ENGINEERS AUSTRALIA

TP1601: Additive Manufacturing

Introduction

Additive Manufacturing (AM), also referred to as 3D printing, has been eagerly discussed for decades now, eliciting hopes of a 3D printer in every home allowing people to print a full assortment of household products directly. This is already realisable for some basic household items, although the current projections of the capability of AM suggest the fullness of these ambitions will not be realised in the foreseeable future[1]. Nevertheless, current development within the field has reached a stage where AM offers real opportunities for fabricators, from full scale manufacturers to hobbyists.

Prior to the last decade, AM systems were cumbersome, imprecise and expensive[2]. However, the improving performance of AM machinery and the affordability of newer products, such as small-scale 3D printers, has meant that AM has become both a complement and competitor to existing fabrication processes.

AM fabrication boasts numerous positive characteristics including the ease, speed and economy with which designers of all levels can develop and fabricate components. Since designs for 3D components are fabricated directly from digital models, the AM community can readily create and share designs individually, through online open source communities and online marketplaces. Yet AM is not a universal solution for fabrication. The scope of appropriate application for AM, while broad, is currently restricted by limitations in material selection, mechanical properties of fabricated components, and typical quality of surface finish, particularly with low-end fabricating machines.

Recently there have been numerous websites and articles promoting the use of AM for the development and fabrication of new Assistive Technologies (ATs) for use by individuals with disability or impairment[3]. Care must be taken to ensure that such designs are appropriate for use with intended individual, that the material selected are safe for use, and sufficiently robust for purpose. While some websites providing AT designs intended for AM fabrication provide safety advice and guidelines for use[4], at this time most do not.

This Position Paper provides an overview of AM as it relates to Rehabilitation Engineering and outlines its potential implications to the areas of application relevant to the National Committee on Rehabilitation Engineers (Australia).

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[1] Cotteleer, M.J. “3D opportunity for production: Additive manufacturing makes its (business) case”, Deloitte Review, Issue 15, 2014.

[2] Earls, A., Baya, V. “The road ahead for 3-D printers” PWC Technology Forecast: The future of 3-D Printing, Issue 2, 2014.

[3] E.g. https://3dprint.com/category/health-3d-printing/ and http://www.abledata.com/sites/default/files/3D%20Printing%20Offers%20New%20Dimension%20for%20Assistive%20Technology_Final.pdf accessed 08/04/16.

[4] E.g. http://enablingthefuture.org/safety-guidelines/

What is additive manufacturing?

Additive Manufacturing (AM) refers to a range of different fabrication processes which form parts by the progressive addition of material. This is distinct from subtractive fabrication where material is progressively removed from a larger stock, (e.g. when fabricating using a mill or lathe), and from other fabrication processes such as injection moulding or vacuum forming.

Much like modern Computer Numerical Control (CNC) subtractive manufacturing, AM utilises Computer-Aided Design (CAD) models as the basis for fabrication. These digital 3D models can be viewed, manipulated and modified using a variety of software packages, allowing existing designs to be adjusted for different situations. The 3D model is converted into a sequence of cross-sectional layers ('slices'). Most 3D printers then fabricate components layer by layer, building each 'slice' on top of the previous one.

While all AM processes involve the progressive accumulation of material to fabricate the final part, the individual processes vary significantly. *1* provides an overview of various AM techniques, the materials that can be used, as well as some comments relating to the relative strengths and weaknesses of each technique.

Table 1: An overview of current AM processes.

