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Reviewed Paper

3D PRINTING ENABLED-REDISTRIBUTED MANUFACTURING OF MEDICAL DEVICES

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Abstract

Recently the home-use segment of medical devices has entered in the loop of Additive Manufacturing (AM) enabled optimizations, this includes CPAP masks, insulin delivery packs and diagnostic tools such as urine-flow meters. Here we analyze the supply chain provision of a specific uroflowmetry device which is originally designed in Europe, manufactured in Asia and which has a range of distribution channels across healthcare systems. This paper analyses the impact of various AM technologies that can enable near-patient manufacture of devices on-demand. Our analysis shows that the cost of design-changes (or product updates), when reflected on the overall lifecycle cost, can be comparable to producing the device locally with a different supply chain arrangement. Furthermore it is suggested that in order to fully exploit the capabilities afforded by AM, the original product's design features must be modified so that built-times are reduced allowing a larger 3D printing-based production capacity.

Keywords: 3D printing, home-use medical device, redistributed manufacturing

Introduction

Currently home-use medical devices are manufactured in large numbers with the overall process being distributed across different countries. Often, devices are manufactured in one country, assembled in a second country, and then delivered to the end-user along a chain of distributors and selling points. The investment in tooling for mass-market devices is substantial and beyond the means of most start-ups and small- and medium-sized enterprises (SMEs) that represent more than 80% of the UK medical industry (BIS, 2010). Manufacture usually represents only part of the final cost of the device, with another large part being represented by costs related to shipping and storage at the industry site and then at the various distribution and selling points.

The possibilities for redistributing manufacturing closer to the end-user (the patient) could have a positive impact on the final cost of the medical device, reduce the time for the device to be available to the patient, improve the patient experience, and offer an opportunity for customisation. In this project, we explored the technical feasibility and the opportunities offered by Redistributed Manufacturing (RDM) applied to home-use medical devices. The aims were to:

- Investigate the technical feasibility of manufacturing an existing medical device using an RDM approach enabled by Additive Manufacturing.
- Quantify the cost of deploying the medical device using an RDM approach.
- Evaluate the likely patient take-up of RDM medical devices.

Methodology

We considered an existing home-use medical device as a case study for this project (The Flowtaker, MMS/Laborie website), a disposable urine flowmeter for single-patient use which was developed by the Northern Medical Physical and Clinical Engineering Department (The Newcastle upon Tyne Hospitals NHS Foundation Trust, UK) and licensed to the major multinational manufacturer of instrumentation for urodynamic (MMS/Laborie). In first instance, we developed a benchmark comparison between the original device and a modified version suited for Additive Manufacturing (AM) in terms of design and manufacturability features. This was done by characterizing the number of individual components that comprise the original device, defining the standard Bill of Materials and analysing particular manufacturability features of the original and new flowmeter.

Next, a similar device with the same shape and geometric attributes was manufactured using Additive Manufacturing (Fused Deposition Modelling, FDM) and the design fully optimized to reach the maximum possible productivity for the selected FDM process. The final part of the study compared the supply chain models for both the conventional manufacturing route, and the envisaged redistributed manufacturing route that would be followed if AM were implemented.

Results

1. Design and manufacturability benchmark

In order to describe the main manufacturability features and the subsequent logistic needs, it is necessary to understand the device's design; the main body of the flowmeter was designed for injection moulding including typical features (Figure 1), such as stress relief lines, pins and runners space, gussets to avoid warping on thin walls, bosses and ribs for counteracting thermal shrinkage inside the mould and ribs to support the thin shell body. All this requires the design and manufacture of production tooling and metal injection moulds. Due to economies of scale and existing manufacturing expertise within the developing team original production moved to Asia particularly due to the need for assembly or electric/electronic components to be fitted on the plastic body.

Figure 1 – Top and reversed-internal view of flowmeter

The current overall design has a part count > 30 components (Figure 2), including plastic elements, electronic components, wiring, connectors and instruction labels. One of the driving cost factors is the initial tooling investment as the device requires four individual injection molds to be sourced. With this in mind, the next step in our analysis was to replicate the plastic components and assessing the current capabilities of existing AM technologies.

