Department of Precision and Microsystems Engineering

Design of a compact wearable arm support utilizing shape optimized compliant shell mechanisms

To be worn underneath the surgical gown

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by

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PREFACE

Before you lies my master's thesis "Design of a compact wearable arm support utilizing shape optimized compliant shell mechanisms". This work is part of an ongoing collaborative project between TU Delft and MIT to offer a significant ergonomic improvement to the laparoscopic theater with the goal of reducing the occurrence of work-related musculoskeletal disorders among laparoscopic surgeons.

The first six months of research leading to this work were carried out at the Massachusetts Institute of Technology, Precision Engineering Research Group in 2017, under the guidance of Alexander Slocum and Nevan Hanumara. The remainder of research and the writing of this thesis were carried out at Delft University of Technology, Department of Precision and Microsystems Engineering in 2017 and 2018, under the guidance of Just Herder and Werner van de Sande.

The main body of the thesis revolves around two research papers. The first reseach paper presents the results of a prior art study on ergonomic body support platforms for laparoscopic surgery, seeking to find out what causes the lack of adoption of such devices and what must be done differently to achieve succesful adoption. The second research paper outlines the development of a novel compact arm support mechanism that is wearable underneath the surgical gown. A number of additional chapters provide background information, the context of these papers in the project and their relation to each other. The main body only reveals the foremost results of the work and chain of activities leading directly to these results. The thesis is extended with a number of appendices that provide additional information and give insight in the process, and other work that is not covered in the main body.

"Perfect solutions that nobody will use do not solve any problems"

Stephanus Johannes Marcellis van der Kemp
Delft, September 2018

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I am equally grateful for my coaches Werner van de Sande and Nevan Hanumara who were always there for thoughtful guidance but at the same time offered me the freedom to manage the course of my own research even when leading to a radical change. I am greatly in debt to you for the countless of hours of discussion, counsel and enthusiasm for my project.

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The Delft Hyperloop II team for delaying my graduation for all the right reasons and continuously reminding me I still have papers to finish as well. It was a year to remember. Go faster, no pressure!

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Contents

CHAPTER 1

INTRODUCTION

1.1. THE ERGONOMICS OF LAPAROSCOPIC SURGERY

Laparoscopic surgery is a type of endoscopic surgery where the patient's abdomen is inflated with CO_2, creating space between the skin and the internal organs. Trocars are placed on the abdomen, functioning as portals for specialized surgical instruments and an laparoscope to be inserted, whilst preventing CO_2 from escaping. As illustrated in figure 1.1, the space that is created gives the surgeon visual and physical access to many of the organs that are located in or near the abdomen without the need for large incisions. The minimal invasiveness of laparoscopic surgery has major benefits for the patient and hospital such as reduced pain and recovery time [1], this combined with providing access to many of the vital organs has led to an increasing number of procedures being carried out through the laparoscopic technique [2].

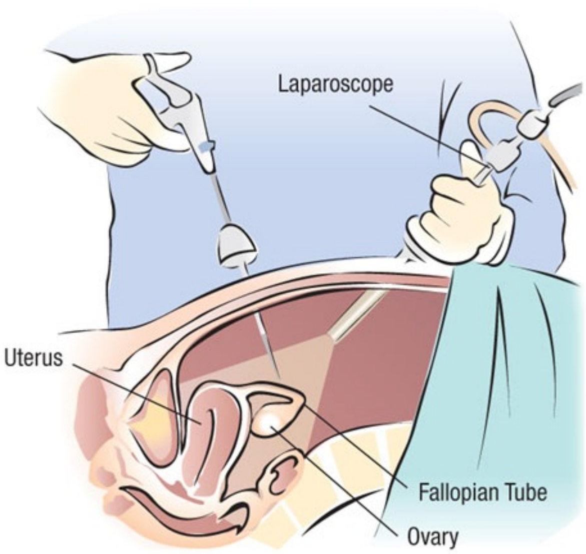

Figure 1.1: An illustration of a laparoscopic procedure

In sharp contrast to the major benefits for patients and hospitals, laparoscopic surgery proves to be much less advantageous to the surgeons themselves, exposing them to significant physical and mental strain [3]. Over the last two decades studies have increasingly warned how poor ergonomics in endoscopic surgery, and particularly laparoscopic surgery, cause fatigue, discomfort and put surgeons at risk of developing work-related musculoskeletal disorders [4–10]. Surveys show that indeed a high percentage, 68 – 86,9%, of endoscopic surgeons report musculoskeletal complaints [3, 11, 12]. For 19.3% of endoscopic surgeons the complaints last post-procedure and 8,29% reported to have continuous discomfort or pain [11]. Work-related musculoskeletal disorders (WMSDs) can affect the surgeon's performance and decision making [13, 14] reduce operating room (OR) throughput, and cause a significant economic burden to the hospital when a surgeon needs sick leave to recover [15]. If the rate of laparoscopic procedures continues to increase, so will the occurrence and severity of WMSDs [3], hence there is an urgent and growing need for ergonomic improvements in the laparoscopic OR.

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1.2. SURGEON SUPPORT PROJECT

To address this issue a collaborative project was initiated between TU Delft and MIT to offer a significant ergonomic improvement to the laparoscopic theater with the goal of reducing the occurrence of WMSDs among laparoscopic surgeons.

Starting with the thesis research by A.A. Waumans in 2014 [16], developing an novel ergonomic body support platform (EBSP). Waumans found that many prior art EBSP designs exist but none had achieved widespread adoption. Upon analysis, many prior art devices were found to be over-constraining, forcing the surgeon in certain healthier postures and affecting the freedom of movement around the OR table. Surgeons indicated wanting to remain fully autonomous and able to (temporarily) assume an unhealthy posture if this is beneficial for completing the procedure, and thus refuse to use such an overstraining device. Furthermore, a gap in the solution space was identified where very few prior art devices focus on promoting postural variation as a strategy for reducing risk of MSDs.

Based on the findings, a ergonomic body support platform was designed that focuses on promoting postural variation by and providing sufficient support without over-constraining. The design consists of a compliant standing platform and a compact chest support with arm rests that is mounted to the OR table as illustrated in figure 1.2. A prototype was built and an in-situ test was performed in the OR. It was found that use of the device lead to reduced load and improved postural reset during short breaks. Lastly, the prototype was demonstrated to 8 surgeons and an OR manager for design feedback. This resulted in generally positive reaction however a number of suggestions for improvement were given. The most frequent comment being that the static arm supports could not always be used as the surgeons are trained to used their shoulders and upper arms for maneuvering the laparoscopic tools.

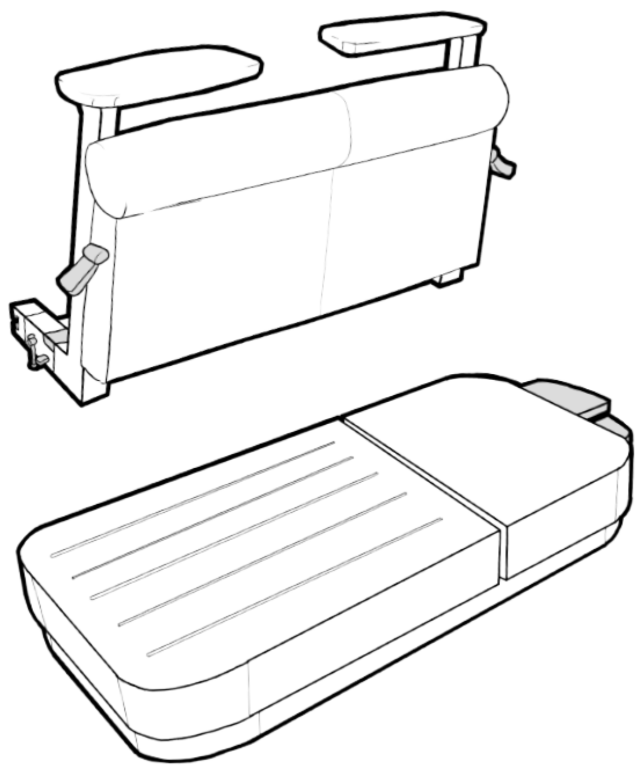

Figure 1.2: Wauman's final design consisting of a compliant standing platform, and a chest support with rigid arm rests that is mounted to the operating table

1.3. ASSIGNMENT

For this thesis, the original assignment was to further develop Waumans support design based on the test result and surgeon feedback that was given, focusing on improving the arm supports. However, during the prior art study of this work it was found that the issues relating to the lack of adoption of ergonomic body supports in the OR are much more complex than anticipated. These findings steered towards developing a wearable arm support instead, this change of strategy is carefully discussed in chapter 3. The goal of the global project remains unchanged; to offer a significant ergonomic improvement to the laparoscopic theater with the goal of reducing the occurrence of WMSDs among laparoscopic surgeons.

1.4. THESIS OUTLINE

In this thesis the line of research is as follows:

1. Identification of factors that are preventing adoption of prior art ergonomic body support platforms. Chapter 2.
2. Formulation of a new solution strategy, a wearable that supports the arms and that is worn underneath the surgical gown, to address factors that are preventing adoption of ergonomic supports. Chapter 3
3. The development of a novel arm support mechanism utilizing compliant shell mechanisms to remain close enough to the arm such it that can be worn underneath the surgical gown. Chapter 4.
4. Discussion, recommendations and conclusion. Chapters 5 and 6.

The main body of the thesis chronologically describes the foremost results and the work directly leading to those results. To provide insight in the other research activities the thesis is extended by a number of appendices.

CHAPTER 2

PRIOR ART STUDY

S.J.M. VAN DER KEMP

This chapter presents the research paper 'Factors impaction adoption of ergonomic body support platforms for laparoscopic surgeons'. This paper was the result of the prior art study phase of this thesis. The paper identifies 5 factors that to various extents have prevented acceptance by surgeons, OR management and hospital management and thereby prevented widespread adoption of EBSPs in the laparoscopic OR.

Draft paper for submission to Surgical Endoscopy and Other Interventional Techniques

Factors impacting adoption of ergonomic body support platforms for laparoscopic surgeons

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Key words: *Ergonomic, body support, platform, surgeon, support, musculoskeletal, complaint, disorder, adoption, acceptance*

Abstract: The physical positions, physical and mental loads and constrained motions of surgeons during laparoscopic procedures are increasingly recognized as leading to a significant rates of longitudinal, work-related musculoskeletal injuries. While multiple ergonomic platforms that provide surgeons' with physical support have been conceptualized, and a few developed into products, this study asked why none have been widely adopted or met with commercial success, despite the apparent abundance of designs. Based on a prior art study encompassing a review of papers, patents and products, 28 unique designs were identified for which sufficient detail was available for analysis. A characterization provides insight in the developments carried out and the explored solution space. Furthermore five factors were identified as pertinent to a solutions' likelihood of adoption by affecting acceptance by surgeons and hospitals.

Introduction

Minimally invasive surgery (MIS) techniques, developed since the 1980's, enjoy popularity due to reduced stress on the patient. However, over the last decade studies have increasingly documented how poor ergonomics on the clinicians' part during laparoscopic surgery can cause fatigue and discomfort and put surgeons at increased risk of developing work-related musculoskeletal disorders (WMSDs) [1–7]. A high percentage, 72.9 – 86.9%, of endoscopic surgeons report work-related musculoskeletal discomfort [7–9]. In 2016 Janki et al. found that 47.5% of laparoscopic surgeons suffer from work-related musculoskeletal discomfort out of which 40.6% experienced discomfort post procedure and for 17.4% continuous discomfort/pain [9].

The high incidence of WMSDs may also have negative consequences for patients and hospital. WMSDs can affect the surgeon's performance and decision making [10, 11], reduce operating room (OR) throughput, and cause a significant economic burden to the hospital when a surgeon needs sick leave to recover [12]. If the rate of laparoscopic continues to increase, so will the occurrence and severity of WMSDs [7].

Physical stress, leading to injury potential, can be investigated as a function of a person's position, its duration, and the load carried [13]. The typically poor ergonomics during laparoscopic procedures stem from the highly constrained tool placements, restricted ranges of motion and extended time in static positions, often with arms extended, as when holding a scope. A particular cause for concern is the length of tools in relation to the adjustability of the operating table and surgeons' heights [14–16]. Although robot-assisted surgery is considered to offer improved ergonomics, with the surgeon in a seated position, compared to traditional endoscopic surgery, it also suffers from its own repetitive motion ergonomic challenges and is limited in application by cost [17].

It is clear there is an urgent and growing need for improving the ergonomics of endoscopic surgery and multiple investigators, inventors and companies have sought to develop ergonomic body support platforms (EBSP) that aim to reduce the average load on a surgeon's musculoskeletal system. These systems span the space from concepts on paper only, to prototypes, to two fully developed products. Some have been tested and shown to reduce the load on the surgeon's musculoskeletal system [18–22].

This raises the question, why, despite showing promise, have EBSPs not been adopted by the medical profession?

This paper presents a state-of-the-art review and analysis of EBSPs, with the goal of identifying whether there are specific factors that are inhibiting acceptance and/or otherwise preventing their widespread adoption. First, a prior art study identified and compiled individual designs, documented in literature, patents and on webpages. These were then characterized based on their physical design, overall strategy towards improving ergonomics, and development stage reached. Based on the characterization, literature, surgeon feedback and observation of the laparoscopic OR qualitative factors were identified that can represent a burden when using an EBSP, affecting acceptance by surgeons, OR managers and/or hospitals. Quantitative metrics were defined to reflect these qualitative factors and used to analyze the prior art designs. This analysis is followed by a discussion and formulation of additional design requirements to improve potential for future designs to be adopted.

Methods

Compilation of prior art designs

A literature study, product search and patent category search were performed to locate prior art designs of EBSPs. These were compiled and organized in an Excel sheet with identifying information comprising of an illustration of the design, timeframe of development, intellectual property status, publications, patents and webpages they were found in, the inventors, location of development, and involvement of companies, universities, hospitals.

To identify papers the Elsevier Scopus database and Google Scholar were used with all sensible concatenations of the search terms shown in Table 1. As the terminology ergonomic body support platform and work-related musculoskeletal disorder is not used universally, a number of variations of terms were used.

Search term	Variations
Ergonomic	-
Body support	*Arm support, Armrest*
Platform	*Orthosis*
Surgeon	*Surgeon's, Surgery, Surgical*
Disorder	*Discomfort, Pain*

Table 1: Search terms and variations

A product search was carried out using the Google search engine the same search terms were used for the literature search. The use of Google images aided in this search as commercial products can be immediately identified through pictures of physical embodiments. In this search the assumption is made that if an EBSP product is currently on the market, it is advertised on the internet. If an EBSP was commercially available in the past but not anymore, it is possible, depending on how long it has been off the market, that this information could not be found.

The patent category search was performed using the Patsnap Patent Search & IP Analytics Software. Two Cooperative Patent Classification (CPC) System categories, which are agreed upon by the European Patent Office and the United States Patent Office, and one Unified Patent Court (UPC) category were identified as encompassing EBSPs. These are detailed in Table 2

Patent category	Description
CPC A61B 90/60	A – Human necessities A61B – Medical or veterinary science; hygiene 90/60 – Supports for surgeons, e.g. chairs or hand supports
CPC A61B 19	Old version of CPC A61B 90/60
UPC 248/118	Armrests or headrests. (used with additional search term; surgeon)

Table 2: Patent categories and descriptions

The scope of the prior art search was limited to exclude ordinary surgical chairs which are already widely used in the OR, variations thereof providing no additional support, and devices that hold tools in place but do not offer support to the surgeon. In addition, patents not describing a complete design, providing insufficient information on the embodiment and how the device operates were excluded from the scope if this information could not be obtained elsewhere.

