Good Feet Variable Arch System for the Treatment of Common Foot Ailments

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MGH 1811

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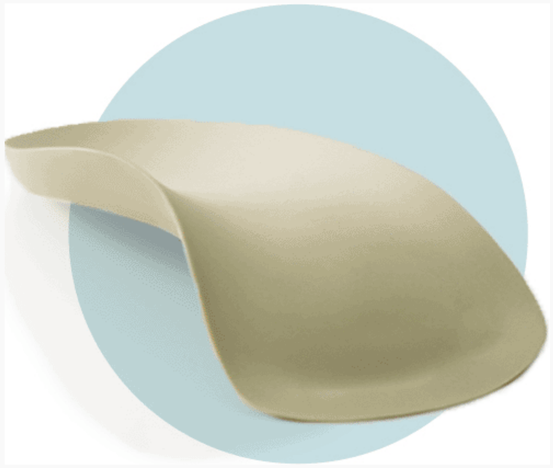
The Good Feet Store®
America's Arch Support Experts

Disclosures

- Dr. Adam Landsman is the **Principal Investigator** of this study.
- Dr. Pamela Mehta is the **Chief Medical Officer** of The Good Feet Store.
- Massachusetts General Hospital and the Department of Orthopedics received financial support from Dr's Own, Inc. for this study to **offset salaries of research fellows and the actual costs of research**. MGH does not support the salaries of **Clinical Investigators**.

Introduction (1 of 2)

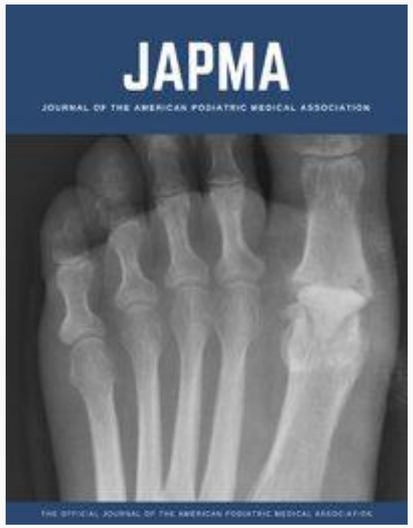
- Good Feet Arch Supports are based on **original Alzner patented designs of the 1960s**.
- Alzner suggested that an arch support in the shape of a normal, healthy foot could help the “misaligned troubled foot” by **supporting the foundation of the foot to allow the foot to copy the neutral foundation**.
- By providing the neutral foundation, the arch support would **realign the bones, muscles, ligaments and tendons** while allowing a flexing action to massage and strengthen the muscles in the foot.

Introduction (2 of 2)

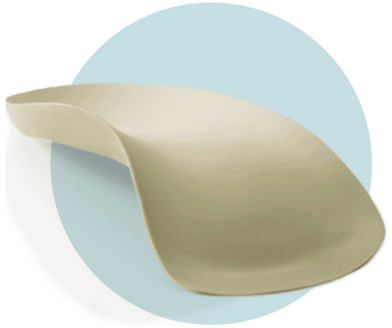
- **2008**: First study with Good Feet to examine the efficacy of an OTC arch support for the **treatment of common foot ailments**.
- Study conducted at the **Weil Foot & Ankle Institute** in Chicago.

***Landsman A**, DeFronzo DJ, Anderson J, Roukis, TS; A Scientific Assessment of Over-the-Counter Foot Orthoses to Determine their Effect on Pain, Balance, and Foot Deformities, J Am Podiatr Med Assoc, 2009 May-Jun 99(3):206-15.*



- **2022**: Good Feet commissions a new study to explore a variation on the Alzner principal of creating a normal foot bed which **allows the misaligned foot to realign itself using a 3-Step Variable Arch System**.

3-Step Variable Arch System

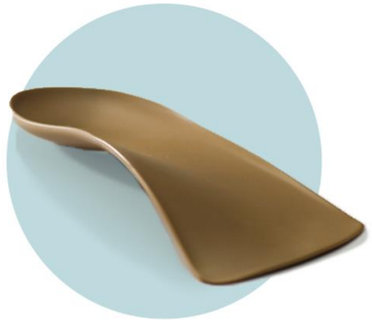


Strengthener

- Reposition and strengthen foot
- Most aggressive support

Maintainer

- Holds foot in optimal position
- Based on Alzner design
- “Tried and true” shape based on 20+ years of refinement



Relaxer

- Allows the foot to rest by providing more gentle support

Study Design

- Prospective trial to examine patients with common foot ailments to better understand their **response to Good Feet 3-Step Arch Support System**.
- **Structural** (qualitative), **subjective**, and **objective analysis**.
- **50 subjects**.
- **Personalized fit** (400+ different styles and sizes) by experienced personnel and used with Brooks Ghost neutral running shoes.
- **Massachusetts General Hospital IRB reviewed and approved**.

Objectives

1. **Measure structural changes** that occur in the foot when wearing arch supports

2. Determine if there is a correlation with **foot position and overall stability**

3. Determine if there are **structural patterns** within the foot that correlate to foot ailments including plantar fasciitis, metatarsalgia, hallux valgus

4. Follow subjects with complaints of pain to determine **if their symptoms improve with 3-Step Arch Support System**

What Does It Take to Conduct This Study?

