UNIVERSITÉ Grenoble Alpes

Application of a biofeedback glove in rehabilitation of distal radius fractures

INTER-UNIVERSITY DIPLOMA OF HAND REHABILITATION

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"The opinions expressed in this work are the sole responsibility of the authors."

Abstract

Virtual reality biofeedback gloves are a new technology and several studies have shown promising results for their effectiveness in neurological rehabilitation. However, research is lacking concerned with their application in hand therapy for orthopedic disorders. Therefore, we conducted a pilot study of a prospective, single blinded, randomized controlled trial and compared rehabilitation results with a standard protocol to a new treatment protocol including a biofeedback glove in distal radius fractures rehabilitation. Although the conclusion of this study is not representative due to low participation number, it reveals a positive impact on rehabilitation: The biofeedback glove seems to lend itself as a valuable tool for upper limb orthopedic disorders. It enables goal-orientated task specific exercises in a personalised, adapted and repetitive manner. In our observations, a positive effect in patient's implication and motivation has been demonstrated.

Further research with a higher number of participants and for a longer treatment duration is needed to achieve a representative result. Possible future implications of virtual reality biofeedback gloves in hand therapy are currently investigated.

Key words

biofeedback glove - hand therapy - virtual reality - distal radius fracture

List of abbreviation

VR: virtual reality

SG: smart Glove

ADL: activities of daily living

FMRI: functional magnetic resonance imaging

DRE: distal radius extremity

DRF: distal radius fracture

CVA: cerebrovascular accident

AROM: active range of motion

CNS: central nervous system

CRPS: Complex regional pain syndrome

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Preface

This thesis is inspired by the development of new technologies in rehabilitation. As we move further into the digital age, new treatment modalities appear, creating new possibilities. What does that mean for our current techniques and what is the true value of these new devices? Are they just another entertaining gadget or could they be effective therapeutic devices? It is becoming increasingly difficult to make a choice amongst the growing variety of gadgets available, to understand which new technologies have real therapeutic impact and which are merely contraptions.

Introduction

Today, a hand therapist's toolbox is very large with a wide variety of treatment options available. The digital age allows us to integrate new technological advances into our current treatments and enables new types of rehabilitation. The development of novel applications is rapidly increasing in several treatment fields. Over the last decades computer-based rehabilitation devices introducing virtual reality (VR) rehabilitation have been developed alongside constantly emerging new technologies. According to Dockx et al. 2016 (1) virtual reality technology is recommended to optimize motor learning in a safe environment, and possibly a worthy alternative to conventional approaches. However, those new modalities come with a significant financial investment. Their costs in relation to their real benefits for rehabilitation remains to be proven. Several surveys (2) have demonstrated therapists' interest and desire to better understand the available tools and their practical implications (3). Among them, VR biofeedback gloves are of special interest in hand therapy.

This thesis is an attempt to investigate if biofeedback gloves might have a beneficial effect in the rehabilitation of orthopaedic disorders.

The first part explores the current state of their application. The second part is dedicated to a self-conducted pilot study about the application of biofeedback gloves in distal radius fractures rehabilitation. The third part is about their possible application in hand therapy.

We declare to have no conflicts of interest.

PART I.

Background

Current use of new technologies in rehabilitation

1. Computer based VR rehabilitation devices and biofeedback gloves

Biofeedback gloves exist in various forms and shapes. Some versions are connected to the whole arm, others just to the wrist and hand. Some possess supporting options with passive robotic assistance or electrical stimulation to facilitate movements. Their purpose can be to assist the patient with activities of daily living (ADL) by giving powered assistance or decreasing tremors. Others give no mechanical aid and serve purely as a biofeedback system. The aforementioned pilot study focuses only on non-assistive biofeedback devices. So far, their efficiency has been studied in many application fields such as cardiovascular, psychological, geriatric and neurological rehabilitation (2). However, few studies (4), (5) investigated if there is a real benefit for supporting the work of health professionals in the orthopaedic field as well (6).

2. Virtual reality biofeedback device in rehabilitation

Biofeedback gloves are gloves connected to a computer-based application, that provide an interactive, multisensory and stimulating environment like real-world experiences and are designed to facilitate movement training. They are often based on activities of daily life and therefore have a functional task-oriented approach. (4)

Table 1 displays different existing biofeedback gloves:

Device	**Purpose**	**Brand**
	Force feedback system	VRgluv TM
	Active range of motion Biofeedback	Neofect smartglove
	Passive assistance motor facilitation biofeedback	Saebo glove
	Haptic feedback by pressure	UC San Diego prototype

Table 1 Examples of different existing biofeedback gloves

Those biofeedback gloves allow an instant return message to the user to help him improve their movements. This return message helps the body to modify its current representation in the cortical structures thanks to the brain's neuroplasticity. Before looking into present studies of those gloves it is necessary to take a deeper look at their effects on the human body and its physiology.

2.1 Definition Neuroplasticity and biofeedback

Neuroplasticity is defined as "the ability of the nervous system to undergo physiological changes as a result of genetic, behavioral, environmental changes and as a neural response to trauma" (7). This neural response is also one of the bases for recovery of lost function following any kind of injury (8). It allows us to recover lost connections and to acquire new ones. One major way to stimulate those neuroplastic changes is biofeedback. Sattar and Valdiya 1998 (9) defined biofeedback as "a treatment method designed to facilitate self-regulation of bodily processes". This commonly used treatment method helps the patient to self-regulate their own body by giving different types of return messages (2). It helps the patient to voluntarily adjust mechanisms in his body by receiving an instant return message of their movements. This helps them to readjust and therefore to improve faster. Frank et al. 2010 (10) gives this simple example: "Biofeedback allows patients to see inside their bodies to regulate their physiology".

Another definition from Andrasik et al. 2007 (11) is as following: "Applied biofeedback is the monitoring and exerting of influence to produce a change in the incoming information. Individuals receive biofeedback on their physical appearance by looking in a mirror". Thanks to this method, patients can perceive and therefore take control over several body functions such as heart rate, blood pressure, and muscle activation. The information fed back to the body can be transmitted by visual, auditory or tactile stimuli to facilitate normal movement patterns (12). Biofeedback systems have shown to give better progression when patients can compare their performance to their able self. (5)

More recently virtual reality (VR) or exercise gaming technologies have integrated those biofeedback signs to induce neuroplastic changes (12).

2.2 Current literature on virtual reality and biofeedback rehabilitation gloves

Recent studies have investigated the role of biofeedback and virtual reality (VR) devices for therapeutic purposes. Emerging from this type of rehabilitation, multimedia devices have been developed to provide those previously mentioned biofeedback cues. Those devices could be compared to an advanced mirror visual feedback system that stimulates the cerebral plasticity due to mirror neuron system engagement. They consist of "target-oriented motor tasks that require planning and coordination of movements" (4). They can also give task-oriented biofeedback and offer several variations to include perceptive and cognitive functions.

Furthermore, functional magnetic resonance imaging (FMRI) studies have demonstrated the occurrence of visuomotor cortical facilitation during VR training (12). One of the challenges faced today in neuromotor rehabilitation is finding ways to provide repetitive and task-oriented training to facilitate motor function recovery (13). Virtual reality biofeedback devices may provide a solution for this kind of need. There are examples in different rehabilitation areas. Effectively, relative to conventional therapies for stroke patients, VR training provides a goal-directed task for the patient, and therefore seems to be more effective and intensive than self-training. It may also boost the motivation of patients and serve as a pleasurable experience during treatment by controlling the level of difficulty and the variability of the task (3). So far various sensorimotor biofeedback devices have shown encouraging results for different therapeutic applications (5).

According to Subramanian et al. 2012 "VR training led to more changes in the mild group and a motor recovery pattern in the moderate-to-severe group indicative of less compensation, possibly because of a better use of feedback." They also state that VR devices that are custom designed according to the needs of the individual have the potential to increase patient engagement by making therapy more fun and interesting. At the same time, such applications allow clinicians to adapt difficulty levels and activities according to patient preferences and rehabilitation goals. Our results suggest that there is additional value in using VR as a training environment to enhance arm motor recovery. Also, in cardiac rehabilitation, according to Chuang T-Y al. 2006 (14) "these study outcomes clearly support the notion that incorporating a VR environment into cardiac rehabilitation programs will accelerate maximum recovery of patients' cardiovascular function."

Those novel techniques are emerging to accelerate rehabilitation processes and seem to show promising results for faster recovery. Huang al. 2006 (15) mention that these visual, auditory and physical interactions can create real-life experiences in an engaging manner and therefore may make them more effective than classic biofeedback. According to Prochnow, D. al. 2013 (16), in neurorehabilitation, VR based devices for rehabilitation activate “mirror mechanisms that can be employed for visuomotor training.”

Doyle, J. al 2011 (17) also emphasize some other important facts about VR feedback gloves and why they are especially useful for rehabilitation purposes. They state that these gloves offer a wide variety of exercises, in which the interactions are hand free, allowing the patient to focus on their movements. Simultaneously, the gloves are easy to set up, which simplifies the process and helps maintaining implication.

3. Virtual reality biofeedback gloves for orthopaedic disorders

However, so far there is inadequate research on the real therapeutic benefits of these systems in orthopaedic rehabilitation, especially the upper extremity, and their efficiency remains to be proven. To date, only one study on frozen shoulders investigated their role in orthopaedic disorders of the upper extremity. In Canada, a recent national survey (3) demonstrated that therapists might have a real interest for VR and active videogame-based treatment, especially in orthopaedic rehabilitation, but they claim that they need to know and learn more about those tools to better integrate them in their clinical practice before applying them. They also state that “reality-enhanced robotics may be integrated with current concepts in orthopaedic rehabilitation shifting from an impairment-based focus to inclusion of more intense, task-specific training for patients with upper extremity disorders, specifically emphasizing the wrist and hand” (4). Maciejasz et al. 2014 (2) and Hakim et al. 2016 (4) confirmed this statement in their survey on robotic devices for upper limb rehabilitation. Bonnechère also found that VR can have a beneficial effect for the body and that it has potential for rehabilitation (18).

Researchers have found promising results in the orthopaedic field concerning frozen shoulders (6), knee arthroplasty (19), orthopaedic telerehabilitation (20) and ankle rehabilitation (21) . Based on the physiological background of rehabilitation and the current promising study results of biofeedback and virtual reality, this kind of new treatment might be a real benefit for hand therapists in the neurological field but also in the wider orthopaedic field. Especially interesting and beneficial for orthopaedic disorders is their influence on our proprioception. Our sense of body awareness provides automatic neuromuscular joint control important for various functional activity demands. This important sensory system depends on the return information from our mechanoreceptors situated in our joint capsular tissues, ligaments, tendons, muscles and skin. Traumas, common in orthopaedic disorders, can damage those structures and disrupt the generation and transmission of adequate proprioceptive input from those receptors, leading to major joint sensory-motor impairment.
Another important impairment resulting from trauma is pain. Persistent pain can create neuroplastic changes, eventually altering the processing of incoming proprioceptive sensory information and leading to joint control deficit.

