SMARTECH MARKETS PUBLISHING

Medical 3D Printing

A SMARTECH PUBLISHING INTERVIEW

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An interview with Scott Dunham, SmarTech Publishing's Vice President of Research.

He is interviewed by Lawrence Gasman.

Lawrence: Good morning. My name is Lawrence Gasman. I am the president of SmarTech. We're the major provider of information and market research and forecasts for the additive manufacturing/3D printing industry, and this is another one of our question-and-answer sessions that we do with our analysts on a regular basis.

The topic today is actually medical 3D printing. Usually, we've talked about a topic that we've just published a report on. In this case, we are covering whole track that we cover. We do reports on prosthetics, implants, and medical modeling. Each one has its separate reports, and two of those just came out. You can find out more about these reports on our Website, which, not surprisingly, is smartechpublishing.com.

I also wanted to mention that we are putting together a conference on 3D printing in the medical space, which will happen in January 2018. We're working with the major publication in the 3D print area, 3dprint.com, to bring that conference to you. You can find out more about the conference and register at https://additivemanufacturingstrategies.com. Here you'll find a description of the conference, and a list of our speakers and the companies from where they come. Although we are not quite through filling the speaking spots, we already have a stellar line up of presenters.

So, without more ado, I'm going to ask Scott Dunham, who heads our research at SmarTech, to take the floor, and I'm going to ask him a few questions that we hope will give our view of what's happening and what will happen in the medical 3D printing space in the next few years and beyond.

Scott, let me kick off with a general question. Medical applications for 3DP have taken off in the last few years. They've moved to becoming practical applications, not just R & D, but there's now so much going on in so many different areas, and it's a very fragmented segment of the 3D printing sector. It's hard to keep up with, really, from a marketplace perspective.

So could you just give us an overview of what the major areas of development are in medical applications for 3D printing and something

in particular about what the state of adoption for these procedures and technologies is at the present time?

Scott: Absolutely, and thanks, Lawrence.

I think an important aspect of this question is that it is very hard to keep track of what's happening in the medical market. Medical applications seem to have a specific appeal or fit within the broader context of 3D printing technologies. It's hard for us to keep up with it all, even though, this is what we do all day every day. That alone speaks to the level of interest from medical research communities and commercial entities alike in this area. If it seems like medical 3D printing is in its own little world, conceptually, in terms of adoption, that's because it is. I actually would argue that you can break out the entire 3D printing industry into three conceptual segments, so there's 3D printing for rapid prototyping. There's additive manufacturing for industrial markets, and then there's AM/3D printing for healthcare.

Why is this? Well, when you really look at it, applications that have to do with healthcare are not like industrial applications. Most of them are based around a template of various elements of the human anatomy. Yet, ideally, each part would probably benefit from being custom-fitted to an individual.

This is an interesting situation. It allows technology like 3D printing to shine, because it keeps the definitional boundaries of parts fairly consistent. For example, there's really a set of definitions that would govern how a titanium hip implant could be designed, like how large it will be, etc. But also the type of parts necessitate the geometric flexibility to tailor devices and parts to an individual.

Through medical imaging technology and 3D printing combined, we now have a unique set of capabilities to serve a goal that is different to what you will find in industrial applications.

Now, as far as an overview of the whole market for medical applications, well, Lawrence, you already touched on that a bit. At SmarTech, we tend to focus on stuff that is potentially very disruptive, as well as that with near-term commercial opportunity.

There's the additive orthopedic segment, for which we published a report this year. This includes orthopedic devices and thigh, hip, knee, maxillofacial, cranial type of devices. That's the biggest single element of the medical market right now, and it tends to be highly focused on metals. This is going to be a major area of penetration in the future.

Then, we have an area that we call personalized surgery. This is what we're talking about when you see organizations like 3D Systems come in with a combination of printed anatomical models for pre-surgical planning, as well as patient-specific 3D-printed surgical cutting and drilling guides. What's interesting here is that there doesn't have to be, and often there is not, actually a printed implant involved. It can be just a traditionally-manufactured implant that's used in some of these cases for personalized surgery. This is a small area today, but something we see growing very, very rapidly in the short and the long term.

