Design and Development process for medical furniture through a case study.

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Abstract

The design process for medical devices requires a good understanding of all those requirements involved in the healthcare industry. Not only making sure that medical standards are met is important, but paying special attention to all the human factors and behaviours related with those procedures for which the device is intended, is essential when approaching the ergonomic perspective of the development process for medical furniture or other similar components/devices.

In order to facilitate the understanding of the process as well as making possible its future use as a reference guide for the development of other new related products, this thesis will be using a case study in which all the procedures and stages of the development will be described and applied under real conditions with the final outcome of a new product based on an Ergonomic Ultrasound Workstation.

The case study will go through the different stages involved on the project. It starts with the gathering of specific information not only about current technology available but also about methods of assessing the kind of operations that are generating these injuries, followed by in-site observations that will help to finally have a real picture of what the current situation is.

This will allow the development of an initial concept design, followed by a component-focused technology review, to give the outcome of a fully working prototype to be evaluated during an experimental stage. Findings from these experiments will be key to obtaining final conclusions as well as to establish the future path to create and sell a high demand solution.

Dedication

To my grandparents, parents and sister.

Acknowledgements

Special thanks to the KTP Committee:

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- Dr. Tom Deakin, R&D Manager at Lablogic Systems Ltd.
- Dr. Matt Carré – Reader in Mechanical Engineering (University of Sheffield)
- Dr. Stephen R. Bradbury – Lecturer in Mech. Eng. (University of Sheffield)
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Sheffield Teaching Hospitals NHS Foundation Trust: Along with the KTP Committee, created a focus group which served as an input source for the improvement of the designs.

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Abbreviations and Acronyms

- **BMI** – Body Mass Index
- **CAD** – Computer-Aided Design
- **CAE** – Computer-Aided Engineering
- **DSE** – Display Screen Equipment
- **EMG** – Electromyography
- **FEA** – Finite Elements Analysis
- **HSL** - Health and Safety Laboratory
- **KTP** – Knowledge Transfer Partnership
- **MSDs** – Musco-Skeletal Disorders
- **NHS** – National Health Service
- **RMS** – Root Mean Square
- **RSI** – Repetitive Strain Injuries
- **U.S.** – Ultra Sound
- **ULDs** – Upper Limb Disorders
- **WRMSDs** – Work-Related Musco-Skeletal Disorders

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1 INTRODUCTION

The purpose of this thesis is to describe and analyse the design process for new medical devices, focusing on medical furniture products. The final outcome of this work is a new design for a sonographer´s couch which is developed with the implementation of as many ergonomic gains as possible, starting from a current model distributed by the company Knight Imaging (fig. 1.1) and finishing with a new product (fig. 1.2) which after this work has been legally registered under the Registered Design Number 5001138. The document also shows an example of how small companies can accommodate recent regulations and changes on principles and expectations of organisations according to their purchasing policies.

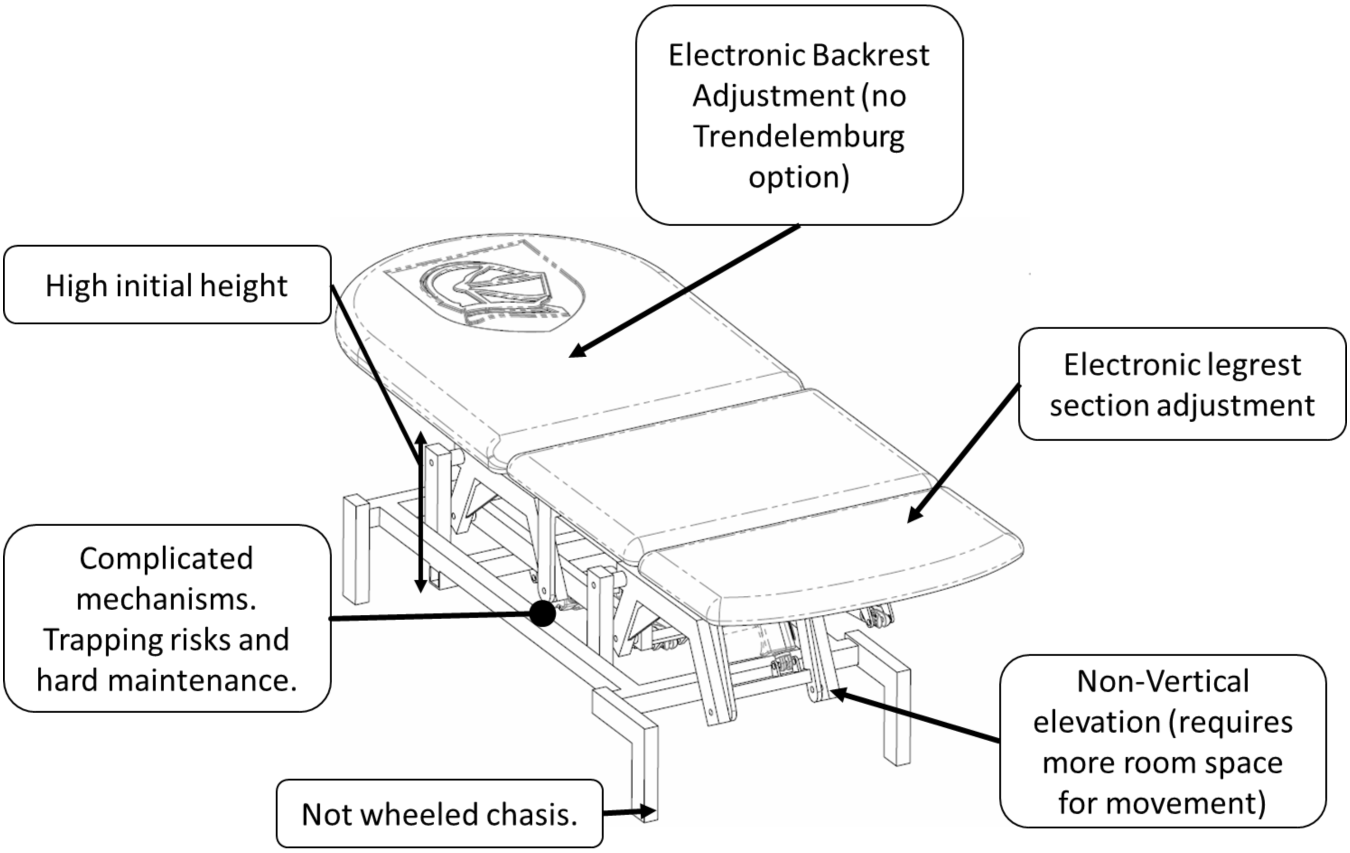

Figure 1.1 Knight Imaging´s Ultrasound Couch Model

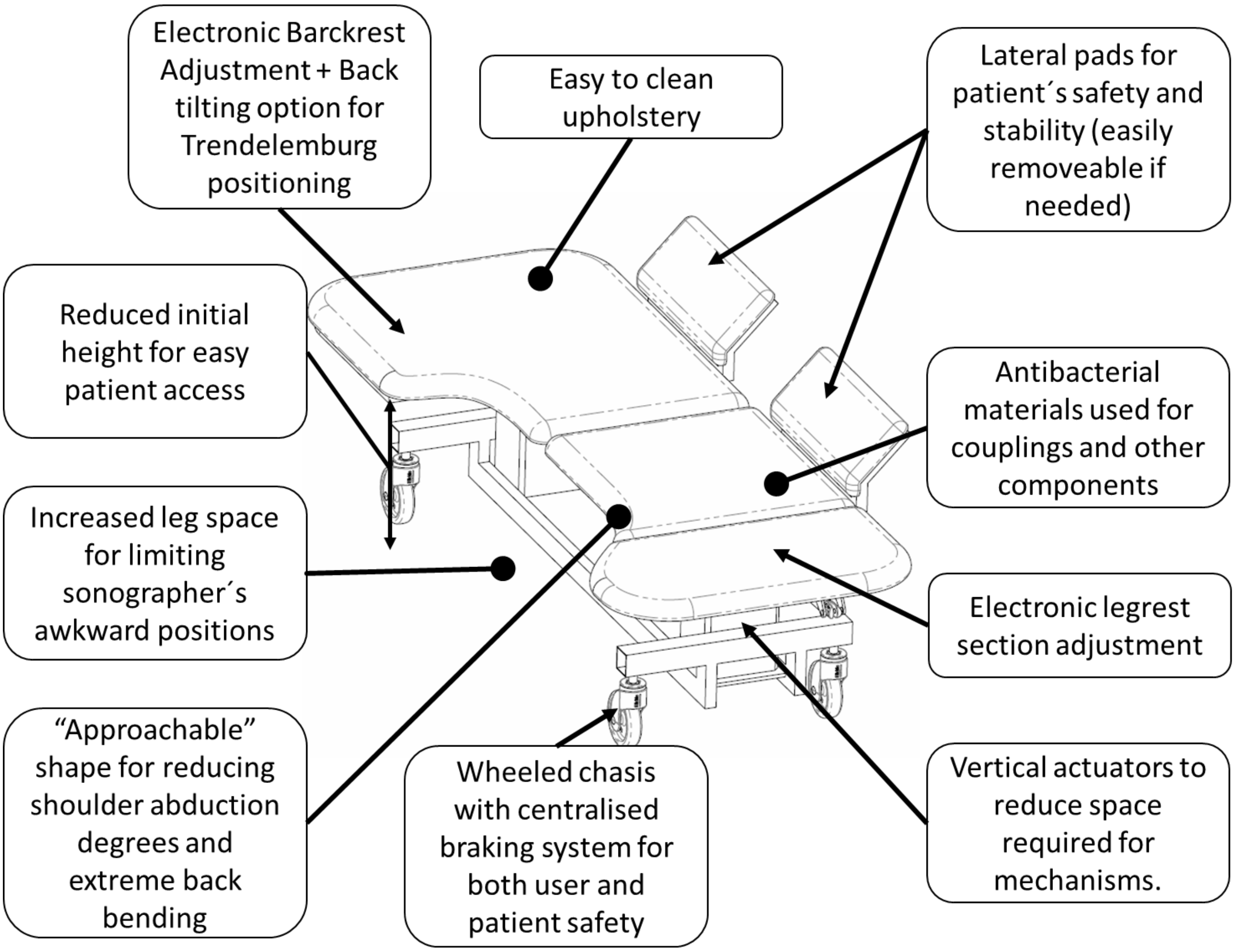

Figure 1.2 New Ultrasound Couch, designed for Knight Imaging and final outcome of the present work.

In the past, when a hospital needed to buy a new device (chair, couch, seat, etc.) they would typically look into different characteristics such as weight limit, trap risks, durability, ease of use, etc. and the person in charge of purchases would be the one who approved the device following the rules of the hospital.

However, during the last few years, organisations such as NHS have been introducing new procedures and quality assessments in order to improve the way departments are managed and controlled. Risk assessments, infection control, ergonomics and comfortability for both patients and professionals, have been added to other increasing issues such as repetitive strain injuries and the growing number of patients with a high Body Mass Index (BMI).

All of these changes have caused some sort of obsolescence to the product range of most of the small companies involved in the distribution of medical devices for hospitals and other medical environments. As high-technology devices are normally developed and distributed by bigger companies, this problem is specific to medical furniture manufacturers and distributors.

The reason why this happens is basically a matter of costs. Small manufacturers have much less access not only to innovation and new technologies, but to new materials and processes that may partially solve the problem easily but, which would require huge investments that normally these kind of companies cannot afford.

For this reason, the most convenient way of adaptation consists of re-engineering and optimisation of products that already exist. There are normally characteristics of those products that buyers want and need, but for reasons previously mentioned above, some departments may reject the purchase of these "outdated" devices.

It happens that in some cases the product was designed so long ago, that the people who worked on its development had already left the company. In other cases, the company was bought by another one and all the documentation was lost since nobody thought that it could be needed in the future. When this is the case, there is no other way of completing a new product development than start understanding the one that is already there by the use of reverse engineering tools.

During this process, it is vital to facilitate a good level of knowledge transfer between organisations. When re-designing something, collaboration can save huge amounts of time since normally small companies rely on their existing and available technology, which can be completely obsolete or just be inadequate for a specific purpose. The simple action of having a discussion about the problem with a supplier, can help them suggest that part or that component which can immediately improve or even solve an issue that could be impossible to adapt with the existing “bill of materials”.

Another way of gaining knowledge about possible solutions is by approaching academic institutions such as universities or technological centres. There are many types of partnerships which are precisely intended to help small and medium companies to become more competitive in the market by the introduction of new technologies or just by providing support and guidance when developing new projects.

The simple fact of having access to a CAD or CAE software which allows (maybe with the collaboration of a student) the company to see possible models and even to do a simple FEA calculation before prototyping can be of a significant assistance to the design process since it saves time and money to the company in the case that they cannot afford a license for the software or they just do not have the required skill to use it.

Based on these circumstances, this work will describe the whole process from draft to production through a real case, since it seems the best way for manufacturers to understand what the stages are and which could be the issues that may appear during the entire product development process.

1.1 DOCUMENT STRUCTURE

In order to make it easier to follow, this thesis has been organised in various parts which are divided at the same time in different chapters. The main idea is that the reader can quickly find what they need in each moment and read how that specific stage of the project was solved. It is hoped that this information will be useful to future researchers or industry.

Initially, there is an introduction to the case on which this work is based in order for the reader to familiarise with the characteristics and the main stakeholders taking part on the project. The document will then be divided into different parts:

- Background research and frame of reference
  - The first section will focus on all the research work that is required before starting any development. Both a literature review and a technology review will help understand which the existing issues with current products are as well as to better know their causes and associated impacts.
- Concept design
  - The section starts with a first assessment on the way users perform their procedures which will give information about what the limits or design boundaries are. It will describe all the tasks involving conceptual and technical design, manufacture, components, suppliers, etc.
- Experimental evaluation
  - Once a prototype unit is ready, the next natural step is to evaluate it under real conditions. Controlled experiments, measurements and clinical evaluations will be described in this part.
- Outcomes and Conclusions.

1.2 Presentation of the case

1.2.1 What is a KTP? (Innovate UK, 2015)

The case study on which this work is based, consists of a Knowledge Transfer Partnership project. A Knowledge Transfer Partnership (KTP) is a part government-funded programme to encourage collaboration between businesses and universities in the United Kingdom.

KTP was launched in 2003, replacing the Teaching Company Scheme (TCS), which had been formed in 1975. The programme is funded by some 17 public sector organisations, and led by the Technology Strategy Board, an executive Non-Departmental Public Body reporting to the Department for Business, Innovation and Skills.

Each KTP involves three 'partners':

- A **company** (this may be a private enterprise, public body or voluntary agency).
- A **knowledge base** (this may be a university or other higher education institution, research organisation or further education college).
- An **associate** (a recently qualified graduate).

The aims of each KTP programme are to facilitate the transfer of knowledge and technology and the spread of technical and business skills to the company, stimulate and enhance business-relevant research and training undertaken by the knowledge base, and enhance the business and specialist skills of a recently qualified graduate.

1.2.2 Participants on the project

The University of Sheffield was in this case the institution acting as a knowledge base for the KTP Project and was be in charge of the knowledge transfer into the company, which was Knight Imaging.

Knight Imaging has developed and sold an extensive range of Ultrasound couches, patient chairs and X-Ray imaging accessories since 1981.

Founded in 1981 by Anthony Knight in Worthing, West Sussex as 'Knight X-Ray Cassette Services,' Knight Imaging originally offered an X-Ray Cassette repair and replacement service. By 1985 the company had become Knight X-Ray and had begun to design and sell Lead Aprons and Ultrasound Couches to hospitals around the UK. The business grew and developed, and in 1995 a merger with the successful Nuclear and Optical Product import company Southern Scientific created the name Knight Imaging.

They have continued to sell Ultrasound Couches, developing ever more versatile, motorised models, as well as supplying X-Ray Viewers and accessories, Lead Aprons and protective wear, and developing the popular SIGMA motorised patient chairs.

1.2.3 The problem

Upper limb disorders (ULDs) in ultrasound have become an increasing problem involving not only personal damage to the careers of many professionals and their wellbeing, but also economic and financial impact causing huge costs to the NHS and other organisations. This point was finally identified by some manufacturers and distributors of medical equipment who are getting more and more concerned about the issue, which represents an important opportunity for them to invest in a new part of the market.

This is the reason why Knight Imaging wanted to tackle the problem of ULDs in order to get advantage on the research and development of new products focused for this special purpose. The company already had a wide range of products in the market, but required some specific research that could bring the necessary inputs to carry out a product development process with the final objective of putting on the market a new and innovative unit.

1.2.4 The project

The aim of the project was to design and develop a new U.S. ergonomic system for ultrasound departments to reduce Upper Limb Disorders in sonographers. In order to achieve this, some steps were required to be taken along the whole product cycle and objectives where established in order to make sure that all the steps were satisfactorily accomplished. These objectives were:

- Carry out a literature review on the general issue of work-related musco-skeletal disorders, focused on the topic of upper-limb disorders related to ultrasound activities.
- Carry out a technology review on the current product ranges of different companies in order to identify possible advances and innovations that had already been developed and that could be implemented into the project.
- Establish issues from the sonographer´s perspective that can represent an important source of information and inputs for the design process.
- Identify a base product that serves as a starting point to introduce any possible improvement.
- To perform several design iterations in order to be able to develop a first prototype of the new unit.
- Carry out different types of evaluations from different perspectives on the prototypes to analyse the new product strengths and weaknesses.
- Establish a final set-up which improves the ergonomics of performing ultrasound operations are performed regarding ergonomic-related issues.

1.3 ESTABLISHING A DESIGN PROCESS

The stages through which the project advances must follow a previously established process that needs to ensure not only a good information input, but a good feedback flow through different stakeholders too. This feedback flow can be achieved by using different techniques that have been developed with the aim of adding value and accelerating product development processes. Some of these engineering techniques are Design for Manufacture, User-Centred design, Reverse Engineering and Co-Design.

1.3.1 Design Process Techniques

1.3.1.1 Design for Manufacture

DFM (Design for Manufacture, Design for Manufacturing or Design for Manufacturability), is the engineering technique that involves designing taking into account manufacturing requirements and limitations. It is important when a company starts a new product development project to take into account their limitations regarding manufacture especially if the company is small or medium sized and does not have easy access to advanced manufacturing systems. It is vital to start thinking on these limitations not only on the prototyping stage, but from the start of the process since this will avoid the project to get blocked by the end of the cycle. Materials, tooling, software, staff specialisation, etc. are factors that could limit the design process and establishing these limitations at the beginning will eliminate further problems on prototyping stages. Design for manufacture can be defined as designing with manufacturing in mind in order to reduce the amount of costs required to manufacture a product and improve the ease with which that product can be made (M. O'Driscoll, 2001).

1.3.1.2 User-Centred Design

User-centred design is a design process that makes designers focus on the needs and requirements of final users of the product. It involves participation of these users throughout the whole process by the use of different research and design tools (questionnaires, meetings, focus groups, evaluations, etc.).

According to the ISO standard 9241-210, Centred design includes the following cycle stages:

- Specify the context of use: Identify the people who will use the product, what they will use it for, and under what conditions they will use it.
- Specify requirements: Identify any business requirements or user goals that must be met for the product to be successful.
- Create design solutions: This part of the process may be done in stages, building from a rough concept to a complete design.
- Evaluate designs: The most important part of this process is that evaluation – ideally through usability testing with actual users – is as integral as quality testing is to good software development.

This project tries to find a solution for final users (sonographers) and this is why User-Centred approach seems to be an important tool for developing an ergonomic product for them.

1.3.1.3 Reverse Engineering

Reverse Engineering is normally used to understand how current products have been designed rather than to design new products. It has been defined as the process of generating engineering design data from existing components, which is a process in which product development follows a reverse order where the existing product is the starting point (B.V. Ramnath, 2016). Otto K. (1998), had also defined Reverse Engineering as what initiates the redesign process wherein a product is predicted, observed, disassembled, analysed, tested, experienced, and documented in terms of its functionality, form, physical principles, manufacturability and assemblability. Considered a method to understand how a product works (Ullman DG, 2010), it seems that the tool will be very useful specially at the beginning when starting boundaries have to be stablished and accommodated to the company´s requirements and current range of products.

1.3.1.4 Co-Design

Co-Design promotes designing with the participation of end users rather than for end users. It is probably a step further than User-Centred Design, since the later involves focusing on the end user from the beginning of the process, but keeping it "away" in some stages of the process. Co-Design requires the participation of end-users during the whole cycle, including not only initial requirements in-put but also actual participation on design activities.

Despite the good first impression of Co-Design techniques, research has proven that there are certain paradoxes that appear when applying these processes under real conditions. These particular paradoxes were described in a study completed by Simone Taffe (2015) that examined the behaviour of end-users when invited to join the designing process:

- The paradox of end-users rejecting designs for themselves: Participants continually jumped in to corroborate or qualify what each other said, suggesting strong ownership of ideas overall.
- The paradox of end-users acting like designers: The two parties are expected to represent their own unique perspectives and stay in their own camps. However, in this study, the end-users appeared to take on the role of a designer.

- The paradox of end-users designing for imagined end-users: During this research, it emerged that users did not identify with their own situation and perspectives. Instead, they joined the designers´ camp to nominate design outcomes for alternative sets of end-users. Thus the final paradox occurred when the end-users began to design for others rather than themselves. It appeared the end-users crossed the bridge to the designers´ side, in assuming the role, language and behaviour of designers and in suggesting design ideas for better-suited audiences than themselves.

The research anticipated that users would develop information strategies for themselves but finally they merged into hybrid designer/end-users and starting designing for alternative end-users rather than for themselves. The conclusion of this study "challenged the assumption that co-design is about designing *with* rather than *for* end-users. The role of end-users changed after they workshopped the information at hand and preferred to design for others rather than act as representative end-users. Participants attempted to design *with* designers *for* imaginary end-users at the same time".

Other effects of this type of design process have been mentioned in literature such as the situation where designers accept users´ opinions as absolute and included them directly in their design solutions causing that not all ideas proposed could be developed. Hence, some ideas could not be included on final designs (Z. Yalman, 2015).

1.3.2 Project limitations and requirements

There are several particularities on the project that can guide the selection of the most suitable design process for the kind of product on which this project is focused. Since this document does not try to represent an evaluation or comparative between design processes but a real case study showing the development of a new product, there is certain flexibility when it comes to establish a process cycle. Different techniques for different stages will be the main idea due to the special characteristics of the project:

- It represents a Knowledge Transfer program between a Knowledge Base and a private company.
- The company is not a large-sized one, but a small-sized one having a strong interdependency from other stakeholders.
- The product is intended for medical environments, which involves a much deeper focus on end users.
- These end users can be identified as the actual user (sonographers) or the patient. On this occasion, the objective is to improve sonographer´s conditions, but patients must be taken into account during the whole development.
- There is a real requirement of the design being finally prototyped and ready for commercialisation.
- There is not enough information about current products for manufacture, this means that improving current products will firstly involve the geometrical analysis of the current range.

1.3.3 Final Design Process

Fig. 1.1 shows an initial stage planning for the whole process with relation to this document´s chapter structure. It has been divided on a typical design process schedule of 4 phases: Explore, Design, Review and Result. It also indicates the interrelationship between the main stages of Design and Review, as there are typically several iterations before reaching the result stage.

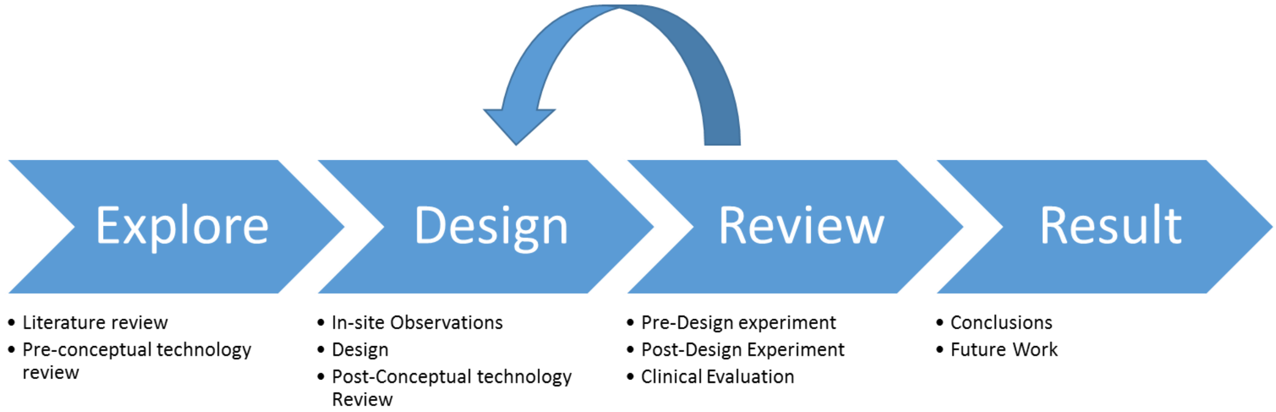

Figure 1.3 Stage-Based design process diagram.

Regarding task distribution and techniques applied, another diagram (fig. 1.2) is prepared to show the main activities involved on the design process and which is the technique applied for each of them. Since some of these techniques have many similarities, there could be some variations on how each activity is approached, but this can be accepted as an example distribution.

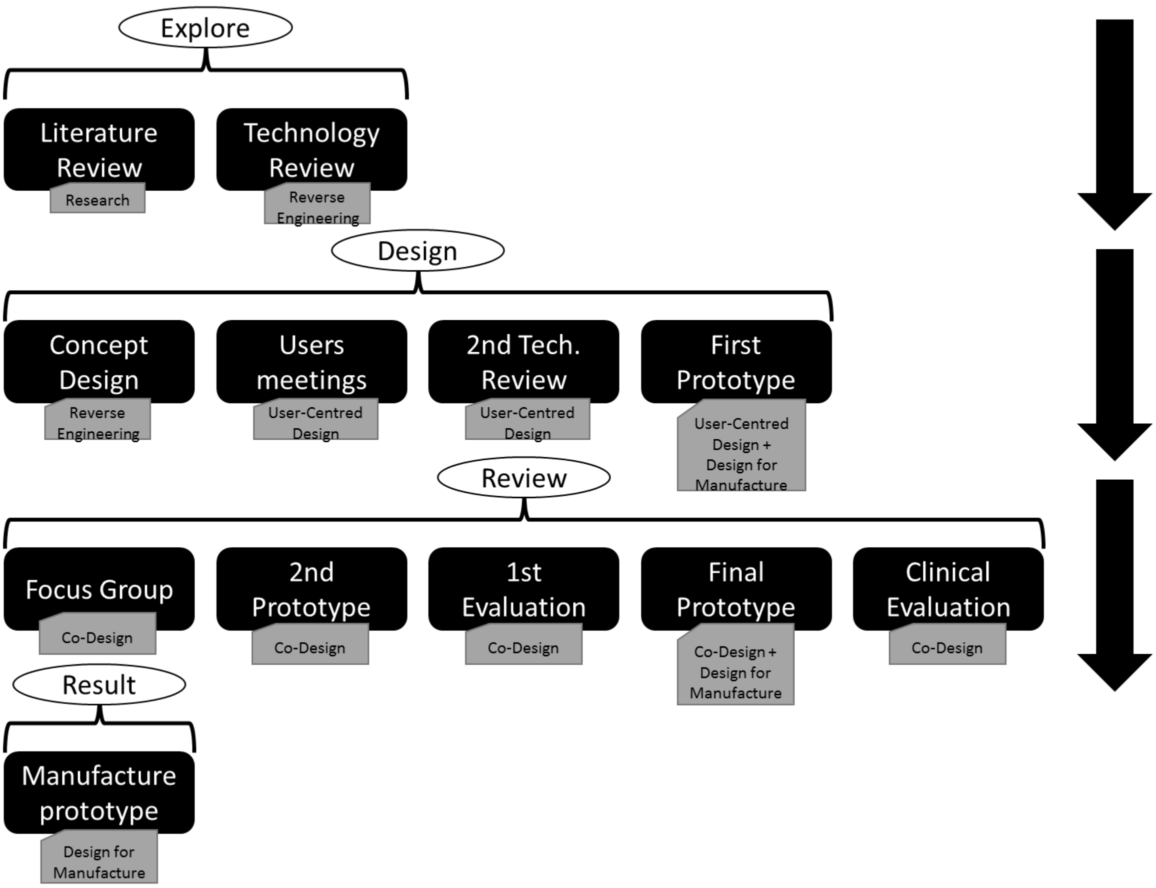

Figure 1.4 Activity-Based design process diagram.

Each of the previous diagrams show a different "dimension" of the design process. The first one shows a "stage-based" path whilst the second one shows an "activity-based" path. This is due to the different relationships between both stages and activities. A 3rd diagram (fig. 1.3) is prepared that tries to clarify the whole process on a single dimension by representing the type of process (technique) for each activity as well as keeping certain chronological order.

