# 3D PRINTING INDUSTRY

Additive Manufacturing and 3D Printing

# Medical & Healthcare

A New Industrial Perspective

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# 3D Printing Industry Report

## 3D Printing & Additive Manufacturing in the Medical and Healthcare Marketplace

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# 3D Printing & Additive Manufacturing in the Medical and Healthcare Marketplace

## REPORT BACKGROUND

With a growing global population, increasing old age in Western economies and increasing healthcare demands in the developing world, Additive Manufacturing (AM) and 3D printing (3DP) presents a compelling commercial proposition to respond to these ever-changing global mega-trends. Whether used to support the manufacture of personalised products or to enable supply chain compression and cost reduction, AM/3DP already provides an alternative to traditional production methods. Therefore, it should come as no surprise that the medical and healthcare sector already represents one of the strongest vertical markets for applications of AM and 3DP. However, as of today, we are barely scratching the surface in terms of the impact this technology base can have on the medical and healthcare sector.

*"We all live in a global village with 7-billion other people. We are all a different shape, different size, different culture, different religion – we all have differing levels of income and different levels of state support – BUT, we ALL value our health and the health of our families above All else. 3D Printing presents a technology that can bring personalised and affordable healthcare to the masses, whilst enabling whole new business models and supply chains to flourish"* ***- Dr Phil Reeves – Report Author***

One of the most exciting future opportunities for 3DP/AM growth comes from the emergence of 'digital healthcare', where patients are benefiting from new automated scanning and diagnostic processes such as CT, MRI, 3D Ultrasound and intraoral laser scanning. This personalised digital data is providing the blue-print for future 3D printed healthcare solutions, from hip and knee implants to dental crowns, from hearing aids to prosthetic limbs, orthotic footwear and prescription eye-glasses. Within this new industry report we will look to quantify these applications and scale their current and future commercial value.

3D Printed 'Robohand' made on a MakerBot Replicator consumer 3D printer using open-source design data - **© MakerBot**

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***"In the context of this report the authors defines and uses the term Additive Layer Manufacturing (ALM) as an umbrella term for the range of technologies & processes used to fulfil the application of Additive Manufacturing (AM), which in turn is defined as the direct production of end-use parts."***

# EXECUTIVE SUMMARY

Within the healthcare sector, Additive Layer Manufacturing (ALM) technologies are being used for a host of different applications. In addition to making prototypes to support new product development, the technologies are also being used to make patterns for the downstream metal casting of dental crowns and used in the manufacture of tools over which plastic is being vacuum formed to make dental aligners. The technology is also being used directly to manufacture both stock items such as hip and knee implants and bespoke patient-specific products such as hearing aids, orthotic insoles for shoes, personalised prosthetics and one-off implants for patients suffering from diseases such as osteoarthritis, osteoporosis and cancer, along with accident and trauma victims. Technology is also being developed for the 3D printing of skin, bone, tissue, pharmaceuticals and even human organs. However, these technologies remain largely decades away from commercial exploitation.

But, we must not imagine that all these applications are cutting-edge or ripe for future exploitation. Some applications, such as the Additive Manufacturing of hearing aids are now very mature, with almost global saturation within the available market. Other applications, such as orthopaedic implants present some growth opportunities, but these are limited to just a small number of new machines sales and relatively small volumes of raw material consumption each year. Other applications such as dental aligners and dental stone models do present more significant future business opportunities for the sale of both machines and materials.

It is estimated that $131.8-million has already been invested in ALM machines used within the medical sector for direct part production, casting patterns and vacuum forming tool manufacture. This figure is expected to rise to $306-million within five years and to $555.7-million within ten years.

In terms of annual revenue, the market for new machine sales will grow from $24-million in 2014, peaking at $56-million by 2020. On average (over a 10-year period) 50% of this revenue will come from the sale of photocurable polymer systems, 23% from metallic powder bed systems and 27% from polymeric laser sintering systems.

At least $83.7-million of material is currently being consumed per annum for direct part production, casting patterns and vacuum forming tool manufacture within the medical sector. This figure is set to rise to $235.8-million within five years and $508.6-million within ten years.

Within ten years, annual materials revenue will be 10X the revenue generated from machine sales, with up to 55% of this revenue generated from the sale of resins for dental stone model production. It is therefore highly likely that 3rd party material vendors will release competitive materials driving down cost, which could in turn reduce revenue estimates.

Beyond stone model, photocurable resins used for dental aligners and hearing aids will account for some 21% of the market (by value), with titanium accounting for 9.6%, nylon 8.6% and cobalt chrome 5.5%. In terms of material volume, demand is set to rise significantly for both photocurable resins and nylon powders, with consumption reaching 1,825 tons and 721 tons respectively.

By monetary value, the stone model and dental aligners markets will be the largest revenue drivers in the future, followed by ophthalmic and vision based products (glasses).

Future material and machine revenue within the medical sector will be driven by the adoption of digital dentistry and the transition of some glasses manufacturers to adopt AM. Polymers, and machines processing polymers, will drive the greatest market growth, with metallic systems gaining adoption, but having little overall impact on revenues.

Within polymeric applications the strongest companies both now and moving forward will be Envisiontec, Stratasys and 3D Systems, as all produce resin based systems suited to the larger commercial opportunities, including dental stone models and dental aligner tools. The companies are also well positioned to service the dental crown and hearing aid markets, albeit these appear to offer little growth opportunity. At this point in time, EOS polymeric technologies are not aligned to any significant medical markets, by value or volume.

Within metallic applications, Arcam has a strong position in medical implant manufacture. However this is a relatively weak market with little material revenue and only a small potential for growth within the machine install base. EOS and other laser based system vendors such as Renishaw, SLM Solutions and Phenix (now part of 3D Systems) are better positioned to service the needs for direct dental implants and lower volume bespoke surgical implants, which both exhibit better growth potential.

In summary, although the medical sector has been an early adopter of AM, and there are signs of saturation in some vertical markets, there are also significant growth opportunities, which exist within known market applications. Undoubtedly, new medical applications will also be found, which have not been considered within this report. These will drive demand for both machines and materials further, affirming the medical sector as a key driver to future ALM growth.

Additive Manufacturing of 'Spectacles' with integral frames and prescription lenses - **© Luxexcel**

## ABOUT THIS REPORT

This report has been formatted into three discrete sections to provide informed guidance to both newcomers to the Additive Manufacturing (AM) / 3D Printing (3DP) industry and industry experts alike. The report is based on detailed analysis of public domain information, as well as exclusive interviews with technology vendors and users. The report also contains forecast data from economic and business modelling undertaken by staff at international AM/3DP research & consulting firm Econolyst.

### *Section 1 – Background to AM/3DP within the medical & healthcare sector*

The first section of this report includes a background to AM & 3DP within the medical & healthcare sector and is aimed at relative newcomers to this exciting technology area. Within this section we look at how additive layer manufacturing (ALM) processes are being used already for different applications across the sector, such as prototypes, casting patterns and tools for downstream production. We then look at the concept of 'Additive Manufacturing', where ALM processes are being used to make 'end-use' parts, such as medical implants, medical devices or surgical tools, before looking at the business drivers behind technology adoption. Finally, we then look at the emergence of consumer & prosumer 3D printing technologies and discuss where such technologies could both enable and disrupt the medical and healthcare value chain further.

### *Section 2 – Detailed medical sub-sector analysis*

In the second section of this report we have segmented the medical and healthcare market into a number of sub-sectors, where AM and 3DP are currently being used for commercial (or near commercial) applications. Within each sub-sector, we provide a narrative detailing how AM/3DP is being used to support the value chain and for what discrete products, services and applications. Within the narrative we then address (where relevant) some of the following issues:

#### Which vendors & technologies?

We identify which global vendors are currently active within each vertical market space and why their technologies provide a strategic fit for each application. We also consider which vendors we perceive to be the leading players in each sub-sector and also those vendors with technologies that could be applied to each sub-vertical market application..

#### Understanding the material supply chain

Here we identify which materials are being used to enable each of the medical and healthcare applications and the scale of material consumption both now and in the future.

### Market penetration & growth opportunity

Here we use global market research sources and data from technology vendors to compare the current penetration of AM/3DP with the overall market opportunity, allowing us to forecast areas of future market growth or potential areas for near term technology saturation.

### Drivers for technology adoption

Here we look at the socio-economic drivers to the adoption of AM/3DP within each of the vertical market sub-sectors and where future change could have a positive or negative impact on AM/3DP growth.

### Technology disruption

Here we look at both the potential disruption of emerging AM/3DP technologies on the current AM/3DP supply chain, but also the emergence of other production solutions that could displace AM/3DP in the future (if applicable).

### Roadmaps & timescales

Here we provide our interpretation of what is needed to address the wide scale adoption of AM/3DP within each vertical market application, the realistic time frame for this adoption to take place and the changes that will take place within those companies that choose to engage.

## *Section 3 – Quick reference tables*

In the third and final section of this report, we have cross tabulated the detailed data provided in section 2, to provide a series of 'quick reference tables'. These tables highlight which vendors & technologies are the most active across the medical market place, which materials present the greatest consumption opportunities, which applications are most likely to grow with increased levels of patient specific data, which subsectors are likely to experience the largest future growth potential, which sectors could suffer from the greatest future technology disruption and the time scales for AM/3DP adoption across the medical & healthcare marketplace.

# BACKGROUND TO AM/3DP WITHIN THE MEDICAL SECTOR

Within this section we will discuss Additive Layer Manufacturing (ALM) processes and technologies and how they are enabling applications such as prototyping, tooling, casting and direct part manufacture. We will look at the business drivers for the adoption and use of these technologies and the impact that this uptake is having on both product makers and consumers. We will subsequently discuss how ALM technology is being applied specifically within the healthcare sector and the potential disruptive nature of consumer 3D printing.

## What are Additive Layer Manufacturing (ALM) technologies

ALM technologies are a group of computer controlled manufacturing processes that are able to produce tangible component parts in a variety of materials. Although there are many different types of ALM processes commercially available, they all share a number of common traits. Namely:

- *They all produce parts sequentially in a layer-upon-layer fashion*
- *They all work through the addition or consolidation of material, rather than the removal of material from stock*
- *They are all controlled directly by computer using 3-dimensional geometry data*
- *They are all able to run unattended with no manual intervention during part manufacture*

3D Systems Stereolithography machine used for polymeric additive layer manufacturing using photocurable monomers- **© Econolyst**

Leading Industry analysts Wohlers Associates, calculate that some 7,771 professional level ALM machines were sold in 2012 alone, taking the cumulative install base of machines to over 56,000 globally. The table over details the primary ALM mechanisms, as defined by the American Standards for Testing Materials (ASTM) F42 committee, in standard ASTM F2792-12a. The table also highlights the materials processed using these different mechanisms, the current commercial vendors producing technologies and systems known to be under development.

| ALM MECHANISM | MATERIAL TYPE | PROCESS DESCRIPTION | COMMERCIAL SYSTEMS (COUNTRY) | DEVELOPMENTAL SYSTEM (COUNTRY) |
|---|---|---|---|---|
| **POWDER BED FUSION** | **Metal** | Direct Metal Laser Sintering<br>Selective laser melting<br>Selective laser melting<br>Selective laser melting<br>Selective laser melting<br>Selective laser melting<br>Selective laser melting<br>Electron beam melting | EOS (Germany)<br>Concept Laser (Germany)<br>Renishaw (UK)<br>Realizer (Germany)<br>Phenix/3DS (France)<br>SLM Solutions (Germany)<br>Matsuura (Japan)<br>ARCAM (Sweden) | |
| | **Polymer** | Laser Sintering<br>Selective Laser Sintering<br>Selective Heat Sintering<br>Selective Mask Sintering<br>High Speed Sintering<br>Selective Laser Printing | EOS (Germany)<br>3D Systems (USA)<br>Blue Printer (Denmark) | FIT (Germany)<br>Sheffield Uni (UK)<br>Renishaw / DMU (UK) |
| | **Ceramic** | Selective Laser Sintering<br>Selective Laser Sintering | Phenix/3DS (France)<br>EOS (Germany) | |
| **DIRECTED ENERGY DEPOSITION** | **Metal (powder feed)** | Direct Metal Deposition<br>Laser Engineer Net shaping<br>Laser Consolidation<br>Laser Deposition<br>Laser Deposition*<br>Laser Deposition*<br>Ion Fusion Formation | POM (USA)<br>Optomec (USA)<br>Accufusion (Canada)<br>Irepa Laser (France)<br>Trumpf (Germany)<br>Huffman (USA) | Honeywell (USA) |
| | **Metal (wire feed)** | Electron Beam Direct Melting<br>Wire & arc deposition (WAAM)<br>Shape Metal Deposition (SMD) | Sciaky (USA) | Cranfield Uni (UK)<br>Nuclear AMRC / RR (UK) |
| **MATERIAL JETTING** | **Polymer** | Polyjet<br>Projet<br>Ink-jetting<br>Reactive jetting | Objet (Israel)<br>3D Systems (USA)<br>LUXeXceL (Netherlands) | University of Nott's (UK) |
| | **Wax** | Thermojet / Projet<br>T-Benchtop | 3D Systems (USA)<br>SolidScape-Stratasys (USA) | |
| | **Metal** | Metal-Jet | | Oce (Holland) |
| **BINDER JETTING** | **Metal** | M-Print / M-Lab | ExOne (USA) | |
| | **Polymer** | 3DP | Voxel Jet (Germany) | |
| | **Ceramic** | 3DP (models & parts)<br>3DP (medical implant)<br>S-Print (sand cores)<br>D-Shape | 3D Systems (Z-Corp)<br>Therics (USA)<br>ExOne (USA)<br>D-Shape (UK) | |
| **MATERIAL EXTRUSION** | **Polymer** | FDM (Dimension & Fortus)<br>FDM (Replicator)<br>FDM (UP)<br>FDM (Cube & BFB) | Stratasys (USA)<br>MakerBot (USA)<br>Delta Microfactory (China)<br>3D Systems (USA) | |
| | **Ceramic** | Extrusion (Bio-printer)<br>Contour Crafting | Envisiontec (Germany) | Uni of South Carolina (US) |
| **VAT PHOTOPOLYMERISATION** | **Photopolymer** | Stereolithography<br>Digital Light processing<br>Digital Light processing<br>SLA / DLP | 3D Systems (USA)<br>Envisiontec (Germany)<br>Asiga (USA)<br>DWS (Italy) | |
| | **Photopolymer (ceramic)** | CeraFab<br>CeramPilot | Lithoz (Austria)<br>3DCeram (France) | |
| **SHEET LAMINATION** | **Hybrids / organic** | Ultrasonic Consolidation<br>MCor IRIS | Fabrisonic / Solidica (USA)<br>MCor (Ireland) | |
| | **Metallic** | Ultrasonic Consolidation | Fabrisonic / Solidica (USA) | |
| | **Ceramic** | Laminated Objet Manufacture | CAMLEM (USA) | |

.* *Technology typically associated with turbine blade repair, but also used for ALM applications*

## How do different Additive Layer Manufacturing mechanisms differ

Each of the different ALM mechanisms detailed in the table above work in a different way, albeit they all produce parts in a layer-upon-layer fashion. The different mechanisms can be defined as follows:

1. **Powder bed fusion** – a group of technologies that use localised heat to melt or sinter layer of powdered materials by manipulating the position of a heat source over a moving build platform.

2. **Directed energy deposition** – a group of technologies that feed material into a moving heat source positioned over a substrate.

3. **Material jetting** – a group of technologies that feed liquid material through a moving print head after which solidification takes place through cooling or chemical reaction on top of a moving build platform.

4. **Binder jetting** – a group of technologies that feed liquid material through a moving print head onto a bed of powdered material casing localised binding or chemical melting of the powder.

5. **Material extrusion** – a group of technologies that feed either solid of semi-solid material into a heated chamber or plunger from which a continuous filament or bead of material is extruded onto either a static or moving build platform.

6. **Vat Photopolymerisation** – a group of technologies that use a range of optical systems to direct light at specific wavelengths onto the surface of a photocurable liquid, causing a localised state change from liquid to solid.

7. **Sheet lamination** – a group of technologies that use either mechanical or thermal energy to cut layers of material from feed stock, which are then subsequently stacked and either thermally or chemically bonded.

A selection of different 3D printed In-the-Ear (ITE) hearing aids - **© Econolyst**

## What are Additive Layer Manufacturing processes being used for in the healthcare supply chain?

As we have already seen, the term Additive Layer Manufacturing relates to a class of technologies under which there are some seven sub-classes and in which there are multiple machines and multiple vendors processing a range of different materials. It is therefore important to consider what these different machines and materials are being used for and how this relates to the medical and healthcare sector.

## Prototypes – 'used and discarded'

Prototypes represent the most common application of parts produced using additive layer manufacturing technologies. We commonly refer to such parts as 'rapid prototypes' and their manufacture as 'rapid prototyping' or RP.

RP is now a well-established process with almost 30-years of industrial application and is currently used widely within new product development. The main benefits of RP are that accurate prototypes can be manufactured quickly and cost effectively, directly from Computer-Aided Design (CAD) data, providing reassurance to designers, engineers, suppliers and marketers alike. Typical applications of RP within the medical and healthcare sector would be in the manufacture of prototypes for products such as electronic & diagnostic device housing, syringes, oxygen masks and ventilators, surgical instruments or components from large capital equipment such as scanners – to name just a small subsection.

Full colour prototype model of a medical defibrillator device 3D printed using a Z-Corp 510 printer* - **© Econolyst**

Given the maturity of RP and its well-documented growth, we will not focus on this application of ALM technologies within this report; rather we will look to areas where we believe there will be significant growth in both machine utilisation and material consumption in the future.



*.* Note – Z-Corporation was acquired by 3D Systems on January 3rd 2012. Z-Corp technology has now been rebranded as part of the 3D Systems Projet range of technologies. The Z-Corp 510 has subsequently been replaced with more up to date Projet solutions*

## Patterns – 'enabling downstream casting'

Like all technologies, ALM technologies do have limitations, whether this is speed, cost, part quality, surface finish, accuracy or mechanical and material properties. However, we must remember that ALM is an enabling process that does not have to stand alone within the supply chain, and can be integrated with other more traditional manufacturing approaches.

One such approach is casting, where typically molten metals are poured into a 'tool cavity' or 'shell'. This allows for the manufacture of parts in a wider variety of materials than those currently available using direct additive manufacturing processes.

Although cavities, shells and even production parts can be made directly using additive manufacturing (which we will discuss later), also it is also possible to make patterns around which a cavity or shell can be formed, a process called Rapid Casting (RC).

A platform of dental crown and bridge patterns made in photocurable polymer prior to investment casting - **© Envisiontec**

## Expendable patterns for investment casting

For almost 20 years, patterns have been manufactured using additive layer manufacturing. These parts have then been used as sacrificial patterns in the 'Investment Casting' (IC) or 'lost wax' casting process – a 5,000 year old technology originally developed in India. With IC, a sacrificial pattern is coated in a 'shell' of ceramic slurry, which is then left to dry. Layers of shell are sequentially built up until the pattern is 'encased' within the ceramic. The shell is then 'fired' at high temperature, giving the ceramic its strength, whilst also 'burning out' the sacrificial pattern. Molten metal is then gravity poured (often under vacuum) in to the resulting cavity. Once the shell has cooled and the metal solidified, the ceramic shell is broken away leaving a metallic facsimile of the original pattern.

Multiple additive layer manufacturing processes are now used to make IC patterns in either polymeric materials or directly in wax. Polymeric processes include 3D Systems' SLA & Projet, Stratasys' Polyjet, Envisiontec, Asiga & DWS technologies. Wax systems, which produce parts that are easier to process by investment casting, include the 3D Systems Projet and SolidScape machines.

Traditionally, IC was only possible using a wax pattern manufactured either by hand or by injecting molten wax into a tool cavity. This of course required the prior manufacture of a cavity, which would take considerable time and could then only be used to make a single 'fixed' geometry.

Within the medical sector the most common application for ALM investment casting patterns is within the reconstructive dental market, where the processes is used globally to make patient-specific dental crowns and bridges. We will discuss this application in detail in section 2.

## Tools – 'enabling downstream manufacturing'

Much in the same way as for casting – ALM can also be used to enable a number of downstream processes through the production of tools and cavities in a process called Rapid Tooling (RT). Typical applications include the manufacture of injection moulding cavities and inserts, which are made using both metallic and polymeric ALM processes. Ceramic processes are also used to make sand casting cores and cavities, with some developmental processes such as Large Area Maskless Photopolymerisation (LAMP) being developed to make direct investment casting shells for complex ceramic moulds. Other applications of additive tooling include press tools for malleable materials such as aluminium, carbon and glass fibre composite layup tools and specialist tools used in the cardboard packaging industry.

A vacuum formed dental aligner shown next to a bespoke vacuum forming tool made using the Stratasys Polyjet process - **© ClearCorrect**

Within the medical sector, the most common application for tooling is within the cosmetic dental market, where individual form tools are being made using a variety of polymeric ALM processes, over which acrylic dental aligners are then vacuum formed. We will also discuss this application in detail in section 2.

