Design and Evaluation of a New Harnessing System for Body-Powered Prostheses

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Design and evaluation of a new harnessing system for body-powered prostheses

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Abstract

Body-powered prostheses are active upper limb prostheses that utilize harnessing of body movements to grasp objects. The high rejection rates (up to 45%) of body-powered prostheses indicate that users are not satisfied with their prostheses. One of the most prominent problems is the discomfort experienced while wearing and operating the prosthesis. In particular, the discomfort is associated with the current harnessing system, the shoulder harness, which causes pain in the axilla area. The goal of this study is to design a new harnessing system for trans-radial amputees, which improves the comfort of wearing and operating the prosthesis without compromising the users ability to operate the prostheses. A new harnessing system is presented and evaluated in comparison with the standard 'Figure of 9 harness'. An experiment was conducted where 20 able-bodied people tested both systems while performing four tasks that evaluated different functional and comfort aspects of the harnessing systems. The results show that the comfort was significantly improved in all tasks with the new design and all functional requirements were met.

Clinical relevance

Improving comfort and prostheses acceptance for body-powered prostheses users.

Keywords

Body-powered, prostheses, harnessing movements, harness, comfort.

Introduction

Body-powered prostheses are a type of active upper limb prostheses that enable amputees to replace part of the function of the missing limb. Currently, body-powered prostheses consist primarily of four parts; a harnessing system, a socket, a Bowden cable and a terminal device (see Figure 1). The harnessing system harnesses the user's body movements, which causes pulling of the Bowden cable and as a result the terminal device opens (voluntary opening (VO)) or closes (voluntary closing (VC)). The harnessing system is usually in the form of a shoulder harness, where the 'Figure of 9' harness is the most commonly used in Europe¹.

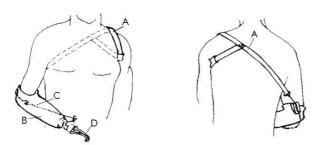


Figure 1. Schematic figure of a conventional body-powered prosthesis². (A) shows the harnessing system, (B) the socket, (C) the Bowden cable and (D) the terminal device.

The main advantage that body powered prostheses have over the other types (see Appendix I) is that they provide force and displacement feedback. By harnessing body movements, the user can use feedback information from proprioception as well as cable excursion and tactile feedback from the harness and socket. These types of feedback enable the user to estimate the opening of the terminal device and the magnitude of the forces exerted³. This feedback is not available in the other type of active prosthesis, the MyoElectric prosthesis. Furthermore, since body-powered prostheses don't require a motor, they are more lightweight and faster than MyoElectric prostheses.

Despite the advantages that body-powered prostheses have, the rejection rate is still high, or up to 45%⁴. The cause for these high rejection rates have been associated with discomfort coming from the axilla loop of the shoulder harness^{5, 6}. In particular, the harness has been found to cause excessive pressure in the axillary area^{7, 8}, skin irritations^{7, 8}, restricted movements^{9, 10} and wear of clothes¹¹. Furthermore, improving the comfort of the harness is ranked high amongst body-powered prosthetic users^{8, 12}. These complaints are truly valid, since achieving sufficient pinch forces in the terminal device requires high activation forces¹³. When producing high activation forces, the pressure and shear on the skin causes discomfort in the

axilla area. Additionally, the harness puts pressure the radial nerve and the axillar artery in the axilla region. Too much pressure on the artery can cause reduced blood flow to the limb and prolonged compression on the radial nerve can cause neuropathy. That results in weakness in certain movements and loss of sensation in parts of the arm and hand¹⁴.

The results from a questionnaire made for this study (see Appendix III) confirms that discomfort coming from the shoulder harness is one of the biggest disadvantage of body-powered prosthesis, particularly in the axilla region. Besides the discomfort, the hygiene and donning/doffing the harness is a matter of complaint both in the users and specialists opinions. Two of these three most common problems with the harness, the discomfort and the hygiene, originate from the fact that the harness is located in the axilla region. The axilla region is an area that usually does not experience a lot of pressure and it is one of the main sources of sweat. All this suggests that in order to increase usage of body-powered prosthesis, the pressure in the axilla area should be eliminated or at least decreased.

To decrease the pressure in the axilla area it is either necessary to reduce the required activation forces or change the harnessing system such that it decreases or eliminates the pressure on the axilla area. The Delft Cylinder Hand is a new terminal device that is already able to deliver sufficient pinch forces using lower activation forces than currently available prostheses¹⁵. Some alternative harnessing systems already exist as well (see Appendix II). The Axilla Bypass ring redirects the pressure usually placed on the axilla, to the deltopectoral groove and the scapula¹⁶. The T-shirt/harness combination distributes the pressure by utilizing stretch in the opposite direction of the harness and in that way decreases discomfort in the axillar region¹⁷. The Anchor System and the Wilmer Elbow Control system are harnessing systems without an axilla loop. In the Anchor System, a base is glued to the skin on the amputated side and the Bowden cable is directly connected to the base¹⁸. In the Wilmer Elbow Control, the opening of the hand mechanism is controlled with flexion and extension of the elbow³.

Further research is necessary in order to understand why these alternatives are not commonly used, but a questionnaire (Appendix III) made for this study indicates that the Axilla bypass ring and T-shirt/harness combination are difficult to position or fixate and that the Anchor System causes skin irritations for some users.

The problem is that body-powered prostheses users are not satisfied with their prostheses. One of the most prominent problems is the discomfort caused by the axilla loop of the harness. Even though alternative methods for harnessing body movements have been introduced, the 'Figure of 9' harness is still most commonly used. Therefore it is safe to assume that there is still room for

improvements and a real need for a new and more comfortable harnessing method.

The goal of this study is to design a harnessing system for trans-radial amputees that improves the comfort of their prosthesis compared to the standard 'Figure of 9' harness. While improving the comfort, the ability to operate the prosthesis should not be compromised. The user should still be able to deliver sufficient activation forces in order to operate the terminal device as well as when using the 'Figure of 9' harness.

To achieve the goal of the study, literature was consulted. To cover gaps in literature, a questionnaire was made and sent to specialists in the field of upper limb prosthetics. The results from the literature and the questionnaire were presented in the introduction and used to come up with requirements for a new harnessing system that achieve the goal of this study. Concepts were developed and evaluated with respect to the requirements and finally, the most promising concept was evaluated and compared to the most common harnessing system available.

Method & Materials

Design criteria

The design criteria are split into 1) comfort requirements, 2) functional requirements and 3) various requirements. Additionally, 4) wishes regarding cosmetics are included. When referring to the requirements, 'req.' is used for short, together with a number and a letter.

I. Comfort requirements

Most importantly, the comfort of wearing and operating the prosthesis should be increased in various circumstances with the new harnessing system. These circumstances must include the following activities:

- a. Performing horizontal movements
- b. Performing vertical movements
- Reaching over the head
- d. Reaching to the floor
- e. Holding slippery or heavy objects (using high forces)
- f. Holding objects for an extended period of time
- g. Performing fast motions
- h. Donning/doffing

2. Function requirements

While increasing the comfort of the harnessing system, the ability to operate the prosthesis must not be compromised. The user must be able to:

a. Create sufficient activation forces in order to open/close all the commercially available

prosthesis. 175 N is sufficient for all VO prostheses¹³ and at least 15 N pinch force for all VC¹⁹.

- b. Deliver sufficient cable excursion to open or close most of the commercially available prostheses. 50 mm is sufficient to open/close most voluntary opening 19 and voluntary closing 13 prostheses (all but Otto Bock VO hand and Otto Bock VC hand with inner and cosmetic glove).
- c. Maintain a stable force level as well as using the 'Figure of 9' harness
- d. Open/close the prosthesis with the same speed and as when using the 'Figure of 9' harness
- e. Pick up objects as easily as with the 'Figure of 9 harness'
- Reach the same locations as with the 'Figure of 9 harness'

3. Various requirements

Additional requirements are the following:

- The device should be easy to clean, i.e. it should be easily detachable from the Bowden cable and made from materials suitable for washing machines.
- b. The device should be suitable for both men and women (i.e. should not put pressure on breast etc.).
- c. The user should power the prosthesis with similar movements as for the traditional 'Figure of 9' harness, namely humeral abduction, humeral anteflexion and shoulder protraction. Thus the user has be able to wear the prosthesis without activating it during walking or bending the trunk. This should be possible without adjusting the harnessing system.

4. Cosmetic wishes

Although increasing the comfort for body powered prosthetic users is the priority, it would be optimal if the following wishes concerning cosmetics, were met as well:

- a. Possible to wear under a T-shirt without being noticeable.
- b. Can be worn under a sleeveless shirt either without being noticeable or at least look natural.
- c. Can be worn without the need of wearing clothing underneath.

Conceptual design

Fixation to the body

The design process was based on where and how it is possible to connect the Bowden cable to the body in order for it to deliver appropriately directed activation forces to the terminal device. The focus was to find solutions that redirect the reaction forces, which are normally exerted on the axilla region, to a different place on the body and/or distribute the forces over a larger area.

The alternative fixation sites found were the upper arm, chest, waist and thigh and the fixation methods for each fixation site are listed in Table 1. By evaluating the fixation sites according to the requirements, some fixation sites could already be eliminated. The thigh and waist fixation are located below the trunk and thus largely affect the users range of motion (req. 2f & 3c). These two fixation sites were therefore eliminated and the remaining options were the upper arm and chest.

Table 1. Methods for fixing a human-prosthesis interface to the body, categorized by fixation site.

| Upper arm | Chest | Waist | Thigh |
|------------------|---|------------------------------------|-----------------------------------|
| Armband + straps | Elastic chest Strap + straps over shoulders | Belt + straps over shoulders | Shorts + straps over shoulders |
| | | | |
| Integrate in a | Integrate in a T- | Shorts + | Thigh band + |
| T-shirt | shirt | straps over | straps over |
| | | shoulders | shoulders |
| | Bra/ Sports Bra | Integrate in a T-shirt | Socks + straps over shoulders |

The fixation methods for the remaining fixation sites can be divided into five categories:

- (1) chest strap with shoulder straps over one shoulder
- (2) chest strap with shoulder straps over two shoulders
- (3) T-shirt modification
- (4) upper arm strap
- (5) (sports) bra.

Since one of the requirements was that the new harnessing systems should be suitable for men and women (req. 3b), a bra could be replaced with a single strap around the chest and a modified sports bra could be designed such that it appealed to men.

After finding possible fixation sites and methods, flowcharts and schematic drawings were used to come up with concepts in each category and pick out the ones that best fitted the requirements (Appendix IV).

Prototypes

The most promising design from each of the five categories were chosen to be developed further and used for making prototypes (see Figure 2). The researcher tested the five prototypes by picking up objects, exerting large forces and moving both arms to the limits of range of motion. When evaluating and testing the prototypes, three designs could be eliminated. Although the T-shirt had been found to be difficult to position, the prototype did not

have that problem. In addition there was still pressure on the axilla area, even though it was decreased, and the hygiene problem was still present. Therefore it was eliminated since the objective was to explore whether new and better solutions were possible. The upper arm strap was eliminated since it causes discomfort on the back and limits the range of motion for the user significantly. The sports bra moved away from the body when the Bowden cable was fixed on the amputated side. When the Bowden cable was fixed on the back, the Sports bra turned and caused pressure on the breasts for female users. In addition it is very tight and is not easy to don and doff. All these reasons supported the elimination of the sports bra prototype.



Figure 2. The five prototypes made and tested. All prototypes are made for a left arm amputation. Top row shows back view of all prototypes, bottom row shows front view of prototypes A-C and the connection site of prototypes D and E. (A) elastic chest Strap together with straps over one shoulder, (B) elastic chest Strap with straps going over both shoulders, (C) T-shirt adjustment, (D) upper arm strap with the Bowden cable running through a bra and (E) sports bra used to connect the Bowden cable to the body.

Out of the five prototypes tested, only the two chest straps (Figure 2A and B) remained and were considered further. The only difference between the two chest straps is the shoulder strap that goes over the shoulder on the amputated side. The shoulder strap on the non-amputated side receives most of the pressure coming from the activation force, because of its direction. However, the shoulder strap on the right side helps distribute the pressure, especially when the activation force is directed in a small angle from the horizontal (smaller than 45°). Furthermore, having straps over both shoulders provides certain symmetry in both pressure and cosmetics, which most people are used to from wearing for example backpacks, brassieres, swimsuits and suspenders. For these reasons, the chest strap with shoulder straps over both shoulders was chosen to be developed further and tested in the experiment described below.

The Chest Strap

The final design of the new harnessing system will from here on be referred to as the Chest Strap (CS). The improved prototype used in the experiment can be seen in Figure 3B. It was made adjustable such that it could fit people of different shapes and sizes. The Chest Strap consists of one elastic strap and four nylon straps. The elastic strap is 10 cm wide and is secured to the chest with Velcro straps such that its size can be adjusted. The nylon straps are connected to the Chest Strap such that their length can be adjusted and are secured with Velcro. Two of the nylon straps (shoulder straps) are connected to the Chest Strap on the front and go over each shoulder. A third strap (back strap) is connected to the Chest Strap on the non-amputated side, under but away from the users armpit. The two shoulder straps and the back strap meet on the back of the user in a ring, where the fourth strap connects the system to the Bowden cable.



Figure 3. The two harnessing systems used in the experiment. (A) The standard 'Figure of 9' harness and (B) the Chest Strap.

Movements

The Chest Strap harnesses the movements from the body in a similar way as the 'Figure of 9' harness does, although the possible shoulder protraction is less. The strap on the non-amputated side only goes over the shoulder and is not as tightly fixed to the shoulder like the 'Figure of 9' harness. As a result there is less effect from the shoulder protraction. Therefore, in order to produce activation forces, mainly humeral abduction and anteflexion are used together with the limited shoulder protraction (req. 3c).

Pressure distribution

The approximate pressure distribution on the body caused by the activation forces, for the Chest Strap and the 'Figure of 9' harness for comparison, can be seen in Figure 4. By analyzing the configurations of the straps and the angle of the activation force, the reaction force distribution can be estimated. In the Chest Strap, the pressure is distributed over the three straps depending on the direction of the activation force (see Appendix V). Usually, the largest reaction forces and thus the most pressure, occur under the shoulder strap on the nonamputated side (Figure 4A). If the angle of the activation force (ϕ_{act}) is small, the strap on the amputated side plays a bigger role in receiving pressure, and if the angle is large the back strap under the armpit will receive more pressure. The elastic chest strap does not undergo a lot of loading; instead it keeps all the straps in their place and secures the system to the body. Regardless of the angle of the activation force, most of the reaction forces are directed to the small area of the axilla for the 'Figure of 9' harness. Therefore it can be stated that the reaction forces from the activation force is distributed over more straps and larger areas when using the Chest Strap compared to when the 'Figure of 9' harness is used (Figure 4B). As a result, in theory, the Chest Strap is expected to be more comfortable.

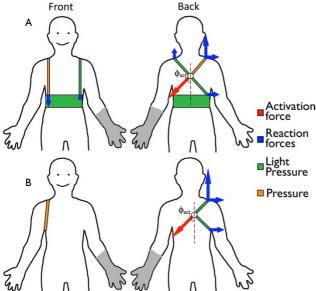


Figure 4. Schematic figures showing force distribution for (A) the Chest Strap and (B) the 'Figure of 9' harness. The amputated side is represented with a grey area and the angle of the activation force with ϕ_{act} . The magnitudes of the forces are arbitrary since they are dependent on the direction of the activation force as well as the size, shape and position of the user.

Participants

The participants in this study were 10 female and 10 male able-bodied students (see Table 2). All participants reported that they were right-handed and without any

motor control or neuromuscular constraints. The subjects were found to represent the Dutch population within this age range (Appendix VI). All participants read an information letter (Appendix VII) before participating in the experiment and signed an informed consent (Appendix VIII). The study was approved by the local ethical committee.

Table 2. Overview of the participants' age, height and weight. Numbers in brackets show standard deviation.

| | Age [years] | Height [m] | Weight [kg] |
|--------|--------------|---------------|--------------|
| Female | 23.4 (±2. 4) | I.7I (±0. 10) | 66.7 (±6. 4) |
| Male | 25.I (±1.5) | 1.87 (±0.07) | 84.5 (±9.6) |

Equipment and set-up

The subjects performed four different tasks described in the protocol below. First, the general test equipment used in all tasks is described and second, the task specific equipment.

Test materials and equipment

During all tasks, the subjects wore a voluntary closing TRS Grip 2S hook (TRS Inc., Boulder, CO, USA). The hook was attached to a prosthetic simulator designed for able-bodied people (see Figure 3). A Bowden cable (0.159 cm diameter cable, Teflon liner and stainless steel housing, Centri AB, Sollentuna, Sweden) connected the TRS hook to the harnessing system. The harnessing systems used in the experiment were the previously described 'Figure of 9' harness (F9) (Figure 3A) and the Chest Strap (Figure 3B). A force sensor was connected between the Bowden cable and the harnessing system in order to measure the activation force (see details in task specific equipment). All force data was collected with a sampling frequency of 100 Hz. The data was recorded using National Instruments data acquisition system with LabView version 11.0.1 (National Instruments Corporation, Austin, TX).

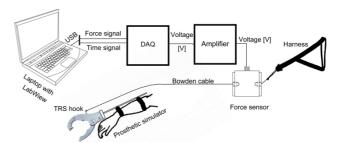


Figure 5. Experiment set-up.

Since comfort is subjective and cannot be measured, body maps (see Appendix IX) and a questionnaire (see Appendix X) were used to quantify the comfort. All data was analyzed in MATLAB version 8.0.0.783 (R2012b) (MathWorks Inc., Natick, MA) and SPSS version 20 (IBM Corporation, Armonk, NY).

