Study on the impact of a passive shoulder exoskeleton on shoulder physical strain in dairy farmers

A survey for the farmer in the milking parlour

By:

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Summary

Absenteeism in the agricultural sector reached 5.22% by 2022. One factor contributing to this figure is the extent of repetitive movements during labour. During the milking process in the milking parlour, repetitive movements occur frequently. A solution to this problem could be a passive shoulder exoskeleton. This exoskeleton supports the user while making movements. This article presents a study looking at the effect of the Ottobock PAEXO passive shoulder exoskeleton on the physical load on the shoulder joint during the milking process in dairy farmers compared to the milking process without an exoskeleton. The study was conducted on 18 dairy farmers or support staff in four different milking parlours. Using MVN XSENS AWINDA, subjects' movements during pretreatment, cluster attachment and dipping were recorded on five cows. These were then translated into physical load on the shoulder joint in ScaleFit. The results showed that there was a clinical but not statistically significant difference ($p=0.234$ in the left shoulder and $p=0.906$ in the right shoulder) in the physical load of the shoulder joint during milking with exoskeleton as compared to without exoskeleton. Thus, despite not showing a statistically significant difference, there is certainly a clinically significant reduction in physical load during milking with the Ottobock PAEXO passive shoulder exoskeleton compared to milking without the Ottobock PAEXO passive shoulder exoskeleton, namely 0.53Nmh reduction in load in the left shoulder and 0.05Nmh reduction in the right shoulder.

Table of contents

Introduction

In 2022, the Netherlands had 13,597 dairy farms with an average of 110.50 cows per farm, resulting in twice-daily milking of this number of cows (Ministry of Agriculture, Nature and Food Quality, 2023). In the green and agricultural sector, the average employee absenteeism rate rose to 5.22% in 2022 from 4.72% in 2021, marking the first time in 20 years that the 5% threshold has been crossed. (Sazas, 2022)

There are different types of milking parlours, such as side-by-side, herringbone, carousel and tandem milking parlours. The milking process involves three main activities: pretreatment, cluster attachment, and dipping/spraying. Working in the milking parlour is perceived as physically demanding, but it is mainly the repetitive operations that contribute to this strain. These are performed at eye level, so a passive shoulder exoskeleton (hereafter PSE) may provide support, given that the shoulders are at 90 degrees anteflexion. (Ministry of Agriculture, Nature and Food Quality, 2023; Wageningen University and Research, 2020)

Repetitive actions include short-term movements that are repeated in almost identical ways, more than twice a minute, and are performed for a minimum of two hours a day, or one hour continuously. (Ministry of Social Affairs and Employment, 2024)

Factors that play a role in the development of shoulder complaints due to repetitive movements are the frequency, duration, range of motion of joints and the force of the action. The following factors have been shown to combine with repetitive movements to lead to an increased risk of physical complaints:

- Too little recovery time: less than five minutes per hour.

Figure 1: Ottobock 16es100=2*. (ManualsLib, s.d.)

- No possibility for micro-breaks: minimum 20 seconds every 10 minutes. Working with vibrating tools;
- Not influencing work pace;
- Must place products precisely, adding to muscle tension.
- Providing strength for a significant part of the day and/or high frequency work.
- High workload.

(Peereboom & Van Scheijndel, 2015)

An exoskeleton is a portable, external structure on the body that supports human strength. There is a distinction between active and passive exoskeletons. An active exoskeleton works with actuators that deliver force/support to a muscle group. Passive systems use materials such as springs, rubber bands, cylinders and dampers to store energy, which is then released during movement. (Sevagram, s.d.)

Research by Maurice et al (2019) shows that while working overhead with a PSE (passive shoulder exoskeleton), the deltoid muscle pars clavicularis is 55% less active, body oxygen consumption is 33% lower, and heart rate is 19% lower. (Maurice et al.,2019)

Another study by Fritzsche et al (2021) showed that a PSE reduced muscle activity and joint reaction forces in relevant body areas. Muscle activity of the deltoid muscle and strain on the glenohumeral joint in the shoulder decreased between 54% and 87%. At the same time, no increase in muscle activity and forces in other body areas was observed. (Fritzsche et al., 2021)

From this comes the following research question: What is the effect on shoulder physical load in farmers and support staff working in one of the four milking parlours during the milking process by using a passive shoulder exoskeleton (Ottobock 16es100=2* & Ottobock 16es100=3*) compared to milking without an exoskeleton?

