Rapid Technologies in medicine:
What can, can't be done and why.

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Abstract

Medicine was already at the very early developments of rapid technologies an interesting and successful field of application. Looking back at the historic evolution, it is surprising that it was possible for such an advanced and at times immature technology to penetrate in an overregulated, conservative area as the medical world. This article looks at recent developments that have managed once more to manouvre within the boundaries of current regulatory affaires: custom made implants and illustrates them with two case studies. One case study clearly shows that Rapid Manufacturing can be used for implants and therefore paves the way for faster, more accurate, better planned implant surgeries than is possible with conventional techniques. The rest of this article shows where the current problems still occur and what could be done in the future to solve them.

1 Introduction

The early adaption of Rapid Technologies (Rx) in the medical environment was due to a combination of factors:

- The need for unique parts, based on patient's data.
- The high added-value reduced the problem of the high cost.
- The extreme complexity of the models made it impossible to use conventional technologies.
- The close technological link between Rx and medical imaging (like CT and MRI).
- The high autonomy of doctors to take decisions on the use of new technology.

Over the years, Rx has been involved in more and more phases of bone related surgery. First of all, RP-models are excellent enhancements to medical images for diagnostic purposes and in a later phase, preoperative planning. For these applications, Rx but also medical imaging gave a qualitative added-value to bone related surgery.

The next step is the use of Rx in the implementation of the planning. This means during surgery. Obviously, this had serious implications on the possible Rx technologies to be used. Two additional aspects needed to be taken into consideration.

- Until now, the patient never came in direct contact with Rx-models. Now, models are used during surgery. This required biocompatibility and sterility of the models.
- Quantitative information is required. Practically, this means that specific accuracy requirements are needed. In medical imaging, this was never an important issue.

The paper uses two case studies to illustrate the process. The first case study was carried out in the framework of a European Integrated Project: Customfit. The patient (see figure 1) has an infected conventional jaw implant.

The second case study is a cranial plate defect. This case study is particulary interesting because it is the first time an plate was implanted that was manufactured with a layered manufactured process.

Both case studies were carried out by Dr. Jules Poukens at the Academisch Ziekenhuis Maastricht, the Netherlands. The design was done at IDEE (University of Maastricht).

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Figure 1: The infected patient

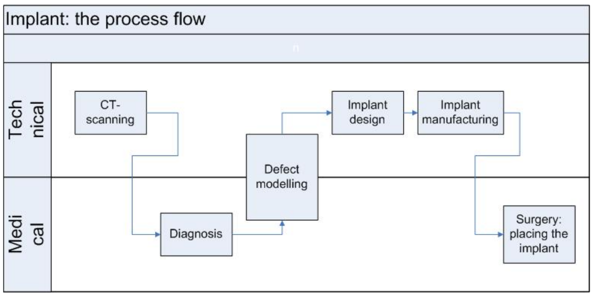

Figure 2: Generic flow of the process

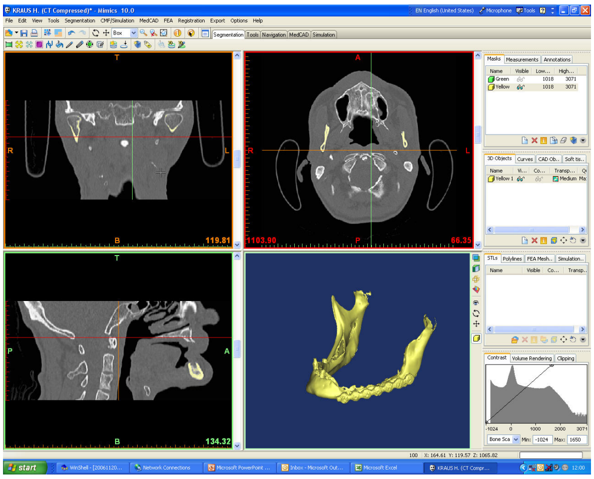

Figure 3: CT-scan of the mandibula

2 Process overview

This first part gives a generic overview of the process as a whole. In the subsequent sections, the different steps will be explained in detail, where appropriate illustrated by two real-life cases.

The different phases of the process are depicted in figure 2. Note the regular switches between technical and medical activities. In real life this corresponds with activites carried out by a technical engineer and a medically trained (and licenced) doctor. The modelling of the defect is in between, because it schould be done by the surgeon but is often delegated to a more technically skilled person.

The last step is surgery. The weakest point of the chain is the lack of validation during the previous phases while mistakes only show during surgery. Quality monitoring (and assurance) should therefore be the main point of interest throughout the process.

