

Ergonomics evaluation of the STARSystem

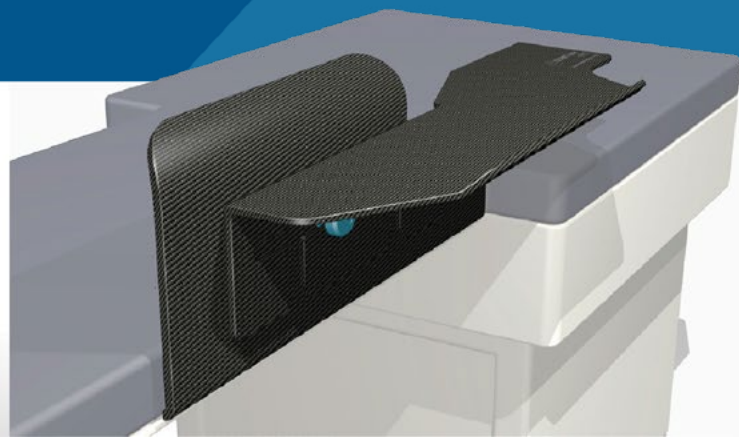
to improve occupational hazards
of interventional cardiology
and neuroradiology.

Felipe Meyer PhD¹, Leonardo Lagos, Mg², and Adrian Garces³

¹Assistant Professor, Ergonomics Department University of Concepción

²Assistant Professor of Physiology of Movement Laboratory, Department of Kinesiology
University of Concepción

³Industrial Designer, Associate Researcher



Abstract

Practicing interventionalists are at risk of work-related musculoskeletal disorders due to poor working postures, lack of ergonomic support during procedures, and the cumulative effect of repeated physical exertion from rising case volumes. This study examines a radial access device, the Adept Medical STARSystem, and its influence on improving occupational hazards in the medical fields of interventional cardiology and neuroradiology through ergonomics.

The research is separated into two parts – quantitative and qualitative. The quantitative method utilised baropodometry study, oscillography, kinematics, and high-speed video systems to measure biomechanic and physiological results. The qualitative method focused on surveys and interviews to evaluate the device's ergonomic advantages based on user perception.

The results indicate that the STARSystem offers better ergonomic positioning for specialists. From improved load distribution on the feet – increasing standing time without discomfort, improved quantity and quality mobility for the operator through freer movement and reduced muscular stress, increased operator safety, more efficient static balance resulting in lower energy cost, improved procedural precision, and reduced setup time compared to traditional systems. 100% of the specialists tested found the STARBoard and STARTable quick to assemble, comfortable to use, and time saving. Only 44% of the users liked the STARSupport. Overall, user perceptions of the STARSystem were positive.

One can conclude that with correct STARSystem use, interventionalists practicing radial access can improve their health, procedural performance, and prevent musculoskeletal pathologies.



Table of contents

»»	Introduction: Problem Statement	4
	Ergonomic, Psychosocial and Organisational Factors	
	Orthopaedic Complications in Interventionalists	
	Summary of Findings	
»»	The Objectives	8
	The device under evaluation	
	Methodology	
	▷ Phase 1: Quantitative Design using Biomechanics and Physiological evaluations	
	▷ Phase 2: Qualitative Design through Surveys and Interviews	
»»	Results	14
	Phase 1: Quantitative Results	
	▷ Baropodometry	
	▷ Oscillography	
	▷ Kinematics	
	Phase 2: Qualitative Results	
	▷ Perception of Component Use	
»»	Discussion	25
»»	References	27

Introduction: Problem Statement

The discipline of ergonomics usually advocates a systems approach for designing work and workplaces. This approach has been developed to address the complex interactions that occur between a worker, their tools, their colleagues, and their work organisation (Moray, 2000).

The complexity of health care environments necessitates a holistic and systematic ergonomics approach to understand the complexity of the system to improve it (Buckle et al., 2006). The operating theatre itself can be a hazardous and stressful environment (Memon et al., 2016). Surgeons must constantly conduct complex procedures under time pressures (Edgar et al., 2000). Doctors are conditioned and trained in a high-paced, productivity-driven environment, where thoughts or complaints related to stress and fatigue are often discouraged or simply ignored (Schlssel & Maykel, 2019).

Today there is significant evidence about the excessive stress surgeons face, both physically and mentally (Ronstrom et al., 2018). Daily workloads for surgeons make them susceptible to a variety of common work-related illnesses. They are exposed to various occupational hazards in their professional work (Memon et al., 2016).

[These hazards include sharp injuries, blood-borne pathogens, latex allergy, laser plumes, hazardous chemicals, anaesthetic gases, equipment hazards, static postures, job-related stress, burnout and psychiatric morbidities, substance abuse and musculoskeletal pain \(Vijendren et al., 2015; Vijendren et al., 2016\).](#)

Some of the main occupational hazards that surgeons are exposed to during their professional life (Vijendren et al., 2015):

- Risk of sharp injuries
- Biological hazard
- Radiation
- Skin-related illness
- Musculoskeletal pain: Back, neck and hand
- Stress

Despite all the advances in medical technology, operating rooms are still not designed ergonomically nor with surgeons' health in mind (Schlssel & Maykel, 2019). For example, operating tables have limited mobility, floor surfaces are hard, and monitors are positioned incorrectly – amongst other issues. Due to ergonomic deficiencies found throughout the operating room, surgeons can face hazardous working conditions.

[This has led to more than 80% of surgeons succumbing to a work-related injury or illness because of sustaining awkward or static positions throughout lengthy operations over a career \(Ronstrom et al., 2018\).](#)

While the focus of the procedure is directed at the patient, there is little concurrent regard for proper posture for the operator. Even when symptoms of discomfort are experienced, they are often ignored. This results in decreased productivity and may ultimately threaten surgical careers (Knuttninen et al., 2021).

In the case of Interventional Specialists (ISs), the lack of ergonomic principles developed for both cardiologists and neuroradiologists contribute to these disorders, which may potentially affect their livelihoods, quality of life, and productivity (Cornelis et al., 2021; Shinohara, 2015). Like any physician who wears protective garments and stands during procedures, ISs are exposed to musculoskeletal disorders (MSDs), which may ultimately lead to work-related stress syndrome. Work-related injuries are common in ISs, often leading to pain while performing procedures or during time away from work (Benjamin & Meisinger, 2018). The ergonomic practices and environments of ISs have not been thoroughly evaluated, exposing these professionals to the risk of work-related MSDs (Cornelis et al., 2021; Knuttninen et al., 2021).

Ergonomic, Psychosocial, and Organisational Factors

This study found that at-risk physicians bear a large burden of work-related MSDs.

To determine which areas of the body are commonly affected by work-related musculoskeletal problems amongst physicians, the Nordic Musculoskeletal Questionnaire (NMQ) was used. It is a standardised questionnaire methodology comprised of 40 forced-choice items identifying the areas of the body causing musculoskeletal problems. It was determined through the NMQ that pain in the neck was most common at 65%, followed by the back, shoulder, and upper limbs at 59%, 52%, and 39% respectively. Of those with a work-related MSD, 12% required a leave of absence, practice restriction or modification, or early retirement.

It is known that the prevalence of musculoskeletal pain increases with years spent in the speciality. This could be attributed to the cumulative effect on the surgeon operating with a poor posture (Chatterjee et al., 1994). A good summary from Benjamin and Meisinger (2018) is presented in **Figure 1**.

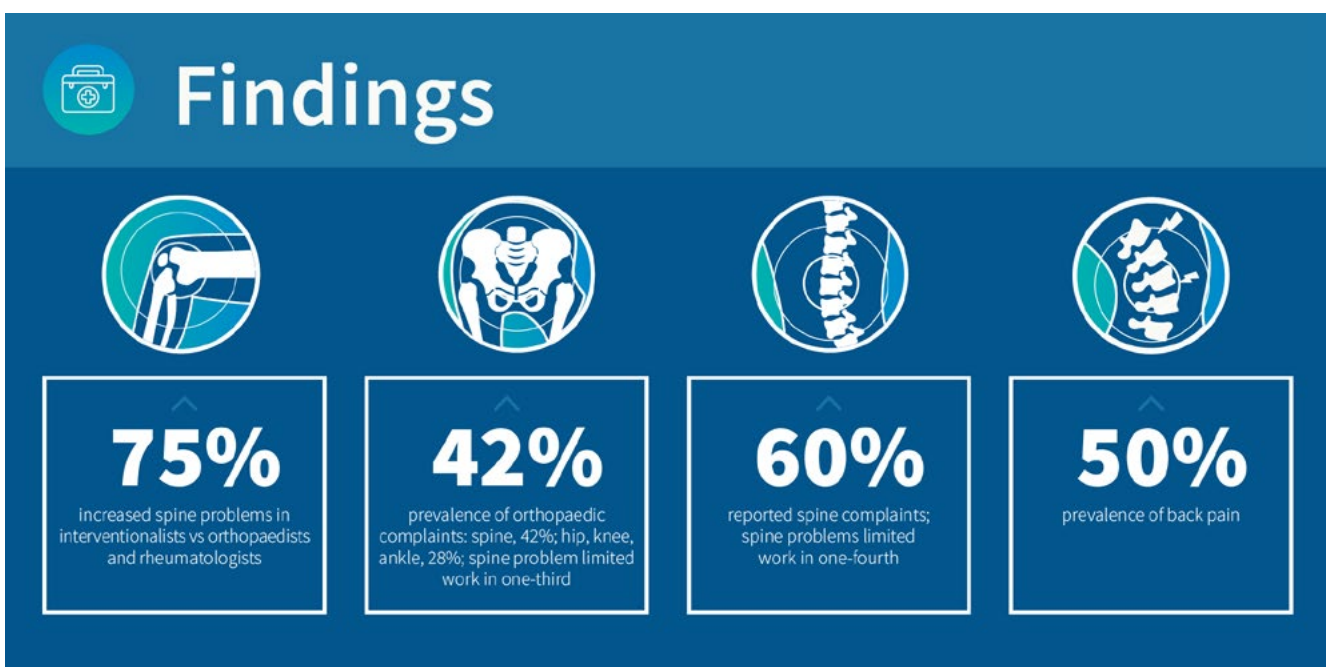
In the case of ISs, the equipment, awkward postures, non-ergonomic equipment, or working conditions can cause an increased occurrence of neck and back pain at least once a week in 50% to 60% of physicians. With almost 30% developing upper extremity injuries, a number that increased in the case of women.

