Original Papers

Potential Effects of an Exoskeleton-Assisted Overground Walking Program for Individuals With Spinal Cord Injury Who Uses a Wheelchair on Imaging and Serum Markers of Bone Strength: Pre-Post Study (e53084)
Alec Bass, Suzanne Morin, Michael Guida, Jacqueline Lam, Antony Karellis, Mylène Aubertin-Leheudre, Dany Gagnon, Montreal Exoskeleton Walking Program (MEWP) Group. 3

Consumer Perceptions of Home-Based Percussive Massage Therapy for Musculoskeletal Concerns: Inductive Thematic Qualitative Analysis (e52328)
Saloni Butala, Pearl Galido, Benjamin Woo. 19

Evaluating the Experiences of Occupational Therapists and Children Using the SensoGrip Pressure-Sensitive Pen in a Handwriting Intervention: Multimethods Study (e51116)
Lena Rettinger, Erna Schönthaler, Andrea Kerschbaumer, Carina Hauser, Carissa Klupper, Lea Aichinger, Franz Werner. 29

Validity and Reliability of a Telehealth Physical Fitness and Functional Assessment Battery for Ambulatory Youth With and Without Mobility Disabilities: Observational Measurement Study (e50582)
Byron Lai, Danielle Wadsworth, Katherine Spring, Chloe Jones, Madison Mintz, Laurie Malone, Yumi Kim, Jereme Wilroy, Holim Lee. 43

A Digital Intervention to Promote Self-Management Self-Efficacy Among Community-Dwelling Individuals With Stroke: Pilot Randomized Controlled Trial (e50863)
Zhaoying Li, Yating Lei, Quoc Bui, Olivia DePaul, Ginger Nicol, David Mohr, Sunghoon Lee, Mandy Fong, Christopher Metts, Stephanie Tomazin, Alex Wong. 58

Results of Gensingen Bracing in Patients With Adolescent Idiopathic Scoliosis: Retrospective Cross-Sectional Feasibility Study (e50299)
Xiaofeng Nan, Tu ba Kuru Çolak, Burçin Akçay, Hua Xie, Liwei Zhao, Maksym Borysov. 77

Quality of Life in Children With Achondroplasia Undergoing Paired Limb Lengthening With an External Fixator and Modified Distraction Control: Observational Nonrandomized Study (e49261)
Vitaly Trofimchuk, Bolatbek Dossanov, Vassiliy Lozovsky, Sergey Khmyzov, Assem Dossanova, Aleksandr Angelov, Andrey Pashenko, Olzhas Zhukonov. 88
Corrigenda and Addenda

Correction: Validating the Safe and Effective Use of a Neurorehabilitation System (InTandem) to Improve Walking in the Chronic Stroke Population: Usability Study (e56041)

Kirsten Smayda, Sarah Cooper, Katie Leyden, Jackie Ulaszek, Nicole Ferko, Annamaria Dobrin.
Potential Effects of an Exoskeleton-Assisted Overground Walking Program for Individuals With Spinal Cord Injury Who Uses a Wheelchair on Imaging and Serum Markers of Bone Strength: Pre-Post Study

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Abstract

Background: As many as 60% of individuals use a wheelchair long term after a spinal cord injury (SCI). This mode of locomotion leads to chronic decline in lower-extremity weight-bearing activities and contributes to the development of severe sublesional osteoporosis and high rates of fragility fracture. Overground exoskeleton-assisted walking programs provide a novel opportunity to increase lower-extremity weight bearing, with the potential to improve bone health.

Objective: The aim of the study is to measure the potential effects of an exoskeleton-assisted walking program on lower-extremity bone strength and bone remodeling biomarkers in individuals with chronic (≥18 months) SCI who use a wheelchair.

Methods: In total, 10 participants completed a 16-week exoskeleton-assisted walking program (34 individualized 1-hour sessions, progressing from 1 to 3 per week). Bone mineral density and bone strength markers (dual-energy x-ray absorptiometry: total body, left arm, leg, total hip, and femoral neck and peripheral quantitative computed tomography: 25% of left femur and 66% of left tibia) as well as bone remodeling biomarkers (formation=osteocalcin and resorption=C-telopeptide) were measured before and after intervention and compared using nonparametric tests. Changes were considered significant and meaningful if the following criteria were met: $P<0.1$, effect size ≥0.5, and relative variation >5%.

Results: Significant and meaningful increases were observed at the femur (femoral neck bone mineral content, bone strength index, and stress-strain index) and tibia (cortical cross-sectional area and polar moment of inertia) after the intervention (all $P<.10$). We also noted a decrease in estimated femoral cortical thickness. However, no changes in bone remodeling biomarkers were found.
Conclusions: These initial results suggest promising improvements in bone strength markers after a 16-week exoskeleton-assisted walking program in individuals with chronic SCI. Additional research with larger sample sizes, longer interventions (possibly of greater loading intensity), and combined modalities (eg, pharmacotherapy or functional electrical stimulation) are warranted to strengthen current evidence.

Trial Registration: ClinicalTrials.gov NCT03989752; https://clinicaltrials.gov/ct2/show/NCT03989752

International Registered Report Identifier (IRRID): RR2-10.2196/19251

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KEYWORDS
assistive technology; bone architecture; bone turnover; osteoporosis; rehabilitation; spinal cord injuries; SCI; spinal cord injury; assistive device; wheelchair; exoskeleton device; locomotion; bone strength; risk; fracture

Introduction

Mechanical loading is a key factor influencing bone strength [1]. Indeed, osteocytes detect and respond to mechanical stimuli by triggering an anabolic state that stimulates bone formation and leads to adaptations in bone geometry (known as the “mechanostat principle”) [1]. Healthy bones are therefore well adapted to the habitual loads regularly encountered during daily function (ie, concept of specificity) [2]. However, after sustaining a spinal cord injury (SCI), up to 60% of individuals use a wheelchair as their primary mode of locomotion—leading to a chronic reduction in lower-extremity weight bearing and reduced mechanical loading [3]. As a result, these individuals experience an accelerated loss in lower-extremity bone mass, particularly if no mitigation strategies are implemented during the first 18 to 24 months following the SCI [4]. This complication, referred to as sublesional osteoporosis, is associated with an increased risk of fracture, notably at the distal femur and proximal tibia [5].

Bone strength is directly related to fracture risk and can be influenced by several characteristics, such as bone mineral density and content, as well as geometry [6]. Measuring areal bone mineral density by dual-energy x-ray absorptiometry (DEXA) remains widely recommended to assess fracture risk in this population [7]. Indeed, low areal bone mineral density has been associated with increased risks of lower-extremity fractures in individuals with SCI as well as in the general population [8]. However, solely relying on areal bone mineral density to assess bone strength may be misleading since DEXA images display 2D (ie, x- and y-axis) representations of 3D structures (ie, loss of the z-axis) [9]. DEXA condenses structures by superposing images, causing “deeper” bones to artificially appear denser (ie, increased bone mineral density) and may lead to misclassifying individuals with a lower risk of fracture [9]. As such, this limits the DEXA’s capability to inform on bone geometry (eg, cross-sectional areas and cortical thickness) [9,10]. Peripheral quantitative computed tomography (pQCT) aims to overcome this limitation by assessing volumetric bone mineral density based on 3D images [11]. Moreover, pQCT can provide additional advantages by analyzing both trabecular and cortical bone compartments separately (ie, bone geometry) and enable the estimation of mechanical properties of strength (ie, resistivity to compression, bending, and torsion).

Although imaging (DEXA and pQCT) can provide an instantaneous “snapshot” of estimated bone strength, it does not directly assess bone turnover (remodeling). Bone turnover rate can provide fundamental information as to whether bone formation or resorption is dominant at the time of measurement. Indeed, serum bone biomarkers (eg, osteocalcin and C-telopeptide) may serve as a precursor indication of a positive therapeutic effect of an intervention, even before changes can be measured with DEXA or pQCT. Osteocalcin is secreted by osteoblasts, is a marker of anabolic bone activity, and has been used in previous studies with individuals with SCI [12]. C-telopeptide, which has also been studied previously in this population, is released during bone resorption and used to characterize catabolic bone activity [13]. Since vitamin D levels can impact bone metabolism, 25-hydroxyvitamin D levels should also be measured as a possible confounding factor when characterizing serum bone biomarkers [7].

Recently, the emergence of wearable robotic exoskeletons has led to new opportunities to develop interventions that can significantly increase lower-extremity weight bearing and mobilization. Among others, a goal of such interventions is to increase bone strength and ultimately mitigate fracture risks (and associated complications) in individuals with SCI. Pilot studies have previously demonstrated that exoskeleton-assisted walking programs are feasible in this population with high rates of satisfaction (95.2%), excellent attendance (ie, 229 completed training sessions out of 234 planned training sessions, 97.9%), and relatively low dropout rates (ie, 1 dropout out of 14 individuals recruited, 7.1%) [14,15]. In terms of learnability and ease of use, most individuals can stand and walk with walking aids and minimal assistance from a therapist by the end of the program (18 to 24 sessions) [15,16]. Walking parameters, including speed and distance, have also been shown to progress consistently and safely over the course of a walking program, especially when individualized progression strategies are used [13,15-19]. Increased walking speed and distance may provide a progressive stimulus for bone strength adaptations, equating to increased intensity and volume for these tissues. Body composition improvements have also been documented following exoskeleton-assisted walking programs, including a decrease in total and regional (ie, lower extremities) body fat and an increase in muscle mass [20]. Overall, these results are encouraging; however, the effects on bone have not been comprehensively evaluated to date.
Thus, the main objective of this paper was to measure the potential effects of a 16-week exoskeleton-assisted walking program on lower-extremity bone density and strength and serum bone turnover markers in individuals with SCI who use a wheelchair [21]. It was hypothesized that immediate positive and meaningful effects would be observed on bone mineral density, mineral content, geometry, and mechanical strength indexes in the lower extremities as well as serum markers of bone turnover (ie, increase in bone formation markers and decrease in bone resorption markers) following the intervention.

Methods

Ethical Considerations

Ethics approval for this study was received on March 14, 2019, from the Centre for Interdisciplinary Research in Rehabilitation of Greater Montreal ethics committee (CRIR-1338-0518). The protocol has been published previously and was registered with the US National Library of Medicine on June 7, 2019 (ClinicalTrials.gov NCT03989752) [21].

Study Design and Participants

This prospective pre- and postinterventional study included adults (≥18 years of age) with chronic (ie, ≥18 months) complete or incomplete SCI. To be included, individuals needed to use a wheelchair as their primary mode of locomotion, understand French or English, and reside (or be able to arrange to reside) within 75 km of the main research site. Individuals were excluded if they had neurologically impairments unrelated to the SCI (eg, multiple sclerosis); had a concomitant or secondary musculoskeletal impairment limiting their ability to safely ambulate (eg, hip heterotopic ossification); had a history of fragility fracture within the past year; or had any other condition that may preclude safe lower-extremity weight bearing, walking, or exercise tolerance (eg, unstable cardiovascular or autonomic system and renal insufficiency). Individuals also had to meet criteria specific to the wearable robotic exoskeleton (Ekso GT; Ekso Bionics) used in this study, including maximum anthropometric measures and minimal lower- and upper-extremity range of motion. Inclusion and exclusion criteria are described in greater detail in the published (open access) protocol [21].

Measurement Times and Intervention

Due to constraints imposed by the COVID-19 pandemic (Multimedia Appendix 1), the 4 measurement times in the published protocol were not possible. Measurement times were only possible before the intervention (2 measurements) and immediately after the intervention (1 measurement). A participant’s preintervention measurements represented the average value between measurements taken before 4 weeks and immediately before initiating the intervention. Postintervention measurements were solely taken immediately following the end of the intervention (ie, within 7 days).

Following preintervention measurements, individuals engaged in a wearable robotic exoskeleton–assisted overground walking program consisting of 34 sessions (60 minutes per session) over a 16-week period. A published algorithm was used to individualize training volume and progression based on osteoporotic profile determined by DEXA [19]. Individuals were classified in 1 of 3 profiles: osteoporosis, osteopenia, or preserved bone mineral density. The number of steps taken per training session was then modulated, starting at 300, 400, and 500, and progressed weekly by 10%, 15%, and 20%, respectively, according to the assigned profile. For all profiles, individuals began with 1 training session per week and progressed to 3 training sessions per week by the end of the program. To maintain a moderate to vigorous exercise intensity during the sessions, walking speed, resting time, assistive devices (ie, walker or crutches), and assistance provided by the therapist were modulated to ensure a rate of perceived exertion of ≥3/10. All training sessions were supervised by a certified physiotherapist, with the help of a second physiotherapist or a physiotherapy technician if necessary.

The exoskeleton-assisted walking program was performed using the Ekso GT exoskeleton. This ready-to-wear exoskeleton has motorized hip and knee joints and semirigid ankle orthoses. Several sensors integrated into the exoskeleton (accelerometers, gyroscopes, pressure sensors, etc) are used to detect weight transfers and movements. Front and lateral spatial targets are used to guide weight transfer with an audible sound emitted when targets are reached. Step initiation depends on the walking mode used. In “FirstStep” mode, front and lateral spatial targets must be reached, followed by the press of a confirmation button by the therapist for stepping movements to be initiated. In “ProStep” mode, stepping is automatically initiated once front and lateral spatial targets are reached (no confirmation button is pressed). In “ProStep+” mode, the lateral spatial target must be reached (no front target is necessary), and the participant must initiate a hip flexion moment to activate stepping. Additionally, the exoskeleton also provides different levels of assistance, from partial (the participant must generate some lower extremity force, and the exoskeleton assists as required) to maximal (the participant does not generate lower extremity force, and the exoskeleton realizes all movements).

Outcomes

DEXA Measurement

Total body, lumbar, and left hip mineral density and content were measured using DEXA (General Electric Lunar Prodigy; standard mode; version 12.30.008). Calibration was executed daily with a standard phantom prior to each test. Participants were asked to fast for at least 8 hours prior to the assessment. Participants were also asked to empty their bladder if they had not done so within the hour preceding the DEXA. Scans were taken following the standardized protocol recommended by the manufacturer. For all scans, participants lay supine, free of jewelry or any other metallic objects. Clothing worn was noted, and participants were asked to wear the same clothing for repeated scans. For lumbar scans, participants’ lower extremities rested on a block to maintain a flexed-hip position and reduce lumbar lordosis, as recommended by the Centers for Disease Control and Prevention [22]. For hip scans, a triangular bracing device attached to the feet maintained the lower extremity in slight internal rotation, as recommended by the Centers for Disease Control and Prevention [22]. Quantitative analysis was provided automatically by the manufacturer’s software. Total

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JMIR Rehabil Assist Technol 2024 | vol. 11 | e53084 | p.5

(page number not for citation purposes)
body, L4 lumbar vertebrae, left arm, left leg, left total hip, and left femoral neck bone mineral densities and contents were selected as outcomes of interest. Total body measurements provided an estimate of the whole skeletal system. Lumbar vertebrae and left arm measurements provided comparators for lower extremity measurements, as changes were not expected to occur at these sites. Left leg measurements provided an estimate of the overall response of the lower extremities, which complemented the more specific pQCT measurements (described hereafter). Total hip and femoral neck sites provided a comparator with the broader osteoporosis literature, as these remain standard measurements for all populations with osteoporosis. When applicable, the left side of the body was selected to match with the pQCT scan sites.

**pQCT Measurement**

All pQCT imaging was realized on the left distal femur and proximal tibia. A standardized scan protocol was developed based on previous recommendations [11]. Calibration was executed daily with a standard phantom prior to each test. For all scans, a voxel size of 0.5x0.5 mm was used, and the scan speed was set to 10 mm/s to optimize resolution for bone and soft tissues. The total length was measured manually for the femur from the lateral femoral condyle to the greater trochanter [11]. To ensure location consistency for repeated scans, scout scans were realized at the knee joint with a reference line placed at the distal limit of the lateral femoral condyle. Following the scout scan, the pQCT was programmed to take one 2-mm slice at 25% of the total bone length calculated from the reference line. For the tibia, the total length was measured manually from the medial malleolus to the medial plateau [11]. To ensure location consistency for repeated scans, scout scans were realized at the knee joint with a reference line placed at the most distal and flattest portion of the tibial plateau. Following the scout scan, the pQCT was programmed to take one 2-mm slice at 66% of the total length calculated from the distal limit of the bone (using the reference line in this study, this equates to 33% from the knee joint). Both sites were selected to optimize for the presence of both bone and soft tissues in the scans.

Prior to quantitative analysis, the quality of all pQCT images was independently assessed by 2 evaluators (AB and MG or JTATL) using a previously published 5-level visual inspection and quality scale, where an image score of 1 indicated high quality and an image score of 5 represented low quality [23]. To further standardize the assessment of image quality, the following criteria were agreed upon between evaluators: score 1, if the image was free of movement artifacts; score 2, if the image was only a few movement artifacts; score 3, if the image had several movement artifacts, but periosteum continuity was not affected; score 4, if the image had several movement artifacts, and periosteum continuity was affected; and score 5, if the image had movement artifacts leading to complete loss of bone continuity. A mean score was calculated for each image. Scans with a mean score greater than 3 were excluded, as such quality of the image has been proposed to be incompatible with quantitative analysis software [23]. Excluded images were treated as missing data, and measurements were computed following an intention-to-treat protocol.

Quantitative analysis of pQCT scans was realized using the manufacturer’s software (Stratec XCT-3000; version 6.20). For all scans, contour mode 3 with a threshold set to 130 mg/cm³, peel mode 2 set to 400 mg/cm³, and separation mode 4 with an outer threshold of 200 mg/cm³ and an inner threshold of 650 mg/cm³ were used [11]. Outcomes of interest were those related to bone mineral density (total, trabecular, and cortical), bone mineral content (total, trabecular, and cortical), bone geometry (cross-sectional areas and cortical thickness), and mechanical strength indexes (bone strength index, stress-strain index, and polar moment of inertia) [7,11].

The software provides 2 measurements for cortical thickness. The first (CRT_THK), referred hereafter as measured cortical thickness, is the mean cortical thickness based on an iterative algorithm that attempts to draw the endosteal and periosteal borders by consecutively comparing neighboring voxels (pixels). Due to occasional failure of the algorithm, particularly in individuals with severe cortical thinning and loss of cortical bone mineral density (ie, many individuals with chronic SCI), the software also provides a second measurement. This measurement (CRT_THK_C), referred hereafter as estimated cortical thickness, is based on a subtraction of endosteal radius from periosteal radius in a theoretical circular model, where total and trabecular cross-sectional areas match those measured. Since measured cortical thickness systematically failed in 2 participants, estimated cortical thickness is also reported in this study.

Estimations of mechanical strength indexes are based on material properties and are calculated as follows. The bone strength index is the product of total bone mineral density squared by total cross-sectional area (ie, bone strength index = total bone mineral density² × total cross-sectional area) and is indicative of resistance to compression [10,24]. The stress-strain index (resistivity to bending) is based on the calculation of the cross-sectional moment of inertia (ie, area moment of inertia or second moment of area) [10,24]. The cross-sectional moment of inertia considers the distance of cortical bone from the central axis of the bone. The greater the distance separating cortical bone from the central axis, the greater the resistivity. To calculate the stress-strain index, section modulus (Z) is computed from the cross-sectional moment of inertia in the transversal plane. Section modulus is then weighted against measured cortical bone mineral density. Thus, resistance to bending is influenced by cortical size, shape, and mineral density [10,24]. Polar moment of inertia is based on the calculation of the cross-sectional moment of inertia in the longitudinal plane [10,24]. Thus, resistance to torsion is influenced by cortical size and shape but not mineral density [10,24]. The pQCT-related variables of interest and their cross-relationships are summarized in Figure 1.
Figure 1. Summary of, and relationships between, outcomes of interest for peripheral quantitative computed tomography.

**Bone mineral density**

Total bone mineral density = total bone mineral content / total cross-sectional area

Trabecular bone mineral density = trabecular bone mineral content / trabecular cross-sectional area

Cortical bone mineral density = cortical bone mineral content / cortical cross-sectional area

**Bone mineral content**

Total bone mineral content = total bone mineral density * total cross-sectional area

Trabecular bone mineral content = trabecular bone mineral density * trabecular cross-sectional area

Cortical bone mineral content = cortical bone mineral density * cortical cross-sectional area

**Bone geometry**

**Mechanical strength indexes**

Bone strength index (resistivity to compression) = (total bone mineral density)² * total cross-sectional area

Stress-strain index (resistivity to bending) = density-weighted section modulus (Z) and is influenced by cortical size and shape as well as cortical bone mineral density

Polar moment of inertia (resistivity to torsion) = cross-sectional moment of inertia in the perpendicular plane and is influenced by cortical size and shape but not cortical bone mineral density

**Blood Samples**

Blood samples were drawn in the morning, following an 8-hour fast, by a licensed nurse into gold-top serum separator and lavender-top anticoagulant ethylenediaminetetraacetic acid tubes. Samples were immediately placed on ice and centrifuged within an hour. Serum (from gold-top serum separator tubes) and plasma (from lavender-top anticoagulant ethylenediaminetetraacetic acid tubes) were collected and stored at −80 °C until analysis. Blood samples were transported on dry ice to a university hospital laboratory at the McGill University Health Centre for analysis after the completion of the study. Serum was used to measure 25-hydroxyvitamin D, and plasma was used to measure osteocalcin and C-telopeptide.

**Statistics**

Descriptive statistics were used to characterize participants. Since the sample size was limited and some outcome measures...
were not normally distributed, nonparametric tests (ie, Wilcoxon signed rank test) were used to compare pre- versus postintervention data. Standardized effect sizes ($r$) were calculated by dividing the $z$ value by the square root of the number of observations and interpreted as being negligible ($<0.1$), small ($≥0.1$), medium ($≥0.3$), or large ($≥0.5$) [25]. Relative pre- versus postintervention median variations (%) were also computed for all outcomes. Given the explorative nature of this study, three criteria needed to be met to reach significance and meaningfulness: (1) the $\alpha$ for statistical tests needed to be $<.10$ to balance the risk of false negatives due to an anticipated lack of statistical power, (2) calculated effect sizes needed to be large (ie, $≥0.5$) for an outcome to be deemed potentially clinically relevant, and (3) relative variation needed to be greater than 5% to be considered as a change exceeding natural variability and potential measurement errors. This threshold has been used in previous work, as the least significant change reportedly varies between 2% and 5% for DEXA and pQCT depending on the location of the scan [12,26]. All statistical analyses were conducted using SPSS (version 28; IBM Corp).

## Results

### Overview

Characteristics of the participants are summarized in Table 1. Among the 10 participants, only 1 had a very minimal motor function in the lower extremities (lower-extremity motor score: 5 out of 50), although it was not sufficient for active participation of the lower extremities during the exoskeleton-assisted walking program. Therefore, the exoskeleton was programmed to detect body weight shifts and realize stepping movements without active participation of the lower extremities (“ProStep” mode with maximal assistance in the exoskeleton) for all participants.

Table 1. Description of the participants (N=10).

<table>
<thead>
<tr>
<th>Participant ID</th>
<th>Sex</th>
<th>Age (y)</th>
<th>BMD profile a</th>
<th>Walking program progression</th>
<th>Neurological lesion level</th>
<th>AIS b</th>
<th>LEMS c</th>
<th>Exoskeleton mode (Ekso GT)</th>
<th>SCI d duration (y)</th>
<th>Weight (kg)</th>
<th>Height (m)</th>
<th>BMI (kg/m²)</th>
<th>Total body fat (%) e</th>
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<tbody>
<tr>
<td>1</td>
<td>Male</td>
<td>41</td>
<td>Preserved</td>
<td>Fast</td>
<td>T8</td>
<td>A 0</td>
<td>ProStep</td>
<td></td>
<td>9.6</td>
<td>66.7</td>
<td>1.71</td>
<td>22.8</td>
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<tr>
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<td>ProStep</td>
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<td>3</td>
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<td>Preserved</td>
<td>Fast</td>
<td>T10</td>
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<td>ProStep</td>
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<td>1.88</td>
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<td>Preserved</td>
<td>Fast</td>
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<td>A 0</td>
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<td>Preserved</td>
<td>Fast</td>
<td>C3</td>
<td>C 0</td>
<td>ProStep</td>
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<td>A 0</td>
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<td>ProStep</td>
<td></td>
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<td>1.86</td>
<td>23.5</td>
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<td>Mean (SD)</td>
<td>N/A f</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>12.8 (11.6)</td>
<td>74.9 (15.0)</td>
<td>1.70 (0.10)</td>
<td>24.4</td>
<td>38.5 (7.4)</td>
</tr>
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</table>

aBMD profile: preintervention bone mineral density profile of the left hip as measured by dual-energy x-ray absorptiometry (DEXA).
cLEMS: lower-extremity motor score on the AIS.
dSCI: spinal cord injury.
eTotal body fat percentage as measured by DEXA.
fIdentifies obesity using criteria recommended by Paralyzed Veterans of America (BMI 22 kg/m² or body fat >22% in men and >35% in women) [27].
fN/A: not applicable.

### DEXA Outcome Measures

Outcome measures for DEXA are summarized in Table 2. Only the left femoral neck bone mineral content met all 3 criteria with a $P=.08$, a large effect size (0.55), and a relative increase of 6% postintervention.
Table 2. Summary of dual-energy x-ray absorptiometry outcome measures (N=10).

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Preintervention, median (IQR)</th>
<th>Postintervention, median (IQR)</th>
<th>P value</th>
<th>Effect size&lt;sup&gt;a&lt;/sup&gt;</th>
<th>∆&lt;sup&gt;b&lt;/sup&gt; (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Areal bone mineral densities (g/cm&lt;sup&gt;2&lt;/sup&gt;)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total body bone mineral density</td>
<td>1.159 (1.060-1.277)</td>
<td>1.145 (1.082-1.267)</td>
<td>.80</td>
<td>0.08 (N)</td>
<td>−1.2</td>
</tr>
<tr>
<td>Left arm bone mineral density</td>
<td>1.046 (0.909-1.155)</td>
<td>1.073 (0.889-1.221)</td>
<td>.51</td>
<td>0.20 (S)</td>
<td>+2.6</td>
</tr>
<tr>
<td>Left leg bone mineral density</td>
<td>1.018 (0.613-0.898)</td>
<td>0.979 (0.442-0.902)</td>
<td>.45</td>
<td>0.24 (S)</td>
<td>−3.8</td>
</tr>
<tr>
<td>Left total hip bone mineral density</td>
<td>0.862 (0.756-0.992)</td>
<td>0.832 (0.755-0.989)</td>
<td>.68</td>
<td>0.13 (S)</td>
<td>−3.4</td>
</tr>
<tr>
<td>Left femoral neck bone mineral density</td>
<td>0.852 (0.765-0.992)</td>
<td>0.908 (0.770-0.947)</td>
<td>.11</td>
<td>0.50 (L)</td>
<td>+6.6</td>
</tr>
<tr>
<td>Bone mineral contents (g/cm)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total body bone mineral content</td>
<td>2759 (2377-3499)</td>
<td>2757 (2365-3466)</td>
<td>.33</td>
<td>0.31 (M)</td>
<td>−0.1</td>
</tr>
<tr>
<td>Left arm bone mineral content</td>
<td>188 (174-236)</td>
<td>202 (173-241)</td>
<td>.65</td>
<td>0.15 (S)</td>
<td>+7.3</td>
</tr>
<tr>
<td>Left leg bone mineral content</td>
<td>393 (300-510)</td>
<td>370 (312-528)</td>
<td>.80</td>
<td>0.08 (N)</td>
<td>−5.9</td>
</tr>
<tr>
<td>Left total hip bone mineral content</td>
<td>28.3 (20.8-34.9)</td>
<td>32.1 (20.2-36.7)</td>
<td>.39</td>
<td>0.27 (S)</td>
<td>+13.5</td>
</tr>
<tr>
<td>Left femoral neck bone mineral content&lt;sup&gt;c&lt;/sup&gt;</td>
<td>4.5 (3.5-6.0)</td>
<td>4.8 (3.6-5.9)</td>
<td>.05&lt;sup&gt;d&lt;/sup&gt;</td>
<td>0.55 (L)</td>
<td>+6</td>
</tr>
</tbody>
</table>

<sup>a</sup> Standardized effect sizes interpreted as N=negligible (<0.1), S=small (≥0.1), M=medium (≥0.3), or L=large (≥0.5).

<sup>b</sup> ∆=relative variation between medians (positive indicates an increase in value from pre- to postmeasurement).

<sup>c</sup> Italics format indicates variables meeting the following 3 criteria: statistically significant difference, effect size ≥0.5, and relative median difference ≥5%.

<sup>d</sup> Statistically significant difference (P≤.10) for Wilcoxon signed rank tests.

**pQCT Outcome Measures**

For the femur, outcome measures for pQCT are summarized in Table 3. Although 9 outcomes were statistically significant (P<.10), only 3 had large effect sizes and sufficient relative changes to be considered as intervention effects. Bone strength index (resistivity to compression; P=.09) and stress-strain index (resistivity to bending; P=.01) increased by 9.6% and 11%, respectively, whereas estimated cortical thickness (P=.01) decreased by 9.9%. Of note, scans at the femur were not possible for 1 participant (participant 10), as his weight and lack of core stability impeded his ability to safely take and maintain the crouched sitting position necessary to set up the femur into the pQCT.

For the tibia, outcome measures for pQCT are summarized in Table 4. Although 6 outcomes were statistically significant (P<.10), only 2 had large effect sizes and sufficient relative changes to be considered potential intervention effects. Cortical cross-sectional area (P=.06) and polar moment of inertia (P=.01) increased by 7.3% and 5.1%, respectively.
Table 3. Summary of peripheral quantitative computed tomography outcome measures at 25% of the left femur (n=9).