The non-exhaustive list of articles below displays promising results for the use of virtual reality in different rehabilitation fields:

Rehabilitation field	Disorder	Author and year
Neurological	Parkinson	Dockx et al. 2016 (1)
	Upper extremity dysfunction	Shin et al. 2016 (6)
	General	Kefaliakos et al. 2016 (22)
	Neuromotor/Sensorimotor	Posada-Gomez et al. 2018 (23) Fluet et al. 2013 (24)
	Chronic stroke Subacute stroke	Subraminian et al. 2012 (5) Fluet et al. 2013 (24) Turolla et al. 2013 (25) Brunner et al. 2014 (26)
Psychological	Anxiety	Repetto et al. 2011 (27)
Cardiovascular	Coronary artery bypass grafting	Chuang et al. 2006 (14)
	Cardiopulmonary	Penn et al. 2018 (28)
Orthopaedic	Motor rehabilitation	Sveistrup et al. 2004 (13)
	Upper extremity	Hakim et al. 2017 (4)
	Frozen shoulder	Si-Huei Lee 2016 (6)
	Knee arthroplasty	Jin et al. 2018 (19)
	Orthopaedic telerehabilitation	Burdea et al. 2018 (20)
	Ankle rehabilitation	Girone et al. 2000 (21)
Pain	CRPS	Sato et al. 2010 (29)
	Chronic pain	Gupta et al. 2017 (30)
Paediatric	Paediatric chronic headache	Shiri et al. 2013 (31)
	Autism	Mesa-Gresa et al. 2018 (32)

Table 2 Non-exhaustive list of articles showing promising results for the use of virtual reality in different rehabilitation fields

Considering the common orthopaedic population in hand therapy and the current modalities and features of biofeedback gloves, we chose a population suffering from distal radius fractures (DRF) for our study. We made this decision for several reasons: First of all, DRFs are the most common type of upper extremity fractures. Hand therapists are confronted with them daily and their complexity can make them challenging and difficult to treat. The second reason behind our choice was their relatively long immobilisation phase varying from 3 to 8 weeks, according to the surgical protocols. The resulting stiffness and diminution of the wrist's cortical representation made them an ideal test group for the VR biofeedback glove. To the best of our knowledge, no study has been performed to this date to investigate the effect of biofeedback gloves in distal radius fracture rehabilitation.

4. Distal radius fracture

The etiology, prevalence and clinical relevance is shortly described. A more detailed description is out of scope for the thesis subject.

4.1 Etiology

DRFs are metaphyseal or physeal fractures and are commonly caused by a hyper-extension mechanism of the wrist. They can be classified into different types of fractures. The most prevalent type of fracture is a Colles' fracture with the distal fragment displaced dorsally compared to a Smith's fracture where the distal fracture fragment is displaced volarly. Further differentiation can be made between intra-articular, extra-articular fractures, comminuted fractures and associated fractures of carpal bones and/or the ulnar styloid. Several classifications for DFRs exist. The below mentioned Fernandez classification is based on the pathomechanics of DRFs and divides them into five categories.

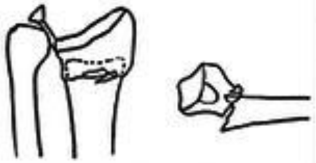
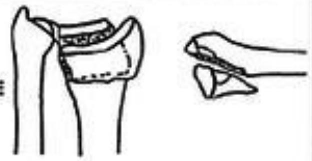
FRACTURE TYPES (ADULTS) BASED ON THE MECHANISM OF INJURY	CHILDREN FRACTURE EQUIVALENT	STABILITY/ INSTABILITY: high risk of secondary displacement after initial adequate reduction	DISPLACEMENT PATTERN	NUMBER OF FRAGMENTS	ASSOCIATED LESIONS carpal ligament, fractures, median, ulnar nerve, tendons, ipsilat. fx upper extremity, compartment syndrome	RECOMMENDED TREATMENT
TYPE I BENDING FRACTURE OF THE METAPHYSIS 	DISTAL FOREARM FRACTURE SALTER II	STABLE UNSTABLE	NON-DISPLACED DORSALLY Colles VOLARLY Smith PROXIMAL COMBINED	ALWAYS 2 MAIN FRAGMENTS + VARYING DEGREE OF METAPHYSEAL COMMINUTION (instability)	UNCOMMON	CONSERVATIVE (stable fxs) PERCUTANEOUS PINNING (extra- or intrafocal) EXTERNAL FIXATION (exceptionally BONE GRAFT)
TYPE II SHEARING FRACTURE OF THE JOINT SURFACE 	SALTER IV	UNSTABLE	DORSAL Barton RADIAL Chauffeur VOLAR rev. Barton COMBINED	TWO-PART THREE-PART COMMINUTED	LESS UNCOMMON	OPEN REDUCTION SCREW-/PLATE FIXATION
TYPE III COMPRESSION FRACTURE OF THE JOINT SURFACE 	SALTER III, IV, V	STABLE UNSTABLE	NON-DISPLACED DORSAL RADIAL VOLAR PROXIMAL COMBINED	TWO-PART THREE-PART FOUR-PART COMMINUTED	COMMON	CONSERVATIVE CLOSED, LIMITED, ARTHROSCOPIC ASSISTED OR EXTENSILE OPEN REDUCTION PERCUTANEOUS PINS EXTERNAL FIXATION INTERNAL FIXATION PLATE, BONE GRAFT
TYPE IV AVULSION FRACTURES, RADIO CARPAL FRACTURE DISLOCATION 	VERY RARE	UNSTABLE	DORSAL RADIAL VOLAR PROXIMAL COMBINED	TWO-PART (radial styloid ulnar styloid) THREE-PART (volar, dorsal margin) COMMINUTED	FREQUENT	CLOSED OR OPEN REDUCTION PIN OR SCREW FIXATION TENSION WIRING
TYPE V COMBINED FRACTURES (I - II - III - IV) HIGH VELOCITY INJURY 	VERY RARE	UNSTABLE	DORSAL RADIAL VOLAR PROXIMAL COMBINED	COMMINUTED and/or BONE LOSS (frequently intra-articular, open, seldom extra-articular)	ALWAYS PRESENT	COMBINED METHOD

Table 3 Fernandez classification based on the pathomechanics of DRF (orthobullets)

4.2 Epidemiology

Distal radius fractures are the most common fracture site in the upper extremity often followed by complications. There are an estimated 40.000 cases each year in France (33) and approximately one-sixth of fractures treated in United States emergency departments (34). A 2017 study by Jerrhag et al. (35) from Sweden showed a 2.0 % increase in DRFs per year for male patients and a 3.4 % increase for female patients aged from 50 to 59 years, between the years from 1999 to 2010. This study also showed that there is a statistically significant increase for the 17 to 64 years age group. The active population is particularly concerned.

4.3 Clinical relevance

The average treatment duration varies but often necessitates a rehabilitation over several months. According to the French health care federation, a distal radius fracture treated orthopaedically implies a sick leave from 10 to 70 days, and 14 to 84 days when treated surgically. The long rehabilitation process and prolonged sick leaves create considerable health care costs and make it a challenging pathology for our society.

4.4 Current treatment of distal radius fractures

According to a 2015 Cochrane review, there is a lot of research about DRF treatment but a low quality of evidence between various protocol of rehabilitation (13). There is no consensus on which method has the highest cost effectiveness by limiting sick leave duration and health care costs.

Several treatment options exist according to the type of fracture and surgical protocol. A non-adapted rehabilitation may increase the risk of complications and bad evolution in the long term, like instability, post-traumatic osteoarthritis, loss of functions.

For this reason, specific rehabilitation principles are necessary (36). Active mobilisation is part of those principles and has to be progressive, protected and adapted. Careful active mobilisation will “facilitate an earlier return to clinically relevant function and potentially allow for an earlier return to daily, work, and sports activities.” (37)

Active range of motion exercises are an important factor in rehabilitation (38). The patient’s implication and motivation during their treatment play an important role in the speed of their recovery. Early active rehabilitation is recommended for stable fractures for a better outcome and earlier return to activities, but load bearing must be avoided until complete fracture healing.

VR may be integrated in an early active rehabilitation protocol, allowing patients a rapid return to ADL related exercises without the risk of external loading, or destabilising the healing fracture site as actual ADL exercises would do. For example, a musician could train on his instruments during VR exercises in the early phases of rehabilitation and stimulate the same brain regions as he would in real life without carrying the instrument or applying pressure and therefore protect the healing fracture site. His loss of neural connections would then be more limited and his return to work possible at an earlier stage.

5. Possible use in orthopaedic disorders

In a fracture, the soft tissue injury that happens around the bone shows the important role of the surrounding structures. Besides the fracture healing, most focus during the rehabilitation will be on recovering the muscle function, tendon gliding, and other soft tissue involved.

One of the main challenges is to treat stiffness after prolonged immobilisation, as it may have induced neuroplastic changes and diminished the proprioceptive feedback. Indeed, cortical representation areas of our body parts increase or decrease depending on use (39).

VR and exergaming technology have been primarily investigated in post-CVA rehabilitation, however. Giggins et al. 2013(12) found that more recent work (12) (17) (40) has shown this type of biofeedback to be effective in improving exercise technique in musculoskeletal patient populations . Patients suffering from stiffness are limited by the physiological effects of their immobilisation but also from pain and apprehension. Using video games might help to distract them and therefore help to increase exercise intensity and duration. "Exercise intensity is a critical factor in motor recovery" (5) but not always easy to adjust. The provided software in virtual reality allows to constantly adjust the intensity. Previous studies have shown the effectiveness of virtual reality devices for neurological patients on their cortical reorganization. Since cortical reorganization is also a very important factor for the recovery in orthopaedic disorders, these effects are also investigated. All of these above-mentioned factors initiated us to try the Neofect Smart glove[1] for patients suffering from distal radius fractures.

The aim of this study is to compare the recovery after distal radius fractures using a visual and auditive biofeedback glove compared to traditional rehabilitation. Our hypothesis is that patients will recover their active range of motion (AROM) faster, have a better functional score when compared with traditional treatment, and that rehabilitation using a specific biofeedback device will have a positive effect on patients' implication and appreciation.

To explore those questions, we conducted a pilot study of a prospective single blinded randomized controlled trial.

[1] Neofect Rapael Smart Glove for Hand Rehabilitation, https://www.neofect.com/en/product/stroke-therapy-hand/ consulted the 10th of January 2018

Part II. Methodology: Pilot study of a prospective single blinded randomized controlled trial

1. The device: a new biofeedback glove

The Smart Glove[2] is a biofeedback glove created for distal upper extremity rehabilitation, in first intention for patient with a central nervous system lesion. The Korean firm who elaborated this device was awarded by the South Korean Ministry of Health in 2018. They have specialized in rehabilitation technology since 2010 and established in Europe in 2015.

The rehabilitation device is composed of a very light weight glove-shaped sensor, 132g, made from elastomer, easy to clean and connected to a screen via Bluetooth. It is adjusted to the patient's hand with an adaptable clip around the forearm and one around each finger. Since it is wireless, the glove allows to effortlessly move the forearm and hand. It is connected to a specific software application that analyses the gloves sensors to capture the wearer's position and motion such as forearm pronation/ supination, wrist flexion/ extension, radial-ulnar deviation, and finger flexion/ extension.

The data is instantly processed by the software with a smart learning algorithm, which can automatically adjust the level of the game's difficulty to keep challenge and motivation balanced.

Figure 1: Neofect Illustration of integrated motion sensor and computer chip

[2] Neofect Rapael Smart Glove for Hand Rehabilitation, https://www.neofect.com/en/product/stroke-therapy-hand/ consulted the 10th of January 2018

Hence, after an initial set-up, the wearer can be autonomous but it is always possible to make manual adjustments during use. The wearer needs to keep focus on training to complete functional oriented specific tasks. Around 45 training games are categorized by movement as follows:

Forearm	Wrist	Fingers	Complex movements
Pronation/ supination	Flexion/ extension in the vertical plane	Flexion/ extension	Associations of forearm, wrist and fingers movements
	Flexion extension in the horizontal plane with gravity eliminated		
	Radial/ulnar deviation in the vertical plane		
	Radial/ulnar deviation in the horizontal plane with gravity eliminated		

Table 4 categorization of movements in games

The system evaluates the range of motion for each functional movement, so the beneficiary can follow its performance and progression with various diagrams and score for further motivation. The application gives auditory and visual feedbacks of performance in real time during the game as well as a summarized overview at the end of each session, which motivates the wearer to improve their gesture.

