Effectiveness of Nonsurgical Interventions for Hallux Valgus: A Systematic Review and Meta-Analysis

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Objective. To conduct a systematic review and meta-analysis investigating the effectiveness of nonsurgical interventions for hallux valgus (HV).

Methods. Medline, CINAHL, Embase, and the Cochrane Library were searched to April 2020, including parallel-group and crossover studies investigating nonsurgical interventions for HV. Two reviewers independently screened articles for inclusion, extracted data, determined risk of bias, and made assessments using the Grading of Recommendations, Assessment, Development, and Evaluation methodology. Risk of bias was assessed using version 2 of the Cochrane risk-of-bias tool. Effect sizes (mean differences or risk ratios, and 95% confidence intervals) were calculated and pooled where possible for the primary outcomes, foot pain, and HV angle.

Results. Eighteen included studies investigated a wide range of nonsurgical interventions for HV. Most studies had small sample sizes and concerns regarding risk of bias. Five separate meta-analyses for foot orthoses, splints, manual therapy, and taping added to foot exercises showed no significant effects on primary outcomes. However, results from 8 studies showed a significant pain reduction with the use of foot orthoses, night splints, dynamic splints, manual therapy, taping added to foot exercises, a multifaceted physical therapy program, and Botox injections. Four studies reported a clinically significant reduction in HV angle with night splints, foot exercises, multifaceted physical therapy, and Botox injections.

Conclusion. There is a low level of certainty surrounding the effectiveness of nonsurgical interventions for HV, but a reduction in pain appears more likely than improvement in HV angle.

INTRODUCTION

Hallux valgus (HV) is a progressive and disabling foot deformity in which the hallux deviates laterally toward the lesser toes, disrupting the alignment of the first metatarsophalangeal (MTP) joint. HV is prevalent and estimated to affect 23% of adults ages 18–65 years and 36% of adults age >65 years (1). HV is associated with both degenerative and inflammatory arthritic conditions. In older adults, a higher frequency of osteoarthritic change in the first MTP joint is associated with increasing HV severity (2). Furthermore, HV is a common finding in rheumatoid arthritis (RA), with research linking HV to painful plantar callosities in the forefront in RA (3).

As the first MTP joint becomes progressively subluxed, foot function is disturbed, leading to postural instability (4,5) and an increased risk of falls in older adults (6,7). People with HV compared to controls experience more disabling foot pain, difficulty with footwear, and concerns about appearance (8), which may lead them to seek corrective orthopedic surgery. HV correction procedures are among the top 10 most common foot and ankle procedures performed by foot and ankle surgeons in the US, causing an estimated economic burden of $325.1 million US dollars in 2011 (9).

Conservative treatment is recommended prior to surgical intervention, and a range of nonsurgical interventions is available, including change in footwear, foot orthoses, various types of toe splints, joint mobilization, taping, and stretching or strengthening exercises (10). However, the effectiveness of nonsurgical interventions for HV is uncertain. A systematic review published in 2014 (11) identified 2 randomized trials investigating foot orthoses for HV, but other conservative interventions had not been evaluated. Therefore, the aim of this study was to conduct an updated...
SIGNIFICANCE & INNOVATIONS

- This systematic review and meta-analysis provides an up-to-date synthesis of clinical trials investigating nonsurgical interventions for hallux valgus (HV).
- A wide range of nonsurgical interventions has been tested in trials for HV, with very low to moderate certainty regarding effectiveness.
- Results indicate that nonsurgical interventions are unlikely to improve HV angle.
- Nonsurgical interventions may improve pain outcomes in the short to intermediate term.

systematic review of the literature surrounding nonsurgical interventions for HV.