Based on this, the following sub-questions were formulated:

1. What is the risk of shoulder physical overload in farmers and support staff working in one of the four milking parlours during the milking process without the passive shoulder exoskeleton?

2. What is the risk of shoulder physical overload in farmers and support staff working in one of the four milking parlours during the milking process with the passive shoulder exoskeleton?

3. What is the difference in risk of shoulder physical overload in farmers and support staff working in one of the four milking parlours during the milking process without and with a passive shoulder exoskeleton?

Materials and Method

Research population

The study population (hereafter N) consists of 18 subjects in total. This study involves the following inclusion and exclusion criteria:

There is no set minimum or maximum criterion for age, height and body size of the subject, as the exoskeleton has universal applicability.

The study is preventive in nature and therefore requires subjects to be in good health, which justifies the choice of these exclusion criteria. The presence of health problems may affect the results of the study, reducing its reliability. Given that subjects are already within Pre-Tec's network, an opportunity sample will be applied (Bakker & Buuren, 2019). In consultation with Pre-Tec, timely arrangements will be made with subjects regarding the measurement timing.

Measuring instruments and measurement protocols

MVN XSENS

MVN XSENS Awinda starter was chosen in combination with the ScaleFit software. This allows analysis of the movements and loads of the subjects' shoulder joint during the milking process. This allows conclusions to be drawn regarding the loads in the shoulder joint, both with and without the PSE, while performing the repetitive actions.

The MVN XSENS Awinda Starter is an advanced wireless motion capture system that captures accelerations and orientations in real-time during human movements. It is designed for precise and flexible applications in motion science research and offers wearable usability. It consists of 17 sensors attached to the body by straps and Velcro. (Movella, s.d.-a)

According to Cudejko et al (2022), MVN XSENS Awinda sensors show a validity of 91% for accelerations and 84.4% for orientations. Testretest reliability for accelerations is 97% when confirmed by an investigator and 84.4% when confirmed by participants. For orientations, test-retest reliability ranges from fair to excellent: 88.9% when confirmed by an investigator and 68.9% when confirmed by participants. In summary, the sensors provide accurate measurements of accelerations and orientations during various activities in healthy adults, where orientation reliability may depend on consistent sensor position replication. (Cudejko et al., 2022)

Scalefit

In the Scalefit software, movements can be converted into loads in different joints, for example the shoulder. This is a literal mirror of the XSENS data, except that the height (in centimetres) and an estimate of the subject's weight (in kilograms) are entered, along with the load (the weight the subject holds in his/her hands, estimated at 1 kilogram). By indicating that the arm is helped by an exoskeleton (the force/support provided by the exoskeleton), a conclusion can be drawn in relation to the load on the shoulder joint. Herein, the shoulder load is set to dynamic considering the movements are made in all directions of movement (Anteflexion, Retroversion, Abduction, Adduction, Exorotation and Endorotation). The load on the shoulder has Newton-metre-hour (Nmh) as the outcome measure.

Assuming Scalefit does not adjust anything to the XSENS data, it will therefore have the same reliability and validity for both.

Measurement protocol

The measurement protocol for the MVN XSENS Awinda starter is outlined in Annex 1, while sensor placement can be consulted on the Movella/XSENS website (Movella, s.d.-b). For the passive shoulder exoskeleton (PSE) (Ottobock 16es100=2* or Ottobock 16es100=3*), a manual is available regarding the correct fitting and application, as described in Annex 2.

The protocol for this study is as follows: first, we sign the Informed Consent (Annex 3) with the subjects, followed by the implementation of steps 1 and 2 of the Annex 1 manual. The settings are checked for correct configuration. Since default settings are used, they are usually already set correctly. The shoulder transmitters are additionally secured using white sports tape, supplied in the backpack of the MVN XSENS Awinda starter pack from Saxion.

Steps 3 and 4 of the Annex 1 manual are then performed. The measurement takes place on the subject during the milking process of five cows, measuring the actions repeatedly. These measurements are carried out in the milking pit during milking.

After the first measurement, the subject is asked to put on the PSE (Ottobock 16es100=2* or Ottobock 16es100=3*). If necessary, step 3 of the manual is followed if sensors have been moved. The measurement is then performed again during the milking process of five cows.