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Preintervention, median (IQR)</th>
<th>Postintervention, median (IQR)</th>
<th>P value</th>
<th>Effect size&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Δ&lt;sup&gt;b&lt;/sup&gt; (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volumetric bone mineral densities (mg/cm&lt;sup&gt;3&lt;/sup&gt;)&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total bone mineral density</td>
<td>355.8 (334.2-470.5)</td>
<td>381.6 (330.8-442.6)</td>
<td>.51</td>
<td>0.22 (S)</td>
<td>+7.3</td>
</tr>
<tr>
<td>Trabecular bone mineral density</td>
<td>87.7 (80.5-113.0)</td>
<td>88.5 (83.6-110.0)</td>
<td>.15</td>
<td>0.22 (S)</td>
<td>+1</td>
</tr>
<tr>
<td>Cortical bone mineral density</td>
<td>905.9 (805.0-968.1)</td>
<td>938.2 (871.5-981.6)</td>
<td>.04&lt;sup&gt;c&lt;/sup&gt;</td>
<td>0.69 (L)</td>
<td>+3.6</td>
</tr>
<tr>
<td>Bone mineral contents (mg/mm)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total bone mineral content</td>
<td>346 (275-434)</td>
<td>341 (266-429)</td>
<td>.05&lt;sup&gt;c&lt;/sup&gt;</td>
<td>0.65 (L)</td>
<td>−1.5</td>
</tr>
<tr>
<td>Trabecular bone mineral content</td>
<td>46.6 (37.9-76.7)</td>
<td>48.0 (39.1-78.4)</td>
<td>.95</td>
<td>0.02 (N)</td>
<td>+3</td>
</tr>
<tr>
<td>Cortical bone mineral content</td>
<td>275 (224-350)</td>
<td>268 (217-343)</td>
<td>.01&lt;sup&gt;c&lt;/sup&gt;</td>
<td>0.89 (L)</td>
<td>−2.5</td>
</tr>
<tr>
<td>Bone geometry</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total cross-sectional area (mm&lt;sup&gt;2&lt;/sup&gt;)</td>
<td>822 (736-1066)</td>
<td>805 (770-1023)</td>
<td>.14</td>
<td>0.49 (L)</td>
<td>−2</td>
</tr>
<tr>
<td>Trabecular cross-sectional area (mm&lt;sup&gt;2&lt;/sup&gt;)</td>
<td>489 (418-700)</td>
<td>472 (435-659)</td>
<td>.46</td>
<td>0.25 (S)</td>
<td>−3.4</td>
</tr>
<tr>
<td>Cortical cross-sectional area (mm&lt;sup&gt;2&lt;/sup&gt;)</td>
<td>312 (233-394)</td>
<td>305 (221-354)</td>
<td>.01&lt;sup&gt;c&lt;/sup&gt;</td>
<td>0.89 (L)</td>
<td>−2.4</td>
</tr>
<tr>
<td>Measured cortical thickness (mm)</td>
<td>4.03 (3.56-4.28)</td>
<td>3.88 (3.31-4.23)</td>
<td>.03&lt;sup&gt;c&lt;/sup&gt;</td>
<td>0.83 (L)</td>
<td>−3.6</td>
</tr>
<tr>
<td>Estimated cortical thickness (mm&lt;sup&gt;d&lt;/sup&gt;)</td>
<td>3.28 (2.89-3.44)</td>
<td>2.95 (2.95-3.35)</td>
<td>.01&lt;sup&gt;c&lt;/sup&gt;</td>
<td>0.85 (L)</td>
<td>−9.9</td>
</tr>
<tr>
<td>Mechanical strength indexes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Compression: bone strength index (g/cm&lt;sup&gt;4&lt;/sup&gt;)</td>
<td>1.35 (1.16-1.60)</td>
<td>1.48 (0.94-1.51)</td>
<td>.09&lt;sup&gt;c&lt;/sup&gt;</td>
<td>0.57 (L)</td>
<td>+9.6</td>
</tr>
<tr>
<td>Bending: stress-strain index (mm&lt;sup&gt;3&lt;/sup&gt;)</td>
<td>2240 (2047-2589)</td>
<td>2486 (2356-2706)</td>
<td>.01&lt;sup&gt;c&lt;/sup&gt;</td>
<td>0.89 (L)</td>
<td>+11</td>
</tr>
<tr>
<td>Torsion: polar moment of inertia (mm&lt;sup&gt;4&lt;/sup&gt;)</td>
<td>48,002 (43,337-72,759)</td>
<td>48,800 (42,470-71,304)</td>
<td>.02&lt;sup&gt;c&lt;/sup&gt;</td>
<td>0.77 (L)</td>
<td>+1.7</td>
</tr>
</tbody>
</table>

<sup>a</sup> Standardized effect sizes interpreted as N=negligible (<0.1), S=small (≥0.1), M=medium (≥0.3), or L=large (≥0.5).

<sup>b</sup> Δ=relative variation between medians (positive indicates an increase in value from pre- to postmeasurement).

<sup>c</sup> Statistically significant difference (P≤.10) for Wilcoxon signed rank tests.

<sup>d</sup> Italics format indicates variables meeting the following 3 criteria: statistically significant difference, effect size ≥0.5, and relative median difference ≥5%.
Table 4. Summary of peripheral quantitative computed tomography outcome measures at 66% of the left tibia (N=10).

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Preintervention, median (IQR)</th>
<th>Postintervention, median (IQR)</th>
<th>P value</th>
<th>Effect size&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Δ&lt;sup&gt;b&lt;/sup&gt; (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Volumetric bone mineral densities (mg/cm&lt;sup&gt;3&lt;/sup&gt;)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total bone mineral density</td>
<td>666.0 (571.1-772.6)</td>
<td>669.2 (554.0-772.4)</td>
<td>.06&lt;sup&gt;c&lt;/sup&gt;</td>
<td>0.60 (L)</td>
<td>+0.5</td>
</tr>
<tr>
<td>Trabecular bone mineral density</td>
<td>97.3 (86.0-105.9)</td>
<td>95.0 (81.3-109.5)</td>
<td>.14</td>
<td>0.47 (M)</td>
<td>−2.4</td>
</tr>
<tr>
<td>Cortical bone mineral density</td>
<td>984.9 (961.0-1007.9)</td>
<td>956.4 (898.2-1004.8)</td>
<td>.07&lt;sup&gt;c&lt;/sup&gt;</td>
<td>0.56 (L)</td>
<td>−2.9</td>
</tr>
<tr>
<td><strong>Bone mineral contents (mg/mm)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total bone mineral content</td>
<td>326 (288-425)</td>
<td>333 (292-427)</td>
<td>.14</td>
<td>0.47 (M)</td>
<td>+2.3</td>
</tr>
<tr>
<td>Trabecular bone mineral content</td>
<td>20.1 (12.5-24.5)</td>
<td>18.0 (13.1-24.4)</td>
<td>.88</td>
<td>0.05 (N)</td>
<td>−10.1</td>
</tr>
<tr>
<td>Cortical bone mineral content</td>
<td>283 (264-394)</td>
<td>288 (270-398)</td>
<td>.09&lt;sup&gt;c&lt;/sup&gt;</td>
<td>0.53 (L)</td>
<td>+1.9</td>
</tr>
<tr>
<td><strong>Bone geometry</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total cross-sectional area (mm&lt;sup&gt;2&lt;/sup&gt;)</td>
<td>602 (425-621)</td>
<td>610 (423-660)</td>
<td>.06&lt;sup&gt;c&lt;/sup&gt;</td>
<td>0.60 (L)</td>
<td>+1.4</td>
</tr>
<tr>
<td>Trabecular cross-sectional area (mm&lt;sup&gt;2&lt;/sup&gt;)</td>
<td>224 (124-274)</td>
<td>217 (124-295)</td>
<td>.34</td>
<td>0.50 (L)</td>
<td>−3</td>
</tr>
<tr>
<td>Cortical cross-sectional area (mm&lt;sup&gt;2&lt;/sup&gt;)</td>
<td>294 (267-388)</td>
<td>315 (273-420)</td>
<td>.06&lt;sup&gt;c&lt;/sup&gt;</td>
<td>0.60 (L)</td>
<td>+7.3</td>
</tr>
<tr>
<td>Measured cortical thickness (n=8; mm)</td>
<td>5.22 (4.74-5.67)</td>
<td>5.31 (4.86-5.53)</td>
<td>.12</td>
<td>0.54 (L)</td>
<td>+1.8</td>
</tr>
<tr>
<td>Estimated cortical thickness (mm)</td>
<td>4.80 (3.96-5.48)</td>
<td>4.70 (4.26-5.78)</td>
<td>.33</td>
<td>0.31 (M)</td>
<td>−2.1</td>
</tr>
<tr>
<td><strong>Mechanical strength indexes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Compression: bone strength index (g/cm&lt;sup&gt;3&lt;/sup&gt;)</td>
<td>2.06 (1.67-2.85)</td>
<td>2.03 (1.63-2.88)</td>
<td>.20</td>
<td>0.40 (M)</td>
<td>−1.5</td>
</tr>
<tr>
<td>Bending: stress-strain index (mm&lt;sup&gt;3&lt;/sup&gt;)</td>
<td>1838 (1346-2294)</td>
<td>1828 (1300-2250)</td>
<td>.58</td>
<td>0.18 (S)</td>
<td>−0.5</td>
</tr>
<tr>
<td>Torsion: polar moment of inertia (mm&lt;sup&gt;4&lt;/sup&gt;)</td>
<td>35,706 (23,560-47,987)</td>
<td>37,539 (23,638-49,806)</td>
<td>.01&lt;sup&gt;c&lt;/sup&gt;</td>
<td>0.79 (L)</td>
<td>+5.1</td>
</tr>
</tbody>
</table>

<sup>a</sup>Standardized effect sizes interpreted as N=negligible (<0.1), S=small (≥0.1), M=medium (≥0.3), or L=large (≥0.5).

<sup>b</sup>Δ=relative variation between medians (positive indicates an increase in value from pre- to postmeasurement).

<sup>c</sup>Statistically significant difference (P≤.10) for Wilcoxon signed rank tests.

<sup>d</sup>Italics format indicates variables meeting the following 3 criteria: statistically significant difference, effect size ≥0.5, and relative median difference ≥5%.

Serum Bone Turnover Biomarkers

Outcome measures for serum bone turnover biomarkers are summarized in Table 5. Only 25-hydroxyvitamin D met all 3 criteria with a P=.03, a large effect size, and a relative increase of 11.4% postintervention.

https://rehab.jmir.org/2024/1/e53084
Table 5. Summary of serum bone turnover biomarkers (N=10).

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Preintervention, median (IQR)</th>
<th>Postintervention, median (IQR)</th>
<th>P value</th>
<th>Effect size</th>
<th>Δ (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone formation (µg/L)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Osteocalcin</td>
<td>18.3 (15.6-19.4)</td>
<td>21.0 (15.3-24.0)</td>
<td>.20</td>
<td>0.69 (L)</td>
<td>+15.1</td>
</tr>
<tr>
<td>Bone resorption (µg/L)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C-telopeptide</td>
<td>0.3 (0.2-0.4)</td>
<td>0.3 (0.2-0.4)</td>
<td>.17</td>
<td>0.43 (M)</td>
<td>−13.8</td>
</tr>
<tr>
<td>Others (nmol/L)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25-Hydroxyvitamin D³</td>
<td>74.5 (62.4-111)</td>
<td>83.0 (66.3-129)</td>
<td>.03</td>
<td>0.69 (L)</td>
<td>+11.4</td>
</tr>
</tbody>
</table>

aStandardized effect sizes interpreted as N=negligible (<0.1), S=small (≥0.1), M=medium (≥0.3), or L=large (≥0.5).
bΔ=relative variation between medians (positive indicates an increase in value from pre- to postmeasurement).
cItalics format indicates variables meeting the following 3 criteria: statistically significant difference, effect size ≥0.5, and relative median difference ≥5%.
dStatistically significant difference (P≤.10) for Wilcoxon signed rank tests.

Discussion

Principal Findings

Results of this preliminary study indicate that the completion of a progressive 16-week exoskeleton-assisted walking program may elicit some beneficial bone adaptations in individuals with chronic SCI who have limited-to-no motor function in their lower extremities and use a manual wheelchair as their primary mode of locomotion.

DEXA Revealed an Increase in Left Femoral Neck Bone Mineral Content, but No Changes in Bone Mineral Densities

Left femoral neck bone mineral content increased significantly and meaningfully following the intervention which is, to our knowledge, a novel and key finding partly supporting our hypotheses. Moreover, a similar trend (ie, P=.11) was also observed in left femoral neck bone mineral density (ie, +6.6% with a large effect size). Indeed, since bone mineral content and density are directly related (ie, bone mineral density = bone mineral content / area), it would be expected for both to change together. Directly comparing our results to the literature remains difficult due to the lack of previously published evidence. This is particularly true with regard to bone mineral content, as this outcome has not been reported in the limited available literature with regard to exoskeleton-assisted overground walking and treadmill-based interventions [12,20,28-32].

Nevertheless, with regard to exoskeleton-assisted overground walking, a pilot study conducted in our laboratory did not reveal any significant changes in total body and total leg areal bone mineral densities, which is consistent with this study [20]. To our knowledge, only 2 other studies have reported areal bone mineral density measurements following exoskeleton-assisted overground walking. First, in a pilot study, an upward trend in areal bone mineral density was reported following 8 weeks of training (1 hour per session, 2 sessions per week). However, the authors neither specify in what body region this occurred nor present data to support this claim [28]. Second, in a pilot randomized controlled trial, including 16 participants with SCI (≥2 years) who use a wheelchair, areal bone mineral density (total hip and femoral neck) decreased in the activity-based exercise training group (60 minutes per session, 3 sessions per week for 24 weeks), whereas it remained stable in the exoskeleton-assisted walking group (60 minutes per session, 3 sessions per week for 24 weeks). It was hypothesized that exoskeleton-assisted walking may provide a sufficient stimulus to maintain areal bone mineral density but perhaps not to augment it [29]. Since this study did not include a comparison group, it remains unclear whether the areal bone mineral densities measured in our participants would have decreased further over the course of the study had they not participated in the walking program. However, all participants in this study sustained their SCI at least 3 years before initiating the study and were deemed to have reached a stable state in terms of bone mineral density. To this effect, it is now well evidenced that bone loss is greatest within the first 18 to 24 months following the lesion and tends to slow considerably thereafter [4]. Although a true steady state in bone mass may never be reached, it would be premature to state that the intervention in this study had a protective effect on areal bone mineral density [33]. Such a hypothesis would be best tested by recruiting participants who recently sustained their SCI (ie, no more than 2 years prior) and including a comparison group.

The effects of treadmill-based walking programs have also been reported in the literature using robotic assistance (eg, Lokomat; Hocoma), functional electrical stimulation, or manual assistance [12,30,31]. To our knowledge, no study has reported bone mineral content, and no changes in areal bone mineral density have been previously found [12,30-32]. Since these programs imply the use of partial body weight support, the gravity-related mechanical effects decreased considerably in comparison to overground walking, which may impede the effectiveness of such programs. This is further highlighted by the fact that treadmill-based walking programs have also been tested in combination with pharmacotherapy (ie, teriparatide) and functional electrical stimulation, which should have optimized the potential effects on bone [12,30].

Overall, this study suggests that exoskeleton-assisted overground walking may elicit a beneficial bone response at the hip that can be detected by DEXA. A combination of pharmacotherapy...
Potential Improvements in Bone Strength as Measured by pQCT

A few pQCT outcomes changed significantly and meaningfully following the completion of the intervention. This result supports our hypotheses in part. Four such outcomes increased, suggesting positive bone strength adaptations: femoral bone strength index (compression), femoral stress-strain index (bending), tibial cortical cross-sectional area, and tibial polar moment of inertia (torsion).

With regard to the femur, to our knowledge, the increase in bone strength index is a novel finding [12,20,30-32,34]. However, an increase in stress-strain index has been previously reported in a case study following robotic-assisted treadmill training [34]. Yet, the amplitude of change reported in this previous case study (right femur=+2% and left femur=+0.5%) was much lower than in this study (ie, +11%), and may not have exceeded natural variability or measurement error. Nevertheless, these findings highlight the importance of including both femoral and tibial measurements with pQCT in this population. Since bone is expected to respond in areas of greatest mechanical strain, certain biomechanical concepts may help partially explain the results in this study [33]. First, although the increase in bone strength index would be expected with increased weight-bearing, the design of the exoskeleton may also contribute to greater compression forces at the femur during heel strike. Indeed, the exoskeleton used in this study uses a brace at the proximal tibia, just below the knee, to counteract the forward velocity of the lower limb (and body) during heel strike. Since the individuals in this study had very little-to-no motoricity in the lower limbs, this forward velocity could not be absorbed to the same extent by musculotendinous structures (ie, through eccentric contraction of the quadriceps) and would therefore be mainly absorbed by the skeletal (ie, femur) and ligamentous structures [35]. Second, due to the oblique orientation of the femoral diaphysis, it is possible that the forces with heel strike and unilateral stance during walking provide greater strain (ie, bending force) to the femur than the tibia, which may have also contributed to the results in this study [36]. Overall, these hypotheses warrant further investigation.

With regard to the tibia, changes in cortical cross-sectional area and polar moment of inertia have been previously reported in 2 treadmill-based interventions [12,34]. However, the relatively small amplitudes of change in these previous studies (ie, −1 to +1.4%) raise questions as to whether these changes can be attributed to more than natural measurement error. In fact, in one of these studies, comparisons with a control group yielded no significant difference for polar moment of inertia (cortical cross-sectional area was not reported in this study) [12]. Interestingly, we have previously hypothesized that the design of current exoskeletons may limit the automatic external rotation of the tibia on the femur (and consequently, the foot) during knee extension [37]. This may have led to increased torsion moments in the tibia, which would not occur during treadmill walking without robotic assistance (ie, knee extension in an open kinetic chain)—and could partially explain the difference in amplitude of change between studies.

Uncertainties Remain Regarding pQCT Outcomes

The fact that the estimated femoral cortical thickness decreased (−9.9%) in this study, which does not align with our hypotheses, could raise concerns regarding the possible negative effects of the walking program on bone strength. Indeed, cortical bone is largely believed to be the primary source of resistance and strength for long bones, such as the femur and tibia [9,10]. To our knowledge, these results have not been previously reported in the femur. In 1 treadmill-based trial, a statistically significant reduction of cortical thickness was reported in the tibia [12]. However, this reduction only occurred 8 months following the completion of the training program and was not statistically different than that of the control group [12]. Of interest, a statistically significant reduction in cortical cross-sectional area was also observed in this study, which most likely is explained by natural variability or measurement error, considering the relatively small magnitude of change (−2.4%). Moreover, when compared to men without SCI, individuals with SCI show reductions in cortical cross-sectional area of approximately 34% [38]. Thus, the clinical significance of a 2.4% reduction in this parameter remains questionable. Nevertheless, reductions in cortical thickness and cross-sectional area may suggest that the analysis software assigned a larger proportion of bone as subcortical (identified in yellow in Figure 1), which could be related to changes in density (ie, increased porosity) at the endosteal border due to bone resorption. This possibility cannot be completely excluded from the results of this study, particularly when considering the small sample size and the limited statistical power. Future studies should pay special attention to the possible negative effects on cortical thickness and cross-sectional area at the femur.

Serum Biomarkers Were Not Able to Contextualize pQCT Findings, but an Unexpected Increase in Levels of Serum Vitamin D Occurred

Serum osteocalcin (bone formation) and C-telopeptide (bone resorption) did not change significantly between before and after the intervention. This provides further evidence with regard to the complexity of the interpretation of the pQCT findings, as it is not immediately obvious whether increased bone formation or resorption was occurring following the intervention. These results were not anticipated, as 4 months of treadmill walking combined with functional electrical stimulation has been shown to significantly increase osteocalcin (+6.4%) and reduce C-telopeptide (−7.7%) levels in individuals with chronic SCI [12]. The variations found in this study (ie, osteocalcin=+15.1% and C-telopeptide=−13.8%) present trends of similar direction and of greater amplitude when compared to those previously reported, although the statistical threshold was not reached.

Serum vitamin D (25-hydroxyvitamin D) increased significantly and meaningfully by 11.4% during the intervention. Although higher vitamin D levels have been associated with greater levels of physical activity, this is generally attributed to increased time exposed to the sun in more active individuals [39]. In this study,
all participants were educated regarding vitamin D supplementation recommendations by Osteoporosis Canada [40]. Participants who were not already taking vitamin D (4/10) were offered 1 year’s worth of oral supplementation. Only 1 participant began taking vitamin D supplementation during the 4-week period before initiating training. However, even when removing this participant, the data remained statistically significant (P = .05). A possible explanation for this finding is the fact that most training sessions were delivered during the transition from winter to summer months. It is well recognized that vitamin D levels tend to be lower during winter months in northern countries such as Canada, as individuals spend more time indoors [41]. Thus, it is possible that the timing of the study coincided with an expected increase in vitamin D levels seen in the general population during the transition from winter to summer [41]. Nevertheless, serum 25-hydroxyvitamin D levels remained within optimal ranges (ie, ≥75 nmol/L) throughout the duration of the study [42]. As such, bone turnover and metabolism are not expected to have been significantly affected. Moreover, vitamin D supplementation, on its own, has not been shown to effectively increase bone mineral density [43]. Therefore, it is not expected that the variations in bone markers in this study can be attributed to the measured changes in serum 25-hydroxyvitamin D levels.

Limitations and Future Perspectives

This study has limitations that warrant consideration when interpreting its results. First, the sample size was smaller than that initially planned due to numerous challenges associated with the COVID-19 pandemic. Consequently, this reduced statistical power and increased the chance of potential type 2 errors (ie, false negatives). Moreover, the relatively small sample size impeded the possibility of conducting additional subgroup analysis. For example, it was not possible to compare participants according to clinical characteristics (eg, gender, osteoporotic status, obesity status, and response to intervention). Unfortunately, this limits progress toward a more personalized approach for the proposed intervention. Second, the absence of bone mineral density–based inclusion or exclusion criteria led to the recruitment of 5 participants (50% of the sample size) with “preserved” bone mineral density. Hence, these participants were inherently less inclined to benefit from the walking program in terms of bone health. Third, this study did not have specific inclusion or exclusion criteria for concomitant bone health treatments. However, a complete list of medications was taken for each participant, and they were instructed to inform the research team if any changes in medications occurred during the project. Of note, none of the participants were receiving antiosteoporosis agents at the time of the study. Participants were also asked to maintain their physical activity levels during the duration of the study, including their regular exercise regime. Fourth, this study did not have a control group, as such, results should be interpreted with caution as it is unknown to what extent the absence of (or relatively small) changes measured would differ from natural variability in time. Finally, the intensity and duration of the intervention may have been insufficient. Bone resorption typically lasts 30 to 40 days, whereas bone formation frequently requires an additional 150 days, for a total bone turnover cycle requiring up to 6 months [10]. Therefore, it is plausible that clinically significant changes in bone strength could take up to 6 months, indicating that the 4-month measurement period in this study may not have been sufficient. For instance, interventions of 6 or more months, with stationary cycling assisted by functional electrical stimulation, have measured positive effects on bone mass, whereas shorter interventions have not [44-50]. Moreover, despite being initially planned, no follow-up assessments were authorized due to the COVID-19 pandemic, and the beneficial changes that may have emerged later in relation to the temporality of bone adaptation were not captured.

Future research should focus on larger sample sizes, with a particular interest on individuals most likely to benefit from the intervention (ie, individuals with reduced bone mass). From a pragmatic perspective, large multicentric trials will be most likely required to have a sufficient sample size to detect a 5% change in femoral bone mineral density (pQCT) and compensate for large natural heterogeneity in this population. In fact, using the data in this study, this most likely entails the recruitment of roughly 200 participants based on Lehr equation (n=8σ²/δ²). Interventions should be of sufficient volume (ie, at least 3 times per week), possibly of greater intensity, and of medium- to long-term durations (ie, at least 6 months) to ensure adequate stimulus and time for complete bone turnover cycles. Follow-up assessments, after the completion of the intervention, are also warranted to assess possible latent adaptations. The addition of a control group also remains relevant to compensate for natural variability and measurement error related to bone imaging and serum sampling. Finally, combining pharmacological interventions (eg, teriparatide) or functional electrical stimulation or both with overground exoskeleton–assisted walking may also warrant consideration.

Conclusions

The results from this paper confirm that a 16-week exoskeleton-assisted walking program may elicit bone adaptations. On one hand, significant and meaningful increases were documented via DEXA and pQCT at both the femur (ie, femoral neck bone mineral content, bone strength index, and stress-strain index) and tibia (ie, cortical cross-sectional area and polar moment of inertia). On the other hand, possible significant and meaningful decreases (ie, femoral cortical thickness) raise concerns. Although positive bone adaptations are emerging, it remains unclear whether completing a 16-week exoskeleton-assisted walking program increases bone strength in individuals with chronic SCI. The need for stronger evidence warrants additional research with larger sample sizes that focus on longer interventions (possibly of greater loading intensity), and combining modalities should be considered (eg, pharmacotherapy or functional electrical stimulation). To do so, national or international collaborations will most likely be required.
Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Project timeline and effects of the COVID-19 pandemic.

References


Abbreviations
- **DEXA**: dual-energy x-ray absorptiometry
- **pQCT**: peripheral quantitative computed tomography
- **SCI**: spinal cord injury
Potential Effects of an Exoskeleton-Assisted Overground Walking Program for Individuals With Spinal Cord Injury Who Uses a Wheelchair on Imaging and Serum Markers of Bone Strength: Pre-Post Study

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Consumer Perceptions of Home-Based Percussive Massage Therapy for Musculoskeletal Concerns: Inductive Thematic Qualitative Analysis

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Abstract

Background: Musculoskeletal pain is a prevalent concern among diverse populations, from the average individual to the elite athlete. Handheld percussive massage therapy devices like massage guns have gained much popularity in both medical and athletic settings. Its application has been prominently recognized in injury prevention and rehabilitation. The expansion of the market to provide handheld percussive therapy devices with varying features and price points has encouraged professional and novice use. While percussive therapy holds similarities to more studied therapeutic modalities, like vibration therapy and soft tissue mobilization, there is limited evidence-based information on the indications and contraindications.

Objective: This study aims to use a qualitative analysis of consumer perceptions to understand the perceived therapeutic potential of percussive massage therapy as a home-based intervention for musculoskeletal concerns of everyday users and elite athletes. Additionally, we aim to gain insight on valuable characteristics supporting its therapeutic potential as well as pertinent limitations.

Methods: The TOLOCO massage gun (TOLOCO) was identified as the best-selling percussive massage therapy device on Amazon. We performed an inductive thematic qualitative analysis on the top 100 positive comments and the top 100 critical comments of the device between June 2020 and April 2023 to determine 4 relevant themes.

Results: The 4 themes identified upon qualitative analysis were pain management, versatility, accessibility, and safety and user education. Consumer reviews indicated use for this percussive therapy device in adolescents, adults, and older people across a spectrum of activity levels. Consumers reported the therapeutic potential of percussive massage therapy in managing wide-ranging musculoskeletal concerns like acute pain, chronic pain, nonsurgical injury rehabilitation, postsurgical injury rehabilitation, and injury prevention. Consumers highlighted the versatility of the device to address person-specific needs as a key feature in supporting its perceived therapeutic benefits. Additionally, consumers frequently commented on the affordability and availability of this device to increase accessibility to home-based care. Some critical reviews emphasized a concern for the quality of the device itself. However, this concern did not translate to the overall modality of percussive massage therapy. Of note, despite strong approval for its therapeutic potential, consumer reviews lacked evidence-based insights on appropriate usage.

Conclusions: Home-based percussive massage therapy holds value with its perceived efficacy in pain management for acute and chronic conditions, as well as in injury prevention and rehabilitation. As a low-cost and readily available device for everyday users and high-performing athletes, percussive massage therapy works toward establishing increased health care accessibility and optimizing health care usage. This home-based intervention can serve to reduce the significant personal and economic burden of prevalent musculoskeletal concerns. However, the limited scientific research on percussive massage therapy raises concerns about the lack of evidence-based care and indicates the need for future studies.

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KEYWORDS
home-based therapy; injury prevention; massage guns; musculoskeletal pain; pain management; percussive massage therapy; rehabilitation; self-management; sports medicine

Introduction
Musculoskeletal pain can significantly impact the physical and mental well-being of a wide range of individuals [1,2]. Not only that, but musculoskeletal pain has also been shown to increase the economic burden on both the individual and the health care system [3-5]. Thus, handheld percussive massage therapy has continued to gain popularity for its application in musculoskeletal pain, injury prevention, and recovery in both the medical and athletic realms. The use of this therapeutic mechanism transitioned beyond the office setting to home due to a vast array of manufacturing companies like Therabody and Hyperice. Now, Amazon’s platform offers a wide variety of percussion massage therapy devices with different features and price points. In increasing accessibility to percussion massage therapy, Amazon opens the market for professional and novice use.

Percussive therapy is said to have originated in the mid-20th century by Robert Fulford and involves the delivery of high-velocity and low-amplitude oscillating forces to the body [6]. It is proposed to be a notable method of myofascial release [7]. The myofascial system works by distributing tension across a network of connective tissue covering muscles, bones, and organs [8,9]. Due to the continuity of this system, tissue overload or repetitive strain injuries in one region of the body can create dysfunctional biomechanics, impairments in functional movement patterns, and referred tension in other regions of the body [8]. In acting as a myofascial release modality, percussion massage therapy can potentially serve to renew the fascial tissues and manage their restrictive distortions.

Percussive therapy is suggested to incorporate components of more well-studied therapy modalities like vibration therapy and conventional massage [10]. Vibration therapy is said to elicit its therapeutic impact on muscle fibers and proprioception, with health outcomes demonstrating improvements in elasticity, mobility, lymphatic and blood circulation, and swelling [11]. Soft tissue, a common modality of conventional massage, has shown similar health benefits with regard to improvements in circulation, range of motion, and muscle relaxation [12,13]. Its suggested mechanism of action involves reducing friction between fascial layers, improving muscle fiber patterns, and reducing the build up of abnormal hyaluronic acid molecules in implicated regions [13]. In combining these approaches, percussive therapy has been postulated to promote biomechanical and molecular functioning by improving circulation and lymphatic flow, increasing range of motion, and reducing pain perception and adhesions [8,10]. There are limitations present in detailing the physiological mechanism of percussive therapy itself, given the lack of current evidence-based research.

Today, percussive massage therapy is widely used and has the capacity to mimic conventional therapeutic approaches by serving as a possible self-myofascial release modality. This paper primarily aims to analyze consumer perceptions of the massage gun, a well-known percussive massage therapy modality, in order to gain further insight on its therapeutic potential as a home-based intervention for musculoskeletal concerns of both the everyday user and high-performing athletes. Additionally, this paper seeks to gather information on valued characteristics that support its therapeutic potential as well as pertinent limitations that comment on its necessity for improvement.

Methods

Study Design
This study used an inductive thematic qualitative analysis to explore consumer perceptions of the therapeutic potential and limitations of home-based percussion massage therapy. Qualitative analysis has been deemed a suitable methodology for drawing insights and perspectives from the human experience [14,15]. The authors used an inductive thematic framework to derive data-driven insights and perspectives on this topic without predetermined input [16].

Data Source
Through Amazon’s search engine, the TOLOCO massage gun was identified as the best-selling handheld massage gun on Amazon. Given the consumer trend toward web-based shopping platforms in combination with Amazon’s diverse market and large influence in e-commerce, the authors found Amazon to be an appropriate data source for consumer reviews [17-19]. The authors performed a qualitative analysis on consumer reviews of this device between June 2020 and April 2023 to interpret consumer perceptions of home-based percussion massage therapy [17,19,20].

Data Collection
The inclusion criteria for this qualitative analysis required the consumer review to be a verified purchase by Amazon, fall between the June 2020 and April 2023 time frame, and include a written review alongside its rating. The authors applied the indicated inclusion criteria to 35,985 total ratings and 7516 verified purchase consumer reviews. The top 100 positive and top 100 critical comments of this subset were used for analysis [17,19,20]. Positive and critical categories were predetermined by Amazon itself. A total of 4 positive consumer comments were discarded as the content was categorized incorrectly or lacked a formal review. Additionally, 2 critical comments were discarded as the content was categorized incorrectly or was incomprehensible. Reviews written in languages apart from English were translated through Amazon’s translate feature. Data was stored on a cloud-based platform. All information was deidentified before data storage and use. Consumer reviews were left unedited for authenticity.
Data Analysis
An inductive thematic qualitative analysis was performed on consumer reviews of the TOLOCO massage gun on Amazon. On initial analysis of consumer reviews, the authors manually developed a codebook based on pertinent key points and common patterns [16]. Some code examples included: “muscle recovery,” “postsurgical care,” “accessories,” “multiple modes,” “price point,” “self-therapy,” “user manual,” “battery defect,” and “longevity.” After the development of this initial codebook, a secondary analysis was conducted to ensure appropriate coding adjustments for all transcripts. The final codebook consisted of a total of 40 codes. After completion of coding, an analysis was carried out on the codebook itself in order to derive 4 distinct themes of percussive massage therapy. Subthemes of the 4 overarching themes were also generated. For example, the theme “accessibility” included subthemes of “affordability” and “availability.” The authors performed a third review of consumer transcripts and applied the relevant identified themes and subthemes to each [15]. Quotes that were found to best represent each theme and subtheme were used to better illustrate consumer perceptions of percussive massage therapy.

Ethical Considerations
The data for this qualitative analysis were gathered from publicly available information. Thus, this research was deemed exempt from the University of California, Los Angeles institutional review board. This study does not qualify as human subjects research and therefore does not require further informed consent or compensation. All public data were deidentified before use. Generative artificial intelligence was not used in the context of this paper.