MATERIALS AND METHODS

Review registration and search strategy. This review was registered with PROSPERO (CRD42019111711) and followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines (12). A systematic search strategy was developed using Medline, CINAHL, Embase, and the Cochrane Library. Two strings of search terms were developed, including medical subject heading (MeSH) terms, key words, and synonyms: 1) “hallux valgus” or “bunion” and 2) “intervention” or “treatment” or “therapy” or “management” or “effects.” Truncation, proximity, and Boolean operators were used as appropriate, and limiters applied for human studies and English language (see Supplementary Appendix A, available on the Arthritis Care & Research website at http://onlinelibrary.wiley.com/doi/10.1002/acr.24603). The first search was conducted without date restriction up to January 2019. An updated search was conducted in April 2020, with date restrictions from January 2018 to April 2020. In addition to the electronic database search, reference lists of included studies and systematic literature reviews were hand-searched, and 1 expert in the field independent to the research team was consulted. Duplicates were removed using Endnote X8 (2019 search) and Covidence (2020 search).

Study inclusion. Predetermined inclusion criteria were based on the PICO framework (Population, Intervention, Comparison, Outcome), where: P = population of human participants diagnosed with HV (clinical or radiographic diagnosis); I = any nonsurgical intervention aiming to improve outcomes in HV; C = any other comparative treatment or no treatment (e.g., wait-list or placebo); O = any measure of treatment effects, including self-reported pain and function, or quantitative measures involving the foot. The following study designs were considered for inclusion, based on the Australian National Health and Medical Research Council Hierarchy of Evidence levels II to III: randomized controlled trials, pseudo-randomized controlled trials, and comparative studies with and without concurrent controls (including crossover studies) (13). Crossover trials were considered appropriate since HV is a relatively stable, chronic condition, and nonsurgical interventions are expected to have temporary effects. Exclusion criteria included populations with recent foot surgery or major trauma. Two reviewers (SEH and BGM) screened all titles and abstracts for potential relevance, warranting full-text retrieval. The same 2 reviewers performed full-text review using Covidence, and reasons for exclusion were noted. Figure 1 outlines a flow chart of study selection.

Data extraction. Data extraction was performed by 2 reviewers (SEH and BGM) independently, using a review template created in Covidence. If >1 published manuscript described the same study, these were treated as a single study for the purpose of data extraction. Details about experimental and comparison interventions or placebo were extracted using the Template for Intervention Description and Replication framework (14). For the purpose of combining similar interventions, the following broad definitions were used: foot orthoses (shoe inserts designed to provide arch support), night splints (any corrective device for hallux alignment worn at rest), dynamic splints (any corrective device for hallux alignment worn during activities of daily living), manual therapy (any type of foot mobilization or manipulation), and foot exercises (strengthening exercises targeting the intrinsic foot muscles). Primary outcome measures for this review were HV angle and self-reported pain. If >1 measure of pain was used, visual analog scales (VAS) or numeric rating scales (NRS) were chosen over other pain questionnaires, resting pain was chosen before walking pain, and average pain was chosen over maximum pain. Means ± SDs and sample size for experimental and control groups were extracted for all outcome measures at baseline and the following periods of follow-up: short-term (≤3 months); intermediate (>3 months and <12 months); and long-term (≥12 months). If 2 follow-up assessments were completed within 1 of the defined time points, the longer follow-up period was selected.

Risk-of-bias assessment. Assessment of risk of bias was performed independently by 2 reviewers (SEH and BGM) using version 2 of the Cochrane risk-of-bias tool for randomized trials (RoB 2) (15). The RoB 2 assesses the risk of bias across 5 domains, and calls for an assessor judgment on the level of bias within each domain and for the outcome estimate overall (low risk = low risk of bias for all domains; some concerns = some concerns for at least 1 domain, and not high risk for any domain; high risk = high risk of bias in at least 1 domain). For crossover study designs, signaling questions from the archived version of RoB 2 for crossover trials were used to inform judgments for the second (deviations from intended interventions) and third (missing outcome data) domains. Reviewers used the Microsoft Excel tool to implement RoB 2 (available at www.riskofbias.info) (15).
If consensus could not be reached, other authors (SEM and HBM) were consulted to achieve consensus.

