Table 1 Primary hazards identified after the risk analysis and possible countermeasures, to minimize the risks

Hazard	Countermeasure
Failure of central components	Implementation of fall-backs or redundancy of the primary components
Failure of a medical device	No new risk, must be regarded by the manufacturer of the device
Affection of the system by malware	Logical separation of the medical IT-network from any other IT-network, e.g. using a gateway
Failures of the network	
Data does not/not in time arrive at the destination	Acknowledgement of each data package
Corruption of data during transmission	SOPs for testing the system
Loss of data during transmission	Protection of the transmitted data using for example checksums
Interoperability failures regarding syntactics and semantics	Standardization of interfaces and protocols used for interconnection and data transmission

affection by malware and hereby the potential failure of systems could be reduce by a logical separation of the medical/OR IT-network and the general clinical IT-network using for example a gateway. Regarding the overall network, the primary failure is data not arriving or not arriving in time at the destination. This hazard could be reduced by organizational measures like a regular check of the network and by a regular automatic system-check, with helps to detect the failure of a device in an early stage. Also the acknowledgement of each data packet, support the recognition of data-losses.

As another important risk control measure, the standardization of interfaces and protocols, has been identified during risk analysis. The standardization of these interfaces is essential, otherwise interoperability will not be given and central management, supervision and control of the different medical devices are not possible, which are important aspects for the risk minimization.

The risk evaluation of the developed integration framework has shown, that new risk may arise due to the integrated used of the different devices in an IT-network based on the SOA paradigm. These risks could be minimized by applying technical and organizational counter measures. All in all it could be shown that an integration of medical devices in the OR based on SOA is a feasible approach.

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Path planning for steerable needles using duty-cycling

M.C. Bernardes[1,2], B.V. Adorno[1], N. Zemiti[1], P. Poignet[1], G.A. Borges[2]
[1]Universite Montpellier 2, LIRMM, Montpellier, France
[2]Universidade de Brasília, LARA, Brasília, Brazil

Keywords Needle steering · Duty-cycling · Path planning · Nonholonomic

Purpose

Robotic systems for automatic needle insertion, and more specifically for steering flexible needles have been a subject of active research in recent years. These steerable needles use their great flexibility and beveled tips to enhance and magnify the natural deflection effect observed in needle procedures [1]. Therefore, they are able to achieve curved trajectories that could be used to avoid sensitive or impenetrable areas inaccessible with the traditional technique.

In robotics, this type of needle can be described as a kinematic system with nonholonomic constraints. As a consequence, motion planning is a complex task and its difficulty increases as we consider the presence of uncertainties due to errors in tip positioning, needle torsional stiffness, tissue inhomogeneity and deformation. Thus, the need of developing a robotic steering system capable of compensating for such effects.

We propose an adaptive approach that constantly updates motion planning using visual information while avoiding obstacle regions and proceeding towards the insertion target. More specifically, the use of ultrasound imaging has been shown extremely attractive since it is safe, affordable and provides information related to tissue properties, target displacement and tool position [2]. For using such type of medical imaging feedback, it is essential to have a fast method for 2D path planning that respects the model's nonholonomic constraints. In this paper, we present a new method that uses duty-cycled rotation of the needle combined with the classical Rapidly-Exploring Random Tree (RRT) algorithm [3] to obtain fast calculation of feasible trajectories and we evaluate its performance in a simulated insertion procedure with simultaneous replanning.

Methods

A. Duty-cycle needle steering

When pushed forward, the natural behaviour of a steerable needle is to bend in the direction of its sharpened tip, following an arc of constant curvature κ. The arc direction can be controlled by twisting the base of the needle to change its bevel orientation. The usual technique for needle steering in a 2D plan [4], called stop-and-turn, explores such idea by alternating the insertion of the needle with occasional stops to perform 180° rotations whenever there is a curvature inversion. In consequence, the needle can only reach points that belong to arcs of curvature κ, reducing path possibilities and constantly leading to dead-end situations.

An alternative is to make use of a duty-cycle strategy that explores needle twisting to achieve different curvature values [5]. This method works by combining periods of pure insertion with periods of

simultaneous insertion and rotation so that any curvature ranging from κ to a pure straight trajectory can be achieved.

B. Arc-based RRT Path Planning

Let the configuration q of a needle be defined by its tip cartesian coordinates and orientation angle. The objective of the planner is to find a combination of circular arcs capable of taking the needle from its initial configuration q_{init} to a final configuration q_{goal} while respecting the nonholonomic constraints. An arc is defined by its curvature and its two extremity configurations. The final extremity of each arc should correspond to the next arc's initial extremity, not only in position but also in orientation, so we have C^1 continuity. The boundaries of the workspace are defined to be the ultrasound image area, and the locations of the targets are considered known and defined by the surgeon.

