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TOWARDS KNOWLEDGE INTENSIVE DESIGN SUPPORT FOR THE MICRO SURGICAL DOMAIN

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1. Introduction

Product miniaturisation is penetrating new industries with the biomedical industry being no exception. Users are demanding products that are lighter and smaller in size, with more functionality, easier handling, more ergonomics etc, enforcing them to be multidisciplinary in nature and thus having more complex and intricate designs. This is particularly true in the micro surgical domain. Surgeons are demanding smaller, safer, more ergonomic, multi-functional, interchangeable, light tools to be able to operate more comfortably. Endoscopic and minimally invasive surgical instruments fall within these specifications. Although the use of these instruments, compared to conventional tools offers a number of benefits to the patient since small incisions result in less bleeding, less chance of infections and post-operative complications, smaller scars, shorter recovery time and thus shorter hospital stay, yet they are much more challenging to design. This is because the knowledge required to design a minimally invasive surgical instrument is beyond the proficiency of a single engineering designer due to the various fields of expertise that are involved. Although some guidance on designing micro scaled products and designing biomedical devices is currently available it is spread in different formats (e.g. manuals and software tools) supporting only particular aspects of the life-cycle. A knowledge intensive computer aided design (KICAD) support system is thus needed to be able to gather all the knowledge from different stakeholders and codify it in computational form. This paper, which is part of ongoing research proposes a framework for providing knowledge to proactively guide designers in the micro surgical domain.

2. State-of-the-art

The following section highlights the tools that are currently available to support design in general, design in the micro domain and design in the medical domain respectively.

Product Development Tools

Design support is needed in all the stages of the design process: conceptual, embodiment and detailed design stages. Different product development (PD) tools are used to aid design during the different stages . During ‘problem analysis’ active tools such as Product Design Specification and Quality Function Deployment are used. Later on in the ‘synthesis’ design activity other tools such as Brainstorming, Morphological Charts, Function Means Tree, whereas tools such as the Failure Mode and Effects Analysis are used in the ‘solution analysis’ design activity. During the different stages the design team members also change. There are times when all the design team members are present for a

review meeting, other times when the designer is working alone in the office and other times when the designer needs to clarify or discuss a design issue with one or a few of the stakeholders in which case an informal meeting is held. PD tools can take different formats: non-computable (paper-based) or computable (software). Knowledge can be represented in different formats too: text only, diagrams only or a combination of both. A study in the framework of the PRESGUIT Project, carried out by researchers at the Universite de la Mediterranee [Dufour et al., 2006] to determine whether textual guidelines are preferred to computable ones, revealed that computerized guidelines are more effective than text based ones and compliance to them is much easier and more efficient. In the area of micro surgery design and development, the questionnaire [Grech, 2008] that was sent to companies working in this domain, revealed that design guidance being followed is in the majority of cases in non-computable format and in text form.

Design Support in the Micro Domain

Although micro scaled devices offer a number of advantages over macro devices apart from compactibility and light weight, as regards to both performance and functionality, they are much more challenging to design and manufacture. It is not a question of using conventional technologies and scaling them down to be able to fabricate smaller sized components, but new design principles and methodologies need to be used.

Albers et al [*Albers* et al., *2003*] suggest that to design correct micro parts, the designer needs to develop the product in a micro-production oriented way, that is starting with defining geometry (2D, $2_{1/2}$D or 3D), geometrical micro dimensions such as feature size and aspect ratios, then moving onto selecting the micro manufacturing process and micro tools having submicron accuracy, and the material/s to be able to produce the parts/features to a high degree of precision, fine detail and close tolerances. However the questions that arise are: Is this method valid for all micro scaled parts? Does it also hold for the production of micro-scaled surgical parts?

Albers et al propose a set of design for micro milling guidelines using a production technology based classification. However since designers generate micro-scale design solutions in terms of part features rather than processes to be able to create microfeatures, Albers et al's guideline format becomes hindered as it assumes a pre-determined production technique. As part of the ongoing research in the micro domain within the Department of Industrial and Manufacturing Engineering of the University of Malta, a set of design for micro milling (DFμM) guidelines [*Vella* et al., *2007*] have been generated for 2½D features and 3D features , to aid designers by showing them the overall effect on the product life-cycle due to the feature parameters. A prototype system has been implemented in a hypermedia based system. The system alarms the designer of any consequences that are brought about by design decisions taken and recommendations are given.