**Data synthesis and analysis.** In studies where bilateral measures were taken (e.g., HV angle) and extracted means ± SDs represented feet rather than participants, the bilateral measures were treated as clustered data and the following additional information was collated: the number of clusters (participants), the average size of each cluster (e.g., 2 feet), and a conservative estimate of the intracluster correlation coefficient was predetermined to be 0.05. The following formula was then applied to determine the effective sample size: \(1 + (M-1) \times ICC\), where \(M\) is the average cluster size and ICC is the intracluster correlation coefficient \((16)\). For crossover study designs, within-person differences were extracted if possible (mean ± SD) for paired analysis \((17)\).

All extracted data were imported from Covidence into Review Manager 5.3 for analysis \((18)\). For continuous outcomes, mean differences and 95% confidence intervals (95% CIs) were calculated using an inverse variance method and random-effects model. We expected that most studies would report pain on a 100-point scale with a direction of lower = better. Where pain outcomes were reported on a 10-point scale, data were multiplied by 10 to convert to a 100-point scale. Where the direction of a pain scale was higher = better, data were converted to negative values so that the direction of mean differences would align across studies. Categorical variables were converted into dichotomous data based on a consensus approach, and risk ratios and 95% CIs

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**Figure 1.** Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow chart of study selection.
| Author, year (ref.) | Study design | Follow-up | Sample size (no.) | Age, years | Sex (M:F) | Experimental group | Comparison groups | Primary outcomes | Secondary outcomes |
|---------------------|--------------|-----------|-------------------|------------|-----------|-------------------|-------------------|----------------|-------------------|
| Orthoses            |              |           |                   |            |           |                   |                   |                |                   |
| Kilmartin et al, 1994 (35) | RCT†         | 3 years   | 122 (139 feet)    | 9–10       | 16:106    | Foot orthoses     | Control (no treatment) | HV angle‡     | IM angle          |
| Reina et al, 2013 (39)  | RCT§         | 12 months | 54 (83 feet)      | 30.6 ± 11.9 | 0.54      | Foot orthoses     | Control (no treatment) | HV angle‡ | IM angle          |
| Torkki et al, 2001/2003 (41,42) | RCT          | 2 years   | 209               | 48 ± 9.7   | 16:193    | Foot orthoses     | Control (waiting list), surgery | Pain VAS | Satisfaction, ability to work, AOFAS, cosmetic disturbance, footwear problems, QoL, global foot assessment |
| Splints             |              |           |                   |            |           |                   |                   |                |                   |
| Chadchavalpanichaya and Chueluecha, 2011 (31) | RCT          | 12 months | 47                | 44.1 ± 15.3 | 3:44      | Night splint      | Control (general foot care, shoes) | HV angle‡     | Satisfaction NRS |
| Chadchavalpanichaya et al, 2018 (32) | RCT          | 12 months | 90                | 60.6 ± 6.6 | 5:85      | Night splint (toe separator) | Control (general foot care, shoes) | HV angle, pain NRS† | Satisfaction NRS |
| Mirzshahi et al, 2012 (36) | RCT         | 12 months | 30                | 8–60       | NR        | Dynamic splint (slipper) | Night splint | HV angle‡ | IM angle, comfort |
| Moulodi et al, 2019 (37) | Cross-over  | 1 month   | 24                | 22.8 ± 1.4 | 12:12     | Dynamic splint    | Night splint | HV angle, pain (FAOS)#| First MTP joint range, FAOS subscales (symptoms, ADL, sport, QoL), IM angle, pain (rest, start-up, walking, running), ADL reduction, AOFAS, first MTP joint range, FAOS subscales (symptoms, ADL, sport, QoL), SF-36 |
| Plaass et al, 2020 (38) | RCT          | 2–10 months | 70              | 50.9 ± 13.6 | 4.66      | Night splint      | Control (no treatment) | HV angle, pain (FAOS)# | IM angle, pain (FAOS)# |
| Tehraninasr et al, 2008 (40) | RCT†         | 3 months  | 30 (60 feet)      | 27 ± 8.9   | 0:30      | Dynamic splint (insole) | Night splint | HV angle, pain VAS† | IM angle |
| Physical therapies  |              |           |                   |            |           |                   |                   |                |                   |
| Abdalbary, 2018 (27) | RCT          | 12 months | 56                | 45.6 ± 6.5 | 0.56      | Manual therapy, exercises, toe separator, footwear advice | Control (footwear advice) | HV angle, pain VAS† | AOFAS scale, IM angle, ankle dorsiflexion, hallux plantarflexion, abduction, and toe grip strength |
| Bayar et al, 2011 (28) | RCT†         | 8 weeks   | 20 (40 feet)      | NR         | 0.20      | Taping and foot exercises | Foot exercises | HV angle, pain VAS# | Walking pain, walking ability scale |
| Brantingham et al, 2005 (29) | RCT          | 3 weeks   | 60                | 50.2       | 0.60      | Manual therapy     | Sham APT (placebo) | Pain NRS | Satisfaction, FFI, AOFAS, pressure pain threshold |
| Broodryk, 2000 (30)  | RCT          | 3 weeks   | 60                | 40.8 (15–65) | 10:50  | Manual therapy     | Sham laser (placebo)  | Pain NRS | Pressure-pain threshold, FFI |