3 Data aquisition

In bone surgery, CT is by far the most commonly used scanning technology, if necessary an MR-scan is added to provide soft tissue information. It is frightening to realise that very little is known about the accuracy of CT-scanning (let alone CT-based modelling). To avoid liability problems later, already approved scanning protocols are used. Keep in mind that these protocols were developed for giving the best possible diagnostic images and do not provide any certainty about the accuracy of the CT-model or the designs based upon them.

Figure 3 shows the CT-images of a mandibula using the Mimics software. Based on the CT-images, Mimics is capable of extracting the surface model of the bone defect. Several "black box" accuracy studies ([3] have been carried out to get an idea of the accuracy of the scan and the resulting surface model. The main idea behind such approaches is to take a phantom model (of which certain dimensions are known) scan it, process the scans to a surface model (interpreting and thresholding), extract the dimensions from the surface model and compare them to the nominal values.

The disadvantage of this method is that it is not possible to see in which part of the process inaccuracies occur. Obviously, it is not possible

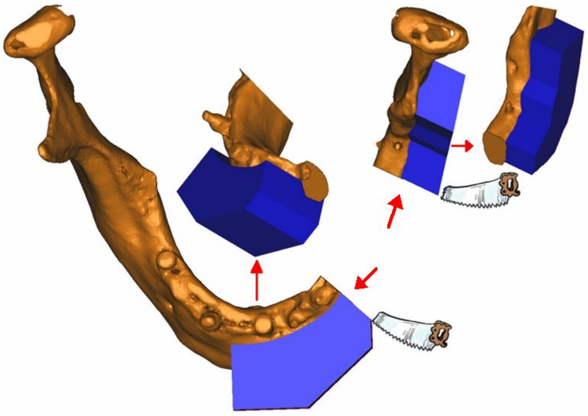

Figure 4: Cutting guides designed based on the planning

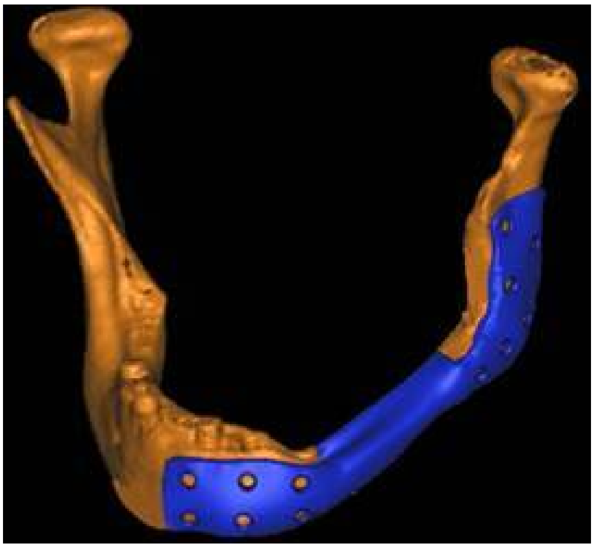

Figure 5: The designed implant

to learn from the mistakes. The above mentioned study resulted however in a scanning as well as a modelling protocol that give predictable results. In most cases, it is possible to reach overall accuracies of about 2 mm for cranio-maxillofacial scans. One conclusion coming from [4] is that without a carefull determination of the correct protocol, deviations (σ with respect to the nominal model) of up to 4.7 mm are possible. Artefacts (dentures, fillings...) can worsen the accuracy (bone density standards do no longer apply [2]).

4 Planning and design

The CT-images together with the surface model of the defect are no longer exclusively used for diagnostic purposes. The images give a clear picture of the geometric aspect of the problem and the surgeon can get an idea on what problems he or she will meet during surgery. With this information it is possible to make a detailed planning of the surgery. For more references see [1].

In the mandibula case, the images show clearly how far the bone is infected. With this knowledge, the surgeon planned where to cut the mandibula. The surface model was used to design two cutting guides that fit the mandibula exactly (shown in figure 4. This way of working made sure that the surgery would take place according to the original planning.

Usually, implants are made of relative flexible material so they can me shaped and reshaped if necessary during the operation. Since the planning can now be done with a controlled accuracy, it is possible to design a custom fit implant based on the surface model of the defect and the planning of the surgeon. The design of the jaw implant is shown in figure 5. Since there was a considerable amount of time between the scanning and the actual surgery, a serious clearance was taken into in account in the design to compensate for the possibility that more bone needed to be removed.