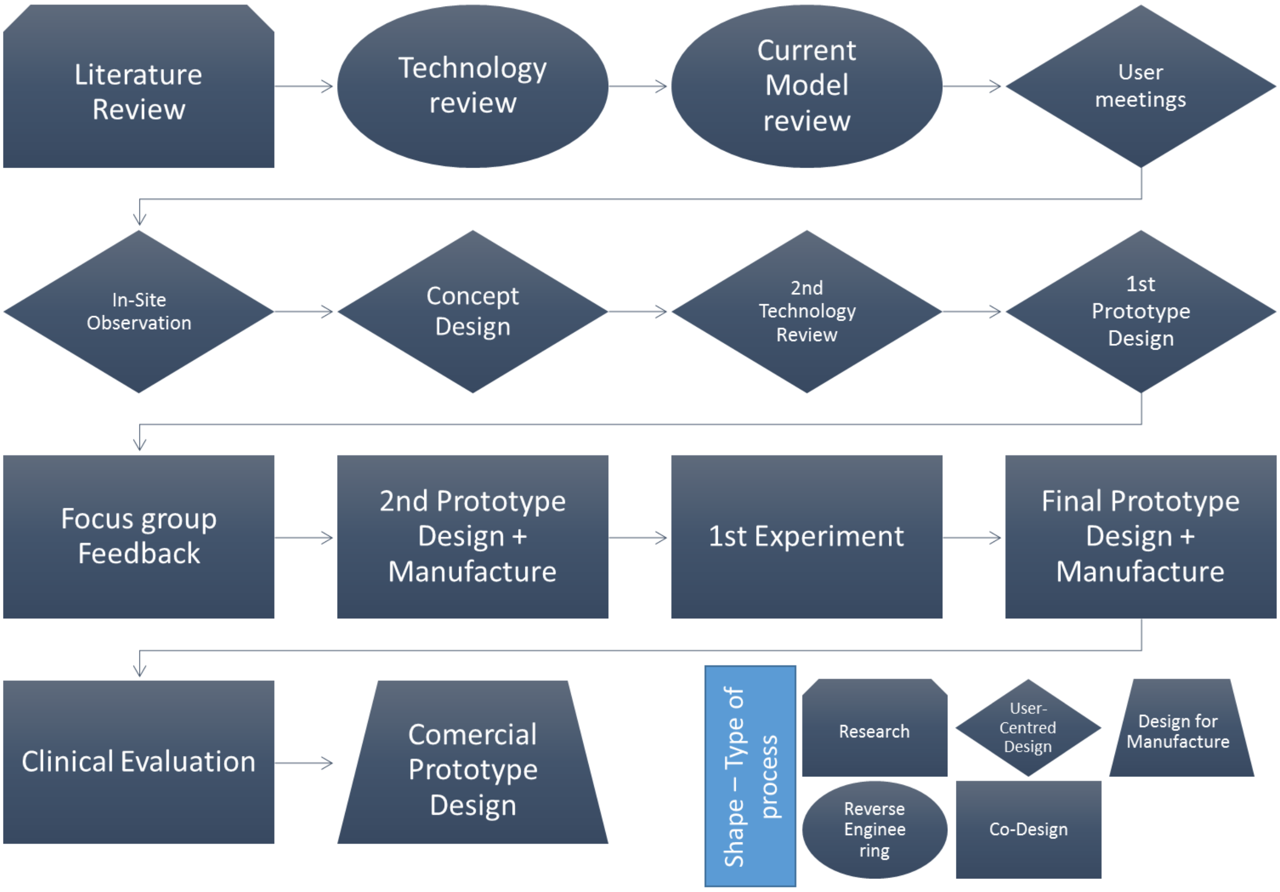

Figure 1.5 Single-Dimension design process diagram.

This diagram is also very similar to the actual document structure since it follows the stage order seen on figure 1.1 by describing the most important activities of the process and it indicates (by using different shapes) which technique could have a better result for each task.

2 Background Research and Frame of Reference

2.1 Literature Review

2.1.1 Introduction

Despite the introduction of several preventative methods, sonographers are still reducing their working hours or retiring early because of work-related injuries"

(R. Quartly, 2013).

This is the conclusion of a recent study by The University of Sheffield after analysing the results of a survey emailed to 329 sonographers across the United Kingdom and answered by 128 of them, as well as outlining the causes and impacts of the problem. The survey demonstrated that a large amount of sonographers (97% of respondents) had suffered pain due to scanning procedures. 73% suffered a work-related injury but only 15% of them believed that their workplace did not reach the minimum industry standards for the prevention of these injuries. This could be interpreted as a generalised idea that Work-Related Musculoskeletal Disorders (WRMSDs) are part of a sonographer's professional career.

Other information obtained from this survey was that most sonographers consider awkward postures and sustained muscular contraction as the most important causes of injuries, which are concentrated in shoulders (74%), neck (58%), wrist (55%) and lower back (41%). Other localised pain was suffered in areas such as upper back and elbow. Only 3% of those that answered stated that they hadn't suffer any pain at all.

A larger survey was completed by Sound Ergonomics (Sound Ergonomics, 2008) in the U.K. too. On that occasion, the number of sonographers who had experienced any kind of pain during scans represented 90% of the 3024 respondents. Due to the amount of professionals answering the survey, we can give good credibility to this study. Shoulder, neck and wrist were again the most common areas of pain. Sustained shoulder abduction, pressure application and neck and trunk twisting were the main reasons of pain given. When sonographers were asked about possible workplace improvements, their most common answers were the adjustability of bed and couch, reduction of the number of scans and replacement of ultrasound machines.

2.1.2 Feedback

Sonographers have reported several issues and opinions and some of them have been classified as a "wish list" for sonographers (Kinghorn RSI, 2012). The most important issues are:

- Reducing the effort needed to displace the adipose fatty layer in high BMI patients.
- Avoiding having to bend their wrists too far away from the neutral position.
- Reducing the degree and frequency of abduction of the scanning arm, and finding an acceptable and non-restrictive way of helping to support its weight.

That is not the first time that aspects like the difficulties to scan obese patients have arisen; in the above mentioned paper written for The University of Sheffield (Quartly, 2013), sonographers reported that more obese patients often induce more pain due to the extra effort that they have to apply to optimise imaging. Sometimes, sonographers have found an improvement by performing paired scans whereby two sonographers work together to complete the scan (Monningtom et al., 2012) but, of course, this solution increases the time needed for scan and it has cost implications.

2.1.3 Economic Impact

Repetitive strain injuries are said to cost European countries between 0.5% and 1.5% of the GNP(Kinghorn RSI, 2012). The monetary costs of work related musculoskeletal disorders have been discussed by most of the authors that have tried to explain this issue. A report published by the NHS in the U.K. (NHS, 2009), sustains that MSDs *"Are the most common type of occupational ill health in the UK",* representing around 40% of all sickness absences and regarding to their accounts, they result in a cost of about £400 million each year. Most of the cases of absence due to MSDs apply to sonographers and the cost can range between £2700 and £3700 per employee, plus the sonographer sick pay for the absent individual (Quartly, 2013). As can be seen, the economic impact of MSDs is huge.

Baker et al. (2002), establishes the costs of musculoskeletal disorders of the shoulder of sonographers to be $641,000, counting worker's compensation, medical expenses (without surgery), staff replacement cost, revenue loss and recruitment costs of new sonographers. In the same document an estimated total cost of implementing an ergonomic workstation for sonography was calculated to be around $158,000 including an examination table, chair, support cushions and a modern ergonomic ultrasound system.

2.1.4 Personal Impact

The benefits of investments in ergonomic instruments or devices are more than clear, all of this without counting other losses such as the productivity of an experienced sonographer and his/her ability to identify potential problems during scans or personal consequences. Tendon, muscular, and neurovascular related disorders are on the rise among sonographers and the damage may not reach its full effect until twenty or thirty years after the injury (Quartly, 2013), forcing about 20% of them (NHS, 2009) to leave the profession or take premature retirement because of the impact of their injuries over their quality of life, which can be very serious in some cases causing unhappiness or a high level of incapacity to perform activities of daily living (ADLs) such as driving or sports.

2.1.5 Current advances

There are other recent studies focusing on the issue of work-related musculoskeletal disorders among professionals developing tasks in sonography. However, the problem is still yet to be adequately solved and it seems that the information that researchers have explained is not enough to help manufacturers as a first knowledge base for developing products that can reduce the impact of MSDs in sonography.

Some advances in different aspects of Health and Safety have improved the circumstances by adapting schedule and workload, increasing the number and frequency of breaks and other kind of measures like health and safety training or risk assessments for sonographers to help them to reduce their exposure to future injuries.

Despite training being given in most cases, it is not adequately addressing MSDs risks and the risk reduction controls are generally not comprehensive enough (Monnington et al., 2012). Some departments have introduced guidance and advice about postural and procedural behaviour, which has been useful to increase professionals' awareness, but the excess of workload and the insufficient rest time schedule usually make it impossible to meet all this guidance. On the other hand, the kind of procedures remain the same, and the physical requirements haven't changed. Sonographers need to apply pressure in awkward positions when using the ultrasound equipment while looking at the transducer, which causes poor postures and pain due to sustained abduction of the shoulder, unnatural alignment of the spine and other dangerous repetitive movements.

2.1.6 Technology

On the side of ergonomic product design, the improvements are not yet as satisfactory as required; some ergonomic elements have been included like tables or chairs with improved adjustability, new ultrasound machines are much more moveable and some new devices can help in scanning tasks, such as arm rest cushions or supports for transducer cables. However, all of these have not resulted in a significant decrease in the number of cases of MSDs in sonography.

Most ultrasound machines are built in a block with both the screen and the controls in the same place. The sonographer must adapt to this position, which means that he/she must be seated parallel to the examination table using one arm to scan and the other to manipulate the control panel. Also twisting his or her neck to see the transducer or the screen and without the possibility to place the legs under the couch or the ultrasound machine due to the non-ergonomic design of these instruments (see figure 2.1).

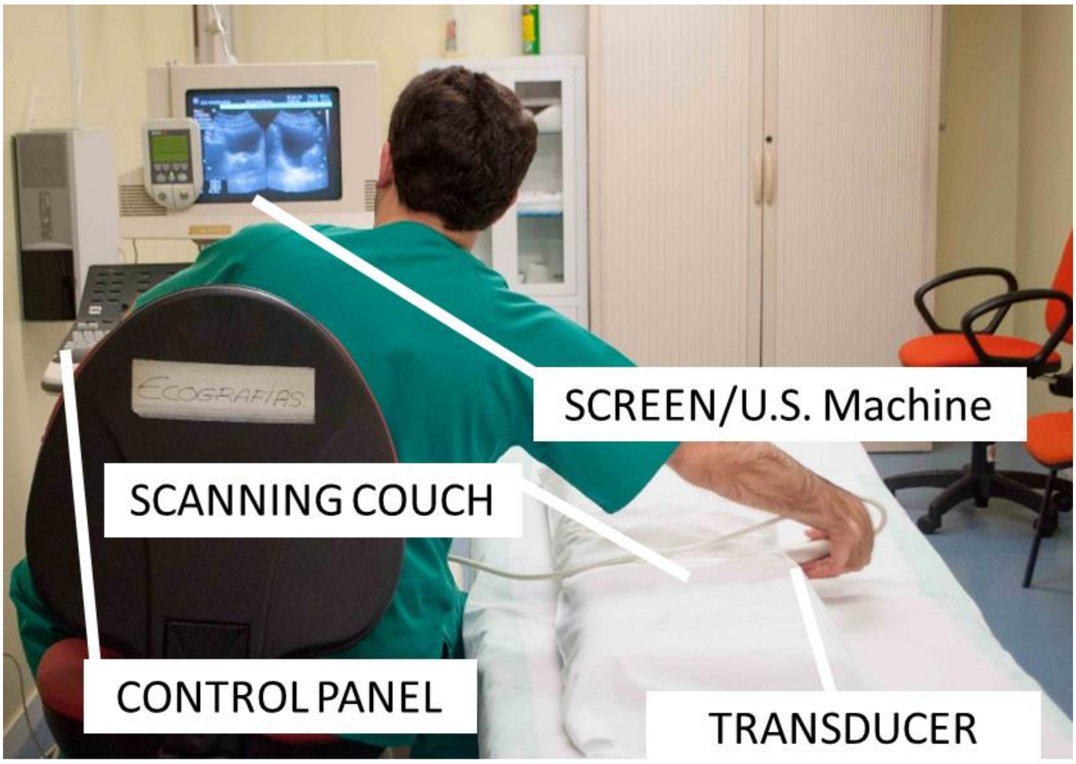

Figure 2.1 - Sonographer overstretching to reach the target.

2.1.7 New product measures

With the intention to avoid postural pain, it will be necessary to allow sonographers to see the screen and the transducer without a large neck twisting, being able to put their feet under the couch and ultrasound machine and having the possibility to perform the scan with just one hand. For some kinds of scan, like echography where pregnant women normally want to see what the sonographer is scanning, complementary screens should be provided.

These are potential improvements that have been mentioned in different papers and reports. Some of them have paid attention to other technological advances such as voice-controlled devices. It is a fact that this kind of technology is still far from being implemented in common tasks like sonography, nobody likes to speak to a machine and even less, so when another person is present. It is seen as too much artificial and could be a barrier to create a comfortable and warm atmosphere with the patient. This technology exists for other purposes such as text dictation or even to control mobile phones and is rarely utilised.

The development of new ergonomic products should go through the design of optimised workstations with good versatility that allow sonographers to choose how they want to perform their work regardless of specific personal characteristics like being right or left handed, height, strenght, etc. In addition, as the Kinghorn Project(Kinghorn RSI, 2012) explains, *"The equipment would also need to be made capable of reverting back to the traditional arrangement quickly and easily".*

2.1.8 A gap in research

In terms of delving into the physical and mechanic limits and necessities of sonographers regarding to their profession, a lack of information and research has been found. It is absolutely comprehensible that the problem still exists and that is because when manufacturers try to design and improve current technologies and products, they do not know where to start or where the limits are to modify the existing design processes.

When thinking about potential improvements, there are some questions that appear regarding to what can or cannot be commercial. Assisting one of the movements that sonographers must perform when scanning could be useful, but could this movement be 100% assisted? The answer is not yet. Unlike other repetitive tasks such as drilling a piece of steel or placing labels on clothes, ultrasound scans need to be more manual since the sonographer must have some control over the transducer and adapt these movements to his/her detection skills. Real-time, physical feedback to the sonographer remains the best approach to carrying out scans efficiently and accurately.

After reviewing the most recent literature, it is clear that the reason for the vast majority of MSDs among sonographers are the unnatural movements and efforts; if, during a scan, they have to apply up to 180N of force with the arm at 90 degrees of abduction, it follows that after years of work the muscles will eventually be damaged. In the Kinghorn project report, it is mentioned that even though pressure of work is blamed for RSI, part-time workers suffer as much as full-timers(Kinghorn RSI, 2012). Equipment-related causes should then be one of the main sources of the problem.

The necessity of laboratory experimental research covering all the scanning procedures and movements is more than clear. Knowing how many times a sonographer has to manipulate the control panel, the movements that they would need to be assisted with, on what axes and planes couches and chairs should be adjustable or what is the maximum pressure that the sonographer has to apply to the patient, are some of the questions that need to be answered before starting any innovative design process. These are the kind of topics that this study will try to clarify in order to bring new information focused on the new product development process for healthcare equipment manufacturers.

2.1.9 Conclusion

All the information gathered previously to this literature review has helped to identify key points such as the issues reported by sonography departments and professionals, the main causes of these problems and both the economic impact and the personal impact of work-related musculoskeletal disorders amongst sonographers. In addition, it has allowed an understanding of the reasons why, despite there are some advances in workload management and training, the number of repetitive-strain injuries within these professionals has not only not decreased or stopped but increased in the last years.

Many testimonies, surveys and other kinds of feedback have been gathered too; the conclusion obtained is that there is an urgent necessity to tackle the problem and find a successful and satisfactory solution which will bring a good economic benefit to healthcare institutions and, most importantly, will improve the quality of life of thousands of people who are developing their professional careers through sonography tasks. Also it is important to mention that most of these injured professionals are forced to avoid performing some daily life activities or even to take early retirement which is another reason for researches and manufacturers in this industry to take action as soon as possible.

2.2 PRE-CONCEPTUAL TECHNOLOGY REVIEW

A review of the products that can be found already in the market is an important step in the product design process, since it helps to have a wide understanding of how these products are engineered and what could be a possible start for a first innovation. Some of the existing products can be a good starting point with only some modifications or the inclusion of additional features designed for ultrasound purposes and that is why a deeper knowledge of the current catalogue will help on the success of the project.

2.2.1 Knight Imaging Current Couches

Knight Imaging has in its catalogue several models of sonography couches, and most of them have different options to customise. Autotilt Beta, Autotilt Delta and Autotilt Echo are the main models offered for ultrasound tasks.

Autotilt BETA

Figure 2.2 - The Autotilt BETA couch (Knight Imaging catalogue).

"Features one, two or three motorised functions in a variety of combinations to suit your individual needs. Upholstery widths of up to 80cm and a maximum weight capacity of 260kg provides optimum comfort and safety for the patient."

This model (fig. 2.2) can be chosen in two different widths (70/80 cm) and there are 4 options regarding the motorisation of its movements. The height range starts in 49.5cm and finishes in 87cm, which is considered as a "low level access height" that helps the accommodation for disabled or wheelchair patients. The maximum weight supported is 260kg, which is high enough for most patients.

Autotilt DELTA

"The Delta 2 is our top of the range ultrasound couch. For optimum ease of patient positioning, this flexible couch features four motors to control height, backrest and foot section adjustment as well as Trendelemburg tilting."

Figure 2.3 - Autotilt DELTA U.S. couch. (Knight Imaging catalogue).

In this case, the DELTA (fig. 2.3) has a full range of motorised movements and an improved mechanism that reduces the space needed for the vertical displacement when adjusting the height, which ranges from 50 to 102 cm (Starts just 0.5cm higher than the BETA). The width options are again 70 or 80 cm which makes the model suitable for bariatric patients. The maximum weight is a bit less than the BETA, 250kg, but still being suitable for most patients.

Autotilt ECHO

Figure 2.4 - Autotilt ECHO couch. (Knight Imaging catalogue).

"This specialist couch for Echocardiography allows the operator the flexibility of being able to carry out the patient examination from either side of the couch."

The ECHO can be considered as the most ergonomic model of Knight Imaging couches (fig. 2.4). It counts with a similar improved mechanism to reduce the space needed for the vertical displacement and allows examination to be performed from both sides. Some special improvements has been introduced such as an included operator seat and a foot rest attached to the couch for his/her comfort.

Autotilt BARIATRIC COUCH

Figure 2.5 - Autotilt Bariatric-design. (Knight Imaging catalogue).

There is an extra model specially designed for bariatric patients (fig. 2.5) which can support up to 325kg and has similar features to the DELTA models, but its height elevation ranges from 43cm to 97cm.

2.2.2 Comparison

Table 2.1 provides a comparison of the Knight Imaging range of Ultrasound Couches.

Table 2.1 - Comparison of the US couches in the Knight Imaging range.

	BETA	**DELTA**	**ECHO**	**BARIATRIC**
Width	70/80 cm	70/80 cm	80 cm	80 cm
Height range	49,5-87 cm	50-102 cm	50-102 cm	43-97 cm
Max. Weight	260kg	250kg	225kg	325kg
Height	Motorised	Motorised	Motorised	Motorised
Backrest	Optional	Motorised	Motorised	Motorised
Foot section	Optional	Motorised	Manual	Motorised
Tilting	Manual	Motorised	Motorised	Motorised

2.2.3 Improvements needed

The current models have a well-covered range of movements which facilitates most of the tasks that need to be performed in sonography, all of them have a large size option to accommodate bigger patients and the maximum weights, which range from 225kg to 325kg. The low starting position seems to be low enough to facilitate the use of disabled or movement-limited patients. However, some potential improvements have been identified in order to improve ergonomics.

With the objective of increasing the comfort of sonographers when using and manipulating these kind of couches, one of the requirements to reach this objective would be to decrease the number and volume of mechanical parts under the couch. The couches have been studied and it has been found that most of these parts are designed for the height adjustment movement. Some improvements have been done in the latest models to reduce the space required for this vertical displacement, normally accompanied by a circular movement of the mechanisms, which requires more space in the room. However, this circumstance could be highly improved by replacing this mechanism by a single and bigger actuator strong enough to avoid vibrations and maintain the stability of the structure.

The parts of the mechanism related with other movements are not a big problem since they are already simplified. One improvement that could be made, would be to decrease the thickness of the frames where the upholstery supports are attached in order to facilitate the operator to place his/her legs below the couch.

The maximum weight supported could be increased by utilising stronger actuators and materials, but it should be studied if there is a real necessity for that since this would increase the final price.

Feet support for the sonographer should be included in all models as well as a more ergonomic chair in case of including it with the couch. Reversibility to allow the scans to be performed from both sides would be a good improvement too.

Another required change in terms of health and safety and hygiene levels is the covering of rotating and mechanical parts. Some of these mechanisms represent a high risk of accidents such as pinched fingers and have too many difficulties for cleaning tasks. Using a light material like plastic or some kind of fabric to cover all these parts would improve this aspects and it will give a better look to the product, making it more commercial and attractive.

However, the most important feature for the new product will be an innovative armrest which can assist the sonographer in some forces, especially the pressure applied with the arm in abduction position. Probably this armrest should be an optional extra since it will increase considerably the final price of the couch.

An improved system to accommodate other devices needed for sonography such as the ultrasound machine will be studied too. The biggest barrier to achieve this is the wide range of different machines, screens, controls, etc. that are currently in the market. However, transforming the couch in a kind of docking centre for sonography workstations would be an important achievement for this project.

2.2.4 Useful already existing products

In this technology review, some interesting products were found that could be useful to the project in order to specify what is being done and what is yet still to be done. Some of the areas of improvement identified and explained in the previous point could be more easily implemented if there are some products that already offer these features.

By studying products that can be found currently in the market it will be possible to design and develop a new one which combines all the requirements to be as ergonomic as possible.

2.2.4.1 "Salli Sonography Chair" (Carbonlite-Medical, £995-£1,180).

This model (fig. 2.6) was specifically designed for sonography, it includes a backrest but the most important innovation is the couple of articulated armrests which can be well adjusted to each sonographer.

Figure 2.6 – Salli Sonography Chair. Carbonite-Medical internet catalogue)

However, there is a main issue with these procedures that is still to be solved. Sonographers have to apply pressure and these armrests only support the static weight of the upper arm (as shown in figure 2.7). They cannot aid in applying the pressure during a scan.

The company already sells to the NHS and it seems that they are working to improve the armrest in terms of pressure application.

Figure 2.7 - Advances regarding arm supporting while scanning (Carbonite-Medical website).

2.2.4.2 Capisco chair

The Capisco (fig. 2.8) chair seems to probably be the most ergonomic model of chair used in sonography according to the opinion of several professionals. It was specially designed for works that require a large amount of movements and different positions.

Figure 2.8 - Capisco Chair (Google Images).

It would be a comfortable option but, again, there is capability for force assistance. Both the saddle seat and this Capisco chair could be implemented in a potential Sonography Workstation ergonomic design.

2.2.4.3 Semi-seated position chairs

A chair that allows a semi-seated position (fig. 2.9) should be studied too. It would facilitate the sonographer to perform the scans on a partially-standing position (it would require a higher scanning couch) which would avoid some heavy neck and waist twisting by allowing them to get closer to the couch. Some models of chair for this purpose have been designed and some of them include leg supports that make this a good option to take into account.

Figure 2.9 - Semi-seated diagram that could be adopted by sonographers. (Google Images)

2.2.5 Ultrasound Machines

A basic ultrasound set-up, as shown in fig. 2.10, has:

- Transducer probe: This sends and receives the sound waves.
- CPU: Computer that does all of the calculations and contains the electrical power supplies.
- Transducer pulse controls: This changes the amplitude, frequency and duration of the pulses emitted.
- Display: The screen which displays the data processed by the CPU.
- Keyboard/cursor: This inputs data and takes measurements from the display.
- Disk storage device
- Printer

Figure 2.10 - Ultrasound room standard Lay-out (Edited from Google Images)

The shape of the probe determinates its field of view, and the frequency of emitted sound waves determines how deep the sound waves penetrate and the resolution of the image. Ultrasound can be done much faster than X-Rays or other radiographic techniques.

After analysing the products being sold by healthcare manufacturers, it has been established out that the vast majority of these products are far from solving MSDs risks even if there are some improvements on design. However, these ergonomic improvements seem to be more oriented to the patient attention than to the professional.

Figure 2.11 - Example of latest design of Ultrasound machines. (Philips Healthcare)

The latest Ultrasound Machines are designed with a much more modern look and their dimensions have been reduced compared to older models. Most of them have articulated screens that allow the sonographer to show the images to the patients but, as mentioned, this characteristic does not improve the ergonomics since the operator still has to be positioned parallel to the patient and twists his/her neck to see the screen or the transducer. In recent years, some improvements have been introduced on these devices such as reduced dimensions of the CPU, improved adjustability of the screen and controls (fig 2.11), remote controls and the implementation of ports for external devices (a feature that allows to connect supplementary screens that could help to increase the ergonomics of the workstation). However, only one of the products analysed has the characteristic of being able to be mounted separately (fig. 2.15) The problem is that it seems to be more like other portable ultrasound machines rather than one that allows the controls to be away from the CPU.

What full ergonomic workstations should have it´s a modular Ultrasound Machine which is designed as a desktop computer: central CPU where features such as the screen, controls and transducer are connected by wires and are able to be far enough from it to be mounted in articulated stands surrounding the couch. Under these circumstances, any attempt to design a new and more ergonomic couch should take into account that the ultrasound machine must be accommodated and that part of the MSDs risk reduction will be related with the machine that each department has and not only the design of the couch.

2.2.6 Transducers

Figure 2.12 - Example of some types of transducers. (GE Healthcare)

There are many companies manufacturing transducers, and there are many kinds of transducers (fig. 2.12) due to the variety of examinations performed in sonography. The differences are basically the frequency and the shape. High frequency probes are used more in vascular and musculoskeletal examinations, the footprint is normally planar and they produce a rectangular image. Low frequency probes are used for abdominal, cardiac and obstetric examinations due to their deeper penetration, they are normally convex and obtain a pie-shaped image.

Even though the transducer can be classified in very little types, each manufacturer (and usually each model of ultrasound machine) has their own catalogue with different handgrips and shapes. This is a fact to take into account since it would be very difficult to design a universal holder for all of them. Any kind of device related with transducers should be designed in a generic way to allow the majority of designs to be mounted.

2.2.7 Other accessories

Other devices have been designed to improve the ergonomics when sonographers are performing scans; some of them are proving useful and have helped to decrease the exposure to musculoskeletal injuries. They are all designed with the intention of keeping a neutral position when scanning, as well as to reduce the strength needed in some tasks.

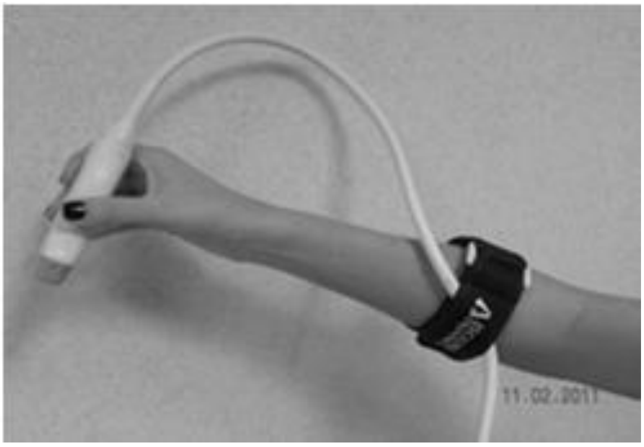

Figure 2.13 - Cable bracelet (Sound Ergonomics)

One of the most useful accessories is the cable bracelet (fig. 2.13), which holds and supports the cable of transducers. It helps to take the strain off the sonographer's hand created by the torque of the instrument. This bracelet has almost eliminated the problem with the cable weight, so it would be a useful feature in a new product design.

Support cushions (fig. 2.14) have also been designed with the objective of reducing fatigue suffered by sonographers during prolonged periods of arm abduction, their advantage is that they can be mounted as needed for each scan.

Figure 2.14 - Support Cushions. (Sound Ergonomics)

2.2.8 Conclusions

After reviewing different technologies, there is a more in-depth knowledge about current products being sold in the market. Understanding about Ultrasound machines and how they work has been improved as well. This study will help in any potential new product development by incorporating current improvements that have already been tested and implemented in sonography workstations.

A considerable advance regarding the couch design seems to have been done by manufacturers even though there may be some extra considerations that they should take into account for future models. A large catalogue that offers different models to adapt for each kind of examination to be done, will cover all the necessities of each department and there are even multipurpose models which reduce the number of couches needed for general examination departments.

However, these improvements have been all made by increasing the number of mechanisms and adding extra options such as side rails or stirrups. Adding even more actuators could help to improve the comfort of both patient and sonographer, but after all improvements have been done, this will be far from solving the prevalence of Musculoskeletal Disorders that these professionals are suffering after years of service.

Regarding to Ultrasound Machines, it seems that manufacturers of these products are not working well with couch and table manufacturers. Most of the models found are still being built in one block. It is true that they have been implemented with articulated screen stands and height adjustability as well as external devices ports and other new features, but if the objective is to reduce the risks of upper-limb disorders, the solution will require a better synergy between all factors involved.

Ultrasound instruments will need to be accommodated in new couches, probably by designing a kind of universal stand for screen and controls that allows improved adjustability in more axes. This versatility should include reversibility to the traditional position and the possibility of being used for both left and right handed sonographers.

Nevertheless, the largest gap identified after this technology review, is the armrest. Nobody has launched a product that helps not only to support arms and shoulders, but also to apply pressure over patients when needed too.

Improving to a high level the design of the couch, introducing new and existing features to get a complete and versatile workstation and offering all of this with a new and innovative device that reduces the most important risk of MSDs, will be an important step forward in how these products are designed, commercialised and utilised. If this is accompanied with training on ergonomic behaviour for sonographers, as well as good workload management and break distribution, there will be a significant reduction in the number of cases of work-related upper limb disorders and consequently the economic losses due to this kind of injuries.

3 CONCEPT DESIGN

3.1 IN-SITE OBSERVATION REPORT

3.1.1 Introduction

As part of the research, an in-site observation was planned in order to obtain information about how sonographers work and which are the procedures and forces that are involved in different kinds of scans.

Another benefit from this observation was the direct contact with professionals which gave the opportunity to get first hand feedback about issues and obstacles that they have to face on their day to day life.

The hospital where the observation took place was the Hospital Clínico Universitario "Lozano Blesa" in Zaragoza (Spain), which is part of the Aragón Health Service. The sonography department gave permission for notes to be taken as well as recording media information such as pictures and video. Patients faces where not recorded in order to keep a high level of anonymity and these observations took three days. Notes, information and feedback gathered during those days, are explained in the following pages.

Most of the time, observations were carried out in emergency departments, so it was difficult to ensure a wide variety of scenarios. Because of this, the range of scans observed was stablished by departmental needs according to operational requirements.

Specialists would be giving instructions as well as would describe the steps involved on the scanning operation to the observer at the same time that he would carry out the scan. The same procedure would be followed for all the observations included.

Day 1

3.1.1.1 Breast scan

The first issues identified were the use of a common office chair (fig. 3.1) as an operator chair, a non-ergonomic couch with manual height adjustability and a fixed machine which didn't allow to extend or adjust the screen or keyboard. The scan was performed without cushion supports and the sonographer had to keep their shoulder and arm in an abduction position. The scan took just 5 minutes, which can be considered a short time.

The sonographer said that he had back discomfort, pain and tiredness. Patients are normally placed in the centre of the couch, being too far from sonographer's hips. The computer was in a separate office where they prepared reports. For these reports, they are provided with Dictaphones which allows them to write without using fingers or wrists.