(Continued)
| Author, year (ref.) | Study design | Follow-up | Sample size (no.) | Age, years | Sex (M:F) | Experimental group | Comparison groups | Primary outcomes | Secondary outcomes |
|---------------------|--------------|-----------|------------------|-----------|-----------|---------------------|------------------|------------------|------------------|
| Choi, 2017 (33)     | RCT          | 6 weeks   | 24               | 20–29     | 0:24      | Foot exercises      | Taping; exercises and taping | HV angle‡        | Postural sway and limits of stability test |
| Du Plessis et al, 2011 (34) | RCT         | 6 weeks   | 30               | 42 (25–65)| 15:15     | Manual therapy      | Night splint      | Pain VAS         | FFI, first MTP joint range |
| Kim et al, 2015 (36) | RCT          | 8 weeks   | 24               | 22.5 ± 2.4| 13:11     | Foot exercises and dynamic splint | Dynamic splint | HV angle‡        | Abductor hallucis CSA, active abduction HV angle |
| Khan, 1996 (25¶)    | RCT§         | 8 weeks   | 60 (80 feet)     | NR        | NR        | Tagetes patula paste (marigold therapy) with felt pad | Placebo paste with felt pad | HV angle, pain VAS** | Width, satisfaction |
| Wu et al, 2015 (43) | RCT†         | 2 months  | 16 (26 feet)     | 42.9 ± 12 | 1:15      | Intramuscular botulinum toxin type A injection | Placebo intramuscular saline injection | HV angle, pain (FFI)# | FFI disability subscale |

* ADL = activities of daily living; AOFAS = hallux-metatarsophalangeal scale of the American Orthopaedic Foot and Ankle Society; APT = action potential therapy; CSA = cross-sectional area; F = female; FAOS = Foot and Ankle Outcomes Scale; FFI = Foot Function Index; HV = hallux valgus; IM = intermetatarsal; M = male; MTP = metatarsophalangeal; NR = not reported; NRS = numeric rating scale; QoL = quality of life; RCT = randomized controlled trial; SF-36 = Short Form 36 health survey; VAS = visual analog scale.
† Cluster randomized controlled trial (unit of analysis feet rather than participants).
‡ Measured on radiograph.
§ Cluster randomized controlled trial (unit of analysis feet rather than participants). Not all participants were randomly allocated to groups.
¶ Insufficient data for quantitative analysis.
# Measured using goniometer.
** Measured on radiograph or photograph.
were calculated using an inverse variance method and random-effects model. Meta-analysis was performed where possible, whenever studies had a similar type of intervention and comparator, and had reported 1 of the same primary outcomes (HV angle or pain). Subgroup analysis by study population (adult versus juvenile HV) was considered if possible, based on the included studies.

Certainty of the evidence was assessed using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach (19). Two authors (SEH and BGM) independently conducted the GRADE assessments using the online GRADEpro tool (available at www.gradepro.org) (19), and other authors (SEM and HBM) were contacted if required to achieve consensus. GRADE considerations included risk of bias, inconsistency, imprecision, indirectness, and publication bias. When considering imprecision of effect size estimates and CIs, a clinically important effect for HV angle was considered to be a mean difference of ≥2.5 degrees based on published minimum detectable change values (20), and a clinically important effect for pain was considered to be a mean difference of ≥10 points.