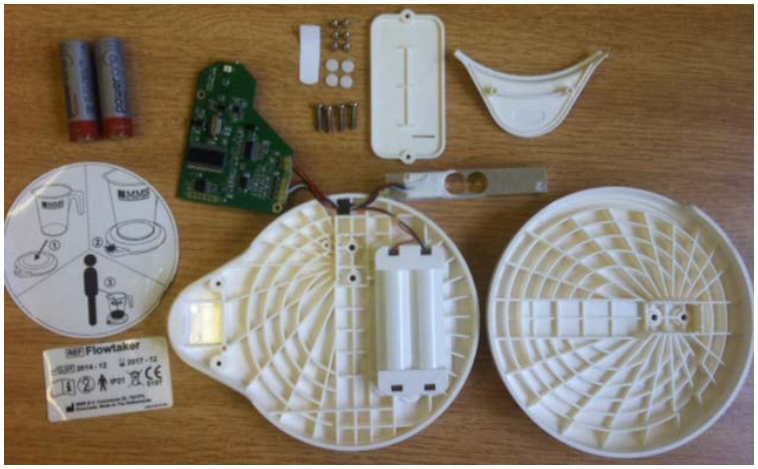

Figure 2 – Disassembled overview on main individual components

Discussion. Comparing 3D printing methods

The original engineering design files of the Flowtaker components were transferred to a 3D-printing (3DP) compatible format allowing us to replicate the same geometry using an additive process. In order to choose the most suitable 3DP technique, we accounted for the following factors:
• Ease of operation in a medical setting.
• Space requirements for equipment, material handling and post processing.
• Cost of ownership or initial investment.

Selective Laser Sintering (SLS) is one of the most established industrial-grade 3DP processes. It offers high printing speeds, minimising the fabrication time. SLS offers fine accuracy (typically 0.1mm) - though far from injection moulding - and overall good repeatability. However, the use of a laser would represent a safety issue in a hospital environment. Additionally, the materials for SLS come in powder form with a particle size of 50-54 microns, which represents another safety risk and would require suitable breathing equipment and ventilation. Initial cost of ownership starts at $200,000 (Wholers, 2013).

Stereolithography (SLA) is another widely accepted 3DP process that uses liquid photopolymers as building materials, which need ultraviolet light as the curing source. It also requires post-curing, which increases the total fabrication time. SLA usually requires the use of supporting structures to prevent deflection of the final product due to gravity, which involves post-processing to remove the supporting structures and it can be difficult to carry out for the lay person. In addition, a limited range of photopolymers can be used as building materials and the materials cost ($100/litre) makes it less attractive than other processes. The printing quality of SLA is better with lower printing speeds; therefore, the printing quality and time length need to be balanced to build a reliable product using the shortest building time. Cost of ownership starts at $2,000 for low-cost units (Wholers, 2013) but can go beyond $150,000 for multi-capacity stations.

Fused Deposition Modelling (FDM) was our selected method as it satisfied the three factors described above. FDM units can be operated in a medical environment with minimum noise and non-toxic fumes produced. The cost of ownership for desktop units starts under $1,000 (Wholers, 2013). However, the main advantage of FDM over other 3DP methods is its capability to use similar materials to those used for injection moulding. This can allow for manufacturing designs without the need for moulds and tooling. FDM as an alternative process. Initial trials showed that, although it was possible to replicate the exact design of the original Flowtaker using FDM with plastic materials, the overall accuracy and part quality was far from the injection moulded version (Figure 3). Furthermore, it required up to 48h to print one single Flowtaker case.