3.1.1.2 Breast biopsy

In this occasion, the sonographer was a female with 14 years of service. She declared that she had some contractures in the cervical area, but not further injuries. However, she knew that another colleague had had rotator cuff injuries and her former boss took premature retirement due to calcifications on his shoulder.

Figure 3.1 - Common chair used for scans. (Prom.ua web catalogue).

It seems that for these kind of scans a high level of pressure is not needed, but she was concerned about the excess of force required in abdominal sonography when scanning obese patients.

In mammography, it seems that the time spent checking pictures and redacting reports is longer than the time spent in the exam room for normal scans (Biopsies take normally longer).

The wrist was the most used articulated area while the back, shoulders, arms and forearms were normally on a good and ergonomic position to avoid future harms. However, not all sonographers had same level of awareness and some of them were less careful with their postures. This behaviour was normally related with younger operators.

For biopsies, more experienced sonographers said that they preferred to perform in a standing position because it was more comfortable. However, very awkward positions were required and they had to ask the patients to allow them to use their bodies as a support due to the inexistence of support cushions for this purpose in the hospital.

A manually adjustable couch was available in this room (fig. 3.2), the problem was that they needed to use a foot pedal located on one side to adjust the height. It would have been better if they had an electrically adjustable model. Normally they perform these operations in teams, involving at least one extra person to help the doctor with the process. This procedure consisted not only in a scan, but it had a little surgery too. The surgery was done in a standing position and the patient was normally very worried about a possible severe illness. This lead to more concern about the patient that about the medical professional´s own postural health.

Figure 3.2 - Manually adjustable couch. (Quirumed.com)

3.1.1.3 Abdominal scan on the emergency service area

In this occasion, the patient was a young girl who was observed in order to carry out a potential appendectomy. The room was in the emergency department and had some differences with respect to the mammography department. The table was too low and even though it was in an apparently correct height, it was impossible to adjust (fig 3.3), neither electrically nor manually. The position adopted by the sonographer was relaxed and not much pressure was required, probably due to patient's circumstances.

Figure 3.3 - Non-adjustable scanning table. (Quirumed.com)

The sonographer remarked that obese patients were much harder to scan. Especially for those sonographers who are all the day performing scans all day (other departments they carry out different tasks instead of being constantly involved with sonography).

3.1.1.4 Possible implementations

There were many potential improvements identified in the observed department, the lack of ergonomics was huge and that could cause several problems of work related injuries in the future. Some of the implementations would be:

- Electrically adjustable couch
- Ergonomic chair
- Alternative screen
- Breast scanning couch
- Support cushions
- Training

Workers reported that they are normally adopting very awkward postures. However, they do not seemed to be very concerned about possible future implications of this behaviour.

3.1.2 Day 2

It was observed that the couch design for ultrasound scans was the most modern in the Hospital. Its functions were:

- Manually adjustable height.
- Individual lockable casters.

Different types of procedure were discussed with the medical professional and are described below.

3.1.2.1 Abdominal scan (unconscious patients)

Consisted on an urgency service, the bed was a typical hospital bed (Patient was transferred from his room). The ultrasound machine was portable and the chair was, again, a normal office chair which was made with a kind of fabric that very possibly didn't meet standards recommendations for medical uses and was far from being ergonomic and adjustable.

Very awkward postures were observed with too much neck twisting. The patient was in an advanced age and semi-unconscious, this made scanning very difficult for the sonographer, who was alone in the room.

3.1.2.2 Breast sonography

The sonographer said that 80% of scans consist of abdominal sonography. They confirmed that it would be preferred if they had an electrically adjustable couch. Some of them believed that higher chairs would be needed for scans where normal hospital beds are used to support patients.

3.1.2.3 Neck scan

The patient was close to the sonographer so the posture (fig. 3.4) seemed to be much more comfortable. Pressure was not needed but wrist freedom is very important for this type of scan. The space surrounding the hand and forearm was limited due to the characteristics in terms of space of the area to be scanned.

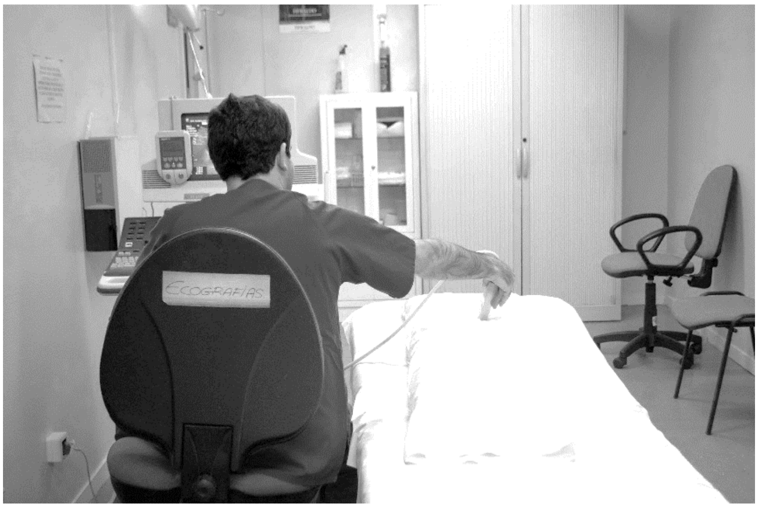

Figure 3.4 - Typical neck scan posture

3.1.2.4 Abdominal scan

In this scan a manually adjustable couch was used again. The chair was more adapted to medical uses, however, wheels were not fully working and a replacement was needed. Staff remarked the lack of budget for these kind of expenses, the ultrasound machine was very old, and it expelled a huge amount of heat to the room which caused environmental discomfort.

3.1.3 Day 3

3.1.3.1 Meeting with sonographer

Figure 3.5 - Standing position example

A large amount of useful information was provided by the last sonographer observed. He bought an ergonomic mouse for himself which was very useful when he had to write reports and other documentation between scans. An important detail that must be taken into account is that he tried to perform scans in a standing position (fig. 3.5) as often as he could. He was asked about the idea of a lateral support for the body to help them to work on this way and his opinion was very positive. However, he did not give a good response when asked about the possibility of using an articulated armrest, the reason given was that he needed to make movements in all angles and planes, and it was felt that any kind of artificial structure would create limitations to these motions.

He mentioned several problems with transducers as well, especially with the shape and the tension created by the wire. It would be very difficult to convince him to alternate between right-handed and left-handed scans since sonographers are all trained in a right-handed way (he compared this case with when musicians plays instruments such as violin or guitar, they are instructed to play in a specific way). He felt a simple centralised locking system for the couch would be a very good improvement since sometimes (especially in urgency services) they need to move patients and some couches have individual brakes, which obligates the sonographer to move around the room. The last issue he raised was a lack of space between machine and couch, but this would depend on the department/hospital set-up.

3.1.4 Conclusions

Once several kinds of scans were observed and some sonographers were asked about opinions and identified issues, it was clear that any attempt to design an articulated armrest would be more complicated than expected due to the necessity of performing motions in many dimensional planes and angles. As mentioned before, an artificial structure supporting the arm would interfere with some of these movements and create an obstacle for completing the scan.

For these reasons, it was decided the design stage of the project should be focused on other kind of solution, such as a side support. It was observed that performing scans in a standing position helped the operator to remove some muscular effort, as well as to reduce the articulation angles which makes procedure postures closer to neutral positions allowing sonographers to perform longer scans without experiencing musculoskeletal fatigue.

In order to make a side rest even more ergonomic and to optimise postures adopted by operators, it was decided a comfortable footrest would be beneficial too. As interviewed professionals declared during the observation, it is better for neck and back to have one foot on a higher resting position in order to maintain an upright comfortable position, as this helps to align the back according to many postural and ergonomic advising manuals.

The overall solution would also be improved with features such as adjustability and ease of mounting, which will make the product more attractive for those who need longer adapting times for workplace changes.

Based on these reasons, it was decided that the design could include features including:

- A bracelet to hold the probe connecting cable and remove tension from the wrist.
- A centralised locking system for the couch.
- A lateral rest to allow sonographers to support their shoulder and back, especially to make scanning easier when in a standing position.
- A footrest for the sonographer.

3.2 Design

3.2.1 Introduction

Initially, the plan was to find an integral solution to the whole problem of Work-Related Musculoskeletal Disorders through the design and manufacture of one unique product which would assist sonographers when scanning by applying the required force on each scan.

Since the project had some financial limitations in terms of budget available, as well as the available technology in the company was not at a high level, the first idea of designing a robotic arm was not discarded during the initial stage after consulting different experts from The University of Sheffield team of Robotics. They explained the difficulties of reproducing the mechanism of the wrist and said that it was probably the most difficult musculoskeletal part of the body to be copied.

Bearing this in mind, it was necessary to find alternative ways of starting an initial concept design. Since this is an industrial project intended to be fully developed and launched to the market, there was a special concern about trying to reduce risks and keep the manufacturability factor as a priority whilst still delivering innovation.

This is why the Knowledge Transfer Partnership between the company and The University of Sheffield was so important.

The final decision was made knowing that ultrasound scans can cause different kinds of injuries depending on the situation of each professional, as well as more than one injury at the same time. For this reason, the concept design was based on a multi-features system which would combine different solutions to create a fully ergonomic ultrasound workstation that could reduce several risks at the same time.

3.2.2 Inputs

In addition to the findings described in previous chapters, useful product information was obtained from members of Knight Imaging staff who were in contact with customers, as well as from direct conversations with professionals and managers from ultrasound departments. This combined set of information was a good starting point for the concept design as it highlighted the most important issues to tackle. These were:

- The mechanisms of current couches are so complicated that they do not allow sonographers to place their legs in a comfortable position.
- The fact that the patient is normally located in the middle of the couch, leaves some space between him/her and the sonographer's hip, forcing them to carry out wider reaching movements which causes back pain.
- In some types of scans (especially pregnancy scans) it is common that the patient wishes to see the screen so they can see the baby. This requires sonographers to adopt awkward postures which is one of the most common risks causing MSDs.
- The transducer cable usually causes strong torsion loads on the sonographer's wrist. This is again an important issue that can make the user develop carpal tunnel syndrome, a very common injury in sonography.
- As explained in previous chapters, shoulder abduction is the biggest risk for sonographers since most of them have reported injuries/pain in this muscular area. Some arm supports have been introduced in ultrasound departments, but the fact that they are designed to move in a single horizontal plane, makes them inadequate in reducing injury risk.
- The standard way of performing an ultrasound scan is a risk in itself. Having the ultrasound machine in front and the patient placed parallel to the

sonographer causes awkward postures to be adopted as well as increasing the number and range of transducer movements required to obtain a good image.

- The chairs available in some ultrasound departments are standard office chairs which are not designed for the purpose of scanning. They can have a backrest which is too big and often lacks adequate adjustability.

3.2.3 Layout

Once different components had been reviewed (see technology review) the initial components included in the ergonomic ultrasound system could be defined as:

- An ergonomic couch
- An adjustable saddle seat
- An arm support
- An ultrasound machine
- A peripheral monitor for the patient

3.2.3.1 Ergonomic couch

The couch is the part of the system that will be directly manufactured by Knight Imaging, whilst the rest of components will be purchased from external suppliers.

The company has some experience with these products since they've been developing and selling a range of ultrasound and treatment couches for years.

Taking in mind the inputs mentioned earlier on this chapter, the couch must:

- Allow users to place their legs underneath.
- Facilitate a comfortable position for the patient while allowing the sonographer to get close enough to avoid awkward postures.
- To be fully electronically adjustable.
- Be easy to clean.

- Have some degree of back tilt for Trendelenburg position.
- Be easily transportable, through a wheeled design.

With this "design boundaries", an initial sketch (fig. 3.6) is produced based on the typical design of similar existing products (wheels do not appear on the concept design as they are just attached under the chassis, will be introduced later on the process):

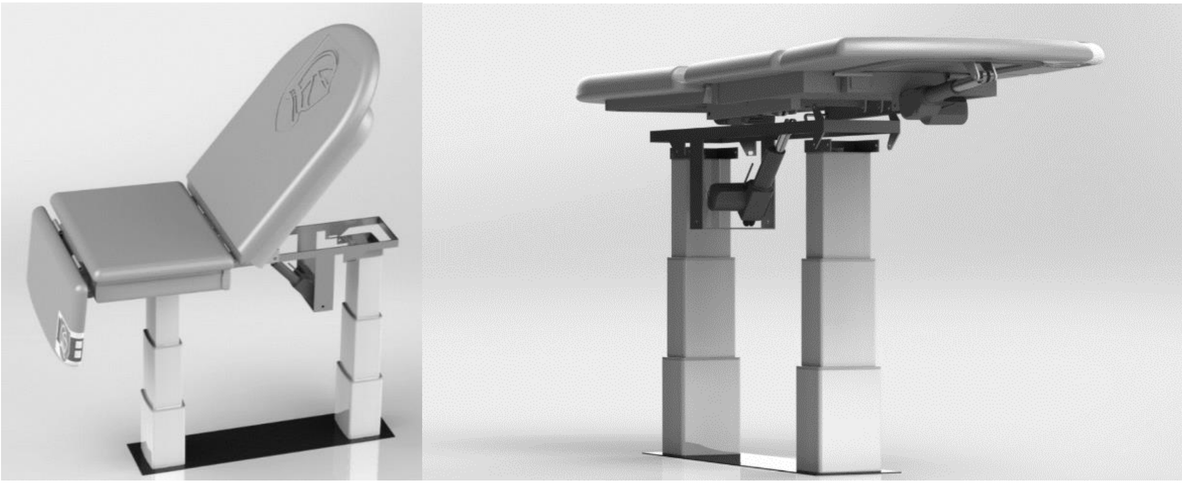

Figure 3.6 - First couch concept design

3.2.3.2 Operator's seat

As has been explained before, the back is one of the most important anatomical areas affected by work related musculoskeletal disorders in ultrasound departments. This is due to the amount of time that sonographers must spend sitting on a chair performing scans.

Sonographers use a type of seat that is not so different from the standard chair that most people use in an office environment. Some of them incorporate different armrests or backrests designed to help with the tasks involved in sonography, but the overall problem cannot be solved by adding features to a standard chair, as it has been shown that the way standard chairs have been designed is not good for the human body.

During thousands of years, humans have been using a similar way of seating which has never been questioned apart from different studies that normally does not go further into a real change on the design and manufacture of new products. This is normally because customers are so used to conventional chairs that it is very difficult to introduce new designs as they refuse the change.

The most important influence of seats when trying to explain musculoskeletal injury risks is the shape of the spine. When somebody sits on a standard chair, both the chest and abdomen get compressed and this has an effect on the efficiency of some important organs due to the unnatural "C" shape of the spine, on which the pelvis rolls back stressing back muscles.

It is true, as some electromyography studies have suggested, that sitting in a reclined posture relaxes trunk muscles which require a lower amount of muscular activity to support the body weight, but this is not necessarily good when trying to avoid low back pain. The ideal posture, should allow the hips to be positioned at an angle of less than 90 degrees (Gandavadi, 2005).

There is a good amount of literature that explains the importance of changing habits and modifying the way how siting is understood. It seems that when using a chair, the most important aspect is not just to have the body relaxed, but to do it on a natural position that doesn't create any risks to the spine. And if this is important in daily life, it is even more important for professionals like sonographers that spend a large amount of time using seats and performing tasks on them. And for this reason, the introduction of a "spine-friendly" chair it's vital on the design of an ergonomic workstation for ultrasound departments.

Shoulder support

It is known that one of the very areas of pain as well as one of the most common causes of injury is the shoulder. This project has always had a special interest on reducing MSDs risks in the shoulder region as it may solve a great portion of the problems related with ultrasound scans.

Postures that involve shoulder rotation above the shoulder plane are linked to a large incidence of this kind of injuries. Angles greater than 45 degrees between the torso and upper arm require much more muscular activity than a relaxed standard posture and this causes an increase of the mechanical pressure on the supraspinatus tendon, which can lead to impaired microcirculation resulting in inflammation. If the inflammation is sufficiently intense, then shoulder tendinitis may become chronic since the degenerative process in rotator cuff tendons and impaired microcirculation may lead to small areas of cell death.

This makes the provision of a shoulder support or arm rest a must when speaking about the design of ergonomic ultrasound workstation. Some similar devices are already in the market as it has been described in the previous technology review, but they are normally just providing a place for the arm to rest passively and not helping the shoulder to perform movements by reducing the demand on the muscles and or reducing the effective weight of the arm at the same time that it preserves a free range of movement.

For this reason, it is necessary to find an alternative design by researching across other industries with similar necessities that might have similar issues and that could have reduced these risks by the introduction of innovative devices that could be implemented into medical environments without reducing their effectiveness.

3.2.3.3 *Other features*

When designing a complete ultrasound workstation, it is required to try to find as many gains as possible, since these gains can help to join and improve the important changes described above. Not only are shoulder injuries, back pain and awkward postures the big problems, but they are always linked to other (and less recurrent) injuries and areas of pain. Reducing the small risks, will also reduce a huge amount of discomfort that prolonged over time, will lead to a more important musculoskeletal disorder.

3.2.3.3.1 Peripheral monitor

Pregnancy scans are a huge fraction of the total amount of scans performed in many ultrasound departments, and for these, having this scans the special characteristic is that patients want to clearly see what the transducer is detecting.

This makes the sonographer work even harder, as they need to allow the patient to see the screen, forcing them to adopt even more awkward postures which heavily increases the risks and damages to their musculoskeletal system.

On any ultrasound workstation design, it would be 100% required to have at least one extra monitor, so patients can see the images captured while the professional can still work with the built-in monitor of the ultrasound machine.

3.2.3.3.2 Transducer cable support

Wrist twisting is another important risk for sonographers, looking for the exact point where they must scan sometimes requires too much effort on the wrist muscles and a prolonged and excessive stress on this area can lead to a carpal tunnel syndrome.

This is normally worst due to the probe cable, which is not light at all and requires extra tension on the wrist to keep the transducer straight and perpendicular to the patient’s body.

There are some cable supports that have been found to be useful, but professionals argue that after some time, they are normally abandoned since it takes too much time to adapt them to every sonographer. In other words: they help, but they are not perfect.

A re-design on this devices or an adaptation that would integrate the cable support into the whole ergonomic system, making it more mobile and not restricting any sort of motion to the professional, would be very advantageous when it comes to reducing the risks of carpal tunnel syndrome or other wrist-related injuries.

3.2.3.3.3 Ultrasound machine

Ultrasound machines manufacturers have been constantly introducing new features and characteristics to their products, making them easier to use as well as improving their accuracy, resolution, mobility etc.

However, even that this is probably the most important piece of equipment on an ultrasound department, manufacturers haven't improved their integration with the other equipment required to perform ultrasound scans and this is part of the cause why ergonomics have not reached this industry.

Adjustability, mobility, flexibility are the most important characteristics that any ultrasound machine should have in terms of ergonomic design, but its integration with the whole environment/workstation must be something to keep in mind as it could completely change the way how ultrasound scans are performed.

In the meantime, it is vital to analyse ergonomic features when purchasing a machine, since a small gain in terms of adjustability can mean a huge difference in the future. The use of old machines, made in one single block and with very limited flexibility should be limited in order to minimise musculoskeletal disorder risks.

3.3 Post-Conceptual Technology Review

3.3.1 The Saddle Seat

In this post-conceptual technology review, a relatively new product called the Saddle Seat has been analysed after studying its possible benefits when replacing standard chairs with this seats.

Research published in November 2005 in the Journal of Therapy and Rehabilitation (Gandavadi, 2005) analysed the "Effect of two seating positions on upper limb function in normal subjects" and compared through the use of electromyography equipment the muscular activity when using a standard chair and a saddle seat.

At the end of the experiment, there was an important difference between those using an "anterior pelvic tilted position" (saddle seat) and those in the "posterior pelvic tilted position" (standard chair). This difference on the pelvic tilting angle is what allows an improved upper limb performance when adopting the anteriorly tilted position (Reissner, 1972). According to another study, the higher sitting position of this chair, the stability of its seat, and its great mobility appears to be less iatrogenic (or accidentally harmful) than other sitting positions (Verkindere, 1998). The same research remarks that the most important novelty of the saddle seat might be the shape of the seat (fig. 3.7), which is concave at the rear and convex at the front. This allows the pelvis to rest on a large surface and not only on two points, which helps the pelvis to be constantly supported in a vertical "S-Shaped" position.

Figure 3.7 - Saddle seat shape (Bambatch website)

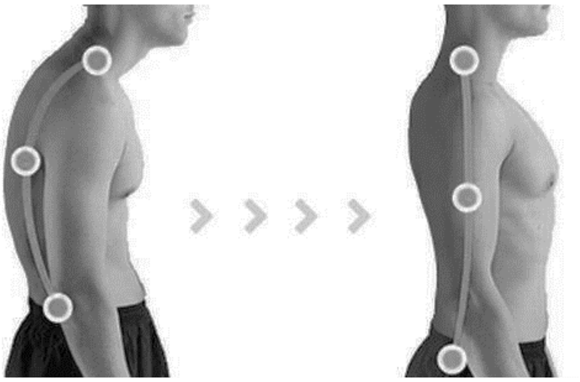

Figure 3.8 - "C" vs. "S" Shaped positions. Bambatch.co.uk

Apart from that, the saddle seat allows a moderate muscular activity, which is positive to keep the muscles working to support the body weight on a natural shape, and this is good not only on a musculoskeletal point of view, but has other many benefits as it keeps the body working, and doesn't allow it to adopt a "energy storage mode". This is explained because when the body is on a fully seated position, the muscles are relaxed and enzyme activity drops by 90 to 95 per cent.

As said above, this "energy storage mode" caused by sitting on standard chairs is another reason to use a saddle seat, since this one keeps the body working lightly while passive sitting uses much less energy. Even worst, other studies have shown that adding curved backs to standard chairs where the user must press back for a healthier posture, have a negative effect on health, causing postural stress which results in back and shoulder pain (Langham, 2013).

The specialist in ergonomic seating technology Chris Langham, explained that the solution would be a seating that provides the correct posture and active support for the spine, as well as supports the head and body against gravity while also maintaining the centre of mass within the optimum base of support.

Finally, he correctly points out that as every person has a unique pelvic angle, seats must be able to match this with different sizes and adjustable tilt. However, any saddle seat or even perching on a bar stool will be better than conventional right-angled seats.

To summarise the benefits of adjustable saddle seats, there is a list of points made by Bambach (an important manufacturer/distributor for these type of seats), which gives a good final idea of what could be improved by changing the way professionals sit on their daily tasks (The Bambatch Saddle Seat website ,2016):

- The hips are at an angle of 45-degree flexion in external rotation and abduction. This allows the pelvis to be positioned in its neutral upright position.
- By providing a secure neutral pelvic position the natural lumbar-pelvic rhythm will in turn ensure that the spine is positioned in its neutral upright 'S' shaped position.
- With the pelvis and spine in their natural, neutral position the shoulder girdle is retracted in its natural position and the neck, head and upper limbs can act in a balanced and efficient way. Conventional seating will result in the pelvis rocking backwards into posterior tilt, causing the spine to change from a natural 'S' shape to a 'C' and the shoulder girdle to protract and roll forward and chin jut out.
- The upper limbs can be maintained in a mid-range position which is beneficial in reducing static load and maintaining muscle length and normal tone.
- The shoulders and arms are relaxed and the hands do not have to act at or near the end range of movement which enables more accuracy and power and minimal fatigue.
- A clear midline assists maintenance of balance and symmetry. This assists in activating the muscles of postural control in a balanced way which allows the development of a symmetrical posture.

- Improved posture will lead to improved head control which means that eyesight is maximized and hand-eye co-ordination is facilitated.
- Allows close access to work surfaces and work tasks.
- Swivel action of the seat reduces the rotational forces on the cervical spine which can lead to degeneration of the vertebrae, neck pain and headaches.
- Thoracic, abdominal and pelvic spaces are maximized resulting in improved lung and internal organ function and circulation.

3.3.2 The Edero Arm Support (Armon)

Despite the lack of satisfactory devices available for the ultrasound market, research was expanded to other industries with the intention of finding a design that could be implemented into this sort of environment.

Initially, there was a focus in the industrial sector, where repetitive strain injuries have a huge incidence too and some ideas were found in a relatively short period of time. A model of tool-support that it's already available in the market (X-Ar Arm from Talemtech LLC), which consists on a spring-based linkage and that supports the weight of heavy tooling used in automotive (fig. 3.9), naval and other heavy industries was the first option considered for the project, and one unit was obtained with the objective of performing some evaluations.

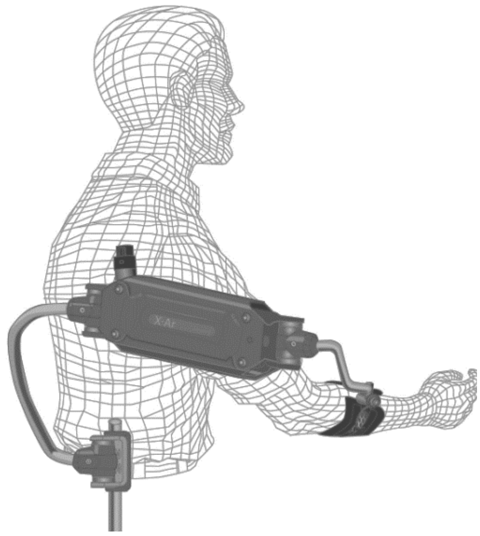

Figure 3.9 - X-Ar Arm support (Talemtech LLC)

However, it was found that the design may not be suitable for medical environments and the technology research continued looking for similar devices.

Coming back to the medical industry, the focus was this time on assistive devices used by people suffering from diseases such as Spinal Muscular Atrophy and other problems related with a limitation of elementary activities of daily living (ADLs). There is a subdivision of assistive devices that are available, which can be classified as robotic manipulations, powered orthoses or non-powered orthoses.

Robotic manipulations and powered orthoses are the most suitable for weakest patients, but for those that still have their own range of movements, can apply some force for accelerating and decelerating as well as to overcome friction and balancing errors, passive devices were preferred.

This case would be very similar to a sonographer that has developed a rotator cuff injury and cannot apply enough strength in order to perform ultrasound scans as he or she could still lift their arm and move it in a wide range of angles. A potentially appropriate model of these kind of arm supports could be the Edero Arm Support (fig. 3.10).

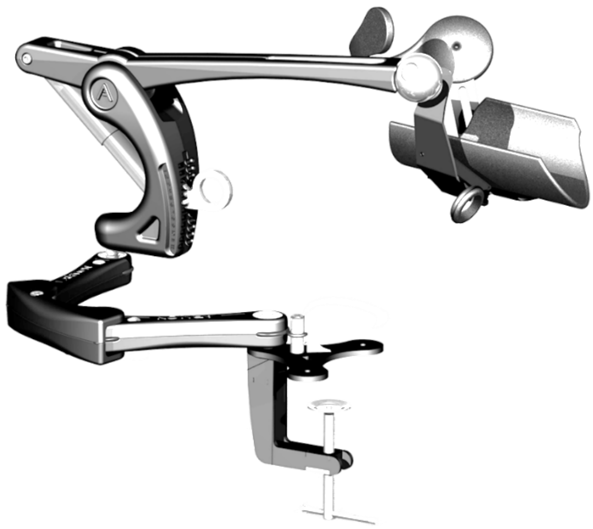
Figure 3.10 - Edero Arm Support (Armon products)

The objective of this device is to reduce the force required to operate the transducer because no control is needed as the device follows the natural arm movement, at the cost of some power requirement for acceleration, deceleration and overcoming friction and balancing error, while keeping a high level of functionality (Mastenbroek, 2007). As explained before, the device was primarily directed at people suffering from SMA, but could be useful for other users such as persons performing computer work or any other activity related with an important RSI risk and, on the contrary of the X-Ar model, this is a much cleaner and medical-looking device.

As this seems to be the best choice for this project, it was decided to advance in the workstation design by incorporating one unit of the Edero Arm Support, which should be an important part of the whole system that will help reduce an important portion of shoulder injury risks.

3.3.3 The Delta + Ultrasound Couch

All the work done in the design of the ergonomic ultrasound workstation is based on small gains provided by different devices that improve the performance of professionals and reduces the most important risks of work-related musculoskeletal disorders. However, these devices must be all linked to each other through a central product, which must be the one where the patient (who is the final user) is being scanned.

The ultrasound couch has been the main challenge of this project, as even though different devices and products were already in the market with the intention of reducing RSI risks, these had never been implemented as a whole system due to the lack of collaboration between manufacturers.

Designing a new and innovative couch that not only would fit all those devices and their gains, but has its own improvements and special features specially designed for sonographers in order to help them improve their working conditions and, of course, to reduce the huge issue of WR-MSDs would be a great advance towards solving the problem.

Figure 3.11 – "Delta+" U.S. Couch prototype (Knight Imaging)

As a result of this work, a new product was finally developed and added to the Knight Imaging catalogue.

Initially, there was a list of specification requirements that the new couch would need to meet in order to be successful and easy to put in the market:

- Height of the couch being lower to facilitate access.
- Better flexibility in terms of adjustment (wider ranges of movement).
- The couch being user-friendly to allow professionals to adjust it easily.
- It cannot be too different from current products in order to avoid being a drastic change.
- It must be as much ergonomic as possible.
- Manufacturing materials have to be anti-bacterial where possible.
- The couch has to be easy to clean and resistant to disinfection processes.
- It has to be structurally safe and stable.
- The design must meet manufacturing limitations.

Knowing these specifications list, the work was focused on looking for little improvements that could be done to a standard current couch, and how to accommodate external devices into it by making them fully compatible, providing a whole integrated system that in general, will reduce most important RSI risks.

Different changes were introduced into the design, and the outcome was a fully ergonomic ultrasound couch that will definitely help reduce risks and make ultrasound scans much simpler and comfortable. These new features are:

- Electronic adjustment for backrest
- Electronic adjustment for legrest
- Electronic height adjustment
- Electronic tilting (forward and backwards) adjustment.
- Electronic braking system to improve product’s mobility and safety.
- Detachable lateral pads to increase safety and comfortability for patients.
- Simplified mechanisms under the couch.
- Ergonomic shape of the couch.
- Special antibacterial components to avoid contamination.

The fact that the couch is 100% adjustable by electronic actuators, makes it very easy to use by one single person even for the heaviest patients, this reduces the amount of time adjusting the couch and the effort made by professionals to locate the patient in a good position.

One of the most important improvements is the improved mechanism, which allows a larger range of motion of the couch, while keeping the mechanisms simple and easy to clean. This creates an empty space under the couch where sonographers can put their legs or give more space for the wheels of the operator seat.

