SMARTECH MARKETS
PUBLISHING

Progressing Orthopedic Implants Through Additive Manufacturing

A SMARTECH PUBLISHING ARTICLE

JULY 2017

Progressing Orthopedic Implants with Additive Manufacturing

By Rachel Park

Looking back over the last decade, it is clear from the vantage point of 2017 that additive manufacturing (AM) has caused significant disruption in *the medical sector.* Indeed, in no other sector has AM had such a profound and dramatic effect on the human condition in terms of improving lives — whether directly at the point of need within clinical environments or communities or indirectly as a manufacturing method for greatly improved medical devices. Currently, despite the direct approach dominating many '3D Printing' headlines as surgeons and clinicians increasingly embrace the AM systems at the point of need for patient-specific applications, it is the latter, indirect approach, that has seen significant results for higher volume, serial production with AM by medical device manufacturers.

The medical sector!

Three little words that are used easily and frequently to describe a behemoth industry where commerce and politics often obscure the raison d'etre — the health of humanity. One of the fastest growing sub-sectors of the medical device industry (itself a subset of the medical industry) is medical implants, specifically orthopedic implants, a field that is leading the way for when, why and how to maximize the potential of 3D printing technology.

The medical discipline of 'orthopedics' is, broadly speaking, concerned with the human skeleton — or, essentially, our bones. A human, adult skeleton consists of 206 bones, a significant proportion of which provide a load bearing function such as the spine, hips, ankles, shoulders, knees and toes. The skull and face come under a further specialized medical categorization: 'cranio-maxillofacial' (CMF).

According to SmarTech's report, "Additive Orthopedics: Markets for 3D-Printed Medical Implants – 2017" *"The global orthopedics market, inclusive of a wide array of products, treatments, and medical practice areas, is massive. Most estimates for market sizing in orthopedics account for devices, implants, procedures, and equipment used in surgical environments. These all-encompassing market sizing estimates show a global market projected to be worth close to $100 billion over the next eight to ten years."*

Moreover, implantable orthopedic medical devices are subject to stringent regulation due to the critical nature of them being placed within the human body to fulfil the function of body parts that no longer work and cannot be repaired, whether as the result of catastrophic injury or worn out through longevity. When such a prognosis is delivered it is invariably amid the suffering of ongoing physical pain that has a tremendous negative impact on an individual life and a long-term — safe — resolution is the desired outcome.

As a recipient — or future recipient — these regulations are desirable in terms of quality and safety. It means that the device manufacturers are put through some hoops to demonstrably prove the efficacy of the implants they develop. Today, that is kind of where we are with many 3D printed implants — still going through the hoops. We're not even half way really. *Going back to the 206 bones of the body, in 2016 the US Food & Drug Administration (FDA) quoted that it had granted*

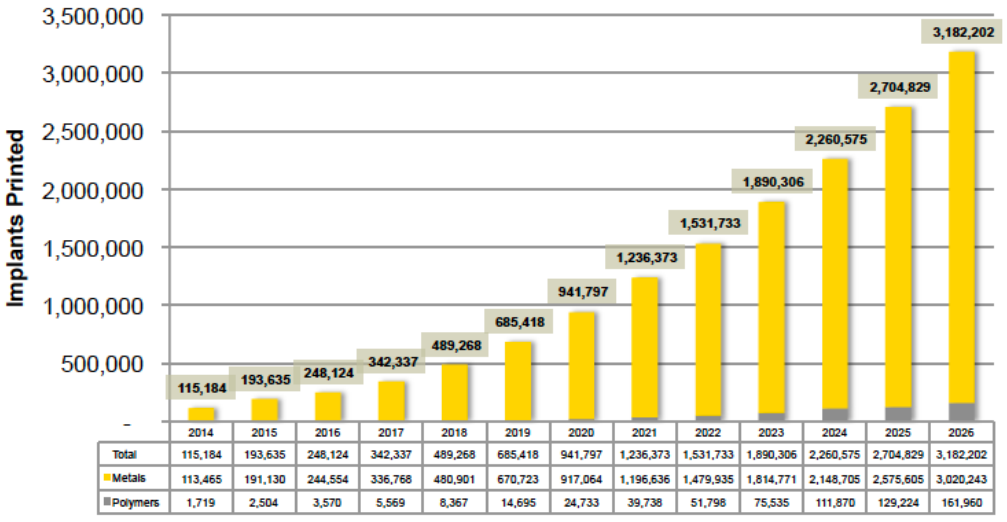
2025 Library Avenue Suite 402
Crozet, VA 22932
http://www.smartechpublishing.com

