11 STRUCTURING KNOWLEDGE FROM SURGICAL OBSERVATIONS FOR DESIGN REUSE

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Due to the many benefits that it offers patients, Minimally Invasive Surgery (MIS) is becoming even more and more popular in a wide range of surgical fields. This paper describes a set of surgical observations that were carried out in order to investigate the problem of swapping of single functional tools that takes place in a particular MIS procedure. Results showed the need for multifunctional end-effectors having modular and interchangeable interfaces. This paper contributes to generating a set of design guidelines from the knowledge captured from a number of medical professionals, from observations made inside the operating theatre and from a review of existing patents. The ultimate aim of capturing and structuring the knowledge is to reuse it in medical device companies involved in design and manufacturing, by incorporating it in a knowledge intensive prototype tool to proactively guide designers in the early stages of design.

Keywords: DFX, Biomedical Device Design, Knowledge Capturing, Life-Cycle Consequences, Design Synthesis Decision Making.

1. INTRODUCTION

Although the shift from open surgery to MIS took place only two decades ago, yet the research that has been carried out related to this new approach has been very extensive, and more is still to be generated as this surgical technique continues to gain popularity. MIS is now being extended to many fields of surgery and can be applied to a number of parts of the body such as the abdomen (laparoscopy), chest (thorascopy), joints (athroscopy), gastrointestinal tract (colonoscopy and gastroscopy), uterus (hysteroscopy) and blood vessels (angioscopy). This is because of its clear benefits to the patients which include: less bleeding, smaller scars due to smaller incisions, less chance of infections and post-operative complications, shorter recovery times and thus shorter hospital stays and reduced hospital costs.

In MIS procedures the surgeon needs to operate under indirect vision, since the procedure is magnified and viewed on a monitor via a camera that is inserted inside the patient's body, and indirect manipulation since tiny tools having very small diameters, that need to pass through tiny incisions, are used to manipulate organs rather than the hands as in the case with open surgery. There exist a wide range of end-effectors that are used during these procedures including forceps, graspers, dissectors, hooks each having their specific function.

2. PROBLEM BACKGROUND

2.1. Design Problem

During MIS procedures, surgeons make use of more than one surgical tool due to different functions that need to be performed. Each of these single-functional tools has a specific function (e.g.: scissors to cut through tissue, grasper to hold the tissue in place, hook to lift and separate tissue that may be blocking other organs etc…). As a result, the surgeon performs a high degree of tool swapping. In a study (Melzer 1996 cited in Frecker *et al.*,[6]) it has been estimated that instrument swapping comprises 10 to 30% of the total time of the operation. This implies that the operation time is lengthened, which means increase in hospital costs. It also results in the surgeon loosing train of thought of the surgical site and increases the risk of hitting organs unnecessarily, due to continual insertion and retraction of the tools.

2.2. Research Problem

Although there exist a number of manual and computer based tools used to support design such as Boothroyd and Dewhurst's Design For Manufacture and Assembly[1] yet in the medical device design domain, there exists the problem of a lack of structured knowledge and design support tools that proactively guide designers during their work. A thorough literature review reveals that although a lot of information exists yet it is not structured and neither life-cycle oriented. There is the need for structuring design knowledge to be able to guide designers during the early stages of design when synthesis decision commitments are taken. This paper contributes to (i) capturing life-cycle knowledge of minimally invasive surgical tools from surgical observations, (ii) structuring it in the form of guidelines and (iii) formalizing it in a format that can be easily interpreted by the computer and (iv) representing in a format that can be easily understood by designers, easily retrievable, expandable and maintainable for design reuse.

3. STATE-OF-THE-ART

3.1. Review of Surgical Instrument Swapping Problems

In a study carried out by Mehta *et al.,*[10] 29 laparoscopic procedures were videotaped and analyzed using time-motion analysis in order to observe instrument maneuver and tool exchange. Figure 1 shows the instrument exchanges that took place. Each oval represents an instrument with the name specified in the diagram. Each arrow represents removal of the instrument at the arrow's tail and its replacement with the other instrument at the head. The number that is written along the arrows is the number of times of instrument exchanges. The common exchanges are summarized in Table 1.

This approach described above is referred to as a 'clinically driven approach' to medical device design (Stassen *et al.,*[13]). It involves the engineer observing the surgeons in their work environment. This is then followed by a discussion between the two (or more) professionals regarding the problems and limitations occurring during the operation, with the intention of drawing up a set of functional specifications for tool improvement(s).

