Evidence-Based Medicine: Foot Imaging for Custom Functional Foot Orthoses

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The purpose of this article is to:

1. Review the literature to determine evidence-based medicine (EBM) criteria for foot imaging
2. Evaluate current foot imaging techniques to determine if they meet the EBM criteria
3. Review and recommend digital foot scanners based on their ability to meet the EBM criteria for capturing foot images

EBM Foot Imaging Criteria for Optimum Clinical Outcomes

Capturing an accurate three-dimensional (3D) image of the foot is the foundation for making custom functional foot orthoses. Numerous techniques are used including plaster casts, STS socks, foam boxes and digital foot scanners. There are four EBM criteria for foot imaging:

1. The foot image must be captured in a nonweightbearing, subtalar neutral position
2. The first ray should be plantarflexed to the end of its range of motion during casting
3. The posterior heel must be captured in the foot image to allow frontal plane correction of the orthosis (forefoot-to-rearfoot balancing)
4. The foot image must obtain a precise 3D representation of the plantar aspect of the foot

The following reviews how the current research establishes these criteria.

Nonweightbearing imaging is the only technique that ensures first ray plantarflexion

McPoil compared nonweightbearing (NWB) vs. semiweightbearing (SWB) foot imaging (plaster negative suspension casts vs. foam impression casts). The authors found that NWB plaster casting was superior to foam box SWB casting since the SWB casting resulted in artificial varus in the forefoot.[1]

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Laughton and McClay-Davis did a similar study comparing two foot imaging techniques: NWB plaster vs. SWB foam impressions.[2] They found that NWB casting had good agreement with the clinically measured forefoot-to-rearfoot relationship. SWB foam impressions had poor forefoot-to-rearfoot agreement and the SWB foot resulted in an artificial increase in varus, likely resulting from first ray dorsiflexion due to weightbearing. This study recommended NWB foot imaging as the most reliable and valid technique.

Therefore, any imaging technique that does not allow NWB is invalid.

The first ray should be plantarflexed to the end of its range of motion during casting

Roukis demonstrated decreased first metatarsophalangeal joint (MPJ) dorsiflexion resulted when first ray plantarflexion was limited. When the first ray was allowed to plantarflex there was an increase in available first MPJ dorsiflexion.[3] In another study, Harradine found that increased heel eversion decreased available dorsiflexion of the first MPJ.[4] When the heel is everted, it dorsiflexes the first ray as a result of the medial pushing into the supporting surface.

If the foot image captures the first ray in a dorsiflexed position, the custom orthotic will hold it in the same position, resulting in decreased first MPJ motion. In order to maximize first MPJ dorsiflexion, the foot image should capture the first ray in a maximally plantarflexed position. Nonweightbearing foot imaging is essential to capture the first ray in this position.

Therefore, any imaging technique that does not capture the position of the 1st ray in a plantarflexed position is invalid.

The posterior heel must be captured in the foot image to allow frontal plane correction of the orthosis

A cadaveric study by Kogler in 1999 found that valgus forefoot wedging decreased tension on the plantar fascia, while varus wedging increased pressure. This study showed unequivocally that the most effective way to decrease strain on the plantar fascia is to evert the forefoot.[5] Valgus wedging can be incorporated into a functional orthosis by capturing the patient's valgus forefoot position during foot imaging. This is achieved by holding the subtalar joint in neutral, maximally pronating the midtarsal joint and plantarflexing the first ray. The foot image must capture a significant portion of the posterior heel since the calcaneal bisection is critical in balancing the forefoot in the frontal plane in the resulting custom functional orthoses.

Therefore, any imaging technique that does not capture the posterior heel is invalid.

The foot image must capture a precise 3D representation of the plantar aspect of the foot

Studies have indicated that orthoses that conform to the arch (total contact) provide better clinical outcomes for many pathologies (metatarsalgia, pes cavus, plantar fasciitis and tarsal tunnel syndrome).[6-10] Mueller showed that total contact orthoses transfered force off of the forefoot to effectively treat metatarsalgia.[6] Kogler suggested that orthoses that conform closely to the arch may be more effective at reducing plantar fascia tension.[7] There is evidence that total contact orthoses improve clinical outcomes for patients with hallux limitus (by raising the base of the first ray allowing plantarflexion) and plantar fasciitis (by decreasing tension on the arch by limiting lengthening of the foot). In order to produce orthoses that conform closely to the arch, foot imaging must capture an accurate 3D representation of the plantar foot.

