Ontology for assessment studies of human–computer-interaction in surgery

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ABSTRACT

Objective: New technologies improve modern medicine, but may result in unwanted consequences. Some occur due to inadequate human–computer-interactions (HCI). To assess these consequences, an investigation model was developed to facilitate the planning, implementation and documentation of studies for HCI in surgery.

Methods and material: The investigation model was formalized in Unified Modeling Language and implemented as an ontology. Four different top-level ontologies were compared: Object-Centered High-level Reference, Basic Formal Ontology, General Formal Ontology (GFO) and Descriptive Ontology for Linguistic and Cognitive Engineering, according to the three major requirements of the investigation model: the domain-specific view, the experimental scenario and the representation of fundamental relations. Furthermore, this article emphasizes the distinction of “information model” and “model of meaning” and shows the advantages of implementing the model in an ontology rather than in a database.

Results: The results of the comparison show that GFO fits the defined requirements adequately: the domain-specific view and the fundamental relations can be implemented directly, only the representation of the experimental scenario requires minor extensions. The other candidates require wide-ranging extensions, concerning at least one of the major implementation requirements. Therefore, the GFO was selected to realize an appropriate implementation of the developed investigation model. The ensuing development considered the concrete implementation of further model aspects and entities: sub-domains, space and time, processes, properties, relations and functions.

Conclusions: The investigation model and its ontological implementation provide a modular guideline for study planning, implementation and documentation within the area of HCI research in surgery. This guideline helps to navigate through the whole study process in the form of a kind of standard or good clinical practice, based on the involved foundational frameworks. Furthermore, it allows to acquire the structured description of the applied assessment methods within a certain surgical domain and to consider this information for own study design or to perform a comparison of different studies. The investigation model and the corresponding ontology can be used further to create new knowledge bases of HCI assessment in surgery.

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1. Introduction

Automation plays a key role in high performance activities such as surgery up to the point when the human and the machine form an inextricable unit [1,2]. Automation is defined as a device or system that accomplishes (partially or in full) a function that was
previously, or conceivably could be, carried out (partially or in full) by a human operator [3].

The use of automation in surgery aims to increase accuracy, efficiency, safety and flexibility of surgical tasks [4]. To reach this it is necessary to use human-centered automation concepts. At the same time the high level of complexity of automated processes creates new risks and dangers, especially within the high-risk field of surgery [5], and thus can lead to errors in the human–computer-interaction (HCI, alternatively called the man–computer-interaction or man–machine-interaction). HCI is the study which examines the interaction between humans and computers and to what extent computers are or are not developed for successful interaction with human beings [6].

The resulting demand is the mandatory investigation of HCI and the automation consequences in surgery, in order to avoid possible errors and to increase the quality of health care [7,8]. Geißler et al. [4] propose a review of the human-centered automation design in surgery and subdivide the possible consequences of automation to the user into eight categories, the so-called human performance consequences. The considerations of Geißler et al. emphasize that the area of HCI research in surgery is complex and requires wide-ranging assessment. Thus the adequate assessment requires approaches focusing especially on the domain of HCI in surgery. There is already a wide range of established approaches considering the HCI in general [3,9]. These approaches need comprehensive adoption to be applicable for the medical domain and further extension for the sub-domain of HCI in surgery. Other existing approaches consider either delimited automation fields [10] or exemplary several concrete automation consequences of automation only [11–13].

An adequate assessment approach has furthermore to comply with legal specifications concerning the investigation process in medicine, i.e. the Medical Device Act [14] and compulsory standards such as DIN EN ISO 14155 [15], DIN EN ISO 14971 [16] and IEC 62366 [17], etc. These legal specifications form the general normative framework for medical investigation.

In a previous work an investigation model for HCI in surgery was developed [18] to facilitate the planning and implementation processes of HCI studies. Furthermore it aimed at providing a framework for study documentation. This investigation model supports systematic assessment approaches for the HCI research, but its application requires an adequate formalization of the inherent concepts. Therefore this article examines three different formalization approaches: Unified Modeling Language (UML), database and ontology. The emphasis was put on assessment studies of HCI within the surgical domain, including clinical and preclinical (laboratory) research. This work shows further the advantages, as well as the limitations of the three formalization approaches and describes the application of an ontology to represent the investigation model. Furthermore, the formalizations provided by four top-level ontologies were compared. The main purpose of the presented work is to choose an adequate top-level ontology to formalize the developed investigation model and to apply this ontology to create an own ontology for HCI assessment studies in surgery.

2. Methods

2.1. Investigation model development

The representation of HCI assessment studies within the developed investigation model [19], proposed in this article, is based on two frameworks: the DIN EN ISO 14155 [15] standard and the framework of Jannin and Korb [10].

The DIN EN ISO 14155 standard for clinical investigation of medical devices for humans is a well-established legal framework within the clinical and scientific community. For the creation of the investigation model, in a first step the contents of the ISO standard were analyzed, and the comprised general requirements concerning the study planning, implementation and documentation were extracted. These requirements served as the basis for the investigation model. Within this development step the adaptation of the extracted contents was performed, with regard to the focus of the investigation model: the ISO standard is intended for general investigation of medical devices and thus focuses on the interaction between the medical devices and patients [15]. But the investigation model is intended for the investigation of HCI in surgery. In this manner the focus shifts to the interaction between the medical devices and surgeons (or other involved medical users). Therefore the extracted requirements were modified and extended accordingly. The choice of the ISO standard also provides an extensive benefit regarding the legal specification. Its requirements were reflected directly on the investigation model contents, thus the adequate application of the model should lead to compliance with legal requirements of the ISO standard and thus with the Medical Device Act.

The framework of Jannin and Korb [10] focuses on the image-guided interventions assessment based on a general hierarchy of levels with regard to assessed properties and study conditions. Jannin and Korb outline the complexity and diversity in image-guided assessment. The framework was chosen because it provides a systematic order considering global health technology assessment methods, which are generally applicable for the assessment of medical devices. Within the development of the investigation model the methodology of Jannin and Korb was used to perform a further specification of the ISO 14155 standard requirements and their extension. Furthermore, the inherent systematic order was used to derive the modular structure of the investigation model.

