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## Podiatry Today

### Feature: Emerging Innovations In Treatment

- [By Brian McCurdy, Senior Editor](#)

In this annual guide to new and emerging modalities and techniques, this author talks to a variety of experts to explore innovations that may enhance treatment outcomes.

As the podiatry profession continues to grow, new technologies emerge to help DPMs address key challenges in providing optimal care for their patients. These modalities include not only novel antibiotics to fight infection but a time-tested therapy that is just gaining prominence in the United States. Podiatrists may also enjoy the benefits of new cryogenic technology, wound care innovations and a re-emerging surgical procedure. Without further delay, let us take a closer look at these emerging innovations.



**1. Bacteriophage Therapy (Phage International).** While there is no shortage of antibiotics to treat bacterial infection, DPMs may want to take another look at a non-antibiotic option for infection that recently debuted in the United States. Although bacteriophage therapy has been in use internationally for decades, it is just now being explored in the U.S. and made its debut earlier this year at the Diabetic Foot Global Conference (DFCon06) as well as the 19th Symposium on the Advancement of Wound Care.

Bacteriophage therapy involves the use of lytic bacteriophage viruses that invade bacterial cells and disrupt the metabolism of the bacteria, according to Phage International. As David G. Armstrong, DPM, MS, PhD, notes, bacteriophage therapy essentially gives bacterium the "flu" and

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the targeted viruses evolve with the evolving bacterium, making resistance less of a problem.

Although delivery issues still must be sorted out, Dr. Armstrong notes that phage technology is still “running at a good clip” in the Republic of Georgia, as well as in Eastern Europe. As Dr. Armstrong mentions, clinics near Tblisi in the Republic of Georgia have been using phage technology since the 1920s and it received much attention until the development of penicillin. Dr. Armstrong says bacteriophage therapy has intriguing promise when it comes to infected wounds in the lower extremity.

“We are in an antimicrobial arms race,” says Dr. Armstrong, a Professor of Surgery, Chair of Research and Assistant Dean at the William M. Scholl College of Podiatric Medicine at the Rosalind Franklin University of Medicine in Chicago. “This race mandates that we develop more and more potent armaments to battle the enemy of bacteria. Unfortunately, these bacteria are smarter than we are and are perpetually a step ahead.”

Although there can be bacterial resistance to phages, Phage International notes it only takes several weeks to develop new phages for resistant bacteria as opposed to several years to develop new antibiotics. The company also notes that for localized use, phages penetrate deeper when infection is present whereas antibiotics decrease in concentration below the surface.

## **Key Insights On Emerging Antibiotics**

**2. Dalbavancin (Zeven, Vicuron/Pfizer).** Given the rising incidence of complicated skin/skin structure infections (cSSSIs), it is vital to have a number of treatment options. One such option may be dalbavancin, which is currently being reviewed for a cSSSI indication by the Food And Drug Administration (FDA). Pfizer says the parenteral lipoglycopeptide antibiotic, which can treat gram-positive infections, has demonstrated “promising results” in phase III studies for cSSSIs.

One advantage of dalbavancin is that patients can take it IV once a week, notes Warren Joseph, DPM, a Fellow of the Infectious Diseases Society of America. In regard to treating cSSSIs, Dr. Joseph says one clinical trial found that dalbavancin (dosed at 1 g IV followed by 500 mg IV at day seven) was as effective as linezolid (Zyvox, Pfizer) dosed at 600 mg IV or PO for 14 days. He says the study found cure rates in the range of 90 percent for dalbavancin and linezolid.<sup>1</sup>

Dr. Joseph is not aware of a trial comparing dalbavancin to vancomycin for skin/skin structure infections. However, citing a study focusing on bloodstream infections, Dr. Joseph notes that dalbavancin demonstrated an 87 percent overall success rate in



*Here is a severe polymicrobial diabetic foot infection with MRSA as the primary pathogenic organism. © Antibiotic*

comparison to a 50 percent success rate for vancomycin.<sup>2</sup>

“None of this is unexpected given the superiority most other newer anti-MRSA drugs have demonstrated when compared to vancomycin,” notes Dr.

