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EDITORIAL

The operating room and the need for an IT infrastructure and standards

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Introduction

A recent report predicted an increase in demand for surgical services to be as high as 14 to 47% in the workload of all surgical fields by 2020 [1]. Difficulties which are already now apparent in the operating room (OR), such as the lack of seamless integration of Surgical Assist Systems (SAS) into the surgical workflow, will be amplified in the near future. There are many SASs in development or are employed in the OR, mostly in an isolated fashion. Their routine use in the OR, however, is impeded by the absence of appropriate integration technology and standards. It is, therefore, necessary to address this situation and to develop strategies for improving surgical/interventional workflows assisted by surgical systems and technologies.

Appropriate use of Information and Communication Technology (ICT) and Mechatronic (MT) systems as part of a re-engineered workflow is considered by many experts as a significant contribution to solve the problem. This will require an appropriate IT infrastructure as well as communication and interface standards, such as DICOM and suitable extensions, to allow data interchange between surgical system components in the OR.

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General motivation for standards in surgery

Because the OR and image-based interventional suites are the most cost-intensive sector in the hospital, the optimization of workflow processes has become of particular concern for healthcare providers, managers, and administrators. The understanding and management of workflows should become an integral part in the planning and implementation of complex digital infrastructures supporting diagnostic and interventional procedures [i.e. interventional radiology, minimal interventional surgery, computer assisted surgical procedures and image guided therapy (IGT)].
Examples of workflow and OR infrastructure-related issues are [2]:

1. Inefficient, ineffective and redundant processes
2. Inflexible "systems" of operation
3. Ergonomic deficiencies which hinder the workflow
4. Data (text, 1D, 2D, 3D, 4D) presentations not adequate, e.g. intraoperative and perioperative
5. Soft knowledge (info + action strategy) presentation not available
6. Scheduling (and tracking/RFIDing) of patients, personnel, operating rooms, equipment etc. not facilitated or coordinated (often the seeds of "busted" schedules)
7. Too long set up times for image-guided and robotic surgery
8. Lack of consistent working practices/guidelines or workflows (the hospital as a high risk and high velocity "production" environment is not scripted enough; there is too much diversity of behaviour)

9. No standardised integration of surgical devices and systems
10. Lack of quantified information on workflow and error handling
11. Communication across disciplines not adequate, e.g. between radiology and surgery.

Possible solutions are:

1. Improve situational awareness
2. Ensure availability of real-time information regarding (peri)operative processes to respond to best practices and variances in actual patient care
3. Develop standard interfaces to integrate seamlessly ICT and MT systems into the OR by taking account of the special needs of imaging and modelling tools within the surgical workflow.

This leads to the concept of an ICT supported OR which may be named surgical PACS (S-PACS) or more specifically a “Therapy Imaging and Model Management System” (TIMMS). A TIMMS should support the essential functions that enable and advance image, and in particular, patient model guided therapy. Within this concept, the image-centric world view of the classical PACS technology is complemented by an IT model-centric world view. Such a view is found in the special modelling needs of a number of modern surgical interventions as compared to the imaging intensive working mode of diagnostic radiology, for which PACS was originally conceptualised and developed.

A TIMMS provides the ICT-based infrastructure necessary for surgical/interventional workflow management of the modern digital operation room (DOR). The concept and design of a TIMMS is based on the assumption that significant improvement in the quality of patient care, as well as ergonomic and health-economic progress in the OR can only be achieved by means of an ICT infrastructure (based for example on a suitable DICOM extension) for data, image, information, model and tool communication. A proper design of a TIMMS, taking into account modern software engineering principles, will clarify the right position of interfaces and relevant standards for an SAS in general and their components specifically.

