The learning effect of biofeedback training with SensiStep

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Preface

Before you lies the result of six years of hard work and dedication. Six years I have spent learning, listening, studying, practicing. Six years, in which I have learned so much about technology, clinical practice, doing research, and everything else that adds up to form Technical Medicine.

One year ago, I started my clinical specialization internship at the Traumatology department at the UMC Utrecht. Overwhelmed at first by everything that I was required to do in the coming year, not knowing where to start, I soon managed to set out a course to follow. A course that would lead me into a year of hard work, but also a year of pioneering into the unknown. And now, one year later, I can present my Master's thesis.

This year was made possible with help of many others. The first I would like to thank is **dr. Taco Blokhuis**, for guiding me through this year. Despite transferring to Maastricht soon after the start of my internship, he was always ready to help me when I got stuck, and his enthusiasm and motivation during the bi-weekly meetings never failed to inspire me to work even harder for an optimal result.

A great deal of thanks also to **Marco Raaben**, PhD student and technical physician at the UMC Utrecht, who I could always turn to on those moments when I knew what I wanted to do, but didn't know how to do that. He has helped me countless times to figure out the best way to analyze my data, when I didn't know what to do with it anymore.

I also want to thank **Paul van Katwijk** for being my mentor the past year. I realize that I have not been a model student, but you always found a way to motivate me to keep pushing myself towards the finish line. And whenever I was lost in rules, regulations, portfolio systems and instruction books, you could always tell me what I had to turn in next (or, a few weeks before).

Another word of thanks goes to **prof. Bart Koopman**, for being both my technological supervisor and chairman of my graduation committee. I realize we haven't met many times, but every time I walked away from your office at the University of Twente, I knew if I was on the right track, and what I should do to further improve my work.

My gratitude also to **prof. Hermie Hermens**, for taking seat in my graduation committee, and taking your time to read my Master's thesis despite your busy schedule.

Also, thanks to **the entire staff of the department of Surgery of the UMC Utrecht**, for allowing me to experience working in an academic medical center. Thank you for showing me the ins and outs of hospital life, and helping me develop my clinical skills.

A great thank you as well to **Johanna van der Meij-Schoneveld**, **Christa van Haren**, **Jutta Hofman** and all of their colleagues that helped me find patients to include in my study. Without you, I would never have achieved this much the past year.

And, of course, an incredible deal of thanks and respect to **all my test subjects**. The protocol was tough and intensive, but you all managed to hold on to the end, providing me with lots and lots of data.

A special word of thanks goes to **Hanneke Keijzer** and **Ingrid Koopmans**. The peer reflection meeting were always so inspiring. Thank you for listening to and accepting the way I felt about the past year, and helping me find my own way to complete this internship without giving up doing what I love.

Also, I would like to thank **Laurens Veltman**, for being my mentor during my short internships in the second year of the Master's program. Thank you for being one of the first among the teaching staff to see me as a person with his own ideas and beliefs, and motivating me to not choose the easy way, but to continue to spend time following my dreams, instead of focusing completely on graduating.

An enormous amount of thanks to **all my family and friends**, for allowing me to take my mind of things, and joining me in everything I do besides studying. I tried to not let graduating prevent me from doing things with you, and I apologize for the times I let you down when I really needed to focus on working towards my Master's degree. We will catch up soon!

And last, but definitely not least, the greatest thanks I can possibly give to **my mom and dad** for always being there for me, listening to me and being genuinely interested in what I do, and always reminding me that I 'must not forget that I also have to graduate eventually'. You guys are the best, thanks for everything!

David Roelofs
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Summary

Research has shown that biofeedback training can help patients with fractures of the lower extremity to achieve safer loading of the injured leg. However, the duration of the effects of biofeedback training are currently unknown. In this study, the duration of the learning effect of training with a biofeedback system is examined, as well as the effects of long-term training.

Eight patients with fractures of the lower extremity, with partial weight bearing (<100% body weight) instructions, rehabilitating in a geriatric rehabilitation center were included. Four days a week, during up to four weeks, they received biofeedback training using the SensiStep system (t=0), during which they could see and adapt their loading pattern based on live biofeedback shown on a tablet. 2, 4, 6, 8, and 24, 48 or 72 hours after t=0, measurements were performed in which the subjects walked a short distance without receiving biofeedback. The retention of the effects of the biofeedback were examined using data from these measurements.

Five patients with a target load of 50% were included. For two of them, it took one week of training before they retained the effects of biofeedback for at least 24 hours. For two others, it took three weeks of training to obtain 24-hour retention. The last patient with a target load of 50% could not achieve 24-hour retention during the inclusion period. One patient with a varying target load (50-80%) did not appear capable of retaining the effects for 24 hours. Two patients with a target load of 10 kg were not capable of achieving their target load while receiving biofeedback.

In conclusion, when receiving one biofeedback training a day, patients with a target load of 50% require 3 weeks of training at most in order to obtain 24-hour retention of biofeedback effects. More research into biofeedback training for a target load of 10 kg is necessary.

Table of contents

1 Background

This chapter will clarify the relevance of this study, by elaborating on the clinical background and the current problems in clinical practice regarding the treatment and healing of fractures. Some information is also provided regarding the current solution to these problems, the SensiStep system. Near the end of the chapter, the goals of this study are described, and an outline of this thesis is presented per chapter.

1.1 Fractures by the numbers

In the Netherlands, 40.000 fractures in the lower extremity occur every year. In most (about 50%) of these cases, the collum femoris (femur neck) is fractured. Half of the remaining cases are fractures of the ankle. The remaining 25% consist mainly of fractures in the lower leg (tibia and/or fibula), pelvis, and femur shaft. [1]

75% of the femur neck fractures occur in patients aged 55 or higher, with the number of fractures rapidly increasing above age 55. Incidence is higher in women than in men (75 vs 25% of all femur neck fractures). [2]

97% of femur neck fractures is caused by trauma as a result of falling. In most cases, the fall occurred inside or around the house. In only 4% of cases, a fall from greater height was the cause of femur neck fracture, and only 15% of femur neck fractures occur as a result of tripping or slipping. [2]

From these numbers, it can be concluded that the most fractures in the lower extremity are femur neck fractures in patients above age 55, as a result of falling without a clearly defined cause. Since fracture healing slows with age, it is important that these patients are treated optimally, to keep hospital stay and duration of rehabilitation as short as possible.

1.2 Fracture healing

A fractured bone is capable of self-repair. This self-repair occurs through four steps: 1) an inflammatory reaction, 2) callus growth, 3) tissue differentiation within the formed callus, and 4) callus resorption and bone remodeling. [3]

Soon after fracture, vasoconstriction occurs to stop the bleeding. The extravascular blood form a blood clot, called the fracture hematoma. Fibroblasts in the fracture hematoma cause gradual granulation of the hematoma. Due to the injury, an inflammatory response is triggered, resulting in migration of leukocytes to the fracture site. Furthermore, the necrotic ends of the bone at the fracture site are removed by osteoclasts. [3]

Next, osteoblasts start forming a cuff of woven bone periosteally, and filling the intramedullary canal, away from the fracture. Closer to the fracture site, fibroblasts and chondrocytes produce their characteristic extracellular matrix to form the soft callus. Capillaries grow into the callus to improve vascularization. After soft callus has been formed, endochondral ossification occurs in the soft tissue near the fracture gap. Starting away from the fracture, and slowly progressing to the fracture site, newly formed bone joins the two fracture ends together. The outsides of the soft callus are reformed into bone first, because the strain is lower in these areas, and finally, the original cortices are joined together by newly formed bone. [3, 4]

After the fracture ends are solidly reconnected, remodeling starts. In this phase, that can last from a few months up to several years, the woven bone is replaced by lamellar bone, matching the original

morphology of the bone. Once the medullary canal is restored, and the callus has been completely remodeled into lamellar bone, the healing process is finished.
[3, 5]

1.3 Improving fracture healing

Four important factors are known to influence bone healing: 1) osteogenic cell population, 2) osteoinductive stimulants, 3) osteoconductive scaffolds, and 4) the mechanical environment. These factors should be optimized to allow for optimal bone healing. However, only one of these factors seems easily accessible through external intervention: the mechanical environment. With an adequate mechanical environment, callus bridging can be optimized. Improving the mechanical environment includes optimization of fixation, axial stress, shear stress, and rotational stress.

In order to optimize fracture healing through the mechanical environment, fixation should aim to stabilize the fracture to minimize shear stress [6]. Both rotational [7] and axial [6] stress will improve fracture healing. However, rotational stress is usually not desired, since this could result in a malunion: fracture healing with the bone in a suboptimal position.

1.4 Influence of axial stress

Axial stress has a beneficial effect on fracture healing. Since this study is focused on fractures in the lower extremity, it is safe to say that axial stress can be induced through weight bearing on the injured leg. Weight bearing influences both bone healing (on a cellular level) and rehabilitation (through influence on other tissues).

On a cellular level, mechanical loading causes a fluid flow in the canicular network of the osteocyte. Due to this physical stimulus, the osteocyte produces signaling molecules. These molecules will then improve bone formation through modulating the activities of osteoclasts and osteoblasts. [8]

Weight bearing has been shown to influence muscle tissue. Several studies have been performed in order to examine this influence, and have shown that microRNAs, which play an important role in muscle development, were significantly affected in the vastus lateralis muscle of healthy young males after 10 days of strict bed rest [9, 10]. Furthermore, regular physical activity can diminish fatty infiltration in muscle tissue with age [11, 12], and muscle mass is positively influenced by high-resistance training [13].

Based on this information, it can be concluded that weight bearing after a fracture in the lower extremity can speed up the recovery. Therefore, it is important that patients who have suffered fractures of the lower extremity start mobilizing as soon as possible.

1.5 Current clinical practice

Since an optimal mechanical environment is necessary to optimize fracture healing, and it is the only factor that can be influenced externally, the treatment of fractures in the hospital is focused on optimization of the mechanical environment. The first step is stabilizing the fracture in an anatomical position. If the X-ray shows that the bone already has an adequate position, a cast can be placed to secure it in that position. If not, the bone might be repositioned to obtain an anatomical position, and the cast is placed afterwards.

If the fracture remains stable after a few days, the cast alone might suffice as treatment. In the lower extremity, a walking cast can be placed around the foot or lower leg to allow (some) weight bearing, and usually after 6 or 12 weeks, the fracture is healed and the patient can exert full weight without the cast.
In many cases, however, the fractures cannot be treated with a cast only, because they are either unstable (and cannot be repositioned) or intra-articular. In these cases, surgical fixation is often necessary. During surgery, the surgeon can reposition the bone fragments in an optimal position and secure them using screws, plates, nails, or wires. Once the fracture is stabilized and the operation is finished, these patients do not require a cast. Instead, a compression bandage is placed for a few days, and after that, they can start mobilizing.
Early mobilization after surgery of the lower extremity is especially important in elderly patients (age >55). This group of patients has a higher risk of complications such as pneumonia, following prolonged bed rest [14]. In order to optimize the chances of early mobilization, the aim of surgery should be to fixate the fracture in such a way, that full weight bearing can be exerted. However, this is not always possible. An example of this are extremely comminuted (multifragmentary) fractures, in which the fragments are held together by the plates and screws only. If a patient were to exert its full weight onto the operated leg, the implanted material would have to bear all this weight. This might cause breaking of either the plate or one or more screws, necessitating another surgery.
To prevent this, patients are often instructed to exert partial weight bearing. This can range from 50% weight bearing, down to only placing the foot on the ground, without exerting any pressure. Usually, this is described as 10 kg weight bearing. Instructions like these allow the patient to mobilize in the early stages of recovery, while ensuring optimal fracture healing. The time in which the patient should exert partial weight bearing is generally 6 weeks after surgery. After that, they are seen by the surgeon in the outpatient clinic, and in most cases, they can exert full weight bearing if the control X-ray shows the fracture has healed.

