TECHNOLOGICAL DEVELOPMENTS IN MEDICAL APPLICATIONS OF RAPID PROTOTYPING AND MANUFACTURING TECHNOLOGY OVER THE LAST DECADE

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ABSTRACT

This paper identifies the most significant technological developments made in medical applications of rapid prototyping and manufacturing (RP&M) over the past decade. This assessment is based on a retrospective analysis of the research undertaken by the Medical Applications Group of the National Centre for Product Design and Development Research (PDR), based at the University of Wales Institute Cardiff (UWIC), UK. The paper describes the state of technology at the inception of the Group in 1998 and then highlights the significant technological developments that impacted on the activities of the Group over the decade to 2008. The paper will also discuss how these technologies have developed since their initial implementation. The paper will conclude with suggested directions future work should take in order to meet clinical and technical needs.

Keywords: rapid prototyping, medical modelling, stereolithography, surgery

1. INTRODUCTION

PDR had been active in RP&M since 1995 and in 1998 identified medical applications as a new and exciting area of development. The first step was to establish a small team to specialise in the area and the Medical Applications Group (MAG) was formed. At that time, PDR had been active for several years in research, product development and RP and was equipped with three-dimensional computer-aided design software (3D CAD), stereolithography (3D Systems SLA 250/40) and laminated object manufacture (Helisys LOM 1015). However, at that point no specific investment in medical applications had been made. Therefore, a thorough review of the state of the art was undertaken to identify technical requirements and formulate an investment plan.

2. SIGNIFICANT DEVELOPMENTS

Since its establishment in 1998, the Medical Applications Group has grown and developed into a recognised centre of expertise in the application of product design and development technologies in medicine. During that time, the Group engaged in collaborative applied research, knowledge transfer and commercial exploitation. These activities placed a range of demands on the available technologies and in many circumstances innovative practices had to be developed to maximise the potential of new technologies.

However, an appraisal of the technological developments over the ten year period 1998 to 2008 shows that there was a small number of critical developments that enabled the achievement of many of the Group's research aims. In chronological order they are:

- Medical scan data import and translation software
- Medically appropriate RP material
- 3D surgical planning and surgical guides
- 3D scanning and surfacing
- SensAble FreeForm CAD
- Direct metal RP/RM
- Direct metal RP/RM using titanium

The following sections provide an overview of each technological development, its impact and how it has developed since its initial implementation.

3. MEDICAL SCAN DATA IMPORT SOFTWARE

The initial review undertaken at the inception of the Medical Applications Group identified the most critical resource requirement was for software that could effectively and efficiently transfer medical scan data into data files that could be used with RP&M technologies. In 1998 there were few options and much of the research at that time required considerable expertise and time to create innovative ways of converting the pixel-based images of CT scans into three-dimensional data required for CAD and RP&M.

The review carried out in 1998 identified the Mimics software from Materialise as the most capable option (Materialise N.V., 2008). The software enabled CT scans to be imported, tissues to be segmented according to density and, crucially, data to be exported directly in a variety of CAD and RP formats (Figure 1). Uniquely at that time, the software was capable of providing not only output data in the *de facto* RP standard STL format but also a range of 2½ D layer formats that could be utilised directly in a number of RP technologies. This provided a more efficient and potentially more accurate workflow by eliminating the creation of an intermediate STL and its subsequent slicing. This resource was critical as the anatomical data it provides forms the basis of nearly all subsequent stages in medical applications.

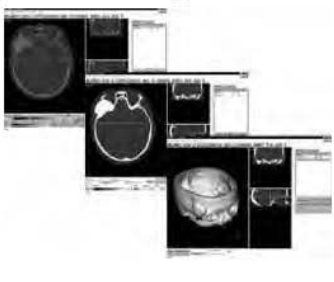

Figure 1: Mimics software

3.1. The situation in 1998

The major impediments of the software in 1998 were caused by a lack of awareness of 3D CT and data transfer. Radiographers responsible for conducting the scans were often inexperienced in retrieving data for a third party and many scanners were not even connected to any kind of network or peripheral device. The problem was compounded by a plethora of different data formats and compression algorithms most of which required a specific translation software option. In addition, high capacity data media were slow and expensive, such as magnetic optical disks (MODs) or digital audio tape (DAT). These also required additional hardware and software resources. Consequently, it could take several days and hundreds of pounds to successfully import a data set for a given patient.

