Journal of Biomedical Informatics 55 (2015) 218–230

Contents lists available at ScienceDirect

Journal of Biomedical Informatics

journal homepage: www.elsevier.com/locate/yjbin

A concept ideation framework for medical device design

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ARTICLE INFO

Article history:
Received 15 December 2014
Received in revised form 23 April 2015
Accepted 24 April 2015
Available online 6 May 2015

Keywords:
Medical device design
Engineering design
Function based design
Ontology
Semantic knowledge management

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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http://dx.doi.org/10.1016/j.jbi.2015.04.010
1532-0464/

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 has not sought to unify the functional basis with a large biomedical knowledge base for the purpose of design. As a result, these applications exist in isolation, and biomedical knowledge cannot be used for automatic reasoning with these functional models.

In the general area of engineering design, our Center for e-Design research team has created several ontological representations of the design process, especially in the areas of engineering analysis, optimization and decision making [32–37]. Recently, McPherson et al. developed a semantic framework in the area of biosimulation to interconnect the engineering ontologies in the e-Design framework with repositories of biological simulations and databases of biomaterials [38]. While this study showed both the feasibility and potential usefulness of cross domain ontologies using engineering and biological concepts, no similar effort has been undertaken to unify engineering and medical ontologies to aid in the medical device design process.

1.5. Objective and scope

In this paper, we present an ontological framework for managing medical knowledge and incorporating it into the early phases of engineering design. The framework was developed to accomplish three distinct but interrelated tasks aimed at improving the design and innovation process. First, it aims to unify a high level understanding of medical concepts, practices, and resources with detailed engineering descriptions of their functional characteristics, as well as a repository of similarly annotated design solutions. Second, it seeks to facilitate automated reasoning both within each domain, as well as across domains, enabling high level inferences not immediately available in any individual field. Finally, this work intends to create a basis for identifying analogous solutions to an engineering problem in a domain agnostic way, so that a designer can incorporate methods and innovations made in other medical specialties or entirely different fields into a medical device design.

The result is the Concept Ideation Framework for Medical Device Design (CIFMeDD), a unified framework incorporating large medical reference ontologies in combination with functional basis models, and a suite of ontologies of patent information. Rather than create new knowledge models of existing domains, the ontology principles of extensibility and interoperability are used to re-use existing medical, engineering, and intellectual property ontologies to develop a novel concept ideation framework for the early phases of engineering design. The following sections detail the steps to construct a framework for integrating information relating to medical science and practice into the early phases of design, focusing on the enhancement of existing functional basis tools with medical information and a repository of design solutions. The usefulness of the resulting framework is demonstrated with the aid of two ongoing medical design case studies.

2. Materials and methods

As noted in Section 1.5, ontologies modeling engineering, medical, and patent knowledge individually exist at least in part, and they serve as the backbone for this integrated semantic medical device framework. These ontologies are modified from their original state and integrated together to allow seamless transfer of information between the different domains and to facilitate identification of new insights and automated inter-domain reasoning.

2.1. Obtaining ontologies from online repositories

The selected ontologies were obtained via reputable online repositories and imported into Protégé version 4.3 using the software's built in import functions and plugins. OWL 2 was chosen for CIFMeDD due to its rich vocabulary for constructing relations between classes, complex object properties, and ability to construct links between properties, all of which were deemed necessary to meet CIFMeDD's reasoning requirements. SNOMED CT was obtained from The National Library of Medicine's Unified Medical Language System website[1], which contains download links for SNOMED CT with a registration. SNOMED CT contains over 400,000 classes relating to all aspects of the medical lexicon. As this ontology contains several hierarchies that are outside the scope of this work, only the relevant sections of SNOMED CT was used as the basis in the development of CIFMeDD. Utilization of a non-complete version of SNOMED CT also dramatically reduces the requirements needed to classify SNOMED with the built in Reasoner. Selected classes and their properties were extracted using Protégé 4.3's built in Refactor tab, which allows a user to extract parts of an ontology based on referenced classes and properties. For this work, the class hierarchies relating to Procedures, Physical Objects, Pharmaceutical and Biological Products, Body Structures, Observable Entities, and Environments and Geographic Locations were retained. Qualifier Value class hierarchy was also kept intact, as this is used throughout SNOMED CT to provide definitions and more detailed knowledge and context to other classes. In addition, the original SNOMED CT Object properties were preserved, including the ***Procedure Device***, ***Direct Substance***, ***Route of Administration***, ***Associated Morphology*** and ***Method*** properties among others. For this work the SNOMED_CT top level classes and the bulk of their child classes were saved into a local OWL ontology and imported into CIFMeDD.

The functional basis ontology was chosen to represent engineering knowledge in CIFMeDD. It was chosen due to its versatility for use in multiple domains and strictly limited vocabulary, both of which lend them to a cross domain application such as CIFMeDD. Specifically, the ability to use a limited and identical terminology regardless of the application or knowledge domain lends is a powerful tool for linking different domains, making cross-domain inferences, and formulating meaningful queries. The functional basis ontology (FBO) was acquired via the UMass Center for e-Design website[2] and was imported directly into Protégé from its online source. Patents and patent metadata were subsequently included using the Patent Upper Level Ontology (PULO), Patent Structure Ontology (PSO) and Patent Metadata Ontology (PMO) [39]. The PULO, PMO, and PSO were obtained from Multimedia Knowledge and Social Media Analytics Laboratory website[3]. This suite of ontologies includes classes and properties to categorize and relate patent data, metadata, and document elements, as well as an upper level ontology to link the patent data and metadata domains to one another.

2.2. Modification of ontologies

2.2.1. Modification of SNOMED CT

While the preexisting object properties in SNOMED CT relate **Procedure**s, **Substance**s, **Body Structure**s, and a number of related qualifiers in the medical domain, additional properties were added to SNOMED CT to enable a more detailed understanding of each procedure from an engineering perspective. The goal was to provide a means to input more detailed information about the design environment of interest, and the entities that interact with it. The class structure acquired from SNOMED CT was modified with additional properties to allow a more meaningful description of medical environments and to model knowledge in a way that is useful for engineering design (Table 1). This was done to enable

[1] http://www.nlm.nih.gov/research/umls/Snomed/us_edition.html.
[2] http://edesign.ecs.umass.edu/ontologies/Framework2.0/FunctionalModel2.0.owl.
[3] http://mklab.iti.gr/.

Table 1
Object properties added to SNOMED CT.

Property	Type	Domain	Range	Inverse	Description
hasSubProcedure	Transitive	Procedure	Procedure	***SubProcedureOf***	A property that indicates that a Procedure has a sub step that is some other procedure
usedInProcedure		Physical object	Procedure		Used to connect a Physical_Object used to complete some procedure to said procedure
hasSubcomponent	Transitive	Physical object	Physical object	***subComponentOf***	Used to assign subcomponents to a larger physical structure. For example, a part of some larger machine
hasEnvironment		Procedure	Environment	***isEnvironmentOf***	Indicates the location in which some procedure is performed
hasUser		Physical_object	Person or pharmaceutical/ biologic product	***userOf***	Assigns a specific user or class of user to an object or tool
performedOn		Procedure	–		Indicates the recipient of some procedure, such as a patient
performedBy		Procedure	–	***performs***	Indicates the individual(s) that performs some procedure
hasEquipment		Environment	Physical_object		Denotes the presence of some physical object in an Environment.
hasPersonnel		Environment	Person	***personnelOfEnvironment***	Indicates that a person is present in some environment
containsSubstance		Environment	Substance		Indicates that an environment contains a substance

SNOMED CT concepts to be related to one another so as to accomplish two distinct goals: first, to model information relating to medical environments and personnel; and then to decompose complex medical concepts into simpler ones that can be used as building blocks to construct a detailed functional understanding. A series of properties were also defined to serve as the inverses of SNOMED CT's preexisting properties to expand the possible class expressions in the new framework.