The developed investigation model is subdivided into six major modules representing the several aspects and processes of study planning, implementation and documentation methodology. The Fig. 1 shows and Table 1 describes the six major modules within the model. Each of these major modules is also subdivided into sub-modules (hierarchical structure). The sub-modules consist of numerous specification and methodical items. Whereas the major modules are more general and can be applied for studies outside the HCl assessment in surgery as well, inspired by the DIN EN ISO 14155 standard contents, the concrete items of the corresponding sub-modules explicitly focus on HCI research in surgery. I.e. the sub-module Product description contains the specification item Clinical procedures, which represents the surgical procedures concerning the HCI to assess. The provided numbering of the major modules indicates the order to follow because of the inherent dependence of its sub-modules on the sub-modules of the previous major modules. E.g. the specification of the Investigation design within the major module Study design specification is only possible after the definition of the study Objectives within the major module Preliminary considerations, or the Product description within the major module Product considerations deals with medical devices and the corresponding reference products to assess and their selection is dependent on the previous specification of the study Objectives and the Investigation design.

Fig. 2 shows exemplarily the contents of the sub-module Investigation design. The Investigation design considers the general specification for study implementation, consisting of Investigation design specification, the assessed Products and comparators, the study Subjects and the Experimental scenario. The item Investigation design specification focuses on the general specification of a HCI study and takes into account the investigation type specification, as a function of study objectives and hypotheses, and the corresponding endpoints of the study. Furthermore, the investigation design specifies the measures and procedures to assess, record
Fig. 1. Structure overview of the investigation model.

Fig. 2. Investigation model sub-module Investigation design.
Table 1
Short description of the six major modules of the investigation model.

<table>
<thead>
<tr>
<th>Module</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preliminary considerations</td>
<td>represent the initial specification of a study, including some general aspects</td>
</tr>
<tr>
<td>Study design specification</td>
<td>represents detailed specification of the investigation type and the related</td>
</tr>
<tr>
<td>Product considerations</td>
<td>summarize information concerning the medical devices being assessed and the</td>
</tr>
<tr>
<td>Adverse events and termination</td>
<td>consider concrete arrangements ordered by the ISO 14155 standard to ensure</td>
</tr>
<tr>
<td>Formal aspects</td>
<td>comprise different aspects building the formal framework of the investigation</td>
</tr>
<tr>
<td>Information for study subjects</td>
<td>consider summarized data describing the study which is relevant to inform the</td>
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and analyze the study parameters, to minimize possible bias, to address compromising factors and to replace the study subjects correctly, if necessary. Products and comparators comprise the general specification of all used medical devices within the study. The item Subjects describe the other side of HCl, concentrating on the specification of the study participants. Therefore, it contains the corresponding inclusion and exclusion criteria and the criteria for subject withdrawal. The specification of subjects further includes the number of trials and the corresponding duration for each subject, the procedures for recruiting and the corresponding duration of the investigation, the required minimal total number of subjects and the minimal and maximal number of subjects for multicenter studies. The item Experimental scenario focuses on the investigated tasks, the corresponding data sets related to these tasks and the environmental setting framing the experimental setup. Furthermore, the specification of the experimental scenario indicates the investigation level, based on a categorization introduced also within the framework of Jannin and Korb [10].

2.2. Formalization in Unified Modeling Language

For the later development steps (e.g. formalization within an ontology) it was necessary to formalize the whole investigation model structure initially using a standardized notation. Therefore, the model was formalized in the form of a Unified Modeling Language (UML) class diagram [20]. The latter was chosen because it provides a rather simple formalization approach and at the same time it contains a wide range of formalization concepts [21]. UML was solely used for the initial (preliminary) formalization of the investigation model, because of its limitations considered in the discussion chapter. The model structure (major sub-modules, sub-modules, etc.) was implemented in UML in the form of part-of-relations (aggregations, compositions, etc.). The dependencies representing the interrelations were represented in the form of dependencies of functions and their parameters. Optional and mandatory entities were categorized by adding the relevant multiplicity.

2.3. Validation with experts

The developed investigation model structure was evaluated in interviews with an interdisciplinary expert team. The team consists of five experts, representing the following five areas of expertise:

- Medicine (specialization in surgery);
- Informatics (specialization in computer assisted surgery);
- Psychology (specialization in human factors);
- Statistics and biometrics (specialization in medical trials);
- Industry (specialization in medical devices).

During the interviews, the six major modules (Fig. 1), the corresponding sub-modules and their items were discussed using a structured interview guideline. The emphasis of the included questions was put on the investigation model structure, the priority of the several model elements within HCl assessment studies in surgery and the immanent interrelations. The interview results were integrated into the investigation model, new elements were added and the structure was modified.

2.4. Requirement analysis

The modified investigation model requires an implementation within an ontology. This should provide a new tool for efficient evaluation and scalable comparison of HCl studies in surgery. Ontologies belong to the category of models of meaning [22] and therefore make a new form of representation and mapping of the information within the investigation model: the ontological approach combines the formalized investigation model contents with computer-based methods of representation and dynamic assessment algorithms, i.e. to detect possible clusters. A further benefit of an ontological approach is the reusability and sustainability of representing information. The research of HCl in surgery is a versatile process, which is closely linked to technical improvements and legal specifications. Therefore, the model implementation has to be modifiable to allow for possible new requirements (within the systems engineering process). Whereas the process is very extensive to adopt, or to restructure the investigation model itself, its ontological representation can be changed directly with operations of the corresponding meta-level ontology. Based on the open world assumption an ontology is a dynamic and flexible implementation approach. Furthermore, it enables data sharing and interoperability.