3.2. The situation in *2008*

Nearly all medical imaging manufacturers have embraced the DICOM (Digital Imaging and Communications in Medicine) format (DICOM, 2008). Widespread use of the DICOM format has largely eliminated problems of importing data and now it is very rare to experience format difficulties when importing CT data. A typical 3D CT scan can be imported in a few minutes. In addition, hospitals have implemented digital transfer of medical image data and access to scan data for transfer is much easier. The ready availability of cheap, high capacity storage media has also removed much of the cost of sending data to a third party. Whereas in 1998 an MOD disk cost about $160 US, a CD-ROM that costs about $0.20 US can effectively store a typical CT scan.

There are now a number of software options that are capable of performing the necessary functions required to enable RP&M from medical scan data available at varying costs. In addition, various specialist functions have been developed, particularly for research applications such as creating three-dimensional meshed data for Finite Element Analysis.

4. MEDICAL RP MATERIAL

The majority of medical modelling carried out at PDR has been done using stereolithography due to its inherent advantages of accuracy and transparency. However, the materials available in 1998 were considered unsuitable for direct medical use and many clinicians were suspicious of the materials' properties. This restricted the use of models to the laboratory when many clinicians wished to utilise the models under sterile conditions in the operating theatre.

4.1. The situation in 1998

A medically approved resin for stereolithography, H-C 9100R and its derivatives,was developed in the late 1990s. Initially developed by a division of Zeneca the resin has been available under a variety of company names until the present, when it is manufactured by Huntsman (Huntsman Advanced Materials, 2008). PDR took the decision to invest in the material in 1999. Initially the level of support was minimal and there were few other users from which to learn, leading to a period of experimentation and development to produce reliable machine settings. The material is acrylate-based which provided low toxicity but also resulted in comparatively high viscosity, which is not desirable in stereolithography. However, effective settings were achieved and the material enabled many medical models to be supplied for use in theatre and was crucial in enabling the development of computer-aided planning and surgical guides. The material also enabled selective colouring, which had many medical applications such as highlighting the roots of teeth in the mandible (Figure 2).

Figure 2: SLA model with selectively coloured teeth

4.2. The situation in 2008

Whilst RP&M materials have improved greatly in the last ten years, there has been little significant development in the availability of material specifically developed and approved for medical applications. In general, processing parameters have improved, leading to higher reliability, reduced build times and lower costs. Physical properties have also improved a great deal, with toughness, flexibility and strength all showing significant improvement. These developments have all been driven by industrial applications and medical applications remain a niche market in comparison. The majority of medically useful RP&M materials are industrial materials that have subsequently been tested to internationally recognised standards, such as ISO 10993 and USP 23 Class VI, and shown to exhibit low toxicity. A small number of materials have been developed for Rapid Manufacturing of specific medical devices, most notably custom-fitting hearing aid shells (EnvisionTEC GmbH, 2008; Dreve Otoplastik GmbH, 2008).

Therefore, although there are some medically acceptable RP&M materials available for several RP&M technologies the choice is still limited. The development of a wider choice of medical materials is an area that should be addressed if the medical sector is to fully exploit the potential advantages of Rapid Manufacturing.

5. 3D SURGICAL PLANNING

After being introduced to 3D CT scans and 3D CAD, clinicians became interested in developing computer-aided 3D surgical planning. Towards the turn of the century several developments were progressing that would enable 3D computer-aided surgical planning. However, this led to the next hurdle, which was how to effectively transfer the virtual plan to the operating theatre. The use of RP&M to produce templates or surgical guides from data derived from the virtual plans was seen as the obvious answer.