1.6 Partial weight bearing

As stated before, partial weight bearing is a good solution for patients with very unstable fractures in the lower extremity. Even walking with the foot just touching the floor (10 kg weight bearing) helps retaining muscle mass and preventing inactivity osteoporosis, and speeds up fracture healing [9-13]. Since partial weight bearing is very different from 'normal' walking, a physiotherapist is asked to help teach patients how to walk while exerting limited weight. The physiotherapist usually employs one of two methods to instruct patients. The first is only used in patients that are only allowed to make foot contact with the floor (10 kg weight bearing). The therapist places their hand on the floor, and the patient is instructed to stand on the hand with their affected leg. Using this method, the physiotherapist has a direct and simple measure of the load exerted by the patient ('if it hurts, they load too much'). Once the patient exerts the right amount of load, they should remember what it feels like to exert that little weight. Then, when walking, they should try to recall that feeling, and load the affected leg in such a way that it feels the same. The second method for training patients is to let them stand on a bathroom scale with the affected leg, loading until the scale shows the target load. Once again, the patient should then remember what it feels like to exert the target load, and then use their memory of this when walking. [15]

Although both methods are used in clinical practice and both seem effective, both methods have serious shortcomings. The first method, standing on the therapist's hand, is a subjective measure, based on the physiotherapist's perception of the weight exerted by the patient. This will certainly cause differences between physiotherapists, possibly confusing the patient because two different therapists might instruct them to exert different amounts of load. Still, this might not be a serious issue, as long as the two therapist's perceptions do not vary too much. A much bigger problem could exist when the target set by the physiotherapist is too high. The therapist might train a subject to exert 20% or 30% loading instead of 10 kg by using this method. If this happens, the physiotherapist risks loading the plate too much, resulting in possible failure of osteosynthesis materials.

The bathroom scale training method is also not suitable. Although the patient will be trained to exert the target load set by the surgeon, it is not suitable for training a patient to walk in a correct manner. Since the bathroom scale training will only occur in a static position, e.g. the patient is standing still, the patient might still exert too much (or too little) load while in a dynamic situation (e.g. walking).

In order to train patients with objective measurements in a dynamic situation, live biofeedback can be used. The SensiStep system (Evalan BV, Amsterdam, the Netherlands) is an ambulatory system that measures the weight exerted on a patient's affected leg (in both static and dynamic situations), and can provide direct feedback to the physiotherapist and/or the patient.
Biofeedback has proved to be an effective training method for partial weight bearing, with studies showing significant differences in weight bearing before and after biofeedback training [15-20]. However, little research has been performed to examine the effects of biofeedback training over a longer period of time. If the rehabilitation process is to be optimized, it is important to know how long the effects of biofeedback training last, and when another training session is required in order for the patient to maintain the prescribed target load.

1.7 The scope of this Master's thesis

This Master's thesis will focus on improving the rehabilitation process by assessing the learning effect of biofeedback training using the SensiStep system. Using an intensive protocol, both the duration of the learning effect following a single training, and the patient's improvement over time through multiple training sessions will be examined.

1.8 Thesis outline

Chapter 2: Research area

In this chapter, the research goals for this study will be introduced and explained. Next, more detailed background information is provided on biofeedback and the SensiStep system. Finally, some preliminary results are presented.

Chapter 3: Gathering the data

Chapter 3 will elaborate on the logistics of the study. A list of necessary materials is presented, as well as criteria for in- or exclusion. Chapter 3 will end with a description of the protocol used in this study.

Chapter 4: Processing the data

In chapter 4, the methods used in data analysis are explained. This chapter also elaborates on the outcome parameters and why these parameters are important.

Chapter 5: Results

This chapter describes the results of the study. Using mostly tables and figures, the results are presented in an accessible manner to allow a quick understanding of the most important findings.

Chapter 6: Discussion

Once chapter 5 has shown what was found in this study, chapter 6 will explain what the implications of these results are. Furthermore, this chapter will elaborate on the limitations of this study, and how these limitations might have influenced the results.

Chapter 7: Conclusion

In chapter 7, a short summary of all chapters will be provided. Next, all new information obtained in this study will be combined to form the final conclusions.

Chapter 8: Future perspectives

In the final chapter of this Master's thesis, the consequences of this study will be described. An explanation is given on the clinical implications of this study, and suggestions are done for future research into this subject.

2 Research area

This chapter will first describe the goals of this study, and the motivation behind these goals. Next, a more detailed explanation on both biofeedback and the SensiStep system is provided, based on a combination of literature and experience. Chapter 2 will end with some preliminary results, using data from another study on biofeedback training with SensiStep.

2.1 Research goals

This study aims to work toward an optimized rehabilitation protocol, with biofeedback training as the method of choice for teaching patients partial weight bearing. Since optimizing the rehabilitation protocol is an ambitious goal that requires research in multiple areas, this study focuses on determining the duration of the learning effect following biofeedback training, and defining the optimal moments to provide biofeedback.

The ultimate goal of biofeedback training is to never let patients exert too much or too little weight. In order for the patient to maintain this amount of load, even without the SensiStep system to help them, training sessions are necessary whenever the learning effect fades and the patient's weight bearing exceeds their limits. If the duration of the learning effect after one or more training sessions can be determined, feedback moments can be planned accordingly.

In order to reach these goals, several questions need to be answered.

- How do you define the beneficial effect of biofeedback training?
  Defining the effects of biofeedback training is more complicated than it seems. Ideally, there would be a single parameter that defines whether or not a patient loads the leg 'good' or 'bad'. However, no such parameter exists. Instead, the SensiStep system provides variables such as average peak load, variation between steps, loading rate, and average step duration. None of these variables can define the effects of biofeedback training by itself (as will be explained in section 2.2), so a combination of two or more of these variables must be made to obtain an adequate description.
- How long does the beneficial effect of a single training session last?
  Research has shown that patients are much better at reaching their target load when receiving biofeedback. However, little is known about what happens once the training is over. Hustedt et al. [16] found that the effects of the training are maintained for 24 hours in healthy young volunteers. One can imagine, however, that this conclusion might not apply to elderly subjects, recovering from a fracture in the lower extremity. Therefore, it is important to answer this question once again.
- Is it possible for a patient to acquire a lasting beneficial effect?
  It is assumed that over time, the learning effect of biofeedback training will fade in every subject. However, it might be possible for a patient to acquire a lasting beneficial effect. If a patient receives enough training, muscle memory might eventually allow them to reach their weight bearing goals without help. By subjecting patients to multiple training sessions, this study will try to find whether or not this is possible.

2.2 Biofeedback

The Merriam-Webster dictionary defines biofeedback as:

'the technique of making unconscious or involuntary bodily processes (as heartbeats or brain waves) perceptible to the senses (as by the use of an oscilloscope) in order to manipulate them by conscious mental control'.

In other words, any method that allows us to perceive a physical process otherwise imperceptible, so that we can consciously influence this process, is defined as biofeedback. Since the amount of weight born on a single leg is usually imperceptible, and can be visualized using SensiStep, the SensiStep system is by definition a biofeedback system.

Origins of biofeedback

The principle of trying to control unconscious bodily processes has been around since over 3000 years. One of the five principal meanings of yoga is described by Jacobsen as 'techniques of controlling the body and the mind' [21]. And even though this is a completely different kind of biofeedback, according to the definition, it qualifies as biofeedback. Whether or not yoga can result in the same amount of consciousness as 'modern' biofeedback can be discussed, but it shows that mankind has always had the desire to control their involuntary functions.

The biofeedback as we know it has only been around since the late 1950's. And although measuring bodily functions is older than that, the act of controlling these unconscious functions, rather than only measuring it, was not extensively researched until Miller and DiCara challenged the dogma that autonomic processes could not be controlled [22, 23]. Kamiya, however, is considered to be the father of biofeedback, after demonstrating that subjects could learn to shift their alpha wave frequency by 1 Hz [24]. As research progressed, more possibilities appeared, using biofeedback not only with EEG, but also with EMG, developing into many different kinds of biofeedback [25].

Biofeedback for partial weight bearing

Although it seems that the two methods for partial weight bearing training as described in section 1.6 also match the definition of biofeedback, this is technically not true. In the method using the physiotherapist's hand, the unconscious process of weight bearing is not made perceptible to the patient, but to the therapist. Using a bathroom scale, weight bearing is made perceptible to the patient, but since this is only done in a static position, the bodily function trained is standing, rather than walking.
Over the past years, Hustedt has performed extensive research into biofeedback training for partial weight bearing in an ambulatory setting [15, 16, 18]. Using an inflatable insole, he could measure the load exerted by healthy volunteers, and provide auditory feedback when a subject crossed the upper or lower limit of the target load range. Using his ambulatory system, Hustedt proved that biofeedback is superior to verbal training and bathroom scale training, that biofeedback training is effective in all age groups, and that the effects of biofeedback training can last up to 24 hours.

2.3 SensiStep

The SensiStep system (Evalan BV, Amsterdam, the Netherlands) is an ambulatory biofeedback system consisting of three major components (figure 1). The first, the sensor, is a small force sensor that can accurately measure the load exerted on it, with a sample frequency of 50 Hz. The system comes with a set

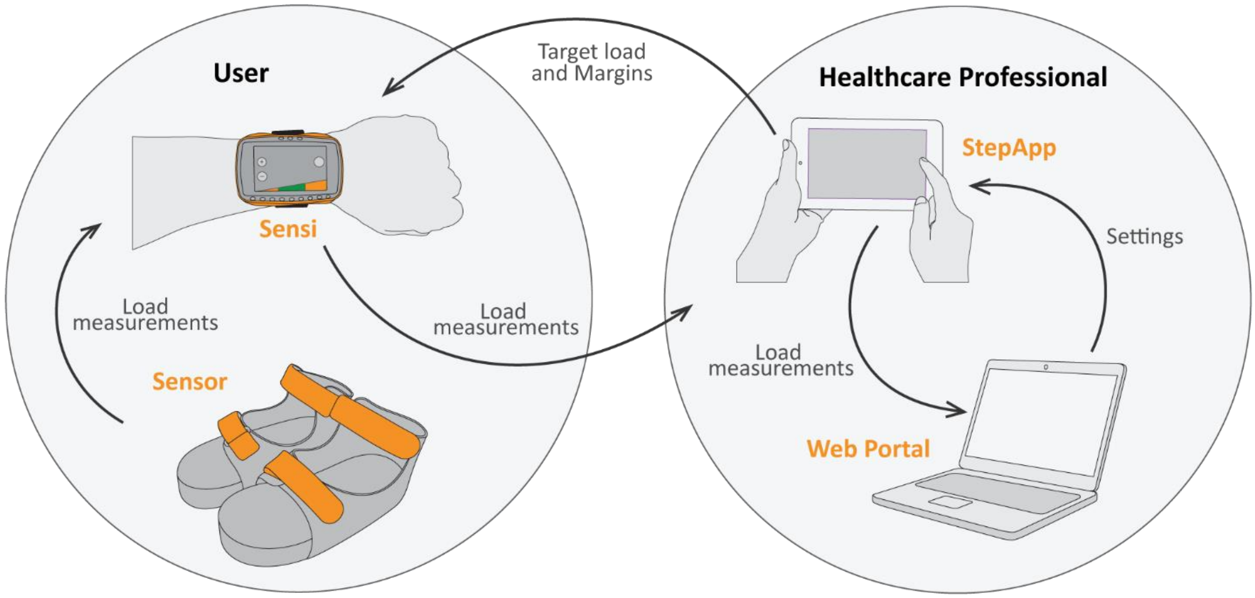

Figure 1 The SensiStep system consists of the sandals with the sensor, the Sensi, the StepApp and the WebPortal. Image from: www.sensistep.nl

of special sandals. The sensor can be placed in the sole of these sandals, with a weight placed in the other sandal for the sake of symmetry and balance.
The sensor itself consists of two metal plates, one above the other. In the center of the lower plate, a small cylinder is mounted. On top of this cylinder rests the center of a leaf spring. On the edges of the bottom side of the top plate, small extensions are placed that rest on the outer edge of the leaf spring. When weight is exerted on the top plate, these extensions will push the sides of the leaf spring down, causing it to bend. Using a combination of magnets and Hall sensors (sensors that vary their output voltage in response to a magnetic field [26]), the spring deflection is converted to an electrical current. The Hall sensors are placed under the top plate, right next to the edges of the blade spring. The magnets are positioned right below the Hall sensors. As the leaf spring bends, the sensors are moved closed to the magnets, resulting in a change in voltage. This change in voltage can then be converted to spring deflection, which, in turn, is related to the exerted force. [27]

The data registered by the sensor is continuously transferred to the Sensi, the feedback module designed for SensiStep. The Sensi can compare the measured load to the patient's specified target load, and provide feedback accordingly. Two feedback options exist for the Sensi: auditory feedback and visual feedback. When auditory feedback is used, a beep from the Sensi is heard when the patient takes a step that exceeds their target load. In case the patient takes steps below the lower limit of the target load, no feedback is provided.
For providing visual feedback, an array of lights is mounted on the Sensi. This array consists of 9 lights, in the following order: 3 red lights, 3 green lights, and 3 red lights. If the patient takes steps that fall within their target load limits, the green lights will be lit. Once a step exceeds the target load, the red lights on the right will light up. If one of the patient's steps falls below the lower limit, the red lights on the left side will light up.
The final component required for the SensiStep to function is the StepApp application, on a tablet that is provided with the SensiStep system. The StepApp is used to start and stop all measurements. Furthermore, the patient data can be entered through the StepApp, as well as the target load and margins. The StepApp can also be used to provide feedback. When a measurement is started, the load exerted by the patient is streamed in real-time from the Sensi to the StepApp. The target load is also visible on-screen (figure 2).