The design of the implant itself requires the possibility to work easily with scanned data. Since models of the skull are extremely complex and literally organic in shape, it is very difficult to do the modelling with conventional CAD-systems. The models coming from Mimics are surface models that are build up out of facets (triangles). They are transferred through an STL-file[1]. Conventional CAD-systems usually can import these files but in order to do operations on these data, it is necessary to convert the facet model into CAD-surfaces through the usually lengthy and difficult process of reverse engineering.

To avoid this problem, the design was done using 3Matic, a software that does design directly on facet models (STL-files). Tests showed that the de-

[1]standard file format for RP/RT/RM applications

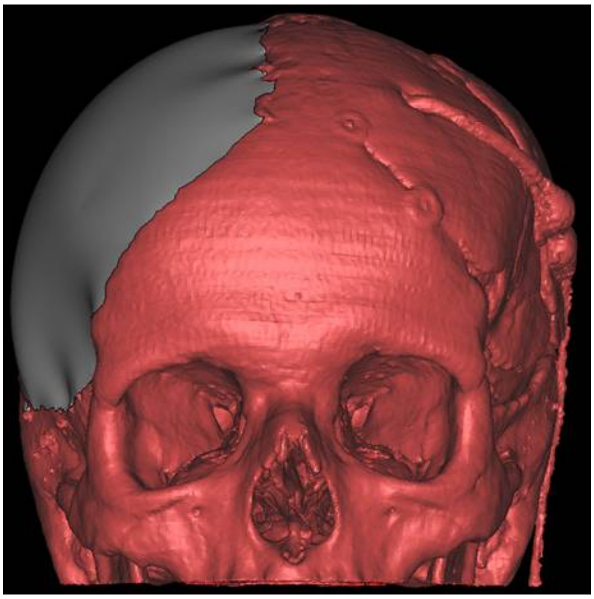

Figure 6: The design of the cranial plate

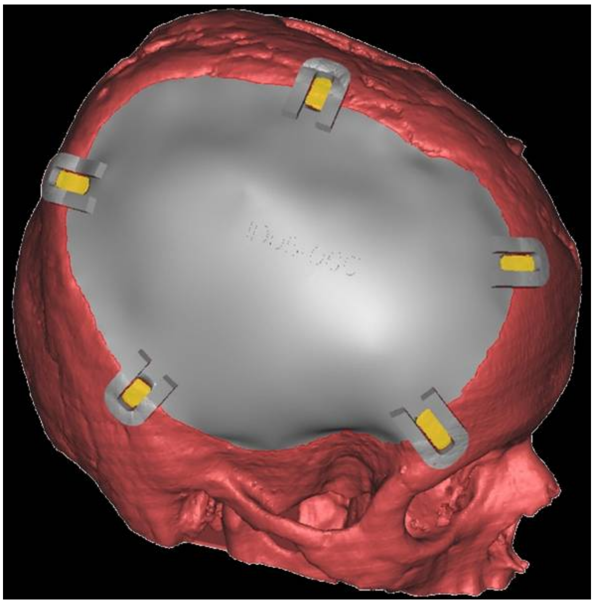

Figure 7: The fixing artefacts on the cranial plate

sign in a conventional CAD system of the jaw implant took 3 times longer than the design in 3Matic. The design of the skull implant (see figure 6) was not possible in conventional CAD.

Designing implants is usually a matter of combining organic, scanned shapes together with engineering components (like fixtures). In both case studies this is clearly visible. On the jaw implant, the holes are made to enable fixing the implant into the existing bone with conventional titanium screws. In the cranial case, fixing artefacts needed to be added to the design (see figure 7). In order to get the correct shape of the cranial plate, the plate was designed based on the mirrored model of the skull.

5 Manufacturing

The implants obviously need to be produced. First of all, medical regulations are very strict in what materials can be used for implants. At this moment, the most commonly used material for implants is titanium. This is not the easiest material to process and certainly not the cheapest. Custom fit implants are usually produced using conventional milling. This is how the jaw implant was produced (see Figure 8). Along with it, a model of the jaw was made, not in titanium but in ABS using FDM (on a Stratasys machine). This model was used to practice the surgery on.

The production by milling is not easy and sometimes it is necessary to make compromises in the design in order to make the implant "millable". Furthermore, due to the struture of most implants, a lot of material is milled away, making it even more expensive. Rapid Manufacturing does not have these shape restrictions and does not generate waste. The cranial implant (see figure 10) was produced using the Electron Beam Melting (EBM) process from Arcam in titanium. EBM is a fast RM process with a low surface finish. This is usually considered a drawback in engineering applications but in bone implants, it improves bone ingrowth and therefore speeds up the healing process.

