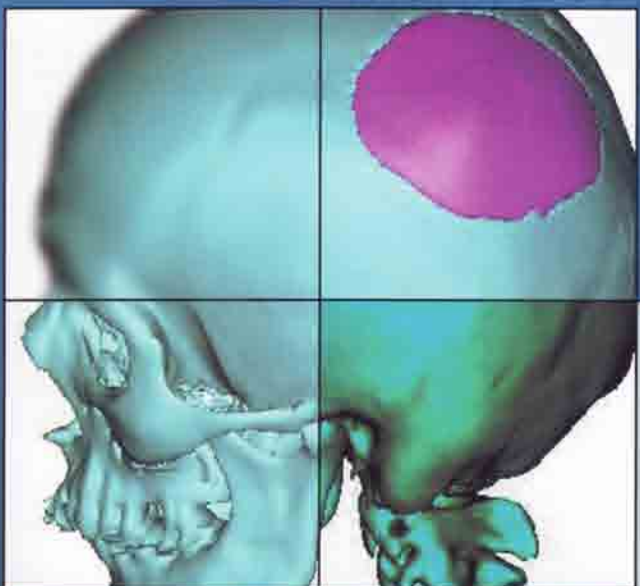
# MEDICAL MANUFACTURING



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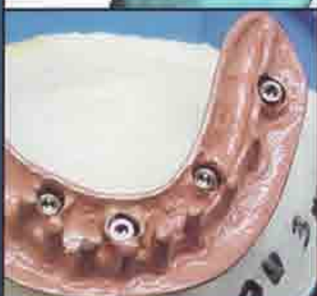

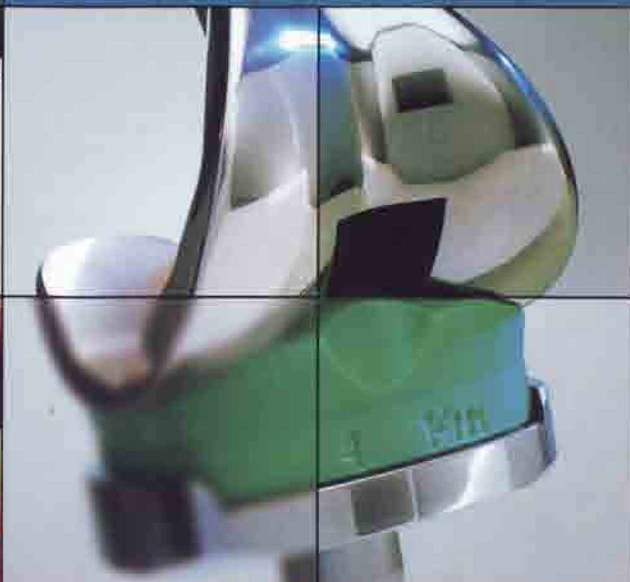

Manufacturing ENGINEERING

SME Society of Manufacturing Engineers

Supplement to Manufacturing Engineering

## Introduction



## Overview



## Outlook



# Rapid Manufacturing's Socio-Economic Benefits

Rapid manufacturing (RM) or direct digital manufacturing (DDM) are the common names given to the production of "series" or "end-use" component parts made using additive layer manufacturing (ALM) processes. Using traditional engineering metrics, these developing manufacturing technologies and processes are frequently compared and contrasted with more mature operations. However, taking the analysis beyond the traditional reveals socio-economic benefits of RM, and how the technology can be used to enable new business models and supply chains.

*Rapid technologies are driving improvements in health and well-being.*

**Custom-fit hearing-aid shells produced using Envisiontec Perfactory.**

Among these areas is the addition of value across the product lifecycle, from customer engagement and new supply chain configurations to new service and supply models. Also, there are the environmental and societal benefits of RM, as well as the ways the technology can and will be used to respond to shifting global demographic and economic patterns, such as the aging population, increasing fuel costs, limited natural resources, and ever-changing consumer trends.

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In principle, RM can reduce or eliminate many stages of the traditional supply chain, reducing lead times, inventory and supply chain transactions, and logistics costs.

Moreover, little if any waste material is generated, (with the exception of certain polymeric processes). This is particularly true of the newer direct-metal powder-bed processing systems. Additive manufacturing processes are therefore lean, yet agile, allowing the manufacture of low-volume batches of component parts, with little manual intervention.

There has been a significant growth in the number of companies using RM across a broad range of industrial sectors. Examples of applications in the health field include hearing-aid shells, dental implants, and surgical guides. Systems are limited, however, in terms of their production throughput, materials choice, accuracy, repeatability, and cost.

**Yet, the benefits of RM** far exceed the economic potential for just low-volume manufacture. In fact, the vast majority of current successful RM business applications are driven by societal wants or societal needs, rather than production-engineering economics.

**Mandible reconstruction manufactured using MCP selective laser melting.**

How does RM best respond to these wants and needs? The Technology Strategy Board, which represents the interests of the UK government in funding science and technology research within business, has identified the health and well-being of the citizen as a key driver around which future products and services are likely to be developed.

As a disruptive yet enabling technology, RM has the potential to impact significantly in all these areas of research, and therefore future business opportunities. Moreover, RM is a great leveler, enabling both large and small enterprises alike to compete within the global economy to service the needs of the growing consumer base.

**To forecast where RM** could be driven by societal needs, it is worth looking at current RM applications and research activity, as much of this is already aligned against these national or arguably global priorities, and will surely lead to increased volumes of RM within the future.