This was desirable as the cost of producing a small RP surgical guide was a fraction of the cost of a model of the anatomy. However, many of the first software products could not interface with CAD or RP software formats. PDR's Medical Applications Group undertook research to overcome these barriers.

5.1. The situation in 2001

Although there were commercial companies beginning to offer products that would enable planning and provide a surgical guide they were proprietary in nature and restricted to dental applications. PDR developed methods of utilising a combination of available CAD technologies to enable 3D planning and surgical guide design for any surgical procedure (Figure 3) (Bibb *et al* 2003a, Bibb *et al* 2003b). Although this worked well it required considerable expertise, several different stages and software resources. The production of the surgical guides was enabled by the application of the medical stereolithography resin although this required careful handling and inconvenient sterilisation methods.

Figure 3: Early surgical guide design.

5.2. The situation in 2008

Surgical planning software has developed well and in dental applications is becoming routine, with several companies offering full planning software and surgical guide services.

However, in the non-dental areas there is still some work to be done in order to fully realise the potential of 3D planning and surgical guides. The planning, surgical guide design and surgical guide manufacture research being carried out at PDR has progressed greatly through the application of FreeForm CAD and Selective Laser Melting, which are described below (Figures 4 and 6).

6. 3D SURFACE SCANNING

PDR realised the potential impact of 3D scanning in 2000 and invested a considerable amount of money in a structured white light 3D scanner. The scanner was accurate and non-contact and the Medical Applications Group conducted research into its application in medicine.

6.1. The situation in 2000

Although accurate, the scanner took nearly a minute to do each acquisition. During this time the patient would be required to be perfectly still, which was difficult to achieve in many circumstances. Multiple software resources were required to convert the acquired data into a sound data file for RP&M and required expensive computers. Converting the acquired data into a valid STL file suitable for RP&M would typically require at least two and often three or four different software packages. The process required considerable expertise and could take a whole working day to achieve a valid closed STL file (Bibb *et al* 2000).

6.2. The situation in 2008

Driven by ever cheaper and more powerful computing and the rapid increase in digital camera technology, there has been a dramatic increase in the number of affordable 3D scanners available. In addition, software development means that many scanners output good STL files directly. Alternatively, there are many dedicated software packages available that can produce a wide variety of valid CAD or RP&M data formats quickly and efficiently. Using technologies such as Photogrammetry, Laser Scanning, and Structured White Light scanning, a three-dimensional surface can now typically be captured in seconds and a valid data file produced for RP&M in a matter of minutes.

7. FREEFORM CAD

One of the major barriers to achieving the aims of the Medical Applications Group was the fact that traditional engineering-based CAD could not satisfactorily import and represent human anatomy or produce anatomically shaped designs. The development of FreeForm CAD was a technological breakthrough for the Group (SensAble Technologies Inc., 2008).

7.1. The situation in 2002

FreeForm's haptic interface and arbitrary shaping capability enabled the import of anatomical scan data and the design of custom-fitting devices such as surgical guides and prostheses. This found immediate application in a number of research areas including prosthetic design, implant design, burns conformers and the surgical guides described earlier. It was also subsequently used in the computer-aided design of removable partial dentures frameworks.

7.2. The situation in 2008

FreeForm has now been used for a wide number of medical applications and its use has been replicated by other researchers in the area (Bibb *et al* 2002, Eggbeer *et al* 2004, Evans *et al* 2004, Eggbeer *et al* 2006). FreeForm is now in routine use in PDR and several services offered by MAG rely on it. Research between PDR and UWIC's Centre for Dental Technology has also led to the development of a dedicated dental version of the software. However, despite incremental improvements the software has not dramatically changed since 2002. A reduction in the cost of the software and hardware required would remove barriers to further implementation in the medical field.

