


Article

Development and Trial of a Prototype Device for Sensorimotor Therapy in Patients with Distal Radius Fractures

Daichi Narita ^{1,2}, Toyohiro Hamaguchi ^{1,*}  and Hiromi Nakamura-Thomas ^{1,*}

¹ Department of Rehabilitation, Graduate School of Health Sciences, Saitama Prefectural University, Koshigaya City 343-8540, Saitama, Japan; 2291022w@spu.ac.jp

² Tokyo Takanawa Hospital, Minato Ward, Tokyo 108-8606, Japan

* Correspondence: hamaguchi-toyohiro@spu.ac.jp (T.H.); nakamura-hiromi@spu.ac.jp (H.N.-T.)

Abstract: This study examined the clinical feasibility of a prototype device (development name: Ghost) for facilitating range of motion (RoM) recovery in the acute phase in patients with distal radius fractures (DRF). The Ghost device involves the administration of a combination of vibratory and visual stimuli. We divided the patients into the Ghost ($n = 10$) and control group ($n = 4$; tendon vibration only) groups. The experimental interventions were administered between the day after surgery and day 7 postoperatively. Traditional hand therapy was provided to both groups once daily from day 7 until day 84 postoperatively and once a week from day 84 until the end of the intervention period. Because vibratory stimulation makes the patient focus on wrist flexion, the primary outcome was the arc of wrist flexion-extension on the injured side, which was measured on days 7, 14, 28, 42, 56, 70, and 84. Analysis of covariance was applied using a bootstrap method to evaluate changes over time and compare them between the groups. Analyses was performed after stratification by age and body mass index. Both interventions improved RoM over time in patients with DRF. Results showed that Ghost has greater efficacy for improving wrist RoM in DRF patients than vibration alone. Treatment with Ghost can result in good RoM improvement during the acute phase of DRF in young patients and those with and normal or low body mass index. Further study is needed to verify our findings and assess the extent of RoM recovery.

Keywords: distal radius fractures; vibration; visualization; rehabilitation; range of motion



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1. Introduction

According to the newest Japanese national guidelines for Distal radius fractures (DRF), which were published in 2017, the annual incidence of DRF in adults (20 years and older) ranges from 10.9 to 14 per 10,000 population and women are 3.2 times more likely to be affected than men. The incidence increases with age, and people aged 70 years or older are approximately two times more likely to be affected than young people irrespective of sex. The same trends have been observed internationally [1]. The main complication of DRF is restriction of range of motion (RoM). Full RoM of the wrist joint and forearm is required for activities of daily living (ADL) involving the upper extremities [2]. Prolonged restriction of using the injured wrist causes joint contracture, which adversely impacts the performance of ADLs [3]. Restricting the use of the injured side is recommended until bone repair is observed [4]. However, during this period, somatosensory inactivity is induced [5], which may cause hesitation and anxiety and reduce wrist joint RoM [6]. This adverse event occurs not only among patients undergoing immobilization for fracture, but also among their healthy counterparts [5,7]. Decreased limb use can cause changes in the cortical representation of the unused muscles [8]. These changes represent a disuse-dependent type of neuroplasticity [9]. Therapists play an important role in ensuring recovery and guiding the improvement of RoM in DRF patients, especially in older women.

One of the currently available interventions for improving the ROM of patients with DRF is somatosensory treatment involving vibratory stimuli [10]. The application of low-frequency vibration to the peripheral nerves may contribute to alleviating pain, resulting in improvement of RoM [11]. Vibration seems to provoke the interaction of the activation of receptors and the adjustment of afferent signals that are possibly acting via the sensorimotor system [12,13]. Another intervention for effectively improving RoM is visual stimulation via a head-mounted display, which activates the hypothalamus and prefrontal cortex [14]. Interventions aimed at improving pain and motor dysfunction are termed movement representation techniques (MRT) [15]. Treatment with MRT involves observing or imagining an intact and painless movement. Sensory stimulation and active movements can be performed simultaneously. The purpose of MRT is to promote painless movements in painful limbs [15]. In recent years, the effectiveness of MRT in patients with DRF has been studied [16]. MRT have been found to improve RoM in patients with knee osteoarthritis [17,18]. Interventions involving combined sensory stimuli, such as somatosensory and visual stimuli, have been reported to more effectively alleviate pain than interventions involving a single sensory stimulus [14]. Virtual training with vibration and visualization during the acute phase of DRF may suppress disuse-dependent plasticity and contribute to subsequent RoM recovery.

Given the interest in improving RoM among patients with DRF, we developed a prototype device that provides a combination of vibratory and visual stimuli that could be used during the early postoperative joint fixation period (patent no. 6425355) [19]. This device consists of a head-mounted display for observing movements of intact hands and a vibrator that stimulates the wrist extensor tendons. We examined its feasibility for clinical use in a preliminary study involving a small sample. We also identified issues that can be addressed in future studies.

This study addressed the following research questions:

- (1) Is the new device applicable to patients with restriction of the wrist joint RoM?
- (2) Does therapy with the new device improve RoM?

2. Materials and Methods

2.1. Study Design and Ethics

This study had an interventional design because it was designed to examine the feasibility of the device. It did not employ a randomized control trial design. This study was approved by the Tokyo Takanawa Hospital Ethics Committee of the Japan Community Health Care Organization (2017-011) and the Saitama Prefectural University Ethics Committee (no. 29536).

2.2. Participants

The inclusion criteria were DRF, surgery with external fixation performed at the Department of Orthopedic Surgery of Tokyo Takanawa Hospital between April 2016 and December 2020, age 20 years or older, and consent to participate in this study. The exclusion criteria were non-invasive treatment for DRF, bilateral fractures, life-threatening health conditions, and cognitive impairment as indicated by a score of <27 on the Mini-Mental State Examination. Patients who experienced postoperative pain and excessive anxiety related to movement of the injured wrist were excluded due to difficulty in measuring RoM.

