

Kinesiology taping reduces the pain of finger osteoarthritis: a pilot single-blinded two-group parallel randomized trial

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Objectives: Osteoarthritis (OA) is the most common arthropathy of the hand, and current treatments carry risks of adverse events. Supportive (kinesiology) tape may be analgesic and provide functional improvement, with a low risk of adverse outcomes. We experimented with supportive tape for OA of the proximal interphalangeal joint (PIPJ) of the finger in this pilot randomized trial.

Methods: This two-group parallel randomized trial recruited adults with OA of the PIPJ of the finger. We excluded patients lacking capacity or the ability to safely apply the tape. Participants were randomized to receive kinesiology tape on the dorsum of the finger, blind to grouping. Pain was the primary outcome, which was recorded on a visual analog scale (VAS). Secondary outcomes were hand function and adverse reactions. Bootstrapped between-group analyses are reported.

Results: Ten patients were included and randomized and provided complete data. There was no significant difference in pain between the groups (mean difference of 0.4 VAS units [95% confidence interval {CI} -1.6, 0.7], $p=0.4$). Overall, the application of kinesiology tape reduced reported pain by 6% (mean reduction of 0.6 VAS units [95% CI 0, 1.2], $p=0.04$). Taping did not affect hand function or digital range of motion. There were difficulties in recruiting individuals owing to the lack of dedicated research staff.

Conclusion: Kinesiology taping may reduce the pain of OA in the finger; however, whether this is a true effect, placebo effect, Hawthorne phenomenon, or due to a statistical error (ie, type 1 error due to underpowering) is unclear. Hence, further trials are required.

Keywords: osteoarthritis, hand, kinesiology, tape, pain, trial, pilot, randomized, PIPJ, proximal interphalangeal joint, digit

Introduction

Osteoarthritis (OA) of the hand is the most common arthropathy worldwide, with a symptomatic prevalence of 67%.¹ After the basal thumb joint, the interphalangeal joints (IPJs) of the hand are most commonly affected.^{2,3} In the UK, 1.9 million people per annum seek medical attention for OA in their hands.³

Most patients with OA of the hand require simple analgesia only, although the treatment options are globally limited by poor quality evidence showing marginal benefit. Topical nonsteroid anti-inflammatory drugs benefit a minority of patients but carry the risk of skin reactions.⁴ Intra-articular injections (eg, corticosteroids, local anesthetics, or hyaluronic acids) are used but lack evidence of a sustained benefit in OA of the basal thumb joint⁵ or IPJs of the hand.⁶ Ultimately, some patients require arthrodesis or arthroplasty, but again, the effectiveness of these operations remains

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controversial because the evidence is of poor quality and lacks patient-reported outcomes, and 28% experience complications.⁷ A systematic review by Bertozzi et al showed little evidence of a sustained reduction in OA pain from traditional hand therapies,⁸ including no significant reduction in pain from advice, static splints, or laser therapy; the combination of therapeutic exercises and manual therapies conferred moderate-quality evidence of a small reduction in pain; magnetotherapy examined in one trial found moderate evidence of a reduction in pain from basal thumb OA. Similarly, Østerås et al showed a small beneficial effect of exercise on hand pain (5% reduction, low-quality evidence), hand function, and finger joint stiffness, but these findings were unlikely to represent a clinically important change.⁹ Therefore, there is a pressing need for simple and low-risk sustained analgesia for symptomatic OA of the hand.

Commercially available kinesiology tapes are widely used, and numerous reviews demonstrate their analgesic effect in various musculoskeletal disorders.^{10–13} The theory underpinning kinesiology tape is that tension applied along the tape (which alters with movement) stimulates mechanoreceptors in the skin, reducing nociception and thus “closing the gate” to pain.^{14,15} While there are no commercially available products for the fingers, the Suture Strip® Plus marketed by Dermasciences (Ontario, Canada) has similar properties. Suture Strip® Plus is made from a waterproof microporous non-woven webbed polyamide/polyester with pressure-sensitive polyacrylate adhesive, which may provide a similar analgesic effect to other kinesiology tapes on a scale applicable to the hand.

