RESEARCH PAPER

BIOMECHANICAL AND RADIOLOGICAL EVALUATION OF A NOVEL DUAL-FULCRUM DYNAMIC SPLINT WITH MEDIAL ARCH RAISE FOR EARLY HALLUX VALGUS CORRECTION: A PROSPECTIVE CLINICAL STUDY

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Received: 24th April, 2026; Revised: 20th May 2026; Accepted: 30th June, 2026; Available Online: 10th July, 2026

ABSTRACT

Background: Hallux valgus is a common progressive forefoot deformity characterized by lateral deviation of the great toe, first-ray instability, and altered foot biomechanics, leading to pain, impaired gait, and reduced quality of life. Conventional conservative treatments primarily relieve symptoms but have limited ability to achieve sustained radiological correction. This study evaluated the biomechanical and radiological effectiveness of a novel Dual-Fulcrum Dynamic Splint with Medial Arch Raise for early hallux valgus correction.

Methods: A prospective single-arm interventional study was conducted among 33 patients aged 18–65 years with early symptomatic hallux valgus. Participants were treated with the custom-designed dual-fulcrum dynamic splint for six months. Clinical and radiological assessments were performed at baseline, 6 weeks, 3 months, and 6 months. Primary outcome measures included Hallux Valgus Angle (HVA), Intermetatarsal Angle (IMA), sesamoid position, and medial longitudinal arch parameters.

Results: Progressive improvement was observed in radiographic alignment, sesamoid position, pain scores, and functional outcomes throughout follow-up. Patients with mild deformity demonstrated greater correction than those with moderate deformity, while treatment outcomes were comparable between sexes.

Conclusion: The novel Dual-Fulcrum Dynamic Splint with Medial Arch Raise demonstrated promising biomechanical and radiological benefits in patients with early hallux valgus. It represents a safe, non-invasive conservative treatment that may delay deformity progression, improve foot function, and reduce the need for surgical intervention.

Keywords: Hallux valgus; Dual-fulcrum dynamic splint; Medial arch raise; Conservative management; Foot biomechanics; Hallux Valgus Angle (HVA); Intermetatarsal Angle (IMA); Radiological evaluation; First-ray instability; Orthotic therapy.

How to cite this article: Kruthikaa Rajindran, Talal Hasan Jumirul Hussain, Nitesh Kumar Rathi, BIOMECHANICAL AND RADIOLOGICAL EVALUATION OF A NOVEL DUAL-FULCRUM DYNAMIC SPLINT WITH MEDIAL ARCH RAISE FOR EARLY HALLUX VALGUS CORRECTION: A PROSPECTIVE CLINICAL STUDY, Int J Drug Deliv Technol. 2026;16(72s): 1335-1354. DOI: 10.25258/ijddt.16.72s.145

Source of support: Nil.
Conflict of interest: None

INTRODUCTION

Hallux valgus (HV) is one of the most common progressive forefoot deformities encountered in orthopaedic and foot and ankle practice. It is characterized by lateral deviation of the great toe associated with medial deviation of the first metatarsal, resulting in a painful prominence over the first metatarsophalangeal (MTP) joint, commonly known as a bunion. Although traditionally regarded as a cosmetic deformity, hallux valgus is now recognized as a complex three-dimensional biomechanical disorder involving osseous malalignment, first-ray instability, soft-tissue imbalance, sesamoid displacement, and progressive collapse of the medial longitudinal arch. These structural alterations ultimately impair gait, reduce walking endurance, compromise footwear comfort, and significantly diminish quality of life.(1,2)

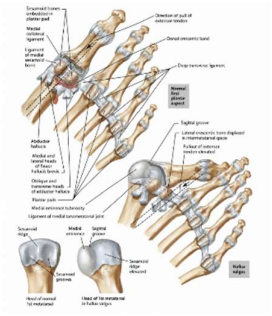

Figure: Plantar Aspect Anatomy of the First MTP Joint in Hallux Valgus – showing sesamoid bones, medial collateral ligament, distorted ligament of medial sesamoid, abductor hallucis, medial & lateral heads of flexor hallucis brevis, oblique & transverse heads of adductor hallucis, and plantar pad