To accomplish an adequate ontological implementation of the investigation model, its intended use, the inherent contents and the results of the expert interviews were analyzed. Based on the methodical approach of Noy and McGuiness [23], which provides a development guideline for ontology designers, three major requirements were identified: realization of the domain-specific view, representation of the experimental scenario and implementation of the fundamental relations. To illustrate these major requirements, as well as for further considerations in this article, in the following, a

study example [24] will be introduced. It should be emphasized that this HCI assessment study is only an example used for the presented article. Within the performed analysis of major requirements further HCI assessment studies were considered [25,26]. The corresponding passages of the example texts are highlighted using italics:

Navigated Control (NC) is a navigation system for surgical milling operations [27], which provides a better overview, safer work environment and shorter milling time in comparison to the navigation-free milling. NC has two modes: the navigated controlled mode and the free mode. When the surgeon performs surgery, he activates the milling instrument with a foot pedal. In the navigated controlled mode the tracked milling instrument stops automatically, if the tip is outside the preoperatively predefined region of interest, even if activated with the foot pedal. In contrast, in the free mode the surgeon is not limited in the use of the milling instrument. These two modes can lead to mode errors: users misclassify the mode resulting in actions that are appropriate for the analysis of the assumed mode, but inappropriate for the true mode [4]. For example a switch error within the NC system occurs without the surgeon noticing this fact. A study was designed to investigate these mode errors. Within this study, a generic phantom was used, which represents several milling tasks near organs at risk. The test persons had to perform multiple milling tasks alternating between navigated controlled mode and free mode. They had to use a foot pedal for instrument activation and a second foot pedal for mode switch. Accordingly the current mode was displayed with software.

The next three sub-sections deal with the three requirements defined for an adequate ontological implementation of the investigation model. An adequate foundational ontology should meet these requirements as comprehensively as possible and thus provide appropriate concepts (types of ontological entities with the corresponding semantic approaches) for the adequate implementation of the investigation model.

2.4.1. Realization of the domain-specific view

The model focuses explicitly on the domain of automation assessment in surgery. Surgery is a special domain in medicine and the integration of automated procedures creates a new, more specific sub-domain, the domain of automation in surgery. To perform an adequate formalization, a domain-specific view is necessary: the investigation model requires an adequate representation of the domain-specific categories, considering the whole process of study planning, implementation and documentation. First of all, it is necessary to represent the general domain of HCI in surgery. Within the investigation model it is called the basic skin, because it states the whole focus of the project. But one needs to take into account that automation can differ in type and complexity [3]. Geißler et al. [4] propose in their review about HCI in surgery, as already mentioned, a concrete categorization of possible automation consequences, the eight human performance consequences, as shown in Table 2. Each of the eight categories requires its own sub-domain to categorize the HCI investigation in surgery according to the mentioned criteria. The resulting eight sub-domains are called the templates of the basic skin (further templates can be appended if required). Templates are abstract categories, which should provide a possibility of modular model adjustment (of its basic skin) to the different investigation types. Whereas the elements of the basic skin are more general, the templates expand their specification and add further sub-elements. Therefore an adequate representation within an ontology requires the implementation of the general domain of HCI in surgery (basic skin) and the corresponding eight human performance consequences (templates).

HCI studies assess either only one or several human performance consequences. In the second case a combination of corresponding templates is required. In the study example, the template Mode Error is considered. An adequate representation of this template requires further specification, then possible within the basic skin. Therefore, the general specification of the environmental setting of the experimental scenario within the basic skin should be additionally completed with the elements “phantom for the surgical procedure” (initialized by the phantom with structures at risk) and “simulation of unexpected mode switch” (initialized by the manipulation of the foot pedal), which belongs to the mode error template.

2.4.2. Representation of the experimental scenario

Representation of the experimental scenario plays an important role within the framework of HCI assessment and should be represented extensively within the ontology. The scenario description within the investigation model consists of three essential sub-elements: investigated tasks (or steps), data sets related to the tasks, and environmental settings. An adequate ontology has to provide appropriate concepts to implement for all these sub-elements. Investigated tasks include a list of surgical steps or procedures to be assessed within the experimental scenario. They are closely related to the clinical workflow and represent partially or in full the surgical context. HCI assessment studies can investigate the whole surgical procedure or only several steps, with regard to the intended (or unintended) use of medical devices or systems. Within the mode error study the investigated task is the milling task. Therefore, the inlay of the generic phantom contains different fields representing different surgical specialties (neurosurgery, orthopedic and maxillofacial surgery etc.), and the study subjects were instructed to mill these fields carefully without injuring the simulated structures at risk.

Data sets represent the data used to perform the investigated tasks. In other words, the experimental scenario is applied by the study subjects using dedicated data sets. These data sets can be anonymous physical phantoms, cadavers (human or animal), animals, clinical data sets, numerical simulations, etc. [10]. To provide a good trade-off between the clinical realism and the controllability, the considered study example uses a phantom, which is mainly based on computed tomography scans of real patients.

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Criteria for human performance consequences summarized by Geißler et al. [4].</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Criteria</strong></td>
<td><strong>Description</strong></td>
</tr>
<tr>
<td>Trust into automation</td>
<td>The belief of a person, that the machine will support him in an uncertain situation [28].</td>
</tr>
<tr>
<td>Commission error</td>
<td>Obey an automatically generated wrong advice without verification and although further contradictory statements are available [12].</td>
</tr>
<tr>
<td>Omission error</td>
<td>A lacking response on a system error, because the automation does not show this system error either [12].</td>
</tr>
<tr>
<td>Complicity</td>
<td>The lack of human control of a (automation) device; i.e. the operator is performing control more seldom than the automation of the system would require [3,29].</td>
</tr>
<tr>
<td>Loss of (manual) skills</td>
<td>With the introduction of new systems, the users may lose the ability to finish a task in the traditional way in case of a system’s failure. Further with automation systems some manual skills may not be taught to the novice surgeons [3].</td>
</tr>
<tr>
<td>Maintaining situation awareness</td>
<td>Situation awareness is the subjective representation of the work environment, i.e. the perception of the elements in the environment within a volume of time and space, the comprehension of their meaning and the projection of their status into the near future [3,30].</td>
</tr>
<tr>
<td>Cognitive workload</td>
<td>Evidence shows that automation can lead to decreasing or increasing mental workload [31].</td>
</tr>
<tr>
<td>Mode error</td>
<td>When a user misclassifies the mode resulting in action that are appropriate for the analysis of the assumed mode but inappropriate for the true mode [12].</td>
</tr>
</tbody>
</table>
Environmental settings within the investigation model comprise the assessment location and the involved environment. The assessment location describes where the experimental scenario will be performed: in a real operating room (OR), in a demonstrator OR (simulated OR) or in a laboratory. The involved environment represents the clinical and/or experimental environment used to perform the investigated tasks, i.e. the minimal OR set up with simulated environment. The mode error study was performed in a demonstrator OR with operating table and all the instruments and devices involved in the navigated milling task: the tracked milling instrument, the foot pedals and the navigation platform together with a position measurement system. Additionally, a control unit was integrated to simulate malfunctions of the mode switch. The assessed surgical procedures were performed in laboratory by medical students.

