Effects of Bunion Bootie® on Hallux Abductus Angle and pain in participants with flexible Hallux Abducto Valgus (bunion)

A prospective study

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Abstract

Objective: The purpose of this study was to investigate the immediate effects of Bunion Bootie® on Hallux Abductus Angle (HAA) and to assess participant's pain experience after one week of intervention. We also evaluated any association between the change in HAA and participants' age, duration of pain and onset of Hallux Abducto Valgus (HAV) deformity.

Materials and methods: 32 participants with symptomatic flexible HAV were recruited. Photograph of participants' foot and manual measurements of HAA with and without wearing the Bunion Bootie® were conducted in one session at the UWA Podiatry Clinic. Participants were required to wear the intervention for one week and to complete a feedback form post-treatment. HAA photo measurements were made with "Knee Registry" smartphone application. Inter- and intra-observer reliability of the smartphone and manual measurement method were also tested.

Results: The mean±SD change in HAA were 10.656˚±4.300˚ and 11.484˚±4.860˚ for smartphone application and tractograph, respectively ($P<0.05$). There was no statistically significant difference between the two measurement methods ($P>0.05$). No linear relationship between the change in HAA and participants' age, HAV onset or duration of pain was observed. Excellent inter- and intra-observer reliability were obtained. Most participants agreed that Bunion Bootie® has helped to resolve their HAV pain and are more likely to continue wearing it in the future.

Conclusion: Albeit preliminary, our data lends support to the proposition that Bunion Bootie® is effective in reducing the pain and HAA in participants with flexible HAV. "Knee Registry" smartphone application is a reliable and time efficient method comparable to manual measurement. Future randomised controlled studies need to be conducted to establish the benefit of our findings for clinical and research purposes.

Keywords: Bunion. Bunion Bootie. Hallux abductus angle. Hallux abducto valgus. Knee Registry. Manchester scale. Pain. Smartphone measurement.

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1. Introduction

Hallux Abducto Valgus (HAV) is the most common forefoot condition whereby the first metatarsophalangeal joint (MTPJ) is progressively dislocated due to deviation of the first metatarsal medially and the great toe (hallux) laterally[1-3]. HAV may be accompanied by a soft tissue and osseous prominence, commonly referred to as a "bunion", on the medial aspect of the first metatarsal head[1,4].

1.1 Aetiology of Hallux Abducto Valgus

The cause of HAV is complex, multifactorial and not fully defined. Some authors suggest HAV is the sign of an underlying condition and should not be treated in isolation[5]. Pes planus, subtalar joint hyper-pronation and first ray hypermobility may be associated with HAV[5,6]. An excessively long first metatarsal has been suggested to have aetiological significance, as the protruding hallux may be more prone to develop valgus[6]. An imbalance of muscles and ligamentous structures has also been suggested as causative, but its importance is unconfirmed[4,6]. The shape of the metatarsal heads does not appear to influence the formation or progression of HAV[6]. Other proposed aetiologies for HAV include neurological conditions, such as Cerebral palsy, where muscle overactivity may cause deformity with minimal bony abnormality[5,7]. Iatrogenic HAV has been reported post tibial sesamoidectomy[6].

Another hypothesised aetiology of HAV is osteoarthritis of the first MTPJ. This condition has been associated radiographically with osteoarthritis of the knee and hand joint[8]. Whilst pain and osteoarthritis at a number of different sites have been linked to foot pain, there is no reported link to HAV[8].

HAV is strongly associated with increasing age and female gender[9]. A systematic review and meta-analysis involving 496,597 participants reported a prevalence of 23% in adults aged 18-65 years, increasing to 36% in adults aged 65 years and above[9]. Females are more likely to

develop HAV, with female to male ratios reportedly as high as 9:1[4,8]. The exact cause of female predisposition to HAV is unknown, with various hypothesis supported and refuted by different studies, as presented in a comprehensive review by Kilmartin and Wallace[6]. To our knowledge, there are no reports addressing whether the female foot structure predisposes to HAV, although a review did consider this possibility[6]. In modern western societies, high heeled and narrow shoes may be a contributing factor to increased HAV prevalence in females[10]. Other possible contributing factors for female predisposition include a wider pelvis and greater angle of femoral inclination, thus causing a greater pronatory force and leading to HAV development[6].

There appears to be a hereditary (autosomal dominant) causation of HAV with incomplete penetrance, meaning the trait is not always expressed[4,6,10]. Penetrance varies between 58-72% of cases[6]. A positive family history of HAV has been reported in 72% of participants with juvenile HAV[5]. This study also found that 29 out of 31 participants showed a pattern of maternal inheritance[5].

Extrinsic factors that may contribute to the development of HAV include ill-fitting shoe gear[5,7,10]. The overlying adventitious bursa of the bunion may become painful if irritated with ill-fitting footwear, whether this is for fashion or occupation[1,4,7]. A study of 605 first metatarsal bones from 5th-17th century human remains in France showed an increasing prevalence of HAV over the centuries, particularly from the 16th - 17th centuries when heeled shoes and stiff leather shoes were introduced[10]. These findings demonstrate the marked impact that footwear has on HAV development. Whilst hallux valgus is more prevalent among shoe wearers, it is unknown whether shoe wearing itself causes HAV as the exact mechanism underlying this condition has yet to be fully characterized[6,7].

HAV is also associated with nodal osteoarthritis, rheumatoid arthritis, self-reported osteoarthritis and rheumatoid arthritis, tarsal coalitions, knee pain and big toe pain[5,8]. It is not yet known whether ethnicity plays a role in the development of HAV[6].

1.2 Prevalence of HAV

Incidence, refers to the occurrence of new cases over a specified time period, typically calculated as a rate or proportion. Prevalence refers to the number of new and existing cases. Prevalence estimates based on surveys in samples from the general population of adults have yielded estimates ranging from 21-70%[1,8,11,12]. The large range is due to differences in ethnic populations between countries (for example, rural Korean, non-Hispanic White, African American, and Puerto Rican) and to different definitions of HAV[1,8,11,12]. Whilst estimates of HAV prevalence varies, two large scale studies report similar prevalence. The study by Menz *et al*. drew upon participants aged 56 years and older in the North Staffordshire Osteoarthritis Project (n=2,831)[1]. A self-reported HAV validated instrument found a prevalence of 36.3% in those greater than or equal to 56 year old population[1]. Roddy *et al.* performed a survey of two general practices in the UK. Their study of 4,249 adults aged above 30 years found a 28.4% prevalence of participant-reported HAV[8].

A systematic review and meta-analysis of a total 496,957 participants found a pooled prevalence estimate for HAV of 23% in adults aged 18-65 years and 35.7% in people aged above 65 years[9]. Prevalence increased with age and was higher in females (30%) compared to males (13%)[9]. Kilmartin *et al.* reported clinical unilateral and bilateral HAV in 96 (1.6%) and 60 (1%) respectively of 6,000 British school children aged 10 years[6].

1.3 Clinical presentation and consequences

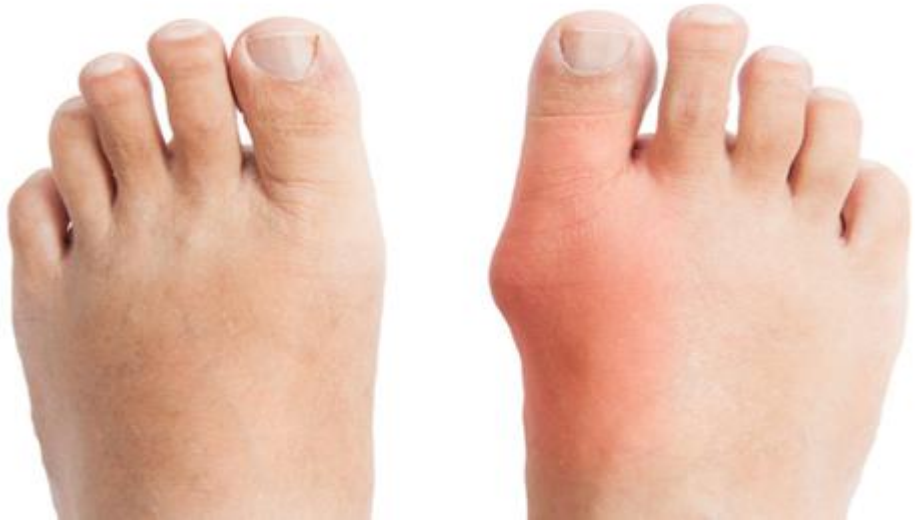

Figure 1. *Presentation of HAV: lateral displacement of hallux, red bulging bony bump*[13]

HAV can be recognised by a bulging bony bump on the medial aspect of the first MTPJ (Fig. 1)[1,2,13,14]. The hallux is often rotated in the frontal plane resulting in the nail facing medially [1,2,14]. HAV may or may not cause symptoms[15]. Lateral displacement of the hallux forces the lesser digits into malalignment, leading to hammer toes or claw toes, altered weight bearing patterns, plantar corns and callus formation[1,4]. Pain around the first MTPJ is frequent when participating in activities while wearing shoes and may be relieved once these are removed[14-16]. Footwear that places pressure on the bump can cause irritation, resulting in swelling, redness or soreness around the first MTPJ[14,16]. Prolonged HAV alters balance and gait patterns, contributes to immobility and poses a risk for falls in the elderly[1,8]. Patients usually complain of difficulty in finding shoes that fit properly because of this deformity[14,16].