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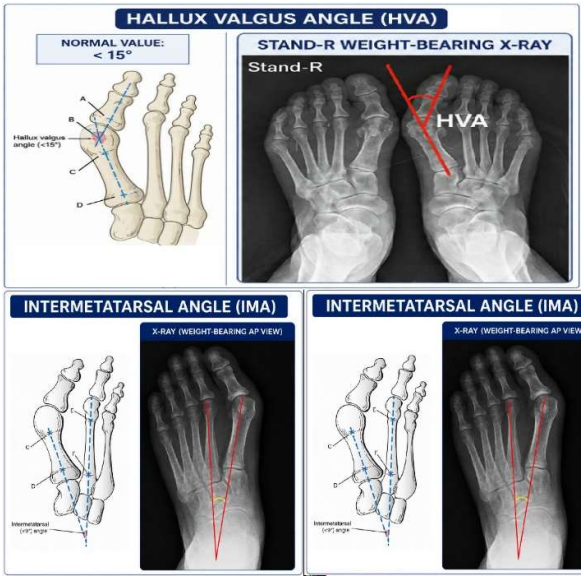
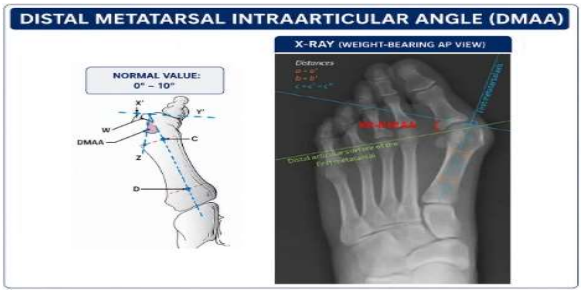
The prevalence of hallux valgus ranges from 23% to 35% in the adult population and exceeds 35% among elderly individuals, with women being affected nearly three times more frequently than men. Multiple intrinsic and extrinsic factors contribute to the development of the deformity, including hereditary predisposition, generalized ligamentous laxity, first tarsometatarsal joint hypermobility, abnormal foot biomechanics, pes planus, and prolonged use of narrow toe-box or high-heeled footwear.(3,4)

The patho-mechanics of hallux valgus involve gradual medial deviation, pronation of the first metatarsal accompanied by lateral deviation and pronation of the hallux. Progressive attenuation of the medial capsule and tightening of the lateral capsuloligamentous structures alter the balance between the abductor hallucis and adductor hallucis muscles, creating a persistent valgus deforming force across the first MTP joint.(5) Lateral migration of the sesamoid complex beneath the metatarsal head alters the mechanical axis of the flexor hallucis brevis tendon, reducing its stabilizing function. First-ray hypermobility and medial column instability further increase forefoot loading, thereby accelerating deformity progression.(6)

Radiographic assessment remains the gold standard for objective evaluation of hallux valgus severity and treatment outcomes. Weight-bearing anteroposterior radiographs allow accurate measurement of the Hallux Valgus Angle (HVA), Intermetatarsal Angle (IMA), Distal Metatarsal Articular Angle (DMAA), and sesamoid position.(7) Hallux Valgus Angle is the principal indicator of deformity severity, while the Intermetatarsal Angle reflects medial displacement of the first metatarsal. Progressive lateral displacement of the sesamoids signifies increasing instability of the first ray and correlates closely with recurrence after treatment.(8)





Increasing evidence also suggests that collapse of the medial longitudinal arch plays a significant biomechanical role in the progression of hallux valgus. The medial arch acts as the primary stabilizer of the first ray during the stance and push-off phases of gait. Reduction in arch height permits excessive pronation of the first metatarsal, increases first tarsometatarsal joint mobility, alters plantar pressure distribution, and amplifies valgus loading across the first metatarsophalangeal joint.(9) Consequently, radiological parameters describing the medial longitudinal arch, including calcaneal pitch, navicular height, talo-first metatarsal angle (Meary's angle), and arch height index, have gained increasing importance in evaluating the biomechanical environment associated with hallux valgus progression and correction.(10)

