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Micro Surgical Design Knowledge Organisation

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Abstract
Designers working in the micro surgical domain lack grouped knowledge and the required design support tools. This paper proposes a methodology for capturing the relevant existing knowledge that is scattered in different formats and organising the knowledge in such a manner so as to be reused by designers working in the medical field. The Design for Micro Surgery (DFμSurg) guidelines captured and formulated are aimed for use in intelligent design support tools to proactively guide designers.

Keywords: structured knowledge, multidisciplinary approach, micro surgery, design reuse

1 Introduction

There is a rapidly increasing trend towards the development and adoption of more and more minimally invasive surgical (MIS) procedures across almost all fields of surgery, meaning more tools need to be designed and produced [1]. This is because of its clear benefits to patients. Small incisions result in less bleeding, less chance of infections and post-operative complications, smaller scars, shorter recovery times and thus reduced hospital stay and hospital costs.

However due to the remoteness of the surgical site, indirect vision and indirect manipulation, it is much more difficult for surgeons to operate compared to open surgery [2]. As a result, surgeons are demanding safer, more ergonomic, multi-functional, interchangeable, light and small tools to be able to operate more comfortably when performing MIS procedures. This means that MIS instruments are more complex and challenging to design than traditional tools due to these specifications and their multidisciplinary nature.

2 State-of-the-art

2.1 Designing Medical Devices

There exist a number of guidelines, directives and rules of thumb concerning the design of medical devices; of particular relevance being the 1993 Council Directive 93/42/EEC [3] and the Design Control Guidance for Medical Device Manufacturers [4]. Examples of these are given in Figures 1 and 2.

REQUIREMENT 8.1

'The devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use'

REQUIREMENT 8.3

'Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened.'

Figure 1. Examples of Medical Device Requirements taken from [3]

RULE OF THUMB 1
'Ensure that the intensity and pitch of auditory signals allows them to be heard easily by device users. Consider the effects of ambient noise'

RULE OF THUMB 2
'Ensure the brightness of visual signals is sufficient to be perceived by users working under various conditions of ambient illuminations. Also, brightness contrast and color contrast can help to optimize legibility'

RULE OF THUMB 3
'Make labels and displays so that they can be easily read from typical viewing angles and distances. Symbol size, contrast, color, and display depth are important characteristics'

RULE OF THUMB 4
'Medical devices should be designed for simple maintenance, because poor maintenance can hinder safe, reliable operation.'

Source: Sawyer, D. 'Do It By Design', 1996

Figure 2. Examples of Medical Device Rules of Thumb , taken from [5]

However as can be seen from Figures 1 and 2, these guidelines are very general and provide very little information to the designer as regards proper design.

Two approaches can be used when designing medical devices. In the first method referred to as the 'technology driven approach', the engineering designer comes up with a design based on the request of the medical professional. However this technique may result in a high-tech instrument having very little clinical value. The second method known as the 'clinically driven approach' is preferred since it involves the engineer observing the surgeon in the operating theatre while operating. A discussion is then held between the two professionals to detect problems in existing instruments so that design specifications are generated to improve the design of existing tools or design novel tools [2]. By this latter technique a quick insight into the medical aspects is given and medical and technical knowledge is shared. Once the product design specification is set up, the next step is to start brainstorming on solutions and come up with early concept designs which are refined with time by aiding them with the generation of prototypes. As outlined in [6] the following 'Design for X' criteria need to be followed:

- Design for Safety
- Design for Optimum Biomaterial

- Design for Reliability
- Design for Human Factors
- Design for Easy Functionality
- Design for Easy Serviceability

2.2 Designing Micro Products

Micro manufacturing does not involve the downscaling of existing conventional processes and technologies to produce smaller parts but in some cases new techniques need to be developed. Whereas macro product development involves *machining* different parts made from different materials and assembling them together, in the case of micro products, monolithic design is preferred, which involves the additional *fabrication* of a single multifunctional component layer by layer [7]. The trend is nowadays moving towards developing single-piece flexible *compliant mechanisms*, rather than mechanically actuated complex rigid-link end-effectors. This is particularly being adopted in the fabrication of micro-scaled surgical end effectors used in minimally invasive surgery (MIS) such as micro-forceps, graspers, dissectors etc.. [8]. Although these end-effectors (such as those used in laparoscopic procedures) at first glance may not seem very different from the tools used in open surgery apart from their size, yet the product design specifications are different due to the fact that MIS involves indirect vision and indirect manipulation and also the method of manufacture is different.

