**Prosser R, Hancock MJ, Nicholson L, and et al. Rigid versus semi-rigid orthotic use following TMC arthroplasty: A randomized controlled trial. Journal of Hand Therapy 2014; 27: 265-271.**

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**Design:** Randomized controlled trial

**Objective:** To examine the effectiveness of semi-rigid orthotic use compared with standard rigid orthotic use following trapeziometacarpal (TMC) arthroplasty on short to medium term outcomes of self-reported pain, range of motion, strength, and function.

**Population /sample size/setting:**

* A total of 56 consecutive patients (mean age 67.8 years, 45 females, 11 males) with osteoarthritis of the TMC joint planning to undergo arthroplasty of the TMC joint were recruited from three hand surgery practices for this study.
* The 56 patients were randomly assigned to one of 2 groups: the rigid orthotic group or the semi-rigid orthotic group.
* Inclusion criteria included adults with osteoarthritis of the TMC joint who were scheduled for arthroplasty using one of two common techniques (trapeziectomy with Ligament Reconstruction Tendon Interposition (LRTI) or simple trapeziectomy).
* Exclusion criteria included rheumatoid arthritis or surgery to other digits or the wrist that would require other forms of orthotic intervention.

**Methods/Interventions/Outcome Measures:**

* Study design was a prospective, randomized, controlled, single-blind study. The randomization schedule was generated by an independent person using a computer generated random numbers table. Subjects were consecutively randomized after consenting and completing the demographic and preoperative measures. Baseline information was collected on patient age, gender, hand dominance, and all the primary and secondary outcome measures.
* Four surgeons performed all the TMC arthroplasties.
* At 10 to 14 days following surgery, the dorsal plaster back-slab used to immobilize the wrist and thumb, and the sutures were removed from all participants. At this time, hand therapy exercises began, and patients were randomly allocated into either the rigid orthotic or semi-rigid orthotic group. Group allocations were placed in sealed opaque envelopes and sequentially allocated to each participant.
* Both orthoses were custom made for each participant. All patients were instructed to wear the orthotic full time, 24 hours per day for 4 weeks, except for exercises.
* The semi-rigid orthosis was fabricated from neoprene with a bonded thermoplastic piece. The neoprene of the semi-rigid orthosis extended from the thumb interphalangeal joint to include the distal two thirds of the forearm. A thermoplastic piece on the radial aspect of the thumb extending from mid proximal phalanx to just below the wrist was bonded to the neoprene with the thumb in maximal comfortable palmar abduction. This orthosis allowed limited wrist (60 to 70% of active range of extension and flexion) and thumb (5 to 25 degrees of MCP flexion and 45 to 55 degrees of TMC palmar abduction and opposition to all finger tips) active motion.
* The rigid orthosis immobilized the thumb from the interphalangeal joint to include the distal two thirds of the forearm. It was fabricated from 2.4 mm thermoplastic and included the thumb metacarpophalangeal (MCP) and TMC joints as well as the wrist (the interphalangeal joint was left free). The thumb was in a palmar abducted position and the wrist was in approximately 300 extension. It did not allow wrist or thumb TMC and MCP joint motion.
* All patients underwent the same active exercise program regardless of group allocation starting 10 to14 days after surgery. All patients were instructed to complete each exercise 10 times, 4 times a day. At week 2, thumb interphalangeal flexion and extension in the orthosis, and wrist flexion and extension out of the orthosis was started. Flexion and not hyperextension were emphasized. At week 4, all patients were advised to use their hand for light, pain free activities with the orthosis on as tolerated. At 6 weeks, a weaning period from the orthosis for light activities and strengthening exercises were started for both groups. At 12 weeks, moderate to heavy activity was begun. Both groups had weekly visits for the first 4 weeks to hand therapy for orthosis and exercise program monitoring.
* The assessor of outcome measures was blinded to treatment group allocation. Patients could not be blinded to their treatment assignments.
* The primary outcome measure was the Patient Rated Wrist and Hand Evaluation (PRWHE). Secondary outcome measures included the Michigan Hand Questionnaire (MHQ), range of motion, and pinch strength. The MHQ is a 37-item questionnaire assessing function, pain, and activities of daily living that are important to patients with hand disorders. Measurements were taken at 4 time points; pre-operatively, at 6 weeks, at 3 months, and one year.
* Sample size power calculations were conducted. Twenty-eight participants were required per group to provide 80% power to detect a difference of 15 points on the PRWHE. For the primary outcome (PRWHE at one year), a *P* value of <0.05 was considered statistically significant. Intention-to-treat analyses were performed.