Conservative management remains the preferred treatment for patients with mild and early-stage hallux valgus. Common modalities include footwear modification, toe separators, orthotic insoles, static night splints, physiotherapy, taping techniques, and exercise programs designed to strengthen intrinsic foot muscles.(11) Although these interventions effectively reduce pain and improve functional outcomes, most fail to produce sustained radiological correction because they primarily address symptoms rather than the underlying biomechanical abnormalities. Static splints apply passive corrective forces only during non-weight-bearing periods, while conventional dynamic splints generally generate a single corrective force at the first metatarsophalangeal joint without stabilizing the medial column or restoring the medial longitudinal arch.(12)

Recent biomechanical research has highlighted the importance of multi-point corrective systems capable of simultaneously controlling first-ray instability and hallux alignment. Dual-fulcrum orthotic concepts are based on the principle of applying corrective forces at two biomechanical levels rather than a single point, thereby improving force distribution while reducing localized pressure and patient discomfort.(13) Incorporating medial arch support into such devices provides additional stabilization of the first tarsometatarsal joint, reduces pronatory forces acting on the first ray, and may facilitate gradual restoration of normal forefoot alignment during weight-bearing activities. Continuous low-load dynamic correction also promotes viscoelastic remodeling of periarticular soft tissues, potentially leading to sustained anatomical improvement over time.(14)

Despite these promising biomechanical concepts, robust prospective clinical evidence evaluating radiological correction achieved by dual-fulcrum dynamic splints remains scarce. Most published studies have focused primarily on pain relief, patient satisfaction, or functional improvement, while few have comprehensively assessed sequential changes in radiographic parameters such as Hallux Valgus Angle, Intermetatarsal Angle, sesamoid position, and medial longitudinal arch characteristics

throughout treatment.(15) Furthermore, the relationship between restoration of the medial longitudinal arch and correction of hallux valgus deformity has not been adequately investigated using serial weight-bearing radiographs.

The present prospective clinical study therefore aims to perform a comprehensive biomechanical and radiological evaluation of a novel Dual-Fulcrum Dynamic Splint with Medial Arch Raise designed specifically for early hallux valgus correction. Unlike conventional orthotic devices, the proposed splint combines dynamic hallux realignment with simultaneous medial arch elevation to stabilize the first ray and optimize load distribution during gait. The primary outcome measures include serial assessment of Hallux Valgus Angle, Intermetatarsal Angle, sesamoid position, and medial longitudinal arch parameters using standardized weight-bearing radiographs at predetermined follow-up intervals. By evaluating radiological correction over time, this study seeks to determine whether simultaneous correction of hallux alignment and medial arch biomechanics provides superior structural improvement compared with conventional conservative treatment approaches. The findings are expected to strengthen the evidence supporting biomechanically integrated orthotic interventions and may establish this novel dual-fulcrum dynamic splint as an effective non-operative strategy for the early management of hallux valgus deformity.(16–18)

Aim

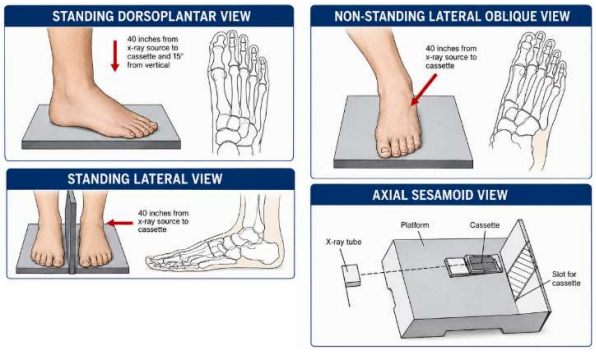
To evaluate the biomechanical and radiological effectiveness of a novel Dual-Fulcrum Dynamic Splint with Medial Arch Raise for early hallux valgus correction by assessing changes in Hallux Valgus Angle, Intermetatarsal Angle, Distal Metatarsal articular angle, sesamoid position, medial longitudinal arch parameters and functional outcomes over a six-month follow-up period.

Objectives

To assess radiological changes in Hallux Valgus Angle, Intermetatarsal Angle, Distal Metatarsal Articular Angle, sesamoid position, and medial longitudinal arch parameters, and to evaluate functional outcomes over the follow-up period.