Initial Evaluation (Day 0)

- Informed consent and screening questions
- Fitting and dispensing shoes and insoles
- Weight-bearing CT with and without insoles
- Weight-bearing X-ray with and without insoles
- Balance test
- Validated questions and measurements
- Gait analysis
- Patient questions

Inclusion and Exclusion

Inclusion

- Men or women ≥ 18 & ≤ 65 years old
- Able and willing to comply with study procedures
- Signed and dated informed consent obtained
- Subjects diagnosed with hallux valgus and / or plantar fasciitis and / or metatarsalgia and associated pain
- Patient has foot pain for at least 30 days
- Willing and able to utilize insole and standardized shoe when walking for 90 days

Exclusion

- Gross asymmetry in feet, where shoe size differs by 2 or more full sizes for right and left foot
- Subject had CT performed within last 30 days for any body part
- Prior partial or total amputation of a foot
- Body weight >300 lbs.
- Unilateral or bilateral foot deformity that would hinder the fitting of OTC arch support, such as Charcot
- Ulcers or open sores on either foot
- Pregnancy

Physical Exam and Questionnaires

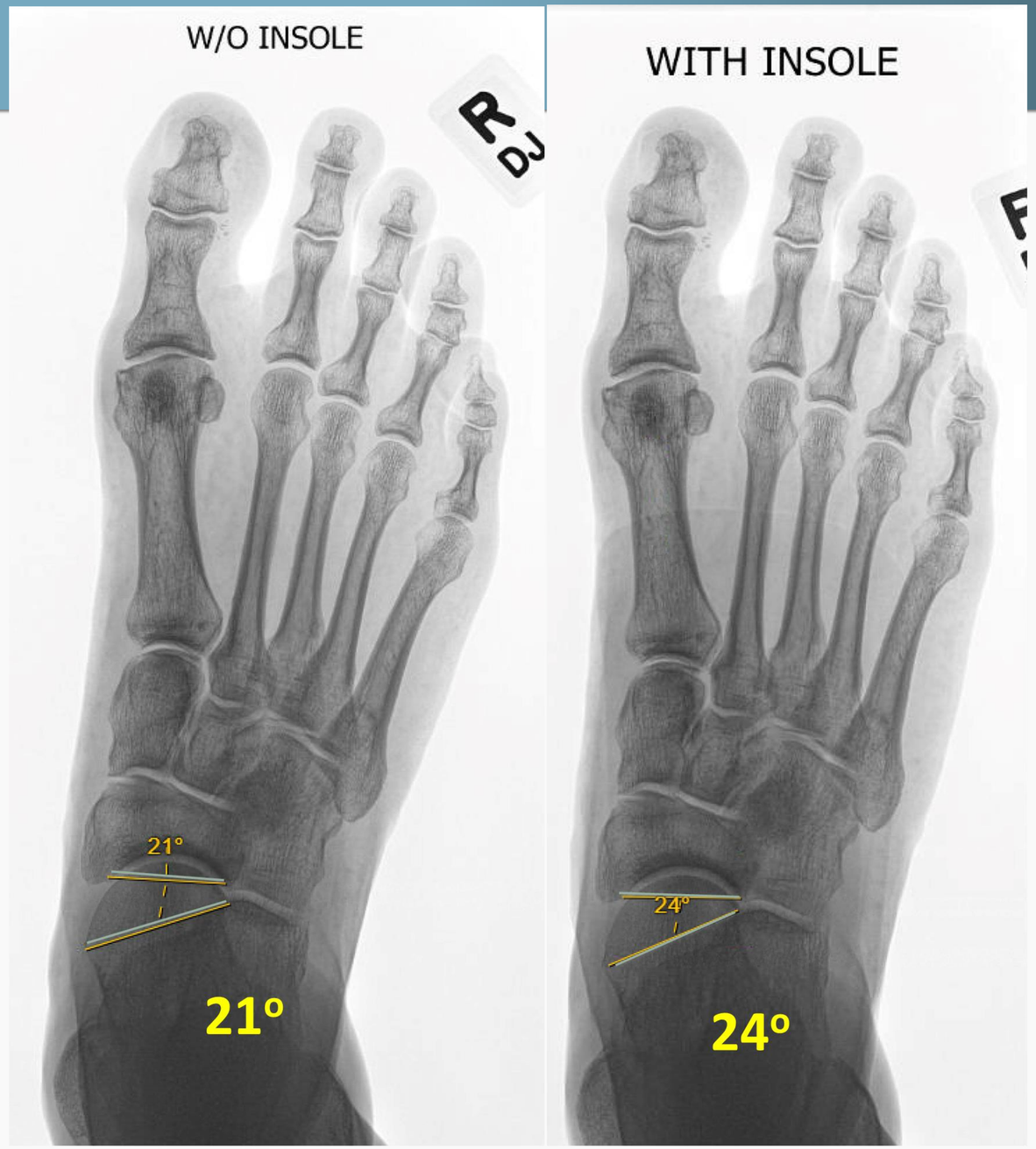
- **Physical exam** by DPM
- **Subjective validated questionnaires**
  - ACFAS Universal Foot Evaluation
  - Delphi Neuroma Scale
  - FAOS Outcome Score
  - PROMISS Pain Intensity
  - PROMISS Global Health Test
  - PROMISS Pain Interference Test
  - Basic Demography Form

The Kit (Day 0)

