

# The Top Ten Innovations In Podiatric Care

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*In the annual roundup of emerging advances in podiatry, this author talks to podiatrists to get their thoughts about new surgical devices, vascular assessment tools and intriguing diagnostic innovations.*

Advances in technology have the potential to reshape and redefine commonly held thought processes and practices in podiatry. This year's list includes a quicker option for assessing microvascular flow, an ankle arthrodesis locking plate and a diagnostic device that may facilitate earlier recognition of lower extremity melanomas.

With that said, let us take a closer look at 10 emerging innovations.

## Getting A Clearer View Of The Microvascular Picture

**1) OxyVu-1 (HyperMed).** While the ankle-brachial index (ABI), toe-brachial index (TBI) and angiograms have proven useful in helping to assess macrovascular issues in patients with diabetes, mainstream diagnostic tools to ascertain microvascular flow were limited to measuring transcutaneous partial pressure of oxygen (TcPO<sub>2</sub>), notes Lee Rogers, DPM, the Director of the Amputation Prevention Center at Broadlawns Medical Center in Des Moines, Iowa.

However, Dr. Rogers says the emergence of the OxyVu-1 system brings another option to the table. He notes this modality employs hyperspectral imaging that enables physicians to see beyond the visible spectrum to detect oxygenated hemoglobin subcutaneously.



The camera system with OxyVu-1 creates an image of hemoglobin oxygenation status with 100-micron resolution, notes HyperMed. The company says the device combines spectral and spatial views to convey information about tissue structure and function, as well as subclinical information that the naked eye cannot see. HyperMed says the product has demonstrated changes in the microvasculature of skin associated with the severity of complications in patients with diabetes and peripheral vascular disease.

Dr. Rogers says the OxyVu-1 system acquires the image in 15 seconds and that physicians usually obtain three or four images of varying foot surfaces. HyperMed emphasizes that one can use OxyVu-1 in real time to predict outcomes, diagnose patients early and identify tissue pathology.

One benefit of the OxyVu-1 that other microvascular assessment tools do not share is that the product stores the images and physicians can view them later to determine the oxyhemoglobin levels in the peri-wound area or the proposed operative site, says Dr. Rogers.

He cites a recent study indicating that the OxyVu-1 predicted wound healing in patients with diabetic wounds. Dr. Rogers points out that the study, which assessed the use of the device in patients with diabetic foot wounds, showed a positive predictive value for wound healing of 93 percent.<sup>1</sup>



Dr. Rogers adds that current research is underway to study the use of this imaging system in predicting the level of amputation healing.

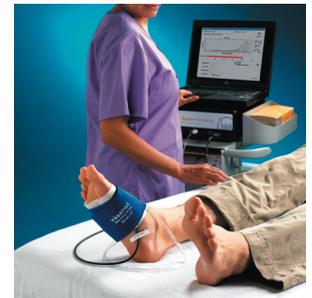
**2. SensiLase (Vasamed).** Another emerging option for assessing microvascular flow and wound healing potential is the SensiLase system.

SensiLase uses skin perfusion pressure (SPP) to measure microcirculatory values and assess the health of capillaries, according to Vasamed. The company notes the device also uses pulse volume recording (PVR), which tracks macrocirculatory values and measures changes in arterial blood volume. The device can help in managing chronic wounds that may be affected by compromised blood flow in the lower extremity, according to Vasamed. The company adds that the product can help determine the level of amputation and be helpful in diagnosing both peripheral arterial disease (PAD) and critical limb ischemia (CLI).

While the TcPO<sub>2</sub> measurement is “dependent on many conditions and is time-consuming,” Dr. Rogers says the non-invasive SensiLase offers a quicker alternative to help predict wound healing.

“One reading per angiosome is needed to predict healing within that angiosome,” maintains Dr. Rogers.

Vasamed says the SensiLase has few site restrictions. Physicians may measure areas including the digits, dorsum and plantar aspects of the foot, as well as necrotic or edematous sites.



“The OxyVu and SensiLase have added to our armamentarium the tools to diagnose microvascular disease in patients with diabetes,” comments Dr. Rogers.

## Inside Insights On Emerging Surgical Devices

**3. LCP Anterior Ankle Arthrodesis Locking Plate (Synthes).** Delayed union and nonunion are common complications that surgeons encounter following ankle arthrodesis in patients with post-traumatic arthritis or Charcot deformity. A new locking plate that offers dynamic compression may help avoid such complications.