Then, finally, for the purposes of our research, there's a rapidly expanding group of prosthetic applications that could include what has happened in the hearing aid market, but also in prosthetic limbs, facial prosthetics, similar devices. We tend to group things like orthotics and external printed braces, medical braces, into this category, as well.

But I mentioned there are five areas. So far we have mentioned only three. The two areas that I won't focus as much today in this session, due to time constraints—are bio-printing applications, which we've also produced a study on this year, and general medical manufacturing, which deals more with the development and manufacturing of medical equipment and instruments.

Lawrence: The end users for 3D-printed medical devices are a very broad bunch of people, and a large teaching hospital would be doing very different things than a smaller specialist office. The question we've been asked is, "What does the impact of 3D printing look like for a hospital?" Roll forward a few years to see where we think we're headed with that.

Scott: Sure. This could be a whole 30-minute topic on its own, but I will say one thing that surprised me over the last five years has indeed been the attitude of big healthcare networks, hospitals and things like that, across the world, to really go after 3D printing directly, and I don't mean from a research perspective. I mean working to bring 3D printing technologies right into the hospital, either directly on-site in a printing lab or maybe within a closely associated service bureau that can utilize by a greater hospital network the print parts that are directly integrated into some of the workflows and ultimately positively affect patients.

This is now turning into an area that radiology could end up driving in the future, because of the critical element that CT and MRI play in actualizing the 3D printing for medical idea. Radiologists throughout the country and around the world are already saying, "Hey,3D printing surgical models and guides is an extension of radiology, so let's bring

that capability closer to the point of care." Personally, I think that's amazing.

As far as contrasting how this integration would look for a hospital, versus maybe a smaller specialist office, I see hospitals building this out fairly extensively, with continued investments to create full-on laboratories that they would run. Right now, there's some great creativity out there on how to get funding for this if you're a hospital, and a lot of times, this routes through a partnership, say, with an associated university. Lots of hospital networks around the world are backed by research institutions, and that connection benefits an institution like a hospital, in terms of access to 3D printing.

Things are not really the same for an independent surgical specialist operating more as a stand-alone practice. So, for these types of specialists, I think the opportunities are going to look more businesslike, and what I mean by that is finding ways to utilize probably something like a low-cost printer to gain a competitive advantage in their market of choice.

You see something like this in dentistry, with corporate dentists starting to tout digital dentistry and market this idea to patients directly; that is promoting the idea of how digital dentistry makes it easier and less invasive and provides them better results. I think the same approach is going to hold true for medical specialists, as well, and it doesn't have to just be an in-house thing for these smaller offices. I can see some challenges there of getting access to the equipment and the costs and everything. They can rely on specialized service providers, as well, who have started crafting 3D printed products and messaging about those 3D printed devices or treatment plans right to the specialists, as a way to pass that on to the patients and consumers.

Lawrence: Let's move on to a different topic. Obviously, materials can be quite different in the context of 3D printing for medicine. Specifically, that comes up in bioprinting, but we're not really talking about that today. But obviously, you've got issues with materials about biocompatibility. Materials for implants also have to last a particular period of time, so maybe you could address the whole materials space and what you see emerging over the next five years or so.

Scott: One of the things, I think, about medical 3D printing in general that also sets it apart from the rest of the additive manufacturing market in some ways, is that the stakeholders in medical are doing a really good job building value with the existing material sets and print systems, rather

than setting their sights on instances in the future where printers and materials have been adapted to fit an existing industry structure.

When you look at the implant side, you've already got near-universal compatibility of TI64 for metal additive manufacturing processes to make implants. There's not a huge impetus in the market to reinvent that wheel, to come up with a new material. There's opportunity to make TI64 perform better in implants through tailoring the design to the capabilities of additive processes. I think this will come in orthopedics, since that's where most of the metal activity is for medical 3D printing.

Pricing the materials might be the biggest change factor to watch over time, given that titanium 64 and other grades of titanium are well-established already. We would expect, here at SmarTech, a gradual erosion of pricing per kilogram on this front, as more additive techniques are adapted to serve additive manufacturing specifically, rather than selling off a powder that makes sense for AM, but are otherwise a byproduct of atomization that's taken place to support other processes. That's one of the reasons, more broadly, why some of the pricing is as high per kilogram as it is on the metal side.