The PSE is immediately donned without prior pause due to time savings, although this would require the ideal measurement of both with and without the exoskeleton, which, however, is not feasible within the time constraints of the study.

Subjects thus give their consent to the use of collected data prior to the study by signing an Informed Consent (Annex 3). Participants will be identified by a number to ensure privacy. All data and processing will be stored in the Saxion Research Cloud, a secure environment with limited access for researchers and supervisors only, protected by a password.

Data analysis

This study contains data from several sites that the researchers assess separately from each other. The data collected by the researchers separately from each other are combined to answer the main question.

Measurement level

The outcomes from the shoulder load moments and the KIM method are ordinal; these data can be categorized and there is a clear ranking. The variable types of parlours and gender are also examined, but these are not important to answer the research question.

Non-parametric key

A non-parametric test does not make specific assumptions about the distribution of the data, unlike parametric tests such as the t-test or ANOVA, which do make assumptions about the distribution of the data.

The Wilcoxon Signed Rank test is a nonparametric test for comparing a (semi-)continuous variable between two paired groups. The Wilcoxon Signed Rank test is often used as an alternative to the paired t-test, because the Wilcoxon Signed Rank test does not assume normally distributed data. The test may always be used, for all ordinal data. (Amsterdam UMC, 2013)

The variables used for the Wilcoxon Signed Rank test are: shoulder load moment (left and right shoulder) and the KIM method.

The other centre measures that can be extracted from the data analysis for our study are: the mean, the median and the standard deviation. Given the clarity which a mean has, it will be used together with the standard deviation and the median will not be mentioned but will be calculated.

To make a statement about the statistical significance of the study, the p-value which comes out of the Wilcoxon Signed Ranked test is examined. To determine whether statistical significance is present, hypotheses must be drawn up: H0(The mean difference is zero) versus H1(The mean difference is smaller than the p-value).

Results

Table 2 shows the following: There is a mean moment in the left shoulder without exoskeleton of 11.6Nmh (SD±2.81) and with the exoskeleton of 11.0Nmh (SD±2.43) $(p=0.234)$. In the right shoulder, this mean moment without exoskeleton is 12.3Nmh $(SD\pm2.77)$ and with exoskeleton 12.3 $(SD\pm3.40)$ $(p=0.906)$. The moment on the left has an average reduction in shoulder load/moment of 0.53Nmh ($SD \pm 1.46$) between without and with the exoskeleton. In the right shoulder, there is a mean reduction in shoulder load/moment of 0.05Nmh (SD \pm 2.37) between without and with the exoskeleton. This amounts to a mean reduction in shoulder load/moment of both shoulders of 0.29Nmh.

Figure 2: Graph of average shoulder moment without and with exoskeleton

| | Moment | Moment | Difference | Moment | Moment | Difference |
|------------------|-------------|-------------|---------------|-------------|-------------|---------------------|
| Subject | Left | Left | Moment Left | Right | Right | Moment Right |
| | Shoulder | Shoulder | Shoulder with | Shoulder | Shoulder | Shoulder with |
| | Without | with | And Without | Without | with | And Without |
| | Exoskeleton | Exoskeleton | Exoskeleton | Exoskeleton | Exoskeleton | Exoskeleton |
| | (Nmh) | (Nmh) | (Nmh) | (Nmh) | (Nmh) | (Nmh) |
| \boldsymbol{l} | 10.7 | 10.7 | 0.0 | 12.8 | 14.0 | -1.2 |
| \overline{z} | 8.9 | 8.9 | 0.0 | 10.6 | 11.2 | -0.7 |
| \mathfrak{Z} | 9.9 | 10.5 | -0.6 | 16.0 | 18.0 | -2.0 |
| $\boldsymbol{4}$ | 13.1 | 11.5 | 1.6 | 13.7 | 12.2 | 1.5 |
| 5 | 16.7 | 16.9 | -0.2 | 16.6 | 15.6 | 1.0 |
| 6 | 17.0 | 12.4 | 4.6 | 10.4 | 13.8 | -3.4 |
| \overline{z} | 9.3 | 10.5 | -1.2 | 8.7 | 3.2 | 5.5 |
| $\mathcal S$ | 13.5 | 11.2 | 2.3 | 13.7 | 16.8 | -3.1 |
| $\mathcal G$ | 11.8 | 11.5 | 0.3 | 14.0 | 14.0 | 0.0 |
| 10 | 11.5 | 11.3 | 0.2 | 12.7 | 12.6 | 0.1 |
| 11 | 8.0 | 6.2 | 1.8 | 10.9 | 9.8 | 1.1 |
| 12 | 10.3 | 10.9 | -0.6 | 6.0 | 8.8 | -2.8 |
| 13 | 9.6 | 11.0 | -1.4 | 15.8 | 14.0 | 1.8 |
| 14 | 13.4 | 13.8 | -0.4 | 10.0 | 8.7 | 2.3 |
| 15 | 15.4 | 14.2 | 1.2 | 13.4 | 10.4 | 3.0 |
| 16 | 9.0 | 7.9 | 1.1 | 13.7 | 12.8 | 1.1 |
| 17 | 11.9 | 10.6 | 1.3 | 9.3 | 11.8 | -2.5 |
| 18 | 7.9 | 8.3 | -0.4 | 13.0 | 13.8 | -0.8 |