Properties were added to more accurately model knowledge in the Procedure class, which can be anything from a surgical operation to some administrative task that relates to a medical environment. The **Procedure** members were first linked to an individual or group of individuals carries out the procedure via a newly defined ***performedBy*** property. Using the concepts organized under SNOMED CT's **Person** class and subclass found under the **Social Context** hierarchy, this property can be used to define a potential product's user base, or individuals with whom it will interact. Where a **Procedure** involves interaction with a recipient of the procedure, an additional link or links was introduced using a newly defined ***performedOn*** procedure. Beyond linking with specific personnel, properties were also used to define the **Procedure** in terms of simpler sub-steps using the ***hasSubProcedure*** property. For example, a more complicated operation might begin with administration of anesthesia, or something as simple as an incision. Additional medical information is represented using the newly defined ***hasEnvironment*** property. The ***hasEnvironment*** property can be used to indicate an operational environment. For example, a procedure might take place in a hospital environment versus a home environment, or in one that is sterile versus non-sterile. Environment specific factors are further mapped out using additional property relations to describe environmental factors relevant to a design. People and objects available in the environment are added via newly defined ***hasPersonnel*** and ***hasEquipment*** properties, so as to document available resources in any given area.

Qualifier Value subclasses are also used in tandem with other classes to better define an environment. For example the ***hasSterility*** property uses subclasses of the **Qualifier Value** class tree can be used to indicate whether an environment or object is sterile, as indicated by the declaration "***hasSterility*** some **'Sterile (qualifier value)'**". This property was used to define three new classes: **Sterile_Object**, a subclass of the **Physical_Object** class, **Sterile_Procedure** a subclass of **Procedure**, and **'Sterile Environment'**, an existing class within SNOMED CT. These were each defined as equivalent to their parent class and having the ***hasSterility*** property asserted as some member of the **True** class, with further assertions placed on the **Sterile_Procedure** class to stipulate a sterile operating environment and tools. Additional properties could also be added to further define environmental factors, or to indicate uncertainty about some operating environment.

A series of property chains were added to the framework to further integrate the new object properties, and allow inferences of useful information not directly asserted in CIF-MEDD (Table 2). The Hermit Reasoner in Protégé [40] was used to evaluate first order logic based on the newly created properties and property chains to make automated inference on the framework. Hermit is an open source OWL 2 compatible Reasoner, capable of determining whether an ontology is consistent. It was selected for this application, as it has built in support for rules and property chains and has been used to successfully classify SNOMED CT previously [41].

The property chains shown in Table 2 ensure that environments and procedures are populated with a more complete set of relevant design data by inferring the presence of people and objects. Property chain 1 ensures that devices used in sub-procedures are recognized as being used in their parent procedure, such as a scalpel being used in a procedure involving an incision. Chain 2 by comparison can help to conclude that the surgeon performing the procedure is also in the operating room. Chain 3 allows the

Table 2
Property chains for automated reasoning on modified SNOMED CT ontology. The terms an parenthesis denote the domains and ranges of each property in the chain.

Num	Property Chain	Explanation
1	usedInProcedure o isSubprocedureOf → usedInProcedure (Physical_object, Procedure) o (Procedure, Procedure) → (Physical Object, Procedure)	If a sub-step of some procedure uses an object, then the procedure must use that object
2	isEnvironmentOf o performedBy → hasPersonnel (Environment, Procedure) o (Procedure, Person) → (Environment, Person)	The person that performs a procedure must be present in the environment where that procedure occurs
3	isEnvironmentOf o Procedure Device → hasEquipment, (Environment, Procedure) o (Procedure, Physical object) → (Environment, Physical object)	An object used in a procedure must be present in the environment where that procedure occurs
4	isEnvironmentOf o 'Using substance (attribute)' → containsSubstance (Environment, Procedure) o (Procedure, Substance) → (Environment, Substance)	Substances used in a procedure are present in that procedure's environment

Reasoner to conclude that environments where procedures take place must contain the procedure equipment, meaning that the scalpel in the previous example must be in the place where the procedure is performed. Chain 4 employs similar logic to place substances in the relevant environment.

2.2.2. Modification of patent ontologies

The patent ontologies were only slightly modified from their original release. First, the ***hasSection*** property was redefined to be transitive, so that a hierarchy of sections can be used to break down an entire patent document. For example, a claims section might be broken down into a series of sections for each level of claims and sub-claims. Because the property is transitive, each of the sub claims would be inferred to be subsections of the parent claim, even if nested in multiple levels. This means that the entire hierarchy can be accessed via a query relatively easily via a defined claims section of a patent. The ***SubCategory*** property was also defined as transitive for similar reasons. A new top level class **Invention** was added to accommodate the design concepts disclosed in patents. This is done so as to draw a distinction between the existing objects found in the **'Physical Object'** classes in SNOMED CT and object concepts described in the patent documents.

2.2.3. Linking of medical ontologies with functional basis ontology

Cross domain object properties and basic logical rules were used to link SNOMED CT to the FBO. This allows medical concepts to be closely related to an engineering functional model, and to specifically associate operations, functions, and flows with the specific concepts that they represent in existing procedures or products. The initial link between a medical concept and a corresponding functional model was created based on the object property ***hasFunctionalModel*** and its inverse ***isFunctionalModelOf***, as well as with the ***submodel*** property and its newly defined inverse ***isSubmodelOf***. With the two ontologies merged in a single framework, other properties added during modification are also used to more intimately associate the two domains. Toward this end, the domains and ranges of several properties were modified to include concepts from both knowledge domains. First, the ***Input_source*** domain was extended to include the **Physical_Object** and **Body_Structure** classes so as to allow flows entering a model from sources outside the model system to have their origin explicitly stated. Subsequently, a new object property ***representedByFlow*** and its inverse (***flowRepresenting***) were also defined to allow various physical things, such as objects, body parts, and substances to be tied to a specific flow in a functional model. For example, the SNOMED CT **Substance** class was redefined as a being a subclass of a **Thing** and ***representedByFlow*** some **Material_Flow** and the Physical object class was redefined as SubClassOf Thing and ***representedByFlow*** some **Object_Flow** using this property. A specific **Substance** might in be tied to a more specific material, such as a **Liquid_flow**. Similar subclass axioms were used to further define the **Body Structure** and **Observable entity** classes as well. For example, a **Signal_flow** might be tied to a specific physiological signal, such as a heartbeat, found in the **Observable entity**. Similarly, additional property chains were subsequently added to allow meaningful automated reasoning using SNOMED CT and the FBO classes and class axioms (Table 3).

Property chain 5 links models of an object's subcomponents to one another. For example, a scalpel has a handle and blade, each of which has functions of their own. Based on this breakdown, chain 5 infers that the individual function of the handle and blade are both sub-functions of the model of the entire scalpel. Chain 6 uses similar logic to associate a model of a procedure with its sub-steps. This linking of models is extended by property chains 7, 8, 9 and 10 which associates object functions, substance functions, methods, and treatment routes of administration with procedures that use them. For example a procedure might use a scalpel to access some tissue, at which point some known surgical method is used to perform an operation via a route of administration. If these area all associated with functional models, the Reasoner will directly link to those models via the ***submodel*** property.

2.2.4. Linking with patent ontologies

The patent ontologies were linked to the functional and medical ontologies with new classes and properties, with the goal of linking each patent to a functional description of the invention disclosed in the patent and patent elements to aspects of that invention. A new property ***discloses*** and its inverse ***disclosedBy*** were added to link members of the newly defined **Invention** class to the patent documents that describe them. Inventions were then linked to the medical realm with the property ***hasEmbodiment*** and its inverse ***isEmbodimentOf***, and they were used to indicate instances where an invention disclosed in a patent document is in part or in whole embodied by some existing entity.