Joseph, an Attending Podiatrist at the Coatesville Veterans Affairs Medical Center in Coatesville, Pa.

### 3. Ceftobiprole medocaryl (Ortho-McNeil).

Another drug in development is ceftobiprole, which is in the midst of phase III trials for cSSSIs.

Ceftobiprole is the first fifth-generation cephalosporin and also the first cephalosporin with activity against methicillin resistant *Staph aureus* (MRSA), according to Mark Kosinski, DPM, a Professor in the Department of Medicine at the New York College of Podiatric Medicine.

Unlike other cephalosporins, ceftobiprole is designed to have a high affinity for PBP2a and therefore will be active against MRSA, adds Dr. Kosinski. As far as advantages go, he says the antibiotic offers gram-positive and gram-negative coverage, and also has a low potential to spur in vitro resistance.

The drug is parenteral only at this point, has good tissue penetration and has been shown to be active against *Pseudomonas aeruginosa*, according to Dr. Kosinski, a member of the Infectious Diseases Society of America.

*organism. Ceftobiprole, which is currently in the midst of phase III trials for complicated skin/skin structure infections, is the first cephalosporin with activity against MRSA, according to Mark Kosinski, DPM. (Photo courtesy of David G. Armstrong, DPM, PhD)*

## Exploring The Advantages Of A New Subtalar Implant

**4. BioBlock (KMI).** The bioBlock is the newest absorbable subtalar implant that may provide optimum treatment outcomes for arthroereisis. As Don Green, DPM, and co-authors noted in a recent *Podiatry Today* cover story, a self-locking wedge implant like the bioBlock prevents the lateral talar process from contact with the floor of the sinus tarsi. These implants also support the talar neck, limit plantarflexion and adduction of the talus, and limit eversion and pronation of the subtalar joint (see “Assessing The Pros And Cons of Subtalar Implants” in the May 2006 issue).

Stephen Offutt, DPM, MS, has used the bioBlock on six patients, whom he says have been “very satisfied” with the results.



*The new bioBlock is a self-locking wedge, absorbable subtalar implant that prevents the lateral wedge from contact*

For skeletally mature patients, Dr. Offutt, a Fellow of the American College of Foot and Ankle Surgeons, uses bioBlock as an adjunct to procedures such as tendon transfers, equinus release and occasionally calcaneal osteotomies. Dr. Offutt points out that 60 percent of skeletally mature patients develop lateral impingement symptoms that may necessitate removing a subtalar implant. However, since the

*with the floor of the sinus tarsi. Stephen Offutt, DPM, says patients have been "very satisfied" with the results.*

bioBlock starts to resorb at 18 months, Dr. Offutt says removal is unnecessary with this implant. For a skeletally immature patient, he uses the bioBlock implant only when a patient's parent is strongly opposed to a metal implant.

Richard Jay, DPM, has been using implants with designs similar to that of the bioBlock successfully for 15 years.

"I have experienced no complications with the plug," notes Dr. Jay.

Dr. Jay has not had to remove any absorbable subtalar implants from patients as the implants resorb on their own. In young children, he has used the bioBlock adjunctively with Achilles tendon lengthening or gastrocnemius lengthening procedures. For adult patients, one can use the product adjunctively in treating posterior tibial tendon dysfunction, according to Dr. Jay, a Professor of Foot and Ankle Orthopedics at the Temple University School of Podiatric Medicine.

## **Can A Portable ESWT Device Provide Easier Treatment?**

**5. Orthospec (Medispec).** Although extracorporeal shockwave therapy (ESWT) is a noninvasive option for various painful conditions, many ESWT devices are large and mostly available in hospitals and surgery centers due to the cost of the devices. The Orthospec, which recently gained FDA approval, is a more portable device that one can use in the office.

Such portability poses several advantages, according to John Hollander, DPM, who has been using Orthospec for a year. The fact that DPMs can have ESWT units in their offices makes for a cost savings since patients do not need to go to hospitals, according to Dr. Hollander, who practices in Santa Rosa, Calif. He also notes that he can perform the procedure with no anesthesia.