Figure 2. Summary of risk-of-bias assessment (using version 2 of the Cochrane risk-of-bias tool for randomized trials). FAOS = Foot and Ankle Outcomes Scale; FFI = Foot Function Index; HV = hallux valgus; NRS = numeric rating scale; VAS = visual analog scale.
Table 2. Summary of findings with GRADE certainty of the evidence*

| Outcomes                                                                 | Mean difference (95% confidence interval) between groups at follow-up                                                                 | Total participants/studies (refs.) | GRADE certainty of the evidence |
|--------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|---------------------------------|
| Orthoses compared to control                                             | No statistically significant difference; the mean HV angle in the orthoses group was on average 1.87 degrees higher (−0.32, 4.06) compared to control at follow-up | 214/2 (35,39)                     | ▲▲▲▲ low†                      |
| HV angle assessed with radiograph (degrees); follow-up long-term         | No statistically significant difference; the mean HV angle in the orthoses group was on average 0.3 degrees (−3.4, 2.8) lower     | 207/3 (31,32,38)                  | ▲▲▲ lower§                     |
| Pain assessed with VAS (0–100 scale); follow-up intermediate and long-term | At intermediate follow-up, mean pain score was 10 points higher (2.2, 17.8) in the orthoses group compared to surgery; at long-term follow-up, mean pain score was 17 points higher (9.4, 24.6) in the orthoses group compared to surgery | 140/1 (41)                        | ▲▲▲▲ moderate‡                  |
| Night splints compared to control                                         | No statistically significant difference; the mean HV angle in the night splints group was on average 0.6 degrees lower (−6.0, 9.2) in the night splints group compared to control | 160/2 (32,38)                     | ▲▲▲▲ low†                      |
| Night splints compared to control                                         | No statistically significant difference; the mean HV angle in the night splints group was on average 0.6 degrees lower (−6.0, 9.2) in the night splints group compared to control | 160/2 (32,38)                     | ▲▲▲▲ low†                      |
| Pain assessed with NRS or FAOS (0–100 scale); follow-up short- and long-term | No statistically significant difference; the mean pain score in the night splints group was on average 7.2 points lower (−16.3, 1.9) compared to control | 160/2 (32,38)                     | ▲▲▲▲ low†                      |
| Dynamic splints compared to night splints                                 | No statistically significant difference; the mean HV angle was 0.3 to 1.2 degrees higher in the dynamic splints group compared to night splints | 106/2 (37,40)                     | ▲▲▲▲ low†                      |
| HV angle assessed with radiograph or goniometer (degrees); follow-up short-term | Inconsistent study results; 1 study reported pain scores 13.4 points lower (−22.3, −4.5), and another study reported pain scores 1.6 points higher in the dynamic splints group (−6.0, 9.2) | 78/2 (37,40)                      | ▲▲▲▲ very low§                 |
| Pain assessed with VAS or FAOS (0–100 scale); follow-up short-term        | No statistically significant difference; the mean pain score in the manual therapy group was on average 13.5 points lower (−51.7, 24.8) compared to placebo | 120/2 (29,30)                     | ▲▲▲▲ very low**                 |
| Manual therapy compared to placebo                                        | The mean pain score in the manual therapy group was 18.3 points lower (−26.0, −10.8) compared to night splints                          | 30/1 (34)                         | ▲▲▲▲ very low†                  |
| Pain assessed with VAS (0–100 scale); follow-up short-term                | The mean HV angle was 3.8 degrees lower (−6.6, −1.0) in the exercise group compared to control                                    | 24/1 (36)                         | ▲▲▲▲ very low†                  |
| Foot exercises and dynamic splints compared to dynamic splints            | The mean HV angle was 8.1 degrees lower (−9.8, 6.5) compared to control at short-term follow-up and 7.1 degrees lower (−8.5, −5.7) compared to control at long-term follow-up | 56/1 (27)                         | ▲▲▲▲ low†                      |
| HV angle assessed with radiographs; follow-up short- and long-term        | The mean pain score was 30 points lower (−36.1, 23.9) compared to control at short-term follow-up and 35 points lower (−41.1, −28.9) compared to control at long-term follow-up | 56/1 (27)                         | ▲▲▲▲ low†                      |
| Taping and foot exercises compared to foot exercises alone                | The mean HV angle was 8.1 degrees lower (−9.8, 6.5) compared to control at short-term follow-up and 7.1 degrees lower (−8.5, −5.7) compared to control at long-term follow-up | 56/1 (27)                         | ▲▲▲▲ low†                      |
| Pain assessed with VAS (0–100 scale); follow-up short- and long-term      | The mean pain score was 30 points lower (−36.1, 23.9) compared to control at short-term follow-up and 35 points lower (−41.1, −28.9) compared to control at long-term follow-up | 56/1 (27)                         | ▲▲▲▲ low†                      |