2.4.3. Implementation of the fundamental relations

Implementation of the fundamental relations is required to adequately represent the numerous entities of the investigation model, based on the considerations of the DIN EN ISO 14155 [15] standard and the framework of Jannin and Korb [10] (e.g. the detailed specification of the investigation design and the corresponding assessment methods). These entities are linked to different types of relations. First of all, there are fundamental relations to represent dependencies and part-of-relations to arrange the main structure. The whole process of investigation planning, implementation and documentation is subdivided into six sections regarding their chronology (Fig. 1), and every section contains additional elements, which are highly interrelated. Furthermore, there are entity-specific relations, e.g. relations describing the roles of the principle investigator, the sponsor and further involved persons, or the roles of clinicians and surgeons within the investigation process. These kinds of relations are directly associated with functions or responsibilities. An adequate ontology has to realize both approaches: the structural relations of the investigation model and the entity specific relations. To exemplify the latter, the relations within the mode error study example are considered: the involved surgeons had an entity-specific role (or responsibility) within the validation step of the generic phantom: they had to benchmark the realism of the milling task itself, the abrasion resistance of the material and the milling haptic [24].

2.5. Evaluation of existing ontologies

Ontologies are generally subdivided into four categories, based on their point of view or the intended task [33]: top-level ontologies, domain ontologies, task ontologies and application ontologies. The corresponding hierarchical structure representing the ontological derivation proposed by Guarino et al. is shown in Fig. 3.

Table 3

<table>
<thead>
<tr>
<th>Value</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completely fulfilled</td>
<td>The ontology provides concepts which can be applied directly (if so, only small adaptations are necessary).</td>
</tr>
<tr>
<td>Partially fulfilled</td>
<td>The ontology provides concepts which can be applied but with further extensions.</td>
</tr>
<tr>
<td>Insufficiently fulfilled</td>
<td>The ontology provides no applicable concepts, thus it is necessary to introduce new approaches and wide-ranging extensions.</td>
</tr>
</tbody>
</table>

Based on this categorical system and the proposed specification, the intended ontological representation of the investigation model belongs to domain ontologies, which should be derived from a more general and domain independent top-level ontology (foundational ontology). Therefore, different top-level ontologies were compared for possible implementation of the investigation model in the form of a separate domain ontology, reflecting the guideline of Noy and McGuinness [23] to consider existing ontologies.

Within the evaluation four top-level ontologies were compared, all of them already established within the scientific community [34,35]: Descriptive Ontology for Linguistic and Cognitive Engineering (DOLCE) [36], Basic Formal Ontology (BFO) [37], General Formal Ontology (GFO) [38–40], and Object-Centered High-level Reference (OCHRE) [41]. These ontologies were evaluated, regarding their advantages and limitations, in terms of the investigation model implementation, based on the previously defined major requirements. For each considered top-level ontology, its inherent semantic and syntax approaches were analyzed and, to the greatest possible extent, applied to implement the investigation model concepts adequately, based on the approach of Noy and McGuinness. To value this extent of the possible implementation a rating scale system was defined (see Table 3).

Based on the evaluation results, the best rated top-level ontology was chosen to implement the investigation model. This ontology was further analyzed and concrete implementation strategies were developed to represent the investigation model contents including sub-domains of HCI research in surgery, the relations of entities to space and time, the considered processes, and properties as well as further relations within the model. Together with the analysis of the major requirements, these strategies should provide a framework for an adequate implementation of the investigation model within the chosen top-level ontology.

3. Results

3.1. Evaluation results of considered top-level ontologies

This chapter gives an overview on the results of the performed evaluation of four top-level ontologies, based on the analysis of the syntactic structures of the corresponding ontologies and their assessment with regard to the previously defined major requirements of the investigation model.

3.1.1. Realization of the domain-specific view within the considered ontologies

DOLCE is an ontology of particulars and its domain of discourse is restricted to them. Particulars are entities that cannot have instances, e.g. in linguistic sciences the proper nouns are normally considered to refer to particulars [36]. Entities that can have instances are called particulars [36]. DOLCE uses universals to characterize and organize the particulars, but DOLCE provides no specification to characterize or organize the universals themselves.
With other words, the latter are not further discussed in DOLCE. Thus, the only way to integrate domain-specific categories is to use particulars, which are subdivided in endurants (particulars, which are wholly present at any time, i.e. all their parts are present), perdurants (particulars, which are only partly present at any time they are present, i.e. some of their proper parts may be not present), qualities and abstract entities. This approach is well applicable for the instantiation of investigation model elements. But the fundamental implementation of the basic skin and the derivation of templates demand adequate semantic concepts to represent the corresponding universals. The latter require wide-ranging adaptation and extension in DOLCE.

**BFO** is a bi-categorical foundational ontology. It is represented by two underlying ontologies: Snap and Span. Snap is an ontology of endurants, which provides a static view of the world (snapshots of the world). Snap represents things that exist at one point in time and the relations between them. It can be used to represent the (static) basic skin of the investigation model and to derive several templates. In contrast, Span is an ontology of perdurants, which represents the dynamic view of the world regarding entities, which persist in time and have temporal parts. It represents things that unfold in time such as processes (e.g. a surgical procedure and its various steps), in which elements from the Snap ontology participate. BFO completes the approach of particulars in DOLCE by adding predicates that correspond to formal universals. However, the performed analysis of Snap and Span has shown that the inherited ontological concepts and the corresponding semantic are more general and require further formalization of fundamental entities to be applicable for the intended domain-specific view.

**GFO** is a foundational ontology and can be applied to any field of interest of the world. It is, however, designed especially for medical, biological and biomedical applications. Hence, its concepts should provide a solid base for application to more restricted domains. The analysis has shown that GFO directly provides categories of domains and sub-domains, which may be linked to all top-level distinctions and categories (these are explicitly considered later). This approach can be directly used to realize the basic skin of the investigation model and to distinguish the several templates as well.