The number of participants required for the analysis was calculated using G^* power [20], with a noncentrality parameter δ 3.1, effect size of 1.4, alpha error of 0.05, and a power of 0.8 by difference between two independent means. The required sample size of actual data was two groups of 10 each, for a total of 20 participants.

Data regarding the following patient characteristics were obtained from medical records: surgical method, sex, age, dominant hand, history of injury, onset date, surgical date, fracture classification (Arbeitsgemeinschaft für Osteosynthesefragen [AO]/Orthopedic Trauma Association fracture and dislocation classification), and bone alignment evaluated

by a medical physician using radiographic parameters. Patients were assigned to the control (tendon vibratory stimulus alone) or Ghost (combined tendon vibratory and visual stimulus) group using the minimization method. To equalize the fracture severity of both groups, group allocation was performed based on the fracture classification (AO classification) and bone alignment (radiographic parameters).

2.3. Prototype: Ghost

The Ghost system comprised a laptop for video viewing, head-mounted virtual reality (VR) display, and vibrator (Figure 1). Videos of the left and right hands were paired with the patient's left and right eyes, respectively, using a parallax barrier so that the patient would have a stereoscopic experience when viewing the video with both eyes. During the application, the two videos were adjusted to positions in which they could be seen as one image (hands) from the patient's viewpoint. White lines on the screen, as seen in front of the patient in Figure 1, were used as the reference to set the positions of the two images so that the resulting image felt three-dimensional (3D). The therapist determined the site for vibration and positioned the images in the application to control the stimulation. Vibratory stimulation was applied to a tendon on the unaffected side, and it therefore did not affect the fracture [10]. However, viewing 3D images can sometimes cause eye strain [21].

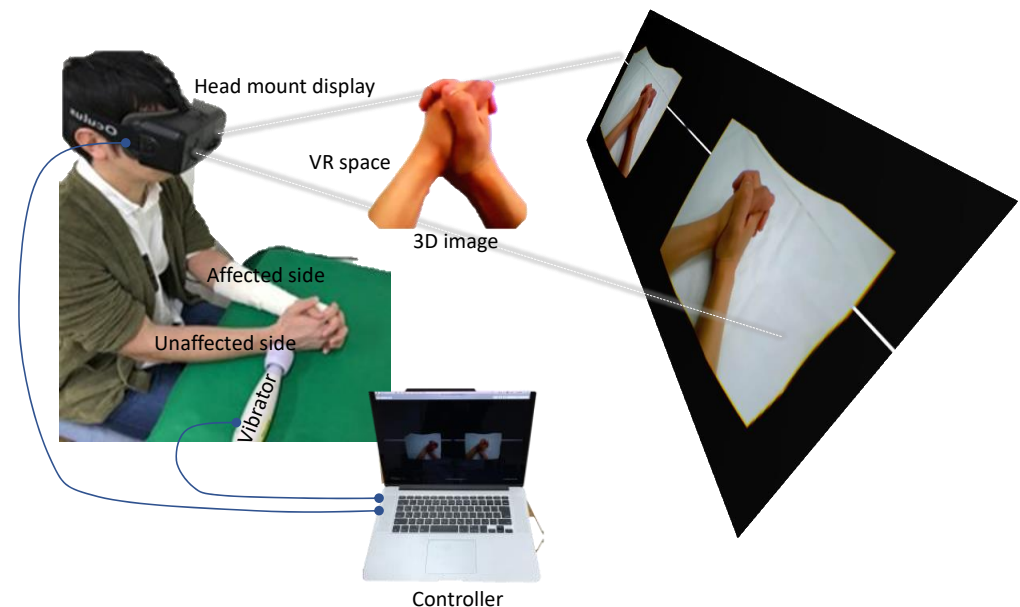


Figure 1. Configuration of Ghost, a device for video observation and vibratory stimulation. 3D: three-dimensional, VR: virtual reality.

A handheld massager was used as the vibrator (Daito Electric Machine Industry Co., Ltd., Osaka, Japan). The video visualization system comprised a head-mounted display (Oculus Rift; Irvine, CA, USA), a control unit (MacBook Pro; Apple Inc., Cupertino, CA, USA), and an originally developed video application.

2.4. Interventions

2.4.1. Patient Limb Position

Patients were seated in a chair with a backrest and a seat height of 45 cm. They placed their palms close together on a desk. They were instructed to close their eyes and relax. Prior to the interventions, the patients in both groups were instructed to immediately inform a therapist if they experienced any discomfort.

2.4.2. Vibratory Stimulus Application

The frequency of the vibratory stimulus was set to 70–80 Hz [13]. A stimulus of 70–80 Hz was applied for 30 s to the extensor carpi ulnaris tendon on the non-injured side of all patients by a therapist using the handheld massager (Figure 1). This 30 s stimulus was followed by a 10 s interval; two repetitions of this process were considered as one set. Three consecutive sets of this intervention were performed once daily. For the control group, only this vibration intervention was performed daily from the day after surgery to 1 week after surgery [10].

2.4.3. Combined Intervention with Vibration and Motion Observation

Vibratory stimulation was performed in the same manner for both the control and the Ghost groups. However, for the Ghost group, the Oculus Rift was used to display a video showing the patient seemingly flexing the wrist joint while vibration was applied to the healthy extensor carpi ulnaris for 30 s. The duration and frequency of the intervention were the same for both groups.