approval for 85 implant devices produced using 3D printing — a significant proportion of which were for emergencies, not pre-planned surgeries.

Considerable research is ongoing into the development of superior, cost-effective orthopedic implants and the 3D printing ecosystem is contributing notably to these developments. An increasing number of medical device manufacturers — large and small — are utilizing an AM approach for the production of standard orthopedic implants to achieve improved design and functionality. The dominant (but not exclusive) process in this specialized medical field is metal powder bed fusion (laser and electron beam powered). These metal additive processes allow for the manufacture of the complex mesh structures of innovative implants that reduce production costs and lead-times compared with conventional manufacturing techniques of such products.

The complexity involved in the production of an orthopedic implant is inherently linked to the ability to simulate bone structure, porosity and a surface texture that produces high-friction and allows for bone ingrowth around the implant. This is where industrial 3D printing excels, in a way that no other single process ever has previously. Which is why increasing numbers of medical device manufacturers are embracing the technology. As you might expect, the medical device sector is a competitive market, with a dual focus on R&D and profit, much like its equally massive sister market of pharmaceuticals. For both, the emphasis is somewhat removed from the point of ***care***, but the medical devices are facilitating improved — and longer lasting — treatments by clinicians that use them for their patients.

Exhibit 2-2: Total Projected AM/3DP Implants, by Material Family, 2014-2026(e)



	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026
Total	115,184	193,635	248,124	342,337	489,268	685,418	941,797	1,236,373	1,531,733	1,890,306	2,260,575	2,704,829	3,182,202
Metals	113,465	191,130	244,554	336,768	480,901	670,723	917,064	1,196,636	1,479,935	1,814,771	2,148,705	2,575,605	3,020,243
Polymers	1,719	2,504	3,570	5,569	8,367	14,695	24,733	39,738	51,798	75,535	111,870	129,224	161,960

Source: SmarTech Publishing

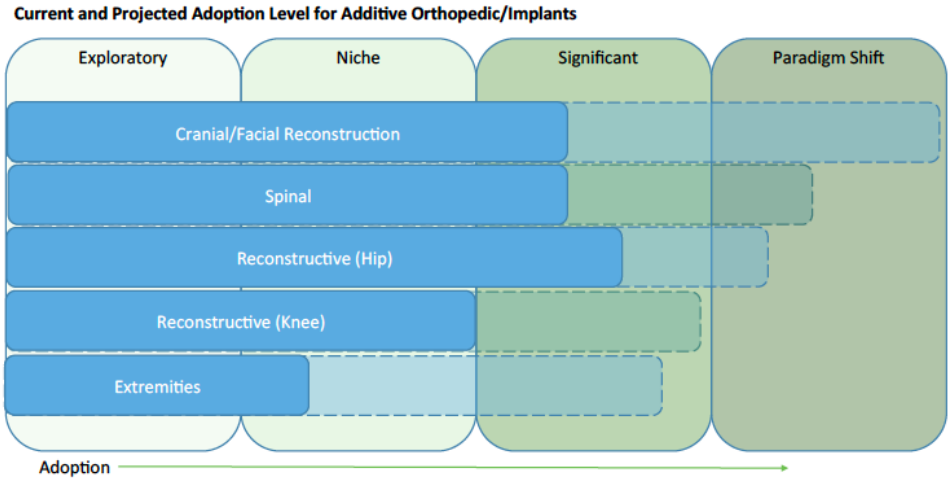
The highly regulated process of orthopedic implant production is not without challenges such as micron level accuracy and contamination risks. As a result, it is not just the hardware that has evolved to meet the demands of this application area but also validated quality assurance

2025 Library Avenue Suite 402
Crozet, VA 22932
http://www.smartechpublishing.com

processes — for the powder material, the build process itself and post processes such as sterilization.