**OCHRE** is an ontology, which combines descriptive adequacy for common sense with formal economy in the basic categories and their axiomatization. OCHRE is an ontology of particulars, similarly to DOLCE. OCHRE is an object-centered ontology and there are no universals included in its domain. The analysis has shown, that OCHRE considers only non-repeatable attributes referred to as tropes (single characteristics of individuals). Similar to DOLCE, this kind of representation is applicable for the instantiation within the abstract categories only and not for the abstract categories representation, which is necessary for the intended domain-specific view, e.g. tropes can be used for the instantiation of the assessment methods for a concrete HCI study example. But it is not possible to apply tropes to represent the different categories of these methods (in terms of universals) without wide-ranging adaptation and extension in OCHRE.

### 3.1.2. Representation of the experimental scenario within the considered ontologies

**DOLCE** includes a fundamental distinction between endurant and perdurant entities. When one regards the whole scenario as being a dynamic sequence of tasks with a participating data set and an environmental setting, the main relation between endurants and perdurants in DOLCE can be applied for its representation: an endurant lives in time by participating in some perdurants. The investigated tasks or procedures can then be represented as perdurants and the participating entities as endurants. Furthermore, DOLCE provides space and time locations as special kinds of individual qualities, which e.g. can be used to specify the environmental setting. Based on these approaches, the experimental scenario can be adequately implemented using the semantic concepts in DOLCE.

**BFO** works basically similar to DOLCE. It considers continuants representing persisting entities that are self-identical through time. Continuants are then participating in occurrents (entities, which unfold over time and do not occur in full at any point of time). To represent the experimental scenario, the Snap-Span trans-ontological approach can be used. The experimental datasets and environmental settings are static sub-elements and can be realized in the form of endurants. The temporal context of the investigated workflow can be implemented within the dynamic Span ontology as a perduring entity. The surgical task can then be represented as a series of instantaneous snapshots linked with occurrents. Due to a large number of snapshots, this kind of representation makes the reasoning on the various events of the surgical task rather cumbersome. Finally, trans-ontological interrelations can be used to combine the several sub-elements into a common scenario.

**GFO** provides the material structures for scenario description. Together with the part-of relations in GFO it can be applied to compose the several experimental scenario sub-elements. Material structures in GFO are individuals that satisfy the following conditions: they are presentials (uniquely determined entities, which are exhibited by a continuant and bound to a time point), they occupy space, they are bearers of qualities, but they cannot be qualities of other entities, and they consist of an amount of substrates. On closer inspection all these requirements fit adequately for a concrete scenario, when its sub-elements are considered as individuals. These individuals are then participating in processes describing the investigated tasks (GFO approaches for process representation and the corresponding participation relationship are considered later in this article). However, to represent the scenario (as a whole) before the instantiation step of investigation model elements, an adequate concept for universals is required. Therefore, the GFO concepts should be further generalized and mapped to categories introducing a new scenario category. To specify sub-scenarios one can use in GFO the relation matpart for part–of relations between material structures.

**OCHRE** distinguishes between thick objects, representing the evanescent wholes, and thin objects, representing the cores of enduring characteristics. Thick objects can undergo changes consisting in successions. These successions and their sums are subclasses of perdurants, the so-called eventualities. They can be used to represent the investigated tasks within the experimental scenario. Then events in OCHRE can be used to represent the left and right boundaries of eventualities (the beginning and the end). For environmental setting and corresponding data sets, one has further to consider the coincidence concept within OCHRE: coincident entities are direct parts of the same thick object. Furthermore, a thick object can be enclosed in another. However, the analysis of OCHRE has shown that the mentioned approaches to represent the experimental scenario are only partially applicable because they are rather general. Therefore, an adequate implementation requires further formalization, as well as additional adequate concepts.

### 3.1.3. Implementation of the fundamental relations within the considered ontologies

**DOLCE** provides two kinds of parthood relations, based on the aforementioned distinction between endurants and perdurants: atemporal and time-indexed parthood. Atemporal parthood is applicable for the representation of parthood relations within the investigation model because most of the entities do not properly change in time. For dependencies within the investigation model DOLCE provides an approach, which supports the dependency...
relation and involves the notion of presence in time as well as modality. Therefore, there are two variants of dependency available: specific dependency and generic constant dependency. The former is defined for particulars and properties, whereas the latter defines properties only (dependency of all instances). Generic constant dependency also meets the requirements of structural dependencies within the model. For example, a study subject is generically constantly dependent on participating in a study. The analysis has shown that the representation of roles considered in the investigation model requires an adaptation of role concept provided by DOLCE regarding its general structure. The role concept in DOLCE can be transformed to social objects, divided into agentive and non-agentive. The proper can be used for roles of persons (investigator, clinician etc.). Non-agentive social objects can be applied to represent norms or regulatory within the investigation process.

**BFO** provides three types of relations: intra-ontological, trans-ontological and meta-ontological relations. The intra-ontological part-to-whole relation between entities within the Snap ontology can be used to represent the investigation model structure and the corresponding dependencies directly. The representation of roles requires more extensive adaptation. The different role types can be represented as substantial universals, which are instantiated by substantial entities. To link the roles with their functions, the latter can be represented by tropes with the inherence relation in BFO. The main focus of BFO, however, is on the realization of tropes, the concept of static roles as universals is, therefore, not stated. An adequate implementation of the fundamental relations of the investigation model in BFO requires wide-ranging extension of its semantic concepts.

**GFO** considers existential dependency and the fundamental part-of relation, which can be used to represent the structural relations. Part-of relations are subdivided into four categories regarding sets, time, processes, and the already mentioned material structures. For the intended approach of the investigation model this classification can be extended to the domain of HCI investigation in surgery. Furthermore, GFO provides three types for modeling roles: relational roles corresponding to the way in which an argument participates in some relation, processual roles corresponding to the manner in which a single participant behaves in some process and social roles corresponding to the involvement of a social object within some society. The semantic specification of these role types in GFO is directly applicable to represent the fundamental relations of the investigation model adequately. Additionally, the authors of GFO indicate that further types can be added.

**OCHRE** provides a basic foundation relation (reflexive and transitive) to implement the model structure. But there is no explicit approach available in OCHRE to implement the dependencies between the several elements of the investigation model. For an adequate representation of the fundamental structure these dependencies have to be completed in form of additional semantic concepts. For roles and functions OCHRE provides non-repeatable relations (relations which are characterized by the participating individuals). In contrast to formal relations like foundation (or partnership), there is a material property of thick objects, which is founded on thin objects of other thick objects, the so-called relational property. Generally this approach can be used to characterize element properties within the investigation model. But OCHRE aims for a formal economy in the basic categories and their axiomatization. Thus, the analysis has shown that these relationships are modest and require wide-ranging extensions.