Upon completion of searches in all search media, the complete list of designs was analyzed for duplicates from the different search media, combining them into one entry in the Excel sheet. If a design was only found in one or two of the three search media, it was attempted to find additional information in the other search mediums using the product name or inventor/researcher names.

Characterization

A characterization analysis was carried out to identify common design themes and to get a sense of the explored solution space. This to aid in the identification qualitative factors inhibiting adoption based on their properties and how they would be used. The selected characterized metrics are shown in Table 3.

Definition of qualitative factors and representing quantitative metrics

A visit to the Mt Auburn Hospital OR showed that much of the OR equipment was stored in racks right outside the OR door as shown in Figure 1. In addition to the racks, there is a storage room for all ORs to share for storing objects that do not fit in the racks. This room is further away from the OR and was said to be quite full. The use of an EBSP classified as larger than a surgical chair in this study was not accepted by the OR manager due to lack of storage space. Considering technological improvements have brought more and more specialized equipment into hospitals, laparoscopic surgery being one example, it is assumed that most OR managers will consider storage of large equipment a burden. Hence, storage is seen as a factor affection adoption of EBSPs in this work.

Characterization metrics	
Functional	Support location: *What type of support modules are used*
	Degrees of freedom: *Does the device offer adjustability or articulating members*
	Strategy towards ergonomic improvement: *Load reduction, improvement of posture and/or encouraging postural variation*
Intellectual property	Patent applications: *How many designs have patent applications, granted patents and abandoned patents*
Development context	Development stage: *For how many design were there prototypes, and how many have ever been on the market*
	Academic or commercial focus: *Was the development in an academic setting or commercial setting*

Table 3: Characterization metrics

Figure 1: Most of the OR's equipment is stored right outside the doors in racks

Time in the OR is expensive, thus a quick turnover in between procedures is important. This is underlined by the presence of TV monitors showing productivity metrics in the hallway connecting to the OR at Mt. Auburn Hospital. If EBSPs require significant setup effort this will be perceived as a burden by the surgeon who is expected to carry out procedures efficiently and certainly the hospital who sets these productivity goals. Therefore the setup effort imposed by the use of an EBSP is considered a factor affection adoption.

Another identified factor is the amount of OR real-estate an EBSP needs. In particular the space directly around the OR table is scare in laparoscopic surgery as evident from Figure 2.

Figure 2: The laparoscopic OR is crowded, OR real-estate is particularly scare around the OR table.

In the thesis by Waumans in 2014 [13] it was identified that some EBSP devices over-constrain the surgeon, forcing certain healthier postures and making it impossible for the surgeon to assume an unhealthy posture temporarily if this is beneficial to the efficient completion of the procedure. This was concluded to be detrimental to surgeon acceptance and thus it is considered a factor impacting adoption and used for analysis in this work.

Lastly, the cost associated with using an EBSP is important for achieving acceptance from the hospital. EBSPs are non-essential to the completion of procedures, and there have been no large scale trials of any ESBP that give indication of a cost reduction that could justify the cost of purchase, sterilization and maintenance. For this reason, cost is considered a factor affecting adoption and it is worthwhile to investigate.

For each factor affecting adoption one or more quantitative analysis metrics were defined that were used to analyze the prior art designs for the identified factors affecting adoption all factors impacting adoption and analysis metrics are summarized in Table 4.

Factor	Analysis Metric
Storage	Device size: Fits in rack of Table 1. [1000 x 600 x 300mm] Doesn't fit in rack but no larger than a surgical chair. [1200 x 750 x 750 mm] Larger than a surgical chair.
Setup effort	Number of adjustable members + mounting actions if any: 0 to 2 steps 3 to 5 steps 6 or more steps
OR real-estate	Device size: Fits in rack of Table 1. [1000 x 600 x 300mm] Doesn't fit in rack but no larger than a surgical chair. [1200 x 750 x 750 mm] Larger than a surgical chair.
	Floor space; Needs no floor space near OR table. Needs floor space near the OR table.
Surgeon autonomy	Need to adjust to device: Device follows user, no adjustment needed User has to slightly adapt to using the device Device requires significant adaptation
Cost	Sterilization: Needs no sterilization or sterile sheathing. Needs sterilization or sterile sheathing.

Table 4: Factors affecting adoption and associated analysis metrics

For each analysis metric, the prior art designs are subdivided in groups that represent different levels of burden. For the factor storage space, the device size is chosen as a quantitative metric representing the burden an EBSP presents for storage. E.g. If an EBSP is estimated to fit in the rack outside the OR shown in Figure 1 it is considered to pose minimal storage burden. If it can't be stored in a rack but is of the size of a surgical chair or smaller it is considered to pose an average level of burden. If it is larger than a surgical chair it is considered the storage of the EBSP poses a significant burden.

Analysis

The analysis of EBSPs subdividing the designs into the different groups of each metric the defined categories relies on the judgment of figures and text describing the EBSPs introducing a certain level of subjectivity. This creates uncertainty for individual data points in certain analysis metrics, however when putting data points for all 28 EBSPs together it gives a reliable indication of the burden presented by EBSPs for each factor.

Results

A total of 52 unique designs of ergonomic supports were found in the compilation of prior art designs. After exclusion of designs that are outside of the scope 28 designs [19, 20, 22–50] were found suitable for analysis.

Characterization

Support modules	Lower arm 20 (71%)	Chest 11 (39%)	Seat 10 (36%)	Elbow 9 (32%)
	(Lower) Back 6 (21%)	Sit-stand 4 (14%)	Head 4 (14%)	Footrest 4 (14%)
	Raising platform 3 (11%)	Hand 2 (7%)	Knee 2 (7%)	Waist 2 (7%)
	Upper arm 1 (4%)			
Degrees of freedom	Rigid/none 0 (0%)	Adjustable 24 (86%)	Articulating 19 (68%)	
Strategy towards ergonomic improvement	Load reduction 28 (100%)	Improvement of posture 5 (18%)	Encourage postural variation 1 (4%)	

Table 5: Characterization of functional aspects

Table 5 shows what type of support modules are utilized in the designs. Any given design can utilize multiple support modules, i.e. 71% of the designs support the lower arm, but in many of those designs there are also other support modules present. The same goes for types of *degrees of freedom or adjustability* and *strategy towards ergonomic improvement*, percentages do not add up to 100%.

Patents were applied for 82% designs, this however is expected given patent search was used as a search method. 46% of designs once had granted patents, for one design the patent was denied, and for nine designs the patents were abandoned. For 13 EBSPs a prototype could be found, and for 2 it is known they made it to market, an articulating arm support by Karl Storz [29], and a large platform by Ethos Surgical [21]. The arm support by Karl Storz was not for sale in the United States at the time of writing and the platform by Ethos Surgical is no longer on the market. Out of the 28 designs, 11 were developed by universities and/or (academic) hospitals, 8 by a company and for 9 designs it is unclear in which context they were developed. Developments took place across the globe indicating global recognition of the problem of WMSDs in laparoscopic surgery.

Analysis

The results of the analysis are compiled in Table 6.

Factor	Analysis Metric	Results
Storage	Device size:	
	Fits in rack of Figure 1	7 (25%)
	Doesn't fit in rack but no larger than a surgical chair.	11 (39%)
	Larger than a surgical chair.	10 (36%)
Setup effort	Number of adjustable members + mounting actions if any:	
	0 to 2 steps	10 (36%)
	3 to 5 steps	13 (46%)
	6 or more steps	5 (18%)
OR real-estate	Device size:	
	Fits in rack.	7 (25%)
	Doesn't fit in rack but no larger than a surgical chair.	11 (39%)
	Larger than a surgical chair.	10 (36%)
	Floor space;	
	Needs no floor space near OR table.	6 (21%)
	Needs floor space near the OR table.	22 (79%)
Surgeon autonomy	Need to adjust to device:	
	Device follows user, no adjustment needed	0 (0%)
	User has to slightly adapt to using the device	26 (93%)
	Device requires significant adaptation	2 (7%)
Cost	Sterilization:	
	Needs no sterilization or sterile sheathing.	0 (0%
	Needs sterilization or sterile sheathing.	28 (100%)

Table 6: Results of prior art analysis based on the defined metrics

For 21 designs (75%) it is not feasible to be stored in the rack of Figure 2, meaning the large majority of designs represent some burden during storage. 18% of devices were estimated to take more than 6 steps to be mounted and adjusted, and 79% of designs need floor space near the OR table. The other 21% are mounted to the OR table rail, the wall or the ceiling. 93% of designs need a small adjustment for using the device, e.g. to use an arm support, the elbow or arm must be placed and kept on the arm support, or the surgeon must align itself with the platform. None of the designs allow the surgeon to carry out the procedure completely as normal, as if it is not there. Finally, notably all devices require sterilization or sterile sheathing as all EBSP designs either have an arm support, a chest support or both and thus are present in the sterile field.

Discussion

Characterization

The results show that out of the 28 EBSPs only two [21, 29] ever made it to market. The Cuschieri articulating arm support by Karl Storz [29], and a large platform by Ethos Surgical [21] shown in Figure 3. The arm support by Karl Storz found in an online catalog and thus is for sale at the moment of writing, however an inquiry to Karl Storz found it is not for sale in the United States. The platform by Ethos Surgical is no longer for sale and the company seems to have gone out of business. The patent was assigned to Pedigo Products, a company that among other equipment sells stools and chairs for the medical industry. It however does not sell an EBSP and it is not known if they are intending to bring the Ethos Surgical platform back to market. This confirms that EBSPs are not yet widely adopted.

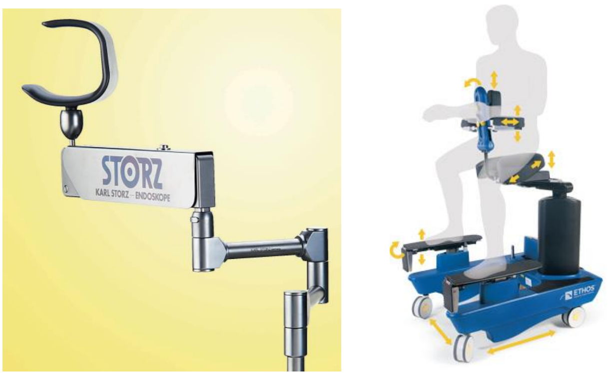

Figure 3: Karl Storz Cuschieri arm support (left) and the Ethos Surgical Platform (right)

Table 5 shows the most used support modules, revealing that supporting the lower arm is seen as an important support module as it is used in 71% of the designs, followed by the chest and seat modules with 39% and 36% respectively. 86% of the designs utilize adjustability and 68% have some form of articulation. Adjustability typically serves to fit surgeons of different sizes or to adjust the EBSP for a specific procedure. Articulation in most cases serves as a means of supporting the surgeon without constraining. In particular arm supports are often designed to articulate such that the arms can be supported whilst providing them the freedom of movement that is required in Laparoscopic surgery.

When looking at the strategy used to improve the ergonomics, in addition to supporting the surgeon physically, five (18%) of the designs also focus on improving posture and one (4%) of the designs encourages postural variation. This confirms much opportunity still lies in improvement of posture and postural variation as identified in the thesis by Waumans in 2014 [13].

Out of the 23 designs for which a patent was applied, 13 (57%) were found to have active patents that are being maintained, 9 (39%) have been abandoned and one (4%) has been denied. Due to the costs associated with maintaining a patent, the patents represent investment of time and money trying to commercialize EBSPs. However, the large percentage of abandonments shows that commercialization is troublesome.

EBSPs have been developed all around the world showing that the problem of WMSDs among endoscopic surgeons is recognized globally and that there is a widely held belief that EBSPs are promising for solving this problem.

Analysis of factors according to representative metrics

7/28 (25%) of the designs were considered small enough to fit in the rack of Figure 1 near the OR in a collapsed state. All other designs, 75%, would have to be stored in the storage room that is further away. 36% of devices are larger than an ordinary surgical chair, and thus their transport presents an effort as well, some devices needing two people to transport. Since EBSP are ideally used every laparoscopic procedure, they could be kept inside the OR as standard equipment. However, if non-laparoscopic procedures are carried out in the OR as well, or not all surgeons wish to use the EBSP, it has to be storable outside the OR. If an EBSP design can be folded down to a compact size that fits in a rack and is lightweight enough to be carried by a single person, this allows for convenient storage and transport.

The setup effort required is minimal for 36% of the designs with an estimated 1-2 steps, corresponding to a quick routine setup that takes a negligible amount of time. 46% of the designs need roughly 3-5 steps which still should not take a significant amount of time. 18% of the EBSPs need more than 6 steps. Given 82% of designs can be setup in approximately set up in 5 steps or fewer, this is not considered a large factor that is causing EBSPs not to be accepted. However, whether the time and effort required for setting up the EBSP is considered worthwhile ultimately depends on how large the perceived benefit of its use is. A surgeon with current and serious musculoskeletal complaints would very likely be willing to spend some effort to setup the EBSP for every procedure due to the significant immediate benefits. However, even a small setup effort can present a boundary for preventative everyday use. A scrub nurse in the OR at Mount Auburn Hospital said the largest irritation during the setup and preparation of the OR is when devices do not fit together, are broken or are missing parts. Therefore EBSPs should strive for easy to setup designs with hardware that is robust and such that parts like fasteners can’t easily get lost.

Figure 2 shows the laparoscopic OR is highly crowded. Around 40% of the floor surface in the laparoscopic theatre is taken, the area underneath the OR table is particularly scarce [51]. Here, the addition of a bulky EBSP can be easily seen as undesirable as it further reduces physical access, visual access, and freedom of movement around the OR table which makes the work environment less ergonomic, rather than more. 21% of designs take this into account and do not need floor space, for example by attaching to the OR table rail. The other 79% of EBSPs need floor space near the OR table and 36% of EBSP designs are larger than a surgical chair. Thus, the majority of EBSPs are competing with critical surgical equipment for scarce OR-real estate, and more than a third of devices are larger than a surgical chair. This limits access to the OR table and freedom of movement around the OR table which is detrimental to the ergonomics and the acceptance by surgeons. Compact EBSPs mounted to the OR table rail minimize this issue.

In prior research respecting autonomy was found to be important for the acceptance of EBSPs [13]. In the same study an inverse relation was found between the surgeon autonomy and the level of support that prior art EBSPs provide. Laparoscopy requires awkward and static postures to complete a procedure [1]. If an EBSP confines a surgeon’s freedom of movement, reduces access to the surgical site, and/or blocks the surgeon from assuming an unhealthy posture that would have temporarily been practical for completing the procedure, it raises concerns about whether the device is slowing down the procedure or even negatively affecting surgical outcome. One way of providing support without limiting the surgeon’s freedom is by articulation mechanisms. The characterization shows 68% of designs incorporating articulation.

In the metric analysis it was estimated to which extent the devices dictate a change to how the procedure is carried out. It was found than none of the EBSPs can be used without any adjustment of the procedure, as if it is not there. In 93% of designs a small adjustment is required is needed, such as aligning with the device and the device not allowing full freedom of movement. 7% of designs require the surgeon to significantly adapt their way of carrying out the procedure to use the device. Following the recommendations of Waumans, EBSPs should respect surgeon autonomy, being able to temporarily assume unhealthy postures if this is required to complete the procedure effectively. This can be achieved by focusing on encouraging healthy posture but not forcing them, and to minimize any obstruction to the surgeon's freedom of movement [13].