The following four types of videos, all with the forearms in the neutral position, were used to display movements: a video of both palms crossed with the left thumb on top, a similar video with the right thumb on top, a video of the wrist joint with extension to the left, and a video of the wrist joint with extension to the right. These videos were used to allow the patient to visualize the limb position, regardless of whether the palms were folded with the left or right thumb up (Figure 1).

The videos that the patients watched were set as follows: both hands were positioned with the palms together and dorsiflexed toward the non-injured side, with maximum dorsiflexion being reached within 10 s; this position was maintained for 2 s, and the hands were returned to the original position within 8 s. Videos were captured using a twin-lens camera (3D FPV camera, Black Bird 1; Russia, 2015) for 3D display with a binocular parallax; additionally, pairs of converted files with a size of 40 × 480 pixels and image resolution of 254 ppi were used. The video file pair was synchronized using a dedicated application and shown to the patient on the head-mounted display at 30 fps.

Videos of the patient with the palms together at rest, with maximum dorsiflexion to the non-injured side for 10 s, with the position maintained for 2 s, and, with the hands returned to the original position for 8 s were sequentially presented for 30 s along with vibratory stimulus applied to the wrist joint (Figure 2). Before the patient observed the video, the therapist confirmed whether the patient’s left or right thumb was on top, and a video with the same limb positioning was selected. The therapist verbally instructed the patients to imagine that their hands were moving in the same manner displayed in the video they were observing. Interventions for both groups started 1 day after DRF surgery and were continued for 6 consecutive days (Table 1).

Table 1. Scheduled interventions and evaluations.

Postoperative Day		1	2	3	4	5	6	7	14	28	42	64	70	84
Intervention	Ghost or control treatment	•	•	•	•	•	•							
	Conventional treatments							•	•	•	•	•	•	•
Evaluation	Range of motion							○	○	○	○	○	○	○

Black circles indicate that the patients were treated during the intervention period. The investigation periods for each instrument are indicated by white circles. Ghost group: vibration with visualization, control group: vibration alone.

2.4.4. Interventions Administered to All Patients

RoM training as exercise therapy was not performed until 7 days after surgery in both groups. As a routine rehabilitation program, RoM training, muscle relaxation, and muscle strength training on the injured side were provided once a day from day 7 until day 84 after surgery, and once a week from day 84 until the end of the intervention period.

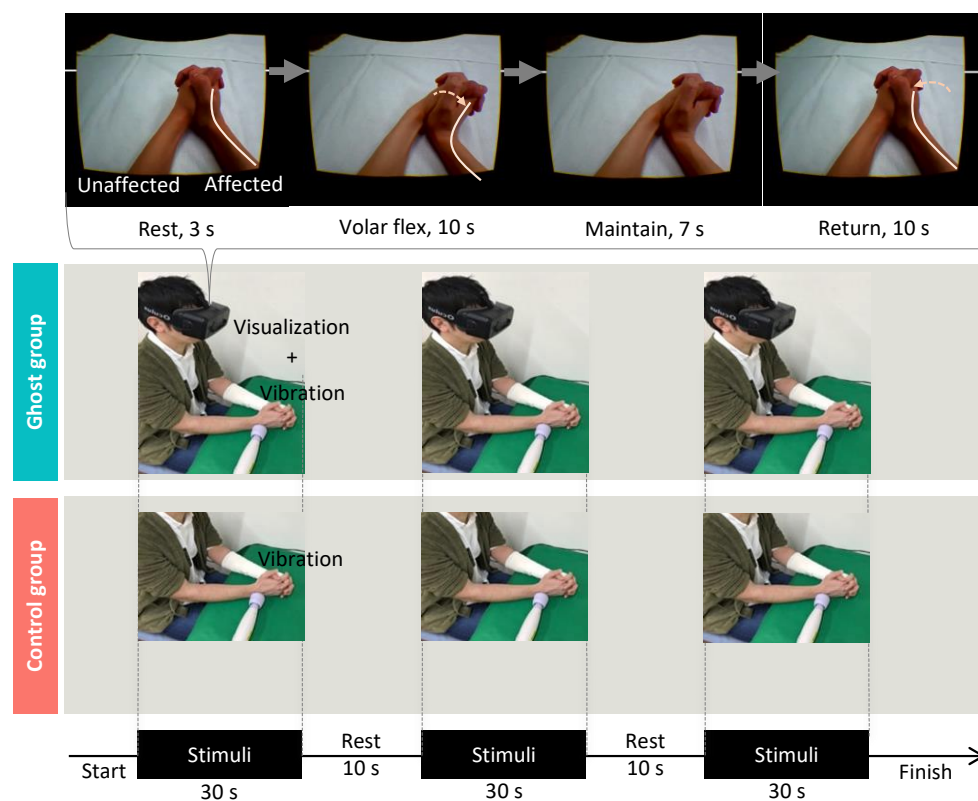


Figure 2. Sequences of stimuli. The upper panel shows the Ghost group. The lower panel shows the control group. Patients in both groups were placed in the resting position with their hands folded.

2.5. Measurement of Intervention Time

The time required to set up Ghost or the vibrator was measured from the time each device was prepared until the initial stimulation was started. In the control group, the tendon of the extensor carpi ulnaris on the unaffected side was identified by the therapist, and the vibrator was turned on to commence the stimulation. The laptop, which was used as the control unit, was turned on, and the head-mounted display was placed on the patients in the Ghost group. The therapist confirmed how the patients' hands were placed (i.e., which hand's thumb was on top) and selected the videos to be displayed through the VR application. The patients were fitted with the head-mounted display by the therapist, and the videos were adjusted so that they could be seen as a single stereoscopic image.