We construct a tree based in the classical RRT by randomly sampling points from the free space and trying to connect them to a tree rooted in q_{init}. To respect the needle constraints, we propose a geometric-based Arc Local Planner that calculates the only arc capable of connecting two points given that the initial point is associated to a given orientation. If the obtained arc respects the curvature range and does not intersect any obstacle, it is added to the tree. The tree is expanded until it can be connected to the target and then a graph search is conducted to return the trajectory. For our adaptive replanning, we suppose that 2D information about the actual needle position is available and provided by an ultrasound tracking system out of the scope of this paper. This visual feedback is used as the needle's new initial configuration and the curvatures of all arcs previously calculated are adjusted to fit it. If a collision is detected or if the new curvature does not respect the maximum limit, then the RRT planner is run again to find a new trajectory.

Results

We used the described arc-based RRT to produce a trajectory for the needle tip and then simulated the correspondent insertion procedure to evaluate the capability of the needle to follow the planned path. It was observed that in an ideal situation (negligible torsional stiffness, tissue homogeneity and no tissue deformation) the needle was able to follow the path perfectly. However, if we add a white noise in needle position to emulate model uncertainties, we see that the result can greatly deviate from the desired goal. Then, we tested the performance of the Arc Local Planner when used as an adaptive process to replan the trajectory along the insertion procedure. Figure 1 illustrates how the online update of motion planning was able to compensate for the uncertainties and that the needle tip reaches the target.

Conclusions

The use of the duty-cycle technique instead of the usual stop-and-turn gave the system more trajectory possibilities. This multiplicity of solutions is specially necessary for the case of steering around obstacles during insertion procedures restricted to a 2D working space. Also, the arc-based RRT planning proved to respect the nonholonomic constraints and be fast enough to be used in an adaptive system.

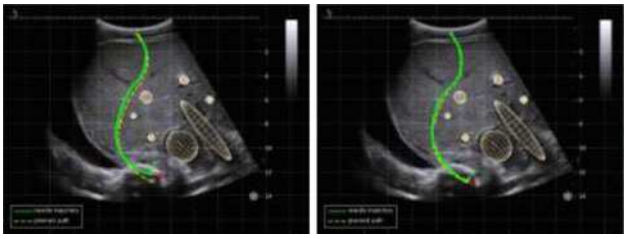

Fig. 1 Simulated needle trajectory without (*left*) and with replanning (*right*)

Future works include the improvement of the final trajectory by using path optimization strategies, and also the investigation of smoother curves such as splines that provide not only orientation but also curvature continuity, which is not observed in the circular arcs concatenation.

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Radioimmunoguided surgery for breast cancer using ^{111}In-Labeled Trastuzumab Fab fragments: safety and feasibility

C.M.B. Holloway[1,2], C. Caldwell[1], L. Ehrlich[1], H. Kahn[1], F.C. Wright[1], M.L. Quan[1,3], R. Reilly[2]

[1]Sunnybrook Health Sciences Centre, Toronto, Canada

[2]University of Toronto, Toronto, Canada

[3]University of Alberta, Calgary, Canada

Keywords Breast cancer · Radioimmunoguided surgery · Radiation dosimetry · Pharmacokinetics · Trastuzumab

Purpose

Optimal breast conserving surgery for cancer maximizes the completeness of tumour removal while minimizing the amount of normal tissue excised. Precise intraoperative delineation of tumour extent is required for accurate surgery. Current methods identify tumour location but not the perimeter of the lesion. Based on animal imaging data showing optimal breast tumour: blood ratio of radioactivity at 72 h after intravenous injection of ^{111}In-Labeled Trastuzumab Fab fragments, we conducted a study to evaluate the safety, pharmacokinetics, radiation dosimetry, and tumour and normal tissue localization of ^{111}In-DTPA-trastuzumab Fab Injection in patients with breast carcinoma whose tumours were immunopositive for HER-2/neu expression.

Methods

Six patients undergoing breast conserving surgery for HER2 positive ductal carcinoma in situ (DCIS) or invasive ductal carcinoma (IDC) were administered 74 MBq (2 mCi) and 0.5 mg protein of ^{111}In-Labeled Trastuzumab Fab 72 h preoperatively. To assess toxicity, we monitored vital signs, blood hematology and chemistry closely after injection until surgery and at 14 and 30 days postoperatively. Blood samples were obtained pre-injection and at 0.25, 0.5, 1, 2, 4–6, 24, 48 and 72 h post-injection and counted in a gamma scintillation counter. Counts were converted to kBq/mL and plotted versus time post-injection (GraphPad Prism® software); the resulting curve was fitted to a one- or two-compartment pharmacokinetic model, and standard parameters were calculated (Table 1).

A 24 h urine collection was performed to permit calculation of elimination half-life. Whole body gamma images were obtained 5 min and 1, 2, 4–6, 24, 48, and 72 h post-injection; SPECT images