The games simulate ADLs, such as catching butterflies or balls, squeezing oranges, fishing, cooking, cleaning the floor, pouring wine, painting fences, and turning over pages, which allows the participants to easily familiarise themselves with the training program and motivates them to perform the tasks.

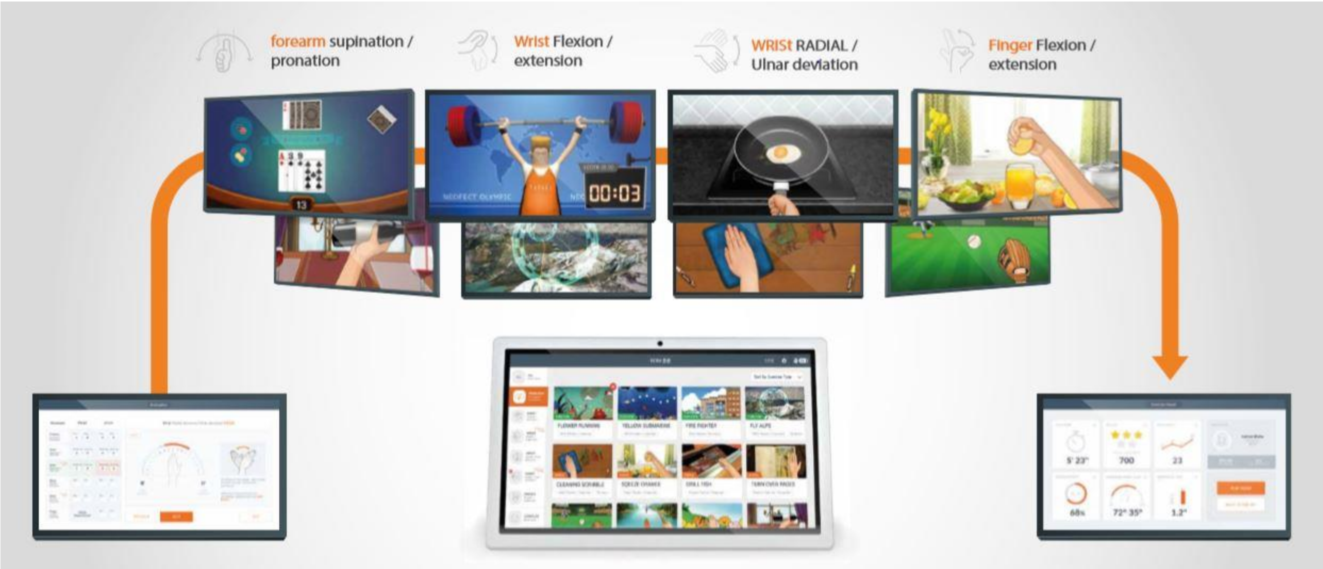


Figure 2 Smart Glove[3] application interface with evaluation, various games, performance results.

To our knowledge the complet set was available for around 8000 euros in march 2018.

[3] Neofect Rapael Smart Glove for Hand Rehabilitation, https://www.neofect.com/en/product/stroke-therapy-hand/ consulted the 10th of January 2018

2. Protocol

2.1 Hypothesis:

After a DRF, rehabilitation which integrates the Smart Glove (SG) in addition to a standard hand therapy protocol, allows a patient to recover better and faster.

Use of the SG in therapy will have a positive effect on patients' implication.

The aim of the study is to evaluate the therapeutic effect of SM for the rehabilitation of distal radius fractures.

The evaluation will focus on:

- The effect of SG on wrist range of motion recovery
- The effect of SG on the self-perception of the ability to perform daily-life activities
- Patients' appreciations of the therapy

2.2 Population

All patients with distal radius fractures were assessed and included in their study if they matched the inclusion criteria listed below.

Inclusion criteria	Exclusion criteria
• A diagnosis of radius distal extremity fracture • All participants gave informed written consent. See annex X • The participants benefit from 3 therapy sessions per week for 9 weeks.	• Patient with complex regional pain syndrome. • Patient with another wrist fracture associated. • Severe cognitive disorders that could impede participation. • Neurologic disorder which causes significant deficit

Table 5: inclusion and exclusion criteria

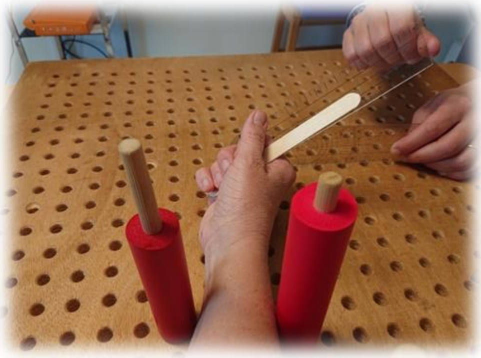
2.3 Outcome measures

The study consists of a 9 weeks intervention period. The measurements will be taken at specific and planned periods during the protocol: at the beginning, after 3 weeks, 6 weeks and 9 weeks.

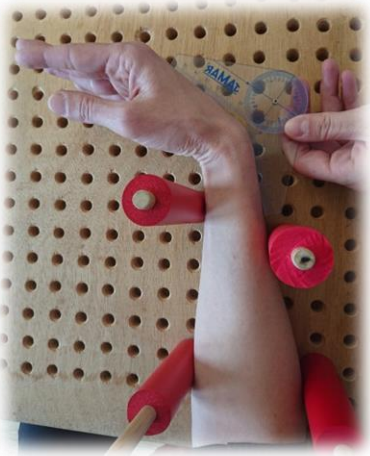
- Active range of motion measures (AROM): with a standard goniometer wrist flexion/extension, radial/ulnar deviation and forearm pronation/supination. The patient is positioned on a peg board in order to eliminate compensations and therapist take the measurements at the end of the planned session. The measurement are then taken according to the protocol (at the beginning, after 3 weeks, 6 weeks and 9 weeks)

- Quick Dash survey: The questionnaire is filled out during the planned session, at the beginning, after 3 weeks, 6 weeks and 9 weeks. See annex.

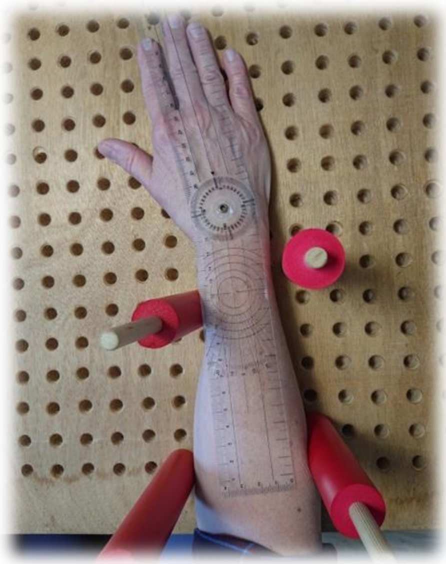
- The qualitative questionnaire is filled out by patient at the end of protocol. See annex.

Pronation /Supination

Flexion/ Extension

Radial deviation / Ulnar deviation

Table 6 AROM assessment

2.4 Standard hand therapy protocol

The common hand rehabilitation protocol was elaborated according to national clinical practice guidelines and recent articles (41),(42). The detailed rehabilitation program is listed in the table below:

Traditional DFR rehabilitation protocol.
The traditional DRF rehabilitation protocol is divided into two different stages:

Stage 1: 0-6 weeks	Stage 2: 6-12 weeks
• control pain and oedema • maintain tendon gliding and cortical representation • preserve ROM of hand, elbow and shoulder joints • PRICE protocol	• active wrist ROM recovery • gentle passive wrist ROM recovery • improvement of stability, proprioception and function

Table 7 traditional DRF rehabilitation protocol

Each session takes place in a common therapy room and includes patient interrogation, hand assessment and follow-up of treatment goals.
Included treatment modalities are water baths of paraffin wax, manual therapy, active and passive mobilisation and strength exercises.

2.5 Intervention group

Each session consists of 40 minutes according to the standard hand therapy protocol and 20 minutes of SG training. The “standard hand therapy protocol” will take place in a common therapy room. The SG training will take place in a separate room with the therapist in a quiet atmosphere to facilitate the patient’s concentration During each training session a therapist will assist the patient. Two different gloves sizes will be used according to the patient's morphology. Patient will be seated, installed on a peg board, to keep the work position stable and limit compensation movements. The therapist will choose exercise games according to the patient’s functional needs and personal preferences. Each session, the patient practices 3 to 4 different games. While he performs his exercises, a therapist watches and supervises the patient’s positions, attitudes and exercises set up. With a motivating attitude the therapist will comment the patient’s performance using SG software results report.

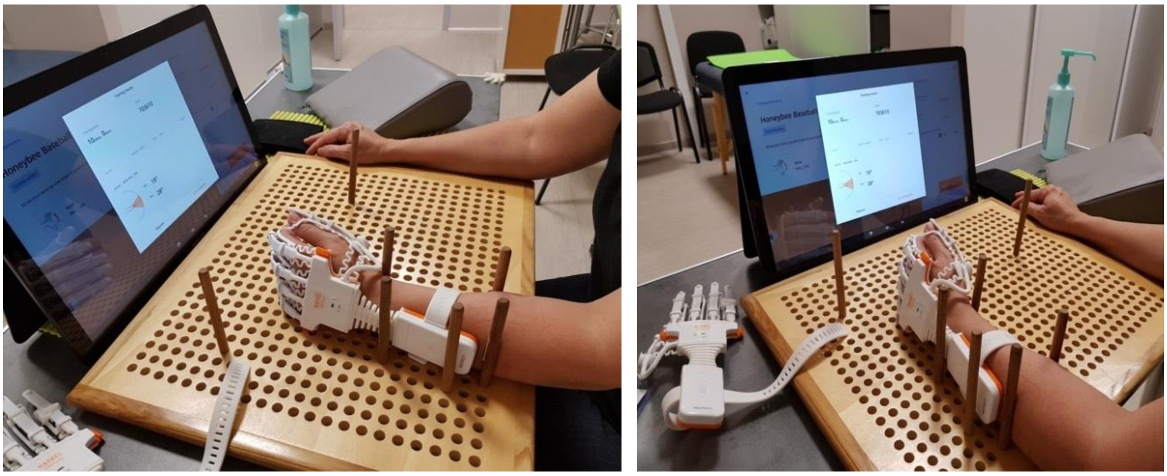


Figure 3 Example of patient installation for flexion/extension exercises

Figure 4 Example of patient installation for radial-ulnar deviation exercises

2.6 Control Group

Each session consists of 40 minutes according to the standard hand therapy protocol and 20 minutes of active ROM exercises related to ADL activities.

2.8 Outcome measurements

We will compare:

- **Mobility** evolution between the control and intervention group.
    - → AROM flexion/extension movement
    - → AROM radial/ulnar deviation movement
    - → AROM pronation/supination movement

To compare progression in groups and facilitate statistical analysis a global AROM movement is calculated. For example, if a patient has 40 degrees wrist extension and 30 degrees wrist flexion, we will consider total AROM flexion-extension movement to be 70 degrees, we will compare as well:

- **Quick dash score** between control and intervention group

- **Qualitative questionnaire answers** between control and intervention group

2.9 Statistical analysis

Statistical analysis will be made in collaboration with professional statisticians[4].