On the polymer side, it's the same story. It goes back to the type of device that you're wanting to print, or you're using. If it's a one-time device, like a medical model or a surgical guide, the current materials are probably acceptable in a lot of ways.

A lot of users don't care much about the specific polymers when you're talking about medical models. They really need to focus more on the function of the model as it relates to materials, bringing materials and print processes to market for, say, full color or transparency in the material itself, different or variable hardness and flexibility factors to mimic tissue. Those are highly valuable functionalities in the context of models. They're being served by specific combinations of print process and material.

But I will say that developments for polymer implants are getting pretty interesting. They're pretty niche right now, but areas such as tech-based implants and cranial and spinal applications, do allow for alternatives to metals and uses a print process that's similar, but there's no need for concern about nailing the metallurgy, which is a pretty complex challenge for many metal implants. Ultimately, there's a big opportunity to produce, going forward in the future, bioactive materials that can be printed using different 3D printing processes.

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All this is highly experimental at this stage, but the concept is that you can tailor a material to be, for example, antibacterial, or some other functionality, and then print a device like a temporary implantable on demand. This is a whole new direction that seems to be quite a few years off, in terms of commercialization, but it's exciting conceptually.

Lawrence: We want to leave some time to talk about market sizing.

Scott, could you talk about how you see the market in quantitative terms and where you see the business opportunities.

Scott: In SmarTech's additive orthopedics report, which deals with the orthopedic implant market, we have estimated the total market for what we call additive orthopedics at the end of 2016. This encompasses machines sold to support device manufacturing, materials used, software tools that were sold to support this, as well as contract manufacturing and clinical engineering services that you sometimes see in this market. The whole value combined at the end of 2016 was a little over $400 million worldwide.

For this year, we're projecting very strong growth, and we think very strong growth has occurred in just a year's time. This sizing, we think, accounts for about half, or a little less than half, of the overall medical 3D printing market size.

In the future, we believe orthopedics will represent one of the strongest overall adoption areas for additive manufacturing and all medical use cases. That means a compound annual growth rate that exceeds the overall medical 3D printing market by about twenty-five percent. You take that further down the line about ten years. We're looking at about a $4 billion market opportunity ten years from now, for just the orthopedic segment.

Ultimately, we think that additive manufacturing will become the majority method of manufacturing orthopedic devices, at least in metals. The question is, when does that milestone get achieved? When does it cross over and become the majority manufacturing process? In fact, we see a gradual and steady implementation of the technology in more and more segments, so over time, as you get further down the line, ten years, maybe a little bit longer than ten years, we see that tipping into the majority for orthopedics.

Lawrence: Let's talk a little bit more about orthopedics. One of the more important data points you actually said in orthopedics is that orthopedic implants made by a 3D printer today aren't patient-specific, so that actually moves away a little from the story around personalized medicine. How

do you see the real value proposition for additive manufacturing and implants, then?

Scott: That's an interesting dynamic. Clearly, patient-specific implants are the most innovative use case and the most potentially disruptive use case, long-term, but for now, they're limited to the extremes, where the typical regulatory clearances that might be required for most devices are going to be eased based on compassionate use case or extreme use circumstances for these patient-specific devices.

That's why you see the news stories about 3D printed titanium rib cages or hybrid hip and pelvic implants and so on. These are used to treat patients that may not, and typically do not, have another viable treatment for their conditions or injuries. So, for all intents and purposes, "patient-specific" is a green-field growth opportunity, as it stands now. But those, overall, are, like you said, a fairly small number of people worldwide that fit the current circumstances that make these possible. The idea is to import some of that same patient specificity in these implants to much more common treatments, like your standard hip, knee, shoulder, or spine procedures that are commonly carried out every year around the world.

This is a different regulatory ballpark that most would call a patient-matched implant, versus a patient-specific implant. Patient-matched implants, would be based on an anatomical template that can be varied in relatively minor ways to really match the anatomy of a given individual. These types of devices don't really exist yet commercially, mostly because they would involve a much different burden of regulatory clearance, so that's ongoing. That leaves another alternative, which is simply producing implants using additive manufacturing that more or less resemble traditionally made implants, and they're just in a range of discrete industry standard sizes, so they're really not patient-specific or matched at all, in terms of geometry.