Results
Findings
The TOLOCO massage gun had a 4.5-star rating with 35,985 total ratings and 7516 verified purchase consumer reviews. Of those 7516 reviews, there were 5936 positive reviews and 1580 critical reviews. In analyzing the top 100 positive reviews and the top 100 critical reviews, 4 pertinent themes were identified: pain management, accessibility, versatility, and safety and user education. Consumer demographics such as age, gender, and location were not readily available unless specified within the consumer review itself.

Theme 1: Pain Management
Pain management was one of the most common positive indications for this device based on consumer reviews, with 51 positive comments discussing some form of therapeutic purpose. Under pain management, consumer reviews suggested the handheld percussive therapy device be adapted to a diversity of patient circumstances, including daily pain, chronic pain, nonsurgical injury management, postsurgical injury management, and injury prevention. Table 1 details information derived from both positive and critical reviews for each category encompassing pain management.

<table>
<thead>
<tr>
<th>Type of pain</th>
<th>Consumer perceptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute aches and pains</td>
<td>I can’t wait for my next Charley horse calf spasm. I am going to jab this gun at max setting into that contacting calf muscle and turn it into tenderized sirloin. Also works well at blasting away muscle knots and tensions in my trapezius area. I am a side sleeper, spend long hours at desk and driving which causes problems. This blasts away deep tissue knots and tension away. I sleep better and wake up with greater range of motion.</td>
</tr>
<tr>
<td>Chronic pain</td>
<td>I used to be a black diamond skier in my youth, and unfortunately, all those young and reckless checks that I wrote when I was younger are being cashed now. I wish I had a time machine so I could go back and tell that idiot how much arthritis I would have when I got older because of the crazy stunts I pulled. Anyway, to wrap things up I absolutely 100 percent strongly recommend these percussion guns to help with all kinds of aches and pains.</td>
</tr>
<tr>
<td>Nonsurgical injury rehabilitation</td>
<td>I have been seeing massage therapists for several months to work on a strained muscle and my T-band and a tight psoas muscle. She used this device to help break up the huge knot in my leg that she and another therapist have been working on for several months. This massage gun did the trick! So, I bought one to have at home as I gently start exercising my leg muscles again.</td>
</tr>
<tr>
<td>Postsurgical injury rehabilitation</td>
<td>Just had a hip replacement and the muscles in my leg and hip knotted up. Got this bad boy and wacked my leg and hip till I couldn’t stand it anymore 3 days later it was gone.</td>
</tr>
<tr>
<td>Injury prevention</td>
<td>I’m training for a 10K and I know my legs are going to be sore and I’m excited to have this to help manage that over the next few months.</td>
</tr>
</tbody>
</table>

Table 1. Consumer perceptions of percussive massage therapy in pain management.

Some consumers mentioned being introduced to this percussive therapy device by health care providers. This prompted consumers to conduct their own research to identify the appropriate at-home percussive therapy device to best meet their health needs. One positive review stated:

A couple of months ago, I didn’t even know massage guns existed. Enter a physical therapist who used one of these on my leg during a session. I was so impressed by how much it helped that I started doing some research and found this gun.

In analyzing the top 100 critical reviews, 17 commented on the product’s capacity to contribute beneficially toward their pain management regimen. A total of 10 consumers felt dissatisfied with the product’s pain management capabilities. Despite the number of critical reviews analyzed, only 1 indicated that percussive massage therapy devices were overall not the best product for them. In critical reviews, common input suggested this particular device was either lacking in intensity or too powerful—issues that might be mitigated by more cushioned attachments, improved quality, or a similar device by a different manufacturer.

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Theme 2: Versatility
Versatility was the second-most commonly discussed key feature of the TOLOCO massage gun. Consumers discussed its various applications supported by the 15 attachment heads and speed adjustability. These various attachments allow for targeted massage of different muscle groups. Both the speed adjustability and the many attachments gave consumers the opportunity to personalize their user experience. Not only that, but consumer experiences also highlighted how the versatility of this percussive therapy device reaches varying populations, age groups, and person-specific needs. For instance, a consumer discussed its benefits for different needs in their own household:

"We have a household full of athletes, and the gun proved invaluable in losing up knots and returning blood flow to aching muscles. Our daughter (a dancer), used in two to three times a week, and I would use it after 4+ hour rides (bicycling)."

Overall, consumers appeared to agree that the versatility of this device contributed to its therapeutic potential.

Theme 3: Accessibility
Of the top 100 positive reviews, 29 consumers discussed accessibility as a key feature of this handheld percussive therapy device. Accessibility was referenced when consumer reviews discussed aspects of either affordability or availability. Regarding affordability, a consumer commented:

"I was recommended by my physiotherapist to use a percussion massage gun to loosen up my calves and shoulders, but I couldn’t justify paying $300 or more for a Theragun."

Another consumer even compared this budget-friendly model to those seemingly more expensive and stated:

"I have the Theragun mini and this gun outperforms the Theragun big time. Waaaay quieter, feels smoother, the attachments are game changing. I was nervous due to the low price, but so far it’s been light years better than my Theragun and light years cheaper."

While not all consumers agreed with this statement, most positive reviews suggested it to be a quality product for its price point.

Most critical reviews commented on the longevity of the device, with consumers stating that they experienced battery or internal defects resulting in product malfunction. In this case, some consumers indicated that they opted for a product replacement as they found percussive therapy to be a cost-effective and ideal method of managing musculoskeletal pain. For instance, a consumer stated:

"After a couple weeks it started making a high-pitched humming sound. Amazon was fantastic about sending me a replacement very quickly. It’s too bad because these are priced very well, and they seem to be built well."

Other consumers returned the device because they found the overall quality to be a point of concern.

Theme 4: Safety and User Education
The final identified theme upon qualitative analysis was safety and user education. While not a direct component of the therapeutic potential and limitations of the device, it is a notable mention to establish better practices for its use. This comprised guidance from both the manufacturer and other consumers as well as established safety features. Consumer recommendations were based on personal knowledge, experiences, or errors, as demonstrated in Table 2. However, no consumer reviews commented on the use of direct evidence-based guidelines to facilitate usage of this device.

<table>
<thead>
<tr>
<th>Consumer experience</th>
<th>Consumer recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personal knowledge</td>
<td>I would advise doing some due diligence and research to make sure you get the right model and brand for you that suits your needs. I also recommend starting slow, with shorter sessions so you don’t overdo it. Muscles can release some chemicals (lactic and Uric acid) during massage and if they aren’t used to these it could make you a little sore at first. It’s like going to a chiropractor. At first it can feel worse, then it feels better. Same kind of thing here but it can be mitigated with a slower titration of time spent daily on massage.</td>
</tr>
<tr>
<td>User experience</td>
<td>Caution is in order when working around thin muscle tissue near bone and joints, since the 12 mm travel distance of the TOLOCO Massage Gun can cause discomfort quickly if there is insufficient tissue depth to lessen the impact on hard structures.</td>
</tr>
<tr>
<td>User error</td>
<td>It would not charge but I finally figured out that I grabbed the wrong charger. So user error, it is still working great now.</td>
</tr>
</tbody>
</table>

Consumer reviews indicated the product manufacturer established safety components, including a user manual and an automatic shutdown feature. Consumers found the user manual to assist in appropriate and optimal product usage by indicating detailed information on how to use the device and its fifteen attachments. The automatic shutdown feature of the TOLOCO massage gun turned off the device after 10 minutes of use to protect both users and the device. A consumer commented:

Speaking of the 10-minute limit, both devices recommend limiting your sessions to 10 minutes at each sitting. This is partly due to physiological reasons and to prevent you from overworking your muscles. But also, you need to give the motor on these kinds of devices some rest to prevent overheating. The Toloco has an auto-shut off function that turns the device off after 10 minutes of continuous use. I appreciate this feature as it protects my device.
In critical reviews, however, a consumer noted their frustration with the 10-minute automatic shutdown feature and stated:

*The biggest thing about it that bugs me is that it shuts off every 10 mins or so and requires me to turn it back on again. This shouldn’t be a problem for people using it less than that, but I use it for an hour at a time and it gets really annoying having to turn it on over and over again.*

**Discussion**

**Overview**

This qualitative analysis of consumer perceptions of the TOLOCO massage gun on Amazon commented on the generalized therapeutic potential of handheld percussive massage therapy. While this paper focused on an individual percussive therapy device and comments on specific features of said device, this qualitative analysis served to gain insight on the therapeutic potential and limitations of using generalized percussive massage therapy as a home-based intervention for musculoskeletal concerns. The qualitative analysis of consumer reviews demonstrated use for this device in adolescents, adults, and older people. Its use was displayed across a spectrum of activity levels, ranging from bedridden to sedentary to high-performing athletes. In analyzing the top 100 positive and top 100 critical verified purchase reviews, 4 pertinent themes were identified: pain management, versatility, accessibility, and safety and user education. Both positive and critical consumer reviews suggested this percussive therapy device addressed wide-ranging musculoskeletal concerns, including daily pain, chronic pain, nonsurgical injury management, postsurgical injury management, and injury prevention. Critical reviews regarding the device’s pain management capacity were primarily regarding device-specific features and suggested identifying an alternative percussive therapy device. The critical reviews highlighted the variability of personal preferences or needs rather than the generalized inability of percussive massage devices to have a therapeutic function. Positive consumer reviews emphasized the budget-friendly nature of the TOLOCO massage gun as a key feature in improving accessibility to the device and therefore its therapeutic potential. However, critical consumer reviews commented on the concern for product quality at lower price points in comparison to their more expensive counterparts. Regarding the final theme, safety and user education, consumer reviews demonstrated this aspect through product-specific safety features, manufacturer manuals, and peer-to-peer guidance. While not directly commented on by consumers, it is apparent that no consumer mentioned evidence-based guidelines for facilitating the use of this device.

Musculoskeletal pain, whether acute or chronic, is a common complaint in the health care system [21,22]. Such pain increases in prevalence with aging and lifestyle factors, such as occupation or lack of physical activity [22]. Both the personal and economic burden of musculoskeletal pain have been demonstrated globally across diverse populations [2,22-24]. For instance, the increasing presence of work-induced musculoskeletal pain in individuals without preexisting conditions has been discussed among nurses, postal workers, agricultural workers, and office workers [24-27]. One can suggest that this concept be readily translated to alternate occupations that also involve long working hours and significant lifting, standing, or sitting, thus being applicable to a vast majority of individuals. Occupation-related musculoskeletal pain is a pertinent common thread among the average individual and is one example that directly increases health care usage and expenditures [2,22]. Not only that, but also such pain increases both absenteeism and presenteeism and therefore negatively impacts employers financially [2]. For the individual, work-related musculoskeletal pain significantly impacts quality of life both physically and mentally [22]. This emphasizes the need to identify appropriate intervention modalities, particularly in the realm of home-based care.

While the mechanism of percussive therapy at the molecular level has not been well defined, its plausible application and health outcomes have been demonstrated by various studies. For athletes, percussive therapy has been found to improve muscle endurance and delay muscle fatigue without compromising muscle performance [10,28]. Some studies have also commented on the capacity of percussive therapy to improve explosive muscle strength, a valuable dynamic for athletes, while other studies claim no significant association in this domain [6,29]. The benefits of percussive therapy can impact everyday users in addition to high-performing athletes. The everyday user may include individuals from ageing or working populations as well as those with orthopedic needs. For instance, working populations—whether involving extended computer usage, long standing hours, or heavy physical labor—experience increasing strain on the body [30-32]. Initially, this strain may present as acute aches and pains, but repeated exposure can increase the potential for greater chronicity of pain [30-32]. Percussive massage therapy can serve as an adequate home-based musculoskeletal pain intervention for the everyday user. In reducing stiffness, increasing muscle relaxation, and improving muscle tone, percussive therapy encourages the flexibility of muscles and tendons and therefore establishes a better range of motion [6,29,33-35]. Not only that, but also in reducing the tension of muscles and tendons, it additionally works to alleviate perception of pain and thus yield psychosocial benefits [6,29]. The TOLOCO massage gun demonstrated the capacity of percussive massage therapy to be an easily accessible therapeutic modality that is readily available within one’s own home. Thus, it gives users the opportunity to take their health into their own hands as well as augment medical rehabilitation for improved health outcomes. A breadth of users found this percussive massage therapy device to be a resourceful tool in their pain management regimen. Additionally, some consumers discussed alternative uses for the device in the context of myalgias secondary to chemotherapy, menstrual pains, and migraines.

It is imperative that we consider the biopsychosocial approach to care when addressing musculoskeletal pain. Acute or chronic pain is recognized as a contributing factor to an individual’s mental health [36-39]. Pain post orthopedic intervention can be associated with long-term disability, increased restrictions in work or daily living, and decreased satisfaction overall [39]. These points of association may explain elevated depression rating scores in this population [39]. Alternately, in considering...
a population of high-performing athletes dedicated to their athletic identity and role in sport, it is apparent that there is an association between sport-related injury and mental health [36-38,40,41]. Over the course of 5 academic years, from 2009-2010 to 2013-2014, over 1 million injuries were estimated within the National Collegiate Athletic Association [42]. Given the rising competition and pressure, it is likely that this number has continued to rise. Sport-related injuries both short-term and long-term, negatively impact current and previous elite athletes [36-38,40]. In understanding the interconnectedness between musculoskeletal pain and perceived stress, anxiety, and depression, it is crucial that we analyze possible points of intervention. For instance, the psychological aspect of chronic low back pain may encompass decreased self-efficacy and autonomy [43]. Home-based percussive massage therapy, when appropriate, can possibly serve to encourage patient connectedness to care and increase patient confidence in caring for themselves. This concept highlights the potential of home-based percussive therapy as one branch of biopsychosocial interventions in patient care.

A total of 2 prominent handheld percussive massage therapy devices on the market are the Theragun by Therabody and the Hypervolt by Hyperice. Both products tend to range between US $100 and US $500—a price range that might not be considered affordable by all. As the therapeutic percussive therapy device continued to gain popularity, numerous manufacturers such as TOLOCO joined the expanding market to produce low-cost products and therefore improve its accessibility. In comparison to the listed prices of the more well-known brands, TOLOCO lists its product at approximately US $50 and intermittently includes discounted prices or coupons. The expansion of this market to include low-cost items is important because, by improving the affordability of these products, one can say it simultaneously increases health care accessibility. Not only that, but also this accessibility allows numerous consumers of varying backgrounds to find personal therapeutic purposes in the device. Additionally, it is imperative to recognize how the burden of musculoskeletal pain disproportionately impacts low-income populations [44-47]. While social determinants of health impede one’s ability to access comprehensive care, it also increases an individual’s risk to such conditions and amplifies the burden of disease [45-48]. The gaps in accessing health care providers, psychosocial support, and health resources perpetuate the disparities experienced by these communities and have negative implications for health outcomes [46,48]. Therefore, creating cost-effective, home-based interventions for musculoskeletal ailments may act as a therapeutic modality for wide-ranging populations and serve as one plausible method of bridging the gap between the health care system and vulnerable populations.

While this percussive massage therapy device has specific safety and user education components, including a user manual and automatic shutdown feature, it is imperative to further evaluate the safety and efficacy of such unregulated, at-home modalities. Previous case reports have discussed the consequences of inappropriate usage of these devices, which include rhabdomyolysis, vertebral artery dissection, and lens dislocation alongside secondary acute angle-closure glaucoma [49-51].

When considering at-home therapy options such as percussive massage therapy, users may not have essential medical knowledge and therefore may be unaware of certain anatomical structures including tissue, bones, and vasculature. They may also not fully understand the possible interaction of this percussive modality with their own underlying conditions. Of note, one user of the TOLOCO massage gun commented on their frustration with the 10-minute automatic shutdown and discussed disregarding the safety feature in place. This highlights the possibility of a lack of user education as well as unregulated use of the device. The authors of the noted case reports equally advocated for detailed evaluation of the safety of such devices in order to better define guidelines for indications and contraindications [49-51]. More comprehensive user education of at-home percussive massage therapy may dissuade such inappropriate usage and consequential traumatic complications while contributing to greater beneficial impacts.

Limitations
This qualitative analysis was conducted on consumer perceptions of a single percussive massage therapy device, despite the abundance of such products on the market. The TOLOCO massage gun was selected based on statistics suggesting that this particular product was the best-selling on Amazon. However, this does not indicate that it is the best-selling percussive massage therapy device in the current expanded market. The variability of these products with regard to their affordability, additional features, longevity, and programming may contribute to consumer perceptions. With this analysis primarily investigating this product from the perspective of serving as a home-based therapeutic modality, it might be implied that not all users have the same background knowledge and understanding of how to use the device optimally. Given that this was a retrospective study on consumer reviews, this analysis only includes perceptions from a snapshot in time from individuals who were willing to comment on the capabilities of and concerns about the product’s usage. In using public data for this qualitative analysis, the authors were unable to facilitate further conversation, gain clarification, or identify sociodemographic characteristics among consumers. Additionally, this analysis does not provide objective or longitudinal data to further define indications or contraindications for percussive massage therapy. Though percussive massage therapy devices are deemed quite popular and beneficial based on consumer perceptions, there is currently limited scientific research available on their underlying physiologic mechanisms. Thus, further exploration with regard to its safety and efficacy is imperative.

Future Research
Previous studies have been conducted on the possible effects of percussive massage therapy. A study demonstrated that localized vibrations induced by massage guns at 38 Hz and 47 Hz can increase circulation to the region and therefore aid in the muscle recovery of healthy young athletes [52]. In the strength and conditioning setting, the use of massage guns allowed for increased muscle strength and explosive muscle performance secondary to delayed fatigue while also reducing musculoskeletal pain perception [6,10,28,53]. Another study...
using ultrasound diagnostics found that the use of massage guns on the thoracolumbar fascia resulted in a reduction in echo intensity in that region due to the movement of hyaluronic acid toward the fascial rim and thus improved lubrication and gliding between fascial layers [54]. While these studies have demonstrated the possible effects of percussive massage therapy and postulated potential reasons for these effects, they were unable to conclusively define the physiologic mechanisms. A study surveyed health care professionals about their perceptions and use of massage guns; however, it also emphasized the lack of current evidence-based guidelines [33,55]. Thus, future research is needed to investigate the underlying mechanisms of percussive massage therapy to better outline its safety and efficacy. Second, this research may create better guidelines to optimize care for different populations and prevent at-home users from sustaining further injury. In the future, it may be valuable to conduct further research on the integration and cost-effectiveness of mobile health apps and sensing technology in conjunction with home-based percussive therapy devices.

Conclusions
Handheld percussive massage therapy devices such as the TOLOCO massage gun hold potential value as a home-based therapeutic modality. The qualitative analysis of consumer perceptions revealed 4 pertinent themes: pain management, versatility, accessibility, and safety and education. Per consumer insight, percussive massage therapy was shown to address pain management for wide-ranging musculoskeletal needs in diverse populations. In providing an opportunity for consumers—from elite athletes to the everyday user—to play an active role in their own health, handheld percussive massage therapy can navigate the intersection of physical and mental well-being and thus encompass a biopsychosocial approach to care. Additionally, this home-based intervention has the potential to work toward addressing the significant economic burden of musculoskeletal pain by reducing and optimizing health care usage and expenditures. In considering the diversity of user needs and circumstances, this at-home modality addressed a pertinent health care concern in that it improved accessibility to care by presenting as both an affordable and readily available device for consumers. The variability of device models with low-cost price points introduces a possible platform for health equity in this domain of care. While this provides users with the opportunity to essentially play a larger role in their own care, future research on the safety and efficacy of home-based percussive massage therapy is imperative and can ultimately serve to promote evidence-based guidelines, further its technological development, and expand its therapeutic potential.

Data Availability
Data sharing is not applicable to this article as no data sets were generated or analyzed during this study.

Conflicts of Interest
None declared.

References


15. Butala et al. JMIR Rehabil Assist Technol 2024 | vol. 11 | e52328 | p.26

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Butala et al


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Original Paper

Evaluating the Experiences of Occupational Therapists and Children Using the SensoGrip Pressure-Sensitive Pen in a Handwriting Intervention: Multimethods Study

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Abstract

Background: The acquisition of handwriting skills is essential for a child’s academic success, self-confidence, and general school performance. Nevertheless, an estimated 5% to 27% of children face handwriting challenges, where the ability to modulate pressure on the pencil and lead on the paper is a key motor component.

Objective: We aimed to investigate the experience with and usability of the SensoGrip system, a pressure-measuring pen system with personalized real-time feedback about pressure modulation, in a clinical setting with children and occupational therapists (OTs).

Methods: A multimethods study was conducted, incorporating qualitative interviews and questionnaires with children, user diaries, focus group discussions, and a usability questionnaire with OTs, along with a questionnaire for parents.

Results: The study involved OTs (n=8), children with handwriting difficulties (n=16), and their parents (n=16), each of whom used the SensoGrip system in up to 5 therapy sessions. OTs reported that the SensoGrip system helped to focus the child’s awareness on handwriting pressure and to measure it objectively. The system received high acceptance and usability ratings from the OTs—usefulness: median score of 4 out of 7; ease of use and ease of learning: median score of 6 out of 7; and satisfaction: median score of 6 out of 7. Participants appreciated that it fosters pressure awareness and motivation to draw and write.

Conclusions: The SensoGrip pressure-sensing system with real-time feedback is a promising tool for pediatric occupational therapy. It supports children with handwriting difficulties to adjust their pressure application during the task. In the future, controlled quantitative trials are warranted to further examine the system’s impact.

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KEYWORDS
handwriting; handwriting pressure; pen; children; occupational therapy; assistive technology; tablet; app

Introduction

Background

The development of handwriting skills is not only important for building children’s self-confidence but is also considered a fundamental element for academic success [1,2] and educational achievement [3]. Numerous studies have indicated that many children encounter challenges in acquiring handwriting skills. According to a review by Hartingsveld et al [4], the prevalence of handwriting problems ranges from 5% to 27%. Handwriting is a multifaceted task that requires the integration of motor, sensory, perceptual, praxis, and cognitive functions [5,6]. An essential motor aspect involves the precise control of pencil pressure and pressure of the lead on the paper, as excessive
pressure on the pen when writing can cause muscle fatigue. Children with handwriting problems have less capacity for idea generation, planning, and revision when they have to focus on the handwriting mechanics [7]. The aim of teachers and occupational therapists (OTs) is that children obtain readable, fluent, and efficient individual handwriting without becoming tired [8]. A survey of 2000 German teachers revealed that sustained writing was a problem for >60% of children in elementary or secondary school, most often based on handwriting-associated cramps (73%) and incorrect pencil grip (68%) [8]. Lin et al [9] observed that children exhibit difficulties in pressure adjustment when learning graphomotor skills. Previous studies have already measured grip or tip pressure (pressure of the pen on the writing surface) using a pen with built-in sensors [10,11]. However, these systems were built for research purposes only. There is a need to investigate the role of pressure in pencil use in a natural setting and to provide direct feedback mechanisms for the children. Biofeedback is a method for changing unconscious movements and perceptions into conscious ones and has already been used in the context of a handwriting training device by the company, “Schneider,” and their pen, “Base Senso.” Biofeedback is known to be effective in the treatment of many musculoskeletal conditions and has been shown to, for example, improve the measures of balance and patients’ exercise techniques [12]. However, to the best of our knowledge, currently, there is no tool that records the child’s pressure and provides individualized feedback to the child and OT. Further limitations of the commercially available technologies include the following: very high acquisition costs; insufficient calibration accuracy; usability issues, as training is required to use the app; incomplete recording of key measurement parameters; and lack of feedback [13].

The SensoGrip Project
The SensoGrip project was launched with the aim of creating a pressure-sensitive pen, focusing on user-centered conception, development, and evaluation. Previously, we had conducted a comprehensive evaluation to understand the needs of all relevant stakeholders, steering the further development process [14]. The project was supported by an interdisciplinary team that included professionals from occupational therapy, physical therapy, special education, medical informatics, computer science, and mechanical engineering. We adopted an iterative development process complemented by simultaneous testing phases to continuously refine the features.

The SensoGrip System
The SensoGrip system consists of 2 components: a smart SensoGrip pen and the SensoGrip mobile app. The pen weighs 24 g, is 140 mm long and 14 mm in diameter, and has a roller pen refill (Figure 1).

Figure 1. The SensoGrip pen with activated feedback LED and the SensoGrip app with line graphs for grip pressure (red) and tip pressure (blue).

The SensoGrip pen contains 2 sensors to measure the pressure applied on the grip area (grip pressure) and the pressure applied by the pen on the paper (tip pressure) respectively. An LED ring is placed between the distal end of the grip area and the pen tip. The LED provides visual feedback about the applied pressures according to the individual settings in the mobile app.
The battery of the pen can be recharged using a standard micro-USB cable.

The SensoGrip app runs on the Android operating system on a customary tablet. It allows for the creation of customer profiles with individual settings and displays real-time or recorded measurements. On the basis of the individual needs and preferences of the child, different feedback modes can be chosen (Figure 2). Upper and lower thresholds are set by the OT to choose the pressure range within which the selected feedback is displayed by the LED. The thresholds are set for the grip pressure and tip pressure separately. Colors for different feedback modes can be chosen individually.

Figure 2. Feedback modes offered by the SensoGrip system. Depending on the mode selected in the SensoGrip app, the LED ring of the SensoGrip pen lights up in individually chosen colors. GP: grip pressure; TP: tip pressure; x: only if pressure is very high.

<table>
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<tr>
<th>Within the range of the set thresholds?</th>
<th>GP</th>
<th>TP</th>
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<tbody>
<tr>
<td>No feedback</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Simple feedback</td>
<td>✓</td>
<td>¡</td>
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<tr>
<td>Advanced feedback</td>
<td>✓</td>
<td>✱</td>
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<tr>
<td>Detailed feedback</td>
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<tr>
<td>Negative feedback</td>
<td>✱</td>
<td>✱</td>
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<tr>
<td>Overpressure feedback</td>
<td>✓</td>
<td>✱</td>
</tr>
</tbody>
</table>

The app provides real-time visualization of pressure data through numerical displays and line graphs for both grip and tip pressures, as illustrated in Figure 1. Users have the option to capture these data alongside a video of the writing hand in action. For ease of analysis, the app allows the display of customizable threshold lines on the graphs, which can be toggled on or off as needed. All recorded data remain retrievable for future reference. In addition, the interface supports the simultaneous comparison of graphs from different sessions. For reporting or further analysis, users can export these data directly into a PDF document.

Aim

This study is part of a pilot study involving a single-case experimental design [15] to assess the effectiveness of the system. The findings concerning the effectiveness of the system, as derived from the Single-Case Experimental Design study, will be discussed in a subsequent publication. The study was registered on ClinicalTrials.gov (NCT05014854). The aim of this paper was to present data about the usability, acceptance, and perceived impact of the SensoGrip system.

The following research questions were used to guide this study:

1. How is the usability characterized?
2. What hurdles exist in the actual use of the individual components?
3. How are the acceptance factors of the system evaluated by the target groups?
4. What is the perceived impact of the system?
5. What are the intended and unintended effects of the system on the target groups?
6. Does the system positively influence children’s motivation and adherence?

Methods

Overview and Procedure

The study was conducted between July 2021 and October 2021 in Vienna and Lower Austria, Austria, across various private practices of OTs. Each participating child engaged in 3 to 7 therapy sessions, during which the OTs integrated the SensoGrip system into therapy. OTs received comprehensive training from the research team. This training included a range of essential skills, such as operating the SensoGrip system, creating patient profiles, fine-tuning feedback settings, interpreting the graphical representation of pressure data, and familiarizing themselves with the procedures for assessment and data upload. Although OTs were expected to incorporate the SensoGrip system into every therapy session for a minimum of 10 minutes, they were granted the flexibility to use it more extensively as needed. The research team supplied a manual containing a variety of recommended therapeutic activities tailored to the SensoGrip
Moreover, the OTs were empowered to personalize the system settings, including the calibration of pressure thresholds for both finger and tip feedback and the selection of feedback types and colors. The integrity and consistency of the intervention’s implementation were carefully tracked through the collection of user diaries, analysis of use data from the SensoGrip pens, and evaluations conducted during posttherapy focus groups and interviews.

To assess the usability and user acceptance of the SensoGrip system and to gain early insights into the perceived impacts of use, a multimethods design was implemented (Figure 3).

**Figure 3.** Study overview and timeline. USE: Usefulness, Satisfaction, and Ease of Use and Ease of Learning.

To obtain a comprehensive understanding of the SensoGrip system’s impact, we included a variety of data collection methods. We conducted qualitative interviews with children and captured their satisfaction with a child-friendly smiley rating scale. OTs provided baseline data about the child’s handwriting issues; regularly documented SensoGrip use, their observations, and the systems’ performance in user diaries; rated its usability using a questionnaire; and participated in a focus group. Parents provided information about the child’s handwriting at home through a baseline questionnaire. They also described their experiences with the SensoGrip system when it was used in the home setting. The methods were chosen carefully to meet the respective needs of the study participants in terms of time, effort, and place and to achieve a combination of qualitative and quantitative results for triangulation.

**Participants**

**Recruitment and Enrollment Procedure**

Participants were recruited using the snowball sampling technique [16], in which initial contacts with OTs in private practices were established through multichannel outreach. This included distributing emails to all pediatric OTs registered in the region, engaging with OT-specific Facebook groups, and leveraging the personal networks of the project team. In addition, OTs were encouraged to use their professional and social networks to further distribute participant invitations. We structured participation into teams or dyads composed of an OT and ≥1 children under their care, with the option to involve the children’s parents or legal guardians. Inclusion in the study was contingent upon meeting the established criteria, and upon indicating interest, OTs were provided with detailed participation checklists and consent documentation. Once eligibility was confirmed and consent was obtained, OTs, their paired children, and the children’s legal guardians were formally enrolled in the study.

**Children**

Children aged between 5 and 10 years and exhibiting difficulties in handwriting, especially in handwriting pressure adjustment were eligible. Children belonging to this age group were selected as the target group because they are in the developmental period during which children typically acquire foundational handwriting skills. OTs assessed the eligibility based on a handwriting pressure checklist, where at least 2 stated criteria had to be present. The checklist contained 6 indicators of excessive writing pressure, 4 indicators of insufficient writing pressure, and 1 criterion for high fluctuations in writing pressure (Multimedia Appendix 1). Children had to be able to follow verbal instructions and maintain attention in graphomotor activities for at least 10 minutes and had to have adequate emotional regulation and age-appropriate psychosocial skills. Children who were not able to hold a pen, owing to stiffened joints or excessive or insufficient muscle tension, could not participate in the study. Children’s eligibility to participate in the study was assessed by their individual OT, who then selected children for the study from their patient group. Before starting the assessment and intervention, children and parents (or legal guardians) signed an informed consent form.

**Occupational Therapists**

OTs were eligible to participate if they had at least 2 years of professional experience in evaluating and treating graphomotor difficulties in children. In addition, they had to provide occupation-based therapeutic services aimed at addressing handwriting challenges. OTs were not eligible if they rejected using technical tools in therapy or stated that they are not used to handling everyday technologies such as smartphones. For a collaborative dyad to be formed within the study, each participating OT was required to enlist at least 1 child from their clinical practice. Informed consent was mandatory; OTs were required to sign an informed consent form before enrolling in the study.
**Parents or Legal Guardians**

Parents or legal guardians were eligible to participate if their child consented to use the SensoGrip system at home between therapy sessions. A prerequisite for participation was proficiency in basic, everyday technology use. Informed consent was obtained before their inclusion in the study.

**Assessments**

A comprehensive set of tools was used to collect both qualitative and quantitative feedback from OTs, children, and their parents.