In the long-term, HAV reduces quality of life and may lead to subluxation of the lesser MTPJ and secondary osteoarthritis of the first MTPJ[1,4]. Surgical correction of HAV is the most commonly performed orthopaedic foot and ankle surgery[1-4]. However, surgery poses some risk, with recurrence being the most common complication of HAV surgery in 2.7%-16% of cases[15].

1.4 Diagnostic assessments and examinations for HAV

1.4.1 History and physical examination

It is important to perform history taking and clinical examination on HAV participants in both standing and seated positions[1,2,4,17]. Lateral deviation of the hallux is evident when the participant is weight-bearing (WB)[4]. The examiner should establish whether the deformity is flexible, i.e., whether it can be corrected by manipulation, and whether motion of the MTPJ is limited by pain, which would indicate osteoarthritis[4,7,17]. The MTPJ is also inspected for active and passive range of motion (normal: 70° of extension and 45° of flexion) and for crepitus[4,18,19]. In addition, tightness of the gastroc-soleus complex, presence of pes planus and contracture of the Achilles tendon should also be evaluated during examination[18-20].

1.4.2 Imaging studies

WB radiographs are the gold standard for assessment of HAV and are useful for grading the severity of the deformity[18-22]. The hallux abductus angle (HAA) is the most commonly used angular measurement (Fig. 2a) and is formed by drawing a line through the longitudinal axis of the first metatarsal and the proximal phalanx[18-22]. HAA can not only monitor the progression of the deformity but also provides an insight into the quality of the first MTPJ and the lesser toe joints[18,20-22]. Many studies have considered HAA of 15° or more to be pathologic, while an angle of 40° and above is considered severe[18,20-,22]. The 1-2 intermetatarsal angle (IMA) is reported to be normal if it is 9° or less (Fig. 2a)[18,20-22]. However, in the clinical setting, obtaining radiographs to grade the severity of HAV is not always feasible and therefore a simpler and safer way to grade HAV is needed[23,24].

1.4.3 The Manchester scale

The Manchester scale is a new, non-invasive system to grade the severity of HAV during WB without the need to obtain measurements from radiographs[23,24]. This scale classifies the severity of HAV based on four standardized photographs of feet: none (grade 1), mild (grade 2, HAA less than 20°), moderate (grade 3, HAA between 20°-30°) and severe (grade 4, HAA between 30°-50°) (Fig. 2b)[23,24]. A high correlation between the Manchester scale score and HAA has been shown, and moderate correlation observed with IMA[24]. The Manchester grading system provides a valid representation of the degree of HAV when compared with measurements obtained from radiographs[25,26].

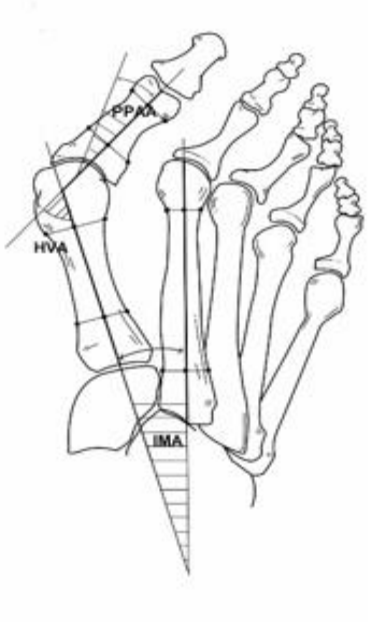

***Figure 2a**. Radiographic measurements of the Hallux Valgus Angle (HVA) another term for Hallux Abductus Angle (HAA), the first intermetatarsal angle (IMA)[18]*

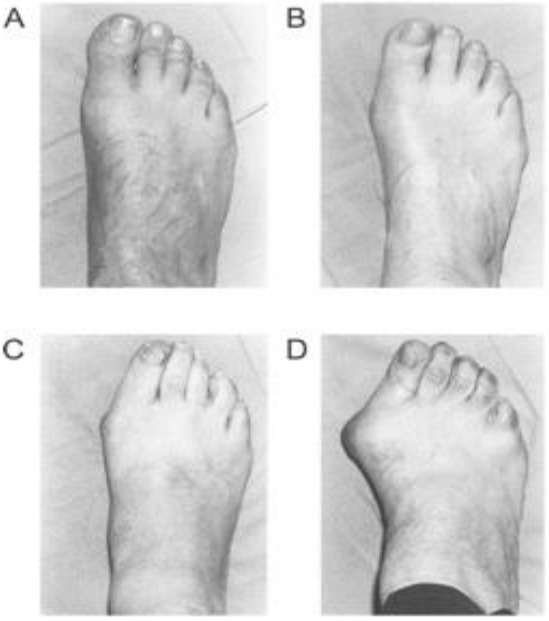

***Figure 2b.** The Manchester scale. (A) No deformity, grade 1; (B) mild deformity, grade 2; (C) moderate deformity, grade 3; (D) severe deformity, grade 4[23]*

The present study will use the Manchester scale to grade the severity of HAV because it is based on photographs of feet rather than relying on radiographs. Recent advances in digital imaging technology has allowed photographic methods to be used for measuring angles of the knee joint, first metatarsal and HAA by employing surface anatomy markings[25-29]. This

method has shown good correlation with radiographic standards, as well as robust inter and intra-observer reliability[27,29]. A smartphone application called "Knee registry" will be used in the present study[30]. This application was developed by the Indian Orthopaedic Research Group and is able to store participant information, clinical photographs and radiographs[30]. It can also provide angular and range of motion measurements of joints by placing the edge of the phone to the appropriate surface and utilise the phone's in-built accelerometer technology[30].

1.5 HAV Treatments

Clinical improvement for HAV is reflected by reduction of HAA and pain. Conservative treatment includes foot exercises, shoe modifications, prefabricated or custom-made orthotics, activity modification, splints, treatment of other foot deformities (such as equinus and pes planovalgus), manual and manipulative therapy (MMT), topical and systemic anti-inflammatory drugs, and local cortisone and anaesthetic injection for associated bursitis[2,17,31-33].

Temporary relief may be achieved by reducing pressure over the bunion with wider shoes or stretchable leather or fabric[4,5]. Anti-pronatory orthotics appear to be ineffective for the prevention of HAV[34]. Budiman-Mak *et al*. evaluated the effectiveness of orthotics in 102 adults with rheumatoid arthritis and found that there was no statistically significant between before and after intervention period on prevention of HAV[34]. Another study by Reina *et al.* in 2013 aimed to determine if the use of custom-made orthotics for 1 year prevented the progression of HAV in 54 women[35]. No significant difference in the IMA and HAA at the conclusion of the study was observed[35].

A Cochrane review of three articles with a total of 332 participants found that conservative treatments (night splints and functional orthotics) were ineffective in relieving pain

experienced by HAV participants[2]. Another study of 30 women compared the effect of night splint versus toe separators and reported that both treatments had little effect on correcting the deformity, although the group treated with toe-separator had significant pain reduction compared to the night splint group[36]. A randomised controlled trial of 30 participants comprising a control group (standard care with a night splint) and an experimental group (MMT) reported no significant difference between these groups in terms of participant reported pain, foot function index and hallux dorsiflexion[33]. However, the outcome measures in the MMT group was sustained at the 1 month's follow-up, whilst the control group regressed[33].

1.6 Bunion Bootie®

Bunion Bootie®, like many other bunion splints, offers non-operative treatment solutions to help relieve HAV discomfort and pain. The manufacturer claims to achieve this by temporarily correcting or improving the toe alignment of the big toe by separating it from the other toes[37]. This American-based company was founded in 2011 by a group of individuals who suffer from bunion pains themselves. The washable, soft and flexible latex-free bunion splint (Fig. 3) is suitable for mild to moderate bunions. By gently separating the hallux and correcting the toe alignment, Bunion Bootie® purports to guard against painful irritation, rubbing, and blister formation and to soothe and relieve stiffness around the first MTP. This ultra-thin barrier made of polyurethane and nylon is only 0.4mm thick, allowing it to be worn in almost any kind of shoes. Bunion Bootie® can also provide post-operative support after any surgery to correct deformity of the hallux or first ray[37].

Bunion Bootie® is sold in the United States (US) and registered with the Food and Drug Administration (FDA) in the US. It does not have Therapeutic Goods Act (TGA) approval in Australia and hence can only be purchase online via their website (www.bunionbootie.com)

or Amazon.com. Bunion Bootie® are offered in different sizes ranging from extra-small to extra-large and cost US$33.95 each.