The other big improvement is the special shape of the couch, which gives sonographers a much more ergonomic access to the patient, allowing them to keep their hips next to the patient and reduce their shoulder abduction angle. This may reduce the space available for the patient to lay down, but thanks to the lateral pads added to the opposite side of the couch, any unsafety sensation is reduced as there is no option to fall from the couch.

In any case, the overall size of the couch as well as the depth of the ergonomic shape can be easily modified according to the customer's needs. Allowing the couch to be specially manufactured for obstetric or other larger patients with a very simple modification.

Thanks to this new couch, it is possible to have a final layout design for an Ergonomic Ultrasound Workstation, and the system is ready to be tested under clinical conditions. Collaboration with professionals is a key here, as their feedback will give the final orientation for the final product, leaving them try it during a clinical evaluation allows to understand what are the strongest and weakest points on the design, so it is easier to make the final modifications before going into the market.

4 EXPERIMENTAL EVALUATION

4.1 METHOD

With the objective of understanding the behaviour of muscular activity when performing scans, a first pre-design experiment was planned. The principal target was to obtain enough information and knowledge about the most damaging postures and movements to fix them as main points of improvement. In order to start with the design process, it was necessary to analyse all movements involved in a scanning task as well as the forces implied. Other information that should be obtained would be the muscular activity, this would help to confirm the efficacy of ergonomic modifications and allow an estimate of the level of improvement that could be reached.

This assessment was utilised to influence in the design process, in the case of developing any mechanism or device which would assist some movements and avoid the sonographer from doing dangerous movements/forces.

The measuring stage of the experiment was done through the use of Industrial Electromyography or a similar method. Electromyography (EMG) has been utilised before in other experiments for analysing issues related with sonography (fig. 4.1) and in other industries to get information regarding the performance associated with the workplace, principally to evaluate light, repetitive work where the

Figure 4.1 - Electromyography equipment for U.S. (Alimed Inc.)

activity of specific muscles is of interest. Ergonomic analyses often use this technique when comparing the specific musculoskeletal stress associated with various work positions, postures or activities and for validation of ergonomic principles.

Through the use of this method, the objective was to get enough information to confirm that by avoiding some postures and efforts, the risks of musculoskeletal disorders can be decreased in sonography by designing products that improve ergonomics in the workplace. To reach this objective, muscular activity measurements (fig. 4.2) were taken in different workplace scenarios (One standard and other improved) and then, by comparison, it will be reflected if efforts increase or decrease.

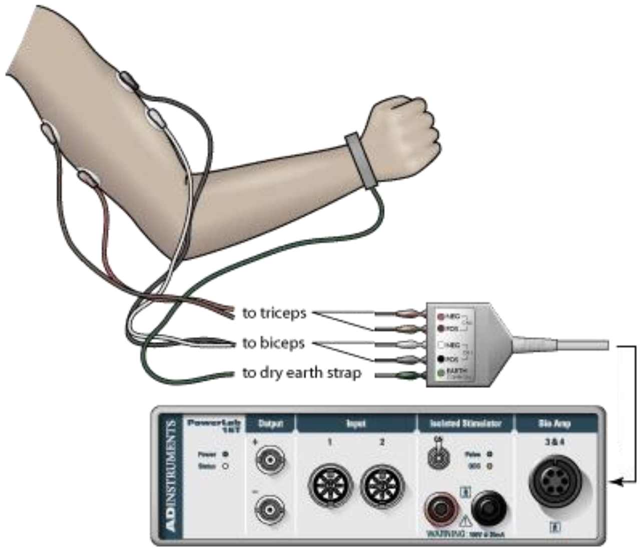

Figure 4.2 - Electromyography set-up. (Medcrome.com)

It has been defined that for issues involving control panel manipulations, left upper trapezius is the muscular region to analyse and for issues involving shoulder abduction, it should be the suprascapular fossa where EMG evaluation must be done.

Muscular activity data was collected using EMG in different scenarios, with the objective of comparing them and checking that present improvements are truly successful, as well as to test any potential prototype to confirm that the product can help to reduce the load and stress suffered by sonographers and avoid work related musculoskeletal disorders.

4.1.1 Muscle groups to analyse

From literature, it is known that the most affected anatomical areas, and therefore those on which the assessment should be focused are:

- Lower Back
- Shoulder
- Forearms
- Neck
- Biceps
- Wrists

4.2 PRE-DESIGN EXPERIMENT

A first experiment was performed in order to obtain confirmation of the ergonomic improvement when using adjustable devices as well as an arm/shoulder support prototype. The objective of this experiment is to confirm that these devices represent a better physical/postural situation during scans by measuring and comparing muscular activity between scenarios.

On this occasion, the experiment involved a single user performing scanning movements on two different scenarios. It consisted on a quick comparative check to verify the viability of the decision of including this kind of support on the system.

4.2.1 Scenario 1

The first scenario consisted of a non-ergonomic situation (standard scanning postures with non-optimised units), the objective was to get the most negative situation that a sonographer could face during scans. Currently hospitals are becoming more ergonomic (by replacing old devices by more flexible and adjustable units), but some departments still exist which seem to be unconcerned about these problems. Conditions of this scenario were:

- Non-adjustable ultrasound machine
- Non-adjustable couch
- Normal office chair
- No arm support

4.2.2 Scenario 2

The second scenario consisted of an up-to-date, improved work environment, where current ergonomic products that are already in the market will be introduced. The changes with respect to the previous scenario were:

- Adjustable ultrasound machine
- Ergonomic seat
- Adjustable Ultrasound couch
- First prototype of a spring-based arm support

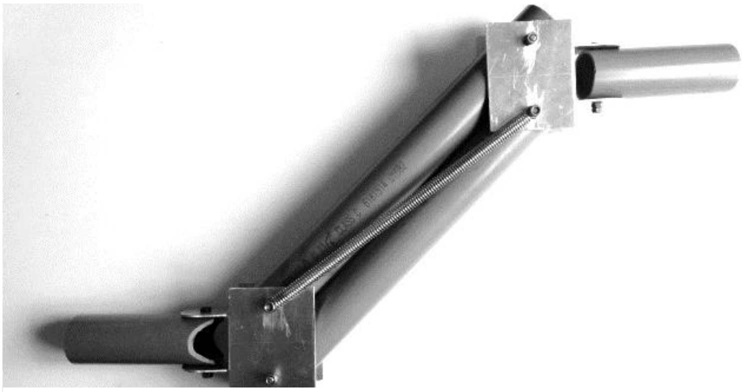

Figure 4.3 - Spring-based arm support prototype

4.2.3 Results

The results for the muscular areas measured (fig. 4.4) seem to represent an important improvement and muscular activity reduction between scenario 1 and 2 (fig. 4.5). The data obtained, which gives a value to this muscular activity depending on how big the effort to perform the movement is, was about 35% lower for upper trapezius and 82% lower for upper trapezius in scenario 2. Even though this first experiment was performed with a very rudimentary arm support, it seems clear that by being able to release some stress from shoulder muscles, tiredness of the sonographer will be reduced. This is taken as a validation as well as a starting point to find a potential device that could be used as a support during ultrasound scans.

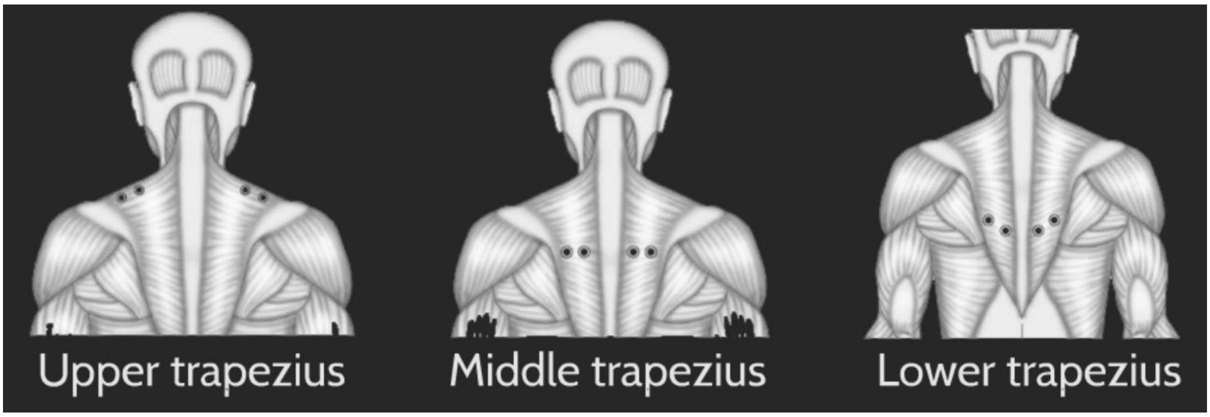

Figure 4.4 - Sensor placement

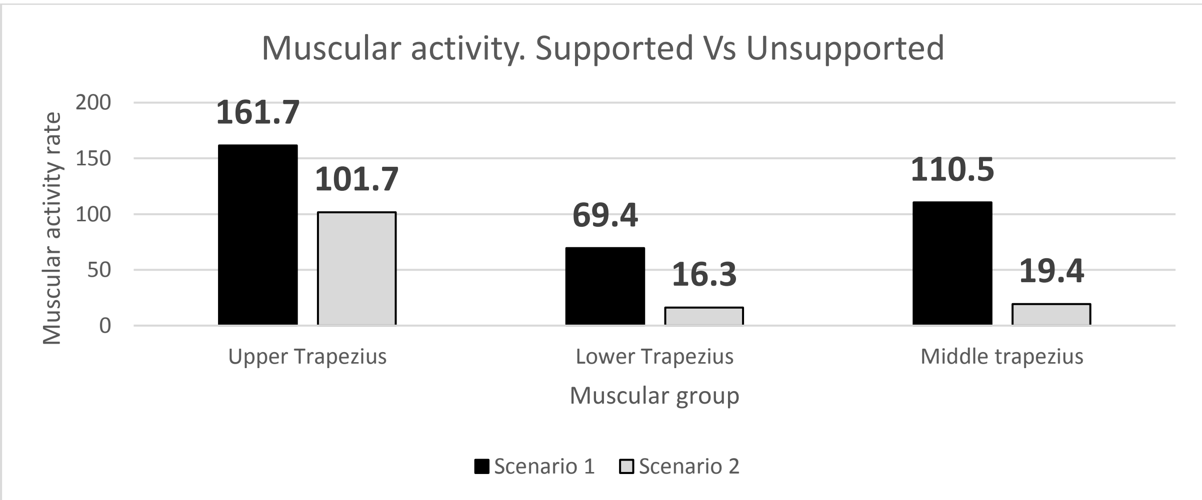

Figure 4.5 – Muscle activity results obtained for scenarios 1 and 2

4.3 POST-DESIGN EXPERIMENT

Once a prototype had been designed and produced the experiment was repeated and on this occasion, the new commercial product was added as a new scenario. The objective of this experiment was to confirm and ensure that the product is truly helping to reduce the load and tension experienced by a sonographer as well as improve their comfort during scans. In this case, the scenario lay-out (fig. 4.6) consisted of:

- Adjustable ultrasound machine
- Saddle Seat + Backrest
- Ergonomic Ultrasound Couch (Delta +)
- Commercial arm support model (X-Ar Arm described in previous sections)

Appendix 4 describes in more detail the procedure followed on the experiment. It basically consisted on three different users performing typical scanning movements on three different scenarios. The differences between scenarios were the number of ergonomic devices included on the system.

4.3.1 Results

In the same way as the previous experiment, there is a clear muscular activity reduction when comparing scenarios. Values differ not only because commercial prototypes (couch, arm support, etc.) were used, but also because participants involved were different and there are some small differences in the way they performed scanning movements. The important outcome is that the "ergonomic" scenario reduces the stress applied over involved muscles by a 40% (fig. 4.6) in the case of the upper trapezius and it has an impact on the lower (53%) and middle (56%) trapezius too. It is important not to compare these reductions between different muscles, since they have a different level of "participation" in the scanning movements. It is the data comparison between the three scenarios on the same muscle that gives a confirmation of the fact that the use of this device is helping the user to reduce the effort required during sustained shoulder abduction by supporting the arm weight.

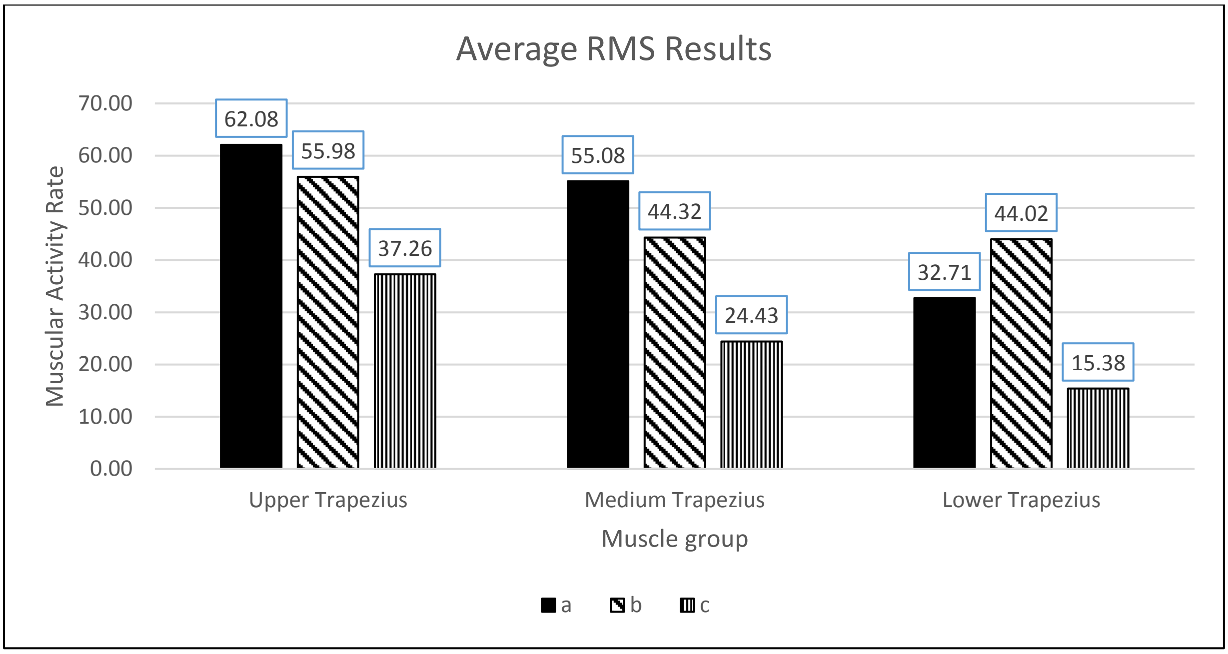

Figure 4.6 - Post-design experiment average results for scenarios A, B and C.

4.4 CLINICAL EVALUATION

In order to confirm not only that the system helps to physically reduce RSI risks, but that the product is commercially viable, it is required that the system is tested under real conditions in a clinical environment.

To achieve this, a clinical evaluation was agreed with the Sheffield Teaching Hospital with the objective of verifying that sonographers would feel comfortable with the new product. A questionnaire was produced which would be filled by professionals after scans.

However, before going into the hospital another evaluation was done by 15 Ultrasound students of the University of Cumbria which filled another questionnaire after using the system for a short period of time (5 – 10 minutes).

The results from this first evaluation (fig. 4.7) were very positive, obtaining a majority of favourable feedback from most students. However they suggested some modifications for future prototypes.

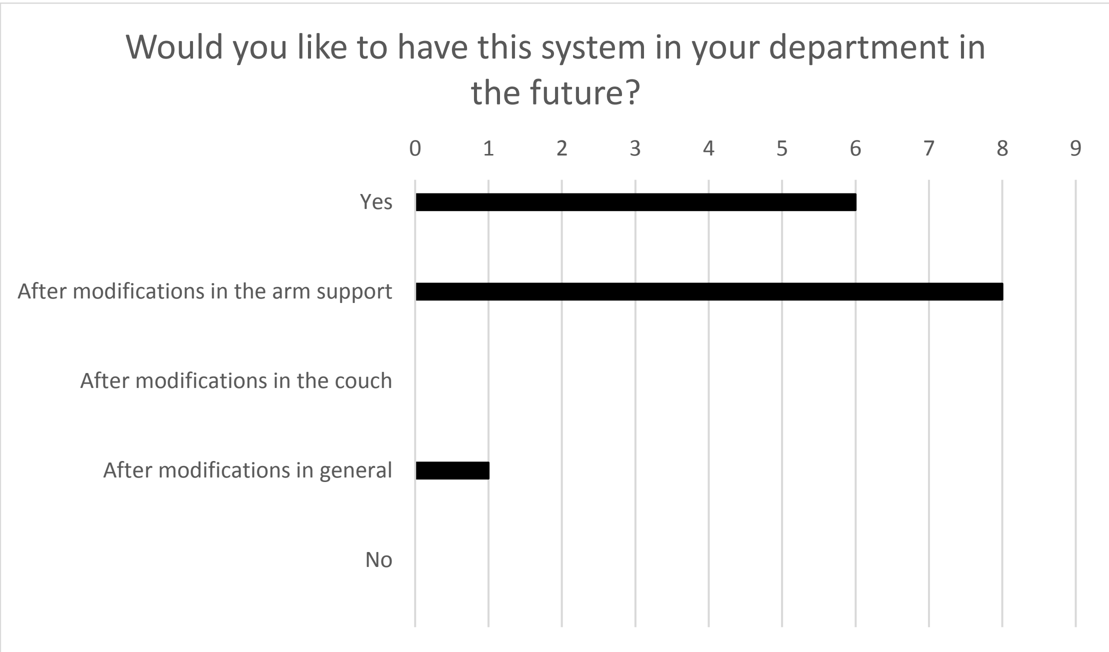

Figure 4.7 - Final conclusion question results after the clinical evaluation trial

Thanks to this first evaluation, it was possible to make some modifications to the ergonomic system by replacing the first arm support (X-Ar) with one more suitable for medical environments and easier to use (Edero Arm Support) as it has been explained in previous chapters.

Another advantage of this new support was that it had been already approved as a Medical Device in order to meet medical standards for CE Marking.

Once these last improvements were introduced, the whole system was installed in a real clinical environment in order to perform a 1-week evaluation with experimented professionals and with real patients (fig. 4.8). The same methodology was used, a similar survey was produced with some modifications specially introduced for the case, as in this occasion the users would not be under training, but performing rea ultrasound scans.

Figure 4.8 - View of the Edero Arm Support during the clinical evaluation (Neck scan)

Table 4.1 - Trial participants' distribution

	Female	Male
Gender	**3 people (60%)**	**2 people(40%)**
Age	**43.8 years (+/- 11)**	
Experience	**13.6 years (2-25 years)**	
Evaluation time (avg)	**7.5 Hours**	

As shown in table 4.1, there was a good distribution of the evaluation population, including a variety of professionals that would represent a typical ultrasound department, including both males and females of different ages and experiences. A good distribution of types of scans was considered too, to avoid huge differences between some scans and others. However, for further research it would be a good idea to evaluate each type of scans separately, including more professionals for each of them.

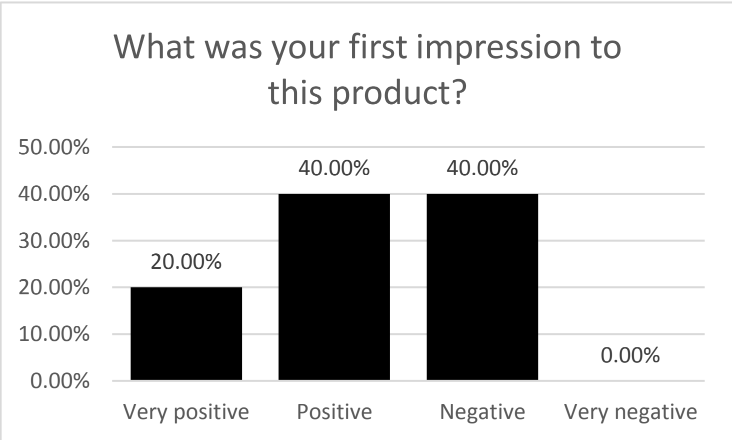

Figure 4.9 – User´s answers when asked about their first impression of the system.

Questions were orientated not only for usability or technical purposes, but for commercial reasons too. This is the case of the first of them (fig. 4.9), asking participants to qualify their first opinions on the product. As it can be seen, even thought there was a positive average, 20% of respondents had a negative first impression of the product, mainly motivated for the impact of design changes in all the devices includes, mostly focusing on the Arm Support due to it being "mechanical/robotic looking". However, it was a good impression to see that something new might be introduced in ultrasound, something that might help reduce some of the problems sonographers are worried about.

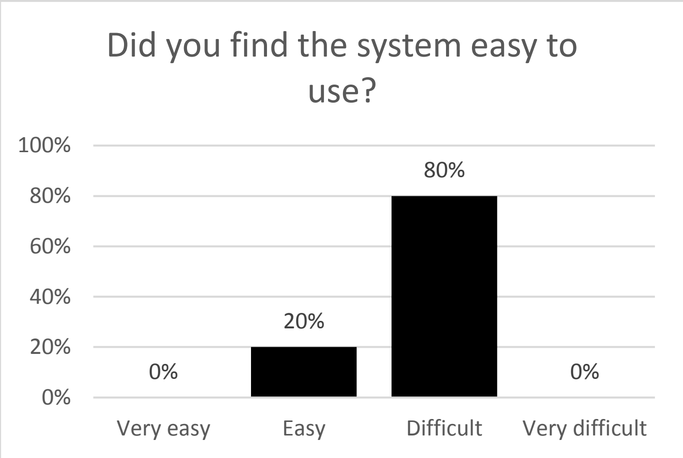

Figure 4.10 – Answers about the ease of use of the workstation.

Another important question was the ease of use of the system (figure 4.10). Most participants stated difficulties when using it. This is an important issue since it could keep professionals away from using these systems or even worse, they could use them incorrectly and aggravate the problem. After analysing these answers it looked like more training should be given prior to evaluations. Setting up the arm support can be very easy, but it can also be very difficult for the first time.

In fact, when the same users were asked about their potential to learn how to use it (fig. 4.11), the answers given were as pessimistic as before, and responses were given in the same direction. The majority of them seemed to believe that they could not get used to the hardware.

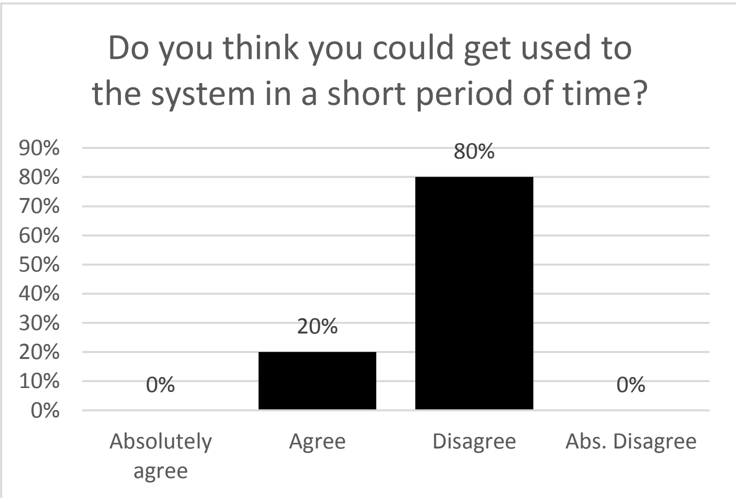

Figure 4.11 – Participants where concerned about not getting used to the arm support operation.

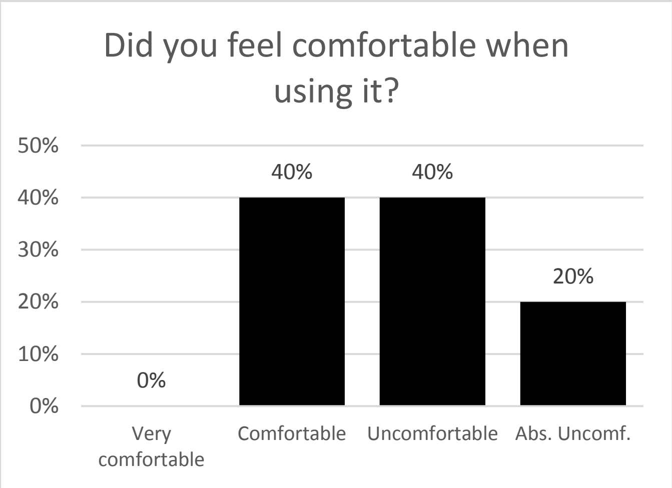

Figure 4.12 – The rate of uncomfortability was high according to the answers given.

In terms of comfort, none of the evaluators felt very comfortable (fig. 4.12), which is understandable due to the differences between their normal working procedure and the new adaptations that they need to take when using the arm support. This can be linked to the lack of training for this support, as in previous experiments where good explanations about the set-up were given, comfortability increased in the very first minutes of use.

There is no a clear perception that the arm support will reduce shoulder tiredness (fig. 4.13), even that the product has been proven to solve many issues involving shoulder muscles (Mastenbroek, 2007). What seems clear is that a poor adjustment of the support can be frustrating when the spring mechanism is too strong or too weak, since this is only increasing the extra effort required by the sonographer to move the arm.

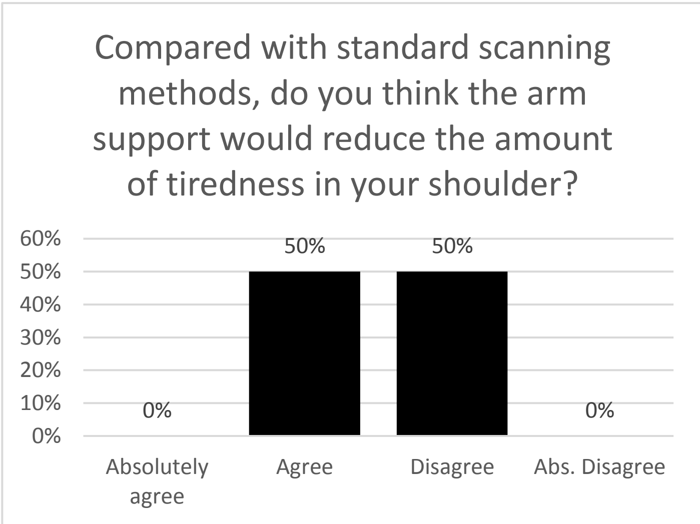

Figure 4.13 – Half of participants said that the arm support could reduce tiredness.

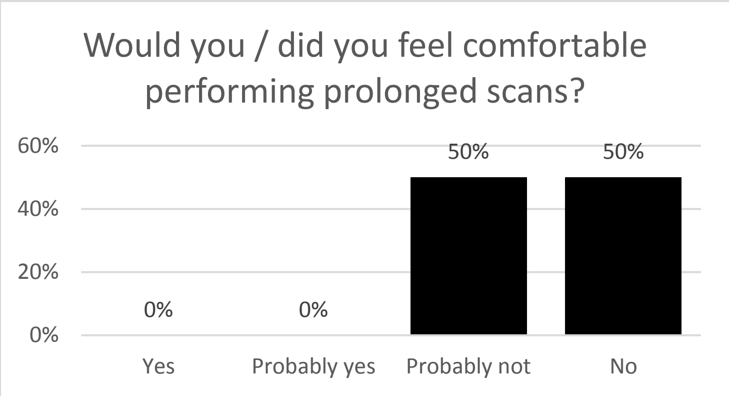

Figure 4.14 – Most users would not be comfortable using the system for prolongued scans.

A pretty clear outcome of this evaluation regarding the Arm Support of the system, is that generally it does not fit comfortably, which is an important aspect to take into account given that none of the users thought that they would feel comfortable when performing prolonged scans (fig. 4.14). It is known that the support works and it's a good implementation for ultrasound departments, but if professionals don't like it, they will not use it. Or at least they won't use it properly.

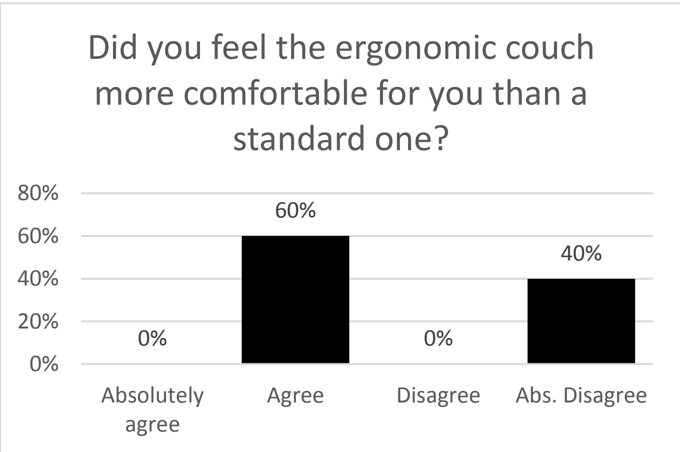

Figure 4.15 – A majority of particpants liked the comfortability of the scanning couch.

When asked about the couch (fig. 4.15), users had some more disagreement. Most users found the new design more comfortable, but some of them were concerned about some details of the product. This was enough to dislike it and stick to the standard model.

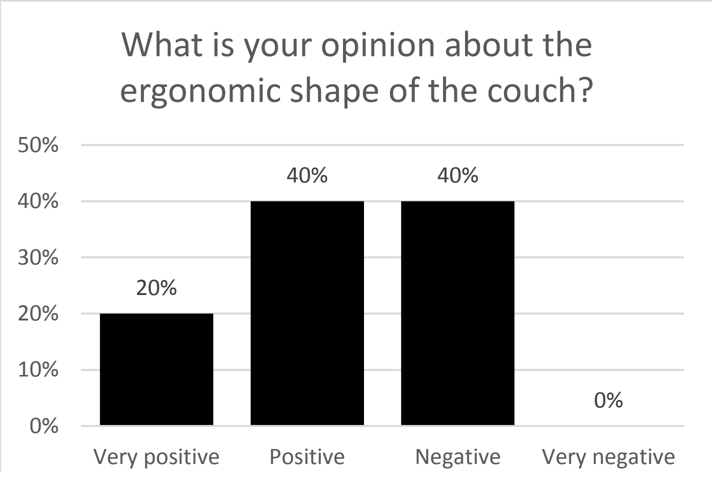

Figure 4.16 – Different opinions about the innovative shape of the scanning couch.

