Identification of Non-technical Roadblocks in Cognitive Robotic Surgery

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INTRODUCTION

Many challenges are still to be overcome, before European robotic community reaches full clearance on how to commercialize surgical robots, even more if they are endowed with some cognitive features. Besides the technical difficulties of developing such devices from the engineering and medical point of view, firm obstacles are also present regarding the social, legal and ethical implications that will arise, once this technology is available and ready to use for surgical purposes. This presents the results reached by the coordinated action Eurosurge to face non-technical roadblocks foreseen in future robotic surgery, including recommendations for the robotic, legal and medical communities involved in this field.

MATERIALS AND METHODS

The objective of Eurosurge is to describe a feasible roadmap for cognitive robotic surgery in Europe to be developed and put into service. One of associated work packages was specific for the obstacles that are not directly linked to the design of the devices, but to legal and ethical aspects associated. Concretely, it focused on three main subjects: the difficulties of dealing with intellectual property (patents), the needs of European rules and regulations to fit and manage devices endowed with cognition and finally, the ethical practice of such robots in the operating room, provided the patients give their consent after being fully informed. Being different the methods used for the analysis in each case, the chapter is divided into three parts.

Analysis of patents

The risks of patent infringement, as well as the strategy to protect one's invention demand a hard bibliographic evaluation task, which is in most cases out of the scope of researchers and developers. Researchers may spend excessive resources by searching; collecting and managing documents without feeling they obtain solid conclusions. Definitely, a patents database specific for surgical robots would facilitate the hard tasks above cited, reducing time consuming efforts. Moreover, making this database available for robotic community, the validity of existing patents could be widely discussed.

An exhaustive search of existing software for patents management has been done, realizing that free license products are not operative to generate a subdatabase, but only expensive commercial products allow it. For this reason, it was decided to create a tailored tool, developed by our own team, which could extract information from a patents free source, according to users' desired queries. The software will be required to search patents and tag them, so that users will be able to classify the documents and build up their own database.

Survey on legal aspects

Due to the nature of the tasks expected to be carried out by cognitive surgical robots, the evaluation of risks is critical and, in case of injury during the clinical procedure, civil liability has to be deeply examined, considering that robots are expected to behave with a certain form of autonomy. In order to foresee the way that laws, rules and regulations will have to contemplate this situation, the current body of European, Italian and Spanish laws referring to surgical robotics has been disseminated. In order to foresee the applicability of current laws in the event that robots are cognitive, a practical case of liability assignment was performed with present legal framework, where potential failures of a cognitive system where identified. The setup used to simulate the scenarios is described in [2], the methodology follows the guidelines of [3] and the result of this study highlighted some valuable considerations to prevent researchers' responsibilities when designing future cognitive systems.

Analysis on ethical aspects

The informed consent process needs to be updated together with technology advances in surgery. Robots endowed with cognitive features will bring more complex forms of autonomy and patients shall be properly informed about the circumstances. The risks and benefits of using such devices ought to be explained with necessary details, but not exceeding to an unnecessary level that might bring confusion to patients. Since there are no referents of cognitive surgical robots yet, the project focused on the informed consent today, by means of bibliographic research; the analysis of written informed consent templates and personal interviews with surgeons and experts in robotics. After evaluating which are the key points of the process, it was considered when, where and how the information should change in case that the robot used in the surgery was cognitive.

RESULTS

Following the structure of the chapter above, the results of the project will also be shown case by case.

Results of the analysis of patents

The first obstacle to develop the patents search and classify tool was to find the source from which the documents would be extracted. It was solved by accessing to MAREC's database [1], which includes 19 million worldwide patents. An interface was developed and integrated in a portal created by Eurosurge. It allows the user to search by keywords and refine the queries by means of Boolean operators, wildcards and constraining words proximity. The results are returned in order of relevance and the user has the chance to select and tag the ones desired. Tags can be introduced by the user or chosen from the list of concepts available in the same webpage. These concepts are validated by expert users in a wiki mode, according to one of the objectives of Eurosurge which is not subject of this paper.

Results of the survey on legal aspects

Apparently, European directives and Spanish or Italian laws present very little differences regarding robotic surgery. Indeed, the terms cognition and autonomy applied to machines do not appear in any text, thus no specific treatment for civil liability in this kind of devices. Applying laws may vary depending on whether the product is defective (manufacturer's liability) or the service (surgeon/hospital's liability).

The first conclusion obtained by the study case is that surgical robots, whatever the level of autonomy they dispose of, need mechanisms for the surgeon to assume the control at any time. Depending on the availability of these mechanisms, civil liability will fall on the manufacturer or on the surgeon. Nevertheless, it will be important in the future to define the autonomy level of the robot and distinguish the applicable law accordingly. The Sheridan's autonomy scale could be a good basis to work with.

On the other hand, it was noticed that European directives concerning robotic surgery (i.e. Directive 93/42/EEC concerning medical devices, or 85/374/EEC on product liability) and recent advances are out of phase. It is obvious that science runs faster than laws are updated. One of the recommendations from Eurosurge is the use of "soft" laws (i. e. ISO rules), which are more dynamic and its geographical applicability is more feasible than harmonizing national laws.

From the regulatory point of view, the only autonomous device currently working in dynamic scenarios, which can be taken as reference is Google's driverless car. Its approval process, though only recognized in three American states, indicate that the best way to demonstrate the product's safety when behaving autonomously is by means of experience. Cognitive surgical robots will need to proof their reliability and, also depending on the level of autonomy they are endowed with, the number of controlled interventions or working hours supervised before they can be considered operative will have to be regulated.

Results of the analysis on ethical aspects

This section summarises the most relevant conclusions from the analysis on the informed consent, considering that the total number of templates analyzed was 87, from 19 different sources, five countries and 38 different surgical specialties. These conclusions also take into consideration the comments received from four surgeons and ten experts in robotics and are divided into three groups, depending on whether the recommendations refer to general aspects of the informed consent process, additional information that should be included or the relationship between patients and the physicians.

The first group remarks the need to include some critical information in the written informed consent, which was not always found explicit along the reviewed templates (i.e. specific risks and benefits, alternative treatment). It is also proposed a modular document, which fits better the level of information that patients request. It consists of a main document with unavoidable information and other annexes, which patients may wish (not) to consult.

The second recommendations group explicitly suggests what kind of information could be included in the modules above mentioned, the availability of which should be expressly stated in the core document: statistics concerning the success rate of cognitive robotic surgery; explanation graphics; associated costs compared to alternative treatments and autonomy limits of the robot, etc.

Finally, almost like a reminder, the report highlights the origin of the informed consent, which is based on human relationship and doctor-patient confidence. The aim is to establish a difference between what is strictly legal and what is ethical in providing information about a new technology.

DISCUSSION

Although significant subjects of cognitive robotic surgery have been deeply analyzed, legal and ethical considerations or even social reactions on autonomous machines in clinical environments are not yet very predictable. Technologically, robotic surgeons are still far from been designed, hence little scientific steps should be progressively considered by the non-technical environments. Probably, one of the most difficult challenges to handle will come from the ethical implications of robots taking their own decisions in critical situations, which have repercussion in humans' life.

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