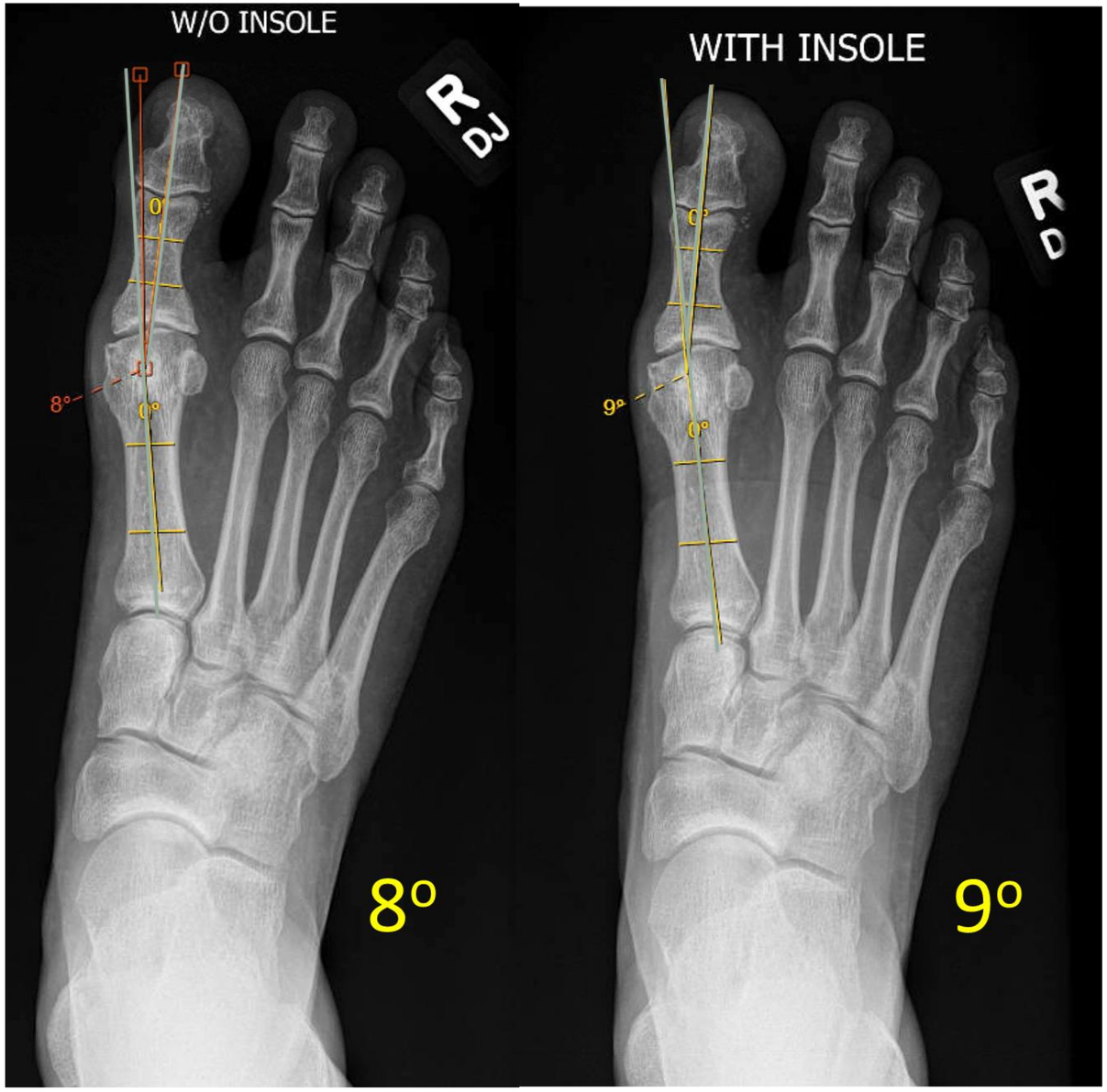
- Brooks Ghost Footwear
- Good Feet Strengthener
- Good Feet Maintainer
- Good Feet Relaxer
- Cushioned Cover
- Velcro “Dots”

X-Rays (Day 0)

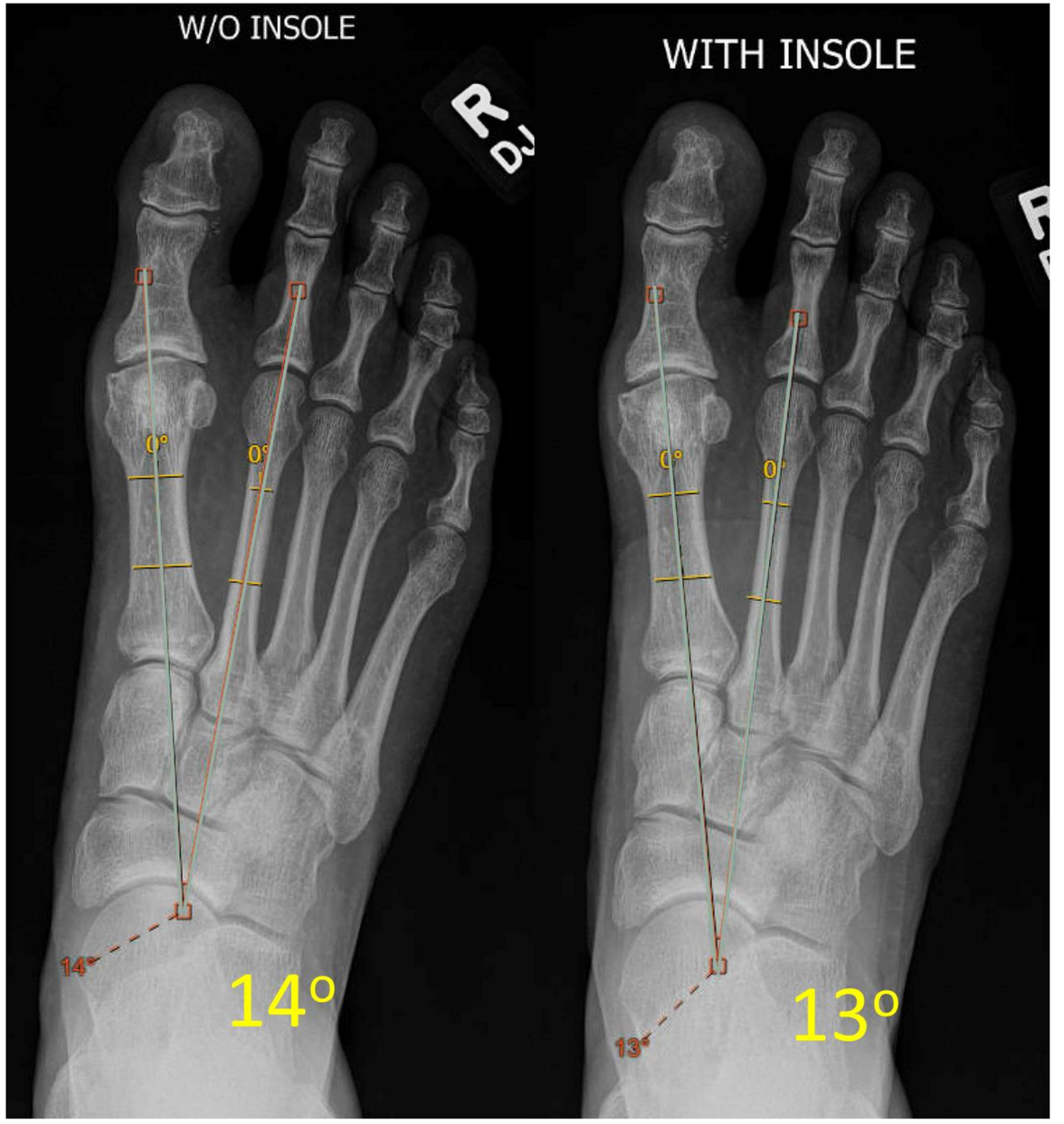
- With and without Maintainer insole
- AP and Lateral views
- Digital analysis
- Measurements include:
  - TSP
  - Hallux Abductus Angle
  - 1-2 Intermetatarsal angle
  - Talar declination angle
  - TN coverage angle
  - 1st metatarsal declination angle
  - Talar declination angle
  - Meary's angle