AM Process	Available Materials	Primary Process	Comments
Polyjet[5]	Various thermoplastics, thermoplastic-like resins and rubber compounds.	Small drops of UV curable material are deposited using inkjet printer heads. UV lights are integrated into the printer to cure the material as it is deposited.	Can be used to create highly precise parts with a wide range of colours and degrees of transparency. Material strength and durability is reduced as a result of this technique. May also create flexible components.
Fused Deposition Modelling (FDM)[6]	Various thermoplastics including ABS, PLA, Nylon and ULTEM offering a range of strength and resistances to temperature, chemicals and flame.	A filament is extruded through a heated print head making the material semi-molten allowing it to be fused to previously deposited material or the printer bed.	Can produce durable, strong components but there are limitations to precision, surface finish and potential for part flexibility.
Ceramic AM[7, 8]	A wide range of ceramic powders. Recent research proposes use of "preceramic monomers" to overcome issues of porosity and shrinkage often associated with powdered ceramic AM.	Ceramic AM again uses a layer of powder deposited evenly over a height adjustable platform. An inkjet print head then 'prints' the layer using a binder which adheres local powder particles. The platform is then lowered, another layer is deposited and the process is repeated. Ceramic AM then requires the fabricated 'green state' component to be fired in an oven as per traditional ceramic manufacturing.	As with the SLS technique Ceramic components with hollows should be designed with 'escape holes' to allow the unwanted material to be removed from the 'green state' component. Ceramic components are high strength, have high thermal resistance and are food safe but often have high porosity and component shrinkage. The recently published "preceramic monomers" are claimed to maintain all the benefits of ceramics while reducing both porosity and shrinkage.

[5] http://www.stratasys.com/3d-printers/technologies/polyjet-technology/ accessed 04/01/16

[6] http://www.stratasys.com/3d-printers/technologies/fdm-technology/ accessed 04/01/16

[7] De Jonghe, L., and Rahaman, M.N. "Sintering of ceramics", Handbook of Advanced Ceramics, Somiya, S. et al. (Eds). Chapter 4.1, 187-264.

[8] Eckel, Z.C., Zhou, C., Martin, J.H., Jacobsen, A.J., Carter, W.B., and Schaedler, T.A., 2016. "Additive manufacturing of polymer-derived ceramics", Science, Vol. 351, Issue 6268, pp 58-62.

Selective Laser Sintering (SLS)[11]	Various plastics, and metal powders, including polyamide with various fillers (glass fibre, carbon fibre, etc.), Nylons, titanium alloy Ti6Al4V, cobalt chromium, stainless steel, nickel alloys Inconel 625 and Inconel 718 and aluminium alloy AlSi10Mg.	Material is deposited in an even layer on a platform. A laser then 'prints' the layer, melting/welding the powered material to form the desired layer. Another layer is deposited on top of the current layer and the process is repeated for the full height of the component.	This process deposits full layers of material, components with hollow pockets will contain undesired, unfused material within these pockets after printing. SLS designs should therefore include 'escape holes' for material to be removed from these pockets after printing. The strength of SLS parts is equivalent to components fabricated using powdered die casting techniques.
Electron Beam Melting (EBM)[12]	Uses metal powders including titanium, tantalum, and nickel-based alloys.	Metal filaments are extruded and melted directly by a local electron beam. Material is initially deposited onto a height adjustable bed which progressively lowers, and subsequent layers are printed onto the previous layer.	Originally conceived in the 1950's EBM provided much of the original interest in AM as a field. An equivalent process to FDM for metals, results in strong durable parts however precision and surface finish are limited.
Bio-Printing[13]	A range of cell types including muscle cells and endothelial cells. These cells after printing behave in the same way as regular tissue, exhibiting both cell division and cell death.	There are two predominant techniques for bio-printing, one that uses inkjet printing (without UV curing), and one that extrudes a paste of 'bio-ink' particles (prepared tissue cells).	The inkjet process subjects cells to significant trauma such that a percentage of cells do not survive. The extruding process is less aggressive to the cells but the hardware is much more expensive.
Stereolithography (SLA)[14]	UV-curable, liquefiable plastics which approximate polypropylene and ABS, as well as materials that have high durability, thermal stability or transparency.	The process uses a height adjustable platform in a bath of liquid UV curable plastic. The platform begins one layer thickness from the top of the bath. A UV laser 'prints' the first layer which cures upon exposure. The platform then lowers by the layer thickness and the process is repeated.	Provides good precision and surface finish for parts, but the materials are limited to UV-curable, liquefiable plastics. Recent materials include suspended ceramic particles to increase hardness, thermal resistance and durability.