**User Diaries (OTs)**

OTs maintained a user diary to record the use of the SensoGrip system, experiences and thoughts about the system, and issues with its usability and functionality. These recordings were a central element, as they allowed to observe several therapy sessions of each child retrospectively without directly participating in the sessions themselves. After each session of use, the OTs self-assessed to check whether any technical issues occurred (yes or no and which?), whether the feedback felt reasonable (yes or no and why?), whether they found the SensoGrip system useful (yes or no and why?), whether the system was intuitive to use (yes or no and why?), and how much they enjoyed using it (5-point Likert scale). In addition, the OTs maintained notes about how the SensoGrip system was integrated into the therapy session. The diary was developed by the project team, and the understandability and quality were assessed along with an OT before starting the trial.

**Usability Questionnaire (OTs)**

At the end of the intervention period, the usability of the SensoGrip system was assessed by the OTs via the standardized Usefulness, Satisfaction, and Ease of Use and Ease of Learning (USE) questionnaire [17,18], translated into German by the research team (Multimedia Appendix 2). It consists of 30 items, attributed to dimensions such as usefulness, ease of use, ease of learning, and satisfaction, which are rated on a 7-point Likert scale (1=do not agree at all; 7=totally agree).

**Smiley Rating Scale (Children)**

Children self-assessed their satisfaction with the SensoGrip system using a 6-point smiley rating scale. Children were asked “How much did you enjoy writing with the SensoGrip pen?” in the first therapy session of the intervention, in which feedback from the pen was deactivated to not influence the baseline measurements for the single-case experimental design study, and in the first therapy session in which feedback was activated. After the final session, they were asked, “How good can you write with the SensoGrip pen?” and “How much do you like the SensoGrip pen?”

**Questionnaires (Parents)**

Before initiating the study, parents or legal guardians were asked to complete a detailed questionnaire designed to understand the child’s handwriting practices at home. It covered several topics, including the frequency and duration of writing activities at home, handwriting legibility, pressure and speed during writing, challenges encountered, and the acceptance and use of tools for writing and learning, along with any related social and emotional concerns. Furthermore, when the SensoGrip pen was used at home between therapy sessions, parents or legal guardians provided end-of-study feedback through a subsequent questionnaire. This follow-up sought to assess their perceptions about the pen’s effectiveness, user-friendliness, and overall impact in the home environment.

**Interviews (Children)**

After the intervention, child participants were interviewed individually by 2 experienced team members, both women, with a background in pediatric occupational therapy. These interviews were deliberately scheduled immediately following the final therapy session at the OT’s office to mitigate any additional stress for the children, a particularly vulnerable group. Parents or legal guardians were allowed to attend the interview, if this was deemed beneficial. The semistructured interviews (Multimedia Appendix 3), which were pretested with age-matched children, explored a range of topics: the children’s enjoyment in using technical tools in general, their previous experience with handwriting, their evaluation of the SensoGrip system’s functionality, the advantages they perceived from its use, their willingness to continue using the system, their suggestions for its improvement, and their 3 most and least effective aspects. The interviews were audio recorded and varied in duration between 10 and 30 minutes per child. In an effort to minimize any potential discomfort, the children were not asked to confirm the accuracy of the interview content.

**Focus Group (OTs)**

OTs participated in a structured focus group interview designed to elicit a comprehensive evaluation of their experiences with the SensoGrip system. The choice of focus group format was intentional; it was selected for its capacity to yield nuanced insights through collective discussions among the OTs. The focus group was facilitated by 2 experienced research team members with a background in pediatric occupational therapy. To ensure a setting that minimized distractions, the focus group was conducted in a quiet meeting room at the university and lasted 108 minutes. An additional researcher documented field notes to capture nonverbal behaviors and observations. The semistructured guide (Multimedia Appendix 3) included open-ended questions along with prompts and probes and covered the following topics: prevalence of handwriting difficulties and, especially, handwriting pressure difficulties in praxis; common concepts and methods for addressing those issues; integration of the SensoGrip system into OT praxis; perceived benefits and barriers when using the SensoGrip system; effects of pressure feedback about children’s handwriting and behavior; ease of learning the SensoGrip system; assessment of the SensoGrip system regarding design and functionality; and suggested improvements for SensoGrip pen and app. The guideline was developed by the research team. A pilot test was not conducted, but the questions were intensively discussed within the team to ensure that the research questions were addressed. If an OT was unable to attend the focus group owing to scheduling conflicts, an individual interview was conducted. This ensured comprehensive inclusion of their insights regarding the SensoGrip system. Consistent with the focus group methodology, this interview adhered to...
the established guidelines and was audio recorded to capture the OT’s feedback accurately. In contrast, the focus group session was video recorded, allowing for precise attribution of comments to the respective contributors. Subsequently, the findings from the study were shared in a public forum, and all the involved OTs were encouraged to attend. This presentation served as an opportunity for participant validation, where OTs could review and comment on the reported results—a process known as member checking.

Data Analysis

Questionnaires and User Diaries
User diary data were systematically compiled into an Excel (Microsoft Corporation) spreadsheet, enabling a detailed analysis of the technical and usability challenges encountered during the SensoGrip system’s operation. Statistical analysis included the calculation of the median and the minimum and maximum scores from the children’s smiley rating scale. Similarly, we computed the median values for the usability ratings derived from the USE questionnaire’s subscales. The frequency distributions of these ratings, along with the smiley rating scale scores, were then visually represented through graphical illustrations.

Qualitative Data
Content analysis based on the procedure suggested by Kuckartz [19] was performed on completely verbatim transcripts of the focus group and interviews by 2 researchers using the software, MAXQDA 2022 (VERBI Software, 2021). This method allows a combination of deductive and inductive coding. Deductive codes were based on the topics that guided the interviews: functionality, stability, usefulness, usability, ease of learning, barriers, performance expectancy, effort expectancy, social influence, hedonic motivation, facilitating conditions, intention to use, effect on handwriting pressure, transfer into daily living, effect on motivation and adherence, effect on therapeutic efficiency, and support in documentation. Then, inductive codes were differentiated into many subtopics such as design, usability, and barriers. The 2 researchers collaborated intensively in the coding and analysis phases to increase objectivity. Working in tandem, they cross-examined each other’s coding decisions and interpretations during the analysis and discussed discrepancies to reach consensus. This approach aimed to reduce individual bias and enhance the reliability of the findings.

Ethical Considerations
The SensoGrip system is defined as a class-1 active medical device according to Rule 12 of Directive 93/42/EEC [20]. Therefore, the evaluation of the system qualified as a clinical trial and was successfully approved by the ethics committee of the City of Vienna under the number EK-21-042-0321. In addition, the study was registered at the Austrian Federal Office for Safety in Health Care [21] as required by national law. The study was monitored on an ongoing basis by a physician and a monitor. No adverse effects occurred.

Results

Description of Participants
Overall, 8 OTs (n=7, 88% women; n=1, 13% men) participated in the study. They were aged between 28 and 51 (mean 37.6, SD 7) years and had between 4 and 30 (mean 13.5, SD 8.2) years of experience in pediatric occupational therapy. All (8/8, 100%) used a smartphone or mobile tablet with 3 to 5 apps (4/8, 50%) or >5 apps (4/8, 50%) on a regular basis. The participating OTs’ acceptance of technology was rather high (Multimedia Appendix 4).

Overall, 16 children (n=3, 19% girls; n=13, 81% boys) were enrolled in the study (Table 1). They were aged between 5 and 10 years. Of the 16 children, 14 (88%) wrote with their right hand, 1 (6%) wrote with the left hand, and 1 (6%) did not have a preferred hand for writing at the time of the study. Their reasons for referral to OT were developmental coordination disorder of fine and gross motor coordination, unspecified developmental disorder of motor function, difficulties in concentration, dyspraxia, sensory integration disorder, autism spectrum disorder, and adaptive disorder.

Of the 16 parents, 9 (56%) reported that their child’s hand grew tired when writing, 7 (44%) reported that their child had to shake their hand for relaxation when writing, and 1 (6%) reported that their child verbalized pain regularly when writing. Of the 16 parents, 10 (63%) thought that fatigue had an influence on the handwriting of their child, 9 (56%) found prolonged writing to be a relevant factor, 7 (44%) perceived that the pen their child was using influenced the handwriting, and 1 (6%) mentioned that time pressure negatively affected handwriting. Of the 16 parents, 4 (25%) rated their child’s handwriting as illegible, 2 (13%) as sloppy, and 1 (6%) as often smudgy. Of the 16 children, 8 (50%) had trouble in maintaining alignment with the line when writing, 3 (19%) imprinted their handwriting on the next page, and 4 (25%) produced very large letters when writing. Of the 16 children, 8 (50%) used special aids for writing such as grip aids with or without molds, weighted writing utensils, or special ergonomic pens. Of the 16 parents, only 2 (13%) confirmed that the aids were helpful. Of the 16 children, 4 (25%) enjoyed their use and 1 (6%) explicitly did not like it. Of the 16 parents, 5 (31%) acknowledged that handwriting problems frequently led to conflicts at home.

Of the 16 children, 8 (50%) reported that their handwriting was improved on the next page, and 4 (25%) produced very large letters when writing. Of the 16 children, 8 (50%) had trouble in maintaining alignment with the line when writing, 3 (19%) imprinted their handwriting on the next page, and 4 (25%) produced very large letters when writing. Of the 16 children, 8 (50%) used special aids for writing such as grip aids with or without molds, weighted writing utensils, or special ergonomic pens. Of the 16 parents, only 2 (13%) confirmed that the aids were helpful. Of the 16 children, 4 (25%) enjoyed their use and 1 (6%) explicitly did not like it. Of the 16 parents, 5 (31%) acknowledged that handwriting problems frequently led to conflicts at home.

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Table 1. Overview of children’s baseline data.

<table>
<thead>
<tr>
<th>Child’s ID</th>
<th>Sex</th>
<th>Age</th>
<th>Handedness</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1</td>
<td>Male</td>
<td>6 y and 11 mo</td>
<td>Right</td>
</tr>
<tr>
<td>C2</td>
<td>Male</td>
<td>6 y and 6 mo</td>
<td>Right</td>
</tr>
<tr>
<td>C3</td>
<td>Male</td>
<td>7 y and 8 mo</td>
<td>Right</td>
</tr>
<tr>
<td>C4</td>
<td>Male</td>
<td>6 y and 6 mo</td>
<td>Right</td>
</tr>
<tr>
<td>C5</td>
<td>Male</td>
<td>9 y and 4 mo</td>
<td>Right</td>
</tr>
<tr>
<td>C6</td>
<td>Male</td>
<td>6 y and 0 mo</td>
<td>Right</td>
</tr>
<tr>
<td>C7</td>
<td>Male</td>
<td>7 y and 8 mo</td>
<td>Right</td>
</tr>
<tr>
<td>C8</td>
<td>Male</td>
<td>5 y and 10 mo</td>
<td>Left</td>
</tr>
<tr>
<td>C9</td>
<td>Male</td>
<td>5 y and 9 mo</td>
<td>Right</td>
</tr>
<tr>
<td>C10</td>
<td>Male</td>
<td>6 y and 9 mo</td>
<td>No preference</td>
</tr>
<tr>
<td>C11</td>
<td>Male</td>
<td>5 y and 8 mo</td>
<td>Right</td>
</tr>
<tr>
<td>C12</td>
<td>Female</td>
<td>9 y and 3 mo</td>
<td>Right</td>
</tr>
<tr>
<td>C13</td>
<td>Female</td>
<td>10 y and 11 mo</td>
<td>Right</td>
</tr>
<tr>
<td>C14</td>
<td>Male</td>
<td>6 y and 2 mo</td>
<td>Right</td>
</tr>
<tr>
<td>C15</td>
<td>Male</td>
<td>8 y and 4 mo</td>
<td>Right</td>
</tr>
<tr>
<td>C16</td>
<td>Female</td>
<td>8 y and 5 mo</td>
<td>Right</td>
</tr>
</tbody>
</table>

Relevance of Handwriting Pressure in OT Practice

According to the participating OTs, the prevalence of handwriting problems among children in their common practice is approximately 30%, and one-third of these children also shows signs of inappropriate handwriting pressure. Problems of handwriting pressure adjustment rarely occur in isolation; they occur in combination with other difficulties related to handwriting grip and letter formation. OTs select therapy approaches to target appropriate handwriting pressure adjustment that include activities to improve body perception in general and occupation-based activities such as drawing and writing with different materials. Common activities mentioned were coloring by hatching with varying intensity or applying padding of varying modalities under the paper. All OTs emphasized that they used a child-centered approach in terms of child-initiated color or topic selection.

Application of the SensoGrip System in the Study

Of the 16 children, 12 (75%) used the SensoGrip system in 5 therapy sessions, 3 (19%) used it in 3 sessions, and 1 (6%) used it only in 1 therapy session. On average the total use time was 77 (SD 34; range 10-135) minutes per child. Reasons for discontinuation of implementing the SensoGrip system were based on unforeseen therapy termination (1/16, 6%) or the child’s pencil grip being very immature (2/16, 13%). The children used the SensoGrip system in a variety of writing and drawing exercises, ranging from playful activities to more structured tasks such as free drawing, tracing, copying, and writing. OTs supported the children in monitoring the feedback from the LED indicator on the pen and in adjusting the pressure on the pen and paper. In addition, the accompanying mobile app was introduced, offering an interactive experience where they engaged in creating specific graph patterns. By varying the pressure on the pen, children learned to manipulate the graphical representations, striving to achieve either high or low pressure readings or to maintain consistent pressure levels. OTs reviewed the children’s handwriting pressure with them, using the graphical data recorded in the mobile app after various writing and drawing activities. In a home setting, 31% (5/16) of the children continued to use SensoGrip between therapy sessions. According to the parents of these 5 children, 1 (20%) child used it daily, 2 (40%) used it multiple times per week, and 2 (40%) used it weekly. Some OTs opted not to send the SensoGrip pen home owing to concerns about potential loss or damage or worries that the pen might not be used as intended or returned for subsequent sessions.

OTs’ Evaluation

Regarding the USE questionnaire’s usefulness subscale, OTs reported a median score of 4 (IQR 3-6) out of 7, indicating a moderate level of perceived utility of the SensoGrip system (Figure 4). During the focus group discussions, OTs gave high ratings to the tablet’s graphical representation of handwriting pressure, valuing it as a particularly useful tool for objectively assessing a child’s performance and informing therapeutic strategies. They noted the advantages of the system’s real-time visual pressure feedback, which was well received by both OTs and children alike. OTs also expressed appreciation for the customizable settings, which allowed them to tailor the feedback to each child’s specific requirements. A notable benefit reported was the SensoGrip pen’s utility in the home environment, where children could continue practicing even when the OT was not present.
I think it is great when they take it home. You just set everything up and say, for example, “This week try to make it light up as much as possible when you do your homework.” [OT 3]

OTs assigned high ratings to the SensoGrip system’s ease of use (median 6, IQR 5–6) and ease of learning (median 6, IQR 6–7), each receiving a median score of 6 out of 7 on a Likert scale, which suggests a high level of usability of the system (Figure 4). They found the graphical analysis of pressure to be intuitive to use and the customization to be straightforward. However, determining the optimal thresholds for each child using the graphical interface proved challenging for some. An OT expressed a preference for adjustment based on numerical pressure values rather than graphical data. To further improve the system’s usability, the OTs recommended enhancements, such as ensuring the mobile app’s functionality even when the
pen is not connected or is charging. This would facilitate uninterrupted access to settings and data. They also proposed a feature to provide isolated feedback about either the finger or tip pressure, which would allow a focused approach to correcting specific pressure issues. Further suggestions included more sophisticated data comparison tools, such as visualizations showing the duration for which a child maintains pressure within the set thresholds and box plot analysis. In addition, a filtering function to extract particular data points was suggested. For future iterations, OTs advocated for the development of an automated progress analysis feature and integration of interactive games into the SensoGrip mobile app to enrich the SensoGrip experience.

The OTs provided a median score of 6 (IQR 5-6) on the satisfaction subscale of the USE questionnaire on a 7-point Likert scale (Figure 4). They pointed out that although they had stated many suggestions for improvement, they would like to use the SensoGrip system in its current development state:

On the other hand, if it would be possible to buy this pen, I would do it... It is actually a good product. [OT 5]

It is really usable the way it is. [OT 2]

Overall, the OTs noted that the use of the SensoGrip system helped to focus the child’s awareness on handwriting pressure and to measure it objectively. An OT expressed that the system helped to identify the specific situations in which the handwriting pressure increased. OTs perceived improvement in handwriting pressure in some children, based on observation. Nevertheless, some children did not benefit from the system.

Children’s Evaluation

During the interview, 69% (9/13) of the children mentioned that they thought the SensoGrip system was useful. They reported an increased awareness of their handwriting pressure when using the SensoGrip pen, which they felt contributed positively to their writing:

It really helps me figure things out. Like, when the pen lights up, I know “oh, the pressure is very low here.” [C15; aged 8 y]

When I do it right, the light turns green. And when I push too hard, then it turns purple. [C13; aged 10 y]

When I push very hard and then soft, the line goes up and down. Then again harder and softer, and so on. [C3; aged 7 y]

Other children did not perceive any differences when writing with the SensoGrip pen or preferred using their normal pen:

No, not necessarily. I can still write better with a pencil. [C14; aged 6 y]

Children assessed their satisfaction with the SensoGrip system using the smiley rating scale (Figure 5).

Overall, 80% (12/15) of the children gave the highest possible rating when asked how much they like the SensoGrip system. Furthermore, 86% (12/14) of the children rated the question, “How good can you write with the SensoGrip pen?” with the highest score (Likert scale score = 6), and 14% (2/14) of the children rated with the second highest score (Likert scale score = 5). In the interviews, they explained that it was “quite easy to write with the SensoGrip (pen)” (child 2 and child 3; aged 6 y) and that it was “easy to hold” (child 15; aged 8 y). However, some children encountered issues when using the SensoGrip pen: a child mentioned that they had trouble keeping the LED light on (child 15; aged 8 y), a child reported that the ink stained their fingers (child 14; aged 6 y), a child found the LED light not sufficiently bright (child 3; aged 6 y), and another
child had difficulties in maintaining a firm grip on the pen (child 3; aged 7 y).

Overall, children reported a medium to high level of enjoyment when using the SensoGrip system. The median rating was 6 (4.25-6) on a 6-point Likert scale (minimum=1; maximum=6), where 6 represents maximum writing enjoyment (Figure 5).

Overall, 92% (12/13) of the children thought that the SensoGrip pen was “cool” or “fun,” and 75% (9/12) of them said that they would enjoy continuing to write with the SensoGrip pen. Only 8% (1/13) of the children mentioned that the feedback puts them “out of control” and that it would not help them with writing (child 14; aged 6 y). They most enjoyed the LED feedback, the sensor technology, and working with the app’s graph:

...That we could draw hills in the app. And the colored light. And that it was so pleasant for my fingers. That were my three favorites. [C3; aged 7 y]
...I could see if I am doing it right. [C13; aged 10 y]
...It feels good in my hands. The light. The feedback. And that it helped me with writing. [C1; aged 6 y]

Some children expressed improvement in writing during the interviews:

Now I can write much better. [C1; aged 6 y]
Earlier I pushed the pen a little harder on the paper and I can see that it is now different. [C13; aged 10 y]
My hand felt a little bit lighter when I was holding the pen like this. [C15; aged 8 y]

Parents’ Evaluation

Among the 5 parents who had the SensoGrip pen used at home, 3 (60%) found the SensoGrip pen to be intuitive or rather intuitive in its use, whereas 1 (20%) felt that it was not intuitive. Overall, among the 5 parents, 2 (40%) were satisfied with the SensoGrip pen, 2 (40%) were neutral about it, and 1 (20%) did not respond. Of the 5 parents, 3 (60%) were in favor of continuing its use, 1 (20%) opted against it, and 1 (20%) did not respond to this specific question.

Participants’ Design Evaluation

Participants evaluated the pen’s design based on various features, as described in Table 2.
Table 2. Opinions about the different design features of the SensoGrip pen. Occupational therapists (OTs) and children’s opinions were obtained from the interviews, and parents’ ratings were obtained using the questionnaire.

<table>
<thead>
<tr>
<th>Design feature</th>
<th>Opinions Children</th>
<th>Parents</th>
<th>OTs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall appearance and design</td>
<td>“Good” (12/13, 92%)</td>
<td>Very suitable: 2/5, 40%</td>
<td>—^a</td>
</tr>
<tr>
<td></td>
<td>“Medium” (C14; aged 6 y)</td>
<td>Suitable: 3/5, 60%</td>
<td></td>
</tr>
<tr>
<td>Size and weight</td>
<td>“Good” (C3; aged 6 y)</td>
<td>Size</td>
<td>“Okay, but could be smaller, thinner, and lighter for better fit for children. Pen’s tip could be a little bit shorter.”</td>
</tr>
<tr>
<td></td>
<td>“Heavier than a conventional pen but great” (C15; aged 8 y)</td>
<td>Very suitable: 1/5, 20%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>“Should be a little bit thinner” (C1; aged 6 y)</td>
<td>Suitable: 2/5, 40%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Indifferent: 1/5, 20%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Not suitable: 1/5, 20%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Comments—Too thick (2/5, 40%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Weight</td>
<td>Suitable: 3/5, 60%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mediocre: 2/5, 40%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Shape</td>
<td>Suitable: 3/5, 60%</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Indifferent: 2/5, 40%</td>
<td></td>
</tr>
<tr>
<td>Material and haptics</td>
<td>“Pleasant” (C3; aged 6 y)</td>
<td>Very suitable: 2/5, 40%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>“It can be held well” (C1; aged 6 y)</td>
<td>Suitable: 3/5, 60%</td>
<td></td>
</tr>
<tr>
<td>Finger sensor position</td>
<td>—</td>
<td>—</td>
<td>“Anti-slip surface was good. Grip moulds could help some children to ensure ergonomic grip.”</td>
</tr>
<tr>
<td>LED position</td>
<td>—</td>
<td>LED should be positioned on the proximal end of the pen (1/5, 20%)</td>
<td>“For some children hard to position fingers on the sensor, to ensure correct pressure measurements. Sensor should be placed nearer towards the pen’s tip.”</td>
</tr>
<tr>
<td>LED</td>
<td>“Funny when it lights up” (C15; aged 8 y)</td>
<td>Colored LED motivated children (3/5, 60%), but also distracted one child (1/5, 20%)</td>
<td>“LED should be positioned on the proximal end of the pen for younger children (ensures better sight of the LED) and on the distal end for older children (ensures simultaneous sight of LED and written text).”</td>
</tr>
<tr>
<td></td>
<td>“Not bright enough” (C3; aged 6 y)</td>
<td>Wish for acoustic feedback (2/5, 40%)</td>
<td></td>
</tr>
<tr>
<td>Pen’s tip and refill</td>
<td>“Well slipping pen tip” (C3; aged 6 y)</td>
<td>Tip runs smoothly on the paper (3/5, 60%)</td>
<td>“Should be brighter. Some wished additional acoustic and/or vibration feedback.”</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ink not erasable (2/5, 40%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pencil lead would be better (3/5, 60%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>“Pencil lead would be better for younger children, colored pencil lead even better. Roller pen ink should be erasable.”</td>
<td></td>
</tr>
<tr>
<td>Battery</td>
<td>—</td>
<td>Runs down too fast (2/5, 40%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Battery display missing (1/5, 20%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>“Poor” battery (1/5, 20%)</td>
<td></td>
</tr>
</tbody>
</table>

^aNot available.

Technical Performance

Overall, the SensoGrip pen and app were found to be technically well functioning. The reported malfunctioning included the following: quick battery depletion and a long time to connect the pen to the app in some cases. Of the 16 SensoGrip pens, 2 (13%) broke. In one case, it fell on the floor, and in another case, a child was applying extremely high pressure on the pen. In one instance, the lead of the pen slipped inside the pen when a child was pressing it with very high pressure on the table. Crashing of the tablet app was reported only once over the test duration.

https://rehab.jmir.org/2024/1/e51116

JMIR Rehabil Assist Technol 2024 | vol. 11 | e51116 | p.39

(page number not for citation purposes)
Discussion

Usefulness, Satisfaction, and Perceived Impact of the System

OTs viewed the SensoGrip system as a valuable addition to their therapeutic toolkit. It met or exceeded the expectations for most, with 7 out of 8 (88%) OTs rating it highly on the USE questionnaire for its usefulness. The system’s graphical display of writing pressure was particularly noted for its effectiveness in analyzing and guiding children’s handwriting interventions. In addition, some children reported improvements in their handwriting, attributing this to the heightened pressure awareness provided by the biofeedback. This tool seems to provide information about sensory-motor processes during writing, which are not inherently perceptible to them [22].

Overall, the OTs were pleased with the system’s performance, finding it enjoyable and effective—a sentiment that remained consistent throughout several weeks of therapy. This consistent satisfaction is indicative of the system’s potential for long-term acceptance, avoiding the pitfall of waning interest over time [23].

Children’s satisfaction was also noteworthy, with almost all (12/15, 80%) expressing the highest level of enjoyment. The interactive feature of the pen lighting up was a favorite. However, caution was advised for children with intellectual impairments, as a child’s difficulty in comprehending the feedback suggested the need for tailored use assessments by OTs, especially given the possible correlation between intellectual and graphomotor challenges.

In summary, the SensoGrip system was recognized for its dual impact: enhancing awareness of handwriting pressure and increasing children’s motivation to engage in writing tasks during therapy sessions.

Usability and Technical Performance

The SensoGrip system earned high scores for user-friendliness from OTs, with a median score of 6 out of 7 on the Likert scale. The ease with which users could learn the system was also rated highly, with scores ranging between 5 and 7. Feedback about future refinements included a preference for a thinner, lighter pen—a sentiment echoed by some children and parents. However, current design limitations prevent the reduction of the pen’s thickness. In addition, the OTs suggested shortening the pen’s tip to allow the child’s hand to be closer to the paper while still keeping the fingers on the pressure-sensing zone on the grip area.

The OTs reported that most children easily adapted to writing with the SensoGrip pen. There was a consideration to reposition the LED to the pen’s proximal end for better visibility for the OT, but the need for children to see the light during writing mandated its placement near the tip. A preference for pencil lead over ballpoint refills was noted, particularly for young children accustomed to pencils. The prototype’s design accommodated a fixed-length ballpoint refill to avoid the complexities associated with a retracting pencil lead and pressure measurement.

Technical performance evaluations throughout the trial revealed that the system functioned at a high level. Most recorded technical issues during the trial were generally minor and typical for technical products, such as battery depletion and slow app response. The only significant technical issue occurred when 2 pens broke owing to falling on the ground and excessive pressure, which was attributed to the limitations of the manufacturing process in which the pen shafts were 3D printed. Despite these incidents, overall technical performance was not deemed to significantly influence user satisfaction or the system’s usability.

Limitations

This study has certain limitations. The selection of OTs was based on their readiness to integrate a technical device into their practice, which may not reflect the perspectives of those with low technical proficiency. Consequently, the findings may predominantly represent the views of OTs who are already inclined toward technology, suggesting a potential bias toward perceiving the system as having considerable potential. This limits the broad applicability of the results across the entire OT population. Children’s overwhelmingly positive feedback about the pen must be considered in light of possible bias, as responses might have been influenced by the desire to provide socially acceptable answers to adults. In addition, the study was conducted within the same institution responsible for developing the SensoGrip system. However, the study’s integrity was maintained by ensuring that the research team was different from the development team. Given the primarily qualitative and explorative nature of the study and the absence of a control group, the findings reflect the subjective experiences of the participants. As such, the reported impacts should be interpreted with an understanding that they do not provide an empirical measure of the system’s effectiveness.

Conclusions

This multimethods study evaluating the SensoGrip pressure-sensitive pen system offers insightful contributions to the field of pediatric occupational therapy. Through the involvement of 8 OTs with varying levels of experience (mean 13.5, SD 7 y); 16 children aged between 5 and 10 years, exhibiting handwriting difficulties; and their parents, the study describes the system’s utility and potential. The participants engaged with the SensoGrip system within a natural, private practice setting in Austria.

Our findings reveal that the SensoGrip system is met with strong acceptance and satisfaction, both from children who enjoyed the interactive feedback and from OTs who recognized its potential as a therapeutic tool. The system was instrumental in enhancing the children’s awareness of handwriting pressure, thus showing the potential to promote more controlled and deliberate movements. OTs reported observing tangible improvement in the children’s pressure modulation over the course of the intervention, which included 3 to 7 therapy sessions. However, the SensoGrip system’s suitability varied among participants, with a subset of children not experiencing the anticipated benefits. These variances highlight the need for personalized approaches in the application of assistive technologies within pediatric occupational therapy.
The study underscores the importance of such assistive technologies in reinforcing the development of fine motor skills. In particular, the real-time feedback component of the SensoGrip system was highlighted as a significant motivator for children, fostering both engagement and enjoyment in the handwriting process.

Although the SensoGrip system has shown promising results in this preliminary exploration, future studies involving controlled quantitative trials are essential to validate and quantify its impact. This study will ideally expand to consider the effects of age, developmental stage, and presence of comorbid conditions on the efficacy of the SensoGrip system.

The feedback from both the children and OTs underscore the potential of integrating technology-based interventions in therapeutic settings. Such interventions contribute not only to skill development but also to the intrinsic motivation of children, which is crucial for sustained engagement and therapeutic success.

Acknowledgments
The authors thank all the participants of this study.

Conflicts of Interest
None declared.

Multimedia Appendix 1
Eligibility checklist for children, assessed by their occupational therapist.  
[PDF File (Adobe PDF File), 78 KB - rehab_v11i1e51116_app1.pdf ]

Multimedia Appendix 2
Usefulness, Satisfaction, and Ease of Use and Ease of Learning questionnaire, German translation.  
[PDF File (Adobe PDF File), 214 KB - rehab_v11i1e51116_app2.pdf ]

Multimedia Appendix 3
Focus group and interview guidelines.  
[PDF File (Adobe PDF File), 103 KB - rehab_v11i1e51116_app3.pdf ]

Multimedia Appendix 4
The participating therapists' acceptance of technology.  
[PNG File - rehab_v11i1e51116_app4.png ]

References


18. Lund AM. Measuring usability with the USE questionnaire. Usability Interface 2001;8(2):3-6 [FREE Full text]


Abbreviations

OT: occupational therapist

USE: Usefulness, Satisfaction, and Ease of Use and Ease of Learning

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Validity and Reliability of a Telehealth Physical Fitness and Functional Assessment Battery for Ambulatory Youth With and Without Mobility Disabilities: Observational Measurement Study

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Abstract

Background: Youth (age 15-24 years) with and without disability are not adequately represented enough in exercise research due to a lack of time and transportation. These barriers can be overcome by including accessible web-based assessments that eliminate the need for on-site visitations. There is no simple, low-cost, and psychometrically sound compilation of measures for physical fitness and function that can be applied to youth with and without mobility disabilities.

Objective: The first purpose was to determine the statistical level of agreement of 4 web-modified clinical assessments with how they are typically conducted in person at a laboratory (convergent validity). The second purpose was to determine the level of agreement between a novice and an expert rater (interrater reliability). The third purpose was to explore the feasibility of implementing the assessments via 2 metrics: safety and duration.

Methods: The study enrolled 19 ambulatory youth: 9 (47%) with cerebral palsy with various mobility disabilities from a children’s hospital and 10 (53%) without disabilities from a university student population. Participants performed a battery of tests via videoconferencing and in person. The test condition (teleassessment and in person) order was randomized. The battery consisted of the hand grip strength test with a dynamometer, the five times sit-to-stand test (FTST), the timed up-and-go (TUG) test, and the 6-minute walk test (6MWT) either around a standard circular track (in person) or around a smaller home-modified track (teleassessment version, home-modified 6-minute walk test [HM6MWT]). Statistical analyses included descriptive data, intraclass correlation coefficients (ICCs), and Bland-Altman plots.