Table 2: Research results

Table 3: Results per parlour

Table 4: Results based on gender.

Table 3 compares the different parlours. In the side-by-side parlour, the average difference in the left shoulder comes to 0.7Nmh (SD \pm 1.40) and in the right shoulder $0.7(SD \pm 3.10)$. In the carousel milking parlour, there is a mean increase of 0.2Nmh (SD \pm 0) in the left shoulder, while a mean reduction of 1.0Nmh (SD \pm 0) is found in the right shoulder. In the herringbone parlour, the mean decrease is 0.5Nmh (SD \pm 1.59) and for the right shoulder, on the contrary, there is an increase in load namely 0.3Nmh (SD \pm 2.18).

Table 4 shows the results based on gender. Here it can be seen that women have a mean decrease in load of 1Nmh (SD \pm 1.13) in the left shoulder and 0.6Nmh (SD \pm 0.71) in the right shoulder. This is a mean decrease of 0.8Nmh in both shoulders. Among the men, there is a mean decrease of 0.5Nmh (SD \pm 1.51) in the left shoulder but, on the contrary, an increase of 0.2(SD \pm 2.50) in the right shoulder which, on the contrary, amounts to a

mean difference of 0.15Nmh for both shoulders.

It was further found that if subjects performed the actions without PSE for an average of 3:20:25 consecutive hours, this would amount to a 100% shoulder strain according to DGUV Information 208-033. (DGUV, 2022/2023)

Discussion

To improve the accuracy of the measurements, it is suggested to either measure one side of the parlour twice (once with and once without PSE) or to measure the entire parlour twice, instead of five cows. This would avoid performing the movements first with one arm and then with the other and collect more data. This is considering that currently an average of two to three minutes of data is available, compared to the one and a half to two hours subjects spend in total milking.

Moreover, it was observed that the subjects clearly moved differently while wearing the PSE. It was repeatedly observed that without the PSE, subjects held their arms closer to their bodies, but on the contrary, with the PSE, they lifted their arms higher. This resulted in an increased load on the shoulders.

The results of this study suggest several aspects that warrant further exploration. One of the most important considerations is to reconsider the study design because of several factors observed in this study. Scalefit gives an indication of the risk when a movement is sustained for a long time. However, when a subject becomes fatigued, the movement may also be different. This could lead to a different risk estimate. For this reason, it would be useful to investigate whether measurements could be taken later in the milking process, when the shoulder musculature is more fatigued, to test the performance of the exoskeleton in different conditions.

Another important finding is that the subjective experience of wearing and using the exoskeleton seems to have more influence than initially thought. During and after the measurements, researchers heard different reactions from the subjects, ranging from negative comments such as "It gets in my way more than it helps me" to positive ones such as "Such a thing is actually quite handy, isn't it?!".

It is important to note that the subjects only worked with the exoskeleton for a short time, so habituation effects may not have been fully accounted for. Therefore, future research should also focus on the habituation and experience of working with a PSE.

The force applied during the three phases of the milking process also shows variability between individual subjects. Some apply significantly more force during pretreatment compared to others, while some may spend more time on this phase.

Moreover, only one measurement was carried out in a carousel milking parlour, which limits the generalizability of the results. It would therefore be valuable to include this parlour more often in follow-up studies to draw clearer conclusions about the use of exoskeletons in different parlour configurations.