The LCP Anterior Ankle Arthrodesis Locking Plate is indicated for arthrodesis of the ankle joint and distal tibia, according to Synthes. The company says the plates are anatomically contoured, feature combination holes in the plate shaft and are available with six or seven holes.

As Lawrence DiDomenico, DPM, notes, anterior ankle arthrodesis locking plates are very helpful in reducing the risks of delayed union and nonunion, which are relatively high for ankle arthrodesis in post-traumatic arthritis and for Charcot deformity. Dr. DiDomenico adds that the plates can be useful when surgeons are dealing with osteopenic bone. He says the Synthes plate emphasizes the protection of the soft tissue envelope and the importance of bone callus formation in uniting an arthrodesis site.

The technology of the plate is based on the ability to obtain a fixed angle and a rigid interface between the screw and plate, notes Dr. DiDomenico, the Director of the Reconstructive Rearfoot and Ankle Surgical Fellowship within the Ankle and Foot Care Centers at various locations in Ohio and the Ohio College of Podiatric Medicine. Dr. DiDomenico says this locking plate facilitates surgical approaches that protect the soft tissues while fostering an environment that is prime for secondary bone healing, and preserving the local osseous vascular supply.

“The locking plate construct might be considered the ultimate external fixator in that it is a rigid structure

placed extremely close to the mechanical axis of the bone,” explains Dr. DiDomenico, a Fellow of the American College of Foot and Ankle Surgeons (ACFAS).

“The construct creates stable elastic fixation and promotes callus formation, which leads to secondary bone healing. Locking plates allow that residual strain that inevitably occurs when (one is) fixating severely comminuted or osteoporotic bone.”

**4. RingFix™ (Small Bone Innovations).** A new external fixation device may prove to be beneficial for patients with various lower extremity conditions. The RingFix debuted last year in the United States after being in use in Europe for 20 years.

Surgeons may utilize the RingFix for Charcot foot reconstruction, triple arthrodesis, ankle fusion, ankle distraction and trauma, according to Small Bone Innovations (SBI).

Robert Frykberg, DPM, has used the RingFix for rearfoot fusions, ankle fusions, pilon fractures and other conditions. He praises the device’s ease of use and innovative design, noting that the product is different from other ex-fix systems in that it is dedicated specifically to the foot and ankle.

The product allows surgeons to attach wires even in awkward positions and comes complete with a full complement of instruments, according to Dr. Frykberg, the Chief of Podiatry at the Carl T. Hayden Veterans Affairs Medical Center in Phoenix.



The company notes that the device is based on Ilizarov principles. Ring sizes include 3/8 rings, 1/2 rings, 5/8 rings, full rings and foot plates. The company also notes that RingFix offers struts and pin/wire holding devices. In addition, SBI says the anodized aluminum rings/foot plates are lightweight and radioopaque.

## Providing Post-Op Protection After Lower Extremity Nerve Surgery

**5. NeuraWrap™ (Integra).** Following peripheral nerve surgery, patients can be exposed to a number of complications, including scar formation, as the delicate tissue heals. However, a new device may offer some post-op benefits in this arena.

The NeuraWrap, which is comprised of type 1 collagen, is designed to protect injured peripheral nerves, according to Integra. The company says the wrap stays in place during the active phase of tissue healing and resorbs completely after healing has occurred.

Integra says NeuraWrap is designed to resist compression from surrounding tissue and to protect the injured nerve from the growth of scar tissue. NeuraWrap’s nerve protection may be particularly helpful in isolating nerves in a highly traumatized wound bed or when surgeons are addressing partially severed nerves, according to Integra.

Richard M. Jay, DPM, uses NeuraWrap for tarsal tunnel repair (posterior tibial nerve) release and the treatment of peripheral nerve injuries within the foot and ankle. Dr. Jay says the product protects patients against adhesion and scars on the nerve. In addition, Dr. Jay uses it for the treatment of crush injuries and in situations in which he needs to release the anterior nerve, deep peroneal nerve or superficial nerve

One advantage of the NeuraWrap is that it is pre-made and one does not have to cut it to fit, notes Dr. Jay, a Professor of Foot and Ankle Orthopedics at Temple University and a member of the surgical staff at the South

Jersey Healthcare Regional Medical Center in Vineland, N.J. Not only does the device protect nerves during healing, Dr. Jay says it allows vascular ingrowth because it is permeable.