Therefore, any imaging technique that does not capture a true 3D image of the plantar aspect of the foot is invalid.

Regardless of the technique used, the evidence listed above shows that foot imaging for custom functional foot orthoses must meet four specific criteria for optimum clinical outcomes.

1. The foot image must be captured in a nonweightbearing, subtalar neutral position
   - This allows proper positioning of the foot for functional foot orthoses. Pressure on the plantar surface, whether the foot is semiweightbearing in a foam box or pressing against the glass plate of a digital foot scanner, will lead to artificial varus in the foot image.
2. The first ray should be plantarflexed to the end of its range of motion during casting
   - Roukis demonstrated that a plantarflexed first ray increased first MPJ dorsiflexion
3. The posterior heel must be captured in the foot image to allow frontal plane correction of the orthosis
   - Posterior heel bisection is a required reference to balance the forefoot in the frontal plane so that the orthosis will support the forefoot valgus position.
4. The foot image must capture a precise 3D representation of the plantar aspect of the foot
   - Precise capture of the plantar contour of the foot is critical in making a functional orthosis that conforms to the arch of the foot. Orthoses that conform closely to the arch are more effective for many pathologies commonly treated with functional foot orthoses.

Foot Imaging Techniques

There are several techniques used to capture an image of the foot for production of custom functional orthoses. The EBM criteria will help you evaluate each technique. Here is a summary of the most common techniques used.

Techniques that Do NOT Meet EBM Criteria (not recommended)

Foam Boxes

Foam box casting is a common foot imaging technique for foot orthotic production. This technique is not recommended for functional foot orthoses since the foot bears weight during image capture. This deviates from the evidence-based criteria.

Contact Digitization

This category includes systems such as Amfit with a variable height pin/piston system. Although this technique allows true 3D capture of the plantar arch, it does not allow for capture of the posterior heel which the laboratory needs to balance the cast and make a functional device.

Pressure Plates and Mats

Pressure platforms advertised as a foot imaging technique for orthotic production do not meet EBM criteria. These systems capture two-dimensional (2D) data and do not capture the posterior heel. 2D data cannot be converted to 3D data. A balanced orthosis cannot be made from pressure mat images since studies indicate that arch height cannot be accurately predicted from footprint pressure measurements.[11-14] In 2006, a study by McPoil found that plantar surface contact area could not be used to predict medial longitudinal arch height and concluded that "the clinician cannot predict the vertical height of the medial longitudinal arch on the basis of the amount of foot plantar surface area in contact with the ground during walking".[15]

Grayscale Pixilation

Grayscale pixilation systems such as PedAlign require the patient to stand on a scanner which takes an enhanced black and white photo of the plantar foot. The brightest areas of the photo are closer to the scanner allowing an estimation of the highest arch point, but actual arch height or contour cannot be determined. This requires a weightbearing foot image which does not meet any of the EBM criteria.

Techniques that Meet EBM Criteria

Plaster Casts and Polyester Socks

The majority of podiatrists still use plaster to capture the foot image as it has been done for the past 50 years. Some practitioners use a newer polyester resin-impregnated material (STS socks) to save time, avoid the mess of plaster, and achieve the same foot image accuracy. Regardless of the material, these techniques meet the EBM criteria for image capture. These nonweightbearing casting techniques are still the gold standard for custom functional orthotic foot imaging and the technique to which all others should be compared.

Digital Foot Scanners

There are two types of digital foot scanners: laser and white-light. It is important to understand the advantages, disadvantages, benefits and limitations of these new technologies. Practitioners should first use the four EBM criteria to evaluate the viability of this technology. In addition, there are other points that need to be considered to determine the benefits to their patients and practice.

The ideal digital foot scanner:

Must meet all EBM criteria for foot imaging

There are some additional considerations when applying the EBM criteria to digital scanners. The scanner must not require foot contact with the glass during foot imaging. Pressure on the foot deforms the plantar arch shape and has great potential to dorsiflex the first ray, similar to foam box and weightbearing imaging. Also, carefully assess the amount of posterior plantar heel capture. Sufficient information for calcaneal bisection is required for frontal plane correction. This critical aspect of the image is being ignored in many scanners.