For possible follow-up research, it is also interesting to investigate questions such as: "What does it mean for a farmer when he increases milking time from one and a half to two hours?" or "What does a break every hour mean?" or "What does doubling time mean?". These research questions provide an opportunity to look deeper into shoulder strain during the milking process.

However, it is important to note that this study is not statistically significant as a p-value of <0.05 was not observed. As a result, no firm conclusions can be drawn from the results. The lack of statistical significance highlights the need for larger sample sizes or adapted methodologies in future studies to validate the findings and gain a deeper understanding of the effects of exoskeletons on shoulder strain in dairy farmers.

For these reasons, the findings of this study call for further exploration and research on the impact of exoskeletons on the workload of dairy farmers, with a specific focus on methodological adjustments and the subjective experience of wearing such devices.

Several options are available for subjects to reduce physical strain on the shoulder. In this study, a PSE was used, which is a good option, but reducing force, hiring a second person or ergonomic milking cups could also be considered.

Conclusion

This study sought to answer the question: 'What is the effect on shoulder physical load in farmers and support staff working in one of four parlours during the milking process by using a passive shoulder exoskeleton (Ottobock 16es100=2* & Ottobock 16es100=3*) compared to milking without an exoskeleton?' To this end, a quantitative study was conducted on four different types of milking parlours.

This quantitative study showed that the moment in the left shoulder during milking without PSE is on average 11.6 Nmh (see table 2). The moment in the right shoulder during milking without PSE is 12.3 Nmh on average (see table 2). Milking with PSE shows an average moment of 11 Nmh at the left shoulder (see table 2). Finally, milking with PSE in the right shoulder shows a moment of 12.3 Nmh (see table 2). The results show an average difference of 0.53 Nmh at the left shoulder, and an average difference of 0.05 Nmh at the right shoulder.

The results show a clinically significant decrease in physical strain during milking with PSE compared to milking without PSE. However, the results show that there is no statistically significant difference between milking with PSE and without PSE $(p=0.234$ on the right and $p=0.906$ on the left).

A clinically significant difference can also be found that during milking in a carousel milking parlour, the right shoulder is loaded more than the left shoulder, while in a herringbone and side-by-side parlour the load is more symmetrically distributed (see table 3). For both, only no statistical significance can be accounted for.

In addition, in women, the physical load on the shoulder joint during milking with a PSE showed a greater decrease than in the male gender (see table 4). This could be explained by the height of the different sexes, e.g. women were also the smallest subjects in terms of height, parlour height or weight of the milking cups. Again, only clinical significance can be accounted for this, not statistical significance.

Thus, the use of a PSE during milking has no statistically significant effect on the physical load on the shoulder joint compared to milking without a PSE. Despite not being a statistically significant difference, there is a clinically significant difference of shoulder physical load in farmers and support staff working in one of the four milking parlours during the milking process due to the use of a passive shoulder exoskeleton (Ottobock 16es100=2* & Ottobock 16es100=3*) compared to milking without a passive shoulder exoskeleton.

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Annexes

Annex 1: MVN Xsens Awinda starter kit manual

Step 1: Booting up the laptop and preparing system

- 1. Make sure the Xsens sensors are charged. The charging stations are located next to the sensors, the corresponding plugs/cords are at the bottom of the Xsens bag.
- 2. Boot the laptop (MU00007 or MU00008) and log in with the appropriate login details (found in the laptop case);
- 3. On the desktop, select the programme 'Xsens MVN 2023.2';
	- a. After starting, the programme sometimes still asks for confirmation of the licence. You can simply click 'next' here.

Step 2: Preparing the measurement

- 1. If you want to measure, it is important that the 'Awinda station' is connected to the laptop;
- 2. After connecting the Awinda drive, click 'File'à 'Start Motion Capture' at the top left;
- 3. In the screen that now appears, choose the configuration you want to measure with (in this case: Upper Body)
- 4. In addition, you enter the body measurements of your subject in this screen. The more of these measurements are entered, the more accurate the system will make the measurements. If you did not measure a part, type a zero to use the default value.
- 5. After you have filled in all the details of your subject, save it in the 'Documents' à 'Xsens subjects' folder by clicking 'Save';
- 6. Turn on the required sensors by clicking the small round button at the bottom of the sensor;
- 7. Attach the required sensors to the subject using Velcro, the shirt and/or tape;
	- a. The sensors are best attached using Velcro by sticking the sensors to the end of the Velcro and thus having both Velcro below and above the sensors. This way, there is the least risk of unexpected movement of the sensors and less chance of losing them during the measurement;
	- b. As far as possible, stick the sensors to fixed points (such as the tibia), to prevent shifts in the skin from affecting the data collected. Preferably, attach the sensors to bare skin or to a tight shirt/pants. With loose clothing, you can also place the sensors under the clothing.
- 8. After confirming, all lights on the puppet in the 'Configuration-window' should light up correctly. If you miss a light, have the test subject move a little and/or check whether the sensor is on (a red light will flash).
- 9. Once all the lights are on, give your measurement session a name at the bottom right and make sure it is saved in the right folder (bottom left).
- 10. Click on 'OK'.