[11] Kumar, S. "Selective laser sintering: A qualitative and objective approach" JOM, Literature Review: Modelling and Characterisation, Oct 2003, Vol. 55, Issue 10, 43-47

[12] Horn, T., "Material development for electron beam melting", https://camal.ncsu.edu/wp-content/uploads/2013/10/Tim-Horn-2013CAMAL.pdf accessed 04/01/16

[13] Jakab, K., et al. "Tissue engineering by self-assembly and bio-printing of living cells", Biofabrication, Vol. 2, 2010.

[14] Palermo, E., "What is Stereolithography?" Online article. http://www.livescience.com/38190-stereolithography.html accessed 04/01/16

What are the benefits of additive manufacturing?

Additive Manufacturing offers many advantages over traditional subtractive manufacturing techniques. These advantages (both currently realised, and those which are still anticipated) have been the driving force behind ongoing development of the field. The fundamental difference between AM and traditional manufacturing is that the process starts from nothing and gradually adds material to sequentially 'build' the component, rather than starting with a stock from which unwanted material is removed. The process of adding material, rather than removing material, gives rise to many of the advantages of AM.

Other advantages arise as a result of AM processes being fundamentally software driven; components are typically designed in CAD and loaded into Computer-Aided Manufacturing (CAM) software native to the AM system. The use of software models facilitates the drawing, modification, innovation and the ready transfer of designs between fabricators, for example through online markets and share sites. It also greatly reduces the need for jigging, part set-up and mid-operation rearrangement that are common in a number of traditional manufacturing processes. Designs can be accessed and fabricated usually with little overheads required for set-up. *Table 2* outlines the numerous advantages of an additive process for component fabrication.

Table 2: Current advantages of AM fabrication.

Advantage[2,15,16,17]	**Comments**
Supplements traditional fabrication	The differing strengths of traditional manufacturing and additive manufacturing processes mean that for some components a better result will be achieved with AM than for others with traditional fabrication processes. This enables superior product manufacturing by enabling the most appropriate fabrication technique to be used for each component in a product.
Increased geometric complexity	AM facilitates fabrication of components with increased geometric complexity. AM allows the fabrication of geometries that could not be fabricated with traditional processes, especially when components have internal pockets and hollows.
Efficient scalable fabrication	Additive Manufacturing has low overheads for set-up and stock storage as compared to subtractive manufacturing. The reduced overhead costs with AM results in cheaper small quantity fabrication runs. As AM suits small scale operations it also enables in-house fabrication which can reduce costs and improve efficiency where fabrication may otherwise be outsourced. The cost benefits associated with scale also increase with complexity of part geometry.
May facilitate complex fabrication processes	One use for AM is to create temporary scaffold structures which can be used to create formwork for further AM processes such as electroless plating.

[15] Crane, J., Crestani, R., and Cotteleer, M. "3D opportunity for end-use products: Additive manufacturing builds a better future", Deloitte University Press, 2014.

[16] Caffrey, T., and Wohlers, T., "Additive manufacturing state of the industry", Online article, AdvancedManufacturing.org, May 2015, 67-78.

[17] Royal Academy of Engineering, "Additive manufacturing: opportunities and constraints", May 2013.