## Additive Manufacturing – 'a potential paradigm shift'

Rapid Prototyping, Rapid Casting and Rapid Tooling are all valuable tools within the modern day supply chain. They mitigate risk, compress lead-times and in some cases significantly reduce the overall cost of manufacturing. However, they still operate within the constraints of a traditional supply chain and as such they are highly unlikely to stimulate radical changes in the way that many products are brought to market.

Imagine then what would happen if the traditional supply chain could be largely mitigated and ALM technologies could be used to realize products directly from computer data. Although still in its infancy, this approach is now being adopted across a range of sectors that have embraced ALM technologies for the production of end-use-parts in a process referred to as 'Additive Manufacturing' or AM.

## The business & consumer benefits of Additive Manufacturing

As a 'tool-less' and digital approach to production, Additive Manufacturing (AM) presents companies and consumers with a wide and expanding range of technical, economic and social benefits.

AM has the potential to change the paradigm for manufacturing, away from mass production in centralised factories constrained by tooling, to a world of mass personalisation and distributed manufacture. Using AM, it is possible to mitigate the need for fixed assets such as tooling, freeing up working capital within the supply chain and reducing business risk in new product innovation. The layer-wise nature of AM also enables the manufacture of highly complex shapes with very few geometric limitations compared with traditional manufacturing processes, enabling the manufacture of parts that cannot easily *(if at all)* be made by traditional methods, due to design complexity.

The layer-wise manufacturing approach of AM can also reduce the amount of raw materials used during production, placing a lower burden on natural resources and the environment. Moreover, AM has the ability to greatly compress the supply chain and allows concurrent manufacture at multiple locations nearer to the point of consumption, which has obvious supply chain benefits to the consumer, the local economy and the environment.

As a digital technology, AM is progressively being integrated with the internet and other digital data sources such as medical scanning, enabling consumers & patients to engage directly in the design process, and allowing true consumer / patient personalisation.

AM is therefore not only a disruptive technology that has the potential to replace many conventional manufacturing processes, but also an enabling technology allowing new business models, new products and new supply chains. The benefits to the business of AM can therefore be summarised as:

1. **Digital & tool-less manufacture** – enabling increased levels of product variance and smaller economic batch production to support specific geographic, demographic or social trends.

2. **Exploiting design freedoms** – enabling the production of products with increasing levels of geometric complexity, with little if no cost penalty.

3. **Distributed manufacture** – enabling production nearer to the point of consumption and potentially transitioning the cross boarded movement of goods across to services (data).

4. **Enabling product personalisation** – coupling economic low volume production in batch sizes of one with complex geometry to realise individualised products.

5. **Offering new experiences in retail & healthcare** – engaging the consumer in the product design experience through online or in-store access to intuitive software tools or 3D scanning.

6. **Addressing emerging markets** – coupling product personalisation with retail accessibility for an aging and changing population demographic.

7. **Greening the supply chain** – reducing material consumption & stock holding, mitigating packaging waste, reducing logistics infrastructure & reduced life-cycle $CO_2$.

## The strategic alignment of AM with the global medical & healthcare sector

*"We all live in a global village with 7-billion other people. We are all a different shape, different size, different culture, different religion – we all have differing levels of income and different levels of state support – but, we ALL value our health and the health of our families above all else."*

It should therefore come as no surprise that the medical and healthcare sector already represents one of the strongest vertical markets for AM, tooling and casting. With a growing global population, increasing old age in Western economies and increasing healthcare demands in the developing world, additive layer manufacturing presents a compelling commercial proposition to respond to these ever changing global mega-trends. Whether used to support the manufacture of personalised products or to enable supply chain compression and cost reduction, AM is already providing an alternative to many traditional production methods & supply chains.

The Bearina IUD – a conceptual contraceptive device made using a consumer 3D printer and a small copper coated coin - **© Ronen Kadushin**

## Applications for additive manufacturing in healthcare

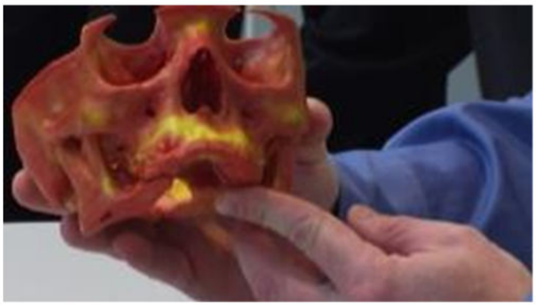
Today AM is being used commercially to manufacture a wide range of healthcare and medical products, from acetabula cups used in hip replacement surgery, to knee implants, cranial patches and maxiofacial implants used in reconstructive surgery. These end-use parts are typically being made using bio-compatible metals such as titanium & cobalt chrome, or specialist polymers such as Polyaryletherketone (PAEK), a semi-crystalline thermoplastic material developed for the use in high-temperature laser sintering.

AM has also found applications in the direct manufacture of disposable polymeric surgical & dental cutting & drilling guides, which are personalised to the individual patient and used by surgeons to ensure precise medical procedures. Metallic AM is also being used to make both bespoke and low-volume surgical instruments for specialist surgical procedures.

AM has also been used for a number of prosthetics applications including bespoke patient specific limb sockets & facial prosthetics produced to match both the form and skin tone of the patient. A number of applications have also been identified to use AM for the production of occupational health and physiotherapeutic devices such as braces, splints and personalised exoskeletons.

Emerging additive layer manufacturing technologies are currently being trialled for the production of bespoke spectacles involving the integral manufacture of both bespoke frames and prescription lenses.

Using coloured additive layer manufacturing technologies and flexible materials, applications have also been found for the manufacture of teaching and training aids for medical and surgical students, such as the production of teachings aids to demonstrate bone density or tumour distribution. Multimaterial processes using both clear and opaque materials are also being used to make scale models of near-team unborn foetuses, which are being purchased as keepsakes by parents.



A full colour 3D printed diagnostic and training aid showing changes in bone density within a patient's skull - **© Econolyst**

Direct AM and Rapid Casting has found a number of applications within the dental sector, including the manufacture of personalised dental bridges and crowns, both in standard Cobalt Chrome materials, but also in noble precious metals such as gold. Rapid Tooling is also being used for the production of individual forming tools over which invisible dental braces are now being manufacture by the million. 'Stone model' tools are also being produced with which dental technicians and orthodontists are able to pre-fit and accurately prepare crowns and bridges.

Conceptually, consumer 3D printing technology has also been postulated as a potential low cost manufacturing method for birth control devices such as UDIs – albeit there have been no clinical trials of such a product to-date.

By unit volume of parts manufactured, by far the largest application for AM to-date has been within the production of personalised In-The-Ear (ITE) hearing aids. These are manufactured to fit exactly into each individual patient's ear(s), providing a device with increased levels of comfort and performance though reduced feedback.

Post-surgical rehabilitation split manufactured using Selective Laser Sintering - **© Peacock Orthotics Ltd**

Other medical applications of AM include the manufacture of low volume healthcare device housings and components. Applications have been seen in the manufacture of parts for specialist MRI scanning machines, microfluidic reactors, blood centrifuges and monitoring systems. In all these cases, traditional manufacturing is simply not cost effective for the low volumes associated with specialist healthcare devices. However, it has been demonstrated that AM can provide a cost-effective production alternative.

AM is currently being used to manufacture patient specific orthotic insoles for shoes, offering personalised posture correction and pain relief.

3D printed facial prosthetics manufactured using 3D scan data and sampling of the patients own skin tones - **© Fripp Design Ltd**

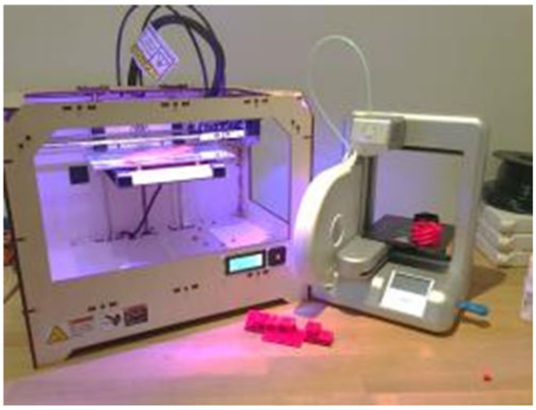
A significant level of global research is currently investigating the use of AM in the manufacture of synthetic biocompatible bone structures or scaffolds, into which new cells are able to propagate, the objective being to alleviate the need to make expensive, time consuming and painful bone grafts. Research is also focused on the production of 'scaffolds' used within clinical research trials and regenerative medicine along with other research into the '3D printing' of cells to form living tissue – initially aimed at pharmaceutical and diagnostic application, but with longer term opportunities in regenerative medicine, where stem cells could one day be used to regenerate new organs such as livers. Early state research is also underway into the production of 'smart pharmaceuticals' made using ALM technologies. We will review each of these applications within section 2 of this report.

AM is also being investigated for the production of products to prevent accidents and injury (personal protective equipment – PPE), such as helmets & projective pads for both sports applications and for motorists. However, we do not cover these applications within this report.

## The advent of the consumer 3D printer

The vast majority of AM applications discussed within this report so far have been enabled using 'commercial - high-end' ALM technologies. These range in price from $20K for a machine capable of producing dental stone models to a high temperature polymeric laser sintering machine costing $1M, but which is capable of producing bio-compatible direct medical implants.

However, within the last four years, there has been a steady growth in the sale of consumer or prosumer 3D printers, which are sold either fully assembled or in kit form. These machines are typically sold for between $500 and $3,000, and are aimed at a new range of users, from professional product designers and architects working in small home offices, to students, hardware hackers, makers and hobbyists. The general consumer is the end goal for the manufacturers, but as of today there are very few general consumers with the skill, knowledge or confidence to utilise a 3D printer effectively and consistently. However, as the capabilities and ease of use improve, together with wider education, it is conceivable that they will become more ubiquitous across the next generation.



Makerbot replicator and 3d Systems Cube consumer 3D printers - **© Econolyst Ltd**

Although greatly limited in their capabilities compared with their 'industrial big brothers', these machines are finding applications in direct part manufacture, inevitably some of which have a medical and healthcare focus. It is also worth noting that the technical capability of some of these machines is maturing rapidly, taking them closer to their commercial counterparts, with capability convergence not a matter of if, but when – possibly within 2 to 3 years' time.

## Consumer 3D printers & healthcare

Consumer 3D printers have to-date been used to make models of viruses and human anatomy derived from MRI & CT scans – albeit, these have purely an educational purpose. But, consumer 3D printers have also been used to make simple rehabilitation aids such as splints for fingers and toes along with far more complex 'mechanisms' such as artificial gripper and hands for amputees and those with congenital deformities.

Although still in its infancy, the potential impact of accessible consumer 3D printing on affordable and localised healthcare could be both profound to the patient but also highly disruptive to the current supply chain. Using open-source data sharing repositories such as Thingivers, or online collaborative design forums such as GrabCAD, designs for new medical products could be undertaken collaboratively online, shared globally across the web and downloaded locally whenever and wherever they are needed. They can then be scaled to the size of individual patients prior to manufacture.

3D printed Robohand downloaded from Thingiverse for local manufacture & assembly - **© Makerbot**

In the longer term, using web, mobile and tablet applications, it is not inconceivable to imagine a world where simple medical and healthcare products could be personalised online through medical device manufacturers' websites and then downloaded or streamed for home manufacture or manufacture within a local pharmacy or retail outlet.

Of course such a business model would require careful planning in order to mitigate product liability issues, protect intellectual property and maintain a robust value chain for the original equipment manufacturer (OEM).

However, such a model could also prove highly disruptive to established medical device and healthcare companies, as it largely eliminates the need for new market entrants to invest in expensive capital equipment or to develop whole sale and retail logistics and supply chains.

Preparation of lens prescription data prior to additive manufacturing - **© Luxexcel**

## Summary of applications and adoption drivers

Within the first section of this report, we have outlined the applications of additive layer manufacturing technologies within the healthcare and medical sector and addressed the drives behind technology adoption. We have discussed many of the current commercial applications and touched on a number of developmental areas that we believe will have significant commercial impact in the future. We have also discussed the emergence and potential impact of consumer 3D printing as both an enabling and disruptive technology. The table below provides a summary of the medical applications discussed in this section against the business drivers to adoption, the application of additive manufacturing in the supply chain and the types of ALM technologies employed.

| | Business Drivers to technology adoption | | | | Additive Manufacturing application | | | Technology class | |
|---|---|---|---|---|---|---|---|---|---|
| | Product personalisation | Economic production | Lead-time compression | Increased performance | Direct part manufacture | Casting pattern manufacture | Tool manufacture | Commercial machine | Consumer / prosumer |
| Hearing and audibility aids | X | X | X | X | X | | | X | |
| Orthopaedic implants | X | X | X | X | X | | | X | |
| Dental aligners and cosmetics | X | X | | X | | | X | X | |
| Facial and limb prosthetics, mobility & rehabilitation | X | X | X | | X | | | X | |
| Orthotic foot ware | X | | X | | X | | | X | |
| Reconstructive dental applications | X | X | X | | X | X | | X | X |
| Ophthalmic & vision opportunities | X | X | X | | X | | | X | |
| Patient specific surgical guilds and aids | X | | | X | X | | | X | |
| Reconstruction, trauma & surgical devices | X | X | X | | X | | | X | |
| Neonatal modelling | X | | | | X | | | X | |
| Diagnostic systems and micro-reactors | | X | X | | X | | | X | |
| Bio-medical scaffold systems | | | X | X | X | | | X | X |
| Soft tissue and cell printing | X | | | X | X | | | X | |
| Birth control | | X | | | X | | | | X |
| Drugs, pharmacology & medical therapies | X | | | X | X | | | X | X |

As the table above demonstrates, the vast majority of applications are driven by the ability to provide patient specific products. Enabling more economic and faster production compared with traditional manufacturing is also prevalent in a number of applications, with increasing product performance less of a business driver to adoption. Direct part manufacturing has far greater adoption in the medical sector than either casting or tooling enabled using additive layer manufacturing processes, with commercial machine platforms being used for the majority of applications.

# HEARING AIDS

More than 5% of the world's population, that's to say 360 million people have disabling hearing loss. This statistic can be broken down further to 328 million adults and 32 million children who suffer from this impairment.

Disabling hearing loss refers to hearing loss greater than 40dB in the better hearing ear in adults and a hearing loss greater than 30dB in the better hearing ear in children. The majority of these people live in low- and middle-income countries. Approximately one-third of people over 65 years of age are affected by disabling hearing loss. The prevalence in this age group is greatest in South Asia, Asia Pacific and sub-Saharan Africa.

In the USA, 17% of the population have hearing loss, but only 20% (or 10.6-million people) actually have a hearing aid. Current production of hearing aids is estimated to meet less than 12% of global need, suggesting some 43 million people are using hearing aids.

In developing countries, fewer than one out of 40 people who need a hearing aid have one. The lack of availability of services to fitting and maintaining hearing aids, and the lack of batteries to sustain them are seen as the main technical barriers to wide scale adoption, together with social implication and cost.

## The market

The global hearing instrument market is estimated to reach $22 billion (US) by 2015. It is considered relatively immune to global economic fluctuations, despite measurable drops in US sales in 2008. The market can be segmented into hearing aids, measurement and testing instruments and implants. Of greatest interest to the AM community are hearing aids, specifically hearing aids with personalized geometry, such as in-the-ear and in-the-canal aids, which must be made to fit the individual patients' ear canals. The hearing aid part of the instrument market was estimated to be worth some $12-billion in 2012.

Conformal hearing aid component 3D printed on a Stratasys Objet machine- **© Stratasys**

The hearing aid market consists of a small number of global providers including Phonak & Unitron both part of Sonova Holding in Switzerland; Oticon & Bernafon both part of William Demant Holdings in Denmark; GN Resound & Widex also in Denmark; Starkey Labs in the USA; and Siemens in Germany. There are then a further 20 or so other smaller companies servicing niche elements of the market and local geographies.

There is an enormous difference in the cost of hearing aids solutions, which can range in price from $150 for an 'off-the-shelf device' up to $4,000 or more for a pair of fully personalized, digital, blue tooth enabled devices. The average life expectancy of a hearing aid is between 3 and 5 years. Between 18-million & 20-million new hearing aids are produced each year with an average selling price between the manufacturer and the audiologist of $1,100 per pair.

## Manufacturing cost

Following an investigation by the German regulator into a potential oligopoly within the hearing aid market, operational costs for some companies have been made available. We know for instance, that for a $1,000 pair (manufacturers cost to the retailer), $250 represents the manufacturing cost, $75 is attributed to R&D, $250 to sales and marketing and $425 in operating costs and profits. Interestingly, such a hearing aid set, with a cost from the manufacturer to the audiologist of $1,000 is typically sold to the consumer for some $3,000.

A detailed analysis of a more complex high-end hearing aid with a bill of materials cost of $360 (rather than $250), suggests that $200 is apportioned to the microphone and speaker components, $100 to the amplification circuit, $10 to the wiring, battery and controls, and some $50 to the manufacture of the enclosure or shell.

## The scale of AM in the hearing aid shell sector

Additive Manufacturing has been used to produce hearing aid shells for almost a decade, with companies including Siemens, Starkey and Phonak all investing in the technology early on. Initially, 3D Systems' Stereolithography (SLA) ALM process was used exclusively for hearing aid shell production. A dedicated dual vat hearing aid shell printer, the Viper HA, was launched in 2004 using Dreve Fototec photocurable materials.

Following the development and commercialisation of other ALM technologies, the hearing aid shell market has diversified its production, with shells now regularly being made on 3D Systems' SLA and, possibly, Projet machines, Stratasys' Polyjet 3D printers and Envisiontec's DLP based platforms.

By unit volume, Envisiontec claims that its machines are now used to produce some 80% of the world's 3D printed hearing aid shells. The company's client Phonak claims to produce some 98% of all its shell-based hearing aids using the EnvisionTec process. Based on resin consumption, Envisiontec estimates that its customers are producing some 10-million shells per annum. This figure seems reasonable if we consider that the total number of hearing aids manufactured annually is no more than 20-million units, but not all hearing aids shells are 3D printed. Sampling the product categories of the leading hearing aid manufacturers, we estimate that no more than 60% of hearing aids on the market have personalised elements, with the lower cost and some behind the ear units having 'standard sized' ear buds. For this reason we believe the global demand for personalised, and therefore 3D printed, hearing aids shells is around to 12-million units per annum in total, which is serviced by multiple 3D printing machine vendors, notably EnvisionTec, Stratasys & 3D Systems.

## AM production capacity and material consumption

Using an STL file for a hearing aid shell we can undertake a number of scenarios to understand the production economics for different AM approaches.

Using a 3D Systems Viper SLA machine (not Viper HA), we calculate that it would be possible to make some 110,800 hearing aid shells per annum, based on an industry standard 77% machine utilization. The cost of the hearing aid shell allowing for machine depreciation, waste, material and labour would be $2.43. Well below the $50 bill-of-material costs discussed earlier. However, we must consider that this cost also includes digital data preparation.

A selection of hearing aid geometries produced using the Envisiontec Perfactory process- **© Envisiontec**

Using an Objet Eden 350 3D printing platform from Stratasys, we calculate that it would be possible to make some 91,494 hearing aid shells per annum, based on 80% machine utilization. The cost of the hearing aid shell allowing for machine depreciation, waste, material and labour would be $1.79.

If we therefore take the higher productivity SLA platform, we could assume that the world's demand for 3D printed hearing aids could be serviced by just 63 machines. Discussions with the technology vendors would suggest that this capacity may already have been reached, with very little growth taking place within the capital equipment market for new systems, largely as a result of the maturity of the 3D printed hearing aid shell market. Any new machines sales are to back fill older platforms, or to respond to new smaller niche market opportunities.

In terms of on-going material revenue, the hearing aid sector is no cash-cow. The typical 3D printed hearing aid shell weights some 0.9 grams. Allowing for support structure material and waste each shell is unlikely to consumer more than 1.2 grams of resin. Hence, 833 shells can be produced from a single Kg of material; with the global demand for material therefore capped at 8,400 Kg.

Although all current 3D printed hearing aid shells are produced from photocurable resins, they are made on different machines, with materials sourced from different vendors. Looking across the applicable vendors, their materials range from $400 per kg down to $180 per Kg. If we assume an average cost of $300 per Kg, we can forecast the materials market for hearing aid shell manufacture to be worth just $2.5M per annum, with little opportunity for growth.

## The future landscape

Clearly, given the current level of saturation, there is little scope for organic growth in either machine sales or resin sales to service the hearing aid industry as it stands. It is likely that some smaller hearing aid companies will transition across to using 3D printing. Albeit, the major players that are already using the technology account for some 80% of the world's hearing devices, leaving little scope for significant growth elsewhere.