The aim of this study was to investigate the perceived benefits of Suture Strip® Plus tape, applied to dorsum of the proximal interphalangeal joint (PIPJ), in patients with established OA. We hypothesized that taping will 1) reduce perceived pain in accordance with the gate theory but also 2) not limit the active range of motion (aROM) of the PIPJ.

Materials and methods

The protocol for this trial is available at www.clinicaltrials.gov (NCT02220374). The study was approved by both The Mid Yorkshire Hospitals NHS Trust (Reference 14/927) and the National Research Ethics Service (Reference 14/YH/1040). The manuscript has been authored in accordance with the CONSORT statement.^{16,17}

Design

This is a pilot pragmatic blocked two-group parallel randomized trial.

Research questions

Primary research question

1. Does taping the dorsum of the PIPJ of the finger affect reported pain?

Secondary research questions

1. Does taping the dorsum of the PIPJ of the finger confer adverse reactions?
2. Does taping the dorsum of the PIPJ of the finger affect reported or objective hand function?

Participants

We included adults (aged ≥ 18 years) attending the plastic surgery outpatient department or hand therapy unit in the host institution, with an established diagnosis of chronic OA of the PIPJ of any finger based on both symptoms and radiographic changes. We excluded patients meeting any of the below criteria, as judged by CP/NH:

- Non-English speakers – this pilot trial was unfunded, so interpreter costs could not be met.
- Those unable to consent or lacking capacity (unable to understand, retain, weigh up or communicate their decision) for any reason.
- Those (patients or carers) who lacked the dexterity to cut and apply the tape to the painful finger.
- Those with an active infection or an unhealed wound on the same hand, as this may confound the outcome.
- Dermatological conditions involving the proposed trial finger, as this may confound the outcome and make tape application impractical.
- Vulnerable or thin dorsal skin on the proposed trial finger which may torn by the removal of the tape. This was a concern of the ethics committee despite no published reports of lacerations from the removal of such dressings.

Participants were instructed to continue their usual medication and not introduce any new non-pharmacological or medical therapies for their OA between recruitment and study completion. No participant underwent any medical intervention (eg, injection or surgery) during the study period. This trial gained approval from the South Yorkshire Committee from the National Research Ethics Service (Reference 14/YH/1040). Written informed consent was provided by all the participants.

Intervention

The trial was conducted over 3 weeks, with three distinct phases. During week 1 no tape was applied; week 2 was the