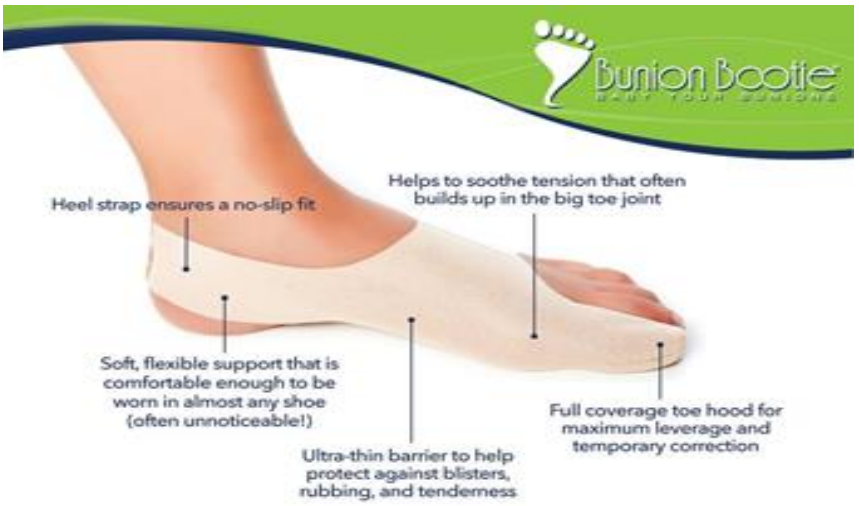

Figure 3. *Bunion Bootie®*[37]

1.7 Rationale for current research

Due to the high prevalence of HAV and the significant reduction in quality of life associated with this condition, there is a strong need for an effective conservative HAV treatment. Since these are currently lacking, the majority of HAV participants resort to costly surgery to correct the HAV deformity[1,2,33]. The University of Western Australia Podiatric Surgery Clinic quotes HAV surgery performed under local anaesthetic ranges from $1,977 to $3,350 per foot[38]. In Australia, the first MTPJ is the most common joint requiring surgery and the fourth most common joint to be operated on after the knee, hip and lower back[39]. Postoperative complications can significantly hinder outcomes and are reportedly as high as 50%, with recurrence being the most common at 2.7-16%[1,2,15,33]. Considering the significant financial cost of surgical options, the absence of sound evidence in favour of conservative treatments, and the impact of HAV on participant quality of life, further studies are clearly required to investigate other treatment options. Bunion Bootie® has not previously been investigated for its effectiveness in HAV treatment and is thus the subject of this study.

As the clinical outcome of HAV is normally assessed through HAV angles, there is a need for a quick and reliable method for angle measurements. Typically, angle measurements are performed radiographically as it is the current gold standard. However, there are some disadvantages associated with X-rays such as harmful ionizing radiation and potential financial costs[40,41]. There has been emerging studies showing that digital smartphone measurements are reliable and valid[40]. This suggests the potential for digital smartphone measurements such as "Knee Registry", to replace traditional radiographic measurements as it is quick, simple and low cost[40]. As a result, "Knee Registry" application is used in this study to measure the HAA due to its potential benefits.

1.8 Aims of this research project

The overall aim of this study is to investigate the effects of wearing Bunion Bootie® in participants with flexible HAV.

The specific research questions to be addressed are:

1. To evaluate the immediate effects of wearing Bunion Bootie® on HAA.

2. To assess pain experienced from HAV before and after wearing Bunion Bootie® for one week.

3. To investigate the relationship between the change in HAA and the participant's age, duration of pain and onset of HAV deformity.

1.9 Hypothesis

Wearing the Bunion Bootie® will reduce HAA and pain in HAV participants. There will be no association between the change in HAA and the participant's age, duration of pain or onset of HAV.

2. Methods and Materials

2.1 Research design

We used a prospective, quasi-experimental and correlational (before-after) research design to investigate for changes in HAA following intervention (wearing of Bunion Bootie®) in participants with HAV. The effect of wearing Bunion Bootie® on pain was also assessed. The research design allows for comparison of results obtained before and after the intervention.

Participants were required to attend the UWA Podiatry Clinic to allow photographs and measurements of HAA with and without wearing of the Bunion Bootie® to be collected. Each participant was provided with a Bunion Bootie® to wear for as long as possible, day and night, during the study period of one week. Participants were also given a feedback form and pre-paid envelope during this session and were advised to complete and return the form by mail. Participants were not required to return the Bunion Bootie® to the investigators.

2.2 Sample size and recruitment

The study recruited a total of 32 participants with HAV who presented to the UWA Podiatry Clinic over the period of August 2016 – October 2016. These participants met all the criteria outlined in Table 1.

To determine whether HAV was flexible or rigid, participants were assessed for the range of motion of their big toe joint (65-75 degrees) as well as manual movement of the big toe toward the body-midline. This pilot study was conducted with the aim of collecting preliminary results on the possible effects of wearing the Bunion Bootie® on HAA and on perceived pain. As no prior studies have been published on this intervention, there is no plausible effect size that would allow a power calculation for sample size. Due to the time

constraints of this project, a control group of HAV participants that did not wear Bunion Bootie® was not included in the study.

Table 1. *Inclusion and exclusion criteria for recruitment of HAV participants*

Inclusion Criteria	Exclusion Criteria
● Flexible mild-moderate HAV ● Aged 18 years or older	● Rigid hallux valgus/hallux rigidus/hallux limitus ● Diabetes or any associated condition such as Charcot Neuroarthropathy, Peripheral Arterial Disease or Peripheral Neuropathy ● History of a systemic condition known to predispose to first metatarsophalangeal joint arthritis (Any type of inflammatory arthritis, infective arthritis, crystalline arthritis or neuromuscular disease) ● Previous history of foot surgery ● Where manual or manipulative assessment is contraindicated, for example in cases of joint instability ● Allergy to nylon and/or polyurethane ● Patients younger than 18 years old

2.3 Ethics approval

This study was approved by the UWA Human Research Ethics Committee (Ref RA/4/1/8625). More detailed information on the ethics application and the response to queries by the Chair of the committee are shown in Appendix 1. Participant consent was obtained using the Participant Consent Form shown in Appendix 2.

2.4 Data collection

Demographic information was obtained using the Data Collection Form shown in Appendix 3. This information was used to screen against the inclusion and exclusion criteria outlined in Table 1 and thus confirm eligibility for recruitment into the study. Eligible participants were provided with a Participant Information Form as shown in Appendix 4 and were invited to attend the UWA Podiatry Clinic where photographs of the HAV foot were taken in a WB position and with or without wearing of the Bunion Bootie®. Participants were instructed to wear Bunion Bootie® continuously for a period of one week. They were given a Participant Feedback Form (Appendix 5) to rate whether Bunion Bootie® has altered their HAV pain and to assess their likelihood of wearing Bunion Bootie® in future. Both assessments were based on a 10-point Likert-type scale. Participants were requested to return the feedback form after 1 week of wearing Bunion Bootie® using the pre-paid envelopes provided. An additional comments section with an open-ended question was included at the end of the feedback form to allow participants to further describe their experience with Bunion Bootie®. Data obtained from the feedback form were gathered and analysed.

2.4.1 Smartphone-based measurements

One observer used a smartphone application (Knee Registry, Indian Orthopaedic Research Group, India) to measure the HAA based on photographs taken of the participant's foot[30]. The observer independently measured the HAA twice on each photograph, with the average of all measurements used for data analysis. A previous study compared radiographic angles of HAV participants in 20 radiographs using an iPhone application (Tiltmeter software) and concluded that this gave equivalent results to the use of a protractor in terms of accuracy of the HAA measurement[26]. Another study of 32 HAV participants compared measurements made using a smartphone accelerometer with computerized measurements[27]. The authors

reported excellent concordance between iPhone and computer-assisted angular measurements for HAA, IMA, and Distal Metatarsal Articular Angle (DMAA)[27]. The inter- and intra-observer reliability in their study was also excellent for HAA, IMA and DMAA[27]. Hence, previous studies have validated the use of smartphone applications for measurement of HAA[26,27].

2.4.2 Manual measurements and standardisation

To further evaluate the validity of smartphone-based measurements, manual measurements using a tractograph were performed as a reference standard for comparison. Two observers used a tractograph to measure the HAA of all the participants in WB position. Manual measurements are prone to error due to variations in the definition of anatomical landmarks between readings. However, several studies have shown that angular measurements obtained from manual use of goniometer and tractograph were not statistically different to computer-assisted measurements and also showed high levels of reproducibility[25,26,28]. This justifies use of the tractograph in the current study to perform manual measurements and thus serve as a reference standard. The method used for obtaining photographs of a participant's foot was standardized by placing the camera on a tripod with a level (Fig. 4) approximately 23cm perpendicular to the foot in order to reduce variability in foot positioning.