Showing the patient the screen while they walk allows them to try to 'aim' their load inside the margins. At this moment, it is not yet known which feedback method (auditory, visual, or the StepApp) provides the best training results.
The data measured by the SensiStep system is also transferred from the StepApp to the SensiStep Web Portal. Researchers can access their patient's data through this web portal, and download it for analysis. For privacy reasons, only the patient's date of birth is shown in the Web Portal. The patient's name is replaced by a code.

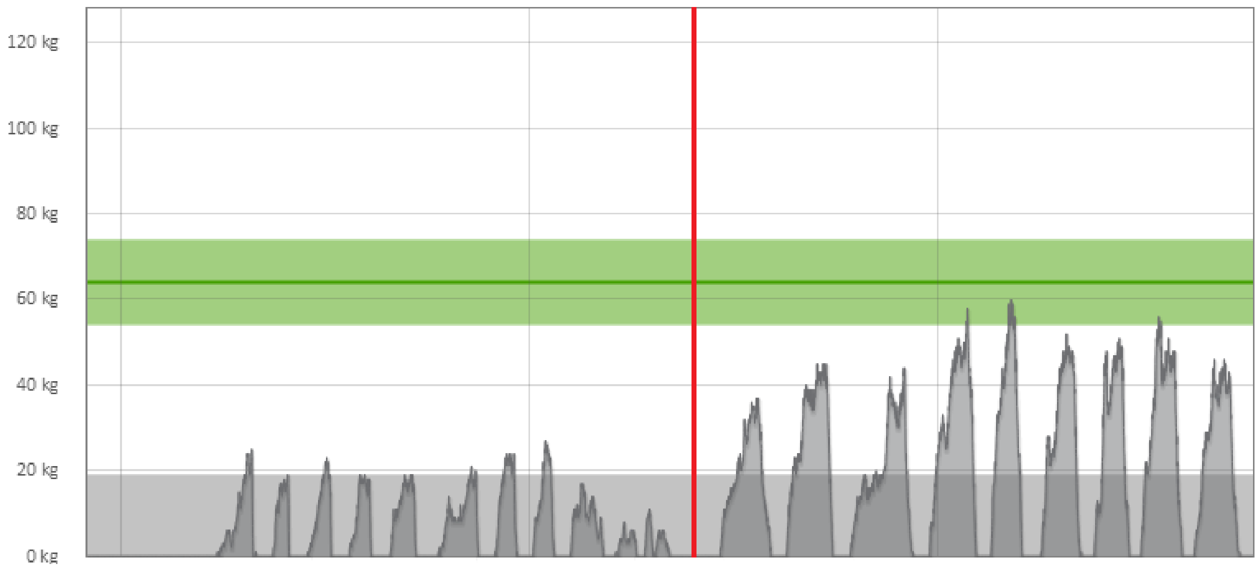

Figure 2 The StepApp screen during a SensiStep session. The green bar shows the target load and its margins. The grey waveforms are the steps as executed by the subject. From the red vertical line onward, feedback was provided.

2.4 Preliminary results

In the Traumatology department of the UMC Utrecht, a study has been recently performed to examine the direct influence of biofeedback on weight bearing, comparing patients with a target load of 100% of their body weight, to patients with a target load of 10 kg [20]. Patients were asked to walk a short distance, twice. The first time, they did not receive biofeedback, and the second time, they did. Some of these patients were measured once a day, for several days. In these patients, it is possible to see whether or not the learning effect was maintained, by comparing the measurements without feedback, to the measurements with feedback on the day before.
Because the limiting factor in patients who have a target load of 100% usually is the pain they experience while walking, rather than difficulty in achieving the target load, only patients with a target load of 10 kg are taken into account when it comes to the learning effect.
There are four patients included in the study with a target load of 10 kg, that have been trained using SensiStep on two or more consecutive days. On the first day of training, before receiving feedback, the mean load over all steps taken by the patients was 17.1 kg (SD 11.3). After receiving feedback, this dropped to a mean load of 8.3 kg (SD 6.5). This is a significant difference ($p<0.001$), indicating that in these patients, biofeedback had a significant effect on the average loading of the injured leg.
On the next day, before receiving feedback, the average load exerted by these four patients was 19.1 kg (SD 8.0). This is not significantly different from the average load before receiving feedback on day 1

(p=0.23). This indicates that in these four patients, the effect of the feedback they received on day 1 has been lost within 24 hours.
In order to optimize rehabilitation, and maintain a constantly adequate loading of the injured leg, it is important to know when to provide feedback. Therefore, the present study, in which the learning effect within the first 24 hours is assessed, will provide vital new information.

3 Gathering the data

In this chapter, the methods used for data collection will be explained. First, the necessary materials and facilities will be defined. Next, the inclusion and exclusion criteria are stated, followed by the protocol used in this study.

3.1 Materials and facilities

In order to perform the measurements necessary for this study, three important materials and facilities needed to be present. First, a complete SensiStep system (sandals, sensor, counterweight, Sensi, and tablet with StepApp) was required. Another necessity for the study was a walking aid for the patients. Since the study is about partial weight bearing, all patients required a walking aid to bear the weight they could not carry on their affected leg.

Lastly, in order to keep all circumstances as similar as possible, a straight hallway of about 10 meters was required. This was the distance the patients needed to walk during each measurement.

3.2 Inclusion and exclusion criteria

Inclusion for this study was performed at several geriatric rehabilitation centers throughout the Netherlands (Cordaan – In het Zomerpark, Nieuw-Vennep; Beweging 3.0, Amersfoort; Woonzorgcentrum De Pol, Nijkerk). Inclusion and exclusion criteria were as follows:

Inclusion criteria:

- >55 years of age
- Unilateral partial weight bearing instructions
- Overall good health
- Plantigrade foot stance

Exclusion criteria:

- Incapable of understanding or following instructions

3.3 Protocol

Once all materials and facilities were present, and patients could be included, the measurements could start. For a period of up to 4 weeks, the patient underwent 4 SensiStep biofeedback training sessions each week, on Mondays, Tuesdays, Thursdays and Fridays. On the first day, before the first measurement, general patient data was collected (name, date of birth, height, weight, affected leg, and target load).

Every day of measurements was divided into 8 steps. First, the patient received feedback training using the StepApp as feedback method (step 1). Once the patient was capable of loading their affected leg within the pre-set margins, the training ended. The training session was then shortly evaluated together with the patient (step 2).

Following the training session, the first measurement was performed (t = 0). The patient was instructed to walk 10 meters without feedback, and to try and load the leg just like during the training session (step 3). This 10-meter walk was repeated 2, 4, 6, and 8 hours after t = 0 (steps 4-7). The final assessment of the learning effect for a single day was a measurement right before the next training (step 8). This means that the final measurement could be 24, 48, or 72 hours after the initial training.

On day 1, a measurement was also performed before the feedback training, even though there had not been a biofeedback training the day before. This was a necessary measurement in order to determine the initial effects of the biofeedback on day 1.

When performing the measurements, it careful attention was paid to the following:

- Since the SensiStep sensor is placed under the middle part of the foot, it was important that the patient maintained a plantigrade foot stance throughout all measurements. If the patient would bear their weight on the front or back part of the foot only, the sensor cannot measure the load correctly, thereby confounding the measurement.
  Furthermore, since healthy individuals walk with their feet in a plantigrade position, maintaining this position while weight bearing is restricted will maintain adequate muscle coordination. This improved muscle coordination will allow the patient to adapt to the normal, unrestricted walking pattern more easily once the restriction is removed.
- Feedback to the patient should *only* be provided during and directly after the feedback training session. All 'regular' measurements were intended to examine whether or not the patient has remembered the instructions from the feedback training. Providing any kind of feedback during these measurements might have confounded the measurement.

4 Processing the data

This chapter will elaborate on the methods used for processing and analyzing the data obtained through the measurements. First, the method for processing the raw data from the WebPortal into several parameters is described. Second, it is important to define what outcome parameters can be used to examine the learning effect. Finally, a description will be given of the steps taken to analyze the chosen outcome parameters, obtained from the processed data.

4.1 Raw data processing

The raw data measured by SensiStep consists only of three parameters: elapsed time (ms), load (kg), and *peak.* The value of *peak* is 1 when the corresponding data point is the peak of a given step, and 0 when it is not. Before the data is ready for analysis, the user can use MATLAB (MathWorks, Natick, MA) to select the relevant time fragment from the obtained data. This will prevent accidental peaks recorded before or after the actual measurement from being taken into account in the analysis. Once a data fragment is selected, an algorithm is run to detect where in the data fragment the steps can be found. This is done by detecting the start of a step through the derivative of the data (when the derivative > 0, the sensor detects an increase in load), and detecting the end of the step whenever the load reaches 0 again.

Once the steps in the data fragment are found, the data can be distilled into 7 different parameters:

- Number of steps per second
  The number of steps per second is calculated by simply dividing the number of steps by the duration of the fragment.
- Average loading rate
  The loading rate is the speed with which the leg is loaded. It is calculated by taking the start of a step, and the peak load, and then calculating the slope of the line connecting the two points (figure 3). An average loading rate is calculated from the loading rates of each separate step. [28]
- Standard deviation (SD) of loading rate
  This is the standard deviation of the loading rates of all separate steps.
- Average peak load
  The peak load is the maximum load measured in a single step (figure 3). Taking the average of the peak loads of all separate steps results in the average peak load in a measurement. Though SensiStep measures the load in kg, the load in % body weight can easily be calculated from the measured load.
- Standard deviation of peak load
  This is the standard deviation of the peak loads of all separate steps. The standard deviation can also be calculated in both kg, and % body weight.
- Average step duration
  By taking the length of each separate step, and then calculating the average, the average step duration in a single measurement can be calculated (figure 3).
- Impulse
  The impulse is defined as the area under the curve during a single step (figure 3).

4.2 Outcome parameters

Not all the calculated parameters are necessary for determining the learning effect. Since the purpose of biofeedback training in this case is to let patients reach their target load, the goal should be accuracy, rather than speed. Therefore, number of steps per second, loading rate, and step duration will not be used for determining the learning effect. The only parameters that can be used are average peak load, and the standard deviation of peak load.