2.6. Outcomes

2.6.1. Primary Outcome: Arc of Wrist Flexion-Extension

The primary outcome was RoM [10,22]. The motion angles of the wrist and forearm on the injured side were measured by an occupational therapist who was certified at the Hand Surgery Evaluation Method Workshop in Japan. Measurements were performed according to the Goniometry Manual of the American Society of Hand Therapists [23] using an analog goniometer. The minimum detectable change measured by an analog goniometer is 6.3 degrees [24]. Therefore, therapists with a hand therapy specialist license measured the RoM to minimize the standard error of the measurements. Although the measured directions of movement were palmar flexion, dorsiflexion, ulnar deviation, radial deviation, and pronation and supination of the forearm (data available in Supplementary Materials), we focused on the arc of palmarflexion-dorsiflexion of the wrist joint, because it was directly related to the intervention with visualization and vibration. Patients were placed in the sitting position and instructed to place their forearms on a desk. The therapist performed three measurements of the angles at which patients actively moved the wrist joint and forearm; then, the average values were calculated.

2.6.2. Secondary Outcome: Feasibility of the Ghost System

To clarify the operation time and efforts required for treatment using the new device, an occupational therapist was interviewed. This survey was necessary to gauge the practical usability of Ghost because it was expected to take more time to operate than the vibrator alone.

2.6.3. Period of Data Collection

Data acquisition was started the day after surgery and continued until up to 12 weeks (84 days) after surgery (Table 1). The Ghost or control intervention was applied during the first week after surgery. RoM was measured on days 7, 14, 28, 42, 56, 70, and 84 after surgery when exercise was permitted. One therapist handled all the sessions, and one session lasted 20 min for both groups. None of the subjects reported fatigue or discomfort during the sessions. In the Ghost group, it took approximately 300 s to explain the intervention and select videos for the first time and approximately 180 s to prepare and install the Ghost device. In the control group, it took approximately 300 s to explain the intervention and approximately 60 s to prepare the intervention.

2.7. Analytic Strategies

We examined the feasibility of Ghost for clinical use during a preliminary study involving a small sample. Age and body mass index (BMI) were selected as independent variables for stratified analysis, as these variables have been found to affect ROM improvements with VR therapy in DRF patients in previous reports [10,22]. For instance, treatment outcomes with the VR system are affected by age and cognitive function [25]. People aged 55–75 years take more time to operate VR equipment and experience more malfunctions than those aged 18–30 years [26]. Therefore, the effects of age should be considered when evaluating any VR system. Body weight has also been reported to affect RoM and ADL recovery in DRF patients. DRF patients who were obese ($BMI \geq 25 \text{ kg/m}^2$) showed better recovery of ADL performance than those with a $BMI < 25 \text{ kg/m}^2$ [27]. Obesity appears to be protective against forearm osteoporosis [28], and previous studies have proposed various mechanisms to explain the relationship between adipose tissue and bone [29–31]. Therefore, age and body weight are confounding factors and should be considered when assessing the effect of therapeutic intervention in DRF patients. We also hypothesized that there is an optimal age and BMI bandwidth at which the device will show the maximum effect in DRF patients.

To conduct a stratified analysis with a small sample, we employed a bootstrap resampling method. This method is widely used in demographic studies [32]. In this study, 1000 bootstrap data values were generated by randomly drawing a series of actual sample RoM data. The resampling data for RoMs were then analyzed using analysis of covariance (ANCOVA) based on group (Ghost vs. control) and time course. The probability distribution was determined using a quantile-quantile plot of the arc of wrist flexion-extension (all estimated data). Bonferroni's post hoc test was used to compare RoM recovery over time [24]. Age and BMI were included as independent variables in the stratified analysis. The statistical significance level was set at 0.05. JASP 0.16 (Retrieved from <https://jasp-stats.org/>, accessed on 30 October 2021) was used for the analyses. This is an exploratory and preliminary analysis to confirm feasibility and cannot be generalized.

3. Results

Of the 41 DRF patients recruited to participate in this study, 20 were included. Twenty-one were excluded because they had received conservative therapy; had bilateral fractures, cognitive decline, severe postoperative pain, or excessive anxiety; or they did not participate in follow-up (Figure 3). Ten patients were assigned to each group, six patients who were discharged within 6 days or complained of pain were excluded before analysis. We planned to re-recruit patients to the control group, but this plan was abandoned due to the coronavirus disease 2019 pandemic. The characteristics of the participants are shown in Table 2. All participants were women. No statistically significant difference was observed in

the radiographical parameters between the groups. In terms of severity, 75% (3/4 patients) and 50% (5/10 patients) of the control and Ghost groups, respectively, were categorized as class C, the most severe category, according to the AO classification (Table 2).

Table 2. Characteristics of patients with distal radius fracture.

Characteristics		Ghost Group, n = 10 (Vibration with Visualization)	Control Group, n = 4 (Vibration Alone)
Sex	Female:Male	10:0	4:0
Age (years)		76 ± 10	69 ± 9
BMI (kg/m ²)		23.0 ± 4.9	22.1 ± 5.6
Affected side	Right:Left	6 (4)	0 (4)
Handedness	Right:Left	10:0	4:0
AO classification		A, 3; B, 2; C, 5	A, 0; B, 1; C, 3
Radiographic parameters (mm)	Volar tilt	14.7 ± 2.1	15.5 ± 1.4
	Radial tilt	8.2 ± 3.1	9.1 ± 1.9
	Radial inclination	0.9 ± 0.8	1.4 ± 0.4

BMI: body mass index, AO classification: Arbeitsgemeinschaft für Osteosynthesefragen/Orthopaedic Trauma Association fracture and dislocation classification.

