Closed Loop: A Classification Framework for Interventional Procedures

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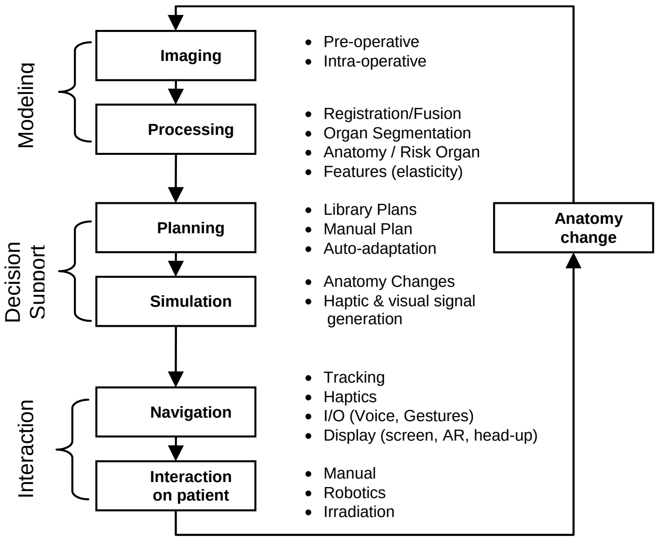
Abstract— **We present a closed-loop taxonomy framework for interventional procedures assisting to understand and locate an increasing number of "buzz-word driven" techniques within the workflow of the interventionalist. Our framework applies equally for open and minimally invasive techniques and emphasizes the fact that all steps within an interventional procedure act as a closed chain, thus none of them can be regarded separately from all others. We give a concrete example of one of the first soft tissue navigation systems introduced to clinical routine since 2002**

Keywords— **Interventional techniques, fusion imaging, soft tissue navigation, RF ablation**

I. INTRODUCTION

The revolution introduced by medical imaging is still evolving. After X-rays several other modalities have been developed giving us new, different and more complete views of the body interior: tomography (CT, MR) gives a very precise anatomical view and allows localisation in space, nuclear medicine gives pictures of metabolism, ultrasound and IR-imaging enable non-invasive imaging, to name only but a few. However, in recent times and with increasing economic pressure challenging the efficiency of medical applications a dominant development became more and more obvious: "better diagnosis alone" is not desired by the health professionals if there is no impact on the therapy procedure. As a result, interventional procedures are gaining importance as compared with pure diagnostics and will become the driving force for the years to come. This new tendency has been announced by various names, such as intra-operative imaging, image-guided therapy, navigation systems, computer-aided treatment, VR/AR in medicine, etc. All players have a diffuse feeling that the above systems should be regarded as parts of a bigger picture; however the lack of a reference classification scheme so far creates a certain level of confusion among practitioners and users.

The ultimate goal of future developments must be on integrating all of the above aspects in what we call to be a holistic and closed loop. Such an integrated reference system unifies particular aspects such as those mentioned above in one unique integrated ubiquitous transparent system. The image below serves as a classification scheme giving a reference model such as a holistic & closed loop of image-involving therapy systems, with an emphasis on minimal invasive procedures.



The driving idea is that clinical procedures are not isolated, but interact with each other – especially every module down the pipeline accesses information generated by another module upstream. Already today it is usual to perform pre-operative image acquisition, (manual) organ segmentation and target setting, treatment planning and its simulation. Some navigation systems are also available. During the intervention organs can (or latest in open surgery will) change position and/or shape. An advanced system must be able to consider such changes intra-operatively by re-acquiring the new anatomy during the intervention and by adapting the initial plan to the new situation. Since the tasks will take place under stress situations, all steps necessary for completing the loop must be integrated and must perform robustly and autonomously: Organs have to be recognized and segmented automatically, the original operation plan must be adapted to the intra-operative registered morphology, the navigation support must be updated accordingly and everything has to be presented to the surgeon in a way supporting his tasks rather than destructing him from his work.

In this paper we emphasize the key aspects of a soft tissue navigation system. Image guidance is essential in the treatment of liver tumours using percutaneous ablative techniques. Apart from careful pre-procedure planning and elaborate post-procedure evaluation, accurate intra-procedure targeting, monitoring, and controlling play a critical role in the success of the technique.

II. FUSION IMAGING VIRTUAL NAVIGATOR

Radiofrequency (RF) ablation is most commonly performed under ultrasound (U/S) guidance, with computed tomography (CT) guidance being reserved for lesions inconspicuous on U/S. However, there are occasions when the liver lesion is only optimally visualized on contrast-enhanced CT, making targeting and monitoring difficult due to lack of real-time imaging guidance. In this scenario, it would be desirable to co-register information from different imaging modalities (e.g., U/S and CT) and such multimodality matching have been utilized in nuclear medicine, radiotherapy, and neurosurgery.