### 3.1.4. Comparison results

The comparison of the considered top-level ontologies has shown (see **Table 4**) that GFO provides the most applicable concepts. Only the representation of the experimental scenario with its sub-elements requires further extensions. The domain-specific view and the fundamental relations of the investigation model can be implemented directly using the existing concepts of GFO.

#### 3.2. Application of GFO for investigation model formalization

GFO was selected to be the most applicable ontology for the implementation of the investigation model. This chapter describes how it can be used for the implementation of further aspects of the developed investigation model.

##### 3.2.1. Sub-domains

GFO supports the consideration of different domains and sub-domains. Every domain is determined by a set of objects, a set of views on these objects and a set of classification principles for these objects. Within the framework of the investigation model the domain of HCI investigation in surgery (basic skin) with corresponding elements is represented in the form of objects. The intended view corresponds to the planning, implementation and documentation process of a study. The sub-domains (templates) can then be specified similarly. The considered mode error study deals with the sub-domain of the mode error investigation. It focuses on the effects of different modes of a medical device on the surgeon. New objects have to be added representing further elements and the view is more specific too.

##### 3.2.2. Space and time

The investigation model includes several elements representing space and time boundaries [42]. Possible time-boundaries within the investigation model are e.g. the anticipated beginning and end of the study, or mandatory time limits for reporting of adverse events. GFO provides time boundaries for time entities (time-regions, time-points etc.) and furthermore the relation of coincidence between two time boundaries. It uses chronoids to handle time. Every chronoid has exactly two extremal and an infinite amount of inner time boundaries (time points). Whereas the extremal boundaries can be used for model elements based on time units (e.g. dates), the inner time boundaries and the coincidence concept can be applied for several parts of the experimental scenario or the subdivision of the investigated tasks. **Within the mode error study the test persons were advised to perform a milling task of different fields representing anatomical structures alternating in navigated controlled and free mode. This entire milling task is a process, which can be ontologically represented in form of a chronoid:**

**Chron(entire_milling_task):**

It has two extremal boundaries (left time boundary and right time boundary):

- lb(start_entire_milling_task, entire_milling_task);
- rb(complete_entire_milling_task, entire_milling_task);

The sequential milling of different fields subdivides the entire milling task into sub-tasks. Therefore, each of these sub-tasks can be represented in form of a new chronoid, i.e. the milling of the first two anatomical fields A and B:

- Chron(field_A_milling_task);
- Chron(field_B_milling_task);

The process of milling the field A is the first sub-process of the entire milling task. Therefore, it starts with the event **start_milling_task:**

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lb(start_milling_task, field_A_milling_task);
rb(complete_milling_task_A, field_A_milling_task);

The right time boundary of a previous sub-task coincides with the left time boundary of the following sub-task because it follows immediately. This coincidence specifies the temporal connection of the sub-task sequence:

lb(complete_milling_task_A, field_B_milling_task);
rb(complete_milling_task_B, field_B_milling_task);

To represent the duration one can adopt the measurement function for chronoids in GFO. I.e. it can be applied to measure the duration of the investigated task:

μ(entire_milling_task);

Analogous to chronoids, the concept of topoids in GFO can be applied to handle with space-focused entities. Topoids can be used within the investigation model representation to implement space-focused entities of the environmental setting (systems and devices included etc.). The simulated OR belongs to them:

Top(simulated_or);

GFO provides for chronoids and topoids the basic relations part-of, boundary-of and coincidence-of-boundaries. These basic relations are necessary to represent relationships between different spatial components of the environmental setting, i.e. one can represent the control room this way, which is part of the simulated OR:

Top(control_room);
part(control_room, simulated_or);

3.2.3. Processes

The investigation model framework should provide a guideline for study planning, implementation and documentation. Therefore, it contains numerous entities to represent the corresponding processes. For their ontological implementation, GFO provides processual complexes, processes and occurrences. Processual complexes are concrete individuals, temporally extended in a time region. The basic relation between temporal complexes and time is determined by the relation prtime(pr, tr), where tr is the time-region, which is associated with the processual complex pr. The set of processes is a proper subset of complexes. The projection prtime(p, c) of a process p to time c, which is uniquely determined. In the mode error study example the process of the milling task is functionally projected to the already mentioned chronoid milling task:

Proc(entire_milling_task_process);
prtime(entire_milling_task_process, entire_milling_task);

These concepts can be applied i.e. to describe the intended use of the investigated device, especially the intended workflow. For this purpose one can use the following three relations procpart(p,q), procmeet(p,q) and procdb(p,t,e):

procpart(p,q) represents that p is a processual part of the process q. Parts of processes are always processes themselves. Using this relation, the entire milling task process can be subdivided into sub-processes:

Proc(field_A_milling_task_process);
Proc(field_B_milling_task_process);
Proc(field_C_milling_task_process);
procpart(field_A_milling_task_process, entire_milling_task_process);
procpart(field_B_milling_task_process, entire_milling_task_process);
procpart(field_C_milling_task_process, entire_milling_task_process);

To represent the sequence of the different processes in GFO, the coincidence of the corresponding chronoids can be used. Time boundaries of chronoids represent two coinciding processes, when these processes are following one another immediately, there is a point in time where the first process ends and there is a point in time where the second process begins [38]. Additionally, the participation-relation for presentals can be used to assign medical devices to the different sub-tasks. I.e. the milling of the anatomical fields A and C have to be performed using the navigated control:

Participes(navigated_control, field_A_milling_task_process);
Participes(navigated_control, field_C_milling_task_process);

The processual part concept is adequate, i.e. in order to subdivide the whole intended use of the investigated device into sub-workflows: installation, preparation for use, intended (surgical) purpose, dismounting and storage of the investigated device. However, this subdivision requires the procmeet(p,q) relation as well (to denote the intended use as a sum of sub-processes).

procmeet(p,q) represents that two processes p and q meet, if their corresponding chronoids temporally meet. If there is a process r such that p, q are processual parts of r and the temporal projection of r is the mereological sum of the temporal projections of p and q, then r is the processual sum of p and q. This concept can be used to represent the sub-processes of the intended use as well as for the elements of the sub-workflows (the interlacement depends on the level of workflow granularity). I.e. the study participants have the opportunity to get familiar with the milling device before they start with the first milling task:

Proc(familiarization);
procmeet(familiarization, entire_milling_task_process);
procdb(p,t,e) represents processual boundaries: p is a process, t a time-point of the temporal extension of p, and e a presental at time-point t being the restriction of p to t. This relation is very useful, e.g. to assign events to processes, i.e. the milling of an anatomical field is completed:

procdb(field_A_milling_task_process, t1, field_A_completed);
Finally the time point t1 can be replaced by the right boundary of the process field_A_milling_task_process to specify its final result.