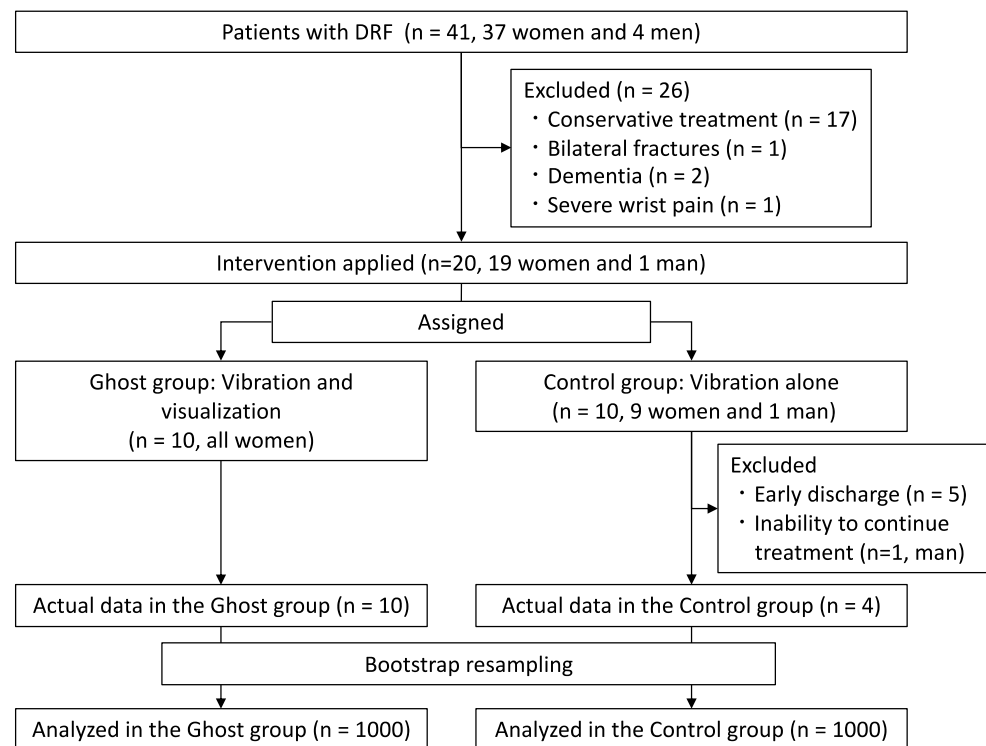


Figure 3. Recruitment procedure for patients with DRF. DRF: distal radius fracture.

As a result of the therapy, improvements were observed in the arcs of motions in the Ghost and control groups during the treatment course (Supplementary File S1). The bootstrap data resampled from actual data are represented in Table 3. ANCOVA revealed a significant interaction between group and time course with the arc of motion as the dependent variable, stratified by age and BMI ($F = 108.29$, $df = 6$, $p < 0.001$, $\eta^2 = 0.003$, Figure 4). The probability of recovery of wrist flexion–extension RoM from day 14 to 82 was greater in the Ghost group (75.8 ± 3.9 to $136.2 \pm 6.1^\circ$) than in the control group (74.1 ± 6.4 to $141.3 \pm 3.7^\circ$, mean difference = 1.9 to 11.4° , $p_{Bonferroni} < 0.001$, Table 4). In the stratified analysis, a larger likelihood of improvement was found in young patients than in old patients ($F = 722.23$, $df = 3$, $p < 0.001$, $\eta^2 = 0.002$, Figure 5). The arc of motion of the Ghost group was larger than that in the control group in patients with normal and low BMI ($p_{Bonferroni} < 0.001$, Figure 6).

Table 3. Actual and estimated arcs of wrist flexion-extension during the postoperative period.

Group	Day 7	Day 14	Day 28	Day 42	Day 56	Day 70	Day 84
Ghost actual (n = 10)	73 (70–79)	92 (82–104)	111 (97–120)	124 (112–132)	130 (126–138)	138 (134–140)	140 (139–141)
Ghost bootstrap (n = 1000)	74 (73–78)	91 (89–96)	118 (111–124)	118 (111–124)	130 (124–134)	133 (129–135)	137 (134–143)
Control actual (n = 4)	74 (71–79)	91 (86–98)	108 (98–117)	118 (112–123)	130 (127–132)	129 (125–136)	137 (129–144)
Control bootstrap (n = 1000)	74 (69–78)	93 (84–99)	121 (113–131)	121 (113–131)	132 (127–136)	138 (134–141)	140 (139–143)

Data are presented as median (1st–3rd quartile range).

Table 4. Comparisons of arc of motion at different time points between the Ghost and control groups.

Postoperative Day	Group	Marginal Mean	95% CI for Mean Difference		Mean Difference	T	<i>P</i> _{Bonferroni}
			Lower	Upper			
7	Ghost	75.881	75.315	76.446	1.909	6.780	<0.001
	Control	73.972	73.406	74.537			
14	Ghost	93.712	93.147	94.278	3.073	11.070	<0.001
	Control	90.639	90.074	91.205			
28	Ghost	112.290	111.724	112.855	7.155	25.777	<0.001
	Control	105.135	104.569	105.700			
42	Ghost	123.076	122.510	123.641	7.344	26.456	<0.001
	Control	115.732	115.167	116.298			
56	Ghost	133.200	132.635	133.766	5.746	20.701	<0.001
	Control	127.454	126.889	128.020			
70	Ghost	140.008	139.443	140.574	9.520	34.298	<0.001
	Control	130.488	129.922	131.053			
84	Ghost	143.065	142.500	143.631	8.680	31.271	<0.001
	Control	134.385	133.820	134.951			

Using analysis of covariance (group × time course) and a post-hoc test. CI: confidence interval.