Should allow all standard functional orthotic prescription options

The digital scanner should not limit what you are able to prescribe. Your prescription options should not alter as a result of the foot imaging technique used. Check for the ability to prescribe options such as medial and lateral heel skives, inversion, sweet spots, and medial flanges.

Should require less time to capture foot image compared to your current technique

Most of the systems we have evaluated are significantly faster than taking plaster casts.

Should be cost effective

This may vary based on the number of casts taken per month. Some scanners include a "per order" charge in addition to the cost of the scanner.

Should be reliable and have a strong support and service infrastructure

Limited or non-existent support from scanner manufacturers may be similar to a computer crash in your office. Check this carefully with the manufacturer.

3D Digital Foot Scanner Review

We reviewed five digital foot scanners currently marketed to podiatrists.

- Sharp Shape Laser Scanner (Sharp Shape, Cupertino, CA)
- VeriScan Podiatric Scanner (Envisic, St Louis, MO)
- iPad Structure Sensor
- TOM-CAT (TOM-CAT Solutions LLC, Perkasie, PA)
- XtremityOne (PAL Health Technologies, Pekin, IL)

Digital Scanners that Meet EBM Criteria for Foot Imaging

These three digital scanners use laser light which has the advantage of curving around objects to accurately capture images, such as the posterior heel. Ergonomics are excellent on the Sharp Shape and VeriScan units, allowing practitioners to take a foot image using the same stance and positioning as you would when taking a plaster cast. The iPad Structure Sensor has a significant drawback relative to the Sharp Shape and Veriscan units in that it requires two people to capture the 3D image. One person to position the foot (while standing behind the foot facing toward the dorsal surface of the foot) and one person to take the minimum of four passes over the foot with the iPad.

Sharp Shape: The functionality, software, and orthotic outcomes have been very good with this scanner. The scan takes less than 5 seconds per foot. Sharp Shape manufactures AOMS, an orthotic manufacturing system used in many orthotic labs, and their scanner could potentially be used for any lab using this system. Support is currently adequate. Sharpe Shape is a very small company, however, and there are concerns whether the support and service infrastructure could handle servicing numerous units. The scanner currently has a utilitarian appearance, not a high-tech appearance one would expect for such a device.

VeriScan: Arguably the most sophisticated of the digital scanners, VeriScan produces an excellent image and is very fast and easy to use. It is an attractive unit with a high-tech appearance. Software is intuitive and easy to use. Like Sharp Shape, however, the company is small and currently has orthotic lab partners handle most of the support. This could be cause for concern.

iPad Structure Sensor: Every orthotic lab that is marketing an iPad scanner is using the Structure Sensor. But the Structure Sensor was not develped to be a foot scanner for functional orthotics and is being shoehorned into a role for which it is not an optimal tool. The iPad Structure Sensor is the least expensive option upfront and because it has no moving parts, is the least likely to need repair. The camera in the iPad is used in combination with the Structure Sensor lens which is attached to the iPad. A minimum of four passes over each foot must be taken for the Structure Sensor software to create a 3D image of the foot. Because it requires two people to take a proper and correct image, the iPad Structure Sensor is the least efficient of the three units that can capture an adequate 3D image of the foot. One lab using the iPad Structure Sensor developed a positioning frame which allows the foot to be placed into neutral position and allows for a one-person operation. The major drawback of this frame is that it does not allow the first ray to be plantarflexed which is one of the EBM foot imaging criteria for optimal clinical outcomes.

Digital Scanners that DO NOT Meet EBM Criteria for Foot imaging

There are two digital foot scanners that do not meet the EBM criteria: TOM-CAT and ExtremityOne. These units use a white light, rather than laser, which does not bend. They do not adequately capture the curvatures of the foot to allow for frontal plane balancing. Both units, according to the manufacturers, function with at least a portion of the foot touching the glass plate on the front of the scanning unit. This can easily lead to dorsiflexion of the first ray and capture of a lower than optimum arch shape. We found that the ergonomics of both units made it extremely difficult to place the foot in standard neutral casting position. The TOM-CAT unit forced us to kneel on the floor and to the side of the foot, which made positioning very difficult. The ExtremityOne is designed to have the patient simply rest their foot on the heel shelf without loading or positioning of the foot.