Efficient scope expansion	AM allows fabrication of a broad range of components, (especially plastic, sterilisable components), without additional capital investment per part associated with retooling and other fabrication overheads. This means a broader range of components can be fabricated with limited additional capital costs as compared to traditional manufacturing
Reduced system complexity	AM can often be used to create complex geometries/structures that are either unfeasible to produce with traditional fabrication processes or require an assembly of a number of components. AM allows for a potential reduction in overall system complexity/number of components. This can result in overall weight reduction and remove areas of weakness around fasteners and fixings of an assembly. AM can also fabricate anisotropic parts with different material properties at different points within a component.
Simplifies iterative design process	In the case of prototyping it is often necessary to make small iterative changes to designs in light of further testing. The design of AM components is typically able to be adjusted with CAD programs and there are usually no additional overheads in the fabrication process for small geometric changes.
Improved bio-implantable devices	As AM can utilise bio-compatible and bio-absorbable materials it is well suited to the fabrication of bio-implantable devices. AM can be used to create bio-implants that are less thermally conductive and more transparent to medical scans than typical implant materials such as titanium.
High fabrication efficiency	Additive Manufacture techniques are highly efficient processes. There is typically very little loss of fabrication material with AM processes resulting in lower material wastage than traditional manufacturing. AM often exhibits lower energy consumption than subtractive fabrication, especially when considering the recovery of waste material from subtractive manufacturing[18].
Reduce risk to fabrication staff	In general, operational safety in fabrication is increased as compared to subtractive manufacturing as the risk of injury associated with AM machines is much lower. While some concerns have been raised relating to the fumes generated by the melting of stock, recent research indicates that the level of these emissions is low, and can be managed through ventilation[19].
Straight forward geometry acquisition	Geometry acquisition is relatively straight forward and non-invasive with 3D scanning devices, including medical scanning devices such as functional Magnetic Resonance Imaging and CT scanners.

[18] Faludi, J., Bayley, C., Bhogal, S., and Iribarne, M. "Comparing environmental impacts of additive manufacturing vs. traditional machining via life-cycle assessment", Rapid Prototyping Journal 2015 21:1 , 14-33

[19] Azimi, P., Zhao, D., Pouzet, C., Crain, N.E., and Stephens, B. "Emissions of ultrafine particles and volatile organic compounds from commercially available desktop three-dimensional printers with multiple filaments", Environmental Science and Technology 2106, Iss. 50, pp1260-1268, ACS Publications, 2016.

What are the limitations of additive manufacturing?

While there are many benefits and advantages of AM, there remain several limitations which prevent AM from making traditional fabrication techniques obsolete. To date a significant limitation has been the cost effectiveness of acquiring AM systems. While the cost of many systems, especially FDM Printers, has fallen dramatically in the last 5 years, there are still a range of other limitations with the current state of AM. These limitations are outlined in *Table 3*.

Table 3: Current limitations of AM fabrication

Current Limitation [2,15,16,17]	**Comments**
Range of materials	The cheapest/most readily available materials have low material strength and often susceptible to heat deformation. While AM can utilise a range of materials inc. plastics, metals, ceramics, wood and organic matter, each material typically requires a separate print head, extruder, or an entirely different device with a different manufacturing technique.
AM system variety	While all AM processes share the concept of adding material together to fabricate a product, they achieve this by a variety of methods, many of which require distinct systems. It is not necessarily feasible to partially manufacture a component with one form of AM and then complete the fabrication with another process.
Material strength of fabricated components	As components are fabricated incrementally the internal material linkages are weaker and overall material strength is typically much lower than in components fabricated by subtractive manufacturing[20]. Components to be fabricated by AM can be strengthened by adjusting designs to reinforce critical weak areas.
Low precision / loose part tolerances	The relatively low precision of entry level (affordable) AM has been an underlying issue since its inception. Precision continues to improve with each generation of system, however AM is inherently less precise than subtractive manufacturing. Current tolerances are typically tenths of a millimetre for good entry level printers, but can be in the order of tens of microns for high end AM fabricators.
Different skill sets required	AM primarily utilises a range of software interfaces throughout the geometry acquisition, manipulation and fabrication process, current highly skilled machinists may require additional training for competence. Conversely, AM specialists may not have expertise in traditional fabrication processes.
Expensive supplementary equipment overheads	There is a range of geometry acquisition equipment which is capable of providing high precision, high resolution, models that can be fed as inputs to AM systems. In the case of acquiring models of internal anatomical geometry this equipment is highly expensive to operate and prohibitively expensive to purchase (eg fMRI), however many cheaper, lower quality options exist for the broad range of geometries (internal and external) that may be of interest.

[20] Simchi, A., Petzoldt, F., and Pohl, H. "On the development of direct metal laser sintering for rapid tooling", Volume 141, Issue 3, Nov 2003, 319-328.