Occurrents represent entities in GFO, which depend on processes. Occurrents are relatively defined with respect to universals, and are classified into events, changes and histories. Events are entities that exhibit a certain behavior relative to a process (every event is a right boundary of a process). A process in GFO can have a starting event and a final event. For the model approach events (or event types) can be used, e.g. to represent boundaries of planning, implementation and documentation processes or possible adverse events, which can occur within the framework of a study. Alternatively, states can be integrated to represent checklists considered within the investigation process. Furthermore, GFO provides an adequate relation discharges(p1,e1, e2, u1, u2, u), to preserve the types of the changed entities, where e1 and e2 capture the pair of coincident process boundaries. This relation implies that p is a process, u1 and u2 are disjoint sub-universals of u, such that e1 and e2 instantiate u1 and u2, respectively. Whereas events belong to universals, changes are associated in GFO with material structures. Thus, they can be applied, e.g. for adverse device effects with regard to application assurance. Histories associate presentals at a certain time-point to a process. They can be used for data documentation within the investigation process, i.e. to specify time points to measure the attention of study subjects performing a milling task.

3.2.4. Properties

Investigation model elements need a specification through their properties, e.g. the device description is specified by the target user group, the intended use, the manufacturer, etc. Within the mode error study example the device description concerns the milling device and the corresponding navigation system. GFO provides properties as a subgroup of attributes. They represent certain characteristics and features. In GFO there are two general relations: hprop(x, y) relates a property bearer x to one of its properties y (with other words the property y inheres in its property bearer x); value(x, y) refers the value x to the property y. Furthermore, property universals of GFO can be used for characterizing several templates within
the investigation model to denote element categories and types. Then the property individuals can be used for template instantiation with properties of concrete studies (e.g. investigation type of a concrete study). For the integration of properties, value structures and measurement systems should be defined. These structures and measurement systems are partially given by the DIN EN ISO 14155 standard [15]. Properties are then associated with corresponding measurement systems and values (for property universals and property individuals). The appearance of values in groups (measurement systems) is a useful concept of GFO to represent value categories or value ranges within several model entities, e.g. there is a definite classification of possible investigation types.

3.2.5. Relations

It was already mentioned that for dependency representation in GFO the existential dependency can be used: an entity $x$ is ontologically dependent on $y$ when $x$ cannot exist unless $y$ exists. Whereas the existential dependency is not further discussed in GFO, the fundamental part-of-relation is subdivided into four categories: part-of relations for sets, for time, and space, for material structures and for processes. Part-of relation for sets $\text{part-set}(x,y)$ can be used e.g. for the specification of the experimental scenario (the sub-elements, especially the data sets):

- $\text{part-set}(\text{investigation\_tasks, experimental\_scenario})$;
- $\text{part-set}(\text{data\_sets, experimental\_scenario})$;
- $\text{part-set}(\text{environmental\_setting, experimental\_scenario})$.

Part-of relation for time $\text{part-t}(x,y)$ and space $\text{spart}(x,y)$: the first can be used e.g. for the recruiting procedures of study subjects, whereas the latter can be applied e.g. for experimental environment. These relations are related to the context of chronoids and topoids presented in the previous section.

Part-of relation for material structures $\text{matpart}(x,y)$ can be used e.g. to represent the experimental environment or the structure of the investigated medical device, e.g. the navigation system assessed within the mode error study consisting of the several components:

- $\text{matpart}(\text{foot\_pedal\_panel, navigation\_system})$;
- $\text{matpart}(\text{mode\_error\_unit, navigation\_system})$.

Part-of relation for processes $\text{procpart}(x,y)$ have a wide range of application within the model, e.g. for the specification of tasks. The application of this relation was already presented in the previous section.

One has further to consider that part-of relations are subdivided into forbidden, optional and mandatory categories. Schulz et al. [43,44] discuss this distinction explicitly with regard to biomedical structures. For the adequate ontological implementation of the model it will be necessary to integrate a similar distinction for the HCI investigation.

3.2.6. Functions

Investigation planning, its implementation and documentation contain several entities, which are directly associated with functions, i.e. there are different persons involved in a study, who are associated with different functions.

GFO provides the definition of functions using the quadruple $\text{Label}(F)$ (set of labels of function $F$), $\text{Req}(F)$ (requirements of $F$), $\text{Goal}(F)$ (goal of $F$) and $\text{Fitem}(F)$ (functional item of $F$). Labels are natural language expressions, whereas the other three elements are function determinants. In GFO one distinguishes between functions and realizations. The latter specify how something is achieved. For the model, the concept of function can be implemented intuitively. A further approach in GFO is the introduction of intended-has-functions. These have a normative character, which allows for assigning such functions to entities that possess them as multifunctions. Within the framework of the model, these concepts can also be used with another interpretation: intended-has-functions for the intended purpose of the investigated medical device.

4. Discussion

The developed investigation model was initially implemented using the UML class diagram. To show the limits of this approach it is necessary to consider the distinction of "information model" and "model of meaning" [22]. In this context the authors take further into account the possible implementation of the investigation model using a database and discuss its limits as well. In conclusion, the advantages of implementing the investigation model in an ontology are shown.

4.1. Implementation using UML

Within its development process, the investigation model was implemented in the form of an UML class diagram. This approach has shown fundamental limitations. There was no possibility to implement the whole relational structure of the investigation model directly concerning the roles and responsibilities of several elements. For every kind of relation, which is not a general part-of-relation or a simple dependency, the definition of a new relational class was required. This resulted in a complex and unclear investigation model structure. Thus, this approach complicated the understanding of the investigation model itself (i.e. by experts) and its core elements, and hindered the possibility of using the model for automatic reasoning.