It is possible that other companies engaged in the manufacture of high end, personalised audibility devices such as in-ear monitoring systems for musicians, armed forces personnel and sporting judges could transition to a 3D printed workflow. However, this is unlikely to have significant impact on the market.

Close-up of a hearing aid produced using the Envisiontec Perfactory process- **© Envisiontec**

Looking to the mid-term, it is possible that low-cost prosumer technologies such as the Form 1 3D printer from Formlabs could provide an alternative production solution, if companies are looking to develop more distributed manufacturing supply chains or production on a local level. However, this will have little impact on the piece part production economics.

In the longer term, research is already underway to develop multi-functional 3D printing technologies capable of producing embedded functionality into electronic devices. Based on the maturity of the current 2D printed electronics industry and its convergence with 3D, we would expect that within 10-years we may be able to print a hearing aid shell with integral speaker, microphone, wiring and controls. This would just require an additional IC & power supply. Cost modelling of such a product suggests that it could be mass-produced for under $15. By 3D printing a large proportion of the electronic systems within the device, it would be possible to reduce the bill-of-materials by some $210 (60%) as well as assembly times and logistics. This could then increase the penetration of the technology, through overall manufacturing cost and subsequent price reduction to the consumer.

# ORTHOPAEDIC APPLICATIONS OF AM

The global orthopaedic market, which includes surgical instruments, prosthetics, orthotics and implants was valued at $43.1-billion in 2011. The market is growing at a rate of more than 9% per annum, and is projected to surpass $48.5 billion by 2015 and $56 billion by the year 2017. This growth is driven by an aging and growing population, rising incidence of age-related conditions such as osteoarthritis and improving orthopaedic surgical procedures.

The US continues to be the largest regional market for orthopaedics. Asia-Pacific constitutes the fastest growing regional market, driven by factors such as steady economic growth, rising personal incomes, improving public healthcare services, and increasing life expectancies, which characterize the majority of the region's economies. Despite the fact that Asia accounts for more than half of the worldwide aging population, the region holds less than 10% of the orthopaedic devices market. China and India are, as expected, leading the growth within this market.

Segment-wise, artificial knee implants represent the largest and fastest growing sub-segment for orthopaedic implants with the fastest growth market for instrumentation coming from the spinal products segment.

## Artificial joints

Of greatest interest to the metallic AM community is the market for orthopedic implants, otherwise known as artificial joints. The artificial joint market was valued at $17.5-billion in 2012 and is expected to grow to $19.4-billion by 2015. The market is typically dominated by a small number of large players including Zimmer, DePuy, Stryker and Biomet, with a number of smaller players such as S&N, Wright Medical, Corin and Exactech also operating in the sector.

Femoral (knee) implant with designed porosity - **© Econolyst**

The most common implants are for hip, knee and spinal replacements, with 181 out of every 100,000 people in the UK having a hip replacement, and 142 people out of 100,000 having a knee replacement. Occurrence rates differ greatly from country to country, with Germany and the USA recording the highest incidents of knee replacements, requiring implants (213 per 100,000 people) and Germany and Switzerland having the highest incidents of hip replacements (296 & 287 respectively out of every 100,000 people)

Within the UK, approximately 160,000 total hip and knee replacements are undertaken each year. Within the USA this figure increases to 719,000 knee replacements and 332,000 hip replacements each year. In addition 53,000 people in the USA have shoulder replacements, and 3,000 have elbow replacements. Within the EU 25 national, some 698,000 hip replacements are undertaken annually, with some 560,000 knee implants undertaken in the same time period. From this geographic data, we would estimate that some three million implants are manufactured annually.

## Product cost

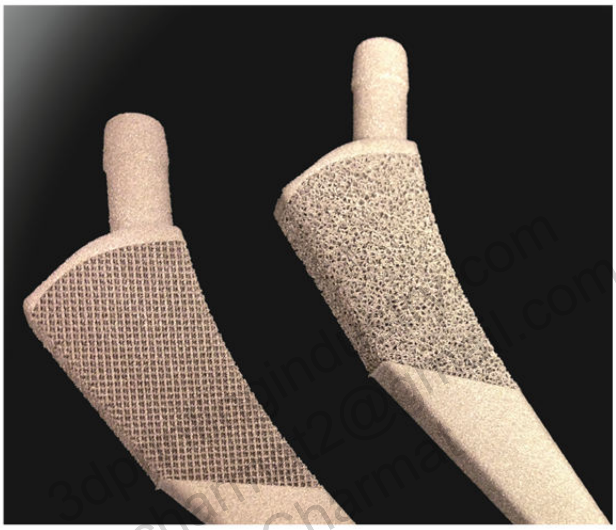
In 2011 the average payment to a hospital for a hip implant was around $11,748. Of this the average purchase price of the artificial implant by the hospital was some $6,278, with the physician receiving some $1,470. The remaining $4,000 represents hospital nursing and administrative fees. Interestingly, the actual average list price from the manufacturer of the artificial hip implant was $14,099, suggesting hospitals are being given up to a 66% discount to use specific implant brands. If we assume a similar trend in knee replacement surgery, the average list price of a $12,000 implant also results in a sale cost of around $6,500.

It is estimated that the average orthopaedic implant (hip & knee) costs some $6,000 (2010 data). Of this, $2,550 is attributed to business costs (selling & administration ect), $1,716 is attributed to manufacturing, $630 to net income, $360 towards R&D costs and $228 as taxes. Assuming an average cost per item of $6,000 and based on production volumes of 3 million per year, we have an estimated industry value of $18 billion, which correlates to our earlier assumption.

So are ALM processes a viable proposition to manufacture $1,716 metallic implants, in a 3 million unit market place?

## Additive Manufacturing of metallic implants

The primary driver for the adoption of AM for the production of orthopaedic implants is not, as some would think, the ability to customise the device to the individual patient, rather it is the ability to increase the performance of the product and drive cost out of the supply chain, by imparting designed surface texture onto the part.



Experimental AM hip stems produced with designed porosity surface texture - © **Arcam AB**

Using AM, it is possible to impart texture onto the surface of the part which promotes Osseo integration of the bone. Typically, this surface texture is achieved through the addition of a secondary ceramic coating or it is achieved using other powder metallurgy processes during the primary manufacturing phase.

The leading AM vendor within the orthopaedic industry is undoubtedly Arcam AB, based near Gothenburg in Sweden. Arcam developed the metallic Electron Beam Melting (EBM) ALM process, with a primary focus on medical and aerospace applications.

To-date (October 2013) Arcam has sold an estimated 145 EBM platforms ranging from $666K to $847K. The company's current Q10 platform, which is aimed at production applications, such as implant manufacture, has a list price of approximately $788,000.

30% of Arcam's install base (approximately 43 machines) is within the medical sector. It is estimated that some 40,000 implants are currently being produced each year using these machines. There are a growing number of CE-certified and FDA-cleared implants produced with the Arcam EBM technology coming to market year-on-year.

Production batch of 108 acetabula cup (hip socket) implants produced in 95-hours © **Arcam AB**

Adler Ortho based in Italy started using EBM production for the manufacture of acetabula cups in 2007. The company has since developed an entire production line built around EBM technology, producing a product line branded Fixa-Ti-Por, which is sold as a porous titanium cement-less implant.

Lima orthopaedic, also based in Italy have also developed a market position for their Trabecular Titanium hip implants also made using EBM, along with US based Exactech, who market their EBM manufactured hip implants under the trade name InteGrip.

## AM productivity and part cost

Using the Arcam EBM process it is possible to produce 108 acetabula cups in a 95-hour build. Allowing for a realistic machine utilization of 70% (based on a mass production scenario), we estimate that it is possible to produce some 7,470 implants on one machine per annum. This figure will be significantly reduced for implants such as hip stems and knees, which cannot be packed as efficiently in the machine, albeit we would expect products such as spinal implants to be manufactured in greater volumes given their smaller size.

We estimate that the production cost of a titanium acetabula cup manufactured using the Arcam EBM process, allowing for machine depreciation, labour and material would be some $150 - $200. This assumes 5-year machine depreciation, 10% material waste, a 90 gram product and feed stock titanium powder costing $700 per Kg.

## Material and machine market

At present Arcam machines are producing less than 2% of the world's implants. This capacity could in fact be supported using just 6 Q10 EBM machines costing $4.7-million and consuming some $2.8-million of titanium powder per annum.

Although EBM parts must be cleaned, post processed (machined), fitted with other non-AM components and sterilised; the increasing uptake by companies including Adler, Lima and Exceltec suggests that EBM is a cost-effective production solution at $150 to $200 per item, given that the final product has a total manufacturing cost of $1,716.

This should imply that there is a significant growth opportunity for AM. However, analysis of leading implant vendors such as Zimmer, DePuy & Stryker shows that these companies have already researched, developed, intellectually protected and implemented other solutions to promote osteo-integration with their implants. It is therefore highly unlikely that they will make a rapid transition to AM having invested significantly in other solutions. We therefore believe that AM will be a technology adopted mainly by smaller implant manufacturers focused on local and regional markets and niche products, such as shoulders, elbows and spines. It is therefore not unrealistic to suggest that within the next 10 years AM could be used for 10% of the global implant market.

To produce 300,000 implants per year would require some 40 Q10 EBM machines representing a capital investment of $31.6-million. These machines would consume some 30-tons of titanium powder costing around $21-million.

## Selective Laser Melting applications

In addition to the EBM process already discussed, it should also be noted that other metallic AM technologies such as Selective Laser Melting and Direct Metal Laser Sintering are also being used to both evaluate and produce implants.

However, given their much slower deposition rate, they are, on the whole, less cost effective for this mass production application, with the exception of much smaller implants such as spinal implants and dental implants. The main application for laser-based metallic AM within the orthopaedic sector appears to be in the trauma fixation part of the market, where the technology is being used to make patient-specific implants.

Metallic laser machine vendor EOS estimates that of its 100 machines currently being used in the medical sector, 70 are for dental applications and 30 are for bespoke orthopaedic implants.

# DENTAL ALIGNER APPLICATIONS OF AM

The dental Orthodontic market, which is currently valued at $0.8 billion, is set to rise to $1.1-billion by 2018. It is estimated that some 2.6-million patients start treatment each year for malocclusion (teeth straightening), valuing each patient interaction at some $423. It should be noted, that this is not the cost of the dental treatment, rather it is the cost of the hardware used during the treatment, such as braces, aligners and fixators.

Of the 2.6-million patients starting malocclusion treatment each year 600,000 are adults and 2-million are below the age of 19.

Historically, dental aligners, or braces, were made using shape memory alloy metal wires, which were stretched across metal pads bonded to a patient's teeth. Although effective, the procedure did have drawbacks, most notably the continual need to revisit the dentist for readjustment, the inability to remove the braces once fitted and the social stigma and aesthetics of having a 'mouth full of metal'. Although new alloy wires and ceramic pads have gone some way to reduce the visual impact of braces, the procedure still requires continual input from a dental professional, so alternatives are becoming popular.

## Additive Manufacturing and invisible aligners

It would be wrong to suggest that dental aligners are being manufactured directly today using AM, as no 3D printed parts are entering the patients' mouths. Rather, ALM processes are being used to make forming tools in the shape of patients' teeth, over which heated clear plastic is being formed under vacuum to make a dental aligner.

Vacuum formed clear dental aligner made using an Objet 3D printed former- **© Clear Correct**

## Align Technologies – industry pioneers

This approach was pioneered by US company Align Technologies (Nasdaq: ALGN), which was formed in 1997. Align developed an integrated process model whereby a patient's teeth could be digitised and viewed in a computer program by the orthodontist, who could then manipulate the teeth to the desired positions. A specialist software program would then work out the path the teeth would need to take and the number of iterations of movement needed to go from the current misaligned position to the desired position. Align has a thicket of patents on this methodology.

By taking a 'digital snap shot' of the intermediate teeth positions, the software is then able to generate a series of 3D printing files with the teeth in the various positions required at each iteration. Using these files, a set of forming tools can then be 3D printed, over which a sheet of non-toxic transparent acrylic can be vacuum formed. The deformed plastic is then cut out from the surrounding acrylic sheet, cleaned, polished and boxed along with the rest of the set. Each box is then clearly marked for the patient, indicating when it should be used and when it should be discarded. The patient-specific benefits of this approach are that the Invisalign aligners are invisible, can be removed at any time and the number of visits to the orthodontist is greatly reduced.

Invisalign braces cost a similar amount to a full treatment of traditional braces, which range from $4,000 to $6,000 depending on the severity of the malocclusion. It will therefore come as no surprise that a large percentage of Align's customers each year are adults.

In 2011 Align technologies shipped 309,335 sets of Invisalign dental aligners, generating the company some $479.7 million. Assuming the majority of this revenue was from aligners, we could assume that each set is sold to the orthodontist for some $1,550. This would seem realistic given the $4,000 to $6,000 cost to the patient.

Since 1997, Align has made some 80-million aligners, servicing some 1.8-million customers. This would imply that each customer receives an average of 44 aligner trays in their treatment.

The number of aligners needed by each patient is dependent on the severity of the malocclusion. Our research would suggest this is never less than 10 aligner 'trays' but can be as many as 48. Align's own documentation suggests an average of 40. Thus, if we assume that the average number of aligners per patient is 40, and Align shipped 309,335 sets in 2011, we can deduct that the company produced some 12.37-million vacuum forming tools using layer manufacturing that year. This equates to some 34,000 aligners per day. Recent reports, suggest that Invisalign are now (Oct 2013) producing some 17-million aligners per annum at a production rate of 46,575 per day.

Vacuum formed aligner **© Clear Correct**



It is believed that in 2001, Align Technologies had sixteen 3D Systems SLA-7000 platforms, which it was using to produce 1-million forming tools servicing 29,000 patients.

It is understood that in 2002, Align then ordered (over an undisclosed period) a further thirty nine SLA-7000 machines, taking their total capacity to 55 machines servicing a demand for some 4-million aligners. Based on this trajectory it could be assumed that Align technologies should now have amassed some 170 large frame SLA machines to service their current demand. However data from 3D Systems suggests that only 65 machines are being used.

We know from studies of SLA owners undertaken by Econolyst in the past that it is not uncommon to run SLA 5000 & 7000 platforms for up to 15-years before replacement, hence we can assume that many if not all of the Align machines are still operational.

However, irrespective of whether Align is still using its original machines, we must consider that the technology in situ will have matured and increased in productivity. It is likely that these machines will be running with newer, higher powered lasers, optical systems, revised software, better packing utilization and improved resin cure speeds. With this in mind, and using an STL file of a set of adult teeth, we have calculated that it should now be possible to produce some 96 aligner forming profiles on an SLA-7000 machine in under an 8-hour period. Applying a machine utilization of 90%, we therefore believe that Align should have in the order of 130 SLA platforms within their business, representing an investment of some $58.5-million. However information from 3D Systems suggests that only 65 machines are currently being used, which would imply that other vendor technology is now in place within Align to support this productivity gap. Our research suggests that this productivity gap is being filled with as many as 40 Envisiontec Perfactory Machines, based on Digital Light Processing (DLP) rather than laser resin curing. Therefore assuming Align has 65 SLA-7000 platforms and 40 Envisiontec systems, we estimate that the company has made a capital investment of circa $35-million, which over a 15-year period does seem conceivable given the scale of the Invisalign operation.

Irrespective of the technology adopted, we estimate with support structures, waste, labour and part material, each aligner tool uses $1.80 of resin, based on a commercial rate of $180 per Kg. This would suggest that Align is consuming some $22.2-million of resin per annum. However, given the company's early adoption, strategic position and significant hardware install base, we must assume it is receiving a sizable discount on commercial resin prices from both 3D Systems and Envisiontec.

We estimate the total manufacturing cost of an aligner tool using an either an Envisiontec perfactory system or 3D Systems SLA-7000, including machine depreciation, waste, labour and material cost to be some $4.00 to $6.00 per unit respectively.

## ClearCorrect – next generation adopters

Headquartered in Houston, Texas, and founded in 2007 by dentists to serve the dental and orthodontic industry, ClearCorrect aims to provide a superior and more affordable clear aligner system. In 2010 the company developed an automated process path based on 3D printing. In only three years, ClearCorrect has developed a competitive market proposition and is competing directly with Invisalign – albeit the company remains a fraction of the size of Align.

In July 2012, ClearCorrect released a YouTube video showing its production facility, housing eight Objet Eden 500V 3D printers. In April 2013 the machine supplier, Stratasys (owner of the Objet product line), put out a press release stating that ClearCorrect had increased its capacity by an additional 30%. From this we can surmise that ClearCorrect now has some 10 or 11 Eden 500V machines, representing an investment of $1.9 million.

Considering the bed size of an Objet Eden 500V and the size of the ClearCorrect formers, we estimate that the company can fit some 80 parts into a print run. Based on a layer thickness of 17-microns, we estimate that it will take approximately 7 hours to print a tray of aligners. Assuming ClearCorrect is running a three shift pattern, this gives them the capacity to produce some 850,000 to 950,000 aligner per annum. This compares to Invisalign who we estimate is producing some 12.37 million units.

The ClearCorrect production facility using Objet Eden 500V printers - **© Clear Correct**

Assuming clear correct is also producing 40 aligners per customer, this gives the company an annual customer base of 23,750 people. Using Econolyst modelling software we estimate that allowing for machine depreciation, labour, waste and material, it would cost less than $4.00 to produce an aligner vacuum forming tool using an Objet 500V.

## Looking to the future

It is interesting to see that within the space of 8 to 10 years, the cost of entry, ownership and operation for an aligner production facility has shifted dramatically from the inception of Invisalign, through to the inception of ClearCorrect. Machines costing $700,000 have been replaced with equally productive technology costing $180,000. This has opened up the market beyond these two leading companies, with a number of other smaller players also starting to emerge.

It is also encouraging to see the opportunity and scope for growth within this market. At present Invisalign and ClearCorrect are penetrating just 17.5% of the potential market for malocclusions realignment. As the use of intraoral scanning increases, so the enabling data driving digital dentistry will also increase, which will undoubtedly drive demand for more 3D printing machines and materials to service this growing market.

# APPLICATIONS OF AM IN FACIAL AND LIMB PROSTHETICS

According to Global Industry Analysts (GIA), the global Orthopedic Prosthetics market — which includes the design, manufacturing and fitting of individual artificial limbs that typically cost $10,000 to $65,000 — is projected to reach US$23.5 billion by the year 2015, spurred by a multitude of factors including an aging global population, rising incidence of degenerative joint diseases and improving healthcare infrastructure in developing countries.

The prosthetics market is driven by a number of contributory healthcare factors including congenital abnormalities (birth defects); loss of limbs through disease and illness such as diabetes and cancer; and loss of limbs through accident, warfare, malice or intentional disfigurement. It is estimated that there are 1-million limb amputations taking place in the world every year. Put into context, one in every 190 Americans is currently living with the loss of a limb or digit. Unchecked, this number may double by the year 2050 as a direct result of diabetes alone. Within the UK it is estimated that between 55,000 and 60,000 people are living with an amputation or congenital deficiency.

Research suggests that for those patients wearing a prosthesis, comfort (or lack thereof) and socket fit represents the greatest dissatisfaction, which in turn suggests that users could benefit from new and alternative production solutions, where products can be better personalized to the needs of each patient.

## Product cost and price

Costs for limb prosthetic devices vary widely. For $5,000 to $7,000, a patient can get a serviceable below-the-knee prosthesis that allows the user to stand and walk on level ground. By contrast, a $10,000 device will allow the person to become a "community walker," able to go up and down stairs and to traverse uneven terrain. A prosthetic leg in the $12,000 to $15,000 price range will facilitate running and functioning at a level nearly indistinguishable from someone with two legs. Devices priced at $15,000 or more may contain polycentric mechanical knees, swing-phase control, stance control and other advanced mechanical or hydraulic systems. Computer-assisted devices start in the $20,000 to $30,000 price range.

Robohand – consumer
3D printed, open source
prosthetic for sub $100
**© Makerbot**

Upper-extremity amputees can buy a non-functional cosmetic hand for $3,000 to $5,000, which allows getting by in public without being noticed. $10,000 will buy a trans-radial upper-extremity prosthesis, which is a functional "split hook" device for below-the-elbow amputees. Cosmetically realistic myoelectric hands that open and close may cost $20,000 to $30,000 or more. These contain processors that inform the amputee as to how much pressure they are exerting on a held object and whether it is hot or cold. A neuro-prosthetic arm (i-Limb, DEKA, Utah Arm3) may cost as much as $100,000.

## AM & prosthetics

The potential for cost-effective low volume manufacture and complex conformal geometry manufacture makes AM an obvious technology candidate for prosthetic production. However, although there are a number of case studies and examples of the technology being used for both prosthetic lower leg and lower arm applications, we have been unable to find any volume manufacturing of either type of device, within either the private sector or within publicly funded healthcare systems.

Notwithstanding, there have been a number of well-documented developments within the open-source 3D printing community, which have shown the potential disruptive nature of AM when coupled with social networking, crowd sourcing and open innovation, which could lead to mass scale technology adoption in the future.

