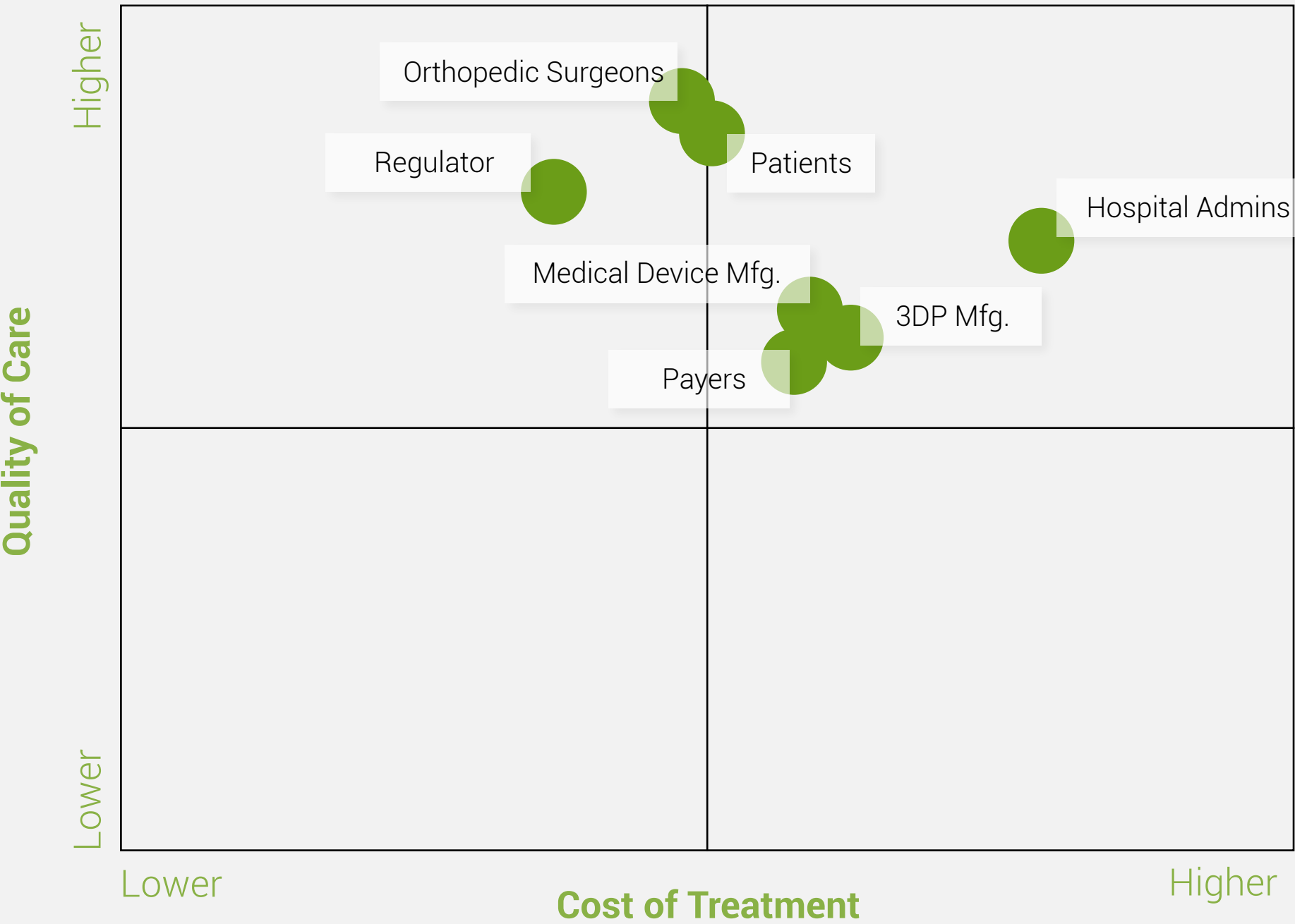
Barriers to Entry vs. Business Potential by Strategic Option



Key Takeaways:

1. The consensus is that all 5 strategic options have the potential to successful with Product Customization and iTunes of 3DP having the greatest potential.
2. However, there are meaningful differences in barriers to entry among the strategic options.
3. Three options, iTunes, Supply Chain Efficiency and Owning the OR have significantly higher barriers than Product Customization and Owning the Patient Journey.

