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Die Risikoanalyse eines Biopsieroboters

Analyzing the Risk of A Biopsy Robot

Werner Korb[1], Martin Kornfeld, Martin Fuerst, Alexander Vogler[2], Wolfgang Birkfellner, Michael Figl[3], Robert Boesecke[1], Joachim Kettenbach[4], Stefan Hassfeld[1], Gernot Kronreif[2]

[1]Universitätsklinikum Heidelberg, Klinik für Mund-, Kiefer-, Gesichtschirurgie
[2]ARC Seibersdorf research GmbH
[3]Medizinische Universität Wien, Institut für Biomedizinische Technik und Physik
[4]Medizinische Universität Wien, Universitätsklinik für Radiodiagnostik

Introduction

For using robots in the operating theatre a safe and intuitive use is as important as precision. Otherwise physicians would not apply the system during clinical trials, whatever the other advantages are. In this paper the basics of risk management and safety of computer- and robot-assisted surgery equipment will be discussed and applied exemplary during development of a biopsy robot. To assure the required safety in a clinical trial a systematic analysis is necessary.

Material and Methods

The developed biopsy robot B-Rob II consists of two electromechanic positioning modules, each of them with a two degrees-of-freedom (DOF). For needle angulation the concept of relative motion of two parallel fingers connected to each other by means of spherical joints was implemented. For easy sterilisation, the two carbon-fiber fingers, the polymer bearings and the needle guide could be disconnected from the needle positioning unit by means of a rapid-change bayonet connection. Further a Polaris optical tracker system is used for calibration and registration. Monitoring of the biopsy process is supported by a custom designed planning software. If there arises a need for a correction of the needle angulation during the intervention (e.g. due to patient/organ movement), this can be simply executed either by means of repeated planning or by manual repositioning using the robot command panel (Fig. 1).
Risk-analysis is an iterative method (see Fig. 2). The possible hazards were identified and the risk of these hazards estimated within a fault tree analysis. Subsequently, after the estimation of the hazards with the use of a FTA, different measures to minimize the risk

were devised. Finally the occurrence and severity was evaluated and opposing the risk and the benefit, resulted in a observably predomination of the usefulness.

Results

The integrated mechanical design of the manipulators allowed high dexterity regardless of the small footprint of the module. The needle positioning unit allowed a 2-DOF needle angulation and a 2-DOF positioning as well as maintaining a software-defined pivot point for angulation. An improved precision of needle guidance and stable access during biopsy was evaluated; thus an improved overall ergonomics for the performing physician, could be anticipated who usually holds both, the US-probe and the puncture needle. In case of CT-guided interventions, both, the patient and the physician, may be less exposed to radiation.

In particular the risk analysis has proven that about the biopsy robot B-Rob II is safe, if appropriate measures are applied.

Discussion

A procedure of how to analyse and how to reduce risks is given in this paper. It has to be considered that a robotic system never can be free of risk , however the risk has to be as minimal as possible, at least until the benefits outweigh the residual risk. Based on our evaluation clinical trials are expected to start within this year.