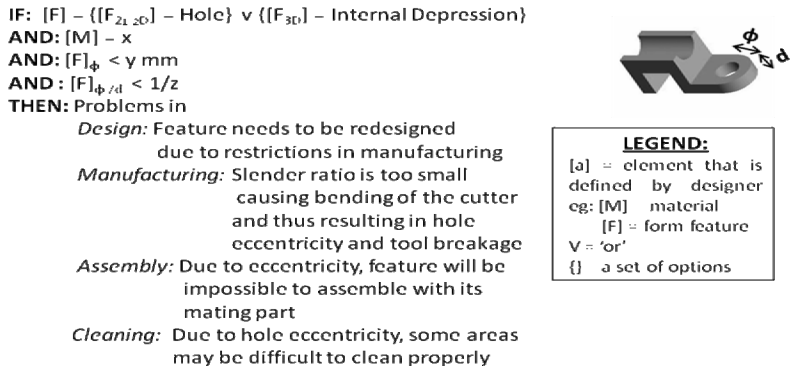

Figure 1. Example of a typical DFμM guideline

This part feature approach is being exploited further and extended to the micro surgical domain, as explained in the following sections.

Design Support in the Medical Domain

The medical device industry is different from other industries in that it demands more sophisticated *design intelligence* due to the many parameters that need to be considered to ensure patient safety. Yet, research carried out at the Cambridge Engineering Design Centre [*Alexander* and *Clarkson*, *2000*] revealed that although there exist a number of regulations, standards, guidance documents concerning medical device design and manufacturing such as the European Directives 93/42 EEC and the Food and Drug Administration Design Guidance for Medical Device Manufacturers, yet they provide very little guidance on good and intelligent design practice.

The majority of guidelines related to human factors engineering – which is a philosophy adopted by many companies to design medical hardware and software tools - are in the form of guidance manuals. These include rules of thumb to be followed by the designer with particular focus on the 'user' with the aim of reducing the chance of errors during the use phase. However, these guidelines are very narrow since they consider one life-cycle phase and ignore any interactions that may occur during the other life-phases of the product.

In the medical domain, the material used plays a very important role in design and needs to be considered at the initial stages of design, thus influencing other design decisions such as the machining process to be used. However information related to material selection for medical device design is very limited. In fact it is only recently that the *first* materials database that supports medical device design has been devised by Granta Design and ASM International. This database, to date, caters for cardiovascular devices and orthopaedic devices [*Buntz, 2008*].

This section shows that, although some form of design guidance in the micro and biomedical fields exists, yet currently it exists i) as scattered information and ii) not life-cycle oriented.

3. Design Problem Background

Design is the most crucial phase in a product's life-cycle, because the commitments taken in this stage, if wrong, will propagate throughout the other life-phases, and result in what are referred to as *life-cycle consequences (LCCs)* which have an effect (positive or negative) on the performance measures such as cost, time and quality [*Borg* et al., *2000*]. Life-cycle engineering (LCE) design ensures that LCCs are kept to a minimum. LCE design utilises a Design for Multi X (DF∑X) approach. The theoretical foundation and contribution model shown in Figure 2 shows the different DFXs that need to be included in the micro surgical domain.

The design problem is that a designers working in the micro surgical domain lack sufficient and grouped knowledge and design support tools. What is needed is therefore a system that would be capable of grouping the relevant life-cycle knowledge, representing the knowledge in a format that is easily understood by all designers, proactively guides the designer before design decisions are taken, alarms the designer of any LCCs, informs the designer about the affect on the performance measures and gives recommendations on how the product can be designed in a better way to improve these performance measures, and allows new data to be inputted into it.