Fig 1: U/S device with integrated NaviSuite

The system consists of an U/S scanner integrated with the Navigation unit (Fig 1). The U/S system provides the U/S image and over a specific interface communicates its characteristics such as the spatial dimension, orientation, and probe field of view. This information permits a right representation in size and orientation of the second modality image. These data provided by the U/S scanner are automatically updated at every change on the console of the scanner. The U/S image is provided either over a digital interface, or trough the video signal and digitalized by a standard frame grabber in order to be presented beside the virtual one.

Fig 2: Side-to-side display of U/S and corresponding oblique CT plane

An electromagnetic tracking system, composed by an transmitter and a small receiver (mounted on the U/S probe) provides the position and orientation of the U/S probe in relation to the transmitter. The electromagnetic tracker works even in presence of objects, tools etc. between tracker and receiver and therefore can be easily placed in any environment, furthermore its cost is much lower than that of an optical tracker. A disadvantage of the magnetic principle is the sensitivity concerning metallic objects close or near the receiver or transmitter. It has been found during the clinical tests that due to some filtering implemented by us, this requirement can be achieved without affecting the clinical routine in noticeable way.

Registration between patient anatomy visible on the real-time U/S image and its preoperatively gathered CT data can be done by a number of ways: by fiducial markers in the CT, by clicking anatomic markers, by manually shifting the CT and U/S images until registration appears acceptable, or by a fully automated method employing multual information registration. After registration is completed, during navigation the system extracts in real time an oblique CT slice at the location and orientation parallel to the U/S image and displays both images side-to-side on the screen. Overlapping of the CT and U/S image enables quick and intuitive test of the registration accuracy (Fig 3). Additional interventional aids include the display of biopsy line in U/S and CT, (magnetic) tracking of the position of the needle, delineating and marking targets in CT visible in U/S, and display of RF ablation area and/or treated volume (Fig 2).

Fig 3: Overlapping U/S and CT, biopsy guideline

III. CLINICAL RESULTS

After some learning curve in setting up the navigation system, we were able to perform the system setup including the registration within 3-5 min. CT-U/S registration is reliable with a mean registration error of 3mm ± 1 mm. The needle-to-target distance is 1.8 ± 0.8 mm. Thus accuracy is very good and sufficient for clinical routine.

Several hundreds patients have been treated in our clinics since 2002, here we present representative results of a study performed in 2006. In 87 patients with liver carcinoma and cirrhosis (51) or liver metastases of colorectal origin (36), 175 malignant tumours identified with multilayer CT were subjected to percutaneous radiofrequency thermal ablation using a real time image fusion system linking volumetric CT scanning with B-mode ultrasound. 96 of 175 (54.9%) tumours were poorly (69) or completely (27) invisible to ultrasound. The results of the treatment (centring precision and size of necrotic area with respect to size of tumour) were verified after 24 hours with CT multilayer scanning using contrast agent. Complete ablation was achieved in 165 of 175 (94.3%) tumours and, notably, in 65 of 69 (94.2%) of tumours with poor ultrasound visibility and 24 of 27 (88.9%) of those completely invisible to ultrasound. There were no major complications (Fig 4).

Fig 4: Performing RF ablations

IV. CONCLUSION

In conclusion, real-time registration and matching of pre-procedure CT volume images with intra-procedure U/S is feasible and accurate. For simple biopsies, an experienced interventionalist will not ask for such a guidance tool (this is different of course for still-not-so-experienced ones!) and, given the cost and its availability, individually applied U/S and CT guidance without image fusion will remain the "workhorses" for biopsy procedures. However for lesion of hardly visible at U/S or CT, or for more complex procedures, such as thermal tumor ablations that require positioning of multiple applicators and puncture of multiple lesions, navigation systems might be of help to reduce puncture risk and procedure time and to allow for more complete and radical therapy.

The main limitations are that the system can not distinguish differences in respiratory excursion and subject motion. To extrapolate the utility in routine clinical practice, precise registration of CT volume images into the patient required proper synchronisation with respect to the respiratory phase and arms' position during CT examination, and patient movement must be avoided. Possible solutions for detection of patient movement would be the implementation of external electromagnetic position sensors to the patient's body. The solution could be based on methods used in radiation therapy, as well as on those used in positron emission tomography–CT image fusion.

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