Lastly, in the cost metric analysis it was found that all EBSP designs are at least partially present in the sterile field and therefore require sterile sheathing and or sterilization for each use. This has the implication that the ESBPs incur a per-procedure cost. Although for some EBSPs their ability to reduce musculoskeletal load was proven, there have been no large scale trials of EBSPs that indicate how much the use of EBSPs will reduce the occurrence of WMSDs. For this reason it is impossible for hospitals to confidently estimate if and by how much the use of an EBSP will result in a cost reduction related to a reduction in sick days. Because of this the use of EBSPs hard to justify as a sound business decision, significantly affecting the acceptance of EBSPs by hospitals. In order to circumvent the requirement for sterilization and the associated costs, the surgeon needs to be supported outside the sterile field, possibly underneath the surgical gown.

Conclusion

There is a clear and growing need for reducing occurrence of WMSDs among endoscopic surgeons. At least 28 EBSPs have been developed as a proposed solution, and for a number of them their ability to reduce musculoskeletal load has been validated experimentally. Despite their promising ability to reduce WMSDs and various commercialization attempts, EBSPs have not achieved widespread adoption. In this work, five factors were identified that are important to achieving acceptance by surgeons, OR managers and hospital management.

The storage of the majority of prior art design requires a significant floor space, just over a third of prior art designs are larger than a surgical chair and thus will also represent a considerable burden in transportation to and from the OR, this is considered to mostly affect acceptance by OR management.

The setup-time required for preparing an EBSP was identified as an important factor due to its impact on OR throughput and work-load. This affects acceptance by hospital and OR management that attempts to maximize utilization of the OR, and the surgeon as it poses additional workload. However, the large majority of designs appeared to only present a minimal burden during setup.

Another factor important to acceptance is the amount of OR real-estate is taken up by an EBSP, in particular floor space right around the OR table. 79% of devices need floor space at the OR table, 36% of designs are larger than a surgical chair and thus require significant space.

The extent to which a device affects the surgeon's autonomy was found important to surgeons. Forcing healthy postures and otherwise constraining freedom of movement, requiring a large adaptation to using the device are considered to negatively affect acceptance. Although the large majority of devices were considered to require a minimal adaptation, all EBSP devices require the surgeon to consciously use the EBSP, aligning with arm supports or being fixed in one location with respect to the patient due to static positioning of the EBSP.

Lastly, all designs were found to be at least partially present in the sterile field such that they incur a per-procedure cost related to sterilization or sterile sheathing. The resulting cost increase of procedures cannot be easily justified with an offsetting cost reduction due to lack of real world use data. A summary is provided in Table 7.

Factor	Conclusion
Storage	Burden caused by the need for storage space affects acceptance by OR management.
Setup effort	Setup effort affects acceptance by the surgeon and the hospital due to the need for maximizing OR throughput.
OR real-estate	The laparoscopic OR is crowded with people and equipment. Floor space around the OR table is particularly scare. The amount of OR real-estate an EBSP requires affect surgeon acceptance.
Surgeon autonomy	Surgeons want to remain autonomous. A reduction of freedom of movement by the EBSP will affect acceptance by surgeons.
Per procedure cost	Per procedure cost affects acceptance by hospitals due to the lack of data indicating a cost reduction to offset the increase in cost.

Table 7: Summary of factors affecting adoption

The consideration of these factors in the design of new EBSPs or the alteration of exiting EBSPs can serve to increase acceptance by all users and thereby improve odds of widespread adoption of EBSPs in the laparoscopic OR.

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CHAPTER 3

SOLUTION STRATEGY

3.1. FACTORS AFFECTING EBSP ADOPTION

The prior art study identifies five factors that are important for achieving acceptance of EBSPs. For four of those factors is was found that a majority of prior art EBSP designs present a moderate to substantial burden that have prevented acceptance by surgeons, OR management and hospital management, and therefore made widespread adoption impossible. As it is not the paper's purpose to judge or discourage, it was decided to leave the paper as neutral as possible, only presenting the information and let readers draw their own conclusions.

Based on the findings of the prior art paper, a number of design requirements were formulated to minimize the burden associated with the use of EBSPs to achieve acceptance by surgeon, OR management and hospital management.

"An EBSP must"

- Be store-able in a rack, or require not storage space at all
- Be Effortless and quick to setup such that OR throughput is not affected significantly.
- Not take up significant OR real-estate
- Respect surgeon autonomy by not constraining freedom of movement
- Not incur per-procedure cost

This set of design requirements present an addition to the functional design requirements of an EBSP for adaptation of prior art designs, or the development of new designs for achieving acceptance by all users such that wide-spread adoption is possible.

3.2. FUNDAMENTAL DIFFICULTY OF EBSP DESIGN FOR ADOPTION

Upon further analysis it was found that for a platform based support it is fundamentally difficult to fulfill all requirements due to contradictions in the design problem. For example, for the designs with static armrests, surgeons indicate that they can barely use them as the arms span a large range of motion during surgery [16]. Adjusting the armrests to a high position makes them obstruct physical access to the operating table, whilst a low position is out of reach for resting on during the majority of the procedure. Continuously adjusting the arm rests is not a feasible option, the frequency at which this needs to happen will be too much of a burden and slow down the procedure. To counter this, many designs have articulating arm supports that move along with the surgeon's arms, continuously supporting them without need for adjustment. However, such articulation mechanisms increase the size of the platform. This again is undesirable as the device has to compete with vital surgical equipment for scarce real-estate around the operating table.

Another critical finding is that all prior art designs are present in the sterile field. The regulations and per procedure cost related with sterilization causes that it is infeasible for individual surgeons with musculoskeletal complaints to purchase and use a device on their own accord. At the same time hospitals cannot justify the cost of purchase and per-procedure cost, given it is unclear how much cost reduction an EBSP will yield to offset this cost. To achieve this, there have to be data on how much the use of EBSPs will reduce occurrence of WMSDs, and there has to be data showing the current cost of WMSDs to hospital. The first is only possible upon a large trial requiring some degree of adoption, causing a chicken and egg problem. Even if such a trial was achieved and gave conclusive prove of a significant reduction of WMSDs among surgeons that use EBSPs, it is unlikely that most hospitals are aware, let alone have accurate data, of the cost caused by WMSDs among their laparoscopic surgeon workforce.

It is concluded that designing a platform based support that adheres to the secondary design requirements for achieving adoption yields a highly constrained design problem. It is estimated that attempting this will very likely yield a design with a high level of compromise. In addition, it is expected that it will be incredibly difficult to create enough economic incentive for hospitals to widely adopt EBSPs in laparoscopic surgery. For this reason, it was decided to re-assess the solution strategy.

3.3. THE SUB-GOWN WEARABLE SUPPORT

A new solution strategy is proposed in the form a wearable body support that is compact enough to be worn underneath the surgical gown.

By being worn underneath the surgical gown, the wearable omits the sterilility requirement by letting the surgical gown act as a free sterile barrier. This means there is no per-procedure cost related to the use of the wearable opening up a previously unexplored business model and strategy towards achieving widespread adoption: To sell directly to the surgeon as opposed to selling to the hospital. This will allow surgeons with musculoskeletal complaints to act as lead users, piloting the use of the wearable. Over some time enough data may be gathered to provide indication of what reduction in WMSDs the use of wearable leads. The availability of this data and lack of a per-procedure cost might ultimately cause hospitals to offer such wearables to all laparoscopic surgeons for preventative use. This subsequently leading to a significant reduction in the occurrence of WMSDs in laparoscopy.

In addition to the new sales model, a wearable based support presents significant advantages over platform based supports:

- Wearables can be compact, store-able on shelves or in closets. Alternatively, it is taken home by the surgeon, such that no storage space is required in the hospital.
- A wearable does not require any floor space, especially when worn underneath the surgical gown its presence will not have a significant effect on the real or perceived crowdedness of the OR.
- The arms can be supported over their entire natural range of motion without large articulating members mounted to a platform or the OR table.
- The physical and visual access to the OR table is not affected.
- The surgeon is free to move freely around the OR and reposition with respect to the OR table without the need for exiting or moving the support. This also stimulates postural variation which is beneficial to the ergonomics.
- A fully passive wearable allows the surgeon to carry out procedures without any adaptation for using it. I.e. it is donned before a shift and can simply be forgotten. This is the ideal situation in terms of respecting surgeon autonomy.
- If donned before the shift, the use of the wearable does not affect the time required to prepare the OR between procedures.

These fundamental advantages make a wearable much better able to adhere to the design requirements defined in paragraph 3.1. However, it must be noted a wearable does not make platform based supports obsolete, as a wearable can be used in conjunction with a platform based support. For example, an arm supporting wearable can be used in conjunction with the standing platform design shown in figure 1.2.

3.4. FINAL SOLUTION STRATEGY

Based on the analysis of prior art study findings, a new strategy was formulated for the surgeon support project: To design a wearable that supports the arms and can be worn underneath the surgical gown.

For this thesis designing the entire wearable ergonomic support is too large of a scope to carry out in a scientific manner, and thus a scope limitation must be applied. In the prior art paper it was found supporting the arms is the most important support module. For the wearable, the main technological challenge is to achieve an arm support mechanism compact enough to be worn comfortably in the sleeve of the surgical gown, therefore this is the focus of the design phase of this thesis. Other support elements to further improve ergonomics, such as incorporation of a back support are therefore outside of the scope of this thesis. Integrating additional support elements in the wearable could certainly improve the design but their feasibility is considered non-critical to the usefulness of the device.

CHAPTER 4

DEVELOPMENT OF A COMPACT WEARABLE ARM SUPPORT

S.J.M. VAN DER KEMP

This chapter presents the research paper 'Compact Wearable Arm-Support for Laparoscopic Surgery Utilizing Shape Optimized Compliant Shell Mechanisms'. This paper presents the results of the design phase of this thesis. The paper presents the design of a compact arm support mechanism that is designed to be worn underneath the surgical gown.

Compact Wearable Arm-Support for Laparoscopic Surgery Utilizing Shape Optimized Compliant Shell Mechanisms

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Key words: *Arm-support, Compact, Compliant Shell mechanisms, Laparoscopic surgery, Static Balancing, Gravity Balancing*

Abstract: Passive exoskeletons that support the weight of the surgeon's arms could yield a significant ergonomic improvement in the Laparoscopic theatre. However, the cost and regulations associated with sterilization complicates adoption of such devices. In this work a compact passive arm support mechanism is designed that can be worn underneath the surgical gown to circumvent sterility requirements. The design utilizes shape optimized compliant shell mechanisms who's geometry can remain substantially close to the body as well as achieve the nonlinear stiffness characteristic that is desired for balancing the arm's weight. A shell design with the desired torque-rotation characteristic is designed using shape optimization and fabricated for validation testing. Measurements show the prototype balances 19% of an average adult's arm weight within ±4 percentage points between 0 and 90 degrees of arm abduction and or flexion. A prototype of the mechanism remains within 34mm of the arm, nearly twice as compact as the state of the art.

I Introduction

Over the last two decades studies have increasingly warned that poor ergonomics in endoscopic surgery, and particularly laparoscopic surgery, cause fatigue, discomfort and put surgeons at risk of developing work-related musculoskeletal disorders (WMSDs) [1]–[5]. Surveys show that indeed a high percentage, 68 – 86,9%, of endoscopic surgeons report musculoskeletal complaints [6]–[8]. WMSDs can affect the surgeon's performance and decision making [9], [10] reduce operating room (OR) throughput, and cause a significant economic burden to the hospital when a surgeon needs sick leave to recover [11]. Hence, there is an urgent need for ergonomic improvements in the Laparoscopic OR.

The poor ergonomics are characterized by static postures [12] which is the result of the fixed entry points of the laparoscope and laparoscopic tools [13], causing the surgeon to remain in the exact same position for extended periods of time. The length of the laparoscopic tools cause a magnified fulcrum effect around the entry point [14], requiring a large range of motion of the arms to maneuver the instruments. An observation of the laparoscopic OR environment at Mt. Auburn Hospital in Cambridge Massachusetts showed that operating the laparoscopic tools and endoscope involves lifting the arms in front of the body for extended periods of time as illustrated in Figure 1.

Figure 1: Prolonged postures with arm abduction and flexion in laparoscopic surgery.

The surgeon indicates that this arms forward posture becomes uncomfortable during lengthy procedures and that an arm support is highly desired. Statistics show complaints are most frequently localized around upper back, shoulder and neck area in laparoscopic surgery [7]. The sustained arms forward postures cause large static loads on the muscles holding up the arms, but also on the upper back muscles to counteract the upper body weight being shifted forward by the arms [15]. The observed postures, the surgeon's feedback, localization of complaints, and the ability of arm supports to reduce load in muscles with most frequent complaints [16] leads to the belief that supporting the arms is an effective method for improving the ergonomics in laparoscopic surgery. However, opponents of arm supports are concerned with them getting in the way of the surgeon [17], being difficult to keep sterile, and barely being used due to the large range of motion spanned by the arms [18].

Wearable arm supports such as the SkelEx [19] and Airframe [20] passive exoskeletons are considered to offer an ideal solution from a functional standpoint as they support the arms over their entire range of motion without obstructing access to the surgical site, or constraining in any way the surgeon's freedom of movement. However, these devices are not compact enough to be worn underneath the surgical gown meaning they need to be either sterilized or covered in sterile sheathing. The per-procedure costs associated with sterilization or sterile sheathing is undesirable and complicate achieving adoption of such devices in the OR.

This work seeks to design a wearable arm support, using compliant shell mechanisms, that is compact enough to be worn underneath the surgical gown such that the sterility requirement and associated per-procedure cost can be circumvented. Compliant shell mechanisms show promise for creating a compact arm support as they are able to achieve the nonlinear stiffness behavior required for balancing the weight of the arm through shape optimization such there is need for an additional cam mechanism [21], [22]. Furthermore, their thin-walled nature allows them to achieve a low profile [22] by following the contours of the arms.

First, the functional requirements are discussed. A model is then presented that determines how the device must support the arm to satisfy the requirements. Then, the conceptual design of the mechanism is shown, followed by the shape optimization approach and the experiments carried out to validate the design. In the results section, the optimized shell mechanism design, measurements of the arm balancing characteristic and compactness of the mechanism are outlined. This is followed by the discussion and conclusions where the performance and compactness of the mechanism is discussed, and recommendations are made for future research.

II Methods

1) Functional Requirements

It is not yet known what level of support is ergonomically optimal. It is assumed that from an ergonomics standpoint the ideal level of support lies between 25% and 50% of the arm's weight, any more load reduction seems excessive and will likely lead to deterioration of the surgeon's fitness, creating an undesirable dependency on the device. The ideal level of support is also subject to preference and it is possible that a larger load reduction is preferred. Thus it is decided the arm support mechanism must be able to support at least 25% and up to 75% of the arm's weight.

Based on observations made during a laparoscopic procedure at Mt Auburn Hospital the working range of motion of the surgeon's upper arm is between 0 and 90 degrees as illustrated in Figure 2. In this range of motion the arm must be supported to achieve consistent support.

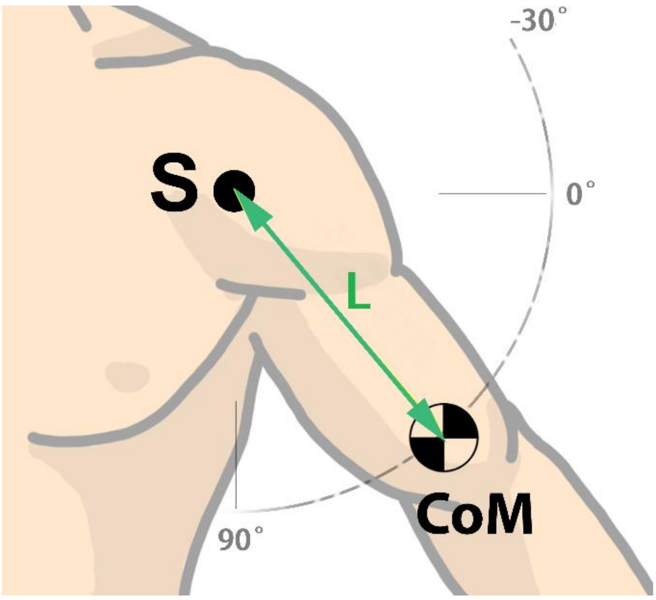

Figure 2: A straightened arm is modelled by a simple pendulum with pivot S at the shoulder joint and a point mass CoM at the center of mass of the arm that is length L away from pivot S. [Adaptation from Dunning et al, 2015].