The patent ontologies were further linked to the FBO via the ***hasFunctionalModel*** property and its inverse ***isFunctionalModelOf***, which were extended to members of the

Table 3
Property chains used for inferences across SNOMED CT and FBO.

Num	Property chain[a]	Explanation
5	isFunctionalModelOf o hasSubcomponent o hasFunctionalModel → submodel (Functional_model, Physical_object) o (Physical object, Physical object) o (Physical object, Functional_model or Operation) → (Functional_model, Functional_model or Operation)	The model of an object has, as its submodels, the models of its subcomponents
6	isFunctionalModelOf o hasSubProcedure o hasFunctionalModel → submodel (Functional_model, Procedure) o (Procedure, Functional_model or Operation) → (Functional_model, Functional_model or Operation)	If a procedure has a subprocedure that has a functional model, then the base procedure's functional model has the subprocedure's model as a submodel
7	isFunctionalModelOf o 'Using object (attribute)' o hasFunctionalModel → submodel (Functional_model, Procedure) o (Procedure, Physical object) o (Physical object, Functional_model or Operation) → (Functional_model, Functional_model or Operation)	If a procedure has a functional model, A, and uses an object with some second functional model, B, then model B is a sub model of model A
8	isFunctionalModelOf o 'Using Substance (attribute)' o hasFunctionalModel → submodel (Functional model, Procedure) o (Procedure o Substance) o (Substance, Functional model or Operation → (Functional_model, Functional model or Operation)	When a substance with some known function is used in a procedure, that substance's function is a sub model of the procedure's functional model
9	isFunctionalModelOf o 'Method (attribute)' o hasFunctionalModel → submodel (Functional model, Procedure) o (Procedure, Qualifier value) o (Method, Functional_model or Operation) → (Functional_model, Functional_model or Operation)	A functional model of a medical method is a submodel of the model of any procedure using that method
10	isFunctionalModelOf o 'Route of administration (attribute)' o hasFunctionalModel → submodel (Functional model, Procedure) o (Procedure, Qualifier value) o (Qualifier value, Functional model or Operation) → (Functional model, Functional model or Operation)	A functional model of a medical treatment approach is a submodel of the model of any procedure using that method

[a] To be technically correct SNOMED CT property restrictions must use Role Groups [42]. Since these chains do not require the use of multiple, grouped SNOMED CT restrictions we have omitted mention of role groups for the sake of clarity.

Invention class and patent classifications. The first connection allows a high level functional model to be assigned to a design concept disclosed in an invention, while the second allows simple functional behaviors to be ascribed to entire classes of patent, such as assigning a model with a **Constrain_function** to a class of fasteners. The newly defined ***implies_function*** property allows a functional model's operations and sub operations to be attributed to specific patent sections mapped with PSO and PULO. Thus, if a claim or section describes some operation mode for the disclosed invention, the model of that invention's functions can be linked to the relevant document elements. With the aid of this new property, along with the PULO and PSOs existing properties ***hasSection***, a patent document structure can be mapped to a functional model of the invention it discloses.

The newly defined properties linking the modified SNOMED CT and FBO framework to the patent ontologies were then incorporated into a series of property chain relations designed to allow automatic inferences using knowledge from across domains (Table 4).

Property chain 11 links **Physical_Object** members to the **Invention** concept they embody using patent documents. For example, if a tool used in a procedure were covered by some patent, then the invention disclosed by that patent would be linked via chain 11 to the object used in the procedure. Chain 12 would then allow the Hermit Reasoner to infer that the object will behave in the manner described in the patent and represented via a functional model of the **Invention**. Property chain 13 allows a general model associated with a patent class to be linked to all inventions disclosed in patents of that class. For example, a patent classification might contain inventions that separate sediment from a liquid. Property chain 13 allows the framework to recognize that all of the inventions disclosed in patents classified that way will have that basic functionality. Property chain 14 simply allows this same inference to be made about its subclasses. Chains 15 and 16 allow aspects of an **Invention**'s functional model to be attributed to specific document elements, such as claims or descriptions. This links the functional understanding to specific document elements. For example, if a patent claim notes a linear actuator, a functional model of that actuator can be attributed to the invention and vice versa.

2.3. Case studies

The ontologies successfully classified without issue using the Hermit Reasoner [40] in Protégé 4.3 indicating that the CIFMeDD is internally consistent. CIFMeDD's usability and usefulness in medical knowledge capture from an engineering design perspective was then explored with the aid of two case studies. A subset of SNOMED CT classes was further defined with additional information using the functional basis and the newly defined object properties. In addition, a number of specific patent classes and patents were defined using similar methods. These included patents relating to each specific medical field considered in the case studies, several patent classes, and links to relevant physical objects and medical concepts.

The first case study focuses on medical knowledge capture, the application of automated reasoning to make useful inferences on this information, and CIFMeDD's ability to render knowledge useful for medical device design applications. The focus of the case study is fat grafting, a cosmetic surgical procedure that uses human fat as a volume filler. The second focuses on the ability to identify functionally similar designs for use in design ideation and exploration of a design space. For this application, the more mature field of bariatric surgeries was used to demonstrate potential uses in an engineering design context.

3. Results

3.1. Case Study 1: Fat grafting surgery

Fat grafting is a cosmetic surgical procedure used to achieve desirable aesthetic effects by adding volume to surface features, resulting in changes to contours. The procedure offers favorable biocompatibility properties achieved using autologous tissue and is appealing to patients in part due to the necessity of liposuction to obtain tissue [43]. The procedure is performed in a sterile operating room and has three primary steps: a tissue harvest performed using liposuction, a processing step in which desirable cells (adipocytes, stem cells) are separated from blood, cellular debris, and other waste, and a tissue grafting step in which isolated tissue is injected into a selected site [44]. The tissue harvest, which is the focus of this case study, is essentially liposuction. The patient is anesthetized and a small incision is made at the harvest site. A mixture of saline and local anesthetic is used to swell the harvest site, constrict blood vessels, and partially break down connective tissue structures that enclose the desired cells. A sharp cannula is then connected to a vacuum source and used to shear the weakened tissue, detaching lobules which are then evacuated to a collection vessel via a negative vacuum pressure [45]. In this case study we focus on CIFMeDD's ability to capture medical knowledge, link it to functional models, and make cross domain

Table 4
Property chains used for inferences utilization the patent ontologies, SNOMED CT, and FBO.

Num	Property chain	Explanation
11	disclosedBy o isPatentOf → hasEmbodiment (Invention, Patent) o (Patent, Physical object) → (Invention, Physical object)	An object (or its subcomponent) that has a patent is an embodiment of the invention disclosed in that patent
12	isFunctionalModelOf o hasEmbodiment → isFunctionalModelOf (Functional model, Invention) o (Invention, Physical object) → (Functional model, Physical object)	An embodiment of an invention with some functional model will also have that functional model
13	isFunctionalModelOf o classifiedPatent o discloses → isFunctionalModelOf (Functional model, Patent class) o (Patent class, Patent) o (Patent, Invention) → (Functional model, Invention)	The invention disclosed in a patent of a class with some functional characteristics expressed in a functional model has those functional characteristics
14	isFunctionalModelOf **o** subCategory → isFunctionalModelOf (Functional model, Patent class) o (Patent class, Patent class) → (Functional model, Patent class)	Subcategories of patent categories with defined functional models have the same functional top level model as their parent category
15	impliedBy o sectionOf o discloses o hasFunctionalModel → submodel (Functional Model, Section) o (Section, Patent) o (Patent, Functional model or Operation) → (Functional model, Functional model or Operation)	The functional model implied by a patent section is a model of the invention it discloses
16	impliedBy o hasSubsection o impliesFunction → submodel (Functional model, Section) o (Section, Section) o (Section, Functional model or Operation) → (Functional model, Functional model or Operation)	Functional models implied by document subsections are submodels of the model that is described in their parent section

inferences that enrich a designer's understanding of the procedure. The operation is performed by a plastic surgeon, and typical patients include both healthy individuals and breast cancer survivors seeking a breast reconstruction via fat grafting [44]. As this procedure was not represented in any significant detail in SNOMED CT, a breakdown of the procedure with a focus on the tissue a harvesting was created using subclass axioms in Protégé (Fig. 1).