Figure 4: FreeForm surgical guide design

Figure 5: FreeForm implant design

8. DIRECT METAL

As already mentioned above, the development of many RP&M applications was hindered by a limited choice of appropriate materials. The stereolithography resin although useful was limited due to its poor strength and required low temperature sterilisation techniques. Metal materials had been in use in RP&M for some years but they relied on mixtures of materials (such as iron and copper, or iron and bronze) that were unacceptable for medical use. They also required multiple process steps and accuracy suffered as a result.

The development of direct laser re-melting of metal powders using fibre lasers (referred to as selective laser melting or direct metal laser sintering) was another significant breakthrough. The availability of an RP&M machine that could produce parts in pure alloys in a single stage process was ideal for achieving some of the Group's aims.

8.1. The situation in 2003

PDR invested a significant amount to acquire one of the first Selective Laser Melting (SLM) machines in the UK (MTT Technologies Ltd., 2008). The machine required the development of new expertise and some experimentation to produce efficient and reliable parameters. The SLM machine was initially used to produce surgical guides. The SLM guides proved superior to the previous stereolithography guides, being stronger, stiffer and therefore smaller and thinner, reducing incisions and improving access for surgeons. The metal guides were also much less likely to suffer from inadvertent damage from surgical instruments and could be autoclaved for rapid and inexpensive sterilisation (Figure 6).

Figure 6: SLM surgical guide design

8.2. The situation in 2008

SLM is still in its early stages of adoption compared to older RP processes such as stereolithography and there is much research being undertaken to make the process more efficient, more reliable and capable of processing a wider variety of alloys. This will in turn reduce costs and enable further exploitation in medical applications. Some applications have been well described but are still not in widespread use. The ability to produce parts in hardwearing corrosion resistant metals is of little advantage in the manufacture of anatomical models but can provide distinct advantages in the production of prototype medical devices and once-off custom-fitting surgical guides. Collaborative research undertaken by PDR and its partners has explored the design, rapid manufacture and application of surgical guides using SLM (Bibb *et al* 2005).

9. TITANIUM

Following on from the development of direct metal processes the ability to produce functional components in titanium has enabled the direct production of implants, such as the example shown in Figure 7. This is significant as it moves into a large and important market that can exploit many potential advantages of RM; not just once-off production.

The ability to produce different micro and macro structures is an important development that is facilitated by layer manufacturing regardless of "speed" which has traditionally been perceived as the principal benefit. This offers the potential to develop implants that have better performance than traditional techniques regardless of production volumes.

Figure 7: Titanium Implant on stereolithography model

10. FUTURE WORK

It can be seen that there has been much progress in the last 10 years. In 1998, a simple anatomical RP model was a novelty, now they are routine in many hospitals. In 1998 the ability to plan a complex operation on the computer and then walk into the operating theatre with only a small, accurate surgical guide was complicated, time consuming and expensive. Now, at least in dental applications, it is a commercial reality. The ability to efficiently scan a patient, use CAD to design a prosthesis and RP to manufacture a pattern for the prosthetists to work from was impossible. Now, whilst not routine, it has been shown to be feasible by research carried out at PDR.

Looking back over these developments it is clear that the impact is shown in two stages. Firstly, the data import software, the medical resin and FreeForm CAD all enabled work that was previously impossible in practical terms. Secondly, the more incremental improvements in software sophistication, computing power and technological development have made medical applications more efficient, more accurate and easier for clinicians to use. Much of the immediate need is to further advance the development of dedicated software, hardware and materials packages that enable an integrated and efficient workflow. These developments will make the difference between something that is technically possible and a genuinely advantageous medical treatment. Beyond that, materials developments are required in order to realise the potential of rapid manufacturing of prostheses, implants and even in the future human tissues.

11. CONCLUSIONS

Since 1998, medical applications of RP&M have developed a great deal, but it is evident that many of the developments were driven by other, largely industrial requirements, and adapted for medical use. Whilst great improvements have been made to the extent that many of the ambitions that the Medical Applications Group at PDR had in 1998 have been achieved we are still long way away from many of these applications becoming routine, efficient and effective medical treatments. There is much research still to be done.

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