3 The Need for DFμSurg Support

As seen in section 2, literature reveals that although guidance on designing medical devices and fabricating micro products exists, yet design guidance in the 'fused' micro surgical domain (referred to as DFμSurg in this paper) is lacking. The shaded area in Figure 3 highlights this missing gap.

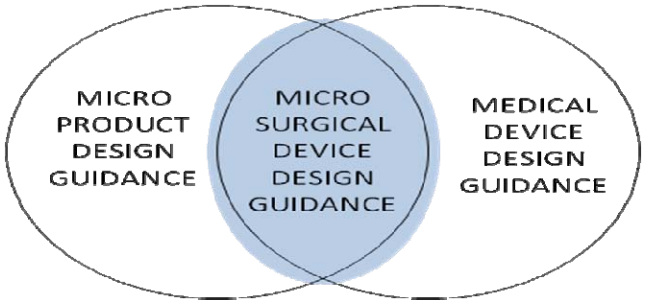

Figure 3. Missing design guidance

The *design problem* is that in the micro surgical domain, designers lack i) sufficient grouped design knowledge and ii) design support tools. There is a need to group together existing knowledge from various stakeholders involved in the micro and surgical domains and representing it in a form that can be reused by designers. Design reuse allows designers to recall previously existing domain knowledge and exploit it to develop solutions to new design problems, without having to waste time and effort in 'reinventing the wheel' amongst other benefits highlighted in [9].

3.1 The Need for Fusion of Micro and Surgical Domain Knowledge

Tomiyama and Meijer [10] explain that for multidisciplinary products to remain innovative in a competitive environment, apart from the need for knowledge integration, there is a further need for knowledge fusion, as shown in Figure 4.

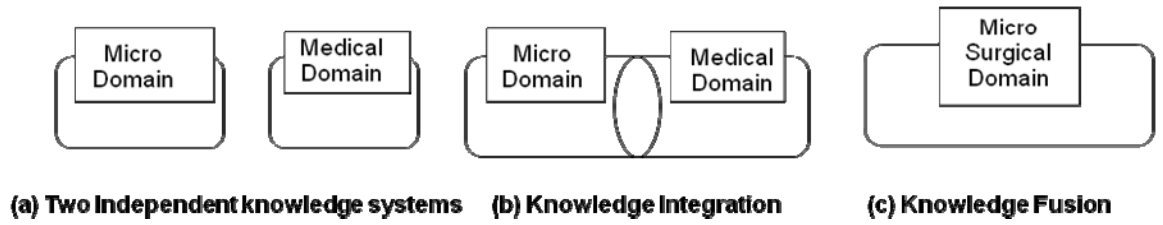

Figure 4. Knowledge Fusion, modified from [10]

This means that when designing products that combine more than one discipline (such as in the case of minimally invasive surgical instruments which involves the use of knowledge from the micro domain and medical domain), the knowledge cannot be simply combined but a new knowledge system (DFμSurg) needs to be created.

3.2 The Need for Re-using Life-cycle Knowledge

During the synthesis phase, designers reuse previous design concepts to solve new problems. Although this may restrict their creativity and limit their innovative skills, yet it saves a lot of time in design. Figure 5 gives a summary of some of the reusable design alternatives for designing and manufacturing the jaws of the end effectors of a micro surgical tool.

