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A concept ideation framework for medical device design

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ABSTRACT

Medical device design is a challenging process, often requiring collaboration between medical and engineering domain experts. This collaboration can be best institutionalized through systematic knowledge transfer between the two domains coupled with effective knowledge management throughout the design innovation process. Toward this goal, we present the development of a semantic framework for medical device design that unifies a large medical ontology with detailed engineering functional models along with the repository of design innovation information contained in the US Patent Database. As part of our development, existing medical, engineering, and patent document ontologies were modified and interlinked to create a comprehensive medical device innovation and design tool with appropriate properties and semantic relations to facilitate knowledge capture, enrich existing knowledge, and enable effective knowledge reuse for different scenarios. The result is a Concept Ideation Framework for Medical Device Design (CIFMeDD). Key features of the resulting framework include function-based searching and automated inter-domain reasoning to uniquely enable identification of functionally similar procedures, tools, and inventions from multiple domains based on simple semantic searches. The significance and usefulness of the resulting framework for aiding in conceptual design and innovation in the medical realm are explored via two case studies examining medical device design problems.

1. Introduction

Engineering design is a demanding process, requiring both ingenuity and a methodical approach to collecting, interpreting, and using information. The specific field of medical device design, however, poses an additional number of challenges for engineering design. Medical environments involve a complex interaction between regulations, a highly diverse user base, a multitude of established, essential procedures, and a vast body of underlying science [1], all of which must be factored into any medical device design process. Adding to this challenge, engineering design teams are typically not composed of medical domain experts and, therefore, often lack detailed knowledge of potential users or use environments [2]. Clinical and biological contexts often drive both customer and design requirements, and similarly, can impose significant restrictions on the set of viable engineering solutions. A failure to fully account for this could negatively impact a design by limiting a team's ability to anticipate and adapt to challenges during the development process. Therefore, given the complexity of medical environments and the need to design within this context, it would be advantageous if existing engineering tools and methods could be adapted to seamlessly include medical knowledge in the design innovation process. However, despite the well understood contribution of clinical perspectives and knowledge to design [3], no formal information framework exists to facilitate the integration of medical knowledge and an understanding of clinical practice and environments into the design process.

1.1. Engineering design

Several methods are used to systematically represent engineering design problems and to generate new concepts based on a designer's understanding of the design space. One such method, functional decomposition, has been shown to be effective to break down a product or system's operation into a series of basic functional steps involving the flows of information, energy, and materials between them [4]. This enables the designer to carefully formulate the design problem in terms of a minimal set of functional behaviors and associated flows [5]. If a well-defined, controlled terminology such as the functional basis [6] is employed in the design process, the resulting model can also aid in design knowledge storage and reuse and form the basis for later design decisions. Thus, the design process based on functional basis models can yield a number of benefits for the designer, including a systematic procedure for the generation of concepts, an established foundation for comparisons of products and concepts, and

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methodical archival of design rationales for the full lifetime of the product's use [5,6–8]. For these reasons the functional basis representation has proven to be a well-established vocabulary for describing functional behaviors in engineering design in non-ambiguous terms [8]. However, since the flows and functions used are nonspecific in terms of how they are implemented in this representation, considerable effort is needed to move from a functional diagram to an actual design. Alternative techniques such as morphological methods also rely on functional decomposition but focus on sub-problems rather than sub-functions. Once a problem is broken into a set of sufficiently simple sub-problems, a designer can then brainstorm potential solutions to each sub-problem. These solutions are then combined with one another until a feasible solution is reached. While potentially useful, the individual solutions rely heavily on the designer's own knowledge base and time constraints, and so potential design applications might be excluded unnecessarily [5]. The Theory of Inventive Problem Solving [9] approaches design by analyzing design functionality and attributes in terms of design contradictions and a prescribed set of inventive principles by which to address them based on how previous designs resolved these contradictions. This seeks to mitigate, eliminate, or harness design contradictions to create a more "ideal" product. However, the prescribed principles are very general and thus not necessarily useful in a specific field [5].