For the support to be intuitive, it is decided that the level of support must be proportional to the load. The load that is caused by the arm's weight varies throughout the range of motion due to the varying moment arm of the weight load with respect to the shoulder joint. This way, when the arms are relaxed in the 90 degree orientation, the arm support must also not apply significant force.

In order to be wearable underneath the surgical gown comfortably the device must as compact as possible. It is assumed to be acceptable if the device requires wearing a surgical gown that is one size larger than what is normally worn by the user, however it should be strived for that it can ultimately be worn under a same size surgical gown. To achieve this, the goal is set that the arm support should not extend outward from the skin by more than 20mm at any point along the arm [23], [24]. Lastly, it is important that the device does not apply significant forces parallel to the skin to avoid chafing.

2) Quantification of requirements

Translating the qualitative support requirement into the exact forces and/or moments that the mechanism must apply to the user's arm was achieved by modelling the arm as a simple pendulum with lower arm extended as shown in Figure 2. Although the lower arm is not often fully extended during laparoscopic surgery, this situation represents a worst case where the arms require the most effort to lift. In this work, the arm weight and length of an average adult are assumed. However, by being able to vary the support magnitude, the arm support is able to be customized for users with different arm lengths and weights.

The shoulder joint is a ball joint with 3 degrees of freedom (DOF). In the model the shoulder joint could be simplified to a 1 DOF revolute joint making use of the axial symmetry between arm abduction and arm extension, and the fact that shoulder rotation has no significant effect on the elevation of the arm's center of mass. The angle of the arm is defined to be 0 degrees at horizontal and 90 degrees when pointed straight down. Throughout this work the angle of the arm is referred to as *arm angle* or α, equivalent to arm abduction, flexion, or combination thereof. Using this model and anthropometric data [25], the gravitational potential of the arm E_{arm} can be analytically expressed as a function of the arm's angle α in equation 1.

$$E_{arm}(\alpha) = M_{arm} * g * (L - L * \sin\alpha) \qquad (1)$$

Here M_{arm} is the mass of the arm, g is gravitational acceleration, and L is the distance between pivot S and the arm's center of mass *CoM*.

To fulfill the requirement of intuitive proportional support the principle of static balancing is applied as illustrated in Figure 3. By balancing the gravitational potential energy of the arm E_{arm} with the potential energy stored in the arm support, the total system energy is constant. This corresponds with supporting 100% of the arm's weight. To achieve 25% support the desired energy characteristic of the arm support is the same but a factor 4 smaller in magnitude. The required torque characteristic at the shoulder can be obtained by taking the derivative of the energy characteristic with respect to arm angle α.

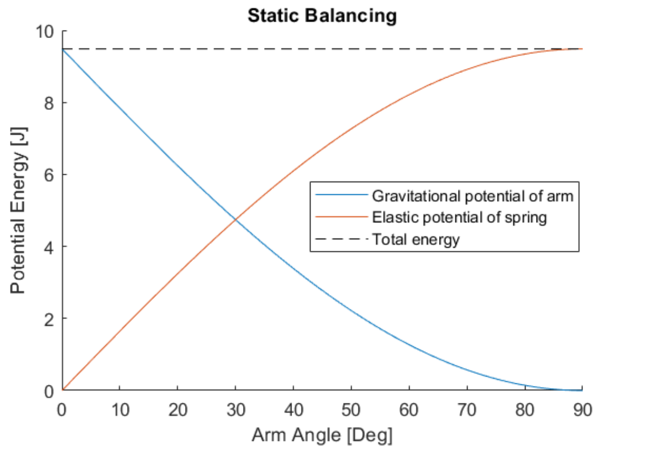

Figure 3: The potential energy characteristic of the arm (blue), Required elastic energy characteristic of the mechanisms to achieve 100% static balancing (blue) and resulting constant total energy (dashed green).

3) Conceptual design

The selected concept is schematically illustrated in Figure 4 and a render is shown in Figure 5. The mechanism consists of a shell mechanism (red) which is mounted to a frame at the shoulders by means of a revolute joint and to support cuffs at the upper arms by means of a prismatic joint.

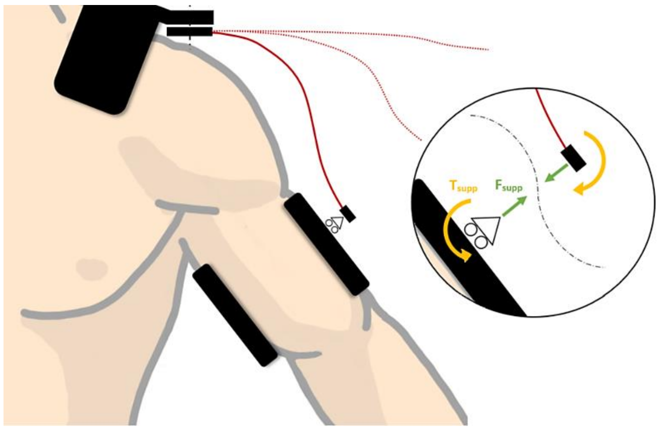

Figure 4: Schematic of the conceptual design. A shell mechanism (red) is attached at the shoulder with a revolute joint, and at the arm with a prismatic joint. The shell applies force F_{supp} and torque T_{supp} to the upper arm. [Adaptation from Dunning et al 2015].

Exactly like the SkelEx and Airframe exoskeletons, it was decided to apply support to the upper arms. This allows for the same load reduction at the shoulder as a lower arm support typical to platform based supports, but significantly reduces design complexity as the upper arm has fewer degrees of freedom with the respect to the torso than the lower arm. Furthermore, the lower arm does not appear to need support as no complaints are reported in muscle groups responsible for lifting the lower arm [7].

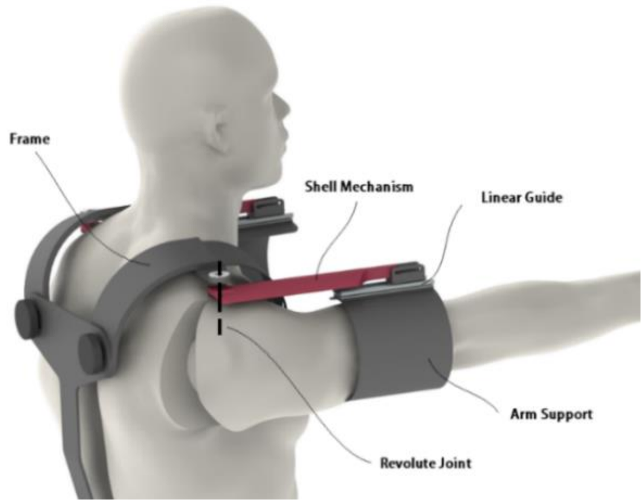

Figure 5: Arm support conceptual design

This arrangement of the shell mechanism and joints creates axial symmetry around the vertical axis of the shoulder joint such that a 1DOF shell mechanism can balance the arm in 2DOF, greatly reducing the design complexity of the shell. The placement of the shell on top of the arm allows the shell to provide support at the same axis of the load. The same could be achieved by placing the shell under the arm, but that causes the mechanism to press against the trunk when the arm is relaxed at 90 degrees.

The prismatic joint at the arm prevents significant shear forces being applied to the skin such that the arm support doesn't cause chafing. It also introduces an additional degree of freedom which deals with an over constraint that would otherwise have been caused by the vertical mismatch between the shell and the axis through the center of the upper arm. This auxiliary degree of freedom has the added benefit that the mechanism does not require exact alignment with the user's skeleton to function properly, improving robustness and ease of use. Furthermore, the prismatic joint and the vertical mismatch of the shell causes the moment arm of F_{supp} with respect to the shoulder joint to become smaller as the arm moves downward, helping to achieve the softening behavior that is required.

The prismatic and revolute joint combined with the bending compliance of the shell mechanism allow the upper arm to move freely in arm abduction and flexion. Shoulder rotation is permitted by the arm rotating inside the support cuff. This arrangement of 4DOF of the mechanism in parallel with the 3DOF of the shoulder allows the arm to move freely in all 3DOF with an auxiliary degree of freedom.

4) Shell mechanism shape optimization

To design a compliant shell mechanism geometry such that the arm support mechanism as a whole provides the right torque-rotation profile is not an intuitive process due to the coupling of kinetics and kinematics in the shell [21]. It was decided to design the shell through shape optimization as it has been demonstrated it can tailor shells to achieve a desired characteristic with organically curved shapes that can closely follow the contours of the body [22].

a. Shell design and parameterization

Selection criteria for the basic shell design are its ability to remain close to the arm and achieve the nonlinear bending stiffness required for balancing the arm. Based on these criteria, the final shell design was selected to be based on a tape spring. As shown in Figure 6 the cross section of a tape spring is a partial circle which can closely follow the circular contours of the arm.

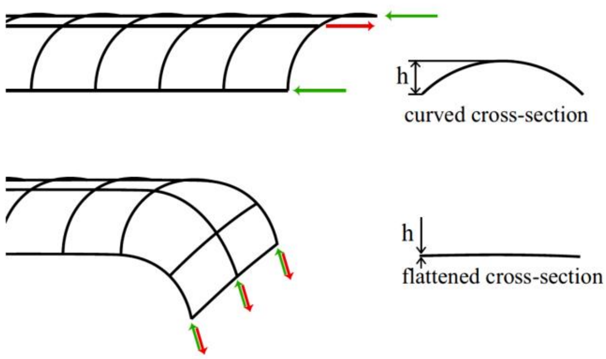

Figure 6: A tape spring is able to achieve highly nonlinear bending stiffness due buckling of the cross section [Credit: Dunning et al 2015].

Upon bending, the cross section flattens locally. This buckling behavior of the cross section allows nonlinear bending stiffness that is required for balancing the arm.

However, it also locally increases the distance between the shell and the arm as the flattened shape cannot closely hug the contours of the arm. This increase in distance can be minimized by having a relatively small subtended angle at the point of bending. The subtended angle being the angle that is spanned by the arc shaped cross section. To have a small subtended angle at the point of bending is feasible because locally reducing the subtended angle reduces the local second moment of area, causing a tendency to bend at that location. A simple proof of concept made from pieces of wood and a section of tape measure were built to validate this behavior.

It has been demonstrated that the stiffness characteristic of a tape spring based shell mechanism can be tuned to a desired nonlinear characteristic through shape optimization [22]. Because varying the subtended angle along the length allows minimization of the distancing created by flattening of the cross section, and because it creates minimal additional manufacturing complexity, it was selected as a parameter in the shape optimization.

Figure 7 shows the final parameterized shell design, a tape spring geometry with a varying subtended angle along the length.

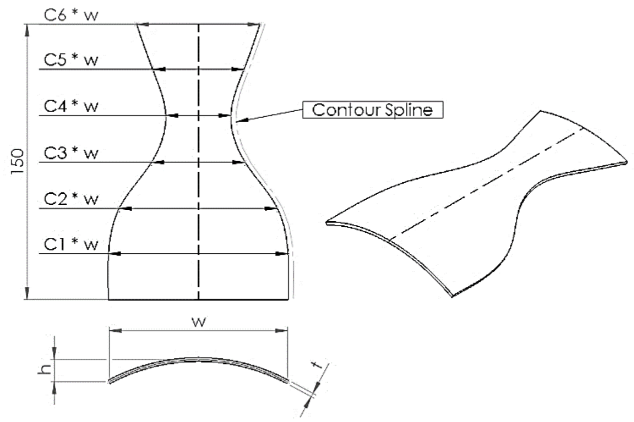

Figure 7: The shell is parameterized with base width w, height h, shell thickness t, and 6 points C1-C6 that define a contour spline that varies the subtended angle of the tape spring along its length. All dimensions in [mm]

Instead of using the subtended angle and radius as parameters, it was decided to use height *h* and width *w* parameters. These parameters span the same design space for subtended angles below 180 degrees, but made it easier to upper bound the width of the shell in the optimization. The final set of parameters are the base width of the shell midplane *w*, the height of the shell *h*, thickness of the shell *t*, and *C1* through *C6* that create a planar curve above the shell, that is projected on top of the shell along its length. The shell is cut at this projected contour, varying the subtended angle along its length. The planar curve geometry is a spline interpolation that starts at the base width and travels through points defined by *C1* through *C6* with the minimal amount of bending possible. The start of the spline has a perpendicularity condition, the end condition at *C6* is free. The length of the shell is left constant at 150mm as it is constrained by the length of the upper arm and the length of the prismatic joint.

Unfilled polycarbonate was chosen as the shell material for its volumetric elastic energy storage density that exceeds that of most other thermoplastics, and its ability to be easily laser cut and thermoformed to achieve the shell design of Figure 7.

b. Shape optimization approach

COMSOL software was selected for the shape optimization for its ability to carry out the entire optimization problem internally, including generation of parameterized shell geometries, modeling of the kinematics and evaluation of the optimization objective. The COMSOL multibody could be used to model the mechanism kinematics and allowed them to be easily adapted to improve the mechanism design iteratively. Some initial experimentation proved COMSOL is able to accurately, efficiently and robustly model large displacements of tape springs.

The parameterized shell design of Figure 7 is recreated in COMSOL using the internal geometry editor. Illustrated in Figure 8 is half of the shell constrained in a multi-body assembly which, using the axial symmetry of the shoulder joint, replicates the kinematics of the mechanism when mounted to the human arm in 1 DOF.

Using the symmetry of the shell design, only half of it is modelled and a symmetry condition is applied to increase computational speed. The mechanism is rotated in a number of gradual steps using a forced rotation at the shoulder revolute joint in Figure 8. The resulting gradual deformation of the shell illustrated in Figure 9. The reaction torque required for rotating the mechanism is recorded resulting in a torque rotation characteristic that directly represents the load reduction the mechanism generates as sensed at the shoulder. This characteristic was then compared with the desired characteristic using least-squares. This results in a number that approaches zero as the torque characteristic converges to the desired torque characteristic in both shape and magnitude, which is used as the objective function *f* to be minimized.

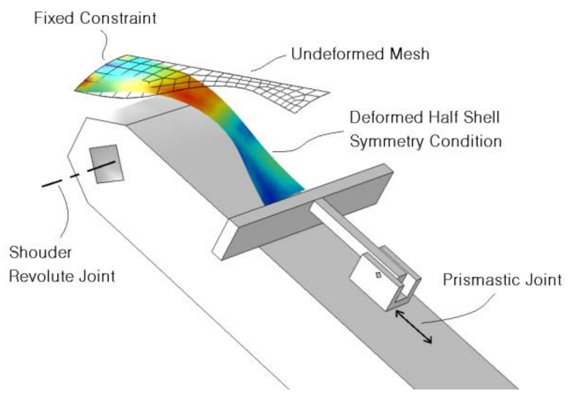

Figure 8: The COMSOL model replicates the kinematics of the mechanism worn on the human arm in 1 DOF.