Results: The mean time to complete the in-person assessment was 16.9 (SD 4.8) minutes and the teleassessment was 21.1 (SD 5.9) minutes. No falls, injuries, or adverse events occurred. Excellent convergent validity was shown for telemeasured hand grip strength (right ICC=0.96, left ICC=0.98, P<.001) and the TUG test (ICC=0.92, P=.01). The FTST demonstrated good agreement (ICC=0.95, 95% CI 0.79-0.98; P=.01). The HM6MWT demonstrated poor absolute agreement with the 6MWT. However, further exploratory analysis revealed a strong positive correlation between the tests (r=0.83, P<.001). The interrater reliability was excellent for all tests (all ICCs>0.9, P<.05).

Conclusions: This study suggests that videoconference assessments are convenient and useful measures of fitness and function among youth with and without disabilities. This paper presents operationalized teleassessment procedures that can be replicated by health professionals to produce valid and reliable measurements. This study is a first step toward developing teleassessments
that can bypass the need for on-site data collection visitations for this age group. Further research is needed to identify psychometrically sound teleassessment procedures, particularly for measures of cardiorespiratory endurance or walking ability.

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KEYWORDS
cerebral palsy; telehealth; young adults; telemonitoring; exercise; therapy; therapeutic exercise; assessment; teleassessment; reliability; usability; disability; youth; physical fitness; videoconference

Introduction

In clinical trials of exercise, conventional measures of physical fitness and function (2 determinants of successful interventions) require participants to be physically present at a laboratory to undergo measurement procedures with specialized equipment. This requirement is burdensome and time-consuming, which negatively affects enrollment rates. In fact, 2 of the most common reasons for nonparticipation in exercise interventions are a lack of time and transportation [1,2]. To overcome these challenges, exercise trials have begun to use web-based videoconferencing to implement intervention protocols and, more recently, collect study outcome data (ie, telemassessments). The obvious benefit of teleassessments is that they negate the need for participants to travel to an on-site research facility. This benefit is critical for advancing scientific knowledge in exercise research.

Clinical exercise interventions are limited by their ability to reach a representative sample size, and this limits the generalizability of study findings. Systematic reviews of exercise research among young adults have reported that clinical trials lacked representativeness. One review reported that only 77% of studies achieved their recruitment targets [3]. Another review reported that 86% of adults who participated in exercise research were Caucasian (mean age 51 years) [4]. Representativeness was worse among clinical populations. Considering people with physical disabilities, reviews have found that the average sample size for randomized controlled trials of exercise is 30 people: 15 per treatment and 15 per control group [1,5,6]. Moreover, a review found that 58.9% of adults with physical disabilities who were contacted to participate in exercise trials were lost before study enrollment and an even smaller percentage of people completed the exercise trial or returned for their follow-up data collection [1]. There is a genuine need for accessible and inclusive ways to increase participation in exercise trials, given that 1 in 4 adults in general and 1 in 2 adults with physical disabilities in the United States do not meet the national guidelines for exercise [7-10]. Achieving the national guidelines for exercise is important for preventing and managing all-cause morbidity and mortality [5,7,11,12].

There are existing studies on telehealth assessments, particularly among middle-aged and older adults [13-20]. Relevant prior works included a study that investigated mobility-focused physical outcome measures, which included the hand grip strength test, the five times sit-to-stand test (FTST), and the timed up-and-go (TUG) test [19]; multiple studies have investigated a remotely delivered version of a 6-minute walk test (6MWT) [21-23]; and a pilot investigated balance and gait assessments [24]. The 6MWT has also been found to be a valid indicator of cardiorespiratory fitness [25-27]. There were similar teleassessment investigations with the movement assessment battery for children (5-11 years old) [28], as well as the TUG test in children and teenagers (6-18 years old) with autism spectrum disorder [29]. Notably, a systematic review found that teleassessments had strong psychometric properties among adults [20], but there are far less investigations among younger age groups, particularly younger age groups with difficulties in gross motor function.

The youth demographic, defined as persons aged from 15 to 24 years according to the United Nations and the World Health Organization (WHO), is important because this is the age range where people adopt sedentary lifestyles that last throughout adulthood. There are 3 reasons why exercise promotion is important among youth: (1) data demonstrate that exercise participation levels are alarmingly low and continue to decline throughout the youth age range [30-33], particularly among youth with disabilities [34-36]; (2) adoption of exercise behavior during youth may increase the likelihood that people are regular exercisers in adulthood [37,38]; and (3) exercise during youth may prevent obesity and cardiometabolic disease in adulthood [39,40]. Moreover, the youth age range is where clinical populations tend to experience functional decline [41]. One study found that people with cerebral palsy (CP) with mobility disabilities experience clinically significant declines in physical function as they age from adolescence to adulthood [42]. Another study on youth with CP found that the probability of walking is highest at age 9 years (68%) and lower at age 18 years (approx. 50%) [43]. Two other studies have revealed the same pattern of functional loss and called for a more comprehensive therapeutic approach beyond the traditional focus on childhood [44,45].

Making an impact on exercise participation will require telehealth-driven exercise trials, with teleassessments that are inclusive of youth with and without disabilities. Inclusive trials are important not only for health promotion but also for disability equity, as fundamentally described in the First Global Physical Activity and Sedentary Behavior Guidelines for People Living with Disability, released by WHO: “Creating opportunities for inclusion in physical activity for people living with disability can help eliminate such barriers by changing perceptions, emphasizing strengths and abilities, promoting personal resilience, and having an upward impact on inclusion in society” [46,47].

Teleassessments that support large-scale exercise trials should include safe, valid, and reliable methods with affordable equipment. Nevertheless, there are few established methods among the youth age range. Additionally, there has not been a psychometric evaluation of a standardized compilation of
A total of 4 tests were included to assess physical fitness and motor function. Tests that require complex coordination or precise timing were not considered due to feasibility concerns. The tests were chosen based on their feasibility and safety to be performed in an average home setting [49], their broad use in research and clinical settings, and their well-researched psychometric properties in the adult population with and without disabilities [50-59]. The teleassessment protocols were modified to better suit the home environment. Picture demonstrations and instructions are included in Multimedia Appendix 1.

The tests were conducted in the following order: the hand grip strength test with a dynamometer, the FTST, the TUG test, and the 6MWT.

**Hand Grip Strength Test (Physical Fitness)**

The participants were instructed to sit in a stationary chair using a Camry digital hand dynamometer. The procedure included 3 trials with each hand, with the elbow flexed at 90°, with a 30-second rest in between trials. For videoconference assessments, the field of view included the participant’s upper body. The participants were instructed to position the laptop camera to include their elbow, the device, and their face to ensure the posture was correct. Several studies have supported the validity and reliability of this test among a variety of populations [51-55].

**Five Times Sit-to-Stand Test (Physical Fitness)**

The equipment included a chair, 24 inches in height, without arm rests. The participants were instructed to sit in the chair and then stand up and sit down 5 times as fast as they could. The time it took to complete the task was recorded in seconds. For the videoconference assessment, each participant was instructed to rotate the chair 90° so that the recording included a profile view of the participant’s entire body (at least the shoulders, hips, and knees); see Figure 1. A repetition was counted as complete only when the participant’s rear contacted the chair. Several studies have supported the validity and reliability of the FTST [60-63].
Timed Up-and-Go Test (Lower Extremity Function)

The participants were instructed to sit in a chair and then to stand up, walk straight to a cone that was placed 118 inches (3 m) away from the chair, turn around, and walk back to sit down in the chair. The time it took to complete the task was recorded in seconds. For the videoconference assessment, the participants were instructed to rotate the chair 90°. They were then instructed to place down the measuring tape starting from the chair. The tape needed to be straight, without wrinkles or folds. The participants were instructed to adjust the camera angle to include their entire body throughout the test, the floor, the chair, and the entire 3 m walkway (Figure 2). The task was considered complete only when the participant’s rear contacted the chair. The reliability and validity of the TUG test have been demonstrated in a variety of populations [56].

Six-Minute Walk Test (Lower Extremity Function and Cardiorespiratory Fitness)

For the in-person 6MWT, participants were instructed to walk as much as possible in 6 minutes around a circular track that was marked by cones. The distance walked was measured with a distance-measuring wheel, which was held by a research staff member, who followed the participant around the track during the test. The 6MWT has a variety of studies supporting its psychometric properties for measuring lower extremity function or walking ability and cardiorespiratory fitness among a variety of populations [21-23,25-27,50,57].

The research team devised a shorter, home-modified version of the 6MWT to reflect the space constraints often found in a participant’s home (Figure 3). The home-modified 6-minute walk test (HM6MWT) followed the TUG test. Thus, from the previous TUG teleassessment setup, participants were instructed to place an additional cone directly at their feet while sitting in the chair. The participants were then asked to move the chair
out of the way of the 2-cone obstacle course. The camera was positioned to include the participant’s entire body throughout the test, the floor, and the entire walkway. The equipment in total included 2 cones and a piece of measuring tape to measure out the 118-inch (3 m) walkway. The assessor counted the number of laps that were completed in 6 minutes. Assessors also estimated the length of the last incomplete lap as a fraction (e.g., 0.25 laps) during the 6 minutes.

**Figure 3.** Laptop camera view of the 6MWT: 6MWT: 6-minute walk test.

### Procedures

All participants completed the 2 types of assessments (tele- and in-person assessments) in a single visit. The order in which a participant completed the tele- and in-person assessments was randomized and counterbalanced. In-person assessments were conducted in a typical laboratory setting. Teleassessments were conducted in a different setting; the space for teleassessments was measured to be a minimum of 10 × 15 square feet to resemble a modest estimate of an average living room. The in-person assessments were performed under the supervision of a research staff member, while the videoconference assessments were conducted using Zoom videoconferencing. For the latter, participants set up each teleassessment with the verbal guidance of the research staff member on Zoom. A caregiver was allowed to assist their child in the teleassessment setup and in performing the tests in order to prevent falls that might occur.

The general procedure was as follows: participants were briefed and provided informed consent; they completed the study surveys (demographic information and videoconference literacy), underwent randomization via a coin flip, and completed the tests under both conditions; and then they completed a follow-up questionnaire on their experience with the teleassessments. Videoconference literacy was assessed via the Video Conference Literacy and Usability Questionnaire, which was modified from the Telehealth Usability Questionnaire [64]. The follow-up questionnaire included 3 open-ended questions: (1) likes about the assessments, (2) dislikes about the assessments, and (3) technical issues or problems they experienced during the assessments. Study staff were also instructed to record problems or issues they observed during the assessments on the data collection form.

Regarding the setting, participant groups (youth with and without disabilities) completed the testing at 2 different university laboratories. The protocols for conducting the assessments were matched between the research teams. To assist with the standardization, assessors were given scripts on how to guide participants in setting up the teleassessments and performing each test.

For study purpose 1, 1 research staff member scored all assessments for youth with disabilities (author BL, a disability exercise specialist with over 10 years of clinical experience). Graduate research assistants scored all assessments for youth without disabilities. For study purpose 2, the videoconference recordings of the functional tests part were scored independently by 2 raters (author LM, a senior disability exercise specialist, and a doctoral student in rehabilitation science), who were blinded to the randomization, assessment type, order, and participant and researcher conversations before and after the assessments. The raters were trained to score by the lead investigator (BL) using an operations manual included in Multimedia Appendix 1. Training included a preliminary assessment of interrater reliability for a sample of 3 participants, from which they had excellent agreement for all assessments (>99% absolute agreement for the hand grip strength test, the FTST, and the TUG test; 96% for the 6MWT). The plan was to retrain them if they achieved less than 95% agreement on the assessments. Study purpose 3, feasibility, included several descriptive metrics: the participant feedback survey; duration to complete the assessments in minutes; problems, issues, or nuances experienced during the testing; and observational feedback from the assessors (recorded on the data collection form).
Equipment

Teleassessment rooms were equipped with a Chromebook brand laptop (Samsung Galaxy Chromebook Professional Laptop, 13.3 inches, with a built-in microphone and web camera). At the start of the teleassessment, the laptop was positioned on the table. Assessment equipment included a hand grip strength dynamometer (CAMRY digital hand grip dynamometer), disc cones, a distance-measuring wheel, and a soft measuring tape that was cut to a 118-inch (3 m) length.

Analysis

For study purpose 1, ICCs were used to examine the convergent validity (ICC-v) between the test conditions. ICC-v values were complemented with Bland-Altman plots to visualize differences in agreement [65]. For the HM6MWT, additional exploratory analyses were performed to identify the optimal multiplier for the laps that would best estimate the distance in meters obtained from an in-person 6MWT. Specifically, the number of laps was first multiplied by a value of 6 m (cones were laid out 3 m away from each other—hence a minimum track of 6 m) and tested, then multiplied by 7 m, 8 m, and so on until the multipliers for the highest ICC-v were identified. For only the 6MWT, Pearson correlation analysis was planned if agreement analyses were not identified through the ICC-v.

For study purpose 2, ICCs were used to examine the interrater reliability (ICC-r) between 2 assessors (a doctoral student in rehabilitation science and a senior exercise physiology researcher). The assessors scored recorded videos of the teleassessments from the 9 (47%) ambulatory youth with CP, since the study team anticipated higher variability of performance due to mobility disability. ICCs and their 95% CIs were calculated using IBM SPSS version 24. For the ICC-v, a 2-way mixed-effects model with absolute agreement was used with single or average measures, as appropriate for each test. For the ICC-r, a 2-way random-effects model was used with absolute agreement and single measures. The ICC interpretation criteria were as follows:

- 0.0-0.5 was considered poor;
- 0.5-0.75, moderate;
- 0.75-0.9, good; and
- 0.9 or higher, excellent [66].

The ICC analyses were first calculated against ICC $H_0=0.75$ to derive the conclusion that the validity or reliability was at least good in terms of agreement, in accordance with the study hypotheses. Further comparison against excellent agreement (ICC $H_0=0.9$) was conducted if preliminary analysis identified good agreement.

For study purpose 3 (feasibility), data on the following items were collected: the duration of both types of assessments, technical usability issues, and problems or adverse events experienced by participants or assessors.

Ethical Considerations

Written informed consent was obtained from all participants prior to their engagement in the study. For completing the study, participants without disabilities were compensated with extra course credit, while participants with disabilities were compensated with a US $60 gift card. The study procedures were conducted separately at each university and approved by the Institutional Review Board of each university (University of Alabama at Birmingham: #300009041; Auburn University: #22-112 EP 2204), with the agreement that study results would be combined for analysis. Participation was kept confidential.

Results

Participant Information

Participant characteristics are shown in Table 1. All 9 (47%) youth with mobility disabilities were ambulatory with a primary diagnosis of CP with a Gross Motor Function Classification System Level of I-III; of them, 8 (89%) were described as hemiplegic in terms of motor disability. One required physical assistance from a caregiver while walking, and another wore a right-leg orthotic device during the tests. One person with CP had mild-to-moderate cognitive disability. There were no statistically significant differences between groups in age, height, weight, or other aspects. Participants generally reported high videoconference literacy and usability scores.

Table 1. Overall participant characteristics (N=19).

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Youth with CP (n=9)</th>
<th>Youth without disabilities (n=10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years), mean (SD)</td>
<td>17.4 (1.9)</td>
<td>19.3 (1.2)</td>
</tr>
<tr>
<td>Sex (male/female), n (%)</td>
<td>5 (56) male, 4 (44) female</td>
<td>5 (50) male, 5 (50) female</td>
</tr>
<tr>
<td>Height (cm), mean (SD)</td>
<td>160.1 (15)</td>
<td>160 (35)</td>
</tr>
<tr>
<td>Weight (lb), mean (SD)</td>
<td>142.7 (38)</td>
<td>149.6 (29)</td>
</tr>
<tr>
<td>Videoconference literacy and usability questionnaire, mean (SD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Usefulness</td>
<td>13.2 (1.6)</td>
<td>12.1 (1.9)</td>
</tr>
<tr>
<td>Ease of use and learnability</td>
<td>12.7 (1.9)</td>
<td>13.1 (1.9)</td>
</tr>
<tr>
<td>Interface quality</td>
<td>17.2 (2.6)</td>
<td>15.3 (2)</td>
</tr>
<tr>
<td>Interaction quality</td>
<td>14.1 (2.9)</td>
<td>10.5 (6.8)</td>
</tr>
<tr>
<td>Reliability</td>
<td>10.6 (2.4)</td>
<td>8.8 (2.1)</td>
</tr>
<tr>
<td>Satisfaction and future use</td>
<td>18.6 (1.9)</td>
<td>16.1 (2.7)</td>
</tr>
</tbody>
</table>
Convergent Validity (Purpose 1)

Table 2 displays the ICC-v analysis results between in-person assessments and teleassessments for the hand grip strength test, the FTST, and the TUG test. Hand grip strength ICC(2,3) analyses, with H₀ = 0.75 (test value calculation vs a null hypothesis of good agreement), demonstrated statistically significant agreement between test conditions for both right-hand (ICC=0.96, 95% CI 0.9-0.99; P<.001) and left-hand (ICC=0.98, 95% CI 0.95-0.99; P<.001) grip strength. FTST test ICC(2,1) analysis, with H₀ = 0.75, demonstrated statistically significant agreement between test conditions (ICC=0.95, 95% CI=0.79-0.98; P=.01). Agreement results remained statistically significant when tested against excellent agreement (ICC=0.92). Bland-Altman plots (Figure 4) supported the ICC analyses and demonstrated strong agreement between conditions for hand grip strength, the FTST, and the TUG test.

Table 2. ICC-va for the hand grip strength test, the FTSTb, and the TUGc test.

<table>
<thead>
<tr>
<th>Test</th>
<th>In-person assessment, mean (SD)</th>
<th>Teleassessment, mean (SD)</th>
<th>ICC-v (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right-hand grip strength (lb)</td>
<td>63 (29.8)</td>
<td>61.9 (26.9)</td>
<td>0.96 (0.90-0.99)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Left-hand grip strength (lb)</td>
<td>61.8 (25.9)</td>
<td>64.2 (28.8)</td>
<td>0.98 (0.95-0.99)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>FTST (seconds)</td>
<td>13.0 (5.9)</td>
<td>15.1 (7.7)</td>
<td>0.95 (0.79-0.98)</td>
<td>.01</td>
</tr>
<tr>
<td>TUG test (seconds)</td>
<td>8.5 (3.2)</td>
<td>9.2 (4.0)</td>
<td>0.92 (0.79-0.97)</td>
<td>.01</td>
</tr>
</tbody>
</table>

aICC-v: intraclass correlation coefficient for validity.
bFTST: five times sit-to-stand test.
cTUG: timed up-and-go.

Figure 4. Bland-Altman plots for agreement between in-person and telehealth assessments of the hand grip strength test, the FTST, and the TUG. FTST: five times sit-to-stand test; TUG: timed up-and-go.

Table 3 displays the exploratory ICC-v analysis results between in-person assessments and teleassessments. Exploratory ICC(2,1) analyses demonstrated that the conversion factor (CF) of a 10.7 lap multiplier provided the highest ICC agreement value (Table 3). However, the HM6MWT 10.7 lap multiplier ICC(2,1), with H₀ = 0.75, did not demonstrate statistically significant agreement between test conditions (ICC=0.95, 95% CI=0.79-0.98; P<.001). However, the agreement result for the FTST was not statistically significant when tested against excellent agreement (P=.17). TUG ICC(2,3) analysis, with H₀ = 0.75, demonstrated statistically significant agreement between test conditions (ICC=0.92, 95% CI 0.79-0.98; P<.001). Agreement results remained statistically significant when tested against excellent agreement (H₀ = 0.9). Bland-Altman plots (Figure 4) supported the ICC analyses and demonstrated strong agreement between conditions for hand grip strength, the FTST, and the TUG test.

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with on-site 6MWT distances (P=.18). Teleassessment 10.7 ICC(2,1) analysis, with H₀ = 0.5 (fair agreement), showed a statistically significant agreement (ICC=0.83, 95% CI 0.62-0.93; P=.01). The Bland-Altman plot showed seemingly poor agreement for the teleassessment to either underestimate or overestimate walking distances compared to those obtained in person (Figure 5). Follow-up Pearson correlation analysis
resulted in a strong positive correlation between both teleassessment laps counted ($r=0.83$, $P<.001$; Figure 6) and teleassessment walking distance with a 10.7 CF ($r=0.83$, $P<.001$) compared to on-site walking distances.

Table 3. ICC-$v^a$ for the exploratory conversions of the HM6MWT$^b$ and the 6MWT$^c$.

<table>
<thead>
<tr>
<th>Test</th>
<th>Converted distance (m), mean (SD)</th>
<th>6MWT distance (m), mean (SD)</th>
<th>ICC-$v$ (95% CI)</th>
<th>$P$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>HM6MWT with x10.6 m/lap (m)</td>
<td>488 (128)</td>
<td>496 (119)</td>
<td>0.83 (0.62-0.93)</td>
<td>.18</td>
</tr>
<tr>
<td>HM6MWT with x10.7 m/lap (m)</td>
<td>493 (129)</td>
<td>496 (119)</td>
<td>0.83 (0.62-0.93)</td>
<td>.18</td>
</tr>
<tr>
<td>HM6MWT with x10.8 m/lap (m)</td>
<td>493 (131.8)</td>
<td>496 (119)</td>
<td>0.83 (0.61-0.93)</td>
<td>.18</td>
</tr>
</tbody>
</table>

$^a$ICC-$v$: intraclass correlation coefficient for validity.

$^b$HM6MWT: home-modified 6-minute walk test.

$^c$6MWT: 6-minute walk test.

Figure 5. Bland-Altman plot for agreement in meters between the 6MWT and the converted HM6MWT with a 10.7 CF for laps to meters. 6MWT: 6-minute walk test; CF: conversion factor; HM6MWT: home-modified 6-minute walk test.
Figure 6. Linear regression analysis between the HM6MWT number of laps and the 6MWT in meters ($r=0.825$, 95% CI 0.593-0.930). The fitted line has a slope of 8.15 and a constant of 120.5. 6MWT: 6-minute walk test; HM6MWT: home-modified 6-minute walk test.

### Teleassessment Interrater Reliability and Disability (Purpose 2)

Hand grip strength ICC\(_{(2,3)}\) analyses, with $H_0=0.75$ (good agreement), demonstrated statistically significant agreement between raters for both right-hand (ICC=1.0, 95% CI 1.0-1.0; $P<.001$) and left-hand (ICC=0.998, 95% CI 0.998-1; $P<.001$) grip strength. These results were the same when tested against excellent agreement ($H_0=0.9$). For the rest of the teleassessment battery (FTST, TUG, and HM6MWT), the ICCs for reliability testing between the 2 raters (ICC-$r$) for the youth with CP are displayed in Table 4. The results demonstrated excellent agreement (tested against $H_0=0.9$) for all 3 rater-dependent tests.

#### Table 4. ICC-$r$\(^a\) for the interrater reliability of the rater-dependent tests.

<table>
<thead>
<tr>
<th>Test</th>
<th>Rater 1, mean (SD)</th>
<th>Rater 2, mean (SD)</th>
<th>ICC-$r$ (95% CI)</th>
<th>$P$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>FTST(^b)</td>
<td>17.0 (7.73)</td>
<td>16.9 (7.75)</td>
<td>0.998 (0.992-1.000)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>TUG(^c)</td>
<td>11.53 (4.57)</td>
<td>11.41 (4.65)</td>
<td>0.999 (0.997-1.000)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>HM6MWT(^d)</td>
<td>36.85 (14)</td>
<td>36.75 (13.86)</td>
<td>0.999 (0.999-1.000)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

\(^a\)ICC-$r$: intraclass correlation coefficient for reliability.
\(^b\)FTST: five times sit-to-stand test.
\(^c\)TUG: timed up-and-go.
\(^d\)HM6MWT: home-modified 6-minute walk test.

### Feasibility (Purpose 3)

For all participants, the time to complete the in-person battery (mean 16.9, SD 4.8 minutes) was on average 20% shorter (16.9/21.1 minutes) than the time to complete the teleassessment battery (mean 21.1, SD 5.9 minutes), and this difference was statistically significant (mean 4.16, SD 5.3 minutes; $P=.003$). Youth with CP took 45% longer (20.4/14.1 minutes) to complete the in-person assessments (mean 20.4, SD 2.4 minutes) than youth without disabilities (mean 14.1, SD 4.3 minutes), and this difference was statistically significant (mean difference 6.33, SD 3.8 minutes; $P=.003$). In addition, youth with CP took 33% longer (24.8/18.7 minutes) to complete the teleassessments (mean 24.8, SD 2.8 minutes) compared to youth without disabilities (mean 18.7, SD 5.7 minutes), with a mean difference of 6.11 (SD 5.4) minutes ($P=.01$). No adverse events, such as falls, occurred throughout the study.

Three participants with CP reported that the HM6MWT made them feel slightly dizzy and was more difficult because of the track’s limited length and the frequent turns resulting from it. Three participants without disabilities reported that the HM6MWT was more difficult due to the space limitation. This idea was supported by all 3 assessors, who observed that participants seemingly had to put more conscious effort into making the turns around the cones, particularly when walking.
at a fast speed. The assessors also noted that cognitive disability seemed to cause variability in turns. The 1 (5%) participant with mild-to-moderate cognitive disability walked in different paths around the cones on each lap: some big paths around the cones and some small tight paths. Some participants adopted head-and-eye-focusing strategies to prevent feeling nauseated when turning. Participants generally reported that the tests were similar between the 2 settings, except for the HM6MWT.

Discussion

Principal Findings
This study investigated the feasibility, validity, and reliability of an inclusive telehealth battery of physical fitness and function among a cohort of youth with and without disabilities. A strength of the teleassessment battery was that it could be delivered with minimal, low-cost supplies. The battery included 4 web-modified tests, and the results of these tests were compared with how they were typically conducted on-site at a laboratory. All 4 web-based tests were modified so that they could be delivered through videoconferencing and within a small home environment. Most modifications were minor, except for the HM6MWT, which included the largest modification: a long-distance track that was converted to a small straight-path walkway. Overall, study findings suggested that the teleassessment battery had accessible feasibility, as indicated by safety and convenience. The mean time for completing the assessments was short, under 30 minutes. No falls, problems, or other adverse events occurred. Findings warrant a true examination of feasibility in a less controlled environment: the participants’ homes. Of note, the study findings showed that a novice and an expert assessor can achieve similar results when conducting the web-based assessments (excellent interrater reliability), which has important practical implications for implementation. First, highly experienced personnel may not be necessary to conduct the teleassessments. Second, a participant who completes an intervention does not need to be scored by the same rater who scored their baseline assessments, thereby reducing scheduling constraints and the burden on research staff. Most importantly, findings largely demonstrated good-to-excellent convergent validity between the tele- and in-person assessments.

Comparison With Previous Work
Regarding validity, the web-modified versions for the hand grip strength test, the FTST, and the TUG test had excellent agreement with scores obtained from the in-person assessments. Researchers and health professionals may feel confident in performing these tests through videoconferencing, when the participant’s environment conforms with the study procedures. As for the HM6MWT, the findings are less clear. The HM6MWT demonstrated only fair absolute agreement with in-person assessments, and this was when analyzed with the best-possible CF for transforming laps walked into walking distance in meters. Bland-Altman plots showed that the web-modified test overestimated or underestimated walking distances by greater than 100 m, which is substantially large, given that the mean walking distance for this age group is 496 m. This finding indicated that the HM6MWT distance in meters (converted from laps) should not be compared with the distance in meters obtained from an in-person 6MWT. Nevertheless, correlation analysis demonstrated strong agreement between the 2 types of test conditions, indicating that the web-modified 6MWT could still be considered a valid assessment. Consequently, the HM6MWT could still potentially be useful for measuring pre- and postintervention changes in walking performance. We would recommend that health professionals consider the number of laps counted as the outcome measure, as opposed to the walking distance obtained through a CF, to avoid confusion with interpretation of these results with in-person walking tests. Of course, further research is needed to support the validity of the HM6MWT. For example, given that the 6MWT is often used as an indirect indicator of cardiorespiratory endurance in clinical populations, there is a need to explore whether changes in HM6MWT laps over time are comparable with changes in cardiorespiratory fitness (criterion validity). There is a dire need for home-based assessments for cardiorespiratory fitness, given that there are (to the best of our knowledge) no scientifically sound assessments for measuring cardiorespiratory fitness remotely at home without specialized equipment and personnel.

Study findings are comparable with those among different age groups. One study reported that a videoconference assessment of the FTST is extremely reliable (ICC>0.9) and the TUG test is highly reliable (ICC>0.7) among older adults [13]. Another study among adults (mean age 37, SD 12.5 years) demonstrated excellent agreement for grip strength (ICC 0.99, 95% CI 0.99-0.99), good agreement for the FTST (ICC 0.84, 95% CI 0.75-0.9), and fair agreement for the TUG test (ICC 0.64, 95% CI 0.47-0.77). The study concluded that untimed measures, such as grip strength, have excellent reliability. For the timed outcome measures, comparison of in-person and telehealth outcomes was not recommended [19]. Likewise, study findings for interrater reliability are consistent with those reported by other investigations that included older adults without disabilities [17,18]. Regarding modifications to the conventional 6MWT, a previous study had children with CP perform the 6MWT over 15 and 30 m courses [67]. The authors concluded that a shorter and narrower walking course could result in more turning and less straight walking paths, both of which could negatively affect or add volatility to the walking distances [67]. This could explain the variable differences observed between the HM6MWT and 6MWT distance results in our study.

Future Considerations
It is important to note that not all youth will prefer teleassessments versus in-person assessments. We would recommend that future trials include both options for youth to complete the assessments. Moreover, our study included simple assessments with minimal verbal instructions. Many exercise assessments require specialized equipment and instructions and complex movements, which will make these assessments difficult to perform via videoconferencing. There is a need to identify innovative measurement methods or technology that can address logistical issues for more complex tasks.
Limitations and Future Directions

This exploratory pilot study had inherent limitations. First, the sample size, although statistically powered for the primary analyses, was clearly not large enough to be a truly representative sample. One of the most notable limitations of our study is that the 9 youth with disabilities all had CP as their preexisting condition and were ambulatory. The result of only youth with CP was a coincidence. Although CP is an umbrella term with overlapping neuromuscular characteristics with traumatic brain injury, spinal cord injury, or other neuromuscular diseases, diversifying the study population would further promote the adoption of teleassessment as a modality of research and clinical assessment. Future research is also needed to identify home-based measures of physical fitness and function for people who are nonambulatory. People who are nonambulatory are underrepresented in exercise trials among people with disabilities and are often excluded from participation [1]. Of note, the study sample was also highly literate with videoconferencing, which will likely not be generalizable to the population.

Second, the study was not conducted in a real-world setting. The teleassessments were conducted in a controlled setting within a research laboratory where Wi-Fi and equipment were well maintained and set up by laboratory staff for use. The necessary space for the teleassessments (approx. 10 × 15 square feet) may also not be available without obstacles in a person’s home. Thus, study findings for feasibility will likely not represent the technical challenges that people may encounter outside the research environment—for example, shipping the equipment to the participants’ homes and calibrating equipment.

Third, this study focused only on convergent validity and interrater reliability. Other aspects of psychometric properties, such as responsiveness and the level of measurements, should be investigated, ideally with clinical populations with disabilities in their youth.

Finally, although the order of the test conditions was randomized, since all tests were performed in a single session, there is still the possibility that a learning effect influenced the results.

Conclusion

This study demonstrated that a teleassessment battery is feasible and certain components of it may be suitable for measuring fitness and function among ambulatory youth with CP and without disabilities. Convergent validity was excellent for the hand grip strength test and good for the FTST and the TUG test. The HM6WT requires further investigation or supportive measures prior to being used in a clinical trial. Standardized instructions for conducting the teleassessments are included in Multimedia Appendix 1. This study fills a gap in research on the youth age group, who are often neglected in research due to their presumed healthiness, not belonging to either children or adults in the narrow sense.

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Data Availability

The data sets generated and analyzed during this study are not publicly available due but are available from the corresponding author upon reasonable request.