In May 2011, South African based tradesman Richard Van-As lost four of his fingers in an industrial accident. Faced with the prospect of life without fingers he decided to make his own. Through the internet he found Ivan Owen a mechanical engineer with a background in special effects, who had some experience in designing and building robot hands as film props.

Together they collaborated online to develop a bespoke solution for Richard. After news of their collaboration was posted on the internet they were each given a MakerBot Replicator 2 prosumer 3D printer to aid collaboration. The resulting prosthetic — dubbed Robohand — enables Richard to have basic use of his hand again.

Richard Van As with Robohand and his MakerBot Replicator 2 **© Makerbot**

Van-As was then approached by the parent of a child with Amniotic Band Syndrome (ABS), a congenital condition caused when fibrous bands of material within the amniotic fluid trap parts of the developing foetus. As the foetus grows, but the bands do not, so the bands constrict, reducing blood circulation and causing congenital abnormality. In some severe cases ABS cases 'natural' amputation of digits such as figures and toes.

### *Scale of the problem*

ABS effects 1 in every 1,200 live births, with 80% of occurrences affecting the hands and/or fingers. From this we estimate that some 90,000 children are born each year with some level of ABS effecting their hands or fingers. Of these children 6,800 are born within G8 countries, 44,600 are born within the G20 nations and 45,400 are born within the rest of the world. There are no preventative measures for ABS and it is expertly difficult to prevent through surgery within the womb.

### *AM solution for ABS*

Using the Makerbot Replicator 2, Van-As and Owen designed a complete hand assembly specifically for children with ABS, which works simply by bending the wrist to clasp the fingers. Almost all of the components have been designed to be manufactured on a consumer 3D printer, with the exception of fixings such as nuts, bolts and washers, cord used as tendons and the socket interface that fits to the patients wrist, which is made from a thermoforming plastic sheet material. All the enabling 3D computer data for the Robohand has been made freely available on the internet for down load, along with assembly instructions.

Robohand thermoplastic socket being fitted to ' young customer' with no digits **© Makerbot**

Econolyst staff recently downloaded the STL 3D Data for the Robohand along with the bill-of-materials, which was then built in-house using a MakerBot Replicator 2 in less than eight hours. A further three hours of assembly time were then needed to put the Robohand together. The 3D printing costs of the Robohand are less than $10. The cost of fixings and ancillary parts is less than $5. The only significant cost is the thermoplastic deformable sheet material used to make the interface cup, which costs some $30 per Robohand. Hence allowing a cost of $15 per hour for assembly, Robohand can be manufactured locally for approximately $100. Moreover, as the ABS child grows, so the deformable interface cup can be reused, along with the fixings, needing only the $10 3D printed parts to be re-manufactured.

The Robohand is very basic in terms of functionality and could arguably be made using other processes such as injection moulding. However, at $100 it is a fraction of the price of other products within this class and has been designed to be manufactured, augmented and maintained locally. Something extremely difficult to do with traditional manufacturing processes.

We do not expect Robohand to have an immediate detrimental effect on the current prosthetics market place. However, we believe it will raise awareness of AM/3DP within the professional prosthetics community, stimulate more open innovation within the healthcare sector and stimulate more healthcare start-up business centres on both centralized and localized AM/3DP manufacturing.

## Augmenting the prosthetics market - fairings

Although not a direct prosthetic device, AM is being used by Bespoke Innovations to manufacture 'fairings' which are worn over the outside of prosthetic devices to provide a personalized aesthetic appearance. Bespoke Innovations, which was acquired by 3D Systems Inc for $7.9-million (cash and shares) in May 2012, uses the Selective Laser Sintering process to manufacture fairings based on the customers own conformal body data and styling requirements. Fairings cost between $4,000 and $6,000 depending on the complexity of the design and finish required. It is fair to say, however, that although fairings have a positive effect on the esteem of the wearer, they are purely aesthetical and have no physiological benefit. They are therefore an expensive add-on to traditional prosthetics and very much a luxury item.

Soft Tissue Prosthesis ear manufactured using modified Z-Corp 3D Printing process - **© Fripp Design Ltd**

## Facial prosthetics

One area where we have seen a concerted effort to achieve commercialization of AM parts is in the field of facial prosthetics. Facial prosthetics are required for a number of reasons, including congenital deformities, such as cleft palates, post-accident and trauma and following a number of mouth and face cancers. Facial prosthetics sit on the skin, often masking the site of the trauma or disfigurement, which may be around the mouth, nose, cheek or ear. Facial prosthetics differ from limb prosthetics in that they are based on mimicking and blending in with soft tissue, rather than providing an interface between existing tissue and a replacement limb.

The quality of soft tissue prosthetics varies significantly around the world, with many patients having no access at all to such medical devices. The high cost and long lead times associated with soft tissue prosthetics within the developed world result from an ostensibly manual production process, which is exacerbated by a decreasing number of technicians and service providers.

Current soft tissue prosthetics are made by taking an impression or mould from the patient's face and then sculpting and casting a prosthesis in medical grade silicon. The final product is then hand painted to match the skin tones of the patient.

## AM of facial prosthetics

One solution to the cost, lead time, skills shortage and invasive nature of traditional soft tissue prosthetics is to use an AM driven solution, something undertaken by UK-based Fripp Design and Research in collaboration with Sheffield University and the Wellcome Trust.

Soft Tissue Prosthesis noses manufactured using modified Z-Corp 3D Printing process - **© Fripp Design Ltd**

The Fripp solution uses photogrammetry to capture the patient's facial features and spectrophotometry to capture their skin tones. A high resolution digital camera is also used to capture the patient's skin texture. Using proprietary algorithms, a haptic interface and 3-matic design software Fripp is then able to generate a full colour 3D CAD facial prosthetic, which is then produced using a modified Z-Corp 3D printing machine with proprietary medical grade materials. The final printed part is then post processed to provide a natural and flexible feel with a fine feathered edge applied to mask the interface between the skin and the prosthetic. The process has reduced the production time of a typical prosthetic from six weeks down to less than 48 hours. Fripp is currently running patient trials in the UK and refining both its production process and business model.

# ORTHOTIC APPLICATIONS OF AM

The global market for Orthopaedic Orthotics is projected to reach US$5.2 billion by the year 2017 from some $4.5-billion in 2012. Growth drivers include a growing proportion of the elderly population, increasingly active lifestyles and product innovations. Today orthotic products address a wide range of medical applications from debilitating diseases such as osteoarthritis and sport injuries, to people with minor musculoskeletal deformities. In addition, the advent of minimally invasive implant surgeries is also pushing demand for rehabilitative orthotics.

Ankle-foot orthotics (AFOs) are the most commonly used type, making up about 26% of all orthotics provided in the United States. According to a review of Medicare payment data from 2001 to 2006, the base cost of an AFO was about $500 to $700. We can therefore assume allowing for inflation that this figure is nearer to $1,000 today.

An AFO is generally constructed of a lightweight polypropylene-based plastic in the shape of an "L", with the upright portion behind the calf and the lower portion running under the foot. They are attached to the calf with a strap, and are made to fit inside accommodative shoes. The unbroken "L" shape of some designs provides rigidity, while other designs (with a jointed ankle) provide different types of control.

## Additive Manufacturing and Orthotics

The image below shows an AFO produced using the Selective Laser Sintering (SLS) ALM process as part of the €5.3-million A-FOOTPRINT research project funded by the European Commission Framework 7 program and involving 12 collaborative partners across Europe.


Personalised articulated AFO manufactured to conformal body scan data using Selective Laser Sintering - **© Peacock Orthotics Ltd**

The A-FOOTPRINT project, which concluded in September 2013, was focused on developing digital methodologies to automate and speed up the manufacture, delivery and supply of personalised orthotic devices by exploiting digital scanning, computer-aided design (CAD) and AM. One of the project partners, Peacock Orthotics based in the UK, has now established an AM orthotic production facility using 3D Systems' SLS process under the brand name Podfo.

Although Peacock Orthotics has chosen not to produce full AFO orthotics using AM, the company has developed a business process chain for digitally produced rigid orthotic insoles (as shown below), which are used to correct posture and gait and alleviate foot and spinal pain.

Podfo Personalised rigid orthotic insole commercially produced by Peacock Orthotics - **© Peacock Orthotics Ltd**

## The AM process chain and business model for orthotic insoles

The Peacock business model starts by 3D scanning a 'last' or foot impression supplied by the podiatrist. The company can also accept digital data supplied directly by a podiatrist derived from non-contact laser or white light scanning of the patient's foot. Using the geometric scan data of the patient's foot and the 'prescription' supplied by the podiatrist, Peacocks' technical staff then use specialist software packages including 3Matic from Materialise and Paromed to generate the shape of the corrective insole.

An STL file of the insole is then sent to a 3D Systems SPro 60 SLS machine running Exceltec black nylon powder. The Podfo business model is based on the production of 70 pairs of orthotic insoles per week (3,640 pairs per year), as it is possible to build 10 pairs of insoles on the SPro 60 platform every 24-hours. Podfo is currently in start-up phase (September 2013) producing around 10 pairs per week.

Peacocks is confident that the Podfo model will catch-on quickly, as the product is only marginally more expensive that traditional orthotics, but benefits from being stronger, far more hygienic and washable, as the conformal geometry of the product eliminates the need for cushioning, which is easily worn and damaged. Although other orthotic devices are being made more durable and lightweight through advanced graphite and carbon fibre materials, these require ostensibly manual process chains, which are both costly and difficult to automate.

## The cost of orthotics manufacture

To the patient, personalized orthotic insoles cost between $400 and $600. This typically includes the fee for the podiatrist and the cost of the orthosis, which is usually made by a specialist company or lab (such as Peacocks). The fee from the lab to the podiatrist for a standard rigid orthotic insole ranges between $90 and $120, suggesting the Podfo SLS solution may be nearer to $150.

## The market for customized orthotics

Within the USA it is estimated that the custom foot orthotic market (for production only) is worth some $160-million to $200-million per year. At an average lab cost of $115 per pair, we can therefore assume that some 1.7-million pairs are made for a population of 314-million (0.5% of the entire population).

If we assume that the market for customized orthotics is largely restricted to developed economies such as the G8 members, it is possible to gain some appreciation of the potential market scale. The G8 member countries currently represent some 14% of the world's 7.1-billion people. 0.5% of this 1-billion people represents a potential customer base for personalized orthotics of 5.1-million patients.

## Future market opportunity

It would be very wrong to suggest that AM would ever displace all other manufacturing processes used within the orthotics market. Current orthotics are made using a variety of processes and materials from light weight high cost carbon fibre orthotic insoles costing some $400 to $500 per pair to manufacture, through to laminated thermoplastic insoles costing less than $30. Given the cited benefits of Podfo over traditional solutions (strength, design, hygiene and durability), it is not inconceivable that the solution could be adopted for 10% of all orthotic cases, as manufacturers look for new and automated production solutions, with the potential to integrate with emerging digital scanning methods. If this were the case, it could forecast that AM would be used to make some 500,000 pairs of orthotics per annum, although it will likely take a number of years (5 to 10) to reach this level of adoption.

## Global AM hardware opportunities for orthotic insoles

Based on production figures from Podfo, and assuming full machine utilization of 90%, some 152 SPro 60 laser sintering machines would be needed to service the demand for 500,000 pairs of orthotic insoles per annum. Of course, should demand increase to such a level, it is highly likely that some orthotic laboratories would transition to larger frame SLS machines such as the 3D Systems SPro 140 or SPro 230, or the EOS P395 or P760 platforms. It is therefore likely that a combination of different platforms will be adopted to suit the needs of different size podiatry laboratories and production facilities.

However, based on SPro 60 capabilities, and a capital cost of some $350,000, we can assume that to service an annual market of 500,000 pairs of orthotic insoles it would require an investment of $53.2-million.

## Material revenues opportunities

At present, rigid orthotic insoles produced using AM are manufactured using nylon powder with the SLS process. Using CAD data for an orthotic insole and machine parameter data for a 3D Systems SPro60 platform, it is therefore possible to calculate the material consumption for the production of orthotic insoles.

20 Orthotic insoles (10 pairs) require some 440 $cm^3$ of laser sintered nylon. However, during the SLS process, not all of the un-sintered material can be reused. If we consider the size and bounding box of the insoles, we find that in order to make 20 insoles, some 8,870 $cm^3$ of material must be thermally cycled. Hence to make 10 pairs of insoles some 8,338 $cm^3$ of un-sintered powder is produced as a by-product, of which only 75% can typically be reused (based on Exceltec powders). Hence to produce 10 pairs of insoles actually requires some 2,524 $cm^3$ of stock nylon powder.

Rigid full foot orthosis produced by selective laser sintering from patient scan data - **© Peacock Orthotics Ltd**

Based on the bulk density of nylon powder used for the SLS process, this represents some 2.1 Kg of material at a cost of approximately $168 ($80 per Kg) or approximately $17 per pair of insoles. Hence to produce some 500,000 insoles per annum (as forecast), would require some 105,000 Kg of material (based on material with a 25% refresh rate) costing some $8.4-million.

## Timescales and roadmap

Given the economics and performance capabilities of the SLS process, we believe that AM does in fact represent a viable manufacturing solution for customized orthotics, which could be scaled across a number of developed ‘high wage’ economies over the next 5 to 10 years. The main barriers to adoption will be the cost of capital equipment and the technical skill-set needed to enable the business process chain. However, like all aspects of healthcare, podiatry is becoming increasingly digital, leading to an ever increasing volume of enabling data.

# DENTAL APPLICATIONS OF ADDITIVE MANUFACTURING

The dental segment of the medial market includes a number of well-developed applications of Additive Layer Manufacturing (ALM) processes, such as the direct and indirect production of dental crowns and bridges, along with the production of stone models and surgical drilling guides. Emergent applications also include the development of implantable abutments and directly manufactured ceramic veneers and teeth.

## Caps, crowns & bridges

A dental crown is a tooth-shaped "cap" that is placed over a tooth to restore its shape and size. A crown also provides strength and improves the visual appearance of the patient's tooth. The crown, when cemented into place, fully encases the entire visible portion of a tooth that lies at and above the gum line.

Dental crowns are also needed to protect decayed or weak teeth from breaking or to hold together parts of cracked teeth. Furthermore, crowns can also be used to restore broken teeth, discoloured teeth or to replace parts of teeth that have been severely worn down. A dental crown can also be applied in such a way as to hold dental 'bridges'.

A bridge is used to support a false tooth or multiple teeth in a gap between two good teeth. A bridge is made up of two crowns for the good teeth on either side of the gap. The two anchoring teeth are called abutment teeth and are used to hold a false tooth or teeth in between. These false teeth are called pontics.

Permanent crowns and bridges can be made from a range of metallic or ceramic materials.

**Stainless steel** crowns are prefabricated crowns that are used on permanent teeth primarily as a temporary measure. The crown protects the tooth or filling while a permanent crown is made from another material.

**Metallic** crowns include gold alloy or a base-metal alloy such as chromium. Compared with other crown types, less tooth structure needs to be removed with metal crowns, and tooth wear to opposing teeth is kept to a minimum. The metallic colour is the main drawback. Metal crowns are a good choice for out-of-sight molars.

**Porcelain-fused-to-metal** dental crowns can be colour matched to adjacent teeth (unlike metallic crowns). However, more wearing to the opposing teeth occurs with this crown type compared with metal or resin crowns. The crown's porcelain portion is also less hard wearing and can chip or break off more easily.

**All-resin** dental crowns are less expensive than other crown types. However, they wear down over time and are more prone to fractures than porcelain-fused-to-metal crowns.

**All-ceramic or all-porcelain** dental crowns provide a better natural colour match than any other crown type and may be more suitable for people with metal allergies. However, they are not as strong as porcelain-fused-to-metal crowns and they wear down opposing teeth a little more than metal or resin crowns.

## Scale of the market

Between 2012 and 2013 within the UK alone 777,200 crowns and 86,700 bridges were fitted. This represents some 1.2% and 0.1% of the population respectively. If we considered similar dental trends across the major industrialised nations of the EU, North America and the Asia Pacific region, which accounts for some 3-billion people, we could conclude that at least 38.4-million crowns and 3-million bridges are produced each year.

## Traditional crown and bridge production

The traditional method of producing crowns and bridges is a very drawn out process, using a multiple stage operation. Traditionally, metal crowns are produced using the lost wax casting process. In this process, an impression of the patient's teeth is taken using a curable alginate mould into which the patient bites. Into this 'negative' mould cavity, a positive set of teeth are then cast in plaster. A dental technician within a dental laboratory then manufactures the appropriate size and shaped crown or bridge in a hard wax material using the plaster or 'stone model' as a guide. The resulting wax pattern is then encased in a ceramic slip, which is allowed to dry. Once the ceramic mould is dry, it is first heated allowing the wax to melt and escape. The mould is then fired to attain structural integrity, after which it is heated again prior to molten metal such as gold being poured into the cavity to produce the crown. The cavity is then broken open revealing the metallic dental crown. The metallic crown is then hand finished by the technician using the stone model as a guide, including the addition of any porcelain veneers. The crown and stone model are then sent to the dentist for any final adjustments prior to the crown being fitting into the patient's mouth.

## Additive Manufacturing of crowns and bridges

Additive manufacturing is suited to the production of all metallic and porcelain-fused-to-metal dental crown types. Porcelain-fused-to-metal crowns represent the most common type of crown, accounting for some 60% of the market. Based on whole market statistics outlined above, we can therefore assume that the market for AM-produced or AM-enabled dental crowns and bridges is some 25-million units per annum.

Small platform of dental crowns and bridges produced in castable polymer **© Envisiontec**

There are two methods of using ALM processes for the production of dental crowns and bridges. In both cases the number of manufacturing steps is reduced significantly compared with the traditional route of manufacture and both involve starting by taking a digital scan of the patient's mouth.

By scanning the patient's mouth the need to produce an alginate tool is eliminated. Using the scan data it is possible to produce a direct stone model of the patient's teeth directly from computer data. Using specialist 3D CAD software, it is then also possible to digitally model the shape of the desired dental crown, which can then be produced using ALM processes in one of two ways.

## Indirect ALM production of crown and bridges

Using wax or resin based ALM systems such as the Objet Polyjet, 3D Systems Projet or EnvisionTec Perfactory, it is possible to 'print' out the casting patterns needed for investment casting. This eliminates the need to make a manual wax pattern, speeding up the production process significantly. The images below show the process for indirect crown and bridge production.

***Step 1*** – produce stone model from intraoral scan data **© Envisiontec**

***Step 2*** – produce castable 3D printed crowns and bridge from 3D CAD data **© Envisiontec**

***Step 3*** – produce investment cast metal crowns and bridge using castable 3D printed patterns **© Envisiontec**

This approach has found favour with many dental laboratories, as the process simply digitises their existing work-flow, allowing them to use their existing investment casting infrastructure.

Using this approach it is possible to produce some 80 to 100 dental crowns and brides on a typical EnvisionTec or Objet machine within an 8-hour period, giving an annual production capacity of 78,840 units per annum, based on 80% machine utilization. Given the disparate nature of the dental industry and the secrecy of machine installations, it is difficult to gain an exact figure on the number of machines being used for casting pattern production today, however discussions with technology vendors suggest as many as 200 machines from companies such as 3D Systems, Objet & Envisiontec may be in use today. Albeit, some are being used to produce stone models rather than dental crown patterns. Assuming therefore that half of these machines were being used for crowns and bridges running at 80% capacity, this would give a global production capability of some 7.9-million crowns per annum, some 31% of demand within the developed nations of the world.

However, we suspect that the machines are being run at a fraction of this capacity, simply as a function of the supply chains in which they are being placed, which are made up of both small and large dental laboratories. In the case of larger labs, the traditional work-flow from multiple dentists may demand the production of 200, 300 or more crowns and bridges per day, hence utilizing larger bed 3D printing machine capacity.

However, for smaller labs servicing a group of local dentist's, then daily production of 10 or 20 crowns may be more realistic – in which case large machines will be run at very low utilization rates.

To service this small lab market, we are seeing new lower-cost, small footprint dental machines starting to emerge, such as the Envisiontec Micro Digital Dental Printer, which is configured to build only 10 crowns or copings per build. We expect these technologies will become prevalent in smaller dental laboratories, whilst larger laboratories will transition from high productivity indirect casting pattern production, to direct crown manufacture using ALM processes.

## Direct ALM production of crown and bridges

It is possible to remove the investment casting stage of crown and bridge production altogether by manufacturing the final metallic component directly using ALM technology.

One way to do this is to use a powder bed binder 3D printing system using metallic powder. This approach was adopted sometime after the year 2000 by the EXONE company under the brand name Imagen. In the Imagen process, gold powder was adhered together using a fluid binder, applied to the powder bed using an ink-jet print head. The 'green state' parts were then removed from the powder and post process fired to achieve full strength prior to the application of porcelain veneers. It is not clear whether this approach is still used today, as there is no longer any record of EXONE selling or supporting this technology.