The mentioned limitations are based on the distinction of information model and model of meaning [22]. Rector et al. discussed that the information model is a model of data structures. It specifies and tests the validity of data structures (conformity with their specification etc.). In contrast, the model of meaning is a model of our conceptualization of the considered context. It represents our understanding of the world (or rather of its parts). An UML class diagram can only represent the information model, it does not support concepts for representation of our view on the world conceptualization.

4.2. Implementation using database

One has further to take into account that the implementation of the investigation model as a database faces similar problems and limitations. This kind of implementation has a better expressivity than a UML class diagram, but a database is an information model as well [22], independent from the used database language. These generic limitations of the possible database implementation will be discussed in the following section with regard to the three major requirements of the investigation model.

4.2.1. Domain-specific view implementation

To integrate the domain–specific view of the investigation model within a database, one can use the database views [45]. A database view is a computed or collated virtual database derived from the physical (stored) database. Its function is to hide, filter or process information, and thus to structure the database description, so it is adapted to user requirements. But the use of database views is fraught with generic problems, especially in the case of data change. The virtual database (view) considers only a subset of the physical database entries. When an operation is applied within the virtual database (to add, change or delete a data entry) and it is consistent in this virtual database, the consistency of the physical database is not guaranteed, because the user can only consider the information given by the virtual database. This general problem is independent from the database language.
4.2.2. Representation of the experimental scenario

To implement the different aspects of an experimental scenario within a database, the standard part-of-relations can be used. To specify these further (i.e. to distinguish in temporal and spatial part-of relations), these relations should be implemented in the form of elements with attributes indicating the corresponding relation type (derivation of sub-relations). A similar alternative to this approach is to leverage the types of entities participating in the corresponding relation. Both implementation approaches are possible, but they result in fundamental limitations concerning the proper discussion of the distinction between model of information and model of meaning [22].

4.2.3. Implementation of the fundamental relations

Similar to the experimental scenario representation it is necessary to clearly distinguish the different relation types when a database is used. Therefore, the relations should be represented in form of database elements with their own attributes. But the domain of HCI assessment in surgery is dynamic. Every change concerning the possible relation participants (or rather the possible types of relation participants) requires subsequent modification of the corresponding domain/ration of this relation to avoid data inconsistency. Therefore, the representation of relations as database elements is not directly applicable and requires further approaches to perform the respective domain/ration modifications.

4.3. Implementation using ontology

The limitations of the information model make a model of meaning necessary, typically in the form of an ontology. An adequate ontology should provide concepts (or classes) to represent the investigation model and fulfill the major requirements. In other words, it should provide a form of generic knowledge background needed for the investigation of HCI in surgery to solve both the limitations within the realized (initial) formalization in UML and the generic limitations of the database implementation.

The ontological implementation of the developed model provides a new form of representation. It represents our understanding of an HCI assessment study in surgery and transfers the model of meaning describing the interrelationships within the study planning, implementation and documentation process in a more formal and understandable way. In addition, the ontological implementation considers the ISO 14155 standard and integrates the established normative concepts for medical device assessment studies.

Furthermore, the ontological representation allows for reusability of the included investigation concepts: the HCI investigation is a versatile process which is closely linked to technical improvements. Therefore, the model has to be modifiable to allow for possible new requirements (within the systems engineering process). In this manner, new templates can be derived, e.g. concerning other investigation requirements or legal specifications. Whereas the process is very extensive to adopt or restructure the model itself (to adopt or extend it for new requirements), its ontological representation can be changed directly with operations of the corresponding top-level ontology. The ontological representation intends to be open to further different expansions and modifications (i.e. it did not exclude the possibility to add new categories). Furthermore, it enables data sharing and interoperability. The investigation model is based on the open world assumption and in this way it is dynamic and flexible.

The representation of the investigation model requires adequate ontological concepts. Four different top-level ontologies were considered, which are well established within the scientific community: DOLCE, GFO, BFO and OCHRE. The use of these ontologies opens up the access to the investigation model. Within the comparison of the considered top-level ontologies, three major requirements were defined, concerning the domain-specific view, the experimental scenario and the fundamental relations within the model. All reviewed ontologies have shown their own potential for a possible model implementation, but the immanent ontological concepts are different in type and scope, which either results in benefits or in disadvantages to fit the major requirements. DOLCE focuses on individuals and contains no universal concepts in its domain, thus several abstract categories within the investigation model cannot be implemented. OCHRE does not include universals in its domain either. It is an ontology of particulars, even more so than DOLCE [36]. OCHRE is characterized by a formal economy of the basic categories, thus it is insufficently applicable for the investigation model. The fundamental distinction in BFO between the static and the dynamic view of the world aims at a new (interesting) structural representation, but it is rather a general meta-ontological framework and requires further wide-ranging formalization. GFO provides the most applicable concepts, which can be applied directly or with few adaptations.

5. Conclusions

The investigation model and its ontological implementation provide a modular guideline for study planning, implementation and documentation within the area of HCI research in surgery with the main focus on possible automation consequences. This guideline helps to navigate through the whole study process regarding the different templates in the form of a kind of standard or good clinical practice. Furthermore, it enables the documentation of study results in a well-structured way.

The ontological implementation of the investigation model provides a new approach of structured information representation of HCI assessment studies. This approach forms the basis of developing new applications e.g. to acquire the structured description of the applied assessment methods within a certain surgical domain and to consider this information for the design of new studies efficiently. In the next steps the ontological implementation can be used further to develop applications for study comparison. Furthermore, the investigation model and the corresponding ontology can be used in future work to create new knowledge bases of HCI assessment in surgery. In addition, it is conceivable to expand the model concepts and to derive new ontological templates for other clinical and research application areas.

Ethical standards

The authors of this article declare that within the presented development of the investigation model (including the corresponding formalization and implementation) no human or animal studies were performed, thus no human or animal study subjects were involved. The mentioned study examples in this article are only references to other publications. These referenced studies are not at all parts of the development process.

Conflict of interest

The authors declare that they have no conflict of interest.

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