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By Liza Walton

On a recent morning, one of the nation's foremost experts on foot and ankle surgery demonstrated a unique artificial ankle that promises to provide relief to suffering orthopaedic patients. Dr. Michael Coughlin, the recently announced Medical Director for Foot and Ankle Orthopaedics at Saint Alphonsus Regional Medical Center, played a key role in introducing the Scandinavian Total Ankle Replacement (STAR) ankle to the United States, where

it will probably receive final FDA approval for surgical use in the next few months.

The STAR ankle is manufactured in Germany by Waldemar Link. The unique, mobile ankle replacement joint was acquired in January 2008 by Small Bone Innovations (SBI), a U.S. company that focuses on products and technologies used to treat trauma and diseases of small bones and joints. The joint's three-part design



includes metal caps on the talus and the tibia, and a free-moving central piece made of polyethylene. If and when it receives final FDA approval, the ankle will be the only free-moving ankle replacement joint currently available in the United States.

With his colleague and mentor, Dr. Roger Mann, an associate clinical professor of orthopaedic surgery at the University of California at San Francisco School of Medicine, Dr. Coughlin began the laborious process of getting the unique joint replacement system approved in the United States 10 years ago. A rigorous U.S. investigational device exemption clinical trial was initiated in 2000, conducted at multiple sites. As the head investigators of clinical trials on the ankle, Dr. Coughlin and Dr. Mann enlisted researchers at Duke University, the University of Texas at Austin, the Mayo Clinic and the Hospital for Special Surgery in New York to study the ankle's effectiveness.

But the \$50-million study was directed from Boise's Saint Alphonsus Regional Medical Center and the Oakland hospital where Dr. Mann practices. An FDA panel recommended approval with conditions on April 24, 2007. According to Anthony G. Viscogliosi, Chairman, CEO and President of SBi, "The current version of the STAR ankle has been used clinically since 1990 throughout the world in 27 countries with over 10,000 implantations. There have been at least 30 clinical papers written and countless presentations given over the past three decades on the STAR ankle."

With more than 18,000 ankle replacement surgeries performed in the United States each year, the STAR ankle has the potential to improve the lives of thousands of orthopaedic patients. If and when it receives final approval, it will be the first and only FDA-approved, noncemented, mobile-bearing total-ankle replacement prosthesis available to patients in the United States. Dr. Coughlin hopes that if and when the ankle receives final FDA approval, Saint Alphonsus Regional Medical Center will be designated a center of excellence for performance of STAR ankle replacement surgery.

Compared to traditional treatment, which restricts motion by fusing the tibia and the talus to provide greater support, the STAR ankle provides patients with the ability to maintain natural motion. "The payoff with this replacement therapy is definitely motion," Dr. Coughlin explains. "People need this and want it. It has the potential to make a tremendous difference in patients' postsurgery quality of life."

One wall of Dr. Coughlin's office is lined with textbooks and bound copies of peer-reviewed articles he has authored or coauthored during his 30-year career. The eighth edition of *Surgery of the Foot and Ankle*, the leading text on the subject that Dr. Coughlin coauthored with Dr. Mann and Dr. Charles Saltzman, was published last year by Elsevier and has been translated into several languages. Dr. Mann, Dr. Coughlin's mentor, also directs the Foot Fellowship Program in Oakland, CA. "I was his first Fellow 30 years ago, at a time when fellowships didn't really exist," says Dr. Coughlin. "He was instrumental in my decision to pursue this area of orthopaedics."



STAR ankle

In 1990, Drs. Coughlin and Mann created the first video textbook of foot and ankle surgery at Saint Alphonsus Regional Medical Center. The textbook was reproduced in China on DVD last year, earning Dr. Coughlin the grand sum of \$1.95 total in royalties. "I asked them if they meant \$1.95 per textbook, and they replied, 'No, \$1.95 total,'" he laughs.

Since 1975, Dr. Coughlin has published 120 peer-reviewed articles. This emphasis on active research is unusual in Boise, which does not have its own medical school. In fact, Dr. Coughlin's commitment to research was one of the qualities that made his recently announced partnership with Saint Alphonsus Regional Medical Center a natural fit.