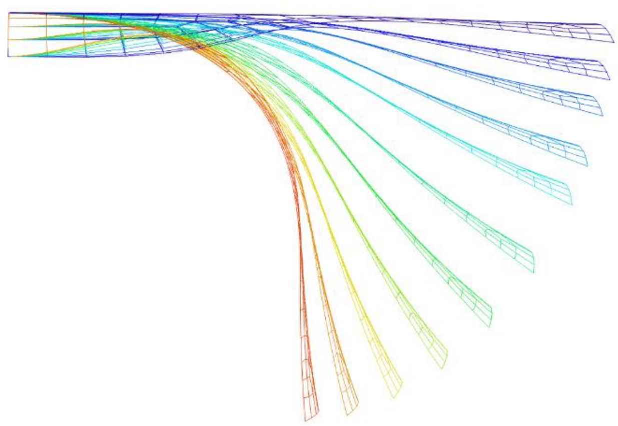

Figure 9: The shell is displaced in gradual steps to capture the torque characteristic.

To avoid designs that result in stresses above the yield stress of the material, the maximum Von Mises stress in the shell σ_{vm} is constrained below the yield stress $\sigma_{0.2\%}$ using an inequality constraint. An additional constraint was added that the shell height *h* can never exceed half the shell width *w* as this would result in shells with subtended angles of more than 180 degrees making donning of the mechanism more difficult.

The final optimization problem is as formulated in equation 2, where *w*, *t*, *h* are in *mm* and *C1…C6* are dimensionless. The design parameters are bound with the shown limits to yield physical designs that fit within a compact space around the arm. Furthermore, *C1…C6* are upper bounded to 1 such that the local width of the shell never exceeds the base width. Initial unconstrained optimizations proved that shells of which the middle is wider than the base causes the shell to buckle right near the base which did not result in the desirable torque rotation behavior.

$$\begin{aligned} &\min_x f(x) \\ &s.t. \\ &\frac{\sigma_{vm}}{\sigma_{0.2\%}} - 1 \leq 0 \\ &\frac{-w + 2h}{w} \leq 0 \\ &0.1 \leq w \leq 100 \\ &0{,}1 \leq t \leq 15 \\ &0{,}1 \leq h \leq 25 \\ &0{,}1 \leq C1 \leq 1 \\ &0{,}1 \leq C2 \leq 1 \\ &0{,}1 \leq C3 \leq 1 \\ &0{,}1 \leq C4 \leq 1 \\ &0{,}1 \leq C5 \leq 1 \\ &0{,}1 \leq C6 \leq 1 \end{aligned} \qquad (2)$$

The optimization was carried out in three steps as outlined in Table 1.

Step	Optimization algorithm	Initial design	Parameters	Rotation step
1	Monte Carlo	Arbitrary	w t h C2 C4 C6	Course
2	Nelder Mead	Result of step 1	w t h C1…C6	Fine
3	Nelder Mead	Result of step 2 with nearest stock t	w h C1…C6	Fine

Table 1: Optimization approach

First a rough step is carried out where the shell contour is defined only by the points of *C2*, *C4* and *C6*, the mesh is course and there are few rotation steps are taken to map the torque characteristic. This allows the highly random Monte Carlo algorithm to perform many iterations quickly. The Monte Carlo algorithm is relatively insensitive to the many local minima that are present in the optimization problem and ends up finding a good rough design. This is then used as the initial design in the second step utilizing a Nelder Mead algorithm with full parameterization, finer mesh and higher rotation step resolution. Figure 10 shows how the characteristic is refined in the second step.

The third step is optional and intended for shells that are made of sheet material. Taking the refined design of step 2, the material thickness *t* is rounded to the nearest available material thickness and not used as an optimization parameter. The optimization is then run again to correct the change of behavior caused by the rounding of *t* to an available stock thickness.

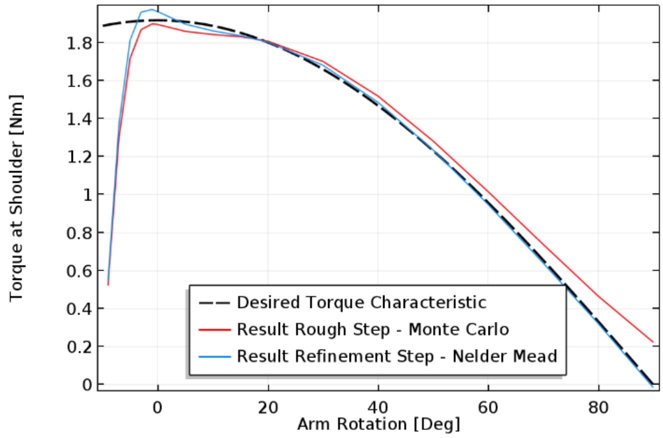

Figure 10: The first step coarsely finds the best general shape resulting in the red characteristic, this is then refined in a second step resulting in the blue characteristic.

5) Experimental validation

a. Torque characteristic

To validate that the mechanism provides the right amount of support and with the correct characteristic, the torque-rotation characteristic of the mechanism was measured on the test setup shown in Figure 11. A custom measurement fixture is mounted to a *ZwickRoell Z005* tensile testing machine with *ZwickRoell KAF-TC* load cell. The measurement fixture simulates the kinematics of the mechanism attached to the human arm in 1DOF and has a pulley system that allows the torque-rotation characteristic to be measured with the linear load cell and actuator of the tensile testing machine. The arm is oriented to pivot in the horizontal plane so that the mass of the pivoting arm does not affect the measurements.

To avoid that the test setup itself introduces significant hysteresis into the measurement, the pivoting arm and free rotating pulley were equipped with ball bearings. Lastly, a steel pull wire was used to minimize the compliance that it introduces to the measurement.

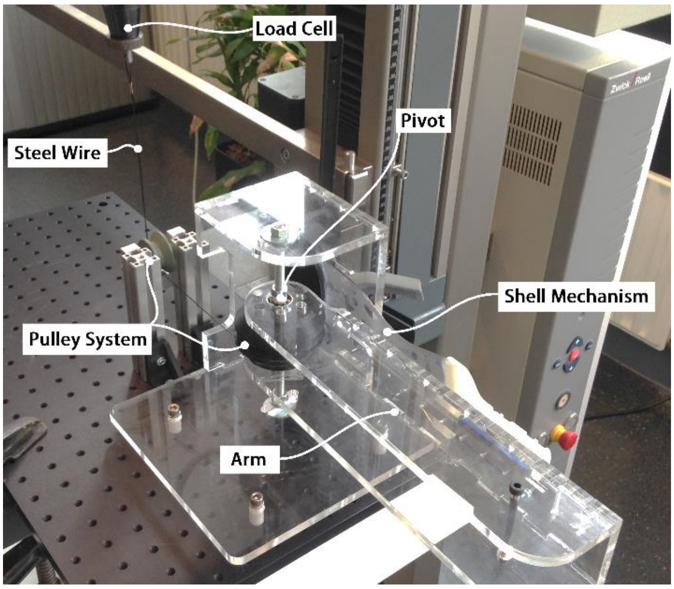

Figure 11: The testing fixture mounted on the ZwickRoell tensile machine for obtaining the torque-rotation characteristic.

b. Experimental validation of compactness

To measure how compact the mechanism is, a prototype of the mechanism was built and attached to a wearable frame as shown in Figure 12.

Figure 12: Alpha prototype of the arm support.

Pictures of the mechanism worn on a bare arm were imported in ImageJ software to measure the maximum distance between the mechanism and arm using an object with known dimensions as calibration. Because the largest distance is not always in the plane of the picture an additional manual measurement was performed and an uncertainty of ±3mm is taken into account. Measurements were taken with the arm at -10 degrees, 45 degrees and 90 degrees.

III Results

1) Optimization results

The optimization proved that using polycarbonate as the shell material did not allow a compact shell design that is able to support 100% of the arm of an average adult. The maximum support that could be achieved in a compact design with polycarbonate is 25%. Increasing the desired support percentage in the optimization without letting the shell grow larger in width and height causes the Von Mises stress to exceed the yield stress constraint.

The optimized shell design that supports 25% for the arm's weight is shown in Figure 7. The maximum Von Mises stress for this design is 68 MPa which is quite close to the flexural yield stress of 72 MPa [26]. The design parameters are listed in Table 2 and its modelled characteristic is shown in red in Figure 13.

a. Torque characteristic measurement

The optimized shell design is manufactured by laser cutting a flat layout of the shell from 2mm polycarbonate sheet and by thermoforming it over an aluminum mold to create the radius. The torque-rotation characteristic measurement results are compared with the desired and simulated characteristics in Figure 13.

Parameter	Value
Width w	97,2 [mm]
Height h	12,2 [mm]
Thickness t	2,0 [mm]
C1	0,99 [-]
C2	0,88 [-]
C3	0,52 [-]
C4	0,36 [-]
C5	0,51 [-]
C6	0,69 [-]

Table 2: Parameters of optimized shell design

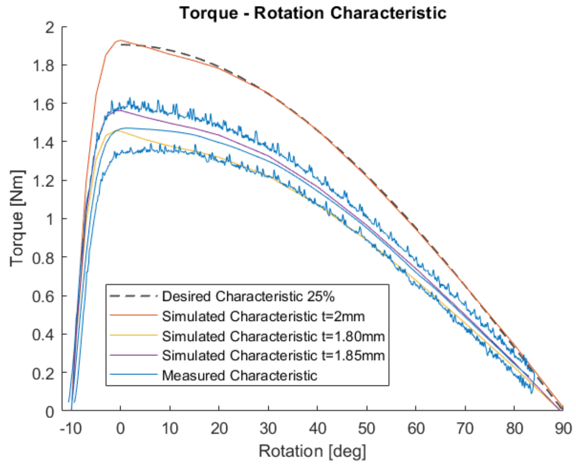

Figure 13: The desired characteristic (black), simulated characteristics (red, yellow, purple) and measured characteristic with hysteresis loop and average (blue).

The measured characteristic is shown in blue in the form of the hysteresis loop and the average of the hysteresis loop. In the hysteresis loop, the top side represents the rotation of the mechanism towards 90 degrees, and the lower side represents the return to 0 degrees.

It is immediately clear that the measured characteristic closely resembles the simulated and ideal characteristics in terms of shape, but is about 24% lower in magnitude. The difference in magnitude was found to be the result of the polycarbonate sheet material, which was in fact not 2mm thick as branded, but measured to be 1.8mm instead. The model used in the optimization was ran with the parameters of Table 2 but with thickness modified to 1.80mm and 1.85mm. The resulting torque characteristics are shown in Figure 13 confirming that the difference in material thickness was indeed responsible for the lower magnitude. The remaining difference between the model and measurement can be caused by imperfections in manufacturing of the shell and finite stiffness in the test setup.

To determine the precision of the balancing performance of the mechanism, a desired characteristic is generated for balancing 19% of the arm's weight, which is the average support magnitude that the mechanism applies as measured in the experiment. In Figure 14 the 19% characteristic is plotted as negative in red, representing the torque that 19% of the arm's weight applies to the shoulder. The measured torque characteristic of the arm support mechanism is plotted in blue. The sum of these characteristics is the residual torque, plotted in green. The residual remains within ±2% of the maximum torque magnitude from 0 to 90 degrees arm angle, thus the mechanism supports 19% of the arm's weight with a precision of ±0,38 percentage points when hysteresis is not taken into account. When hysteresis is taken into account, the achieved precision is ±4 percentage points.

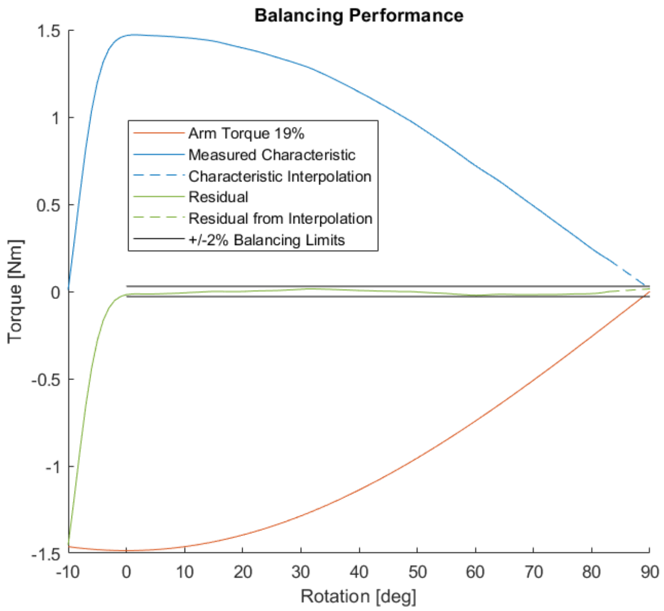

Figure 14: The balancing quality of the mechanism is found by summing the scaled 19% arm torque characteristic (orange) and the measured characteristic (blue), resulting in the residual torque (green). The residual torque remains within ±2% of the maximum torque (black).

2) Compactness

The maximum distance between the arm and the mechanism was measured to be 34mm ±3mm with the arm at 45 degrees. With the arm oriented to -10 degrees and 90 degrees the maximum distances were measured to be 29mm and 24mm ±3mm respectively. These maximum distances were measured at the interface between the shell and the fixture connecting the shell to the arm support cuff, shown in white at the top right corner of Figure 12. As apparent in Figure 12 the height of the linear guide creates a distance between the arm and the mechanism, reducing the compactness of the mechanism. Another observation is that the radius of the shell is larger than that of the arm, and therefore the distance between the shell and arm is greatest at the edges where shell is at its widest.

IV Discussion

1) Functioning of the conceptual design

The wearable prototype shows the kinematic layout of joints work well, the upper arm is free to move in all 3DOF without feeling restricted. The prismatic joint avoids uncomfortable forces parallel to the skin, however due to the large moments and forces applied to it a plain linear guide without ball bearings did not suffice, causing too much hysteresis.

It was found the arms could not be comfortably raised above -10 degrees as the shells do not willingly bend upwards. Although there needs to be no support outside the range of motion, it is still important that arms are free to move in their entire range of motion as otherwise the device will feel restrictive. This can be achieved by increasing the range of motion of the shell mechanism or adding an additional revolute joint between the revolute shoulder joint in Figure 5 and the frame. This revolute can be rested against a mechanical stop in normal operation, but will allow the mechanism to fold upwards if the arms are raised above -10 degrees.

It was found the arm support cuffs apply significant moments on the arm as a result of support torque T_{supp}, and thus it is beneficial these are made as long as possible and they need to be firmly attached to the arm. Potentially, these moments can be reduced if they are taken into account as constraints in the optimization of the shell mechanism. An unexpected beneficial property of the shell mechanism is its compliance in torsion, this allows some shoulder rotation even with an arm support cuff that is tightly attached to the arm.

2) Torque characteristic

The goal was set to achieve at least 25% and up to 75% support of the average adult's arm between 0 and 90 degrees. In addition it was required that the level of support scales with the load as it changes over the range of motion to achieve an intuitive support.

Although the inaccurate 1.8mm shell thickness caused the measured support to be only 18%, the model predicts that same shell design with the correct 2mm shell thickness can support 25% of the arm without exceeding the yield stress. Thus, the minimal support requirement was met, but more research is needed to increase the support magnitude without compromising the compactness.

An opportunity to increase the support magnitude in a compact design is seen in applying different shell materials that can store more elastic energy per volumetric unit than polycarbonate. In addition, during the optimization it was found that materials with a high yield strain allow for thicker shells. The larger material volume of these shells allows them to store more elastic energy if the volumetric energy storage density of the material is not disproportionately lower. As can be seen from Figure 12, doubling the thickness of the shell will only result in a marginal decrease in compactness. Other options include compounding multiple polycarbonate shells on top of each other, improving stress distribution and reducing the range of motion in which there is support.

The noisy hysteresis in the measurement is the result of the linear guides which were under dimensioned for the torque that the shell applies, causing the circulating ball bearings to run poorly. It was already suggested to reduce the torque T_{supp} that the mechanism applies to the arm through a constraint in the optimization, which would help reduce the strain on the linear guides as well. However, ultimately it is interesting to see if the linear guide can be omitted with a shell design that deforms in such a way that it can be attached rigidly to the arm support cuff, making the mechanism free of hysteresis in the balancing DOF.