A repeated measure variance analysis model including a random effect of the patient is used to compare groups and progression in time with respect to the range of motion. Therefore, the interaction between the group and the week is compared within the study to test whether there is an increase in the movement amplitude for each group over weeks. An analytic factorial correlation structure with equal diagonal order one is used to model the dependence between weeks. A heterogeneous variance term for each group is added to the model to improve the homogeneity of the variance of the residues.

[4] David Emond, M.Sc. Stat.ASSQ A.Stat., Consultant statistique Delta statistique, Gaspé (Québec) https://deltastatistique.ca/

3. Results

3.1 The population

Baseline characteristics of the participated patients		
Characteristic	**Test Group N =6**	**Control Group N=6**
Age (average in years)	50 ±7	53 ±18
Male	3	4
Female	3	2

Figure 5 baseline characteristics of the participated patients

3.2 Statistical analysis calculations

Quantitative results

a. **Mobility results:**

The tables 8 to 10 show the results for the statistical analysis of the comparison of AROM for pronation and supination, flexion and extension, radial and ulnar deviation between the test and intervention group in a 3-week interval. A type 3 test of fixed effects is used to calculate if P is <0.05, determining if there is a significant difference between our groups. The column Pr >F lists the p-value for the effect of the classification variable on the response to measure how large the F statistic is for this analysis.

Type 3 Tests of Fixed Effects		
Effect	**F Value**	**Probality (Pr) > F**
Group	0.12	0.7377
Week	4.15	0.0330
Week*Group	1.45	0.2794

Table 8 Calculations 'results of fixed effects test for AROM pronation-supination movement

Type 3 Tests of Fixed Effects		
Effect	**F Value**	**Probality (Pr) > F**
Week*Group	0.83	0.4987

Table 9 Calculations 'results of fixed effects test AROM flexion-extension movement

Type 3 Tests of Fixed Effects		
Effect	**F Value**	**Probality (Pr) > F**
Week*Group	1.86	0.2058

Table 10 Calculations 'results of fixed effects test for AROM radial/ulnar deviation movement

The hypothesis is the following: "After a distal radius fracture, rehabilitation of patients which integrates the Smart Glove (SG), will recover their active range of motion (AROM)" better and faster.

Comparing groups in the time with P value > 0.05, there is no significant interaction between groups and weeks with respect to AROM flexion-extension movement, pronation-supination movement and radial-ulnar deviation movement.

With a P value > 0.05, there is no significant difference between groups in the time in AROM radial-ulnar deviation movement, also in pronation-supination movement and flexion-extension movement. Evolution in time is substantially identical in both groups: AROM progresses.

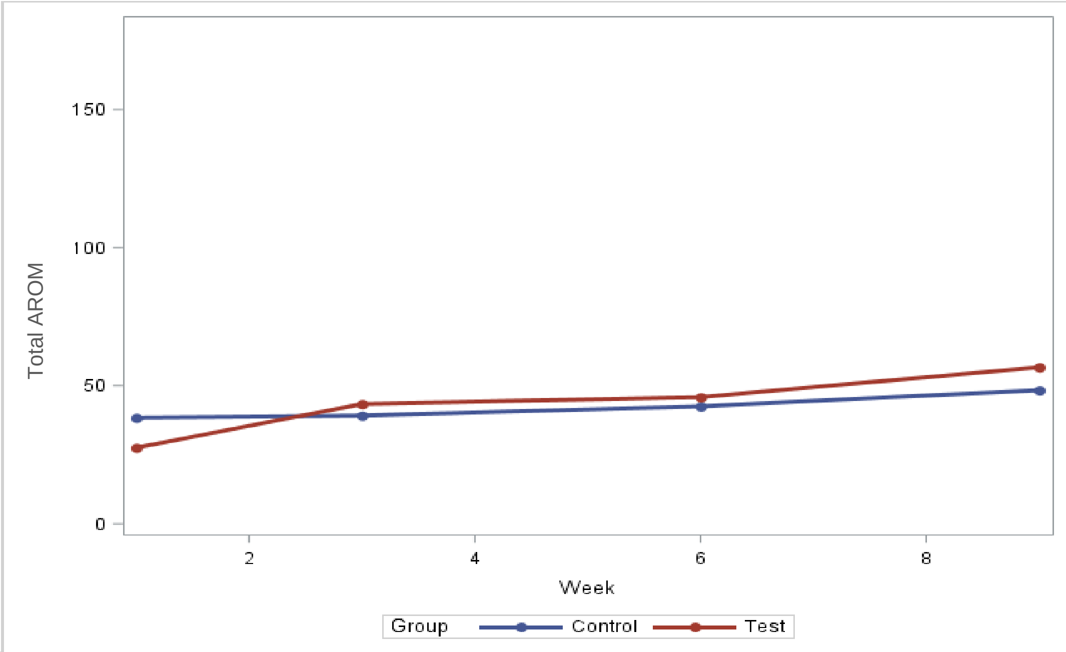


Figure 6 Graphic: Evolution of the AROM radial/ulnar deviation movement, in degrees, for each group

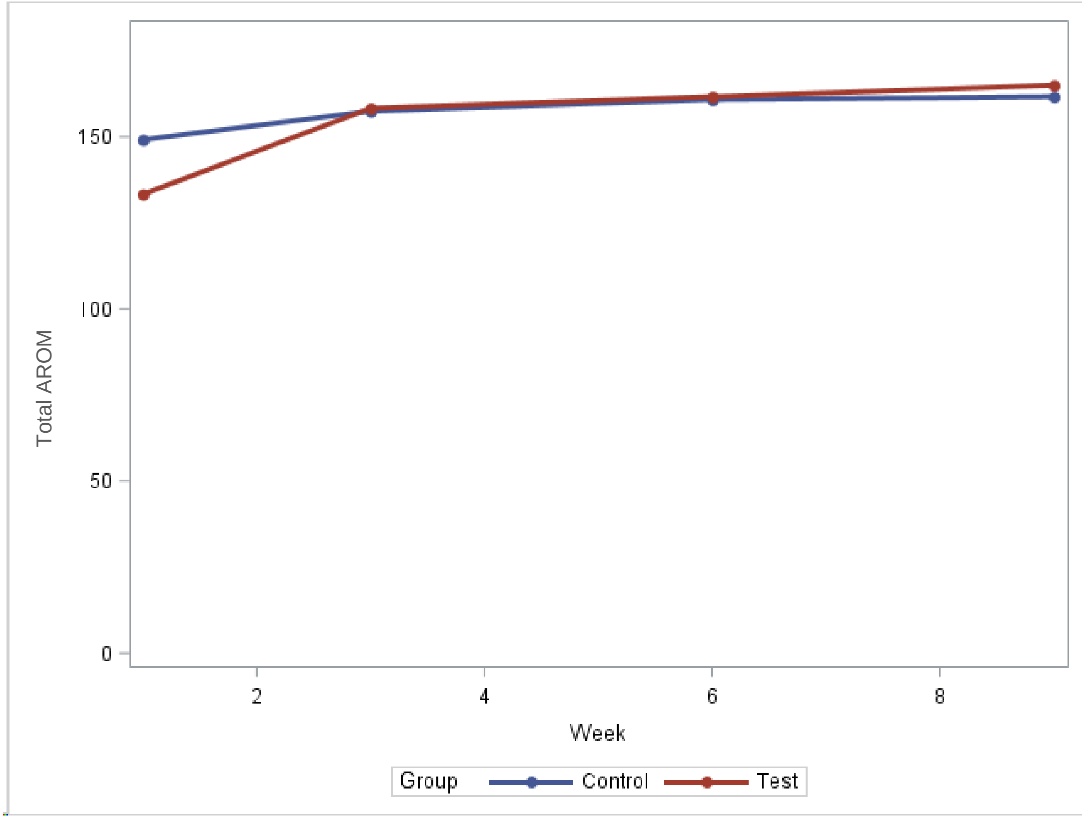


Figure 7 Graphic: Evolution of AROM pronation-supination movement, in degrees, for each group

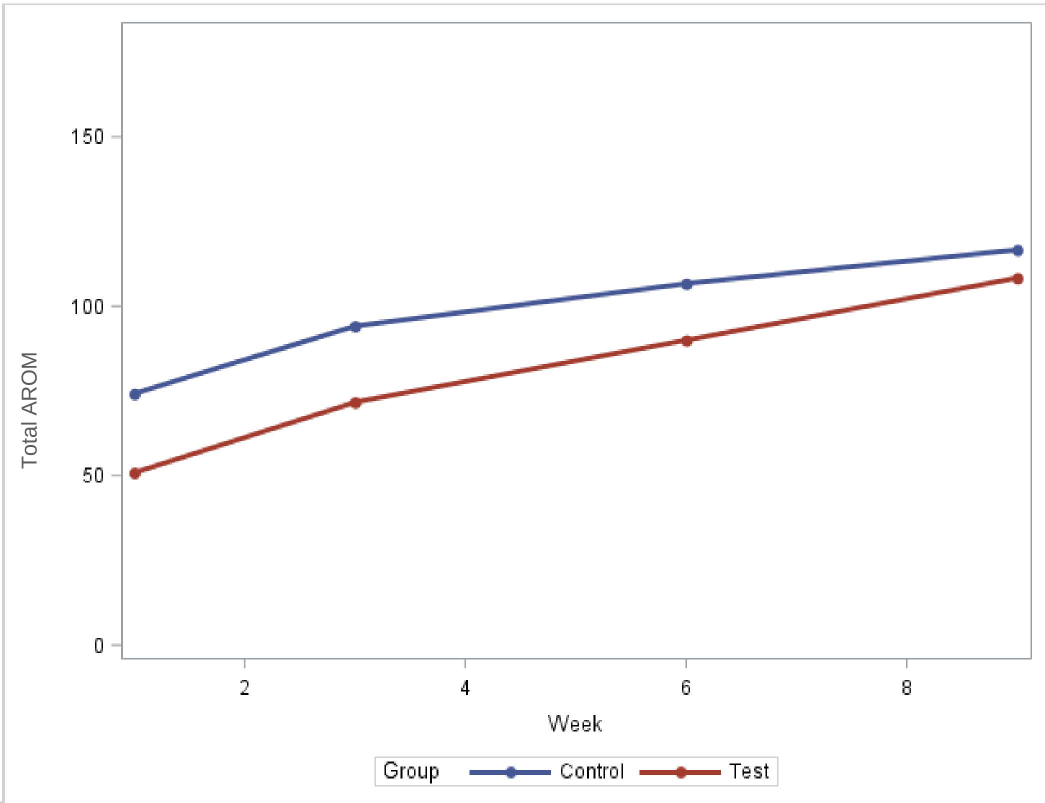


Figure 8 Graphic: Evolution of AROM flexion-extension movement, in degrees, for each group

b. Quick Dash results:

The same analysis as used for the comparison of the AROM is applied to compare groups and weeks with respect to the Quick Dash score. Interaction between the group and the week is added to the model to test if the evolution of the Quick Dash score differs for each group. An analytic factorial correlation structure with equal diagonal order one is used to model the dependence between weeks. A heterogeneous variance term for each group is added to the model to improve the homogeneity of the variance of the residues.