Task specific materials and equipment

S-BEAM ZFA 980 N load cell was used in task 1 and a S-BEAM mini 445 N load cell in tasks 2 and 3 (Altheris, The Hague, The Netherlands). Both load cells were calibrated before the experiment. A LabView program recorded the activation forces and displayed them in real time on a screen, together with a reference force in task 3.

A standard box and blocks test (BBT) (Patterson Medical, Inc., Bolingbrook, IL) was used in task 3 as well as a timer to count down from 1 minute.

For task 4, two boxes 24.5x34x7 cm (width, length, depth) were fixed in a vertical line to a wall, with an adjustable height of an increment of 5 cm. The two boxes served as locations for picking up and placing an object and their height was adjusted according to the participants' height (see Table 3). The object was a cylindrical plastic object of height 30 cm and upper/lower diameters 29/19 cm (see Figure 6). Two smaller objects were placed in the cylinder such that it weighed approximately 1.5 kg. A **SHAP** stopwatch (University of Southampton, Southampton, UK) was used such that the participants could time themselves.

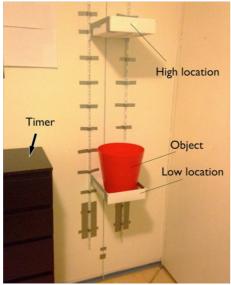


Figure 6. Typical set-up for task 4. Low location holding the cylindrical object and the high location directly above it. The timer (not visible) was located on the subject's left hand side.

Table 3. Locations in task 4 related to percentage of body height.

| Location | Percentage body height |
|----------|------------------------|
| High 4 | 120% |
| High 3 | 110% |
| High 2 | 100% |
| High I | 80% |
| Low 3 | 50% |
| Low 2 | 30% |
| Low I | 0% |

Equipment fitting

The prosthetic simulator was comfortably fixed to the left arm of the participants with Velcro straps. The hook was rotated in a position of the participants choosing (pronation/supination). The housing of the Bowden cable was fixed to the prosthetic simulator under the participant's wrist and in a point approximately 1/3 of the upper arm length, above the elbow.

The 'Figure of 9' harness had an adjustable axilla loop and was adjusted to the participant by locating the ring between the shoulder blades, approximately over the T4 vertebrae (Figure 3A). The Bowden cable was neither slack nor tensioned when the subject held the right arm in horizontal humeral flexion (humeral angle 90°) and the left arm relaxed to the vertical (humeral angle 0°).

The Chest Strap was fixed firmly but comfortably on the subject's rib cage, such that the lower part of the Chest Strap lined approximately to the thinnest part of the waist. The attachments of the shoulder straps to the Chest Strap were adjusted such that the straps did not cover the breast or were under the armpit. The lengths of the shoulder straps were adjusted such that the ring was located approximately on the T2 vertebrae (Figure 3B). Like for the 'Figure of 9' harness, the Bowden cable was neither slack nor tensioned when the subject elevated the right arm and relaxed the left one. The harnessing systems were worn on the bare skin of the male subjects and over a bra of the female subjects.

Protocol

Four tasks were designed to test the new harnessing system with regard to the requirements and to compare it to the standard 'Figure of 9' harness. In total, the participants performed each task two times using the two harnessing systems in a random order per test subject. The participants were in a seated position (adjustable to their preference) in tasks 1-3 and standing in task 4.

After every task, the participants were asked to indicate on a body map the level and nature of discomfort or pain on the body (see Appendix IX). Three colors were used; green representing sensation or feeling, orange representing irritation and red representing pain. The participants were asked to color the areas where they felt a sensation/irritation/pain with the appropriate color and associate them with a number 1 or 2, depending on the intensity of the feeling. The participants were also asked to associate the color with one of three letters where P represented pressure, S represented shear and F represented muscle fatigue.

To evaluate whether the comfort and functional measures reflected the participants' opinion on which one of the systems they preferred, a final questionnaire was presented after the whole experiment. The participants were asked to choose between the systems while wearing them passively and actively, when considering cosmetics and finally overall (see Appendix X).

Before starting the measurements, the researcher explained to the subject how VC body-powered prostheses work, demonstrated the three possible movements to close the terminal device (humeral abduction, humeral anteflexion and shoulder protraction) and explained that these movements could be combined according to the subject's convenience.

Task I - Maximum force measurement

The first task was designed to measure the maximum activation forces people are able to deliver with the two harnessing systems (req. 2a), observe whether sufficient cable excursion is achieved (req. 2b) and to evaluate the comfort in extreme scenarios (req. 1e).

Instructions: The subjects were instructed to deliver as high activation forces as possible for the duration of 5 seconds. This was repeated 3 times with a rest of maximum 30 seconds between trials.

Training: The participants practiced by using a combination of body movements while looking at the force level they produced. When the participant felt that he/she had found a good strategy to create high forces, the measurements were started.

Task 2 – Constant force measurement

The second task was designed to evaluate people's ability to reach and hold a relatively high force with the harnessing systems (req. 2c) and to evaluate the comfort for an extended period of time at same force level for all participants (req. 1f).

Instructions: The second task was to follow a reference force of 100 N for 10 seconds at a time. The reference force was presented on a laptop screen with a white line and the measured activation force exerted by the user with a red one. An audio cue indicated when the 100 N force began and ended. The participants were asked to match the reference force as fast and precisely as possible. This was repeated 6 times with 5 second breaks in between.

Training: The participants practiced by performing the task with a lower reference force of 50 N until the subject could reach and hold the reference force consistently for two blocks in a row.

Task 3 - Box and blocks test

The third task was designed to evaluate people's speed and performance using both harnessing systems (req. 2c, 2d & 2e) as well as the comfort while making horizontal (req. 1a) and fast movements (req. 1g).

Instructions: The subjects were instructed to use the TRS hook to move as many blocks as possible, one at a time, over the barrier in one minute. This was repeated three times, with a break between according to the participant's wishes.

Training: The participants practiced by moving blocks over the barrier until he/she was able to pick up 5 blocks in a row and release them, smoothly and without dropping them

Task 4 - Low/high task

The fourth and last task was designed to evaluate the range of motion in the vertical direction (req. 2f) and the comfort while making such movements (req 1b, 1c & 1d).

Instructions: The fourth task was self timed and the subjects were instructed to use both hands (TRS hook and sound hand) to pick up an object from a low location and move it to a high location, and reverse. This was repeated 6 times (or as many times while the participant is able to reach the locations) for different combinations of high and low locations. The length of the movement and the height of the high location increased, but the height of the low location decreased (see Table 4). In total there were 12 movements, 6 from low to high and 6 from high to low.

Training: The participant practiced by performing task maximum of 3 times for every height level without timing.

Table 4. The order of movements in task 4, where the object is picked up from location 1 and placed in location 2. See heights of each location in Table 3.

| Movement nr. | Location I | Location 2 |
|--------------|------------|------------|
| 1 | Low 3 | High I |
| 2 | High I | Low 3 |
| 3 | Low 3 | High 2 |
| 4 | High 2 | Low 3 |
| 5 | Low 2 | High 2 |
| 6 | High 2 | Low 2 |
| 7 | Low 2 | High 3 |
| 8 | High 3 | Low 2 |
| 9 | Low I | High 3 |
| 10 | High 3 | Low I |
| 11 | Low I | High 4 |
| 12 | High 4 | Low I |

Data analysis

The description of the data analysis is split into functional, comfort, questionnaire and statistical analysis. The data analysis presented in this paper was performed for the genders combined. The data analysis was also done for the genders separately (see Appendices XI, XII & XIII).

Comfort analysis

The comfort was evaluated using body maps. The two harnessing systems were divided into the areas shown in Figure 7, where joints are represented with letters (A, B, etc.) and the areas between them represented with the two closest joints (A-B, B-E etc.). The colored body maps were translated into comfort scores ranging from 0 to 6, where 0 represents no color (no discomfort) and 6 represent red color level 2 (severe discomfort). Each colored area was given an appropriate comfort score within a task, for both harnessing systems. The shear and pressure results were combined since the participants had often trouble distinguishing between the two feelings. The fatigue results were not analyzed, but it was important for the subjects to separate the fatigue discomfort from shear and pressure.

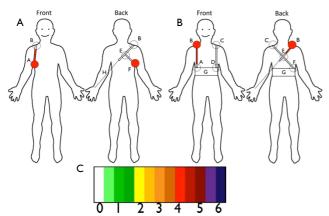


Figure 7. Areas of the body maps, on the (A) 'Figure of 9' harness and (B) Chest Strap. Stress areas are indicated with the colour red. (C) The colour spectrum used to translate the comfort scores into visual body maps.

For each task, the mean comfort scores for each area were calculated across all participants as well as the standard deviation from the mean value. The mean comfort scores were then translated into a color in the color spectrum shown in Figure 7C and the collective scores represented visually on a body map, separately for each task and harnessing system. Furthermore, the number of participants experiencing pain, irritation and sensation was counted to also compare number of participants experiencing discomfort when using the harnessing systems.

For the statistical comparison of the two systems, three adjoining areas where most participants reported highest comfort scores were combined. The highest scores within these areas from each participant were used to compare the comfort of the 'Figure of 9' harness and the Chest Strap. These areas, which from now on will be referred to as 'stress areas', are areas F, A and A-B for the 'Figure of 9' harness and areas A-B, B and B-E for the Chest Strap (indicated in red in Figure 7).

Functional analysis

The functional analysis was different for each of the four tasks as described below.

Task 1: Activation forces were measured during a 5 second maximum force measurement. The absolute maximum force (max_{act}) within the three trials was used when comparing the two harnessing systems.

Task 2: Activation forces were measured during 6 blocks of a 100 N reference force for 10 seconds with 5 second breaks in between. The time until the 100 N reference force was reached was calculated (t_{ref}) for each of the 6 blocks and compared for both harnessing systems. The mean error from the reference force (err_{act}) and the standard deviation from the mean (dev_{act}), after the reference force was reached, were calculated as well. The means of err_{act} and dev_{act} during the last 5 blocks were calculated and compared between the two systems.

Task 3: Activation forces were measured during the one-minute that the blocks were displaced. The number of blocks was counted for each of the three trials and only the trial with the highest number of blocks displaced was used when comparing the two harnessing systems.

Task 4: The time for each of the 12 movements was measured and the mean and standard deviation across all subjects calculated. The mean movement time and the standard deviation were plotted versus movement number and compared between the two harnessing systems. In addition, the number of subjects able to complete each movement was counted and the results presented in a bar plot.

Questionnaire analysis

The comfort and function were evaluated together in a questionnaire, presented to the subjects in the end of the experiment. The answers where the participants chose between the two harnessing system were collected and presented in a bar plot. The arguments behind the choices were collected, keywords in the answers identified and the ratio of participants for each keyword calculated from the whole group.

Statistical analysis

Non-parametric statistical tests were used since the data was not always normally distributed. A related-samples

Wilcoxon signed rank test was used to evaluate the both the functional and comfort differences between the standard 'Figure of 9' harness and the new Chest Strap. Independent-samples Mann Whitney U test was used when comparing differences between groups of different subjects. Results were considered significant with a confidence interval of 95% (p < 0.05).

Results

The results are divided into comfort results, functional and questionnaire results, as indicated in the data analysis section. Even though comfort is a subjective measure, the comfort results are presented first since the main goal of this research is to increase the comfort of wearing a body powered prosthesis.

Comfort results

The results from the body maps are presented visually, according to areas for task 1 in Figure 8. The visual representation of the results is the only result presented separately for female and male participants. The activation

forces are highest in task 1 and as a result the pressure on the body. Therefore task 1 is the most representative for discomfort and the visual results are only shown for task 1 (see visual results for other tasks and values used in Appendix XII). The results show that the axilla area (area A) scores highest with the 'Figure of 9' harness and the top of the right shoulder (area B) or under the front right strap (area A-B) for the Chest Strap. These and the adjoining areas, namely areas F, A and A-B for the 'Figure of 9' harness and areas A-B, B and F, were combined and previously defined as stress areas for the respective harnessing systems. The results from the stress areas of the body maps are presented in boxplots provided in Figure 9. The results show that the Chest Strap receives significantly lower comfort scores (less discomfort) from the genders combined in all four tasks. The number of participants that reported pain, irritation, sensation or no feeling in the stress areas for both harnessing systems is provided in Table 5. The results show that in all tasks, irritation was reported 41 times and pain 28 times when using the 'Figure of 9' harness. However, irritation was reported 31 times and pain only 4 times when using the Chest Strap.

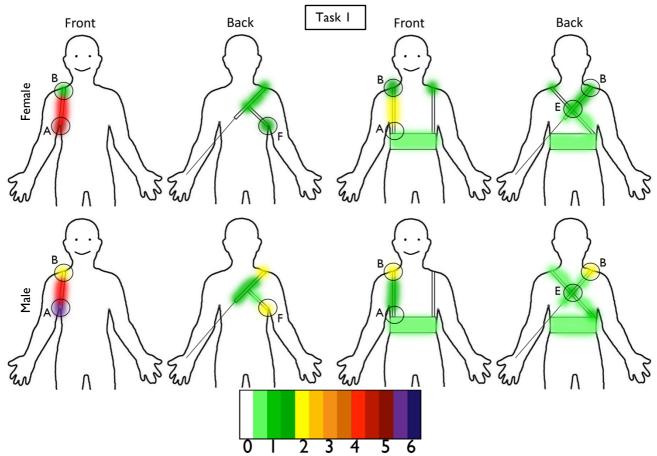


Figure 8. Visual body map results for tasks I together with relevant area labels. Data collected from female and male body maps separately and mean comfort scores from all participants used to select an appropriate colour for the corresponding area.

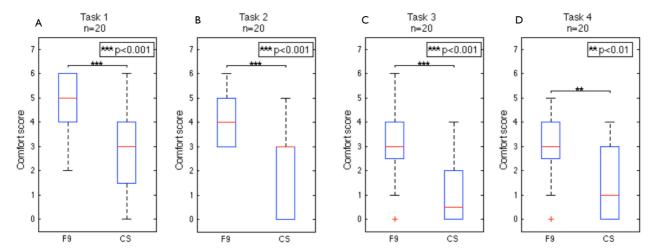


Figure 9. Boxplots showing the distribution of comfort scores in the stress areas for each task; (A) task 1, (B) task 2, (C) task 3 and (D) task 4. Comfort score from each participant is the highest (most discomfort) score from the three areas within the stress areas (areas A, A-B and F for F9 and areas A-B, B and B-E for CS). F9 represents the standard 'Figure of 9' harness and CS represents the new Chest Strap. Significant differences between harnessing systems are indicated with stars. Results shown for all participants (n = 20).

Table 5. Number of participants that reported pain, irritation, sensation or no feeling in the stress areas for both harnessing systems. Combined results from male and female participants, n=20.

| | | 'Figo | ure of 9' harn | ess | | | Chest strap | |
|--------|------|-------|-------------------|------|------|------|-------------------|------|
| | | [No | o. of participant | :s] | | [No | o. of participant | cs] |
| | Pain | Irr. | Sens. | None | Pain | Irr. | Sens. | None |
| Task I | 14 | 5 | I | - | 2 | ı | 4 | 3 |
| Task 2 | 9 | I | - | - | 2 | 10 | 1 | 7 |
| Task 3 | 3 | 12 | 3 | 2 | - | 3 | 7 | 10 |
| Task 4 | 2 | 13 | 2 | 3 | - | 7 | 4 | 9 |
| Sum | 28 | 41 | 6 | 5 | 4 | 31 | 16 | 29 |

Pain = number of participants that reported pain, Irr. = number of participants that reported irritation, Sens. = number of participants that reported sensation, None = number of participants that didn't colour these areas.

Functional results

Figure 10 provides plots representing the functional results for all tasks.

Task 1: The absolute maximum activation forces (max_{act}) that the participants were able to produce in task 1 are plotted in Figure 10A. There was no significant difference in max_{act} between the 'Figure of 9' harness and the Chest Strap. All but two subjects were able to deliver 175 N activation force and all subjects closed the TRS hook completely, with both harnessing systems.

Taks 2: The mean error from the 100 N reference force (err_{act}) for the last 5 blocks was compared for both systems and the results are shown in Figure 10B. The standard deviation from the mean activation force (dev_{act}) after the 100 N reference force was reached is shown in Figure 10C. Figure 10D shows the time until the 100 N reference force was reached (t_{ref}) for all participants. The differences in err_{act} and dev_{act} were not significant between using the 'Figure of 9' harness and the Chest Strap. t_{ref} was

significantly shorter when using the 'Figure of 9' harness than the Chest Strap where the mean difference was 0.2 sec.

Task 3: The maximum number of blocks displaced by all subjects using each of the harnessing systems is shown in Figure 10E. There was no significant difference in the number of blocks displaced between the two harnessing systems.

Task 4: The time that the participants measured themselves while moving the plastic object vertically is shown in Figure 10F. The results show the mean movement time of the subjects that were able to complete the movements, but not all subjects were able to complete every movement (Figure 10G). The movement times in movements 3, 4, 5, 7 and 8 were significantly shorter using the Chest Strap than the 'Figure of 9' harness, while the difference was not significant in other movements.