How is AM applicable to Rehabilitation Engineering?

The advantages of AM make it a good fit to small scale fabricating operations like those offered by some Australian Rehabilitation Engineering services and larger companies involved in commercial product fabrication. When working with individual clients, AM offers the capability to readily fabricate custom AT components to meet that client's needs. AM is also suited to the fields of orthotics and prosthetics where achieving an end product that matches the complex and unique geometries of the individual is critical to achieving an optimal client outcome. AM is also expected to see significant application in the area of implantable devices, given its capacity to fabricate complex single-piece geometries in bio-compatible and bio-absorbable materials. These potential application areas for Rehabilitation Engineering are discussed below.

Custom-made components

One of the most straight forward and useful ways of employing AM is in the design and fabrication of custom components. There are many instances where moderate strength, low tolerance components are more than adequate to facilitate a solution to a given problem. For example, non-standard components such as clamps, mounts and fittings, can be manufactured to mount AT devices or products to a client's bed, chair or table. These custom components are typically required in short runs, often in instances where there is limited funding available for expensive commercial solutions. The benefit of a custom solution is that it allows for the specific requirements of the individual client to be incorporated into the design of the AT device or product, for limited overhead expense. In many cases it may be possible to work directly with the end user to cooperatively design a component, involving them throughout the design process. Such collaborations can also focus on more broadly applicable AT designs to meet needs as identified by clients directly or through therapists. A number of online communities and competitions exist where interested designers can access specific design briefs to develop solutions for clearly defined problems[21].

The ease and cost efficiency with which new designs can be developed or existing designs modified in CAD will drive innovation, as previous barriers to prototyping are significantly lowered. This will result in a greater variety of new designs, developed with varying degrees of consideration of essential principles of design relating to appropriateness and safety. Designers of custom components should be encouraged to think broadly about the implications and assumptions of their designs, while consumers and end-users should also consider whether the benefits of using components adequately outweighs any associated risks.

Prostheses and orthoses

AM has been used in the research and development of complete prosthetic limbs since the early 2000s[29]. Commercial prostheses and orthoses are often expensive and are accessed through

[21] * Annual i-CREATe competition,
* Engineers Australia: Biomedical College Better Technology Awards,
* Engineers Without Borders design briefs.

[29] Contoyannis, B., Cumbo J., Dempster B., Groot P., and Nye D., 2001. Advanced Prosthesis Design And Manufacturing Techniques Using Computer Manipulation And Rapid Prototyping. World Congress ISPO, Glasgow, 2001.

prescription by a specialist prosthetist or orthotist. In Australia there are funding and provision schemes that will provide prosthetic limbs to individuals who need them however these schemes have limited resources and clear prescription guidelines determining what will be funded[30]. It is not uncommon for individuals to need multiple prosthetic options for the same limb to suit different activities (such as recreational activities) which are not covered under the general provision schemes. In other places there are no such schemes, and historical access to prosthetics has been extremely limited[31]. In such cases, AM provides an appealing opportunity for low cost alternatives that can be readily fabricated by anyone with access to a 3D printer and the component files.

AM processes are already being used to successfully fabricate prostheses for individuals (often children) who are unable to afford or access custom prostheses through traditional funding and provision schemes[32]. There are now a growing number of designs for prosthetic limbs which have been designed by individuals or small groups of people and then developed by interested on-line communities[33].

Well-designed prostheses and orthoses provide an increased degree of functional capability and independence to the user, fit cleanly to the user, provide a good surface of contact with a safe loading profile, and limit health and safety risks as much as possible.

Improvements in functional capability will partly be as a result of the design of the device but also as a result of the education and training that is provided alongside the actual device. Typically prostheses become more effective as the users gain experience with using them and develop an understanding of the correct operation, capabilities and limitations of the device.