While age and cumulative exposure to stress at work are risks for developing any of the problems mentioned earlier (Knutninen et al., 2021),

up to 80% of younger physicians may also develop this issue. This may be due to their limited experience and operational skills. However, a bias towards under-reporting discomfort may exist due to the general culture, or the survivor effect, whereby only healthier surgeons continue to operate (Cornelis et al., 2021).

In the case of the interventional cardiologists, Klein et al (2015) mentioned after a survey that 6.9% of operators have had to limit their caseload because of radiation exposure and 9.3% have had a health-related period of absence. Furthermore, 49.4% of operators reported at least one orthopaedic injury: 24.7% cervical spine disease, 34.4% lumbar spine problems, and 19.6% hip, knee or ankle joint problems. Age was most significantly correlated with cervical injuries: hip/knee or ankle injuries, and lumbar injuries.

Figure 1. Image below shows study findings from Benjamin & Meisinger, 2018. The data refers to the percentage of physicians tested.



Orthopaedic Complications in Interventionalists

In summary, these professionals experienced low back pain more than other hospital workers involved in bending, awkward static posture during operations and exposure to psychological stress for a long time. Characteristic factors are also,

- a) uncomfortable and repetitive movements of the upper limbs;
- b) long-lasting static head posture;
- c) stress and/or fatigue due to emotional distress, or anxiety.

Sleep disturbances, cognitive dysfunction, poor quality of life and pain behaviour were found to be significant factors involved in MSDs (Schlussel & Maykel, 2019).

According to Schlussel and Maykel (2019),

[the alteration in body mechanics when placed in constrained, asymmetric, and prolonged positions results in tissue stress and injury due to overexertion or imbalance.](#)

They also mentioned that improper working postures place muscles, tendons, and ligaments at risk. Abnormal loads and strains result in damage to bones, joints, and cartilage (Schlussel & Maykel, 2019).

Rosenblatt et al (2018) described how the three most common errors in ergonomic posture are excessive forward head position, sustained uncomfortable elevations, and asymmetrical weight-bearing. Furthermore, neurapraxia may occur because of nerve compression or ischemia. In more than 50% of surgeons, posture alone has contributed to their symptoms.

In addition to bad posture within the Angio suite, ISs must comply with recommendations to limit their radiation exposure to themselves. For example, using a lead apron. The lead apron is a heavy piece of radiation protection, weighing up to 7 kilograms, which should be worn by all staff working in this environment.

[This extra weight, however, can increase pressure in the lumbar or cervical areas \(Monaco et al., 2020\).](#)

ISs are often unaware of recommendations or guidelines designed to improve their comfort while operating. There is a significant lack of any formal ergonomic education, especially for minimally invasive procedures. Several modifiable risk factors can be adjusted in the operating room to provide a safer working environment. Strengthening, stability, and exercise programs directed by a trained therapist may also be employed to improve surgeons' musculoskeletal health (Schlussel & Maykel, 2019).

Ronstrom et al (2017), say that surgeon musculoskeletal pain has theoretical subsequent consequences, including poor outcomes, lost revenue, and surgeon burnout. A surgeon distracted by pain is unlikely to operate with maximum precision and focus. For example, over 50% of surgeons with musculoskeletal pain report that pain negatively affects their performance in the operating room.

ISs daily workloads can exert a physical strain on their bodies so it is not surprising that surgeons can be prone to pain, based on the types of equipment they frequently used. If not addressed appropriately, the nature and severity of pain can reduce the working lifespan of a surgeon.

Summary of Findings

To combat this cumulative effect of repeated physical exertion, it is fundamental that ISs interventions focused on equipment and behaviours.

The specialities described a gross lack of awareness and an unmet need for ergonomics education (AlQahtani et al., 2016). Insufficient knowledge in ergonomics certainly contributes to overloading the musculoskeletal system. Other main issues include a lack of appropriate devices to provide support to the operator, such as non-ergonomic surgical instruments, the lack of additional and/or mobile monitors, lack of auxiliary equipment such as ergonomic chairs or platforms supporting selected body segments of surgeon (Memon et al., 2016).

It is observed that occupational hazards pose a huge risk to ISs personal well-being. However, many pay little attention to their health, and neither do they seek the appropriate help when necessary. As such, the importance of early awareness and education alongside prompt intervention is duly emphasised. Increased attention to the health, economic, personal, and social implications of these injuries is thus essential for appropriate management and future prevention (Vijendren et al., 2016). The time has come to recognise and address them (Memon et al., 2016).

Holden (2020) indicates that the past decade has shown growing patient centredness in ergonomics research, health practices, and healthcare pertaining to patient posture. However, there remains a breadth of patient-centric issues that remain unexplored, such as patient comfort during short-medium procedures.

As patient safety is a constant priority for ISs, most of them neglect basic ergonomic principles during procedures as well as their own health, as already observed in surgery (Cornelis et al., 2021).

Finally, and unfortunately, little basic science research has been implemented to address and evaluate operating room ergonomics. The wide variety of operative techniques, disease locations, and patient position all alter the operating room environment. These factors contribute to how the operative field is visualised, the way surgical instruments are manipulated, and ultimately, surgeon stance and posture.

Therefore, it is necessary to explore new ways to improve both surgeon and patient posture, and experiences during procedures. As indicated by Cornelis et al, “To further optimize the performance and well-being of ISs, and meet the needs and demands of the patients and care, research in ergonomics is now mandatory in interventional radiology” (Cornelis et al 2021, pp. 2-3).

The prevalence and impact of MSDs on ISs practice requires increased awareness and prevention.

Improvements in interventional procedure ergonomics could alleviate these symptoms, improve productivity and performance, reduce time off work, extend careers, and ultimately improve patient care. Training programs focused on ergonomics are now mandatory in the design of medical devices and interventional suites.



The Objectives

The primary objective of this study is to evaluate the Adept Medical STARSystem under an ergonomic perspective, in the medical fields of interventional cardiology and neuroradiology. The secondary objective is to examine the ergonomic advantages for interventional specialists.

The device under evaluation

» Adept Medical's STARSystem: Use, purpose, and components

The STARSystem comprises of three components, used to assist a physician with radial artery access to perform transvascular interventions using guidewires, sheaths, catheters, etc.

The STARBoard is an arm supporting structure that presents the right or left arm, and radial artery access location to the physician. It comprises of multiple adjustable elements that allow it to be positioned in differing ways to suit the patient, physician, or procedure.

The STARTable is a horizontal working surface positioned closely to the radial artery of the patient's wrist, large enough to support the procedural equipment. It includes a radiation shield which is outside the scope of this study.

The STARSupport is an attachment that allows the patient's left arm to be lifted on to their stomach allowing the physician to maintain a right-side procedural working position.

Figure 2. Image below shows the Adept Medical STARBoard.



Figure 3. Image below shows the Adept Medical STARTable.



Figure 4. Image below shows the Adept Medical STARSupport.



Figure 5. Images below shows the Adept Medical STARSystem setup.



Methodology

A two-phase mixed-methods approach was used. Mixed method is a procedure for collecting, analysing, and/or integrating both quantitative and qualitative data at some stage of the research process within a single study to gain a better understanding of the research objective. This study design is most useful when the researcher wants to assess trends and relationships with quantitative data but also be able to explain the reason behind the resulting trend. Therefore, when used in combination, quantitative and qualitative methods complement each other and allow for more robust analysis, each taking advantage of their strengths.

The research is separated into two phases:

Phase 1: Quantitative – An ergonomics approach with a focus on Biomechanics and physiological methods.

Phase 2: Qualitative – Surveys and Interviews

» Phase 1: Quantitative Design using Biomechanics and Physiological evaluations

Participants

The subjects (n=4) chosen had no prior knowledge of or experience with the equipment. For research purposes, they received verbal instructions about the assembly of the device, and the body postures meant to replicate clinical activity, i.e., Without Clinical Posture (WCP) and With Clinical Posture (CP). The stretcher test subject was an adult simulation dummy.

Sampling

Opportunity sampling

Methods and instruments used

An ergonomics approach with a focus on Biomechanics and physiological methods.

Baropodometer

The baropodometric examination consists of the evaluation of foot pressures and their relationship with the distribution of body loads that are reflected in the base of support. Baropodometer 40x40 SensorMedica, Italy, 2020. Freestep software was used.