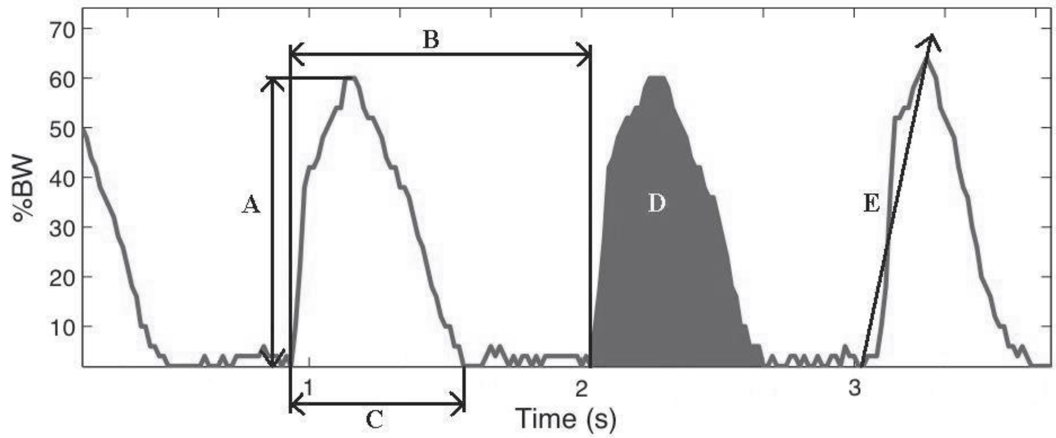

Figure 3 Parameters derived from SensiStep measurements. A) Peak load, B) Stride duration, C) Step duration, D) Impulse, E) Loading rate. [28]

It would be best if the learning effect could be determined through looking at a single parameter. However, both peak load and its standard deviation are not suitable by themselves. When using only the average peak load, it might seem that the patient has perfectly reached their target load. When looking at the data itself, however, one might find that there was large variation between steps, with almost all steps above and below the limits. The average might seem adequate, but one can imagine that this would not be an example of 'good' loading.

The same goes for the standard deviation of peak load. If the peak loads of all steps in a single measurement are very close together, but outside the target limits, the standard deviation will suggest 'good' loading, but the raw data tells otherwise.

In short, to determine the learning effect, a combination of average peak load and peak load standard deviation is necessary.

Figures 5 and 6 show the flowcharts used to determine whether or not the learning effect is maintained throughout a single day, using a combination of both standard deviation and average peak load. The following steps are taken throughout the flowcharts:

- First, the t=0 measurement (directly after feedback) is examined, in order to set the limits that define when the learning effect is lost. If the t=0 measurement falls within the predefined limits (target load ± 5%, SD < 5%), these remain the limits throughout the entire day. However, if the t=0 measurement does not fall within the limits (either average peak load exceeds the limits or SD > 5%), the limits for the rest of the day should also be defined differently, since it is assumed that the t=0 measurement is the best performance of the day.

  If the average peak load at the t=0 measurement exceeds the limits, the feedback effect is determined (the absolute difference between the measurement before and after feedback (or: the difference between the t=24/48/72 measurement of the day before and the t=0 measurement)). If the average peak load of any measurement of the day exceeds the average peak load of the t=0 measurement ± 50% of the feedback effect, the learning effect is lost.

  When the SD at the t=0 measurement is greater than 5%, the new SD limit for the day is the SD at the t=0 measurement (figure 4).

After this step, two flowcharts are used. One to check if the average peak load remains within its limits throughout the day, the other one to check the same for the SD.

	If SD at t=0 < 5%	If SD at t=0 > 5%
If average peak load at t=0 falls within target load ± 5%	Limits: Average peak load = target load ± 5%. SD = 5%	Limits: Average peak load = target load ± 5% SD = SD at t=0
If average peak load at t=0 does not fall within target load ± 5%	Limits: Average peak load = average peak load at t=0 ± 50% of the direct effect of feedback SD = 5%	Limits: Average peak load = average peak load at t=0 ± 50% of the direct effect of feedback SD = SD at t=0

Figure 4 In order to determine the limits that define whether or not the learning effect is lost, the t=0 measurement is taken into account according to this scheme.

The flowchart for the average peak load takes the following steps:

- First, it checks if the average peak load for each measurement falls within the limits (note that the limits are defined based on t=0). If this is the case, the learning effect is maintained throughout the entire day, based on average peak load alone.
- If not, the following step is to check if the SD of all average peak loads is below 5%. Since the limits are defined according to t=0, the average peak load at t=0 will always fall within the limits. Therefore, if the SD of all average peak loads combined exceeds 5%, there has to be at least one measurement in which the average peak load exceeds the limits. In this case, the first measurement exceeding the limits is defined as the recorded moment the learning effect is lost.
- In case the SD < 5%, the average peak load throughout the day is calculated (the average of all average peak loads). If it falls within the limits, all measurements lie close together, and the average is adequate, meaning that the learning effect is maintained throughout the entire day.
- If this final average does not fall within the limits, the first measurement in which it exceeds the limits is defined as the moment the learning effect is lost.

To examine the learning effect when it comes to SD, the following steps are taken:

- The first check is to see if there are measurements in which the SD exceeds the limit (as defined by t=0). If not, the learning effects lasts the entire day.
- If there are measurements in which the SD exceeds its limit, the first of these measurements is defined as the moment the learning effect is lost.

These flowcharts each provide a moment in which the learning effect is lost. Since average peak load and SD are equally important for 'good' loading, the learning effect is deemed lost whenever one of the two fails.

To examine the process of forgetting within the first 24 hours after the training session, the average peak load and SD for each day will be plotted for all subjects. A trend line will be calculated in order to determine the average forgetting effect following a single training. To see whether or not the learning effect lasts longer as more training sessions have been performed, the data is visualized by taking the results from each day. All 'learning effect durations' are then plotted in a single graph for each patient.

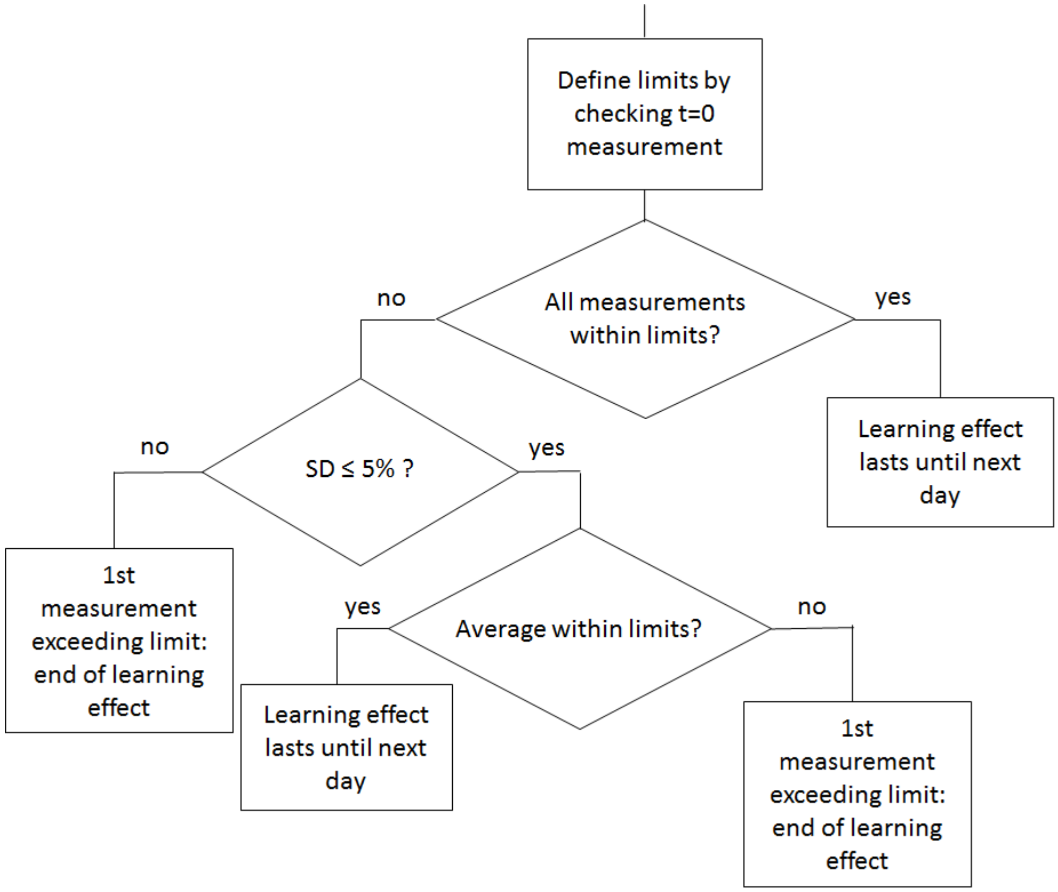

Figure 5 Flowchart for determining when the learning effect is lost on a given day of measurements, looking only at the average peak load throughout that day.

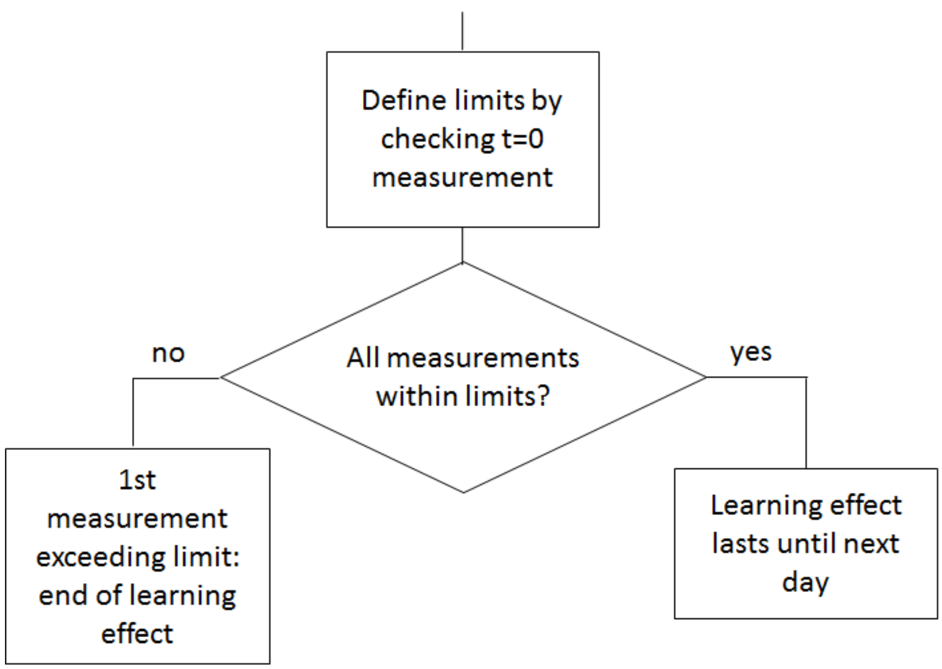

Figure 6 Flowchart for determining when the learning effect is lost on a given day of measurements, looking only at the standard deviation throughout that day.

5 Results

In this chapter, the results from the analysis described in chapter 4 are presented. An overview of the patients included in the study is provided first, followed by graphs depicting the results per patient. A short description on each of these pictures is also provided.

5.1 Patient characteristics

Table 1 shows the general characteristics of all included patients. Five of the participants had a target load of 50% body weight (BW), two were instructed to load 10 kg, and one of the participants (subject 5) had a varying target load, starting at 50% BW, but increasing by 10% each week.

Table 1 Patient characteristics.

Subject no.	**Age**	**Sex**	**BMI**	**Diagnosis**	**Treatment**	**Target load**	**Inclusion duration (weeks)**
1	82	Female	23.9	Periprosthetic femur fracture	Operative fixation	50% BW	4
2	81	Male	28.4	Collum fracture	Total hip replacement	50% BW	4
3	72	Female	32.3	Cup prosthesis failure	Cup revision	50% BW	4
4	82	Female	24.2	Collum fracture	Hemiarthroplasty	50% BW	4
5	80	Female	29.3	Cup prosthesis failure	Cup revision	50-80% BW	3
6	83	Female	32.7	Periprosthetic femur fracture	Operative fixation	10 kg	2
7	83	Female	22.5	Cup prosthesis failure	Cup revision	10 kg	3
8	75	Male	26.3	Periprosthetic femur fracture	Operative fixation	50% BW	2

5.2 Forgetting curve

Figures 7 and 8 show the average peak loads and SDs for day 1 of measurements for all subjects with a target load of 50%. Since the target load is 50%, it follows from figure 7 that subjects 1 and 3 appear capable of maintaining an adequate average peak load up until t=8 hours. Subjects 2 and 4, however, are consistently loading too much, throughout the entire day. Subject 8 also tends to overload, with an average around 55%.
Looking at the SD (figure 8), however, the roles seem reversed. Subjects 2 and 4 show SDs around 4%, while subjects 1 and 3 show SDs of up to 7%. The SD of subject 8 varies from 5 to almost 17%.
Plotting a trend line through the data for this day (figure 9), shows a slightly declining average peak load throughout the day, from 60% down to 53%.
Looking at the same figures, with the data from a few days later (figures 10 and 11), it is clear that the average peak load of all subjects is approaching 50%, compared to figure 7. Figure 11 also shows that the SD for all measurements is below 5% on this day.
A trend line through all points on this day (figure 12) shows an almost horizontal line, suggesting that on average, the learning effect does not decline throughout the entire 24 hours.