Type 3 Tests of Fixed Effects		
Effect	**F Value**	**Pr > F**
Week*Group	1.60	0.2666

Table 11 Calculations 'results of fixed effects for the Quick Dash score

At the five percent threshold there is no significant difference between groups in the Quick Dash score. At the five percent threshold there is no significant interaction between the group and the week with respect to the Quick Dash score.

c. Qualitative results:

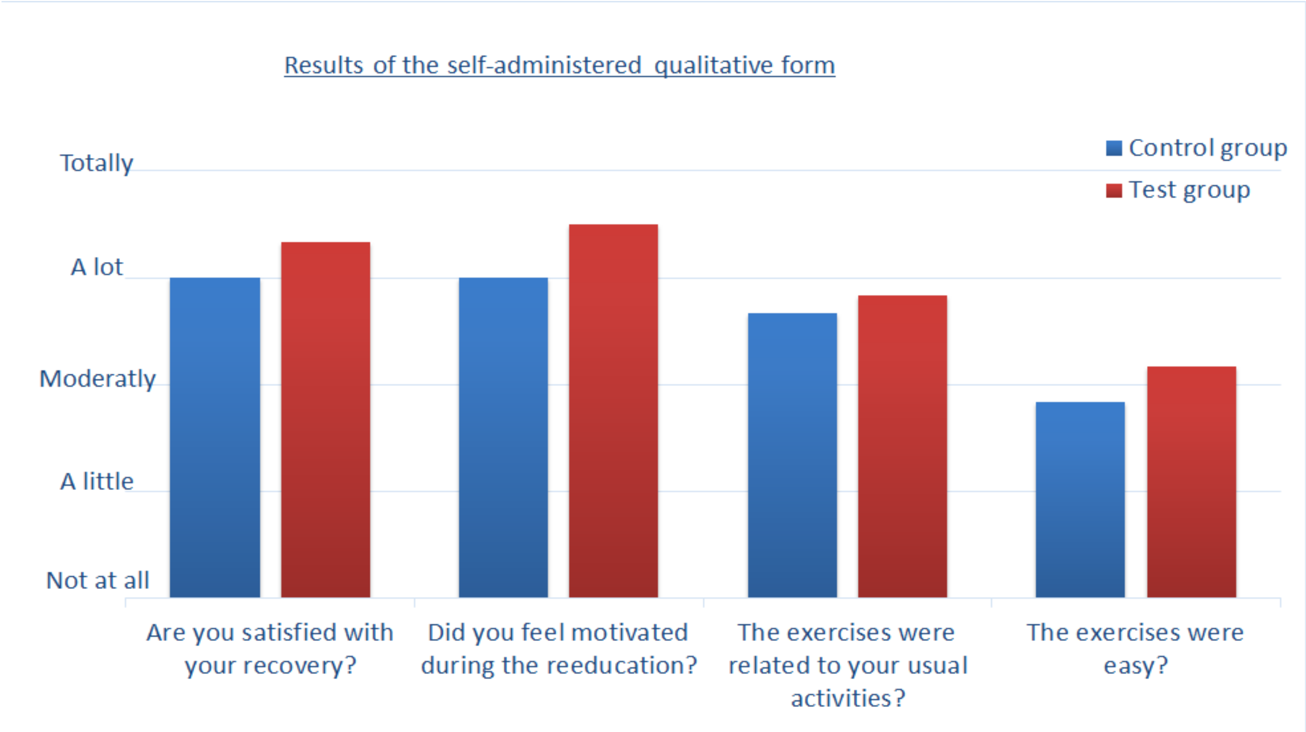


Figure 9 Diagram: results of the self-administered qualitative form

As illustrated in figure 9, there is a slight, yet not significant difference on patients' implication and appreciation between answers from control and test group.

Part III. Discussion

1. Study results

1.1 Limitations

The low number of enrolling patients can be explained by the inclusion criteria and limited timeframe of the study as well as protocol duration. Results of such limited sample are not representative to the population. Although it is not possible to generalize he findings, it can encourage further studies into the field. The control and the test group did not have the same characteristics, with different patient age for example, which can also impact recovery and results.

The functional outcome of DRF treatment depends on many parameters on which the therapist has no influence: individual ability to heal and adapt (36), the delay in which the patient starts the rehabilitation. Patient compliance can also influence results with the realisation some are more or less assiduous of self-rehabilitation exercises.

1.2 Quantitative results

Even though the quantitative results have proven to be of no statistical significance between the current treatment and the new SM treatment for this study size, there is good AROM evolution in both groups with significative progress in each movement measured and also in the Quick Dash score. With these results it is not possible to answer positively to the hypothesis: After a distal radius fracture, rehabilitation who integrates the Smart Glove in addition to standard hand therapy protocol, patient will recover better and faster.

The rehabilitation's success also depends on other non-objective parameters elaborated below.

1.3 Qualitative results

Even though the results are not significant, we can observe that patients who used SG in the test group seem to be more satisfied with their recovery and felt more motivated during the rehabilitation. SG offer some novelty, challenging and diversified exercises and require a cognitive commitment. These are determining factors of motivation (43).

The patients find that exercises were a little bit more related to usual activities, maybe thanks to daily life games with SG (sports, cooking, etc).

They evaluate exercises more difficult than the control group, which could be explained by the high level of concentration necessary to achieve SG exercises and by the constant difficulty adaptation level from exercises.

Globally, qualitative results from questionnaires give a positive point of view from patients.

We can positively answer to the hypothesis, that the use of the SG in the therapy will have a positive effect on patients' implication. However, taking the limited sample size into consideration, it is not possible to affirm if the patient's implication is significantly better in the test group than in the control group.

1.4 Therapist's observations during SG rehabilitation

Using this new technology seems to have been a pleasant and beneficial experience for the patient as well as for the therapist. According to therapist's observations, patients were very enthusiastic to work with the SG. While focusing on the games, they gave their maximal potential to perform exercises. The games are dynamic with music and auditory feedback from performance. Patients were captivated by the exercises, potentially improving their performance and feeling less limited in their movements. Even after weeks of therapy, motivation and challenge were still present. Patients were interested in knowing their results studying the curves of evolution given in the results folder from software. It seems certainly more attractive than standard AROM exercises. The visual feedbacks with various representations (progressions curves, various diagrams, score, percentage) helps patient understand better and therefore imply more in their exercises.

To measure AROM we chose a traditional manner (goniometer) because we observed some differences between SG AROM score and real effective AROM measured by therapist. SG sensors are very sensible, and when the patient changes his position, the measurement reference might become biased and this could create some measurement discrepancies. Technology is constantly improving so we can be optimistic for its evolution. Further studies[5] are in progress with the goal to demonstrate the effect of the Smart Glove's use on functional recovery and also on quality of life. The device is intuitive to work with, easy and quick to set up for a new patient. Familiarization with the software takes only a few sessions. The setup is fast and the diversity of games allows adaption to each patients age and preferences.

[5] A new clinical test of RAPAEL Smart Gloves is in progress since october 2018 directed by Stanford Medical Center in US for the Journal of American Academy of Neurology and concerned stroke patients. https://clinicaltrials.gov/ct2/show/NCT03741400 consulted on march 2019

2. Possible implications of SG in hand therapy

For more patient's autonomy in treatment

During sessions, roles of the therapist were to choose adapted games to the patient's needs, be present to install, control and correct arm position, which was intended to help them them to wear the glove. This was done in order to ensure good participation for the study. With more experience, however, it seems possible to imagine this type of technology to support a therapy process, that gives more autonomy to the patient. For example, a patient could use the SG by himself during therapy. Therapists could assist only for first SG session and then select a specific games list for the patient, or prepare it on software in order to let him work autonomously with the SG. Although, virtual reality equipment comes at a significant initial financial cost, the benefit of an autonomous rehabilitation therapy could possibly free up skilled healthcare professionals and therefore be cost-effective in the long-term.

For an evidence-based practice

One major advantage of the use of a VR biofeedback glove is that the delivered software registers all the movements executed. AROM is measured and registered, as well as the amount of movements executed during the games. Today, in an evidence-based practice as we seek access to those quantifiable data those are valuable information. Being able to follow up closely in an objective manner on every treatment session gives a lot more transparency to the patient as well as to the therapist. A diagram can show the exact rehabilitation process and makes it easy to see if the treatment needs adjustment.

For an early active rehabilitation

Early active rehabilitation is recommended for stable fractures for a better outcome and earlier return to their activities but load bearing must be avoided until fracture healing.

VR could be integrated in an early active rehabilitation protocol allowing patients a rapid return to ADL related exercises without the risk of external loading destabilising the healing fracture site as real ADL exercises would do. The external forces applied during therapeutic exercises should not exceed 159 Newton in case of plates and 140 Newton in case of internal fixators during the first 4 weeks. For example, a musician could train on his instruments during VR exercises in the early phases of rehabilitation and stimulate the same brain regions as he would in real life without carrying the instrument or applying pressure and therefore protect the healing fracture site. His loss of neural connections would be less and his return to work earlier.

For motor imagery and multi-sensory stimulations

Motor imagery is a well-established treatment form. The fact that the primary motor cortex (M1) and secondary motor areas, such as premotor cortex (PMC), supplementary motor area (SMA) and the parietal cortices, are not only activated during overt motor execution, but also during the imagination of that same motor task allows therapists a wide variety of treatment options. Graded motor imagery, mirror therapy and other tools are used to facilitate movement execution, modification or recovery. Multi-sensory action-observation systems as such used in VR are therefore believed to enhance the patient's ability to (re)learn impaired motor functions through the activation of these internal representations (44). Indeed, imitation based learning, including motor observation, is a major part of the games provided. Since mirror neurons are not only activated during observation but especially during the execution of an observed movement VR might be even more efficient than traditional motor imagery.

For CRPS and chronic pain

One obvious reason for the beneficial effect of VR on pain is distraction. Due to its immersive nature of the visual and auditive stimuli and the active participation of the patient, he has to concentrate on the given task and will automatically pay less attention on his pain. But besides distraction, the are also several other benefits. One major advantage is that it can be used a tool for patients to play an active role in pain management. Perception of control over using VR pain has been studied (30) and showed increased pain threshold and tolerance, lower time estimation of pain, and an increase in the patient’s perception to tolerate or decease pain. VR will not directly affect pain but it could help patients to learn new behaviour strategy and to better cope with their pain.

Part IV. Conclusion

The evaluated biofeedback glove seems to be a valuable tool for upper limb orthopaedic disorders for several reasons. It enables to give goal-orientated task specific exercises in a personalised, adapted and repetitive manner. According to our observations, a positive effect in patient s' implication and motivation has been demonstrated.

Due to the easy set-up and the fact that the patient is following a video game, he could gain more autonomy in his rehabilitation process and could even use the tool by himself giving him more responsibility for his recovery.

There are numerous possible future developments for those gloves. Therapists could offer it as home practice to patients or use it as a competitive stimulator in their practice.

Further research with a higher number of participants and for a longer treatment duration is needed. However, it is important to keep in mind that this tool is complementary and does not intend to replace a therapist. Distal radius fractures are complex injuries with many possible complications and their treatment not only needs to be according to their specific guidelines but also tailored to each patient's specific needs.

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Annexes

FORMULAIRE D’INFORMATION ET DE CONSENTEMENT

Vous êtes invité(e) à participer à un projet de recherche. Le présent document vous renseigne sur les modalités de celui-ci. L’étude est réalisée dans le cadre du mémoire présenté par HANS Laure et ZIEGLER Mareike pour l’obtention du diplôme Inter-Universitaire Européen de Rééducation et d'Appareillage en Chirurgie de la Main à Grenoble.

1 Raison de votre participation : Vous avez eu une fracture au niveau du poignet et bénéficiez d’une rééducation spécifique.

2 Objectif de l’étude : Evaluer le protocole de rééducation et son impact sur votre récupération. Nous souhaitons évaluer nos moyens de traitement et comparer leur efficacité sur votre récupération.