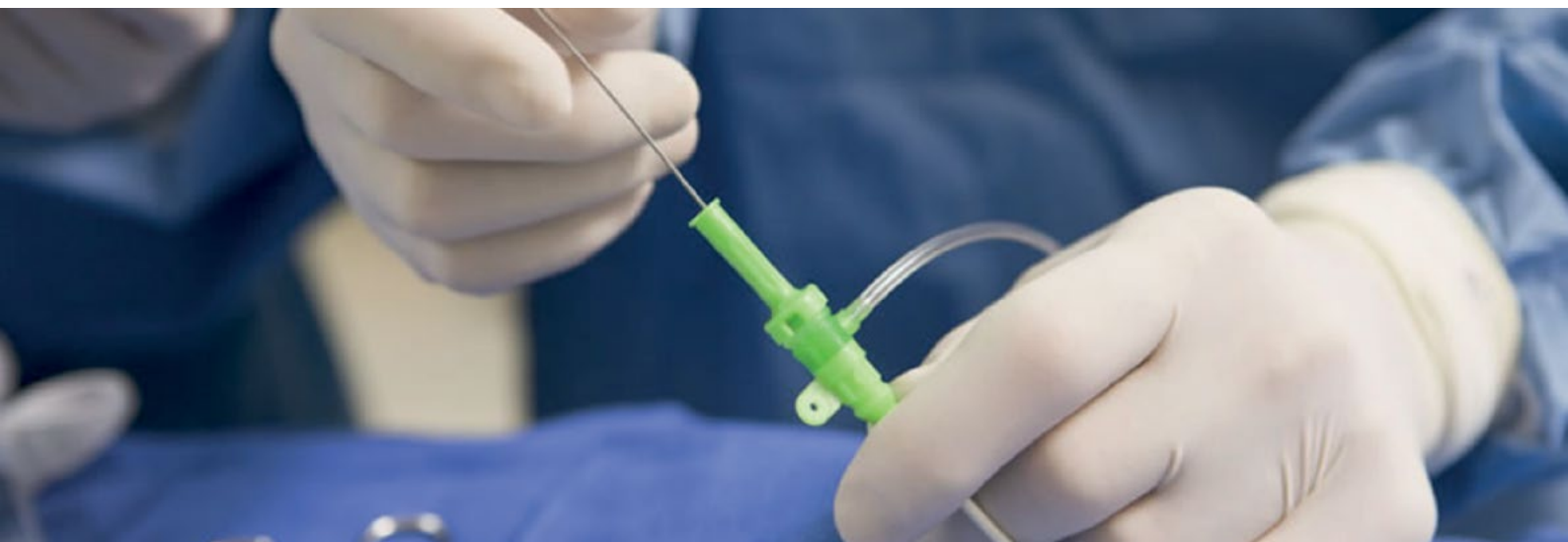
Oscillography

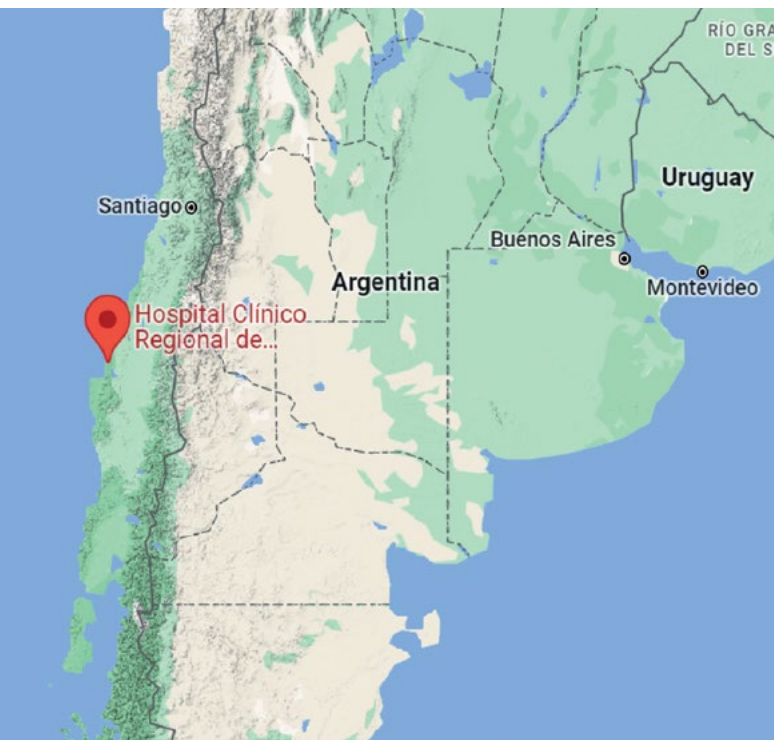
Oscillography studies the displacement of the plantar centre of pressure, which is influenced by the rest of the body. For the oscillography, the function designed for it in this same baropodometric device was used.

Kinematics

Kinematics is the study of motion of a system of bodies without directly considering the forces or potential fields affecting the motion.

- High speed video capture system:
 - ▷ It is used to capture images and videos in high speed, this to capture times and angles of body movements.
 - ▷ 330fps cameras, USB 3.0, systematized in Kinovea software were used.
 - ▷ Reflective markers: these were placed with double-contact tape at bone reference points commonly used in biomechanics studies: pinna, C7, acromion, radial head, ulnar styloid process, greater trochanter, posterior iliac spines.





Product testing location

This study was done in the practice and simulation laboratory for both the Ergonomics and Kinesiology Departments at Universidad de Concepción, between December 2021 and March 2022.

The research team replicated the environment used by medical and nursing teams which were known in the surgical areas of the medical centres which saw previous visits and interviews.

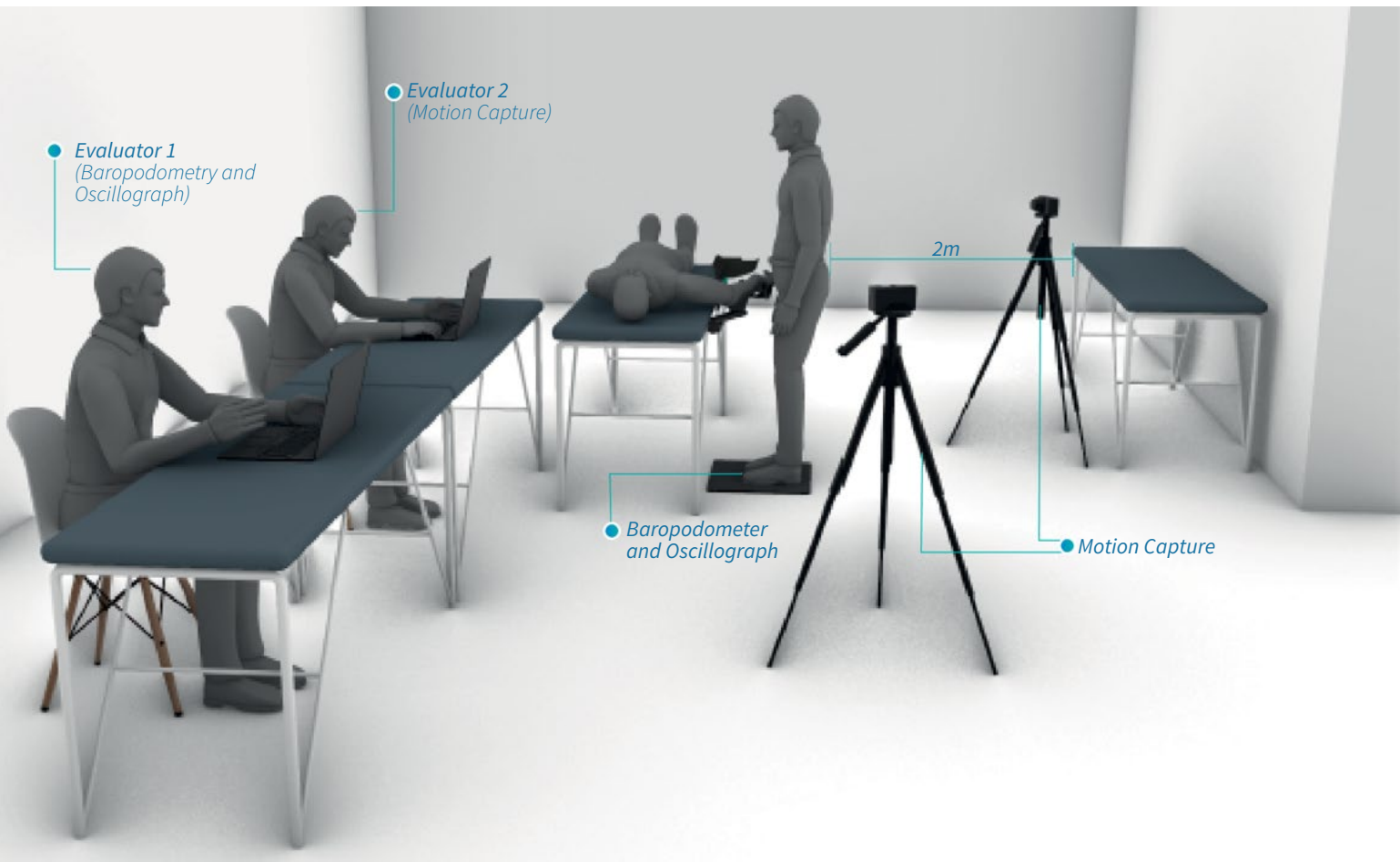
Variables

The following variables were considered for all studies:

- Basal
Standing naturally, feet shoulder width apart, arms down on sides, no STARSsystem. This is used to compare procedures with and without the STARSsystem devices. The initial evaluation is always done at Basal WCP.
- Reference
Standing, feet shoulder width apart, arms bent at 90 degrees – forearms parallel to the ground.
- With Clinical Posture (CP)
Standing, next to the bed, manipulating patient hand and forearm with both extremities. View is aimed at hands and forehead, simulating screens used in procedures. This position was used at the time the intervention was performed.
- Without Clinical Posture (WCP)
Standing, frontal view, arms down to the sides, feet shoulder-width apart.
- With STARSsystem (SS)
STARSsystem device used during research process. Refers to the use of all three components: the shoulder stabiliser (STARSupport), elbow and hand (STARBoard), and lateral table (STARTable).
- Without STARSsystem (WSS)
Refers to traditional patient positioning without the use of the STARSsystem device. Placed on the bed, generally in a semi-Fowler's position or supine decubitus: shoulder abducted, semi-flexed elbow, hyper-extended wrist supported by an external element in the dorsal position, held in place with a gauze-type band.

Figure 6. Product testing location. Regional Hospital Guillermo Grant Benavente (Public) in Chile.

Figure 7. Image below shows the simulated laboratory set up.