There was a good acceptance of the ergonomic shape of the scanning table (fig. 4.16). It is very well known the problems sonographers have trying to reach some points of the patient as well as accommodating them as close as possible to their hips, this might be the reason why they saw this design as a very good improvement to the couch. Finally an ultrasound couch was different than other couches used for very different purposes, and they had a specialist product for their tasks.

However, one of the main concerns of the manufacturer was about the new width of the couch, since it could be too narrow and create some troubles for bigger patients, who might feel instability or falling risk at some point.

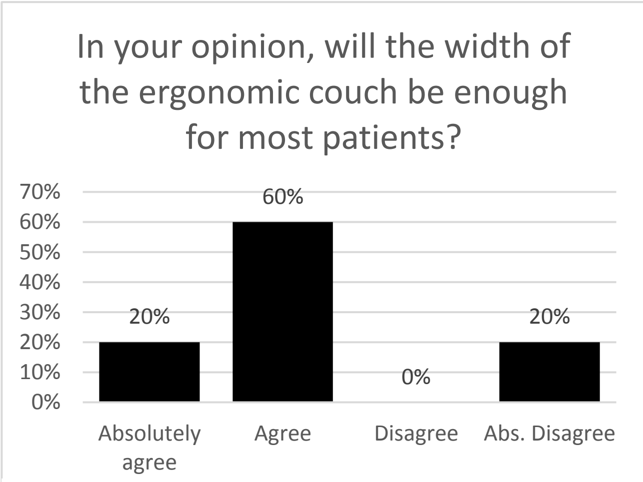

Figure 4.17 – The optimised width seemed appropiate according to the answers.

Nevertheless, professionals confirmed that the width would be appropriate in most cases (fig. 4.17), and for special patients they could always use a different model focused on this special purpose. However, the design of the mechanisms allows an easy replacement of the cushioned area of the couch. Departments would only need to ask for a slightly wider couch and it would be easily manufactured and fitted with the required size. Offering different sizes or a manually interchangeable padding would allow to fit most patients and would increase the versatility of the couch design.

Figure 4.18 - Clinical Evaluation during a neck scan

From this manufacturer's concern about the width, came the idea of installing two lateral pads on the couch, in order to make some patients feel safe and to add an extra cushioning area. These pads were easily removable in case the sonographer needed to scan from the opposite side of the couch. Some evaluators disliked this (fig. 4.19), but it is fair to say that the reasons they gave are of little importance. Obviously these

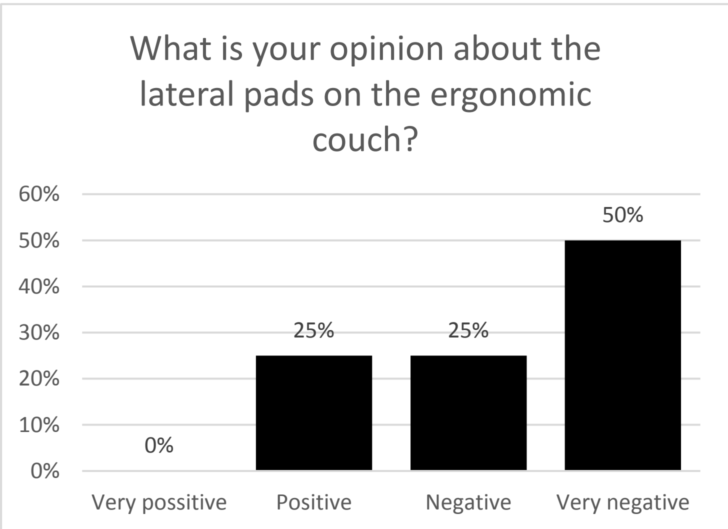

Figure 4.19 – Users had some concerns about the lateral pads.

pads should be removed for some types of scans where the operator must move around the patient as well as he/she would need to access the couch from the "shaped" side. In any case, this is a useful feature, but this will require further design work in order to make it easier to use/hide.

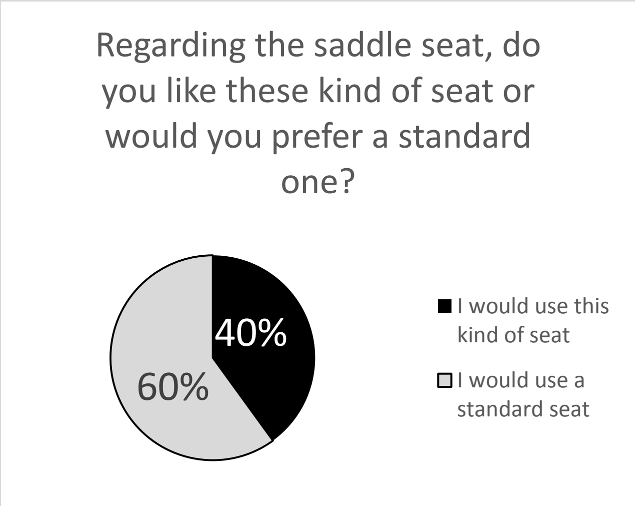

Figure 4.20 – The saddle seat could not be liked by some potential users.

The other big part of the system, the "Saddle-Seat" brought some discrepancies too. It seems this is a very personal choice and some users prefer to stick to the standard one while others prefer to use the Saddle-Seat (fig. 4.20). Literature has demonstrated the benefits of this style of seats, mainly by facilitating the natural "S" shape of the dorsal spine (Gandavadi, 2007), but it seems the product does not look familiar enough for some users. It will be always good to have the option though, leaving them the decision about what design they prefer to use.

A final question was asked in order to evaluate the conclusion of the professionals participating in the trial process. The objective was to see if they would like to have one of these systems in their working place. Answers were very positive and only about a 20% gave a negative response (fig. 4.21). The remaining 80% were clearly in favour of the new workstation, some of them conditioning their opinion to the introduction of changes in the couch (20%), probably focused on the lateral pads as explained earlier in this chapter. Another 20% would just use it as it is. These were probably the ones who received initial training when the system was installed on the department, as they were told how to adjust the different elements properly. Finally, the remaining 40% would be happy to work with the system but just after some modifications in the arm support, which seems to be the critical feature of the product not only for being the main obstacle for new users, but a very important improvement for reducing RSI risks too.

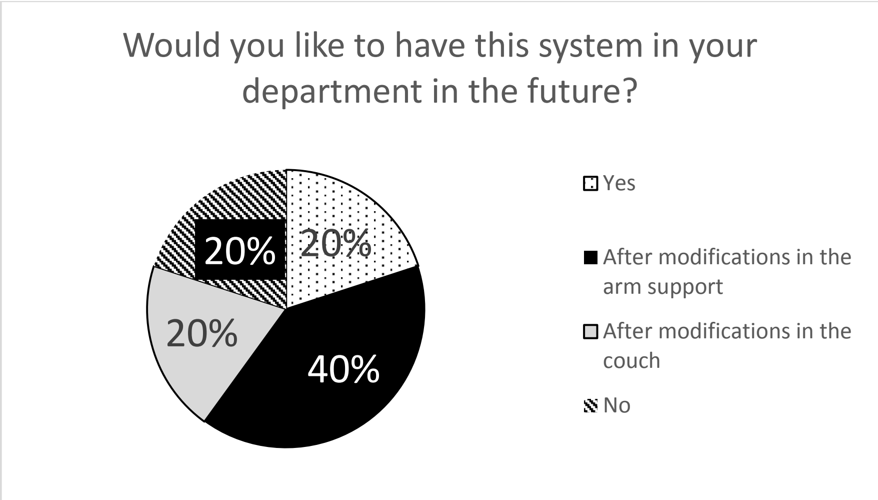

Figure 4.21 – Most participants would like to have the system in the future after some modifications on its design.

Open questions were included on the survey too, which may help understand some of the answers obtained and presented above. Again, the importance of involving final users (sonographers) on the new product design process is clear, as they will always add a valuable feedback to the research, and sometimes solving an important issue is much easier when they take part on the decisions. These open answers must be taken into account when introducing new modifications on the product in order to improve it.

Shoulder Support Open Feedback:

-Could the support be more like a glove or sleeve, with the removal of the metal bracket that catches the patient's abdomen during pregnancy scans? The arm support needs some work on the Intechon (?) and the Velcro in the way.

-Too much pressure on the arm pulling it down. Did not support my arm. Made arm pit ache plus arm muscles burn (?).

-Uncomfortable at back of upper right arm. Difficult to strap on. Patient moved leg and knocked it on support.

Ergonomic Couch Open Feedback:

-Good Idea, needs better idea of allowing patient to get on and off from the opposite side to where sonographer sits.

-Too narrow for pregnant patients as we also have to scan them on sides

-No stirrups so unable to perform TUS examinations. Didn't use lateral pads as this restricted the patient getting on the couch.

-I found the couch uncomfortable when using a standard chair because the patient was too far from me. The chair would not go closer due to the base of the chair and the wheels of the couch crashing.

-The lateral pads get in the way where the patient get into the scan. I tried removing the lower one but the support still gets into the way. If the patient gets on from the other side: 1) I have to move my scanning chair out of the way. 2) There is a risk they will use the scan machine as a support and press the keyboard by accident. I don't think the lateral pads add much to the patient's comfort during the scan. The controls for elevating bed etc. are not clearly labelled.

5 CONCLUSIONS

Developing new products can be an incremental process. Analysing market needs, specifications and potential customers will always increase chances of success, however there is an important trial-error factor in the final outcome.

It is important to always try to control as much as can be controlled, leaving the less amount of randomness as possible. In order to know where the process is and which decisions have to be taken, communication with customers is vital since these focus groups will give a very valuable feedback to the people involved in the project.

As well as from customers, this feedback must be obtained through other means such as suppliers and manufacturers.

In this specific case, collaboration between a knowledge organisation (The University of Sheffield) and an experienced company (Knight Imaging) has delivered a good outcome.

Despite a final product not been launched into the market, the base of a good and commercially viable product has been settled with a positive feedback from customers, who were always involved in the development and posteriorly in the evaluations.

Of course, there were some concerns about several aspects of the design and usability of the product, but none of them seem unachievable after a few design iterations. It is known that there is huge room for this kind of product in the ultrasound industry as more and more professionals are claiming for it, so further work over it would be very profitable in the short term.

On the bad side of the case, some lack of preparation for the clinical evaluation can be observed as some of the participants were not properly trained on the use of the system described, causing some problems when adjustments weren´t correctly made thus some negative opinions were obtained during the questionnaire stage.

Previous evaluations and experiments were very positive and with a very good feedback, but the difference was that a person involved with the project had been present during the whole evaluation with the participants, assisting them and explaining how to use it. It was common that at the beginning, users did not like the arm support, but after a few adjustments of the device, all of them started to think that it was a great help when scanning. This is the reason why further evaluation should be carried out; because there is clear evidence that users can feel much better once they know how to manipulate the product.

There is a huge expectation between professionals involved in the project, who have participated at some point on it, to know what the final outcome is and have the opportunity to introduce this new scanning method in their departments. This could massively reduce the incidence of work-related musculoskeletal disorders amongst them and in consequence, medical organisations will see how the financial costs of these injuries are drastically reduced.

As previously explained, it is very important to keep pushing on this research/development, in order to take advantage of the opportunity given by this expectation and the inertia generated by this research.

6 FUTURE WORK

By the end of this project, a fully completed product has not been launched into the market since more work seems to be required on this field in order to fill the gaps that have appeared during the research. Even though the outcomes from different trials and evaluations seem very promising, there is a need for a final design iteration which could be implemented by a new clinical evaluation which this time should serve as a real and commercial launch for the new product (or group of products).

As some of the devices involved on the workstation design are provided by different manufacturers (i.e. arm support), it is important to obtain a full description of what is included as well as to stablish the different configurations offered in terms of sizing, materials, additional devices etc. Some medical departments will require an arm support, others will just get the scanning couch and others could ask for a fully ergonomic ultrasound system. It is important then to establish what the company wants to sell and under which conditions.

In the particular case of the scanning couch, which is the part of the system that presumably will be manufactured by the company, it will require a final technical file, which will not only fix the different characteristics of the manufactured parts but also will include details of commercial and standard components (materials, sizes, standards, etc.). A supply agreement should be considered too in order to stablish a purchasing method including order quantities, spare parts inventory etc.

A similar agreement needs to be obtained with the suppliers for the devices of the system as they are more complicated components than simple bearings or foam. In this case warranty and service must be discussed too, to ensure that the customer will be able to obtain any kind of required maintenance or reparation.

Especially critical will be the technical service of the arm support, as this is a key part for the reduction of injuries and any failure on this device could cause even more trouble than if it was not used. Training about how to set-up the weight adjustment as well as how to put the bracelets must be given to any potential user of the system since knowing these procedures is vital for risk reduction. This necessity was identified during different evaluations, as users felt the arm support was uncomfortable at the beginning of the trials until they were instructed about how to accommodate their arm weight to the device by using the adjustment feature.

Regarding the size of the couch, it is a fact that some users could find it a bit too narrow, and that is why an option of choosing different sizes should be given to the customer. Some departments will need a wider couch, whilst others probably could find the standard width enough for their ultrasound room, taking into account that the narrower the couch is, the closer the sonographer is to the patient, decreasing this way the stress supported by the muscles involved on scanning tasks.

As the couch design is owned by the distributor company, it is easy to set some margin parameters since it will not be manufactured under a "push" system, but under "pull" system. This allows the manufacturer to modify some dimensions on the couch without adding any considerable increase to the costs.

This project has given the outcome of a new product for which the current demand is constantly increasing due to the growing incidence of these kind of injuries. The rest of the product lifecycle must be completed with some final engineering work as well as a good marketing strategy which should start with larger and deeper clinical evaluations along other hospitals. This will undoubtedly provide a final conclusion about how the current design of the product can be improved in order to represent a commercial solution to many professionals.

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8 APPENDICES

Appendix 1: BMUS Abstract

- Abstract submitted to the British Medical Ultrasound Society conference in 2014, presented in December 2014 at Emirates Old Trafford and published on the conference proceedings.

IMPROVING THE KNOWLEDGE OF WORK-RELATED MSDS AMONGST SONOGRAPHERS THROUGH ANALYSIS OF SOME POSSIBLE SOLUTIONS

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ABSTRACT

In recent years, there have been a number of studies into the causes[1], effects[2] and impacts[3] of work-related musculoskeletal disorders (MSDs) amongst sonographers. These studies have shown an increase in the number of cases[4] as well as the financial impact that these injuries are causing to organisations such as the NHS and the effects on the individuals[5]. Our study seeks to improve understanding of the effects related to both the workplace design and sonographer posture and assess potential solutions using a design engineering approach.

A range of ergonomically-focused sonography products already exist, but they are widely dispersed in the market and difficult to be implement in sonography workplaces and configurations. A combined design solution to implement ergonomic improvements is the ultimate goal of our work.

The first stage of the study uses observations of, and interviews with sonography professionals in order to obtain first-hand feedback about work-related injuries. On-site observations were carried out at the Lozano Blesa Hospital, Zaragoza, Spain.

An experiment has been designed, based on the observation and interview findings, which uses Surface Electromyography (EMG) to measure muscle activity in different ergonomic scenarios. The analysed EMG data will help to establish the optimal postures for a range of sonography procedures and also be used to select the best potential solutions to the problem of MSDs amongst sonographers.

The last stage will involve a second EMG-based experiment to assess the efficacy of commercially available ergonomic products to measure their potential impact.

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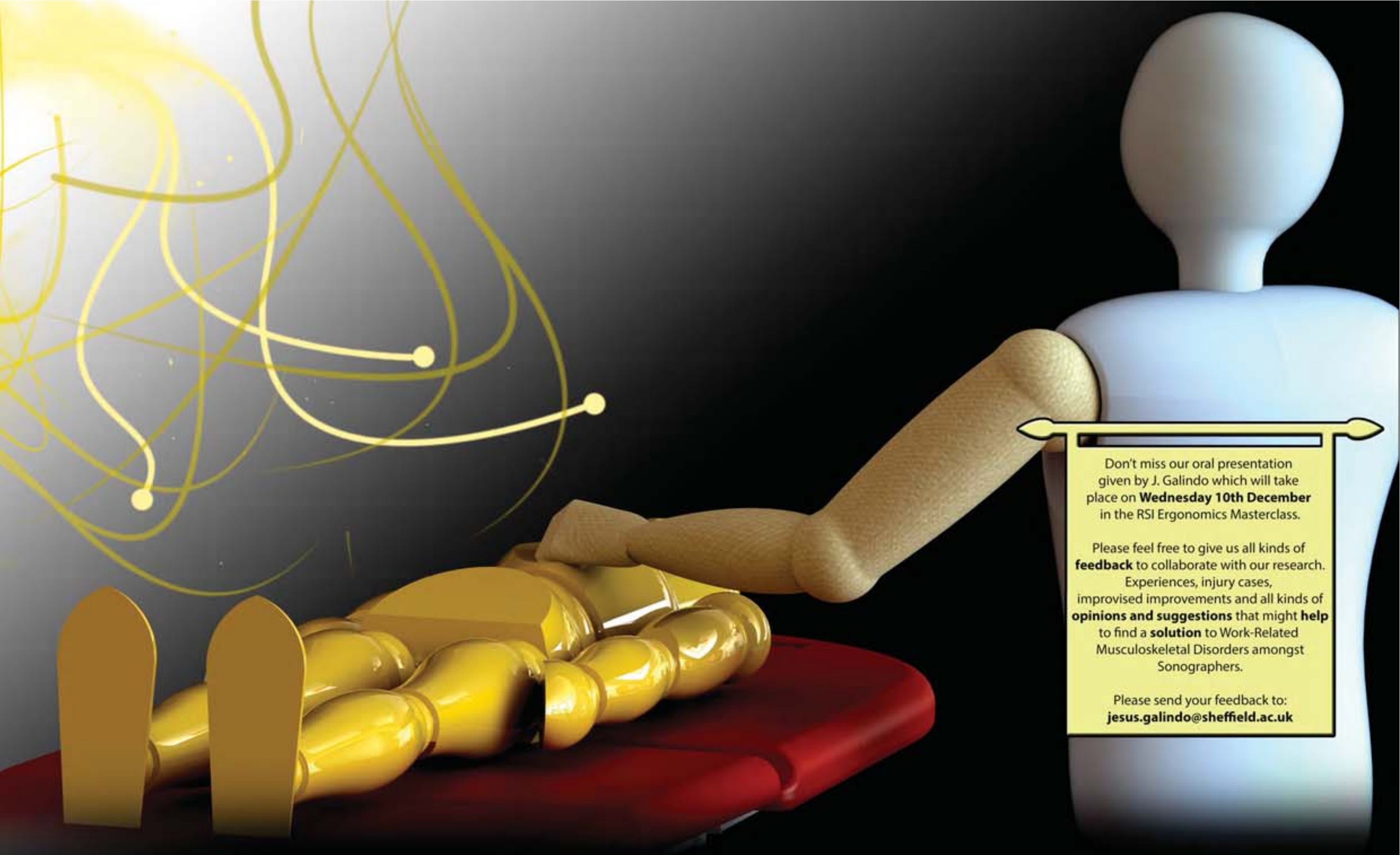
Appendix 2: BMUS Poster

- Poster presented during the BMUS Conference in December 2014. A presentation was given to explain ultrasound professionals the advances on the research of work-related musculoskeletal disorders amongst sonographers.



Don't miss our oral presentation given by J. Galindo which will take place on **Wednesday 10th December** in the RSI Ergonomics Masterclass.

Please feel free to give us all kinds of **feedback** to collaborate with our research. Experiences, injury cases, improvised improvements and all kinds of **opinions and suggestions** that might **help** to find a **solution** to Work-Related Musculoskeletal Disorders amongst Sonographers.

Please send your feedback to:
jesus.galindo@sheffield.ac.uk

Improving the Knowledge of Work-Related MSDs Amongst Sonographers Through Analysis of Some Possible Solutions

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Causes

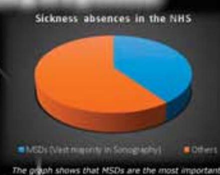
Many industries have been researching the way of improving and optimising their productive processes, with the objective of making work tasks simpler and more comfortable for operators and in most cases, these improvements have become a true success for both companies and work force. However, ultrasound scans still have an important lack of ergonomic improvement given the high prevalence of Work-Related Musculoskeletal Disorders (WRMSDs) amongst sonographers. People involved in ultrasound tasks are especially vulnerable to suffer from these kinds of injurie due to sustained motion as well as other duties such as lifting and positioning of patients.

Example of ergonomics applied in other activities. https://www.goddardtech.com

NIOSH Ergonomic adivce for construction workers guidance

Effects

The impact of WRMSDs can be analysed from different points of view. The professional who suffers the injury has to spend time scanning in pain which will probably lead to a more severe injury and finally to a premature retirement with not only an important financial cost but with a possible impact on their personal daily life too. For companies and organisations, the effect is primarly economic due to the huge costs that an injured operator involves. Days leave, sick payment and sometimes injury claims add to the extra costs of employing a replacement sonographer. This could have an impact on healthcare users as well, since it might require rearrangement of personnel schedules and this would have repercussions on the quality of the service.



The graph shows that MSDs are the most important reason of absences in the NHS [5] R. Quartly, "Impacts of Work-Related Musculoskeletal Disorders amongst Sonographers."

Ergonomic relationship

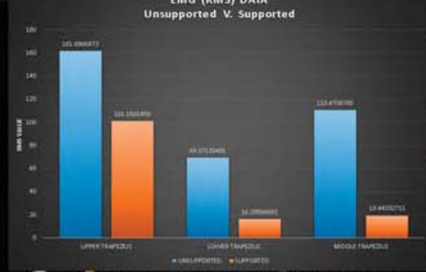
Modern ultrasound machines are, despite some improvements regarding adjustability, very similar to older models, forcing sonographers to adopt a completely non-ergonomic posture. All other industries have been investing efforts in the research of methods to keep worker's posture as close to the neutral position as possible. However this is not happening with manufacturers involved in ultrasound equipment and medical devices. It is important to think of a re-design of ultrasound workplaces as well as in new devices to assist sonographers with their efforts to reduce MSDs risks. Collaboration between manufacturers and healthcare organisations is very important to achieve this objective.

An example showing the lack of ergonomics existing in sonography tasks. Hospital Lozano Blesa (Zaragoza, Spain).

One of the different existing models of Electromyography kits. Cometa Systems Https://www.cometaystems.com

Evaluation

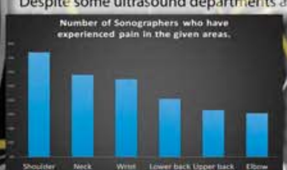
There has been some academic research to quantify the importance of RSI risks in sonography. Their main goal is normally to identify which are the most serious factors in the procedures involved in scaning routines and to find those ultrasound specialities suffering the biggest quantity of injuries as well as if there are any other aggravating factors such as patients weight. The vast majority of these data has been obtained through the use of Electromyography systems. It is a tool specially used in ergonomic analysis and could help to study and test those products that manufacturers could be developing in the future by comparing muscular activity levels with and without the assistance of those potential new devices.



Experimental test performed during this project showing the effectiveness of using a support to reduce the muscular activity of the shoulder

Areas to Improve

Despite some ultrasound departments are including health and safety guidance to reduce the risk of work-related injuries as well as using administrative actions to improve work schedules and trying to increase the number of breaks between scans, the most important risk factors might be related to a lack of ergonomic adjustments. Shoulder abduction and wrist position have been demonstrated to be involved in most of the injuries reported, and this is due to the design of the workplace which is at the same time, forced by the design of ultrasound equipment.



[5] R. Quartly, "Impacts of Work-Related Musculoskeletal Disorders amongst Sonographers."

Future Work

The final aim of this study is to find how RSI risks can be reduced through the intervention of engineering actions. The design and development of a product prototype that would reduce an important part of these risks is the objective. Solving the entire problem is not easy without the collaboration of the whole industry, but by eliminating part of the factors we will be improving the quality of sonographer's work.

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The University Of Sheffield. Knight Imaging LabLogic

Appendix 3: Information sheet

- Example of the information sheet given to the voluntaries participating on the EMG experiment to assess the reduction of RSI risks in the shoulder muscles by using an articulated arm/shoulder support.

Information Sheet

Research Project: **KTP 9337 – EMG Evaluation of Improved Ultrasound Workspace**

- You are being invited to take part in a research project.
- Please take time to read the following information carefully.
- Ask us if there is anything that is not clear or if you would like more information.

Project purpose

Evaluation by Surface Electromyography of the muscular activity when performing ultrasound scans in standard versus improved workstations.

Why have I been chosen?

You have been chosen because you make up part of a key group of participants who we wish to study.

Do I have to take part?

Taking part in the research is entirely voluntary and **you may stop participating at any time.**

What will happen to me if I take part?

You will also be asked some further questions for the purpose of gathering information. These questions will include your age, and gender, and will be used in the analysis of the study. You will be made anonymous for the study purposes, and will not be identifiable post testing. A contact email address will be taken, in-case any issues arise. This will not be kept with any of the other information.
Photographs may be taken for the purpose of explanation in the final report, and to allow for greater comparison between the data; you may request not to be photographed at any time. Any photographs that are taken won't have the subject identifiable.
You will then be asked to move your arm over a series of points in a specific sequence for a number of times during a period of 5 – 10 minutes in total in order to record data from 6 sEMG (Surface electromyography, a method to measure muscular activity from the surface of the skin) sensors that will be placed (adhesively) on your trapezius muscles (back area). These sensors can't do any harm at all and doesn't release any kind of electric signal (they are only receptors). The whole study should take no more than 30 minutes with preparation etc.

If you feel at all uncomfortable at any point, please stop and let the researcher know. **You can stop at any time.**

Will my taking part in this project be kept confidential?

All the information that we collect about you during the course of the research will be kept strictly confidential. You will not be identified in any reports or publications.

Who has ethically reviewed the project?

This project has been reviewed by the Ethics Committee of the Department of Mechanical Engineering, University of Sheffield.

Will I be recorded, and how will the recorded media be used?

'The audio and/or video recordings of your activities made during this research will be used only for analysis and for illustration in conference presentations and lectures. No other use will be made of them without your written permission, and no one outside the project will be allowed access to the original recordings.'

Contact for further information

If you have any concerns, before or after taking part in this study please contact the following:

Dr Matt Carré

Email: M.J.Carre@sheffield.ac.uk

Or

Mr Jesús Galindo

Email: jesus.galindo@sheffield.ac.uk

Thank you

Appendix 4: Experiment report

- Report giving the results of the EMG experiment as well as explaining the method followed during these procedures.

Experiment report

Description

The experiment has de objective of demonstrate the reduction on muscular activity in the upper body while performing ultrasound scans with an optimised ergonomic workstation.

The data will be obtained with surface electromyography receptors and will later be processed following the instructions given by Eleanor Criswell on the book "Cram's Introduction to Surface Electromyography" for the RMS Method.

The RMS method consists on a mathematic formula to transform raw data into a measurable figure that can later be compared against the one obtained in different scenarios.

Knowing that sEMG data has both positive and negative signals, the steps for the RMS method are (summarising) first to square all the values (to eliminate negative values), then to calculate an average of the squares and finally to obtain the square root of that average.

The number obtained will be compared in graphs with the rest of scenarios.

Sensors will be placed in three different points of the trapezius:

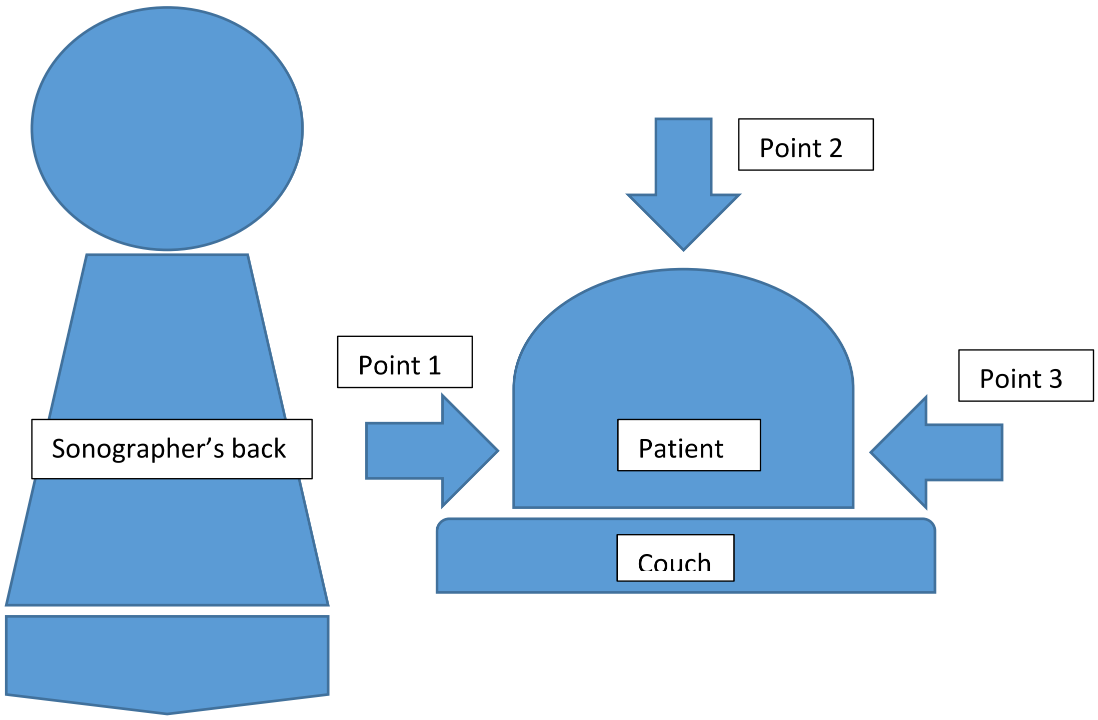
- Upper Trapezius
- Middle Trapezius
- Lower Trapezius

All the instructions about how to proceed with the placement as well as the reasons why these are the muscles involved with shoulder lateral abduction are explained in the book mentioned before.

Procedures

The procedure will consist on the repetition of movements typically involved in abdominal scans during 5 minutes and keeping each position for 5 seconds.