(Continued)
When considering inconsistency of effects, forest plots were visually inspected and heterogeneity was assessed using the I² statistic. Considerable heterogeneity was considered to be indicated by an I² value >75% (24). Publication bias was assessed via visual inspection of funnel plots, with SE plotted against effect sizes for primary outcomes. For each intervention category, conference abstracts and trial registrations were reviewed and compared to published trials.

**RESULTS**

**Search.** The database search yielded a total of 7,781 records, and after removal of 3,246 duplicates, 4,535 records remained. Reference list searches revealed another 14 potentially relevant records, and expert consultation also noted 1 of these studies. Thus, a total of 4,549 records were screened. After title and abstract screening, 4,450 studies were determined to be ineligible, and 3 articles could not be sourced via library services or direct contact with authors. Full text was reviewed against inclusion criteria for 96 studies, and exclusion reasons noted (Figure 1). Twenty articles (18 unique studies) met eligibility criteria. Two studies did not report sufficient data for quantitative analysis, and the required data could not be sourced after contacting the authors (25,26). Therefore, 16 unique studies were included in the meta-analysis and risk-of-bias assessment (27–43).

**Included studies.** Table 1 summarizes selected characteristics of 18 included studies. Studies were conducted in 11 countries, including Egypt, Finland, Germany, Iran, the Republic of Korea, South Africa, Spain, Taiwan, Thailand, Turkey, and the UK. Seventeen studies used parallel-group experimental designs, and 1 crossover study was included (37). A total of 1,026 participants were included (95 men and 841 women, based on 16 studies reporting sex). Sample sizes ranged from 16 to 209 participants, with only 4 studies having a sample size larger than 60 participants (32,35,38,41). Seven studies recruited patients with HV from outpatient clinics (26,27,31,32,34,38,41), 6 studies used convenience sampling (29,30,33,35,37,40), 1 study reported a combination (39), and 4 studies did not report their recruitment methods (25,28,36,43). Fourteen studies confirmed a diagnosis of HV using radiographs (26,27,29,31–36,38–41,43). Chronic conditions (such as RA) were not considered to be an exclusion criterion, but no eligible studies were found that focused on these populations. Follow-up periods ranged from 3 weeks to 3 years. Three included studies investigated the effects of foot orthoses compared to no treatment (35,39,41), and 1 of these studies included a third study group that underwent surgery (41). Six studies investigated the effectiveness of other devices, including various designs of dynamic splints (26,37,40) and night splints (31,32,38). Seven studies investigated physical therapies, including manual therapy (29,30,34), foot exercises (33,36), taping (33), or a combination (27,28,33). One study investigated intramuscular botulinum toxin type A (Botox) injections (43), and another study reported the effects of marigold therapy (Tagetes patula paste with a felt pad) (25).

In addition to the primary outcomes (HV angle or pain), other physical outcome measures included intermetatarsal angle, abductor hallucis cross-sectional area, first MTP joint range of motion, pressure-pain threshold, postural sway, toe grip strength, and hallux plantarflexion or abduction strength. A wide range of self-reported outcome scales was used, including VAS and NRS, the Foot Function Index, the hallux-metatarsophalangeal scale of the American Orthopaedic Foot and Ankle Society, and the Quality of Life Scale. Two categorical variables reported by 1 study (41) were converted into dichotomous data for extraction and analysis (footwear problems: none = no, and moderate/severe = yes; global foot assessment: better = yes, and as good as/worse = no).