Protocols

The protocol used for each subject consisted of the following tests, always in the same order:

- Baropodometry
15-second evaluation time per test at 400 Hz of capture.
Data visualised in 2 and 3 dimensions.
 - ▷ Basal, WCP, WSS
 - ▷ CP, SS
 - ▷ CP, WSS
- Oscillography
60-second capture time. Data obtained via raw data, graphic oscillography representation, and frequency table.
 - ▷ Basal, WCP, WSS
 - ▷ CP, SS
 - ▷ CP, WSS
- Kinemetry
2D system located in lateral and posterior vision of evaluated subject, used to know angles and time.
 - ▷ Basal, WCP, WSS
 - ▷ CP, SS
 - ▷ CP, WSS

Figure 8. Image below shows the adult simulation dummy, positioned to use the STARSsystem.



The angles identified in the study were:

- Neck flexing angle
Evaluated between a vertical axis from the acromial marker and another in the earlobe.
- Column flexing-extension angle
Evaluated as the vertical projection taken from the greater trochanter marker and the acromion marker.
- Shoulder flexing angle
Angle formed by the markers located between the radial head and acromion.
- The time and motion study
Time studies were used to determine the duration of tasks occurring under specific conditions. Motion study evaluated movements and how they can improve work methods.

- Assembly of Adept Medical device
A 2D system was located in the lateral and posterior vision of the evaluated subject. A chronometer was used for the time study, with the start being the signal indicated by the evaluator, and the end, the moment when the device was fully assembled, and the patient was correctly located. 2 tests were done per user.

The STARSsystem was placed on a stretcher 2 meters from where it had to be set up. This is the area behind the camera on **Figure 8**.

Time was measured from when the operator surveyed was next to the starting point, 2 metres away from the simulation dummy, as seen on **Figure 7**.

» Phase 2: Qualitative Design through Surveys and Interviews

Participants

Interventional Radiology & Interventional Neuroradiology (Same area), Interventional Cardiology (Hemodynamics) (n=20)

Sampling

Opportunity sampling

Methods and instruments used

Different instruments were used to explore and better understand the results of the first phase.

- Survey
See **Figure 9**.

- Face-to-face Interviews
Interviews were conducted with representatives of the different medical centres to form an in-depth understanding of their work systems relating to function and operability.

- Data collection methods and sources
Medical doctors and nursing staff of the city of Concepcion, Chile were contacted for data gathering. A meeting was organised to discuss and present the questions and scope for evaluation. The interview process was carried out face-to-face and online in single or double sessions of 20 to 60 minutes during the months of November 2021 - January 2022.

Product testing location

Regional Hospital: Guillermo Grant Benavente (public)

Survey Design

A survey was designed with means of verification using a Likert scale.

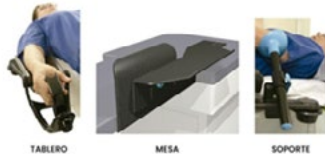
A categorical Yes/No response was added to each question asked. It was considered that the evaluation should allow open answers to be proposed. For this, observations were made that complemented the initial information obtained.

The survey was adjusted to answer the main objective of evaluating a medical device. This survey was accepted without comments on structure or content by the interviewees. At the end of each interview, an open question was added to obtain exclusive data based on the experience of each interviewee. For the survey questions, see **Figure 9**.

Figure 9. Image below shows the Survey Questions used.

Survey Questions

- 1) Indicate your position or specialty.
- 2) Indicate the procedure(s) performed.
- 3) Approximately how long did the procedure(s) last?
- 4) Select the STARSYSTEM components used according to the procedure(s) performed



- Tablero (STARBoard)
- Mesa (STARTable)
- Soporte (STARSupport)

- 5) Based on the use of each component, indicate if applicable.

	Tablero (STARBoard)	Mesa (STARTable)	Soporte (STARSupport)
Montaje rápido	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Fácil de regular	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cómodo de usar	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Se adapta a mi posición	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Tiene precisión	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ahorra mi tiempo	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Tablero (STARBoard)	Mesa (STARTable)	Soporte (STARSupport)
Quick Assembly			
easy to regulate			
comfortable to use			
suits my position			
help me with accuracy			
Save me time			

- 6) Did you remove any component of the STARSYSTEM during the procedure?*

	Si (YES)	No (NO)
Tablero (STARBoard)	<input type="checkbox"/>	<input type="checkbox"/>
Mesa (STARTable)	<input type="checkbox"/>	<input type="checkbox"/>
Soporte (STARSupport)	<input type="checkbox"/>	<input type="checkbox"/>

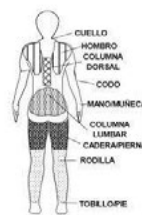
- 7) Did your position around the stretcher change? (Left Right)

- 7.1) If the previous answer is affirmative, indicate the component that bothered you when changing its location.

- 8) According to the procedure performed, how useful do you find the components of the STARSYSTEM?

	Muy útil (Very useful)	Poco útil (Not useful)	No lo usé (I have not used)
Tablero (STARBoard)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Mesa (STARTable)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Soporte (STARSupport)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- 9) What part of the body improves when using the STARSYSTEM?



Neck | Shoulder | Spine | Elbow |
Hand/wrist | Lumbar Spine |
Hip/legs | Knee | Ankle/foot

- 10) With what mark would you rate the safety in the use of the STARSYSTEM

Very Unsafe 1 2 3 4 5 6 7 Very Safe

- 11) With what grade would you rate the efficiency in the use of the STARSYSTEM

Very inefficient 1 2 3 4 5 6 7 Very efficient

- 12) With what note would you rate the comfort in the use of the STARSYSTEM

Very uncomfortable 1 2 3 4 5 6 7 Very comfortable

- 13) With what mark would you rate the appearance of the STARSYSTEM

Bad appearance 1 2 3 4 5 6 7 Good appearance

- 14) What did you like the most about STARSYSTEM? Please answer briefly.

- 15) What did you like the least about STARSYSTEM? Please answer briefly.

- 16) Would you recommend the STARSYSTEM?

Results

The first part refers to the results of phase 1 quantitative approach, separated into the results of the Baropodometry study, Oscillography, and Osteokinematics studies. The second part presents the results of phase 2 qualitative approach. Finally, a discussion about the findings, and the conclusion at the end.

Phase 1: Quantitative Results

» Baropodometry Study

Five baropodometric aspects were evaluated in the study of plantar pressure distribution. 1) Load distribution between left and right feet; 2) Load distribution between left forefoot and hind foot; 3) Load distribution between right forefoot and hind foot; 4) Maximal pressure point for left and right feet; 5) Surface difference.

The distribution of loads between left and right feet improves from 42/58% to 53/47%, **Figure 10**. This means that the load distribution between both feet is more symmetrical when using the STARSystem (SS), **Figure 11**. Even better than a non-surgical position at 40/60%. This has a positive impact, since it generates improved weight distribution in the spinal column and lower body, allowing for more comfort with prolonged bipedal activity.

Figure 10. Baropodometric Study (WCP, CP SS, and CP WSS) associated with distribution of loads between left and right feet.

Variables studied	Reference (ideal)	Basal Without Clinical Posture (WCP)	Clinical Posture With STARSystem (CP SS)	Clinical Posture Without STARSystem (CP WSS)
Left foot load distribution (percentage)	50	40	53	42
Right foot load distribution (percentage)	50	60	47	58

Figure 11. Image below shows pressure in both feet (gr/cm²), With Clinical Posture and With the STARSystem (CP SS).

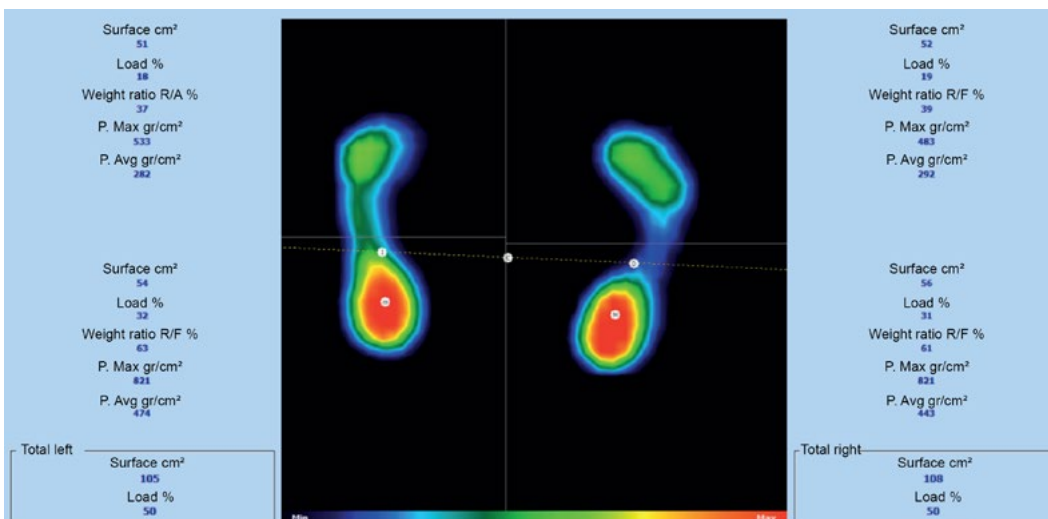
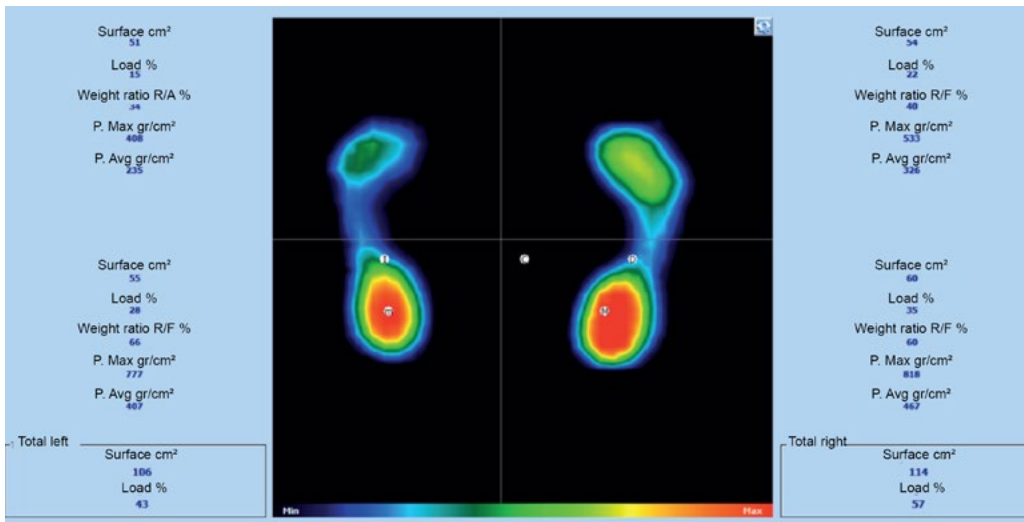


Figure 12. Image below shows pressure in both feet (gr/cm2), With Clinical Posture but Without STARSystem (CP WSS).