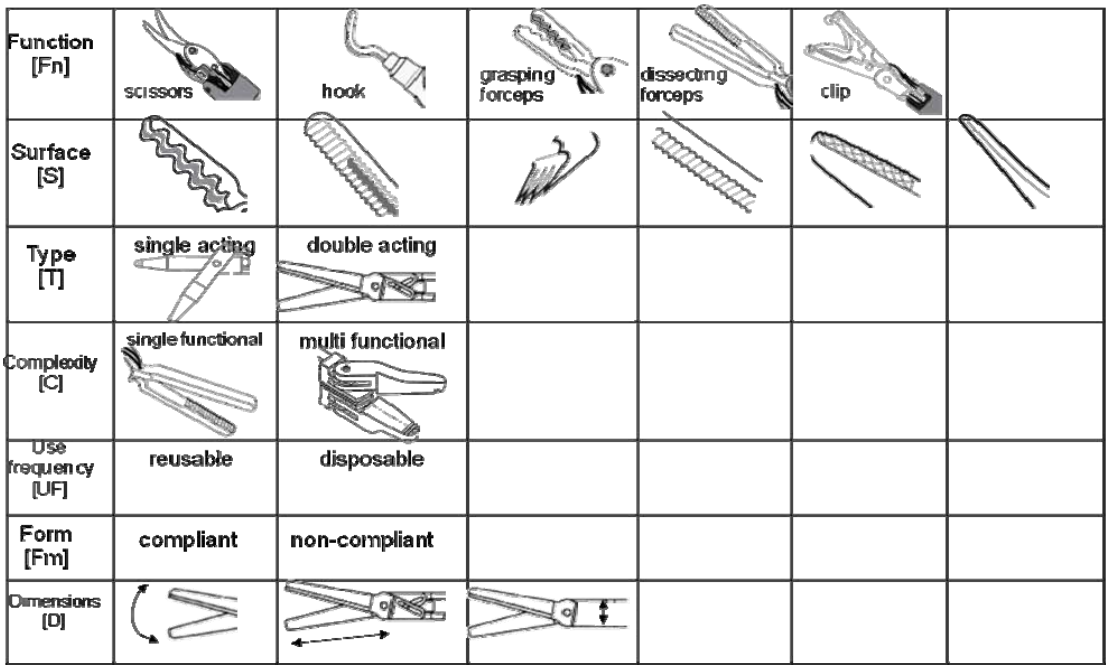

Figure 5. Reusable Alternatives for Micro Surgical Design and Manufacture

As demonstrated in Nowack's action-centred design model in [11], when a designer selects an element from a number of *choices* within the library of elements, it means that he/she has taken a *synthesis decision commitment* (SDC). Each SDC has an influence on the other life-cycle phases and brings with it a number of *life-cycle consequences* (LCCs) [12]. Each LCC can be either intended or unintended depending on whether the designer was/was not explicitly aware of the consequences that are generated once the commitment is taken. When an unintended LCC is made explicitly known to the designer then it can be: a) good - if it provides additional knowledge that confirms and reinforces the SDC or b) problematic - if it motivates the designer to explore other alternatives. For example, if a certain material is chosen to be used for the end-effector of a laparoscopic tool on the basis of its anti-

corrosiveness, biocompatibility and ability to perform well and withstand the change in pressure when insufflation is performed (design requirements specified by the use phase) it may be the wrong choice if the other life phases, such as the cleaning phase, are not considered. This is because the design requirements needed for the cleaning phase may be in conflict with those needed for the use phase. For example the chosen material may not be capable of withstanding the high pressure steam during autoclaving or the high frequency sound waves during ultrasonic cleaning. Alternatively, the chosen material may have a tendency of being scratched easily providing cavities for the deposit of bacteria which generates negative LCCs.

Although medical device manufacturers have made great progress in technology, yet the focus is many times on the use phase – that is the function of the product during surgical procedures. Other life-cycle phases and considerations are often neglected in the product development and design phase, as discovered by a relevant survey [13]. As discussed in [10] to ensure product development with optimum quality, low cost, short time-to-market and environmental friendliness, multi-disciplinary integration of different types of product life-cycle knowledge is needed.

4 Knowledge Classification

As explained by Tomiyama et al [14] knowledge can be classified into 2 dimensions and 3 combinations: unrecognized and tacit, recognized and tacit or recognized and codified, as shown in Figure 6. For knowledge to be recognised it needs to be codified into a human-recognizable form which can be *non-computable* (such as manuals, catalogues, notebooks) or *computable* (such as electronic libraries, databases, knowledge intensive computer aided design (KICAD) tools). Tacit knowledge is a form of knowledge that can be recognized implicitly or explicitly. Implicit knowledge is general and human knowledge based on personal perspectives, intuition, emotions, know-how, experience etc... whereas explicit knowledge is product related information (such as concepts, part solutions, solution principles) and process related knowledge (such as methods, tools and design procedures). Both types of knowledge are needed in design [15].