3 Qu’implique votre participation ? Aucun changement dans votre traitement, aucun soin ni aucun coût supplémentaire. Vous vous engagez à suivre régulièrement la thérapie au rythme de 2 à 3 séances par semaine. Cela ne modifie en rien votre prise en charge ni votre suivi médical. Nous utiliserons les informations générales vous concernant (ex : âge, sexe) ainsi que les données médicales spécifiques (ex : pathologies, mobilité, résultats des bilans et réponses aux questionnaires), vous resterez anonyme.

4 Participation : La participation à l’étude se fait de façon volontaire, non rémunérée et librement consentie. En cas de refus, aucune conséquence sur la suite de votre prise en charge ; ni sur la qualité des soins qui vous seront prodigués, ni sur la relation avec le thérapeute. Dans ce cas, aucune donnée vous concernant ne sera enregistrée et exploitée pour les fins de l’étude.

5 Confidentialité : Vos données personnelles recueillies à l’occasion de cette étude seront analysées par des moyens informatiques, sans mention de vos nom et prénom. Les rapports contenant vos données ne seront pas rendus publics. Si les résultats de l’étude sont publiés, votre identité restera confidentielle. Conformément à la loi du 6 janvier 1978 relative à l’informatique, aux fichiers et aux libertés, vous pourrez exercer à tout moment votre droit d’accès et de rectification aux données vous concernant. Les représentants de l’organisateur de l’étude, les vérificateurs, la Commission d’Ethique Médicale ou les autorités de santé peuvent avoir accès à votre dossier médical afin de contrôler les procédures de l’étude ou les données, sans violer les règles de confidentialité.

Je soussigné (e),…………………………………………………………………………

Je suis libre de participer ou non, d’abandonner ma participation à l’étude à tout moment sans qu’il soit nécessaire de justifier ma décision et sans que cela n’entraîne le moindre désavantage pour moi.

Les données qui seront utilisées dans le cadre de cette étude sont : les réponses des questionnaires remplis.

Mon nom, les réponses aux questionnaires et mes informations personnelles seront gardées confidentielles.

J’accepte que les résultats de cette étude, qui seront toujours anonymes, soient diffusés à des fins scientifiques et/ou que les données fassent l’objet de traitements ultérieurs en respectant les règles déontologiques de la communauté scientifique.

Je consens de mon plein gré à participer à cette étude.

Consentement libre et éclairé,

Signature : ________________________lu et approuvé

Fait à ________________________ , le ________

Questionnaire QuickDASH sur les incapacités reliées à une atteinte aux membres supérieurs

Evaluer votre capactié à faire les activités suivantes au cours de la dernière semaine en encerclant le numéro dans la colonne appropriée. Répondez en vous basant sur votre capacité à réaliser la tâche sans vous soucier de comment vous l'effectuez ou de quelle main vous utiliser pour réaliser l'activité.

		Pas de difficulté	Difficulté légère	difficulté moyenne	difficulté sévère	Incapable
1	Dévisser un couvercle neuf ou serré.	1	2	3	4	5
2	Faire de gros travaux ménagers (ex. laver les murs, laver le plancher).	1	2	3	4	5
3	Transporter un sac de commission ou un porte-document (valise).	1	2	3	4	5
4	Laver votre dos.	1	2	3	4	5
5	Utiliser un couteau pour couper des aliments.	1	2	3	4	5
6	Activités de loisirs durant lesquelles vous bougez votre bras librement (ex. bricolage, jardinage, vélo, etc.).	1	2	3	4	5

		Pas du tout	Un peu	Moyennement	Beaucoup	Extrêmement
7	Au cours de la dernière semaine, dans quelle mesure votre problème au bras, à l'épaule ou à la main a-t-il nui à votre famille, amis, voisins ou groupes? (encerclez un chiffre)	1	2	3	4	5

		Pas limité du tout	Légèrement limité	Moyennement limité	Très limité	Incapable
8	Au cours de la dernière semaine, avez-vous été limité dans votre travail ou dans vos activités habituelles à cause de votre problème au bras, à l'épaule ou à la main? (encerclez un chiffre)	1	2	3	4	5

Evaluer la sévérité des symptômes suivants au cours de la dernière semaine. (encerclez un chiffre)

		Aucune	Légère	Modérée	Sévère	Extrême
9	Douleur au bras, à l'épaule ou à la main.	1	2	3	4	5
10	Picotements ou fourmillements au bras, à l'épaule ou à la main.	1	2	3	4	5

		Pas de difficulté	Difficulté légère	difficulté moyenne	Difficulté sévère	Tellement de difficulté que je ne peux pas dormir
11	Au cours de la dernière semaine, dans quelle mesure avez-vous eu de la difficulté à dormir à cause de votre douleur au bras, à l'épaule ou à la main? (encerclez un chiffre)	1	2	3	4	5

Adaptation du QuickDASH version canadienne de l'*Institute for Work & Health 2006.*

Le QuickDash

Instructions

Ce questionnaire porte sur vos symptômes ainsi que sur votre capacité à réaliser certaines activités.

En vous basant sur votre condition de la dernière semaine, veuillez répondre à toutes les questions, en encerclant le numéro approprié.

Si vous n'avez pas eu l'occasion de réaliser une activité au cours de la dernière semaine, faites de votre mieux pour choisir la réponse qui serait la plus juste.

Répondez en vous basant sur votre capacité à réaliser la tâche sans vous soucier de comment vous l'effectuez ou de quelle main vous utilisez pour réaliser l'activité.

Résultats

Score de 11 à 55	**Converti sur 100**
11	0
12	2,27
13	4,55
14	6,82
15	9,09
16	11,36
17	13,64
18	15, 91
19	18,18
20	20,45
21	22,73
22	25
23	27,27
24	29,55
25	31,82
26	34,09
27	36,36
28	38,64
29	40,91
30	43,18
31	45,45
32	47,73
33	50
34	52,27
35	54,55
36	56,82
37	59,09
38	61,36
39	63,64
40	65,91
41	68,18
42	70,45
43	72,73
44	75
45	77,27
46	79,55
47	81,82
48	84,09
49	86,36
50	88,64
51	90,91
52	93,18
53	95,45
54	97,73
55	100

Adaptation du QuickDASH version canadienne de l'*Institute for Work & Health 2006.*

Questionnaire personnel

	Pas du tout	Un peu	Moyenne ment	Beaucoup	Totalement
	0	1	2	3	4
Etes-vous satisfait de votre récupération ?					
Vous êtes-vous sentis motivé pendant la rééducation ?					
Les exercices étaient en lien avec vos activités habituelles ?					
Les exercices étaient faciles ?					

Additional observations: Progression for control and test group

In both groups, control and test, there are significant differences between weeks the five percent threshold, the P value is < 0.05. This means that, as weeks go by,
AROM evaluates significantly in both groups and for each movement measured.
The system of letters of the table below makes it possible to affirm that the AROM of each movement measured at the ninth week is significantly higher than the AROM at the first week. There are significant AROM progresses for each measured movement in time and in both groups.

Bonferroni Grouping for Week Least Squares Means (Alpha=0.05)		
LS-means with different letter are significantly different.		
Week	**Estimate AROM (degrees)**	**LS-means**
9	112	A
1	62	C

Table Flexion-extension AROM average at week 9 and week 1

At week 1, the average AROM for flexion-extension movement is 62 degrees and it increases at week 9 to 112 degrees.

Bonferroni Grouping for Week Least Squares Means (Alpha=0.05)		
LS-means with different letter are significantly different.		
Week	**Estimate AROM (degrees)**	**LS-means**
9	52	A
1	32	B

Table Radial-ulnar deviation AROM average at week 9 and week 1

At week 1, the average AROM for radial-ulnar deviation movement is 32 degrees and it increasing to week 9 with 52 degrees.

Bonferroni Grouping for Week Least Squares Means (Alpha=0.05)		
LS-means with different letter are significantly different.		
Week	**Estimate AROM (degrees)**	**LS-means**
9	163	A
1	141	B

Table Pronation supination AROM average at week 9 and week 1

At week 1, the average AROM for pronation-supination movement is 141 degrees and it increasing to week 9 with 163 degrees.

With P value < 0.05, there are significant differences between weeks in the QUICK Dash score. In both groups, the score evaluates in time the same way.

Bonferroni Grouping for Week Least Squares Means (Alpha=0.05)		
LS-means with different letter are significantly different.		
Week	**Estimate score in %**	**LS-means**
1	53	A
3	35	B
6	20	C
9	12	D

Table Comparison in the time of the Quick Dash score

There is significative progress for the Quick Dash score in the time, in both groups.

At week 1, average score is 53 % and gradually decreased to 35 % week 3, 20% week 6, down to 12 % at week.

Complete statistics results

Gender

Table of Group by gender			
Group	**gender**		
Frequency Row Pct	**Female**	**Male**	**Total**
Control	2 33.33	4 66.67	6
Test	3 50.00	3 50.00	6
Total	5	7	12

This table shows the distribution of patients in each group by gender.

Fisher's Exact Test	
Table Probability (P)	0.3788
Two-sided Pr <= P	1.0000

An exact Fisher test is used to compare groups with respect to sex. At the five percent level, there is no significant difference between groups with respect to gender.

Statistics results for Quick Dash score

Model Information	
Data Set	LH.DONNEES
Dependent Variable	Quick_dash_score
Covariance Structures	Variance Components, Factor Analytic
Subject Effect	Patient(Group)
Group Effect	Group
Estimation Method	REML
Residual Variance Method	None
Fixed Effects SE Method	Kenward-Roger2
Degrees of Freedom Method	Kenward-Roger2

A repeated measures model of variance analysis including a random effect of the patient is used to compare groups and weeks with respect to the "QUICK Dash" score. Interaction between the group and the week is added to the model to test if the evolution of the "QUICK Dash" score differs for each group. An analytic factorial correlation structure with equal diagonal order one is used to model the dependence between weeks. A heterogeneous variance term for each group is added to the model to improve the homogeneity of the variance of the residues.

Number of Observations	
Number of Observations Read	48
Number of Observations Used	48

Forty-eight observations are included in this analysis.

Type 3 Tests of Fixed Effects				
Effect	**Num DF**	**Den DF**	**F Value**	**Pr > F**
Group	1	9.92	0.89	0.3671
Week	3	7.81	23.92	0.0003
Week*Group	3	7.81	1.60	0.2666

At the five percent threshold, there is no significant difference between groups in the QUICK Dash score.

At the five percent threshold, there are significant differences between weeks in the QUICK Dash score.