Authors’ Contributions

BL, DW, and JW contributed to the initial manuscript draft. BL, CSJ, KS, MM, DW, LAM, YK, and HL assisted with the data collection and statistical analysis. BL and HL were largely responsible for the manuscript revisions. All authors contributed to the final manuscript. No artificial intelligence software or program was used in the writing of this manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Manual of procedures.

[DOCX File, 360 KB - rehab_v11i1e50582_app1.docx ]

References


Abbreviations

- 6MWT: 6-minute walk test
- CF: conversion factor
- CP: cerebral palsy
- FTST: five times sit-to-stand test
- HM6MWT: home-modified 6-minute walk test
- ICC: intraclass correlation coefficient
- ICC-r: intraclass correlation coefficient for reliability
- ICC-v: intraclass correlation coefficient for validity
- TUG: timed up-and-go

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A Digital Intervention to Promote Self-Management Self-Efficacy Among Community-Dwelling Individuals With Stroke: Pilot Randomized Controlled Trial

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Abstract

Background: Digital interventions provided through smartphones or the internet that are guided by a coach have been proposed as promising solutions to support the self-management of chronic conditions. However, digital intervention for poststroke self-management is limited; we developed the interactive Self-Management Augmented by Rehabilitation Technologies (iSMART) intervention to address this gap.

Objective: This study aimed to examine the feasibility and initial effects of the iSMART intervention to improve self-management self-efficacy in people with stroke.

Methods: A parallel, 2-arm, nonblinded, randomized controlled trial of 12-week duration was conducted. A total of 24 participants with mild-to-moderate chronic stroke were randomized to receive either the iSMART intervention or a manual of stroke rehabilitation (attention control). iSMART was a coach-guided, technology-supported self-management intervention designed to support people managing chronic conditions and maintaining active participation in daily life after stroke. Feasibility measures included retention and engagement rates in the iSMART group. For both the iSMART intervention and active control groups, we used the Feasibility of Intervention Measure, Acceptability of Intervention Measure, and Intervention Appropriateness Measure to assess the feasibility, acceptability, and appropriateness, respectively. Health measures included the Participation Strategies Self-Efficacy Scale and the Patient-Reported Outcomes Measurement Information System’s Self-Efficacy for Managing Chronic Conditions.

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(page number not for citation purposes)
Results: The retention rate was 82% (9/11), and the engagement (SMS text message response) rate was 78% for the iSMART group. Mean scores of the Feasibility of Intervention Measure, Acceptability of Intervention Measure, and Intervention Appropriateness Measure were 4.11 (SD 0.61), 4.44 (SD 0.73), and 4.36 (SD 0.70), respectively, which exceeded our benchmark (4 out of 5), suggesting high feasibility, acceptability, and appropriateness of iSMART. The iSMART group showed moderate-to-large effects in improving self-efficacy in managing emotions ($r = 0.494$), symptoms ($r = 0.514$), daily activities ($r = 0.593$), and treatments and medications ($r = 0.870$), but the control group showed negligible-to-small effects in decreasing self-efficacy in managing emotions ($r = 0.252$), symptoms ($r = 0.262$), daily activities ($r = 0.136$), and treatments and medications ($r = 0.049$). In addition, the iSMART group showed moderate-to-large effects of increasing the use of participation strategies for management in the home ($r = 0.554$), work ($r = 0.633$), community ($r = 0.673$), and communication activities ($r = 0.476$). In contrast, the control group showed small-to-large effects of decreasing the use of participation strategies for management in the home ($r = 0.567$), work ($r = 0.342$), community ($r = 0.215$), and communication activities ($r = 0.379$).

Conclusions: Our findings support the idea that iSMART was feasible to improve poststroke self-management self-efficacy. Our results also support using a low-cost solution, such as SMS text messaging, to supplement traditional therapeutic patient education interventions. Further evaluation with a larger sample of participants is still needed.

Trial Registration: ClinicalTrials.gov 202004137; https://clinicaltrials.gov/study/NCT04743037?id=202004137&rank=1

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KEYWORDS

digital intervention; feasibility; mobile health; participation; rehabilitation; self-efficacy; self-management; stroke; technology; telehealth; telemedicine; text messaging

Introduction

People receive limited inpatient rehabilitation services after a stroke, with an average rehabilitation stay of 18.6 days [1]. Those with no major motor impairments (eg, neurologically mild stroke) are often discharged from acute care without rehabilitation [2,3]. Stroke survivors are at risk for developing depression [4], experiencing reduced quality of life [5], and having an increased chance of stroke recurrence [6,7]. Moreover, restricted participation in home, community, work, and social activities following stroke is common [8,9] and can last over 6 months [10]. Stroke survivors often manifest chronic neuropsychiatric symptoms (eg, fatigue, depressed mood, and cognitive dysfunction), which can impact their stroke recovery and delay or prevent a return to prestroke social roles [11]. Thus, learning strategies to manage poststroke symptoms and cope with challenges after transitioning back to community living is essential in stroke rehabilitation [9]. Self-management programs, also known as therapeutic patient education interventions [12], could help stroke survivors improve health management and participation in home, work, and community activities [11,13]. Most stroke self-management programs use a self-efficacy–building approach to promote and maintain active participation in home and community activities poststroke [14]. Improving self-efficacy to manage symptoms and chronic conditions ultimately leads to enhanced participation [11,13]. A systematic review of 22 studies (N=1761) investigated the influence of interventions supporting self-management skills on poststroke outcomes. Given the heterogeneity of the findings, no meta-analysis was conducted. However, the results showed that self-management interventions based on self-efficacy principles could improve the quality of life, depression, daily activities, and physical functioning in stroke survivors [15]. Targeting self-efficacy in managing symptoms and behaviors becomes a critical behavioral approach to addressing the long-term consequences of stroke [15,16]. Self-management interventions are well suited to mobile health (mHealth) technologies [17,18] as mHealth delivery methods offer several advantages, including increased access for individuals who live in rural areas or have limited transportation options. Additionally, mHealth technologies provide the potential for real-time monitoring and feedback, the ability to tailor intervention components to individualized needs, and the ability to reduce administration costs [19,20]. A meta-analysis of 14 randomized controlled trials (N=1597) focused on examining what theories were applied to the development of technology-based self-management interventions and investigating their effectiveness in improving depression, anxiety, fatigue, and self-efficacy for people with neurological disorders. The results showed that cognitive-behavioral and social-cognitive theories are the 2 most common theories used to develop technology-based self-management interventions in individuals with neurological disorders. In addition, cognitive-behavioral theory–based interventions were effective in enhancing self-efficacy and reducing depression, anxiety, and fatigue. In contrast, social-cognitive theory–based interventions were effective in reducing depression only [21]. In particular, this review found large effects in enhancing self-efficacy and reducing anxiety and moderate effects in reducing depression and fatigue. Although this meta-analysis showed promising results for neurological disorders, the study populations in these 16 studies did not include people after a stroke. Thus, research is needed to verify that this evidence applies to people after a stroke. To harness the benefits of the mHealth delivery, we developed a technology-supported self-management intervention, the interactive Self-Management Augmented Rehabilitation Technologies (iSMART) intervention, adapted from the face-to-face, stroke-focused psychoeducation program Improving Participation after Stroke Self-Management (IPASS) [11,13]. iSMART simplified the original IPASS psychoeducation sessions and added text messaging and behavioral coaching components [22]. We integrated SMS text messaging into iSMART because it is easily
customized to individual needs and accessible to anyone with a cell phone [23,24]. Live health coaches, based on behavioral activation [25], supplement psychoeducation sessions to support intervention uptake and promote effective collaboration, negotiation, and motivation while encouraging individuals to take responsibility for their recovery and wellness by fostering healthy behaviors [26].

To test this novel intervention’s feasibility and potential benefits, this study aimed to (1) evaluate the acceptability, appropriateness, and feasibility of iSMART in individuals with stroke and (2) establish the preliminary effect size of iSMART in improving self-management self-efficacy in individuals after stroke. We hypothesized that (1) iSMART would be feasible to deliver and be acceptable to people with stroke and (2) iSMART would result in a moderate effect for improving poststroke self-management self-efficacy.

**Methods**

**Design and Recruitment**

We conducted a parallel, 2-arm, nonblinded, randomized controlled trial of 12-week duration. Participants were recruited from a stroke registry at a university-affiliated acute care hospital between January and March 2021. Using a random number generator guided by a biostatistician, participants were randomized to receive either the iSMART intervention or a manual of stroke rehabilitation (attention control). All participants in both groups continued receiving standard-of-care rehabilitation services their treating physicians recommended.

**Participants and Randomization**

Potential participants (N=31) were recruited between January 2021 and March 2021 based on the following inclusion and exclusion criteria. Inclusion criteria were (1) mild-to-moderate stroke (National Institutes of Health Stroke Scale scores ≤13) [27], (2) ischemic or hemorrhagic stroke, (3) aged 18 years or older, (4) English-speaking, (5) ≥3 months after stroke, (6) self-identified as having ≥1 chronic condition, and (7) mobile phone ownership. Exclusion criteria were (1) preexisting neurologic or psychiatric disorder (eg, dementia or schizophrenia), (2) severe poststroke cognitive impairment (Short Blessed Test score ≥9), (3) history of functional problems (Premorbid Modified Ranking Scale score ≥2) before the stroke, (4) severe aphasia (Boston Naming Test <10) [28], and (5) visual problems that make reading words on the device difficult.

Of the screened individuals who had a stroke, 24 were randomized (CONSORT [Consolidated Standards of Reporting Trials] diagram; Figure 1).
Procedures

Overview

This study was a remote clinical trial, that is, a clinical trial performed remotely, including the interaction between the experimenter and participant and the assessment of outcomes [29]. Study staff contacted potential participants from a stroke research registry at a university-affiliated hospital in the Midwestern United States to explore their interest in the study. After that, study staff sent participants a secure link through email or SMS through the REDCap (Research Electronic Data Capture; Vanderbilt University) [30] and scheduled video or phone sessions to assist participants in completing the consent form and screening test for eligibility. Eligible participants were randomly allocated to the iSMART or control groups using a random sequence computer-generated program to ensure allocation concealment. Neither study staff nor participants were masked for randomization assignments. Following consent, participants underwent a remote enrollment, at which iSMART participants were oriented to technologies used in the study (ie, the videoconferencing platform and SMS) by study staff. Study staff also obtained the phone’s operating system (Android or iOS) and linked the phone number to the web-based iSMART platform used to send and receive text messages from participants. Participants in both groups started their allocated interventions after all participants completed baseline testing. The intervention lasted for 3 months. After completing their allocated interventions, all participants completed a postintervention assessment. Participants in both groups continued to receive health services as prescribed by their clinicians. Participants in the iSMART group were compensated US $300 for completing the allocated intervention and outcome measures and data plan coverage. Participants in the control group were compensated US $120 for completing the allocated intervention and outcome measures. No messages were sent to participants in the control arm, so they were not compensated for data usage. The trial ended in June 2021.

The iSMART Intervention

The iSMART was a 12-week, technology-supported, coach-guided, self-management intervention comprising 3 components: psychoeducation, behavioral coaching, and text messaging. A licensed occupational therapist served as the coach in this study. The psychoeducation component was built upon the Social Cognitive Theory [31] and the person-environment-occupation-performance model [32] and implemented through weekly, 2.5-hour sessions in a group videoconferencing format. These sessions focused on teaching participants self-management strategies, including problem-solving, decision-making, positive thinking, communication, and accommodation, for managing symptoms and supporting participation in home, work, community, and social activities.

The coaching component was built on behavioral activation theory and modified from the Revised Treatment Manual of the Brief Behavioral Activation Treatment for Depression [25]. It was implemented weekly in 0.5-hour sessions in a one-to-one videoconferencing format. Individual coaching sessions engaged participants in collaborative goal setting with the coach to identify values and select personal activity goals from 25 predefined goals. The coach then entered the selected goals into the web-based iSMART platform so participants could receive messages customized to their chosen goals. These goals target improving participation in different life areas, including daily responsibilities, relationships, interests and recreation, education and career, and mind, body, and spirituality derived from the behavioral activation manual [25].

The text messaging component was adapted from previous studies, with effectiveness demonstrated in hospital workers [33,34] and adults with severe mental illness [35]. We adapted and pretested text messages with the planning group members, intending to increase the uptake by individuals with stroke (details in the next paragraph). Text messages were sent following the predefined schedules, including goal reminders (delivered on Mondays), goal monitoring (Tuesdays), mood monitoring (daily), self-management tips (Thursdays to Saturdays), ecological needs assessment (Saturdays), and motivational messages (Sundays). Figure 2 provides snapshots of these messages.
We formed a planning group, including 2 stroke rehabilitation clinicians, a stroke survivor, a technologist, and a self-management expert, to guide the intervention adaptation using a systematic intervention-mapping process [22,36]. During this adaptation process, we applied the behavior change wheel [37] and behavioral change technique taxonomy [38] to specify strategies that help individuals change self-management behaviors. Specifically, we identified 7 behavioral determinants most likely to affect the intervention goal and outcomes, including knowledge, behavioral regulation, skills, self-efficacy, motivation, negative and positive affect, and social and environmental support. We also identified the mechanisms of action (eg, beliefs about capabilities, values, knowledge, and motivation) most likely to affect the selected behavioral determinants. We then used the linkage table published by Carey et al [39] to match the behavioral change techniques (eg, information about health consequences, information about social and environmental consequences, instructions on how to perform the behavior, and feedback on behavior) to each of the mechanisms of action. Finally, to ensure iSMART should be applied to the selected behavioral change techniques, we developed a set of empirically supported strategies and integrated these strategies into different parts of the 3 treatment components. Details of the intervention development of iSMART, including the theoretical framework, mechanisms of action, behavioral change techniques, and the set of empirically supported strategies, are described elsewhere [22].

Control Intervention

Participants in the control group received a study-specific manual comprising stroke-specific information based on resources from the American Stroke Association and the Canadian Stroke Association. Manual content includes stroke overview, stroke prevention, rehabilitation, fatigue, weight management, fitness, medication, sleep, balance, healthy eating, emotional changes, social support, home modifications, and return to work or school. This study staff made telephone calls once a week to ask if participants had any problems while reading the manual and encouraged participants to read through the manual. The study staff did not deliver any iSMART content.

Outcome Measures

Feasibility Measures

Rates of retention and engagement were automatically recorded through the web-based iSMART platform. We defined retention as the rate at which participants completed or remained in the study and engagement as the rate at which participants responded to text messages. We defined retention and engagement rates as $\geq 80\%$, based on a previous technology intervention that showed participants who achieved these criteria demonstrated better outcomes [35]. The project found that
participants who met the criteria would demonstrate better target health outcomes. Participants also completed three 4-item implementation measures postintervention: the Feasibility of Intervention Measure (FIM), the Acceptability of Intervention Measure (AIM), and the Intervention Appropriateness Measure (IAM) [40]. Weiner et al [40] found that these measures had strong structural validity with .89 for FIM, .85 for AIM, and 0.91 for IAM and test-retest reliability with .88 for FIM, .83 for AIM, and .87 for IAM. However, no discriminant validity of these measures was studied [40]. We defined the benchmark for high feasibility, acceptability, and appropriateness as the mean score of 4 (out of 5) on the FIM, AIM, and IAM.

**Self-Efficacy Measures**

Participants completed the Participation Strategies Self-Efficacy Scale (PS-SES) and the Patient-Reported Outcomes Measurement Information System’s Self-Efficacy (PROMIS-SE) for managing chronic conditions at baseline and postintervention. PS-SES is a 35-item measure to assess self-efficacy in using participation strategies to manage home, work, community, and communication [41]. Lee et al [41] found that the Cronbach α coefficients of internal consistency of PE-SES were high (α=.884 to .926).

PROMIS-SE consists of five 4-item short forms to assess self-efficacy for managing daily activities, medications, treatment, symptoms, emotions, and social interactions [42]. Confirmatory factor analyses confirmed the multidimensional structure of the PROMIS-SE.

**Data Analysis**

Participants who completed the intervention were selected for data analyses, as we did not compute any missing values of outcomes for those who did not complete the study. Demographic characteristics between the 2 groups were evaluated using Fisher exact tests or Wilcoxon rank sum tests. Considering the small sample size of this study, we computed nonparametric analyses with median scores of FIM, AIM, and IAM and self-efficacy measures. We reported both mean and median scores for resolution purposes.

We compared retention and engagement rates and the FIM, AIM, and IAM scores of the iSMART intervention with the predefined benchmarks. We conducted Wilcoxon rank sum tests to evaluate any differences between the groups on FIM, AIM, and IAM scores. To establish the effect sizes for change in self-efficacy, we computed change scores from baseline to postintervention. We then compared the change scores between the 2 groups using Wilcoxon rank sum tests. Due to the small size, any demographic differences between groups at baseline may have artificially inflated the group difference in study outcomes. Thus, we also examined any significant changes for each group using Wilcoxon signed rank tests. We used effect sizes to interpret the intervention effect instead of statistical significance (ie, P≤.05) [43]. We defined small effects if 0.1≤r<0.3, moderate effects if 0.3≤r<0.5, and large effects if r≥0.5 [44]. We reported effect sizes as they were independent of sample size so that we could express the size of an intervention effect regardless of the size of the study [45].

**Ethical Considerations**

All participants provided informed consent. The ethics committees of Washington University (202004137) and Northwestern University (STU00215743) reviewed and approved this study. We registered the study at ClinicalTrials.gov (202004137). We reported this study adhering to the CONSORT statement [46,47].

**Results**

**Participants**

Participant flow is presented in Figure 1. A total of 31 participants were screened, 24 were randomized, and 22 (iSMART: n=13 and control: n=9) completed the study. Table 1 shows the baseline characteristics of the participants.
Table 1. Clinical and demographic information of the participants.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Overall (n=24)</th>
<th>Control (n=13)</th>
<th>iSMART(^a) (n=11)</th>
<th>(P) value(^b)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (SD)</td>
<td>59 (12)</td>
<td>57 (12)</td>
<td>62 (11)</td>
<td>.35</td>
</tr>
<tr>
<td>Sex, n (%)</td>
<td></td>
<td></td>
<td></td>
<td>&gt;.99</td>
</tr>
<tr>
<td>Male</td>
<td>14 (58)</td>
<td>8 (62)</td>
<td>6 (55)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>10 (42)</td>
<td>5 (38)</td>
<td>5 (45)</td>
<td></td>
</tr>
<tr>
<td>Marital status, n (%)</td>
<td></td>
<td></td>
<td></td>
<td>&gt;.99</td>
</tr>
<tr>
<td>Married or cohabiting</td>
<td>13 (54)</td>
<td>7 (54)</td>
<td>6 (55)</td>
<td></td>
</tr>
<tr>
<td>Separated, divorced, or widowed</td>
<td>7 (29)</td>
<td>4 (31)</td>
<td>3 (27)</td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>4 (17)</td>
<td>2 (15)</td>
<td>2 (18)</td>
<td></td>
</tr>
<tr>
<td>Total household income (US $), n (%)</td>
<td></td>
<td></td>
<td></td>
<td>.18</td>
</tr>
<tr>
<td>0 to 14,999</td>
<td>3 (12)</td>
<td>0 (0)</td>
<td>3 (27)</td>
<td></td>
</tr>
<tr>
<td>15,000 to 34,999</td>
<td>5 (21)</td>
<td>2 (15)</td>
<td>3 (27)</td>
<td></td>
</tr>
<tr>
<td>35,000 to 54,999</td>
<td>4 (17)</td>
<td>4 (31)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>55,000 to 74,999</td>
<td>3 (12)</td>
<td>2 (15)</td>
<td>1 (9.1)</td>
<td></td>
</tr>
<tr>
<td>75,000 or more</td>
<td>7 (29)</td>
<td>4 (31)</td>
<td>3 (27)</td>
<td></td>
</tr>
<tr>
<td>Do not wish to answer</td>
<td>2 (8.3)</td>
<td>1 (7.7)</td>
<td>1 (9.1)</td>
<td></td>
</tr>
<tr>
<td>Premorbid disability (Modified Rankin Scale), n (%)</td>
<td></td>
<td></td>
<td></td>
<td>.77</td>
</tr>
<tr>
<td>No symptoms</td>
<td>20 (83)</td>
<td>11 (85)</td>
<td>9 (82)</td>
<td></td>
</tr>
<tr>
<td>No significant disability</td>
<td>3 (12)</td>
<td>2 (15)</td>
<td>1 (9.1)</td>
<td></td>
</tr>
<tr>
<td>Slight disability</td>
<td>1 (4.2)</td>
<td>0 (0)</td>
<td>1 (9.1)</td>
<td></td>
</tr>
<tr>
<td>Stroke severity (NIH(^c) Stroke Scale), mean (SD)</td>
<td>3.5 (4.2)</td>
<td>1.8 (3.1)</td>
<td>5.5 (4.7)</td>
<td>.06</td>
</tr>
<tr>
<td>Residential status, n (%)</td>
<td></td>
<td></td>
<td></td>
<td>.21</td>
</tr>
<tr>
<td>Alone</td>
<td>8 (33)</td>
<td>6 (46)</td>
<td>2 (18)</td>
<td></td>
</tr>
<tr>
<td>With others</td>
<td>16 (67)</td>
<td>7 (54)</td>
<td>9 (82)</td>
<td></td>
</tr>
<tr>
<td>Financial responsibilities, n (%)</td>
<td></td>
<td></td>
<td></td>
<td>.46</td>
</tr>
<tr>
<td>Dependent</td>
<td>23 (96)</td>
<td>13 (100)</td>
<td>10 (91)</td>
<td></td>
</tr>
<tr>
<td>Primary or partial responsibility</td>
<td>1 (4.2)</td>
<td>0 (0)</td>
<td>1 (9.1)</td>
<td></td>
</tr>
<tr>
<td>Race, n (%)</td>
<td></td>
<td></td>
<td></td>
<td>.68</td>
</tr>
<tr>
<td>Black</td>
<td>9 (38)</td>
<td>4 (31)</td>
<td>5 (45)</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>15 (62)</td>
<td>9 (69)</td>
<td>6 (55)</td>
<td></td>
</tr>
<tr>
<td>Stroke diagnosis, n (%)</td>
<td></td>
<td></td>
<td></td>
<td>&gt;.99</td>
</tr>
<tr>
<td>Hemorrhagic</td>
<td>4 (17)</td>
<td>2 (15)</td>
<td>2 (18)</td>
<td></td>
</tr>
<tr>
<td>Ischemic</td>
<td>20 (83)</td>
<td>11 (85)</td>
<td>9 (82)</td>
<td></td>
</tr>
<tr>
<td>Stroke side, n (%)</td>
<td></td>
<td></td>
<td></td>
<td>.75</td>
</tr>
<tr>
<td>Bilateral</td>
<td>1 (4.2)</td>
<td>0 (0)</td>
<td>1 (9.1)</td>
<td></td>
</tr>
<tr>
<td>Left</td>
<td>7 (29)</td>
<td>3 (23)</td>
<td>4 (36)</td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>9 (38)</td>
<td>6 (46)</td>
<td>3 (27)</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>7 (29)</td>
<td>4 (31)</td>
<td>3 (27)</td>
<td></td>
</tr>
<tr>
<td>Time since stroke (days), mean (SD)</td>
<td>1245 (1079)</td>
<td>957 (1059)</td>
<td>1585 (1048)</td>
<td>.09</td>
</tr>
<tr>
<td>Education (years), mean (SD)</td>
<td>15 (3)</td>
<td>14 (3)</td>
<td>15 (3)</td>
<td>.55</td>
</tr>
<tr>
<td>Number of the previous stroke, mean (SD)</td>
<td>2 (4)</td>
<td>2 (2)</td>
<td>3 (5)</td>
<td>.18</td>
</tr>
</tbody>
</table>

\(^a\)iSMART: interactive Self-Management Augmented by Rehabilitation Technologies

\(^b\)Value is significant at \(P<.05\).
Feasibility Measures

Retention and Engagement

A total of 2 participants in the iSMART group withdrew from the study, resulting in a retention rate of 82% (9/11) that exceeded the predefined benchmark. Reasons for withdrawal included (1) time conflicts with the group sessions and (2) a family issue unrelated to the intervention. The engagement (SMS text message response) rate across all participants was 76%, ranging from 22% to 96%. Although the overall engagement rate was slightly below the predefined benchmark, only 2 out of 9 participants had response rates less than 80% (ie, 22% and 49%).

Feasibility, Acceptability, and Appropriateness

The mean scores of FIM, AIM, and IAM for the iSMART participants were 4.11 (SD 0.61), 4.44 (SD 0.73), and 4.36 (SD 0.70), respectively, which met our benchmarks, suggesting high feasibility, acceptability, and appropriateness of the iSMART intervention (Table 2). Participants in the iSMART group rated higher FIM, AIM, and IAM scores than those in the control group, with a moderate effect for feasibility ($r=0.449; P=.04$) and large effects for acceptability ($r=0.505; P=.02$) and appropriateness ($r=0.540; P=.01$).

Table 2. Feasibility, acceptability, and appropriateness measures between the interactive Self-Management Augmented by Rehabilitation Technologies (iSMART) and control groups.

<table>
<thead>
<tr>
<th>Measures</th>
<th>Control (n=13)</th>
<th>iSMART (n=9)</th>
<th>Wilcoxon statistic</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Median (IQR)</td>
<td>Mean (SD)</td>
<td>Median (IQR)</td>
</tr>
<tr>
<td>FIM$^a$</td>
<td>3.48 (0.65)</td>
<td>3 (3, 4)</td>
<td>4.11 (0.61)</td>
<td>4 (4, 4.25)</td>
</tr>
<tr>
<td>AIM$^b$</td>
<td>3.60 (0.66)</td>
<td>3.5 (3, 4)</td>
<td>4.44 (0.73)</td>
<td>5 (4, 5)</td>
</tr>
<tr>
<td>IAM$^c$</td>
<td>3.54 (0.63)</td>
<td>3.5 (3, 4)</td>
<td>4.36 (0.70)</td>
<td>4.25 (4, 5)</td>
</tr>
</tbody>
</table>

$^a$FIM: Feasibility of Intervention Measure.
$^b$AIM: Acceptability of Intervention Measure.
$^c$IAM: Intervention Appropriateness Measure.

Self-Efficacy Measures

Figures 3 and 4 show the PS-SES and PROMIS-SE change scores, illustrating significantly greater improvements in the iSMART group than in the control group. Table 3 shows the between-group effect sizes. All between-group effects were favorable to the iSMART group. PS-SES home management ($r=0.571; P=.008$), PS-SES community management ($r=0.500; P=.02$), and PROMIS-SE medications and treatments ($r=0.506; P=.02$) showed large effects. PS-SES work ($r=0.464; P=.03$), PS-SES communication management ($r=0.478; P=.03$), and PROMIS-SE emotions ($r=0.313; P=.15$) showed moderate effects.
Figure 3. Changes in Participation Strategies Self-Efficacy Scale (PS-SES) scores after intervention. iSMART: interactive Self-Management Augmented by Rehabilitation Technologies.
Figure 4. Changes in Patient-Reported Outcomes Measurement Information System’s Self-Efficacy (PROMIS-SE) scores after intervention. iSMART: interactive Self-Management Augmented by Rehabilitation Technologies.
Table 3. Pre- and postintervention self-efficacy scores between the control and interactive Self-Management Augmented by Rehabilitation Technologies (iSMART) groups.

<table>
<thead>
<tr>
<th>Outcome measures</th>
<th>Control (n=13)</th>
<th>iSMART (n=9)</th>
<th>Between-group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre, mean (SD)</td>
<td>Post, mean (SD)</td>
<td>Pre, median (IQR)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PS-SES&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Home management</td>
<td>105 (12.6)</td>
<td>97.5 (16.3)</td>
<td>106 (96, 113)</td>
</tr>
<tr>
<td>Community management</td>
<td>82.8 (16.5)</td>
<td>81.3 (17.8)</td>
<td>82 (77, 100)</td>
</tr>
<tr>
<td>Work management</td>
<td>60.6 (10.8)</td>
<td>58.8 (9.5)</td>
<td>65 (56, 68)</td>
</tr>
<tr>
<td>Communication management</td>
<td>67.4 (15)</td>
<td>65.5 (14.6)</td>
<td>72 (66, 79)</td>
</tr>
<tr>
<td>PROMIS-SE&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emotions</td>
<td>47.1 (9.1)</td>
<td>46.1 (8.6)</td>
<td>49.6 (38.8, 53.2)</td>
</tr>
<tr>
<td>Medications and treatments</td>
<td>46.1 (8.7)</td>
<td>45.1 (9.1)</td>
<td>43.5 (40.4, 50.4)</td>
</tr>
<tr>
<td>Social interactions</td>
<td>44 (8.5)</td>
<td>44.3 (9.4)</td>
<td>42.5 (37.3, 48.4)</td>
</tr>
<tr>
<td>Symptoms</td>
<td>49.4 (8.8)</td>
<td>51.1 (8.1)</td>
<td>49 (44.8, 52.8)</td>
</tr>
<tr>
<td>Daily activities</td>
<td>47.7 (8.2)</td>
<td>49 (6.7)</td>
<td>47.7 (42.7, 51.2)</td>
</tr>
</tbody>
</table>

<sup>a</sup>PS-SES: Participation Strategies Self-Efficacy Scale.
<br>
<sup>b</sup>PROMIS-SE: Patient-Reported Outcome Measurement Information System’s Self-Efficacy.

Table 3 further shows the within-group effect sizes. The iSMART showed moderate-to-large effects of increasing the use of participation strategies for management in the home ($r=0.554$; $P=14$ [large]), work ($r=0.633$; $P=0.06$ [large]), community ($r=0.673$; $P=0.04$ [large]), and communication activities ($r=0.476$; $P=14$ [moderate]). In contrast, the control group showed small-to-large effects of decreasing the use of participation strategies for management in the home ($r=0.567$; $P=0.05$ [large]), work ($r=0.342$; $P=0.26$ [moderate]), community ($r=0.215$; $P=0.44$ [small]), and communication activities ($r=0.379$; $P=0.21$ [moderate]).

In addition, the iSMART showed moderate-to-large effects of increasing self-efficacy in managing emotions ($r=0.494$; $P=16$ [moderate]), symptoms ($r=0.514$; $P=11$ [large]), daily activities ($r=0.593$; $P=11$ [large]), and treatments and medications ($r=0.870$; $P=0.01$ [large]), except a small effect of increasing self-efficacy in managing social interactions ($r=0.182$; $P=40$).

In contrast, the control group showed small effects of decreasing self-efficacy in managing emotions ($r=0.252$; $P=38$), symptoms ($r=0.262$; $P=0.43$), daily activities ($r=0.136$; $P=0.61$), and treatments and medications ($r=0.049$; $P=81$), except no change in self-efficacy in managing social interactions ($r=0.049$; $P=.88$).}

**Discussion**

**Principal Findings**

This study evaluated the feasibility and established preliminary effect sizes of iSMART, an mHealth intervention for improving self-efficacy for chronic stroke management, in a group of community-dwelling stroke survivors. Our results showed that iSMART is feasible and acceptable for mild-to-moderate chronic stroke survivors. Participants also showed moderate improvements in most self-efficacy measures after completing the iSMART.