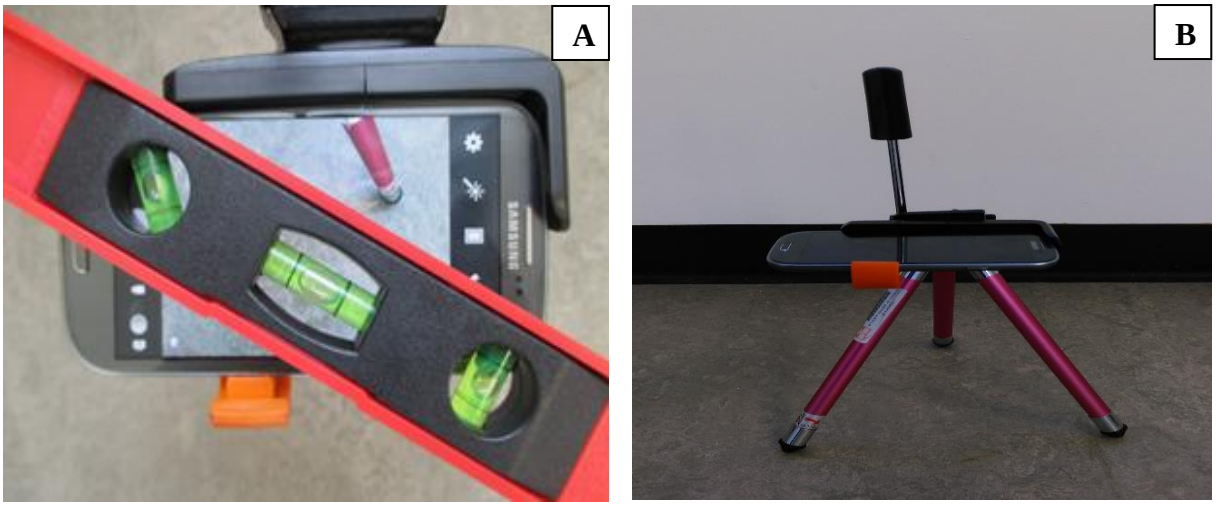

Figure 4. *A) Camera levelled before each photo session; B) Camera setup with tripod*

Bisection lines for the first metatarsal and the hallux were drawn using a black pen on the participants' foot as shown in Fig. 5, to improve anatomical visualisation when wearing the Bunion Bootie®. These lines served as a reference point for measurement and helped to improve the consistency of measurements.

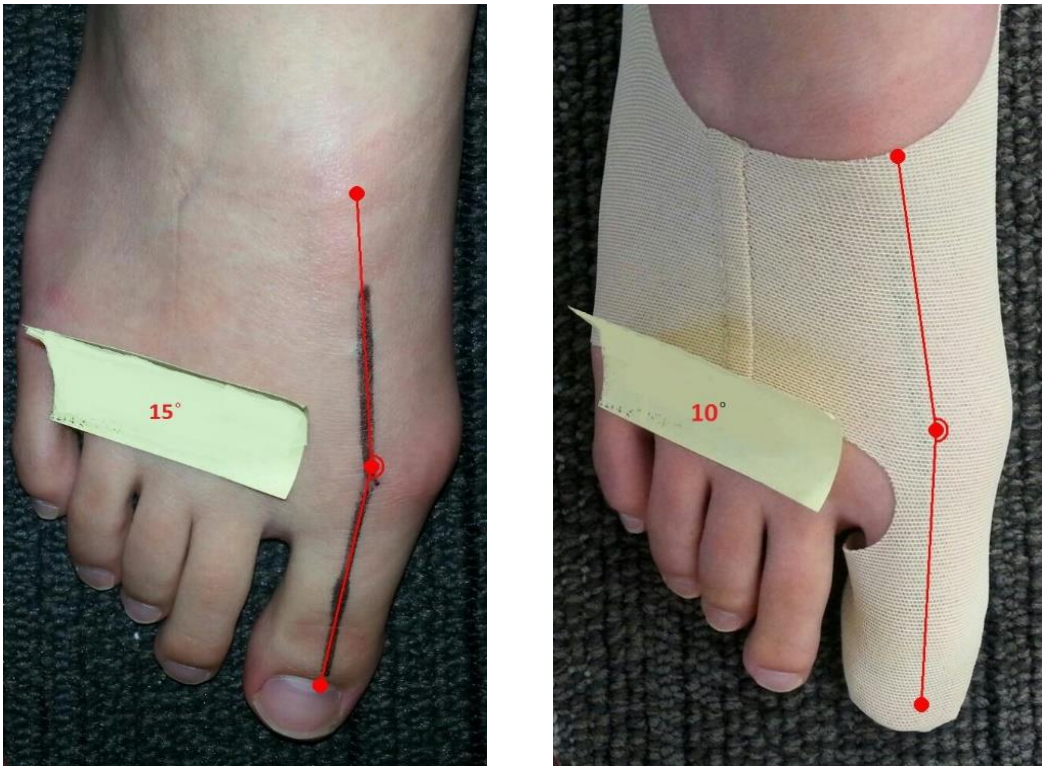

Figure 5. *Manual (black line) and smartphone (red line) measurement on participant's foot A) (left) Without Bunion Bootie®. B) (right) With Bunion Bootie®. Note the reduction in HAA*

2.4.3 Inter- and intra-observer reliability

To determine the accuracy of results, the inter- and intra-observer reliability of the HAA measurement was assessed. For HAA measurement by the smartphone application, intra-observer reliability was tested by randomly repeated measurements of 10 participants to establish the concordance for repeated measurements performed by a single observer. This was also applied to test for the intra-observer reliability with manual measurement. Inter-observer reliability was also tested. Both observers measured the HAA manually for the same 10 participants chosen at random. This was done to evaluate the consistency in the HAA measurements between two observers.

2.5 Statistical analysis

All results were entered into Microsoft Excel table format and SPSS software was used for statistical analysis. Due to the small sample size the data are inherently non-parametric. However, for the purpose of this study a normal distribution was assumed for statistically analysis with mean ± Standard Deviation (SD) will be utilised for each of the demographic variable including age, duration of pain of HAV, onset of HAV, HAA before (without Bunion Bootie®) and after (with Bunion Bootie®) the treatment as well as the changes in HAA after the intervention.

Multiple regression analysis was used to investigate whether the change in HAA can be predicted based on age, duration of pain and onset of HAV deformity. Inter-observer reliability was evaluated using Intra-class Correlation (ICC) to measure the level of agreement between observers and within repeated measurements of one observer.

Parametric methods of data analysis were used to examine the relationship between variables. Paired-sample T-test was used to compare between the HAA measurements obtained with and without Bunion Bootie®. The same test was conducted to compare the HAA measurements obtained from smartphone measurements with the values measured manually using a tractograph.

Data obtained from the feedback form were gathered and analysed. The median value of participants' rating scale on the likelihood of wearing the Bunion Bootie® in the future as well as its effect on their HAV pain were calculated. Results from the questionnaire were represented in a table. Responses obtained from the open-ended question were reviewed.

3. Results

Thirty two participants were included in this study. The demographic data collected includes age, gender, family history and onset of HAV (years), duration of pain (years), other medical history, previous treatment for HAV, footwear as well as the presence of pain. The characteristics of participants in our study are shown in Table 2.

Table 2. *Characteristics of participants included in the study. Values are mean ± standard deviation (SD), range, number of participants and percentages*

Characteristics of participants at inclusion	Value
· Female	28 (88%)
· Age	42.156 ± 17.4746 (20-71)
· Onset of HAV (years)	12.27 ± 9.668 (1-40)
· Duration of pain (years)	6.39 ± 4.930 (0.167-20)
· Family history of HAV	28 (88%)
· Previous treatments:	
- None	21 (66%)
- Orthoses	8 (25%)
- Felt padding	2 (6%)
- Toe spacer	2 (6%)
· Other medical history:	
- None	18 (56%)
- Pes planus	2 (6%)
- Morton's neuroma	1 (3%)
- Plantar fasciitis	1 (3%)
- Eczema	1 (3%)
- Right knee reconstruction	1 (3%)
- Other	8 (25%)
· Footwear:	
- Closed shoes	28 (88%)
- High heels	3 (9%)
- Thongs	2 (6%)

3.1 Smartphone-based and manual measurements of HAA

Using paired T-test, there was statistically significant reduction of the post-treatment HAA compared to the pre-treatment, when measured using the smartphone application (p-value of 0.000) as shown in Table 3 and Fig. 6. The mean change in HAA obtained from the smartphone application and manual measurements were less than 1˚ in difference.

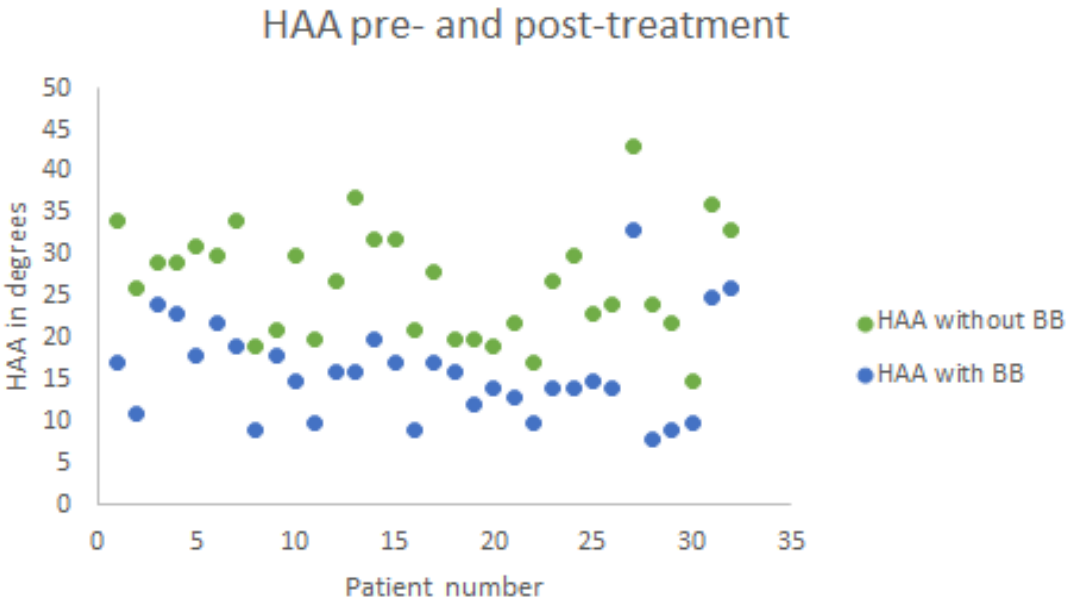

Figure 6. *Scatter plot of HAA values pre- and post-treatment of Bunion Bootie®*

Paired T-test was also conducted for the two measurement methods, showing no significant differences between pre- and post-treatment measurements obtained from the smartphone application and the manual measurements using a tractograph (Data shown in Table 3).