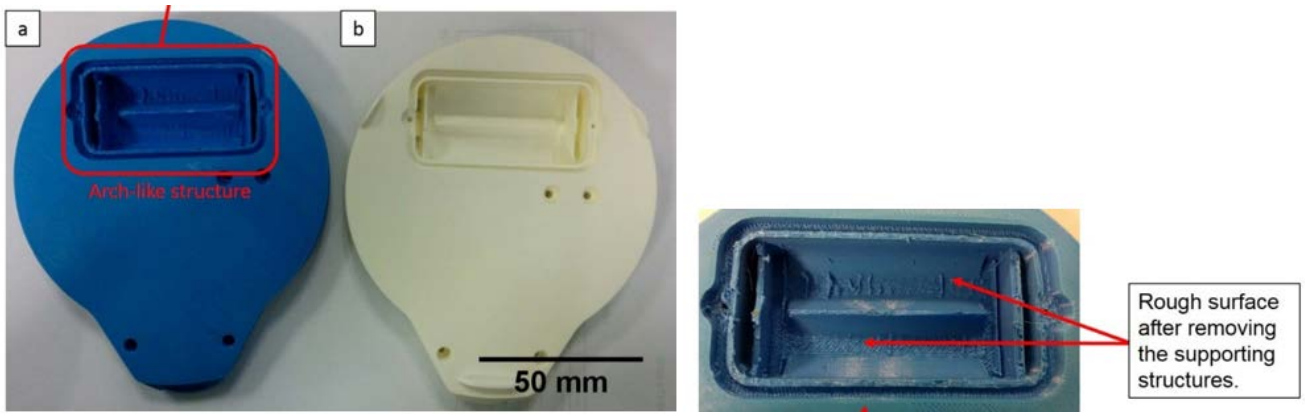

Figure 3. Comparison of FDM printed (a) and injection moulding (b) plastic part.

Consequently, we decided to revise the design of the device in order to overcome the manufacturing constraints posed by the original design and to harness the advantages offered by FDM. This also required a complete re-design of the electronics board and sensing components. Figure 4 shows the new design of the electronic components and the corresponding polymer case with a printing time drastically reduced to 5h/case. The new design successfully consolidated and/or eliminated extra components, largely reducing manufacturing time and need for assembly.

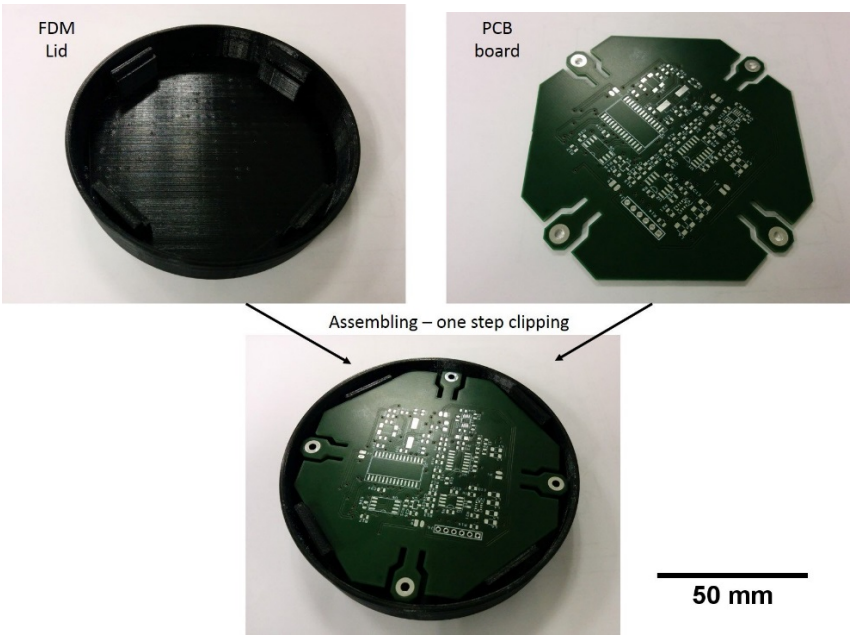

Figure 4. Optimized FDM concept

2. Supply chain models

Although the re-designed flowmeter is still far from the market, we envisaged a number of scenarios that could potentially benefit from an Additive Manufacturing-enabled redistributed supply chain model. The traditional in-clinic pathway to assess patients with urinary problems requires the patient to attend the hospital. The Flowtaker offers a novel possible pathway where the patient can perform the measurement in the comfort of his home as opposed to performing the tests at a designated hospital by appointment only. In the current manufacturing model, the manufacturing and assembling process is distributed across different countries; the final distribution to patients across the UK, Europe and North America takes place through a chain of various distributors. Manufacture only accounts for a fraction of the final cost whereas distribution, storage and handling take a considerable portion of the final retail price (Figure 5 and 6).