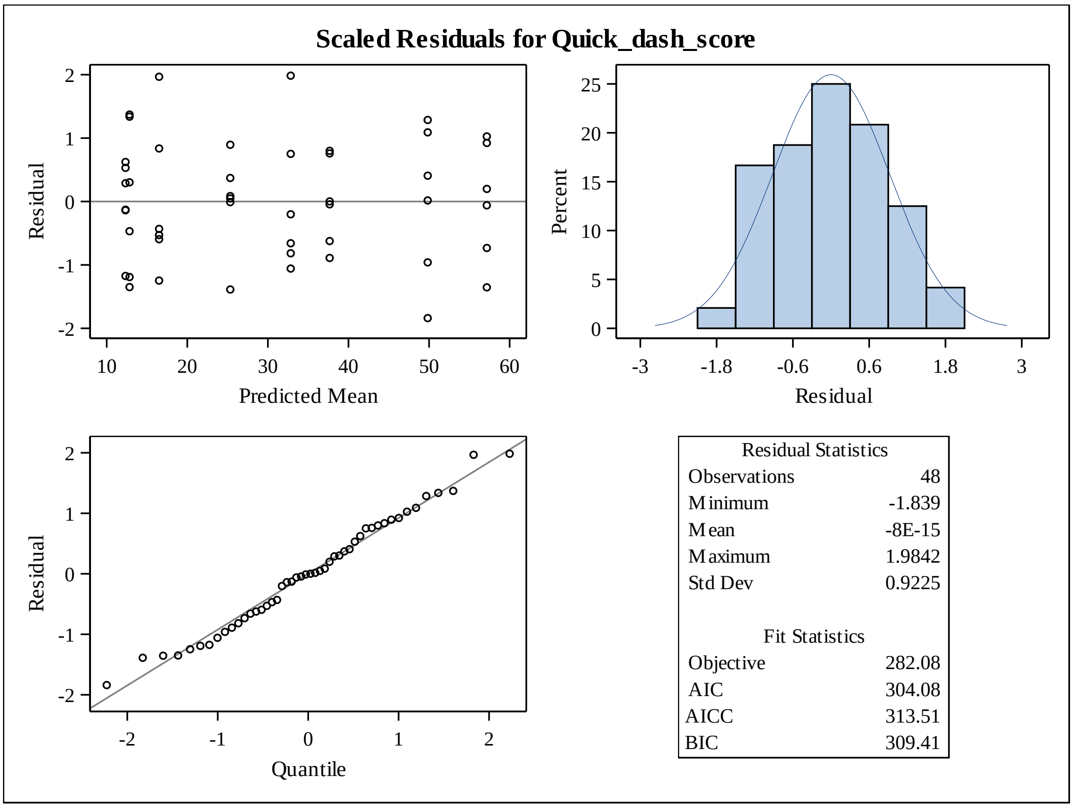
At the five percent threshold, there is no significant interaction between the group and the week with respect to the QUICK Dash score.

Least Squares Means							
Week*Group	Control	6	16.5000	3.8809	8.58	4.25	0.0024
Week*Group	Test	6	25.3333	4.1926	10.9	6.04	<.0001
Week*Group	Control	9	12.3333	3.8835	8.9	3.18	0.0114
Week*Group	Test	9	12.8333	4.3531	9.2	2.95	0.0159

This table shows the Least Squares Average Quick Dash estimate for each group and week combination.

Bonferroni Grouping for Week Least Squares Means (Alpha=0.05)		
LS-means with the same letter are not significantly different.		
Week	**Estimate**	
1	53.5000	A
3	35.2500	B
6	20.9167	C
9	12.5833	D

The system of letters of the previous table makes it possible to affirm that the score "QUICK Dash" in the first week is significantly higher than the score "QUICK Dash" in the third week, the sixth week and the ninth week. In addition, the "QUICK Dash" score in the third week is significantly higher than the "QUICK Dash" score in the sixth week and the ninth week. Finally, the "QUICK Dash" score in the sixth week is significantly higher than the "QUICK Dash" score in the ninth week.



Statistical results for AROM flexion-extension movement

Model Information	
Data Set	LH.DONNEES
Dependent Variable	Total_ROM_FLEX_EXT
Covariance Structures	Variance Components, Banded
Subject Effect	Patient (Group)
Group Effect	Group
Estimation Method	REML
Residual Variance Method	None
Fixed Effects SE Method	Kenward-Roger2
Degrees of Freedom Method	Kenward-Roger2

A repeated measures variance analysis model including a random effect of the patient is used to compare groups and weeks with respect to the range of flexion-extension. The interaction between the group and the week is added to the model to test if the evolution of the amplitude of the flexion-extension movement differs for each group. A non-structured second order correlation structure is used to model the dependence between weeks. A heterogeneous variance term for each group is added to the model to improve the homogeneity of the variance of the residues.

Number of Observations	
Number of Observations Read	48
Number of Observations Used	48

Type 3 Tests of Fixed Effects				
Effect	**Num DF**	**Den DF**	**F Value**	**Pr > F**
Group	1	14.9	7.11	0.0177
Week	3	13	28.62	<.0001

Type 3 Tests of Fixed Effects				
Effect	**Num DF**	**Den DF**	**F Value**	**Pr > F**
Week*Group	3	13	0.83	0.4987

At the five percent threshold, there is a significant difference between groups in the range of flexion-extension.

At the five percent threshold, there are significant differences between weeks in the range of flexion-extension.

At the five per cent threshold, there is no significant interaction between the group and the week with respect to the range of flexion-extension.

Least Squares Means							
Effect	**Group**	**Week**	**Estimate**	**Standard Error**	**DF**	**t Value**	**Pr > |t|**
Week*Group	Control	1	74.1667	9.7823	5	7.58	0.0006
Week*Group	Test	1	50.8333	4.1667	5	12.20	<.0001
Week*Group	Control	3	94.1667	9.5465	7.57	9.86	<.0001
Week*Group	Test	3	71.6667	3.6597	4.99	19.58	<.0001
Week*Group	Control	6	106.67	6.9277	5.96	15.40	<.0001
Week*Group	Test	6	90.0000	3.0797	6.73	29.22	<.0001
Week*Group	Control	9	116.67	8.5310	5	13.68	<.0001
Week*Group	Test	9	108.33	5.5777	5	19.42	<.0001

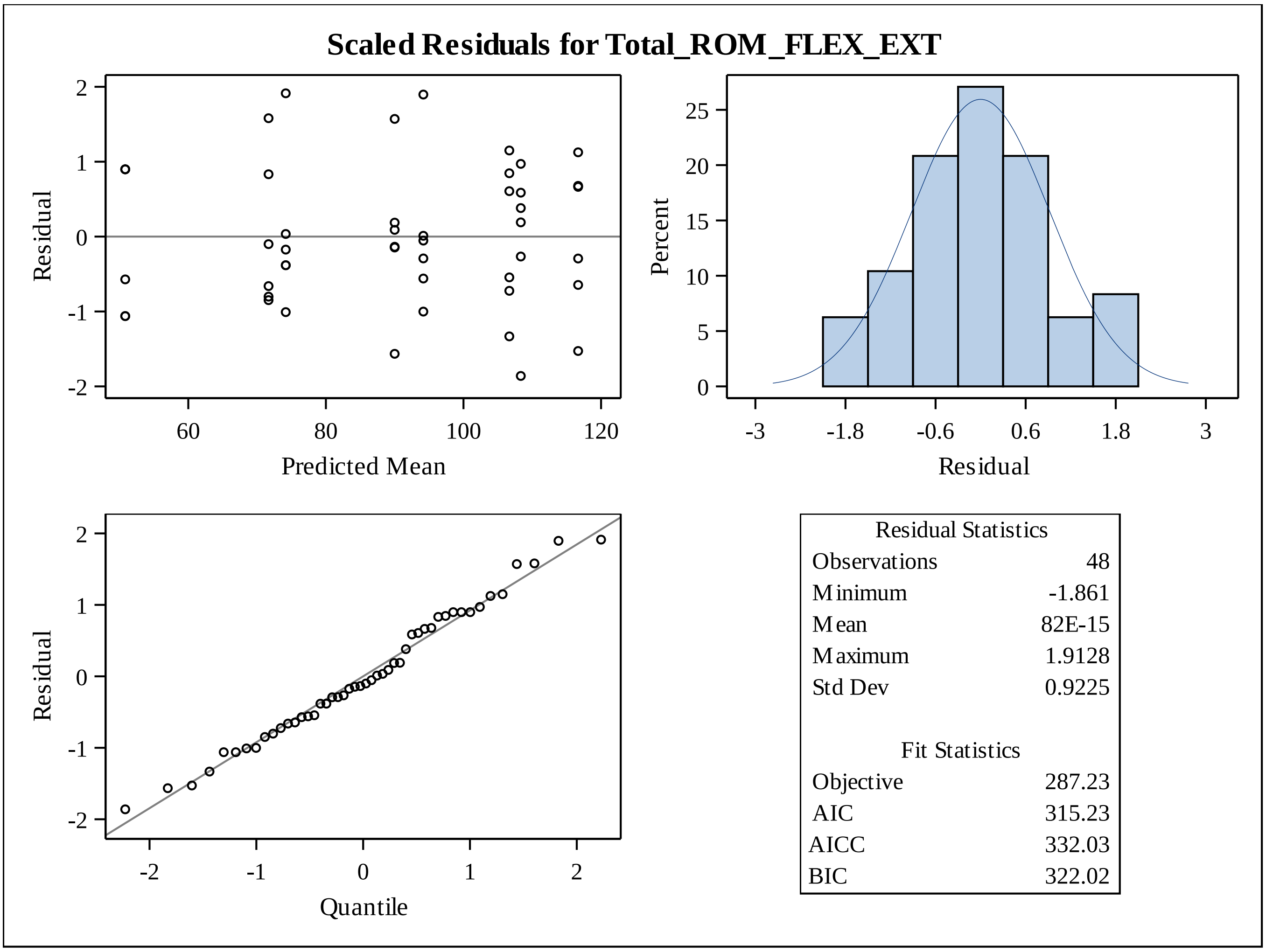
This table presents the estimate of the least squares mean of the range of flexion-extension for each group and week combination.

Bonferroni Grouping for Group Least Squares Means (Alpha=0.05)		
LS-means with the same letter are not significantly different.		
Group	**Estimate**	
Control	97.9167	A
Test	80.2083	B

The system of letters of the preceding table makes it possible to affirm that the amplitude of the "flexion-extension" movement of the control group is significantly higher than the amplitude of the "flexion-extension" movement of the test group.

Bonferroni Grouping for Week Least Squares Means (Alpha=0.05)		
LS-means with the same letter are not significantly different.		
Week	**Estimate**	
9	112.50	A
6	98.3333	B
3	82.9167	B
1	62.5000	C

The letter system of the previous table asserts that the amplitude of the flexion-extension movement at the ninth week is significantly higher than the amplitude of the flexion-extension movement at the sixth week, at the third week. and the first week. In addition, the amplitude of the flexion-extension movement at the sixth week and the third week is significantly higher than the amplitude of the flexion-extension motion in the first week. The flexion-extension movement of the group -test.



Assumptions of normality of the residues and homogeneity of the variance of the residues are verified.

Statistics results for AROM pronation-supination movement

Model Information	
Data Set	LH.DONNEES
Dependent Variable	Total_ROM_PRO_SUP
Covariance Structures	Variance Components, Heterogeneous Autoregressive
Subject Effect	Patient(Group)
Estimation Method	REML
Residual Variance Method	None
Fixed Effects SE Method	Kenward-Roger2
Degrees of Freedom Method	Kenward-Roger2

A repeated measures variance analysis model including a random effect of the patient is used to compare groups and weeks with respect to the range of motion "pronation-supination". Interaction between the group and the week is added to the model to test whether the evolution of the amplitude of the pronation-supination movement differs for each group. A heterogeneous autoregressive correlation structure is used to model the dependence between weeks.

Number of Observations	
Number of Observations Read	48
Number of Observations Used	48

Type 3 Tests of Fixed Effects				
Effect	**Num DF**	**Den DF**	**F Value**	**Pr > F**
Group	1	14.2	0.12	0.7377
Week	3	11.3	4.15	0.0330
Week*Group	3	11.3	1.45	0.2794

At the five percent threshold, there is no significant difference between groups in the range of pronation-supination.

At the five percent threshold, there are significant differences between weeks in the range of pronation-supination.