Quality of Care: Evaluating Relative Importance by Key Stakeholders



Key Takeaways:

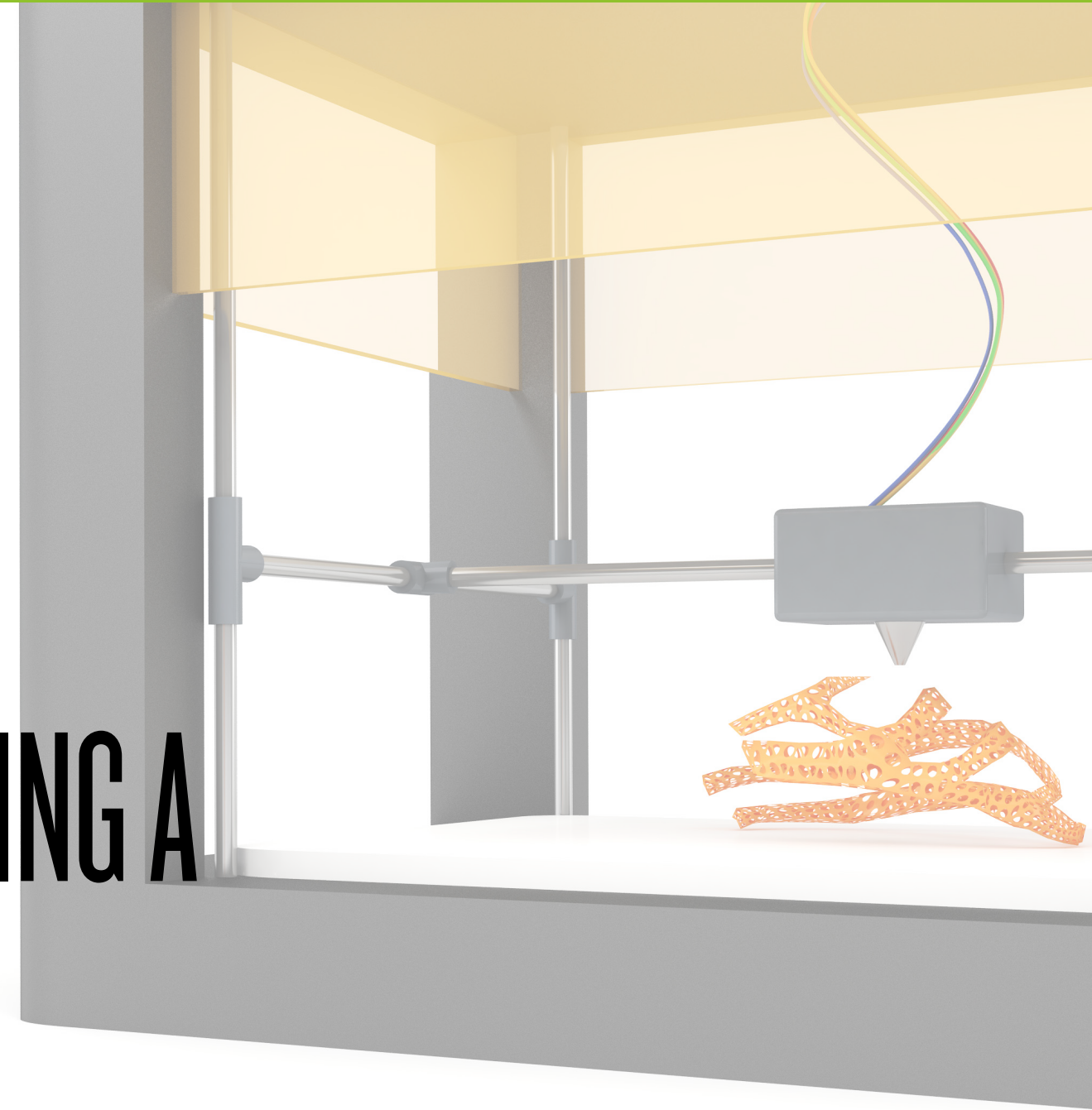
- 1. All stakeholders regarded that quality is very important for the success of the industry and the technology adoption. Quality in this case generally meant better outcomes and patient experience.
- 2. Majority of stakeholders also find the cost very important, particularly those that have to produce and pay for them: payers, hospital admins and manufacturers.
- 3. Patients fall somewhere in the middle on cost factor depending on whether they pay for the procedure themselves or not. Surgeons and regulators (not payers) do not find cost an important factor.