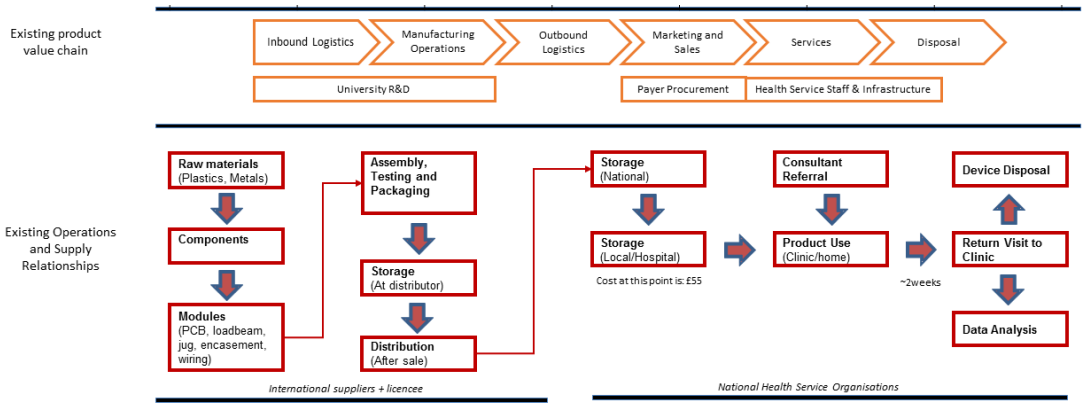

Figure 5 Overall supply and value chain for the existing Flowmeter model

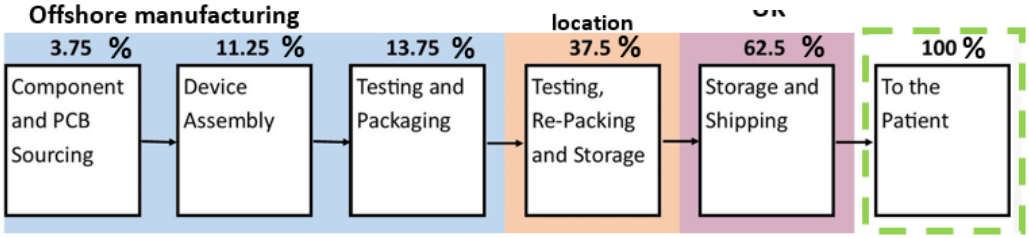

Figure 6. Simplified percentage contribution of various supply chain elements on the final product cost

These figures clarify the role of 'pure manufacturing' as a minor contributor to cost and show that in a re-distributed manufacturing scenario the intermediate and later storage + assembly + shipping stages have a larger contribution. This is particularly relevant when exploring a 3D printing scenario as manufacturing costs when using additive technologies are normally higher when compared to traditional high volume production.We believe that the patient pathway offered by the Flowtaker could be further enhanced by the possibility to manufacture and assemble the device closer to the patient by using RDM technologies. We are exploring two different possible strategies: manufacturing close-to-patient, and manufacturing in-the-home.

Manufacturing close-to-patient. This model can open new opportunities for rearranging the conventional supply chain for home-use medical devices by gaining efficiency and reducing the overall lead times. In particular, we envisage a small community manufacturing facility in healthcare centres and pharmacies. In this scenario manufacturing takes place near-the patient environment and in non-dedicated/ non-industrial facilities which can be pharmacies (i.e. Boots) GP practice and regional hospital units. This local manufacture fashion is enabled by the adoption of office-friendly 3DPrinting units (most likely FFF technology) to be operated by a resident expert with enough basic knowledge to:

- Receive hospital/GP prescription for a flow taker device
- Prepare a digital 3D file according to prescription
- Select appropriate 3D printing filament and prepare 3D printer parameters
- Remove, post process and assemble 3D printed structure to off-the shelf electronics subassembly.