Dr. Coughlin now trains a fellow each year in the surgical techniques he performs at Saint Alphonsus Regional Medical Center. Roughly 25 physicians apply for the fellowship each year. Photos of past fellows line the walls of his clinic. Fellows assist Dr. Coughlin with seeing patients in clinic and help with surgery. "They are literally my partners for a year, working right with me," he says.

As a nationally recognized foot and ankle expert, Dr. Coughlin gained popular notice for his critiques of high-fashion footwear's negative effects on feet, featured on *Good Morning America* and *Dateline NBC*. With two daughters, he is keenly aware of the allure of beautiful shoes. "Manolo Blahniks look great, but they don't do much to help the foot," he says. "High-fashion footwear is like a high-calorie dessert. If you wear these shoes all the time, you can injure your foot. There are plenty of stylish flat shoes available. The only purpose of shoe wear is to protect the foot. If it doesn't fit the foot's form, it can be harmful."

As a physician, Dr. Coughlin is also keenly aware of the role obesity plays in causing foot problems. Noting that our entire body weight is concentrated on two joints smaller than golf balls, Dr. Coughlin gives the image of a woman walking in high heels on asphalt on a hot day. "There's so much pressure manifested on the ankle joint when the patient is overweight," he notes. "We really have a challenge here in America. We need to focus on health and



PHOTO BY JASON HUNSBERGER

fitness. Many of the problems I see are common in people who are overweight.” Dr. Coughlin has practiced privately in Boise, ID, and will assume the position of Medical Director of Foot and Ankle Surgery at Saint Alphonsus Regional Medical Center this month. He previously served as chief of orthopaedics at Saint Alphonsus Regional Medical Center and president of the Idaho Orthopaedic Society. He is also a clinical professor of surgery, department of orthopaedics, Oregon Health Sciences University. Dr. Coughlin was the youngest president of the American Orthopaedic Foot & Ankle Society in 1990, and was the only American to serve as

president of the International Federation of Foot & Ankle Societies from 2003-2005. “My daughters told people I was president of the world,” he jokes.

In addition to research, Dr. Coughlin has applied his clinical and surgical experience to inventing practical devices that directly improve foot surgery. He holds several patents for medical devices, including ankle and metatarsal plates. Integra, a worldwide leader in orthopaedic devices, distributes two of his plates: one designed for treating arthritis of the big toe joint plate, and the other that sits on the metatarsal for bunion treatment. He recently demonstrated

BSU Researchers Test Shoe/Turf Interaction for NFL

Dr. Michael Coughlin's connection to the National Football League led to an innovative study of interactions between shoes and artificial turf that may have far-reaching consequences for the way turf is installed and maintained. The subcommittee recently became interested in anecdotal evidence from clinical doctors about an increase in high ankle sprains and turf toe injuries that seemed to correspond to the advent of new generations of artificial turf. High ankle sprains are usually rare and can be very debilitating, requiring lengthy rehabilitation, while turf toe is a common, painful problem for NFL athletes.

The NFL committee decided to commission an unbiased study of shoe interaction with artificial turf to determine whether changes in footwear, turf or both could decrease the incidence of injury for players. As head of the committee, Dr. Coughlin approached Boise State University biomechanical engineering professor Dr. Michelle Sabick and Kinesiology Department Chair Ron Pfeiffer about researching the problem. The NFL awarded a \$115,000 grant to BSU to develop the Turfbuster, the first computer-driven measuring device for horizontal, vertical and torque traction.

Seth Kuhlman, Lab Manager for the BSU Center for Orthopaedic & Biomechanics Research, designed the device in just three weeks and built it in two months. The Turfbuster uses two pneumatic cylinders to create pressure on an artificial foot, which interacts with the turf vertically, horizontally and with torsion. The traction measurements are a ratio between applied vertical force and horizontal movement. "Part of our initial goal was to establish the correct load we should test for," explains Kuhlman. "Most artificial turf is tested for traction at an unrealistic load, somewhere between 25 and 40 pounds. We determined that 220 pounds — the average weight of an NFL player — was the optimal load for traction testing."