## Can A Handheld Device Aid In Identifying Malignant Lesions?

**6. MelaFind® (Electro-Optical Sciences).** Lower extremity lesions can sometimes be similar to one another in clinical presentation, making the identification of malignant lesions a challenge. One device, which is currently being studied, takes advantage of a database of lesions and may make the decision to biopsy clearer for clinicians.

MelaFind offers a handheld imaging device that produces multiple wavelengths of light to examine characteristics of suspicious pigmented cutaneous lesions up to 2.5 mm deep, according to the company. The system compares the obtained information to a database of melanomas and benign lesions. The company notes that the database consists of 6,000 biopsied lesions from 4,500 patients.



Electro-Optical Sciences says the MelaFind compares the patient's lesion by using an algorithm to distinguish melanoma from benign lesions and provides information on whether or not one should biopsy.

Jay Grife, DPM, JD, notes that melanoma is the deadliest type of skin cancer and is responsible for approximately 80 percent of all skin cancer deaths. Unless one detects melanoma early and the melanoma is subsequently excised with proper margins, Dr. Grife notes the patient survival rate is poor.

Studies show that dermatologists identify melanoma correctly only 60 to 70 percent of the time, according to Dr. Grife, who has provided medical malpractice advice on issues such as malignant lesions in the lower extremity. He says MelaFind has been designed to recommend biopsy for melanoma with 99 percent accuracy.

Dr. Grife adds that the technology can diagnose lesions as small as 2 mm, which could be beneficial in facilitating early diagnosis. However, there might be some disadvantages, such as false positives, according to Dr. Grife, a Fellow of the American College of Foot and Ankle Surgeons.

MelaFind is currently in the midst of clinical trials. Electro-Optical Sciences will reportedly submit MelaFind later this year for potential approval by the Food and Drug Administration (FDA).

## How A New Boot May Keep Patients On Balance

**7. Evenup™ (Evenup Corp.).** Patients may be “off balance” while wearing a cast on one foot and a regular shoe on the other. With the Evenup, patients will notice an improvement in their gait and balance, according to the Evenup Corp.

Michael Downey, DPM, notes that the Evenup is for patients wearing Cam-walkers or cast boots on one extremity while wearing their own shoe on the other extremity. As he says, the product “evens up” the limb length difference caused by the Cam-walker or cast boot.

“Before the Evenup was available, patients would often complain of hip or back pain due to the height of the Cam-walker or cast boot, and the resultant gait change,” notes Dr. Downey, the Chief of the Division of Podiatric Surgery at Penn Presbyterian Medical Center in Philadelphia.

The Evenup is available in three sizes and two thicknesses, and the company says a shoe sole evaluation and trial fitting are necessary. The company cautions that patients should not run or drive while wearing the boot,

and should also be careful when walking on slippery or uneven surfaces.

## **Can Measuring Temperature Help Prevent Diabetic Foot Ulcers?**

**8. TempTouch® (Diabetica Solutions).** The TempTouch is a noninvasive infrared temperature measurement device that provides patients with an early warning of inflammation, according to Diabetica Solutions, which was formerly known as Xilas Medical. The company adds that once the device detects inflammation, patients are able to offload or reduce activities.

As Lawrence Lavery, DPM, says, the TempTouch “is the first active prevention tool that has consistent evidence that it works.” He notes that the instrument is designed to identify stage 1 ulcers, which are classified by the National

Pressure Ulcer Advisory Panel as having changes in the temperature color or texture of soft tissue before there is a break in the skin.

“(Having an instrument that identifies stage 1 ulcers) is a completely novel concept when it comes to the diabetic foot,” explains Dr. Lavery. “This is similar to having a glucose monitor for the foot. It is a way to identify and diagnose pathology that is otherwise ‘silent.’”

Dr. Lavery says this is a particularly important development for high-risk patients with diabetes who have a history of foot ulceration. Even with appropriate footwear and insoles, 30 percent of this population still develops ulcers, according to Dr. Lavery. He says the same patient population has a three- to fourfold reduction in ulcers when they use home temperature monitoring.

Among the TempTouch’s advantages are its ease of use, notes Dr. Lavery, a Professor in the Department of Surgery at the Texas A&M Health Science Center College of Medicine. The device reportedly costs \$150 but Dr. Lavery says this is relatively cost-effective in comparison to a several-week course of antibiotics to resolve a diabetic foot ulceration.