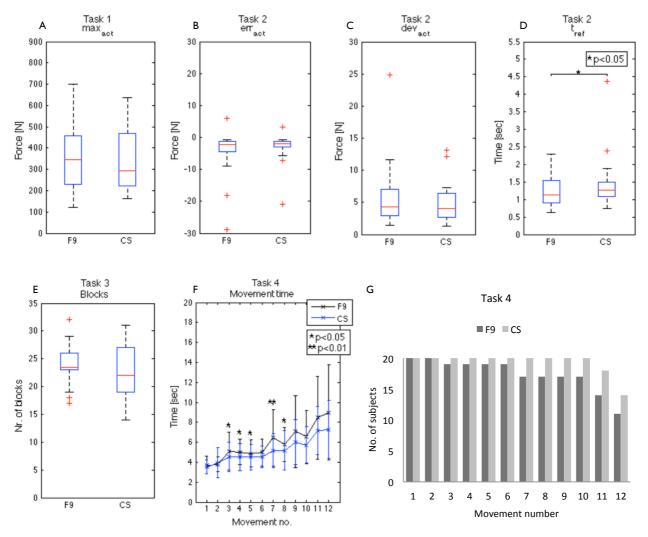


Figure 10. Functional results for all subjects and all tasks. (A) Maximum activation forces produced in task 1. (B) The mean error from the 100 N reference force, after the reference force had been reached, (C) standard deviation from the mean activation force and (D) the time until the reference force is reached in task 2. (E) Number of blocks displaced in one minute in task 3 and (E) mean (indicated with an x) and standard deviation (error bars) of the movement times over all subjects, for each height location combination in task 4. Significant differences between harnessing systems are indicated with stars (*).

Final questionnaire results

The results from the final questionnaire, where the participants chose which system they preferred in different situations, are provided in Figure 11. 60% of all participants preferred the Chest Strap passively (Figure 11). Comfort was the biggest factor in the choice, whether it was in favor of the Chest Strap (55% of all subjects) of the 'Figure of 9' harness (20% of all subjects). Additionally 20% of all subjects mentioned that they felt that the Chest strap was more secure on the body (see Appendix XV).

75% of all participants preferred to wear the Chest Strap actively (Figure 11). Reasons given for choosing the

Chest strap over the 'Figure of 9' harness while wearing it actively included better comfort (75%), better range of motion (25%), less fatigue (20%) and better control (20%). Subjects that preferred the 'Figure of 9' harness while wearing it actively mentioned better control (30%) and the ability to produce more force (15%) (see Appendix XV).

75% of all participants preferred the 'Figure of 9 harness when considering the cosmetic appeal of the systems (Figure 11). The increased amount of straps introduced by the Chest Strap was mentioned by 65% participants for choosing the 'Figure of 9' harness over the

Chest Strap. Two female participants also mentioned that the Chest Strap introduces some undesirables grooves into the abdominal area, causing them to prefer the 'Figure of 9' harness. However, 15% of the subjects mentioned the symmetry that the Chest Strap provided and thus a more natural look than having straps on one side (see Appendix XV).

In the end, 75% of all participants chose the Chest Strap over the 'Figure of 9' harness overall (Figure 11), when considering all previous questions and the fact that they had to wear it all day. Reasons for choosing the Chest Strap over the 'Figure of 9' harness included more comfort (75%) and better control (20%). Advantages that the 'Figure of 9' harness had over the Chest Strap included, less material (15%) and less warmth (15%) (see Appendix XV).

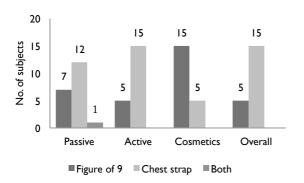


Figure 11. Preferred system in terms of passive and active (while operating) wearing, cosmetics and overall. Results for all participants (n = 20).

Discussion

The goal of this study was to design a more comfortable harnessing system while not compromising the user's ability to operate the prosthesis. The new harnessing system was compared to the standard 'Figure of 9' harness with experimental procedures, using both using comfort and functional measures. The results were used to evaluate whether the comfort was improved without decreasing the function and to choose the better harnessing system.

Comfort

The subjects usually reported discomfort (pain or irritation in the stress areas 69 times out of 80 over all tasks) in the axilla region when using the 'Figure of 9' harness, which agrees with previous findings in literature^{7, 8}.

The comfort scores across all subjects were significantly lower (less discomfort) while using the new Chest Strap than the standard 'Figure of 9' harness in all four tasks. In addition, during all tasks, pain was reported 28 times out of 40 when using the 'Figure of 9' and only 4

times out of 40 when using the Chest Straps. That suggests that comfort was increased with the new Chest Strap in all tested circumstances, which included;

- performing horizontal movements (req. 1a)
- performing vertical movements (req. 1b)
- reaching over the head (req. 1c)
- reaching to the floor (req. 1d)
- holding slippery or heavy objects (using high forces) (req. 1e)
- holding objects for an extended period of time (req. 1f)
- performing fast movements (req. 1g)

Function

The mean of the maximum activation forces that all subjects were able to produce was 362 N (±173 N). These values are significantly higher than those reported from Taylor ²⁰. There the mean ranged from 250 N – 280 N, depending on which movement was used, and the standard deviation was not specified. The data from Taylor was obtained from 50 able bodied subjects, where the age, height and weight were not specified. A difference in age range, height and weight can greatly influence the maximum activation forces delivered. In addition, Taylor's study was over 60 years ago and the fitness of the population may have changed since then.

All participants that were able to produce a 175 N activation force with the 'Figure of 9' harness could do it with the Chest Strap as well (req. 2a). Two participants were not able to deliver 175 N and would not be recommended to choose a terminal device that requires such high activation forces with either harnessing system. All participants were able to close the TRS hook and thus deliver 50 mm cable excursion (req. 2b). The reference force in task 2 ranged from being 14% to 83% of the maximum activation force delivered using the 'Figure of 9' harness and between 16% and 62% using the Chest strap.

No significant difference in function was found between the two harnessing systems in tasks 1 and 3. No significant difference was found in the mean error from the reference force and in the deviation from the mean between the two systems in task 2. However, the time until the reference force was reached (t_{ref}) was significantly shorter when using the 'Figure of 9' harness than the Chest Strap in task 2, where the mean difference was 0.2 seconds. The difference in t_{ref} was not found to be significant when evaluating the genders separately (Appendix XIV). Finally, in 5 out of 12 movements in task 4, the time to complete the movements was shorter using the Chest Strap than using the 'Figure of 9' harness. The difference in movement time was not significant between the two harnessing systems in the other 7 movements.

These results suggest that users are able to:

- deliver equally high activation forces with both harnessing systems (req. 2a)
- reach a high reference force and maintain it equally well with both harnessing systems (req 2c)
- pick up and move objects equally fast and well with both harnessing systems (req. 2d & 2e)
- reach at least the same locations equally fast with both harnessing systems (req. 2f)

Final questionnaire

The results from the final questionnaire show that majority of the participants prefer to wear the Chest Strap both passively (60%) and actively (75%). The fact that more people preferred to wear it actively indicates that when operating the prosthesis, the subjects started to value the fact that the Chest Strap distributes the pressure more over the body and thus causing less discomfort. The drawback of the Chest Strap seems to be the increased amount of straps visible, since majority of the participants preferred the 'Figure of 9' harness regarding cosmetic appeal. In the end, when the subjects evaluated which harnessing system they would prefer to use in their daily life, 15 out of 20 participants chose the Chest Strap. Finally, majority of the subjects mentioned that they thought the Chest Strap was more comfortable, regardless of their preference reported in the last question.

The winning design

Using the results from this experiment, it was easy to choose the winning harnessing system. The Chest Strap proved to be more comfortable than the 'Figure of 9' harness in all tested circumstances and the subjects were able to perform equally well with both harnessing systems in all functional measures except one (t_{ref}). It is unlikely that body powered prosthesis users would value the slight difference in reaction time more than the comfort of wearing the prosthesis. Furthermore, a possible factor in the higher reaction time might be a slightly longer learning curve is required for the Chest Strap, since it is not as directly anchored to the body as the 'Figure of 9' harness.

When the design criteria are evaluated, all the tested comfort requirements were met with the new design. The comfort while donning/doffing the Chest Strap has not been tested yet (see limitations and future work). All the functional requirements were met as well, when evaluating the speed of opening/closing the prosthesis (req. 2d) with the number of blocks displaced, not t_{ref}. The device should be easily detachable from the Bowden cable and suitable for washing machines by choosing suitable materials (see recommendations). The Chest Strap proved to be suitable for both genders (req. 3b) and it was powered with similar movements as the 'Figure of 9' harness (req. 3c). Finally, the cosmetic wishes were at least partially met. The

experiment proved that the Chest Strap could be worn underneath clothing without much discomfort (req. 4c). The Chest Strap will only be noticeable underneath tight clothing (req. 4a) and the symmetry of the straps makes it look quite natural under sleeveless shirts (req. 4b).

Limitations of the study

First of all, a limitation of this study is that the participants are only wearing the harnessing systems for about half an hour, whereas body-powered prosthetic users will have to wear it the whole day. The results from this experiment are thus only valid for testing the short-term comfort and functional requirements.

Another limitation is that only able-bodied subjects tested the new design, but they do not know the drawbacks of the current harnessing systems as well as body-powered prostheses users do. Therefore, especially the results from the final questionnaire could be different if amputees were asked

Body-powered prosthetic users in general mostly need to use their prosthesis while performing two-handed tasks, since they can use their sound hand for one-handed tasks. Two-handed tasks are typically either complex tasks (tie shoelaces, bind a ponytail, etc.), or tasks that need one hand to hold an object and the other to make a maneuver (open, close, change configurations, etc.). One simple two-handed task was included in the study and holding a constant force simulated a second two-handed task. The function during complex two-handed task was not tested for the Chest Strap.

Since the participants were asked to perform four different tasks, it can be expected that a learning curve could have affected the results. To minimize learning effects, simple tasks that require relatively little training were chosen to be included in the experiment. In addition, the participants were allowed to practice before each task with both harnessing systems and the order of which the harnessing systems were presented to the participants was randomized.

Comfort while donning/doffing was not tested since the prototype used in this experiment was not yet in its final form and improvements can be made for easy donning and doffing. The complex donning and doffing of the Chest Strap was necessary for it to fit participants of all shapes and sizes.

Recommendations and future work

The results from this study indicate that the comfort of operating a body-powered prosthesis is increased with the Chest Strap during a short amount of time for able-bodied people. After that it is necessary to confirm whether the comfort is increased for a longer wearing time and for amputees. Body-powered prosthetic users must be asked to wear the Chest Strap during their daily live activities

(ADL) and confirm that the comfort is indeed increased with this new design and the function is not compromised in ADL tasks.

To improve the design of the Chest Straps the following steps could be taken:

- A more breathable (but still stretchy) material could be chosen for the strap around the chest.
 These types of materials are often seen in sport clothing and supports (e.g. knee and ankle supports).
- A thinner strap around the chest should be tested since a 10 cm wide strap might be unnecessarily thick.
- The shoulder straps are currently double with Velcro in between and therefore rather stiff. Another method of fixing the shoulder straps to the Chest Strap would be better, such that a single strap would be sufficient and as a result a more flexible strap that causes less shear forces on the skin.
- An improved system could be pre-adjusted for each user such that it only has to be fastened in the front and therefore possible to don and doff like a vest.
- To improve the cosmetic appeal of the Chest Strap, it should be in a single, neutral color such as black.
- Finally, the possibilities of integrating the Chest Strap in a bra could be investigated. On option could be to extend the strap that is already around the chest in a bra and connect the shoulder and back straps.

Conclusion

In this paper, a new design of a harnessing system for body-powered prosthesis was presented and tested in comparison to the standard 'Figure of 9' harness. The goal was to design a harnessing system that improves the comfort of wearing a body powered prosthesis, while not compromising the ability to operate the prosthesis. Even though the cosmetic wishes were not completely met, the results of this experiment showed that the new harnessing system, the Chest Strap, fulfilled all the tested design requirements set in the beginning. Most importantly, the Chest Strap proved to be more comfortable during all the tested circumstances. While improving the comfort, the Chest Strap allowed the users to operate the TRS hook equally well or better in all functional measures except one, compared to the 'Figure of 9' harness. Finally, majority of the participants chose the Chest Strap over the 'Figure of 9' harness when asked which system they would like to use in their daily lives.

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Appendix I - Types of Upper Limb Prostheses

Several different types of upper limb prostheses are currently commercially available, ranging from cosmetic arm prostheses to externally powered prosthetic hands. Upper limb prostheses can be divided in to two categories; active and passive prostheses. Passive prostheses are either completely passive with no joints or the kind that can be switched from one configuration to another manually. Active prostheses allow grasping by means of either harnessed body movements or an external power source. The following chapter briefly reviews the different types.

Passive prostheses

There are two types of passive prostheses; cosmetic prostheses and passive 1 DOF prostheses. Cosmetic prostheses (Figure 12A & B) mostly serve as a cosmetic replacement of the missing limb. These prostheses are lightweight and have a natural look, apart from the fact that they always remain in the same configuration. Cosmetic prostheses can be used for pushing or to stabilizing objects while using the healthy hand. Passive 1 DOF prostheses (Figure 12C) usually have a movable thumb that can be moved from one configuration to another with the healthy hand21.



Figure 12. Passive upper limb prostheses. (A) Male cosmetic hands, (B) female cosmetic hands both from Centri²² and (C) passive I DOF hand from Otto bock²¹.

Active prostheses

Body powered prostheses

Body powered prostheses are controlled with body movements, where a shoulder harness is connected through a cable to a terminal device. When the cable is pulled the terminal device either opens or closes, depending on whether it is voluntary opening or voluntary closing. A voluntary closing prosthesis is open by default and forces from the body are harnessed to close the prosthesis. In that way, the user can control the amount of force that is applied to the object that is to be picked up. A voluntary opening prosthesis is closed by default and a cable is pulled via a shoulder harness to open the prosthesis. With that kind of prosthesis, a default force will be applied while picking up every object, and can only be altered by changing the spring/rubber band. Mainly three types of terminal devices are currently used. These are the functional split hook (Figure 13A&B), the TRS hook (Figure 13C) and the body-powered hand prosthesis (Figure 13D&E). The split hook is usually voluntary opening and the TRS hook is a voluntary closing prosthesis. The body powered hand terminal devices are available both voluntary opening and closing.



Figure 13. Body powered terminal devices. (A) Voluntary opening split hook from Hosmer orthotics and prosthetics, (b) Voluntary closing split hook from Hosmer orthotics and prosthetics ²³, (C) Voluntary closing grip prehensor from TRS Inc ²⁴, (D) a voluntary opening hand from Hosmer orthotics and prosthetics and (E) a voluntary closing hand from Hosmer orthotics and prosthetics²⁵.

MyoElectric prostheses

Myoelectric prosthetic hands (Figure 14) are externally powered devices that are controlled by signals from the muscles. EMG electrodes, placed on the agonist and antagonist of the forearm, receive potentials from the muscles and signal the motor to open or close the hand. Until recently, the myoelectric prostheses have mainly been capable of 1 DOF movements apart from the rotation of the wrist, which is done manually. The 1 DOF prostheses function very similarly as the body-powered prostheses since they only open and close, with the main difference the control.



Figure 14. Examples of common commercially available myoelectric 1 DOF terminal devices. (A) Myoelectric hook from Motion Control Inc.²⁶, (B) Electric greifer from Otto Bock²⁷ and (C) MyoHand VariPlus Speed (without a cosmetic glove) from Otto Bock²⁸.

Recently, multi-articulating prostheses have emerged in attempt to create a better functioning and a more natural looking prosthesis. The hands have multiple motors that control different fingers and pre programmed positions for various grip types. Three hands are currently available, the iLimb Ultra from Touch bionics (Figure 15A), the Michelangelo hand from Otto Bock (Figure 15B) and the BeBionic V3 from Steeper (Figure 15C).



Figure 15. Commercially available multi-articulating myoelectric hands, without cosmetic gloves. (A) i-Limb Ultra from Touch bionics²⁹, (B) Michelangelo from Otto Bock³⁰ and (C) BeBionic V3 from Steeper ³¹.

Appendix II - Harnessing systems and alternatives

This appendix presents the most common harnessing systems and alternatives.

Commonly used harnesses

Two types of harnessing systems are currently mainly used; the 'Figure of 8' harness (Figure 16A) and the 'Figure of 9' harness (Figure 16B).

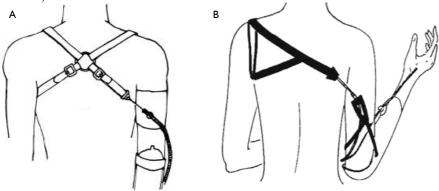


Figure 16. The most common harnessing systems currently used. (A) 'Figure of 8' harness used in combination with a ring⁷ and (B) 'Figure of 9' harness³.

The 'Figure of 8' harness consists of an axilla loop that encircles the non-amputated shoulder, and an anterior support strap that goes over the shoulder on the amputated side. The anterior support strap is connected to an inverted Y suspender that secures the socket in its place. A control attachment strap is connected to the axilla loop on one side and a triceps pad that then connects to the Bowden cable on the other side. The Bowden cable is then finally connected to the terminal device, and by pulling the cable, the terminal device is either opened or closed, depending on whether it is voluntary opening or voluntary closing. The 'Figure of 9' harness is basically the same apart from the anterior support strap, which is not present. Instead of suspending the socket from the harness, a tight socked is used such that it is secure on its own ³².

Alternative harnessing systems

One of the main problems with the traditional harnessing systems described above is the high pressure they cause on the axilla region. To decrease the pressure in the axilla area it is either necessary to reduce the required activation forces or change the harnessing system such that it decreases the pressure on the axilla area (modify the axilla loop) or avoids it entirely (removing axilla loop). The following list the existing alternative harnessing systems.

Remove the axilla loop

The Debra Latour anchoring system (Figure 17) was recently designed, where the axilla loop is completely left out and instead a base is glued to the skin medial to the scapula on the amputated side¹⁸. The Wilber elbow controlled was developed in TU Delft and is controlled with flexion and extension of the elbow.