Table 3*. Comparison of pre- and post-treatment HAA measured by smartphone application and tractograph*

HAA	**Mean ± Standard Deviation**		**P-value**
	Smartphone	**Tractograph**	
Pre-treatment	26.719˚ ± 6.591˚	26.984˚ ± 6.685˚	0.304 (> 0.05)
Post-treatment	16.062˚ ± 5.797˚	15.500˚ ± 6.085˚	0.139 (> 0.05)
P-value	0.000 (<0.05)	-	-
Difference	10.656˚ ± 4.300˚	11.484˚ ± 4.860˚	-

Multiple regression analysis was performed to investigate the relationship between the change in HAA measured from the smartphone app and participants' age, onset of HAV (years) and duration of pain (years). Results showed a weak Correlation Coefficient - R value of 0.487 and a R^2 of 0.238, which indicates that only 23.8% of the change in HAA after treatment period can be explained by participants' age, onset of HAV or duration of pain. Linear regression F-test was performed showing a non-significant P-value of 0.052. Moreover, the statistical significance of the regression model was tested for all the listed predictors showing non-significant P-values of 0.387, 0.250 and 0.377 for participants' age, HAV onset and pain duration respectively. With all P-values greater than 0.05, we can assume that there is not a linear relationship between the change in HAA after wearing Bunion Bootie® for one week and participants' age, HAV onset or duration of pain.

3.2 Inter- and intra-observer reliability of HAA

Inter-observer reliability was assessed with ICC of 0.992 and 95% Confidence Interval of 0.973-0.998. Excellent agreement for the average HAA manual measurements performed by the two observers using a tractograph was observed. Intra-observer reliability for the repeated manual and smartphone measurements performed on ten randomly chosen participants revealed 90% agreement. This is because all measurements were identical except for one. From the results of this study, we can conclude that there is excellent inter- and intra-observer reliability for measurements of HAA.

3.3 Participants' feedback

A total of thirty-two participant feedback forms were collected after a week of treatment. A 10-point Likert-scale was used for the participants to rate whether Bunion Bootie® altered their HAV pain and to assess their likelihood of wearing Bunion Bootie® in future. A median value of 4/10 was obtained for the scale on HAV pain after one week of the treatment. It demonstrates that most participants noticed that Bunion Bootie® has helped to resolve their HAV pain. As a result, most of the participants are more likely to continue wearing Bunion Bootie® in the future. This is supported by the median score of 8/10 for their likelihood of wearing BB in the future. Responses of participants to the Bunion Bootie® after the treatment period were collected and analysed. The data are shown in Table 4 and Fig. 7. Values are represented in number and percentage (%).

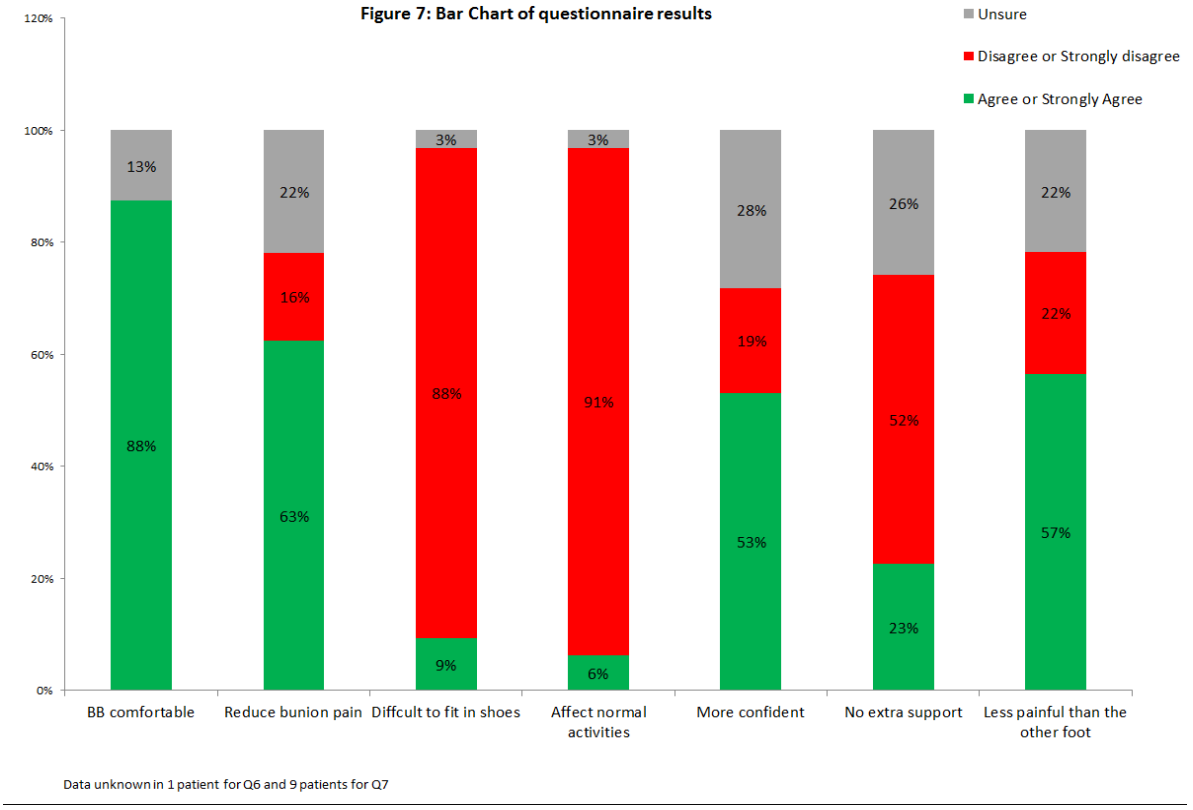

Figure 7. *Bar Chart of Questionnaire results*

Table 4. *Participants' responses to Bunion Bootie® after one-week-treatment*

Question	Strongly agree	Agree	Unsure	Disagree	Strongly disagree	no data
It is comfortable to use the BB during the treatment period	9 (28%)	19 (59%)	4 (13%)	0 (0%)	0 (0%)	0 (0%)
BB helps to reduce the bunion pain	10 (31%)	10 (31%)	7 (22%)	5 (16%)	0 (0%)	0 (0%)
BB is difficult to fit in most of the shoes	1 (3%)	2 (6%)	1 (3%)	11 (34%)	17 (53%)	0 (0%)
BB prevents me from doing my normal physical activities	1 (3%)	1 (3%)	1 (3%)	11 (34%)	18 (56%)	0 (0%)
My foot looks more normal and I feel more confident	3 (9%)	14 (44%)	9 (28%)	5 (16%)	1 (3%)	0 (0%)
BB does not give me extra support for my foot	1 (3%)	6 (19%)	8 (25%)	9 (28%)	7 (22%)	1 (3%)
BB made my foot less painful than the other foot	7 (22%)	6 (19%)	5 (16%)	5 (16%)	0 (0%)	9 (28%)

4. Discussion

HAV is a complex deformity of the foot that is prevalent in both the general and aging populations[1,2,18]. There is substantial divergence over the conservative treatment of HAV. Some recommend the use of splints, exercise and proper footwear while others consider such non-operative treatment as ineffective[3,17,31-36,42,-45]. Despite the prevalence, effective treatments are limited to surgical procedures, with anecdotal evidence for conservative measures. No studies have been conducted to assess the effectiveness of Bunion Bootie® in relieving HAV discomfort and pain in participants with flexible HAV.