The sequence of movements will be Point 1 → Point 2 → Point 3 → Point 1 → Point 2…

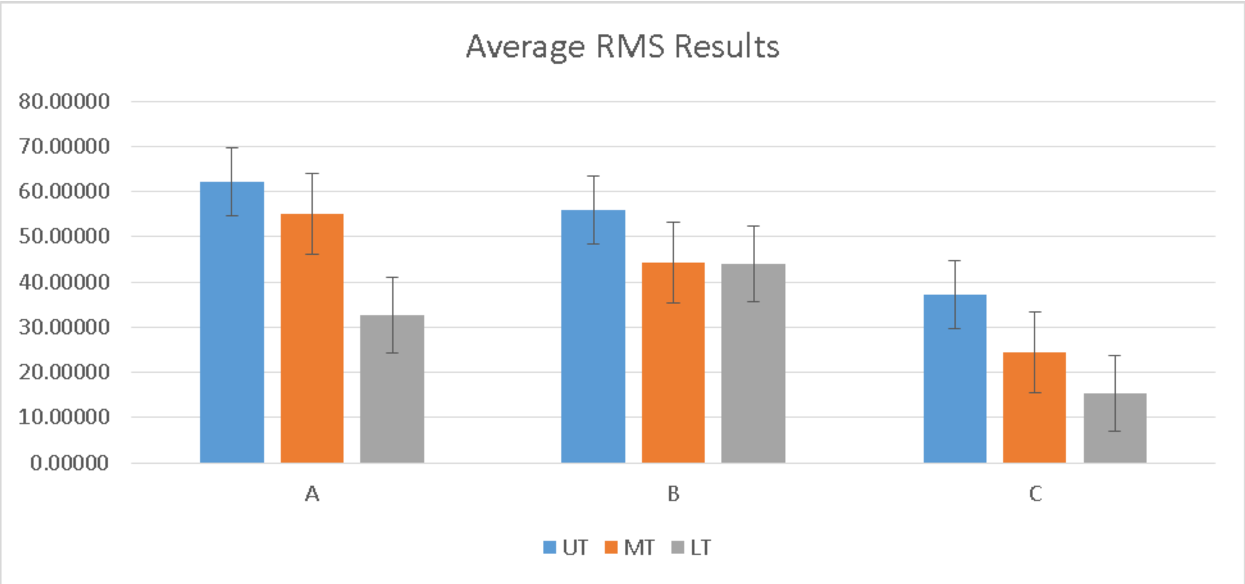


Scenarios

The characteristics of each scenario are described on the following table:

Scenario	Ergonomic Couch	Ergonomic Chair	X-Ar
A	NO	NO	NO
B	YES	YES	NO
C	YES	YES	YES

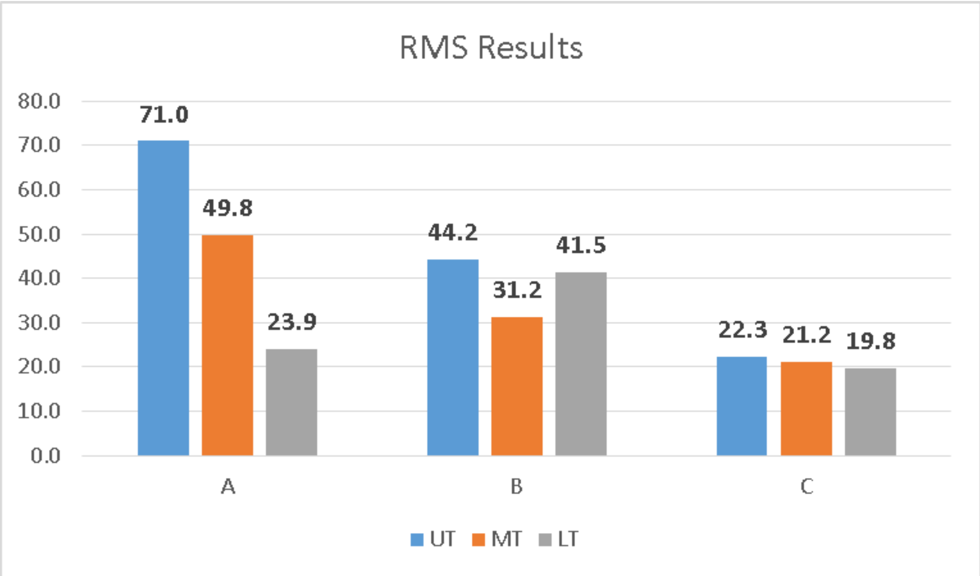
Average results



Experiment 1

Date	20/07/2015
Gender	Female
Age	20
Height	1.68
Weight	53
Hand	Right-handed
Scenarios	1,2 and 3

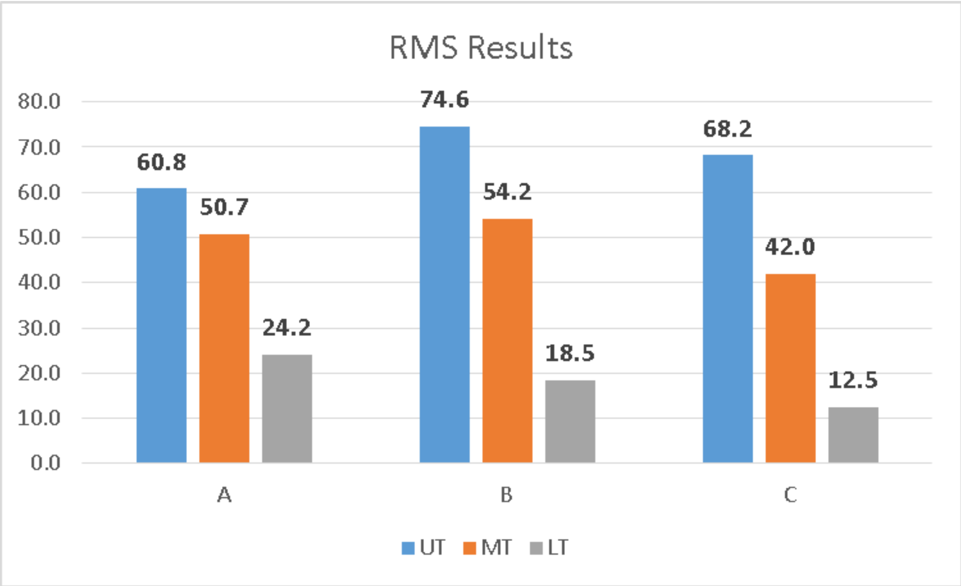
Scenario	UT	MT	LT
A	70.98261	49.82372	23.93523
B	44.2453	31.19363	41.45299
C	22.2627	21.16032	19.79991



Experiment 2

Date	*04/08/2015*
Gender	Male
Age	25
Height	1.80
Weight	77
Hand	Right-handed
Scenarios	1,2 and 3

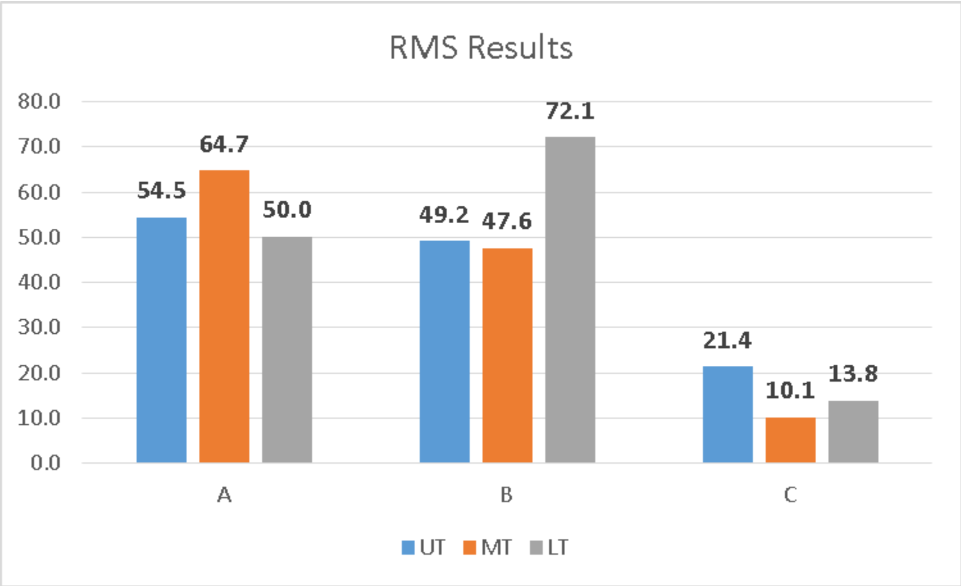
Scenario	UT	MT	LT
A	60.7983	50.70863	24.16085
B	74.5560	54.23864	18.48521
C	68.1642	42.00156	12.53361



Experiment 3

Date	*04/08/2015*
Gender	Male
Age	29
Height	1.77
Weight	78
Hand	Right-handed
Scenarios	1,2 and 3

Scenario	UT	MT	LT
A	54.4578	64.71587	50.04197
B	49.1539	47.55650	72.12496
C	21.36342	10.13469	13.81219



Appendix 5: D4H Paper

- Paper submitted to the Design4Health conference and presented at Sheffield in July 2015 in front of professionals involved with Ultrasound and other activities in the medical sector. The paper was published on the conference proceedings.

DESIGN4 HEALTH
2015 European Conference

User-Informed re-design of a sonography system to reduce Work-Related Musculoskeletal Disorders

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[3]LabLogic Systems Ltd., Sheffield, UK

Abstract

The Prevalence of Work-Related Musculoskeletal Disorders is still increasing amongst professionals in ultrasound imaging departments. The significance of these injuries in the healthcare sector arises from multiple consequences: that they have a high financial impact causing huge costs to the NHS and other organisations, but also on the careers of professionals and their wellbeing. The objective of the work described here is to find possible solutions to this growing problem in order to advance the design of an ergonomic work environment for sonographers. This work is being done in collaboration with healthcare professionals as well as being supported by manufacturing companies, distributors and academia. The final deliverable is to have a mechanical prototype tested and ready to be used by a sonographers' focus group in order to get feedback from end users that would help to improve the design and following appropriate modifications, proceed with a final design to be developed and then evaluated under clinical conditions.

Keywords: Medical device design; Work-related Musculoskeletal Disorders; WRMSD; RSI; Sonography; Ultrasound; Shoulder Support; EMG; Electromyography

DESIGN4 HEALTH
2015 European Conference

Introduction

Following a period of study of the importance of work-related musculoskeletal disorders amongst sonographers, comparing the collation of industry wide surveys (Quartly 2013), numerous on-site observations and meetings with professionals, the causes, effects and impacts of work-related musculoskeletal disorders in sonography (Burnett & Campbell-Kyureghyan 2010; Bastian et al, 2009; Murphy & Russo 2000) have been identified in this work. The information gathered to date has led to further research into possible solutions and the feasibility of proposed design ideas and products to reduce these negative effects. The gathered data suggests that the shoulder is the part of the body that is most prone to injury amongst practising sonographers (Figure 1). Therefore, it is decided to focus on shoulder and the support option.

The assessment and reports provided by the focus group have established a list of key areas for design focus. During this period different design aspects such as anthropometrics, comfort, materials, manufacturing practicalities and economic costs were taken into account. Special attention was paid to the issue of infection control, highlighted as an ever increasingly important consideration for medical departments.

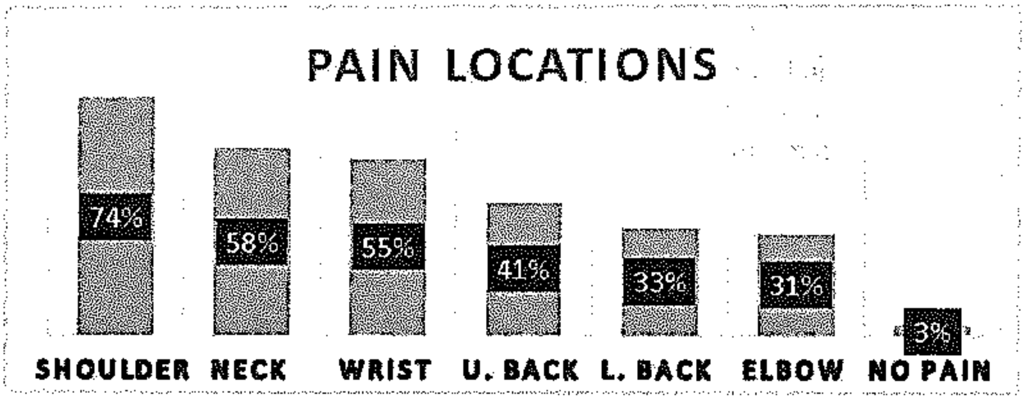

Figure 1. Results from prototype EMG experiment

This work on the shoulder support forms a part of a wider project aiming to significantly reduce the incidence of work-related musculoskeletal disorders in sonography which is focused on the design of a totally user-friendly and adjustable ergonomic environment to be installed in ultrasound workplaces.

Feasibility Study

> "Despite the introduction of several preventative methods, sonographers are still reducing their working hours or retiring early because of work-related injuries" (Quartly, 2013)

Was the conclusion reached by a recent study by the University of Sheffield, stated after analysing the results of a survey responded to by 128 UK-based sonographers (39% resp. rate), as well as

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outlining the causes and impacts of the problem. The survey demonstrated that a large number of sonographers (97% of respondents) had suffered pain due to scanning procedures. 73% suffered a work-related injury but only 15% of them believed that their workplace did not reach the minimum industry standards for the prevention of these injuries. These all point to the notion that Work-Related Musculoskeletal Disorders (WRMSDs) are a common part of a sonographer's professional career.

Other information obtained from this survey was that most of them consider awkward postures and sustained muscular contraction as the most important causes of injuries, which are concentrated in shoulders (74%), neck (58%), wrist (55%) and lower back (41%). Other localised pain is suffered in areas such as upper back and elbow. Only 3% of those that answered stated that they hadn't suffered any pain at all.

A larger UK-based survey was completed by Sound Ergonomics in 2008 (Sound Ergonomics, 2008). On that occasion, the number of sonographers who had experienced any kind of pain during scans represented 90% of the 3024 respondents. Shoulder, neck and wrist were again the most common areas of pain. Sustained shoulder abduction, pressure application and neck and trunk twisting were the main reasons of pain given. Sonographers were asked about possible workplace improvements too, their most common responses concerned the adjustability of bed and couch, reduction on the number of scans and replacement of ultrasound machines with newer models.

Professionals' Feedback

Sonographers have reported several issues and opinions and some of them have been classified as a "wish list" for sonographers (Kinghorn RSI, 2012). The most important issues identified are:

- Reducing the effort needed to displace the adipose layer in high BMI patients.
- Avoiding having to bend their wrists too far away from the neutral position.
- Reducing the degree and frequency of abduction of the scanning arm, and finding an acceptable and non-restrictive way of helping to support its weight.

That is not the first time that aspects like the difficulties of scanning obese patients have arisen; in the mentioned above paper written for the University of Sheffield (Quartly, 2013), sonographers reported that more obese patients often induce more pain due to the extra effort that they have to apply to optimise imaging. Sometimes, sonographers have found an improvement by performing paired scans whereby two sonographers work together to complete the scan (Monningtom *et al*, 2012) but, of course, this solution increases the time needed for the scan and has cost implications.

Financial Impact

Repetitive strain injuries are said to cost European countries between 0.5% and 1.5% of the GNP (Kinghorn RSI, 2012). The monetary costs of work-related musculoskeletal disorders have been discussed by most of the authors that have researched this issue. There have been two primary

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estimations, one each for both the UK and the US. The first one (NHS, 2009), states that MSDs *"Are the most common type of occupational ill health in the UK"* representing around 40% of all sickness absences and regarding to their accounts, it results in a cost of about £400 million each year. Most of the cases of absence due to MSDs are applying to sonographers and the cost can range between £2700 and £3700 per employee, plus the sick pay for the absent individual (Quartly, 2013). As can be seen, the economic impact of MSDs results in a large financial loss.

Another estimation analysed in a US-based report (Baker *et al*, 2002), establishes the costs attributed to a musculoskeletal disorder on the shoulder of a sonographer as much as $641,000, counting the worker's compensation, medical expenses (without surgery), staff replacement cost, revenue loss and recruitment of new sonographer costs. In the same document an estimated cost of implementing an ergonomic workstation for sonography was calculated being the total around $158,000 including examination table, chair, support cushions and a modern ergonomic ultrasound system.

Personal Impact

The benefits of investments in ergonomic instruments or devices are more than clear, all of this without counting other losses such as the productivity of an experienced sonographer and his/her ability to identify potential problems during scans or personal consequences. Tendon, muscular, and neurovascular related disorders are on the rise among sonographers and the damage may not reach its full effect until twenty or thirty years after the injury (Quartly, 2013), forcing about 20% of them (NHS, 2009) to leave the profession or take premature retirement because of the impact of their injuries over their quality of life. This impact can be very serious, in some cases causing depression or a high level of incapacity to perform activities of daily living (ADLs) such as driving or sports.

Solutions assessment

Shoulder as a key area

A considerable improvement regarding couches design seems to have been achieved. A large catalogue that offers different models to adapt for each kind of examination to be done will cover all the necessities of each department and there are even multipurpose models which reduce the number of couches needed for general examination departments.

Nevertheless, the largest gap identified after this technology review is the armrest. To date, nobody has developed a product that helps not only to support arms and shoulders, but to apply pressure over patients when required, even thought this is probably the kind of effort that causes the most and the worst injuries among sonographers. Based on this, and keeping in mind the previously mentioned list of most important areas of pain (Quartly, 2013), it is clear that the

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shoulder should be the first target to point when attempting to design any potential device intended to help reduce musculoskeletal injury risks.

By reducing the effort on the shoulder, other areas are expected to have their stress reduced too. This is the case of the neck and back, since part of the effort sustained by the shoulder is usually transferred to these muscles due to a loss of strength in the arm.

To confirm this, an experiment has been designed in order to verify that by supporting the shoulder, muscular stress will be reduced.

Surface Electromyography (sEMG)

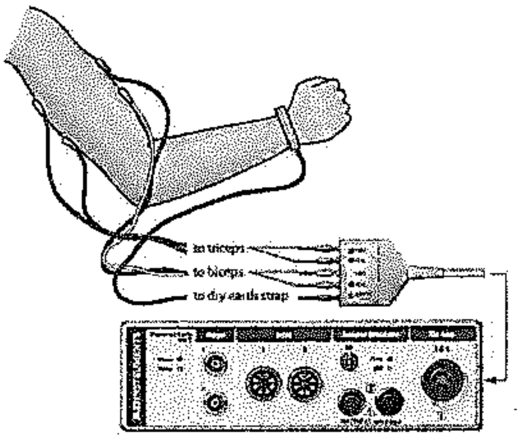

Figure 2. sEMG equipment. (Google images)

Electromyography (EMG) has been utilised before in other experiments for analysing issues related with sonography and, in other industries, to get information regarding performance associated with the workplace, principally to evaluate light, repetitive work where the activity of specific muscles is of interest. Ergonomic analysers often use this technique when comparing the specific musculoskeletal stresses associated with various work positions, postures or activities and for validation of ergonomic principles.

With this system we are able to collect muscular activity data in different scenarios, with the objective of comparing them and check that present improvements are truly successful, as well as test any potential prototype to confirm that the product can help to reduce the load and stress suffered by sonographers and avoid work related musculoskeletal disorders.

The first pilot experiment is performed in two different scenarios in order to obtain an estimation of possible improvement in terms of shoulder effort. The first scenario consisted of a normal range of motions including shoulder abduction at different degrees (0, 45 and 90 degrees) without any support. The second scenario includes an additional support under the arm intended to help during sustained shoulder abduction.

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The muscles to be assessed are Upper Trapezius, Middle Trapezius and Lower trapezius, positions defined by Eleanor Criswell (Criswell, 2011).

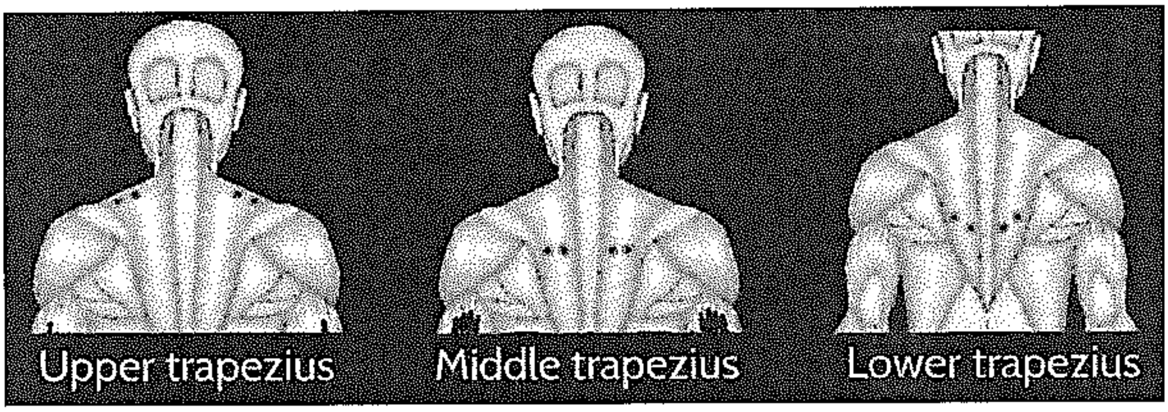

Figure 2. Sensor placement. (Criswell 2011)

The results (Figure 4) show an important improvement and muscular activity reduction not only in the shoulder area (upper trapezius), but in the back muscles too (middle and lower trapezius). This is taken as a validation and as a starting point to find a potential device that could be used as a support during ultrasound scans.

Design process

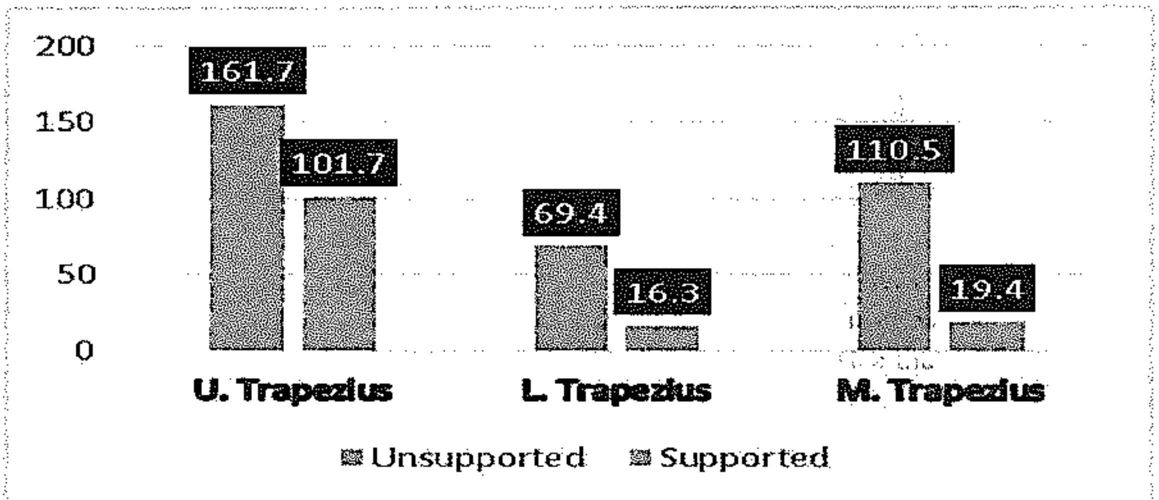

Figure 3. Results from pilot experiment

The objective is to find a system of supporting the shoulder without blocking any range of motion required in ultrasound scans. The device should keep the weight of the shoulder but without adding any extra effort requirement when moving the arm. This idea seems very close to the "zero

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gravity" concept used in cinema when recording dynamic scenes to avoid vibrations during camera displacements, called "Steadicams".

Iso-Elastic concept

Steadicam is a device used by video makers to stabilise and eliminate shaking and rolling during video shooting. First introduced in 1976, its appearance has revolutionised the way movies and sports competition are recorded. There are three elements that make up of the device; an iso-elastic arm, a sled that holds the camera equipment and a supportive vest.

The specific system that is of interest to this project is the iso-elastic arm where it absorbed both the weight of the camera and vibration caused by user displacements. That system would be used to support sonographer's body weight and reduce shoulder abduction stress by attaching it to the shoulder. The spring in the system will pull the arm and hence provide an opposite force to neck, back and forearm muscles.

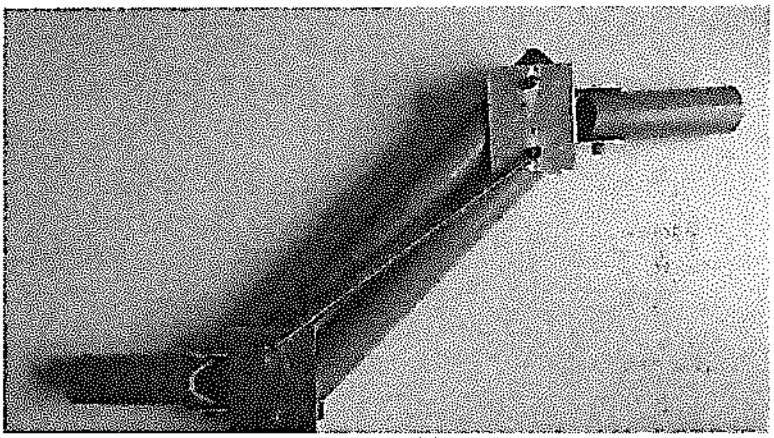

Figure 4. Support Device first prototype

The idea is to make one similar device like the Steadicam but with one single arm with one end attached to the sonographer's shoulder and another end attached to the chair or ultrasound scanning couch. Instead of being at front like Steadicam, the arm will be suspended from behind hence it wouldn't block any movement during scanning.

Prototype Assessment

Once a first prototype has been designed and manufactured, and before looking at other possible designs improvements or manufacturing methods, another experiment has been performed in order to validate the iso-elastic arm support idea.

In this case, the two scenarios consist again in normal scanning movements focusing on shoulder abduction, one without any support and another using the shoulder support device prototype.

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Again, there is a clear muscular activity reduction when comparing both scenarios (Figure 6). The use of this device is helping the user to support the arm weight which reduces the effort required during sustained shoulder abduction.

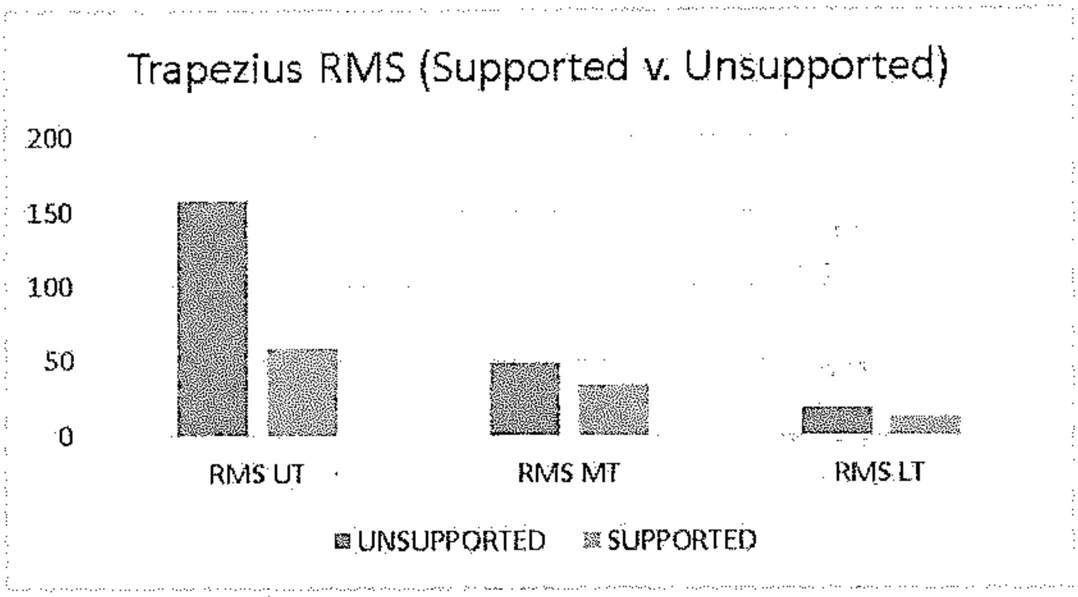

Figure 5. Results from prototype EMG experiment

Future work

The option of a device that helps reduce shoulder abduction-related effort will clearly reduce injury risks. The most important obstacle to achieve this, will be related with the design process since it is not easy to accommodate these kind of support in an ultrasound environment due to the huge amount of different movements that sonographers need to perform during scans.

Next steps include further re-design of the device in order to optimise it and to be able to perform a clinical test with professionals involved on it. Their feedback will be the most important to know before starting a final product design since their answers and questions will give the information required to continue with its development.

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Appendix 6: Project Concept and Definition

- Project plan document written for Knight Imaging with the objective of explaining and settling the purposes and outcomes of the new medical couch product. It includes not only descriptions and specifications but estimations of both project PERT and gantt diagrams as well as a description and definition of all the stakeholders involved.

DELTA+ ULTRASOUND COUCH

Preliminary project concept and definition

Concept

Customer needs

The increase of the prevalence of work-related musculoskeletal disorders amongst sonographers is increasing the importance these injuries when ultrasound departments decide to do acquisitions of new equipment. They are clearly trying to reduce these risks and that's why they look for products that include extra features which have been specifically designed to reduce the risks that scan procedures represent for professionals as well as the extra costs implied when injuries happen.

Starting viability

Knight Imaging distributes medical couches with a good quality and are well rated by customers. The company wants to make an extra effort to develop a new product which would be exclusive for the company (some of the current products are very similar to competitor's). The knowledge gained during a previous product development will help to achieve this objective so the chances of success are high enough to go ahead with this project.

Alternatives

A technology review was done before in order to find possible products that are already in the market and can be added to Knight Imaging's catalogue. Several options were found, however, all of them were out of our established boundaries which were price, adjustability and focused in general ultrasound scans. Apart from that, none of them included any extra feature specifically designed to reduce RSI risks.

Numbers

Due to the innovative aspect of this new product, there is no reference for a selling price. However, the company wants to make a minimum of 40% profit margin. In terms of time, the project should be completed before the end of the year. By completed, the company understand to have a fully functional model in order to demonstrate it in congresses and medical equipment conferences.

People involved

J.G. will be the person in charge of this development and no extra resources will be required until manufacture. Just feedback from other individuals will be required at some specific points. Regarding Stakeholders, Knight Imaging will be implied as company, customers will be consulted by the creation of a focus group and an external manufacturer will be giving feedback during the development as well. Suppliers will be taken as stakeholders too.

Brainstorming

Some possible issues have been already identified in these kind of products after research carried during previous projects.