Therapy imaging and model management system and its interfaces

The standard which comes closest to provide the basis for the design of TIMMS interfaces is DICOM. Standardisation in the context of DICOM aims at providing support to fulfil a number of design criteria derived from software engineering principles when realising ICT systems for medical activities. Engineering of ICT systems for the assistance of surgical interventional activities implies the specification, design, implementation and testing of computer assisted surgery (CAS) or IGT systems. A number of components for such systems have been developed in academic and industrial settings and are applied in various surgical disciplines. In most cases, however, they are stand-alone systems with specific ad hoc propriety or vendor interfaces. They can be considered as islands of IT engines and repositories with varying degrees of modularization and interconnection.

Figure 1 shows abstraction of seven engines with associated repositories, which may form part of an SAS. Ideally they should be integrated by a suitable TIMMS infrastructure.

Considering software engineering principles, such a system needs to be designed to provide a highly modular

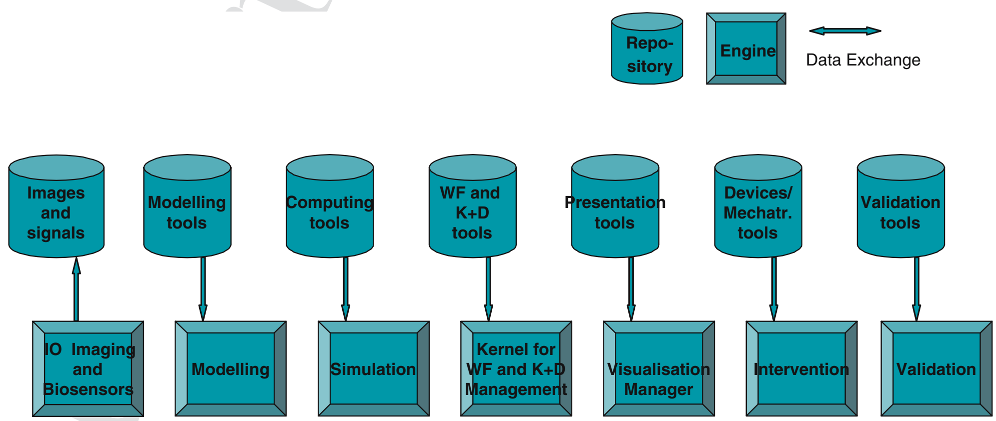

Fig. 1 Components of a Surgical Assist System

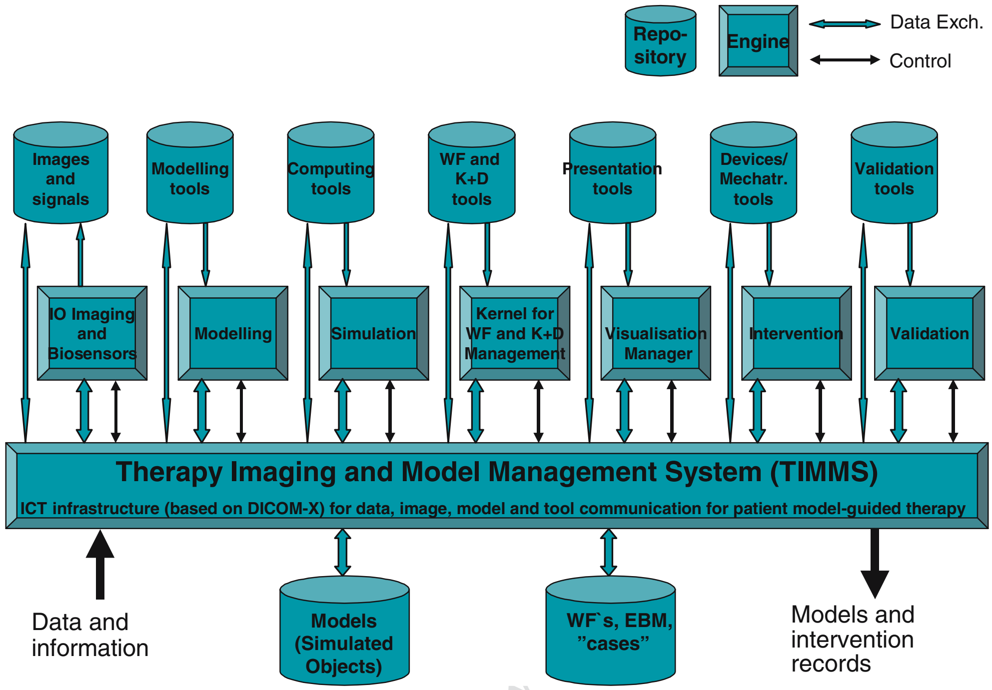

Fig. 2 Therapy Imaging and Model Management System (TIMMS)

structure. Modules may be defined on different granulation levels. A first list of components (e.g. high- and low-level modules) comprising engines and repositories of an SAS, which should be integrated by a TIMMS, is currently being compiled within the DICOM WG 24 "DICOM in Surgery" (http://www.medical.nema.org/).

Figure 2 shows a concept of a high-level generic modular structure of a surgical assist system. The high-level modules are abstracted from many specific CAS/IGT systems which have been developed in recent years. In general, a combination of these can be found in most R&D as well as commercial SAS systems. A central position in Fig. 2 is occupied by the "Kernel for workflow and knowledge and decision management". It provides the strategic intelligence for preoperative planning and intraoperative execution. Often this module or parts thereof is integrated into some of the other engines, as the need demands.