1.2. Research in medical device design

While there no formal framework for incorporating medical knowledge into the engineering design process, a body of research has explored different aspects of the medical device design process in detail. A review by Shah et al. concluded from current literature that the involvement of clinicians and potential device users in development and evaluation is costly in terms of resources but is ultimately critical to the functional and economic success of a medical product [3]. Additional research has analyzed and compared the effectiveness of methods of collecting information from clinical personnel or other potential device users [1]. Ergonomics and human factors have also been investigated from both a safety and usability standpoint. These studies include analyses of design features in purchasing at hospitals [10] and interview-based recommendations of how to ensure the safety of a design [2]. However, current work has not adequately addressed how to effectively use this feedback once it is obtained. Ultimately, these studies provide useful guidance for a designer but not necessarily a pathway to effectively integrate user inputs and knowledge into the design process.

The medical design process has also been looked at in terms of the underlying methodology. Studies have outlined the device development process in the US [11] and Europe [12], but these are representations of the process and only provide a description of the steps involved in medical device design. This does not necessarily extend to a method of how to best overcome design challenges. Other researchers have focused the design process from a strategic, methods-centric, and decision making perspective. Their studies include investigative development strategies among industry members [13], a stage-gate model for use in industry, in which decisions to continue are based off a series of criterion at each gate [14], and a concurrent engineering approach in which product attributes common in medical device design are used to evaluate a product throughout the design process [15]. A limited body of work has assessed the regulatory aspect of medical device design, and how design affects regulatory approval [16]. While these design approaches are potentially useful from project management and assessment standpoints, they are also largely descriptive and do not address how design tasks are accomplished or how medical environments affect the design process. Thus, many aspects of design process have been investigated in detail, but there exists no framework at present to better utilize information for innovation and effective engineering design in the medical device realm. This shortfall points to the need for medical knowledge management.

1.3. Biomedical knowledge management

In the biological sciences, there has been widespread use of semantic web technologies to create large number of ontologies mapping out various sub-domains of the field. Because of the nature of ontologies and semantic web, these are in theory naturally interoperable, and they can be easily interlinked to one another to create hybrid knowledge frameworks [17,18]. Moreover, a number of consortiums such as OBO Foundry [19] and the National Center for Bioontology [20] now exist to collect, curate, and freely distribute the growing number of ontologies of biology and medicine. Though individual ontologies are often isolated to individual fields of study, the existence of multiple large repositories of domain specific knowledge represents a potent opportunity to create useful frameworks for interdisciplinary fields like medicine and potentially medical device design.

Healthcare and medicine, in particular, have made extensive use of knowledge management frameworks for use in education [21], mapping medical properties over time [22], data integration in clinical trials [23], and electronic health records among other applications [24]. In the medical community the development of a number of ontologies in related sciences has fueled the creation of a number of large, curated, healthcare knowledge frameworks. There has been a concerted effort to overcome compatibility issues between frameworks, culminating in projects like the National Library of Medicine's Universal Medical Language System [25] to integrate disparate medical terminologies under a single semantic framework. The UMLS acts as a top level semantic network and thesaurus to mitigate conflicts between independently developed medical ontologies so as to overcome barriers to integration of dispersed medical systems. Within this overarching framework, there are a number of ontologies for different aspects of medicine. One such is the recently added Systematized Nomenclature of Medicine Clinical Terminology (SNOMED CT) [26], an internationally maintained ontology for use in electronic health records that attempts to encompass all aspects of medical practice, such as pathologies, procedures, and social concepts, in a single class hierarchy.

1.4. Engineering knowledge management

A body of research has produced semantic frameworks for use in engineering design. In the area of functional modeling, an ontological framework has been used to create taxonomies of functions for the purpose of creating and documenting functional models and design reasoning. Past efforts have included efforts such as the Functional Behavior Representation Language FBRL [27], an ontology of functional concepts [28], and the functional basis ontology (FBO) [6,7], which is simply a formal semantic representation of the functional basis described above. While the potential uses for these ontologies are quite broad, few tools exist to expand their use into specific areas such as medical device design. The functional basis ontology has however been shown to be sufficient to describe biological processes. A number of authors have described individual uses of the functional basis ontology to describe biological phenomena for use in biomimetic design [29,30]. Other work has examined methods of associating biologically meaningful keywords with engineering functions within the functional basis ontology [31]. This is potentially useful from an understanding standpoint, but overall past research in this area