On the 13th day (figures 13 and 14), all average peak loads are grouped closer together, centering around 53%. All SDs also remain below 5% throughout the day. The trend line is once again close to horizontal. Although not all figures are shown here, the data shows that the trend lines for all days show no significant decline, never exceeding the 45-55% limits. The SD also rarely exceeds 5% throughout all four weeks.

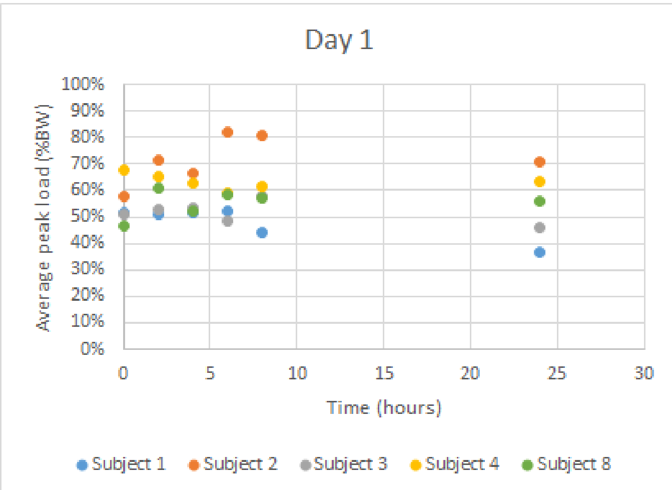

Figure 7 Average peak load on day 1. All measurements on day 1 for all subjects with a target load of 50% BW are shown.

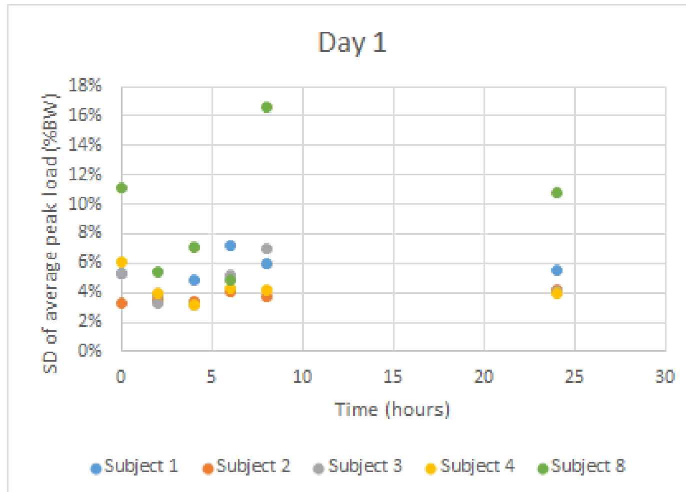

Figure 8 SD on day 1. All measurements on day 1 for all subjects with a target load of 50% BW are shown.

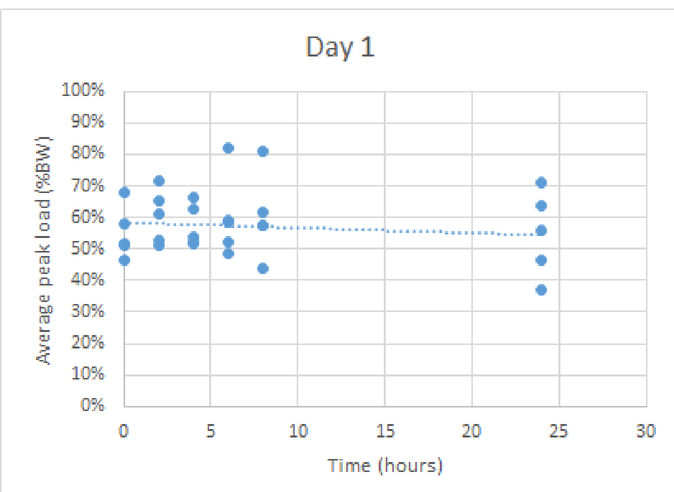

Figure 9 Average peak load on day 1, showing all measurements for all subjects with a target load of 50% BW and a trend line through all points.

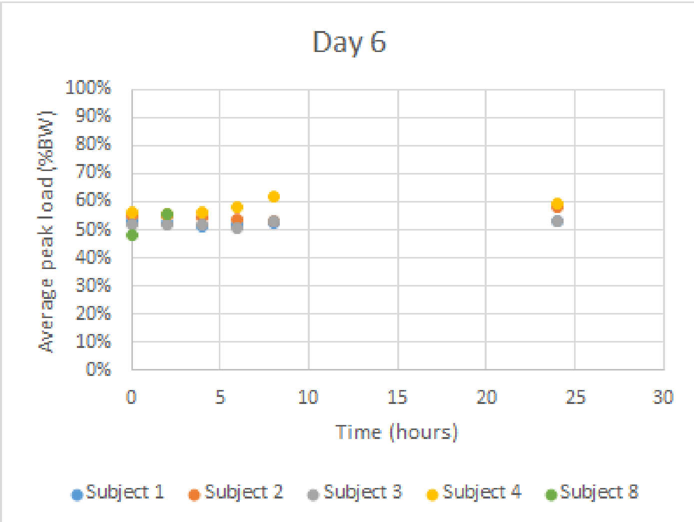

Figure 10 Average peak load on day 6. All measurements on day 6 for all subjects with a target load of 50% BW are shown.

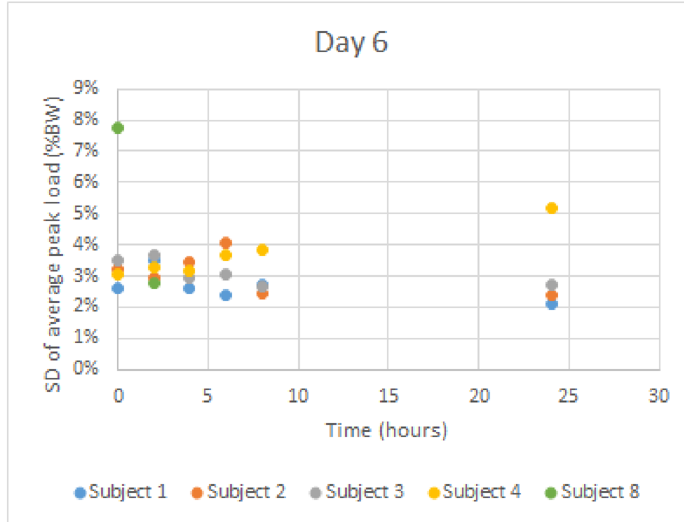

Figure 11 SD on day 6. All measurements on day 6 for all subjects with a target load of 50% BW are shown.

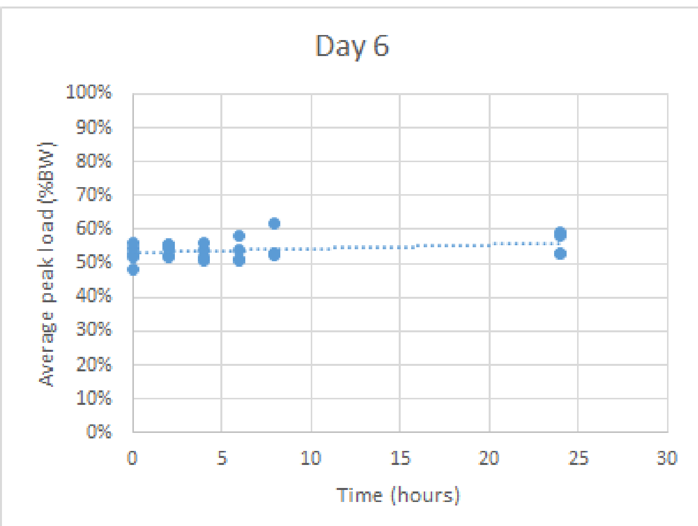

Figure 12 Average peak load on day 6, showing all measurements for all subjects with a target load of 50% BW and a trend line through all points.

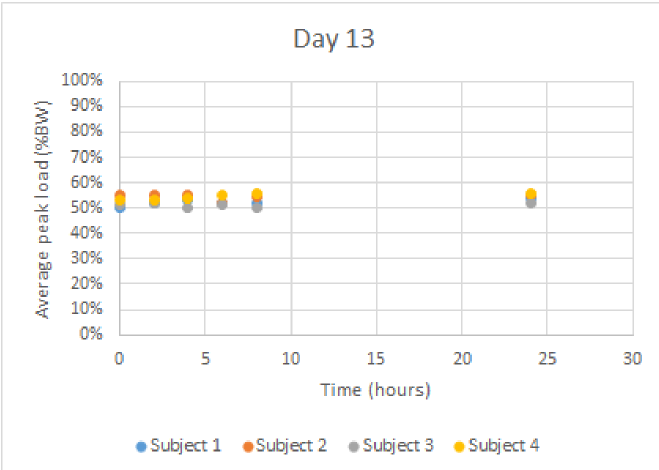

Figure 13 Average peak load on day 13. All measurements on day 13 for all subjects with a target load of 50% BW are shown.

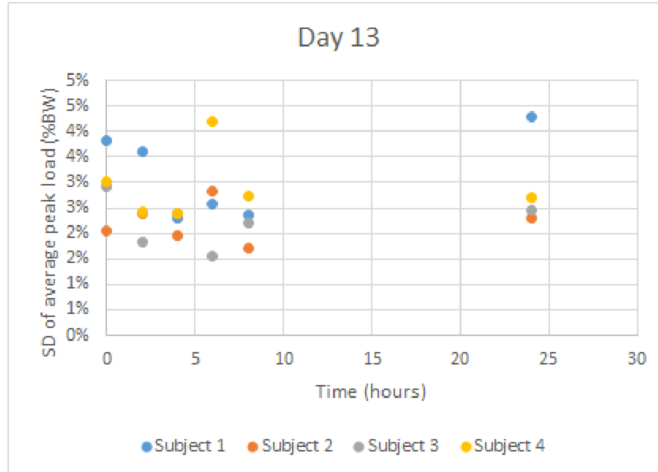

Figure 14 SD on day 6. All measurements on day 6 for all subjects with a target load of 50% BW are shown.

Figures 15 and 16 show the same figures of average peak load and SD, but for the group with a target load of 10 kg. Subject 6 loads too much on the first day (average around 30 kg), starting at an average peak load of 37 kg right after receiving feedback training. Throughout the day, the average peak load seems to become lower. Subject 7 loads an average of around 15 kg throughout the entire day. A trend line through figure 15 shows a slight decline throughout the day, from 23 to 21 kg (figure 17).
For both subjects, the SD is consistently high, varying from 11 kg to 22 kg for subject 6, and 5 kg to 11 kg for subject 7.
On day 4 (figures 18 and 19), subject 6 still overloads the entire day. The average peak load throughout the entire day is slightly over 25 kg. For subject 7, the average peak load seems to be around 18 kg. The trend line shows a decline from 22 to 19 kg over the course of the day (figure 20).
The SD for both subjects exceeds the limit throughout day 4, with subject 6 showing an average SD of 9 kg, and subject 7 showing an average SD of 7 kg.

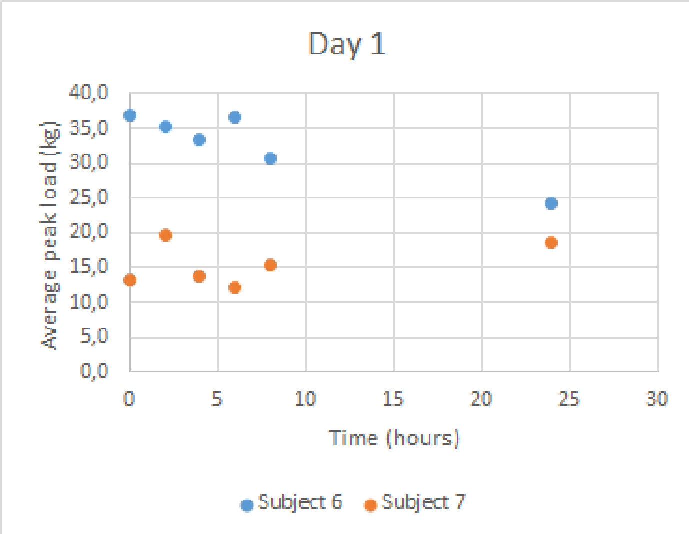

Figure 15 Average peak load on day 1. All measurements on day 1 for all subjects with a target load of 10 kg are shown.