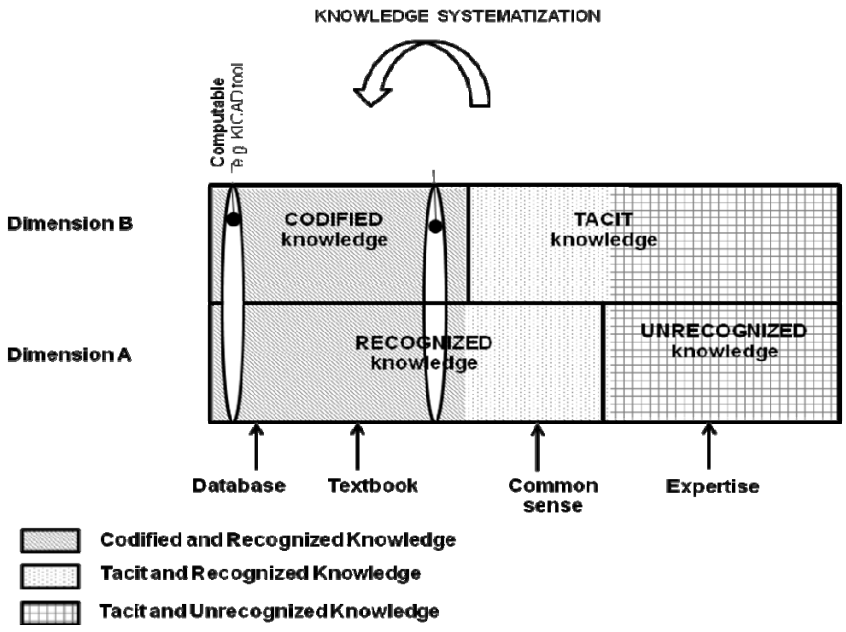

Figure 6. Knowledge Classification, modified from [14] and [12]

Tomiyama et al [14] refer to the leap from recognized tacit knowledge to recognized codified knowledge as 'knowledge systematization'. The following sections give a more comprehensive model applied to the micro surgical domain based on Tomiyama et al's model [14] and the MOKA life-cycle given in [16].

5 Knowledge Organization

To be able to create a new knowledge system the knowledge needs to be identified and captured (section 5.1), grouped (section 5.2), structured (section 5.3) and formalized to be converted into a codified format as summarised in Figure 7.

Figure 7. Knowledge Organization steps

5.1 DFμSurg Knowledge Acquisition

Knowledge can be acquired in different forms. Experimental knowledge is collected after conducting a set of experiments. Experiential knowledge is the knowledge gained through experiences from past learnt lessons. Knowledge acquisition requires two steps: i) the identification of potential knowledge resources and ii) the capturing of the knowledge as described in the next sections.

5.1.1 Knowledge Identification

The knowledge required to design an MIS instrument is beyond the proficiency of a single designer due to the various disciplines involved and the breadth of knowledge that needs to be considered across the various life-cycle phases. Experiential knowledge is distributed among a number of stakeholders working in the different product life phases and experimental knowledge is documented in various sources, as indicated in Figure 8. What is needed is a system that collects the 'jigsaw puzzle pieces' of knowledge and orders them to form the complete micro surgical design 'puzzle'.

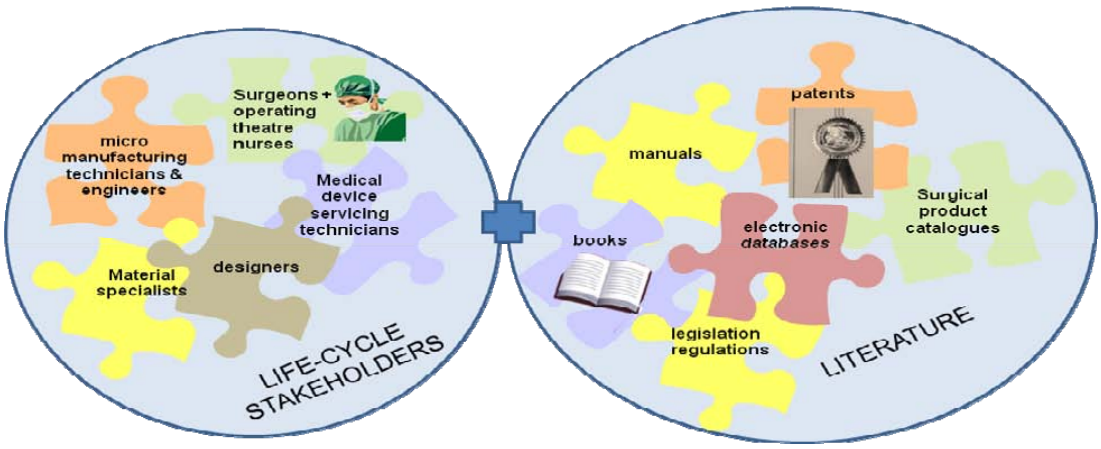

Figure 8. Potential Resources of Micro Surgical Domain Knowledge

5.1.2 Knowledge Capture

The 'bits and pieces' of knowledge from literature are easier to capture since they are explicit though problems of access, confidentiality and copyright make it a more tedious task. Implicit knowledge is much more difficult to capture as it involves organising informal or formal one-to-one meetings with the stakeholders who may not be so readily available. Another difficulty with capturing implicit knowledge is that since the stakeholders are knowledgeable in different areas to the designer, difficulty may arise as regards misunderstanding of the jargon used and different terminologies for the same words. The challenge is to convert the information given by the stakeholders into relevant design reusable knowledge.