4. Research Problem Background

In today's competitive environment, for a company to increase its success, it is essential for it to make use of *integrated product development (IPD)*, to ensure that all of the aspects of product function and design, such as materials, manufacturing, use issues, environmental impact concerns, product

marketing and business management are linked together into a single discipline that is targeted towards optimising overall performance (ensuring maximum quality, minimum cost and minimum time-to-market). Apart from this for company's to remain at the head of technology, it would be even more useful if a *dynamic product development* (DPD) approach is used [*Ottosson, 2004*]. This allows the possibility for the company to create, develop, and market add-on new product variants and thus achieve new solutions.

Since design is a continuous learning process and the knowledge is continuously changing due to the fact that each time knowledge is used, new knowledge is being generated, design knowledge needs to be represented by a Knowledge Intensive System [*Blessing* and *Wallace*, *2000*]. From a research perspective, there is the need to capture, group, model and structure relevant DFX knowledge related to the micro surgical domain. The research being carried out aims at filling this missing gap, by generating a knowledge intensive computer aided design (KICAD) support tool. The knowledge embedded in the KICAD system will be able to proactively support designers working in this domain, and will ensure that both IPD and DPD are practised.

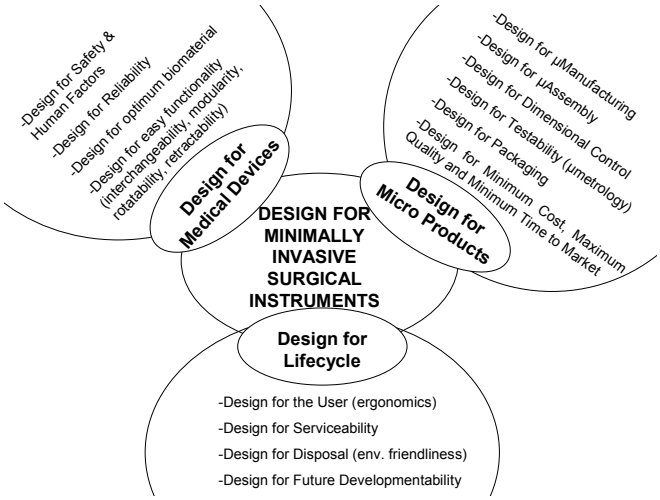

Figure 2. The main DFXs needed to design reliable minimally invasive surgical instruments

5. Product Life-Cycle Stakeholder Practice

Engineering designers are experts in their particular area of study, that is design. To be able to design surgical instrument parts containing micro-scaled features, designers cannot work on their own, using their own expertise and intuition, without some form of knowledge input from stakeholders that work in the medical and micro sectors, and the other life-phases of the product.

During the past decade there has been a shift from a user-centred design process to a participatory design approach - a shift from designing *for* the users to designing *with* the users. The Participatory Design Approach (PDA) was first introduced in the world of web development in 1992 but has since then been extended to other fields. Rasoulifar et al [*Rasoulifar* et al., *2007*] have applied the PDA to design a minimally invasive spinal surgical tool. The design procedure that is proposed by Rasoulifar and Thomann involves a design team that consists of only two people - the engineering designer and the surgeon. An online questionnaire that was sent to a number of international companies working in the design and/or manufacturing micro surgical domain [*Grech*, *2008*] proved that the same approach that Rasoulifar et al adopted, is also adopted in industry. The questionnaire revealed that in the

majority of cases, the people present at design meetings are the designer and medical professionals. It is true that the surgeon is continuously using the surgical instrument and is probably the stakeholder that can forward the greatest amount of knowledge by suggesting ways of improving ergonomics, safety etc…from his/her own experience. However, just as the surgeon can provide relevant feedback to the designer, other stakeholders involved in the other product life phases, can also forward useful knowledge, and their expertise should not be underestimated. For example, the technician is continuously assembling and disassembling the instrument and can suggest ways of improving the design by reducing the number of parts, whereas the operating theatre nurse who handles the instruments to the surgeon or passes them through the ports or trocars, can suggest ways of improving ease of insertion of instruments, micro-gadgets for easier methods of handling instruments, improved micro-features/parts to reduce wear and tear.