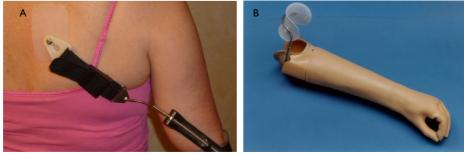


Figure 17. (A) Debra Latour anchor system in use. (B) Wilmer Elbow controlled prosthesis.

Modify the axilla loop

Two types of modified axilla loops do exist; a T-shirt/harness combination (Figure 18) and the axillar bypass ring (Figure 19). The T-shirt/harness combination consists of a stretchy T-shirt and a harness that is sewn into it. The combination then allows stretch in the opposite direction of the harness to decrease discomfort in the axillar region. In the direction of the harness, the combination doesn't stretch and in that way allows body movements to be harnessed and transfer forces to the terminal device ¹⁷.

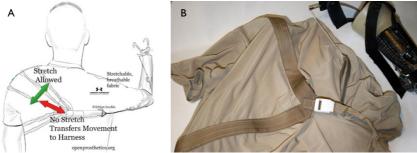


Figure 18. T-shirt/harness combination. (A) schematic drawing and (B) prototype (figures adapted from 17).

The axilla bypass ring is made out of ABS-plastic or leather. Instead of putting pressure on the axilla region like a standard harness, it redirects it to the deltopectoral groove and the scapula ¹⁶.

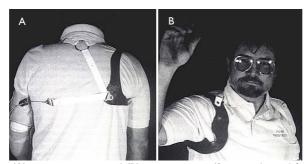


Figure 19. Axilla bypass ring (A) posterior view and (B) anterior view (figures adopted from Collier and LeBlanc 16).

These three are the main alternatives available. Other solutions have been published (see **Figure 20**) such as a Chest-strap harness, Parachute ring and a Suspender over each shoulder.







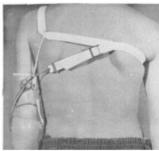


Figure 20. Less known alternatives for the traditional harnessing systems. (A) Suspender over each shoulder ³⁴ and (B) Parachute ring ³⁵. None of these alternative harnessing systems are commonly used, but further research is necessary to investigate the reasons why.

Conclusion

The harnessing systems that are most commonly used cause discomfort in the axilla area. Several alternative systems have been published in order to decrease the discomfort. Despite for these alternatives, the 'Figure of 9' and 'Figure of 8' harnesses are still most commonly used. Further research is necessary to investigate the reason for why the alternative have not been accepted.

Appendix III - Harness questionnaire for upper limb prosthetic specialists

It is clear from literature that discomfort from the harness is the main cause of rejection rates for the body powered prostheses. But what is not completely clear is what exactly is the source of this discomfort. It has been mentioned that excessive pressure and skin irritation coming from the axilla loop are problems, as well as restricted movements. But in order to get a clear picture of the problems, specialists in the prosthetic field were contacted in the form of a questionnaire. In that way, it is possible to get insight from specialists working with body-powered prosthetic users, about their experiences gained by working with the users and listening to their opinions. The questions used can be seen in Table 6. They were mostly open ended since the receivers were not that many and such that the specialists could express their opinions, without the questions directing them to the author's previous assumptions. In addition to these questions, there was room for some additional remarks or suggestions.

Participants

The questionnaire was sent to 77 people and 7 responses were received. The questionnaire was anonymous unless the participants offered their contact information for some follow up questions. The participants are professionals working with upper limb prosthetic users in the Netherlands. Replies were received from occupational therapists (57%), physicians (29%) and certified prosthetists and orthosists (CPO) (14%) working in rehabilitation centers (57%), hospitals (29%) and orthopedic technical centers (14%).

Procedure

The questionnaire contains 11 questions, 7 of which directly address body powered prostheses, harnessing systems or their alternatives. The other questions are for about the participants' background and for additional remarks. Most of the questions (9) are open-ended questions where the participants can express their opinions, without the questions directing you towards assumptions made beforehand. The complete list of questions can be seen in Table 6.

Table 6. Questions used in the questionnaire sent out to upper limb prosthetic specialists.

What kind of facility do you work at?

What is your position/education?

What do you as a specialist think that needs to be improved in current body powered prostheses?

What is the primarily used harnessing system in you facility?

- Figure of 9 harness
- Figure of 8 harness
- Other

What do you as a specialist think that are the biggest disadvantages about the harnessing systems?

What do body-powered prosthetic users think that are the biggest disadvantages about the harnessing systems? Is there any difference between current and previous users?

Do you agree or disagree with the following statement? Why (not)?

"The harness system was often cited as the cause of skin irritation and upper body pain leading to discomfort and disuse of the prosthesis." (Biddiss 2007)

Are you aware of any of the following alternative harnessing systems?

- Debra Latour anchor system
- T-shirt/harness combination
- Axillar bypass ring

If yes, what is you experience of those systems?

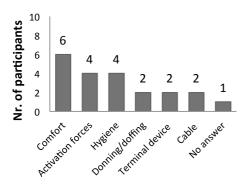
Advantages? Disadvantages? Did the users like the alternatives? Were the systems used in special cases? etc.

Results

Keywords addressing the same element in the open-ended questions were gathered to be able to compare the answers from different participants. All answers were carefully checked such that all relevant elements were included in the analysis.

Body powered prostheses

When asked what needs to be improved in current body powered prosthesis, all participants that gave answers (one participant didn't answer this question) mentioned the harness in some way, in particular the wearing comfort of the prosthesis and harness. Majority of the participants addressed that the large activation forces are a problem (67%) as well as the hygiene related to the harness (67%). The complete results and explanations of the answer elements can be seen in Figure 21.



| Comfort | The comfort of wearing the prosthesis and often in particular the harness. |
|---------------------|--|
| Activation forces | The high activation forces required to open/close the terminal device. |
| Hygiene | Harness gets dirty and smelly quickly. |
| Donning/ doffing | Worn underneath clothing so donning/doffing is difficult. Difficult to make the movement to put the prosthesis on without help. |
| Terminal device | Stiffness of the cosmetic glove. Cable connections hard to use with one hand. |
| Cable | The length of the cable is not adjustable. Strong people tend to break the cable. |

Figure 21. The chart shows elements addressed in answers to the question 'What do you as a specialist think that are the biggest disadvantages about the harnessing systems?'. Each of the elements on x axis were addressed directly or indirectly in the number of answers on y axis.

Harnessing systems

Both the Figure of 9 and figure of 8 harnessing systems seem to be used within these facilities although the 'Figure of 9' harness is primarily used (see Figure 22).

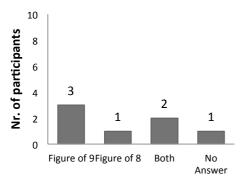
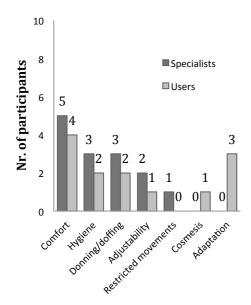


Figure 22. Overview of the use of the Figure of 9 and 8 harnessing systems within the participants' facilities. The option 'both' is used when the participant checked both options but didn't specify which harnessing system was primarily used.

When asked what the biggest disadvantages about the harnessing systems are, both in the specialists and the users opinions, the uncomfortable wearing came up most often in both cases. In particular the discomfort in the axilla area was dominant in the answers. The complete keywords in the answers can be found and explained in Figure 23.



| Comfort | The comfort of wearing the harness, in particular in |
|---------------|--|
| | the armpit. |
| Hygiene | Harness gets dirty and smelly quickly. |
| Donning/ | Worn underneath clothing so donning/doffing is |
| doffing | difficult. Difficult to make the movement to put the |
| | prosthesis on as well as avoiding twist in the straps. |
| Adjustability | Harness not always easy to adjust or position. |
| Restricted | Users can't move freely, especially with voluntary |
| movements | closing prosthesis. |
| Cosmetics | Harness visible under clothing, old fashioned. |
| Adaptation | Difficult to get used to the necessary shoulder |
| | movement and the harness on the body, in particular |
| | in the armpit. |

Figure 23. The chart shows elements addressed in answers to the question 'What do [(you as a specialist)/(body powered prosthetic users] think that are the biggest disadvantages about the harnessing systems?'. Each of the elements on x-axis were addressed directly or indirectly in the number of answers on y-axis. Answers are combined from what the specialists think and what in their opinion body powered prosthetic users think.

All the participants knew about the Debra Latour anchor system as an alternative to the traditional harnessing systems (see Figure 24). All but one had some experience using it, but all of them had comments about either skin irritations or problems with attaching the anchor. Fewer participants knew about the T-shirt/harness combination and the Axilla bypass ring and only one participant had experience using each of these alternatives.

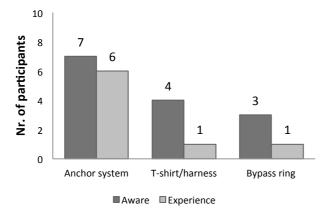


Figure 24. Results for participants knowing about (dark grey - aware) the alternatives to the traditional harnessing systems and using them (light grey - experience).

Discussion and Conclusions

The results from the questionnaire confirm that discomfort coming from the shoulder harness is the biggest disadvantage of body-powered prosthesis, in particular in the axilla region. Besides the discomfort, the hygiene and donning and doffing the harness is a matter of complaint both in the users and specialists opinions. Two of these three most common problems with the harness, the discomfort and the hygiene, can be assumed to originate from the fact that the harness is located in the axilla region. The axilla region is a sensitive are that does usually not experience a lot of pressure and it is one of the main sources of sweat. To conclude, in order to increase usage of body powered prosthesis, it is necessary to change the shoulder harness such that it is not located in the axilla region.

Appendix IV - Design process

The design process started with some brainstorming. The focus was to find solutions that redirect the forces, which are normally exerted on the axilla region (Figure 25A), to a different place on the body (Figure 25B) and/or distributed the forces over a larger area to decrease the pressure on the body.

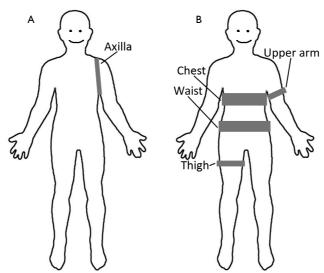


Figure 25. Locations of the body for fixating a harnessing system. (A) Current fixation sites and (B) possible alternative fixations sites.

After finding possible locations to fix the human prosthesis, possible fixation methods were found. The different solutions can be seen in Table 1 and are sorted by different fixation sites.

Table 7. Methods for fixing a harnessing system to the body, categorized by fixation site.

| Upper arm | Chest | Waist | Thigh |
|------------------------|---|--------------------------------|------------------------------------|
| Armband + straps | Elastic chest strap + straps over shoulders | Belt + straps over shoulders | Shorts + straps over shoulders |
| Integrate in a T-shirt | Integrate in a T-shirt | Shorts + straps over shoulders | Thigh band + straps over shoulders |
| | Sports Bra | Integrate in a T-shirt | Socks + straps over shoulder |

These methods were evaluated according to the requirements that have been set. Both of the fixation sites *waist* and *thigh* are fixated below the trunk with all fixation methods with straps over the shoulders and are therefore are sensitive to bending of the trunk. In addition the *thigh* fixation site will be affected by walking. These fixation sites do therefore not fulfill the requirement of allowing bending of the trunk in all directions without opening or closing the prosthesis and are for that reason already eliminated.

The remaining options were the upper arm and chest fixation sites. The fixation methods for these fixation sites can be divided into four categories; 1) chest strap, 2) T-shirt modification, 3) upper arm strap and 4) sports bra. Flowcharts were made for each of the categories, listing all sensible solutions. Many options are possible for an elastic chest strap, by arranging the shoulder straps in different configurations. For that reason, two flowcharts were made on listing the configurations on the front of the body (Figure 26A) and one listing the ones on the back of the body (Figure 26B). They were then further organized by whether the shoulder straps go over one or two shoulders and by the number of fixation points between the chest and shoulder straps. Flowcharts summarizing the options using an upper arm strap (Figure 27A) and the T-shirt options (Figure 27B) organized by fixation sites were made as well. In addition to the flowcharts, an option using a sports bra still remains.

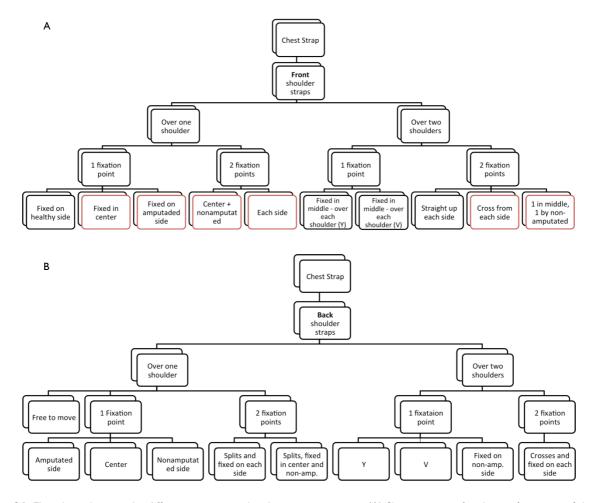


Figure 26. Flowchart showing the different options in the chest strap category. (A) Shows options for the configuration of the shoulder straps on the front and (B) shows options for the configuration of the shoulder straps on the back. The top two levels indicate whether the configurations below are in front or back of the body. The third level splits the flowchart according to whether straps are going over one or both shoulders. The fourth level divides the flowchart further depending to the number of fixation points between the chest strap and shoulder straps. The fifth and last level finally describes the options according to either the location of the fixation sites from level four and/or configuration of the straps.

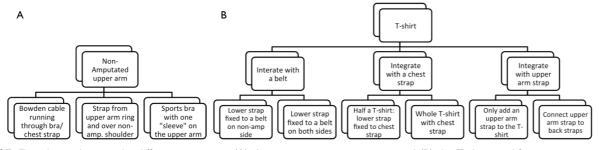


Figure 27. Flowcharts showing the different options in (A) the upper arm strap category and (B) the T-shirt modification category divided according to a fixation site, additional to the original design by Kuniholm.

The flowcharts provided an overview of all the ideas that emerged in the brainstorming and made it easy to eliminate more options (shown in red on Figure 26A) according to the following requirements:

- The device should be suitable for both men and women
- It should not put pressure on sensitive areas such as the breast for female users

Schematic drawings were made for the remaining options. The remaining options using an elastic chest strap were a total of 14 (Figure 28), five of which have a strap coming over one shoulder and 9 over both shoulder. Five options of modifications of a T-shirt remained. Three of them are shown in Figure 29, and two are added when an upper arm strap is combined with the other two. Three configurations of an upper arm strap remained (not counting the option integrated in a T-shirt), and they are shown in Figure 30. The fourth option shown in Figure 30 is an option using a sports bra to connect the Bowden cable to the body.

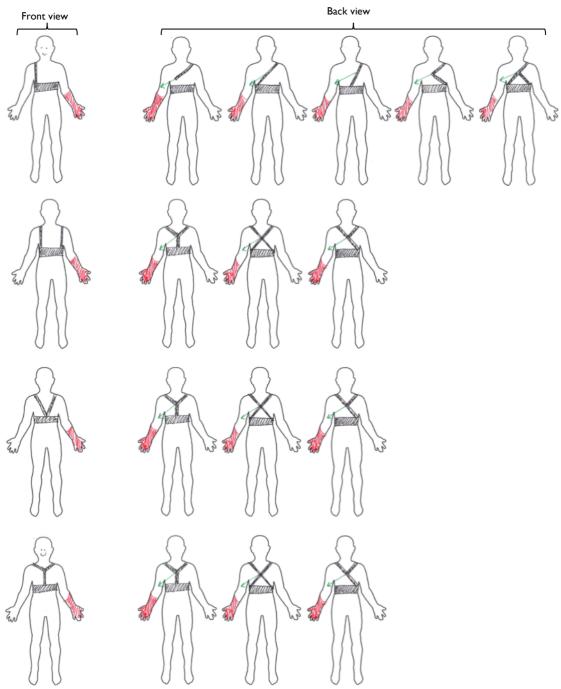


Figure 28. Schematic figures of all the remaining options for the elastic chest strap. The first column shows the various configurations on the front of the body and the rest of the column show remaining configurations on the back of the body for the corresponding row. The amputated arm is shown in red, the straps are shown in black and green the Bowden cable and the arrow pointing in an approximate direction of the activation force.

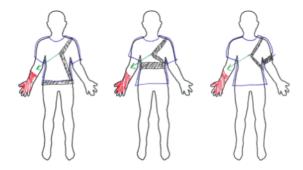


Figure 29. Back view of the T-shirt options. Combination of options is also possible. The T-shirt is shown in purple, the straps in black, red represent the amputated arm and green the Bowden cable and the arrow pointing in an approximate direction of the activation force.

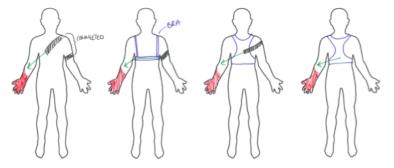


Figure 30. Back view of the upper arm strap and sports bra options. Purple represents the appropriate piece of clothing (brassiere or sports brassiere), red the amputated arm, black the straps and green the Bowden cable and the arrow pointing in an approximate direction of the activation force.

After considering the remaining options using the schematic figures, the most promising design from each of the four categories was chosen to develop further and make a prototype. Two designs were chosen from the chest strap category, one that goes over one shoulder and one that goes over two.