The first aim of this study was to evaluate the immediate effects of wearing Bunion Bootie® by comparing smartphone measurements of HAA with and without Bunion Bootie® on HAV participants. A significant decrease in mean of HAA by smartphone measurement ($10.656^{\circ} \pm 4.300^{\circ}$) was observed when wearing Bunion Bootie®, as compared to HAA measurements without Bunion Bootie®. This finding supports our hypothesis as we predicted that wearing the Bunion Bootie® would reduce the HAA measured on HAV participants. The reduction in HAA demonstrates that Bunion Bootie® did temporarily correct/re-align the big toe, moving it closer to its normal position. Tehraninasr *et al.* revealed that usage of night splints failed to produce any significant improvement in HAA[36]. A recent study conducted in June 2016, evaluated the effect of a dynamic night-splint, a comparable product to Bunion Bootie®, 70 participants reported that the splint only aided in reducing the pain level but did not influence the deformity[42]. Although both aim to have the same effect, that is re-aligning the 1st MTPJ with an aim to relieve bunion pain, Bunion Bootie® is more advantageous than night or dynamic splits as it can not only be worn quickly but also comfortably and discreetly fit in most shoes due to its soft, thin flexible material[37]. Furthermore, the Bunion Bootie® may be worn during the day and at night. Whilst the exact aetiology of HAV is unknown, weight bearing activities combined with inappropriate footwear is a contributing factor of

HAV. Therefore, a bunion splint such as Bunion Bootie®, which can be worn during weight bearing activities, may halt the development of the deformity.

Several previous studies have validated that digital measurements to be of equivalent or improved reliability to the traditional goniometer technique[46]. A study by Meng *et al.* comparing 20 HAA measurements from a smartphone and protractor reported that both methods have equivalent accuracy with an intra-observer variability of ±3.1° and ±3.2° and inter-observer variability of ±9.1° and ±9.6°, respectively[26]. Likewise, our study also displayed concordance with findings from previous studies with no statistically significant difference between the measurements obtained from smartphone and manual measurements ($P>0.05$).

Results from our study are considered to be reliable due to great consistency of the HAA measurements within a single observer using both tractograph and smartphone as well as between two different observers manually. This was statistically supported by excellent inter-observer reliability (ICC of 0.992) and intra-observer reliability (90% identical repeated measurements performed by an observer). Despite the high inter- and intra-observer reliability from our study, these measurements were conducted by final year podiatry students and were not compared against experienced podiatrists.

Measurement of radiographic angles is the gold standard for assessing severity of deformity and to guide appropriate treatment decision[28,46]. However, radiographic measurement may not always be feasible. Garrow *et al*. reported that the Manchester scale demonstrated excellent inter-observer repeatability with a combined kappa-type statistic of 0.86, proving that it is a reliable grading method to be used[23]. Menz *et al*. also assessed the Manchester scale in 138 people and obtain equivalent results (Intra-observer reliability weighted kappa of 0.78 to 0.90)[24]. This indicates that the Manchester scale can be used with confidence to

document the severity and incidence of HAV. Nevertheless, obtaining radiographs to grade HAV is still the standard protocol prior to surgery or diagnostic assessment. Therefore, it should be adhered to when possible. Especially, if looking into operative treatment as the Manchester scale, while it provides a useful overall indicator of the degree of angular deformity associated with HAV, it does not take into consideration of other factors like sesamoid displacement or degree of joint degeneration, which may be of equal or greater clinical importance in relation to the functional impact of the condition.

The second aim of this study was to assess the pain experienced from HAV before and after wearing Bunion Bootie® for one week. The manufacturer of Bunion Bootie® has claimed to help relieve HAV discomfort and pain by temporarily correcting or improving the alignment of the big toe by separating it from the other toes[37]. Our findings supported the statement claimed by Bunion Bootie®. The feedback received from our participants for the question, "On a scale of 1-10, how has Bunion Bootie® affect your bunion pain? 0 - pain resolved and 10 - pain worsened" showed a median of 4/10 after a week of wearing Bunion Bootie®, illustrating that most participants noticed an improvement in their HAV pain. For the next question, "On a scale of 1-10, how likely are you to continue wearing Bunion Bootie® in the future?", we received a median score of 8/10 which demonstrates that most of our participants are keen to continue wearing Bunion Bootie® in the future. These results are in agreement with du Plessis *et al.* as they showed statistically significant reduction in pain and disability with MMT and night splint[33]. Plaaß *et al.* reported significantly less pain in the dynamic splinting group when compared to controls[42]. A randomised clinical trial by Bek and Kurklu comparing 3 different conservative treatments showed pain relief was achieved after 3-months of night splints and mobilizations techniques but not for toe separators[43]. In contrast, Tehraninasr *et al.* reported significant reduction in pain intensity for the group that received insole and toe separator, but no significant reduction in pain for the night splint group after

3-months[36]. Hence it is clear that there has been mixed results in the literature and our finding on pain in HAV participants significantly contributes to the lack of evidence available for conservative treatments of HAV.

In addition to addressing the second aim, the feedback form also collected additional information on participants' experience after wearing the Bunion Bootie®. A total of 88% and 62% of participants agreed/strongly agreed that Bunion Bootie® was comfortable to wear and that it has helped to reduce the bunion pain, respectively (data shown in figure 7). 88% and 91% of the participants disagreed/strongly disagreed that Bunion Bootie® was difficult to physically fit into most of the shoes and prevented them from doing normal physical activities, respectively. Mixed responses were received from the open-ended question as several minor complications were reported, such as blisters, pain and discomfort, numbness, burning pain and tingling of toes at night, pressure around the big toe and rubbing of lesser toes, pressure on toenail, and ingrown toenail. Several of these participants have other foot deformities such as pes planus, hammer toes, plantar fasciitis and Morton's neuroma that may have contributed to their complications. Positive comments received include reports of improvement in pain and comfort, easy to use, helped to reduce irritation in shoes, and a participant was able to wear shoes that they were not able to before. Few responses indicated that the product lost its elasticity after a short period of wear and that the straps occasionally slipped off. Most previous studies reported no serious adverse reactions or side effects with the use of night splints, MMT or toe separators, which are compatible with our findings[33,36,42]. du Plessis *et al.* noted that 2 participants in their study experienced temporary discomfort and/or stiffness from MMT, which were benign and quickly resolved[33]. Anecdotal reports from previous splint users generally involve minor pain and discomfort, especially during long-duration and night wear with no serious complications.

The final aim of this study was to investigate whether the change in HAA can be associated with participant's age, duration of pain and onset of HAV deformity. Albeit preliminary, this trial is the first to investigate these relationships. The data of listed predictors were collected for the analysis. Our findings indicated that there is a weak correlation between the change in HAA and the participant's age, duration of pain and HAV onset, which was demonstrated by a low correlation coefficient value ($R=0.487$, $R^2=0.238$). In other words, only 23.8% of the change in HAA after treatment period can be explained by participants' age, onset of HAV or duration of pain. Moreover, further multiple regression analysis was performed showing no linear relationship between the change in HAA and participants' age, HAV onset or duration of pain after treatment period ($P>0.05$). That is to say, none of the listed factors is a significant predictor for the change in HAA. The findings herein support the hypothesis of our study. Furthermore, in the literature, most of the previous studies regarding conservative treatments of HAV have recorded participants' age such as studies by Reina *et al.*, Karabicak *et al.*, Farzadi *et al.* and du Plessis *et al.*[33,35,44,45]. However, data about participants' duration of pain or HAV onset have not been collected. As a result, future definitive trials with detailed data of participants including duration of pain and onset of the HAV should be considered to test the correlation between HAA change or the effectiveness of the conservative treatments and relevant factors to confirm our findings.

Our study is the first to investigate the efficacy of Bunion Bootie® in reducing pain and HAA in participants with HAV. The before-after study design enabled us to observe the effects of our intervention within a certain timeframe, which is one week for this study. All participants were their own set of control and hence no control group was gathered. This, however, means that our study does not account for any confounding factors that may have affected our results. Our sample included a majority of females (88%) from a wide range of age (20-71 years) that varies in their onset and duration of pain. High prevalence of family history was reported for

our cohort of participants. There is a chance of selection bias in our sample as majority of the participants were recruited through the UWA Podiatry Clinic or through advertising within the university (UWA), with a few members of the general public recruited in our study. This indicates that our results may not be generalizable and does not represent the wider population. Even though all participants reported HAV pain, we did not take into account the severity of the pain and did not have a baseline pain level recorded. Future studies should take this into consideration.

Despite the relatively small sample size of thirty-two participants, our results were consistent. Several significant findings include a significant reduction in HAA with Bunion Bootie® ($P<0.05$), no significant differences between the measurements obtained using a smartphone app and manual measurements ($P>0.05$), and overall positive feedback on pain with minor complications experienced by participants. Although excellent inter- and intra-observer reliability were also obtained, the measurements were performed by final year podiatry students and not experienced podiatrists. This indicates that the data collected is reproducible, even though the accuracy remains questionable due to the lack of training and experience of the students. A study comparing Doppler ultrasound interpretation of students and registered podiatrists have shown no statistically significant difference between the overall abilities of student podiatrists and registered podiatrists[47]. As Doppler measurements are significantly more complex and technician-dependent when compared to manual tractograph measurements, it is likely that student measurements are comparable to those of experienced podiatrist. Further, studies may be conducted to compare the abilities of students and registered podiatrists for manual measurements. In terms of validity of our findings, no statistically significant difference was achieved between smartphone measurements and manual measurements (established reference standard). Additionally, another study by Srivastava *et al*. in 2010 revealed that manual measurement of HAA is more prone to errors

and that computer-assisted method were more time efficient and reliable with lower error of measurements[28]. This demonstrates the potential of the smartphone app, “Knee Registry” for clinical use in HAV diagnosis for grading severity and in deciding treatment options without exposing participants to unnecessary radiation, which saves time and reduce cost.