**Risk of bias.** Results of the risk-of-bias assessment are outlined in Figure 2. The most common domains raising serious
concerns were deviations from intended intervention, where 5 studies (31%) (28–30,33,40) did not report adherence, and missing outcome data, where 5 studies (31%) (28–30,33,40) did not report how many participants were included in the final analysis and/or there was unclear reporting of study dropouts. Only 3 studies (19%) had a registered clinical trial protocol (32,38,43).

No studies had a prespecified statistical analysis plan with sufficient detail, and thus all studies were judged as having at least “some concerns” in the fifth domain of “selection of the reported result.”

Visual inspection of funnel plots by intervention category revealed asymmetry in the funnel plot for physical therapies, indicating bias toward publication of studies showing a positive effect of the experimental intervention. Therefore publication bias was strongly suspected and was considered a factor in the GRADE assessment.

**Effectiveness of nonsurgical interventions.** Table 2 shows a summary of findings and GRADE certainty of the evidence across 10 comparisons for the primary outcomes. Forest plots in Figures 3 and 4 display individual study results (mean differences and 95% CIs) at different follow-up points for HV angle (Figure 3) and pain (Figure 4). For both primary outcomes, lower values indicate improvement, and therefore negative effect sizes demonstrate an effect in favor of the experimental intervention compared to the control group or comparison intervention. The crossover trial (37) did not provide sufficient statistical information for a paired analysis, thus the post-intervention mean was taken from each period and analyzed in a similar manner to parallel-group trials. This approach was considered preferable to excluding the trial, but it was not considered appropriate for inclusion in meta-analysis (16). Meta-analyses were performed for foot orthoses versus control (HV angle) (35,39), night splints versus control (HV angle and pain) (31,32,38), manual therapy versus placebo (pain) (29,30), and taping and foot exercises versus foot exercises (HV angle) (28,33). None of these meta-analyses showed significant differences between groups following intervention. However, significantly reduced HV angles were reported by 4 of 12 studies.
that measured this outcome (27,32,36,43), and significantly reduced pain scores were reported by 8 of 11 studies that measured this outcome (27–29,34,38,41,43). Significant effects in favor of the experimental intervention were found across studies involving convenience samples (29,40), those recruited from outpatient clinics (27,32,34,38,41), samples of young adults (36,40), older adults (32), and mixed ages (27,29,34,38,41,43) (Table 1). A subgroup analysis of treatment effects according to age of study population could not be performed due to the lack of studies in juvenile populations.

Studies reported a wide range of secondary outcome measures (see Supplementary Table 1, available on the Arthritis Care & Research website at http://onlinelibrary.wiley.com/doi/10.1002/acr.24603). Self-reported function and satisfaction outcomes showed similar trends to self-reported pain outcomes. However, Torkki et al (41,42) reported a unique self-report variable, “footwear problems,” reporting that those in the foot orthoses group experienced more footwear problems compared to the surgery group. One study reported that manual therapy increased first MTP joint range of motion compared to night splints (34). Foot exercises were shown to increase the cross-sectional area of the abductor hallucis muscle (36). Participants undertaking a multifaceted physical therapy program compared to controls showed improvements in toe grip, hallux plantarflexion, and hallux abduction strength (27).

DISCUSSION

This systematic review and meta-analysis aimed to synthesize the current state of the evidence for effectiveness of nonsurgical treatments for HV. Overall, results indicate a low level of certainty surrounding the effectiveness of nonsurgical interventions for HV, but reduction in pain appears more likely than improvement in HV angle. This synthesis will aid clinicians in evidence-based decision-making, given the vast range of nonsurgical treatments available for HV.