Materials and Methods

This prospective single-arm interventional clinical study was conducted in the Department of Orthopaedics, Saveetha Medical College and Hospital, Chennai, over a period of 12 months. Thirty-three patients with early symptomatic hallux valgus (Hallux Valgus Angle 15°–40°), aged 18–65 years, meeting the inclusion criteria were enrolled using purposive sampling. Each participant was fitted with a custom-designed Dual-Fulcrum Dynamic Splint with Medial Arch Raise and followed for six months. Clinical and radiological assessments were performed at baseline, 6 weeks, 3 months, and 6 months. Primary radiological outcome measures included the Hallux Valgus Angle (HVA), Intermetatarsal Angle (IMA), sesamoid position (Hardy–Clapham grading), and medial longitudinal arch parameters obtained from standardised weight-bearing foot radiographs. Statistical analysis was performed using SPSS version 26.0, with $p < 0.05$ considered statistically significant.



Inclusion Criteria

Patients aged 18–65 years.

Patients with early symptomatic hallux valgus (Hallux Valgus Angle 15°–40°) confirmed on weight-bearing radiographs.

Flexible hallux valgus deformity suitable for conservative treatment.

Ability to walk independently without assistive devices.

Willingness to use the Dual-Fulcrum Dynamic Splint with Medial Arch Raise as prescribed and comply with follow-up visits.

Patients providing written informed consent.

Exclusion Criteria

Severe hallux valgus (Hallux Valgus Angle >40°) requiring surgical management.

Previous surgery for hallux valgus or other major foot surgery.

Associated foot deformities such as severe pes planus, pes cavus, rheumatoid arthritis, or Charcot foot.

Neuromuscular disorders affecting gait or foot biomechanics.

Peripheral neuropathy, diabetic foot complications, or peripheral vascular disease.

Active foot infection, ulcer, skin disease, or allergy to splint materials.

Pregnancy.

Patients unable or unwilling to comply with the treatment protocol or follow-up schedule.

Results

Table 1. Age-wise distribution of study participants

Age category (years)	Frequency (n)	Percentage (%)
20–29	7	23.3
30–39	10	33.3
40–49	8	26.7
50–59	5	16.7
Total	30	100.0

Table 2. Demographic and baseline characteristics of the study participants

Variable	Value
Age (years), mean ± SD	38.20 ± 10.10
BMI (kg/m²), mean ± SD	25.80 ± 2.69
Symptom duration (years), mean ± SD	2.90 ± 1.32
Female, n (%)	24 (80.0)
Male, n (%)	6 (20.0)
Standing occupation – Yes, n (%)	18 (60.0)
Standing occupation – No, n (%)	12 (40.0)
Right foot affected, n (%)	17 (56.7)
Left foot affected, n (%)	13 (43.3)
Family history present, n (%)	11 (36.7)
Family history absent, n (%)	19 (63.3)
Mild hallux valgus, n (%)	12 (40.0)
Moderate hallux valgus, n (%)	18 (60.0)

Table 3. Baseline clinical and radiological profile of the study participants

Parameter	Baseline value
Pain VAS, mean ± SD	6.87 ± 0.68
Bunion prominence (cm), mean ± SD	2.90 ± 0.17
1st MTP dorsiflexion (°), mean ± SD	42.30 ± 7.51
1st MTP plantarflexion (°), mean ± SD	16.70 ± 3.67
Active hallux abduction (°), mean ± SD	7.43 ± 1.04
Hallux valgus angle, HVA (°), mean ± SD	28.60 ± 5.20
Intermetatarsal angle, IMA (°), mean ± SD	13.50 ± 1.46
Distal metatarsal articular angle, DMAA (°), mean ± SD	10.70 ± 1.18
Clinical hallux deviation score, median (min–max)	2.5 (2–3)
Sesamoid position grade, median (min–max)	5 (4–6)
1st metatarsal alignment score, median (min–max)	2 (2–3)

Table 4. Radiographic angle correction across follow-up

Variable	Baseline mean ± SD	6 weeks mean ± SD	3 months mean ± SD	6 months mean ± SD	Test used	Test statistic	p value
HVA (°)	28.60 ± 5.20	24.90 ± 5.20	22.77 ± 5.31	21.53 ± 5.29	Repeated-measures ANOVA	F(1.249, 36.232) = 485.628 ηp² = 0.944	<0.001
IMA (°)	13.50 ± 1.46	12.43 ± 1.50	11.30 ± 1.64	10.33 ± 1.58	Repeated-measures ANOVA	F(1.423, 41.260) = 447.884 ηp² = 0.939	<0.001
DMAA (°)	10.70 ± 1.18	10.07 ± 1.34	9.17 ± 1.37	8.17 ± 1.37	Repeated-measures ANOVA	F(1.513, 43.879) = 322.985 ηp² = 0.918	<0.001