5. Conclusion

In summary, albeit preliminary, our data lends supports to the proposition that Bunion Bootie® is effective in reducing the pain and HAA in participants with flexible HAV. Moreover, “Knee Registry” smartphone application seems to be a reliable method replacing traditional manual tractograph to measure the HAA. Future randomised controlled studies with bigger sample size and longer follow up could be considered to firmly establish the benefits of Bunion Bootie® and the application of smartphone measurement which would be vastly helpful for clinical and research purposes.

6. Conflict of interest

The authors declare no conflict of interest.

7. Funding

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Appendices

Appendix 1: Ethics application and the response to queries

Our Ref: RA/4/1/8265

12th July 2016

Dr CaiXia Li

Manager, Human Ethics

Dear Dr Li,

Human Research Ethics Application – Response to modifications per request

Effects of Bunion Bootie® on Hallux Abductus Angle in participants with flexible Hallux Abducto Valgus: A prospective study

Supervisor: Associate Professor Jennifer Bryant

Student(s): Nur Farhanah Ho binte Muhammad Firdaus Ho, Trang Le Thu Nguyen, Shen Rui Yap, Weng-Jern Leong

1. **Is there any previous research regarding the Bunion Bootie? If so, please provide a summary. If not, please outline the literature search strategy used to confirm that there is no previous research. There is no previous research regarding the Bunion Bootie.**

   A search of the following databases with key-words "Bunion+Bootie" showed no previously conducted scientific studies and no journal articles citing or investigating Bunion Bootie®; UWA One Search, google scholar, MEDLINE, PubMed, Cochrane Library, AUSThealth.

2. **The Committee is of the view that this is not a controlled study but is a before - after study, which is regarded as the weakest level of evidence for a medical intervention. In this design each patient serves as their own control but there is no capacity in the design to control for temporal confounding (i.e. the natural history of the disease may be responsible for any change over time). Please revise the application form to categorise the study as a before - after study. Please provide a commitment to the Committee that any presentation or publication will emphasise that a before - after study is not a controlled trial and that the results have only low levels of validity. It is not the role of the Committee to make recommendations regarding study design but was there a reason why a controlled trial was not chosen as the study design? Is it feasible to recruit patients with bilateral HAV and then randomise the foot to which the Bunion Bootie is applied?**

   A before-after research design was chosen to investigate the change in Hallux Abductus Angle (HAA) from wearing an intervention (Bunion Bootie®) and its effect on HAV pain in participants with Hallux Abductus Valgus (HAV). The before-after study design is not a controlled trial and hence, no control group will be gathered for the study due to time constraints of the student project (around 1 month is allowed for participant recruitment) and it is not feasible due to the likelihood of a small sample size. Each participant will serve as their own control and it is understood that the results have only low levels of validity with no capacity to control for temporal confounding. For participants with bilateral HAV, treatment will be applied for only one HAV foot to allow for the participants to compare the effects of HAV pain of one foot to the other. There is a specific question for participants with bilateral HAV (Please refer to Participant Feedback Form – Appendix 5).

3. **Is the Bunion Bootie regarded as a medical device? Is it (or should it be) registered by the Therapeutic Goods Administration? Do the manufacturers make any claim as to the medical effectiveness of the device?**

   A search of the Australian Register of Therapeutic Goods revealed that there is no approval for the medical product Bunion Bootie®. It is a product from the United States that is registered with the United States Food and Drug Administration and can be bought by Australians through the company website. It is not on the shelves or distributed by any particular distributors in the Australian market. This is a thin, light, soft and easily removable product. It is therefore, a very low risk intervention. Although there are a number of similar splint products available in Australia, none appeared to have Therapeutic Goods Administration approval.

4. **At session 2, should photos with and without wearing the bootie be taken, so as to allow comparison with the same set of photos that are taken at baseline.**

   Due to the time constraints of this student project, our study has been modified to measure the immediate change in HAA for before and after wearing the Bunion Bootie® in HAV participants, instead of the original plan of measuring the change in HAA before and after wearing the Bunion Bootie® for 6 weeks. Participants will only attend one session for photographs of the HAV foot to be taken with and without wearing the Bunion Bootie®. Therefore, a comparison will be made between the two photographs taken during that session.

5. **Please provide a justification of the sample size. It may be sufficient to indicate that this is a pilot study because there is no prior information about a plausible effect size to allow a power calculation, and that the purpose of this study is to obtain such information as well as evaluate study methods and feasibility. Please also consider**

whether the sample size is sufficient to evaluate factors associated with 'response'? If not, please remove this component from the proposal.

A small sample size of approximately 20-25 participants are expected as this is a pilot study conducted with the aim of gathering information on study methods and feasibility for performing future studies on this novel intervention. As there are no prior studies conducted on this intervention, we are unable to obtain a plausible effect size to allow for power calculation.

6. **Please provide a justification for why a 6 week period of intervention is regarded as an appropriate timeframe in which to evaluate the device.**

   The study is no longer utilising a 6-week period as a timeframe to evaluate the device. A 1-week period will be used instead to evaluate the effect of Bunion Bootie® on HAV pain of the participants, while immediate measurements will be performed on the HAV foot before and after wearing the Bunion Bootie® to obtain the change in HAA. This modification in our study is due to the time constraints of the student project. A 1-week period is deemed to be sufficient to observe any immediate change in pain experienced by the participants.

7. **What treatment will be provided to patients who decline to participate in the trial? Will this treatment be provided to trial participants (i.e.testing standard care plus the Bunion Bootie)? The PIF needs to explain the level of the standard of care provided, and state whether this will be provided to all trial participants. If the same standard of care is provided to all participants, how will researchers know if any changes are due to the standard of care or the device?**

The only current proven and definitive treatment option for HAV is surgery. Surgery is reserved for severe cases including intolerable pain and disabling deformity. Participants who present with severe HAV will be referred to a podiatric surgeon for specialist advice.

Participants selected for this study will have mild to moderate HAV. Participants with mild to moderate HAV are best monitored to determine if the deformity will stabilise or deteriorate. HAV is a progressive deformity which does not spontaneously resolve. Therefore, the HAV condition will not improve. Since HAV is a condition that will not spontaneously resolve and because the "standard of care" is to monitor the HAV condition, the committee can be assured that any change in HAA and/or pain will be solely due to wearing of the Bunion Bootie®.

All participants who decline to participate in this study will be "treated" by monitoring the progression of their HAV and to contact the UWA podiatry clinic if concerns arise or their HAV worsens. Furthermore, this will be explained to participants in the PIF (Please refer to Appendix 4).

8. **Will participants be able to retain the Bunion Bootie at the end of the 6 week study period? This should be explained in the PIF (either way).**

   Participants will be able to retain the Bunion Bootie® at the end of the 1-week study period. PIF has been revised to reflect this and to inform participants that they will be able to retain the Bunion Bootie®.

9. **Q18. The use of a Likert scale is not a qualitative method and the answer to this question should be revised to No.**

   Q18. The answer to this question has been revised to NO.

10. **Q33. Suggest revising answer to No (unless indigenous participants are a specific focus of the study).**

Q33. The answer to this question has been revised to NO as indigenous participants are not a specific focus of this study.

11. If Bunion Booties are being provided by the company, is there a contract between UWA and the Company? If so, please provide a copy. If not, can the Committee be reassured that there is no conflict of interest with any investigator and the company and that there is no restrictions placed on the investigators by the company, particularly in relation to publication and presentation of results.

There is no contract between UWA and the Bunion Bootie® Company. The Committee can be assured that there is no conflict of interest with any investigator and the company and that there is no restrictions placed on the investigators by the company, particularly in relation to publication and presentation of results. When the investigators informed the Bunion Bootie® Company of our research, the company was willing to supply us with 10 pieces of the product. However, this does not pose any conflict of interest between UWA and the Bunion Bootie® Company and any investigator and the Bunion Bootie® Company.

12. **The PIF may benefit from some element of restructuring. The committee suggests:**

13. a). That the purpose of the research, to compare outcomes at the start of the study with findings after the participant has worn the Bunion Bootie for 6 weeks, is explained at the beginning of the PIF.

14. b). The categorisation of the study into parts A and B doesn't particularly seem to make sense and should be revised. What is essential is that the participants know that they will be asked to wear the device for six weeks, the measurements (and how

long they will take) at the start of the study, and the measurements (and how long they will take) at the end of the study, 6 weeks later.

The PIF has been revised to:

a) The purpose of the research, to compare outcomes at the start of the study with findings after the participants has worn the Bunion Bootie® for 1 week, has been explained at the beginning of the PIF.

b) Participants know that they will be asked to wear the device for 1 week to evaluate the effect of Bunion Bootie® on HAV pain and the HAV angle will be measured with and without wearing the device at the start of the study (which will take about 10-15 minutes).

Please refer to the PIF (Appendix 4).

15. Consent Form: is it possible to participate without photos (or the feedback form) being taken (the Committee's understanding is that agreement to be photographed is a mandatory requirement). If photos are mandatory please remove the tick box from the Consent Form and replace with a statement that relates to photographs of feet being collected.