The ability of the mechanism to deliver zero torque at 90 degrees appears to be the result of the S shape of the shell deformation that can be recognized in Figure 9. The direction of the curvature of the shell near the arm support cuff indicates that the shell applies a negative support torque T_{supp} as defined in Figure 4 when the mechanism is rotated. This allows the net torque at the shoulder to become zero even if the shell still applies a positive force F_{supp}.

The model was altered to record reaction force F_{supp} along with its moment arm around the shoulder, and reaction torque T_{supp}. Figure 15 shows the contributions of F_{supp} and T_{supp} towards the net torque revealing that indeed T_{supp} applies a negative support torque. The large magnitude of opposing torque is unnecessary, putting large moments on the prismatic joint, increasing hysteresis. The magnitude of opposing torque can likely be reduced with a penalization in the optimization. This will also reduce the torque that the support cuffs apply on the arm.

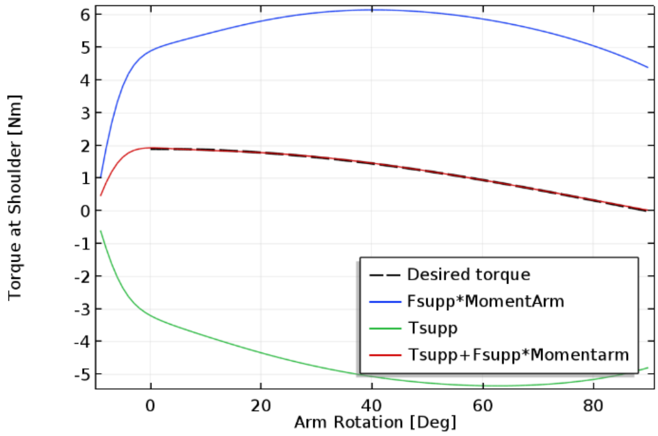

Figure 15: At 90 degrees T_{supp} tries to lower the arm whilst F_{supp} tries to raise it with equal strength, resulting in a zero net torque.

3) Compactness

Although the ultimate goal of staying within 20mm of the arm was not met, the prototype device remains within 34mm of the arm which presents a substantial improvement over state of the art designs. To the knowledge of the authors, the most compact arm support devices that are available on the market are the SkelEx and WREX [19], [20]. It is conservatively estimated that the SkelEx extends 64mm away from the skin and the WREX was estimated to extend 65mm from the arm [23], [24]. In 2015 Dunning et. al. created a prototype arm support that remains within 59mm of the arm, however it only allows the upper arm to move in one vertical plane [23].

At 34mm the prototype of the design presented in this work remains 47% closer to the body than the state of the art devices. In this comparison must be noted that the state of the art devices are capable of offering a higher magnitude of support. However, the presented mechanism offers a previously unavailable solution for applications where partial load reduction is sufficient and substantial compactness is required.

As apparent in Figure 12, the shell has the potential to remain closer to the arm, but a large gap is created by the linear guide that acts as the prismatic joint. A more compact solution might be possible with linear guides with a side-mount capability.

Fundamentally, the shell is a 2mm thick piece of material that can almost perfectly hug the contours of the arm if given the right radius. It can remain close to the arm during bending if the bending radius is controlled to follow the contours of the shoulder. However, the flattening of the cross section that occurs on deformation of the shell increases the distance between the arm and the shell.

The flattening of the cross section is integral to the nonlinearity of tape springs, thus it is interesting to see if the same nonlinearity can be achieved by collapsing the cross section not to a flattened shape, but to an arc of the same radius as the undeformed cross section, but with reduced subtended angle. Such a collapse behavior might be achievable through topology optimized cutouts in the shell. By collapsing this way, the shell can remain closer to the body throughout the range of motion.

Given the optimization only optimized the design for torque characteristic and not for compactness, it is likely that incorporation of a compactness objective could yield a more compact design.

In Figure 7 it is shown that the mechanism remains close to the arm upon full rotation. Despite representing a first attempt of such an arm support mechanism and low cost materials used for the prototype, the wearable prototype can be worn under XL scrubs by a user that normally wears M size clothing. Given the room for improvement that was identified, it is expected that subsequent design iterations will be able to fit under a surgical gown that is one size larger or the same size of what is normally worn by the user.

V Conclusion

The goal of this work was to develop an arm support mechanism based on compliant shell mechanisms that is compact enough to be worn underneath the surgical gown during laparoscopic surgery.

An arm support mechanism is presented that remains within 34mm of the arm, almost twice as compact as prior art arm supports. A prototype of the mechanism supports 19% of the arm’s weight with an accuracy of ±4 percent points between 0 and 90 degrees of arm abduction and/or flexion. The prototype and measurements carried out demonstrate that compliant shell mechanisms are useful for achieving highly compact wearable support mechanisms.

For the intended application, more research is needed to further decrease the size of the mechanism such that it can be worn under a normally sized surgical gown. A model showed the device is able to support 25% of the arm’s weight in its current design which might be enough of a load reduction to yield a significant ergonomic improvement in the laparoscopic OR. For future work it is recommended to start carrying out user testing with simulated laparoscopic surgery, albeit with oversized surgical gowns. This serves to obtain surgeon feedback on the device, establish if the device reduces complaints during prolonged surgery, and to gather electromyography data, such that it can be determined if additional load reduction is required. In addition, a wearable must still be designed for integration of the arm support and possibly other support modules, to offer a complete solution for the laparoscopic OR.

Acknowledgements

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CHAPTER 5

DISCUSSION

5.1. SUMMARY OF PROCESS AND RESULTS

The original assignment for this thesis was to further develop an ergonomic body support platform with the purpose of offering a significant ergonomic improvement to the laparoscopic OR. During the early stages of research it was recognized that there must be fundamental issues that are causing the lack of the adoption of EBSPs. An in depth study of prior art designs, including a patent search and observation of the laparoscopic OR environment lead to a research paper that identifies a 5 factors that are preventing the acceptance of EBSPs by surgeons, OR mangers and hospitals. A set of additional design requirements were proposed to alter existing or develop new EBSP designs with the purpose of achieving adoption.

Based on further analysis this thesis concludes that to develop a platform based ergonomic support that adhere to the proposed design requirements for adoption yields an over constrained design problem, and likely will yield significant compromises in the design, instead of an elegant and effective solution. In addition, it was found that the per-procedure cost had to be eliminated to achieve a feasible sales model. These findings yielded the decision to pursue a different solution strategy. It was the author's decision not to share this view in the research paper and let the readers draw their own conclusions, possibly leading to other promising designs and strategies.

An alternative solution strategy was found in the form of a wearable ergonomic support that can be worn underneath the surgical gown. Its fundamental properties for achieving an elegant, highly effective and adoptable solution were outlined. The development of an arm support mechanism compact enough to be worn in the sleeve of the surgical gown was established as the most critical technological hurdle and the research focus for the remainder of the thesis.

A methodical design phase lead to a novel compliant shell mechanism based arm support concept which has the fundamental ability to remain very close to the arm such that it can be worn comfortably inside a sleeve. A wearable proof of concept prototype of the arm support validated the functional and practical feasibility of the concept. The shell design was selected and parameterized in such a way that it remains close to the arm, is easy to manufacture and can achieve the nonlinear torque characteristic that is required for balancing the arms.

A shape optimization is carried out in COMSOL yielding an easy to manufacture shell design that is simulated to follow the target torque characteristic within +/- 4%. The ability for the mechanism to follow the target characteristic with such precision and to go all the way back to zero torque at maximum displacement was not expected, making the mechanism interesting for other applications, such as arm supports for Duchenne muscular dystrophy and compact passive assist in actuated robotic revolute joints. Measurements on a test setup and alpha prototype show the device balances 19% of the arm's weight. The discrepancy between the 25% target was attributed in inaccuracy of the shell material thickness. Rerunning the simulation with adjusted shell thickness validates the accuracy of the model.

An alpha prototype of the mechanism was mounted on a wearable frame and it was measured that the design remains with 34mm of the arm. It can be easily worn under XL sized scrubs when the subject normally wears M sized clothing. This proved the device is already wearable under a surgical gown that is 2 sizes larger, proving the feasibility of the proposed wearable and its potential to yield a significant ergonomic improvement in the laparoscopic OR.

5.2. EX-ANTE EVALUATION - DESIGN APPROACH

Before the design phase, a literature study and observation of laparoscopic procedures were carried out to fully understand the problem, its fundamental causes and the effects. This yielded a thorough comprehension of what functions the device needed to fulfill in order to improve the ergonomics of laparoscopic surgery and reduce the risk of WMSDs.

Subsequently an in depth prior art study yielded great insight in what causes the current lack of adoption, and what additional design requirements need to be fulfilled to obtain acceptance by surgeons, hospital and OR management, and to achieve a viable business model. All being prerequisites for achieving widespread adoption such that a significant reduction of WMSD occurrence can be achieved.

An analysis of all design requirements, both functional and adoptability requirements yielded the conclusion that the design of EBSPs according to these requirements yields an over-constrained design problem. This resulted in finding an alternative solution strategy that adheres to most adoptability requirements a-priori because of fundamentally advantageous characteristics. A critical technological risk was the feasibility of achieving an arm support mechanism compact enough to be worn underneath the surgical gown. In addition, the prior art study and functional analysis by Waumans [16] show that supporting the arms is one of the most important functions for an ergonomics support in the laparoscopic OR. Therefore, this was chosen as the scope to focus on for the remainder of research.

The FRDPARCC design methodology [17] was used as the basis for the design of the arm support. Listing all requirements and analyzing each of them separately to understand the physical first principles behind achieving the respective functions. These analyses were then used to formulate a set of strategies for achieving each requirement. Using this framework of requirements and strategies, countless sub-solutions were generated that represent ideas, physical phenomena and conceptual embodiments of components for the final concept. Multiple sub-solutions were investigated using Lego Technic, models made out of wood, tape springs and other rapid prototyping materials. A list of design specifications was generated in must-plan-wish gradations, representing minimal, planned and ideal levels of performance, allowing a post-ante evaluation of the design. A few concepts were generated from the sub-solutions. From the concepts, the presented compliant shell mechanism based arm support could easily be chosen as the clear winner. Its own geometric nonlinearity allows it to achieve the nonlinear torque response required for balancing the weight of the arm without the need for a rigid mechanism parallel to the arm. In prior art exoskeletons and arm supports such rigid members parallel to the arm play an integral role in achieving this nonlinearity without applying considerable shear forces on the skin [18]. By omitting the need for rigid members parallel to the arm and only needing the actual energy storing component that is a thin walled shell who curvature can closely follow the contours of the arm, a fundamentally more compact arm support mechanism can be achieved.

With the conceptual design established, the detailed design phase involved shape optimization of the shell mechanism to achieve the desired torque characteristic for balancing the arms. The decision of choosing shape optimization as a design tool was based on prior work indicating its ability to achieve organically shaped shells than can remain close to the body and have relatively evenly distributed stresses compared to other design methods [19]. Evenly distributing stresses means that more energy can be stored per volumetric unit of material which throughout this work has been proven important to achieve a significant magnitude of support.

Keeping in mind the manufacturability difficulty of prior art shell mechanisms at the PME lab, three shell designs and parameterizations were formulated keeping in mind the methods required to manufacture them. Starting with a very simple to manufacture geometry with limited design parameters, to a intermediate parameterization and a complex parameterization based on a prior art design [19] proven to be able to achieve a highly tuneable characteristic for gravity balancing. The strategy was to start with the most simple shell geometry and to increase the geometric complexity until the design specification for the torque characteristic was achieved to at least the 'must' level. The first gradation did not meet the requirements, but the second gradation of geometric complexity resulted in a near perfect torque characteristic in the FEM model. It is still a relatively easy to manufacture geometry with a single constant radius over the entire length of the shell.

The design process always directed arrows in one clear direction resulting in a deterministic concatenation of design choices. However, there are certainly opportunities for further improvement.

The optimization process was based on prior art methods for achieving a desired force-displacement characteristic [19] and no compactness objective was implemented in the optimization. Including a compactness objective is expected to further improve the compactness of the shell design, in particular upon deflection. Furthermore, the optimized shell design applies a noticeable amount of torque T_{supp} on the user's arm, this can become uncomfortable and can be reduced with the application of a constraint in the optimization. In the long term, it is foreseen that formulating a purpose built topology optimization method for compactness can achieve meta-material inspired shell designs that are virtually molded over the top of the skin surface, leaving only material thickness and small displacement margins as the maximum distance between skin and device. Appendix E elaborates on the potential of cast elastomers combined with topology optimization.

5.3. POST-ANTE EVALUATION - PERFORMANCE ASSESSMENT

The alpha prototype of the wearable arm support and the test setup allow both qualitative and quantitative assessment of the design performance. It was evaluated if, and to which extent, the design adheres to the design requirements and specifications. Furthermore, the performance was compared to prior art and physical limits to determine how well it performs.

The global set of design requirements for ergonomic supports for laparoscopic surgery are summarized in table 5.1. This set includes both functional requirements from the functional analysis by Waumans [16], and the adoptability requirements identified in the prior art study.

Global functional requirements	
Category	Functional Requirement
Functional	Reduce load
	Improve posture
	Promote postural variation
Adoptability	Requires little storage space
	Effortless and quick setup
	Takes up minimal OR real estate
	Does not affect surgeon autonomy
	No per-procedure cost

Table 5.1: All functional requirements for ergonomic supports in the laparoscopic OR, wearable or platform based. Consist of functional category requirements resulted from Wauman's thesis and an additional set of adoptability requirements resulting from the prior art study.

The strategy choice and scope limitation of focusing on developing a compact arm support mechanism required the definition of an component level set of functional requirements specific to the arm support which is shown in table 5.2. This set includes requirements that translate relevant global level requirements to component level requirements. E.g. *Does not affect surgeon autonomy* in the global set translates to *Full range of motion* in the component level set for the arm support mechanism.

The performance of the final design was compared to the design specifications, illustrated by the colored cells in table 5.2. The establishment of the specifications is covered in the design paper of chapter 4. The final design meets all requirements that were set out at the start of the design phase to *must* of *wish* levels. Only 25% of load reduction could be achieved in a compact design corresponding to the *must* level specification. More work is needed to establish exactly what support magnitude is ideal, and if it is higher, more work is needed to increase the support magnitude without compromising compactness. Opportunity is seen in using elastomers as shell material to achieve increased support magnitude, which is further discussed in appendix E.

The arm support was easily wearable in scrubs of size XL by a user that normally wears size M, given a surgical gown is a similar loose fitting piece of clothing it is considered the arm support is wearable under scrubs two sizes larger than nominal. This represents the *must* level as the surgical gown ideally is properly fitted. More work is needed to further increase the compactness of the design such that it can be worn under a properly fitted surgical gown. The specifications for achieving a natural feeling support and allowing full range of motion are achieved to the planned level as discussed in the design paper in chapter 4.

Component level functional requirements for arm support mechanism	Design specifications		
	Must	Plan	Wish
Reduce torque load at shoulder caused by weight of arm	Support up to 25% of arm torque on average over the displacement	Support up to 50% of arm torque on average over the displacement	Support up to 100% of arm torque on average over the displacement
Support feels natural	Support torque may not vary more than +/- 30% of the ideal characteristic	Support torque may not vary more than +/- 10% of the ideal characteristic	Support torque may not vary more than +/- 1% of the ideal characteristic
Full range of motion	Device range of motion equals working range of motion of surgeon	Device range of motion equals or exceeds natural range of motion but no support outside of surgeon working range of motion	Device range of motion equals or exceeds natural range of motion, fully supported
Fits under surgical gown	Wearable under 2 sizes larger surgical gown	Wearable under 1 size larger surgical gown	Wearable under nominal size surgical gown

Table 5.2: The functional requirements and design specifications for the arm support mechanism. The achieved levels of performance shown in color

5

The performance is compared with theoretical limits and prior art designs in table 5.3. The upper arm support design by Dunning et. al. [18] remains within 59mm of the arm, however it only allows the arm to move in 1DOF and thus cannot be used in the application of laparoscopic surgery. To the author's knowledge, the SkelEx is the most compact prior art wearable arm support that allows free arm movement in all DOFs, estimated to be 63mm away from the arm.