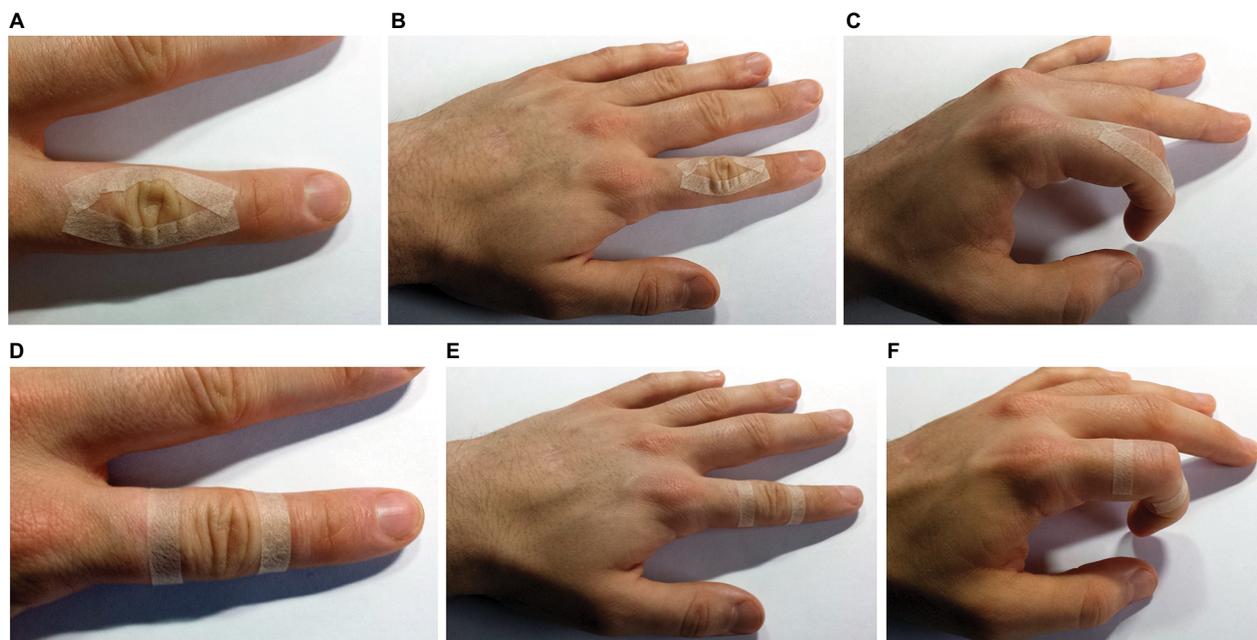


Figure 1 The upper row of photographs (A–C) show the configuration of tape hypothesized to provide a benefit and so applied to participants in the intervention group. The lower row of photographs (D–F) shows the hypothesized placebo configuration used in the control group.

experimental week and participants applied the tape daily; week three was the washout period when no tape was applied.

Both the groups were taught to apply $\frac{1}{4}$ inch Suture Strip® Plus tape to the dorsum of the symptomatic PIPJ during week 2. Participants in the intervention group were taught to apply the Suture Strip® Plus tape in the configuration which is hypothesized to be supportive and so carry analgesic potential for the PIPJ (Figure 1). This configuration was based upon the theory and application instructions for kinesiology products (application inline with the action of underlying muscles/tendons, to stimulate cutaneous stretch receptors, so that at the PIPJ, this would be parallel to the extensor tendon). Participants were given face-to-face training by CP/NH and a step-by-step photographic guide of how to measure the lengths of Suture Strip® Plus tape required (mid-point of the metacarpophalangeal joint-PIPJ to midpoint of the PIPJ-distal interphalangeal joint) and apply them over the symptomatic PIPJ, in an elliptical configuration, with the extremities of the tape overlapping. In comparison, the control group were taught to apply the tape in a configuration hypothesized to deliver no analgesic effect (ie, be a placebo) over the dorsum of the PIPJ (parallel to the articular surfaces of the PIPJ, with one strip proximal and one distal) as shown in Figure 2. Participants were instructed to apply the tape every day during week 2 and retain it for as much as the day as possible (eg, apply it first thing in the morning and remove it at night). If the tape fell off, became wet, or tore, then

participants were instructed to replace the tape. We applied the tape during the day, so that the analgesic benefit could be realized and functional impairment (if any) quantified.

Outcomes

The primary outcome measure was change in reported pain between the groups over time. Pain was reported daily over the 3-week trial period using a paper-based 100 mm visual analog scale (VAS) without intervals. The VAS was a straight line with “no pain” at one end and “worst imaginable pain” at the other. A VAS was chosen because participants could accurately record their pain perceptions without limitation (eg, by a Likert system) and measurement differences of 1% may be captured. Participants were given the paper VASs and asked to complete one per day, at the same time each day.

To investigate our secondary outcomes of interest, participants completed a QuickDASH¹⁸ on the 7th, 14th, and 21st day of the trial (the end of each week); patients were given all three and asked to complete one at the end of each week. This validated patient-reported outcome measure of upper limb function provided a functional assessment at each phase. Participants were telephoned weekly to enquire about adverse events/reactions. At the end of the trial, we provided participants with the opportunity to share their thoughts (written or verbally) of the tape, how it integrated with their day-to-day life, and how we may improve the treatment. aROM was measured by using a Roylan finger