Meta-analyses showed that foot orthoses do not improve HV angle, and splints do not improve either HV angle or pain. Other
meta-analyses showed no significant short-term pain reduction with manual therapy, and no significant improvement in HV angle when taping was added to foot exercises. However, results from 8 studies showed significant pain reduction with foot orthoses (41), night splints (38), dynamic splints (40), manual therapy (29,34), taping added to foot exercises (28), multifaceted physical therapy (27), and Botox injections (43). Differences between groups at follow-up were clinically significant in each of these studies, with the exception of foot orthoses (41). A clinically significant reduction in HV angle was reported by 4 studies using night splints (32), foot exercises (36), multifaceted physical therapy (27), and Botox injections (43).

Conflicting results may be explained by the diversity of nonsurgical interventions employed, for example different types of splints, manual therapy techniques, or foot exercises. Study samples differed in terms of recruitment method, and a sample of patients seeking treatment for symptomatic moderate-to-severe HV may respond differently compared to a convenience sample of young adults or those with mild HV. Results should be interpreted in light of study characteristics outlined in Table 1.

This analysis builds on a previous systematic review of 2 randomized trials published in 2014 (11) by employing broader inclusion criteria and including 7 new studies published since 2014. This synthesis will inform patient-centered management for HV, including setting expectations for outcomes that are likely to be modifiable. While HV angle may not change significantly, pain is a potentially modifiable outcome, with other outcomes such as range of motion and muscle strength also potential indicators of improvement. Multifaceted interventions should be considered, incorporating a combination of footwear advice, foot orthoses, manual therapy, exercises, or Botox injections, depending upon examiner experience and patient preference, which are important pillars of evidence-based medicine, along with the best available evidence from the literature (44).

Limitations of this review should be considered when interpreting the findings. First, the search was limited to studies published in English, and despite this search filter, a small number of studies were found published in other languages and thus were excluded (45–48). Systematic bias is unlikely to be introduced by English-language restriction, but inclusion of more studies may have improved precision (49). The issue of publication bias must also be considered, as this bias was strongly suspected in the physical therapies. This review did include gray literature wherever possible, with 1 included thesis (30), but 2 other theses were unable to be sourced (50,51). Finally, there was a substantial amount of statistical heterogeneity across studies combined in the meta-analyses.

Acknowledging the overall low quality of the studies included in this review is important, as the low quality reduces the confidence in the reported effects. Many studies had significant risk of bias due to not reporting adherence, study dropouts, or missing data. There was poor reporting of group randomization and sample characteristics, and the high proportion of female participants may suggest recruitment bias. While participant blinding was not always possible, blinding of examiners was often unclear or not performed. Sample sizes were small, leading to imprecision of effect-size estimates and the potential for type 2 error. Over half of the studies (10 of 16) used follow-up periods of 3 months or less, and thus long-term effects were only reported for some interventions. Finally, investigation of potential harms or adverse outcomes were not reported, and thus could not be evaluated.

After reviewing the current state of the evidence, some recommendations for future research are presented below. First, several studies were limited by only measuring HV angle and not reporting on symptoms or self-reported function. Second, longer follow-up periods would be advisable, as only 6 studies followed participants for ≥12 months. Third, examining how different populations respond to interventions would be worthwhile. Only 1 study has been conducted in a juvenile HV population (35), another 3 studies included young adults (33,36,37), and some studies included both juvenile and adult patients (26,30). HV severity worsens with increasing age (1), and some interventions may be more effective in the early stages of deformity (10). Future trials should clearly report age and severity of HV of their participants. Finally, future trials should document adherence and adverse events to provide insights into the practicality, acceptability, and safety of these interventions.

In conclusion, this review provides guidance to clinicians regarding nonsurgical options for treatment of HV and provides recommendations for planning future clinical trials in this area. There is a very low to low level of certainty around most effect estimates presented, but there is moderate certainty that foot orthoses may reduce pain in the intermediate term, and moderate certainty that pain and HV angle may improve with Botox injections. Further high-quality randomized trials with adequate sample sizes and robust methodology are needed to investigate nonsurgical treatments for HV given the high cost of surgery to the health care system (9) and the potential benefits of early intervention (36).

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AUTHOR CONTRIBUTIONS

All authors were involved in drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be submitted for publication. Dr. Menz had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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