The design of this work achieves a 43% reduction in size over the prior art. Compared to the SkelEx the design of this work is almost twice as compact. However, it must be noted that the SkelEx can achieve a much higher magnitude of support. A 19% load reduction was achieved which can not compete with the SkelEx which can easily support 100% of the load, as it is designed to carry additional load carried by the user, e.g. heavy tools. For the intended application 100% balancing is likely not required or even desireable, it is however interesting for other applications to see if the device can provide more support. In the design of this work, support is only applied in the working range of motion as opposed to the full natural range of motion for the SkelEx. This is not an issue for the intended application but could be improved to fit the need for other applications where the arms must be supported above the horizontal plane coinciding with the shoulder joint. The device of this work shows considerable balancing precision at +/- 2%, however hysteresis effects caused primarily by the prismatic joint in the mechanism decrease this performance to +/- 10%, hence it is interesting to see if the prismatic joint can be made obsolete in an alternative design. Lastly the design requires more donning steps than the design by Dunning et al, resulting in a slightly longer donning time. It is however considered that 20 seconds is not a significant burden and similar to putting on a pair of shoes.

5.4. RECOMMENDATIONS FOR FUTURE WORK

5.4.1. APPLICATION DRIVEN

First, it is proposed to complete the design of the wearable. It is important the wearable redistributes the load that is taken from the arms across the body in a comfortable way that causes no excessive pressure points

	This work	SkelEx	Dunning et al 2015	Physical/theoretical limit
Compactness	Maximum 34mm from the arm	Maximum 63mm from the arm	Maximum 59mm from the arm	0mm from the arm
Load reduction at shoulder joint	19% reduction	100% reduction possible	9% reduction.	100% load reduction
Range of motion	Natural range of motion, not supported outside working range of motion	Natural range of motion. Fully supported.	Range of motion limited to 1DOF, supported in working range of motion	Full natural range of motion. Fully supported
Balancing precision	Support deviates 2% from characteristic, 10% including hysteresis	Near ideal characteristic possible, some hysteresis inevitable	Support deviates 13% from characteristic, 20% including hysteresis	0% deviation of ideal characteristic, no hysteresis

Table 5.3: Performance comparison of the design with state of the art and theoretical limits.

or load on other muscle groups. Furthermore, it may be desired to include more supports modules in the wearable.

Using elastomer shells to increase the support magnitude of the arm support to any desired level, a beta prototype can be built that is ready for user testing. It is suggested to carry out user-tests involving simulated surgery on a laparoscopic trainer. By carrying out multiple simulated laparoscopic procedures with and without the wearable with various test subjects, several comparisons can be made. Using electromyography(EMG) it is possible to compare the average muscle load on the muscle groups that suffer most frequent complaints, and through monitoring of fatigue and discomfort it is possible to directly prove that the device reduces fatigue and discomfort in-situ. These measurements will mostly serve as validating and quantifying the ergonomic improvements, but what is possibly even more interesting is to see if these ergonomic improvements yield an increase in surgeon performance. Tracking error rates, precision, time needed for certain operations and other performance data could, depending on the size of the experiment, give indication or prove the wearables ability to improve surgeon performance. If so this would radically increase chances of achieving adoption, and change the perspective on such devices from ergonomic aides, to ability augmenting tools.

5.4.2. CURIOSITY DRIVEN

Opportunity is seen in using elastomers as shell mechanism material, yielding larger ranges of motion, increased magnitude of force, and/or compacter shell designs. The casting process used for elastomers yields enormous advantages over common shell manufacturing techniques as well. This is elaborated upon in appendix E.

The material properties and casting production process combined allow a range of new opportunities in the design of compliant shell mechanisms. Some of the possible opportunities that come to mind are:

- The integration of electronics and sensors in compliant shell mechanisms by molding the shell around them.
- Composite shells by molding various materials on top of each-other.
- Using a soluable mold or cores in the mold, it is possible to integrate fluidic or pneutmatic muscles inside shell mechanisms.
- Using a soluable mold, it is possible to create meta-material like shell mechanisms utilizing advanced topology optimization techniques.

It is therefore considered highly interesting to further investigate the use of elastomer casting as shell mechanism material and manufacturing process.

Chapter 6

Conclusion

A wearable ergonomic body support that is worn underneath the surgical gown could be the solution to the high occurrence rates of work-related musculoskeletal disorders among laparoscopic surgeons.

This work found that platform based ergonomic body supports for laparoscopic surgery have not been met with adoption or commercial success at least in part due to 5 factors that affect acceptance by surgeons, OR management and hospital management. In particular the storage space that is required for the majority of EBSPs and the per-procedure cost related to the use of all EBSPs were found to be inhibiting the acceptance by OR and hospital management. A set of additional design requirements was proposed to alter existing or design new ergonomic supports with the purpose of achieving acceptance.

It was concluded that a wearable ergonomic body support that is worn underneath the surgical gown has inherent beneficial properties for achieving acceptance. Some of the foremost benefits include eliminating per procedure cost, taking up no OR real-estate and requiring little storage. By eliminating per-procedure cost, such wearables open up a previously unexplored opportunity towards achieving widespread adoption; to sell directly to the surgeon as a personally owned device.

Literature showed that supporting the arms is one of the most important functions for ergonomic supports in laparoscopic surgery due to the predominately arms-forward posture required for operating the laparoscopic tools. To achieve an arm support mechanism compact enough to be worn under the surgical gown was identified as the foremost technological risk regarding the feasibility of the wearable and thus this work set out to prove the feasibility of said arm-support.

A compact wearable arm support mechanism design was presented that utilizes the fundamental ability of compliant shell mechanisms to remain close the body. The alpha prototype remains within 34mm radial distance of the arm, a 47% improvement of the state of the art. In the FEA model used by the optimization, the mechanism with optimized shell was predicted to support 25% of an average adult's arm. Due to inaccuracy in the polycarbonate sheet material thickness, the shell prototype was measured to balance 19% of an average adults arm weight. The measurements prove the feasibility of an arm support wearable underneath the surgical gown that achieves a significant load reduction. Furthermore, it serves as a case study demonstrating the ability of compliant shell mechanisms to achieve highly compact support mechanisms providing precise nonlinear support characteristics of significant magnitude in easy to manufacture geometries. This makes such mechanisms interesting for applications seeking these properties such as inconspicuous arm supports for Duchenne Muscular Dystrophy.

Based on the results of this work a beta prototype can be built for use in simulated surgery user-testing to directly validate reduced muscle load, fatigue and discomfort, but could also show the device improves surgeon performance during prolonged procedures. If successful, the device can be developed commercially with substantial higher chance of achieving widespread adoption in the laparoscopic OR over prior art devices.

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Appendices

CHAPTER A

OBSERVATION OF LAPAROSCOPIC OR ENVIRONMENT

Observation of Laparoscopic Procedures at Mount Auburn Hospital in Cambridge Massachusetts.

(a) (b)

Figure A.1: Most OR equipment is stored in racks right outside the OR doors for easy access (a), the hallway walls right outside the OR are jam packed with larger equipment (b).

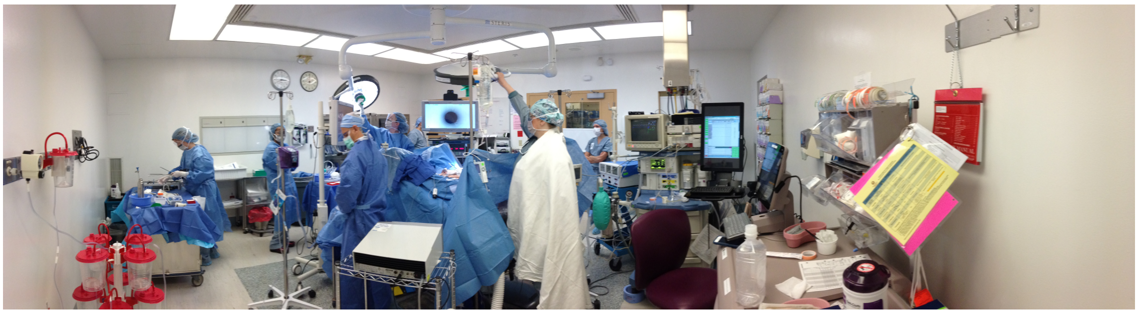


Figure A.2: The OR itself is also immensely crowded with people and equipment

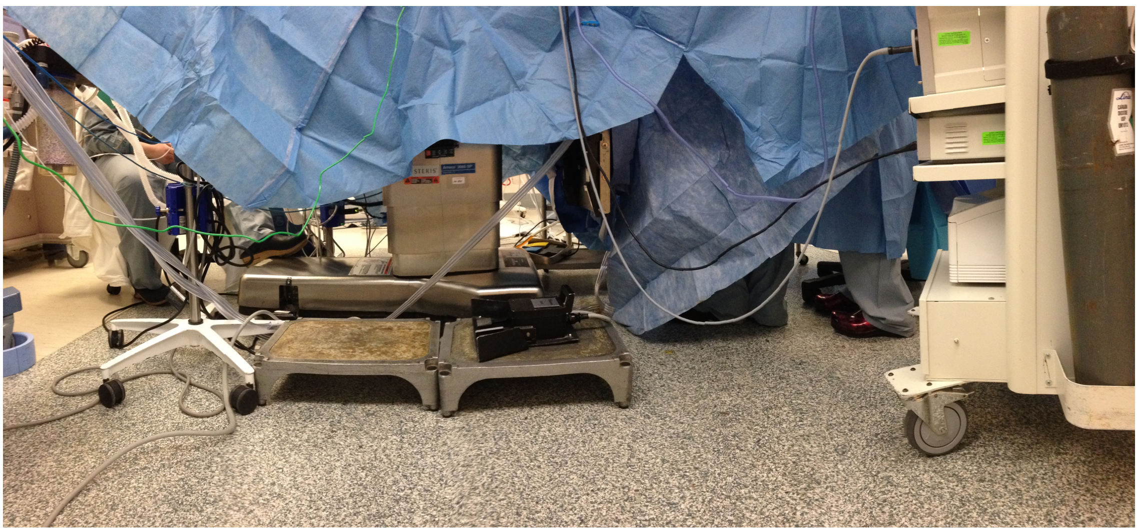
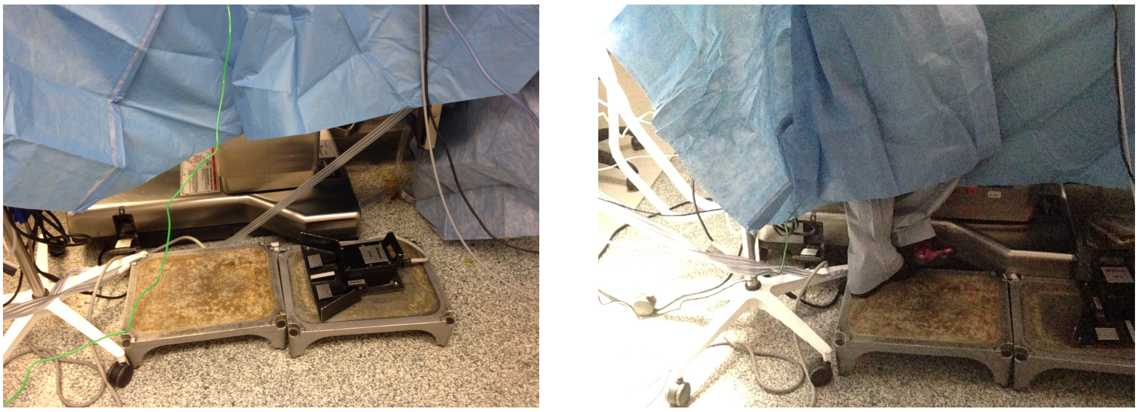


Figure A.3: The floor space around the OR table is particularly crowded. Surgeons stand on steps because the OR tables cannot be adjusted low enough for laparoscopic procedures.

(a) (b)

Figure A.4: Typical postures during laparoscopic surgery with upper-arm abduction and flexion.



(a) (b)

Figure A.5: Laparoscopic surgery often involves use of foot pedals which have to share the space on the already small raised platforms (a), The surgeon is all the way in the corner to get a different angle and assumes a strange stance that rotates the upper body towards the surgical site (b).

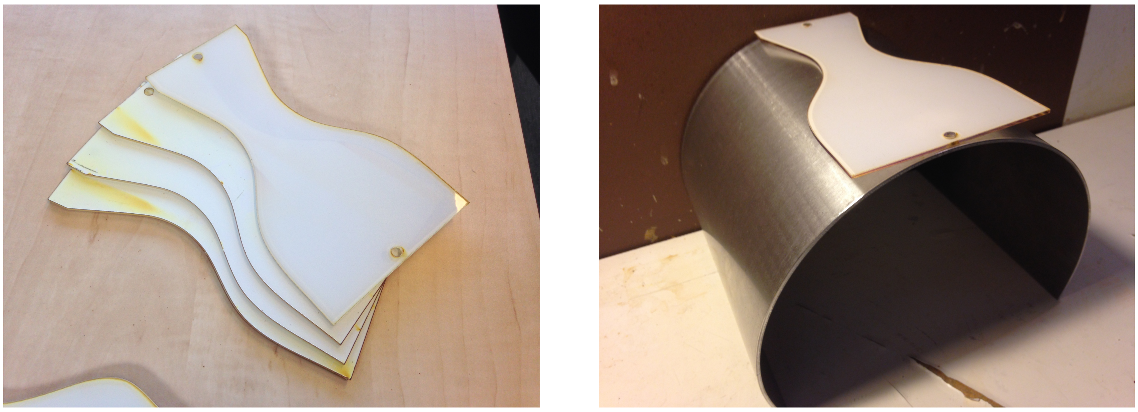
CHAPTER B

POLYCARBONATE SHELL MANUFACTURING

The shells used in the prototype and test setup were manufactured by lasercutting flat layouts of the shell from polycarbonate shell. An aluminum sheet was rolled such that its outer radius equals the desired inner radius of the shell, creating a simple mold for thermoforming the single constant curvature in the shells. The shell blanks were dried at 110 degrees celcius in a simple oven to avoid bubbles forming inside the material during the thermoforming.

A dried shell layout blank was placed square on top of the mold into a cold oven. The oven was heated to the start of glass transition around 150 degrees celcius after which the temperature is slowly raised until the shell blank wraps itself over the mold assisted by gravity alone. As soon as the shell was flush with the mold it was removed from the oven to cool slowly. The opaque spots are where the mold imprinted its surface roughness on the polycarbonate. At the clear spots the material was not resting its weight onto the mold, likely due to the minor stiffness that is still present during glass transition. However, a visual inspection of the shell in good lighting shows that the shell has a very consistent curvature throughout opaque and clear regions. Figures B.1 and B.2 illustrate the process.

This process has a major benefit over vacuum forming. In vacuum forming, the sheet material is stretched over the top of a mold causing the material thickness to become inconsistent in a way that is difficult to predict or control. In this method the material is not stretched and thus the thickness is not affected.



(a) (b)

Figure B.1: Flat layout blanks of the shells were lasercut from polycarbonate sheet (a), A 2mm piece of aluminum is rolled to the inner radius of the shell on which the flat blank is placed to be square against the edge of the mold (b).