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DAY 4

VIABLE APPROACHES FOR BUILDING A BUSINESS CASE



Evaluating 3 of the 5 business cases

(2) Product Customization, (4) Owning the Patient Journey, (5) iTunes of 3DP

What needs to happen for specific option to succeed in the marketplace?

“The business case should center on “value”. The 3 strategic options are what differentiate this innovation from others. In sales, the focus of price and differentiation of your product or service provides growth. The 3 strategic options give the innovation’s stakeholders **sustainability, momentum** and **value.**”



Pamela Dotson, M.S., MHL
Quality Improvement

“Easiest thing to succeed – **Lower cost machinery** is emerging and will be a given as the industry continues to explode and innovate at such insane pace.”



Jerry Ennett
CEO at Taurus 3D

“Becoming the iTunes: The business case would be around constructing a system that generated revenue from **facilitating the transaction between surgeon, printer and hospital trust**, without overcharging.”



Iain Hennessey
Clinical Director of Innovation at Alder Hey Children’s Hospital

“Option 2 and 4: Establishing a **hi-end facility** for experimental treatments with 3DP implants for patients with complex cases who otherwise face amputation or arthrodesis. Such facility can cater to self-pay patients and function in the framework of Investigational device and/or Humanitarian and/or Custom Device Exemptions.”



Alex Kosik
Serial Entrepreneur, Mentor, Angel

The role of key stakeholders:

“Each stakeholder will need to be fully engaged and held accountable. This includes **the patient**. The patient should must responsible and compliant with the physician’s and manufacturers advice.”



Pamela Dotson, M.S., MHL
Quality Improvement

PATIENT

“We should consider “**regionalization**” of orthopedic joint implant services where healthcare organizations and physicians choose to collaborate in a joint-venture type of partnership in order to drive both volume and value to patients who are initially willing to pay for the service.”



Anne Tanner
Executive Director, Acute Care Services

REGULATOR

“However, I believe that the **surgeon plays the greatest** role of whether or not this product will succeed.”



Brandon Barrett
DPM

ORTHOPEDIC SURGEON

Conducting a premortem:

If the technology does not become successful, it is not going to be because of a single stakeholder or lack of strategic options. It will be because of lack of leadership among multiple stakeholders.

“I think that the Product Customization may have the greatest chance of failing because of **variation in the product**. I would have to say that the surgeon has the greatest chance of succeeding because they are provide value to their patient, the hospital administrator and the payer, whether the product is successful or not.”



Pamela Dotson, M.S., MHL
Quality Improvement

“**Easiest thing to fail – Educating existing surgeons** may be hard, so initially maybe hospitals hire specialists and slowly (20-30 years) it becomes part of the curriculum at med school? Also re-teaching designers to use equation based design platforms for customization is difficult.”



Jerry Ennett
CEO at Taurus 3D

“It requires strong clinical leadership to **advocate the benefit/potential benefit** to patients. Align the other factors behind this and this should result in the most likely to work.”



Iain Hennessey
Clinical Director of Innovation at Alder Hey Children's Hospital

“When considering doing a premortem of analysis as to what can possibly lead to failure I do **not** believe that it would be **one specific stakeholder** that would lead to failure.”