Prosthesis and orthosis users should also be made aware of safety concerns that arise from using the device. These may be considered as direct concerns, relating to the interface between the user and the device, and indirect concerns, relating to interactions between the user and their environment. Ensuring a good, comfortable and safe fit of the prosthesis to the user requires a good model of the geometry to be mated to and a good understanding of the underlying anatomy of the site. Geometries of body surfaces can be acquired directly and non-invasively using 3D scanning, allowing for designs that accurately fit the end user's body. Understanding the anatomy of the site will direct the design of the prosthesis to relieve pressure around risk areas such as bony prominences, while ensuring good loading around areas that are more able to sustain higher pressures.

[30] For example: Prosthetic Limb Service Funding Guidelines. http://www.enable.health.nsw.gov.au/__data/assets/pdf_file/0015/276000/Prosthetic_Limb_Service_Funding.pdf accessed 13/04/16

[31] For example: Bio-Inspired Technology Group. http://www.bitegroup.nl/category/prosthetic-devices/accessible-prostehitcs/ accessed 13/04/16

[32] Andrei, M. "$42,000 prosthetic hand outperformed by $50 printed cyborg beast" Online article. ZME Science. http://www.zmescience.com/research/inventions/prosthetic-hand-cyborg-beast-21042014/ accessed 05/01/16.

[33] For example: Enabling the Future. http://enablingthefuture.org/ accessed 05/01/16.

Indirect safety concerns include the potential consequences of an inappropriate or poorly fitted prosthesis, such as having it slip or come off unintentionally. Poorly fitting lower limb prosthesis for example, could result in the user losing balance and stumbling or falling, which in turn may result in an injury either to themselves or others.

Implantable devices and components

AM is increasingly used in the fabrication of implantable devices and components. The fabrication of implantable components by traditional fabrication methods can be extremely expensive. This is due, in part, to the complex geometries that are often required, and to the need to individualise designs to meet client-specific needs. The cost associated with the fabrication of complex, one-off components is significantly reduced by using AM processes as the underlying fabrication procedure, as this is largely independent of geometry or complexity.

A well-designed implantable device has minimal impact upon the body beyond the function for which it has been implanted. As such implantable devices should be designed to be small, light-weight, bio-compatible or bio-absorbable, have thermal conductivity equivalent to surrounding tissue, not have any adverse reaction to local tissue and be robust against damage and failure. AM processes are well suited to facilitate precise, small-scale fabrication of bio-compatible, implantable components without the high overhead costs that would be incurred fabricating a similar component using traditional fabrication processes.

There are already a number of bio-compatible materials which can be used with AM to fabricate implantable medical devices. The selective laser sintering (SLS) and electron beam melting (EBM) processes are both capable of producing bio-compatible components from:

- Titanium (Ti6Al4V),
- Cobalt Chrome, and
- Polyetheretherketone (PEEK).

The development of implantable components is already one of the leading areas of adoption of AM fabrication, and this is set to continue as the technology becomes more mature, particularly with regard to precision and range of materials. In the past few years, collaborations between engineers and doctors have yielded many innovative designs for clients made feasible through AM processes. These designs include the recent development and implantation of a printed titanium heel prosthesis[34] or the development of the 'Bio-pen' for surgeon controlled application of live cartilage tissue[35].

A further advantage of the AM approach to component fabrication is the simplified way in which existing geometries can be acquired and then adjusted or replicated, as needed, to meet the client's needs. Several current medical scanning processes are able to output 3D computer models of the

[34] CSIRO Press Release, "CSIRO produces 3D heel in world first surgery". Online article, 22 October 2014. http://www.csiro.au/en/News/News-releases/2014/3D-Heel-In-World-First-Surgery/ accessed 05/01/16.

[35] University of Wollongong Press Release. "Biopen to rewrite orthopaedic implants surgery". Online article, 04 December 2013. http://media.uow.edu.au/releases/UOW162797.html accessed 05/01/16.

regions of interest within the body. These models can be readily manipulated to form the basis of the design for implantable devices. In this way, geometry acquisition and fabrication procedure should be straight-forward.

