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Outcome quality assessment by surgical process compliance measures in laparoscopic surgery

Sandra Schumann[a], Ulf Bühligen[b], Thomas Neumuth[a,*]

[a] Innovation Center Computer Assisted Surgery, Universität Leipzig, Semmelweisstr. 14, D-04103 Leipzig, Germany
[b] Department of Pediatric Surgery, University Medical Center, Liebigstr. 20a, D-04103 Leipzig, Germany

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ABSTRACT

Objective: The effective and efficient assessment, management, and evolution of surgical processes are intrinsic to excellent patient care. Hence, in addition to economic interests, the quality of the outcome is of great importance. Process benchmarking examines the compliance of an intraoperative surgical process to another process that is considered as best practice. The objective of this work is to assess the relationship between the course and the outcome of surgical processes of the study.
Materials and methods: By assessing 450 skill practices on rapid prototyping models in minimally invasive surgery training, we extracted descriptions of surgical processes and examined the hypothesis that a significant relationship exists between the course of a surgical process and the quality of its outcome.
Results: The results showed a significant correlation with Person correlation coefficients >0.05 between the quality of process outcome and process compliance for simple and complex suturing tasks in the study.
Conclusions: We conclude that high process compliance supports good quality outcomes and, therefore, excellent patient care. We also showed that a deviation from best training processes led to a decreased outcome quality. This is relevant for identifying requirements for surgical processes, for generating feedback for the surgeon with regard to human factors and for inducing changes in the workflow in order to improve the outcome quality.

1. Introduction

The development of the digital operating room is an ever-progressing topic [1,2], and the complexity of the systems and the concomitant challenges posed to surgeons and other medical and technical staff are rapidly increasing. To cope with these growing demands and to develop new and sensible systems, it is indispensable to assess, manage, and evolve the surgical processes that are intrinsic to patient care.

Within the management of surgical processes, in addition to economic interests, the outcome quality is of great importance. By means of evaluating key performance indicators, the outcome quality can be determined. Postoperative pain, patient satisfaction and length of stay are some of these key performance indicators [3,4].

To improve the outcome quality, standards and recommendations for performing surgical processes were developed [3,5]. Compliance with these standards is controlled by quality assurance measures. Process benchmarking to compare processes with the best-known processes, the best practices allow for quality improvements to be made [6].

The outcome quality is considered to be good if the process conforms to the standards, whereas deviation from the standards leads to decreased quality. Analysis of this common sense relationship for surgical process standards is the subject matter of this work.

Three main components were identified by Donabedian for evaluating the quality of medical care [3]: the quality of outcomes, the assessment of the examination of the care process itself and the setting in which the medical care takes place. Furthermore, he assessed all the fundamental principles of evaluating this matter, including data sources and data collection, empirical evidence, normative standards and measurement scales, and thereby pointed out the manifold problem areas that exist within the evaluation of the quality of medical care. One key issue of this work is the analysis of the correlation between the course of a surgical process and the outcome of the process. Hence, two of the three components identified by Donabedian will be directly interrelated.

* Corresponding author. Tel.: +49 341 97 12001; fax: +49 341 97 12009.
E-mail address: thomas.neumuth@medizin.uni-leipzig.de (T. Neumuth).

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The correlation between the distance measurements of surgical processes and the outcome quality allows for analysis of the following hypothesis: surgical processes that are at a greater distance from the best surgical process will lead to worse training outcomes.

Hammermeister et al. concluded that if all three elements of Donabedian's quality triad (processes, structures and outcomes) are used, then the improvement in outcome quality proceeds most efficiently and effectively [4]. The strengths and weaknesses of outcome-directed assessments and improvements to the quality of care were reviewed. Furthermore, a summary of the current knowledge of the linkages between outcomes and the processes and structures of care was given. In most reports, no details regarding these processes have been described. The relationships between processes of care and outcomes have only been reported regarding patient analysis.

Several authors have applied these measures to hospital business processes, in order to systematically improve hospital business processes [5], to relate process compliance with patient risk factors [7], or to improve quality management methods [8]. Furthermore, Schmutz and Manser [9] conducted a literature review to examine the impact of team process behaviors, including coordination, leadership, and communication, on clinical performance. They found strong effects indicating that team processes significantly influence clinical performance in most studies.