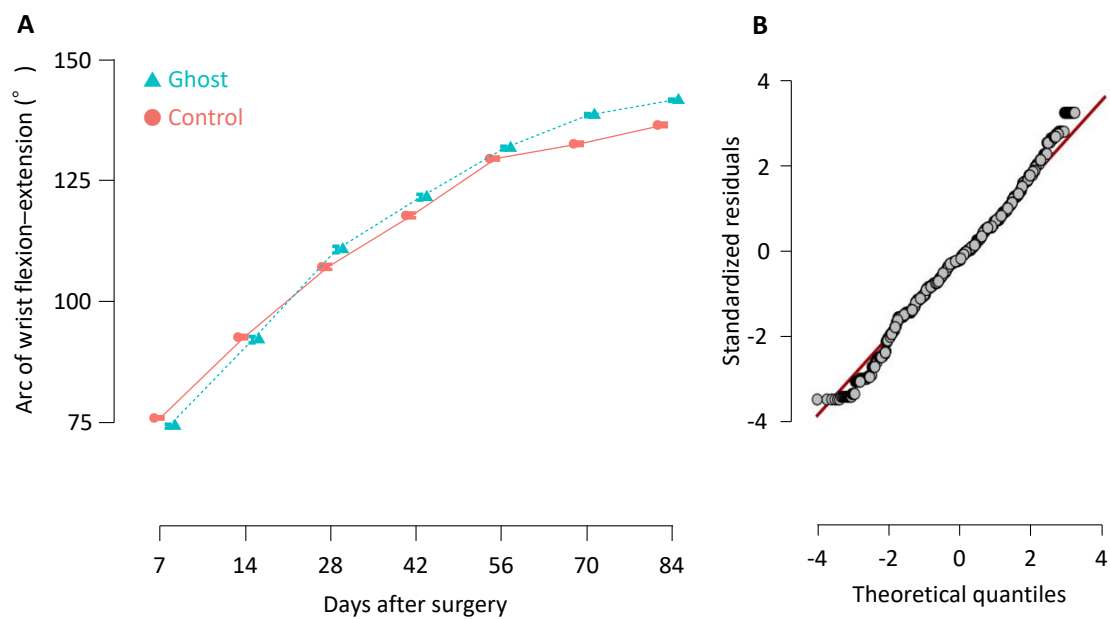


Figure 4. Between-group comparisons of changes in the arc of wrist flexion-extension using bootstrap data. The data points are slightly jittered horizontally to improve visualization. (A): Change in arc of motion over time compared between the Ghost and control groups. The Ghost group showed significantly greater change over time than the control group (*P*_{Bonferroni} < 0.001). The blue-green triangles and dashed line indicate Ghost group data, whereas

the red circles and solid line indicate control group data. The plots for each group comprise 7000 bootstrap data points (1000 participants \times 7 observation points). (B): Quantile-quantile plot of arc of wrist flexion-extension using all estimated data for determining the probability distribution.

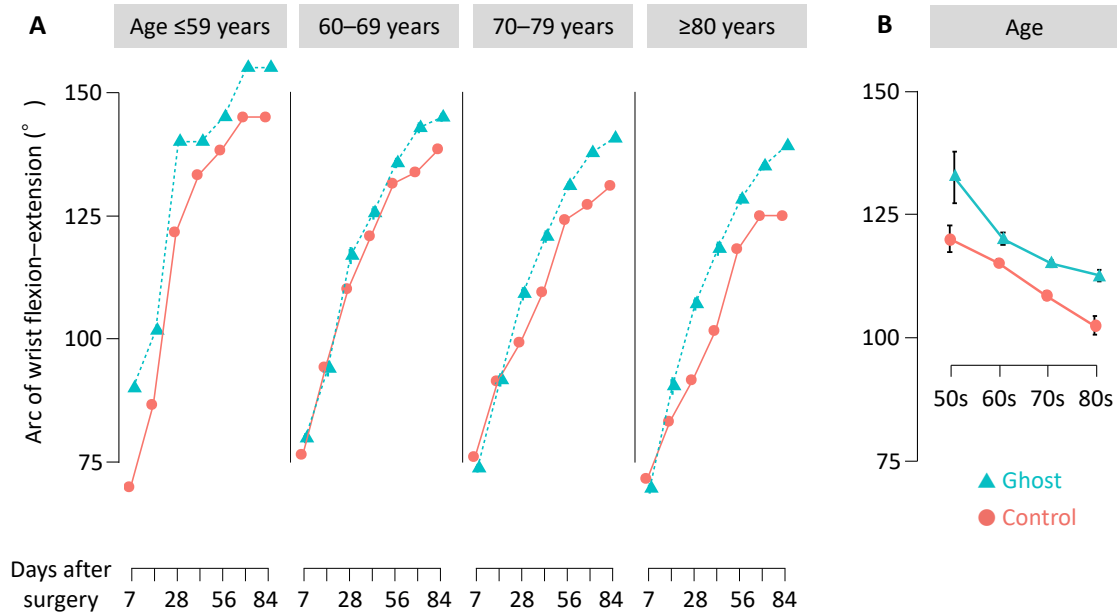


Figure 5. Between-group comparisons of changes in arc of wrist flexion-extension stratified by age. (A): Change in arc of motion over time stratified by age and compared between the Ghost and control groups. The blue-green triangles and dashed line indicate Ghost group data, whereas the red circles and solid line indicate control group data. The plots for each group comprise 7000 bootstrap data points (1000 participants \times 7 observation points). (B): Descriptive plots for comparing the change in arc of motion by 10-year groups. Significant interaction (group \times age) was found in arc data adjusted by time course using analysis of covariance ($F = 40.61$, $df = 3$, $p < 0.001$, $\eta^2 = 0.001$). The arc of motion of the Ghost group was higher than that of the control group across all age groups ($p_{Bonferroni} < 0.001$). The arc of motion of the injured wrist joint was larger in younger patients than in older patients ($F = 722.23$, $df = 3$, $p < 0.001$, $\eta^2 = 0.002$). Characters and bars indicate the marginal mean and standard deviation respectively.