**Previous Works and Study Implications**

We observed sufficient retention (82%) and engagement (SMS text message response) rates (76%) in the iSMART group. In addition, the iSMART group showed greater ratings than the control group on all 3 implementation measures, suggesting that iSMART is a feasible self-management program for stroke management.
survivors. The iSMART had a similar retention rate to those reported in mHealth interventions for pediatric weight management (78%) [48], antiretroviral therapy (85%) [49], and tuberculosis treatment (87%) [49]. The text message response rate was similar to other mHealth interventions targeting behavior changes in neuropsychiatric conditions. Suffoletto et al [50] reported 74% to 97% messaging response rates in an education and behavioral support intervention using text messages to assess daily symptoms and provide support to adults with mild traumatic brain injury. Although we found that a larger portion of the iSMART participants met the engagement criteria (>80%), 2 out of 9 participants had response rates less than 80% (ie, 22% and 49%). The wide range of engagement was commonly found in other technology-based interventions for stroke survivors. For example, Guidetti et al [51] developed a technology-supported intervention for stroke survivors in Sweden and Uganda and stated that participants responded to 44% to 100% (mean 78%) of the text messages they received. A recent study of mHealth weight management intervention in adults with mental illness from which the iSMART was derived found that participants who met the criteria (>80% of text responses) in the first month of intervention had greater weight loss than those who did not [35]. These results suggest that future technology-based interventions may enhance intervention responses and effectiveness by increasing participants’ engagement up to the criteria that may maximize health and rehabilitation outcomes. Future studies are needed to formally test the engagement criteria and examine their relationships with treatment responses and outcomes for iSMART in stroke survivors.

Our findings indicated that iSMART yielded moderate-to-large effects in improving self-efficacy in using participation strategies for home, work, community, and communication management. Future interventions in improving participation outcomes following a stroke should make it a key behavioral target, given its beneficial mediating effect on mobility and participation [52]. Participants who completed the iSMART intervention showed moderate-to-large effects of increasing self-efficacy in managing emotions, symptoms, daily activities, and treatments and medications. In contrast, the control intervention only yielded small effects. The beneficial effects of the iSMART intervention are consistent with other technology-supported self-management interventions that were effective in increasing self-efficacy and perceived participation in everyday life among stroke survivors [51,53]. This study also observed that mHealth delivery might amplify treatment effects. Compared to a nontechnology-based self-management intervention (ie, IPASS) that the iSMART was derived from, the SMART showed superior effects than the IPASS [11]. Nevertheless, because this study had a small sample (N=22), interpretations of these results should be very cautious. A future study using a larger sample size and using the face-to-face self-management program as a control is warranted to test the additional benefit of mHealth delivery of self-management interventions.

**Limitations and Future Directions**

This study had several limitations. We did not conduct the intent-to-treat analysis in this pilot study. The intent-to-treat analysis has been considered the standard approach to randomized controlled trial analyses [54]. A future, definitive trial will complete this analysis to avoid biased estimates. In addition to the constraints associated with a small sample size, participants were recruited from a single institution, restraining the generalizability of the findings. We found a trend toward statistical significance for greater stroke severity and longer time since stroke in the iSMART group at baseline than the control group, which may have artificially inflated the difference between groups on study outcomes. For this feasibility study, we examined the intervention score changes using within-group models to avoid this potential bias and found results favoring the iSMART group. Nevertheless, future, and larger-scale studies are needed to examine if these factors were potential covariates affecting the treatment outcomes. We used 3 implementation measures to examine the treatment’s acceptability, appropriateness, and feasibility. Notably, these measures were fairly correlated, and their discriminant validity was not thoroughly tested. Thus, future research would benefit from further exploration of the discriminant validity of these constructs. This study did not collect information on how social support, built environment, technology access, and other environmental barriers impact intervention engagement in individuals with neuropsychiatric conditions, including stroke [55,56]. Future studies should examine whether these barriers mediate or modulate the impact of iSMART on poststroke outcomes.

Future research should consider the co-design approach when designing or adapting digital interventions to increase participant retention and engagement. Co-design is a process in which targeted end users and other relevant stakeholders’ partner with the research team to work together in all aspects of intervention development, testing, and dissemination [57]. Co-designed digital interventions are more effective than traditional approaches, where researchers and clinicians primarily design interventions [58]. This approach is particularly beneficial when collaborating with underrepresented and minority communities because the co-design allows for conceptual or tool redevelopments and refinements based on the social, linguistic, and cultural needs of partnership groups [59]. Future studies of iSMART will need to engage more stroke survivors and caregiver stakeholders in user-centered design activities, especially those from underserved communities, to identify which characteristics of the intervention, individual users, and the care environment best facilitate iSMART implementation and effectiveness [60].

This study only examined the effect of iSMART on self-efficacy over 12 weeks. Future studies are warranted to examine the long-term impact on self-efficacy and other disability outcomes, such as the reintegration of everyday living, quality of life, and perceived recovery in stroke survivors. iSMART included three intervention components. While considering all components together as a complex intervention, we found this intervention to have adequate feasibility and positive initial effects. A specific approach, the multiphase optimization strategy framework [61], has been used to test the performance of individual intervention components in the development of technology-supported interventions such as weight loss [62], palliative care [63], and physical activity promotion [64].
future study is needed to identify the iSMART components (main effects or interactions) that contribute meaningfully to improvement in intervention engagement and health outcomes in people after stroke. Future research may test the multiphase optimization strategy approach to identify if all or some intervention components are needed to optimize the iSMART intervention.

Conclusions
This study provides preliminary evidence to support the feasibility of delivering iSMART, a technology-supported self-management intervention to help stroke survivors increase self-efficacy for managing chronic conditions and supporting home, work, and community participation. Our findings support using a low-cost solution, such as text messaging, to supplement traditional therapeutic patient education interventions. More research is needed to provide more robust efficacy data to support the benefits of the iSMART intervention.

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Data Availability
The data generated and analyzed during this study cannot be sufficiently deidentified and, therefore, cannot be made publicly available due to ethical considerations. Deidentified data can be made available for further research from the corresponding author on reasonable request.

Authors' Contributions
AWKW, GEN, and DCM contributed to the study’s conception and design. OD and AWKW contributed to the preparation of the materials. QB contributed to data management and analysis. ZL, YL, and AWKW wrote the first draft of the manuscript. All the authors commented on previous versions and read and approved the final manuscript.

Conflicts of Interest
GEN has received research support from the National Institutes of Health (NIH), the Health Resources and Services Administration, the Barnes Jewish Hospital Foundation, the Washington University McDonnell Center for Systems Neuroscience, the Mallinckrodt Institute of Radiology, and the Usona Institute (drug only) and has served as a consultant for Alkermes, Inc. CarelonRx, Otsuka, and Sunovion. DCM reported research support from the NIH. He has served as a consultant for Otsuka Pharmaceuticals, Optum Behavioral Health, the Centerstone Research Institute, and the OneMind Foundation. He receives royalties from Oxford Press and has an ownership interest in Adaptive Health. SIL reported on research support from the NIH. MWMF has served as an independent contractor for Isaac Ray Forensic Group and Michigan Avenue Neuropsychologists. CLM has an ownership interest in Infinite Arms. He reported on subcontracts from the NIH and VA Headache Centers of Excellence. AWKW reported on research support from the NIH, the National Institute on Disability, Independence, and Rehabilitation Research, and the Craig H Neilsen Foundation. No other disclosures were reported.

Multimedia Appendix 1
CONSORT-eHEALTH (V 1.6.1).
[PDF File (Adobe PDF File), 1174 KB] [rehab_v11i1e50863_app1.pdf]

References


Abbreviations

AIM: Acceptability of Intervention Measure
CONSORT: Consolidated Standards of Reporting Trials
FIM: Feasibility of Intervention Measure
IAM: Intervention Appropriateness Measure
IPASS: Improving Participation after Stroke Self-Management
iSMART: interactive Self-Management Augmented by Rehabilitation Technologies
mHealth: mobile health
NIH: National Institutes of Health
PROMIS-SE: Patient-Reported Outcomes Measurement Information System’s Self-Efficacy

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Corrigenda and Addenda

Correction: Validating the Safe and Effective Use of a Neurorehabilitation System (InTandem) to Improve Walking in the Chronic Stroke Population: Usability Study

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Related Article:
Correction of: http://mhealth.jmir.org/2023/1/e50438/

In “Validating the Safe and Effective Use of a Neurorehabilitation System (InTandem) to Improve Walking in the Chronic Stroke Population: Usability Study” (JMIR Rehabil Assist Technol 2023;10:e50438) the authors made three linguistic improvements, added one missing acknowledgment, and changed the corresponding author:

In the first sentence of the Discussion, the original text reads as:

The goal of this study was to validate that participants representative of InTandem’s intended use population can safely and effectively use InTandem, through the completion of critical tasks, and demonstrate knowledge and comprehension of materials

The word “demonstrate” should be “demonstration of” to align to the phrasing of “completion of critical tasks” and will now read as:

The goal of this study was to validate that participants representative of InTandem’s intended use population can safely and effectively use InTandem, through the completion of critical tasks, and demonstration of knowledge and comprehension of materials.

In the first paragraph of the “Strengths and Limitations” section, the original text reads as:

The accumulated evidence for InTandem includes a feasibility study that resulted in clinically relevant improvements in speed...

The authors removed the “a” between “in” and “clinically relevant” and the text now reads as:

The accumulated evidence for InTandem includes a feasibility study that resulted in clinically relevant improvements in speed...

In the “Background on Formative Testing” section, the original text reads as:

(2) the identification of which interactions with the product users needed the most education and were less immediately intuitive out of the box.

The text should include “on” after “education” and will now read as:

(2) the identification of which interactions with the product users needed the most education on and were less immediately intuitive out of the box.

The authors neglected to acknowledge a colleague in the Acknowledgments section which originally read as:

This work acknowledges the intellectual contributions made by the broader team at EVERSA NA and MedRhythms. We thank Chrissy Stack, Jennifer Lavanture, Holly Roberts, Barbara Heikens, and

Acknowledgments:
This work acknowledges the intellectual contributions made by the broader team at EVERSA NA and MedRhythms. We thank Chrissy Stack, Jennifer Lavanture, Holly Roberts, Barbara Heikens, and

Related Article:
Correction of: http://mhealth.jmir.org/2023/1/e50438/
Lauren Steidl for their contributions to and coordination of this paper, and Eric Richardson for study support during both formative and validation research activities. This work was supported by MedRhythms.

And will now read as:

This work acknowledges the intellectual contributions made by the broader team at EVERSANA and MedRhythms. We thank Chrissy Stack, Jennifer Lavanture, Holly Roberts, Barbara Heikens, and Lauren Steidl for their contributions to and coordination of this paper, Ashley Levesque for her manuscript preparation support, and Eric Richardson for study support during both formative and validation research activities. This work was supported by MedRhythms.

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In addition, we have updated the author metadata to indicate that authors KES and SHC (first two authors) contributed equally.

The correction will appear in the online version of the paper on the JMIR Publications website on February 21, 2024, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.
Results of Gensingen Bracing in Patients With Adolescent Idiopathic Scoliosis: Retrospective Cross-Sectional Feasibility Study

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Abstract

Background: Bracing is an essential part of scoliosis treatment. The standard of brace treatment for patients with scoliosis today is still very variable in terms of brace quality and outcome. The Gensingen brace is a further developed Chêneau brace derivative with individual design, which can be adapted through computer-aided design.

Objective: This study aims to generate a template to obtain a database for prospective multicenter studies study to analyze the results of high-corrective asymmetric Gensingen brace treatment for patients with adolescent idiopathic scoliosis (AIS).

Methods: A template for the database was created, which contains the patients’ basic data (age, menarcheal status, Risser Sign, curve pattern, and daily brace wearing time), the Cobb angles of curvature, and the cosmetically relevant angles of trunk rotation (ATR). A retrospective review of medical records of patients with AIS, who met the Scoliosis Research Society’s inclusion criteria for brace studies, was performed to test the feasibility of the template. Template items were filled in by the researchers.

Results: Out of 115 patients between 2014 and 2018, the complete data of 33 patients followed up at least 3 months after complete Gensingen brace weaning could be analyzed. The mean age was 12 years, the mean Cobb angle was 33.6°, and the mean Risser value was 0.7 at the beginning of the treatment. The mean improvement in the Cobb angle on in-brace x-ray imaging was –26.1° (80% of in-brace correction). The Cobb angle of the major curvature changed as follows: curve stabilization was achieved in 7 (21.2%) cases, and curve improvement was achieved in 26 (78.8%) cases. None of the patients showed a curve progression. The Cobb angle was significantly reduced in the brace at the end of treatment and at follow-up evaluation (P<.001). ATR improved significantly for thoracic (P<.001) and lumbar curves (P<.001).

Conclusions: The database proved to be informative in the assessment of radiological and clinical outcome parameters. The example data set we have generated can be a helpful tool for professionals who work in clinics but do not store regular patient data. Especially with regard to different patient collectives worldwide, different results may be achieved with the same standards of care. In addition, the results of this study suggest that above-average correction effects with a full-time brace application lead to significant improvements in the Cobb angle after brace treatment has been completed.

(JMIR Rehabil Assist Technol 2024;11:e50299) doi:10.2196/50299

https://rehab.jmir.org/2024/11/e50299
KEYWORDS
scoliosis; brace treatment; feasibility study; outcome; skeletal; spine; back; musculoskeletal; curvature; spinal; database; template; design; brace; orthopedics; injury; rehabilitation; Gensingen brace; conservative brace treatment; Idiopathic Scoliosis; orthopedic; injuries; data science; data management

Introduction

3D spinal deformities, called scoliosis, can have different causes. What most forms of scoliosis have in common is that they tend to progress in curvature during periods of increased growth. In most cases (between 80% and 90%), scoliosis affects otherwise healthy individuals and first appears during the pubertal growth spurt [1-4].

Treatment of adolescent idiopathic scoliosis (AIS) consists of corrective exercise treatments, the application of various braces, and surgical treatment [5]. High-quality studies support the use of physical therapy measures [6-8] and brace application [9-13].

Scoliosis can progress rapidly, especially in adolescence—a period of rapid growth. Therefore, it is very important to apply evidence-based treatment approaches promptly. When patients are meaningfully “observed” rather than braced, a curve progression of 6° within a period of 6 months is between 20% and 40% more likely in growing children and adolescents [1]. Hence, it is crucial that patients with AIS receive conservative management treatments as soon as possible after their diagnosis, especially if they are premenarchial and still have significant growth potential [14].

Despite the existing evidence for treatment with braces, there is a significant variation in the success rates of different brace applications and even within individual brace families. Meanwhile, it is crystallizing that highly corrective asymmetric braces are superior to a more symmetrically compressive thoracolumbosacral orthosis. However, even with asymmetric brace applications, the quality of treatment is highly variable [15]. Therefore, to ensure patient safety, only computer-aided design (CAD) brace series should be used, which are subject to a quality management program and that use standardized adjustment algorithms corresponding to the curvature pattern [15-17].

One of these brace series is the Gensingen Brace (GBW) [18,19], used in our centers and other centers worldwide. Based on our clinical experience, we hypothesize that the progression of curvature in children with AIS treated with GBW can be stopped and that there would be improvements in curvature in a certain proportion of the cohort [19,20].

Although GBW efficacy has been demonstrated in previous studies published in the literature, follow-up studies after completion of treatment are limited [19,20].

The purpose of this study is to test the feasibility of a prospective multicenter study by generating a database, including radiological and clinical outcome parameters. For this purpose, the database has been tested with a retrospective review of medical records of patients from 1 center.

Methods

Ethical Considerations

This retrospective cross-sectional study was conducted in accordance with the tenets of the Declaration of Helsinki. Ethics approval for the study was obtained from the Ethics Committee of Bandirma University (2022/195). The parents of each child were informed of the study procedures, and written consent of the caregivers and participants was obtained which in accordance with the ethics committee’s guidelines. The data set did not contain any identifiable information.

Study Design

This paper reports the results of treatment with a GBW for AIS in a retrospective nonrandomized feasibility study.

Recruitment

Patients who were admitted to Nan Xiaofeng’s Spinal Orthopedic Workshop and Schroth Health Technology centers between 2014 and 2018 and were treated with a GBW and followed up at least 3 months after complete brace weaning were included in this study.

A template for the database to be tested was created, which contains the basic data of the patients and their Cobb curvature angles and the cosmetically relevant angles of trunk rotation (ATR). A retrospective review of medical records of patients with AIS, who met the Scoliosis Research Society’s (SRS’s) inclusion criteria for brace studies [20], was performed, and the investigators then filled in the template. These criteria were as follows: female patients with prescribed brace treatment for AIS, aged between 10 and 14 years, with a Cobb angle between 25° and 40° for at least 1 structural curve, during growth with a Risser stage between 0 and 2, premenarcheal or less than 1 year after menarche, and without previous treatment [21].

Patients with nonidiopathic scoliosis; other orthopedic, neuromuscular, or rheumatic diseases; mental or psychiatric problems; iliac crest ossification of Risser stage 3-5, or continuing treatment were excluded.

According to the current guidelines, it is recommended that patients with Risser stage 0-3 and a scoliosis progression risk of more than 60% according to the Lonstein and Carlson [22] formula should start bracing treatment. In this study, risk of progression was calculated and brace treatment was recommended to the patients. For brace treatment to be effective, full-time use was recommended [23].

All children in this study used the GBW (Figures 1-3).
Figure 1. A 12-year-old minor patient with a single lumbar curve of 32° treated with a short Gensingen brace (GBW) with full in-brace correction (middle picture). Final outcome 12 months after brace weaning with a curvature of 22° with a nicely recompensated clinical appearance (right).

Figure 2. A 12-year-old minor patient with a single thoracic curve of 48° treated with a functional 3-curve balanced with a minor and shorter lumbar countercurve and Gensingen brace (GBW) with full in-brace correction (middle picture). Final outcome 9 months after brace weaning with a curvature of 28° with a nicely recompensated clinical appearance (right).
Figure 3. A 12-year-old minor patient with a Lenke 6 combined curve of 45° (thoracic) and 40° (lumbar) treated with a functional 4-curve, double curvature and Lenke Gensingen brace (GBW) with good in-brace correction (middle picture). Final outcome 15 months after brace weaning and a curvature of 37° (thoracic) and 32° (lumbar) with a nicely recompensated clinical appearance (right). In particular, a Lenke 6 pattern is not as easy to correct with a brace like other curve patterns.

The GBW is a further developed Chêneau brace derivative with individual design, which can be adapted through CAD. Customization, accuracy, and quality control of scoliosis braces are significantly aided by CAD. By using this technology, braces can be generated specifically for each patient's particular spinal curve pattern, resulting in more effective and comfortable treatment. The individual production steps have already been described in the literature [18]. First, the patient is scanned, and patient data are collected and entered into the database together with the x-ray image. Based on these data, the basic model corresponding to the curvature pattern is first selected from the brace library.

The patient’s scan is cropped and scaled. Then, the selected brace is inserted into the scene and adjusted in accordance with the individual’s body shape. Then, the correction algorithms specified for the particular pattern and curvature strength (Cobb angle) are applied accordingly. The result is a brace model that reflects the respective curvature pattern and the individual entities of the patient [24].

The following brace weaning process was applied. For curves with an initial curve grade of ≤35, the brace wearing time was decreased by wearing the brace for 16 hours per day for 3 months, 12 hours per day for 3 months, and at night for 6 months. For curves above the initial grade of 35, brace treatment was terminated by wearing a brace for 16 hours per day for 12 months, 12 hours per day for 12 months, and 6 months at night.

Database Template

The template for the database contained the following: the patient’s age (in years) before starting treatment and the menarcheal status (in months) were recorded. Risser’s sign and curvature pattern, according to the Augmented Lehnert-Schroth (ALS) classification, were evaluated on pretreatment x-ray imaging. The Cobb angle and ATR were evaluated as primary outcome measures. The progression factor was calculated with the Cobb angle, patient's age, and Risser's finding. Daily brace-wearing time was recorded by asking parents and patients.

Risser's sign determines bone maturity, growth rate, and progression risk of a patient with scoliosis. It has been reported to be reliable and sensitive in determining bone maturity. Risser grading was assessed on the anteroposterior radiograph. The epiphyseal plate starts becoming visible from the lateral edge of the anterior superior iliac spine, progresses medially, and finally fuses at the posterior superior iliac spine. Degree of completion was indicated as a percentage: grade 1: ≤25%; grade 2: between 26% and 50%; grade 3: between 51% and 75%; and grade 4: between 75% and 100%. When the epiphyseal plate is fully fused to the ilium, it is defined as being grade 5 [25].

Curve classification was performed in accordance with the ALS classification that was developed as an expansion of the Lehnhert-Schroth classification and included eight different curvature types: (1) 3CH: functional 3-curve, with hip prominence; (2) 3CTL: functional 3-curve, thoracolumbar, which implies a functional 3-curve with hip prominence and a thoracolumbar apex at thoracic vertebra 12; (3) 3C: functional
3-curve balanced with a minor and shorter lumbar countercurve; (4) 3CL: functional 3-curve lumbar with a long lumbar countercurve; (5) 4C: functional 4-curve, double curvature; (7) 4CL: functional 4-curve with major lumbar curvature; and (8) 4CTL: functional 4-curve with major thoracolumbar curvature (and an apex at lumbar vertebra 1) [26].

The Cobb method was used to measure the degree of curvature: vertical lines were drawn on the superior and inferior vertebral endplate lines of the neutral vertebrae on the anteroposterior x-ray image of the whole spine [27], and the angle of the 2 vertical lines was recorded. X-ray images were taken at four stages: (1) before treatment (baseline), (2) at 4 to 6 weeks after the brace was fitted (in-brace), (3) at the end of treatment, and (4) at follow-up assessment after brace weaning. All braceless x-ray images were taken at least 24 hours after removal to eliminate the brace effect. All x-ray measurements were taken independently by the same experienced orthopedist. The difference between the Cobb angle at follow-up and that before treatment were calculated. Based on this difference, 3 possible outcomes are distinguished in accordance with the International Society On Scoliosis Orthopaedic and Rehabilitation Treatment’s guidelines: curve correction ($\leq -5^\circ$ Cobb angle), curve stabilization ($>-5^\circ$ and $<5^\circ$ Cobb angle), and curve progression ($\geq 5^\circ$ Cobb angle) [23].

The ATR is the most commonly used method for clinical and cosmetic assessment of scoliosis. ATR of 86% repeatability is supposed to be a reliable measurement. A change of 2° in interobserver measurements is considered significant [28]. ATR are measured using a special inclinometer called a scoliometer (according to Bunnel [28]). The patient was asked to bend forward with relaxed arms (Adam’s forward bend test). The scoliometer is placed on the back of the patients, and the maximum degree of each curve was recorded [28]. ATR measurements obtained before treatment and at follow-up assessment were analyzed.

The risk for progression of the Cobb angle was calculated using the progression factor formula in accordance with Lonstein and Carlson [22]:

$$\text{Risk for Cobb angle progression} = \text{Cobb angle} - \left(3 \times \text{Risser stage}\right) / \text{chronological age (in years)}$$

The International Society On Scoliosis Orthopaedic and Rehabilitation Treatment’s guidelines and the validated Schroth Best Practice Academy Guidelines suggest using this formula to decide treatment indications and avoid over- and undertreatment [29,30].

According to this formula, observation is recommended for cases with a risk factor of 1.4 and below ($<40\%$ incidence of progression), physiotherapy is recommended for cases with a risk factor of 1.4-1.6 (between 40\% and 60\% incidence of progression), and brace treatment is recommended for cases with a risk factor of 1.6 and above ($>60\%$ incidence of progression) [31].

Statistical Analysis

Data analysis was performed using SPSS (version 16; IBM Corp). The Shapiro-Wilk test was used to test the normality of each variable. $P$ values less than .05 were considered statistically significant for a 2-tailed test. Mean (SD) values and minimum and maximum values were determined using descriptive statistics.

Repeated-measures ANOVA was used to compare Cobb angle values at baseline, in-brace, end of treatment, and follow-up, and a paired samples $t$ test was used to compare ATR values at baseline and follow-up.

Results

Out of 115 patients from 2014 to 2018, complete data of 33 patients who could be followed up at least 3 months after complete brace weaning have been analyzed. The mean age was 12 years, the mean Cobb angle was $33.6^\circ$, and the mean Risser value was 0.7 at the beginning of the treatment (Table 1). Based on the ALS classification, most cases (45.5\%) had a 3C scoliosis pattern (major thoracic curve). A total of 18 of the patients were premenarcheal, and menarche had started in 15 patients (mean 5.7 months).
Table 1. Baseline demographic and clinical characteristics of patients.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (SD; range)</td>
<td>12 (1.06; 10-14)</td>
</tr>
<tr>
<td>Risser value, mean (SD; range)</td>
<td>0.7 (0.8; 0-2)</td>
</tr>
<tr>
<td>Main Cobb angle (°), mean (SD; range)</td>
<td>33.6 (8.1; 22-50)</td>
</tr>
<tr>
<td>Angle of trunk rotation (°; thoracic), mean (SD; range)</td>
<td>9.4 (5.1; 2-21)</td>
</tr>
<tr>
<td>Angle of trunk rotation (°; lumbar), mean (SD; range)</td>
<td>5.5 (4.05; 0-15)</td>
</tr>
<tr>
<td><strong>Main curve location, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Thoracic</td>
<td>26 (78.8)</td>
</tr>
<tr>
<td>Lumbar</td>
<td>7 (21.2)</td>
</tr>
<tr>
<td><strong>Augmented Lehnert-Schroth curve classification, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>3CH(^a)</td>
<td>5 (15.2)</td>
</tr>
<tr>
<td>3CL(^b)</td>
<td>15 (45.5)</td>
</tr>
<tr>
<td>3CN(^c)</td>
<td>5 (15.2)</td>
</tr>
<tr>
<td>4C(^d)</td>
<td>6 (18.2)</td>
</tr>
<tr>
<td>4CTL(^e)</td>
<td>2 (6.1)</td>
</tr>
</tbody>
</table>

\(^a\)3CH: functional 3-curve, with hip prominence.
\(^b\)3CL: functional 3-curve lumbar with a long lumbar countercurve.
\(^c\)3CN: functional 3-curve, compensated.
\(^d\)4C: functional 4-curve, double curvature.
\(^e\)4CTL: functional 4-curve with major thoracolumbar curvature.

The mean treatment period with the brace was 33.6 (SD 10.1, range 15-51) months, and the mean follow-up duration was 12 (SD 6.1, range 3-35) months. Daily brace wearing time in the first year of the brace treatment was 21.3 (SD 1.2, range 16-22) hours. All patients reported wearing the brace for at least 20 hours each day, with the exception of 1 who only wore it for 16 hours.

The mean improvement in Cobb angle on x-ray imaging performed in the brace was –26.1° (SD 6.8°, range –43° to –12°; Figure 4), which implies a correction effect in the brace of 80%. The difference in Cobb angle at baseline and follow-up was –11.7° (SD 6.8°, range –24° to 0°; a 35% improvement from the initial value). The change in ATR at baseline and follow-up was –4.5° (SD 4.5°, range –13° to –6°; a 49% improvement from the initial value), and the change in lumbar ATR was –3.2° (SD 4.2°, range –12° to –7°; a 62% improvement from the initial value). Changes in the Cobb angle and thoracic and lumbar ATR values at the end of treatment were significant (Table 2).

**Figure 4.** Changes in the main Cobb angle over time.
Table 2. Changes in the Cobb angle and angles of trunk rotation (ATR).

<table>
<thead>
<tr>
<th>Outcome measurements</th>
<th>Value, mean (SD; range)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Main Cobb angle (°)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>33.6 (8.1; 22 to 50)</td>
<td>&lt;.001a</td>
</tr>
<tr>
<td>In-brace</td>
<td>7.4 (7.9; –11 to 25)</td>
<td>&lt;.001b</td>
</tr>
<tr>
<td>End of treatment</td>
<td>19.7 (9.3; 2 to 42)</td>
<td>&lt;.001b</td>
</tr>
<tr>
<td>Follow-up</td>
<td>21.8 (9.2; 3 to 42)</td>
<td>&lt;.001b</td>
</tr>
<tr>
<td><strong>Thoracic ATR (°)</strong></td>
<td></td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Baseline</td>
<td>9.4 (5.1; 2 to 21)</td>
<td></td>
</tr>
<tr>
<td>Follow-up</td>
<td>4.4 (2.6; –2 to 12)</td>
<td></td>
</tr>
<tr>
<td><strong>Lumbar ATR (°)</strong></td>
<td></td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Baseline</td>
<td>5.5 (4.05; 0 to 15)</td>
<td></td>
</tr>
<tr>
<td>Follow-up</td>
<td>2.3 (2.3; –3 to 8)</td>
<td></td>
</tr>
</tbody>
</table>

aRepeated-measures ANOVA.
bPaired samples t test.

The mean progression risk factor was 2.6 (SD 0.7, range 1.43–4.55), which, in the case of untreated scoliosis, would correspond to a probability of progression of far more than 95% reported by Lonstein and Carlson [22]. According to the SRS’s criteria, curve stabilization was achieved in 7 (21.2%) cases, and curve improvement was achieved in 26 (78.8%) cases. None of the patients had a curve progression in this sample with a probability of progression of far more than 95% reported by Lonstein and Carlson [22].

The improvement in the Cobb angle achieved in the brace was negatively moderately correlated with the pretreatment Cobb angle ($P=.008$, $r=–0.452$). There was a positive moderate correlation between the amount of change in Cobb angle obtained at the end of treatment and the amount of improvement obtained in the brace ($P<.001$, $r=0.593$).

**Discussion**

**Principal Findings**

Our study shows that the template generated can be used for future prospective multicenter studies. On analyzing the data we saved in the template, the results showed that the GBW, which provides a 3D correction, is effective in stopping curvature progression and reducing the angle of curvature in adolescents with idiopathic scoliosis who continue to experience vertebral growth and are at high risk of progression.

Brace treatment and scoliosis-specific exercise methods are the most widely used, accepted, and effective treatment methods for patients with AIS [6-11,31,32]. Extensive evidence in the literature shows the effectiveness of brace treatment [15,33,34]. Previous studies have reported that brace treatment stops progression, corrects moderate curves, and reduces the rate of surgical indication [33-35]. Our results show that besides stopping curvature progression with high-correction full-time bracing also potentially improves the Cobb angle and ATR.

After the onset of the initial deformity, it is generally accepted that AIS progresses with asymmetric vertebral growth that occurs during the growth spurt. Adolescence is one of the periods of rapid growth. It has been reported that children with a high risk for progression during the rapid growth period experience progression in their curvature when left untreated [31].

In this study, the risk of progression was >95%, according to the formula developed by Lonstein and Carlson [22]. However, when growth was complete and in subsequent evaluations, it was found that there was no progression at all. The Cobb angle did not increase by ≥5° in any patient.

The patient population included in this study does not differ significantly from the cohorts of previously published studies in terms of age, maturity, menarcheal status, Cobb angle, and curvature pattern distribution [18,19]. Weiss et al [19] assessed 28 patients with AIS with a mean age of 12.7 years and Cobb angle of 30.5° using the GBW. However, they carried out their final evaluation an average of 24 months after brace treatment was initiated. They reported that the in-brace correction in their sample was from 33.9° to 15.9°, indicating an average correction of 52.7%.

In another study, Weiss et al [18] observed 167 patients with AIS who were treated with a GBW over a period of at least 18 months. The authors reported a 47%-52% rate of correction of the Cobb angle of the main curve in the brace [18]. When we calculated the success rate in accordance with the Cobb angle obtained in the brace, the treatment success rate was 80% in our cases.

In previous studies [18,19], the success rate at the end of treatment was between 86% and 92% in different subcohorts, but in our study, progression in curvature was stopped and no longer observed in all children. Therefore, GBW’s success may be considered as 100% in this study. Since the brace design worldwide follows standardized CAD algorithms and the
material (high-density polyethylene) does not differ from that used in other studies, the specifics of the studied collective might play a role. The cohort studied is from mainland China, and it is possible that the patients included in this study take brace treatment more seriously than may be the case in other countries. Another factor may be that brace treatment in China has to be financed by the patients or their parents themselves, which may also improve their motivation to wear the brace.

The main curvature Cobb angle at first diagnosis was >40° in 8 children included in this study. Considering that the Risser grade is low and the growth potential of these children is high, it is predicted that the curvatures will most likely progress. However, children with a curvature of >40° completed their treatment with an average of 16.7° (range 2°-34°). Based on these results, the use of GBWs significantly reduces the need for surgical treatment in children with AIS.