Regarding the load distribution between left forefoot and hind foot, we can see in **Figure 11**, **Figure 12**, and **Figure 13**, that load distribution has a positive physiological response and is better distributed when SS, 41/59 (%) versus WSS, 36.5/63.45 (%) for the left foot. WSS generated a load imbalance towards the left hind foot, also fomenting trunk rotation to compensate for this imbalance. In the case of right forefoot and hind foot, it's improved with SS, 52.5/47.5 (%) versus WSS, 44/56 (%).

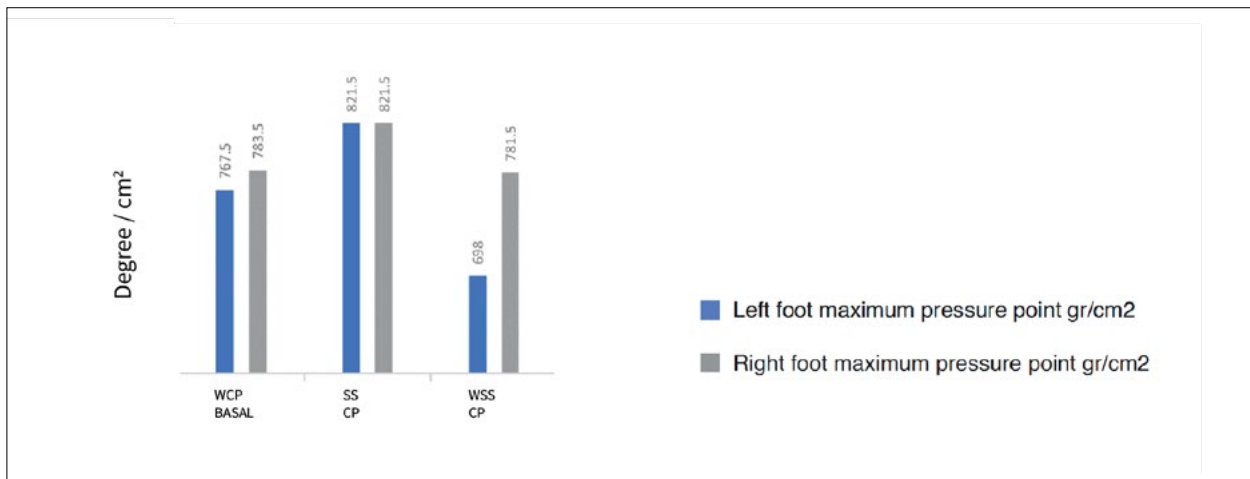
The right foot was the “agile” foot, making it possible to compensate for upper trunk movements. When SS was used, this presented a slight anterior load, which involves improvements in balance reaction, and thus a better control of the support base thanks to this lower support.

Figure 13. Baropodometric study, Reference (ideal), Basal Without Clinical Posture (WCP), Clinical Posture With STARSystem (CP SS) and Clinical Posture Without STARSystem (CP WSS) associated with load distribution between forefoot and hind foot expressed in percentage.

Variables studied	Reference (ideal)	Basal Without Clinical Posture (WCP)	Clinical Posture With STARSystem (CP SS)	Clinical Posture Without STARSystem (CP WSS)
Left forefoot load distribution (percentage)	45	27.5	41	36.5
Left hind foot load distribution (percentage)	55	72.5	59	63.5
Right forefoot load distribution (percentage)	45	43.5	52.5	44
Right hind foot load distribution (percentage)	55	56.5	47.5	56

The maximum pressure point for the left and right foot is a symmetrical value and denotes the correct distribution of loads between both extremities, see **Graph 1**. It is improved by 17.6%, from 698 gr/cm² to 821.5 gr/cm² for the left foot, and 5.1%, from 781.5 gr/cm² to 821.5 gr/cm², for the right foot.

Graph 1. Maximum pressure point found during the study across Basal, Basal WCP, CP SS, and CP WSS, for left and right foot.



Finally, when evaluating the surface difference, the STARSystem presents better plantar surface difference due to improved load symmetry. The difference was 7cm², 113 for the left foot and 106 for the right foot with the STARSystem. Without STARSystem the difference was 12cm², 114 for the left foot and 126 for the right foot, **Figure 14**.

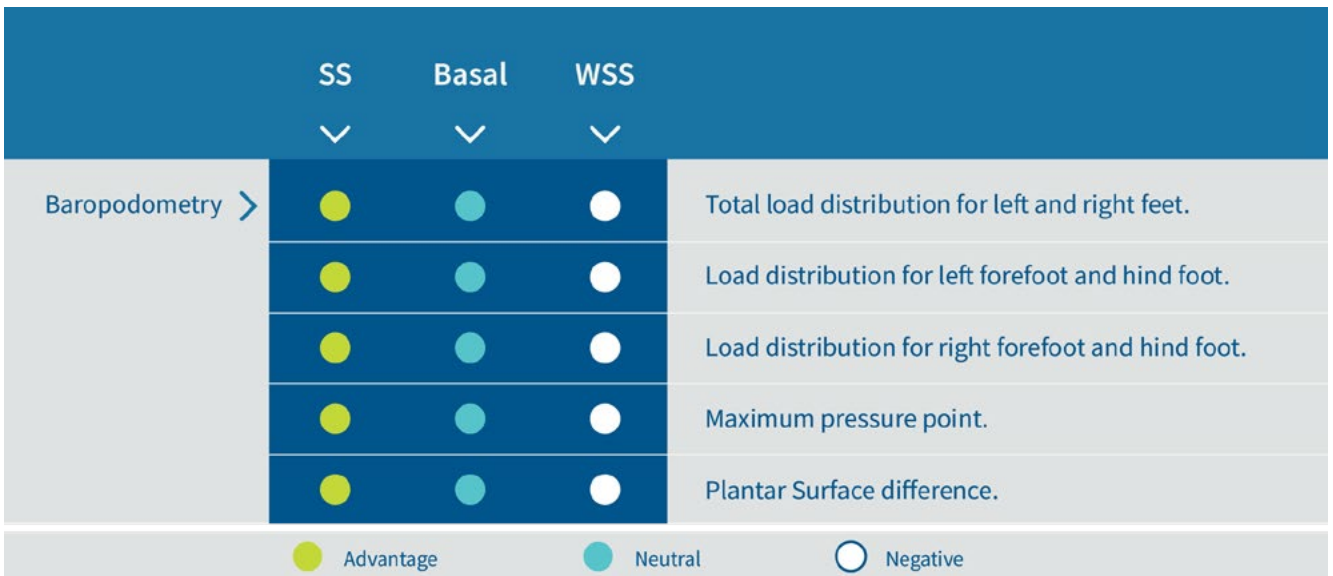
Figure 14. Baropodometric study related with left and right foot support area (cm²).

Variables studied	Basal Without Clinical Posture (WCP)	Clinical Posture With STARSystem (CP SS)	Clinical Posture Without STARSystem (CP WSS)
Left foot support surface area (cm ²)	100.5	113	114
Right foot support surface area (cm ²)	121	106	126

A summary of the baropodometry study, involving tests With Clinical Posture (CP), and implementation of the STARSupport (a shoulder support), shows improvement in the support base conditions; from better load distribution between both feet, better load distribution within the foot (forefoot and hind foot), and more equal pressure, **Figure 11** and **Figure 12**.

From a biomechanical viewpoint, these conditions improve musculoskeletal performance since they avoid any long-term trunk rotations or overloading posterior muscles such as the ischiotibial or gastrocnemius. This is relevant as a static uninterrupted posture will increase the risk of long-term back pain through a sustained isometric contraction of the lumbar extensor muscle group. Even with low-grade efforts of 2% of maximum voluntary muscle contraction, this results in decreased tissue oxygenation and risks subsequent injury. Further injury occurs as muscles and tendons accumulate lactic acid and toxins secondary to the compression of veins and capillaries when maintained in these static positions.

Figure 15. Below is the test result summary from the baropodometry measurements.



>> Oscillography

Four aspects were evaluated for the Oscillography measurement. These were: 1) Sampling frequency; 2) Postural circumference length; 3) X and Y oscillation delta; and 4) Median speed.

The sampling frequency observed when using STARSsystem was identical to the Basal. This shows the decreased neuromusculoskeletal workload to control the position, **Graph 2**. Humans are healthier when we are in low frequencies. High frequencies mean stress or central nervous system alterations. The lower frequency shown in **Graph 2** indicates a positive effect.

The postural circumference length is a representation between the total displacement of the person and the time taken to do the test. When using STARSsystem there was greater total displacement, **Figure 16**. This fact demonstrates that subjects, despite having lower frequency, had a greater overall run. This indicates improved quality and quantity of movement for the same given action. The subject covered more distance,

indicating a better corporeal response, since the postural adjustments are more precise.

Graph 2. Sampling frequency Basal Without Clinical Posture (WCP), Clinical Posture With STARSsystem (CP SS) and Clinical Posture Without STARSsystem (CP WSS).