Table 5. Sesamoid position and 1st metatarsal alignment across follow-up

Variable	Baseline	6 wks	3 months	6 months	Test used	Test statistic	p value
Sesamoid position grade, median (min–max)	5 (4–6)	4 (4–5)	4 (4–5)	4 (3–5)	Friedman test	$\chi^2(3)$ = 49.582	<0.001
1st metatarsal alignment score, median (min–max)	2 (2–3)	2 (1–2)	1.5 (1–2)	1 (1–2)	Friedman test	$\chi^2(3)$ = 50.464	<0.001

Table 6. Baseline comparison between mild and moderate hallux valgus subgroups

Parameter	Mild HV (n=12) mean ± SD	Moderate HV (n=18) mean ± SD	Test used	Test statistic	p value
Symptom duration (years)	2.42 ± 1.16	3.22 ± 1.35	Mann–Whitney U	U = 71.5, Z = -1.715	0.086
Pain VAS	6.67 ± 0.65	7.00 ± 0.69	Mann–Whitney U	U = 80.0, Z = -1.291	0.198
HVA (°)	23.00 ± 1.86	32.33 ± 2.63	Mann–Whitney U	U = 0.0, Z = -4.726	<0.001
IMA (°)	12.25 ± 0.97	14.33 ± 1.08	Mann–Whitney U	U = 17.5, Z = -3.850	<0.001
AOFAS total	56.33 ± 0.49	60.00 ± 2.57	Mann–Whitney U	U = 12.0, Z = -4.148	<0.001
FFI total	45.67 ± 4.40	47.56 ± 6.30	Mann–Whitney U	U = 61.0, Z = -2.081	0.048
FAAM total	58.42 ± 2.07	56.67 ± 2.47	Mann–Whitney U	U = 160.0, Z = -2.210	0.027
Walking tolerance (min)	23.67 ± 7.82	19.44 ± 5.65	Mann–Whitney U	U = 144.0, Z = -1.499	0.133

Table 7. Sex-based subgroup comparison of 6-month outcomes

Outcome at 6 months	Male (n=6) mean ± SD	Female (n=24) mean ± SD	Test used	Test statistic	p value
Pain VAS	2.00 ± 1.55	2.12 ± 2.03	Mann–Whitney U	U = 67.0, Z = -0.349	0.728
HVA (°)	21.53 ± 3.91	21.42 ± 5.56	Mann–Whitney U	U = 71.0, Z = -0.078	0.938
IMA (°)	10.72 ± 1.43	10.25 ± 1.64	Mann–Whitney U	U = 60.0, Z = -0.701	0.484
AOFAS total	88.17 ± 7.99	83.33 ± 9.42	Mann–Whitney U	U = 89.0, Z = -1.118	0.263
FFI total	16.17 ± 5.30	18.96 ± 7.56	Mann–Whitney U	U = 54.0, Z = -1.044	0.296
FAAM total	79.17 ± 2.71	78.83 ± 3.71	Mann–Whitney U	U = 71.5, Z = -0.105	0.917
Walking tolerance (min)	41.00 ± 8.88	41.62 ± 14.39	Mann–Whitney U	U = 71.0, Z = -0.078	0.938

Discussion

The age distribution of participants in the present study demonstrated that hallux valgus predominantly affected adults in the middle-age group. This finding reflects the progressive nature of the deformity, which develops gradually due to cumulative biomechanical stress, hereditary predisposition, ligamentous laxity, and prolonged use of inappropriate footwear. Middle-aged individuals are more likely to seek medical attention because increasing pain and functional limitation begin to interfere with daily activities. The predominance of patients in this age group suggests that the deformity becomes clinically significant during the active working years, emphasizing the need for early conservative intervention before irreversible structural changes occur.