In this study, a template prepared by the investigators was filled with the help of a retrospective review of medical records. Our study shows that it would be appropriate to use this template in future prospective studies and the data intended to be recorded in this template can indicate treatment effectiveness for brace treatment. An international multicenter study considering the SRS’s inclusion criteria for brace treatment studies seems feasible.

Our study supports the conclusions of other studies regarding the corrective effect of the brace [36,37] and confirms previous findings in this field, which show that above-average corrective effects with full-time brace application lead to significant improvements in the Cobb angle after completion of brace treatment [38,39].

Evaluation of the treatment outcomes with the Cobb angle, which is still accepted as the gold standard today, the establishment of the study sample group considering the SRS’s brace study criteria, and continuation of the follow-up of the children after the end of treatment can be considered as the strengths of the study.

Limitations

The study’s limitations include our inability to determine the changes specific to different curve patterns, the fact that the effectiveness of the brace was not evaluated at different daily wearing times, and the fact that daily brace wearing time was recorded in accordance with the participants’ families statement. We suggest investigating the effectiveness of brace treatment in different curvature patterns and different wearing times with larger sample groups in future studies.

Conclusions

The results of this study suggest that above-average correction effects with full-time brace application lead to significant improvements of the Cobb angle upon completion of brace treatment. The example data set we have generated can be a helpful tool for professionals who work in clinics but do not store regular patient data. Furthermore, prospective multicentral studies with large samples can be conducted by collecting the same data at different centers.

Data Availability

The data that support the findings of this study are available upon request from the authors.

Authors’ Contributions

XN, HX, and LZ conceptualized the study. XN, TKC, and BA designed the study. TKC, BA, and MB supervised the study. XN, HX, LZ, and MB collected the data. TKC and BA carried out the analysis. HX, LZ, and MB conducted the literature review. XN, TKC, BA, HX, LZ, and MB drafted the manuscript. XN, TKC, and BA critically reviewed the manuscript. The manuscript has been read and approved by all named authors.

Conflicts of Interest

None declared.

References


Abbreviations

3C: functional 3-curve balanced with a minor and shorter lumbar countercurve
3CH: functional 3-curve, with hip prominence
3CL: functional 3-curve lumbar with a long lumbar countercurve
3CTL: functional 3-curve, thoracolumbar
4C: functional 4-curve, double curvature
4CL: functional 4-curve with major lumbar curvature
4CTL: functional 4-curve with major thoracolumbar curvature
AIS: adolescent idiopathic scoliosis
ALS: Augmented Lehnert-Schroth
ATR: angles of trunk rotation
CAD: computer-aided design
GBW: Gensingen Brace
SRS: Scoliosis Research Society

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Quality of Life in Children With Achondroplasia Undergoing Paired Limb Lengthening With an External Fixator and Modified Distraction Control: Observational Nonrandomized Study

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Abstract

Background: Transosseous distraction osteosynthesis is prioritized in orthopedic care for children with achondroplasia. However, difficulties encountered during treatment and rehabilitation directly impact patients’ quality of life. Using rod external fixators within a semicircular frame for osteosynthesis is less traumatic compared to spoke circular devices. Their straightforward assembly and mounting on the limb segment can help significantly reduce treatment duration, thereby improving children’s quality of life during treatment and rehabilitation.

Objective: This study aimed to conduct a comparative analysis of the quality of life (measured by postoperative pain syndrome, physical activity, and emotional state) among children with achondroplasia undergoing paired limb lengthening using either an external fixator with modified distraction control or a circular multiaxial system developed by the authors.

Methods: This was an observational, prospective, nonrandomized, and longitudinal study with historical control. The study group consisted of 14 patients ranging from 5 to 15 (mean 7.6, SD 2.3) years old with a genetically confirmed diagnosis of achondroplasia. All patients underwent paired limb lengthening with a rod external fixator and a modified distraction control developed by the authors. A total of 28 limb segments, among them 4 (14%) humeri, 8 (29%) femurs, and 16 (57%) tibias, were lengthened in 1 round. Unpublished data from the previous study served as the control group, comprising 9 patients (18 limb segments) of the same age group (mean age at surgery 8.6, SD 2.3 years), who underwent limb lengthening surgery using a circular multiaxial system—2 (11%) humeri, 6 (33%) femurs, and 10 (56%) tibias. The Wong-Baker Faces Rating Scale was used to measure pain symptoms, while the Russified Pediatric Quality of Life (PedsQL) v4.0 questionnaire assessed quality of life.

Results: During the latent phase (7 to 10 days after surgery), a more pronounced decrease in the indicators of physical activity and emotional state on the PedsQL v4.0 questionnaire was noted in the control group (mean 52.4, SD 4.8 versus mean 52.8, SD 5.5 points according to children’s responses and their parents’ responses, respectively) compared to the experimental group (mean 59.5, SD 6.8 points and mean 61.33, SD 6.5 points according to the children’s responses and their parents’ responses, respectively). The differences between the groups were statistically significant (P<.05 for children's responses and P<.01 for parents’ responses). Importantly, 6 months after surgery, these quality-of-life indicators, as reported by children in the experimental group, averaged 70.25 (SS 4.8) points. Similarly, their parents reported a mean of 70.54 (SD 4.2) points. In the control group, the corresponding values were 69.64 (SD 5.6) and 69.35 (SD 6.2), respectively. There was no statistically significant difference between the groups.

Conclusions: The external fixator with modified distraction control developed by the authors provides a higher standard of living compared with the circular multiaxial system during the latency phase.

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KEYWORDS
achondroplasia; external fixator; quality of life; transosseous osteosynthesis; paired limb lengthening; bone growth disorder; dwarfism; limb lengthening; circular multiaxial system; hereditary disease; limb reconstruction; children; youth; pediatric; bone disorder; orthopedics; rehabilitation; bone; growth; disorder; genetic

Introduction
Achondroplasia is a hereditary disease characterized by a deceleration in bone and cartilage growth. The term “achondroplasia” was first used in 1878 by Jules Parrott, and in 1900, the neurologist Pierre Marie first described the main features of the disease in children and adults. According to the International Classification of Diseases (ICD-10), this pathology is classified in chapter XVII “Congenital malformations, deformations, and chromosomal abnormalities” (Q00-Q99), specifically in the section “Congenital malformations and deformations of the musculoskeletal system.” More specifically, it falls under code Q77, which encompasses osteochondro dysplasia with defects of growth of tubular bones and spine. Within this category, Q77.4 is specifically designated for achondroplasia. This congenital skeletal disorder in children belongs to the group of systemic dysplasias [1] and is associated with a defect in the zone of cartilage proliferation [2].

At birth, children in this nosological group display a proximal shortening of the upper and lower extremities, a relatively short and narrow trunk, trident-shaped hands, and macrocephaly with hypoplasia of the middle third of the face and a protruding forehead. Growth parameters at birth are usually slightly less than normal, but with age, there is a progressive lag from the normal values (total shortening of the limbs is especially pronounced in the upper arms and thighs). Infants with achondroplasia are most characterized by decreased muscle tone, causing them to learn movement and walking skills later in life.Intellect and cognitive abilities are not affected by this malformation [3,4]. A review of the specialized literature showed that the incidence of achondroplasia varies widely from 1:15,000 to 1:30,000 newborns, regardless of gender or race [5]. The main cause of achondroplasia is a de novo mutation in fibroblast growth factor receptor-3 (FGFR3), which leads to a disruption of the endochondral ossification mechanism [6].

Despite a wide array of pathological symptoms, disproportional dwarfism remains central in defining the stereotypes and lifestyle of patients living with this condition. It is characterized by significant limb shortening and deformity. The combination of external and radiological manifestations in the musculoskeletal system, which are exacerbated in the process of growth, strongly influences the way these patients perceive themselves and lead their lives. This issue is particularly marked in childhood, where more attention is paid to a person’s appearance [7,8].

Currently, transosseous distraction osteosynthesis is prioritized in orthopedic care [9,10]. This method is based on the general biological property of tissues to respond by regeneration to dosed stretching [11]. The conventional approach for uniform tubular bone lengthening typically involves 1 mm per day in 0.25 mm fractions across 4 sessions [12]. However, the period of osteosynthesis in this mode varies from 4 to 18 months, which correlates with the planned magnitude of lengthening [13,14]. Challenges encountered during treatment and rehabilitation significantly impact patients’ quality of life [15]. Traditionally, the Ilizarov circular system has been utilized for limb lengthening in patients in this nosological group [9]. The features of this equipment, as well as the fundamental studies on reparative tissue regeneration processes and the proposed surgical intervention options, remain highly relevant to this day [16]. However, the complexity of the design, its excessively bulky nature, and its many parts can lead to long assembly times and require an increased time under anesthesia. In turn, these factors contribute to challenges during rehabilitation, limiting the use of this type of external fixator in pediatric practice [17]. Nevertheless, external fixators are the most common in the treatment of patients with achondroplasia in many countries [18-20]. According to the available literature, osteosynthesis with rod external fixators based on a semicircular frame is less traumatic compared to spoke circular devices. Moreover, rod fixators lead to less disruption of venous and lymphatic outflow in the postoperative period [20]. Rod fixators are more compact in appearance and provide sufficient rigidity to aid in bone fragment stabilization. Their straightforward assembly and mounting on the limb segment can help significantly reduce surgery duration, which is important in paired limb lengthening [21]. The authors developed a bar external fixation device with a distraction control system that showed better results than the circular multiaxial system regarding fixation time, regenerative length, deformation angles, pain intensity indexes, and complication rates [11]. This study aims to compare the quality of life (focusing on postoperative pain syndrome, physical activity, and emotional state) of children with achondroplasia undergoing paired limb lengthening using 2 different methods: an external fixator with modified distraction control and a circular multiaxial system developed by the authors.

Methods
Study Design
This was an observational, prospective, nonrandomized, and longitudinal study with a historical control. The experimental group included 14 patients, including 8 (57%) males and 6 (43%) females, aged between 5 and 15 (mean 7.6, SD 2.3) years. All patients had a genetically confirmed diagnosis of achondroplasia and received treatment at the state municipal enterprise “Multiprofile City Children’s Hospital No 2” in Astana, Kazakhstan, spanning from August 2018 to January 2020. All patients underwent paired limb lengthening using a rod external fixator with modified distraction control developed by the authors. A total of 28 limb segments, including 4 (14%) humeri, 8 (29%) femurs, and 16 (57%) tibias, were lengthened in 1 round. All operations were performed by the same team of surgeons. The patients were dynamically followed up for 18 months.
Unpublished data from the previous study were used as the control group, which comprised 9 patients, including 3 (33%) males and 6 (67%) females, matching the same age group (mean age during surgery 8.6, SD 2.3 years). Patients in the control group also had a genetically confirmed diagnosis of achondroplasia and underwent limb lengthening surgery using a circular multiaxial system between January 2012 and July 2018. A total of 18 segments of tubular bone were lengthened in the control group—comprising 2 (11%) humeri, 6 (33%) femurs, and 10 (56%) tibias. All operations were performed by the same team of surgeons as in the experimental group. This study did not involve a clinical trial.

**Clinical Examination**

Patients underwent preliminary clinical and radiological assessments. The clinical evaluation included orthopedic and neurological status: assessment of ligamentous elasticity and mobility of the knee joint, presence of torsional deformities of the lower extremities, child growth, and proportionality of the skeletal structure. The radial diagnostic protocol included radiographs of both lower extremities in straight projection over the entire length in a bipedal standing position with the correct orientation of the patellas (facing forward). Angular changes in the extremities were analyzed based on the radiographs obtained. The patients were examined by various specialists, including a pediatrician, endocrinologist, neurologist, cardiologist, and otolaryngologist, during the preoperative phase to identify any concomitant pathologies and mitigate intra- and postoperative complications.

**Operative Technique**

Surgical treatment was performed under general endotracheal anesthesia. During the surgical procedure, a semicircular external rod fixator design with a distraction mechanism of the authors’ modification was used (Figure 1). The operations were performed simultaneously on 2 identical segments, according to the tibia-tibia and femur-femur schema. To minimize the traumatic nature of the surgical intervention, a closed corticotomy of the middle third of the diaphysis was performed.

**Figure 1.** A semicircular external rod fixator design with the authors’ modified distraction mechanism. (1) Mechanism of the fixator in the form of a 2-section sliding structure. External rod section with internal thread and 2 rods with an external millimeter thread. (2) Supporting bases on which the distraction system is fixed when installing an external fixation device on a limb segment. The 1-mm distraction step is performed by axial rotation according to the marks. (3) Nut stabilizing internally threaded rods on the proximal threaded rod.
Postoperative Rehabilitation

Postoperative rehabilitation for patients with achondroplasia comprised 3 steps: a latency phase, a period of distraction and consolidation, and a period of functional adaptation of patients after device removal. The latency phase lasted 7 to 10 days, depending on the duration of postoperative edema recession and pain intensity. Lengthening was initiated at the end of the latent phase on the 7th to 10th day after surgery, with an average daily distraction rate of 0.75 mm. Restorative treatment was initiated on the second day after surgical intervention with constant parental involvement.

The amount of exercise depended on pain levels, distal limb swelling, and the patient’s psychological state. To prevent contractures of adjacent joints, the focus was on passive-active exercises ranging from 5 to 10 minutes, up to 3 times a day. Under medical supervision, patients were gradually mobilized to stand upright using walkers for up to 5 minutes and were taught to walk within the room. During distraction, the time of passive and active joint development sessions increased to 40 minutes, occurring 5 to 6 times a day, while the walking duration extended to 15 minutes.

The hospital stay for patients typically ranged from 10 to 14 days, adhering to the Republic of Kazakhstan’s Standard of Medical Care in Hospital Conditions. The hospital stay was determined based on the duration of the latency phase (period of postoperative edema recession and reduction of pain intensity). Subsequently, patients were discharged to outpatient treatment. Distraction and consolidation timing were assessed using radiographs. Control examinations with radiographs were performed every 10 days. During the examination, external fixator stability, joint function, and the presence of neurological and vascular disorders were evaluated. Based on the radiological appearance of the regenerate and assessment of joint mobility, the distraction rate was corrected (either decreased to 0.75 mm/day or increased to 2 mm/day). During the stabilization period, when performing joint development, an emphasis was placed on increasing muscle strength. Moreover, physical therapy classes remained intense, and the patients were taught to walk without additional support.

After reaching the possible segment length, the distraction process for the regenerate was halted, and the patients were examined monthly during the consolidation phase. After removing the fixators, a period of functional adaptation began that lasted up to 18 months after surgery. A key principle during this stage involved a gradual and appropriate increase in load. The treatment approach involved massaging the muscles of the thigh, lower leg, and humerus, coupled with physical therapy and thermal procedures. Furthermore, passive mobilization of all ranges of motion in the hip and knee joints was undertaken, with an emphasis on enhancing knee joint flexion. Patients were recommended to swim and exercise using simulators. Additionally, sanatorium-resort treatment was geared toward recovering all body systems following inpatient surgical treatment. Patients and parents were trained in the proper care of the medical device and rods and were instructed to adhere to the prescribed limb lengthening (distraction) schedule.

Quality of Life Assessment

Postoperative pain is a complex response to tissue trauma during surgery. A pronounced postoperative pain syndrome increases the likelihood of postoperative complications, prolongs the patient’s recovery period and subsequent rehabilitation, reduces physical activity, and worsens the patient’s psychoemotional state. Postoperative pain intensity is determined not only by the extent of damage but also by psychological factors (accompanying emotional state and anxiety). In this regard, postoperative pain syndrome, physical activity, and patients’ emotional states were considered when assessing quality of life.

The Wong-Baker Faces Rating Scale was used to assess the pain syndrome [22]. When working with this rating scale, a child had to choose 1 of the 6 faces drawn that corresponded to how they felt. The first face represented 0 points and indicated “no pain,” while the sixth face represented 5 points and indicated “severe pain.” Pain was assessed in the latency and distraction phases.

To assess the quality of life, a questionnaire was administered using the Russified Pediatric Quality of Life (PedsQL) v4.0 questionnaire [23]. This questionnaire has 23 five-point scales reflecting the patients’ current state: level of physical activity, emotional state, satisfaction with social role (satisfaction with communication with peers), and engagement in kindergarten/school. During this study, it was not feasible to correctly assess outcomes related to social role satisfaction and kindergarten/school attendance using the scales while the patients were still in the hospital. Therefore, quality of life was assessed only on the scales of level of physical activity and emotional state. The questionnaire consists of 2 parts: an assessment of a child’s quality of life (from age 5 years) and an assessment of a child’s quality of life by their legal representative. The children and their parents were instructed to select a number that reflected the frequency of difficult situations over a certain period, where 0 was never, 1 was almost never, 2 was sometimes, 3 was often, and 4 was almost always.

The number of points was calculated by the questionnaire key. First, the results were reversed and converted to a linear 100-point scale, where 0 was 100, 1 was 75, 2 was 50, 3 was 25, and 4 was 0. Next, the survey results were tallied. The results of each item in the block were added up, and the resulting sum was divided by the number of items in the block. A score higher than 75 was considered optimal. In the third stage, the authors calculated the total score for each item and divided the result by the number of items. The questionnaire was administered in the preoperative, latency, distraction, and consolidation phase, as well as during dynamic follow-up (6, 12, and 18 months after surgery). The questionnaires were processed blindly.

Statistical Analysis

The t test for the independent samples was used to assess the reliability of the differences between the experimental and control groups. The Student t test for dependent samples was also used to assess the reliability of differences within the groups at different stages of the study [24]. At P<.05, the null hypothesis of no relation between the parameters was rejected. Statistical calculations were performed using the SPSS software (IBM Corp.).

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Ethical Considerations
The research was conducted in accordance with the Standard of Good Clinical Practices (GCP) to the Order of the Minister of Health and Social Protection of Kazakhstan (May 27, 2015; no 392) and the ethical standards of the Declaration of Helsinki, amended in 2013. Parents were informed in advance about the purpose of the planned surgery. Parents or legal guardians signed informed consent for the surgical intervention, rehabilitation treatment, and publication of the findings without identifying themselves. The study was reviewed and approved by the Human Research Ethical Committee of Astana Medical University (reference number 333).

Results
In 9 (64%) patients in the experimental group, the lengthening results were evaluated as "excellent." This means that the planned elongation value had been reached, the deformation of the bone regenerate did not exceed 2 degrees, joint function was excellent (absence of contractures), and consolidation was successful based on radiographs. In 4 (29%) of patients, the lengthening results were evaluated as "good," indicating the planned elongation value had been attained, with slight deformation of the bone regenerate (not exceeding 4 degrees), the presence of easily treatable contractures, and successful consolidation confirmed by radiographs. In 1 (7%) of cases, the results were classified as "satisfactory." In these cases, the planned elongation was not fully achieved, there was some deformation of the bone regenerate (not exceeding 8 degrees), and there was a presence of contractures, but consolidation was successful according to radiographs.

Most patients achieved a lengthening value close to the planned value and correction of deformity, with minimal deviation that was not statistically significant. The average lengthening values were 8.5 (SD 0.6) cm, with the humerus length increasing by an average of 53% (SD 5%), the tibia by 52% (SD 8.2%), and the femur by 30% (SD 6%). The fixation period, including the distraction phase, averaged 83.8 (SD 3.7) days, with a specific average duration of 76 (SD 1) days for the humerus, 83.9 (SD 3.2) days for the tibia, and 87.5 (SD 2.5) days for the femur.

No contractures were observed during the latency phase or after the end of the distraction phase. However, during the distraction stage, 1 (7%) patient experienced knee joint contractures during hip lengthening, and 2 (14%) patients had ankle joint contractures due to heel tendon shortening, which resulted from failure to follow the treatment regime and joint development recommendations. The most common complaint reported by patients and their parents was minor inflammation of the soft tissues around the rods, which was resolved with conservative treatment. No cases necessitating rod removal or a second operation were noted. In the control group, the fixation time in the device averaged 101.4 (SD 5.4) days and the length of the regenerate averaged 6.6 (SD 0.8) cm. In 4 (29%) cases, knee joint contracture persisted, and 1 (7%) case of needle fracture was recorded.

Regarding pain, on the second day after the operation, the pain index in 13 (93%) patients in the experimental group was rated at 3 points on the Wong-Baker scale and at 4 points for 1 (7%) patient. However, by the end of the latency phase, the pain index in all patients was 0. In the control group, the Wong-Baker pain score was 4.1 (SD 1.02) on the second day and decreased to 1.7 (SD 0.8) at the end of the latency phase.

Before the surgery, quality of life scores on the PedsQL v4.0 questionnaire (measuring physical activity and emotional state) in the experimental group averaged 78.67 (SD 5) in the children's responses and 78.25 (SD 5.1) in their parents' responses. In the control group, these scores were 78.8 (SD 4.4) for the children and 78.0 (SD 5.4) for their parents. Thus, there were no differences in quality-of-life scores between the 2 groups before surgery.

As expected, during the latency phase following surgery, there was a significant decrease in physical activity and emotional state scores on the PedsQL v4.0 questionnaire in both groups when compared to the preoperative period. However, this decrease was more pronounced in the control group, with scores averaging 52.4 (SD 4.8) points by the children and 52.8 (SD 5.5) points by their parents. In contrast, in the experimental group, these quality-of-life scores decreased to 59.5 (SD 6.8) points according to the children's responses and 61.33 (SD 6.5) points according to their parents. These differences between the groups were statistically significant (P < .05 for the children's answers and P < .01 for their parents). At the same time, the experimental group showed a statistically more pronounced decline in the quality of life when the humerus was lengthened compared to the tibia and femur (P < .01). However, in the control group, such differences in quality-of-life changes between the lengthened segments were not observed.

By 6 months after surgery, there were improvements in physical activity and emotional state scores in both groups. These quality-of-life indicators on the PedsQL v4.0 questionnaire in the experimental group averaged 70.25 (SD 4.8) points according to the children's responses and 70.54 (SD 4.2) points according to their parents. In the control group, the corresponding scores were 69.64 (SD 5.6) points and 69.35 (SD 6.2) points, respectively. There was no statistically significant difference between the groups. There was also no difference between the lengthening segments in either group.

At 18 months after surgery, quality-of-life indicators (physical activity and emotional state scores) in both groups exceeded preoperative scores. In the experimental group, the average score was 84.3 (SD 2.5) group for the children and 85 (SD 2.5) points for their parents. These increases were statistically significant (P < 0.1). In the control group, the average score was 81.33 (SD 3.5) points for the children and 82.0 (SD 3.6) points for their parents, but the differences from preoperative scores were statistically unreliable. Furthermore, differences in quality-of-life scores between the experimental and control groups 18 months after surgery were statistically unreliable. The results of the PedsQL v4.0 quality of life questionnaire, completed by the patients and their parents in both groups, are shown in Tables 1 and 2.
Table 1. Results of transosseous osteosynthesis using the advanced rod monolateral external fixator and PedsQL\textsuperscript{a} v4.0 questionnaire scores completed by patients and their parents in the experimental group (N=14).

<table>
<thead>
<tr>
<th>Gender</th>
<th>Age (years)</th>
<th>Segment</th>
<th>Consolidation period (days)</th>
<th>Planned lengthening (cm)</th>
<th>Lengthening results (cm)</th>
<th>PedSQL\textsuperscript{a} v4.0 questionnaire scores</th>
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<tr>
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<td>Preoperatively</td>
<td>Latency phase (7-10 days after surgery)</td>
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<td>Child:</td>
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<td></td>
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<td></td>
<td>Parent:</td>
<td>Parent:</td>
</tr>
<tr>
<td>Male</td>
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<td>Tibia</td>
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<td>10</td>
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<td>Left: 8.5</td>
<td>Parent: 80</td>
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<td>85</td>
<td>8.5</td>
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</tbody>
</table>

\textsuperscript{a}PedSQL: Pediatric Quality of Life.
Table 2. Results of transosseous osteosynthesis using the circular multiaxis system and PedsQL\textsuperscript{a} v4.0 questionnaire scores completed by patients and their parents in the control group (N=9).

<table>
<thead>
<tr>
<th>Gender</th>
<th>Age (years)</th>
<th>Segment</th>
<th>Consolidation period (days)</th>
<th>Lengthening results (cm)</th>
<th>PedsQL\textsuperscript{a} v4.0 questionnaire scores</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Preoperatively</td>
</tr>
<tr>
<td>Female</td>
<td>7</td>
<td>Humerus</td>
<td>90</td>
<td>Right: 7</td>
<td>Child: 75</td>
</tr>
<tr>
<td>Female</td>
<td>7</td>
<td>Femur</td>
<td>105</td>
<td>Right: 8</td>
<td>Child: 80</td>
</tr>
<tr>
<td>Female</td>
<td>13</td>
<td>Femur</td>
<td>105</td>
<td>Right: 7</td>
<td>Child: 76</td>
</tr>
<tr>
<td>Female</td>
<td>14</td>
<td>Tibia</td>
<td>103</td>
<td>Right: 7</td>
<td>Child: 78.3</td>
</tr>
<tr>
<td>Female</td>
<td>14</td>
<td>Tibia</td>
<td>110</td>
<td>Right: 5</td>
<td>Child: 76</td>
</tr>
<tr>
<td>Male</td>
<td>7</td>
<td>Femur</td>
<td>107</td>
<td>Right: 5</td>
<td>Child: 76</td>
</tr>
<tr>
<td>Female</td>
<td>6</td>
<td>Tibia</td>
<td>97</td>
<td>Right: 6</td>
<td>Child: 86</td>
</tr>
<tr>
<td>Female</td>
<td>7</td>
<td>Femur</td>
<td>105</td>
<td>Right: 6.5</td>
<td>Child: 80</td>
</tr>
</tbody>
</table>

\textsuperscript{a}PedSQL: Pediatric Quality of Life.

Figure 2a-c also shows the postoperative progression of a 10-year-old patient diagnosed with achondroplasia who underwent paired limb lengthening with a rod external fixator equipped with the authors’ modified distraction control. The patient and her parents reported a significant improvement in her quality of life after the surgical intervention and rehabilitation.
**Discussion**

**Principal Findings**
This study compared quality-of-life indicators (measured by postoperative pain syndrome, physical activity, and emotional state) in children with a genetically confirmed diagnosis of achondroplasia undergoing transosseous distraction osteosynthesis using 2 different external fixators systems: a rod system with the authors’ modified distraction control and a circular multiaxial system (Ilizarov system).

As expected, the results confirmed a decline in the quality of life for patients in both groups during the latency phase. However, patients in the control group (using the circular multiaxial system) experienced a more significant decrease in quality-of-life satisfaction, as reported by both the children and their parents/caregivers, compared to the experimental group using the rod fixator with the authors’ modified distraction control. Moreover, the control group reported more intense pain syndrome compared to the patients using the authors’ modified semicircular distraction system. During the later postoperative period under a dynamic observation, these differences decreased, and the level of satisfaction with the quality of life was statistically significantly higher in the main group 18 months after surgery than in the preoperative period.

Although orthopedic surgery for the treatment of achondroplasia has made significant advancements and continues to evolve, most practitioners have yet to agree on a surgical approach to the treatment of children and adolescents with this condition. Furthermore, the optimal fixator compositions for different age groups of patients are not specified [9]. A high rate of complications persists, which may be due to noncompliance with age-specific aspects of surgical treatment [17]. Several postoperative management issues remain unresolved [16].

In a recent study utilizing the PedsQL 4.0 questionnaire to assess the quality of life in children with achondroplasia (reported by the children and their parents/caregivers), it was observed that parents perceived their child’s quality to be lower in all domains compared to people of average height. This is due to physical limitations, barriers, and various challenges reported by children and adolescents to their parents. Notably, the children themselves also rated their quality of life significantly lower than the healthy control group, except in the emotional domain, where their scores were similar to the healthy group. It is important to understand that the diagnosis of achondroplasia and its consequences impact not only a child but also the entire family, as family members must adapt to the unique needs of the child [7].

Surveys conducted among patients with achondroplasia and their family members, both before and after treatment, consistently answer in favor of the need for limb augmentation [8,17]. Currently, the primary method for addressing growth deficit in patients with achondroplasia involves surgical distraction osteosynthesis [9,10]. The possibility of drug-assisted limb lengthening, particularly with the drug Vosoritide, is being studied. While the results are encouraging, at present, this trend cannot serve as an alternative to surgical treatment [4].

During surgical treatment, transosseous osteosynthesis is the most commonly used method, involving the use of external bone-anchored supports placed above the skin’s surface. However, patients are required to wear these systems throughout the distraction and consolidation period of the regenerate, which can last up to 18 months, depending on the planned degree of limb lengthening. This inevitably impacts a patient's quality of life. In response to this concern, internal fixation systems have
been developed, such as the Precice system with magnetic control over distraction speed [25,26], and combined systems like LON (Lengthening Over Nail) and LATN (Lengthening and Then Nailing), which halve the time of fixator use [27-29]. However, these systems cannot always serve as an alternative to fixators because they use expensive titanium rods. The Precice system has limitations in bone diameter, cannot be used for humerus lengthening, and the procedure itself must be well planned since no postoperative changes (other than distraction rate) can be made [27]. The LON and LATN systems require additional surgical intervention. Consequently, the development of lighter and more comfortable fixators remains urgent.

Traditionally, limb lengthening for patients in this nosological group has been performed using a multiaxial system, known as the Ilizarov system. While this system shows good results in reparative tissue regeneration processes, its complex design and cumbersomeness can impact patients’ quality of life, which is especially significant in pediatric practice [9,16,17]. To address this, rod fixators built on a semicircular frame with a simpler and lighter design are gaining popularity [20,21]. The authors have introduced a rod fixator with modified distraction control. A previous article demonstrated the advantage of this system over the circular multiaxial system, highlighting improvements in fixation time, achieved regenerative length, correction of deformities, pain intensity, and complication rates [11].

This study establishes that the authors’ rod fixation with modified distraction control facilitates an improved standard of living compared to a circular multiaxial system in the latent phase. Consequently, this advancement not only allows patients with achondroplasia to move freely from the first days after surgery but also to gradually develop strength in the lengthened limb.

Conclusions

The rod fixator with modified distraction control developed by the authors significantly enhances the quality of life compared to the circular multiaxial system in the latency phase. Employing this fixator technique for paired surgical lengthening in children with achondroplasia ensures stability throughout the distraction process, provides a strong and uniform regenerate, contributes to a significant reduction in complications, and allows patients to regain full physical activities in a shorter time. With its high stability, the device creates favorable conditions for psychological and physical adaptation during treatment and demonstrates a significant advantage over the circular multiaxial system. Considering the cost-effectiveness of this developed fixation system, it can contribute to delivering quality orthopedic care for patients with achondroplasia.

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Declaration of Patient Consent

The patient’s parent has given informed consent for the patient’s images and other clinical information to be published in a medical journal. The patient’s parent understands that the patient’s name and initials will not be published and due efforts will be made to conceal their identity, but complete anonymity cannot be guaranteed.

Data Availability

The data sets generated and/or analyzed during this study are available from the corresponding authors upon reasonable request.

Authors’ Contributions

All authors contributed to the study’s conception and design. VT, BD, VL, SK, AD, AA, AP, and OZ performed the material preparation, data collection, and analysis. VT wrote the first draft of the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

References


**Abbreviations**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
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<tbody>
<tr>
<td>ICD</td>
<td>International Classification of Diseases</td>
</tr>
<tr>
<td>FGFR3</td>
<td>fibroblast growth factor receptor-3</td>
</tr>
<tr>
<td>GCP</td>
<td>Good Clinical Practice</td>
</tr>
<tr>
<td>LON</td>
<td>Lengthening Over Nail</td>
</tr>
<tr>
<td>LATN</td>
<td>Lengthening and Then Nailing</td>
</tr>
<tr>
<td>PedsQL</td>
<td>Pediatric Quality of Life</td>
</tr>
</tbody>
</table>

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