The other approach for direct manufacture of dental implants, which is being used at many sites globally, is crown and bridge production using Selective Laser Melting (SLM) or Direct Metal Laser Sintering (DMLS). In this approach the 3D CAD file of the patient's crown or bridge is fed directly into a metallic ALM system, which uses a laser beam to directly melt metal powder at near 100% density into the desired geometry.

Full platform of dental caps and crowns produced using the EOS Direct Metal Laser Sintering process © **EOS**

It is estimated that there may be as many as 130 metallic laser melting platforms currently in operation across the world producing dental crowns and bridges, including at least 70 machines from EOS, 40 machines from Phenix (now part of 3D Systems), with the remaining machines supplied by companies including SLM Solutions, Concept Laser, Renishaw and Realizer. We are also aware of at least one Arcam EBM machine being used for bridge manufacture at Swedish company Dentware.

Based on a typical 250 mm x 250 mm machine bed, we estimate that it is possible to produce some 300 crowns and bridges within a 24-hour period. Hence allowing for a realistic utilization of 80%, we estimate that one metallic laser melting platform could produce some 87,600 crowns and bridges per annum. Based on an estimated install base of 130 machines, ALM used within dentistry already has the capacity to produce some 11.4-million crowns and bridges, this being some 45% of global demand. We do however feel that this figure is far in-excess of actual production volumes, suggesting that current machines are not being run anywhere near 80% utilization.

Partial denture manufactured using EOS Direct Metal Laser sintering **© EOS**

## Global opportunity for machines and materials

Assuming direct metal laser melting was to become the sole method of production for metallic dental crowns and bridges, the global annual demand within the developed world could be fulfilled with just 288 machines running at 80% utilization. This would require an additional 158 machine installations globally, representing an investment of some $79-million.

The average cobalt chrome dental crown weighs between 1 and 3 grams. Allowing for support structure and process waste, it would not be unrealistic to assume an average material consumption of 2.5 grams of metallic powder per crown. Hence, we can produce some 400 crowns per 1Kg of material feed stock. Based on a supply price of $300 per Kg, this equates to some $0.75 per cobalt chrome crown. We estimate the production cost of a cobalt chrome dental crown to be some $5.00 each allowing for machine depreciation, material consumption, waste and labour – based on 80% utilization.

Assuming a global market of 25-million crowns and bridges, we could estimate demand for some 62,500 Kg of cobalt chrome powder, representing annual materials revenue of $18.75-million.

In reality we do expect that over the next 10-years the dental market within the developed world will transition to one driven by digital dentistry and 3D intraoral scanning. However, this digital data will be processed by different sized dental laboratories, with different infrastructures. Larger labs will transition to direct metal production, whereas the smaller labs will adopt technologies to make castable patterns.

## Stone models

As we have already discussed, within the dental workflow, stone models are also used by both laboratory technician and dentists to check the fit of crowns, bridges, partial dentures and implants. As we experience the transition towards more digital dentistry, so we will see more and more digital stone models replacing traditional plaster cast models.

Dental stone model of a lower jaw **© Stratasys**

From an ALM perspective, we believe stone models represent a significant business opportunity above and beyond castable dental crowns, as being larger; the models require more machine capacity and consume much higher volumes of resin.

Our analysis suggests that it would be possible to print some 80 stone models on a large frame machine, such as an Objet Eden 500V, in an 8-hour period. Or it would be possible to print 20 stone models on a smaller machine such as an Objet 30 OrthoDesk or 10 models on a Perfactory 4 DDP in a similar time period.

It should be noted that for most dental corrections, an upper and lower stone model is required. However, only one set of stone models is required per patient irrespective of the number of crowns or bridges being fitted. For this reason we would estimate that the global annual demand for stone models (plaster or digital) is somewhere between 20-million and 35-million individual models (upper & lower), making an average of 13.75-million stone model sets.

To service such demand, the production of 13.75-million stone models sets would require somewhere in the order of 500 large frame machines, 2,000 medium sized machines, or 3,500 small platform machines.

Based on a simple analysis of a stone model STL file, we estimate that there are some 100g to 150g of resin in a simple stone model set. Therefore, allowing for waste, we estimate that some 1.75-million Kg of resin would be required for the production of 13.75-million stone model sets. Using a base resin cost of $200 per Kg, this represents a market of some $350-million.

At $200 per kg, each stone model set contains some $25 of resin. Machine depreciation, labour and material waste accounts for an additional $10 per set, making a stone model set around $35 to produce – this does however compare favourably with an alginate and plaster model which requires a significant level of skilled labour.

## Abutments

For some patients it is not possible to save a tooth using a crown or to use adjacent teeth to anchor a bridge. In these cases the tooth and root are removed and the crown is connected onto the top of an implanted abutment, which is screwed into the patient's jaw bone. The market for dental abutments is currently worth some $4-billion per annum.

There are two types of dental abutment – threaded and porous. Threaded abutments are literarily screwed into the patient's mouth, whilst porous abutments are adhered into the patient's mouth, with bone ingrowth into the porosity providing full fixation strength.

Selective Laser Melting (SLM) has been investigated for the manufacture of porous implantation screws with integral abutments, with clinical trials showing this to be a viable approach to manufacture. Moreover, economic studies have shown that up to 1,400 implants can be made in a single machine within a 50-hour build, with the resulting parts having a fraction of the manufacturing cost of other porous implants.

At present however, this approach to manufacture is not being used commercially, largely due to investment in other manufacturing approaches by the major dental implant companies, who are now keen to recoup their investment in research & development, intellectual property and production processes.

## Drilling guides

ALM processes are also being used to make drilling guides for surgical dental procedures such as the implantation of abutments. This is covered in the surgical guides section of this report.

## Looking to the future

Undoubtedly AM applications within the dental sector will continue to experience significant growth over the next 10-years, driven by an increase in digital dentistry, intraoral scanning and increased oral healthcare globally.

We can also expect to see other technological developments, such as the production of direct ceramic dental implants made using direct laser and resin based systems. German company Envisiontec has already launched a bio-compatible resin under the brand name E-Dent.

E-Dent is a glass-filled photopolymer for use on the Envisiontec DDP printer. With CE medical, and FDA 510K approval, E-Dent represents the first printed material approved for use in the mouth as a temporary crown.

Temporary dental restoration made using biocompatible E-Dent material **© Envisiontec**

Other companies and research groups are also looking at the direct sintering of medical grade ceramic materials such as zirconia, which could be used to make direct crowns, which could be fitted directly onto implanted abutments. Albeit, direct crown production is also the subject of much research within the CNC machining community, which is already producing 5-axis machined zirconia crowns.

# OPHTHALMIC APPLICATIONS OF AM

According to the US National Eye Institute some 225-millon people in the USA (75%) uses some form of corrective lenses, 38-million being contact lenses and 187-million being eye-glasses.

It is estimated by the US vision correction institute that some 4.2-billion people need corrective lenses. However, only 1.7-billion people get corrective lenses, with 2.5-billion within the developing world going without due to low incomes. Of the 1.7-billion people receiving corrective lenses, 125-million are using contact lenses, with the remaining 1.575-billion wearing glasses.

According to data from research firm Global Industry Analysts Inc. the global market for eyeglasses is projected to reach $113.2 billion by 2018. Growth in the market will be driven by shifting fashion preferences of customers towards trendy and sporty eyeglass frames to create a style statement. Eyeglasses have today shed their utilitarian image of being just a vision correction contraption to become a key fashion accessory. Innovative materials for lenses and frames and other technological advances have resulted in several new designs with better aesthetic appeal, style and quality. Eyeglasses with lightweight material frames such as Nitinol and titanium with polycarbonate lenses have become immensely popular in recent years. Currently in vogue are frames with brighter, bolder, multi colours, and with rectangular shapes. The trend mirrors a move away from the rimless frames of circle and oval shapes.

There are now three distinct markets for eye glasses. These being vision correction, eye protection and simply fashion, which is based on glasses with non-corrective lenses sold for the aesthetics of the frames and lens shape.

## Product cost and price

The cost of eye glasses differs greatly depending on both the source and the product choice. Glasses can be sourced through two primary value chains, these being corrective prescription glasses made to suit the individual wearer and non-prescription ready to use glasses known as readers, which are manufactured with a range of different corrective lenses. It was estimated by manufacturer Essilor International that 440-million 'readers' were sold in 2011, ranging from $8 to $20. Taking an average cost of $14, we can therefore assume that pre-manufactured 'readers' account for just $6.1-billion. Assuming this increased to some $10-billion by 2018, the remaining $103-billion of sales by this date must therefore relates to the manufacture and sale of prescription glasses, which typically retail or between $50 and $200, albeit designer brands can command a much higher price.

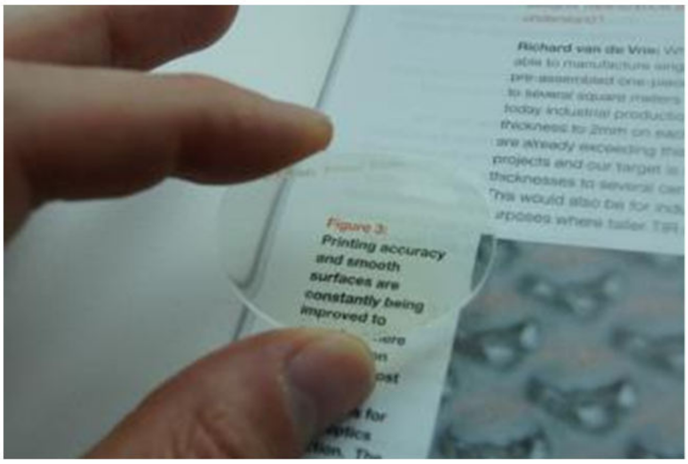
It is estimated that the cost of prescription eye glass manufacture is in the order of $8 to $14 depending on the scale of the manufacturing operation, including the manufacture of lenses and frames, and assembly.

## Additive Manufacturing and glasses

It is hard to imagine that there are any large scale glasses design and manufacturing companies in the world today that are not using Additive Layer Manufacturing to support their product development and prototyping activities. However, the transition from prototyping to end-use part manufacture using ALM technologies has been a very recent development.

After two years of research and development, in August 2013, Protos 3D Printed Eyewear launched a crowd sourced funding campaign to bring their personalized eyewear concept to market. Protos uses a combination of laser sintering and a proprietary flexible thermoplastic polymer to manufacture bespoke glasses that are personalized to the customers face shape using data derived from just a front and side profile photograph. Using propitiatory algorithms, Protos is able to derive critical facial features and shape affecting the fit of the glasses, using just these two images. At present Protos has some 24 different styles of 3D printed frames, each of which is personalized using the algorithms derived from the photos. A prescription lens is then manufactured using traditional production techniques and manually assembled with the 3D printed frames.

The current crowd sourced funding model has a single pair of personalized frames with either prescription lenses or non-prescription sunglass lenses available for $249, this being an equivalent price to many designer frames.




3D printed lenses with corrective capability produced using Printoptical technology - **© Luxexcel**

However, Protos is not alone in its endeavours, as other companies such as Beehive, Mylaka Mylon, Make Eyewear & PQ Eyewear are all offering bespoke laser sintered frames for either prescription or sun glasses. However, Protos does appear to have the most well developed digital process chain.

## Manufacturing cost of additive manufactured glasses frames

Using an STL file for a standard 'thick rim' glasses design, we calculate that using a laser sintering system, such as an EOS P395, it would be possible to produce some 550 pairs of spectacle frames in a single 45 hour build. Accounting for machine depreciation, material consumption and labour, we estimate manufacturing costs of some $4.00 per frame set. Comparable with traditional manufacturing costs.

## Market scale for AM glasses frames

Designer glasses account for approximately 10% of all prescription glasses sold. It is therefore not unrealistic to assume that some 100-million pairs of branded and designer glasses are sold globally each year. However, a simple browse of any online spectacles website will shows you that the vast majority (approximately 80%) of all glasses have metal frames. Hence, we could assume that approximately 20-million pairs of polymeric designer glasses are produced each year.

As stated, we estimate that it is possible to make 550 pairs of glasses with an EOS P395 machine within a 45-hour build period. Applying a sensible utilization figure of 85%, it is therefore theoretically possible to produce some 91,000 pairs of glasses per machine per annum. Hence, if AM were to displace all current methods of plastic frame designer glasses manufacture, there would be a market for some 220 laser sintering systems of P395 size.

## AM material consumption for frames

Protos is using its own proprietary plastic powder for laser sintering. We have no indication where this is sourced or for what cost. However, assuming it performs like many other laser sintering powders, not all un-sintered powder will be reusable. Our estimates suggest that to produce 550 pair of glasses would consumer some 14 Kg of powder, based on a 50% used powder refresh rate. This equates to some 2,310 Kg of material per machine per annum, or $40-million per annum in material sales if 220 laser sintering platforms were being used.

## Additive Manufacturing of lenses

The Protos business model shows what is possible using current commercial ALM technology to manufacture glasses frames, which are durable and aesthetically pleasing. However, the flexibility of the product design will always be constrained by the ability to manufacture conformal lenses. At present the Protos business model has 24 lens shapes around which bespoke frames are produced. Although a highly automated process, lens manufacturing technology is currently not able to produce totally bespoke lenses in terms of their shape.

However, it is now possible to produce prescription lenses using the Printoptical additive manufacturing technology developed by Dutch company LUXeXcel.


3D printed integral lenses with colour printed frames produced using Printoptical technology - **© Luxexcel**

The LUXeXcel process is a hybrid technology that couples 2D inkjet printing onto a substrate with the deposition of material in the Z-axis. LUXeXceL uses a number of modified wide format inkjet printers to 'jet' photocurable materials onto optically clear substrates. By matching the diffractive index of the cured photocurable material with that of the substrate, it is possible to generate a 3D lens. By controlling the deposition of a curable material and by modifying fluid dynamics, it is possible to generate a 3D lens or perfectly smooth structures. The company has also developed and patented proprietary technology to eliminate the stair-stepping effect typically associated with layer based manufacturing processes, meaning there is no post processing required to achieve an optical quality lens.

Moreover, by also integrating colour inkjet printing into the process, LUXeXceL is also able to offer unlimited personalization in terms of frame aesthetics, which can include block colours, tints, branding or even images.

However, the Printoptical process does have some limitations, in that it can only work at present by printing onto a flat substrate, albeit the company is developing ways whereby in the future, it will be possible to print onto curved surfaces. As such there are some current geometric limitations to the eye glasses that can be produced, as after printing, the resulting product is effectively 'cut-out' of a flat sheet of material, prior to manual assembly. For this reason we feel that the current technology will only have limited applications in the designer eyewear sector – even though it may provide a cost effective production solution for mass prescription glasses manufacture within the developing world. In the future we do expect LUXeXceL to develop capable technologies for entire eyewear manufacture unconstrained by geometry.

## Timescales and roadmap

Given the current penetration of AM within the established eyewear sector, we believe it will be some time (3 – 7 years) before a significant volume of glasses frames are produced using AM. Even then, the business model will only work if vendors are able to offer both a superior fit and superior personalization to existing products.

At present, most prescription glasses are bespoke manufactured, in that they are fitted to the wearer's face manually by a technician on collection – or they are manipulated by the wearer when delivered. Their primary purpose is to correct vision, which they do using highly personalized lenses. We do not believe that the offer of improved fit alone, or the cache of '3D printed manufacture' will stimulate a large market for additively manufactured eyewear, as there is little market differentiation to the current product. Rather we would expect to see future growth coming from the coupling of technologies, where consumers are given the latitude to engage in the design process, either in-store or over the internet, and where frame shapes and aesthetics can be manipulated by the consumer prior to purchase.

Different technologies would then be needed to manufacture the frames and lenses prior to assembly, with processes such as laser sintering being used for the frames and the Printoptical process used for the lenses. Such an approach would use shared digital data for the lens shape, with the consumer input resulting in a laser sintered frame and the prescription input resulting in the lens.

# SURGICAL GUIDES

Additive Manufacturing (AM) is good at making accurate, complex components that are often not cost-effective to produce using more traditional manufacturing processes, or in some cases are simply too complicated to make using traditional processes. One such AM application is in the manufacture of surgical guides, where AM is not being used to make a medical implant, but rather it is being used to make an accurate guide used to assist a surgical procedure, such as the placement of an implant or to align a trauma fixation plate.

## Surgical guides used in dentistry

AM is currently being used by a number of companies to produce surgical guides used in dental implantation procedures. Using scan data from the patient's mouth, along with CT scans and X-rays, the dental surgeon uses specialist software tools to identify the exact location of the holes that must be drilled into the patient's jaw into which abutments are then fixed (see dental section for more details on abutments, page 52).

With the software, the 3D geometry of a drilling guide for the abutments is created, with the guide then being produced with AM using a variety of different polymeric systems, including Stereolithography, Polyjet and Projet 3D printing.

Dental surgical drilling guide produced using a resin base ALM platform
**© Envisiontec**

## Surgical guides used in orthopaedic implant procedures

*In a very similar* way to dental drilling guides, a number of applications for guides have also been found in orthopaedic surgery, most notably in knee replacement surgery (see section on orthopaedic implants for statistics on knee replacements, page 28).

The use of AM manufactured guides for knee surgery has being pioneered by Massachusetts based company Conformis, which was founded in 2004. The Conformis business model is to advance patient care by utilizing imaging technology to create personalized, patient-specific implants and instrumentation.

The Conformis process chain starts by using CT scan data of the patient's knee. From this data and using proprietary software, the surgeon is then able to plan the entire knee replacement procedure digitally, working out exactly how much or how little bone needs to be removed from the current joint to facilitate a new implant. From this computer model a series of up to 15 bespoke cutting and drilling guides are then automatically designed and manufactured using the Selective Laser Sintering process. The guides are then sterilised and packaged along with the patient-specific replacement knee components and all the surgical tools that are required to undertake the procedure.

Because the Conformis approach reduces natural bone loss through accurate cutting guides, made using AM, it has been proven that this approach results in faster recovery times and less patient swelling. A further benefit  is reduced hospital costs, as the solution comes with a suite of disposable guides and instruments, eliminating the need for both instrument stock holding and sterilisation.

Belgium company Materialise also offers a range of surgical cutting and drilling guides produced from CT scan data using the Selective Laser Sintering process. These guides are specifically for drilling the holes needed for the fixation of plates used in femur, tibia, ulna and radius surgery. The guides are also used to accurately locate the position of cut lines used where bone must be removed, such as knee replacement surgery.

## Market scale & opportunity

Both Conformis and Materialise are privately held companies, and as such we are not party to their annual production figures. Suffice to say, Conformis has just secured an additional $136-million of round E funding, which will support its continued expansion across North America and into other territories such as the EU and Far East.

As detailed in the orthopaedic section of this report, the global market for knee replacement surgery is significant, as is the number of corrective and trauma driven surgical procedures undertaken annually. If AM of cutting and drilling guides can be shown to increase patient recovery, reduce operating costs and improve surgical success rates, then it is highly likely that this will be a significant growth market, requiring multiple machine installations and significant material consumption.

Unfortunately at this time we have insufficient data to scale the current or future market for this application.

# TRAUMA, BESPOKE IMPLANTS & SURGERY

As a technology group that is capable of producing very complex geometries — economically in low volumes — Additive Manufacturing (AM) is perfectly suited to supporting one-off surgical cases and less common surgical procedures, where instrumentation may be costly.

## Trauma & bespoke implants

Over the last five years a significant number of bespoke surgical implants have been produced globally using both laser and electron beam melting of metallic powder, including both pure and titanium alloys. Applications have included implants for maxiofacial, cranial and jaw reconstruction surgeries following both traumatic injuries and the removal of tumours. Other applications include the production of bespoke hip implant sockets for patients with osteoarthritis and osteoporosis, along with a host of specialist trauma fixation plates used in reconstructive surgery of faces, arms and legs.

Bespoke hip socket produced for a patient with osteoarthritis using Electron Beam Melting **© Econolyst**

We estimate that some fifty laser and electron beam melting machines are currently being used for bespoke applications of this type. However, it is impossible to gauge how productive these machines are or their material consumption. Suffice to say, they will most likely be running at a very low utilization rate, in order to remain responsive to the needs of patients.

Bespoke eye socket & cranial reconstruction made using Electron Beam Melting **© Econolyst**

A number of specialist companies have emerged to support bespoke medical applications of this type, including Xilloc Medical based in Maastricht; Medical Modelling Incorporated in Golden

Colorado; and LayerWise in Leuven, Belgium. A number of university and government funded research labs are also used to support local hospitals with specialist cases, along with some service bureaux. The Walter Reed army medical centre in Washington, DC also houses an Arcam EBM system on site, which is used to manufacture bespoke implants for military casualties.