In this re-distributed model (Figure 7) centralized overseas manufacture takes place only for internal circuit-board/electronics, then this is shipped to individual regional locations (pharmacy) where on-site 3D low cost 3D printers are used to produce the rest of the plastic components on demand. In this new model we acknowledge the cost contribution of the initial design stage as it is assumed that the potential of 3D printing is based on personalization, design changes, upgrades and continued improvement, so this initial stage is set to remain active throughout the life of the new device supply chain.

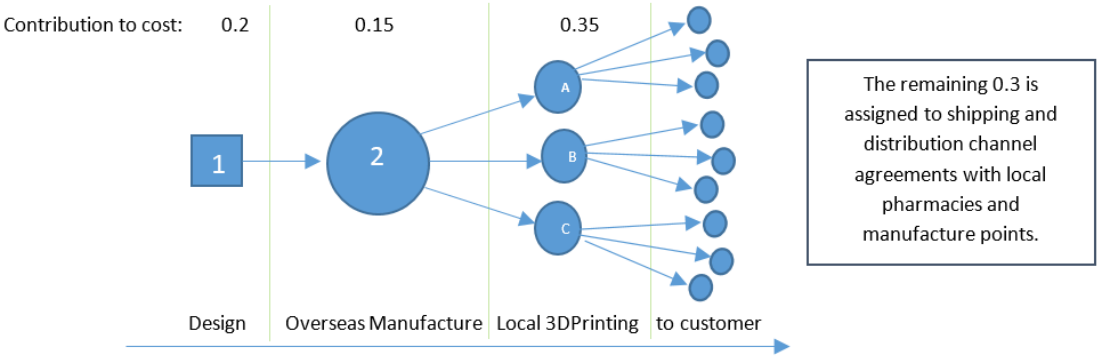

Figure 7. Re-distributed Scenario 1 and cost distribution

Manufacturing at home. Although this scenario is currently technically feasible, it poses a challenge to the MedTech manufacturing industry to secure the quality and reliability of the medical devices which are printed at home, as all non-electronics manufacturing and assembly would be "outsourced" to the patient's home. This model relies on the end customer having a 3D printing unit available either at home or at community centres (Fablabs, Makerspaces, online bureaus, etc.), so the cost of producing and assembling the device is placed on the

back end on the supply chain. We have estimated that the initial design stage would also increase its contribution to the final cost (Figure 8) as this stage will be key to design and generate 3D files which can be reliably exported and printed on a variety of 3D printing units. This will include 3D file integrity checks, 3D printing trials and materials testing before the medical device files are released to the public. This cost contribution also requires the manufacturer to setup and host a 3D file repository where users can download verified 3D print files for the relevant device in similar fashion to current online 3D printing repositories (thinginverse, grabCAD, youimagine, etc.)

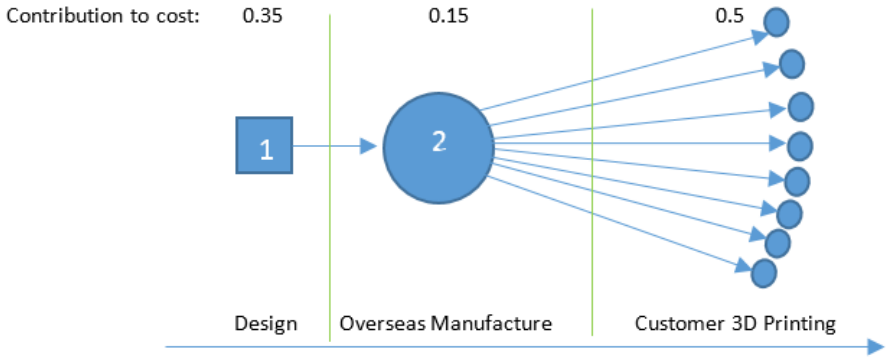

Figure 8. Re-distributed Scenario 2 and cost distribution

The final pricing of the device in this scenario remains a challenge as the patient's contribution to manufacturing and assembly eliminates the intermediate storage, distributions and subassembly stages, potentially lowering the final price of the device. It is more likely that this model will not completely substitute the conventional supply chain but it can be made available to a pool of customers who value the quicker availability at the expense of performing the assembly and non-critical parts manufacture in-house.