Low-level modules (LLMs) responsible for interfacing and communication are embedded in each of the engines and repositories given in Fig. 2. LLMs should be derived from a single or from a combination of several distinct surgical workflows. In the latter case, there are sometimes referred to as surgical integration profiles (SIPs). An LLM may be a surgical function or related activity using information objects, which ideally, may be part of different types of interventions. In order to identify LLMs which satisfy the previous requirements, it is of critical importance to select a representative set of surgical/interventional workflows which cover the domain of interest for standardisation of image and model-guided interventions. This selection should not only focus on the present state of the art of surgery, but also take into account future potential developments of patient image and model-guided interventions.

Modelling engine and repository of TIMMS

Standards relating to medical imaging and communication are well defined by DICOM and are an integral part of TIMMS. Most of the Image and Presentation States IODs, which are defined in DICOM, etc. are also relevant to surgery.

Models and associated management have not been considered in DICOM intensively, except through some work done in DICOM WG 07, WG 17 and WG 22. Modelling and simulation in surgery, however, are key functions for SAS's pre- and intraoperatively. Interfacing of tools which support these functions comprises a relatively new scope for DICOM.

To define model and simulation, a definition by Balci [3] may be used "A model is a representation or abstraction of something such as an entity, a system or an idea. Simulation is the act of experimenting with or exercising a model or a number of models under diverse objectives including acquisition, analysis and training." As indicated in Fig. 2, both modelling and simulation are critical components of an SAS, particularly for planning and intervention activities.

It will be a significant extension of current DICOM efforts to complement the image-centric view with a model-centric view for developing DICOM objects and services. Some IODs which make use of the concept of a model are listed in DICOM PS 3.3 as part of annex C 8.8. “radiotherapy modules”. Currently, approximately 40 modules have been specified for radiation therapy. They imply a limited spectrum of data types and data structures with different degrees of complexity, e.g. simple lists or tree structures. In the context of a TIMMS, a more comprehensive view on modelling than for example in RT, will be necessary. Not only as regards the modelling tools for generating different types of data structures, but also with respect to the modelling engine which carries out the modelling task. This engine will occupy a central position in the design of an SAS and the TIMMS infrastructure.