- The space under the couch is not enough to allow the sonographer to adopt a comfortable position.
- The current shape/design of ultrasound couches doesn't allow the sonographer to get the patient close enough in some kinds of scans.
- Head rest are not always required, but mountable head rests are not a good option because they get lost very easily.
- The transducer wire creates torque forces in the sonographer's wrist, which is one of the most important areas of pain.
- Shoulder is the biggest area of pain and causes most of the MSDs.
- Neck is one of the most important body parts under high risk.

Preliminary organisation

It is expected to start with the project once that current developments have been finished. A good starting point would be August which would give a space of 4-5 months to complete the project.

Definition

Purpose

The porpoise is to develop a new product to improve the competitiveness of Knight Imaging in the market, to gain presence in the U.K. and try to open new a new market in Continental Europe.

Goals

The main objective is to improve the offer of ultrasound couches that are already in the market through the implementation of new features to reduce MSDs risks amongst sonographers.

Context – dependences

Knight Imaging has been working in the development of new products focused on customer's needs since 2013. Currently there are three projects being developed and most of the knowledge gathered during those project will be applied to the one described in this document. In terms of dependences, the only restrictions caused by other projects are related with the starting date, initially fixed for August 2015.

Expectations

The company expects to have a new product in the market for the end of the year or early 2016. This product will be part of the ultrasound couches section on the catalogue and will be designed focusing on the customer in order to add extra value to the product. The idea is to offer an exclusive couch which will have a slightly higher cost, but will still be competitive given the extra features included in order to improve work conditions of sonographers and their patients.

Implied people

- Knight Imaging
    - Jesús Galindo
    - Andrew Williams
    - Andy Tozzeano
- The University of Sheffield
    - As a KTP Knowledge Base
- G'Shaw and Sons
    - As manufacturer
- Linak
    - As actuators provider
- Other suppliers
- Sonography Focus Group

Success criteria

- Completing the project by the end of the year
- Having a fully functional model starting 2016
- Added features help reduce RSI Risks
- The company profit margin is above 40%
- The product meets all requirements for medical approval
- The product receives good feedback from Focus Group and other users

Project Tasks and Times

Item	Task	Precedences	Optimistic Time	Realistic Time	Pesimistic Time	Expected Time	sq V
A	Voice of Customer		10	15	20	**15.0**	**2.777778**
B	Design Matrix		1	2	4	**2.2**	**0.25**
C	Concept Design	A,B	5	8	10	**7.8**	**0.694444**
D	Current product review	C	1	2	3	**2.0**	**0.111111**
E	Components review	C	1	2	3	**2.0**	**0.111111**
F	Possible Modifications	D	2	4	5	**3.8**	**0.25**
G	Components required	F	1	2	3	**2.0**	**0.111111**
H	Prototype Design	F	8	12	15	**11.8**	**1.361111**
I	Contact Suppliers	E	2	5	7	**4.8**	**0.694444**
J	Suppliers selection	I	1	2	3	**2.0**	**0.111111**
K	Prototype Design Adjustments	H,J	1	3	7	**3.3**	**1**
L	Manufacturing Plan	K	3	4	6	**4.2**	**0.25**
M	Technical Drawings	L	4	7	11	**7.2**	**1.361111**
N	Components adquisition	M	10	15	20	**15.0**	**2.777778**
O	Manufacture	M	7	10	20	**11.2**	**4.694444**
P	Assembly	N,O	5	7	10	**7.2**	**0.694444**
Q	Test	P	3	7	15	**7.7**	**4**

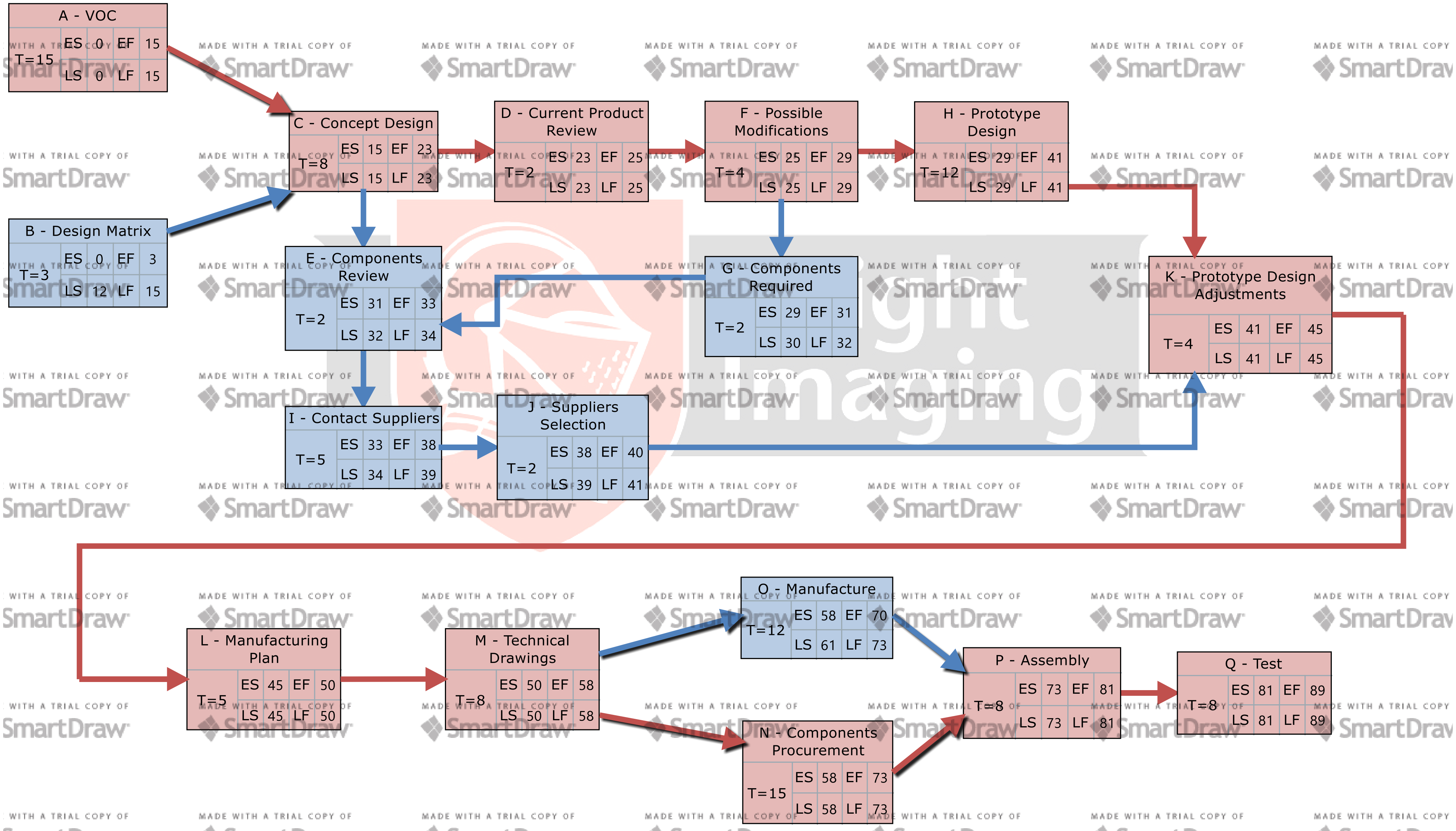
$$Di = \frac{a_i + 4m_i + b_i}{6}$$

$$V_i^2 = \left(\frac{b_i - a_i}{6}\right)^2$$

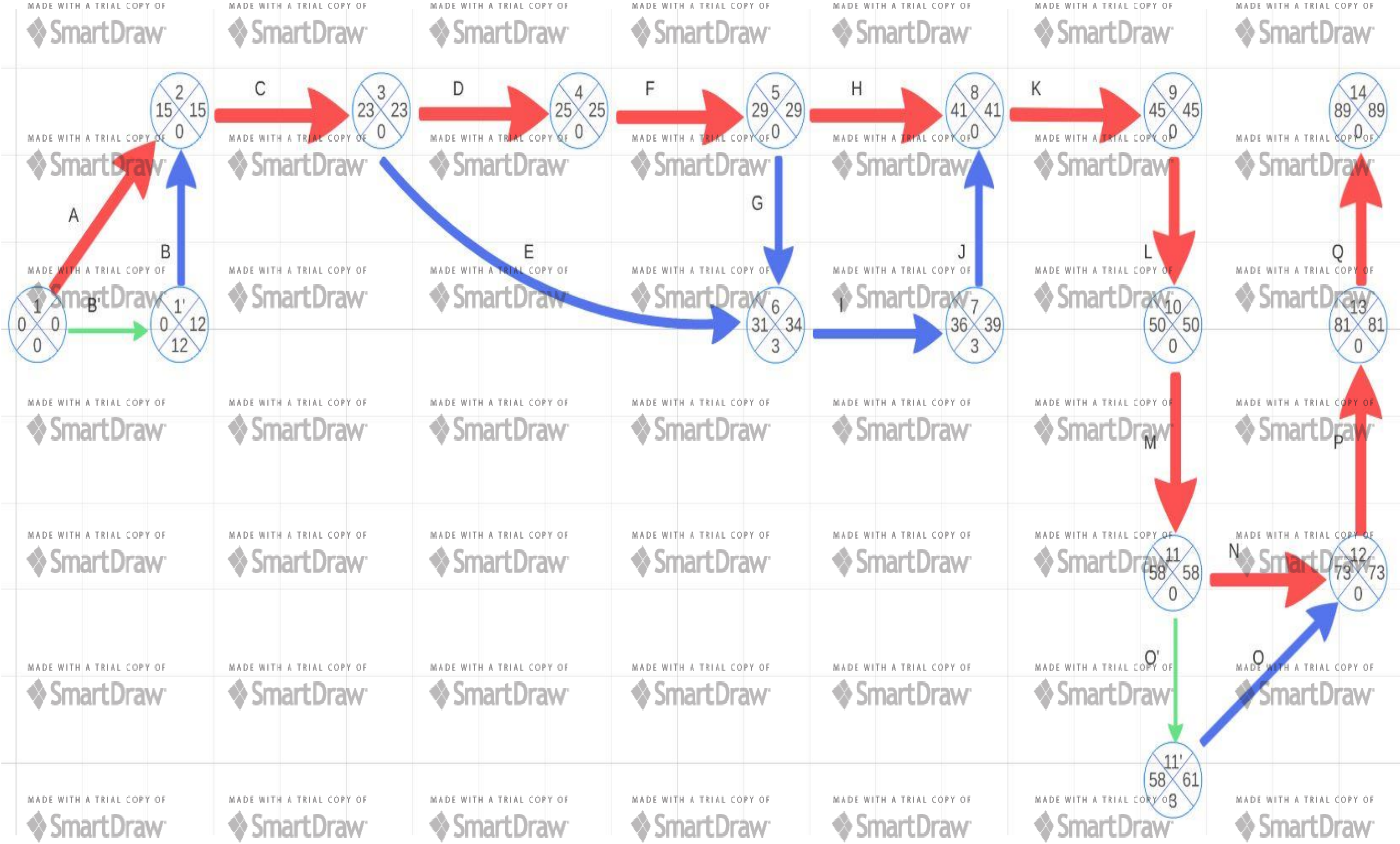
Di = Expected Time
V_i^2 = Variation

a = Optimistic Time
m = Realistic Time
b = Pessimistic Time

CPM (Critical Path Method)



PERT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61
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12
73
73
0
13
81
81
0
14
89
89
0

Project Time

	Critical Path:						
A	Voice of Customer		10	15	20	15.0	2.777778
C	Concept Design	A,B	5	8	10	7.8	0.694444
D	Current product review	C	1	2	3	2.0	0.111111
F	Possible Modifications	D	2	4	5	3.8	0.25
H	Prototype Design	F	8	12	15	11.8	1.361111
K	Prototype Design Adjustments	H,J	1	3	7	3.3	1
L	Manufacturing Plan	K	3	4	6	4.2	0.25
M	Technical Drawings	L	4	7	11	7.2	1.361111
N	Components adquisition	M	10	15	20	15.0	2.777778
P	Assembly	N,O	5	7	10	7.2	0.694444
Q	Test	P	3	7	15	7.7	4
					Total Var.		15.27778

Knowing the variation of time, an appropriate total expected time will be calculated in order to ensure a good probability of accomplishment.

We fix a probability of 99.87% of finishing the project in the given period of time.

$$P\left(\eta' \leq \frac{T\text{-}M}{V}\right) = F\left(\frac{T\text{-}M}{V}\right)$$

From tables, we obtain P(…) = 3 (for 99.87%). Then:

3 = (T-M)/V ;

T = Project Time

M = Expected time (obtained with CPM)

V = Squared root of Variation = √15.27778 =

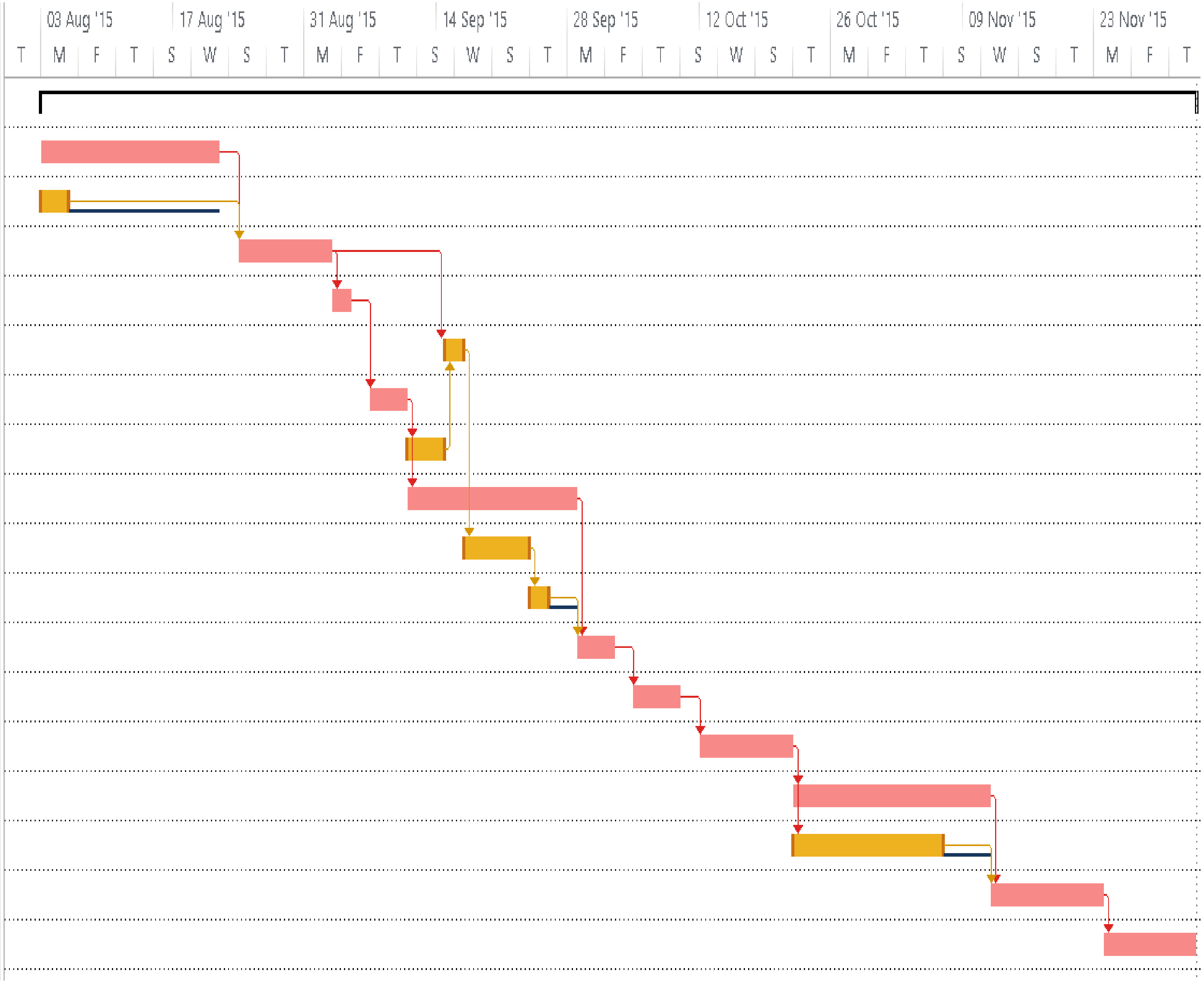
3 = (T – 89)/3.9

T = 100.7

So the probability of finishing the project in **100 working days is 99.87%.**

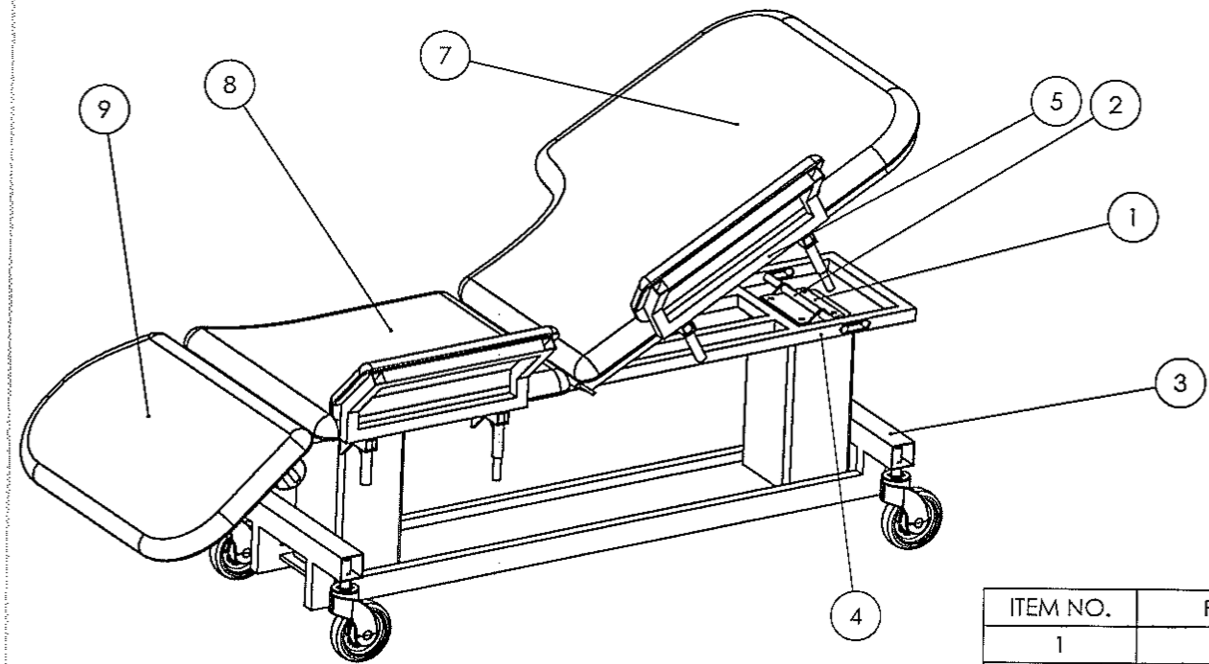
Gantt

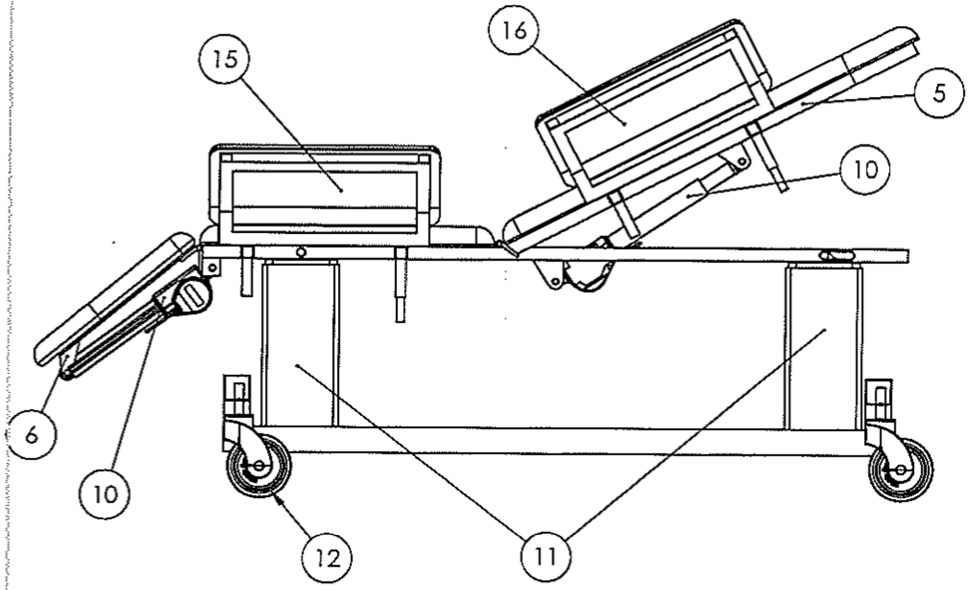
ask Name	Start
Delta+	**Mon 03/08/15**
A - VOC	Mon 03/08/15
B - Design Matrix	Mon 03/08/15
C - Concept Design	Mon 24/08/15
D- Current product review	Thu 03/09/15
E - Components review	Tue 15/09/15
F - Possible modifications	Mon 07/09/15
G - Components required	Fri 11/09/15
H - Prototype Design	Fri 11/09/15
I - Contact Suppliers	Thu 17/09/15
J - Suppliers selection	Thu 24/09/15
K - Prototype Design Adjustments	Tue 29/09/15
L - Manufacturing Plan	Mon 05/10/15
M - Technical Drawings	Mon 12/10/15
N - Components adquisition	Thu 22/10/15
O - Manufacture	Thu 22/10/15
P - Assembly	Thu 12/11/15
Q - Test	Tue 24/11/15



Appendix 7: Sketch drawings

- Technical drawings of the general design of the new product for Knight Imaging. It includes a detailed view of the lateral pads described in previous sections.





ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12	Ø		
15			
16			

	NAME	DATE	PROJECT NAME	TITLE:
DRAWN	J Galindo	12/08/2015	Delta Plus	Assembly View
CHK'D			PROJECT CODE	
APPV'D				

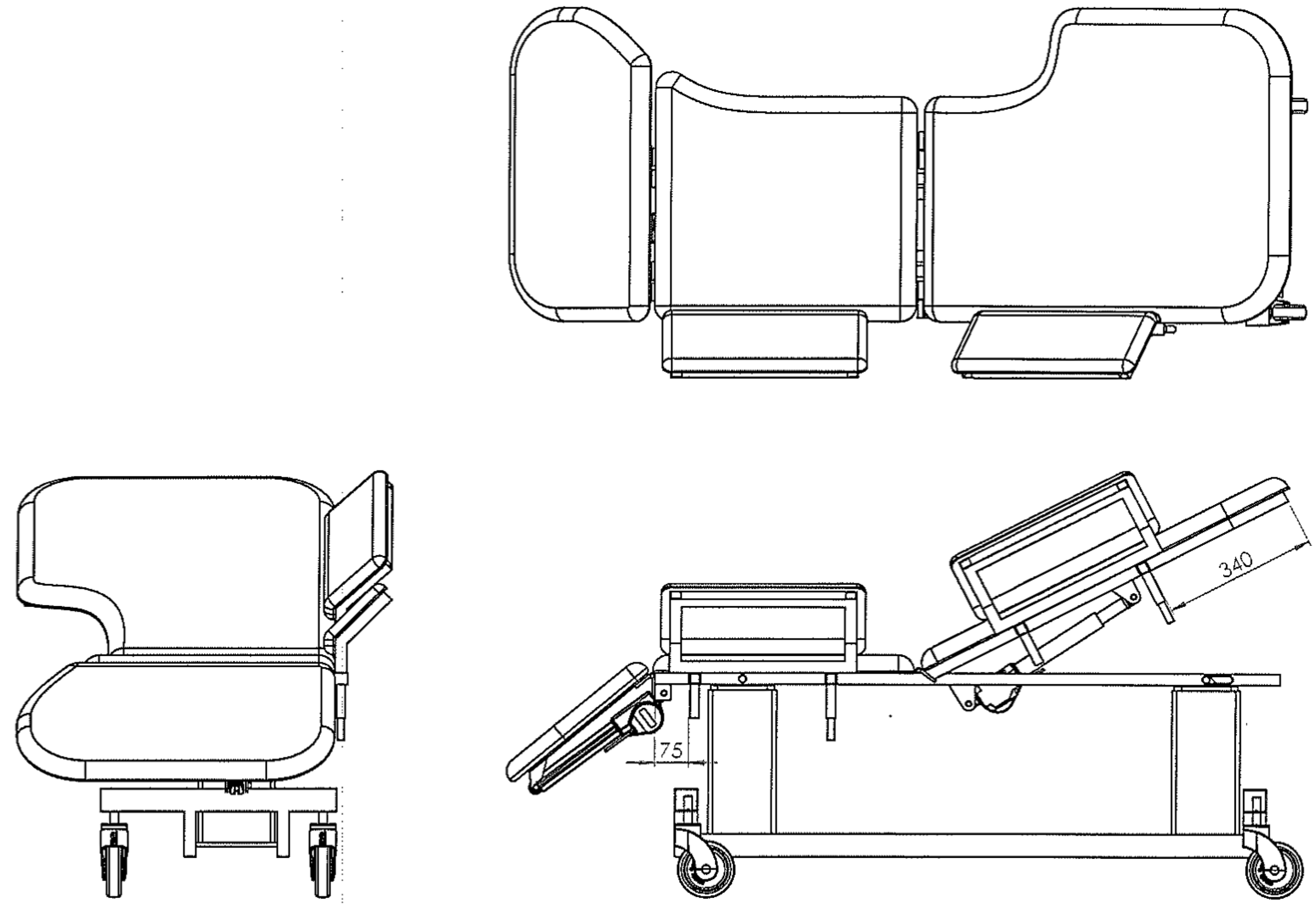
Knight Imaging

STANDARD: UNE - EN - ISO

MATERIAL:

DWG NO. A3

WEIGHT: SCALE:1:10 SHEET 1 OF 1



	NAME	DATE	PROJECT NAME	TITLE:
DRAWN	J Galindo	12/08/2015	Delta Plus	General View
CHK'D				
APPV'D				

Knight Imaging

STANDARD: UNE - EN - ISO

MATERIAL:

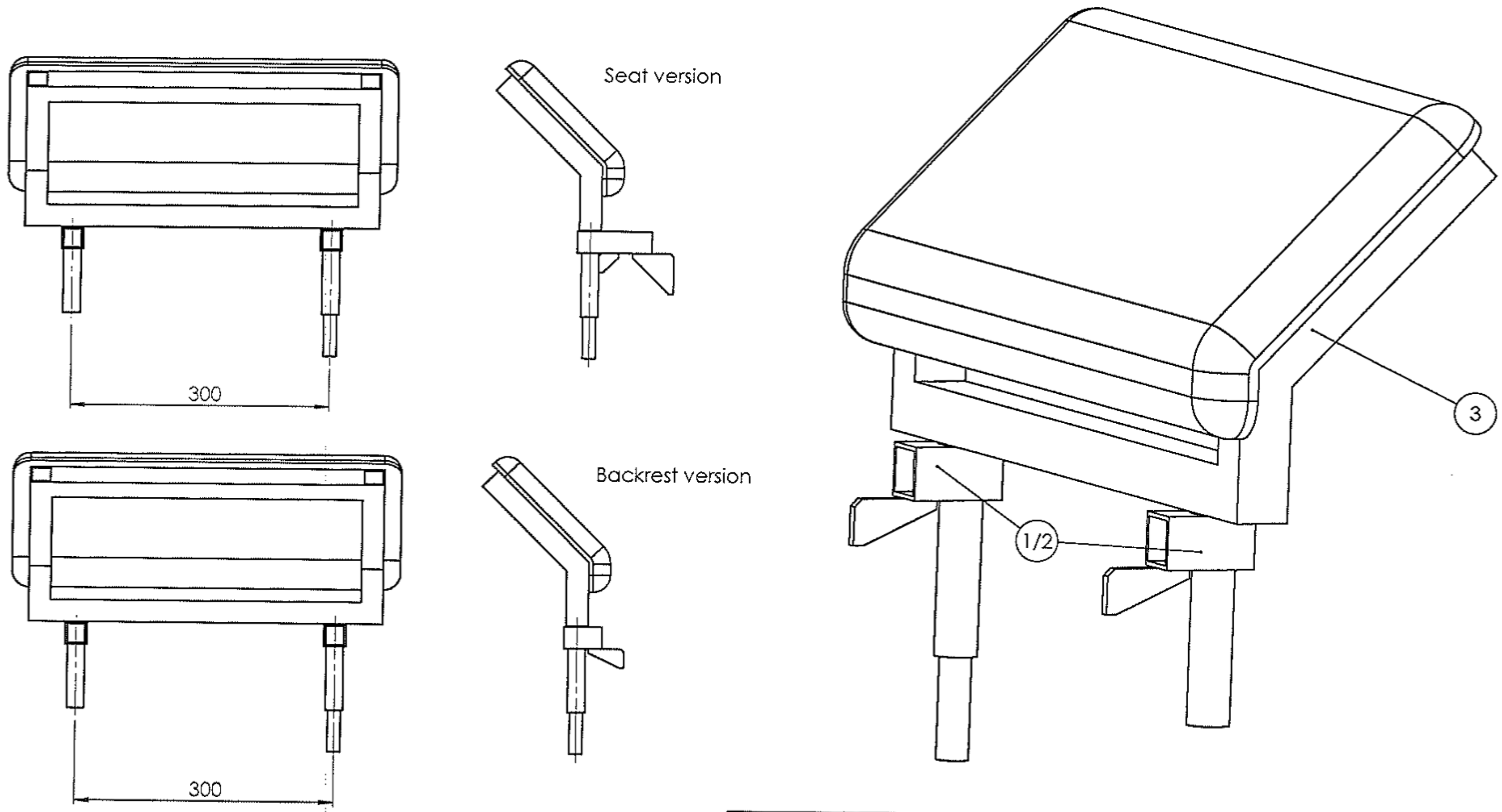
DWG NO.

A3

WEIGHT:

SCALE:1:10

SHEET 1 OF 1



ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1			
2			
3			

	NAME	DATE	PROJECT NAME	TITLE:
DRAWN	J Galindo	12/08/2015	Delta +	Lateral Pads
CHK'D				
APPV'D				

Knight Imaging

STANDARD: UNE - EN - ISO

MATERIAL:	DWG NO.	A3
WEIGHT:	SCALE:1:5	SHEET 1 OF 1

Appendix 8: Survey results from the University of Cumbria evaluation

- Summary of the answers given by ultrasound students during the evaluation carried on in collaboration with the University of Cumbria in order to obtain feedback from professionals who had been involved with ultrasound at some level when using the first prototype of ultrasound workstation. Some of them had years of experience working on these kind of departments.