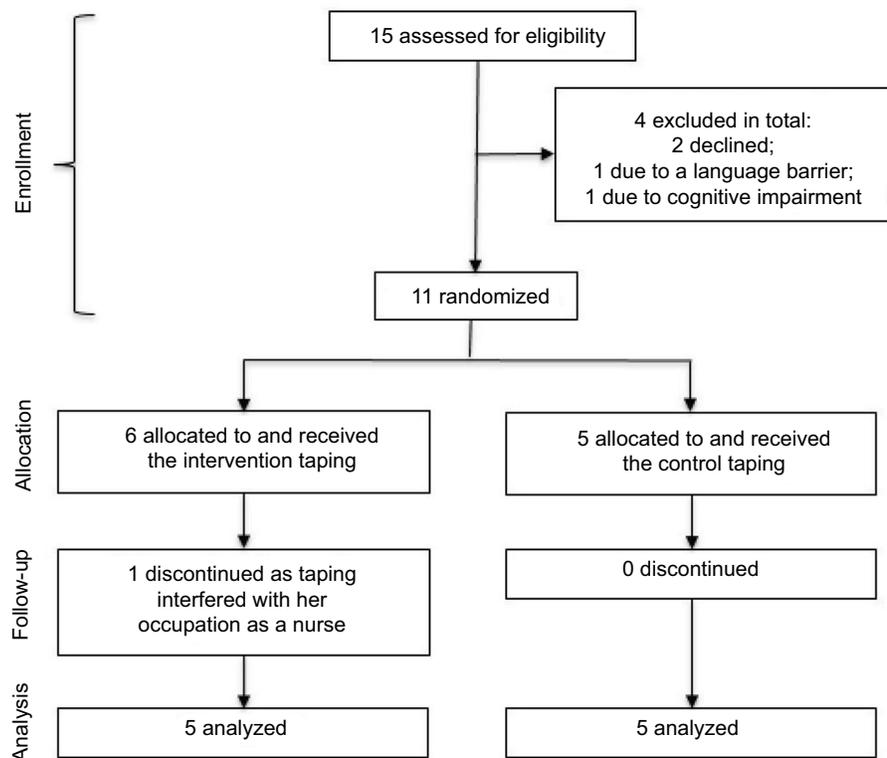


Figure 2 A flow diagram of participant inclusion.

goniometer (Patterson Medical) in degrees by CP/NH in the affected digit, both with and without tape, at baseline and at the end of the trial.

Sample size

There are no published data on which to base a power calculation. We estimated a clinically relevant difference in pain between groups to be 10% (10 mm). Therefore, assuming equal standard deviations of 10%, we required 32 subjects (16 per group) for 80% power at a 5% significance level. We planned for a 50% rate of enrolment and 20% attrition and hence originally planned our recruitment to last for 6 months. However, the recruitment proved difficult, and this pilot trial was extended for 8 months, but still we failed to recruit the required sample size; these difficulties are discussed.

Randomization, allocation and blinding

Participants were randomized 1:1 according to a random number table, with random block sizes of 4 and 6. Group allocations (as Group 1 or Group 2) were concealed in sequentially numbered, sealed opaque envelopes. There was no stratification. Consenting participants were randomized by an independent third party (the receptionist of the Hand

Therapy Department). Envelopes were drawn in turn and opened, and the group allocation was recorded in a dedicated research diary. Thereafter, the allocation (Group 1 or 2) was conveyed to the therapist (CP/NH) in the absence of the participants.

The hand therapist (CP/NH) could not be blind to grouping because they were teaching the taping method to the participants and were involved in the trial conception, design, and planning. However, which method of taping is effective (if either are effective at all) is uncertain, and hence, the opportunity for bias is debatable. The participants were blind to grouping as their documentation read “Group 1” or “Group 2”, and they were not privy to the hypothesized beneficial configuration of tape. There is no prior research on this topic which participants could use to subvert the blinding. Both the therapists were taught how to apply the tape and conduct the trial in an identical manner.

Statistical analyses

Anonymous outcome data were provided to RGW at the conclusion of the trial. Groups were decoded from Group 1 to Control and Group 2 to Intervention, and data were analyzed unblinded. Pain was analyzed by normal methods because the measures of centrality were similar; histograms

approximated the normal and between-group differences with 95% confidence intervals (CI) could be generated. Between-group and within-group changes in pain and range of motion were analyzed by linear regression. To improve the accuracy and thus the external validity of confidence intervals for our estimates, we used lossless nonparametric bootstrapping by resampling by replacement with 1,000 iterations.¹⁹ Quick-DASH outcomes are strongly skewed and so presented as medians with interquartile ranges (IQRs) and compared with the Mann–Whitney *U*-test. Changes in Quick-DASH scores were analyzed by using Friedman's two-way analysis of variance by ranks. Categorical variables are presented as frequencies (with percentages) and compared with Fisher's exact test. Analyses were planned on an intention-to-treat (ITT) basis. Significance was set at $p < 0.05$.