Invisalign is a well-documented dental product manufactured by Align Technology (Santa Clara, CA) using ALM tooling. Although not manufactured using RM materials, the Invisalign business model is predicated on the flexibilities of additive manufacturing, where each dental aligner is made using a customized forming tool. However, although visually more attractive, less invasive, and far more flexible in terms of orthodontist interaction than traditional dental braces, it could be argued that the Invisalign product is driven more by consumer "want," rather than by consumer "need," as other dental-brace technologies already exist.

More driven by need is the demand for geometrically customized hearing aids. These are produced by a number of companies using RM, including Siemens, Phonak, Minerva and Starkey Laboratories. The key benefits to the user, above and beyond traditional hearing aid products, are both increased comfort and increased performance through reduced feedback. A range of RM processes are now used for hearing-aid manufacture, including stereolithography, perfactory, and polyjet printing.

RM has also found applications in the manufacture of dental implants. Here, two separate technology solutions are being used to address both consumer wants and patient needs.

Sirona Dental Systems (Salzburg, Austria) uses direct metal laser sintering from EOS GmbH (Munich) to produce CoCrMo bridges and crowns directly using patient scan data. By replacing the traditional investment casting approach, Sirona has managed to get the unit price of crowns below £13.50 (about $20), this being significantly less than the cost of the traditional approach. RM is therefore being used to support affordable healthcare solutions for those elements of society most in need.

Inversely, Imagen Inc. (Irwin, PA), a division of Ex One, uses 3-D printing of binder onto noble metal powders to produce dental caps and crowns in precious metals, including gold. Although aesthetically more pleasing as a substrate than CoCrMo, this approach is clearly more expensive, and is driven by the customer's desire for a premium product, rather than the need for a practical dental solution.

**One area where RM is** being applied to healthcare as a direct result of patients' needs is in the manufacture of customized surgical implants and procedural guides. To date, both laser-based and electron-beam ALM systems have been validated for the manufacture of surgical implants. The MTT Technologies Group (Stone, Staffordshire, UK) selective laser melting process is now being used to manufacture a range of medical implants and cutting guides, including maxiofacial implants, cranial fixings, and saw and drill guides.

The Arcam AB (Mölndal, Sweden) electron-beam melting process is also being used for personalized "patient-centric" cranial implants, and also in the volume production of acetabular cups with embedded porosity to promote cell ingress.

Significant global research is also underway to manufacture tissue engineering scaffold and constructs using RM, which are customized to the individual patient. This is driven by the patient's need for effective healthcare.

This use of a synthetic RM scaffold replaces far more invasive methods using donor material from other sites in the patient's body, reducing operating theater time and potential infection.

**At the present time,** we are only just scratching the surface of potential RM applications to improve healthcare delivery and increase the quality of life.

A recent medical devices and practitioners focus group, facilitated by the author as part of a British government fact-finding exercise into emergent technologies, identified significant opportunities for RM across the healthcare sector, most notably as a direct result of the aging and increasing population.

The UK has an aging population as a result of a decline in the mortality rate and an increase in past fertility rates. This has led to a smaller percentage of the population being under the age of 16 and a greater percentage over 64.

In every year since 1901 (with the exception of 1976), there have been more births than deaths in the UK, and the population has grown due to natural change. Until the mid-1990s, this natural increase was the main driver of population growth. Since the late 1990s there has still been a natural increase, but net international migration to the UK has also been an increasingly important factor in population change. The net result is that more people require affordable and responsive healthcare than ever before. This picture of population growth is mirrored across much of the developed world.

Given the toolless flexibility and geometric freedoms of RM, the technology is well positioned to respond to the needs of these emerging groups, as every patient is a unique shape, size, weight, and density.

(about $133 billion). This compares to a domestic aerospace market of £22.7 billion (about $33.5 billion) during the same period. In short, four times more was spent on healthcare in the UK than in the entire aerospace sector. It should be noted that this figure excludes private healthcare expenditure, private dental expenditure, and healthcare products, services, and devices sold for export.

**Acetabular cups manufactured using Arcam electron beam melting.**

In summary, healthcare is a large, vital and growing sector. It is people-centric and driven primarily by the needs of society rather than the wants of the consumer. It could be argued, however, that private healthcare is driven by both needs and wants, where patient choice is driven by purchasing power. Here, RM is a perfect fit.

Traditionally RM has been seen as a cost-effective production technology used as an alternative to

## Examples of RM applications in the health field include hearing-aid shells, dental implants, and surgical guides.

**RM, therefore, becomes particularly pertinent** in situations where traditional products and devices will no longer meet the needs of the user. Examples identified during focus groups include hand grips, tools, and mobility aids for those with osteoarthritis or rheumatoid arthritis. Other applications where a human-body form can be mapped onto RM part surfaces also have the potential to improve quality of life. Such applications include conformal seating surfaces for the infirm, prosthetic limb interface, trusses and support pads for degenerative muscular disorders, orthotically designed footwear, braces for fractures, and dislocation realignment splints.

So, is health and well-being a worthwhile marketplace for RM research and business exploitation? In 2005, the UK budget for the National Health Service was £90 billion

traditional processes. Perhaps RM is better seen as a compliment to existing technologies such as molding, machining, and casting through the production of new products and services not yet realized through traditional manufacturing processes.

Further, much of the knowledgeable RM community at present stems from the rapid prototyping community, which by its very nature was engaged in traditional production supply chains, such as molding, casting, and machining. In the future, however, the demand from RM will be driven from much further up the supply chain, at a point where the production methodology becomes almost irrelevant to the customer. Customers and consumers will merge as one, and the critical attributes of a product will be its carbon footprint and customer-centric fitness for purpose.