Another detail of implantable components that suits AM is that it is often desirable for the structure of these components to have high porosity. A porous structure reduces the weight of potential components limiting any resulting imbalance or weight-related stressing of existing tissue. In external prostheses, porosity also promotes airflow around the mounting tissue reducing humidity which can lead to tissue irritation and damage[36]. Porosity may also be used beneficially to promote tissue-integration with the host body through improved bone ingrowth and osseointegration in internal prostheses[37]. Porous structures are difficult and expensive to achieve with traditional fabrication processes while with AM porosity can be easily implemented.

One of the most exciting and difficult areas of current exploration in the field of AM is that of bio-printing. Bio-printing uses the same concepts of AM as other component fabrication but uses live tissue as the printing material. There are currently two techniques being developed for bio-printing, the first uses a inkjet process with tissue cells suspended in a 'bio-ink', the second extrudes the 'bio-ink' like a paste. Under the correct conditions, the tissue in this 'bio-ink' will naturally fuse together to create a single piece of connected tissue. Preliminary studies have shown that tissue printed in this way exhibited cell division and cell death in a way that is similar to naturally occurring tissue[38].

While the suitability of AM for the fabrication of implantable components is clear, it is necessary to acknowledge the risks and limitations involved. The current limited range of materials, the high risks associated with surgery itself, risks of infection or rejection, the stability, reliability and durability of the implanted material, all represent risk factors that need to be considered with the design and development of implantable devices. Any intended use of implantable devices should be done in consultation with experienced medical staff from relevant clinical fields.

Regulation of AM Fabrication

A significant consequence of the digital nature of designs for components that can be fabricated using AM processes is that it is difficult to regulate and provide quality assurance for these designs[39]. This gives rise to the reasonable concern that, through negligence or naïvety, end users may be provided with fabricated designs that are inappropriate, or even potentially harmful. The range of design considerations for Assistive Technology is non-trivial, though easily overlooked, if focusing only on one outcome. In Australia the Therapeutic Goods Administration (TGA) advocates 15

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[36] Faulkner, V., and Pritham, C. "A below-knee prosthesis with a porous socket" *Orthot Prosthet* 27.1 (1973).

[37] Wei J Q, Cai X, Wang Y, et al. "Osseointegration of hollow porous titanium prostheses loaded with cancellous bone matrix in rabbits." *Chin Sci Bull*, 2012, 57: 2615-2623, doi: 10.1007/s11434-012-5189-9

[38] http://organovo.com/science-technology/bioprinted-human-tissue/living-human-tissue/ accessed 13/04/16

[39] Andrews, T.M., "Can we really 3-D print limbs for amputees? The pros and cons of printing prosthetics" Online article. The Atlantic, August 23, 2013. http://www.theatlantic.com/health/archive/2013/08/can-we-really-3-d-print-limbs-for-amputees/278987/ accessed 05/01/16.

'Essential Principles' for the design of medical devices[40]. The first six of these principles relate to all medical device designs, while the remaining nine apply in specific cases only (for example, Principle 15 only refers to in-vitro devices).

The TGA defines a medical device as something which is[41]:

- Used on humans,
- Has therapeutic benefit(s)
- Generally has a physical or mechanical effect on the body or are used to measure or monitor, functions of the body.

In Australia the Therapeutic Goods Administration (TGA) is the regulator for the importation, manufacture and sale of medical and assistive devices. This framework covers all devices, from those which are mass-produced, to unique, custom-made components and devices intended for a specific individual. The regulation around these devices requires the device manufacturer (whether a commercial company or individual fabricator) to register the device and demonstrate its safety, the veracity of its therapeutic claims, and compliance with standards of manufacture[42, 43]. The TGA also requires that custom-made medical devices are provided under the direction of a medical professional[44]. The TGA currently requires the manufacturer/supplier to cover the costs of demonstrating compliance and subsequent registration.

What are the implications for Rehabilitation Engineering / Biomedical Engineering?

The implications of this technology for existing Rehabilitation and Biomedical Engineers is two-fold; first as adopters and users of AM, and second as critical evaluators of components and devices that have been fabricated using AM.