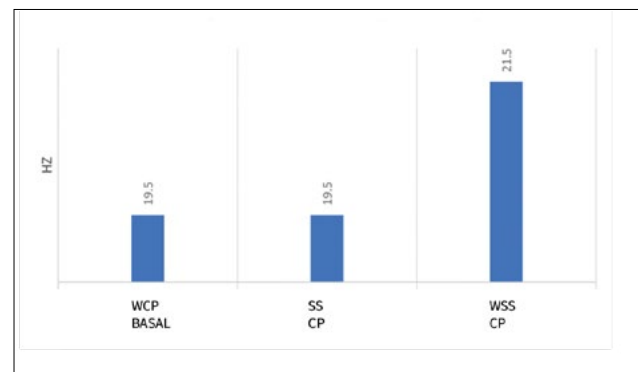
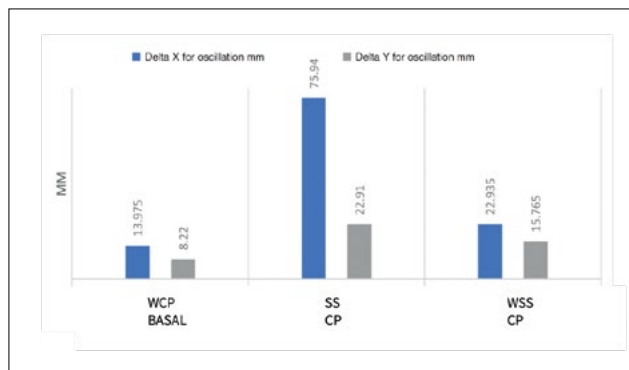


Figure 16. Postural circumference length Basal Without Clinical Posture (WCP), Clinical Posture With STARSsystem (CP SS) and Clinical Posture Without STARSsystem (CP WSS).

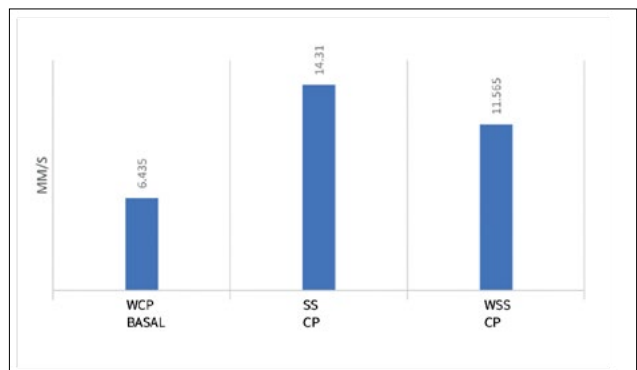
Bipedal oscillography (60 s)	Basal Without Clinical Posture (WCP)	Clinical Posture (CP) With STARSsystem (SS)	Clinical Posture (CP) Without STARSsystem (WSS)
Postural circumference length < 300 mm	381.5	813	688

The evaluation of the oscillation delta, in X and Y, SS indicates Delta X is related to the amount of movement in the frontal plane, i.e., lateral movements. For SS there was greater mediolateral displacement than WSS, **Graph 3**. This indicates greater displacement and lateral reach of the upper body, which is reflected in the support base. SS allows for more, and better lateral displacement than WSS. This would reflect the comfort of the equipment, which allows the physician to “move” more naturally with SS while doing procedures.

Graph 3. Evaluation of the oscillation delta Basal Without Clinical Posture (WCP), Clinical Posture With STARSystem (CP SS) and clinical posture Without STARSystem (CP WSS).



Graph 4. Evaluation of the median speed, delta Basal Clinical Posture (WCP), Clinical Posture With STARSystem (CP SS) and Clinical Posture Without STARSystem (CP WSS).



In the Oscillography study, the median speed refers to the median velocity in mm/s reached throughout the test. For the use of SS, the value was greater than for WSS. This is in relation to the greater displacement achieved with SS.

As a conclusion of the Oscillography study, the STARSystem device generates a greater lateral and anteroposterior run of the mass center, although stronger in the lateral aspect, in musculoskeletal terms, it means less work for the hips and ankles (frontal plane) and less work for the knees (sagittal plane). This is in contrast with WSS, where while the general run is shorter, the largest displacement is anteroposterior, which overloads the knee joints, spinal column and posterior muscles including the paravertebral, ischiotibial, gastrocnemius, etc.

Figure 17. Below is the test result summary from the oscillography measurements.

	SS	Basal	WSS	
Oscillography >	●	●	●	Oscillation delta.
	●	●	●	Ellipse long and short rope.
	●	●	●	Median velocity.
	●	●	●	Median oscillation.
	● Advantage	● Neutral	○ Negative	

» Kinematics

These aspects were evaluated for the kinematics measurement.

1. Installation time; 2. Neck flexion; 3. Shoulder flexion, and 4. Trunk flexo-extension.

The table below in **Figure 18** compares installation time between the 1st and 2nd time. For all tests, the second attempt was always faster than the first. On average, the full STARSsystem assembly took around 1 minute. User assembly time was improved over time. The STARSsupport and STARBoard assembly took on average 41 seconds, and the STARTable took 22 seconds.

Figure 18. Installation time for STARSsystem, STARSsupport and STARBoard.

Test	Average (hh:mm:ss)	1st time (hh:mm:ss)	2nd time (hh:mm:ss)	Difference from 1st to 2nd (hh:mm:ss)
Installation time for STARBoard and STARSsystem	0:00:41	0:00:50	0:00:32	0:00:18
Installation time for STARTable	0:00:22	0:00:24	0:00:21	0:00:04
Total time	0:01:04	0:01:15	0:00:52	0:00:23

Associated with neck flexion, **Graph 5** and **Figure 19**, shows that neck flexing with the STARSsystem is 20.6° less. This involves lower overloading of the muscles which extend the neck, perform deep neck flexing, and the stabilising complex

for the shoulder joint, along with allowing for better neck rotation. When head posture is maintained too far forward, it results in tension and pain in the upper torso, ultimately causing degenerative changes in the cervical spine and shoulder girdle.

Graph 5. Angular displacement. Shown across SS and WSS, in relation to shoulder flexing, trunk flex-extension, and neck flexing.

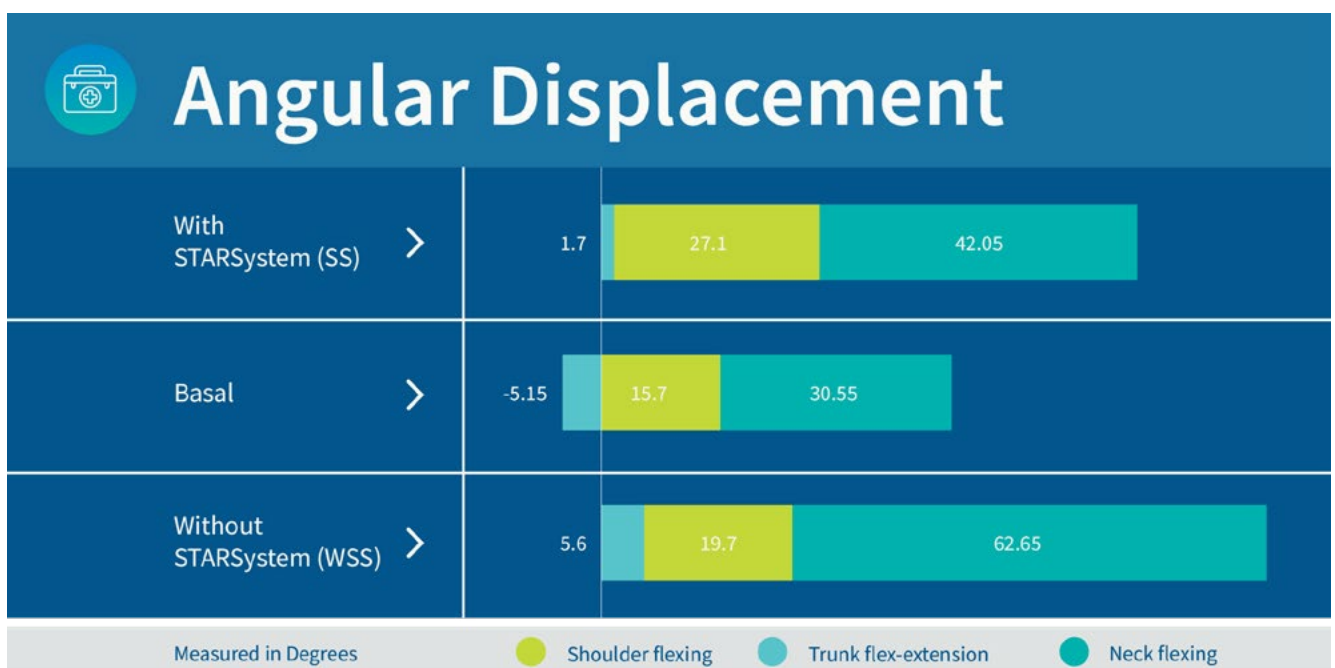


Figure 19. Angular variable. Difference(°) between delta Basal Without Clinical Posture (WCP), Clinical Posture With STARSystem (CP SS) and Clinical Posture Without STARSystem (CP WSS) for Neck flexion, Shoulder flexion, and Trunk flexo-extension.

	Basal	SS	WSS
Angular variables	WCP	CP	CP
Neck flexing °	30.55	42.05	62.65
Trunk flexing-extension	-5.15	1.7	5.6
Shoulder flexing	15.7	27.1	19.7

For every inch that the head moves forward in space, the relative weight on the spine increases by 10% (approximately 4.5 kilos), resulting in an increased demand on the joints supporting the head. Regrettably, many of these positions are performed subconsciously from poor habits that are adopted over time. Failure to become aware of these positions increases the workload placed on the spinal column, and microtrauma accumulates in the tissue.

Shoulder flexing was 7.4° greater with STARSystem, **Graph 5** and **Figure 19**. This is understandable, since the lateral table and hand support allow for better displacement to manipulate the subject and the surgical toolkit. Since there is a greater active shoulder range, a lower neck and spinal range is possible.