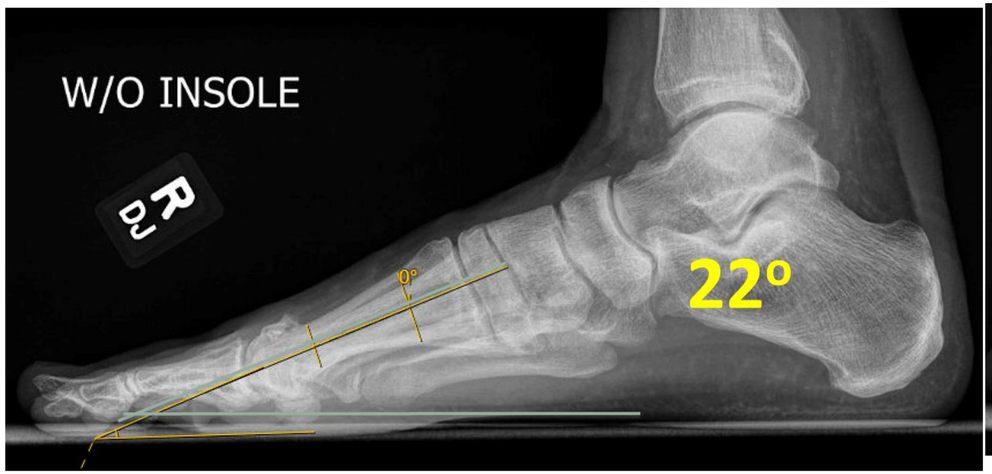
Talonavicular Coverage Angle



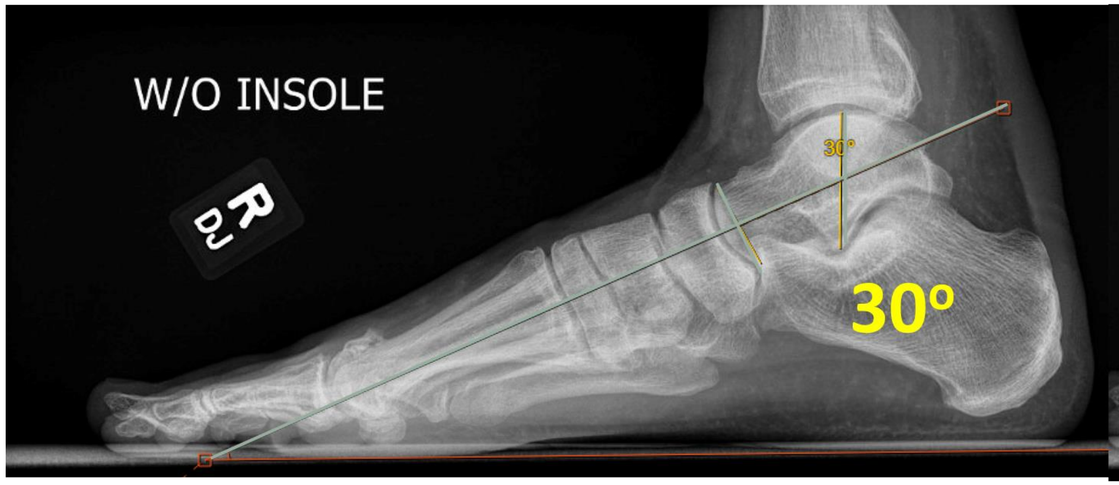
Hallux Abductus Angle



1-2 Intermetatarsal Angle



1st Met Declination Angle

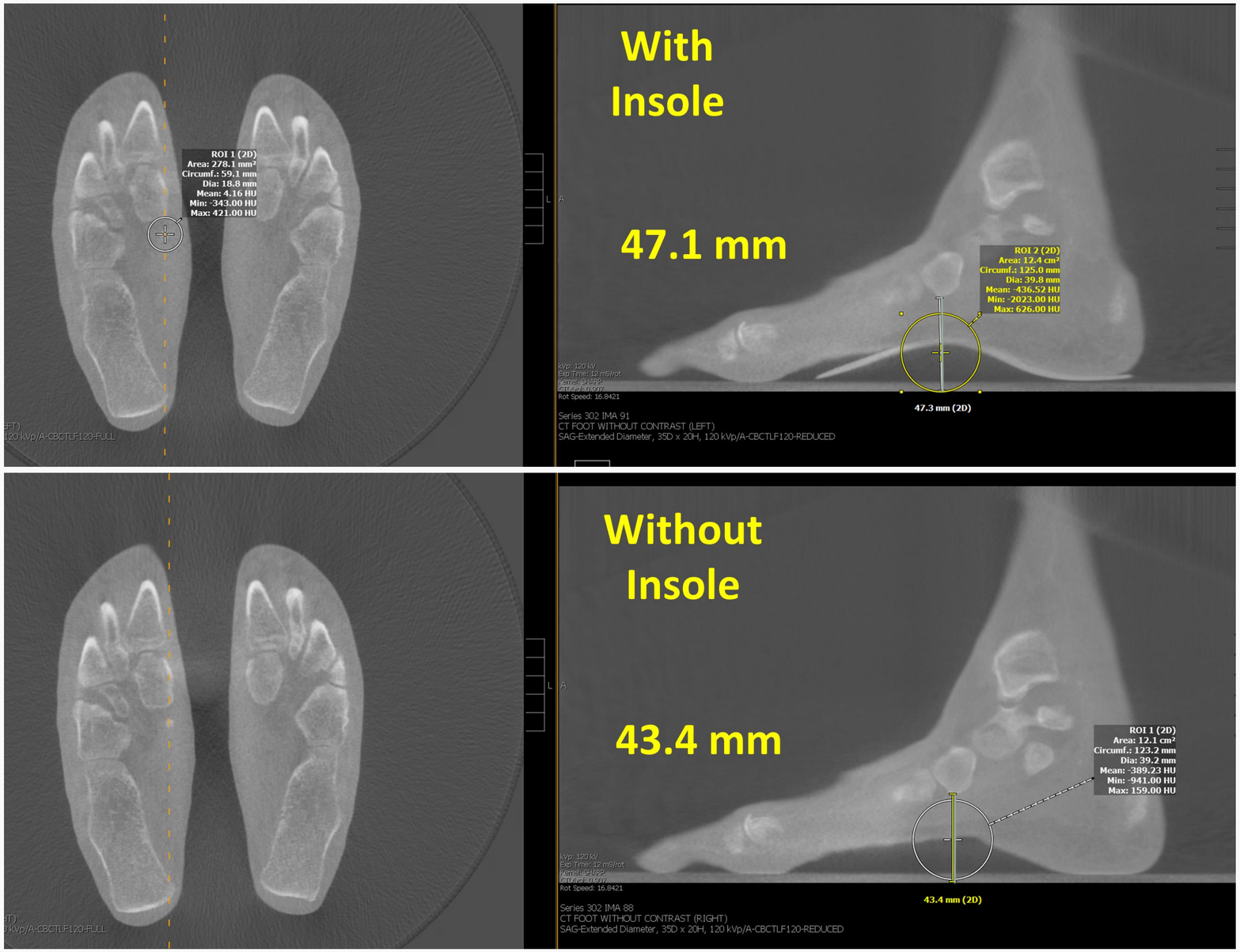


Talar Declination Angle

Weight Bearing CT scans

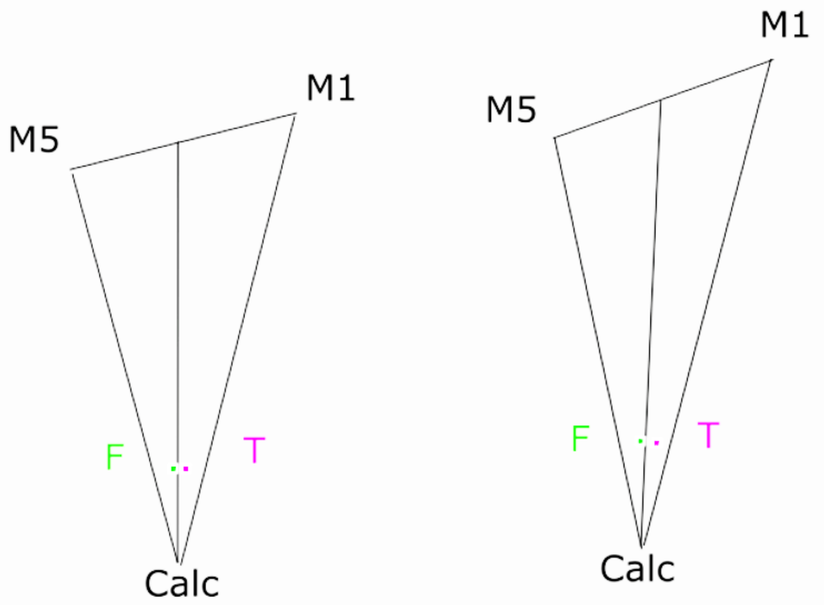
Weight Bearing CT scans for 3-D assessment of changes in foot position and alignment

- **Eliminates Parallax**
- **With and without arch support in place**



Weight-Bearing CT Scan Foot and Ankle Offset (FAO Index)

- **FAO Index** used to categorize foot type, and can be used to measure subtle changes in foot alignment
- Standardized markers to be used with WBCT scans