**Results:**

* A total of 53 patients completed the study. Three were lost to follow up. Twenty-six subjects were in the rigid orthotic group and 27 were in the semi-rigid orthotic group. All participants had experienced symptoms for 12 months or more prior to surgery.
* Only 3 participants underwent trapeziectomy alone with the remaining 53 patients undergoing trapeziectomy with ligament reconstruction tendon interposition.
* Participants allocated to the semi-rigid orthoses group had somewhat higher baseline PRWHE scores (indicating greater pain and disability), however they also had higher pinch strengths (greater strength) than those in the rigid orthotic group. The differences in these outcome measures were not statistically significant.
* At one year follow-up, there was no significant between-group difference in the primary outcome of total PRWHE score (0.47, 95% CI -11.5 to12.4). The confidence intervals did not even contain the MCID of 15 points providing conclusive evidence that the rigid orthotic was no better, or worse, than the semi-rigid orthotic. There were no differences between groups for the PRWHE subscales of pain and function.
* For the primary outcome of total PRWHE score, within group comparisons showed continuous improvement in function and decreased pain for the participants between the preoperative mean scores, and all follow-up mean scores for both groups.
* For the secondary outcome measures, MHQ total score, range of motion, and three point pinch grip, there were no significant differences between the two orthoses at any of the 3 follow-up time points.
* Six participants experienced postoperative complications, four from the rigid and two from the semi-rigid orthotic group.

**Authors’ conclusions:**

* The results of this study show that in the postoperative management at one year following TMC arthroplasty, there is no significant difference in pain, function, range of motion, or strength between the group who wore rigid orthoses and the group who wore semi-rigid orthoses.
* This study is the first randomized controlled trial to provide evidence that a semi-rigid orthosis performs as well as a rigid orthosis following TMC arthroplasty. Pain and function outcomes for the semi-rigid orthosis group were as good as the rigid orthosis group.
* There was no significant difference between the two groups at one year for the primary outcome of PRWHE scores or for any secondary outcome.
* The confidence intervals for the primary outcome of PRWHE total score do not cross the clinically important difference between groups which was set a priori of +15 points. This provides strong evidence that the study did not miss any worthwhile effects.
* The results of this study are most generalizable to patients following LRTI, since only 3 patients underwent trapeziectomy alone.
* This study had a relatively low rate of adverse events (10.7%) compared to the typically reported rate of adverse events associated with LRTI of 22%.
* The semi-rigid orthosis eliminates the cost of a second orthosis as it can be converted to a soft orthosis simply by removal of the thermoplastic piece.
* Clinically, either orthosis could be recommended. Patient satisfaction regarding comfort was not evaluated, however it could be postulated that the semi-rigid orthosis may be more comfortable, perhaps have less adverse effects, and may be more cost effective than a rigid orthosis. Patient comfort, cost and availability may determine choice between orthoses in clinical practice.
* Further investigation of rates of adverse events between different types of orthoses is warranted.
* Future research could investigate if there is a need for any immobilization of the wrist and thumb apart from the TMC joint, after TMC arthroplasty.

**Comments:**

* This study supports the conclusion that the rigid orthosis and semi-rigid orthosis (allowing more wrist and thumb motion) used from 2 to 6 weeks following TMC arthroplasty performed equally well in this study.
* There was no significant difference between the two groups for the primary outcome of PRWHE scores at one year or any of the follow-up time points or for any secondary outcome at any of the follow-up time points.
* This study achieved high rates of follow-up for the six week, three month and one year assessment with only 3 participants lost to follow-up.
* A strength of the study was its use of an identical exercise program initiated at the same post-surgery time point for both groups, so that a definitive, singular investigation of the effect of the two orthoses types could be carried out. All of the patients in this study began mobilization two weeks following surgery.
* Strengths of this study included outcomes assessor blinding, an adequate sample size and power, and primary outcome clearly designated.
* One weakness of the study was that a preoperative clinical difference (PWHRE scores) between groups was present that should have been normalized by the randomization process, but was not. This baseline imbalance may influence outcome, and could introduce chance bias. A strength of the study was that the analysis adjusted for this baseline imbalance between groups, thus eliminating this source of bias.
* The study did not evaluate patients’ satisfaction to wearing either orthotic. Asking patients about how they felt when wearing the orthotic would have been beneficial.
* A possible source of error in this study is patient-related factors such as inconsistent wearing of the orthotic. Patients were not required to report compliance with orthotic use, and monitoring was not conducted. This is a failure of the study to measure a factor that could influence the outcome.
* Analysis data on differences between groups in demographic characteristics were not given, and so it is unknown if the groups differed significantly in any of the demographic characteristics.

**Assessment*:***

* This adequate study provides some evidence that in the postoperative management at one year following trapeziometacarpal (TMC) arthroplasty, there is no significant difference in pain, function, range of motion, or grip strength between patients who wore standard rigid orthoses and patients who wore semi-rigid orthoses from 2 to 6 weeks following TMC arthroplasty.