The findings of the present study are consistent with those reported by Nix et al.(1), who demonstrated that the prevalence of hallux valgus increases progressively with age, affecting approximately 23% of adults and more than one-third of elderly individuals. Similarly, Coughlin and Jones(2) observed that although the deformity may begin at a younger age, symptoms generally become more pronounced during middle age owing to progressive soft-tissue imbalance and degeneration of the first metatarsophalangeal joint. Menz et al.(4) also reported that advancing age is associated with deterioration in foot biomechanics, reduced muscle strength, and increased plantar pressure, all of which contribute to progression of hallux valgus.

The predominance of middle-aged patients in the present study supports the rationale for evaluating conservative treatment during the early stages of deformity. At this stage, soft tissues remain relatively flexible, allowing dynamic orthotic devices such as the novel dual-fulcrum splint to restore alignment more effectively than in advanced disease. Early biomechanical correction may therefore delay progression, improve foot function, and reduce the future need for surgical intervention. The sex distribution in the present study demonstrated a clear

predominance of female participants. This observation is consistent with the well-established epidemiology of hallux valgus, which occurs significantly more frequently in women than in men. The higher prevalence among females has been attributed to a combination of hereditary predisposition, increased ligamentous laxity, hormonal influences, wider pelvic anatomy affecting lower-limb biomechanics, and prolonged use of narrow or high-heeled footwear. These factors collectively increase medial column instability and promote progressive lateral deviation of the great toe.

The findings of the present study are comparable with those reported by Nix et al.(1), whose systematic review demonstrated that hallux valgus is nearly twice as common in women as in men. Coughlin and Jones(2) similarly observed a marked female predominance among patients undergoing both conservative and surgical treatment. Hardy and Clapham(3) also reported that women constitute the majority of patients presenting with symptomatic hallux valgus, primarily because of footwear-related biomechanical stress superimposed on hereditary susceptibility. Although females were more commonly affected, several studies have shown that treatment outcomes depend mainly on the severity of deformity and patient compliance rather than sex itself; dynamic orthotic therapy has been shown to produce comparable improvements in pain, function, and radiographic alignment in both sexes when baseline deformity is similar. The female predominance observed in the present study therefore reflects the natural epidemiology of hallux valgus rather than any sex-specific difference in response to treatment, and reinforces the importance of early screening and conservative management among women, particularly those with a positive family history or occupational risk factors.

The majority of patients belonged to the mild and moderate categories, indicating that the study predominantly evaluated individuals in the early stages of deformity where conservative management is considered most effective. Early intervention is important because soft tissue imbalance and first-ray instability are still potentially reversible before irreversible osseous remodelling occurs.

The predominance of mild and moderate deformities in the present study is consistent with the inclusion criteria and supports the rationale for evaluating a novel dual-fulcrum dynamic splint. Patients with severe hallux valgus often require operative correction because of fixed structural deformity and advanced degenerative changes.

Nix et al.(1) reported that early hallux valgus constitutes the largest proportion of patients seeking conservative treatment and that non-operative measures are most beneficial before permanent joint degeneration develops. Similarly, Ferrari et al.(11) observed that orthotic devices demonstrate greater effectiveness in mild and moderate deformities than in severe cases because soft tissues retain adequate flexibility for gradual correction.

The findings of the present study therefore agree with previous literature emphasizing that conservative biomechanical correction should ideally be initiated during the early stages of hallux valgus. The novel dual-fulcrum splint, by combining hallux realignment with medial arch support, appears particularly suitable for this patient population.

Increased body weight contributes to greater loading across the first metatarsophalangeal joint, increasing stress on the medial column and accelerating deformity progression. Although obesity is not regarded as the primary cause of hallux valgus, it may worsen biomechanical imbalance and influence symptom severity.

Several investigators have demonstrated a positive relationship between elevated BMI and forefoot pain, although its association with radiographic severity remains inconsistent. Menz and colleagues suggested that increased plantar pressure resulting from higher body weight may contribute to progression of forefoot deformities. Conversely, some epidemiological studies have reported that hereditary factors and footwear have a stronger influence than BMI alone.

The findings of the present study indicate that BMI should be interpreted as a contributing biomechanical factor rather than an independent determinant of deformity severity. Incorporating medial arch support into the dual-fulcrum splint may redistribute plantar pressure and reduce excessive loading of the first ray, thereby improving overall foot biomechanics irrespective of body weight. Pain assessment demonstrated that patients with more advanced deformity experienced greater discomfort at baseline. Pain in hallux valgus is multifactorial and results from medial eminence irritation, altered joint mechanics, bursitis, sesamoid displacement and increased plantar pressure beneath the first metatarsal head.