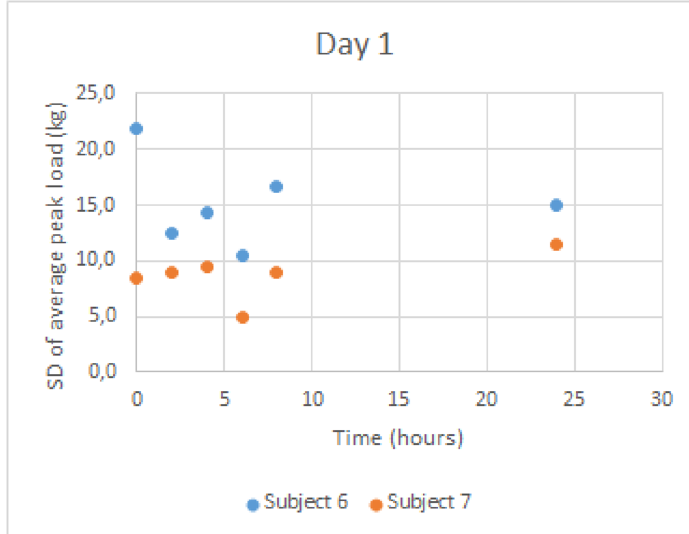

Figure 16 SD on day 1. All measurements on day 1 for all subjects with a target load of 10 kg are shown.

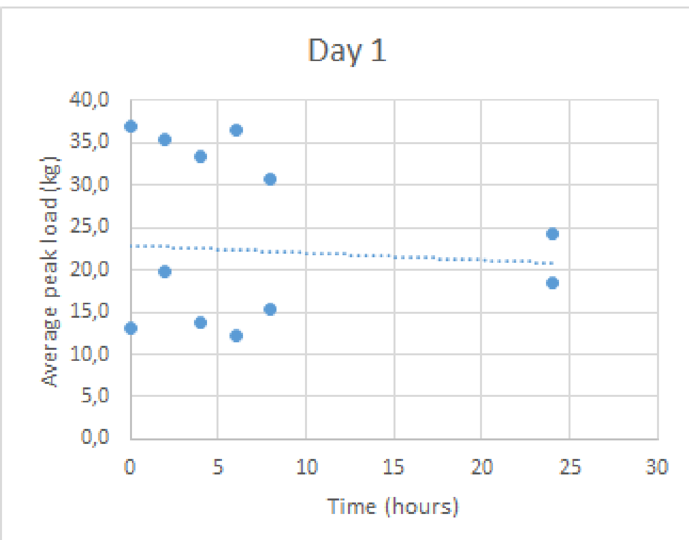

Figure 17 Average peak load on day 1, showing all measurements for all subjects with a target load of 10 kg and a trend line through all points.

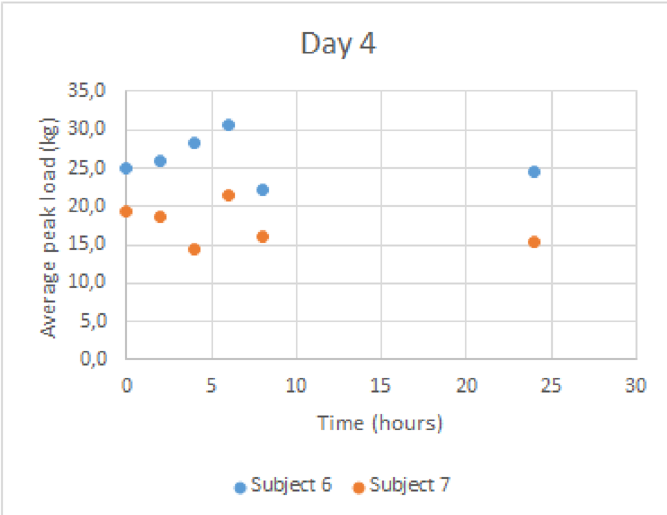

Figure 18 Average peak load on day 4. All measurements on day 4 for all subjects with a target load of 10 kg are shown.

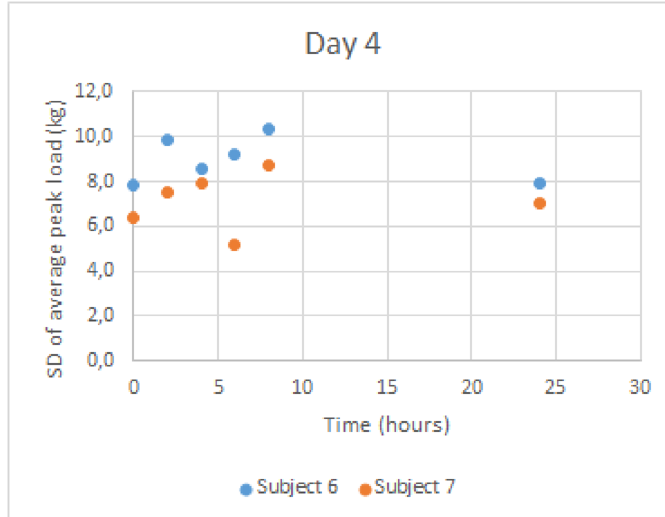

Figure 19 SD on day 4. All measurements on day 4 for all subjects with a target load of 10 kg are shown.

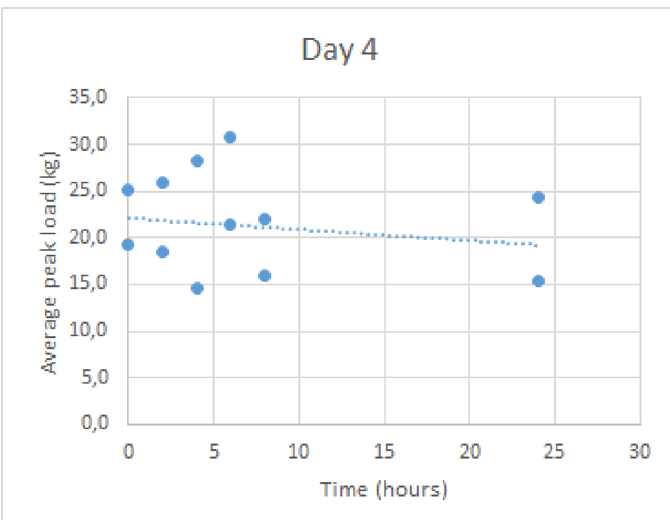

Figure 20 Average peak load on day 4, showing all measurements for all subjects with a target load of 10 kg and a trend line through all points.

5.3 Overall effects of biofeedback

The figures from the previous sections suggest that over time, variation in the 50% group decreases and all average peak loads center around a single value. Plotting the SD of all average peak loads over a single day for each day results in figure 21. Over time, the variation decreases exponentially, from 10% on day 1, to 2% on day 16. The average peak load over each day also decreases, from 58% BW on day 1, to 53% BW on day 16 (figure 22).

For the 10% group, both average peak load and average SD decrease slightly over time (figures 23 and 24). Average peak load decreases from 24 kg to 23 kg over 5 days, and average SD decreases from 12 kg on day 1 to 9 kg on day 5.

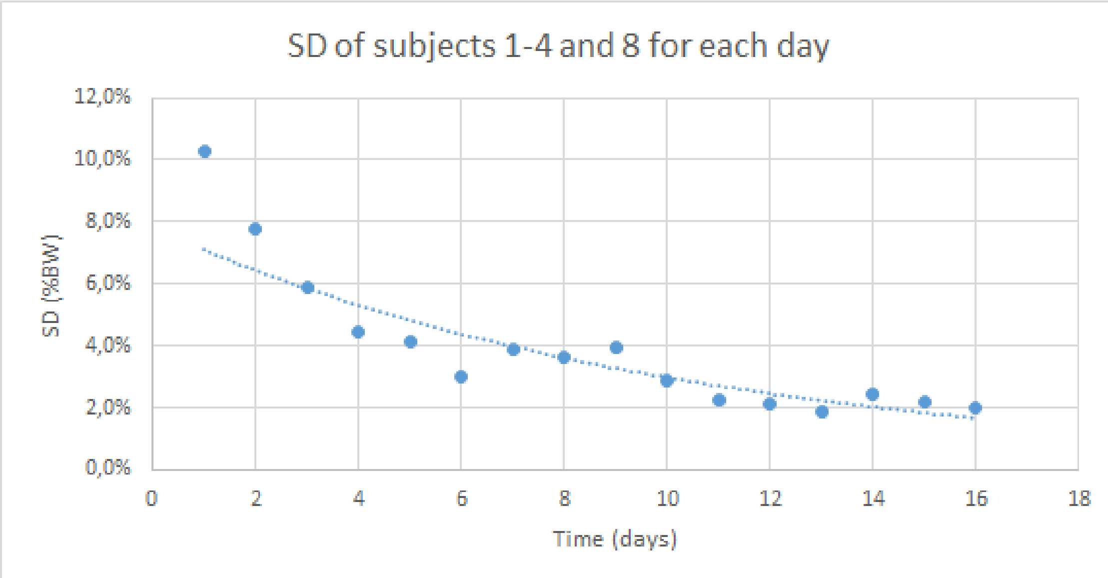

Figure 21 SD of average peak loads of subjects 1-4 and 8 per day of measurements. A clear decline is visible.

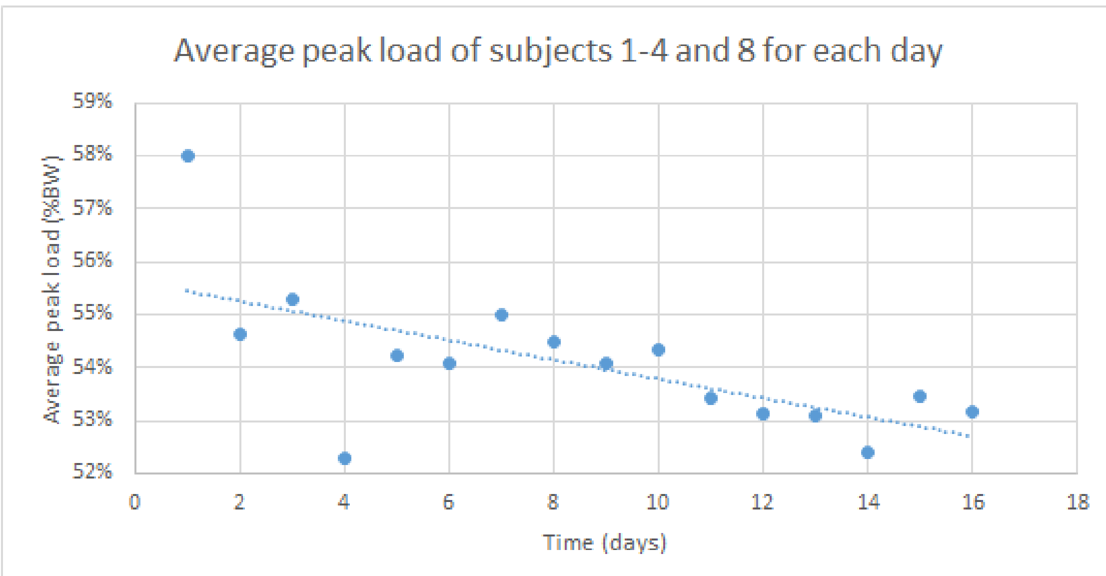

Figure 22 Average peak load of subjects 1-4 and 8 per day of measurements. Over time, the average peak load approaches 50% BW.