In addition to the asserted properties, the property chains and class definitions mentioned in the Section 2 above mean the Reasoner is able to make a number of inferences. First, as noted in Fig. 1, procedure must be performed using a sterile technique, as indicated by the ***hasSterility*** property. A design engineer, however, would likely be more interested in having this information directly related to a procedure being considered. Using the definitions of a sterile procedure and its asserted subclass axioms ('***Using device (attribute)***' only **Sterile_Object** and ***hasEnvironment*** only '**Sterile environment (environment)**'), the Reasoner concludes that the operating environment and surgical devices must also be sterile. This is effectively a constraint placed on any device that interacts with the procedure, which is something a design engineer would need to be aware of early in the design process. Similarly, as declared in the framework, the functional models linked to each aspect of the procedure are not themselves connected with the asserted class axioms. Instead, they are constructed separately and linked to procedures and methods used throughout SNOMED CT. However, the property chain relations 5, 6 and 7 allow automatic inference of the relations between procedures and sub procedures and models and sub models (Fig. 2).

In this case, the intricacies of the tissue harvest are directly linked to the detailed information connected to its liposuction sub-step. The liposuction procedure is more complex, with multiple sub-operations, each defined with their own functional model in their subclass axioms. The same is true of the other sub-steps. This capability opens up considerable potential for easy and effective knowledge re-use. If various classes of basic medical procedure are defined in terms of a set of simple functional models, one can easily construct the skeleton of a model for a more complicated procedure by simply breaking it down into its most basic series of steps and their associated methods. This means that any knowledge defined in the framework can very easily be reused to define medical procedures or concepts that share attributes.

The functional effects of drug substances are also accounted for using a combination of the properties listed in Table 2. As noted at the beginning of this case study, a tumescent containing a local anesthetic is infused into the harvest site during the surgery, swelling tissue and causing blood vessels to constrict as a result of the anesthetic [44]. This constricting effect is important from a procedural perspective and from the perspective of a designer in this space. Constricted vessels limit blood loss, leading to a less contaminated aspirate being removed by liposuction and preventing serious trauma for larger grafts. The functional model of the introduction of the tumescent into the body is shown in Fig. 3.

As can be seen in Fig. 3, the delivery of the tumescent is modeled as a **Delivery of anesthetic** procedure, which is in turn defined as ***Using substance (attribute***) some member of the **Local anesthetic** class. The **Local Anesthetic** class is itself defined as a subclass of its parent class and as having some functional model corresponding to its chemical effects. This model can in turn be linked to various body structures such as blood vessels to further model the specific details of the procedure. This knowledge, the necessary elements are present to infer via property chain 9 that the functional model of the local anesthetic contained in the tumescent is inferred to be part of the procedure model created in this case study.

With a detailed model of the procedure created and enriched automated inferences, the groundwork is laid to make additional inferences about the fat grafting procedure considered in this case study. For example, the model can be used to study if it might be useful to know of other procedures or devices that perform functions that are similar to those achieved via a procedure or device used in the fat grafting operation. In the case of liposuction, a simplistic model might note that a negative pressure is supplied to a tool that is used to cut tissue, and that this pressure aids in the removal of the tissue from the body cavity (Fig. 4).

Here, one aspect of the procedure that might be of interest to a designer is an alternative method of removing tissue from the

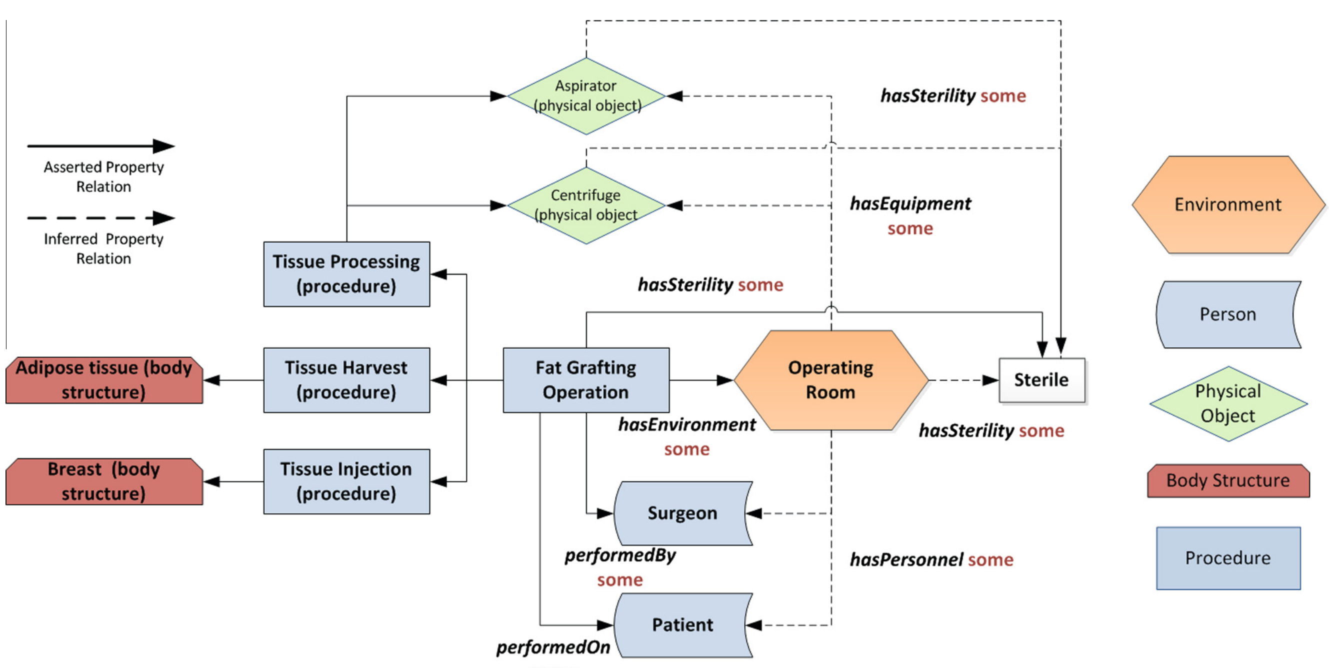

Fig. 1. Breakdown of a fat tissue harvest as entered in the ontology.