5.2 Knowledge Grouping

The bits of knowledge that are captured need to be grouped under the relevant life-phase categories forming a life synthesis elements library as shown in Figure 9.

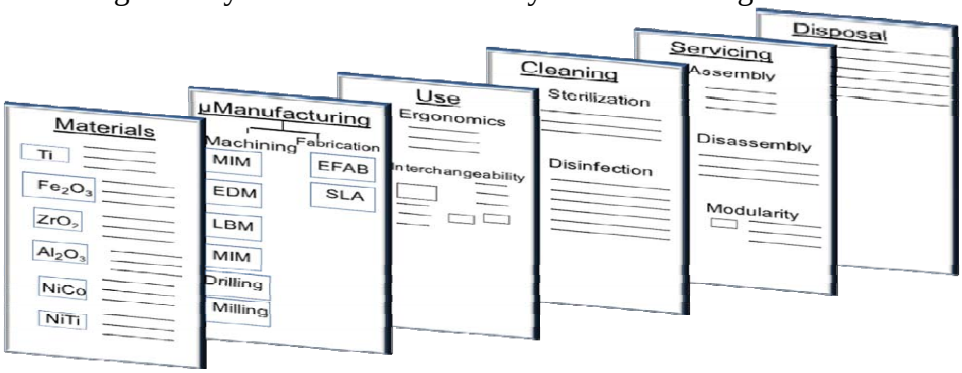

Figure 9. Library of life phase knowledge

5.3 Knowledge Structuring

For ease of codification and knowledge maintenance purposes, it is important to structure the knowledge base. This needs to be done in two dimensions:

a) individual guideline format; and

b) indexing of all guidelines generated to ensure ease of retrieval of the correct guideline at the right time in a specific design scenario.

Since this research is an extension to previous research carried out at the Department of Industrial and Manufacturing Engineering by Vella et al in [17] and Borg in [12], a similar structure has been adopted involving the following steps:

a) Arranging the elements into classes and kind_of taxonomies in a hierarchical manner (Figure 10);
b) Assigning notations to the elements;
c) Representing the knowledge in guideline format in an 'easy to understand' way for the designer pointing out the LCCs and giving recommendations on how to improve the design (Figure 11).