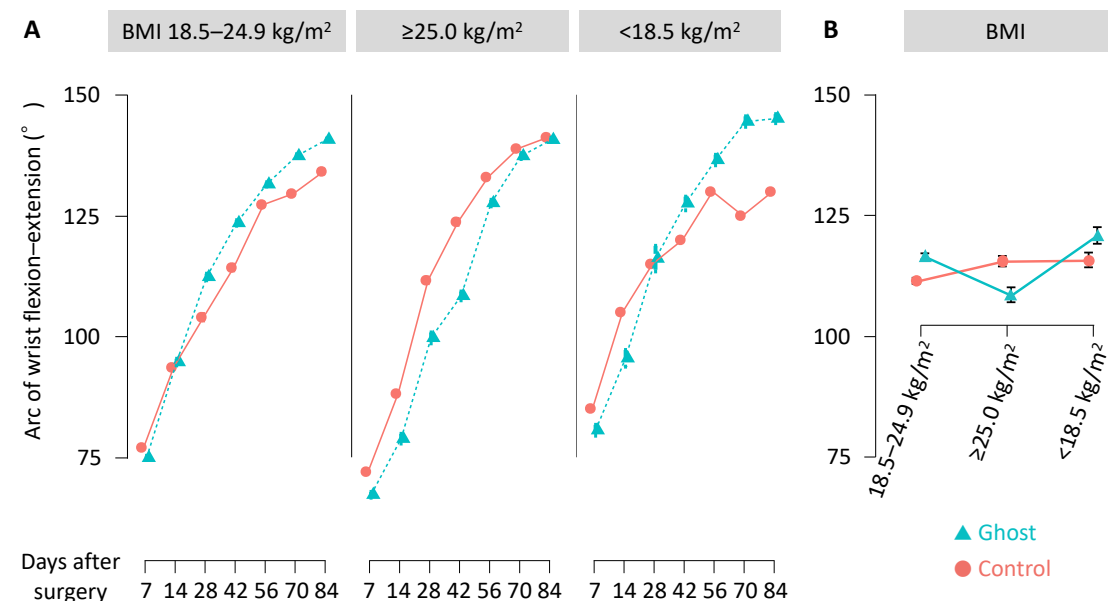


Figure 6. Between-group comparisons of changes in the arc of wrist flexion-extension stratified by

BMI. (A): Change in arc of motion over time stratified by BMI and compared between the Ghost and control groups. The blue-green triangles and dashed line indicate Ghost group data, whereas the red circles and solid line indicate control group data. The plots for each group comprise 7000 bootstrap data points (1000 participants \times 7 observation points). (B): Descriptive plots for comparing the change in arc of motion by BMI. Panels are arranged as follows: left: normal BMI as a reference, center: obese, and right: underweight. Significant interaction (group \times BMI) was found in arc data adjusted by time course using analysis of covariance ($F = 174.70$, $df = 3$, $p < 0.001$, $\eta^2 = 0.004$). In individuals with normal BMI and those who were underweight, the arc of motion of the Ghost group was greater than that of the control group ($p_{Bonferroni} < 0.001$). Conversely, in obese patients, the RoM of the control group was greater than that of the Ghost group ($p_{Bonferroni} < 0.001$). Characters and bars indicate marginal mean and standard deviation respectively. BMI: body mass index.

4. Discussion

The results of this study were obtained using a preliminary inference analysis. During DRF treatment in the acute phase, the wrist joint must be immobilized; however, somatosensory inactivity must be overcome. Therefore, possible solutions need to be explored. This study shows that Ghost can be used for treatment in this phase. Statistical analyses revealed that both interventions resulted in a significant improvement in the RoM over time in patients with DRF. In addition, the arc of wrist motion was larger in the Ghost group than the control group. Recovery of RoM after treatment with our new therapeutic technique that used somatic and visual stimuli differed depending on age and BMI. This study also provided data on wrist joint RoM recovery following interventions in the acute phase in patients with DRF. Based on these results, our next study will be on the large-scale implementation and verification of the effects of the Ghost device and the extent of RoM recovery that can be expected according to the patient's age and BMI.

The BMI of patients with DRF affected RoM recovery, and younger patients recovered more than older patients. Differences in the arc of motion between the Ghost and control groups were estimated to be less than 10° , and these results did not indicate superiority of the new device. The 95% confidence interval of the minimum detectable difference (MDD₉₅) has been reported to determine a patient's recovery [24]. The MDD₉₅ of the arc of motion of wrist flexion–extension measured using a manual goniometer has been reported to be 18° [24].

Previous studies of interventions using vibratory stimuli [10] and the evaluation in DRF patients did not investigate changes in RoM during the acute phase [33]. Chung et al. reported that the recovery of strength of muscles involved in forearm pronosupination in patients with DRF is approximately 40% at 6 weeks after surgery, and a period of approximately 18 months is required for complete recovery [34]. Our actual data was from a small sample, but it was of the RoM in the acute phase. Intervening in the joint fixation period and improving the RoM even slightly may significantly support the recovery of DRF patients.

A person's tactile threshold increases with age [35,36]. Atkins et al. reported that patients in their 60s were more likely to make mistakes in a VR environment and were slower to move than those in their 20s [26]. The mean age of the patients in the Ghost and control groups was 76 and 69 years, respectively. Previous studies have suggested that vibration and VR were more effective therapies in younger patients than in older patients such as those included in this study. Future studies should examine whether young patients adapt well to a VR environment and experience strong sensory stimulation using the Ghost system.