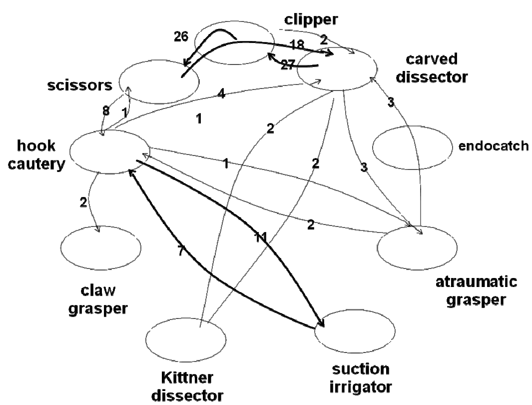


Figure 1. State transition diagram of instrument exchanges in laparoscopic procedures cited in mehta *et al.*[10]

Table 1. Instrument exchange probability in laparoscopic procedures.

Initial instrument	Subsequent instrument	Probability of exchange (%)
Dissector	Clipper	75.0
Clipper	Scissors	89.7
Scissors	Dissector	66.7
Hook cautery	Suction / Irrigation	68.8
Suction / Irrigation	Hook cautery	87.5

(Common Instrument Exchanges in Laparoscopic Procedures[10]

4. SURGICAL OBSERVATION ANALYSIS

4.1. Selecting the Case-Study

There exist several types of endoscopic procedures, however a number of the most commonly performed procedures (eg: colonoscopy, gastroscopy etc…) are diagnostic meaning that viewing of the organs takes place with very little organ manipulation. Laparoscopic procedures are a type of endoscopic MIS surgery where a lot of tool swapping takes place due to many functions that need to be performed in order to manipulate the abdomen. Even though arthroscopy seems to be more commonly practiced locally, as shown in Table 2, yet laparoscopy is of a greater interest to our Department due to the fact that tinier tools are used and quite an extensive amount of research on the micro level is being carried out. For these two reasons, laparoscopy was chosen as the case-study. A summary of the operations that took place at the local general hospital compiled by Janulova[7–9] indicates that as the years go by the amount of laparoscopic procedures is on the increase. One of the most common laparoscopic procedures in which a lot of swapping takes place in the removal of the gall bladder known as Laparoscopic Cholecystectomy (LC) which is described in the next section.

4.2. Laparoscopic Cholecystectomy

In order for the surgeon to be able to view the organs more separately and distinctively and have enough space to operate, the patient's body is insufflated with carbon dioxide (CO_2). According to Cuschieri[4]) CO_2 is used because it is absorbed readily by the body and excreted easily by the lungs, it is transparent in colour and thus does not interfere with the surgeon's view, and it is non-flammable. Four incisions are then cut through the patient's abdomen as shown in Figure 2. Incision D is used to pass the laparoscope (camera) through. Incisions A and B are used to pass the graspers through to be able to grasp and elevate the gallbladder. Tool swapping occurs through incision C due to the number of actions that need to be performed such as dissecting the excess tissue around the gall bladder, cutting the cystic artery and the cystic duct, freeing the gall bladder and removing it once it has been freed. Figure 3 gives a summary of the main procedural steps done in LC.

4.3. Surgical Observations

Nine LC procedures, performed by four different surgeons, were viewed. The tools entered through incision C were noted and tabulated as shown in Table 2. These observations show that the most commonly used end-effectors are the clips, dissector, scissors, grasper and hook. Different surgeons use different instruments depending on the technique that they learnt while studying their surgical skills and also depending on their preference of tools, which vary from one manufacturer to another. It can be noted that Surgeon P who was observed in more than one operation performed exactly the same sequence of tool swapping. Surgeon O who happened to be the only female surgeon was the only surgeon to use the hook to dissect the gallbladder from the liver instead of making use of the dissector. However with this tool, she was the one to perform the highest number of swaps.