Results

Figure 2 demonstrates the participant inclusion in this study. One female was randomized but dropped out before any outcome data could be recoded; hence, ITT was impossible.

The mean age of participants was 62.4 years (SD 8.4). There were three males and two females in the control group, and five females in the intervention group ($p = 0.4$). Seven were right-handed with no between-group difference ($p = 0.5$). Hand dominance was not associated with laterality

of the trial digit ($p = 0.5$). There were three smokers (one in the control group). Five participants were working. The use of regular oral analgesia was balanced.

There was no significant difference in the change in pain between group, from baseline to week 1 (mean reduction of 0.5 VAS units [95% CI $-1.7, 0.8$], $p = 0.9$). For the whole sample, the application of kinesiology tape reduced reported pain by 6% (mean reduction of 0.6 VAS units between weeks 1 and 2 [95% CI $0, 1.2$], $p = 0.04$), although there was no between-group difference (mean difference of 0.4 VAS units [95% CI $-1.6, 0.7$], $p = 0.4$). After the washout period, the analgesic effect of taping persisted to week 3 as there was no change in VAS pain scores compared to week 2 (95% CI $-0.3, 0.6$) or baseline (95% CI $-1.6, 0.1$), but again, there were no between-group differences ($p = 0.1$). Figure 3 summarizes pain scores over the trial period.

Quick-DASH scores were not affected by taping (Table 1). For the intervention group, there was no significant change in the Quick-DASH general scores ($p = 0.6$) or work module scores ($p = 0.4$). Similarly, for the control group, there was no significant change in quick-DASH general scores ($p = 0.1$) or work module scores ($p = 0.9$).

Taping did not affect the range of motion in any finger joint (Table 2). At baseline, taping did not change the total aROM for the sample overall (95% CI of change $-63, 19^\circ$) or per group ($p = 0.4$). No issues were reported by seven patients.

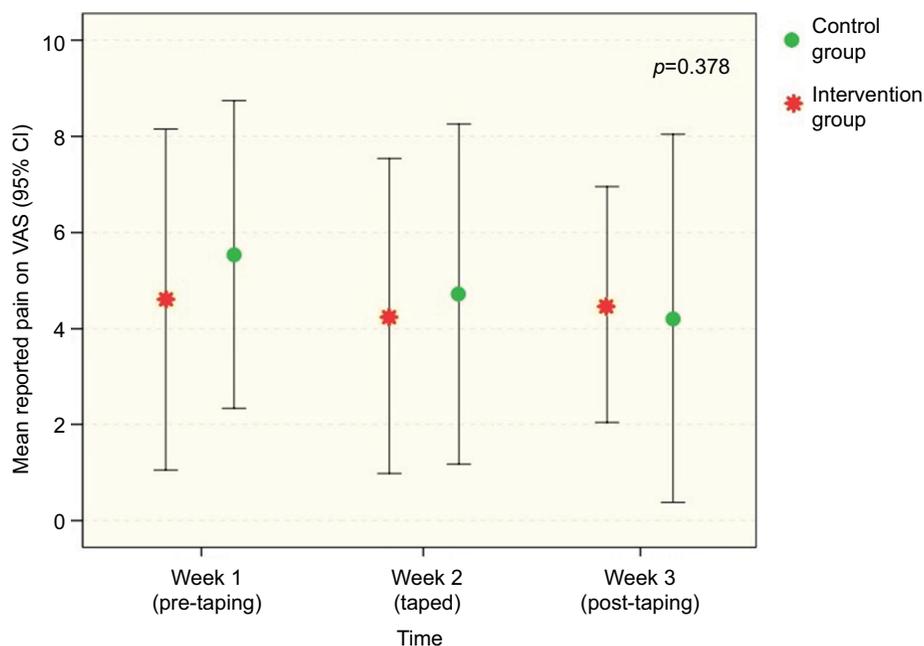


Figure 3 A plot showing mean reported pain between groups (with 95% CI). The intervention group is shown as a red star, the control group as a green dot. **Abbreviations:** CI, confidence interval; VAS, visual analog scale.