Within surgery research, there are many authors who have compared different surgical methods to the quality of outcome. These authors used technical methods, such as Mehndiratta et al. [10], who used a color-coded versus gray-scale DCE-MR imaging display, as well as clinical methods, such as Baccari et al. [11], who evaluated the outcome after laparoscopic repair of large incisional hernias. Teoh et al. [12] assessed several outcome measurements of a double-blinded, randomized, controlled trial of laparoscopic single-site access versus conventional 3-port appendectomy. Theodosopoulos et al. [13] analyzed surgical outcomes of 5000 neurosurgical procedures in a prospective study; the outcomes for neurosurgical treatments were reported based on point-of-care interactions recorded in the electronic medical record.

Nøhr [14] reviewed ten evaluation studies to investigate the extent to which these studies reflect the structure, process, and outcome of the conceptual framework. It was found that all of the evaluation studies focused on structure measures. Nøhr stated that evaluation studies must strive to also evaluate process and outcomes measures in order to create adequate computer programs to support medical decision-making.

In summary, the outcome quality in surgery and medical care is a very important research topic. Some authors have focused on processes or methods, while others have focused on the outcomes themselves. There are a few studies that related the flow and the outcome of processes; these studies, however, assessed this relationship on a qualitative level. To the best of our knowledge, there is no publication in the medical field that has assessed this relationship on a quantitative level. In this paper, we quantitatively assessed the relationship between the workflow and the outcome of surgical processes, resting upon data recorded in a mockup scenario. Furthermore, the workflow-analysis was based not just on some of the key points, but rather comprises all performed steps of work at a high level of granularity.

In Section 2, the study setup, clinical datasets, and distance measurements (Levenshtein distance and Adjacency distance) are introduced. The results of the correlation analysis for the selected surgical tasks are depicted in Section 3. Finally, the results are discussed, and an outlook for future work is provided in the discussion.

Table 1
Major work steps for the analysis during the study.

Step	Description
1	Data acquisition of the 450 different surgical processes with ordered activities
2	Blinded review of the outcomes of the 450 surgical processes with marks
3	Process grouping according to strategy and task
4	Identification of the best practice (process with best quality) in each group
5	Calculation and averaging of distance measures and the difference in quality between best practice and all other processes of each combination of strategy and task
6	Statistical analysis with Pearson correlation coefficients between the differences of quality and distance measures

2. Materials and methods

2.1. Study overview

The data sets consisted of surgical cases obtained during surgical training sessions in the context of pediatric surgery. The surgical processes were obtained by observation during training sessions in minimally invasive surgery in the Department of Pediatric Surgery of the University Medical Center Leipzig in 2011. Observation was supported by a software tool called the surgical workflow editor, which was validated in previous studies and showed a data acquisition accuracy of greater than 90% [15].

The main work steps for acquisition, preprocessing, and analysis of the data are shown in Table 1.

2.2. Clinical data acquisition

Surgical processes consist of surgical activities and can be modeled by means of formal and structured languages [16]. Thus, surgical process models (SPMs) are an abstract concept used to represent surgical processes analogous to business processes. SPMs are used to study, analyze, and optimize surgical processes, as well as to evaluate technical support systems in the operating room [17]. The aggregate of all work steps in a single surgical case (one patient or one surgical session within a training system) is referred to as an individual surgical process model (iSPM) [18]. Each activity in an iSPM is associated with a surgical work step in the underlying surgical process.

In each training session, members of two subject groups, one consisting of five novices and the other of five expert surgeons, each performed three different tasks (cutting, simple suturing, and complex suturing) by applying different surgical strategies. A sequence of work steps was required in order for a task to be performed. A Pelvitrainer [19], which represented the abdomen, and silicone manikins, on which several tasks were performed, was used (see Fig. 1). The surgical strategy variations involved applying different instrument types and incision points: single incision with angled laparoscopic instruments, triple incision with straight laparoscopic instruments, and triple incision with angled laparoscopic instruments. The subjects repeated each task and each incision/instrument combination five times. Thus, the evaluation data set contained 450 iSPMs and a total of approximately 28,600 activities.

The work steps of the 450 training sessions were recorded using the ICCAS surgical workflow editor [20] and contained a high level of information. Decomposition of the surgical processes into single surgical motions followed the hierarchical decomposition approach of MacKenzie et al. [21,22].