These observations clearly show that there is too much tool swapping and this can be reduced drastically if the design of the tools is altered to make them *multi-functional*. The term multi-functionality can have two meanings: either referring to a combination of end-effectors into one tool which can be

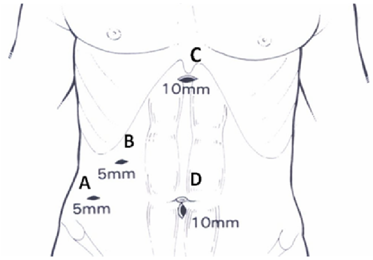


Figure 2. Laparoscopic cholesystectomy incisions cited in paterson-brown & garden.[12]

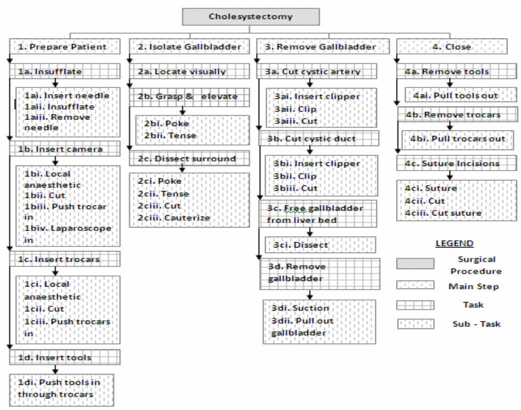


Figure 3. Laparoscopic cholesystectomy procedural steps.

Table 2. Operations viewed at mater dei hospital, malta.

Operation 1	Incision C	Operation 2	Incision C	Operation 3	Incision C
Surgeon M		Surgeon N		Surgeon O	
	Dissector		Dissector		Grasper
	Clips		Clips		Hook
	Scissors		Scissors		Clips
	Clips		Clips		Scissors
	Scissors		Scissors		Hook
	Clips		Scissors		Clips
	Scissors		Laparoscope		Scissors
	Dissector				Hook
	Grasper				clips
					Hook
					Grasper
Operation 4	Incision C	Operation 5	Incision C	Operation 6	Incision C
Surgeon P		Surgeon P		Surgeon P	
	Dissector		Dissector		Dissector
	Clips		Clips		Clips
	Scissors		Scissors		Scissors
	Clips		Clips		Clips
	Scissors		Scissors		Scissors
	Laparoscope		Laparoscope		Laparoscope
Operation 7	Incision C	Operation 8	Incision C	Operation 9	Incision C
Surgeon P		Surgeon P		Surgeon P	
	Dissector		Dissector		Dissector
	Clips		Clips		Clips
	Scissors		Scissors		Scissors
	Clips		Clips		Clips
	Scissors		Scissors		Scissors
	Laparoscope		Laparoscope		Laparoscope

triggered on or off individually or else redesigning the end-effectors in such a way so that with the same pair of jaws more than one function may be performed. The undergraduate dissertation by Muscat[11]) describes the design decisions that were taken to design a multifunctional tool that combines scissors, grasper, hook and dissector in one pair of jaws. A prototype of the design has been machined at the Department to a large scale and currently ongoing research through a nationally funded project is being carried out to improve its design and to scale it down and machine it to the correct size, taking into consideration micro manufacturing limitations, cleaning, servicing, and the other life phases of the product.

5. KNOWLEDGE CAPTURING

Following the observations at the operating theatres, discussions with medical professionals, visits to laparoscopic tool suppliers, viewing of patents, and designing and machining the prototype a lot of lessons were learnt. As Duffy *et al.,*[5] point out it would be a pity for designers to have to 'reinvent the wheel' if such knowledge is not captured for reuse and to facilitate other design projects.

6. KNOWLEDGE ORGANISATION

Once the bits of information and knowledge are captured, the toughest part is to group and (a) organise the knowledge, (b) structure it into guidelines, (c) formalize it in a format that is interpretable by the computer and (d) represent it in a format that is understood by the designer.

The basic properties that can be manipulated by designers, as defined by Tjalve (1979), include: structure (of the whole product), form (of the individual features), material, dimensions and surface quality. The laparoscopic tool was initially broken down into its sub-assembly, parts and form features to understand its structure and focus was placed on the end-effector. Knowledge related to the other basic properties was grouped into separate design compartments to facilitate steps (b), (c) and (d).

7. DESIGN GUIDANCE

During the early stages of design, the designer needs to take *design decision commitments*. These can be of two types[3]: *individual* (e.g. choosing medical grade stainless steel as a material to fabricate the base of the end-effector) or *interacting*, in which case a set of commitments interact together. As described in the Phenomena Model[2], both these type of commitments generate *consequences*. Consequences can be of various types and a combination of: good, problematic, intended or unintended. Guidelines offer guidance to the designer by forwarding *recommendations* to the consequences generated.

