Treatment of trigger finger with metacarpophalangeal joint blocking orthosis versus relative motion extension orthosis: a randomized clinical trial

Study design

This study was conducted to compare the efficacy of metacarpophalangeal (MCP)-blocking orthosis with relative motion extension (RME) orthosis in patients with trigger finger between June 2021 and March 2022 at a university hospital. The study was approved by the University Institutional Research Ethics Board. Patients were informed about the study and provided written informed consent before enrolment. The inclusion criteria were patients diagnosed with Stage 1-3 trigger finger, A1 pulley triggering and aged between 18 and 60 years. We excluded patients with trigger thumb, multiple trigger fingers on one hand, neurological disorders, rheumatologic diseases, pregnancy, and patients who had received a steroid injection in the affected finger within the previous six months or who had previously undergone trigger release surgery.

Power analysis was performed using G*Power 3.1 to test the difference between pre-treatment and post-treatment means with a two-tailed test, (primary outcome was pain and function), and an alpha of 0.05. A total sample of 30 participants was required to achieve a power of 0.90.

Study sample

Patients were randomly assigned in a 1:1 ratio to either the MCP-blocking group or the RME group, using a simple random sampling method. Patients were numbered according to their admission to the clinic. Randomization was performed using a random number table system. Starting with the MCP-blocking group, each group was assigned a number in turn. Patients in the MCP group received an MCP-blocking orthosis, and patients in the RME group received an RME orthosis for six weeks. All patients received patient education, activity modification, and flexor tendon gliding exercises as part of the rehabilitation program.

Intervention

The custom MCP blocking orthosis was made of a 6-mm-thick thermoplastic material that extends from the palm over the MCP joint and includes a ring around the proximal phalanx. It is designed to block the MCP joint in flexion of 10°-20° while allowing full range of motion of the proximal and distal interphalangeal joints. The RME orthosis was fabricated from 3.2-mm-thick thermoplastic material with the affected finger positioned at an extension of approximately 10°-20° relative to the adjacent fingers. Both orthoses were fabricated in about 20-30 minutes, with the RME orthosis taking slightly less time than the MCP orthosis. If necessary, modifications were made to alleviate the discomfort associated with the orthosis, such as placing a strap over the proximal phalanx in patients with edema. Patients were instructed to remove the orthosis only for hygiene.

Measurements

Demographic information obtained during the pre-treatment assessment included: age, gender, affected finger, dominant hand, duration of symptoms and occupation. The primary outcome measures were performed twice, before and after treatment at six weeks. The primary outcomes were pain and function. Pain intensity was assessed using a numeric pain rating scale (NPRS). Functional status was assessed with the Disabilities of Arm, Shoulder, and Hand Questionnaire (DASH).

Satisfaction with the orthosis was a secondary outcome of this study. The Quebec Assistive Technology User Satisfaction Evaluation (Quest 2.0) was used to assess patients' satisfaction with their orthoses. Of the 12-item Quest instrument, 8 items evaluate the characteristics of the assistive device in terms of dimensions (size), weight, adjustments, safety, durability, ease of use, comfort, and effectiveness. The remaining four items evaluate service, including service delivery, repairs and service of the assistive device, professionalism of service, and follow-up service. The instrument also included an assessment of satisfaction with the device on a five-point scale. In the final section, participants were asked to select the

three most important items related to the assistive device from 12 short satisfaction statements.

Since emotional status is related to disability in trigger finger patients, the Beck Depression Scale (BDS) and the Beck Anxiety Scale (BAS) are used to determine the severity of depression and anxiety, respectively. A higher score indicates more severe depression or anxiety.

Statistical analysis

Descriptive analyses were presented using means and standard deviations and using medians and interquartile ranges (IQR) for the non-normally distributed and ordinal variables (using frequency tables for the ordinal variables). The normal distribution of the continuous variables was tested using visual (histogram and probability plots) and analytical methods (Shapiro-Wilk test). DASH, BDS and BAS scores was normally distributed; the NRPS and Quebec scores, age, gender, affected hand and finger, symptom duration were not normally distributed. The Student T test was used for normally distributed data and two-tailed Wilcoxon signed rank test was used for non-normally distributed data to compare pre-treatment and post-treatment results. The Mann-Whitney U test was used to analyse the difference between two groups. The significance level was set at $p < 0.05$.