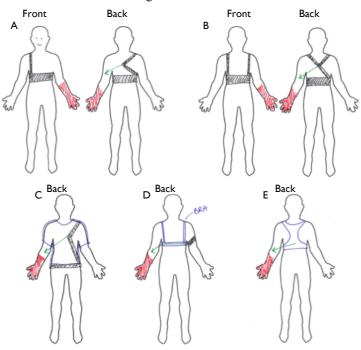


Figure 31. The five remaining designs used to make prototypes. (A) elastic chest strap together with straps over one shoulder, (B) elastic chest strap with straps going over both shoulders, (C) T-shirt adjustment with an integrated belt, (D) upper arm strap with the Bowden cable running through a bra and (E) sports bra used to connect the Bowden cable to the body. Purple represents the appropriate piece of clothing (T-shirt, brassiere or sports brassiere), red the amputated arm, black the straps and green the Bowden cable and the arrow pointing in an approximate direction of the activation force.

The following five designs were chosen:

- (1) One shouldered chest strap (Figure 31A) was chosen rather than the other one shouldered chest strap since the force distribution is assumed to be optimal. The reaction forces to the activation force are split between the strap that goes over the shoulder and is connected to the chest strap on the front of the body and the strap that is connected to the non-amputated side of the trunk. Out of the 5 different one-shouldered designs, this one is thought to cause the least pressure on the body and thus the least discomfort.
- (2) Two shouldered chest strap (Figure 31B) was chosen out of the other two shoulder chest straps. The type of back configuration was chosen the same way as for chest strap 1. It is assumed that the most force distribution is acquired by adding a strap over the shoulder on the amputated side to chest strap 1. The front configuration was chosen because of the direction of the activation force causes the shoulder straps to move towards the neck of the user. It is assumed to be minimized for the chosen configuration.
- (3) T-shirt with a belt (Figure 31C) was chosen out of the other T-shirt designs because it had been reported that the T-shirt was difficult to fixate. To fix that it is possible to fixate the lower part of the t-shirt to something that is already frequently worn (i.e. a belt).
- (4) Upper arm strap with a bra (Figure 31D) was chosen out of the other upper arm strap designs since it requires minimum extra straps and can be integrated into clothing that is already worn by women. The bra can be replaced by a chest strap for men.
- (5) The Sports bra (Figure 31E) is alone in its category and was therefore chosen to be tested out by making a prototype.

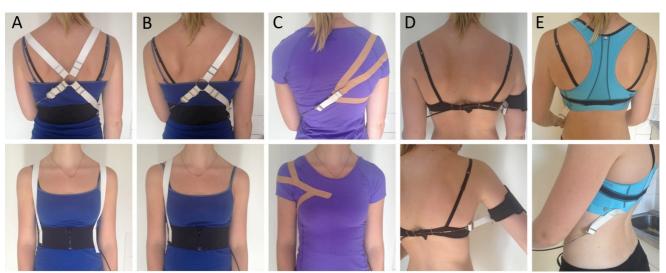


Figure 32. The five prototypes made and tested. All prototypes are made for a left arm amputation. Top row shows back view of all prototypes, bottom row shows front view of prototypes A-C and the connection site of prototypes D and E. (A) elastic chest strap together with straps over one shoulder, (B) elastic chest strap with straps going over both shoulders, (C) T-shirt adjustment with an integrated belt, (D) upper arm strap with the Bowden cable running through a bra and (E) sports bra used to connect the Bowden cable to the body.

Prototypes were made for the five designs (Figure 32) and tested using a prosthetic simulator. The tests were made to find out whether the concepts work in practice. At this point it was not necessary to make any measurements. Instead, the author performed several tasks with each prototype, which included picking up an object and move it around a table, closing the terminal device using very high forces and testing the range of motion wearing the prototype. The findings of these preliminary tests can be found in Table 8.

Table 8. Findings made during preliminary tests on the five prototypes. Overview of possible movements to power a prosthesis with each prototype as well as advantages and disadvantages of each prototype.

| One shouldered chest strap | Movements | Humeral abduction |
|----------------------------|---------------|---|
| • | | Humeral anteflexion |
| | | Limited shoulder protraction |
| | Advantages | Comfortable |
| | · · | Good range of motion, non-amputated hand free to move |
| | Disadvantages | Shoulder straps may cause discomfort against bare skin, especially during |
| | Ü | protraction |
| | | Chest strap may be warm |
| | | Fewer movements to power prosthesis |
| Two shouldered chest strap | Movements | Humeral abduction |
| | | Humeral anteflexion |
| | | Limited shoulder protraction |
| | Advantages | Comfortable |
| | | Good range of motion, non-amputated hand free to move |
| | Disadvantages | Shoulder straps may cause discomfort against bare skin, especially during |
| | | protraction |
| | | Chest strap may be warm |
| | | Fewer movements to power prosthesis |
| T-shirt improvement | Movements | Humeral abduction |
| | | Humeral anteflexion |
| | | Shoulder protraction |
| | Advantages | Comfortable |
| | | No need for adjustments to increase comfort from Kuniholm's design |
| | | Good range of motion, non-amputated hand free to move |
| | Disadvantages | Whole T-shirt, does not fit underneath all clothes |
| Upper arm strap | Movements | Humeral abduction of both arms |
| | | Humeral anteflexion of both arms |
| | | Shoulder protraction |
| | Advantages | Many movements to power prosthesis |
| | Disadvantages | Discomfort experienced due to friction from the Bowden cable |
| | | Very limited range of motion |
| | | Upper arm strap visible under clothing |
| | | Long Bowden cable -> friction losses |
| Sports bra | Movements | Humeral abduction |
| | | Humeral anteflexion |
| | Advantages | Short Bowden cable |
| | | Good range of motion, non-amputated arm free to move |
| | Disadvantages | Bowden cable connected at one place with a small area -> the sports bra moved |
| | - | away from the body |
| | | Not a desirable design for men |
| | | Fewer movements to power prosthesis |
| | | Difficult to don and doff |

The T-shirt didn't need any further improvements to increase comfort so it was eliminated since the objective is to design something new. The upper arm strap was eliminated since it limits the range of motion of the user significantly and also causes discomfort on the back. The sports bra was eliminated since it moved away from the body, and a sport bra designs may no appeal to male users. In addition it is very tight and is not easy to don and doff.

Out of the five prototypes tested, two chest straps remain and are considered further. The only difference between the two chest straps is the shoulder strap that goes over the shoulder on the amputated side. The shoulder strap on the non-amputated side takes most of pressure coming from the activation forces, because of the direction of the activation forces. However, the shoulder strap on the right side helps distribute the pressure when the activation forces are directed more downwards than in the opposite direction of the shoulder strap on the non-amputated side. Furthermore, having straps over both shoulders provides certain symmetry in both pressure and cosmetics, which most people are used to from

wearing for example backpacks, brassieres and suspenders. For these reasons, the chest strap with shoulder straps over both shoulders was chosen to develop further and test in an experiment.

Conclusion

The design process included brainstorming based on where and how it is possible to connect the Bowden cable to the body in order for it to deliver appropriately directed activation forces to the terminal device. The brainstorming resulted in many various ideas of different qualities. After the brainstorming, some of the design ideas were eliminated according to the requirements. Finally, one design from each of the five remaining categories was chosen based on force distribution and cosmetics. These five designs were evaluated further with a prototype. Two of the prototypes clearly stood out and in terms of comfort. After further evaluation, one prototype was chosen to evaluate further in an experiment.

Appendix V - Force Distribution Analysis

The approximate pressure distribution on the body caused by the activation forces for the 'Figure of 9' harness and the Chest Strap can seen in Figure 33, Figure 34 and Figure 35. By analyzing the configurations of the straps and the angle of the activation force, the reaction force distribution can be estimated.

The pressure is distributed over the three straps depending on the direction of the activation force. Generally, the activation force is more or less in line with the back of the shoulder strap on the non-amputated side and therefore the reaction forces on that side are large (see Figure 33), especially for the 'Figure of 9 harness' where there are only reaction forces on that side. With the chest strap, the reaction forces and thus the pressure are divided over a more number straps and larger areas. When the angle is larger (Figure 34), some of the pressure is shifted to the lower strap on the non-amputated side, and when it is smaller (Figure 35), the pressure is distributed over both shoulders. The elastic chest Strap does not undergo a lot of loading, but instead keeps all the straps in their place and secures the system to the body. With the 'Figure of 9' harness, almost all of the pressure is directed to the axilla area regardless of the angle of the activation force.

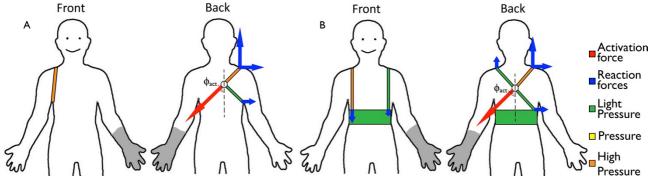


Figure 33. Schematic figures showing force distribution for (A) the Chest Strap and (B) the 'Figure of 9' harness. The amputated side is represented with a grey area and the angle of the activation force with ϕ_{act} . The magnitude of the forces are arbitrary since they are dependant on the direction of the activation force as well as the size, shape and position of the user.

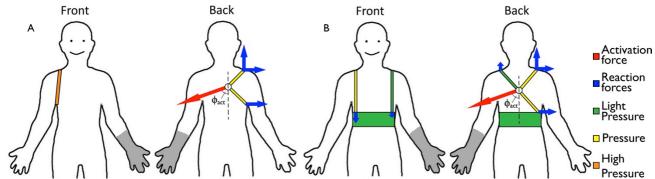


Figure 34. Schematic figures showing force distribution for (A) the Chest Strap and (B) the 'Figure of 9' harness, when the angle of the activation force (ϕ_{act}) is large. The amputated side is represented with a grey area and the angle of the activation force with ϕ_{act} . The magnitude of the forces are arbitrary since they are dependant on the direction of the activation force as well as the size, shape and position of the user.

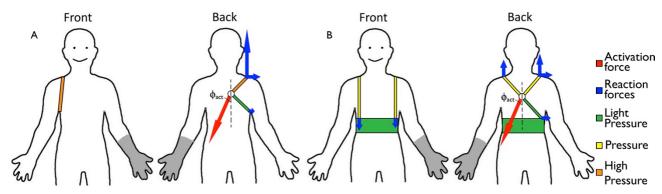


Figure 35. Schematic figures showing force distribution for (A) the Chest Strap and (B) the 'Figure of 9' harness, when the angle of the activation force (ϕ_{act}) is small. The amputated side is represented with a grey area and the angle of the activation force with ϕ_{act} . The magnitude of the forces are arbitrary since they are dependant on the direction of the activation force as well as the size, shape and position of the user.

Conclusion

The reaction forces from the activation force is distributed over more straps and larger areas when using the Chest Strap compared to when the 'Figure of 9' harness is used. As a result, in theory, the Chest Strap is expected to be more comfortable.

Appendix VI - Participants

The participants of this study were all able bodied and in ages between 19 and 27 years old. To check whether this group represents the general population, the height and weight of the participants was compared to Dutch adults of ages between 20 and 30 (see Table 9). The mean height of the subjects is slightly higher than the mean for Dutch adults, however all but one female and one male subject were within standard deviation limits. The mean weight of the female subjects was very similar but slightly higher for the male subjects, where all but two subjects were within limits of standard deviation. Therefore it can be concluded that the participants of this study represent the Dutch population quite well.

Table 9. Overview over participants' age, height and weight. Numbers in brackets show standard deviation.

| | Age [years] | Height [m] | Weight [kg] | |
|---------------------------------|--------------|---------------|--------------|--|
| Female | 23.4 (±2. 4) | I.71 (±0. 10) | 66.7 (±6. 4) | |
| Male | 25.I (±1. 5) | 1.87 (±0. 07) | 84.5 (±9. 6) | |
| Female _D 36 | 20-30 | 169 (±0.07) | 66 (±9) | |
| Male _D ³⁶ | 20-30 | 185 (±0. 08) | 80 (±14) | |

Female and male represent the participants in this study. Femaleo and maleo represent the means for Dutch adults³⁶.

Appendix VII – Information letter

Comparison of comfort and operation of two different arm prosthesis operation systems.

Introduction

The users of upper arm prostheses complain about discomfort while wearing the commercially available arm prosthesis operation system (shoulder harness). To decrease the discomfort, the users wear the shoulder harness over clothing, in spite the cosmetic disadvantages. During this research, a new system has been developed in attempt to increase the user comfort. This experiment is done to confirm whether the problem is solved with this new system. It will be investigated whether the new systems are more comfortable and whether the user is able to operate a typical prosthesis at least as well as with the conventional one.

Goal

The goal of this research is to design a prosthesis operation system that is more comfortable than the traditional harness, while still allowing the user to operate their prosthesis as well as before.

Participation requirements

For the best possible comfort estimation you are requested to wear the systems on bare skin, without upper body clothing (except underwear for example a bra). In case you are not comfortable with performing the experiment without a shirt, please inform the researcher!

During this research we would like to investigate subjects without any motor control / neuromuscular constraints. In case you have motor control / neuromuscular constraints please inform the researcher!



Figure ${f 1}$. Prosthesis operation systems used in the experiment.

Tasks

You will be asked to perform the following 4 tasks wearing a prosthetic simulator and each of the three harnesses. You will finish all the tasks with one harness and then start again with the next one. You will be able to practice before each measurement.

Task 1

You will be asked to create as high forces as you can for 3 seconds. You will be asked to repeat that three times with some rest in between.

Task 2

You will see a white line on a laptop screen that represents the reference force. You will also see a red line, which represents the measured force that you reproduce. You will hear a beep, which is your cue to reach the white reference

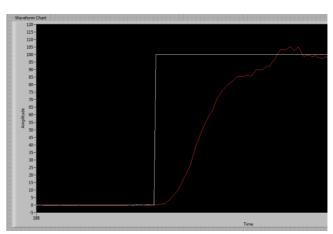


Figure 36. Screenshot of the laptop screen for task 2.

line as fast as possible and follow it as precisely as you can for 10 seconds. After 10 seconds you will hear another peep and you can rest for 5 seconds until you hear the next peep. This will be repeated 6 times in total.

Task 3

You will use the hook to move as many blocks as you can, from the left side of the box over the barrier to the right side, in one minute. You will repeat this three times.



Figure 3. Blocks used for task 3.

Task 4

You will use both hands (right hand and prosthetic simulator) to move an object between places of different heights. You will move the object from a low location to a high location and back. This will be repeated 6 times, for different combinations of low and high locations

| rigii 4 |
|---------|
| High 3 |
| High 2 |
| High I |
| |
| Low 3 |
| Low 2 |
| |
| |
| LowI |

Uiah 4

Figure 4. Low and high locations for task 4.

Rights and duties

Your participation in this experiment is on your own free will. You can stop participating in the experiments anytime – also during the experiments - without the need of giving any reason. In case the results from this experiment will be published, no connections can be made to you as a person.

We will save your data anonymously. Only the main researcher has access to your personal details that can be connected to your research data. Third parties can only access your data with your explicit permission.

This research is approved by the local ethical committee of the TU Delft. If you have any questions you can ask the researcher.

Researcher contact information

Thora Gudfinnsdottir

e-mail: thorag@gmail.com phone: 06 28555176

Appendix VIII - Consent form

I agree in participating in this research.

Comparison of comfort and operation of two different arm prosthesis operation systems.

I have read the participant information letter for this research. I was able to ask questions and am satisfied with the answers to my questions. I had sufficient time to decide whether I want to participate in this study.

I am aware that the participation is of my own free will and that I can withdraw from the experiment at any time.

I know that my research data is kept anonymously and can be seen by a group of researchers. Only the main researcher (Thora Gudfinnsdottir) has access to my personal details that can be connected to my research data. Third parties can only access my data with my explicit permission.

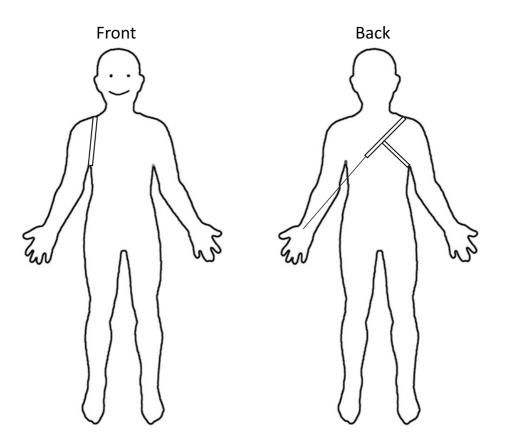
I am giving consent that my research data may be used for the purposes mentioned in the information letter.

I am giving consent that my personal details may be saved for the duration of 5 years.

| Name subject: | |
|--|--|
| Signature: | _ Date: / / |
| | |
| declare that I informed the subject comp | letely about the mentioned research. |
| Whenever I gather more information dur permission of the subject, I will inform hi | ing the experiment, which might influence the m/her in time. |
| Name researcher: Thora Gudfinnsdottir | |
| Signature: | Date: / / |

Appendix IX - Body Maps





P: Pressure on skin S: Shear on skin F: Muscle fatigue

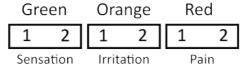
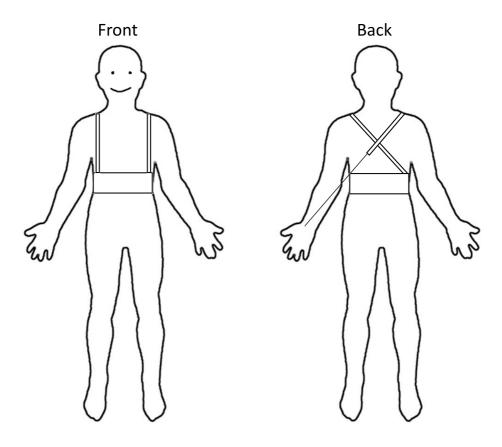


Figure 37. Body map used for the 'Figure of 9' harness. The participants are asked to colour the areas where they felt a sensation/irritation/pain with the appropriate colour (green/orange/red) and associate them with a number 1 or 2 depending on whether the feeling is closer to the one below or above. The participants are also asked to associate the colour with one of three letters where P represent pressure, S represents shear and F represents muscle fatigue.