Bespoke mandible (jaw) reconstruction made using Selective Laser Melting **© Econolyst**

In addition to metallic ALM processes being used for bespoke medical implant manufacture, it should be noted that German technology vendor EOS also produces a polymer laser sintering machine for similar medical applications. The EOS P800 system has a high temperature bed capable of melting powders up to 385˚C. The machine has been designed and configured to process PEEK, a highly stable bio-compatible polymer, which has been used successfully in a number of medical applications including the manufacture of cranial patches and plates. Undoubtedly, ALM processes have a significant part to play in bespoke and direct implant production. However, compared with stock orthopaedic implant manufacture, this will be a relatively small market place in terms of both machine uptake and material consumption. As more surgeons become familiar with the technology, adoption will increase. It is also likely that much of this demand will be serviced by existing machine platforms, which currently run with low utilization rates.

## Surgical instruments

Some specialist medical procedures are only rarely performed of necessity, meaning that the demand for such specialist surgical instruments is limited. In some cases, very specialist procedures are only carried out by a handful of surgeons making the manufacture of assistive instruments very expensive.

Metallic AM has been used successfully by a number of medical companies for such instrumentation, including DePuy Spinal (part of Johnson & Johnson) and Ranier Technology Ltd. In both cases, the EOS Direct Metal Laser Sintering system was used to produce specialist spinal surgery instrumentation. Moreover, by applying AM it was also possible to make more complex instruments, with increased functionality.

Given the high cost of metallic ALM processes compared with casting or machining techniques, we do not expect wide spread use of the technology in this application, resulting in very few machine sales or materials revenue.

# NEONATAL MODELS

One of the primary applications of ultrasound is to produce images of human foetuses, along with the scanning of cardiovascular disorders and other soft tissue damage. The ultrasound market was worth some $4.8-billion in 2012, and is expected to reach $6.1-billion by 2017, representing a CAGR of 4.9% from 2012 to 2017.

One of the key factors contributing to this market growth is the increase in the sales of 3D/4D ultrasound equipment, which is the enabling technology needed to drive AM part production. Although ALM processes have been used for many years to make diagnostic medical models using CT, MRI and more latterly 3D Ultrasound, it is only within the last year that we have seen any concerted effort to couple the two technologies together to manufacture 'end-use products', namely neonatal models of foetuses produced as gifts and keepsakes.

## Current market penetration

In January 2013 Japanese medical engineering firm Fasotec started using Objet Polyjet 3D printers from Stratasys to convert both MRI and 3D Ultrasound scans into a range of high value 'gifts'.

Initially the company produced its 'shape of an angel' product using the Objet Connex multimaterial 3D printer using data derived from MRI scans (as shown below). The product, which was sold for approximately $1,200, showed a late stage (8 to 9 month gestation period) foetus within the silhouette of the mother. However, due to uncertainty over the possible side effects of MRI on unborn babies, the company decided to change its strategy to use only 3D Ultrasound data.
Unfortunately, using even the latest state-of-the-art ultrasound equipment, it is not possible to produce the resolution or 'tissue segmentation' seen within an MRI scan, and as such the company was forced to look for alternative 'products' to the one shown above.

Shape of an Angel – Multimaterial 3D printed foetus and mother derived from MRI data & sold for $1,200 - **© Fasotec Co. Ltd**

Using 3D Ultrasound the company has been able to produce data suitable for the 3D printing of foetus faces, which they are now producing and selling for some $500, branded as a 'face of an angel'. 'Face of an angel' is printed as a single material, single colour product – again using the Objet Polyjet technology platform.

'Face of an Angel' is a spin-off of Fasotec's main business, which involves producing patient-specific 3D medical models for medical institutes. However, working with just one affiliated clinic in Tokyo the company has, to-date, produced some 13 models for clients. Although a relatively slow start, the company is confident that there is a significant market place for this application, which is easily saleable through adding affiliated clinics using 3D/4D Ultrasound.

Face of an Angel – Single material 3D printed foetus face derived from 3D Ultrasound data & sold for $500 - **© Fasotec Co. Ltd**

## Manufacturing cost & sale price

We estimate that the face of an angel product would cost less than $100 to print using an Objet Polyjet machine, including machine depreciation, material consumption, waste and labour. Of course the sale price of $500 also includes data preparation from the enabling 3D Ultrasound data, which may take a number of hours of skilled technician time.

Using a relatively inexpensive, professional, entry-level 3D printer, such as an Objet 30 Pro ($30K), we estimate that it would be possible to produce some 1,022 face of an angel type products per annum based on a realistic 70% machine utilization. Given the size and shape of the products and the amount of support structure material required, we estimate that each model would use some 0.1 Kg of resin (allowing for waste), resulting in around 100 Kg of material consumption per annum per machine. Given an average price of material (build and support) of $250 per Kg, a facility producing 1,022 'face-of-an-angel' type products would consume some $25,000 of material per year.

*"In Japan, our birth rate is decreasing year by year and so are the number of children per family. Our sense of value for pregnancy and giving birth has been constantly changing. We believe more and more people want to enjoy and keep this special moment of being pregnant. Now there is an option to keep their precious memories, not in a fragile memory, not on a flat paper or picture, but as a "3D model" that you can "touch and feel" to look back on a special time"*
***Tomohiro Kinoshita - Fasotec Co***

## Global demand opportunities

According to the United Nations there were just over 1-million births in Japan in 2011. Within the UK, there were 761,000 births over a similar period, centred on 147 maternity facilities, giving an average birth rate of 5,176 per facility. It could therefore be assumed (using a similar healthcare profile) that a country with a birth rate such as Japan would require somewhere closer to 200 facilities.

Fasotec has been working with just one facility to generate demand for 13 AM products within a 10-month period. It could therefore be assumed that there may be a demand for as many as 3,120 'face of an angel' products within Japan each year across all maternity clinics. However, this figure does not take into consideration 'recreational' 3D/4D scanning which is becoming increasingly more popular in the developed world.

Research suggests that there are over 100 privately operated 3D/4D neonatal baby scanning facilities within the UK alone, offering 'baby bonding' services. If we take these types of facility into consideration, it could be forecast that demand for face-of-an-angel type products may be nearer to 5,000 units per annum from a country such as Japan. Based on the current low-level startup demand for the product, it should be noted that this penetration represents just 0.5% of all births within the country.

Globally there were just over 135-million births in 2011. Of course a very large proportion of these births were to mothers with no access to even the most basic ultrasound scanning technology, let alone access to 3D/4D ultrasound scans, costing between $150 and $300 per session. If we therefore exclude those economies considered to be at the 'base of the pyramid' and only include G20 nations, the 2011 birth rate drops to 67.7-million, dropping further to 10.2-million if we consider only births within the G8 nations, where people are far more likely to want such a high value product.

## Emerging global demand for AM neonatal baby models

Taking birth rate statistics for just the G8 Nations and assuming demand of just 0.5% for 3D/4D products such as 'face of an angel', we estimate that there could be current demand for some 51,000 products per annum today. To produce these products would require some 50 Objet 30Pro type 3D printers, with a capital cost of some $1.5-million and a recurring annual resin consumption of $1.3-million.

# MICRO-FLUIDIC CHIPS & DIAGNOSTICS

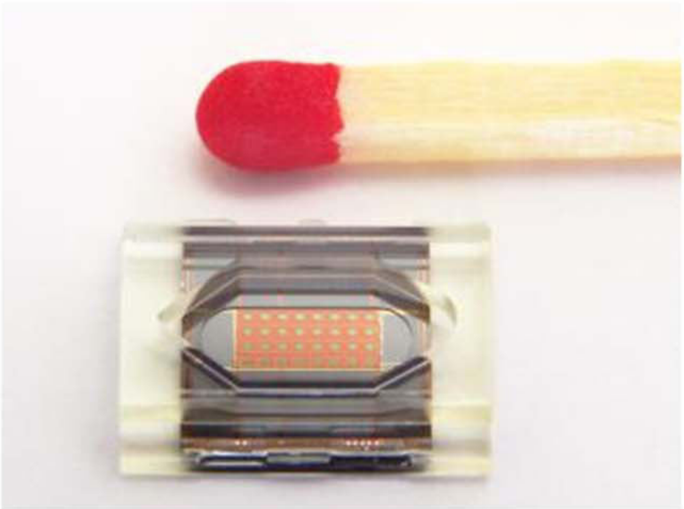
One interesting, yet small scale application of Additive Manufacturing (AM) within the medical sector is in the production of microfluidic reactors and chips used for a range of diagnosis, pharmacology and drug testing applications using lab-on-a-chip type technologies.

Microfluidics is a multidisciplinary field intersecting engineering, physics, chemistry, nanotechnology and biotechnology, with practical applications for the design of systems in which small volumes of fluids are handled. Microfluidics deals with the behaviour, precise control and manipulation of fluids that are geometrically constrained to a small, typically sub-millimetre scale. In short, microfluidic systems are able to move and mix together very small amounts of different liquids in a very precise way, often using nothing but capillary action as a motive force.

Microfluidic reactor using capillary action to mix exact ratios of reagent materials **© microTEC**

Since 1996, German company microTEC has been making a range of microfluidic devices using ALM processes. These devices include fluidics for the synthesis and analysis of medical reactions, including electrical and optical analysis. microTEC fluidic devices have integrated electrodes, valves, heating and cooling elements, micro-actuators, micro-needles and micro-filters with high aspect ratios. The parts are manufactured using the RMPD mask process. RMPD, or Rapid Micro Product Development, was developed by microTEC technologies and is a process where 3D structures are generated in a photo polymerization process, but where the process is optimised for small scale parts, resulting in cost-effective mass part production systems for micro-scale devices.

The RMPD mask method is used for life science applications were fluidics need a very fine structure with a high accuracy along the z-direction, as well as sharp edges, which are essential when using the capillary effects as a way of moving and mixing liquids. The materials used in RMPD for medical applications are tested for biocompatibility. For multi-material micro systems the RMPD mask process is combined with 3D-Chip Size packaging to realise fluidic parts with integrated semiconductor components (as shown over).



Microfluidic reactor with embedded microelectronic diagnostics **© MicroTEC**

Unfortunately, microTEC has been unable to identify or secure any high volume applications for its AM microfluidic medical diagnostic reactors, with the company producing just 8,000 units last year. The company does however produce many hundreds of thousands of microfluidic devices for other non-medical applications.

microTEC's own pricing schedule suggests that a basic 2-layer chip can be purchased for €4.50, with a more complex micro-chip sized package costing some €11.50. Taking an average of €8.00 per microfluidic device, this gives a total annual revenue from the medical sector of just €64,000 or $86,577.

It should however be noted that microTEC is focussed on polymers and multi-material microfluidics and does not produce any reactors for chemical and/or high temperature reactions, which are manufactured using metal and ceramic materials and used more extensively in the medical diagnostic sector.

# BIOLOGICAL SCAFFOLDS

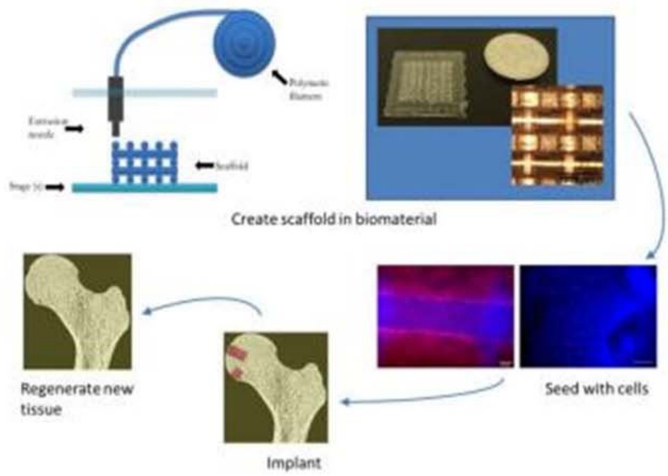
The human body has an amazing ability to heal itself. However, sometimes the level of trauma, damage or disease encountered by the body is too great for the body to repair and external interventions are needed to assist in the healing process. Historically, these interventions have involved the implantation of devices made from biocompatible metals or polymers. Although these solutions have proved effective for some conditions and in most patients, they are not ideal or suited to all. One solution to the limitation of current implantology is the development of regenerative medicine. The principle behind regenerative medicine is to allow the body to heal itself, often with the help of an external stimulus, such as a bio-absorbable scaffold, which can be used to stimulate the growth of new cells before dissolving into the patient's body once new cells have matured.

## Additive Manufacturing scaffolds

For a number of years, AM/3D printing has been investigated as one way of making bio-medical scaffolds. AM is particularly well suited to scaffold manufacture as it is possible to make highly complex shapes with large surface areas together with controllable levels of porosity. These are all important attributes when trying to build a construct with a primary purpose of tricking nature into generating cells.

The process of scaffold manufacture starts with a 3D computer design of the scaffold structure, including the size and shape of the scaffold and the spacing of internal features (designed porosity). The scaffold is then 3D printed using a range of different technologies including filament extrusion, photocurable lithography, selective laser sintering or powder binding using bio-compatible materials such as collagen, alginate, PLGA, PEC or Polycaprolactone.

The 3D printed scaffold is then seeded with the appropriate human cells and nurtured, before being implanted into the patient, where the cells continue to grow and propagate. Over time, the 3D scaffold is then absorbed within the body and the void left by the scaffold populated by living cells.




The principle of scaffold printing **© Kenny Dalgarno, Mark Birch and Sotiria Toumpaniari, Newcastle University and the Arthritis Research UK Tissue Engineering Centre**

However, 3D printing of biomedical scaffolds is in its infancy, with commercial biomedical scaffolds currently being manufacturing using other more developed processes such as electro-spinning and powder compaction. These types of scaffold are already being used for musculoskeletal reconstruction and bone engineering, and to support the regrowth of cartilage, ligament tissue, muscle tissue and blood vessels. During manufacture, scaffolds can also be seeded with drugs, which can aid cell propagation and prevent implant rejection.

As of today, 3D printed scaffolds are being used only in early phase I clinical trials and pre-clinical research. It is generally accepted that the technology is some 5 to 10 years away from mass market adoption and exploitation. However, the need for implants is on-going, albeit if problems can be treated earlier, when they are small, it may be that the need for a full joint replacement can be delayed or even mitigated. The main aim of AM scaffold research is to be able to treat things early, where currently there is no solution.

## Case study of an AM biomedical scaffold

Although scaffolds built using ALM processes are largely being used for pre-clinical or early stage clinical research, the technology has been used in practice for life saving surgical procedures where no other solution was available.

In February 2012, doctors at the University of Michigan hospital used an additively manufactured bioresorbable splint to treat an infant with severe tracheobronchomalacia. Approximately 1 in 2,200 babies are born with tracheomalacia, a condition whereby the tracheal cartilage in the throat softens and leads to collapse. In severe cases, such as the infant treated, both the trachea and bronchus give way, leading to a complete collapse of the airway resulting in suffocation. With no other surgical remedy, the doctors involved in the case were forced to look towards AM as their only clinical solution.

Using data taken directly from a CT scan of the patient's airway, the doctors then used 3D modelling software to design a splint that perfectly matched the patient's windpipe. A number of slightly different scale models were then 3D printed in the biodegradable polyester - polycaprolactone.

Having chosen the most appropriate size scaffold, the splint was implanted outside of the bronchus, with sutures passing through the splint to tether the trachea through the inside. In place, the resulting splint expands the bronchus and inflates the trachea. As the patient grows, so the splint is designed to open up, with the entire splint designed to be absorbed into the patient's body within three years, by which time the patient's windpipe will have matured and strengthened.

In this particular case, the splint was inserted at no cost, as the entire procedure was considered a research project. Albeit the raw material used is very inexpensive, with a polycaprolactone splint of this type costing less than $10 to make using 3D printing technology, with the manufacturing process completed in less than 24 hours.

## Commercialization of scaffold systems

Simple 3D printed bio-resorbable scaffolds used to replace broken and lost bone were first commercialised in the late 1990's by US company Therics. Therics developed and marketed products for the orthobiologics segment of the orthopaedic and neurological markets called TheriForm & TheriWedge. These products were made using a digital micro fabrication process, which was derived from the MIT patented powder bed 3D printing system that uses an inkjet print head to deposit a binder onto a powder. The same process licenced to companies such as Z-Corporation (now part of 3D Systems), EXONE and Voxeljet. TheriForm, which was developed with MIT, enabled the manufacture of porous microstructures for bone graft implants with internal channels that encouraged cell and tissue growth.

Therics became part of the Theken group of companies and was acquired by Integra Life Sciences Corporation in August 2008. However, analysis of the current Integra product portfolio makes no reference to the original Therics product or the use of AM in the manufacture of any Integra surgical implants. It would therefore appear that AM is no longer used in the manufacture of biological implants by Therics.

At this time the only commercial ALM machine tool vendor producing a bespoke bio-printer capable of producing scaffold constructs is Envisiontec who have sold in-excess of 100 of their 3D Bio-plotter solution.

# SOFT TISSUE & CELL PRINTING

Imagine a world where there was no transplant waiting list, a world where failing organs could be replaced with fully working organs made using the patient's own cells, with no chance of rejection or the need to take anti-rejection drugs or therapies. Now imagine a world with no dialysis, no pace makers and no daily injections of insulin. This is the long terms vision of researchers engaged in one of the most exciting future areas for 3D printing – tissue and cell printing.

The overarching ambition of cell printing is to one day be in a position where human healthy cells can be taken from a patient's body, multiplied within the laboratory and then placed within a 3D printing machine along with bioresorbable materials. The concept is to print the physical structure of the desired (damaged) organ in the bioresorbable material, whilst also placing the correct cell types at the correct location in the printing matrix along with the necessary drugs and nutrients. The resulting 3D structure would then be nurtured before implantation into the patient's body. In the longer term the printing might even take place directly into the patient's body using 3D printers within operating theatres.

So why is this form of extreme regenerative medicine so compelling? A patient dies every 30 seconds from damage/diseases that could have been treated with tissue regeneration or replacement — a statistic that is likely to worsen over time with the aging population. Globally, at least 200,000 people are on waiting lists for kidneys, and many more have no access to transplantation or dialysis services at all. The World Health Organization (WHO) estimates that currently, organ transplantation covers only 10 percent of the global need. In 2011 there were some 112,422 organ transplants according to the organization of donation and transportation, as detailed below, which in turn suggests that as many as 1 million people will die through lack of a transplant.

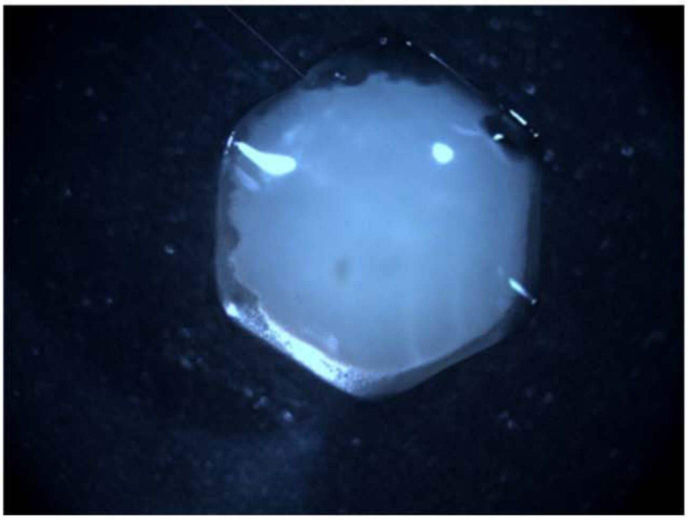
| Total | Kidney | Liver | Heart | Lung | Pancreas |
|---|---|---|---|---|---|
| Europe | 24,009 | 8,586 | 2,281 | 1,622 | 803 |
| Americas | 29,768 | 9,206 | 2,854 | 2,070 | 1,461 |
| Africa | 488 | 36 | 24 | 5 | 12 |
| Eastern Med | 6,080 | 980 | 101 | 36 | 15 |
| South East Asia | 5,819 | 953 | 13 | N/A | 3 |
| Western Pacific | 9.954 | 3,966 | 323 | 210 | 86 |
| **Total – 112,422** | **76,118** | **23,721** | **5,741** | **4,278** | **2,564** |

"Making" organs presents an almost unimaginable business opportunity.

## 3D printing of cells and soft tissue

As one would imagine, cells and tissue printing is a hot topic in both the media and the research community. However, expectations must be tempered by realism in terms of the commercial viability of this approach and the current level of scientific understanding.

A team at Wake Forrest University in the USA is widely championed as leading in the development and exploitation of bio-printing, with research lead by Professor Anthony Atala. Although Wake Forrest has, for a number of years, demonstrated the ability to 'make' semi-functional organs such as livers and bladders within a laboratory; this has been via seeding and nurturing scaffold systems, rather than direct printing.



3D Printed liver cells with vascularisation **© Organovo Inc.**

Researchers have, however, demonstrated the principles behind 3D cell printing, positioning cells within a functional matrix in a pre-determined order. Wake Forrest has now extended this work into early stage pre-clinical trials of skin printing, where the team is printing skin cells directly on to burns victims, who are not suitable candidates for skin grafts. However, by their own admission, they are many years — if not decades — away from 3D printing functional organs suitable for human implantation.