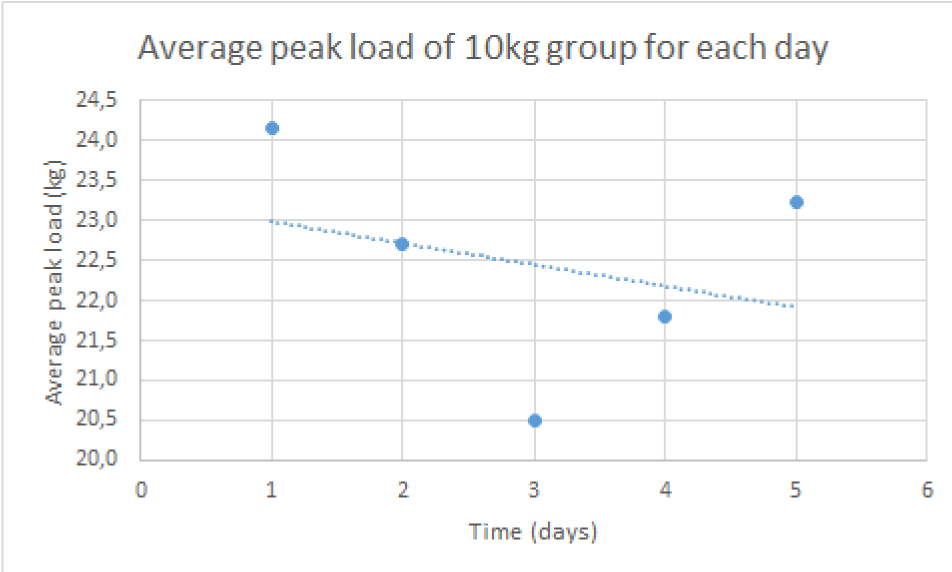

Figure 23 Average peak load of subjects 6 and 7 per day of measurements. The average peak load decreases slowly over time.

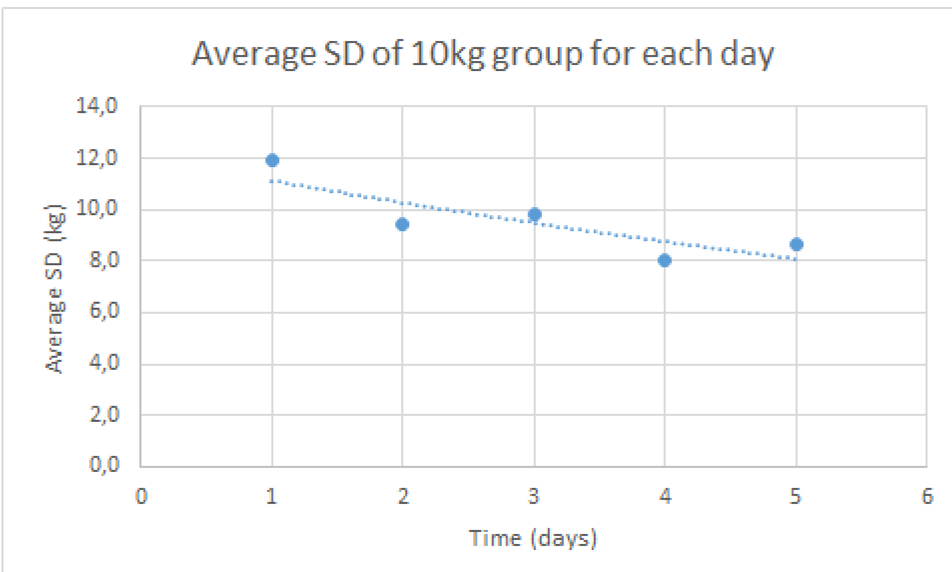

Figure 24 Average SD of subjects 6 and 7 per day of measurements. The average SD shows a decline as time progresses.

5.4 Long-term learning effect

Figure 25 shows an example of the plots made to assess the long-term learning effect of one biofeedback training a day. The plotted nodes in the figure show the duration of the learning effect for each day, determined using the flowcharts from (figures 5 and 6). A green node indicates that the learning effect was maintained throughout the entire day, up until t=0 on the next day of measurements. A red node indicates that at that time, the learning effect was first recorded to be lost (in other words, a red node at 8 hours suggests that the learning effect was lost somewhere between 6 and 8 hours after training). Figure 26 shows the results for all subjects.

From figure 26, it follows that all four subjects with a target load of 50% eventually managed to maintain the learning effect for 24 hours or more. For subjects 2 and 4, this was only achieved in the fourth week of measurements (starting at day 13). Subjects 1 and 3 succeeded in maintaining the learning effect starting within the first few days.

Figure 26 also shows that for subjects 6 and 7, the learning effect was never maintained 24 hours. Subject 6 maintained the learning effect for somewhere between 8-24 hours on the first day, but after that, both subjects never maintained the learning effect for over 4 hours.

Subject 5 shows a different pattern, only maintaining the learning effect for a longer period of time during a few days, on days 5 and 7. This subject's retention does not exceed 8 hours throughout all other days.

Figure 27 shows the long-term learning effect for all subjects in a single plot. Although the duration of the learning effect over all subjects varies from 0 to 72 hours in the first days, the duration appears to increase over time. The plotted trend line in figure 27 shows that over all subjects, the duration of the learning effect increases from 11 hours on day 1, to 38 hours on day 30. On day 15, the trend line indicates that the learning effect is maintained for an average of 24 hours.

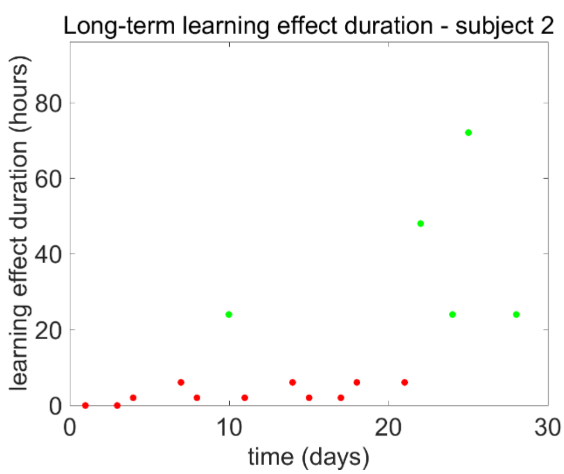

Figure 25 Example of long-term learning effect plot. Green nodes indicate days in which the learning effect was consistently maintained. Red dots indicate when the learning effect was lost.

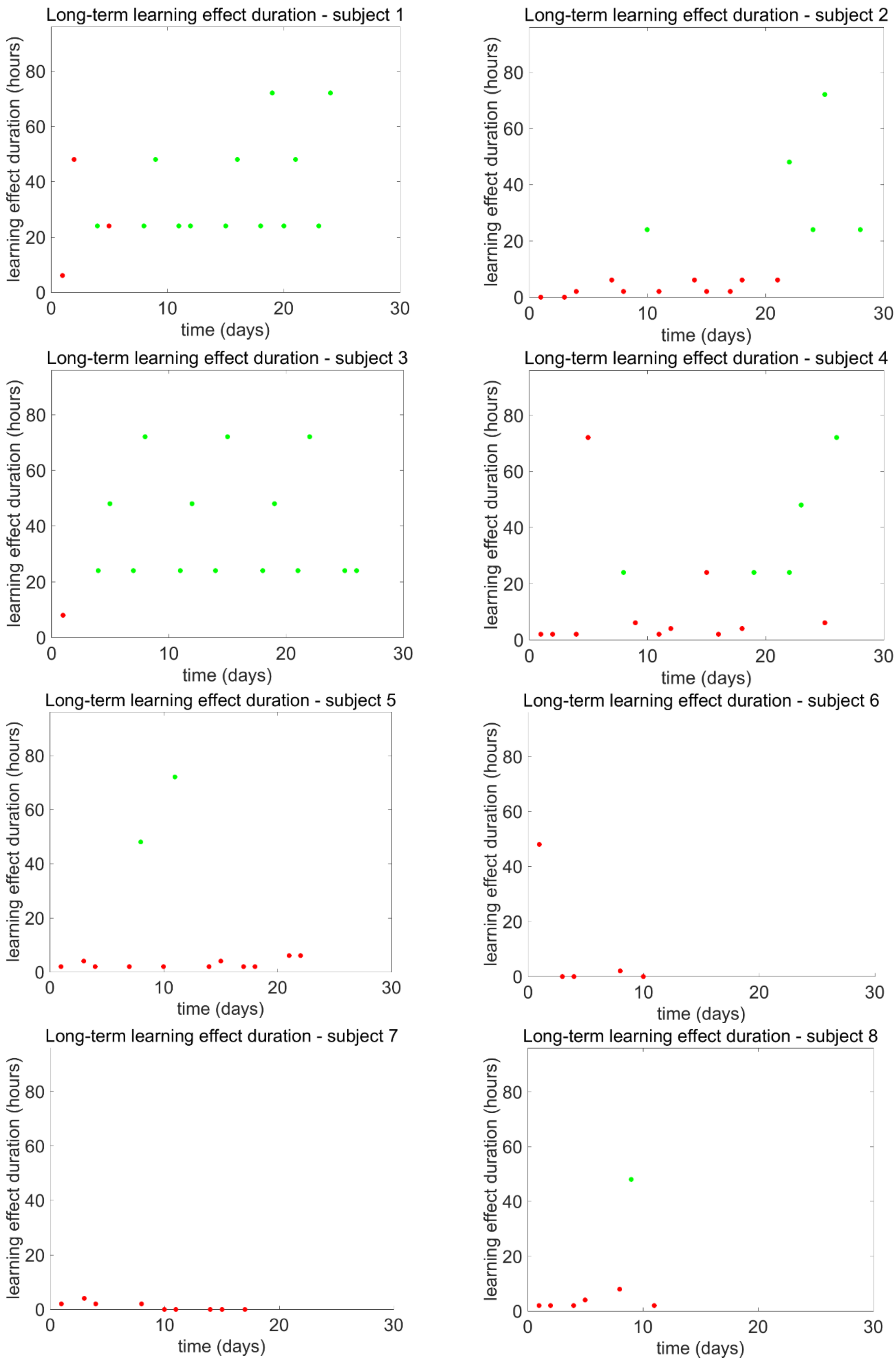

Figure 26 Long-term learning effect results for all subjects

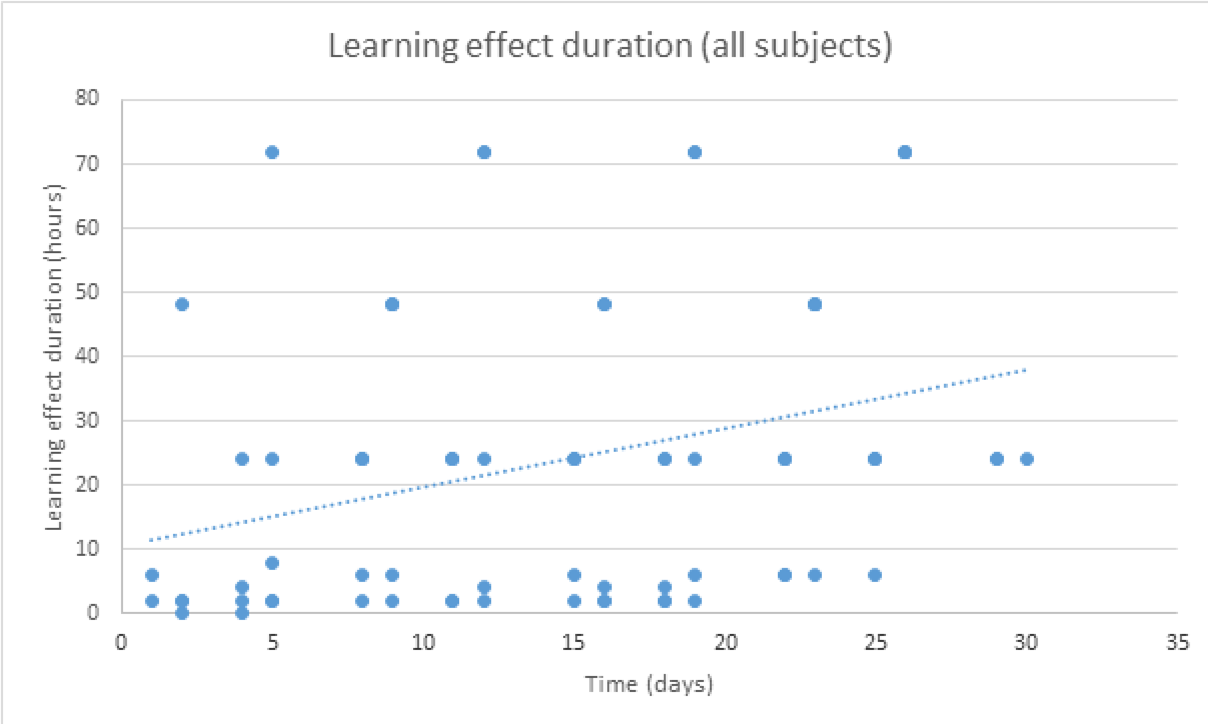

Figure 27 Long-term learning effect results for all subjects in a single figure. The dotted line is a trend line through all points.