The knowledge from various stakeholders involved in the life-cycle phases of the product needs to be captured, then converted and represented in computational form to create the KICAD tool. This will aid designers by proactively supporting them and ensuring that they arrive at a solution that is life-cycle oriented to reduce LCCs, cheap to manufacture, but of good quality and which can produced in a short time. This is explained in Figure 3.

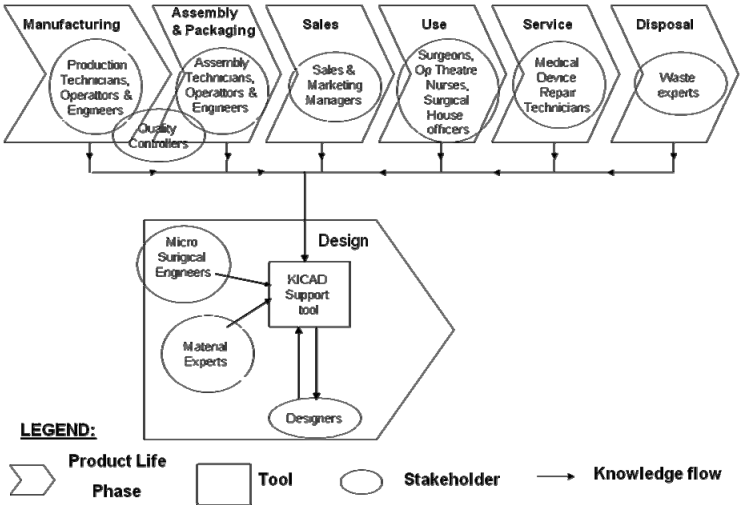

Figure 3. Knowledge Transfer to and from the KICAD system

Some of the benefits of such a tool include:

- Less wastage of space and paper due to compactness of software;
- Less time to arrive at a solution due to less chasing around for documents and stakeholders, meaning less time to market;
- Less chances of LCCs due to life-cycle oriented approach meaning less costs due to errors;
- Easier communication amongst designers.

6. System Architecture for the KICAD tool

The architecture in Figure 4 is based on work already carried out by reseachers from the Department of Industrial and Manufacturing Engineering of the University of Malta in collaboration with

researchers working at the Department of Design, Manufacture and Engineering Management of the University of Stratclyde [*Borg* et al., *2000*].

However although the representation of the knowledge and the way it is used is similar, yet due to a different domain being saught, different knowledge is generated – thus although the architecture is similar, the knowledge base differs.

Based on the identified system requirements, the architecture for the KICAD tool consists of the following as shown in Figure 4:
i) *knowledge base* – which contains a library of design elements and stores the LCC knowledge computed as rules and facts;
ii) *inference engine* – that interprets the LCC knowledge and is able to draw conclusions. It is also able to generate new knowledge when a new design element is added or more LCC knowledge is added by means of a *maintenance system*;
iii) *working memory* – which stores the current LCCs and generates an evolving model of the part.