Kuhlman took the device on the road in the summer of 2008, testing the artificial turf at five different NFL stadiums and grass turf at two additional stadiums. In two weeks, they traveled 5,000 miles and took thousands of measurements. Kuhlman was impressed with the level of cooperation the NFL turf managers provided. "They were great," he notes. "They gave us everything we needed in terms of access."

The initial data indicated that a variety of external factors might affect the way an individual artificial turf surface interacts with an athlete's shoe. In fact, though one of the attractions of artificial turf versus grass fields has been the promise of easier maintenance, no surface is truly maintenance free. "In designing artificial turf, we can engineer it to any specifications," Dr. Sabick explains. "But everything from installation to turf maintenance can affect the traction values."

Though Dr. Sabick could not make hard recommendations to the NFL committee or turf managers based on the initial study, the researchers' ultimate goal is to use their data to establish standards for artificial turf installation and maintenance. "We hope to obtain additional funding to expand our data sample and create meaningful measurements," she says.

Seth Kuhlman, Lab Manager for the BSU Center for Orthopaedic & Biomechanics Research, with the Turfbuster at Bronco stadium





PHOTO BY JAMES MAX

the devices to French surgeons while operating on some French patients. “The company is very innovative,” Dr. Coughlin says. “The titanium-plate screw holes are different colors for different lengths, which eliminates mistakes. The tempering of the metal produces different colors.”

For Dr. Coughlin, device design was a natural outgrowth of problems he directly confronted in surgery. “I became involved in developing devices several years ago,” he says. “I wanted to create the ideal plate to fit the joint, a plate that could simplify the process for foot and ankle surgeons. The bend in the plate mimics the natural curve of the joint, making the surgery easier to perform.”

Dr. Coughlin also directed a study of a bone stimulator device that speeds up the healing process for orthopaedic patients. The handheld device emits a low-dose ultrasound, administered through a hole in the patient’s cast for 20 minutes each day. It’s so effective that patients can often cut their cast-wearing time in half. When physicians first used the treatment, they didn’t understand exactly how ultrasound

worked to stimulate bone growth.

But recent studies at the microcellular level suggest that the ultrasound causes bone cells to “shimmer” slightly, stimulating bone healing. There are no known adverse side effects to the treatment. “The treatment had been available for several years, but we did the first foot and ankle studies and published three groundbreaking articles,” Dr. Coughlin explains. “The FDA now uses a technique that we developed with a Saint Alphonsus radiologist to measure the process and amount of bone healing.”

Dr. Coughlin’s interest in feet probably began in childhood. His father was just the second orthopaedist to practice in Idaho and performed several foot and ankle surgeries at Saint Alphonsus Regional Medical Center. His appreciation for this vital limb has only increased during his years of practice. “The foot really is the platform that the human body works from,” he says. “In fact, what separates humans from lower species is the size of our brain and the development of our feet, which made it possible for us to walk upright. The foot is a very complex structure that is too often given second-class status in orthopaedics.”

He is especially aware of the difference he can make in patients’ lives by alleviating their pain. He most commonly sees patients with bunions, arthritis of the ankle and the foot or injuries. With 28 bones in the foot,

he sees everything from athletes with repetitive stress fractures to trauma from falls. “My patients will come in and say, ‘I know this isn’t very important,’” he says. “But even little toes and toenails can negatively impact a patient’s quality of life.”

Dr. Coughlin notes that first-line physicians should consider referring patients to a foot and ankle specialist when they present with symptoms including specific areas of pain such as neuromas (painful inflammation that can occur in the nerves on the bottom of the foot), abnormalities such as bunions, or when they can’t walk or participate in sports because of foot pain. “Specific areas of pain, deformity, swelling or weakness that keep the foot from doing what it’s supposed to are all reasons to see a foot and ankle surgeon,” he says. ■

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