Finally, trunk flexo-extension with the STARSystem is almost zero (1.7°) compared to the almost 6° present when the operator is WSS, **Graph 5** and **Figure 19**. This allows for better lower body work, and less work in the abdominal core. Due to the force of gravity, improper posture will accentuate cervical

lordosis and thoracic kyphosis to maintain lumbar lordosis. This effect on the spinal column results in altered biomechanical loading on muscles, ligaments, and joints that can trigger long-term injuries. This abnormal compensation in position may ultimately result in a decrease in truncal height (Schlussel, 2019).

The frequent uncoordinated and repetitive motions of the upper extremities and prolonged static head and back postures inflict unnecessary stress on the spinal column. Improper head and neck angles result in cervical discomfort and have also been associated with posture fatigue. Numbness, stiffness, and pain in the shoulders, neck, arm, and wrists have been reported by 8 to 18% of surgeons.













Finally, using CP SS allows for an angular configuration which is more ergonomic for the neck, shoulder and spinal column, **Graph 5** and **Figure 20**. This decreases postural overload and muscle fatigue associated with static work conditions. Correct STARSystem use helps the medical team to improve their health status, prevent musculoskeletal pathologies, and have better performance within clinical processes.

Figure 20. Below is the test result summary from the osteokinematics measurements.



The results of the different tests across Baropodometry, Oscillography, and Osteokinematics, show that using the STARSystem has advantages for the user, **Figure 21**.

Figure 21. Summary of tests done With Clinical Posture and STARSystem (CP SS), Basal Without Clinical Posture (WCP), and With Clinical Posture Without STARSystem (CP WSS).

	with STARSystem (SS) ∨	Basal WCP ∨	Without STARSystem Medical (WSS) ∨	
Baropodometry >				Weight distribution
Oscillography >				Balance
Osteokinematics >				Angles and velocity
	 Advantage	 Neutral	 Negative	

Phase 2: Qualitative Results

>> Perception of Component Use

Below are the results of the survey in the Hemodynamics Department in Concepcion Regional Hospital.

Number of Specialists testing the devices

- 3x Medical Technologists
- 6x Cardiologists
- 3x Neuroradiologists
- 1x Hemodynamist
- 2x Nurses
- 1x Higher level Nursing Technician

Type of Procedures Performed

The average time across all these procedures is 45 minutes. Complication, 4 hours. And quick interventions, 20 minutes.

- 7x Coronary angiographies
- 6x Angioplasties
- 3x Percutaneous valve implants
- 1x Right catheterisation
- 1x Close birth defects
- 1x Brain angiograms

Figure 22. The figures below indicate the average times across the different procedures.



Timings of Procedures Performed

The average time across all these procedures is 45 minutes. Complications, 4 hours. And quick interventions, 20 minutes, **Figure 22**.

Perception of the device and perceived complexity

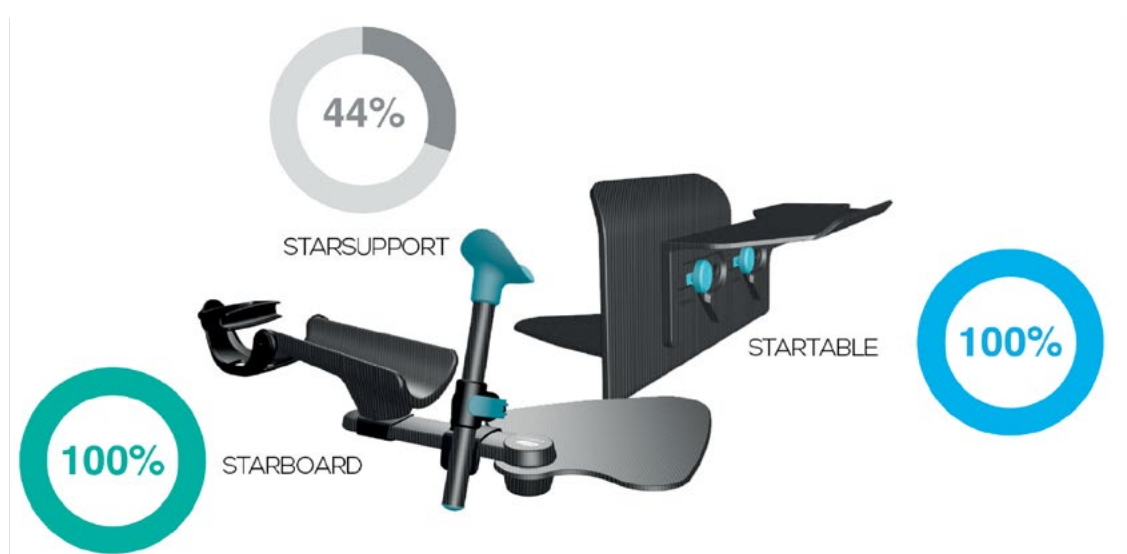
100% of the specialists that tested the devices liked both STARBoard and STARTable, **Figure 23**, with 100% saying they would recommend it.

Listed are the features the participants liked best about the STARSsystem, STARBoard and STARTable.

- The STARTable is very useful in procedures for leaving operating materials on.
- The patient does not pronate the wrist when using the STARBoard.
- The STARBoard improves the position to operate by radial.

44% of the specialists like the STARSsupport. They mentioned that it was seen as the most complex to use. However, 100% recognise that is a better option than what they have today.

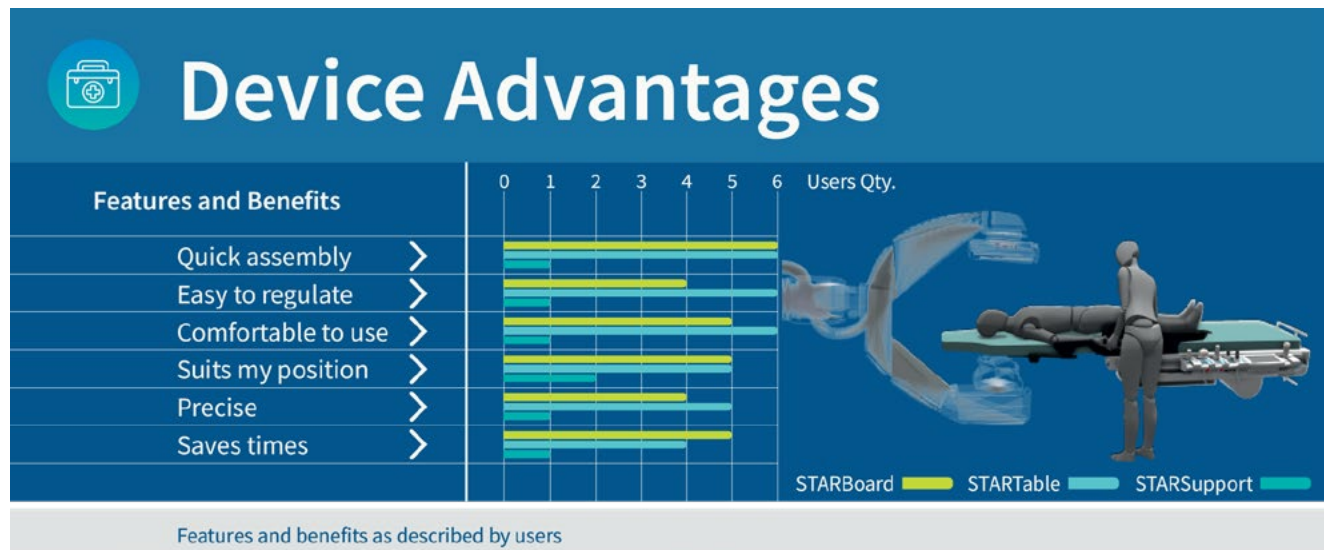
Figure 23. The figures below indicate the percentage of participants who liked the specific STARSsystem component tested.



Shows the percentage of users that liked the specific STARSsystem component tested.

Other advantages of the STARSsystem as mentioned by the specialists include: quick to assembly, easy to regulate, comfortable to use, suits the position, improves the precision, and saves time, **Graph 6**.

Graph 6. This graph shows the features best liked about the devices, as determined by the participants.



Even though biological hazards were not part of the survey, nor the study objectives, users have reported that using STARSsystem led to less patient blood loss, especially at the start of the intervention. This is relevant as by virtue of their profession, surgeons have the greatest risk of exposure to blood-borne pathogens, given their numerous encounters involving the use of sharp instruments on patients. The blood-borne pathogens that are most involved in occupational transmission are hepatitis B virus, hepatitis C virus, and human immunodeficiency virus. The typical general surgeon experiences 0.8 injuries per 100 hours of operating time, or 210 injuries throughout the course of a career, resulting in a 6.9% lifetime risk of contracting hepatitis C and a 0.15% lifetime risk of developing HIV.