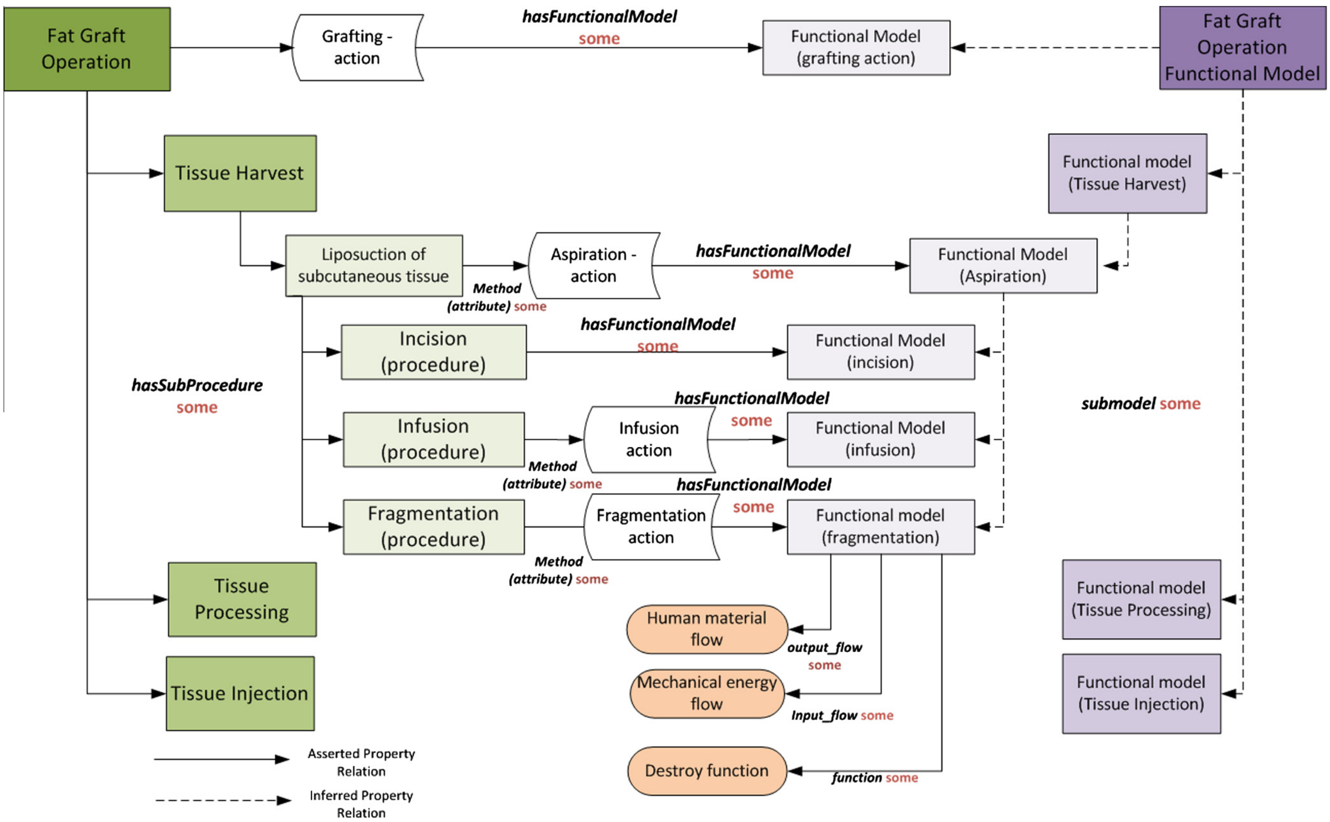

Fig. 2. Fat grafting procedures (left) and their respective functional models (right). The relations between functional models are inferred by the Reasoner based on the relation between procedures using chain 9.

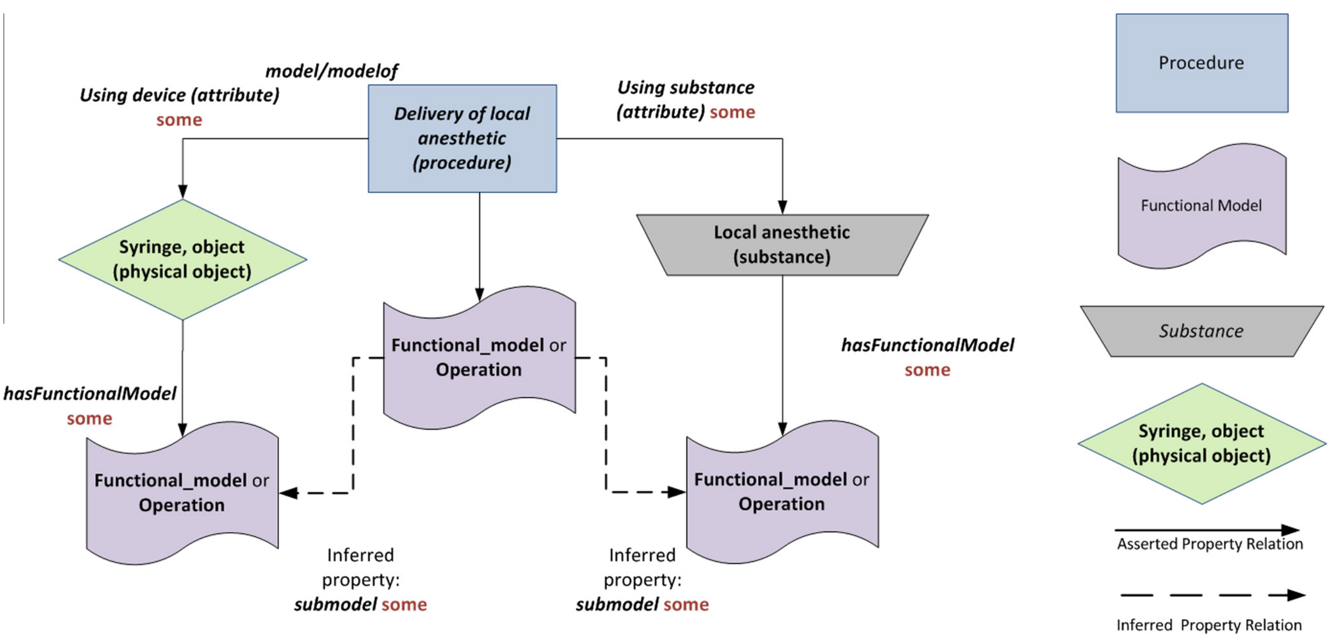

Fig. 3. Administration of tumescent using a syringe as represented in the framework. Based on the functional model of the syringe in this procedure and the substance delivered, the framework infers the effects of the tumescent are part of the model.

body. Liposuction requires the use of a large and often very expensive aspirator to supply the negative pressure (i.e. vacuum) that is used to remove tissues from the body. A potential area of interest for a designer would be to learn about alternative methods of generating a negative pressure that are already used in other medical applications. They could either be a different procedure or device. Without an integrated medical device design tool such as CIFMeDD, even relatively straightforward information such as this could be difficult to obtain. However, with the aid of our CIFMeDD, designers can systematically find, study, analyze and compare

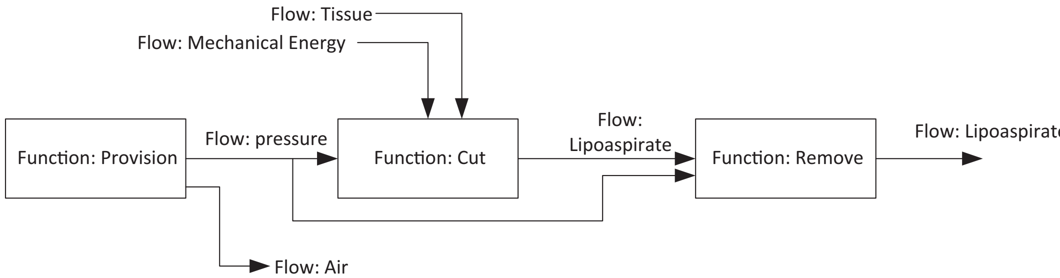

Fig. 4. A simplified functional model of a liposuction procedure.

similar designs. In this case, the key functionality can be recognized as the supply of pressure, as represented in the liposuction model with the **Provision_function**, and the **output_flow** of a **Pneumatic_flow** (pressure). Because tools in the framework can be associated with functional models of their operation, concepts with similar functional models can be identified using a description logic (DL) query in Protégé 4's DL Query tab. As can be seen in the reasoning presented in Fig. 5 below, the linked domains allow a simple query to conclude that **Physical Object**s of the class **Syringe, device (physical object)** are also able to supply pressure.