Table 1 Primary and secondary outcomes

Placebo	Time point	Group		Mean difference (95% CI)	p-value
		Placebo	Intervention		
Mean reported pain on VAS (SD)	Pre-Tape	4.6 (2.9)	5.5 (2.6)	0.9 (-2.4, 4.2)	0.6*
	Taped	4.3 (2.6)	4.7 (2.9)	0.4 (2.9, 3.8)	0.8*
	Post-Tape	4.5 (2.0)	4.2 (3.1)	-0.3, (-3.3, 2.8)	0.9*
Median Quick-DASH (IQR)	Pre-Tape	53.1 (50, 56.3)	31.3 (25, 62.5)	n/a	0.1 [‡]
	Taped	21.6 (13.6, 29.5)	50 (36.4, 54.5)	n/a	0.1 [‡]
	Post-Tape	27.3 (17, 38.6)	47.2 (36.4, 63.9)	n/a	0.3 [‡]
Median Quick-DASH work module (IQR)	Pre-Tape	53.1 (50, 56.3)	31.3 (25, 62.5)	n/a	0.8 [‡]
	Taped	50 (50, 50)	25 (18.8, 56.3)	n/a	0.8 [‡]
	Post-Tape	27.3 (17.1, 38.6)	47.2 (36.4, 63.9)	n/a	0.7 [‡]

Notes: *Derived from linear regression, with lossless nonparametric bootstrapping by resampling by replacement with 1,000 iterations. [‡]Derived from Mann-Whitney U-tests. A higher Quick-DASH score indicates greater disability.

Abbreviations: CI, confidence interval; IQR, interquartile range; n/a, not applicable; SD, standard deviation.

Table 2 Change in aROM

Group	Joint	Mean total aROM in degrees (SD) without tape applied		Absolute mean difference (95% CI)	p-value
		Baseline	End of trial		
Intervention	MCPJ	71 (12)	69 (13)	3 (-10, 15)	0.6
	PIPJ	58 (23)	57 (17)	1 (-13, 16)	0.8
	DIPJ	48 (14)	47 (9)	1 (-12, 14)	0.9
Placebo	MCPJ	68 (4)	72 (6)	-4 (-9, 1)	0.1
	PIPJ	74 (15)	77 (14)	-2 (-8, 3)	0.3
	DIPJ	62 (11)	62 (11)	0 (-7, 7)	0.9

Notes: Changes in measured aROM from baseline to the end of the trial (ie, over 3 weeks) in the intervention and control groups. Changes compared by linear regression, with lossless nonparametric bootstrapping by resampling by replacement with 1,000 iterations.

Abbreviations: aROM, active range of motion; CI, confidence interval; DIPJ, distal interphalangeal joint; MCPJ, metacarpophalangeal joint; PIPJ, proximal interphalangeal joint; SD, standard deviation.

Negative feedback was provided by three participants, and one participant dropped out, which are described below:

- Two 72-year-old participants, one male (placebo group) and one female (intervention group) stated that they “perceived no benefit”. The male reported a “flare of OA in week three”, which he attributed to the tape.
- 54-year-old female working in catering (intervention group) – “occasionally had to remove the tape as it felt uncomfortable”. This was qualified with a verbal explanation that sometimes it felt too tight, particularly when bending the finger.
- 52-year-old health care worker (randomized to the intervention group) – this participant dropped out after randomization and provided no outcome data. She was telephoned once recruitment had concluded to enquire about her experience, and she reported that once she had seen the tape applied and tried it at home; she felt that

it was incompatible with her occupation as a health care professional.

Discussion

All available treatments for OA of the hand carry risks of adverse reactions and offer modest benefits, based upon low/moderate quality evidence. Therefore, we sought to investigate a novel and low-risk simple analgesic to supplement the array of management options.