8. KNOWLEDGE STRUCTURING & REPRESENTATION

Knowledge structuring concerns the following issues:

(a) classifying reusable elements into taxonomies in such a way that allows for the addition of new elements;
(b) generating an indexing code of the reusable elements;
(c) generating an individual guideline format;
(d) indexing all guidelines.

Table 3 explains the indexing code. Table 4 gives an *example* of two guidelines that were generated following an evaluation that was held amongst designers and surgeons to discuss the machined prototype (Diagram A) and its improved version (Diagram B).

Through such guidelines designers can obtain an insight and foresee possible life-cycle consequences for the commitments that they take, and hence decide which is the best design solution. Tables 5 and 6 guide the designer regarding the effects that such commitments have on the performance measures: manufacturing cost, manufacturing time and product quality. These results influence the designers' decisions and enable them to arrive at a solution that is life-cycle oriented.

9. FUTURE DIRECTIONS AND CONCLUSIONS

This paper presents some emerging results from ongoing research related to a national funded project. Work is still taking place to capture more life-cycle knowledge in order to improve the prototype's

Table 3. Guideline indexing code.

End effector : H – hook D – dissector G – grasper S – scissors	**Form:** B – Base **[F]** T –Teeth E - Enclosure t - tip	**Material Type:** M - metal v – vanadium m – molybdenum t – titanium a – aluminium MA - metal alloy st- stainless steel z - zirconia wc – tungsten carbide nc- nickel cobalt P – polymer s – silicone SMA – shape memory alloy n – nitinol	**Dimension:** Ø - diameter r - radius t - thickness w - width l – length ^ angle
Surface (S) Texture f – flat r – ribbed d – diamond	**FORM {F}** r- rectangular c – circular t – triangular sp - hemispherical		**Machining Process:** LBM – laser beam machining EDM – electro discharge machining MIM – metal injection molding mM – mesomilling
Surface Finish: r – rough s – smooth			

[ ] – feature property
( ) – feature parameter
{ } – form feature
< - less than
>- greater than
<= less than or equal to
>= more than or equal to

E – end-effector
F – form
B – biomaterial
S – surface texture
SF – surface finish
M – micro manufacturing process

Table 4. Guideline examples.

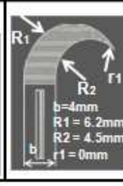
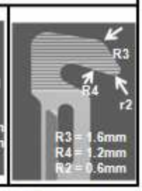
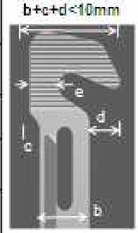
Guideline No.	Guideline 1	Guideline 2
Reasoning	Tool needs to pass through 10mm trocar for LC	Sharp tips damage the tissue
IF	$(Ø)_{(hook)}$ <=10mm	Protruding metal tip is sharp
THEN *(Consequence)*	Tool will not be able to be inserted/ removed	This may cause internal bleeding which is dangerous for patient
THEREFORE *(Recommendation)*	Reduce b to e to gain some width for hook	0.5mm =< $(r)_{(tip)}$ <=1mm
Diagram	a + b >10mm  b+c+d<10mm 	 

Table 5. Comparing manufacturing performance measures for prototype A and B for guideline 1.

		COST	TIME	QUALITY		COST	TIME	QUALITY
a + b >10mm 	MANUFACTURING	✓	✓		b+c+d<10mm 	✓✗	✓✗	
	USE			✗✗				✓✓
	CLEANING							
	SERVICE							
	DISPOSAL							

LEGEND ✓ Favourable ✓✓ Very Favourable ✓✗ Semi-Favourable
✗ Not Favourable ✗✗ Not Recommended

design. The knowledge organization and guideline structure both still need further improvement. The ultimate objective is to embed the guidelines into an intelligent computer aided design support tool so as to pro-actively guide designers working in the minimally invasive surgical design domain.

Table 6. Comparing manufacturing performance measures for prototype A and B for guideline 2.

	COST	TIME	QUALITY	COST	TIME	QUALITY
MANUFACTURING	✓	✓		✓	✓	
USE			✗✗			✓✓
CLEANING			✓✗			✓
SERVICE			✗ Grinding			
DISPOSAL			✗ Attention needed			

LEGEND ✓ Favourable ✓✓ Very Favourable ✓✗ Semi-Favourable ✗ Not Favourable ✗✗ Not Recommended

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