Underweight Asian patients with femoral fracture have been reported to have poor ADL performance and lower rates of discharge to home than overweight or obese patients [37]. In contrast, Acosta-Olivo et al. reported that DRF severity and obesity were not related to recovery [38]. Montague et al. reported differences in functional recovery according to BMI [27]. Obesity is associated with the impaired T-cell regulation, characterized by an increased number of cells, and dysregulation of vitamin D metabolism [39,40]. Even in

our small data, BMI was associated with DRF recovery, and we therefore recommend that BMI and nutritional status be considered when validating new therapies.

Alleviated pain may contribute to improved RoM [3,10]; therefore, a vibratory stimulus was provided to all patients during this study. We did not report on the patients' pain intensity. The quantity of deformed sensory receptors is increased in soft tissues around joints in patients with fractures or joint degeneration [41]. Because of the increased quantity of deformed sensory receptors and increased concentration of pain-transmitting substances, patients perceive pain for a long time. Because of trauma and surgical joint invasion, the levels of pain-related neuropeptides, such as substance *P* and bioactive mediators, increase [42]. Patients with DRF are likely to experience pain during the acute phase because of this mechanism. Vibration at a frequency of 80 Hz suppressed the activation of calcitonin gene-related peptide-positive neurons, which are involved in pain associated with joint fixation [43]. In patients with DRF, vibratory stimulation improves brain activity in the primary motor cortex and somatosensory area, improves wrist joint RoM, and alleviates pain and anxiety [10]; subjective pain is diminished by actual exercise [44]. In other words, it was speculated that vibratory stimulation of the tendon, without somatic movement, resulted in brain activity similar to that when exercise is performed [45]; hence, a pain reduction effect was achieved. The results of this study suggest that the intensity of pain decreased during the period after DRF when patients were prohibited from moving by applying an external stimulus to the injured area, which promoted subsequent joint movement and improved RoM. Future studies should report on improvements in pain and anxiety.

This study has some limitations. First, because this study was conducted as a preliminary experiment to examine the feasibility of Ghost, patients were not randomly selected. Patient randomization and blinding or placebo interventions should be performed to demonstrate the dominance of Ghost. Whether this inference analysis fits the actual measurement should be analyzed by adding more cases in the future. Because of the small sample size, more patients in the control group than the Ghost group had a severe fracture (75% vs. 50%, respectively), although the severity was comparable in both groups in the resampled data. There was no difference in RoM after conventional treatment was started (7 days postoperatively), but the pre-intervention fracture severity of the control group was more than that of the Ghost group (Table 2, AO classification). Consequently, it can be assumed that RoM recovery after the intervention was worse in the control group than in the Ghost group. In future studies, the effect of Ghost should be verified after controlling for fracture severity using the AO classification. Secondly, all the study participants were women. Epidemiological studies show that DRF commonly occurs in older women [46,47]. Future studies must include young men and those with sports injuries. Third, Ghost is still under development and the device used in this study was a prototype; therefore, the quality of the visual stimuli and procedure may have influenced the results. Researchers who were familiar with Ghost required approximately 10 min to operate the device. However, Japanese insurance covers interventions for outpatients with musculoskeletal issues for only 20 min per session. Therefore, to expand the applicability of Ghost, the procedure must be simplified to allow therapists to use the device within a short time without errors. Fourth, this study merely reported the arc of motion of flexion–extension of the wrist joint. Forearm supination involves the proximal and distal radioulnar joints, which consist of the radius and ulna, and trauma from DRF affects the radius [48]. Moreover, DRF is frequently associated with ligament lesions [49]. Pronosupination after DRF helps the recovery of bones and soft tissues that comprise the wrist joint. Forearm supination is used for toilet activities and changing clothes [2]. The forearm is also in the supination position during meals [50]. Therefore, forearm pronosupination is indispensable for the activities of daily living. Because other arcs of motion were not analyzed during this study, the treatment effects on them should be verified through future studies. Fifth, a previous study obtained data regarding brain activity during visual stimuli; however, it included healthy young adults [51]. We did not have the brain imaging data of patients with DRF during this study.

Brain activity data may help to identify patients who easily perceive visual illusions and those who do not. Sixth, during previous studies, some patients reported eye-squint fatigue when observing 3D images continuously for a long period of time [21]. Although no patient in this study reported such fatigue, the quality of the visual stimuli needs to be improved. Future studies should examine the appropriate duration of the visual stimuli for patients with DRF. The image quality of the Ghost stimuli and the procedure need to be improved. Lastly, in Japan, occupational therapists focus on encouraging DRF patients to use their injured limb for ADLs. Patients with DRF in Japan are usually hospitalized for 2–3 days for fixation, and they receive occupational therapy on an outpatient basis. RoM improvement in patients with DRF is influenced by the amount the injured limb is used [52], highlighting the importance of prevention of somatosensory inactivity. The effectiveness of Ghost for improving the amount the injured limb is used should be examined in future studies.

5. Conclusions

This study implies that Ghost is a clinically feasible intervention and can be used during the acute phase of DRF in older women as it is associated with no adverse effects. Furthermore, there were no problems in the functioning of the Ghost equipment.

6. Patents

Patent No. 6425355.

Supplementary Materials: The following supporting information can be downloaded at: <https://www.mdpi.com/article/10.3390/app12041967/s1>, File S1: raw data.

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Institutional Review Board Statement: This study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Tokyo Takanawa Hospital Ethics Committee of the Japan Community Health Care Organization (2017-011) and the Saitama Prefectural University Ethics Committee (no. 29536). This study protocol was registered in the University Hospital Medical Information Network, Clinical Trials Registry System (no. 20200215-123054).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The data presented in this study are available in Supplementary Materials.

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