This is the bulk of what's out there today for additive, in terms of production volume, well above eighty percent, maybe even ninety percent. So, as you can imagine, the value proposition for these additively standard implants is a lot different than those which are either patient-matched or patient-specific. Make no mistake, though. There is value in applying additives in this way, given a comparatively or relatively short time to evaluate the result in a patient.

Additive manufacturing of standard-sized implants thus far has shown that it can provide structural performance benefits through tailored porosity on the surface of an implant that's manufactured in a single

process, in a highly controllable process, like AM, rather than this traditional multi-stage manufacturing process, where there's less control over that porosity, and you have a difference in metallurgical performance between the bulk of the implant, and then they're applying this porous outer coating in a second process. You get two zones of metallurgical performance, and you generally don't want two different-behaving zones in an implant. So additive actually has a strong value proposition, even making implants that aren't tailored and matched geometrically to a patient at all.

Lawrence: What do you see as the major challenges or barriers that are impacting the medical 3D printing segment, both from the perspective of the individual segments like personal surgery or orthopedics, but also as a whole? And how do you think they're most likely to be overcome, or indeed will they be?

Scott: There's no doubt we tend to talk about all the opportunities and the growth patterns and all that stuff, but there's definitely always challenges associated. We've already touched on some of the ones for orthopedics. As we have already noted, the regulatory picture is one of the biggest challenges. Here companies are pursuing, in the U.S., an FDA 510(k) clearance, which is not really an ideal certification, necessarily, but it is a short-term solution. There is also a broader challenge in medical 3D printing; specifically that there's not going to be anything that's brought to market, especially in such a high-classification medical device, before there's a long historic body of research to support, whether or not this is beneficial to patients, and whether there's any downsides or complications.

Right now, in the orthopedic segment, we're just getting past what would be the earliest, shortest length of acceptable research or post-op research, which is a ten-year period. We're into the tenth and eleventh and twelfth year of some of the earliest implants actually going into patients. So, as that evolution progresses further and further more implants will go into patients. That in turn will help make regulatory challenges easier, because there will be a greater and greater body of research to support whether or not these challenges are overcome.

The largest orthopedic companies in the industry are not necessarily, at this stage. They are not yet willing to stake their reputation on a process like additive manufacturing when compared to other existing manufacturing processes, it is still relatively unproven. There are already short-term research results that are showing positive things, but until you get to a larger and longer body of evidence, they're still considered somewhat unproven.

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In the personal surgery segment, there are some similar challenges. We haven't really defined or figured out exactly when something like an anatomical model needs to be classified as a medical device. Obviously, you want to bring some sort of surgical planning model into the operating room, but to do that, it probably does need to be classified as a device. And It needs to be able to be sterilized if it's in the operating theater with you.

So, there are some things that we're still trying to figure out there, but the great thing about the personal surgery segment is, there's a lot of opportunities that really have low or no regulatory hurdles in their path. These include opportunities like printed anatomical models that are used just in the development of other medical devices.

I don't want to understate the importance of that for the future. You can print a model of, say, a heart, or something like that, and other companies can then use that model, which is based on real human anatomy, to develop their own other medical devices. They can test concepts and things like that, so that's definitely a big area that we see in the future, along with models for training medical professionals in the future.

You can also 3D print really realistic training models, and there's little to no regulatory requirements for modeling and stuff like that, so that's one of the great things about the personal surgery segment. There's a lot of different directions in which it can go. If it runs into resistance from some of these regulatory challenges and medical research challenges, there's other ways to bring value.

Lawrence: Thank you a lot, Scott. That was very interesting. I think there are a lot of business opportunities out there in medical 3DP. For those of you who want to know more, please go to SmarTech's website, www.smartechpublishing.com, and pull down the tab that says "medical and dental topics," and you'll find everything that Scott talked about today, plus reports on bioprinting and dentistry, and if you want to know more about those reports, and especially if you want to buy some, please contact our business development director. His name is Rob Nolan. You can find him at rob@smartechpublishing.com.

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