However, he emphasizes that the TempTouch is just a part of the overall prevention and treatment picture.

“It has to be used as part of a prevention program. It is not a panacea,” cautions Dr. Lavery. “Patients have to be involved. They have to take part in their own care. It is a novel tool for patients to use.”

## **What You Should Know About A New Plaque Excision System**

**9. Diamondback 360° Orbital Atherectomy System (Cardiovascular Systems Inc.).** When referring diabetic patients for a vascular consult, one should be aware of a recently FDA-approved plaque excision system that may offer potential benefits over existing systems.

The Diamondback 360° Orbital Atherectomy System uses centrifugal force to excise hard, calcified plaque, according to Cardiovascular Systems. The company notes that the device’s orbiting motion removes plaque while reducing the potential for stress or injury to the media layer. Cardiovascular Systems adds that the Diamondback 360° device has an expanded capability for treating a wide range of vessel sizes and the average procedure time is three minutes.

In his experience working with an endovascular surgeon, Guy Pupp, DPM, notes that the Diamondback device is an improvement over the present systems because it is especially useful for hard calcified plaque, which he says is “prominent” in patients with lower extremity complications from diabetes. Dr. Pupp notes that other endovascular methods have not been especially effective for patients with diabetes as there have been

complications such as vessel perforations and embolization.

Cardiovascular Systems emphasizes that the device utilizes “differential sanding,” which reportedly decreases the risk of perforations and dissections to the arterial wall.

“The small ‘sanded particles’ are much smaller than a red blood cell and embolization is rare,” explains Dr. Pupp, an Attending Staff Physician within the Department of Podiatric Medicine and Surgery at the Providence Hospital and Medical Center in Southfield, Mich.

Given his favorable experience in referring patients with diabetes to endovascular surgeons who have utilized the Diamondback 360° device, Dr. Pupp says the device offers “another modality to facilitate successful wound healing and successful limb salvage surgery, especially in our diabetic population.”

## **Real-Time PCR: A Viable Alternative To Routine Culturing Practices?**

**10. Real-Time PCR (Applied Biosystems).** While polymerase chain reaction (PCR) can be a useful tool for helping to diagnose infectious diseases, the emergence of Real-Time PCR may eventually have greater benefits in the wound care realm.

Polymerase chain reaction (PCR) is a commonly utilized technique to exponentially amplify DNA via in vitro enzymatic replications, according to Stephanie Wu, DPM. Dr. Wu notes that PCR can be helpful in diagnosing infectious diseases.

However, the emergence of Real-Time PCR may eventually have greater benefits in the wound care realm.

Dr. Wu says Real-Time PCR enables physicians to view the actual increase in the amount of DNA as it is amplified as opposed to traditional PCR techniques that measure the endpoint or plateau. She also notes that traditional PCR uses agarose gels, which lead to poor resolution when it comes to detecting amplification at the endpoint of the PCR reaction. Traditional PCR can also be time-consuming as it takes “days for us to obtain the results,” notes Dr. Wu, an Assistant Professor in the Department of Surgery at the Dr. William M. Scholl College of Podiatric Medicine at Rosalind Franklin University of Medicine and Science.

On the other hand, Dr. Wu says Real-Time PCR offers a more rapid alternative with greater sensitivity and specificity.

“Real-Time PCR offers several advantages over conventional PCR such as increased sensitivity, rapid cycling times and a reduced risk of contamination,” explains Dr. Wu.

The amplified sensitivity and specificity with Real-Time PCR enables physicians to detect pathogens and quantify viruses, according to Dr. Wu. In a previous article (see “New Advances In Predicting Wound Healing” in the July 2007 issue), Dr. Wu noted that studies on this modality “suggest that less than 15 to 30 percent of the bacteria (identified with Real-Time PCR) may be identified or enumerated by routine culture techniques.” If this modality can aid with more precise identification of bacterial loads from biofilms, Dr. Wu noted in the article that Real-Time PCR may have unique benefits in measuring the efficacy of wound care treatments.

Dr. Wu says there are some disadvantages with Real-Time PCR. She cites the cost of the assay, noting it is substantially higher than the costs of either microscopy or conventional PCR. There is also a need for specialized Real-Time PCR analyzers (equipment), according to Dr. Wu. In addition, she cites a risk of false negative reactions due to mismatches and says the number of amplifications detected is limited by the number of fluorophores.

## ***References:***

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