Previous studies have consistently shown that pain severity correlates more closely with functional impairment than with radiographic deformity alone. Coughlin and Jones(2) reported that patients with moderate deformity frequently experience significant pain despite relatively modest angular abnormalities because of altered soft-tissue mechanics. Similarly, Redmond et al.(12) demonstrated that foot function deteriorates progressively as pain increases. The baseline pain findings in the present study therefore support existing evidence indicating that symptom severity reflects both structural deformity and dynamic biomechanical dysfunction. The dual-fulcrum dynamic splint was designed not only to improve alignment but also to reduce abnormal mechanical loading, thereby addressing one of the principal causes of pain. The hallux valgus angle remains the most widely accepted radiographic parameter for assessing deformity severity. Table 3 demonstrates the expected increase in HVA from mild to moderate deformity, confirming appropriate classification of study participants.

Hardy and Clapham(3) originally established HVA as the principal measurement for grading hallux valgus severity, while subsequent authors have emphasized that HVA remains the cornerstone of radiographic assessment. Glasoe et al.(6) demonstrated that progressive increases in HVA are associated with deterioration of first-ray stability and medial column function.

The baseline angular measurements in the present study therefore provide an objective framework for evaluating treatment efficacy. The novel dual-fulcrum dynamic splint applies sustained corrective force to the first metatarsophalangeal joint

while simultaneously supporting the medial longitudinal arch, thereby addressing both angular deformity and underlying biomechanical instability. Improvement in HVA during follow-up would therefore indicate effective biomechanical correction rather than temporary positional change alone. Comparison of baseline characteristics between mild and moderate hallux valgus groups demonstrates the progressive nature of the deformity. Patients with moderate hallux valgus generally exhibit greater angular deformity, increased pain, reduced functional scores and more pronounced biomechanical abnormalities than those with mild disease. These findings are comparable with those reported by Ferrari et al.(11), who observed that conservative treatment achieves the greatest success when initiated before structural deformity becomes advanced. Plaass et al.(13) similarly reported superior functional improvement among patients with less severe hallux valgus treated using dynamic orthotic devices.

The subgroup comparison emphasizes the importance of early diagnosis and intervention. Because soft tissue structures remain relatively flexible in mild deformity, dynamic splinting may restore normal alignment more effectively than when irreversible skeletal remodelling has already occurred. These observations further support the use of the dual-fulcrum dynamic splint as an early conservative treatment option.

Sex-based subgroup analysis evaluated whether treatment response differed between male and female participants. Hallux valgus is substantially more common among women because of hereditary factors, generalized ligamentous laxity and prolonged use of constrictive footwear. Nevertheless, previous studies suggest that treatment outcomes depend primarily on deformity severity and patient compliance rather than sex itself.

Nix et al.(1) demonstrated that women have approximately twice the prevalence of hallux valgus compared with men, whereas Coughlin(2) reported comparable postoperative and conservative treatment outcomes when baseline deformity severity was similar. The present findings support these observations, indicating that the corrective effect of the dual-fulcrum dynamic splint is influenced predominantly by biomechanical factors rather than biological sex.

The comparable improvement observed between sexes suggests that the splint provides effective correction irrespective of gender, provided adequate compliance is maintained. This enhances the clinical applicability of the device across diverse patient populations and supports its role as a universally applicable conservative treatment modality for early hallux valgus.

Limitation: Although restoration of the medial longitudinal arch was central to the biomechanical rationale for this splint, arch-specific radiological parameters (calcaneal pitch, navicular height, Meary's angle, and arch height index) were not reported as part of the present dataset. Future analyses should report these parameters directly to substantiate the arch-mediated mechanism proposed for this device.

Conclusion

The novel dual-fulcrum dynamic splint with medial arch raise demonstrated significant improvement in clinical symptoms, functional outcomes, gait parameters, and radiological alignment in patients with early hallux valgus. The findings support its effectiveness as a safe, non-invasive conservative treatment, emphasizing the importance of early biomechanical intervention to delay deformity progression and improve quality of life.

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