Thus, the framework facilitates identification of functionally equivalent sets of objects. Similarly, by removing these class restrictions, one could also search the entire database without regard for field of use, thus providing a potential for finding even non-obvious uses of existing technology.

3.1.1. Discussion of results

From the Fat Grafting Case study, it can be seen that CIFMeDD captures information related to an existing medical procedure, enriches that information with a set of simple automated inferences, and then that information can be used as the basis to identify an alternate class of tools. By combining SNOMED CT and the FBO, CIFMeDD enables a user to make queries of the information entered to find functionally similar procedures, and potentially objects, substances, or any other thing whose behavior can be functionally modeled. This is a potentially powerful tool to work within some established procedure and identify alternative methods of achieving the same end. The addition of patent data allows this same method to be extended to open-ended inventions, enabling a field of agnostic means to search for functional behaviors that might be of use in related contexts.

3.2. Case Study 2 – Bariatric surgery

Case Study 1 (Section 3.1) focused primarily on effective capture of medical knowledge and basic reasoning across domains. This second case study touches upon the ways one might use this information and the automated inferences that can subsequently be made based upon that knowledge. The goals of Case Study 2 are twofold: first, to show how a very basic, initial understanding of medical goal can be used to determine current treatment and device operations in a medical field, and second to determine alternative design options based on these current treatments and existing intellectual property. In this case study the application domain is bariatric surgery, a fairly mature medical field where a diverse range of treatment options are available. We will look at the ability of CIFMeDD to identify relevant medical knowledge based on a concept idea for an obesity treatment. Similar to the fat grafting case study patent data, **procedures**, and medical device individuals relating to the bariatric field of medicine were entered into the framework using the class structures and new properties added into the modified ontologies. In addition, the individuals from the fat grafting and patent case studies were left intact and unaltered for use as necessary throughout the study.

Surgical operations are used in some cases to treat obesity by limiting a person's caloric intake, leading ot weight loss over time [46]. A common method is to shrink or constrict the stomach, which can have the effect of helping to create a mechanical barrier to overconsumption among other potential pathways. When this happens, the interior volume and cross section of the patient's stomach is reduced, inhibiting the passage and food and meaning that a smaller bolus causes the stomach wall to stretch [47]. As a result, the patient feels satiated and is thus less likely to eat in excess. In practice, this is accomplished through a number of means including surgeries to remove part of the stomach or by deforming the stomach with a surgical band to achieve a similar result. Based on this general idea, a simple functional description of the concept pathway focusing on stomach altering treatments can be generated as shown in Fig. 6.

Given an objective based on the weight loss pathway described above, it would be helpful for a designer to know if there is already some existing procedure or medical device used to accomplish this goal. Using Protégé's built in DL Query tab, the ontologies can be queried based on this functional model created using the FBO. Based on the functional model, one might want to know the existing medical techniques for constricting an object, as well as patents describing methods to do so. Since this a very general query, additional medical data can be used to limit the search results to individuals that act upon the stomach. Thus, one might look for classes and individuals with a designated anatomical site

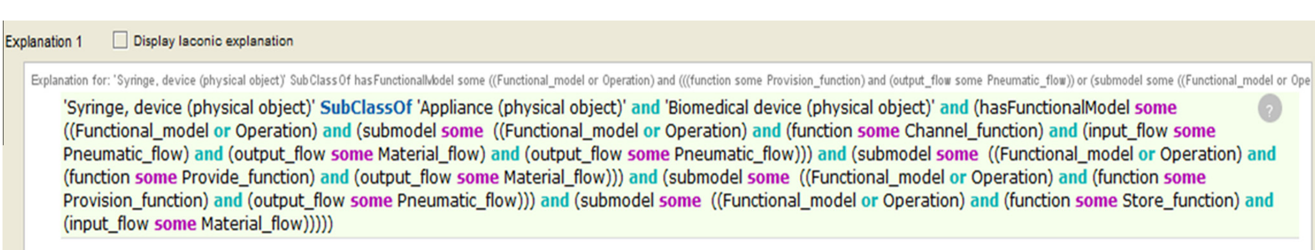

Fig. 5. DL Query and results showing procedures in which tissue is removed in the framework.

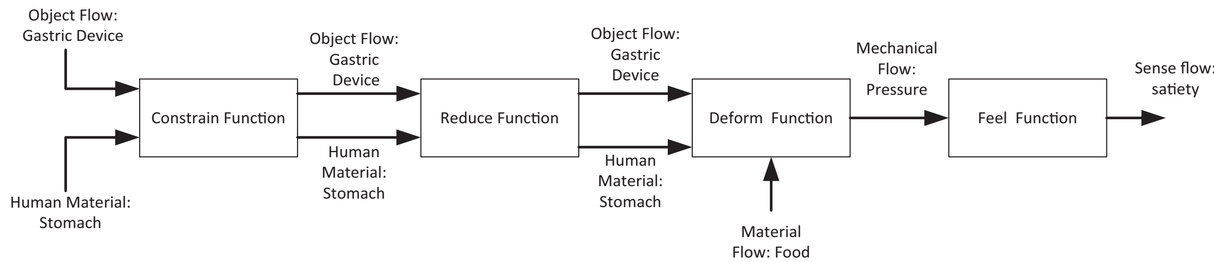

Fig. 6. A simplified functional representation of a generic bariatric treatment method made with the Functional Basis. A medical device is used to constrain the stomach, reducing its volume and causing it to be quickly deformed by incoming food. This results in a feeling of satiety.

(***hasAnatomicalSite***) referring to the stomach, and whose functional model contains some operation with a **Constrain_function**. When this query is run, the Reasoner is able to recognize a number of classes that meet these criteria, including an existing gastric band in SNOMED CT and a remotely adjustable gastric band disclosed in one the patents entered into the framework (Fig. 7).

This result provides a useful background for understanding the procedure that would be otherwise difficult to obtain quickly. Already, based on a very general idea to constrain the stomach, a number of potential pathways are described. From this result, a designer can easily determine that encircling the stomach is one way to achieve the objective. What is notable in this query is that the linkage of the patent domain with the FBO allows the Reasoner to infer based purely on patent class and an associated anatomical site from SNOMED CT that the band is a device that constrains the stomach. While a powerful demonstration, this particular example is somewhat limited. Due to the simplicity of the query, many tangentially related objects such as a laparoscopic stapler (commonly used in bariatric surgery) and various medical fasteners were included in the results. Since this is only tangentially related to the topic of interest (weight loss), a more refined query is needed.

Other aspects of the initial functional model might yield different and potentially more useful results for a designer investigating potential pathways to target, or mechanisms to achieve specific goals. The **Constrain_function** specified in the initial search is largely a means to the desirable end of shrinking the stomach. As in the functional model above, this goal can be represented using the FBO as one that has a **Reduce_function** linked to an observable measurement, such as a volume associated with the stomach via the ***Associated Morphology*** property in SNOMED CT. This combination very specifically points to models in which stomach volume is reduced. Combined with the linkages created using properties and chains, this means that relevant **Invention**s can be selected with greater specificity (Fig. 8).

Compared to the stomach restriction case, this search is someone broader, incorporating **Physical Object** members such as gastric balloons, and device concepts for a gastric balloon and other devices that have been disclosed and modeled in patents. Just as in the stomach constricting example, a potentially broader search could again be useful. All of the procedures and medical devices considered thus far ultimately operate by causing the patient to feel a sense of satiety, leading to a decrease in overall food consumption. This can again be represented by a fairly simple operation using the FBO and SNOMED CT classes to provide specificity to a query of the framework. In this case, a query can search for instances or classes operating on the stomach, and including a model with a **Sense_function** and an output flow linked to the **Observable Entity** representing satiety (Fig. 9).