Participant ID Harness Task



P: Pressure on skin

S: Shear on skin

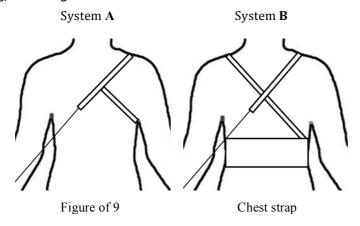
F: Muscle fatigue



Figure 38. Body map used for the 'Figure of 9' harness. The participants are asked to colour the areas where they felt a sensation/irritation/pain with the appropriate colour (green/orange/red) and associate them with a number 1 or 2 depending on whether the feeling is closer to the one below or above. The participants are also asked to associate the colour with one of three letters where P represent pressure, S represents shear and F represents muscle fatigue.

Appendix X - Final Questionnaire

Instructions: Please answer the following questions as well as you can. You are asked to consider a few scenarios and choose which system you like the best for that scenario. Beside each option are empty lines for explaining why, please use them freely. It would be great to receive any feedback you are willing/able to give.

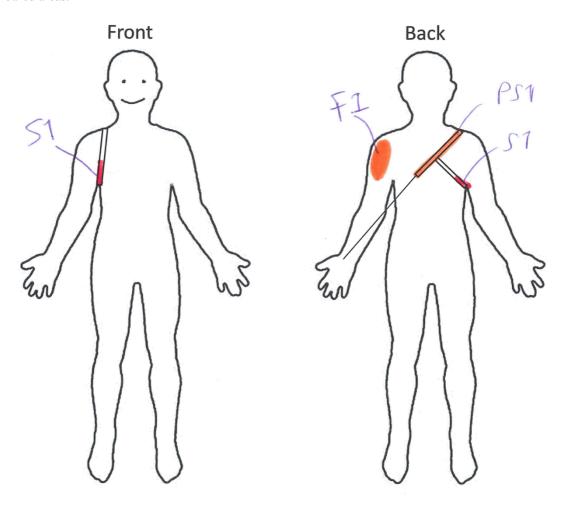


| Which system d | d you prefer to wear passively , system A or B? |
|-----------------|--|
| System | . Why? |
| | |
| | |
| | |
| Which system d | d you prefer to operate (wear actively), system A or B? |
| System | . Why? |
| | |
| | |
| | |
| | |
| Considering hav | ing to wear this every day, for all occasions, underneath every type of clothing |
| which system do | you find most cosmetically appealing, system A or B? |
| System | . Why? |
| | |
| | |
| | |
| | |

| All above co | nsidered, whi | le also thin | ıking about | wearing this | all day, duri | ng all seasor | ns; would you |
|---------------|----------------|--------------|-------------|--------------|---------------|---------------|---------------|
| prefer to use | e system A or | B? | | | | | |
| System | Why? | | | | | | _ |
| | | | | | | | _ |
| | | | | | | | _ |
| | | | | | | | _ |
| | | | | | | | _ |
| | | | | | | | |
| | | | | | | | |
| Any comme | nts or suggest | tions? | | | | | |
| | | | | | | | _ |
| | | | | | | | |
| | | | | | | | - |
| | | | | | | | _ |
| | | | | | | | - |
| | | | | | | | _ |

Appendix XI - Raw Body Map Data

Examples of raw data from the body maps are shown in Figure 39 and Figure 40. The data from these body maps were given a comfort score ranging from 0 to 6, where 0 represented no colour, 1 represented green level 1 and so on until 6 represented the colour red level 2. The shear and pressure data were combined such that the higher comfort score for each area was used (when applicable). The comfort scores were organized into the areas shown in Figure 41 according to the coloured areas.



P: Pressure on skin

S: Shear on skin

F: Muscle fatigue

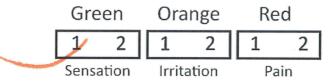
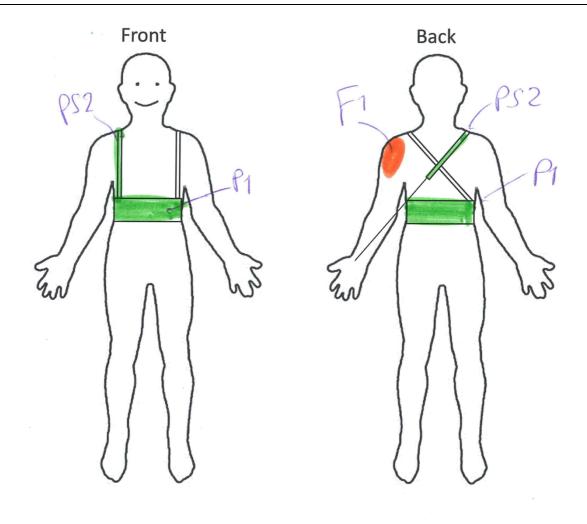


Figure 39. Coloured body map from one participant using the 'Figure of 9' harness in task 3.



P: Pressure on skin S: Shear on skin F: Muscle fatigue



Figure 40. Coloured body map from one participant using the Chest Strap in task 3.

Appendix XII - Body Map Results

This appendix contains the complete results from the body maps, divided into areas of the harnessing systems seen in Figure 41. First detailed results for each task are presented and finally combined results and statistical analysis.

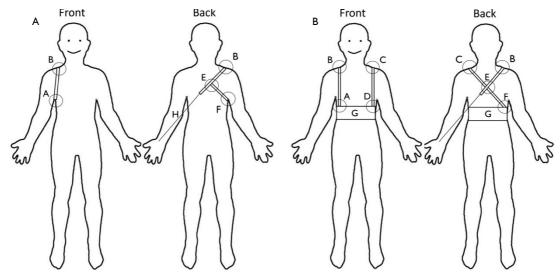


Figure 41. Areas of the (A) 'Figure of 9' harness and (B) Chest strap.

Task I

Table 10 provides the complete results from the body maps in task 1 where mean comfort score and standard deviation are listed for each area. In addition, the number of participants that reported pain, irritation and sensation are listed. Figure 42 provides a visual representation of the mean comfort scores according to area. The results from task 1 were split in two groups, where the participants that produced the highest forces were in one group and the ones that produced lower forces were in the other. Table 11 show the results from the statistical comparison of both the maximum forces produced and the comfort scores, to check whether correlation is between strength and pain.

Table 10. Combined results from body maps in task I

| | | | | Fig | ure of 9 | | Chest strap | | | | | | | |
|------|------|------|-----------|------------|----------|------|-------------|------|--------|---------|-------|--------------|--------|--|
| | | | [Nr. of | f subjects | s] | [Com | f. Score] | | [Nr. o | subject | s] | [Comf. Score | | |
| Area | Gen. | Col. | - Pain | lrr. | Sens. | Mean | St.dev | Col. | Pain | lrr. | Sens. | Mean | St.dev | |
| Α | F | 10 | 5 | 4 | Ţ | 4.5 | 1.4 | - | - | - | - | - | - | |
| | М | 10 | 9 | 1 | - | 5.4 | 1.0 | _ | - | - | - | - | - | |
| В | F | 2 | I | I | - | 0.8 | 1.8 | 5 | - | 4 | I | 1.4 | 1.4 | |
| | М | 6 | 3 | 1 | 2 | 2.2 | 2.6 | 6 | - | 4 | 2 | 1.8 | 1.7 | |
| С | F | - | - | - | - | - | - | 3 | - | 2 | I | 0.8 | 1.5 | |
| | М | _ | - | - | - | - | - | | - | - | 1 | 0.2 | 0.6 | |
| D | F | - | - | - | - | - | - | - | - | - | - | - | - | |
| | М | - | - | - | - | - | - | 1 | - | - | 1 | 0.2 | 0.6 | |
| E | F | 2 | I | I | - | 0.9 | 1.9 | 2 | I | I | - | 0.8 | 1.8 | |
| | М | 4 | 1 | - | 3 | 0.9 | 1.6 | 4 | I | 1 | 2 | 1.2 | 1.9 | |
| F | F | 2 | I | I | - | 1.3 | 2.2 | ı | - | I | - | 0.3 | 0.9 | |
| | М | 5 | 3 | I | 1 | 2.2 | 2.6 | 3 | I | - | 2 | 0.9 | 1.9 | |
| G | F | - | - | - | - | - | - | 3 | - | - | 3 | 0.3 | 0.5 | |
| | М | - | - | - | - | - | - | 3 | - | - | 3 | 0.4 | 0.7 | |
| A-B | F | 8 | 5 | 3 | - | 3.8 | 2.2 | 5 | 2 | 2 | I | 1.9 | 2.4 | |
| | М | 8 | 7 | - | 1 | 4.1 | 2.6 | 3 | - | 2 | 1 | 0.9 | 1.5 | |
| C-D | F | - | - | - | - | - | - | - | - | - | - | - | - | |
| | М | _ | - | - | - | - | - | 2 | - | - | 2 | 0.3 | 0.7 | |
| B-E | F | 3 | ı | ı | I | I | 1.8 | 3 | - | 2 | I | 0.8 | 1.5 | |
| | М | 4 | 1 | - | 3 | 0.9 | 1.6 | 3 | - | 1 | 2 | 0.7 | 1.4 | |
| C-E | F | - | - | - | - | - | - | - | - | - | - | - | - | |
| | М | - | - | - | | _ | - | 2 | 1 | - | 1 | 0.7 | 1.6 | |
| F-E | F | ı | - | - | I | 0.1 | 0.3 | - | - | - | - | - | - | |
| | М | 4 | - | 1 | 2 | 0.7 | 1.1 | 2 | - | - | 2 | 0.3 | 0.7 | |
| E-H | F | - | - | - | - | - | - | 2 | ı | - | ı | 0.6 | 1.6 | |
| | М | 3 | 1 | _ | 2 | 0.8 | 1.6 | 3 | _ | 1 | 2 | 0.7 | 1.3 | |

Area = the corresponding area of the harness shown in Figure X, Gen. = gender (F=female/M=male), Col.= number of participants that coloured the area, Pain = number of people that coloured with a colour representing pain, Irr. = number of people that coloured with a colour representing irritation, Sens = number of people that colored with a color representing sensation, mean_{all} = the mean score of all subjects, m_{col} = the mean sore of all subjects that coloured the specific area.

Table 11. Overview over *p* values to check whether the difference in comfort scores is significant depending on strength.

| | | | | Figure of | f <mark>9</mark> harne | ss | | | | Ches | st strap | | | |
|--------|-----|------|-------|-----------|------------------------|----------|--------------|-------|-----|-------|----------|-----------|-------|--|
| | Gen | | Score | | | Force [N | 1] | Score | | | | Force [N] | | |
| | | High | Low | p val | High | Low | p val | High | Low | p val | High | Low | p val | |
| Task I | F | 4.6 | 4.4 | 0.690 | 285.I | 172.3 | 0.008 | 3.2 | 3.4 | 0.841 | 277.9 | 195.6 | 0.008 | |
| | М | 6 | 4.8 | 0.032 | 608.6 | 383.3 | <u>0.008</u> | 2.2 | 2.0 | 1.000 | 516.7 | 348.4 | 0.008 | |

F9 Female = p values calculated from the comfort scores of female subjects for F9, F9 Male = p values calculated from the comfort scores of male subjects for F9, CS Female = p values calculated from the comfort scores of female subjects for CS, CS Male = p values calculated from the comfort scores of male subjects for CS,

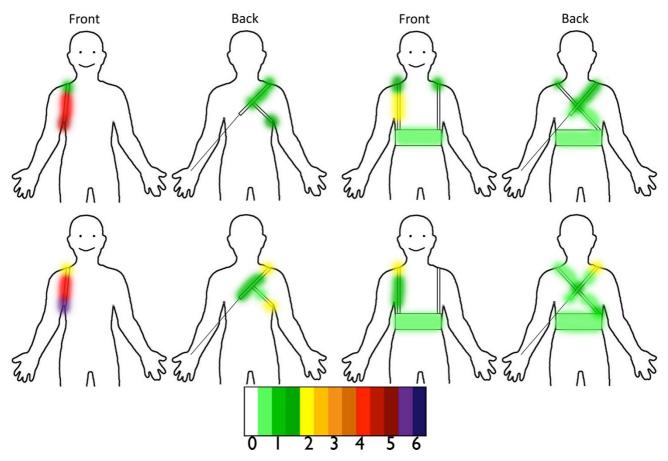


Figure 42. Visual body map results for task I. Data collected from female (top) and male (bottom) body maps separately and mean comfort scores from all participants used to select an appropriate colour for the corresponding area.

Task 2

Table 12 provides the complete results from the body maps in task 1 where mean comfort score and standard deviation are listed for each area. In addition, the number of participants that reported pain, irritation and sensation are listed. Figure 43 provides a visual representation of the mean comfort scores according to area.

Table 12. Combined results from body maps in task 2.

| | | | | Fig | ure of 9 | | Chest strap | | | | | | | |
|------|------|------|---------|-----------|----------|-------|-------------|------|--------|---------|----------------|-------|-----------|--|
| | | | [Nr. of | f subject | s] | [Com | f. Score] | | [Nr. o | subject | <u>.</u> s] | [Com | f. Score] | |
| Area | Gen. | Col. | Pain | Irr. | Sens. | Score | St.dev | Col. | Pain | Irr. | Sens. | Score | St.dev | |
| Α | F | 10 | 5 | 5 | - | 4.1 | 1.2 | - | | | | | | |
| | М | 9 | 3 | 6 | - | 3.6 | 1.6 | 2 | - | - | 2 | 0.2 | 0.4 | |
| В | F | 2 | - | 2 | - | 0.6 | 1.3 | 5 | - | 5 | | 1.5 | 1.6 | |
| | М | 5 | - | 3 | 2 | 1.1 | 1.4 | 4 | - | 2 | 2 | 0.7 | 1.4 | |
| С | F | - | - | - | - | - | - | ı | - | - | I | 0.1 | 0.3 | |
| | М | - | - | - | - | - | - | 3 | - | - | 1 | 0.3 | 0.5 | |
| D | F | - | - | - | - | - | - | - | - | - | - | - | - | |
| | М | - | - | - | - | - | _ | 2 | - | - | 2 | 0.2 | 0.4 | |
| E | F | 5 | - | 2 | 3 | 1.2 | 1.1 | 6 | - | 4 | 2 | 1.4 | 1.4 | |
| | М | 4 | - | 1 | 3 | 0.7 | 1.5 | 4 | - | 4 | - | 1 | 1.5 | |
| F | F | 4 | 2 | 2 | - | 1.8 | 2.1 | - | - | - | - | - | - | |
| | М | 5 | 1 | 3 | 1 | 1.7 | 2.5 | 3 | - | 1 | - | 0.7 | 1.1 | |
| G | F | - | - | - | - | - | - | 2 | - | - | 2 | 0.2 | 0.4 | |
| | М | - | - | - | - | - | - | 4 | - | - | 4 | 0.3 | 0.5 | |
| A-B | F | 7 | 4 | 3 | - | 3 | 2.3 | 3 | 2 | - | I | 1.2 | 2.1 | |
| | М | 7 | 2 | 2 | 3 | 2.2 | 2.4 | 3 | - | 1 | 2 | 0.2 | 1.0 | |
| C-D | F | - | - | - | - | - | - | - | - | - | - | - | - | |
| | М | - | - | - | - | - | - | 2 | - | - | 2 | 0.2 | 0.4 | |
| B-E | F | 3 | - | ı | 2 | 0.7 | 1.2 | 6 | - | 5 | I | 1.6 | 1.5 | |
| | М | 4 | - | 1 | 3 | 0.7 | 1.1 | 3 | - | 3 | - | 0.7 | 1.4 | |
| C-E | F | - | - | - | - | - | - | - | - | - | - | - | - | |
| | М | - | - | - | - | _ | - | 3 | - | 3 | - | 1.1 | 1.6 | |
| F-E | F | 4 | - | 2 | 2 | 1 | 1.5 | 1 | - | ı | - | 0.3 | 0.9 | |
| | М | 4 | - | 1 | 3 | 0.7 | 1.3 | 2 | - | 1 | 1 | 0.4 | 1.0 | |
| E-H | F | 3 | - | - | 2 | 0.4 | 0.7 | 6 | ı | 3 | 2 | 1.7 | 1.9 | |
| | М | 4 | _ | - 1 | 3 | 0.7 | 1.1 | 3 | _ | 3 | _ | | 1.5 | |

Area = the corresponding area of the harness shown in Figure X, Gen. = gender (F=female/M=male), Col.= number of participants that coloured the area, Pain = number of people that coloured with a colour representing pain, Irr. = number of people that coloured with a colour representing irritation, Sens = number of people that colored with a color representing sensation, mean_{all} = the mean score of all subjects, m_{col} = the mean sore of all subjects that coloured the specific area.

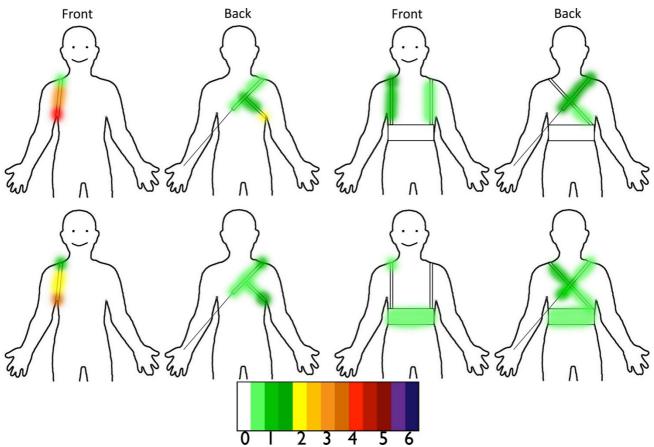


Figure 43. Visual body map results for task 3. Data collected from female (top) and male (bottom) body maps separately and mean comfort scores from all participants used to select an appropriate colour for the corresponding area.

