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RAPID PROTOTYPING AND MANUFACTURING IN MEDICAL PRODUCT DEVELOPMENT

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Abstract: *Rapid Prototyping (RP) and recently Rapid Manufacturing (RM) have been key factors in the development of the manufacturing industry in assisting in the development of new products. Fortunately, the application of these technologies has been realised in the medical industry. Additive manufacturing is used by surgeons to create physical models from CT/MRI data. The fabrication of these models has exploded into a popular research area combining engineering, material and medical expertise to lead to innovative designs and applications. Long-term growth in the additive fabrication industry will come from designs that are difficult, time-consuming, costly, or impossible to produce using standard techniques (RPA: SME, 1997). Growth will occur with advances in current additive processes which are coupled with breakthroughs in new materials. Not only is the development of hard tissue models (e.g. bone) considered, but research is also conducted in the field of soft tissue development (e.g. muscles). The applications of RP and RM are as diverse as the medical issues that arise. RM of custom design medical prostheses proves to be an economically viable solution, not only because it is faster to produce but it gives the designer freedom of creation too. The paper discusses some interesting medical case studies as well as new advancements in direct metal freeform fabrication and its potential to revolutionise the medical industry. Possibilities of further research in this field will also be highlighted. Case studies conducted through the research are all novel, and not merely a reproduction of research already conducted elsewhere. Furthermore, the research team are not "specialising" in a specific medical application field, but a wide array of case studies conducted (in severe cases where no other possibilities for help/support exist) will be presented, which contributes to originality and contributes to new knowledge in this field.*
Key words: *Rapid prototyping; medical applications; rapid manufacturing*

1. PROBLEM STATEMENT

Improvements of Layer Manufacturing processes have brought about the shift of Rapid Prototyping (RP) to firstly Rapid Tooling (RT) and secondly Rapid Manufacturing (RM) (Kruth *et al.* 2005) and the medical industry was one of the first industries to embrace this opportunity. The authors' research is aimed at proving the appropriateness of RP technologies in a medical environment to create a paradigm shift towards the use of RP for individually manufactured medical items; promoting the use of the technology in the medical environment; building a record of successful (practical) case studies that can be used for reference purposes by medical practitioners; gaining expertise and training in the reverse engineering (RE) aspects (from CT system to .STL files); and to investigate the direct laser sintering of Titanium for customised implants.

2. LITERATURE REVIEW

RE and medical image-based technology today enables construction of 3D models of anatomical structures of the human body based on anatomical information from scanning data such as computerised tomography (CT) and magnetic resonance imaging (MRI) (Hieu *et al.* 2005)**.** Although virtual models are helpful many medical applications can benefit further having the physical models (Gibson, 2005)**.** These physical 3D models can be manufactured in a wide range of materials (from plastics to metals to biocompatible materials) and sizes (from big models to microstructures) (Hieu *et al.* 2005). Furthermore advances in scanning and manufacturing technologies allowed more technological approaches to customisation in the medical field (Dalgamo *et al.* 2006)**.** With customised implants the possibility arise that original anatomy can be restored as accurately as possible and that 3D models can be used for surgical planning thereby minimising surgery time and related costs (D'Urso *et al.* 2000) **.**

The initial focus of the Centre for Rapid Prototyping and Manufacturing (CRPM) was on industrial applications. During 2004 CRPM became active in medical applications. Since then the research team has had successful collaboration with various Orthopaedic and Plastic surgeons in South Africa as well as in the UK. The researchers support medical teams with pre-operative models of the region of interest to assist with the surgery or customised implants usually at a stage where conventional medical techniques or practices no longer apply.

3. METHODOLOGY

CT data are used as a starting platform, to enable the development of 3D CAD data for RP operations**.** The CT scans are imported into MIMICS, a general-purpose segmentation program for gray value images, which performs segmentation by thresholding to identify bony structures or soft tissue. The region of interest can then be masked and calculated as a 3D model which can then be exported in the form of an RP machine ready .STL file. These files can be manipulated further using Magics RP/RP Tools/CopyCAD (surface creation) and design modeling using Powershape before the prototype or implant is manufactured using either an RP technology or 5-axis CNC machining.

