

NEWS

IMAGINE

State researchers making strides in repairing knee injuries

By **MaryLynn Schiavi**
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This monthly column explores ideas, insights and discoveries made in New Jersey that are shaping our future.

Considering that each year there are 1.5 million meniscus tears, resulting in 800,000 meniscectomy surgeries, we might assume that we are harder on our knees than those who ran before us, but according to one New Jersey researcher, we would be jumping to the wrong conclusion.

According to Dr. Charles Gatt, co-founder of the newly established NovoPedics Inc., based in New Brunswick, which is developing a revolutionary implant for those with serious knee injuries, modern people are not necessarily harder on their knees. We just plan to use them far longer than any other generation.

"People are living longer and overall healthier lives and remaining active throughout their lives," Gatt said. "We see men playing basketball into their 70s and women playing soccer in their 40s and 50s."

With a commitment of funding up to \$500,000 from Foundation Venture Capital Group (FVCG), also based in New Brunswick, Gatt and co-founder Dr. Michael Dunn are moving toward a solution that could help millions of people with knee injuries get back in the game.

Composed of fibrocartilage, the meniscus is a crescent-shaped structure that serves to evenly distribute weight across the bones of the knee.

The first product NovoPedics Inc. is developing is Meniscofix™ — a unique biodegradable fiber-reinforced design similar to the native meniscus.

"It can be attached to either soft tissue or bone, allowing it to be used in either



Dr. Charles Gatt (left) and Dr. Michael Dunn are developing Meniscofix, which has shown promising results and could be a source of relief for the 1.5 million people who suffer from meniscus tears yearly. COURTESY OF JUSTIN RICE

partial or total meniscus replacement surgery," Dunn said.

Currently, there is no FDA approved product for replacement of the meniscus, so treatment options are limited at present to replacement with allograft (cadaver) tissue, bone realignment surgeries and total knee replacement surgery.

What studies show

According to Dunn, the preclinical studies have shown that the Meniscofix implant has mechanical properties similar to that of the normal meniscus of the knee.

"This is due to a unique patent-pending design that utilizes high-strength fibers arranged similarly to fibers in a normal meniscus," Dunn said.

But Meniscofix also goes a few steps further.

"After surgical replacement of the meniscus, it induces regeneration of new meniscus tissue, which also has properties similar to that of the native meniscus," Dunn said.

While the implant is designed to degrade within the body after a period of about two years, new meniscus tissue grows within the implant by the patient's own healing response.

"After about two years, the implant is gone, but a new functional meniscus has taken its place. This new meniscus is expected to last for the lifetime of the patient," Dunn said.

While Gatt said they can't promise patients the knees of a 20-year-old, they believe the new therapy could provide greatly enhanced mobility and reduction of pain.

Dunn and Gatt are encouraged by the results achieved eight months post-implantation, and in September they expect to have the results of yearlong data.

Rejection unlikely

The body's rejection of the implant is unlikely because it is composed of synthetic fibers and purified collagen, according to Dunn.

"There are no human or animal cells in the implant that might cause rejection," he said. "However, a small percentage of patients are allergic to animal collagen, which is why a simple skin test would be performed prior to surgery."

Additional benefits include a decrease in the chance of arthritis developing after surgery.

When a significant portion of the meniscus is removed and not replaced with

an implant, this is a partial or total meniscectomy that changes the biomechanics of the knee, resulting in much more pressure and stress on the articular cartilage.

"These abnormal biomechanics lead to osteoarthritis of the knee because the cartilage tissue breaks down under the extraordinary mechanical loads, but Meniscofix prevents arthritis by spreading mechanical loads over a large area within the knee," Dunn said.

Finish line years away

The team is expecting clinical trials to begin within the next three to five years, which means a conservative estimate for FDA approval is seven years.

"This timeline might be accelerated if we partner with a large medical device company," Dunn said.

James M. Golubieski, president of FVCG, is excited about Meniscofix's potential.

"Few treatment options currently exist for significant meniscus knee injuries," he said, "and Meniscofix has already shown strong results through in vivo proof-of-concept studies."

"We look forward to helping advance this important research that could have far-reaching effects for those suffering with debilitating knee injuries," added Dr. George F. Heinrich, vice chair and chief executive officer of FVCG.

In addition to founding NovoPedics, Gatt and Dunn are faculty members at Robert Wood Johnson Medical School.

Gatt, chairman, Department of Orthopedic Surgery, specializes in sports medicine. Dunn is associate professor of orthopedic surgery and founding director of Orthopedic Research Laboratories there.

For more information, visit <http://www.foundationventure.com/Portfolio>.