Task 3

Table 13 provides the complete results from the body maps in task 1 where mean comfort score and standard deviation are listed for each area. In addition, the number of participants that reported pain, irritation and sensation are listed. Figure 44 provides a visual representation of the mean comfort scores according to area.

Table 13. Combined results from body maps in task 3.

| | | | | Fig | ure of 9 | | | Chest strap | | | | | | | |
|------|------|------|---------|----------|----------|------|-----------|-------------|---------|----------|----------|------|-----------|--|--|
| | | | [Nr. of | subjects | <u>[</u> | [Com | f. Score] | | [Nr. of | subjects | <u>[</u> | [Com | f. Score] | | |
| Area | Gen. | Col. | Pain | lrr. | Sens. | Mean | St.dev | Col. | Pain | Irr. | Sens. | Mean | St.dev | | |
| Α | F | 6 | - | 4 | 2 | 1.9 | 1.7 | - | | | | | | | |
| | М | 9 | 3 | 5 | I | 3.4 | 1.7 | 2 | - | - | 2 | 0.2 | 0.4 | | |
| В | F | 2 | - | ı | ı | 0.4 | 1.0 | 4 | - | ı | 3 | 0.7 | 1.1 | | |
| | М | 6 | 1 | 2 | 3 | 1.4 | 1.7 | 4 | - | - | 4 | 0.6 | 0.8 | | |
| С | F | - | - | - | - | - | - | - | - | - | - | - | - | | |
| | М | - | - | - | - | - | - | 2 | - | - | 2 | 0.2 | 0.4 | | |
| D | F | - | - | - | - | - | - | - | - | - | - | - | - | | |
| | М | - | - | - | - | - | - | 2 | - | - | 2 | 0.2 | 0.4 | | |
| Е | F | 2 | - | I | ı | 0.4 | 1.0 | 2 | - | - | 2 | 0.3 | 0.7 | | |
| | M | 4 | - | 2 | 2 | 0.8 | 1.2 | 4 | - | I | 3 | 0.8 | 0.7 | | |
| F | F | 3 | - | 3 | - | 1.1 | 1.8 | - | - | - | - | - | - | | |
| | М | 5 | 2 | 2 | I | 1.8 | 2.1 | 2 | - | I | I | 0.5 | 1.1 | | |
| G | F | - | - | - | - | - | - | ı | - | - | I | 0.1 | 0.3 | | |
| | M | _ | - | - | - | - | - | 4 | - | - | 4 | 0.4 | 0.5 | | |
| A-B | F | 5 | - | 3 | 2 | 1.3 | 1.6 | 2 | - | I | I | 0.5 | 1.1 | | |
| | М | 6 | I | 3 | 2 | 1.7 | 1.9 | 3 | - | - | 3 | 0.4 | 0.7 | | |
| C-D | F | - | - | - | - | - | - | - | - | - | - | - | - | | |
| | М | - | - | - | - | - | - | 2 | - | - | 2 | 0.2 | 0.4 | | |
| B-E | F | ı | - | I | - | 0.3 | 0.9 | 3 | - | I | 3 | 0.6 | 1.1 | | |
| | M | 4 | - | I | 3 | 0.6 | 1.0 | 4 | - | I | 3 | 0.8 | 1.1 | | |
| C-E | F | - | - | - | - | - | - | - | - | - | - | - | - | | |
| | М | _ | - | - | _ | - | - | 3 | - | I | 2 | 0.6 | 1.1 | | |
| F-E | F | 3 | - | 2 | ı | 0.7 | 1.3 | - | - | - | - | - | - | | |
| | М | 3 | - | - | 3 | 0.4 | 0.7 | 3 | - | I | 2 | 0.6 | 1.1 | | |
| -E-H | F | ı | - | - | ı | 0.1 | 0.3 | - | - | - | - | - | - | | |
| | М | 4 | _ | 2 | 2 | 0.8 | 1.2 | 5 | _ | 1 | 4 | 0.9 | 1.1 | | |

Area = the corresponding area of the harness shown in Figure X, Gen. = gender (F=female/M=male), Col.= number of participants that coloured the area, Pain = number of people that coloured with a colour representing pain, Irr. = number of people that coloured with a colour representing irritation, Sens = number of people that colored with a color representing sensation, mean_{all} = the mean score of all subjects, m_{col} = the mean sore of all subjects that coloured the specific area.

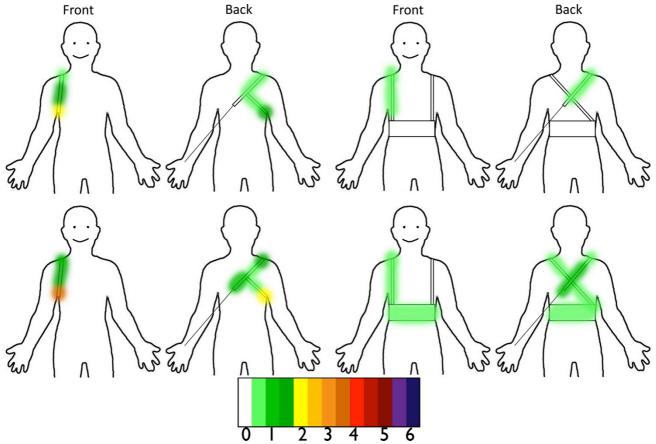


Figure 44. Visual body map results for task 3. Data collected from female (top) and male (bottom) body maps separately and mean comfort scores from all participants used to select an appropriate colour for the corresponding area.

Task 4

Table 14 provides the complete results from the body maps in task 1 where mean comfort score and standard deviation are listed for each area. In addition, the number of participants that reported pain, irritation and sensation are listed. Figure 45 provides a visual representation of the mean comfort scores according to area.

Table 14. Combined results from body maps in task 4.

| | | | | Fig | ure of 9 | | Chest strap | | | | | | | |
|------|------|------|---------|------------|-----------|-------|-------------|------|---------|------------|-------|-------|-----------|--|
| | | | [Nr. of | f subjects | <u>s]</u> | [Com | f. Score] | | [Nr. of | f subject: | s] | [Com | f. Score] | |
| Area | Gen. | Col. | Pain | lrr. | Sens. | Score | St.dev | Col. | Pain | lrr. | Sens. | Score | St.dev | |
| -A | F | 7 | I | 5 | I | 2.3 | 1.9 | - | - | - | - | - | - | |
| | М | 8 | 1 | 6 | I | 2.7 | 1.6 | 1 | - | - | 1 | 0.1 | 0.3 | |
| В | F | 4 | - | 2 | 2 | 0.8 | 1.2 | 7 | - | 5 | 2 | 1.7 | 1.4 | |
| | М | 5 | 1 | 2 | 2 | 1.4 | 1.9 | 4 | - | 2 | 2 | 0.9 | 1.3 | |
| С | F | - | - | - | - | - | - | ı | - | I | - | 0.3 | 0.9 | |
| | М | - | - | - | - | - | - | 3 | - | I | 2 | 0.5 | 1.0 | |
| D | F | - | - | - | - | - | - | - | - | - | - | - | - | |
| | М | | | | | | | 1 | - | - | 1 | 0.1 | 0.3 | |
| E | F | 3 | - | ı | 2 | 0.6 | 1.1 | 2 | - | I | I | 0.4 | 1.0 | |
| | М | 4 | - | 1 | 3 | 0.7 | 1.1 | 4 | - | I | 3 | 0.7 | 1.1 | |
| F | F | 3 | - | 3 | - | 1.1 | 1.8 | - | - | - | - | - | - | |
| | М | 5 | I | 3 | I | 1.5 | 1.8 | 3 | - | - | 2 | 0.2 | 0.4 | |
| G | F | - | - | - | - | - | - | 5 | - | 2 | 2 | 1.1 | 1.4 | |
| | М | - | - | - | - | - | - | 4 | - | I | 3 | 0.7 | 1.3 | |
| A-B | F | 3 | - | 2 | I | 0.8 | 1.3 | 1 | - | - | ı | 0.2 | 0.6 | |
| | М | 5 | - | 3 | 2 | 1.3 | 1.7 | 3 | - | I | 2 | 0.5 | 1.0 | |
| C-D | F | - | - | - | - | - | - | - | - | - | - | - | - | |
| | М | | - | - | - | - | - | 2 | - | - | I | 0.2 | 0.4 | |
| B-E | F | 3 | - | 2 | ı | 0.7 | 1.3 | 4 | - | 3 | I | 1.1 | 1.6 | |
| | М | 4 | - | 2 | 2 | 1 | 1.5 | 3 | - | 1 | 2 | 0.6 | 1.1 | |
| C-E | F | - | - | - | - | - | - | ı | - | ı | - | 0.3 | 0.9 | |
| | М | - | - | - | - | - | - | 3 | - | 1 | 2 | 0.5 | 1.0 | |
| F-E | F | 3 | - | 2 | I | 0.9 | 1.4 | 2 | - | 2 | - | 0.6 | 1.3 | |
| | М | 3 | - | - | 3 | 0.4 | 0.7 | 2 | - | - | 2 | 0.2 | 0.4 | |
| E-H | F | 4 | - | ı | 3 | 0.7 | 1.1 | - | - | - | - | - | - | |
| | М | 4 | _ | 1 | 3 | 0.7 | 1.1 | 3 | - | - | 3 | 0.4 | 0.7 | |

Area = the corresponding area of the harness shown in Figure X, Gen. = gender (F=female/M=male), Col.= number of participants that coloured the area, Pain = number of people that coloured with a colour representing pain, Irr. = number of people that coloured with a colour representing irritation, Sens = number of people that colored with a color representing sensation, mean_{all} = the mean score of all subjects, m_{col} = the mean sore of all subjects that coloured the specific area.

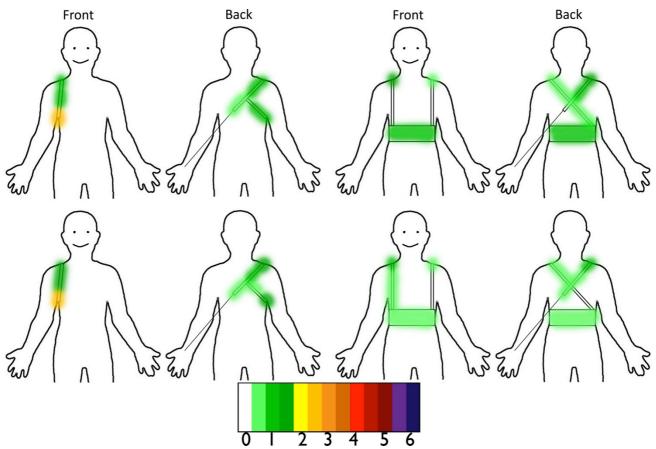


Figure 45. Visual body map results for task 3. Data collected from female (top) and male (bottom) body maps separately and mean comfort scores from all participants used to select an appropriate colour for the corresponding area.

Task summary

The single highest comfort scores (most discomfort) were collected for each subject regardless of area and are presented in Table 15. The highest comfort score within the stress areas were collected and are presented in Table 15. The scores in the stress areas were statistically compared between the harnessing systems (see Table 16) and between the genders (Table 17). Boxplots showing the results from the stress areas for the genders separately are shown in Figure 46. Finally, the difference in comfort scores was compared for each system depending in which of the harnessing systems was used first and the results shown in Table 18 and Figure 47.

Table 15. Result overview over the single highest comfort score the participants gave each system. Underlined comfort scores represent the higher comfort score between the two harnessing systems. Underlined p-values represent significant difference between the comfort scores of the 'Figure of 9' harness and the Chest Strap.

| | | | | Fig | ure of 9 | 7 | | | | Cho | est Stra | P | | |
|---------|------|------|---------|----------|----------|------------|-----------|------|---------|----------|----------|------|---------|---------|
| | | | [Nr. of | subjects | | [Com | f. Score] | | [Nr. of | subjects |] | [Com | 6 value | |
| | Gen. | Pain | Irr. | Sens. | No | Mean | St.dev | Pain | Irr. | Sens. | No | Mean | St.dev | p value |
| Task I | F | 5 | 4 | ı | - | 4.5 | 1.4 | 3 | 5 | 2 | - | 3.4 | 1.6 | 0.047 |
| I ask I | M | 9 | 1 | - | - | <u>5.4</u> | 1.0 | 3 | 3 | 1 | 2 | 3.2 | 2.0 | 0.011 |
| Task 2 | F | 5 | 5 | - | - | 4.2 | 1.3 | 2 | 7 | ı | - | 3.4 | 1.0 | 0.071 |
| rask z | M | 4 | 6 | - | - | 4.2 | 1.2 | - | 6 | 1 | 3 | 2.2 | 1.6 | 0.011 |
| T1-2 | F | - | 6 | 3 | ı | 2.5 | 1.4 | - | 2 | 4 | 4 | 1.2 | 1.2 | 0.072 |
| Task 3 | M | 4 | 5 | I | - | 3.9 | 1.3 | - | 1 | 4 | 5 | 1 | 1.2 | 0.004 |
| Task 4 | F | I | 7 | 2 | - | 3.0 | 1.2 | - | 6 | 2 | 2 | 2.2 | 1.5 | 0.203 |
| rask 4 | М | 2 | 6 | 1 | 1 | 3.2 | 1.5 | - | 1 | 4 | 5 | 1 | 1.2 | 0.007 |

Gen. = participant gender, Pain = number of participants that reported pain, Irr. = number of participants that reported irritation, Sens. = number of participants that reported sensation, No = number of participants that didn't color these areas, Mean = mean comfort score of all participants specified, St.dev = standard deviation from the mean comfort score, p value = calculated significance between the mean comfort scores.

Table 16. Result overview for the stress areas. Comfort scores are combined such that the highest score from the three areas is picked and average between all participants. Table shows combined scores for areas A-B, A and F for the 'Figure of 9' harness and for areas A-B, B and B-E for the Chest Strap. Underlined comfort scores represent the higher comfort score between the two harnessing systems. Underlined p-values represent significant difference between the comfort scores of the 'Figure of 9' harness and the Chest Strap.

| | | | | Fig | ure of ' | 9 | | | | Che | st Stra | Р | | | |
|------|------|------|---------|----------|----------|------------|-----------|------|---------|----------|---------|------|-----------|---------|-------|
| | | | [Nr. of | subjects | s] | [Com | f. Score] | | [Nr. of | subjects |] | [Com | f. Score] | p value | |
| | Gen. | Pain | Irr. | Sens. | No | Mean | St.dev | Pain | Irr. | Sens. | No | Mean | St.dev | Seper. | Comb. |
| Task | F | 5 | 4 | 1 | - | 4.5 | 1.4 | 2 | 6 | 2 | - | 3.3 | 1.6 | 0.031 | 0.000 |
| I | М | 9 | 1 | - | - | <u>5.4</u> | 1.0 | - | 5 | 2 | 3 | 2.1 | 1.6 | 0.005 | 0.000 |
| Task | F | 5 | 5 | - | - | 4.2 | 1.3 | 2 | 6 | ı | ı | 3 | 1.4 | 0.026 | 0.000 |
| 2 | M | 4 | 6 | - | - | 4.2 | 1.2 | - | 4 | - | 6 | 1.3 | 1.7 | 0.005 | 0.000 |
| Task | F | - | 6 | 2 | 2 | 2.4 | 1.6 | - | 2 | 4 | 4 | 1.2 | 1.2 | 0.107 | 0.001 |
| 3 | М | 3 | 6 | I | - | 3.8 | 1.2 | - | ı | 3 | 6 | 1.0 | 1.4 | 0.007 | 0.001 |
| Task | F | I | 6 | - | 2 | 2.6 | 1.7 | - | 5 | 2 | 3 | 1.8 | 1.5 | 0.142 | 0.002 |
| 4 | М | 1 | 7 | I | 1 | 3.0 | 1.3 | - | 2 | 2 | 6 | 0.9 | 1.3 | 0.010 | 0.002 |

Gen. = participant gender, Pain = number of participants that reported pain, Irr. = number of participants that reported irritation, Sens. = number of participants that reported sensation, No = number of participants that didn't color these areas, Mean = mean comfort score of all participants specified, St.dev = standard deviation from the mean comfort score, p value, seper. = calculated significance between the mean comfort scores of the genders separately, p value, comb. = calculated significance between the mean comfort scores of the genders combined.

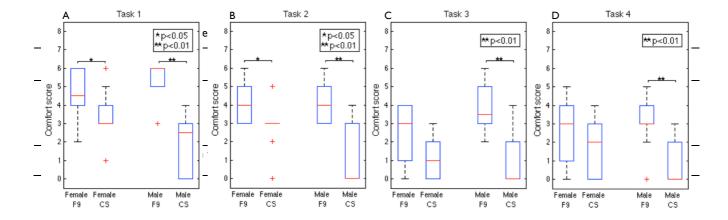


Figure 46. Boxplots showing the distribution of comfort scores in the stress areas for each task; (A) task 1, (B) task 2, (C) task 3 and (D) task 4. Results shown separately for female (n = 10) and male (n = 10) participants. Significant differences between harnessing systems or genders are indicated with stars.