Step 3: Calibrating a test subject

- 1. Calibrate your subject by choosing a calibration option on the left side of the screen. Xsens recommends choosing 'N-pose+Walk'.
- 2. Make sure your subject stands at a clearly recognizable point with his arms along his body. After standing still for a few seconds, ask him to walk forward, turn around and return to the same spot and then stand still again. (Follow the instructions on the screen).
- 3. The system now automatically calculates all required values. If the quality of the calibration is not good enough, you will be notified of this and can choose to repeat the calibration again.
- 4. Should a sensor move or fall during your measurement, start again at step 1 of calibration.

Step 4: Taking a measurement

1. After calibration, start a measurement by clicking the red 'record button'. Let the test subject do an activity of their choice (make sure they stay within 20 metres of the Awinda station during their activity) and press the same button again at the end of the measurement.

Step 5: Analysing the measured data

- 1. At the top left of the screen, click 'File'à 'Open' and choose the measurement you want to analyse.
- 2. After opening, the data will first be processed (for a long measurement this can take a few minutes), after this you can view everything from the measurement.
- 3. At the top left of the 'Navigator', click the arrow for 'MVN System 1' to find the data you need. Many times, you will probably use the 'Joints' heading to show the different joint angles in a graph, but you can also choose to present the speed of a particular segment, for example.

Ottobock Shoulder Quick Fit Guide

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Ottobock Shoulder Quick Fit Guide

Annex 3: Informed Consent

Saxion University of Applied Sciences Enschede Academy Healthcare

Statement on audiovisual recordings and participation research:

Investigating the impact of a passive shoulder exoskeleton on shoulder physical strain at dairy farms.

No confidential information or personal data from or about you will be disclosed in any way, all data collected will be anonymized.

The undersigned, ___________________, residing at ___________________, hereby declares:

- 1. Giving permission for audiovisual recordings of myself.
- 2. To have been informed by the Academy of Health student responsible for making the recordings of the purpose for which the recordings will be used.
- 3. To have no objection to the use of the relevant recordings within the Academy of Healthcare, Saxion University of Applied Sciences Enschede for educational purposes.
- 4. Have the right to view the unfinished and/or completed product at all times.
- 5. Reserving the right to withdraw the consent given at any time, which means that the relevant audiovisual recordings and any copies will be destroyed immediately. In the event of death, this right shall pass to an immediate family member.
- 6. Got enough information about the study. I was also able to ask questions. My questions were sufficiently answered. I had enough time to decide whether to participate.
- 7. That I know that participating is voluntary. I also know that I can decide at any time not to participate after all or to stop the study. I don't have to give a reason for that.
- 8. That I consent to the collection and use of my data to answer the research question in this study.
- 9. That I know that my data will be used only for the purpose of this study and that my data will be kept and reported anonymously.
- 10. That I know that for the purpose of monitoring the study, some people may have access to all my data. These are researchers connected to Saxion's academy of health care, or by an external assigned monitor. I consent to such access by these individuals.
- 11. That you do not have musculoskeletal/tendon complaints of the upper extremity or other pathologies involving loss of strength (example: ALS/MS).
- 12. You are not currently under treatment with a physio/manual or other therapist for upper extremity complaints.

□ no

consent to keep and use my research data for 15 years for the above research.

• I give □ well

□ no

permission to approach me again for a follow-up survey after this study.

• I want to □ well

□ not

participate in this study.

Subject's name:

Signature: Date : D

I declare that I have fully informed this subject about the said study.

If information becomes known during the study that could affect the subject's consent, I will inform him/her in a timely manner.

--

Investigator's name (or representative):

Signature: \Box