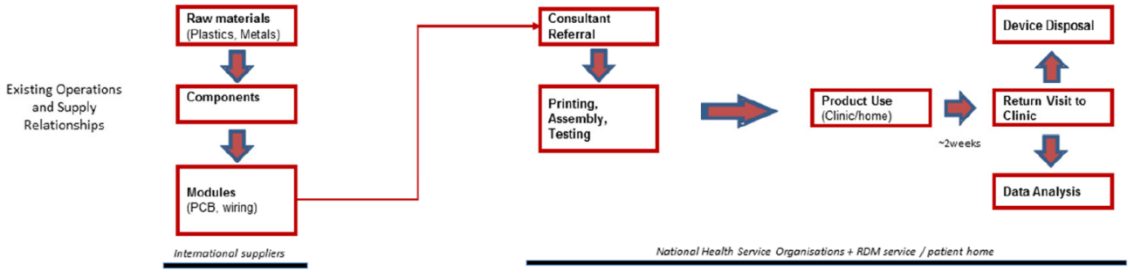

Figure 9. An RDM supply chain scenario where manufacturing happens after the device has been prescribed to the patient.

Discussion

The new provision chain will need to be designed according to the service needed (Slack et. al, 2010) that means Redistributing Manufacturing will take different forms according to the regional customer needs. For home-use medical devices, this can mean production will be relocated closer to the points of higher prevalence of certain medical conditions, as this can critically reduce waiting times for treatment. This is not currently possible by following conventional process routes; therefore, the combination of AM-enabled production and RDM principles can help plan and justify the creation of clustering locations where strategic manufacturing must happen.

Quality control is currently performed at the centralized manufacturing locations and quality assurance carefully follows strict medical device directives and standards (MDD, 1993; BS-EN-60601, 2006). Whether it is dimensional accuracy, product/shape conformity or durability tests, a scenario where manufacturing is redistributed away from a central location can pose regulatory challenges: will regional hospitals become specialized manufacturers for niche devices? Will regulatory bodies open up to non-centralized production models?

The current cost model comprises of the following elements: R&D, design, licensing, manufacturing, assembly, shipping and storage. A novel AM-enabled cost model that considers variations in manufacturing scenarios can potentially eliminate both the shipping and storage elements. However, Baumers et al (2016) also identified additional sources of cost in AM-enabled fabrication such as post-processing and multiple-part building. AM-enabled manufacturing would also offer an opportunity for customization of the final device with respect to size, geometric specifications, functional features, colours and material.

Current manufacturing can reach production capacities of several thousand devices per week. Based on our re-designed optimized device with a total print time of 3-5h, it would be possible to manufacture between 5–8 devices per day locally using a single FDM unit. Obtaining consistent throughput information will be vital for the control of the overall process. During our preliminary analysis we concluded that one AM process (FDM) has the potential to substitute the conventional process followed for our specific case study. However, it has been demonstrated that different AM technologies are also suitable for different medical devices such as foot orthotics SLS), CPAP respirators (DLP, inkjet) or hearing aids (SLA).

Conclusion

This feasibility study explored the possibilities for replacing existing operations normally adopted for a sample medical device case study. The flowmeter introduced as the basis of this study was redesigned and produced using alternative manufacturing methods and the main implications of such change have been discussed. Given the novelty of the topic and subject area it is not expected to perform a comprehensive analysis of the total supply chain per se, but to point at the immediate critical changes that a redistributed concept can bring into the medical device manufacturing arena.

Multiple challenges for operations management were identified, the most crucial being regulatory, quality and costing issues. The advantages of flipping production and distribution from a centralized model to a strategically re-distributed model are still to be confirmed and two key factors will be: 1) patient take up, and 2) practitioners/healthcare systems adoption. Given that the technical possibilities of such change are readily available, more feasibility studies taking into consideration different devices will be instrumental in documenting this potential paradigm change.

Acknowledgements

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