Design and manufacturing of custom-made implants for Orthopaedics: quality management at the Point-of-Care

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Summary

For the personalization of orthopaedic implants to be realized at the point-of-care (POC), the adoption of procedures according to the quality management system from the International Standardization Organization, i.e. ISO 9001:2015, can improve their biomechanical based modelling and design steps, in addition to facilitate the processes for authorizations, orders, deliveries etc. The present work reports a recent full diagrammatic procedure and the relevant experience in a national reference orthopedic centre, for discussion and dissemination.

Introduction

Orthopaedic surgery using custom-made implants [1] is becoming popular because of the special severe conditions of many single patients and of the present quicker and cheaper processes from medical imaging to implantation of patient specific surgical treatments [2-4]. Unfortunately, the two major phases, i.e. designing and manufacturing, are mostly relegated to industry, whereas the former shall be much better performed at POC, where surgeons and bioengineers can discuss alongside the specific medical conditions, the optimal personalized solution, and the relevant surgical planning, together with arranging the administration and all the necessary actions and services in support to these special surgeries. Unfortunately very few are the experiences nowadays where this optimal combination of professionals is established in hospitals [5,6]. The present paper reports major aspects of this full procedure, as defined and arranged recently in the POC of the authors.

Methods

The POC is assumed to have the following instruments and tools: a) software tools for anatomical modelling, implant designing, surgical operation planning, and in case case-management; b) 3D printers to manufacture 3D models (typically by plastic filaments) and 3D surgical guides (typically by resins and stereolithography). The present procedure is meant to be applied in the following clinical indication and for the following products: 3D digital anatomical models, 3D biomodels and prototypes, custom-made surgical guides in support to surgery (for osteotomy, or off-the-shelf implants), and full-custom-made (FCM) implants including also the corresponding surgical guides.

Results and Discussion

In a first phase, from clinical examination and medical imaging of the patient, a decision is taken as to whether a FCM implant is necessary, or the other products are sufficient. The development of a FCM has three major processes (Figure 1): within the staff of the POC (left column), in connection with the external company for the final details and the manufacturing (central column), and the internal management (authorizations, ordering, check-in etc.; right column).

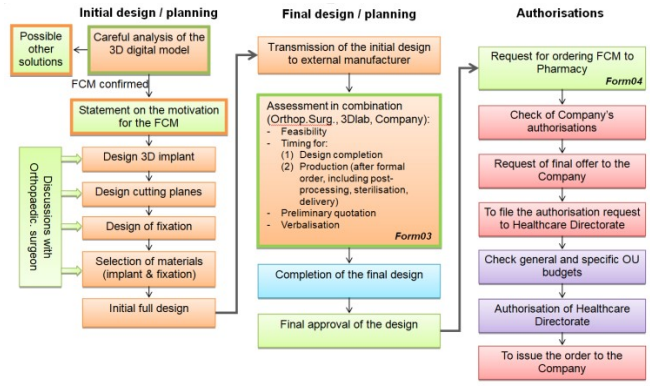

Figure 1: Diagrammatic representation of all the steps for the development of a FCM surgery.

Conclusions

Despite the current easier access to techniques and tools for the design of custom-made implants, and also to additive manufacturing for their production, very few are relevant experiences at POC. The present procedure guides the major phases for biomechanical modelling and designing, but also checks, forms, responsibilities, authorizations, orders, deliveries etc. at POC. The output can be either the full project for the custom-made implant, or solely the patient specific instrumentation for a standard implant off-the-shelf, but also allograft from bone banks. Within case-management tools, biomechanical analyses can be included. 3D models of the case, either digital or physical, are always provided to the surgeon; these are valuable for reporting, tracking, communication with the patient and medical education.

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