In the first case, biomedical and rehabilitation engineering groups are well placed to understand the application of AM to their own domains. Working directly with clients, and with appropriate input from technical, medical and allied health staff, engineers can provide insight into how the provision of Assistive Technology, in addition to other therapeutic intervention, can help to address a client's needs. Typically the design issues that a biomedical/rehabilitation engineer encounters are relevant to small client populations or individuals and so the scale of component fabrication is equivalently small. AM offers manufacturing processes that are well suited to the fabrication of small runs of components with limited associated overheads. In such cases, AM will complement existing fabrication processes and manufacturing hardware that are currently used, but it would not be an

[40] https://www.tga.gov.au/manufacture-medical-devices-quality-management#gep/ accessed 14/04/16

[41] https://www.tga.gov.au/what-medical-device/ accessed 14/04/16

[42] Brett, J., and Coverdale, K., "Manufacturing devices for clinical use: 3D printing in healthcare", Queensland Hospital and Health Services handout, August 2015.

[43] Brett, J., and Coverdale, K., "Therapeutic goods legislation: Custom-made medical devices", Queensland Hospital and Health Services handout, August 2015.

[44] https://www.tga.gov.au/custom-made-medical-devices/ accessed 15/04/16

effective substitute in all instances. AM is also well suited to rapid design iteration which can allow experienced engineers, clinicians and technicians to work with the client to develop innovative prototype solutions to identified problems, within a short timeframe.

In the second case biomedical and rehabilitation engineers may encounter components and devices that have been manufactured or fitted by a third party that needs to be critically evaluated for appropriateness and safety. If the field of AM grows as predicted in industry projections[45], there will be a significant increase in the number of components being fabricated using AM, including components made by hobbyists and individual fabricators. There will be many instances where engineers will encounter custom components that have not undergone any quality assurance process. These components should be reviewed to ensure that they are both safe and appropriate for the client's needs.

How is this likely to change in the foreseeable future?

Additive Manufacturing has reached a critical point where the cost of some devices is now low enough that it is an affordable option for individuals and small scale fabricators. This is likely to result in significant consumer investment in the field that will drive further innovation and improvement. Looking to the future it can be reasonably expected that AM fabricators will continue to improve in the following ways:

- Processes will become more refined (strength and precision will both continue to improve),
- Material range will increase,
- Cost of fabricator systems and materials will decrease,
- Increasing prevalence, more individuals and small companies will offer AM services,
- Number of available designs will continue to increase.

Conclusion

Additive Manufacturing fabrication systems have become increasingly affordable such that AM for fabrication is no longer solely the domain of specialist manufacturing companies. As the field continues to mature, AM systems will become an increasingly commonplace tool for individuals and groups who are interested in small scale fabrication. This progress will be mirrored with the further development of online communities where people will be able to post, view, download and purchase designs which are ready to be printed, or which can be modified to suit[33].

With its low barrier to entry, AM can be readily used to fabricate components and devices intended as Assistive Technology. The internet provides a powerful forum for end users to advertise their needs and for fabricators to advertise their capabilities. The combination of these factors will give rise to a rapid design and development period that can be used to good effect by engineers, working directly with clients and clinicians, to quickly develop innovative solutions to address their needs. It

[45] Canalys, "3D printing market to grow to US$16.2 billion in 2018," news release, March 31, 2014, http://www.canalys.com/newsroom/3d-printing-market-grow-us162-billion-2018#sthash.jovzItNE.dpuf. accessed 04/01/2016

will also allow devices to be made directly for end users by fabricators, a process which could easily circumvent or ignore the existing regulatory requirements for design quality and safety assurance. This may result in products and devices being fabricated and provided that are unsuitable or even dangerous to the user.

AM represents an exciting new approach to component design and fabrication but it does not make traditional manufacturing processes obsolete. Rather, it is simply another tool that may be used to expand the repertoire of existing biomedical and rehabilitation engineering facilities. Engineers should view AM as a useful process, well suited to some, but not all, fabrication requirements. Indeed there will be many cases where AM will be a better option than either traditional manufacturing or purchasing a commercial component, but it is not a universal solution.