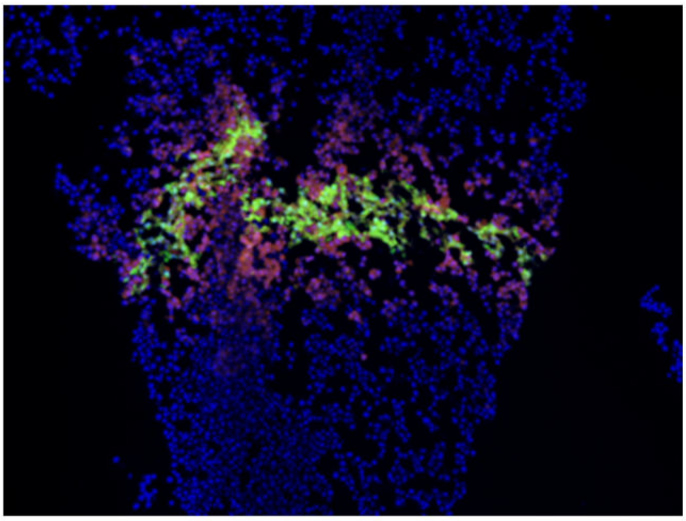
## Commercial 3D bio-printing

The commercial possibilities of 3D bio-printing have not gone unnoticed. In 2007, US Company Organovo was formed to commercialise work from the University of Missouri-Columbia centred on 3D organ printing. Organovo is an early stage regenerative medicine company focused on developing a range of human tissues and disease models for medical research and therapeutic applications.

3D Bio-printer experimental production rig **© Organovo Inc.**

Organovo initially raised $3M of angel finance in 2008 before securing a number of research grants to further their work in 2009. By 2010 the company was able to demonstrate the production of blood vessels. The company then announced that it would be focusing on the development of tissue models for use in drug discovery trials. In 2012 Organovo raised $15.2M through an IPO. Today the company has a market capitalisation of $434.6M and has detailed the key features of a 3D printed human liver.

The company is now focused on vascular bio-printing to manufacture new arteries and tissue patching, where small patches of replacement material will be stitched into the body and the production of therapeutic tissue for drug discovery trials. In the short- to medium-term, therapeutic tissue may prove to be the most significant market for 3D bio-printing, as large pharmaceutical companies currently spend upwards of $1-billion on the development of a new drug, which can then get rejected at the human trial stage. However, using 3D bio-printed materials from multiple donors, critical clinical trials could be undertaken much earlier in the development cycle, saving drug companies may millions of dollars.



A representative histology stain of a 3D printed liver showing the organization of the various cell types **© Organovo Inc.**

In summary, we believe that 3D bio-printing has the long term capability to eclipse other applications of 3D printing in terms of societal and economic impact. However, we must not allow excessive media coverage to cloud our judgement. 3D bio-printing is still in its infancy, most likely with a rate of maturity not that dissimilar to a real human. We therefore do not expect this technology to be commercially viable for at least a decade, with wide scale adoption taking another 10-years beyond that.

## BIRTH CONTROL

It is important to state at the outset of this section that Additive Layer Manufacturing (ALM) technologies are not currently being used to produce or enable the production of any form of birth control system or device (beyond supporting prototyping). However, in 2012 the idea was proposed by Ronan Kadushin for the manufacture of the Bearina IUD, a very low cost contraceptive device combining 3D printing as the production method with the simple principle of using copper as a spermicide.

The concept of the Bearina IUD is to use 3D printing to enable the manufacture of very low cost, *locally produced* contraceptive solutions for the developing world. The Bearina IUD (as shown below) is proposed as a simple device constructed from a 3D printed body containing a small copper coin.

The Bearina IUD – a conceptual contraceptive device made using a 3D printer and a small copper coated coin - **© Ronen Kadushin**

Although currently an untested and unapproved concept – the disruptive nature of using 3D printing to enable such a product should not be overlooked.

### Market penetration & growth

The global contraceptives market — including drugs, hormonal & copper IUDs, vaginal rings, subdermal implants, diaphragms, male and female condoms and sponges — was valued by Transparency Market Research at **$16 billion** in 2011. The market is expected to grow at a CAGR of 5.5% from 2012 to 2018, to reach an estimated value of **$23.3 billion by 2018**.

The main market drivers for this growth are the high global prevalence of women with unmet contraceptive needs, government and NGO initiatives to promote contraceptive products, implementation of the patient protection act and rising global prevalence of sexually transmitted infections (STIs). The main market restraints are the side effects associated with the use of contraceptive drugs and devices, the rapidly aging population in high wage economies and rising prevalence of infertility.

In 2007 there were an estimated 162 million women using IUDs. This figure had increased to 169 million by 2012, with IUD's representing 23% of all contraceptives used globally by women. A typical

IUD has a life-span of between 5 and 10 years depending on make, with many being removed early for health and discomfort reasons – we can therefore assume an average product life span of six years, suggesting that some 27–28 million new IUD's are produced and fitted annually.

## Manufacturing cost & sale price

IUD's are medical devices and must be correctly fitted by a medical professional to ensure successful operation. The typical cost of an IUD as a contraceptive solution, including exams, tests and insertion, ranges from $600 to $1,000. This figure increases to $1,500 if the cost of both placement and removal are taken into consideration.

Globally the purchase price of physical IUDs differ greatly. For example, a Beyer Mirena IUD costs $840 to purchase from a pharmacy in the USA with full FDA approval, but the same product can be purchased in Canada (without FDA approval) for $270 and in Australia for $240.

At these costs, as a contraceptive solution, the IUD is way beyond the reach of the vast majority of the global female population. Furthermore, it is estimated that an IUD actually costs less than $4 to manufacture, with the sales delta being a function of clinical validation cost, organisational overheads, distribution chain costs and profits.

Assuming the lower sale price of $240, based on 27-million units per annum – IUD production represents a $6.7 billion segment of the global contraceptive market. So how disruptive could additive manufacturing (AM) be, if the processes and materials were clinically validated?

## Drivers for AM adoption

Although it would be more cost effective to injection mould the body of the Bearina, this would not allow for the vast array of different copper coins used around the world in different developing nations. The concept of the Bearina is to use simple CAD tools to modify the product design to fit the available copper insert in different countries. The concept of localised manufacture using consumer (or local professional) 3D printers would then also significantly reduce the supply chain, which in the case of medical devices can be both complex and expensive. In short AM enables customised, low cost and localised manufacture.

So is AM of the Bearina IUD economically viable?

## Production using Additive Manufacturing

Using STL files produced by Ronan Kadushin, we have undertaken economic analysis of IUD production using both professional and consumer 3D printing systems. It should be noted that we have based this analysis on the most appropriate technologies for the application – however, this was an analysis based on economics and not efficacy, and therefore we are not in any way recommending these technologies or materials for this application without validation and approval.

**Professional solution** – We calculate that using a commercial plastic Laser Sintering (LS) machine (based on an EOS P395 platform) it would be possible to produce up to 33,600 IUD's over a 36-hour build cycle, enabling a total annual production of some 5.7-million parts per annum from one machine run at a realistic 70% utilization rate. This would suggest the current global demand for IUD's could be supported with just five (5) P395 Laser Sintering platforms costing some $1.5-million. In total these machines would consume some 17,207 Kg of material per annum. Based on current material prices (nylon equivalent), this equates to some $1.3-million of material consumption per annum (allowing for process waste).

Based on these production figures, and allowing for material consumption, waste, labour and machine depreciation, we believe it is possible to produce an IUD using LS for only $0.21. It should be noted that the Bearina IUD can be purchased from Shapeways online for some $1.21.

**Consumer solution** – We calculate that using a consumer FDM machine (such as a MakerBot Replicator 2), it would be possible to print 48 IUDs over a 1 hour 14 minute build cycle, enabling a total annual production of 156,680 IUDs per annum from one machine based on a realistic 50% utilization rate. This would suggest the global demand for IUDs could be supported with 171 Makerbot Replicator 2 machines costing some $239K. In total these machines would consume some 5,508 Kg of material per annum. Based on current material prices (ABS equivalent), this equates to some $504k of material consumption per annum.

Based on these production figures, and allowing for material consumption, labour and machine depreciation, we believe it is possible to produce an IUD using consumer FDM technology for only $0.07.

48 Bearina IUD's produced on a Makerbot Replicator 2 in 1h 14 minutes - **© Econolyst**

## Timescales and roadmaps

As we have seen AM could be used today as a cost effective way of manufacturing products of the size and scale of the Bearina IUD. This could be done at a competitive price point to injection moulding using both consumer & professional ALM technologies.

However, before any such products were to reach the market, they would require thorough clinical validation and appropriate certification in the counties in which they were to be used. At this time, Bearina is just a concept and to our knowledge is not being investigated for commercial exploitation.

It is highly unlikely that products such as Bearina would ever displace traditional healthcare products such as the BAYER Mirena within the developed world, given the constraints and global economic pressures within the healthcare market. However, using AM it is conceivable that new, smaller companies could emerge within specific geographic regions or countries to service the contraceptive needs of the developing world. This could be done cost effectively both in terms of capital investment and final piece part price using AM – hence, styling the potential export growth of Western healthcare products sold as 'long-cycle products'. However, as we have seen, irrespective of the future clinical validation of AM for IUD production or even a significant uptake in IUD's as a contraceptive solution, the market for AM hardware and materials would remain very small, with IUD's making little impact on the global supply of either AM hardware or materials.

## DRUGS AND PHARMACOLOGY

We are all different, with different healthcare needs, different immune systems, different DNA and in some cases different genes. For these reasons, many people are not suited to 'off the shelf' drugs and need far more tailored therapies for different diseases, infections or hereditary conditions.

The Tufts Centre for the study of drug development, suggests that there will be a 15% year-on-year increase in the demand for personalized medicines in the coming decade. These medicines will largely be focused around oncology, immunity and anti-infection. However, there are barriers to the development of such personalised therapies, given that the cost of developing a new approved drug is estimated by Tufts to be some $1.2-billion. Hence, there is both a commercial and societal need to find new ways of developing and delivering both personalised and affordable medicines.

### 3D printing and drug delivery

3D printing has been hailed as a potential solution both to reduce drug development costs and to enable personalized healthcare. Researchers at the University of Glasgow in Scotland are already using 3D printing systems to rapidly assess the compatibility of different compounds, by taking different constituents and passing them through a 3D printer. Using this method, real time chemical synthesis of the compounds can be initiated resulting in a chemical reaction leading to a new drug. The long term goal is to develop systems whereby low cost 'common chemicals' could be fed into a 3D printer and mixed 'on-the-fly' resulting in either a tailored or low-cost pharmaceutical solution. However, it is estimated that such systems are some 5 to 10 years away from being viable within a pharmaceutical laboratory and 10 to 20 years away from being a commonplace technology within the shopping mall or drug store.

The other compelling benefit of the 3D printed drugs approach, is the ability to not only mix the exact quantities of active drugs required for the individual patient, but also to change the size of the dose and the location of the active ingredients within an ingestible pill. This 'selective printing' could then be used to control the release time of active ingredients into the patient's body increasing the physiological benefits of the drug.

However, these are currently all hypothetical constructs, which pose significant issues to drug regulators, physicians and large pharmaceutical companies. For instance, how do we know that a complex cocktail of drugs will not have a detrimental effect on a patient, how can we measure the impact and efficiency of bespoke drugs, and what will be the cost of such 'real-time' monitoring to health services? From a clinical perspective – how will we translate patients' ailments into bespoke prescriptions, and how will we design the optimum pharmaceutical in real-time? From a manufacturing perspective, we must also consider issues such as product traceability, cross contamination during manufacture and between active components along with the inevitability of counterfeiting.

In reality, we believe that it will be a number of decades, if at all, before 3D printing makes any significant impact on the pharmaceutical supply chain. Albeit, it will no doubt find adoption within drug development both as a way of rapidly assessing compounds and as a way of producing tissue on which drugs will be tested.

# EVALUATING THE MARKET OPPORTUNITY

In this final section of the report, we have pulled together the key facts and figures detailed in the previous sections. We have, wherever possible, used available data combined with original data collated by Econolyst and used this to produce sensible forecasts for how we expect the application of additive manufacturing (AM) in the medical industry to grow over the coming decade, and the impact that this growth will have on both machine sales (hardware) and material sales (consumables). We have also highlighted which technology vendors are best positioned to respond to different medical opportunities and growth markets, and which vendors currently hold the leading positions. Finally, we have also provided links to each and all of the commercial organisations detailed within this report for further reference.

## Forecasting the scale of application growth

Within business there is no crystal ball. However, there are grounded ways of forecasting future trends based on an analysis of the current size, growth and dynamic of the market into which products and services are being sold, along with other influences such as competition and the cost and complexity of new technology adoption. To support any forecast on the future demand for ALM machines or consumables, and the revenue that this demand will generate, we must first forecast the likely growth of each of the medical sub-sectors within this report, using our current estimation of penetration as a benchmark.

### Hearing aids

We believe that the market for 3D printing hearing aid shells is reaching saturation. Future machine sales will only come from back-filling redundant technology, increasing population within western economies and a small percentage of new market growth coming from new market penetration into other specialist audiology products. For this reason we do not think that it is unrealistic to set future growth at just 3% per annum for cumulative machine installations.

For the purposes of our forecast we will assume that all hearing aids are made on technologies costing an average of $200,000 (based on an average of SLA, Projet, Polyjet & Perfactory). We will also assume a base line of 63 machines in use today (at this average price point) and material consumption per machine of 133 Kg per annum at a cost of $300 per Kg.

### Orthopaedic applications

At present AM is being used to produce just 2% of the world's orthopaedic implants, which would suggest a significant opportunity for growth. However, many of the larger implant manufacturing companies have invested heavily in alternative R&D to develop products not made by AM. It is therefore unlikely that these companies will change their production technologies readily within the next decade. For this reason we think that AM will be restricted to smaller orthopedic companies, who command some 20% of the global market place. Therefore, we think that it is realistic to forecast that 10% of implants will be made using AM within the next decade.

Allowing for low machine utilization within R&D organisations, we believe that the current supply of 2% implants could be serviced by just six Arcam EBM machines costing some $780K each. 10% of the market could be serviced by 40 machines. We forecast that each machine would consume some 750 Kg of material per annum at a cost of $700 per Kg.

### Dental aligners

Invisible dental aligners manufactured using 3D printed tools already account for 17.5% of the dental aligner market. Given the rate of growth of invisible dental aligner companies, increasing geographic penetration and increasing competition (driven by lower cost machines), we believe it is not unrealistic to assume 50% market penetration within the next ten years.

At present we believe the dental aligner market, based on 17.5% penetration, is being serviced using some 117 machines (3D Systems SLA, Objet Eden & Envisiontec Perfactory). Moving forward, we would expect the market to be driven by lower cost platforms, such as Envisiontec Perfactory & Objet Polyjet, rather than SLA. Given their slightly lower overall productivity we would expect some 500 machines would be required to service 50% of the dental aligner market. These machines have a typical purchase price of some $180K and would each consume some $130,000 of resin per annum.

### Facial & limb prosthetics

We do not see the prosthetic market as being significant to global AM growth. The industry is largely built around specialist technicians and occupational therapists working directly with patients. These practitioners already use easily malleable materials to shape prosthetics directly onto the patient's body. Although current manufacturing methods can result in uncomfortable prosthetics, there is no evidence to suggest that AM would be any better.

Within the next ten years we would expect some of the larger prosthetics companies to adopt AM for specialist applications and components, but this is unlikely to be more than 20 machines in total. To service the prosthetics industry, we would expect companies to acquire Laser Sintering platforms from EOS or 3D Systems costing some $400K each. We would not expect material consumption to exceed 600 Kg per machine per annum at a cost of $90 per Kg. We have not scaled the facial prosthetic market, as there is uncertainty about the scale of demand.

#### Orthotics

At the moment we are only aware of one 3D Systems sPro 60 machine being used commercially for the production of Orthotic insoles. However, given the obvious benefits of the additive manufacturing approach and the productivity of the technology, we forecast that 50 machines will be used for this application within the next 10 years. These applications will be based around laser sintering technology, with the machines costing some $350,000. Each machine will consume some 690Kg of material at a cost of $80 per Kg.

### Dental – crowns & bridges

We believe that some 100 ALM machines are currently being used to manufacture expendable patterns for dental crowns. These machines have the capacity to support some 31% of the dental crown demand within the western world. We also believe that some 130 direct metal laser melting machines are also being used, with the capacity to support a further 45% of global demand. Albeit none of these machines are being run at capacity – yet.

Within the next decade, we do not think that it is unrealistic to assume that 90% of dental crowns within the developed world will be produced using ALM, given increased use of digital dentistry, increasing labour costs and skills shortages. Given the dynamic of the industry we would expect 45% of these crowns and bridges to be made by large dental laboratories using the selective laser melting of metal, and a further 45% produced using indirect investment casting patterns.

To service this market, an additional 45 medium sized polymeric machines will be required (such as Envisiontec Perfactory or Objet Eden 250 machines). The typical cost of these machines is some $70K. We would estimate that each machine would consume some 350 Kg of resin per annum (including support material) at an average cost of $270 per Kg.

In addition to the polymeric machines, there will be some demand for new metallic ALM machines, albeit the global install base of machines is sufficient to supply global demand. However, it would appear that metals machines in the dental industry are not run at high utilization rates. As such we believe there may be scope to double the install base of metals machines within the next decade from 130 machines to 260 machines. These 130 machines will have an average list price of approximately $350K (based on an average of Phenix, EOS, Renishaw, Concept Laser & SLM Solutions prices). We would expect each machine to consume some 250 Kg of cobalt chrome powder at a cost of $300 per Kg.

## Dental – stone models

The production of stone models presents a significant opportunity for AM, as the models are relatively large compared with other medical products such as dental aligner moulds, hearing aid shells or dental crowns. For this reason they demand more capacity to produce and use more materials.

As we have already stated, the increased use of intraoral scanners, labour costs and skills shortages are likely to drive the transition to digital dentistry, which could account for up to 90% of the market place within ten years. If such penetration were to be reached then it could be forecast that some 12.4-million stone models sets would require 3D printing.

This would require somewhere in the order of 1,800 medium sized machine platforms costing some $70K each. At present we estimate that some 200 such platforms are in use. Each machine would consume some 172 Kg of material at $200 per Kg.

## Ophthalmic applications

It is unrealistic to assume that AM will displace all injection moulding of designer glasses within the next ten years. However, given the benefits AM presents in terms of product personalisation and ergonomics, there may be scope for AM to take some 20% of the market.

We know that to support the total global supply of polymeric designer glasses using AM would require some 220 polymeric laser sintering machines – based on an EOS P395 system. Hence, we can assume that 20% of this market could be supported with 44 machines, each costing some $290K. At present we are unaware of any machines dedicated to glasses manufacture. Based on a 50% material refresh rate, we estimate that each machine would consume some 2,310 Kg of powder per annum at $80 per Kg

## Surgical guides

As stated in section 2 of this report – we do not have sufficient data on the scale of the cutting guide market to make any forecasts about current or future growth – we hope that in future editions of this report we will be in a position to present such analysis.

## Trauma & surgery

We estimate that some 50 metallic systems are being used globally to support bespoke medical device manufacture and surgery. These machines are a combination of largely Selective Laser Melting (SLM) machines and a smaller number of Electron Beam Melting (EBM) machines, with an average cost of some $500K. We would expect the install base of these machines to at least double in the next decade as the technology becomes more pervasive within the healthcare sector. However, we would not expect these machines to consume significant amounts of raw material compared with machines producing stock implants, which are being run as part of a high utilization production line. We would expect these machines to consume some 250 Kg of material (titanium) priced at $700 per Kg.

## Neonatal medical models

At present just one Objet 30Pro machine is being used to support neonatal modelling. At full capacity this machine should be consuming some 86 Kg of material per annum at a cost of $300 per Kg. Within ten years we would expect to see 50 such machines in use globally each costing some $45K.

## Microfluidic chips

We do not see microfluidics having a significant impact on machine or material sales.

## Biological scaffolds & soft tissue and cell printing

At this point in time biological scaffolds, soft tissue and cell printing are used solely within research organisations and as such there is no robust data on the cost of machines or materials. Nor are we able to forecast the effective scale of the market. We will revisit the commercial opportunity for scaffolds, soft tissue and cell printing in future reports.