With Insole

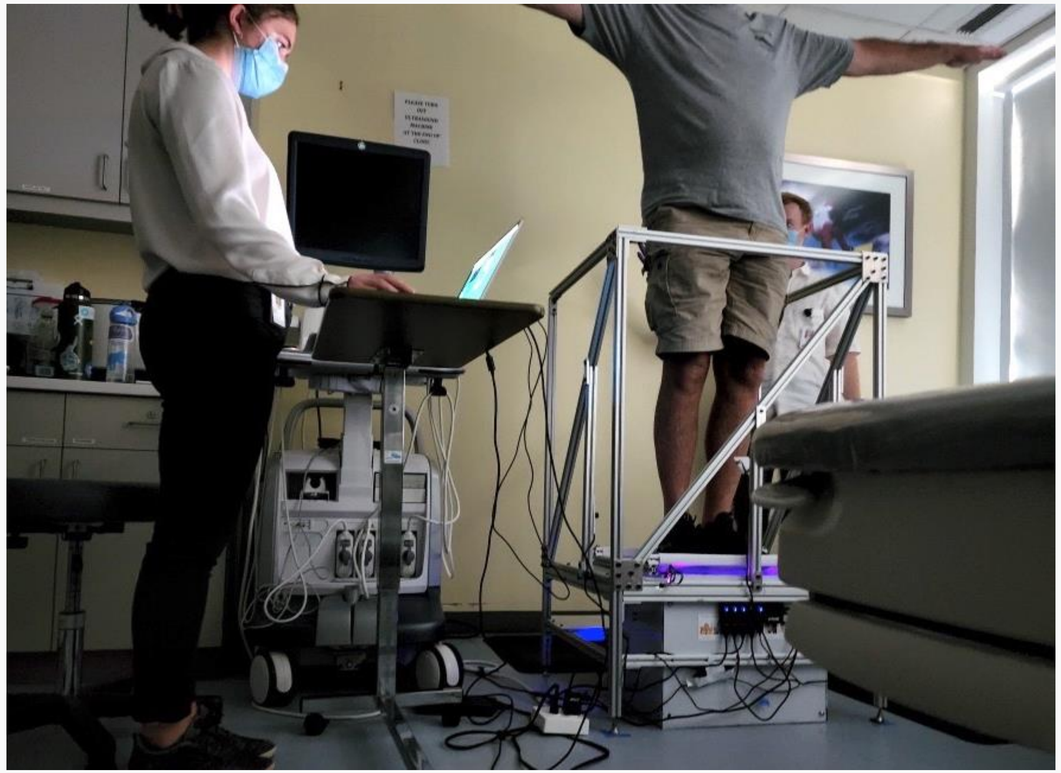
F T Distance=1 mm

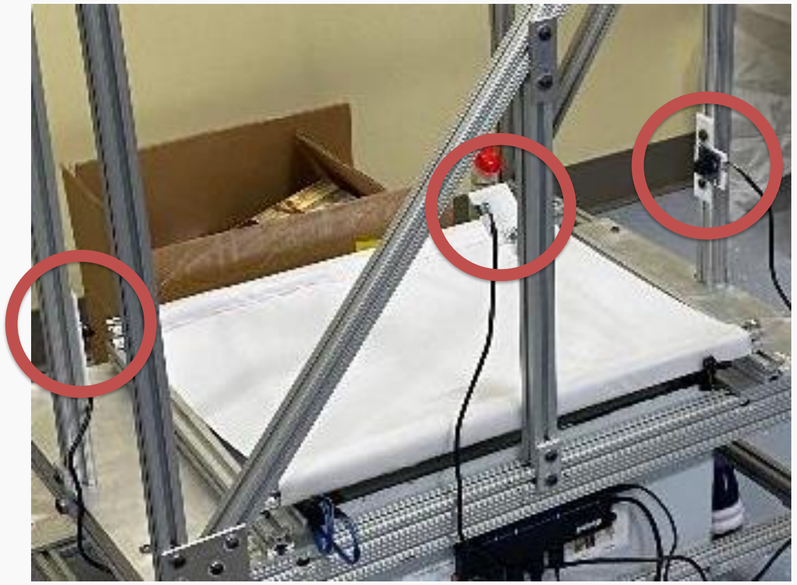
Without Insole

F T Distance=2 mm

Balance Measurement (a.k.a. Sway)

- **Custom-made instrumentation** by our research team
- Simultaneously photographs foot position and measures shifts in center of mass to accurately **determine stability and balance**
- Information is **highly reproducible**





- Platform with strain gauges
- Cameras to record foot position
- Sampled at 60Hz for 10 seconds

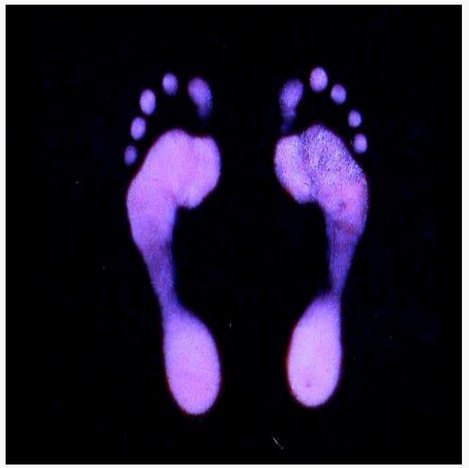
Balance Measurements

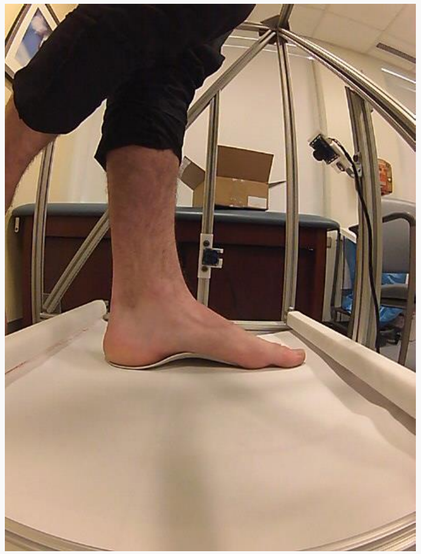
Measured in three conditions:

- Barefoot
- Shod without insoles
- Shod with insoles

Three poses:

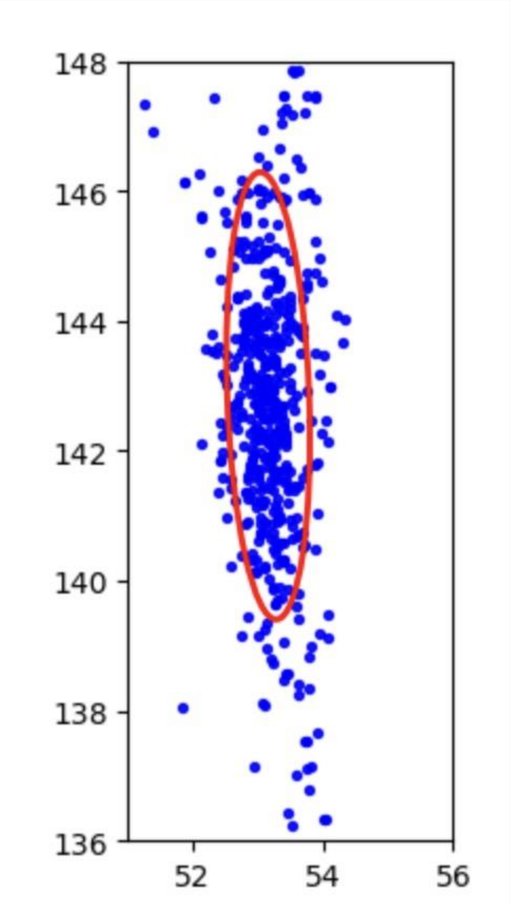
- Normal stance
- Romberg eyes open
- Romberg eyes closed

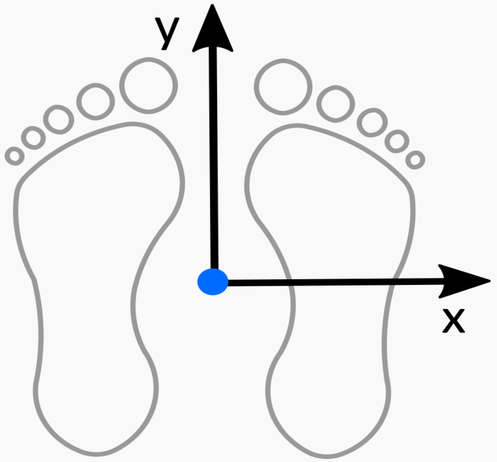




Analysis:

- **COP sway** calculated in medio-lateral and antero-posterior directions (mm)
- A **secondary analysis** done to:
  - Fit an ellipse to the data
  - Calculate the **ellipse area**
  - Calculate the **ellipse angle**
  - Total **path length**
- Comparisons made between different **poses and conditions**

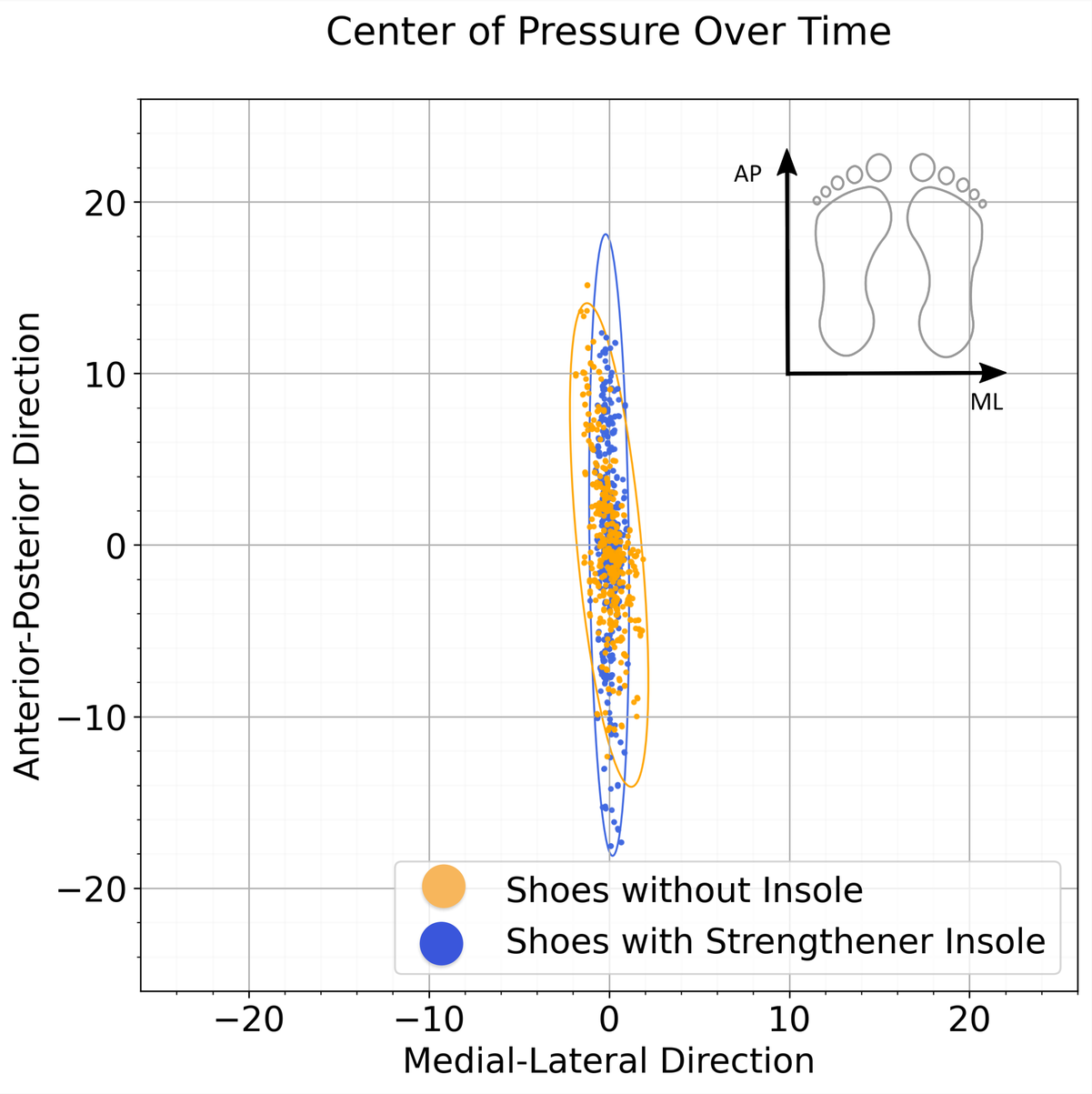





```
Centroid: (53.15594010197999, 142.8489282533992)
Ellipse Width: 6.888765955572204 Ellipse Height: 1.2608205913658304
Area of Ellipse: 6.8215741505986225
Total Path Length: 390.333641971732
Orientation Angle (in degrees): -87.88856263903119
```