Consent Form: The tick box from the Participant Consent Form has been removed. Statements related to data collection including obtaining photographs of participants' feet, has been added.

Please refer to the Participant Consent Form (Appendix 2)

16. The advertisement must be revised as it makes an assertion for which it appears that the aim of the research is designed to test. If it is already known that the device improves angle, then what is the purpose of this study?

The advertisement has been revised without assertion that the aim of the research is designed to test. Please refer to the flyer/advertisement (Appendix 6).

17. **The feedback from reads more like marketing information than a scientific evaluation of the effect of the intervention. Questions related to "how likely are you to recommend or did it meet your expectation" should be deleted. Questions should focus on participant experiences related to their symptoms, not their expectations nor their recommendations. In Question 3, the phrasing of the stems should be adjusted so that there is a balanced mixture of positive and negatively asserted phrases.**

The participant feedback form has been revised as follow:

- Questions related to "how likely are you to recommend or did it meet your expectation" has been deleted and replaced to, "On a scale of 1-10, how has Bunion Bootie® affect your bunion pain?" and "On a scale of 1-10, how likely are you to continue wearing Bunion Bootie® in the future?". These questions now focus on participants' experiences relating to their symptoms, not their expectations nor their recommendations.
- In Question 3, the phrasing of the stems have been adjusted so that there is a balanced mixture of positively and negatively asserted phrases.

Please refer to Appendix 5.

Appendix 2: Participant consent form

The University of Western Australia
Cnr Park and Crawley Avenues
UWA Podiatry Clinic
M422, 35 Stirling Highway,
Crawley, Perth Western Australia 6009
Email: clinic-podiatry@uwa.edu.au
Ph: (08) 6488 4522

Participant Consent Form

Project Title: Effects of Bunion Bootie® on Hallux Abductus Angle and pain in participants with flexible Hallux Abducto Valgus (bunion): A prospective study

Thank you for volunteering to participate in this study investigating the immediate effect of Bunion Bootie® on the Hallux Abductus Angle (angle of the deviated position of the big toe toward the second toe) and completing a questionnaire after wearing the Bunion Bootie® for 1 week.

I_____(full name) (the participant) have read the information provided and any questions I have asked have been answered to my satisfaction. I agree to participate in this study, realising that I may withdraw at any time without reason and without prejudice.

I understand that all identifiable (attributable) information that I provide is treated as strictly confidential and will not be released by the investigator in any form that may identify me. The only exception to this principle of confidentiality is if documents are required by law.

I have been advised as to what data is being collected (including photographs of my feet), the purpose for collecting the data, and what will be done with the data upon completion of the research.

I agree that research data gathered for the study may be published provided my name or other identifying information is not used.

I understand that I may withdraw my consent to participate at any time without reason or prejudice and that my record of participation will be destroyed, unless otherwise agreed.

_____ _____

Signature of Participant Date

_____

Contact details (mobile phone number preferred)

Approval to conduct this research has been provided by The University of Western Australia, in accordance with its ethics review and approval procedures. Any person considering participation in this research project, or agreeing to participate, may raise any questions or issues with the researchers at any time (see information sheet for contact details) In addition, any person not satisfied with the response of researchers may raise ethics issues or concerns, and may make any complaints about this research project by contacting the Human Research Ethics Office at The University of Western Australia on (08) 6488 3703 or by emailing to humanethics@uwa.edu.au

All research participants are entitled to retain a copy of any Participant Information Form and/or Participant Consent Form relating to this research project.

Appendix 3: Data collection form

DATA COLLECTION FORM

Date of assessment:_____

Participant #:_____ Genie ID: _____

Date of birth:_____ Date of clinical presentation: _____

Variables	Participant's information	Additional Comments
Age		
Gender		
Onset of HAV		
Duration of pain of HAV		
Previous treatment or foot surgery		
Other deformities/ medical history		
Family History (Y/N)		
Footwear		
Pain (Y/N)		

Appendix 4: Participant information form

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Achieve International Excellence

The University of Western Australia
Cnr Park and Crawley Avenues
UWA Podiatry Clinic
M422, 35 Stirling Highway,
Crawley, Perth Western Australia 6009
Email: clinic-podiatry@uwa.edu.au
Ph: (08) 6488 4522

Participant Information Form

Project Title: Effects of Bunion Bootie® on Hallux Abductus Angle and pain in participants with flexible Hallux Abducto Valgus (bunion): A prospective study

Investigators: Nur Farhanah Ho Binte Muhammad Firdaus Ho (UWA, DPM Student)
Trang Le Thu Nguyen (UWA, DPM Student)
Shen Rui Yap (UWA, DPM Student)
Weng-Jern Leong (UWA, DPM Student)

Research Supervisor: Associate Professor Jennifer Bryant

The purpose of this study is to investigate the change in Hallux Abductus Angle (HAA) from wearing an intervention (Bunion Bootie®) and its effect on pain in participants with Hallux Abducto Valgus (HAV) after 1 week of treatment. You have been identified as a suitable participant as you meet the inclusion criteria.

If you agree to participate in this study, you will be required to attend one session conducted by the investigators for HAA to be measured on the HAV foot with and without wearing the Bunion Bootie®. **Photographs** of your affected foot will be taken using the Knee Registry smartphone application when you are standing. Bunion Bootie® will be provided and you will be expected to wear it every day for as much as possible in a period of 1 week. The Bunion Bootie® may be worn with or without shoes.

You will also be given a **feedback form** on the same day. After a week, you will need to complete and mail it back to us with the given prepaid envelope. Participants are given the Bunion Bootie® free of charge and you are not required to return it to the investigators.

The Bunion Bootie® should feel snug, but not uncomfortable when worn. Please discontinue wearing the Bunion Bootie® and contact the UWA Podiatry Clinic if you begin to experience the following symptoms after Bunion Bootie® is worn on the affected foot:

- Pain
- Tingling
- Discomfort
- Itchiness
- Numbness
- Discoloration of skin

If you become newly diagnosed with the following conditions, please contact the UWA Podiatry Clinic as you may be excluded from the study for your own safety:

- Diabetes / Charcot neuroarthropathy
- Peripheral arterial disease
- Peripheral neuropathy
- Joint arthritis of the big toe joint and the foot
- Neuromuscular disease
- Foot surgery of any form
- Allergy to nylon and/or polyurethane
- Fungal nail infection of the big toe
- Ingrown toenail of the big toe

All information is strictly confidential, and the feedback form data will be anonymous. No individual responses or the status of your consent to participate will be made available. All hard copy and electronic data will be securely stored at the UWA Podiatry Clinic to maintain confidentiality.

Participation is voluntary. No direct benefit may be obtained by you from participation in this research study. However, it is hoped that your experience with Bunion Bootie® will provide you with a better understanding of HAV and the different types of conservative treatments available. The results of this study may act as a catalyst for changes and potential development for more effective conservative treatment for Bunion.

You have the right to withdraw your consent to participate at any time during the research. You may withdraw at any time without reason and without prejudice. If you are willing to consent to participate in this study, please complete the attached consent form.

Approval to conduct this research has been provided by the University of Western Australia with reference number RA/4/1/8265, in accordance with its ethics review and approval procedures. Any person considering participation in this research project, or agreeing to participate, may raise any questions or issues with the researchers at any time. In addition, any person not satisfied with the response of researchers may raise ethics issues or concerns, and may make any complaints about this research project by contacting the Human Ethics office at UWA on (08) 6488 4703 or by emailing to humanethics@uwa.edu.au. All research participants are entitled to retain a copy of any Participant Information Form and/or Participant Consent Form relating to this research project.

Appendix 5: Participant feedback form

PARTICIPANT FEEDBACK FORM: Effects of Bunion Bootie® on Hallux Abductus Angle and Pain in participants with flexible Hallux Abducto Valgus (bunion): A prospective study

Participant Name (please print):

Thank you for your participation in the Bunion Bootie® research project! We would greatly appreciate your feedback at the end of the 1 week trail on the Bunion Bootie® treatment. Please complete the questionnaire below and return via mail in the prepaid envelope to the UWA Podiatry Clinic.

1. On a scale of 1-10, how has Bunion Bootie® affect your bunion pain? (Please circle the number that best fits your response)

0 1 2 3 4 5 6 7 8 9 10

Pain resolved Pain worsened

---

2. On a scale of 1-10, how likely are you to continue wearing Bunion Bootie® in the future? (Please circle the number that best fits your response)

0 1 2 3 4 5 6 7 8 9 10

Highly unlikely Highly likely

---

3. Please tick the following column that best describes your response to Bunion Bootie®.

Opinions	Strongly Agree	Agree	Unsure	Disagree	Strongly Disagree
It is comfortable to use the Bunion Bootie® during the treatment period					
Bunion Bootie® helps to reduce the bunion pain					
Bunion Bootie® is difficult to fit in most of the shoes					
Bunion Bootie® prevents me from doing my normal physical activities					
My foot looks more normal and I feel more confident					
Bunion Bootie® does not give me extra support for my foot					
Answer if applicable (bunion present in both feet): Bunion Bootie® made my foot less painful than the other foot.					

4. Besides the points raised above, what do you think of Bunion Bootie®?

_____

_____

_____

Appendix 6: Flyer/Advertisement