## Birth control

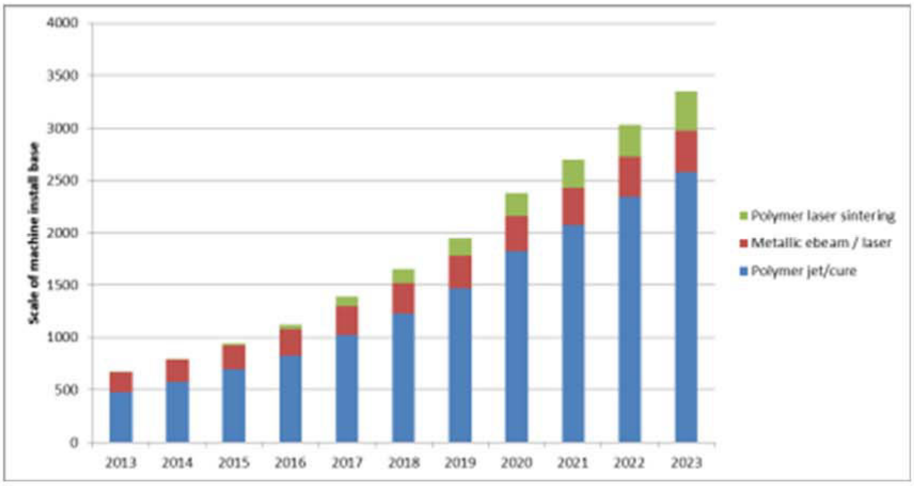
Within the next ten years, we feel that it is highly unlikely that any form of birth control will be 3D printed, given the current limitations of the technology and the regulatory framework surrounding medical devices and contraception. Irrespective of this, based on the Bearina coil example used in this report, the global market could be serviced with just 5 EOS P395 machines consuming some $1.3M of material per annum. As such we do not see birth control as accretive to the market growth of medical AM.

## Drugs and Pharmacology

At this point drug printing is restricted to very early stage research and as such there is no robust data on the future cost of machines or materials. Nor are we able to forecast the effective scale of the market. We will revisit the commercial opportunity for drug printing in future reports.

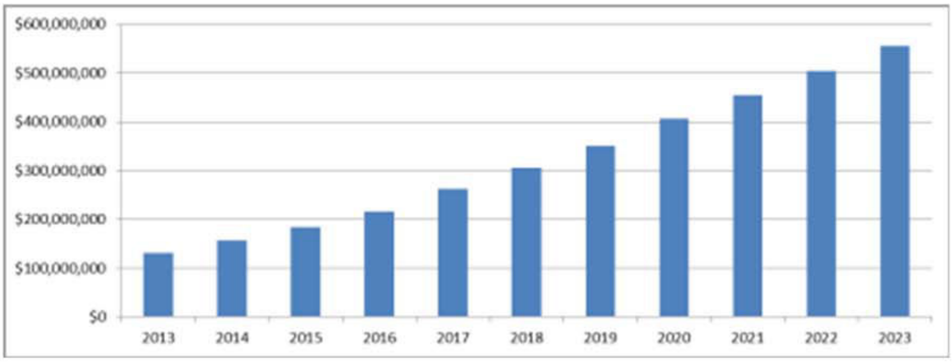
# Forecasting market growth for machine sales

Based on our analysis, we calculate that for the medical sub-sectors reviewed within this report; at least 671 ALM machines are currently being used for direct part production, casting patterns or vacuum forming tool manufacture within the medical sector. This figure is set to rise to 1,655 machines within five years and some 3,347 machines within ten years. These machines will largely fall into three categories – metallic powder bed systems using laser or electron beam melting, laser sintering of polymeric powders and the photo curing of thermosetting polymers. The growth and distribution of machines by type is shown below based on our forecast of technology adoption within each of the medical sub-sectors.



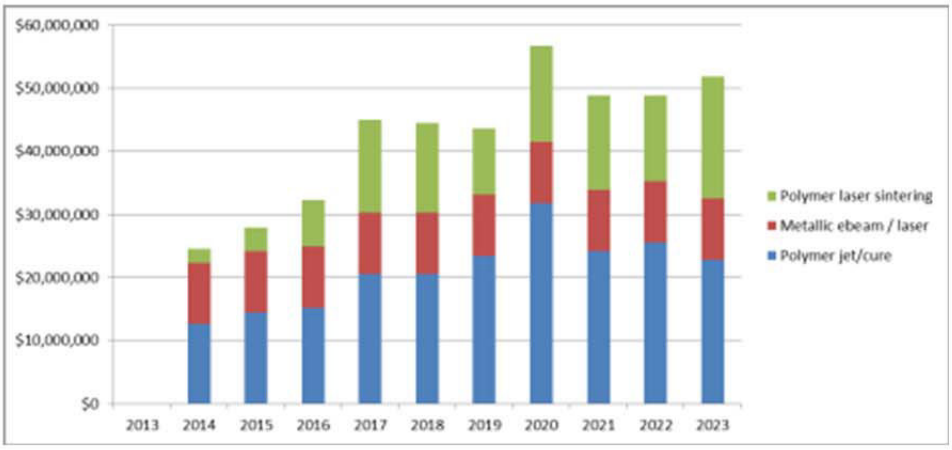

Scale of current and future machine install base based on technology type **© Econolyst**

We estimate that the current install base of ALM machines being used for medical direct part production, casting patterns and vacuum forming tool manufacture, represents a current investment of $131.8-million. We expect this figure to rise to $306-million within five years and $555.7-million within ten years. It should be noted that a large percentage of this growth (20%) is driven by the continued adoption of dental stone models.




Cumulative value of the machine install base used to service medical part demand **© Econolyst**

In terms of annual revenue we expect the market to grow, from machine sales of $24-million in 2014, peaking at $56-million by 2020. On average (over a ten year period) 50% of this revenue will come from the sale of photocurable polymer systems, 23% from metallic powder bed systems and 27% from polymeric laser sintering systems.



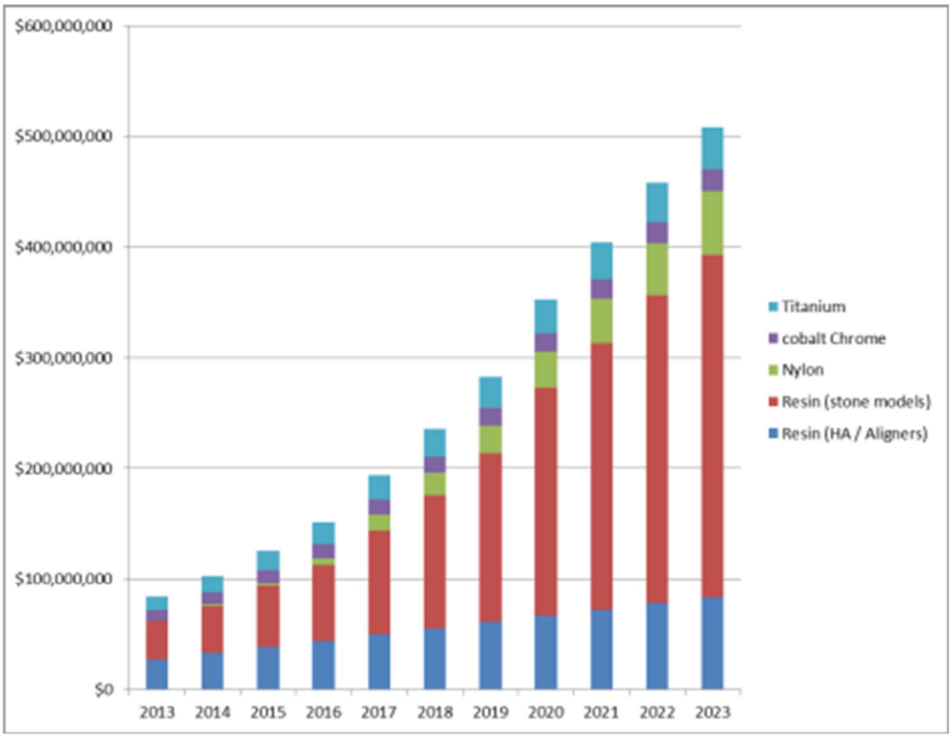

Annual sales revenue from medical machine platforms by platform type **© Econolyst**

## Forecasting market growth for material sales

Based on our analysis, we calculate that for the medical sub-sectors reviewed within this report; at least $83.7-million of material is being consumed per annum for direct part production, casting patterns or vacuum forming tool manufacture within the medical sector. This figure is set to rise to $235.8-million within five years and $508.6-million within ten years.

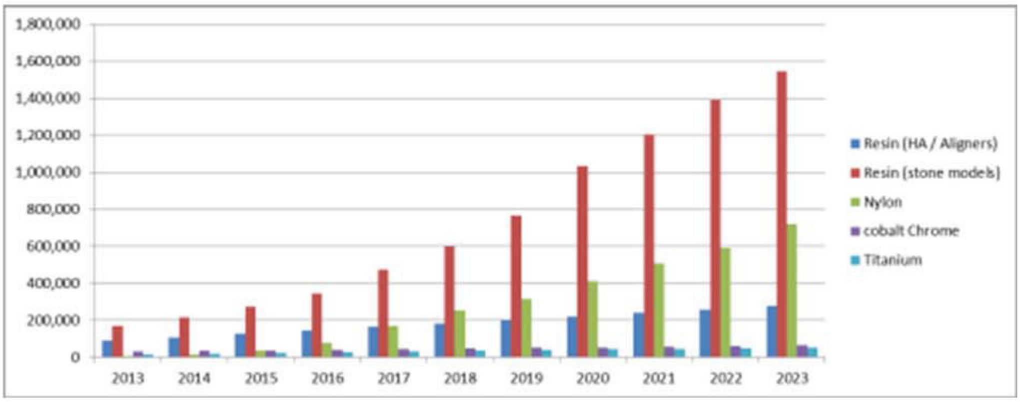
Within ten years we forecast that annual materials revenue will be 10X the revenue generated from machine sales. It should be noted that the vast majority of this revenue (55%) will be generated from the sale of resins for dental stone model production. We would offer a word of caution here, as given the scale of this market opportunity, it is highly likely that 3rd party material vendors will release competitive materials driving down cost. This in turn may reduce these revenue estimates.

Beyond stone models, we expect photocurable resins used for dental aligners and hearing aids to account for some 21% of the market (by value), with titanium accounting for 9.6%, nylon 8.6% and cobalt chrome 5.5%.



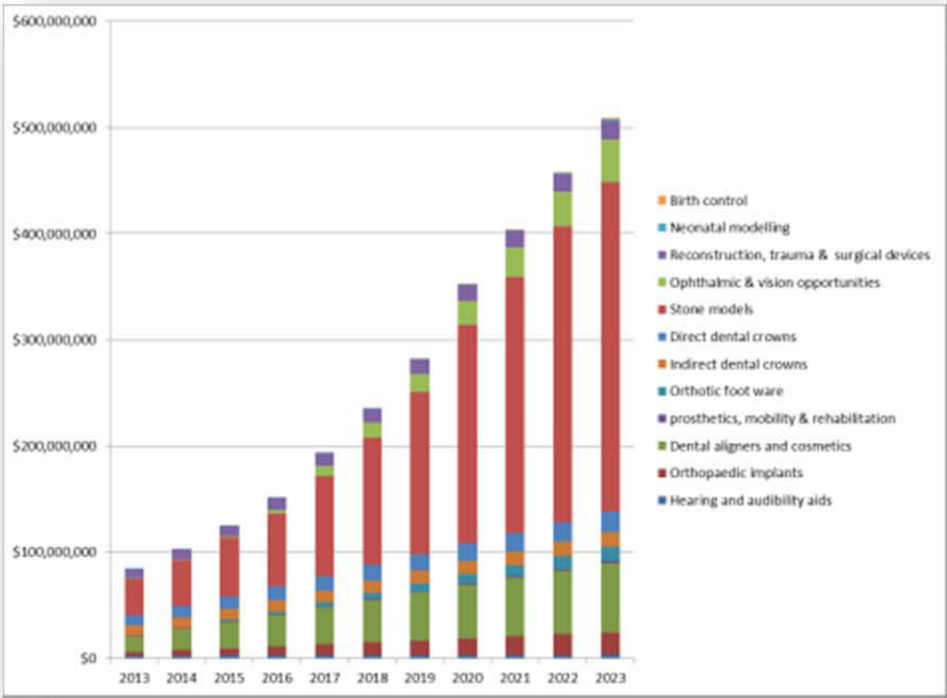

Annual sales revenue generated by different types of material © **Econolyst**

In terms of material volume, we expect demand to rise significantly for both photocurable resins and nylon powders, with consumption reaching 1,825 tons and 721 tons respectively.




Annual production of different medical materials by weight (Kg per annum) **© Econolyst**

By monetary value we expect the stone model and dental aligners markets to be the largest revenue drivers, followed by ophthalmic and vision (glasses).




Distribution of material revenue by medical application area **© Econolyst**

In summary, we can conclude that within the next ten years, future materials and machine revenue within the medical sector will be driven by the adoption of digital dentistry and the transition of some glasses manufactures to adopt AM. Polymers and machines processing polymers will drive the greatest market growth, with metallic systems gaining adoption, but having little overall impact on revenues.

## Mapping vendors with applications

Given that we have now identified the types of machines and materials that are likely to drive the future growth of the ALM medical market place, the table below considers which machine vendors could benefit from this growth, and identifies which vendors are currently leading in terms of sales.

| Application | Raw Material | Process | Lead vendor | Adopted vendors | Potential vendors |
|---|---|---|---|---|---|
| Hearing and audibility aids | Resin | Polymer jet/cure | Enviziontec | Stratasys / 3D Systems | DWS |
| Orthopaedic implants | Titanium | Metallic ebeam / laser | Arcam | EOS / Renishaw / SLM | Concept Laser / Realizer |
| Dental aligners and cosmetics | Resin | Polymer jet/cure | 3D Systems | Enviziontec / Stratasys | DWS / EOS |
| Prosthetics & rehabilitation | Nylon | Laser sintering | Unclear | EOS / 3D Systems | Voxeljet |
| Orthotic foot ware | Nylon | Laser sintering | 3D Systems | Unclear | EOS / Voxeljet |
| Indirect dental crowns | Resin | Polymer jet/cure | Enviziontec | Stratasys / 3D Systems | DWS |
| Direct dental crowns | Cobalt Chrome | metallic laser | EOS | 3D Systems / Renishaw | Concept Laser / Realizer |
| Stone models | Resin | Polymer jet/cure | Stratasys | 3D Systems / Enviziontec | DWS |
| Ophthalmic & vision | Nylon | Laser sintering | EOS | 3D Systems | None |
| Trauma & surgical devices | Titanium | Metallic ebeam / laser | EOS | Arcam / Renishaw / SLM | Concept Laser / Realizer |
| Neonatal modelling | Resin | Polymer jet/cure | Stratasys | None | None |
| Birth control | Nylon | Laser sintering | None | None | EOS / 3D Systems |

However, we must also be conscious that not all of these medical applications present the same business opportunity in terms of future machine sales or materials revenue. The table below shows that same information but apportions a high, medium and low revenue value to both the materials and machine opportunity in each sector base on forecast annual sales revenue.

| Application | Material | Hardware | Lead vendor | Adopted vendors | Potential vendors |
|---|---|---|---|---|---|
| Hearing and audibility aids | Very Low | Low | Enviziontec | Stratasys / 3D Systems | DWS |
| Orthopaedic implants | Low | Low | Arcam | EOS / Renishaw / SLM | Concept Laser / Realizer |
| Dental aligners and cosmetics | Medium | Very High | 3D Systems | Enviziontec / Stratasys | DWS / EOS |
| Prosthetics & rehabilitation | Very Low | Very Low | Unclear | EOS / 3D Systems | Voxeljet |
| Orthotic foot ware | Low | Low | 3D Systems | Unclear | EOS / Voxeljet |
| Indirect dental crowns | Low | Very Low | Enviziontec | Stratasys / 3D Systems | DWS |
| Direct dental crowns | Low | Very High | EOS | 3D Systems / Renishaw | Concept Laser / Realizer |
| Stone models | Very High | Very High | Stratasys | 3D Systems / Envisiontec | DWS |
| Ophthalmic & vision | Medium | Low | EOS | 3D Systems | None |
| Trauma & surgical devices | Low | Medium | EOS | Arcam / Renishaw / SLM | Concept Laser / Realizer |
| Neonatal modelling | Very Low | Low | Stratasys | None | None |
| Birth control | Very Low | Very Low | None | None | EOS / 3D Systems |

## Assessing the position of vendors within the market place

We can now identify which vendors are aligned to the largest market opportunities based on the suitability of their technology offering and how this will impact overall on their relative positions within the market place.

Within polymeric applications the strongest companies both now and moving forward are Envisiontec, Stratasys and 3D Systems, as all produce resin based systems suited to large applications, including dental stone models and dental aligner tools. The companies are also well positioned to service the dental crown and hearing aid markets, albeit these appear to offer little growth opportunity. At this point in time, EOS polymeric technologies are not aligned to any significant medical markets.

Within metallic applications, Arcam has a strong position in medical implant manufacture. However this is a relatively weak market with little material revenue and only a small potential for growth within the machine install base. EOS and other vendors such as Renishaw, SLM Solutions and Phenix (now part of 3D Systems) are better positioned to service the need for direct dental implants and more bespoke surgical implants.

## HYPERLINKS TO EXTERNAL RESOURCES

Within this report we have made mention of a wide variety of technology vendors and users. The table below provides an A-Z list of these companies and organisations along with hyperlink to their websites where you can find a wealth of additional information.

| Reference | Web link |
|---|---|
| 3D Systems | http://www.3dsystems.com/ |
| Adler Ortho | http://www.adlerortho.com/page_1/index.php |
| A-Footprint | http://www.afootprint.eu/ |
| Align Technologies | http://www.aligntech.com/Pages/Home.aspx |
| Arcam AB | http://www.arcam.com |
| Asiga | https://www.asiga.com/ |
| ASTM F42 | http://www.astm.org/COMMITTEE/F42.htm |
| Bearina | http://www.ronen-kadushin.com/ |
| Beehive | http://beehivedigitalmanufacturing.tumblr.com/ |
| Biomet | http://www.biomet.com/orthopedics/ |
| ClearCorrect | http://clearcorrect.com/ |
| Concept Laser GmbH | http://www.concept-laser.de/ |
| Conformis | http://www.conformis.com/ |
| Corin | http://www.coringroup.com/ |
| DePuy | http://www.depuy.com/about-depuy/depuy-divisions/depuy-orthopaedics |
| DePuy Spinal | http://www.depuy.com/about-depuy/depuy-divisions/depuy-spine |
| DuPont Children's hospital | http://www.nemours.org/welcome.html |
| DWS | http://www.dwssystems.com/ |
| Envisiontec GmbH | http://envisiontec.com/ |
| EOS GmbH | http://www.eos.info/en |
| Exactech | http://www.exac.com/ |
| EXOne Company | http://www.exone.com/ |
| Fasotec | http://www.fasotec.co.jp/ |
| Fripp Design and Research Ltd | http://www.frippdesign.co.uk/ |
| Integra Life Sciences | http://integralife.com/index.aspx?redir=Spine-Surgeon |
| Lima Orthopedic | http://www.lima.it/ |
| LUXeXceL | http://www.luxexcel.com/ |
| Make Eyewear | http://www.makeeyewear.com/ |
| MakerBot Industries LLC | http://www.makerbot.com/ |
| Materialise | http://www.materialise.com/ |
| microTEC GmbH | http://www.microtec-d.com/ |
| Newcastle University | http://www.ncl.ac.uk/mech/staff/profile/kenny.dalgarno |
| Organovo | http://www.organovo.com/ |
| Peacock Orthotics Ltd | http://www.podfo.com/ |
| Phonak | http://www.phonak.com/ |
| PQ Eyewear | http://pq-eyewear.com/ |
| Protos Eyewear | https://crowdfunding.protoseyewear.com/3d-printed-eyewear-tailored-to-fit-you |
| Ranier | http://www.ranier.co.uk/ |
| Realizer | http://www.realizer.com/ |
| Renishaw | http://www.renishaw.com/ |
| Robohand | http://robohand.net/ |
| Siemens Hearing aids | http://hearing.siemens.com/UK/en/home/home.html |
| SLM Solutions GmbH | http://www.slm-solutions.com/en/ |
| Starkey | http://www.starkey.com/ |

| | |
|---|---|
| Stratasys Inc | http://www.stratasys.com/ |
| Stryker | http://www.stryker.com/en-us/index.htm |
| University of Michigan Hospital | http://www.umich.edu/ |
| University of Glasgow | http://www.chem.gla.ac.uk/cronin/ |
| Wake Forrest University | http://www.wakehealth.edu/WFIRM/ |
| Walter Reed Medical Centre | http://www.wrnmmc.capmed.mil/SitePages/home.aspx |
| Wohler Associated | http://wohlersassociates.com/ |
| Zimmer | http://www.zimmer.com/en-US/index.jspx |

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Econolyst advises both additive manufacturing systems vendors on future business and technology strategy, and technology users on the business benefits of AM adoption. Econolyst has worked on a diverse range of projects to integrate AM into sectors from healthcare to warfare, computer gaming to consumer goods, and from recreation to education.

Econolyst also acts as advisors on AM/3DP to a number of financial institutions, hedge funds and venture capital partnerships, in addition to government agencies around the world. Econolyst contains a multidisciplinary team of consultants, engineers, researchers, economists and supply chain professionals - all focused on the AM/3DP economy.