Summary and Recommendations

There are currently five viable options for 3D foot imaging that meet the four EBM criteria:

1. Plaster casts
2. STS Sock
3. Sharp Shape Foot Scanner
4. VeriScan Podiatric Scanner
5. iPad Structure Sensor

Digital scanners will likely grow rapidly over the next few years given the cost and efficiency benefits along with recent technological advances. Sharp Shape and VeriScan are not likely to go through any significant changes in the near future and can be considered mature technology. All provide images that fit the criteria to produce custom functional foot orthoses. They are completely accurate and their images are as good as plaster.

Foot Imaging Techniques that Meet EBM Criteria

	Physical Modeling		Digital Foot Scanners		
	Plaster	STS Sock	Sharp Shape	VeriScan	iPad
Allows NWB suspension cast technique	Yes	Yes	Yes	Yes	Yes *requires 2 people*
Captures sufficient posterior heel for frontal plane correction	Yes	Yes	Yes	Yes	Yes
Provides accurate 3D image of plantar aspect of foot	Yes	Yes	Yes	Yes	Yes
Ergonomics	Excellent	Excellent	Excellent	Excellent	Poor *requires 2 people*
Speed *(*from initiation of image capture to image available for evaluation)*	9 min (casting + clean-up)	6 min (casting + clean-up)	4 sec*	4 sec*	10 sec* *requires 4 passes*
Per image charge	Shipping	Shipping	None	$2.50 per order	Transfer fees may be charged
Software Usability	NA	NA	Excellent	Excellent	Excellent
Support Infrastructure	NA	NA	Minimal	Minimal	Unknown
Lab Network Size (US) *(**Approximate. All are expanding networks)*	All Labs	All Labs	14 – 20**	11**	*Many labs are marketing under their own brand name*

Making a Choice

Digital foot scanners are faster and more efficient than plaster casting or the STS sock. La Trobe University performed a cost-benefit analysis comparing digital scanning to plaster casting. Time comparisons for capturing the image of both feet included preparation, casting, prescription writing, and clean-up. Total time required was approximately 11 minutes with plaster and two minutes for a digital scanner. Cost comparisons assumed that a podiatrist's time was worth $100 – $150(AUD) per hour. The calculated cost per patient for plaster was $27.94 to $49.60(AUD). Digital scanning cost $3.30 to $10.00(AUD). The scanner required less time and lower cost compared to using plaster (costs did not include capital cost for scanner).[16.] Busy practitioners who cast for a lot of orthotics will find increased efficiency and a rapid return on investment with any of the scanners.

Once you make the decision to purchase a scanner, the choice of scanner will depend on several factors. The ability to use a particular scanner with a preferred lab may certainly affect your choices. If you select a digital foot scanner that meets all four EBM criteria, it may make your practice more efficient without compromising your orthotic therapy quality and clinical outcomes.

If you use a lab that accepts scans from one of the EBM scanners, use this general guideline to determine your potential increase in efficiency and return on investment (ROI) based on scanner costs.

Pairs Orthotics Casted / Month	Recommended casting technique for optimum efficiency and ROI
Less than 10	Plaster or STS sock
10+	Sharp Shape, Veriscan

Financial Disclosures:
Dr. Huppin is in private practice and has used several digital imaging units in his practice. He has no financial relationship to any scanner manufacturer. He is the Medical Director for ProLab Orthotics. ProLab does not currently manufacture, sell, or have any vested interest in any digital scanners.

Dr. Scherer, an owner of ProLab Orthotics, is a Clinical Professor at Western University of Health Sciences (College of Podiatric Medicine) and past Professor and Chairperson of the Department of Applied Biomechanics at Samuel Merritt University. He authored the book: "Recent Advances in Orthotic Therapy: Improving Clinical Outcomes with a Pathology Specific Approach."He has no financial relationship to any scanner manufacturer. ProLab does not currently manufacture, sell, or have any vested interest in any digital scanners.

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