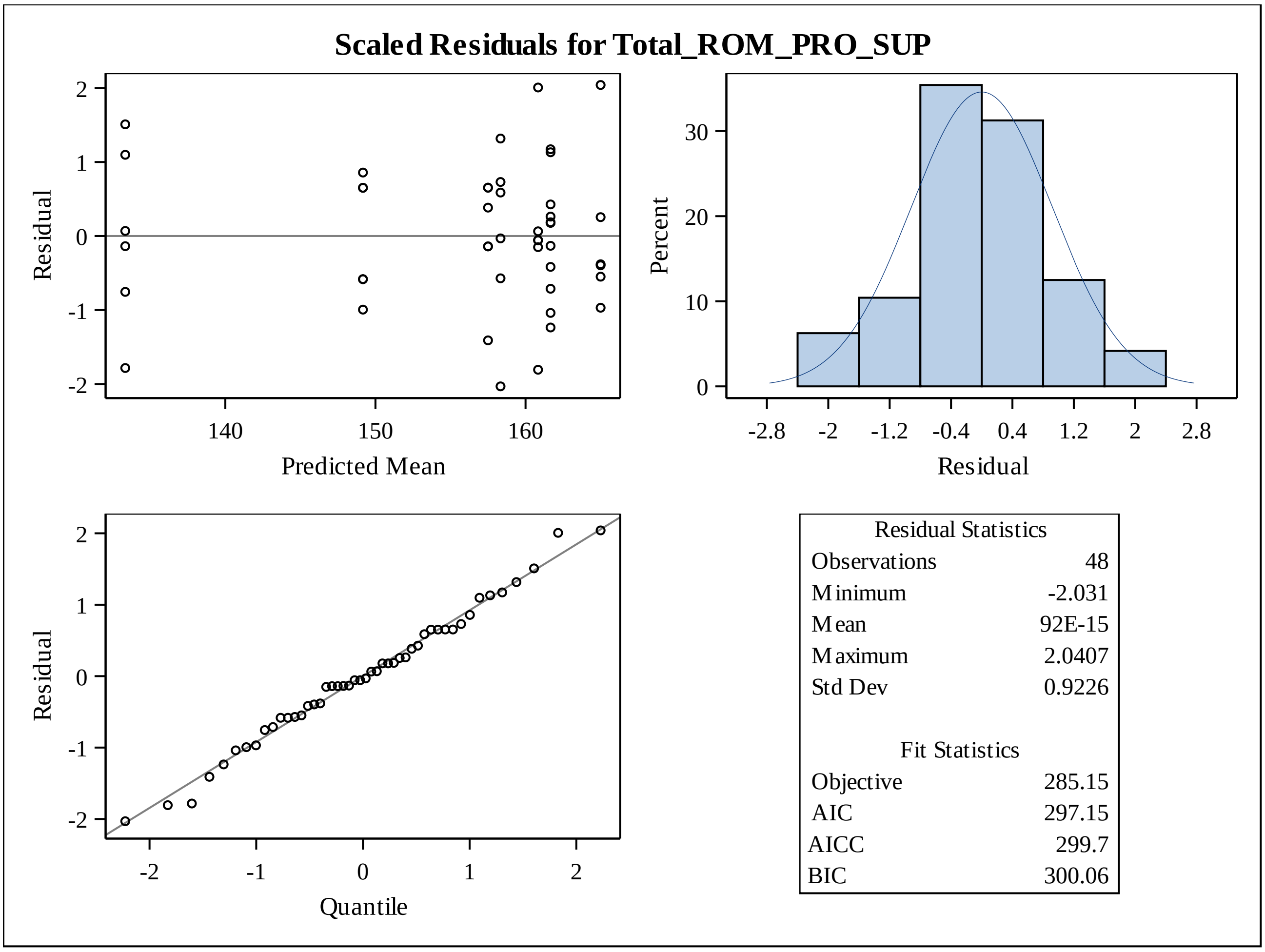
At the five percent level, there is no significant interaction between the group and the week with respect to the range of pronation-supination.

Least Squares Means							
Effect	**Group**	**Week**	**Estimate**	**Standard Error**	**DF**	**t Value**	**Pr > |t|**
Week*Group	Control	1	149.17	10.1059	11.3	14.76	<.0001
Week*Group	Test	1	133.33	10.1059	11.3	13.19	<.0001
Week*Group	Control	3	157.50	5.7175	15.3	27.55	<.0001
Week*Group	Test	3	158.33	5.7175	15.3	27.69	<.0001
Week*Group	Control	6	160.83	4.7031	13.1	34.20	<.0001
Week*Group	Test	6	161.67	4.7031	13.1	34.37	<.0001
Week*Group	Control	9	161.67	4.2463	10.2	38.07	<.0001
Week*Group	Test	9	165.00	4.2463	10.2	38.86	<.0001

This table presents the estimate of the least squares mean of the range of pronation-supination for each group and week combination.

Bonferroni Grouping for Week Least Squares Means (Alpha=0.05)		
LS-means with the same letter are not significantly different.		
Week	**Estimate**	
9	163.33	A
6	161.25	A
3	157.92	A
1	141.25	B

The system of letters in the previous table asserts that the amplitude of the "pronation-supination" movement at the ninth week, the sixth week and the third week is significantly higher than the amplitude of the "pronation-supination" movement. In the first week.



Assumptions of normality of the residues and homogeneity of the variance of the residues are verified.

Statistical results AROM radial ulnar deviation movement

A repeated measures variance analysis model including a random effect of the patient is used to compare groups and weeks with respect to the range of motion "pronation-supination". Interaction between the group and the week is added to the model to test whether the evolution of the amplitude of the pronation-supination movement differs for each group. A heterogeneous autoregressive correlation structure is used to model the dependence between weeks.

Model Information	
Data Set	LH.DONNEES
Dependent Variable	Total_ROM_RD_UD
Covariance Structures	Variance Components, Factor Analytic
Subject Effect	Patient (Group)
Group Effect	Group
Estimation Method	REML
Residual Variance Method	None
Fixed Effects SE Method	Kenward-Roger2
Degrees of Freedom Method	Kenward-Roger2

Number of Observations	
Number of Observations Read	48
Number of Observations Used	48

Type 3 Tests of Fixed Effects				
Effect	**Num DF**	**Den DF**	**F Value**	**Pr > F**
Group	1	7.51	0.04	0.8525
Week	3	9.04	9.96	0.0032

Type 3 Tests of Fixed Effects				
Effect	**Num DF**	**Den DF**	**F Value**	**Pr > F**
Week*Group	3	9.04	1.86	0.2058

At the five percent threshold, there is no significant difference between groups in the range of motion "radial deviation - ulnar deviation".

At the five per cent threshold, there are significant differences between weeks in the magnitude of the radial deviation - ulnar deviation movement.

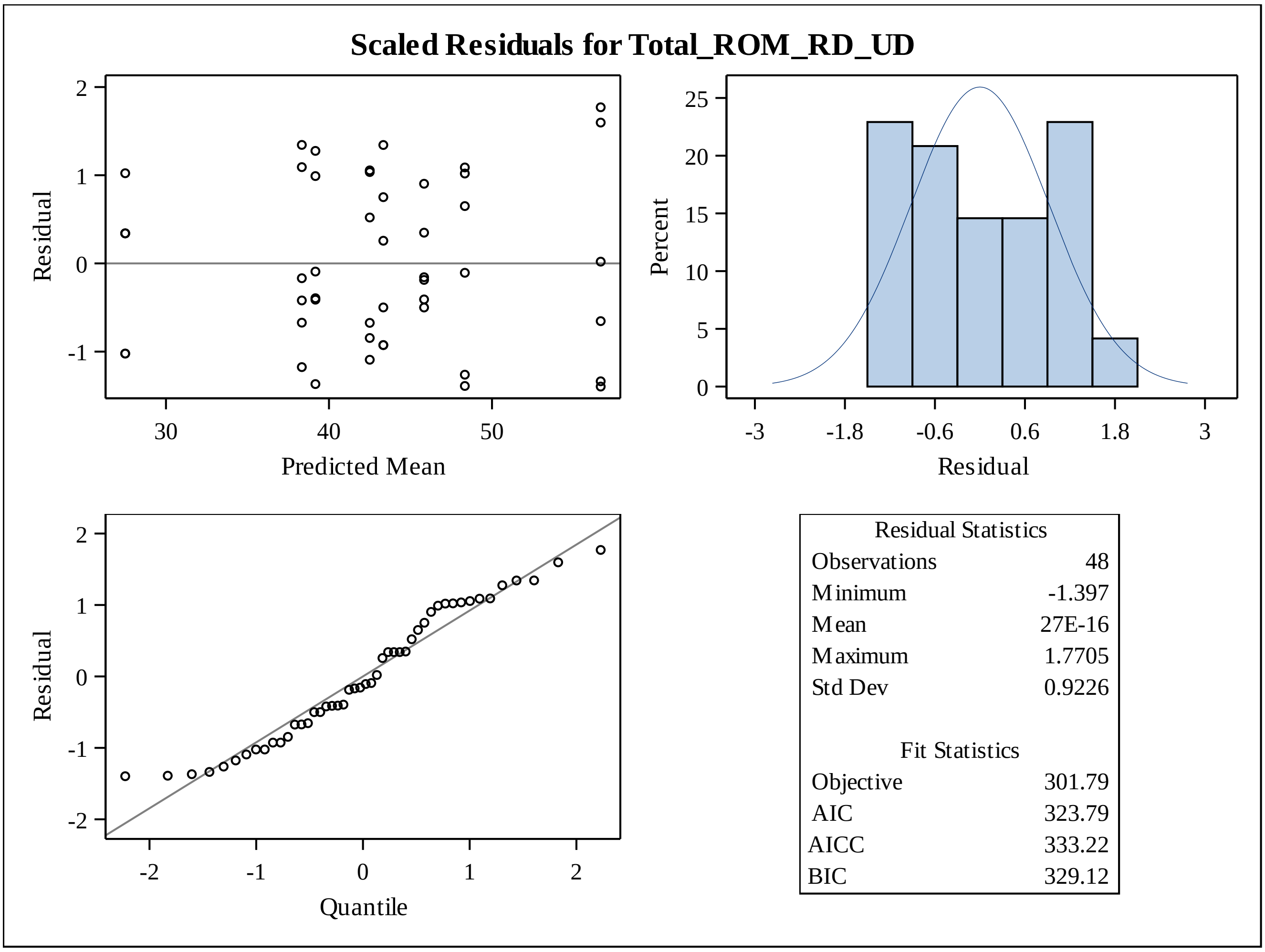
At the five per cent threshold, there is no significant interaction between the group and the week with respect to the range of motion "radial deviation - ulnar deviation".

Least Squares Means							
Effect	**Group**	**Week**	**Estimate**	**Standard Error**	**DF**	**t Value**	**Pr > |t|**
Week*Group	Control	1	38.3333	8.0979	4.99	4.73	0.0052
Week*Group	Test	1	27.5000	3.0183	6.05	9.11	<.0001
Week*Group	Control	3	39.1667	3.9010	7.81	10.04	<.0001
Week*Group	Test	3	43.3333	7.1536	5.02	6.06	0.0017
Week*Group	Control	6	42.5000	3.8864	7.75	10.94	<.0001
Week*Group	Test	6	45.8333	8.0512	5.01	5.69	0.0023
Week*Group	Control	9	48.3333	3.3505	13.9	14.43	<.0001
Week*Group	Test	9	56.6667	6.2483	4.99	9.07	0.0003

This table presents the estimate of the least squares mean of the range of motion "radial deviation - ulnar deviation" for each group and week combination.

Bonferroni Grouping for Week Least Squares Means (Alpha=0.05)			
LS-means with the same letter are not significantly different.			
Week	Estimate		
9	52.5000		A
6	44.1667	B	A
3	41.2500	B	
1	32.9167	B	

The system of letters of the previous table makes it possible to affirm that the amplitude of the movement "radial deviation - ulnar deviation" at the ninth week is significantly higher than the amplitude of the movement "radial deviation - ulnar deviation" at the third week and in the first week.



Assumptions of normality of residues and homogeneity of variance of residues are verified.