This final query shows a broader view of the potential pathways toward treating obesity, most of which are actually invention

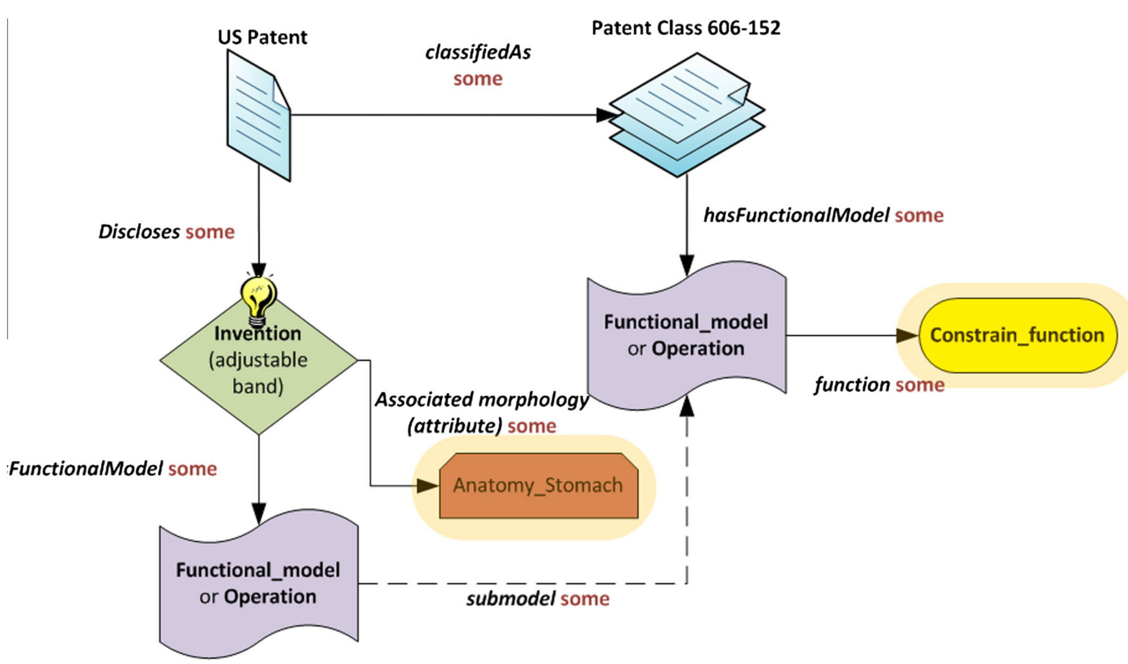

Fig. 7. Example of reasoning used to determine that an object constrains the stomach.

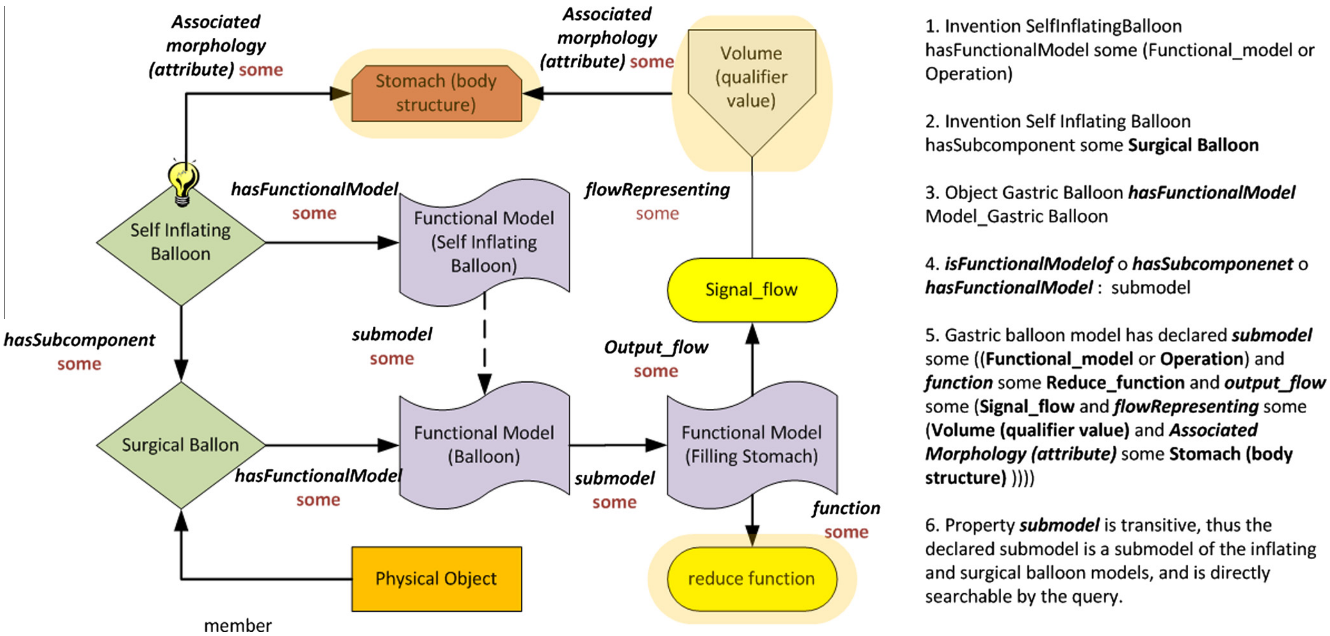

Fig. 8. Reasoning used to identify an invention in the framework that reduces the volume of the stomach.

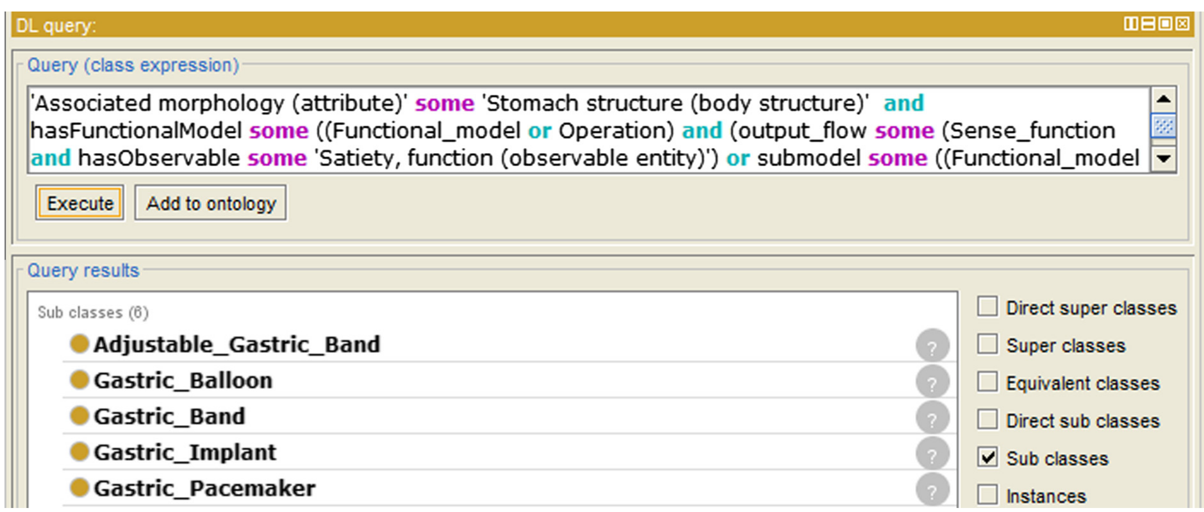

Fig. 9. Results of searching for objects that cause a person to feel satiety.

concepts disclosed in various patents that were entered into CIFMeDD. The results include devices similar to those returned by previous searches, as well as an electrode device described in a patent. By doing so this formulation returned a potential approach to weight loss not even considered in previous queries, and demonstrates the potential power of using these linked domains to uncover novel inferences from existing knowledge.