6 Time to think ahead

The process as described above clearly has proven its usefulness. Within the paper, two case studies illustrated this. One should however keep in mind that behind those two "case studies" there are two lives that have been extended and improved. Thanks to the skills of the surgeon (Dr. Jules

Figure 8: The jaw implant with the ABS jaw model

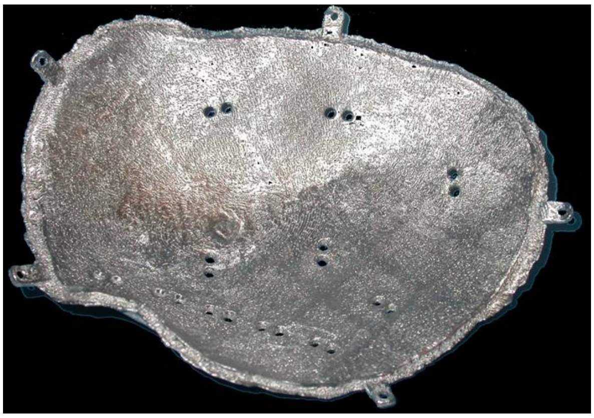

Figure 10: The cranial implant produced with EBM

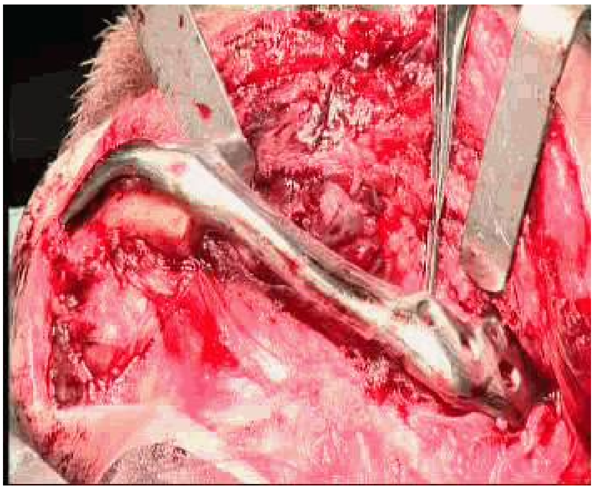

Figure 9: The jaw implant surgery

Figure 11: The cranial implant surgery

Poukens), those two people have a life again.

There is however still quite some room for improvement. Mainly three issues became clear during the case studies:

- The accuracy of the system should be determined more accurately and if possible improved. To compensate for this, both case studies incorporated a significant safety margin. If taken smaller, the healing period of the patient could be reduced significantly. Furthermore, less surprises would occur during the surgery so the surgery time (and the corresponding risk) could be reduced. Validation of each step should be introduced.

- The time should be reduced considerably. This was partially solved by using RM in the cranial case. During the surgery of the jaw implant, the infection appeared to have spread further and more bone than originally planned needed to be removed. This was taken into account in the design of the implant but it would be better if it was avoided in the first place. This means basically that lead times in planning, design and manufacturing should be reduced considerably.

- The last issue is the most difficult one. Metal implants have many disadvantages:
  - They do not have the same mechanical properties as natural bone. This implies that the load distributions on the bone/implant contstruction is completely different from the natural case. The load distribution controls the natural regeneration of bone tissue within the body so this could get completely deregulated.
  - They do not follow the evolution of the natural bone. This makes it very difficult for children. Where the natural bones do grow, the implant remains rigid, resulting in deformations of the body.
  - It does not integrate other anatomical features like blood vesels and nerves.
  - It is very temperature sensitive. With a large implant, patients can no longer go outside during cold winters or hot summers (forget saunas).

The three issues, force us to focus on three areas of research: accuracy of CT-scans and modelling, speeding up the process chain and material developments. Especially in material science, a completely new approach is needed. At this moment, a lot of research is done on materials that are not only biocompatible (like titanium) but that are even bioresorbable and stimulate natural bone growth. At the same time they can act as a placeholder for the bone to grow. In the future, it should be possible to tune the materials in such a way that they can be made patient specific and will be replaced by natural bone after a period of time.

References

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[2] J. Bright, D. Felsenberg, W. Kalender, C. Langton, A.M. Laval-Jeantet, Regsegger, and G. Van der Perre. Multicentre european comacbme study on the standardisation of bone densitometry procedures. *technology and Health Care 1*, pages 127–131, 1993.

[3] Jörg Schneider, René Decker, and Willi A. Kalender. Geometric accuracy in medical modelling. *Phidias network newsletter, No. 3*, december 1999.

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