Results from the survey about the Knight Imaging Ultrasound Ergonomic System University of Cumbria U.S. Students

Initial data

Participants: 15

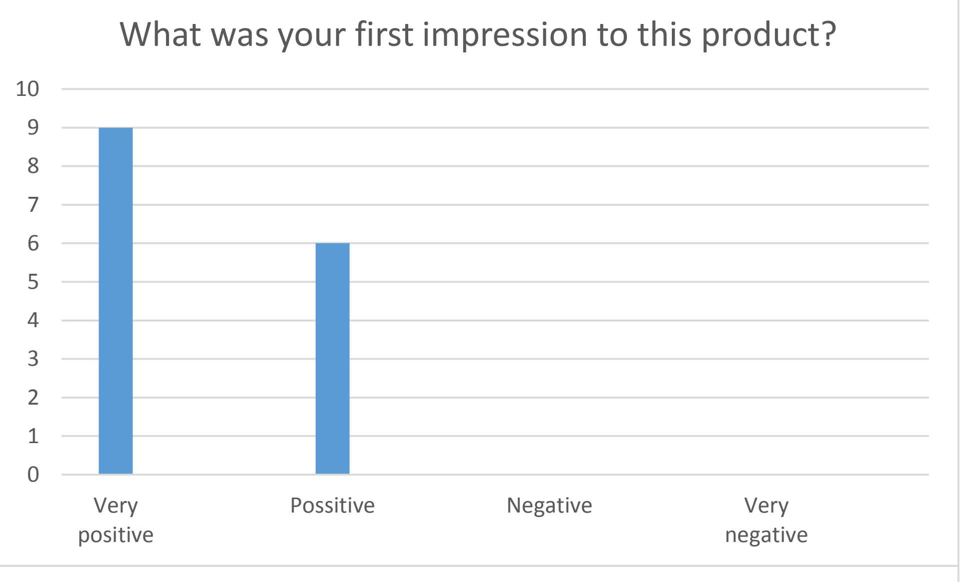
Female: 12

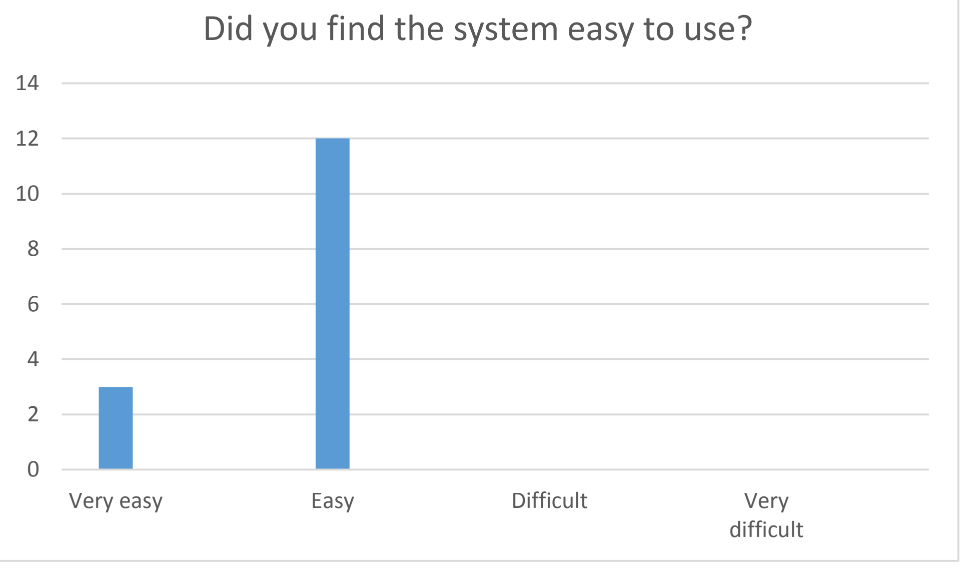
Male: 3

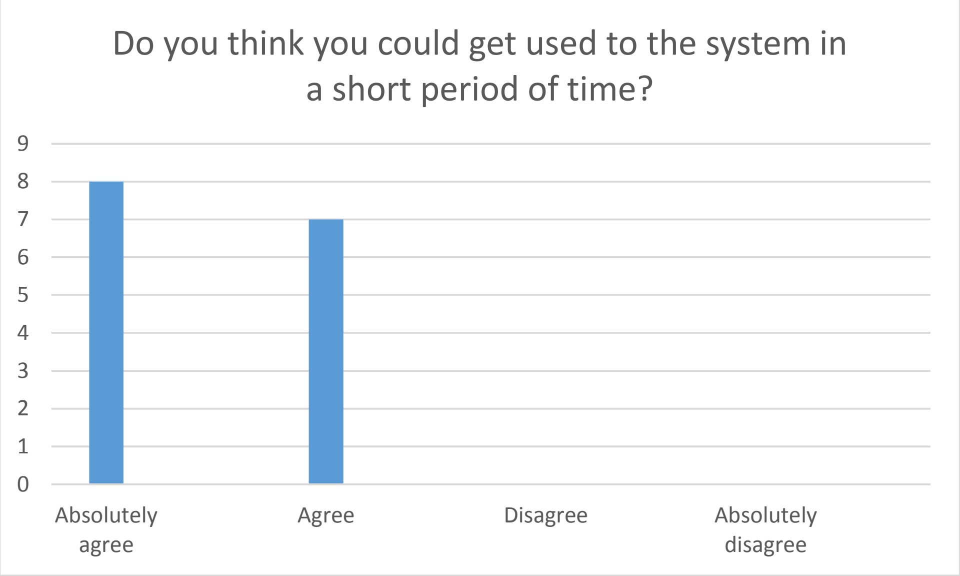
Average age: 28.5 Years (22 – 40)

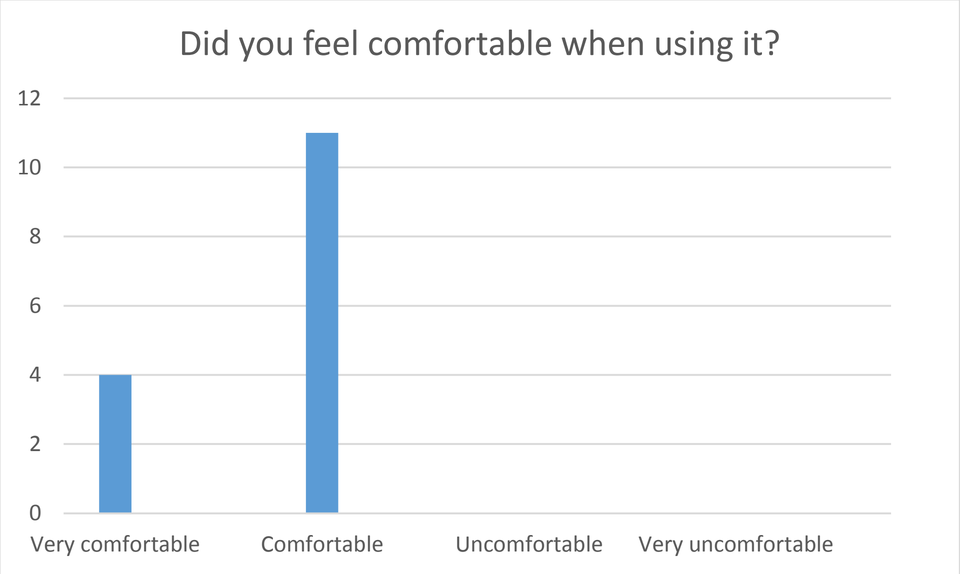
Average scanning experience: 9.6 months (0 – 30)

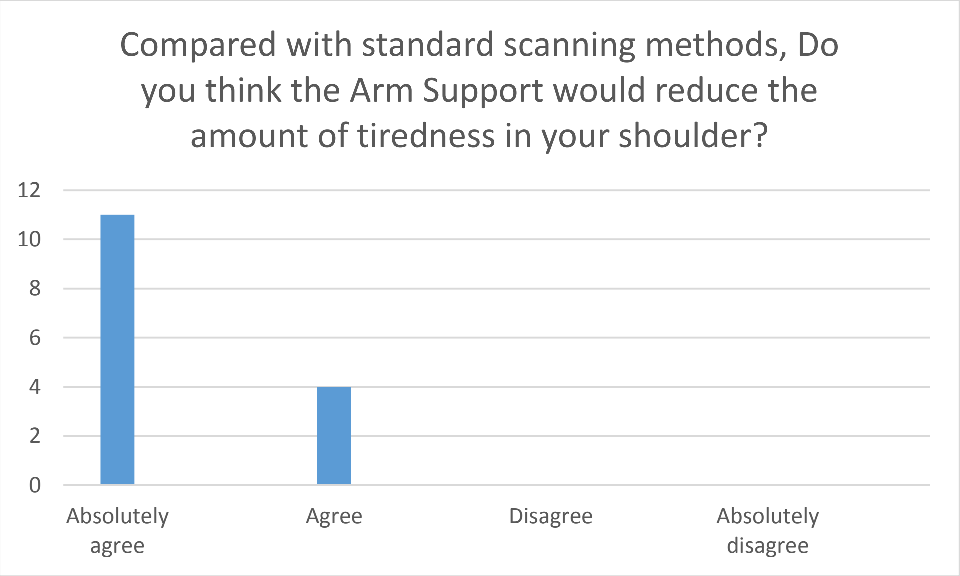
Selection questions

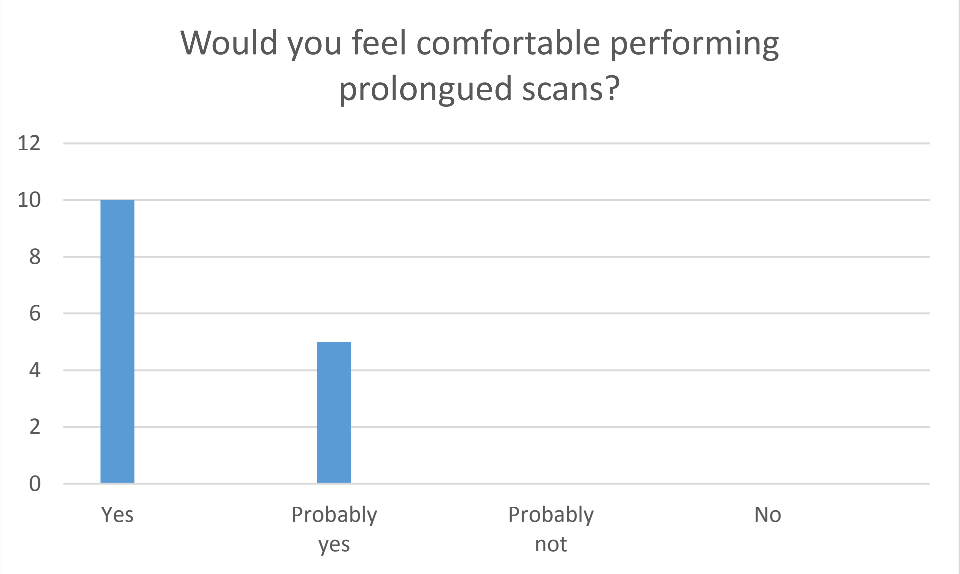


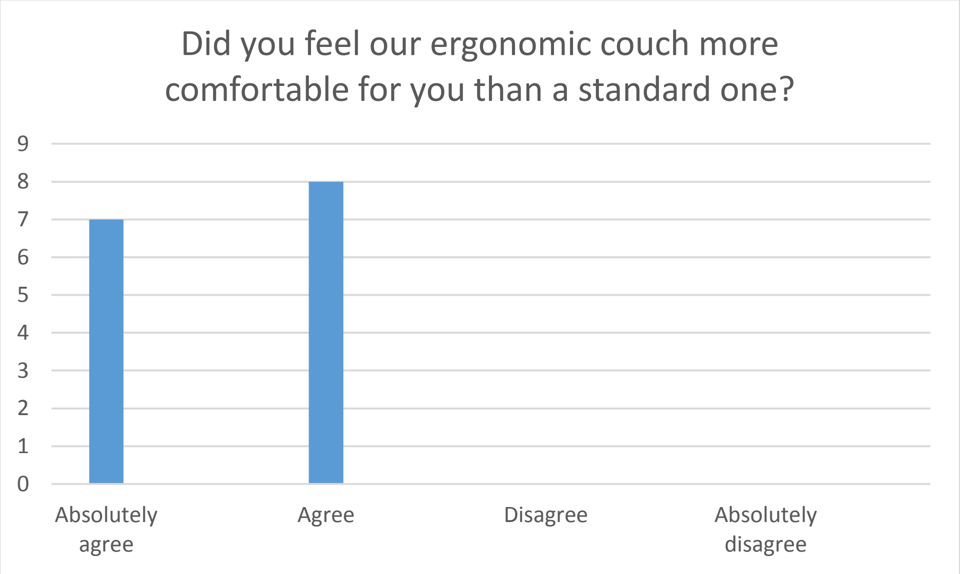


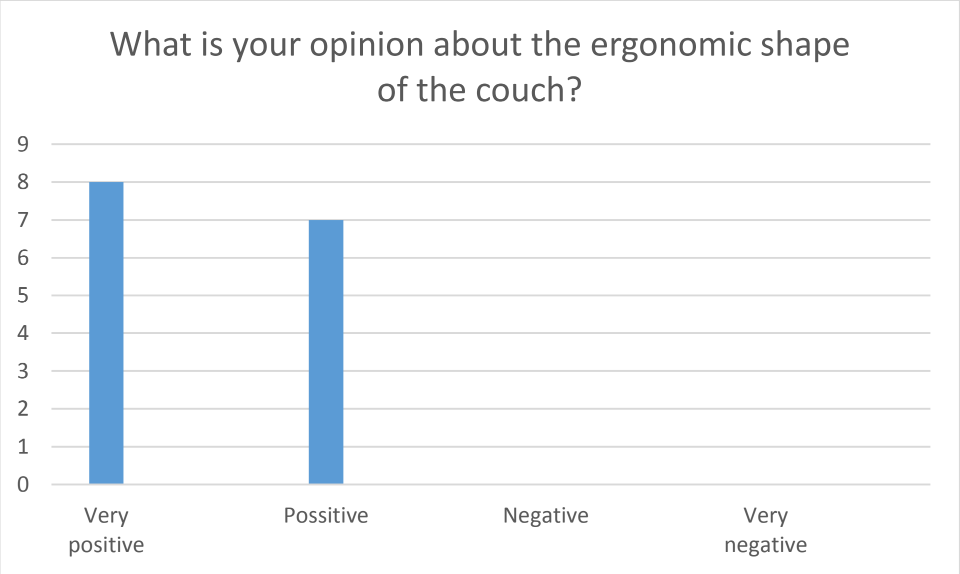

Do you think you could get used to the system in a short period of time?
9
8
7
6
5
4
3
2
1
0
Absolutely agree
Agree
Disagree
Absolutely disagree

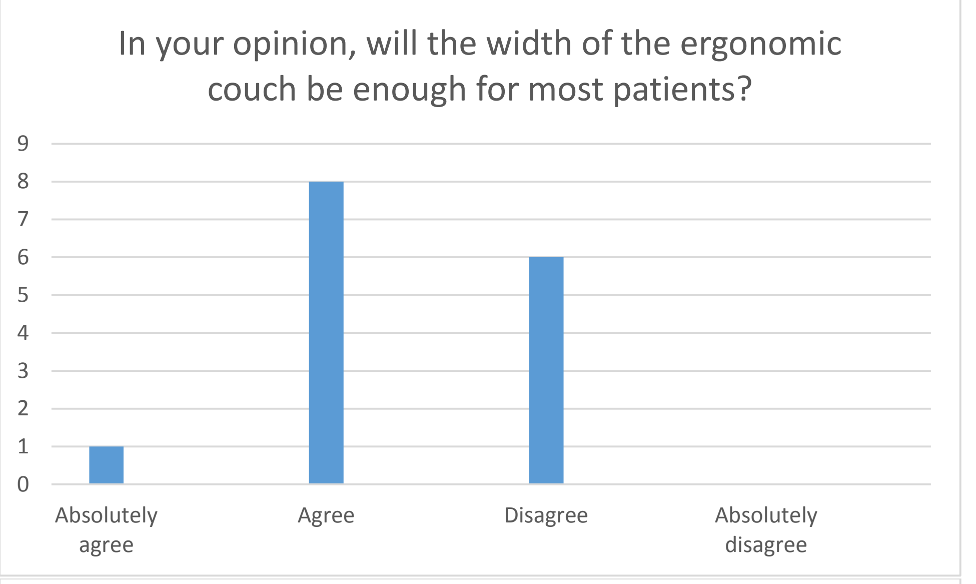

Did you feel comfortable when using it?
12
10
8
6
4
2
0
Very comfortable
Comfortable
Uncomfortable
Very uncomfortable

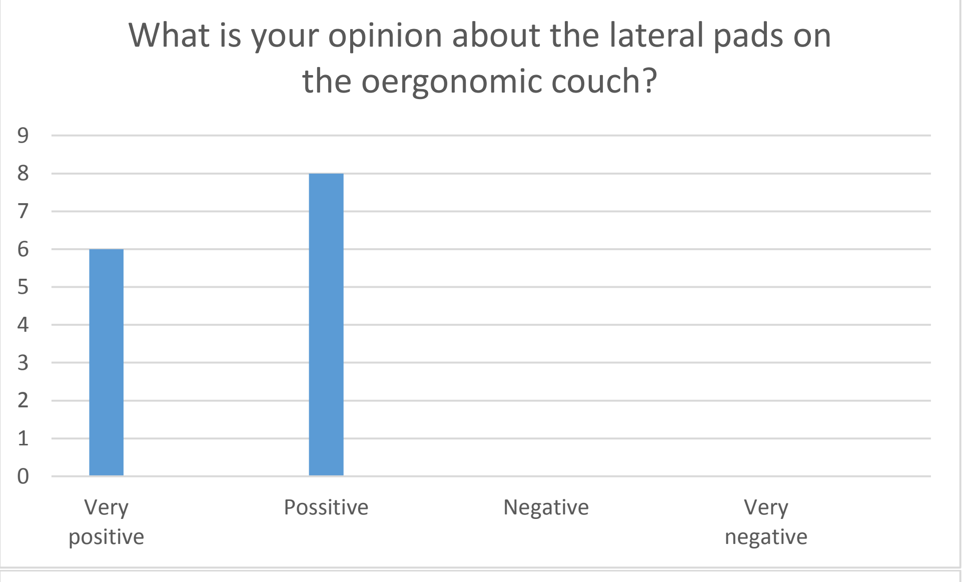

Compared with standard scanning methods, Do you think the Arm Support would reduce the amount of tiredness in your shoulder?
12
10
8
6
4
2
0
Absolutely agree
Agree
Disagree
Absolutely disagree

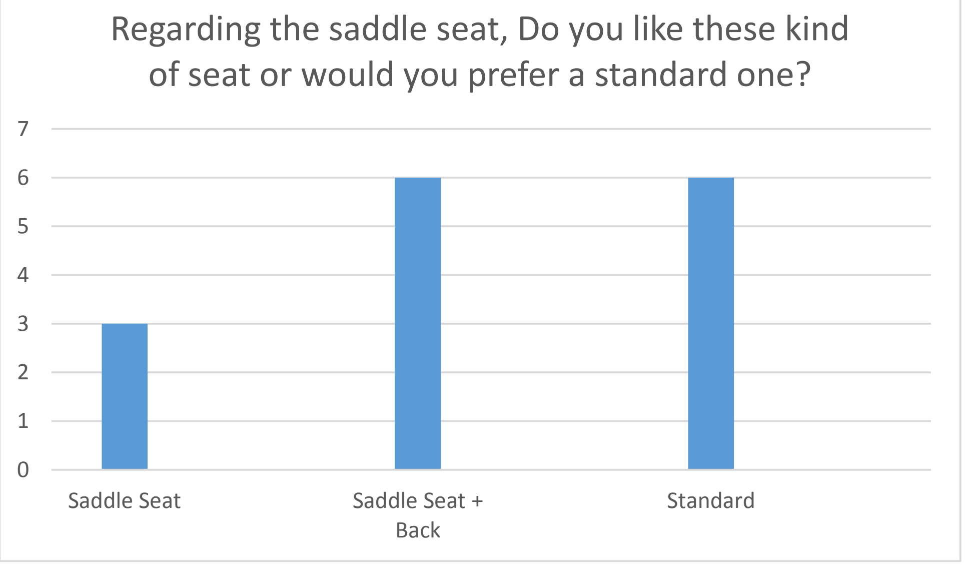

Would you feel comfortable performing prolongued scans?
12
10
8
6
4
2
0
Yes
Probably yes
Probably not
No

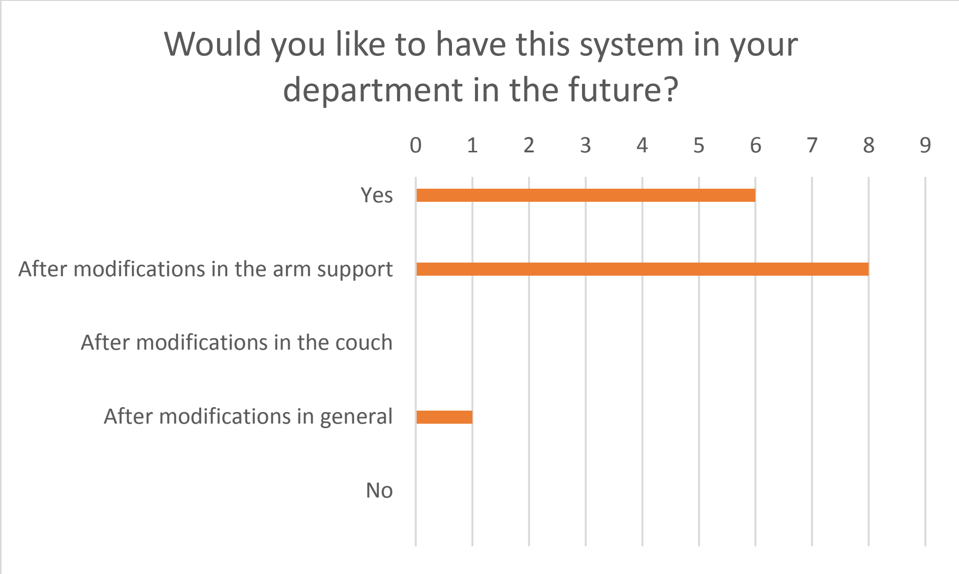

Did you feel our ergonomic couch more comfortable for you than a standard one?
9
8
7
6
5
4
3
2
1
0
Absolutely agree
Agree
Disagree
Absolutely disagree


What is your opinion about the ergonomic shape of the couch?
9
8
7
6
5
4
3
2
1
0
Very positive
Possitive
Negative
Very negative


In your opinion, will the width of the ergonomic couch be enough for most patients?
9
8
7
6
5
4
3
2
1
0
Absolutely agree
Agree
Disagree
Absolutely disagree


What is your opinion about the lateral pads on the oergonomic couch?
9
8
7
6
5
4
3
2
1
0
Very positive
Possitive
Negative
Very negative


Regarding the saddle seat, Do you like these kind of seat or would you prefer a standard one?
7
6
5
4
3
2
1
0
Saddle Seat
Saddle Seat + Back
Standard



Open questions

- What kind of modifications do you think the Arm Support should have in order to be adapted for medical environments?
  - Go lower height easier / more adjustable
  - Ability to be used lower/higher.
  - Plastic or Leather cover for infection control
  - Bottom of the cuff needs to be padded/flatter for carotid scans so it is better on patient's chest.
  - Personally, I had to apply a bit of pressure/force to push it down even when it was set at the lowest so it might be handy to set the force a bit lower.
  - Safer material around arm support
  - Digital adjustment for spring resistance
  - Material needs to be easy to clean on support
  - The control should be easier for the user to adjust themselves without help
  - Remove hook
  - Elbow support
  - Arm support should be able to go lower
  - Easier for user to adjust throughout scan
  - To be extended for wrist support
  - I think if the arm support could travel up and down then it would be convenient and easy to be able to scan the calf.
- In terms of visual characteristics, do you think the arm support should have different colours? Which ones would you suggest?
  - No (x2)
  - Black (x2)
  - Needs to be wipeable. Don't think colour is important. (x2)
  - Same colour as chair
  - Neutral (x2)
  - Similar to scanner
  - Pink
  - Good visual and easy to clean

- In general, do you feel the system improves your comfortability during scans and reduces RSI Risks?
    - Yes (x12)
    - Definitely
    - Agree
    - Yes, it really takes the pressure off your arm and reduces resistance
- Open Feedback - Arm Support
    - Excellent Idea for DVT scans to reduce strain on shoulder (patient standing). Not so much for AAA or scans where patient can lie supine.
    - Is it timely to set up?
    - Very mobile. The hook may cause issues on the side of the arm rest.
    - Different sizes for different size arms
    - May not be suitable for DVT scans when patient is sat down
    - Doesn't seem like it would work for DVT scans where the operator has to bend to reach the calf.
    - Elbow support
    - Would be difficult to complete a DVT scan. Also, should take into consideration ward scans.
    - Good product but could be good with modifications such as a wrist support
    - Would be difficult to complete a DVT scan.
- Open Feedback - Ergonomic Couch
    - Can get closer to patient.
    - If the arm rest could be flattened to increase the width of the bed also allowing patients to get on and of the bed easily instead of being on the same side of the sonographer.
    - Width is good for getting closer but not so good for larger patients. Lateral pads are okay except for when bed is up against a wall.
    - Needs to be available in different sizes
    - Wider bed
    - Good to make patients feel safe
    - Needs to be wider for obese patients.
    - It is easy to clean
- Open Feedback - Saddle Seat
    - Needs a back support
    - None, very comfortable
    - Needs a back for lumbar support.
    - No back rest, too much temptation to slouch
    - Needs back rest/support
    - Rolls back a lot
    - Change to back rest on seat
    - Too wheely and no back rest.

Appendix 9: Summary from the clinical evaluation survey

- Summarised version of the survey taken during the clinical evaluation at the Royal Hallamshire Hospital. This document includes all the answers in a single document, so it´s easier to analyse answers given. It also contains the open feedback questions transcription.

The University Of Sheffield.

Department of Mechanical Engineering

Innovate UK
Technology Strategy Board

Knight Imaging

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United Kingdom

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Fax: +44 (0) 114 222 7890
Email: jesus.galindo@sheffield.ac.uk

Knight Imaging Ergo-Delta Ultrasound System Questionnaire

1. What is your gender?
   Female **60%**
   Male **40%**

2. What is your age?

   43.8y

3. How long have you been performing ultrasound scans (In years or months if less than 1 year)

   13.6y

4. Which kind of scans do you normally perform?
   (Please give a percentage. Ex. Pregnancy 80% Vascular 15% Musculoskeletal 5%)

   Obstetric 40%

   Gynaecology 25%

   Pregnancy/Abd 35%

5. What was your first impression to this product?

Very positive	Positive	Negative	Very negative
1	2	2	

6. How much time have you been using it during the evaluation?

38h in total / 7.5 avg

7. Did you find the system easy to use?

Very easy	Easy	Difficult	Very difficult
	1	4	

8. Do you think you could get used to the system in a short period of time?

Absolutely agree	Agree	Disagree	Absolutely disagree
	1	4	

9. Did you feel comfortable when using it?

Very comfortable	Comfortable	Uncomfortable	Very uncomfortable
	2	2	1

10. Compared with standard scanning methods, do you think the Arm Support would reduce the amount of tiredness in your shoulder?

Absolutely agree	Agree	Disagree	Absolutely disagree
	1	1	

11. Would you / did you feel comfortable performing prolonged scans?

Yes	Probably yes	Probably not	No
		2	2

12. Did you feel the ergonomic couch more comfortable for you than a standard one?

Absolutely agree	Agree	Disagree	Absolutely disagree
	3		2

13. What is your opinion about the ergonomic shape of the couch?

Very positive	Positive	Negative	Very negative
1	2	2	

14. In your opinion, will the width of the ergonomic couch be enough for most patients?

Absolutely agree	Agree	Disagree	Absolutely disagree
1	3		1 (Standard size preferred)

15. If not, how much length would you add? (cms)

16. What is your opinion about the lateral pads on the ergonomic couch?

Very positive	Positive	Negative	Very negative
	1	1	2

17. Regarding the saddle seat, do you like these kind of seat or would you prefer a standard one?

I would use this kind of saddle seat	I would prefer this seat but adding a backrest	I would use a standard seat
- 2		- 1 - 2

18. In terms of visual characteristics, do you think the arm support should have different colours? Which one would you use?

Black is fine x2

19. In general, do you feel the system improves your comfortability during scans and reduces RSI Risks?

Unsure without continued use No Couch yes / Arm Support no

20. Would you like to have this system in your department in the future?

Yes	After modifications in the Arm Support	After modifications in the Couch	Modifications general	No
1 (Only couch)	2	1		1

21. Open feedback (negative points, clinical perspective, usability issues, questions, etc.):
    a. Arm Support

Could the support be more like a glove or sleeve, with the removal of the metal bracket that catches the patient's abdomen during pregnancy scans. The arm support needs some work on the Intechon(?) and the Velcro in the way.

Too much pressure on the aim pulling it down. Did not support my arm. Made arm pit ache plus arm muscles burn(?).

Uncomfortable at back of upper right arm. Difficult to strap on. Patient moved leg and knocked it on support.

    b. Ergonomic Couch

Good Idea, needs better idea of allowing patient to get on and off from the opposite side to where sonographer sits.

Too narrow for pregnant patients as we also have to scan them on sides

No stirrups so unable to perform TUS examinations. Didn't use lateral pads as this restricted the paient getting on the couch.

I found the couch uncomfortable when using a standard chair because the patient was too far from me. The chair would not go closer due to the base of the chair and the wheels of the couch crashing.

The lateral pads get in the way where the patient get into the scan. I tried removing the lower one but the support still gets into the way. If the patient gets on from the other side: 1) I have to move my scanning chair out of the way. 2) there is a risk they will use the scan machine as a support and press the keyboard by accident. I don't think the lateral pads add much to the patient's comfort during the scan. The controls for elevating bed etc are not clearly labelled.