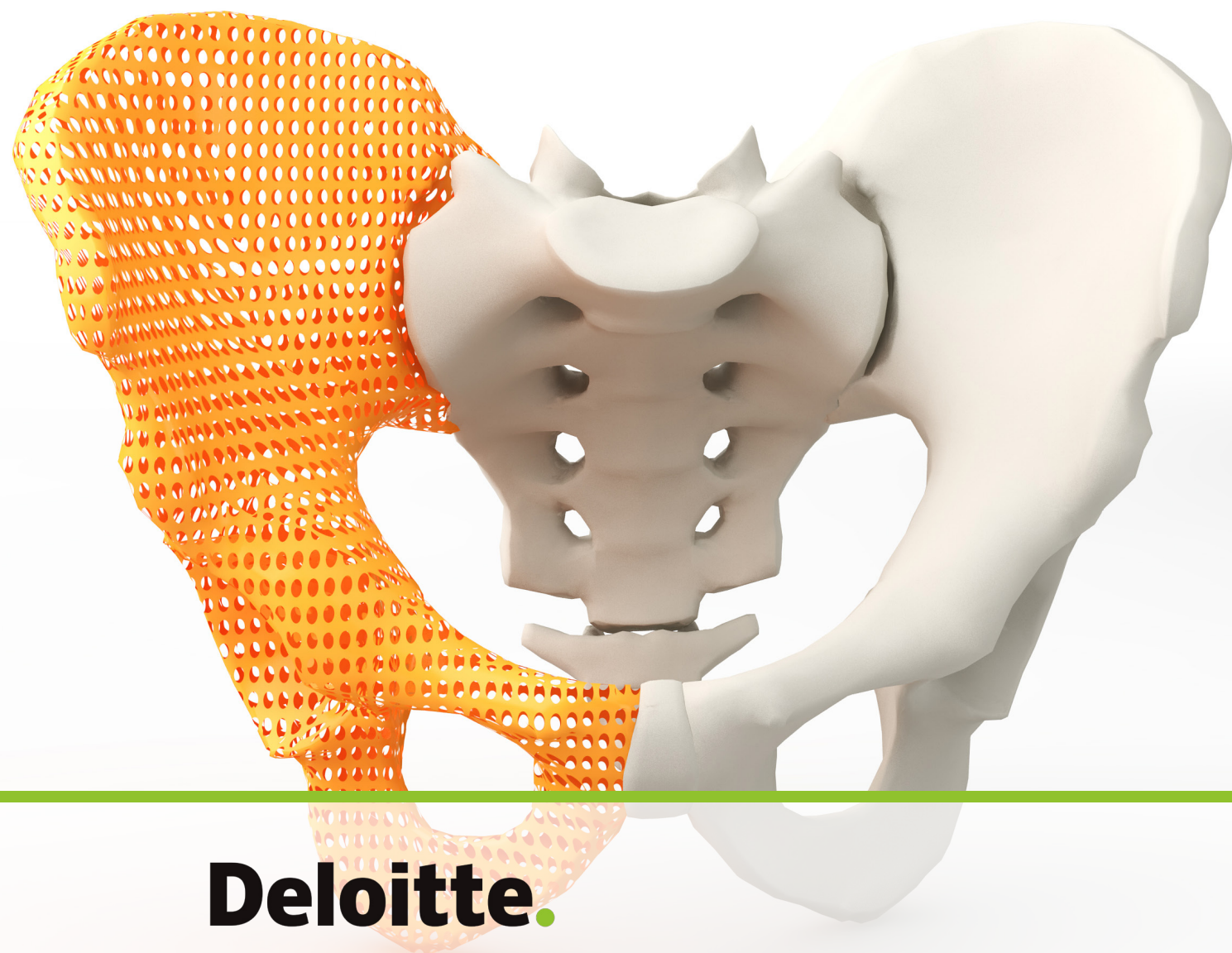


Brandon Barrett
DPM

CONCLUSIONS AND RECOMMENDATIONS

Primary focus area:

1. We started with 5 strategic options and 7 stakeholders in the 3DP market to identify the option that has the greatest chance of success and the role the stakeholders play as promoters or barriers to realize the value of this technology.
2. A meaningful effort needs to be put into identifying the value-added potential of 3DP joints. The most straightforward and easiest way to capture that is through conducting 30-day and 90-day readmission studies. There are 3 advantages to this:
 - A. It can be an entirely analytical exercise without the need to conduct expensive and long-term pre-post clinical studies.
 - B. There is a clear value proposition associated with reducing readmission rates that can easily be conveyed.
 - C. Centers for Medicare and Medicaid (CMS) looks at readmission rates as a key quality indicator for providers and payers, and showcasing improved readmission rates will go a long way to get the reimbursement buy-in from the most important healthcare payer in the market.
3. The best opportunity and lowest risk is becoming the iTunes of 3DP marketplace. Although all strategic options received their fair share of recommendations, the iTunes model stood out for a few of reasons:
 - A. The market lacks a platform that brings together all the stakeholders together in an efficient and effective way. Given that the biggest advantages of 3DP are the ability to localize and speed up customized joints, a platform that makes that process more efficient will make the technology's greatest value proposition more meaningful.
 - B. The platform model bypasses some of the complexities and barriers associated with the other models. In essence, this approach becomes agnostic as to who are the winners and losers in the marketplace and will remain relevant regardless of how the market evolves.
 - C. Finally, this model also has the greatest potential to bypass the greatest barriers in the marketplace: that of regulation and payment. Although the model is as dependent on regulatory approval and reimbursement models, it is not directly impacted by those decisions as there are other actors who will be much more actively engaged in removing those barriers.



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