(a) (b)

Figure B.2: At glass transition temperature the blank wraps itself around the mold radius by gravity alone, this avoids stretching of the material that happens in vacuum forming. (a), The finished shells (b) .

CHAPTER C

TEST SETUP

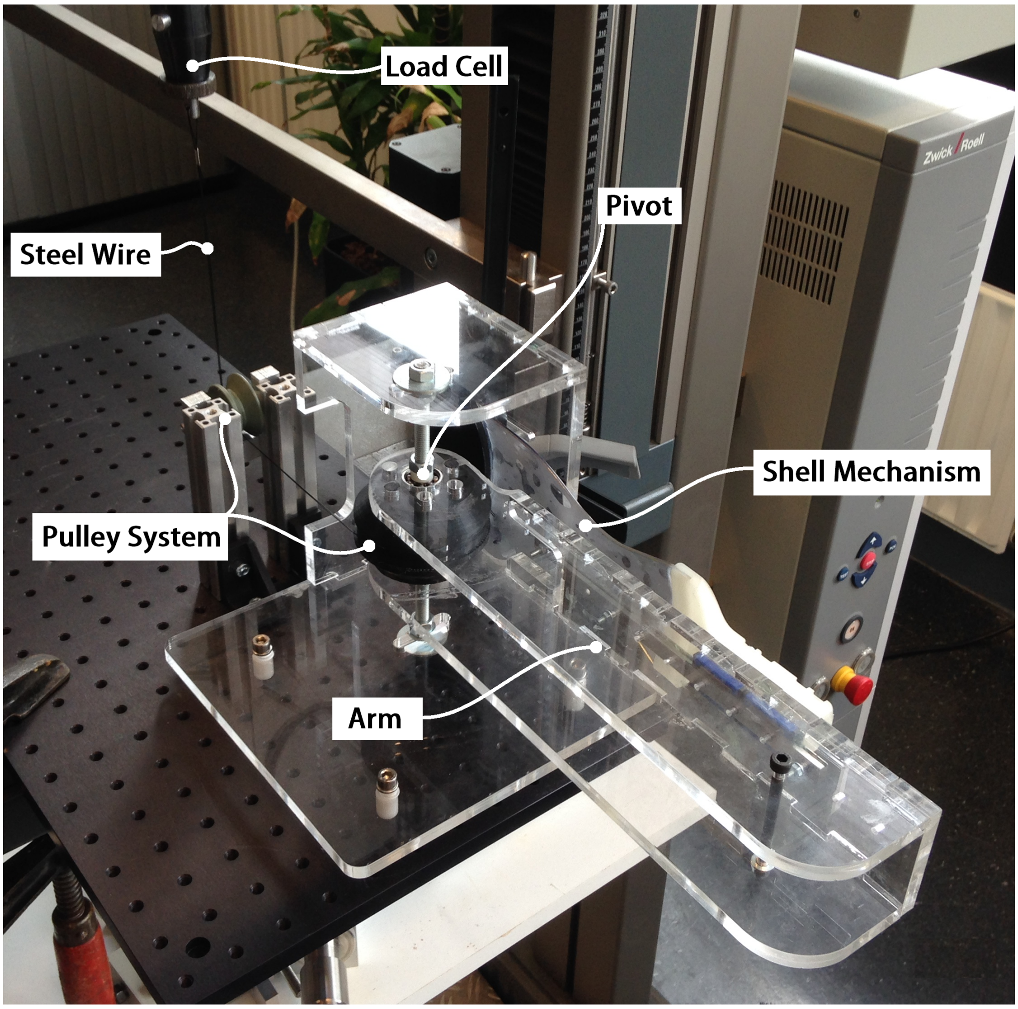


Figure C.1: A purpose built test fixture simulates the kinematics of the upper arm in 1DOF to which the arm support mechanism is mounted. It is horizontally oriented to measure stiffness behavior can be measured directly without having to subtract gravitational effects.

Figure C.2: The mechanism is displaced back and forth to obtain the hysteresis loop.

Chapter D

Prototype

An alpha prototype and wearable frame were built for as a proof of concept and measuring the compactness of the device. The frame's design is out of the scope of this work and arbitrary. The frame was built with thermoformed ABS sheets of various thicknesses, a much more compact frame can be achieved with stiffer materials such as carbon fiber reinforced plastics or aluminum. The mechanism consists of the exact same shells used in the test setup but with different 3D printed fixtures for mounting to the arm cup and the shoulder pivot. In a cast elastomer shell the fixtures can be easily integrated into the shell part, increasing compactness by not needing overlapping joints.

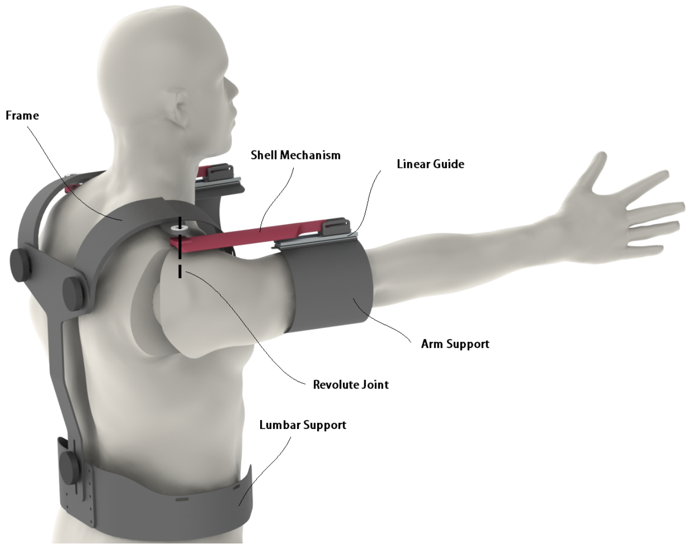
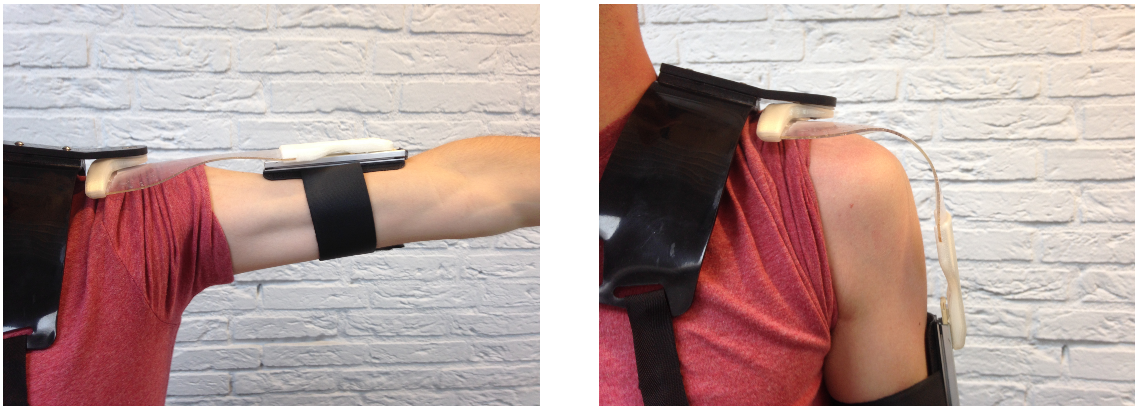


Figure D.1: Isometric render of the alpha prototype. The frame is outside the scope of this work and an arbitrary design.



(a) (b)

Figure D.2: The mechanism with the arm at 0 degrees (a), and 90 degrees (b).

(a) (b)

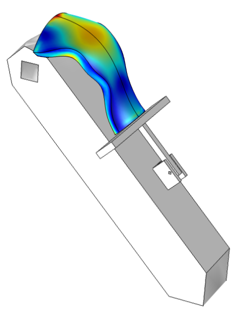
Figure D.3: Rear perspective (a), Top view demonstrating the pivot at the shoulder (b).

CHAPTER E

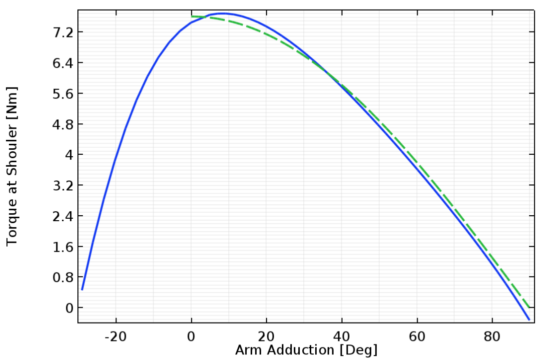
CAST ELASTOMER SHELL MECHANISMS

Originally, polycarbonate was chosen as the shell material for its energy storage capacity and ability to be thermoformed. However, during the optimization phase it appeared it doesnt have enough energy density to support more than 25% of the arm in a compact design. The length of the shell was limited to the distance between the elbow and shoulder and increasing the width would cause a large distance between the arm and the shell on either side, making it harder to fit in a sleeve. To make the shell a milliliter or two thicker would have no significant impact on its compactness but cause an enormous increase in support magnitude due to the bending stiffness increasing with the third power with thickness. However, this causes stresses to exceed the 0.2% yield stress limit at full displacement which means the shell is no longer storing elastic energy but deforming plasticly. Needing a higher average force over the same displacement means needing a higher amount of energy storage. Because elastic energy scales with the square of elongation and proportionally with stiffness, it was found that polyurethane and similar materials can store more elastic energy per volume. Furthermore, it was recognized that a shell of a material with a larger elastic strain limit allowed for a thicker shell that would not plastically deform at full displacement. In other words, not only is it more energy dense, it allows for more material in the shell, further increasing the total energy storage ability. This discovery was made too late in the process to explore sufficiently for writing a paper on, however it was still attempted to make a shell for the arm support mechanism of this thesis using polyurethane.

First the optimization was run with Smooth-On SmoothCast 60D polyurethane set as the material. Given that the modulus and strain at yield were not provided in the specification sheet, these had to be very roughly estimated from the elongation at break and stress at break. This resulted in quite a thick shell, going from a 2mm polycarbonate shell to 10mm of polyurethane. The shell however still fits snugly against the contours of the arm and supports 100% of the arms weight according to the validated model. The optimized geometry was exported to SolidWorks to make a negative mold. The mold can be easily scaled to take into account the shrinkage of the material, in this case 1%. The mold was 3D printed using a very sparce fill ratio to conserve material and consists of two separable parts. The printed mold is shown in figure E.2. SmoothOn SmoothCast 60D comes in two components that need to be mixed to a prescribed ratio. A red dye was used to add color. To remove air bubbles from the mixed polyurethane requires vacuum degassing, however the low viscosity of this particular kit allows reasonable quality parts without need for degassing. To match the parts performance with the model it is highly recommended to perform vacuum degassing, but for this first trial it

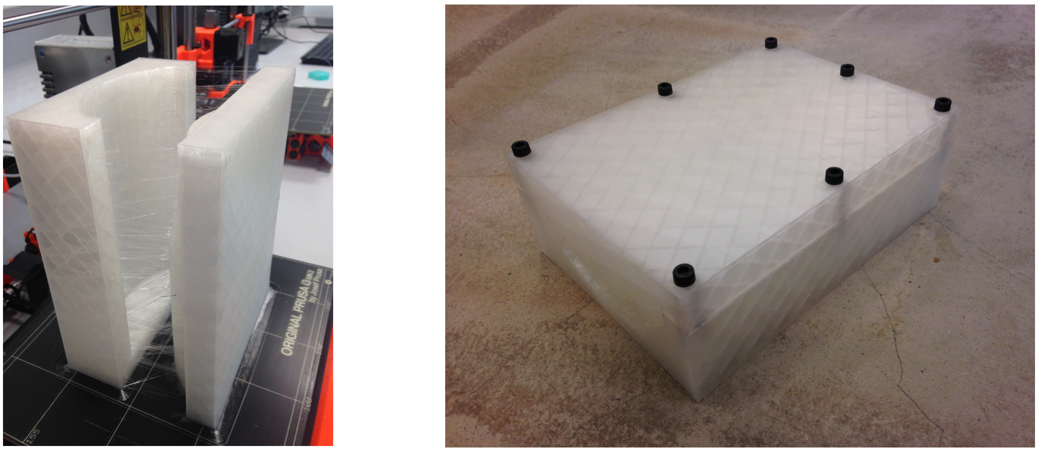


(a)



(b)

Figure E.1: Optimized polyurethane has same width and length but is significantly thicker at 10mm. (a), The polyurethane shell is capable to balance 100% of the arms weight (b).



(a) (b)

Figure E.2: Printing of the mold halves. (a), The mold halves are self-aligning and assembled with fasteners (b).

(a) (b)

Figure E.3: The polyurethane comes in two components that need to be mixed after which it can be poored into the mold. (a), The mold was filled from the top and left to cure for 20 minutes (b).

was not required to have an exact performance. Using appropriate safety gear in a well ventilated room the liquid mixture is poured into the mold and left to cure for 20 minutes as shown in figure E.3. The curing happens at room temperature though the curing reaction is exo-thermal and did cause the thermoplastic mold to deform after two uses. A slower curing polyurethane and/or more temperature resistant mold would fix this. For small series it is commonplace to make silicone rubber negative molds and for mass production it is possible to use injection molding. The resulting shell turned out to be much too stiff, this was attributed to the rough estimation of the modulus. For many polyurethanes meant for hobby use, such engineering data is not provided. It is however always possible to cast some dumbbell shaped testing pieces for carrying out tensile tests. The measured (nonlinear) modulus can then be entered into the optimization model.

Throughout the process, the benefits of the casting process became more and more evident. Common manufacturing techniques for making shells are thermoforming of thermoplastics, cold forming of metals, and mold layup of glass fiber or carbon fiber reinforced plastics. Thermoforming of thermoplastics stretches the stock material over the mold, causing variations of shell thickness, making their behavior differ from the optimized modeled response. Furthermore, thermoplastic stock thickness is not always consistent and only available in integer steps. The layup of fiber is an expensive and labor intensive process, controlling the thickness is difficult. Cold forming thin metals, and spring steels in particular is difficult as a large amount of over-bending is required to achieve the desired radii, this requires specialized equipment. Like with thermoplastics the metal stock must be chosen in integer thickness steps which is undesirable for the optimization..

The casting of polyurethane has the following benefits over state of the art shell materials and manufacturing methods:

- Polyurethanes, urethanes, and liquid silicone rubbers are available in a large range of hardnesses and stiffnesses, which allows choosing the exact right material for a given application. E.g. soft robotics.
- Casting allows the production of enormously complex shells at relatively low cost and with considerable consistency and accuracy.
- Casting with soluble molds allows enormous design freedom with can be used in topology optimizations for spatial compliant shell mechanisms with meta-material like properties.
- Casting allows the integration of electronics in the shell and making composite shells. E.g. a stiff polyurethane in the core and softer polyurethane on the outside would increase the elastic energy storage efficiency in bending.
- Most polyurethanes can be colored with dyes and other additives to customize appearance and other properties.
- Many polyurethanes are highly impact resistant and wear resistant, causing them to be robust in use. The large plastic deformation before break typical to elastomer limits the risk of a sudden failure of the shell in forced displacement applications.
- The thickness of the shell is determined by the mold and shrinkage during curing which allows a continuous range of shell thicknesses in the optimization, and precise control of fabricated shell thickness.
- The casting process allows easy and low cost prototyping, but is also suitable for small series and mass production.

Practical aspects related to using elastomers as shell material that need to be investigated are:

- Obtaining the nonlinear modulus and achieving accurate modeling in FEA for optimization.
- Effects of material hysteresis.
- Creep, compression set, fatigue and other aspects that can influence the usable lifetime of the shells.