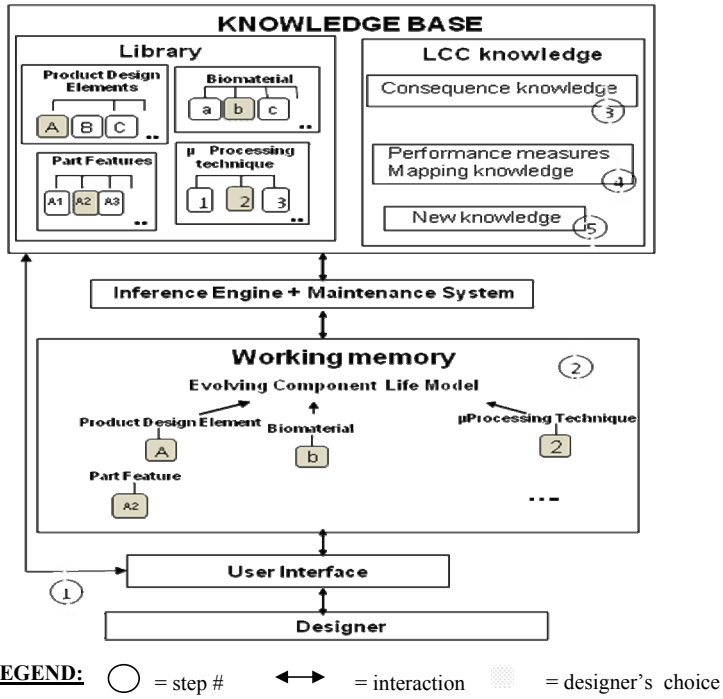

Figure 4. Architecture for a KICAD **Tool for the Micro Surgical Domain**

The knowledge base consists of two sections: i) the library of reusable design elements and ii) the LCC knowledge which is the knowledge that is gathered from the various life-cycle stakeholders and which needs to be computed in the form of 'facts and'inference rules'. The performance measures such as time, cost and quality vary depending on the choices made by the designer. This system will provide proactive guidance to designers informing them on the life-cycle consequences that will arise and the affect on the performance measures before a decision is taken. It will also be capable of forwarding recommendations to the designer on how the machining process parameters can be improved.

6.1 Typical Scenario

Assume that a designer needs to design a *form feature* (such as a hole) in a *part* (such as the top plate) of the *sub-assembly* (such as the interchangeable part of the end-effector) of a laparoscopic tool, as seen in Figure 5.

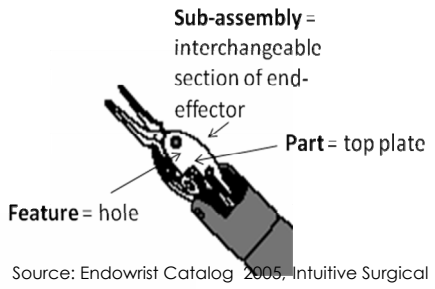

Figure 5. Example of micro surgical feature

Using the system architecture described above, the designer searches for design elements in the library and is informed on which design elements are currently present in the library (step 1). Based on the designer's choice a component life model starts to be evolved (step 2) . The evolving model is monitored by LCC knowledge (step 3). LCCs are evolved informing the designer about the consequences and recommendations are also given . The mapping of the performance measures changes according to the design decisions taken and consequences inferred (step 4). This is repeated for a number of times, each time analysing the LCC knowledge and comparing the PM mappings. Due to this proactive guidance given in the synthesis stage of design, the designer is then in a position to decide on which is the best solution. An example of a PM mapping is given in Figure 6. The numbers are fictitious and used for explanatory purposes. Any new knowledge can be inputted to allow design improvements and thus be updated with technology advances (step 5).

	TIME	COST	QUALITY
Design	**10**	**11**	**9**
Manufacturing **Assembly**	**5** **4**	**8** **7**	**7** **10**
Use	**-**	**-**	**-**
Cleaning	**12**	**7**	**4**
Service	**8**	**14**	**5**
Disposal	**10**	**11**	**6**
TOTAL	**45**	**51**	**31**

Figure 6. Performance measures mapping

7. Conclusions

Although guidance on designing micro-scaled products and medical devices exists, yet knowledge in the micro surgical domain is not readily available. This paper points out that there is a need to capture and group knowledge in this domain to aid designers in the synthesis stage of design. To contribute to this missing gap, the architecture for a KICAD tool is proposed in this paper. This tool will be able to group knowledge from a number of stakeholders involved in the different phases of the product life cycle aiding designers in their work, alarming them of any LCCs, and giving recommendations to improve the design, while informing them of the affect on time, cost and quality for the different life-

phases. Designers working in this domain save a alot of time that would otherwise be wasted in trying to group bits of data. This ensures shorter time-to-market, which is needed in such a competitive industry. It also guarantees DPD since new-product variants may be added. The system architecture is an adaptation of research already carried out at the Department. Yet a different domain is being exploited with a different knowledge base. The micro surgical domain has been chosen as it is an area that has revolutionised surgery practice during the past decade and which is envisioned to keep on undergoing technological improvements in the coming years. This KICAD tool can be exploited in other domains that are) multidisciplinary in nature, ii) involve complex designing and iii) which require life-cycle oriented product development to ensure maximum safety (or for other reasons). Obviously the knowledge, LCCs and performance measure data will change depending on the industry/domain targeted.

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