Towards a process for Augmented Surgery Evaluation

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Abstract

Quality evaluation in the field of Augmented Surgery (AS) is strategic for public health policy. Such an evaluation is complex, multi-factorial and not standardized. It first implies to be able to discover and to formalize the knowledge on the domain targeted by the device and to structure it. This paper presents the application of this approach to the evaluation of the Delivered Medical Service (DMS) during navigated knee surgery. Encouraging results are reported: a new relevant criterion has been discovered for the DMS evaluation of a device in AS.

Keywords:

Augmented surgery, Delivered medical service, Computer-assisted surgery, Quality, Medical device, Surgical model.

Introduction

In this work, we define Augmented Surgery (AS) as a set of surgical steps requiring the modeling of the surgeon's expertise (mathematical, biochemical modeling, etc.) guided towards a precisely defined target, in order to maximize the benefit/risk ratio. An Innovative Medical Device (IMD) used during AS assists the surgeon in performing his surgical act. Such an IMD may suffer from difficulties in establishing what its real added-value is. Nowadays, it becomes essential to obtain proofs of it (for public health policies). In the AS field, we began to define the Delivered Medical Service (DMS), which relates more to experience with users and is evaluated *a posteriori*. It may refer to a lot of domains such as learning, ergonomy, usability, other. The DMS of a device is relative to a given type of surgery, for a given category of patients having a given pathology**.** As this notion is complex to define, we focus only on the modeling of surgical procedures, on the identification of relevant concepts for evaluating DMS in AS field, and how such evaluations can be improved. As the surgical intervention is made of a set of different time-ordered steps, the DMS has to take into account each step, instead of focusing only on the global result of the surgical intervention.

Methods

We have restricted the AS knowledge domain to the case of Anterior Cruciate Ligament navigated surgery. This surgery consists in replacing a damaged ligament by a graft to restore an optimal functionality. The IMD is an image-less acquisition system based on knee modeling. It allows recording informative data about the surgery (temporal and parameter clinical levels). A specific visual representation of these recordings has been developed that helps expert implication and enables him to take part to the incremental modeling process. From this Surgical Process Model, new information is discovered and validated, from which new knowledge are inferred. This knowledge, once standardized, will be used to acquire relevant data which will enable to estimate the device's DMS.

Results

Procedures visualization enable identification of the notion of linear surgical procedure, which is a procedure with no more than one backward return during different steps of the surgery. Laxities are a relevant parameter to characterize clinical results: their decrease after navigation reflects a positive result. The decrease in laxity seems to be the same whatever the linearity of the procedure. Pre and post navigation laxities are higher in linear procedures than in non linear ones with statistical significance. This new information might generate a new knowledge: a surgery with small laxities uses all the capabilities of the IMD, in order to be very precise. Do we need such a device to optimize surgeries with small laxities? Is the linearity notion really relevant to estimate DMS?

Conclusion

To evaluate the DMS of a device is our objective. Representation of the *a priori* knowledge about the surgical procedure and of the information gathered during its performance is required in order to allow such an evaluation. In the long run, we would like to structure the knowledge domain of DMS in the AS field.