Table 18. Overview over *p* values to check whether the difference in comfort scores is significant depending on which harnessing system the subjects used first. Underlined comfort scores represent the higher comfort score between the two harnessing systems. Underlined p-values represent significant difference between the comfort scores when the 'Figure of 9' harness or the Chest Strap is used first.

| | | 'Figure of 9' harness | | | Chest strap | | |
|--------|--------|-----------------------|------------------|---------|------------------|------------------|---------|
| | Gender | mean F9 first | mean CS first | p value | mean F9 first | mean CS first | p value |
| Task I | F | 4.4 | 4.6 | 0.690 | 3.2 | 3.4 | 1.000 |
| | М | 5.4 | 5.4 | 0.548 | 0.8 | <u>3.4</u> | 0.008 |
| Task 2 | F | 4.4 | 4.0 | 0.690 | 3.2 | 2.8 | 1.000 |
| | М | <u>4.6</u> | 3.8 | 0.421 | 0.6 | 2.0 | 0.310 |
| Task 3 | F | 2.6 | 2.2 | 0.690 | 1.4 | 1.0 | 0.610 |
| | М | 4.0 | 3.6 | 0.690 | 0.8 | 1.2 | 0.548 |
| Task 4 | F | 2.0 | 3.2 | 0.222 | 1.6 | 2.0 | 0.841 |
| | М | 2.4 | 3.6 | 0.222 | 0.2 | 1.6 | 0.222 |

Mean F9 first, the mean comfort score of the subjects that used the 'Figure of 9' harness first, Mean CS first, the mean comfort score of the subjects that used the Chest Strap harness first, p value = significance in comfort scores checked between which system was used first.

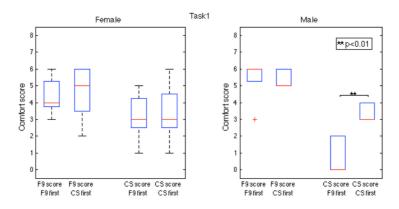


Figure 47. Boxplots showing the distribution of comfort scores in the stress areas according to which harnessing system was used first. Results shown separately for the comfort scores for the harnessing systems and whether the 'Figure of 9' harness (n = 5) or the Chest strap (n = 5) was used first. Significant differences between harnessing systems are indicated with stars.

Discussion & Conclusion

The comfort scores were significantly lower for the Chest Strap than the 'Figure of 9' harness in tasks 1 and 2 for both genders, and also significantly lower in tasks 3 and 4 for the male participants. Furthermore, fewer participants reported pain or irritation in all four tasks when using the Chest Strap.

The male subjects that wore the 'Figure of 9' harness first gave the Chest Strap significantly lower comfort scores in task (Figure 47). The reason for these results is most likely that when using the less uncomfortable harness first, the subjects tend to give discomfort a relatively high score. Then when trying the more uncomfortable harness, they have already used a high score for the first one and the difference between the two becomes less than if the more uncomfortable harness is used first.

Appendix XIII - Raw force data

Examples of raw force data are shown in Figure 48. In task 1, the maximum reference force of all attempts (3 for each harnessing system) was identified and used in the data analysis (Figure 48A). In task 2, the six blocks were separated and the time until the reference force was identified. Then the mean error from the reference force and the standard deviation from the mean were calculated (Figure 48C and Figure 48D). In task 3, the activation forces during the 1 minute that the subject was moving blocs was recorded and the maximum activation forces in each successful movement identified (Figure 48B)

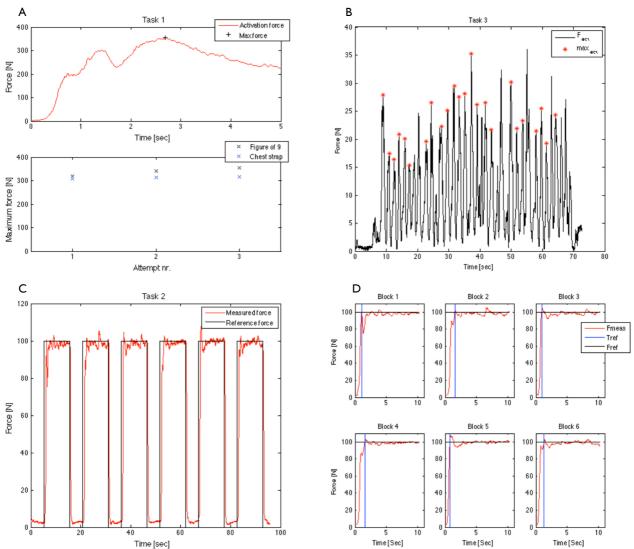


Figure 48. Raw data force data from one participant. Data from (A) task 1: 5 second recording of activation forces where the maximum activation force is shown with a black plus (+) (top) and maximum forces from each attempt using each of the harnessing systems (bottom). (B) task 3: force recorded over the 1 minute where the subject moved blocks. (C) tasks 2: force recorded over six ten second blocks of 100 N reference force and 5 second rests in between. (D) task 2: each of the six blocks plotted separately together with the reference force and the time until the reference force was reached.

Appendix XIV - Functional results

The functional results from tasks 1, 2 and 3, with statistical comparison between the systems, are presented in Table 19. The statistical comparison between the genders for the same three tasks is presented in Table 20. The results from task 4 are presented with statistical comparison of the harnessing systems and genders in Table 21. The results are presented separately for female and male subjects with plots in Figure 49. The number of participants able to complete each movement is presented in Figure 50.

Table 19. Overview of the results for the first three tasks. Tables shows the mean, median and standard deviation compared between the two systems for all the results, as well as the *p* value representing the statistical significance of the difference between the 'Figure of 9' harness and the Chest Strap.

| | | Mean | | Median | | St. dev. | | p value | |
|---------------------|--------|-------|-------|--------|-------|----------|-------|----------|--------------|
| Variable | Gender | F9 | CS | F9 | CS | F9 | CS | Separate | Combined |
| max _{act} | F | 228.7 | 236.8 | 228.2 | 221.2 | 78.I | 71.9 | 0.878 | 0.198 |
| [N] | M | 496.0 | 432.6 | 458.8 | 466.8 | 113.0 | 116.5 | 0.093 | |
| erract | F | -7.27 | -4.49 | -4.15 | -3.04 | 9.81 | 6.41 | 0.445 | 0.391 |
| [N] | М | -1.81 | -1.63 | -1.47 | -1.65 | 1.10 | 0.46 | 0.959 | |
| var _{act} | F | 8.58 | 6.43 | 6.47 | 5.95 | 6.26 | 3.61 | 0.169 | 0.351 |
| [N] | М | 3.47 | 3.48 | 2.97 | 3.35 | 1.66 | 1.76 | 0.799 | 0.351 |
| t ref | F | 1.29 | 1.41 | 1.24 | 1.36 | 0.52 | 0.44 | 0.139 | 0.020 |
| [sec] | М | 1.24 | 1.51 | 1.09 | 1.21 | 0.47 | 1.05 | 0.093 | <u>0.028</u> |
| Nr. of | F | 24.1 | 23.4 | 23.5 | 21.0 | 3.7 | 4.7 | 0.645 | 0.210 |
| blocks | M | 24.5 | 22.8 | 33.1 | 23.0 | 4.5 | 5.8 | 0.261 | 0.210 |
| mmax _{act} | F | 27.1 | 26.3 | 23.5 | 25.4 | 7.1 | 2.8 | 0.721 | 0.765 |
| [N] | M | 32.3 | 31.9 | 33.1 | 31.1 | 6.6 | 5.9 | 0.959 | |

 max_{act} = maximum activation force, err_{act} = mean activation force after reaching the 100 N reference over the last 5 blocks, var_{act} = variation from the activation force after reaching the 100 N reference over the last 5 blocks, t_{ref} = the time until the 100 N reference force was reached, nr. of blocks = the number of blocks displaced, max_{act} = the mean maximum activation forces for each block displacement, Gen. = gender, F = female, M = male, mean = calculated mean, median = calculated median, St. dev. = calculated standard deviation.

Table 20. Table showing the *p* values representing the statistical significance of the difference between the genders for the 'Figure of 9' harness and Chest Strap separately. Underlined p values represent significant difference.

| | p value | | |
|---------------------|--------------|--------------|--|
| Variable | F9 | CS | |
| max _{act} | <<0.05 | <<0.05 | |
| err _{act} | 0.019 | 0.123 | |
| var _{act} | <u>0.001</u> | <u>0.043</u> | |
| t ref | 0.739 | 0.315 | |
| nr. of blocks | 1.000 | 0.684 | |
| mmax _{act} | 0.105 | <u>0.023</u> | |

 max_{act} = maximum activation force, err_{act} = mean activation force after reaching the 100 N reference over the last 5 blocks, var_{act} = deviation from the activation force after reaching the 100 N reference over the last 5 blocks, t_{ref} = the time until the 100 N reference force was reached, nr. of blocks = the number of blocks displaced, max_{act} = the mean maximum activation forces for each block displacement

Table 21. Overview over *p* values to check whether the difference in movement time between the 'Figure of 9' harness and the Chest Strap is significant (harnessing systems, female and male separate) and whether the difference is significant between the genders (genders, F9 and CS sepeate). Underlined p-values represent significant difference.

| | | p value | | | | | | |
|------------|--------|--------------------|--------------|---------|-------|--|--|--|
| | | Harnessing systems | | Genders | | | | |
| Movem. nr. | Female | Male | Both genders | F9 | CS | | | |
| 1 | 0.445 | 0.415 | 0.279 | 0.123 | 0.019 | | | |
| 2 | 0.374 | 0.415 | 0.856 | 0.165 | 0.063 | | | |
| 3 | 0.203 | 0.173 | 0.038 | 0.400 | 0.075 | | | |
| 4 | 0.093 | 0.066 | 0.014 | 0.278 | 0.190 | | | |
| 5 | 0.059 | 0.441 | 0.033 | 0.447 | 0.105 | | | |
| 6 | 0.386 | 0.066 | 0.056 | 0.079 | 0.123 | | | |
| 7 | 0.018 | 0.161 | 0.009 | 0.227 | 0.089 | | | |
| 8 | 0.110 | 0.263 | 0.049 | 0.036 | 0.165 | | | |
| 9 | 0.401 | 0.263 | 0.148 | 0.236 | 0.075 | | | |
| 10 | 0.260 | 0.263 | 0.118 | 0.167 | 0.009 | | | |
| 11 | 0.310 | 0.345 | 0.182 | 0.181 | 0.136 | | | |
| 12 | 0.116 | 0.273 | 0.059 | 0.030 | 0.001 | | | |

Movem. nr. = the movement number (see Table 3 and Table 4), harnessing systems female = significance between the systems for females, harnessing systems male = significance between the systems for males, harnessing systems both gender = significance between the systems for the genders combined, genders F9 = significance between the genders for the 'Figure of 9' harness, genders CS = significance between the genders for the Chest Strap.

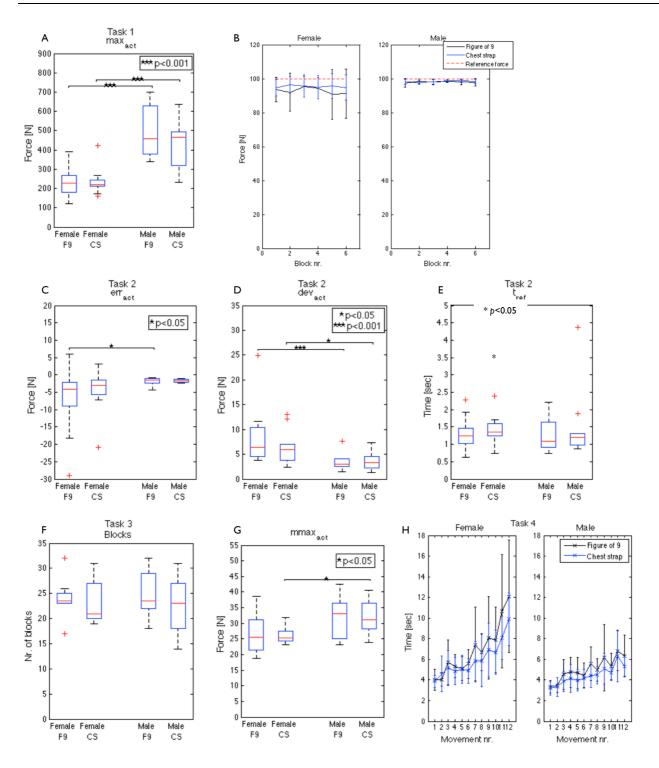


Figure 49. Functional results for all tasks. (A) Maximum activation forces produced in task I. (B) The mean error from the 100 N reference force, (C) variation from the mean and (D) the time until the reference force is reached in task 2. (E) Number of blocks displaced in one minute in task 3 and (E) movement times for each height location combination in task 4. Significant differences between harnessing systems or genders (for tasks 1,2 & 3) are indicated with stars.

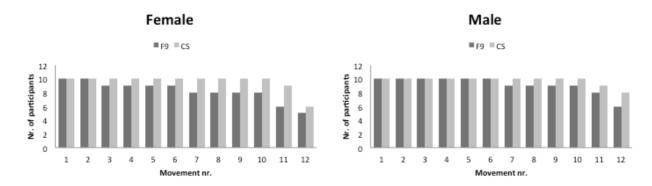


Figure 50. Number of female (left) and male (right) participants able to complete each movement using the 'Figure of 9' harness and Chest Strap.

Discussion & Conclusion

No significant functional difference was found between the two systems when the results from the genders were analyzed separately. When the all results were analyzed together, t_{ref} in task 2 was found to be significantly lower for the 'Figure of 9' harness than the Chest Strap. Furthermore, the movement time in task 4 was found to be significantly lower in 5 out of 12 movements for the Chest strap than the 'Figure of 9' harness.

The male subjects were able to deliver significantly higher activation forces than the female subjects, with both harnessing systems. These results were expected since men are generally stronger than women.

The mean activation forces are significantly closer to the reference force for both systems and the standard deviation for the 'Figure of 9' harness is significantly lower for the male participants than for the female ones. Namely, the male participants were able to follow the reference force more precisely than the female participants, especially with the 'Figure of 9' harness. That can be explained by the fact that the male participants were able to create higher activation forces in task 1 and are therefore stronger and more able to produce and hold steady an activation force, which is as high as 100 N.

The maximum forces in task 3 were significantly higher for the male participants than the female participants when using the Chest Strap but now when using the 'Figure of 9' harness. That means that the male participants are using higher forces than the female participants, which makes sense since the male participants are generally stronger (see max_{act}

Appendix XV - Final Questionnaire Results

In the final questionnaire, the participants were asked to answer which system they preferred while wearing them passively and actively, concerning cosmetics and finally overall (considering all previous questions). Together with choosing which systems, the subjects were asked to give reasons for the choice. The following are the results, where each subject could list more than one reason as well as advantages and disadvantages of each system. Keywords from each answer were gathered and keywords representing same or similar advantages over the other system combined (see Table 22).

Results from the answers about wearing passively are shown in Figure 51 and wearing actively in Figure 52. Results from the questions regarding cosmetics is presented in Figure 53 and overall in Figure 54.

Table 22. Keywords shown in result figures and explanations and/or details about the keywords.

| Advantage | Explanation/details |
|----------------------|--|
| Control | Includes: speed, fine movements, open hook, use |
| Range of motion | Includes: freedom, less constrained |
| Comfort | Includes: less irritation, less pain, lighter, less aware |
| More force | Able to produce more force |
| Less fatigue | Less fatigue experienced while operating |
| Less material | Includes: less visible |
| Symmetry | Includes: symmetrical force distribution, symmetrical look |
| Less warm | Includes: less sweating |
| More secure | Includes: stable, support, even, less loose |
| No pressure on waist | No pressure on the waist such that grooves/curves in the skin/fat are formed |

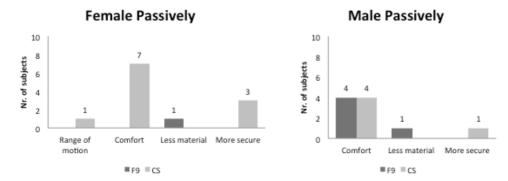


Figure 51. Advantages over the other system while wearing passively. Results from the female participants on the left and male on the right.

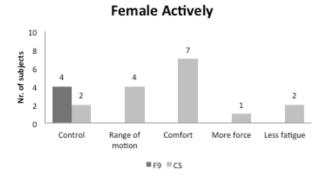


Figure 52. Advantages over the other system while wearing actively. Results from the female (top) and male participants (bottom) shown separately.

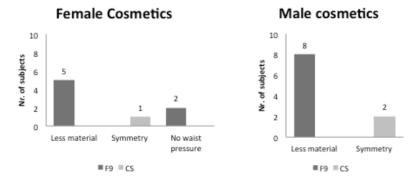
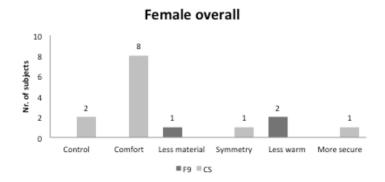


Figure 53. Advantages over the other system concerning cosmetics. Results from the female participants on the left and male on the right.



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Figure 54. Advantages over the other overall, while considering previous questions as well. Results from the female (top) and male participants (bottom) shown separately.

Conclusion

The results from the final questionnaire show that majority of the participants prefer to wear the Chest Strap both passively (60%) and actively (75%). The drawback of the Chest Strap seems to be the higher number of straps visible, since majority of the participants preferred the 'Figure of 9' harness regarding cosmetic appeal. But finally, when the subjects evaluated which harnessing system they would prefer to use in their daily life, 15 out of 20 participants chose the Chest Strap, where majority of the subjects mentioned that they thought the Chest Strap was more comfortable, regardless of their preference.