By default, the broader the spectrum of different types of interventional/surgical workflows which have to be considered for standard interfacing support, the more effort has to be given for designing appropriate IOD modules and services. The following list contains some examples of modelling tools and aspects, derived from different types of surgical workflows, which may have to be considered in DICOM WG 24:

- Geometric modelling including volume and surface representations
- Properties of cells and tissue
- Segmentation and reconstruction
- Biomechanics and damage
- Tissue growth
- Tissue shift
- Prosthesis modelling
- Fabrication model for custom prosthesis
- Properties of biomaterials
- Atlas-based anatomic modelling
- Template modelling
- FEM of medical devices and anatomic tissue
- Collision response strategies for constraint deformable objects
- Variety of virtual human models
- Lifelike physiology and anatomy
- Modelling of the biologic continuum
- Animated models
- Multiscale modelling
- Fusion/integration of data/images
- Registration between different models including patient, equipment and or
- Modelling of workflows
- ...

It will be one of the first tasks of DICOM WG 24 “DICOM in Surgery” to agree on a list of relevant models to be considered for DICOM IODs etc.

Steps towards a DICOM in surgery

It is recognised by the DICOM Working Group 24 “DICOM in Surgery”, which is concerned about standards and interfaces in the OR, that the specification, design and implementation of the LLMs and their associated objects and services are a demanding creative activity. It should be carried out on an international level comprising partners with competencies in ICT, CAS, IGT and minimal invasive interventions. Medical image processing and patient-specific modelling in particular, are important competencies required for the successful realization of an ICT-based infrastructure for the OR. In order to obtain a clearer view on where standards for surgery may need to be developed, all interfaces for data exchange and control communication, as indicated in Fig.2, need to be further examined and specified at an appropriate level of detail.

With this objective in mind, a detailed design and implementation work of a TIMMS-like OR infrastructure is in progress at the Innovation Center Computer Assisted Surgery (ICCAS), Leipzig and the University of Southern California (USC), Los Angeles. The work carried out by ICCAS in Leipzig forms the basis for designing interfaces for the seamless integration of different CAS engines and repository modules. Such modules are being developed in centres active in computer and robot-assisted interventions on a worldwide basis. The work carried out at USC focuses on specific software engineering aspects of information systems design, in particular to make certain that a TIMMS will guarantee fault-tolerance, security, reliability, disaster recovery and HIPAA compliance. It is hoped, that this work can be aligned to and complemented with projects carried out by other institutions, for example by CIMIT, TATRC and by members of the Japan Institute of CARS.

The knowledge gained in the process of interfacing different modules from a variety of institutions will be transferred to the DICOM Working Group 24 “DICOM in Surgery”. It is recognised that the competence for this type of work, i.e. ICT infrastructure developments for the OR and definition of appropriate standards is possessed by only few institutions (academic and industrial) in the world. To enable a close cooperation between these institutions, there is a need for:

1. Establishing a clinical user community from many surgical specialities which participates in the selection of characteristic surgical workflows and requirement specifications for planning and interventional tools.
2. Exchange of engineering expertise for TIMMS components, design and implementation work following a philosophy of an open architecture approach [4].
3. Development of low-level modules for interface design for a selected number of TIMMS engines and repositories following a philosophy of open source software (Bazaar model) [5].
4. Specification and design of a fault tolerant and HIPAA compliant infrastructure for the OR taking account for example of Grid technology [6].
5. Implementing prototype interfaces and testing on an international basis, to be carried out, for example, by a group which may be part of the Image Management Toolkit (ImTK) consortium [4].
6. Knowledge transfer of relevant results to DICOM WG 24 “DICOM in Surgery”.
7. Improve situational awareness through knowledge transfer to the healthcare community in general (suppliers, users and vendors), by means of workshops, tutorials, training sessions, conferences and appropriate publications.

In the process of realizing the above, it can be expected, that surgeons, interventional radiologists, hospital management as well as buyers and vendors of OR equipment will be made aware of the new business potentials made possible by a suitable DICOM standard. By using this standard, their business situation will improve not only by more streamlined workflows, but also by a safer and higher quality patient care.

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