In 2017, there are a number of standard additively manufactured orthopedic implants that have made it all the way through the hoops, and into (relatively) high volume production. Acetabular systems for hip replacements were one of the earliest 3D printed medical implants to receive approval and accreditation and standard knee and spinal implant devices produced with AM are catching up, with ankle implant systems also making progress.

Exhibit 2-1: Potential Adoption Level for 3D-Printed Medical Implants



Source: SmarTech Publishing

Increasing numbers of companies are working directly to develop standard additively manufactured orthopedic implants for different parts of the body. Each one demands specific anatomical research conducted in parallel with process and often material development, meaning it is not something that happens quickly in terms of getting the approval required for clinical use.

The orthopedic medical device industry is dominated by a small number of multi-billion conglomerate organizations, notably Stryker, DePuy Synthes, Zimmer Biomet (these two merged in 2015), and Smith & Nephew, all of which are now visibly conducting R&D with AM for a range of innovative devices. Stryker was among the earliest adopters.

However, smaller, specialist medical device manufacturers have emerged over the last decade that have developed proprietary AM materials / processes for orthopedic implant development and production, with a notable thrust in the upward trajectory since 2015. Companies such as 4WEB Medical, Additive Orthopedics, Emerging Implant Technologies, SI-BONE and OSSDsign are building reputations around AM driven business models. Oxford Performance Materials's is another notable company in this area, with somewhat greater longevity. OPM's

OsteoFab process combines laser sintering with its proprietary material formulation for patient-specific cranial, facial and spinal orthopedic implants.

This indirect approach to additive orthopedic implants is dominant, largely, I believe, because industrial AM machines do not currently easily lend themselves to a point of care environment i.e. a hospital. However, there is increasing evidence that AM is being used at the coal face – within clinical environments, with the clinicians directly involved. Just one non-scientific marker of this trend is the number of surgeons and clinicians speaking on the 3D Printing / Additive Manufacturing conference circuit. I've lost count of the number I have heard speaking now, all with compelling stories based on their first-hand experiences and commitment to the technology base for their work and improving the lives of their patients. And I believe there is great potential here — for increased volumes of patient-specific implants, manufactured at the point of need with time and cost benefits.

There are also a couple of companies that truly stand out as early beacons for this trend, which will only increase in the future.

Materialise has long advocated the use of additive manufacturing for medical applications. With a software and service background, I doubt there is any other company that has done more to further this application in the real world. The work at Materialise is right across the medical spectrum, but a great deal of focus has been placed on working with medical professionals and medical device companies on the development of patient-specific implants and its implementation record has been phenomenal.

One of the organizations that Materialise works closely with is the US based Mayo Clinic — truly a beacon of personalized 3D printed clinical excellence, IMHO. I was fortunate to hear Dr. Jay Morris, a clinician at the Mayo Clinic, speak at the Materialise World Conference earlier this year and I also met him at Rapid + TCT a few weeks later.

It is no secret that the ecosystem involved in additive manufacturing is expansive and requires expertise and experience to coordinate the process effectively for consistent results. But that is precisely what the Mayo Clinic team is doing, according to Dr Morris. The AM applications at the Mayo clinic cover the medical spectrum (medical models, surgical tools and guides etc) but do include implants. A prerequisite for success with AM that Dr. Morris cited at the Mayo Clinic is the centre's integrated approach with multiple disciplines (virtual planning, design, 3D printing and surgical teams) all together under one roof to facilitate communication and progress more quickly than would happen at disparate locations. Like I said — a beacon!

Currently the greatest impact opportunities for AM are for the production of standard orthopedic implants. Well-documented global demographics, which continue to show an ageing population, will likely mean that demand for replacement implants will only increase. However, custom-manufactured orthopedic implants, particularly for patients suffering from trauma, will, I believe continue to increase too, albeit at a slower rate.

Additive Orthopedics: Markets for 3D-Printed Medical Implants – 2017