Dr. Hollander has used the device to treat plantar fasciitis, retrocalcaneal pain, Achilles tendonopathy and intermetatarsal neuromas.

Another advantage of the device, according to Medispec, is the one-time, 25-minute treatment whereas other ESWT devices usually involve multiple treatments. The company says that unlike with other ESWT devices, the Orthospec does not require an imaging device and one can use the Orthospec to treat a wide area.



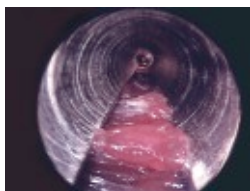
*The Orthospec is a portable extracorporeal shockwave therapy device. Its portability and one-time treatment option are key benefits, according to John Hollander, DPM.*

## **Pertinent Pearls On Advances In Podiatric Surgery**

**6. Endoscopic gastrocnemius recession.** With the increasing popularity of endoscopic techniques,

one DPM feels the endoscopic gastrocnemius recession (EGR) is re-emerging with increased usage of the procedure among foot and ankle surgeons.

One can perform the endoscopic gastrocnemius recession with the patient supine, the procedure facilitates smaller incisions and permits the surgeon to visualize the nerve, according to Amol Saxena, DPM, who developed the procedure in 2000. As Dr. Saxena notes, several companies make the equipment for the endoscopic gastrocnemius recession and a few more companies are interested in doing so.



*Amol Saxena, DPM, developed the endoscopic gastrocnemius recession and believes it will become a standard treatment in the future. This intraoperative photo shows the cutting of the gastroc aponeurosis.*

Surgeons perform gastrocnemius recessions at least 10,000 times a year, according to Dr. Saxena, who says the endoscopic gastrocnemius recession is better than tendo-Achilles lengthening, which is performed about 20,000 times a year.

"I believe this technique will become the standard in the future just like

arthroscopy is for the knee," comments Dr. Saxena, a Fellow of the American College of Foot and Ankle Surgeons.

"Few studies remain published on the results of EGR and more careful evaluation of this technique is certainly required before it can be safely advocated for general use," writes Dr. Saxena with Chris DiGiovanni, MD, in an orthopedic text to be released early next year. "With increased experience, however, we believe the EGR may eventually be perceived as potentially more efficient, safer and preferable to formal open and percutaneous gastrocnemius recession techniques."

**7. EZ Frame (Signal Medical).** For a hybrid external fixation frame that is user-friendly and offers a short learning curve, the EZ Frame may be an option. The product is useful for offloading plantar wounds and can be helpful in treating osteomyelitis, according to the company.

Signal notes that the device's rocker bottom foot plate permits weightbearing at the physician's discretion and one can adjust the device's plantar plate or remove it to offload ulcers or change dressings.

The EZ Frame also uses wires only in the foot in order to minimize complications, according to Signal Medical. The company notes the device also offers the benefits of a lower learning curve and shorter operating time, and comes packaged as a complete unit.

In a recent *Podiatry Today* article, Amy Duckworth, DPM, presented a case study involving the FDA-



approved EZ Frame device to help treat a patient with diabetes, severe posterior tibial tendon dysfunction and pes plano valgus deformity. As she notes, surgeons performed a triple arthrodesis and applied the EZ Frame with four pins, located in the calcaneus, talus, navicular and across the metatarsals.<sup>3</sup>



*One may use the EZ Frame to offload plantar wounds or to help facilitate the treatment of osteomyelitis.*

"The obvious advantages to employing this modality for diabetic foot reconstruction are guarded weightbearing, enhanced stability and the preclusion of proximal pin sites," notes Dr. Duckworth.<sup>3</sup>

## **What Are The Advantages Of A New Neuropathy Medication?**

**8. Pregabalin (Lyrica, Pfizer).** Numerous options are available to treat diabetic neuropathy and one drug that has emerged recently is Lyrica. Pfizer notes the drug is the only FDA-approved therapy to treat both diabetic peripheral neuropathy and postherpetic neuralgia.