4. RESULTS

4.1 Case study 1: Pelvis and femur

Various case studies involving the pelvis and femur have been performed. In most instances these are extreme cases involving cancerous growths, polio as well as rectifying mistakes made during previous operations. The 3D model in Nylon Polyamide was used for surgical planning and also for implant design as can be seen in the following sequence of photographs (Fig. 1). The implant was manufactured in Titanium using a DMU60T 5-axis CNC milling machine and was done in collaboration with ISIQU.

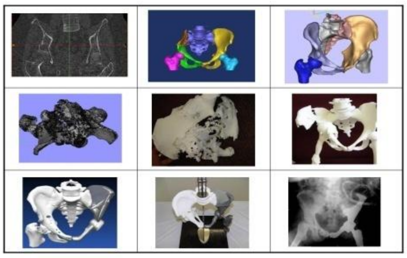

Fig. 1. Process for pelvis and femur implant design

4.2 Case study 2: Pectoralis Major Muscle

Analyses of the pectoralis muscle data were performed and surgical planning for one of the studies performed to see the visual effect of such an operation. CT data of a female patient were used for the isolation of the soft tissue. The isolation of the data proved to be difficult as only CT data and not MRI data were available. The representative volume of the pectoralis major muscle was obtained and mirrored using MIMICS, and a prototype built of the volume. A silicon mould was manufactured in Brazil and has consequently been implanted successfully into the patient (Fig. 2).

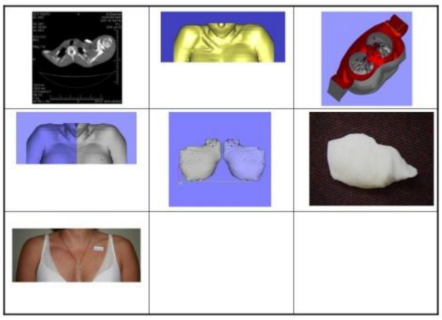

Fig. 2. Pectoralis implant development process

4.3 Case study 3: Eye Socket

The study was done in collaboration with University of Wales, Cardiff and Morriston Hospital in the UK. The patient has part repaired facial cleft and cleft palate and needed a lip revision, augmentation of the anterior maxilla, a revision of the skin cleft scar which has to be opened to access the orbit on the right. The eye is non-seeing and about 1 cm lower than the left eye. The skin is tight over the area. The .STL data from CT scans were used to generate the RP slice files and an implant was manufacture directly in Titanium using the EOS M270 XDTiLS RP machine. After sintering the implant was cleaned and polished and fitted to a SLA model of the patient's skull (Fig. 3). The eye socket has been successfully implanted.

Fig. 3. Titanium eye socket implant

4.4 Case study 4: Scapula

In this case study it was necessary to manufacture three implants after a wide resection removing the scapula, shoulder joint and proximal humerus of a patient were performed. The CT data of the healthy region of interest were mirrored and the .STL file and 3D model presented to the surgeons. The .STL file was then used to create a surface using COPYCAD and design modelling using PowerSHAPE was performed (Fig.4).

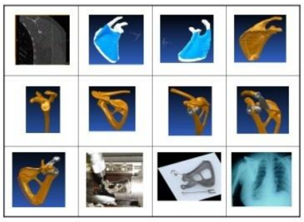

Fig. 4. Scapula implant development process

5. CONCLUSIONS

The 3D model manufactured case studies 1, 3 and 4 assisted the surgeons do pre-operative planning and to use .STL file in combination with CopyCAD and PowerSHAPE to firstly design and secondly to fit the implant to the model.

The second case study provides evidence that a 3D model can be calculated of missing soft tissue by mirroring existing soft tissue. The manufactured nylon prototype can then be used to create a mould.

6. FUTURE RESEARCH

According to Park 2006 the future of RM appears to be bright and the potential that these technologies offer to manufacturing industry should not be underestimated. The vast majority of new applications yet to be achieved with RM have not been conceived. Based on previous successes achieved, as well as the impact that the manufacturing of custom designed implants can have both socially and economically, the team has set its goals on direct production of metal implants using RM. During the production of an implant using conventional CNC milling a vast amount of material is wasted, which is not the case with direct Laser Sintering technologies. Close collaboration with surgeons is essential to promote this technology.

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