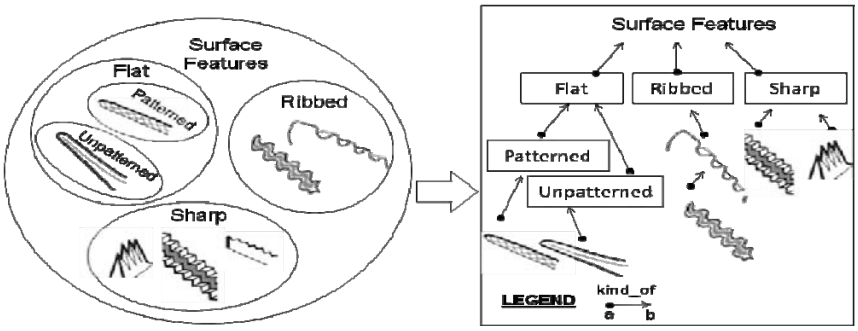

Figure 10. Knowledge Structuring

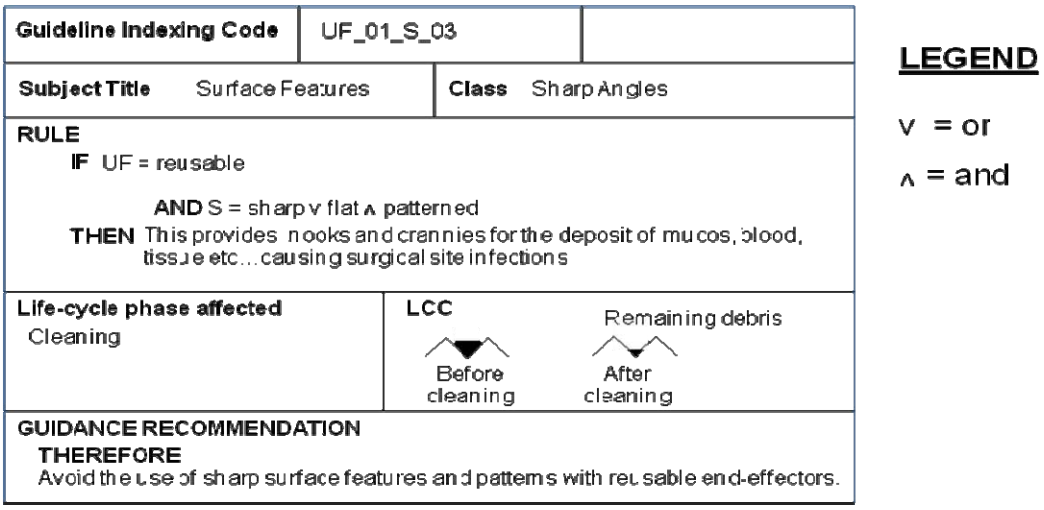

Figure 11. Individual Guideline Format

The 'IF' x 'THEN' y guideline format has been used, so that the design support guidelines can be easily formalized (represented by a programming language), thus allowing for the possibility to be embedded in a knowledge intensive computer aided design support tool.

As already explained in section 3.2, each SDC gives rise to one or more LCCs. Figure 12 highlights the difference between non-interacting LCCs (marked in dashed lines) and interacting LCCs (marked in solid lines) as explained in more detail in Borg's Phenomena Model [12].

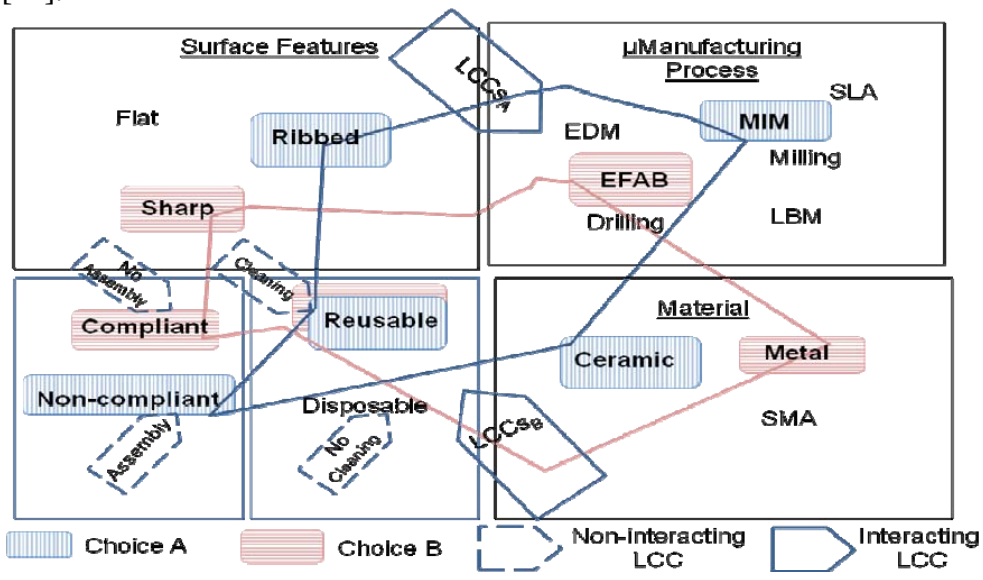

Figure 12. Distinguishing between non-interacting and interacting LCCs

6.0 Conclusions

The work presented in this paper sets the base for the organisation of a new knowledge system regarding the fused micro surgical domain. More knowledge needs to be acquired from research institutes and companies that are involved in micro manufacturing, medical device design, medical device servicing, so as to be able to generate more design guidelines and formulate a more complete jigsaw puzzle as shown in Figure 13.

Figure 13. Improvement from non-computable (manual) to computable (KICAD tool) DFμSurg structured knowledge

Once this is achieved, the next step would be to incorporate this knowledge and integrate the guidelines in a knowledge intensive computer aided design (KICAD) tool so as to make the work of the designer easier and faster. The architecture for such a KICAD tool is given in [6]. Instead of having to look up guidance in a manual of guidelines (which is already a step forward than having to waste a lot of time collecting the 'bits and pieces' of knowledge from different sources and stakeholders) the designer would be able to select elements from the e-library. The working memory generates the evolving component product model and guides the designer by forwarding the relevant recommendations. New design elements may be added to the system and the inference engine would be capable of generating new knowledge.

Acknowledgements

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