We have shown a potential analgesic effect of taping, which warrants further investigation. Our pilot trial data suggest that taping in either orientation reduces pain by ~6% (95% CI 0%, 12%). Although we found no between-group differences (ie, the primary outcome), this effect is interesting and potentially clinically important because most medical and surgical interventions aimed at relieving pain from OA of the hand offer minimal reductions in pain (if any),^{4,6,8} at the cost of potentially serious complications. More importantly, the expected reduction in pain could be as great as 12% or nil; the lower limit of this confidence suggests that taping does not make patients worse, which means that kinesiology taping could be trialed with little risk of harm. However, there was one episode of symptom flare and whether this is part of the natural history of the disease or an adverse reaction remains unclear. We observed no stiffness post-taping which is advantageous as splint-based therapies and surgery usually result in stiffness; whether there is truly no stiffness with taping or we have failed to detect it is still unclear. Furthermore, we observed a short-term persistent analgesic effect from taping which endured beyond the removal of the tape. Overall, whether any observed changes in the measured outcomes are due to a Hawthorne, placebo, or true effect cannot be ascertained from this study, and a definitive randomized trial is now warranted. This would ideally be designed as

taping versus no taping, for symptomatic OA of finger joints. Thereafter, if an analgesic effect is observed, then kinesiology tape could be compared to other patterns of taping and other therapies (eg, splints, exercises, and medication, as taping is likely to consume fewer resources) and to determine whether it can delay surgery; all such studies should be conducted as randomized trials with concurrent economic analysis.

Recruitment to clinical trials is difficult,²⁰ and randomized trials in hand surgery are still uncommon. Therefore, an important learning point from this pilot trial is how clinicians can improve recruitment. Some explanations (and remedies) about why trials fail to recruit are well summarized²¹ and may have included 1) the absence of a dedicated researcher to oversee daily activities and 2) the lack of a supporting trial unit. Our trial was designed and run by full-time clinicians, and the surgeons are notoriously poor at recruiting patients to clinical trials.²² Therefore, we recommend that future trialists seek dedicated research staff to manage the trial. Furthermore, studies supported by trial units are more successful,²³ and so aspiring researchers should seek the support of a clinical trials unit.

Limitations

At the outset, we did not know which method of taping was beneficial (if at all), and moreover, the absence of a true control (no tape) prevents exploration of the placebo effect. This is important because the placebo effect typically reduces OA pain with a pooled effect size of 0.51.²⁴ As the mechanism of action of kinesiology taping is not well understood, future researchers should randomize participants to a taping intervention compared to no intervention (ie, no taping).²⁵ Range of motion measurements are likely to be biased in favor of no difference because the therapist measuring the outcome and the participant both knew the digit was subject to experimentation, and we measured motion 1 week after removal of the tape, so any stiffness may have resolved. Whether the management of OA of the hand in secondary care is generalizable to the community is debatable. Our follow-up was very short, and hence, we are unable to comment upon adherence to treatment, likelihood of adverse reactions, or long-term effectiveness. We did not specify a minimum clinically important difference (MCID) given the absence of data on hand OA; a reduction in OA pain of 4% is detectable using patient-reported outcome measures,²⁶ however, the recent network meta-analysis by da Costa et al²⁷ concerning simple analgesia for OA pain suggested that the MCID effect size should be -0.37 (equating to a

9 mm difference on a 100 mm VAS). This is complimented by Singh's work on OA pain which established the numerical (MCID) equivalent of "much better" as -33% , while -15% means "slightly better."²⁸ Therefore, our difference of 6% (6 mm on a 100 mm VAS, equating to a Cohen's effect size of -0.22) is unlikely to reach the accepted MCID. Furthermore, future researchers should consider the need for a minimum pain for entry, for example, to detect a MCID of -9 mm on a 100 mm VAS,²⁷ the patients should have a baseline pain of at least 9 mm. We recommend that future trialists take stock of these limitations to improve their own studies.

Conclusion

We have shown that supportive tape on the dorsum of PIPJs affected by OA may reduce perceived pain. Whether this pain reduction is due to kinesiology taping or not requires further investigation.

Availability of data

All available data from this trial are presented in the article. We would welcome any third-party scrutiny, and interested parties should contact the corresponding author.

Acknowledgments

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Disclosure

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