As can be seen by the widely varying query results for this case study, use the functional basis in tandem with SNOMED CT and a patent ontology provides a potentially powerful tool to better utilize and understand existing medical data. Considering different aspects of a simple weight loss concept allows a user to identify a variety of different existing mechanisms of approaching a new device and to explore ideas well outside the original queries. As the mechanism searched for with the query became broader, a greater variety of functional approaches were revealed. This requires knowledge from all three original ontologies, as well as the inferences made using the rules entered to yield a meaningful result. In this case study, SNOMED CT acts as a repository of various procedures and tools, while also serving as the basis to restrict a search such that it is meaningful to the domain under consideration, or to introduce specific desirable concepts. The patent ontologies provide a potentially large repository of device concepts, many of which can be automatically assigned functional behaviors based on their classification using the Reasoner. Finally the FBO provides the backbone of the search, by acting as a unifying terminology between the medical domain and the broader set of inventions in the patent database.

4. Discussion

At present, there are very few tools to integrate knowledge medical science and practice into the engineering design process for medical devices, and even fewer to use and reuse this knowledge to better understand a design environment and alternatives. While a number of methods exist to collect information, retrospectively assess designs, and guide device development stages, current research does not adequately address the challenge of effectively using medical knowledge to guide designers who lack domain specific expertise. Here, we present a knowledge-based framework to assist in the early stages of medical device design by linking knowledge from the clinical medical directly to the engineering design domain, and provide a basis to reason across the two. By including an additional link to the patent database with the functional basis as a common terminology, CIFMeDD allows direct comparison of existing objects and methods to a potentially vast design repository containing candidate design solutions from many disciplines. Furthermore, the system enhances existing knowledge to inform the design process with automated reasoning to identify similarities between knowledge contained in class axioms in SNOMED CT in various medical fields. The resulting medical device framework enables one to record and contextualize medical knowledge as it relates engineering design process, use this knowledge to gain further insights about medical science practice, and to use these insights to identify potential design concepts or pathways. CIFMeDD provides a basis for automated reasoning between the different domains by representing medical and engineering knowledge and interlinking these domains with meaningful and useful relations.

The usefulness of CIFMeDD is demonstrated with the aid of two medical device design case studies. The results show that by unifying domains, patent metadata can be used to gain a basic functional understanding of design concept disclosed in an intellectual property disclosure. The same unification allows complex medical concepts to be described in relatively simple terms via functional models and their sub models. The new property relations combined with automated reasoning moreover allowed useful inferences to be made explicitly throughout the framework, enriching knowledge already contained in the framework. Because this information is unified in a single framework, it can to used to better understand a medical knowledge area as in the first case study, and using that understanding to identify useful design concepts as in Case Study 2. These powerful inferences can in turn be used to better understand a design's requirements based functional models, and to use those inferences to identify design concepts or opportunity areas based on the patent database.

A number of additional benefits arise when functional and engineering information are merged and used to enhance one another as in this framework. First and foremost, this process allows engineering reasoning that was used to define a design problem, as well as the medical science and practice information on which the design was based to be preserved in unambiguous terms for future reference. Beyond this immediate level, medical ontologies are retooled in this application to allow for a description procedures and concepts. Complex operations are thus broken down into approachable sub-operations, and they can act as a reference for a design engineer considering modifications to the process, or who is attempting to innovate in some similar process. While medical ontologies such as SNOMED CT do associate different medical concepts in this way, the functional design goals of this project have led to modifications that support a finer level of simplification. Because a common language is used to describe medical treatments and concepts, as well as design concepts from the patent database, these can be queried interchangeably, as in the case studies. As a result a designer can quickly and easily assess existing tools for gaps, and identify novel design concepts by querying existing patents and inventions.

Under this framework a medical concept is described in terms of existing practice, deconstructed, and provided basic functional descriptions using the FBO. Because the terminology used is theoretically a near universal representation of the medical field (as opposed to domain specific as is often the case in medicine), it can easily be reapplied to consider additional medical concepts. For example, the low level surgical procedures such as incisions and simple tools shown in Case Study 1, could just as easily be applied to the understanding of a bariatric surgery found in the queries shown in Case Study 2. As a result, useful clinical knowledge is represented and saved for later use in the design process, and such information are readily available for use in future design work, as well as when investigating novel concepts during the innovation process. By interlinking these knowledge domains, the framework presented in this paper enables automatic reasoning to reach conclusions from the interaction of different medical and engineering concepts. These inferences can thus form the basis to better represent a design problem and to ultimately find potential solutions.

The approach used by CIFMeDD differs fundamentally from existing medical device design frameworks, as well as techniques for engineering design. Most medical device methods have focused on the process of development, be it the necessary decision making steps [10,14,48], information gathering techniques [1], or the necessary components for a medical device design. Instead, CIFMeDD approaches the issue from a different perspective, instead focusing on the use of domain specific knowledge relating to medical processes to construct models that aid in concept development and innovation in the medical realm. This allows rapid creation of detailed functional models based on a pre-defined understanding of how a procedure is carried out. It also facilitates the creation of new medical concepts from existing classes that have been fully defined using functional models. As a result, the existing knowledge capture benefits realized in the Functional Basis are extended for highly efficient knowledge reuse. This approach also offers the benefit of linking these concepts of one medical process to any other functionally similar process in the medical domain, as well as to the broader repository of design knowledge found in the patent database. Thus, it assists in a morphological design by providing a means to easily locate potential solutions for design sub-components by searching across many technical areas for functionally similar behaviors. This combination of rendering medical knowledge more usable to a design engineer and utilizing it to facilitate multiple approaches to engineering design represents a significant change from the methods discussed previously for medical device design.

This work does have several limitations. The design alternatives presented in the case studies represent only a small subset of the possible candidate solutions in each domain. In a fully implemented version of CIFMeDD with detailed breakdowns of procedures and more extensive functional modeling of the medical and patent domain, this limitation would be greatly mitigated. Thus, this limitation is largely a function of the large breadth of medical knowledge that would need to be modeled using this method, rather than a inherit flaw in the method itself. It is also notable that there is significant room for knowledge reuse even with the limited scope of the current examples. For example, the functional model associated with the procedure Incision in the first case study can easily be incorporated in any procedure involving an incision as a sub-step. Another limitation is due to the use of a subset of SNOMED CT rather than the whole distribution. While this was done to reduce complexity and limit the computational requirements of classifying SNOMED CT, this will have an impact on the ability to express and model certain medical concepts within the resulting framework. Integration with a complete version of SNOMED CT with additional modifications along the lines described in this paper would provide the added capability to describe features such as patient specific information that might correspond to more complex medical devices. While it is beyond the scope of this concept ideation framework, future work should investigate ways to incorporate these details into the medical device design concept ideation. That said, there is still significant benefit for concept ideation even when these details are explicitly contained in the framework. Furthermore, devices that are simpler and more focused in their application, or they simply rely on the judgment of a clinician rather than a designer may not require such additional information at the conceptual design phase.

In summary, CIFMeDD offers significant benefits to a medical device designer. The close relationship between a product's functional model and the existing practice is potentially valuable, as existing practices have specific, clinical reasoning and underpinnings that can be extended to the product itself. With the additional benefits gained by interlinking this information in a semantic framework, the integrated CIFMeDD framework helps to overcome the difficulty of effectively using medical knowledge in engineering design, while ensuring that the generated and captured knowledge is readily available in the future. Its implementation in a semantic web platform makes it readily extended to additional knowledge domains. The use of ontologies further ensures that the problems are better defined, inferences are easily made, and the basis for the definitions and inferences are clearly preserved.

Conflict of interest

None declared.

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