6 Discussion

This chapter will elaborate on the results shown in chapter 5. First, an interpretation of the results of subjects 1-4 and 6-7 is provided, along with a possible explanation. Next, the limitations of this study are explained, and finally, if possible, the methods used to minimize the effects of these limitations are assessed.

6.1 Forgetting curve

Based on the results described in section 5.2, several conclusions can be drawn. First, patients in the 50 % group show that the effect of training is maintained during 24 hours, indicated by the plots in figure 7 and 8. In these plots, the trend line stays within the limits for both average peak load and SD. These results match with the results found by Hustedt [16], who found a 24-hour retention of biofeedback effects in healthy, young volunteers. However, when looking at each subject separately, it is clear that not all subjects retain the learning effect for this duration, with subjects 2, 4, and 8 often exceeding the limits of average peak load in the first days of measurements.

For subjects 6 and 7, it is clear from figures 15 and 16 that differences exist between the two subjects. Subjects 6 tends to continuously overload, while subject 7 only overloads slightly, with the average within the limits. For both subjects, SD also exceeds the limits, but the SD of subject 6 is consequently higher than the SD of subject 7. On day 4 (figures 18 and 19), even though subject 6 still greatly overloads, both average peak load and SD are reduced as compared to day 1. This indicates that subject 6 does benefit from training, even though the target load is never reached.
Even though the average peak load for subject 7 appears to be higher on day 4 as compared to day 1, the SD is lower on day 4. Similar to subject 6, the limits for both average peak load and SD are never met. However, the lower SD can indicate that subject 7 has become more self-conscious about their loading of the affected leg, and is actively trying to keep all steps as equal as possible.

6.2 All subjects benefit from biofeedback

The data presented in section 5.3 shows another important finding: as time progresses (figures 7, 10, and 13), the differences between subjects in average peak load are reduced. In other words: the standard deviation of all these measurements combined appears to decrease.
To obtain figure 21, the standard deviation of all average peak loads for a single day (in other words, all points from figures like figure 7), is calculated, and for all these days, this average is plotted. Figure 21 clearly shows that the standard deviation does indeed decrease over time.
Although this indicates that all subjects approach the same average peak load over time, this does not directly indicate that all subjects approach the desired average peak load (in this case, 50% BW). Figure 22, however, shows not the standard deviation over each day, but the average peak load (in other words, the average of all points in figures like figure 7). The trend line shows that the average peak load over a single day, appears to approach 50%. Therefore, it can be concluded that all subjects approach the same target value over time, and that this target value is 50% BW. In other words, it can be concluded that biofeedback helps the subjects approach their target load, and that this effect starts from the first training.

For the group with a target load of 10 kg, figures 23 and 24 show that both average peak load and SD decline over the days. Average peak loads decrease from 23 kg to 22 kg, and SD from 11 kg to 8 kg. Throughout the first days of measurements, both parameters exceed the limits. However, the displayed decline might indicate that if training is continued for a longer period of time, subjects with a target load of 10 kg might also approach their target load.

Previous research by Raaben et al. has suggested that for the 10 kg group, the SD is the most important indicator of feedback effects [20]. Average peak load in that study was reduced from 14 kg to 9 kg following feedback training, and SD from 10 to 6 kg. Differences exist between the study by Raaben et al. and the present study, however. In the former, the average peak load before biofeedback training was within the limits. In the present study, however, the average peak load before biofeedback training greatly exceeded the limit. Even though SD might be the most important indicator of feedback effects in this case, as well, getting the average peak load within the indicated limits should be prioritized in order to minimize stress on the fracture area.

6.3 Long-term learning effect

In section 5.4, the results of long-term biofeedback training are presented. A distinct difference was observed in the subjects with a target load of 50% (subjects 1-4 and 8). Subjects 1 and 3 required only a few days of training, before they could maintain the desired load throughout the entire day, whereas subjects 2, 4, and 8 could not manage this within the first weeks. From the fourth week, however, subjects 2 and 4 managed to maintain the desired load throughout the entire day, as well. These differences appear to indicate different behavior in subjects, or different learning skills. With the small number of subjects per group, it is too early to differentiate between these variables at this point. However, if this effect is confirmed in a larger population, patients with faster learning capabilities could do with fewer training sessions each week. Based on patient characteristics, no cause for the difference between the groups could be found at this point.

For subjects 6 and 7, who were allowed to load only 10 kg, the plots in figure 22 look different from the others. These two subjects were never able to maintain the learning effect for 24 hours. Furthermore, as opposed to subjects 1-5, the learning effect in these subjects appeared to be lost at t=0 several times. This indicates that their weight bearing was, in fact, less adequate than the measurement right before that, without receiving feedback. This could mean that these subjects did not benefit from biofeedback training. Extrapolating that conclusion and stating that patients who are instructed to load 10 kg do not benefit from biofeedback training, however, would be premature. Not only has research shown otherwise [20], but for subjects 6 and 7, other factors might have confounded the measurements. For example, both subjects initially only loaded the affected leg on the toe, since that is how they were initially instructed by the physiotherapist. For this study, they were instructed to maintain a plantigrade stance, and attention was paid to that, but it is possible that these subjects still occasionally loaded the toe only, resulting in occasional underloading.

Loading too much has also occurred in these subjects. All subjects mobilized using a walker, but in the case of subjects 6 and 7, they were required to bear 90% of their weight on their arms. Not only did this result in shoulder pains in both subjects, both might have lacked the strength to bear all their weight on their arms. Furthermore, at the moment in which the weight is transferred from the unaffected leg to the arms, the walker is placed in front of the subject. This causes them to have to bear 90% of their weight on their arms, while not being able to fully extend them. Bearing that much weight on one’s arms is less difficult when the arms are extended, perpendicular to the ground. With the walker in front, the elbows might function as a hinge, resulting in a greater risk of falling. In order to counter this, both subjects might have loaded their affected leg more.

Subject 5’s target loads varied over time. Starting at 50% BW, the target load increased by 10% on days 2, 6, and 10. This caused difficulties in examining the long-term learning effects. Looking at the raw data only, however, shows several interesting findings. Between days 2 and 6 (in other words, target load 60% BW), the average peak load started around 70%, but lowered to around 60% in these few days, resulting in a 48-hour retention at day 5. Between days 6 and 10, the average peak load was stable around 70%, but the

SD was often high (up to 14%). This also goes for days 10 to 13, where the average peak load was managed around 80% after starting around 70% on day 10, but SD was consistently too high (up to 12%).
Based on this data, it is not possible to place subject 5 in one of the two groups suggested before. However, it is not adequate to say that subject 5 did not display a learning effect at all. Progress was visible, with the 48-hour retention at day 5 as proof. However, the continuously changing target load made it difficult for the subject to adapt, causing little retention the following days.

6.4 Limitations

This study had several limitations. The most important limitation to the study was the small number of subjects. It is difficult to form solid conclusions based on data from this few subjects. Although the current data suggests 2 groups exist in the 50% loading group, for example, more subjects are necessary in order to prove a significant difference exists.
Furthermore, not all subjects were included in the study for the full 4 weeks. In case of subjects 5-7, the reason for stopping participation was that these subjects had an appointment with their surgeon, and following that appointment, their target load was increased to 100%. All available data was used in this study, but since the results from subject 1-4 suggest that after three weeks of training, subjects might be able to achieve their weight bearing goals, and maintain this for at least 24 hours. In case of subjects 5-7, participation was terminated before the fourth week started. It is possible that these subjects would have managed to maintain the effects of feedback for at least 24 hours, if another week of training was performed.
Another factor that might have influenced the results is the instruction the subjects received from their physiotherapist before being included in the study. Especially in the case of subjects 6 and 7, the instructions they received earlier might be one of the reasons for confounding of the data, since, as stated before, they mainly loaded on the front part of the foot, even after being instructed to maintain a plantigrade stance.
Finally, most studies only take average peak load into account when discussing results [16, 19, 29], but looking at average peak load alone is not sufficient for assessing the learning effect. It has been shown that biofeedback also has great immediate effects on SD [20], and therefore, it is important to take SD into account when assessing the learning effect. In this study, both average peak load and SD were considered, and a method was devised for combining both factors in order to obtain relevant results. Because the learning effect was never analyzed using a comparable method, there is no way to accurately compare the obtained results to those from other studies.

7 Conclusions

Chapter 1: Background

Fracture healing is a complicated process which benefits from loading of the fractured bone. Following surgery for a lower extremity fracture, full loading of the fractured bone may cause complications. Partial weight bearing can induce the benefits of weight bearing, without the risk of causing complications. The only adequate method for instructing patient in partial weight bearing is biofeedback.

Chapter 2: Research area

Using the SensiStep, an ambulatory biofeedback system, patients can be instructed for partial weight bearing. This study focuses on analyzing the learning effect of such training. Attention is paid to both the short-term (forgetting) effects, and the effects of long-term daily training.

Chapter 3: Gathering the data

Seven subjects with initial target loads of 10-50% of their body weight were trained and followed for up to four weeks. Four days a week, subjects received a training session in the morning, followed by control measurements after 2, 4, 6, 8, and 24/48/72 hours.

Chapter 4: Processing the data

Using MATLAB, the data was analyzed by automatic selection of the steps from the measurement. Next, several parameters were calculated from these separate steps. For this study, only average peak load and standard deviation were used. Using a combination of both variables, the moment in which the learning effect had diminished could be detected.

Chapter 5: Results

Initial data analysis showed that on average, the effects of biofeedback were maintained for over 24 hours, starting from day 1. However, 24-hour retention was only obtained after 1 week of training in 2 subjects, and after 3 weeks of training in 2 other subjects. The other subjects showed no 24-hour retention in the duration of the study.

Chapter 6: Discussion

Based on the obtained results, three groups are suggested. First, a group that will quickly acquire 24-hour retention. Second, a group that will acquire 24-hour retention after long-term training. Third, a group that does not acquire 24-hour retention. However, the number of participants was small, and several factors might have confounded the results.

General conclusion

In conclusion, it can be stated that it is possible for patients with partial weight bearing instructions to acquire 24-hour retention of the effects of biofeedback. However, the amount of training this takes may vary. In subjects with a target load of 10 kg of their body weight, 24-hour retention was not achieved. More research into this subject is necessary in order to obtain solid results.

8 Recommendations

In order to truly understand the learning effect of biofeedback training, additional studies are required. These studies should focus on expanding the data obtained in the current study. Including more patients, and analyzing all combined data will strengthen the conclusions, or possibly change them.

If more data is present, a possible course of action would be to devise a method for predicting the learning process in a given patient. If an estimation can be made as to how long it will take for them to obtain 24-hour retention (or longer), the rehabilitation protocol and training schedule can be adapted to improve the patient's performance.
If all patients can be divided into several groups, as suggested in this study, the first full day of measurement might provide an indication of patient performance. This was demonstrated in this study, but validation is necessary.

Eventually, a method could be developed for analyzing the forgetting process in such a way, that another biofeedback training session would be provided at the moment the learning effect diminishes (for example, if average peak load exceeds the limits). If a system such as SensiStep would be used continuously by a subject, the system could continuously calculate the average peak load and SD over a given period of time, using a moving window. If the limits are exceeded, the subject receives a signal on, for example, their phone, and a biofeedback training session can commence, using the phone as display for the feedback (similar to the StepApp).

Finally, more research into patients with a target load of 10 kg BW is necessary. Mobilizing with a walker does not seem the optimal method. Different walking aids should be considered. Using biofeedback, the difference between walking aids can be determined, and an optimal method for 10 kg loading can be devised.

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