Gary Jolly, DPM, has found Lyrica to be an "incredibly good drug" to treat diabetic neuropathy. He says it has an advantage over gabapentin (Neurontin, Pfizer) in that pregabalin is effective at low doses, significantly reducing the risk of potential side effects. Furthermore, pregabalin is clinically effective after several days of treatment while gabapentin needs about six weeks to achieve significantly high serum levels, according to Dr. Jolly, a Fellow, Past President and Director of Fellowship Training of the American College of Foot and Ankle Surgeons.

He notes that for some patients with severe symptoms, clinicians may combine pregabalin with duloxetine HCl (Cymbalta, Eli Lilly) for a synergistic effect.

In terms of potential drawbacks, Dr. Jolly says it can be a challenge to get the various prescription plans to approve pregabalin as most plans require DPMs to use gabapentin first before considering pregabalin. Accordingly, Dr. Jolly says there is a three-month delay before patients can start on Lyrica.

"The fact that the FDA has not approved gabapentin for treating neuropathy but has done so for Lyrica has somehow escaped the insurance companies' attention to date," comments Dr. Jolly. He adds that Lyrica and Neurontin are fairly close in price so he is "not sure why insurance companies are making (Lyrica) difficult to prescribe."

## **Utilizing The Benefits Of Cryosurgery**

**9. CryoProbe™ (H&O Equipments).** Cryosurgical technology has surfaced in recent years as a method of treating various lower extremity skin conditions. A newer version of the technology is the portable Cryoprobe unit. As the company

notes, the Cryoprobe combines a high pressure jet with low temperatures. Treatment time only takes 15 to 30 seconds and H&O Equipments says patients will experience "little to no discomfort."



*A newer version of cryosurgical technology is the CryoProbe. Gary Dockery, DPM, has found success in using the device on benign lower extremity lesions such as verrucae and seborrheic keratosis.*

Gary Dockery, DPM, has found the Cryoprobe helpful in treating various benign lesions of the lower extremity, including verrucae, skin tags, seborrheic keratoses and molluscum contagiosum. As he explains, the handheld device uses small cartridges to convert nitrous oxide gas into liquid N<sub>2</sub>O at minus 127° F under pressures of 725 psi.

"Since it is small and appears very high-tech, it is well accepted by older patients and children. There is very little discomfort with its use and the results are excellent," notes Dr. Dockery, a Fellow of the American Society of Podiatric Dermatology and a Fellow of the American College of Foot and Ankle Surgeons.

## **A Versatile Wound Care Option**

**10. Dermacyn™ Wound Care (Oculus Innovative Sciences).** One newly developed modality may prove to be a worthwhile adjunct in facilitating good wound care. According to the company, clinicians may employ Dermacyn, a super-oxidized and non-toxic water product, to help debride and clean acute and chronic dermal lesions, such as stage I to IV pressure ulcers, diabetic ulcers and post-surgical wounds.

Matthew Regulski, DPM, the Director of the Wound Center of Ocean County, N.J., uses Dermacyn for "any type of wound" at his facility. Those wounds include arterial wounds, venous wounds, immunopathic wounds and inflammatory wounds. Dr. Regulski's staff pre-treats the wound with a Dermacyn soak for 10 minutes prior to debridement. He notes he will also use the product in conjunction with grafts, human growth factors and autologous platelet gels. In addition, Dr. Regulski uses the product in pulse lavage and with products like Versajet (Smith and Nephew) and VAC Therapy (KCI).

Calling Dermacyn "quite revolutionary," Dr. Regulski cites a number of advantages. He notes it destroys bacteria, resistant strains, viruses, fungi and spores, and also can inhibit the release of histamine from mast cells and pro-inflammatory cytokines like TNF-alpha, IFN-gamma and



*Dermacyn can be helpful in moistening absorbent wound dressings and debriding and cleaning various lower extremity lesions. Matthew Regulski, DPM, uses it on arterial wounds, venous wounds, immunopathic wounds and inflammatory wounds.*

interleukins.

With Dermacyn, one can sterilize a wound in as few as three applications and Dr. Regulski adds that its sterilization properties are so effective that he now uses very little silver or cadexomer dressings. Dr. Regulski adds that Dermacyn is non-cytotoxic and non-genotoxic, and his patients have not had oral, ocular or skin irritations.

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