Sway Scatter Graph

- **Data sampled at 60Hz for 10 seconds** (resolution 500Hz)
- **Best fit** with an ellipse and then calculate area as well as maximum medial / lateral, anterior / posterior excursion
- Order of testing with and without insoles is **randomized**
- **Test repeated** at each visit



Physical Exam, questionnaires, and sway measures are **repeated every month** (Day 30, 60, 90).

Weekly survey sent by email to gauge compliance of all participants.

Enrollment

- **Seeking 50 participants**
- **47** enrolled to date
- **43** have completed the study
- **3** dropped out due to
  - Back Pain
  - Broken Ankle (unrelated)
  - Discomfort

Preliminary Findings

Insole type	Duration used (days / week)
Strengthener	4.22
Maintainer	3.32
Relaxer	2.23

Strengthener usually cannot be tolerated full time during 1st month.
Most switch to Maintainer almost immediately.

Preliminary Findings and Data

- **Plantar Fasciitis (n=29)**
  - Statistically significant decrease in pain using validated PROMIS pain intensity score (p=0.039)
  - At 30 days most report **50% reduction in pain** including post static dyskinesia and focal pain intensity
  - At 90 days, most report **85% reduction in pain**

- **Metatarsalgia (n=14)**
  - Need more data for statistical significance with PROMIS pain intensity score
  - Trend shows **25% reduction in pain** at 30 days
  - Trend shows **40% reduction in pain** at 90 days

- **Sway and Balance data**
  - Patient-specific insoles **improve stability** when compared to shoe without insole condition

Preliminary Conclusions

- 3-Step Good Feet Arch System is successfully altering foot mechanics to **provide relief from plantar fasciitis and metatarsalgia, while improving balance and stability**

- **Our data also shows . . .**
  - **Overall decrease in pain in 82% of the cases**
  - Decreased **back pain**
  - Decreased **knee pain**
  - Decreased **neuroma pain**

Claims : DRAFTS NOT FOR USE

CLAIM 1

The 3-Step Good Feet Arch Supports Systems are successfully altering foot (architecture, shape, position) to provide relief from plantar fasciitis and metatarsalgia.

REASONS TO BELIEVE

Eliminate leading causes of foot pain with the Good Feet Arch Support System.	Reshape & re-position your foot to eliminate pain with Good Feet's Arch Supports' easy 3-Step System.	Stop heel & forefoot pain by reshaping & re-positioning your foot with Good Feet's Arch Support System.

Claims: DRAFTS NOT FOR USE

CLAIM 2

At 90 days, most patients with plantar fasciitis report a statistically significant reduction in pain.

REASONS TO BELIEVE

Reduce plantar fasciitis & heel pain in just 90 days with the Good Feet Arch Support System.	Walk pain-free in under 90 days.	Proven pain relief in just 90 days with the Good Feet Arch Support System.

Claims: DRAFTS NOT FOR USE

CLAIM 3

Our study shows a trend of approximately 40% reduction in metatarsalgia pain at 90 days.

REASONS TO BELIEVE

Reduce the pain in the ball of your foot by nearly 40% in just 90 days.	Join the thousands of Good Feet customers who saw a 40% decrease in foot pain in just 90 days.	Stop pain in the ball of your foot from slowing you down in under 90 days.

Claims : DRAFTS NOT FOR USE

CLAIM 4

The 3-Step Good Feet Arch Support Systems are successfully altering foot (architecture, shape, position) that showed improvement in balance and stability.

REASONS TO BELIEVE

Reshape your foot to experience better balance and stability with our 3-Step System.	Align your whole body and experience more balance and stability with your personalized Good Feet Arch Support System.	Get back your balance and stability with our easy 3-step Good Feet Arch Support System.

Claims: DRAFTS NOT FOR USE

CLAIM 5

Arch support insoles can bring about anatomical changes, especially in the forefoot area of patients with metatarsalgia.

REASONS TO BELIEVE

Reshape your feet and beat the pain in the ball of your foot for good with your personalized Good Feet Arch Support System.	Don't let the pain in the balls of your feet slow you down.	The Good Feet Arch Support System transforms your foot shape for relief that lasts.

Thank You!