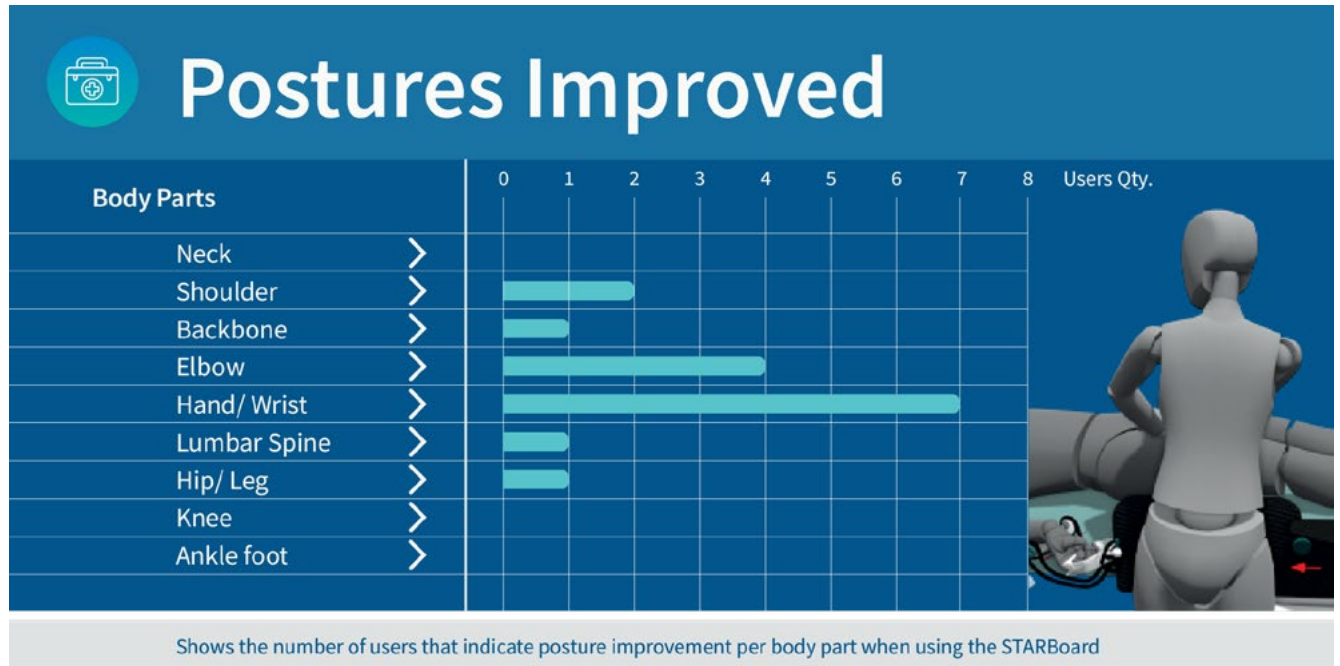
Figure 24. The below image shows the simulation dummy with the STARSsystem setup.



Body parts that improved posture with the STARSsystem

The specialists that tested the devices mentioned that their hand/wrist, elbow, and shoulder are the main areas that improved using the STARSsystem, **Graph 7**. They also said that the patients appear to have significantly improved postures on their hand, wrist, elbow, and shoulder when using the STARBoard.

Graph 7. This graph shows body parts with improved postures when using the STARSsystem, as determined by the participants.



Discussion

Different studies that were mentioned at the beginning of this research indicate high estimates of work-related MSDs, compounded poor practices that affect an operator's ability to continue practicing, and a high demand for interventions with poor ergonomic solutions. These findings are worrisome in the context of an impending shortage of surgeons and interventionalists and the large public investment required to train such specialists. Studies demonstrate high estimates of burnout, depression, and attrition among physicians during and after training. When considered together, these data suggest that some aspects of medical culture may be detrimental to the mental, emotional, and physical health and career longevity of physicians, and subsequently may be detrimental to the volume and quality of patient care.

Beyond these points, ergonomic research in the field of ISs remains limited. Studies state that surgeons and interventionalists lack awareness of applied ergonomics recommendations. Basic ergonomic studies also indicated that support of the shoulder, elbow, and wrist significantly improves the accuracy, task performance and surgeons' comfort. Therefore, ergonomics must be integrated in the interventional radiology workplace. It is apparent that the ISs community lacks cohesive occupational safety standards designed to minimise work-related musculoskeletal injuries. Based on our test results, the STARSystem could be a great element to use during ISs interventions.

Like workers in other occupations, interventionalists have a right to practice their profession in a safe environment. Their health and career longevity rely on the commitment to bringing awareness and action to this issue.

» Conclusion

Under this ergonomics evaluation, one can conclude that the use of the STARSystem in interventional procedures does improve the occupational hazards of interventional cardiology and neuroradiology, offering a positive impact on posture, health, procedural performance, and preventing musculoskeletal pathologies.

The STARSystem offers:

- Better ergonomic positioning for specialists under both quantitative and qualitative points of view. With the added benefit of the patient also having their positioning improved.
- Better load distribution on the feet: The distribution of load is more symmetrical between the left and right foot, generating improved weight distribution on the spinal column and lower body, allowing the operator to stand for an increased period of time without discomfort. Maximum pressure points were improved by 17.6% for the left foot, and 5.1%, for the right.
- Better quantity and quality mobility for the operator. The greater mediolateral displacement measured with SS indicated a greater reach of the upper body, reflecting the comfort and security provided by the device. This allows the operator to move more freely and naturally, with reduced muscular stress.
- Lowered energy cost through a more efficient static balance, decreasing the neuromusculoskeletal workload to control the clinical posture.
- Reduced assembly time compared to traditional systems. The STARSupport and STARBoard can be assembled in 41 seconds on average, while the STARTable can be assembled in 22 seconds on average.
- Improved neck rotation, with neck flexing at 20.6° less, meaning a lower overburdening of the muscles that extend the neck, perform deep neck flexing, and stabilise the shoulder joint.
- Almost zero trunk flexo-extension which leads to better lower body work, and reduced work in the abdominal core.
- Increased safety for the operator, through the additional support of ergonomic devices, and easy access to operating tools.
- Improved precision during the different procedures: 31% of specialists indicated precision with the STARTable, 25% of specialists with the STARBoard, and 6% of specialists with the STARSupport.
- Improved posture for the specialists' hand/wrist as indicated by 43% of specialists tested.
- Reduced patient blood loss, especially at the start of the intervention.

» Final recommendation

A better knowledge of ergonomics can considerably reduce MSDs and must be implemented early in the career. The implementation of an ergonomics program in the ISs course appears valuable at the earliest phases of medical training. However, the ergonomics of surgery need not solely rely on equipment, as there are several measures surgeons can employ in the operating room that will protect their health. For example, alternating surgeon participation during complex and lengthy operations allows for periodic rest breaks. Changing posture, reduction in the time in the interventional room, and a reduction in the overall caseload may reduce the occurrence of MSDs.

When possible, sitting is better than standing from an ergonomic perspective. Routine 10-minute breaks every 2 hours where the operating team and surgeon leave the room, and micro breaks of two minutes every 20–40 minutes may be considered. Results demonstrated that micro-breaks did not increase operative duration, disrupt the workflow of the procedure, or cause any distractions. Surgeons reported a 34% improvement in mental focus and a 57% improvement in physical performance, and following this investigation, almost 90% of surgeons wanted to incorporate micro-breaks into their practice.

Finally, practical recommendations such as physical exercise training to develop strength, resistance, coordination, and stabilisation in ISs might be noteworthy to prevent MSDs. These exercises preserved flexibility and involved neck flexion, extension, and lateral rotation; backward shoulder roll and chest stretch; upper back and hand stretch; low back flexion and extension; gluteus maximus contractions; and foot and heel lifts for lower extremity and ankle stretches. Encouraging results were demonstrated with an improvement in both physical and mental performance, with no impact on case duration.



References

1. Moray N. Culture, Politics and Ergonomics. *Ergonomics*. 2000;43:858-68.
2. Buckle P, Clarkson PJ, Coleman R, Ward J, Anderson J. Patient safety, systems design and ergonomics. *Appl Ergon*. 2006;37(4):491-500.
3. Memon AG, Naeem Z, Zaman A, Zahid F. Occupational health related concerns among surgeons. *Int J Health Sci (Qassim)*. 2016;10(2):279-91.
4. Edgar M, Mansfield A, Thomson J. Surgeons under stress (II). Update following the college seminar/workshop on pastoral care. *Ann R Coll Surg Engl*. 2000;82(3 Suppl):87-8.
5. Schlussek AT, Maykel JA. Ergonomics and Musculoskeletal Health of the Surgeon. *Clin Colon Rectal Surg*. 2019;32(06):424-34.
6. Ronstrom C, Hallbeck S, Lowndes B, Chrouser KL. Surgical Ergonomics. In: Köhler TS, Schwartz B, editors. *Surgeons as Educators : A Guide for Academic Development and Teaching Excellence*. Cham: Springer International Publishing; 2018. p. 387-417.
7. Vijendren A, Yung M, Sanchez J. Occupational health issues amongst UK doctors: a literature review. *Occup Med (Lond)*. 2015;65(7):519-28.
8. Vijendren A, Yung M, Sanchez J, Duffield K. Occupational musculoskeletal pain amongst ENT surgeons - are we looking at the tip of an iceberg? *J Laryngol Otol*. 2016;130(5):490-6.
9. Knuttinen M-G, Zurcher KS, Wallace A, Doe C, Naidu SG, Money SR, et al. Ergonomics in IR. *Journal of Vascular and Interventional Radiology*. 2021;32(2):235-41.
10. Cornelis FH, Razakamanantsoa L, Ben Ammar M, Lehrer R, Haffaf I, El-Mouhadi S, et al. Ergonomics in Interventional Radiology: Awareness Is Mandatory. *Medicina*. 2021;57(5):500.12. Benjamin JL, Meisinger QC. Ergonomics in the Development and Prevention of Musculoskeletal Injury in Interventional Radiologists. *Techniques in Vascular and Interventional Radiology*. 2018;21(1):16-20.
11. Chatterjee A, Ryan WG, Rosen ES. Back pain in ophthalmologists. *Eye*. 1994;8(4):473-4.
12. Klein LW, Tra Y, Garratt KN, Powell W, Lopez-Cruz G, Chambers C, et al. Occupational health hazards of interventional cardiologists in the current decade: Results of the 2014 SCAI membership survey. *Catheterization and Cardiovascular Interventions*. 2015;86(5):913-24.
13. Monaco MGL, Carta A, Tamhid T, Porru S. Anti-X Apron Wearing and Musculoskeletal Problems Among Healthcare Workers: A Systematic Scoping Review. *International Journal of Environmental Research and Public Health*. 2020;17(16):5877.
14. AlQahtani SM, Alzahrani MM, Harvey EJ. Prevalence of musculoskeletal disorders among orthopedic trauma surgeons: an OTA survey. *Can J Surg*. 2016;59(1):42-7.
15. Holden RJ, Cornet VP, Valdez RS. Patient ergonomics: 10-year mapping review of patient-centered human factors. *Applied Ergonomics*. 2020;82:102972.

