

Once OA Pain Starts, It's Hard to Stop.

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An Interview with Pero Sore, M.D.

Senior House Officer, National Hospital of the Faroe Islands

Owner, MedCare Clinic, Faroe Islands

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In our last issue of *Kneed to Know*, we profiled Drs. Lars Engebretsen and Thomas Torgalsen, who treat Norway's top Olympic/Paralympic athletes at the Norwegian Olympic Centre in Oslo.

In this issue, we continue our look at the impact of nSTRIDE APS in top athletes by talking with Pero Sore, M.D., Senior House Officer at National Hospital and owner of MedCare Clinic on the Faroe Islands. Dr. Sore is licensed by the Union of European Football Associations (UEFA), the governing body of European football and the umbrella organization for 55 national associations, and a specialist in internal medicine and rheumatology with knowledge of and experience in sports medicine. He began practicing on the Faroe Islands, located between Iceland and Norway in the North Atlantic Ocean, in 1994. Among other patients, Dr. Sore has treated football players

from the Danish national team and England's Premier League.

Dr. Sore says that professional athletes with knee osteoarthritis (OA) face the unique challenge of being expected to continue to perform at high levels, despite their condition.

"Generally speaking, even with knee OA, professional athletes can't reduce their performance and functional level if they want to keep on with their sport. There is no room for compromise," said Dr. Sore. "Non-athletes tend to have much more possibility in this regard and more options for rest if knee OA is affecting their daily physical activity or professional lives."

Regardless of this difference, Dr. Sore says treatment approaches remain basically the same for athletes and non-athletes, but that each patient must be individually evaluated from the perspective of how soon they should be treated, how frequently, and depend on the expected or desired functional level target. Other aspects that must be factored into treatment decisions

include the patient's availability and the intensity of care with which they are comfortable. For elite athletes, Dr. Sore always begins by questioning why they are experiencing knee OA.

"In high-performing athletes, there is usually some other history before knee OA presents, which makes it necessary to perform careful clinical and image diagnostics, if not arthroscopy."

The type of athlete he is treating also informs Dr. Sore's clinical approach. Contact sport athletes, such as football or handball players, or those who play a sport which demands changing direction in a split second, such as tennis or badminton, are more exposed to knee injuries related to the menisci and ligaments, as well as secondary complications of knee OA. Runners tend to be at higher risk for extra articular pathology, such as infrapatellar tendinitis or iliotibial band syndrome.

In December 2017, Dr. Sore treated a 25 year old Danish national football team player with nSTRIDE APS, in combination with Bone Marrow Aspirate and shock wave therapy (SWT) in same session. Four years prior to treatment, the player suffered an ACL rupture in his right knee while playing in the Premier League in England. The injury was threaded with reconstruction, and the player experienced a good response to the surgery. In June 2015, the player underwent re-arthroscopy and the removal of multiple chondral loose bodies, partial lateral meniscectomy and chondroplasty. He subsequently

developed chronic pain and knee hydrops after every game.

Dr. Sore also treated a 22 year old professional football player who had experienced rotation trauma of his right knee in 2015. An MRI at that time indicated a lateral posterior menisci lesion. The player developed extension deficit in the knee, and underwent a repeat MRI in 2017, which indicated a grade IV (6.5 mm) chondral lesion of the lateral femoral. In January 2018, Dr. Sore treated the patient with nSTRIDE APS, combined Bone Marrow Aspirate and SWT. The athlete has been without complaint since treatment, playing football on high level. nSTRIDE APS was also Dr. Sore's treatment of choice in 2017 for a third professional football player who developed severe knee OA after a 2007 surgery to reconstruct the ACL in his right knee. The 33 year old is still playing football, at a slightly lower competitive level.

"All three of the football players are satisfied with their treatment results and are able to continue to play the sport they love," said Dr. Sore. "Those are very gratifying outcomes from my perspective."

Dr. Sore said he didn't have any specific expectations about how nSTRIDE APS would perform when he began using the product, and planned to simply try it and see what happened. Though he says it is not easy to compare, Dr. Sore generally finds the results achieved with nSTRIDE APS to be better than he expected and it's use will continue grow in his practice.

"Two weeks after nSTRIDE APS treatment, the player experienced total recovery," said Dr. Sore. "Ever since, he has played every game in the Danish league on a high level, without missing one match because of injury."

nSTRIDE APS Launches in Canada



Zimmer Biomet is very excited to announce that we recently received nSTRIDE APS approval from the Health Products and Food Branch (HPFB) of Health Canada!

This past spring we conducted an nSTRIDE APS launch training with more than 30 attendees from all regions of Canada. We expect Injections and Centers of Excellence to be established this summer throughout the country. To date, nSTRIDEAPS injections have been administered in more than 30 countries around the world, with particularly strong activity in the EMEA and APAC regions. Zimmer Biomet expects additional upcoming registrations and launches in both New Zealand and Australia in the fall.

Putting Patients First — An Interview with Joel Higgins

Senior Director of Development,

Biologics General Manager, Diagnostics Division, Zimmer Biomet



From Joel Higgins’s perspective, Zimmer Biomet’s commitment to and prioritization of patient safety boils down to these two words: “Patients first.”

As Senior Director of Development for Biologics and General Manager of the Diagnostics Division, Joel has watched the company embody and express this commitment throughout his 30 year tenure at Zimmer Biomet.

“In every day-to-day decision and all product development decisions, the patient is our central focus. When deciding on a course of action, we always examine the options through the lens of how we would proceed if one of our family members was the patient on the receiving end.”

Patient safety has been Zimmer Biomet’s hallmark since the company’s founding by J.O. Zimmer in 1927. A local salesman, Mr. Zimmer worked nights in his basement to develop his idea for a new aluminum splint design, through which x-rays could easily pass to enable doctors to better assess healing progress. His dedication to what was best for the patient has continuously guided the company’s development in the 90-plus intervening years. Today, that concept is articulated in the second of Zimmer Biomet’s five Guiding Principles, “commit to the highest standards of patient safety, quality and integrity.” Along with the other four principles, this concept ladders up to support the company’s overall mission of alleviating pain and improving the quality of life for people around the world.

nSTRIDE APS is proof of Zimmer Biomet’s “patients-first” philosophy. As Joel points out, development of nSTRIDE APS has been extraordinarily thorough, starting with bench top testing and proceeding successively through small animal, large animal, first-in-human, Phase 1 research and subsequent pivotal trials. nSTRIDE APS was developed through a research program that is second to none and studied extensively from the patient perspective, with particular focus on safety.

Feedback from the orthopedic community has reinforced to Zimmer Biomet that specialists appreciate the rigorous nSTRIDE development program.

“We regularly receive comments from the podium that key opinion leaders are impressed with the development approach we have taken with this product,” said Joel. “They recognize and appreciate the extreme levels we’ve gone to for optimal patient safety and efficacy.”

Joel himself lives by the “patients first” mantra, making it a point to attend all monthly patient and customer feedback meetings and ensure that any questions or issues are addressed and resolved as quickly as possible. The importance of patient safety was continually apparent to him and reinforced throughout his Zimmer Biomet career, whether he was working on trauma products that necessitated intuitive, easy-to-use systems for often sub-optimal care situations or pioneering a new manufacturing process that ensured the consistency of raw materials, which ultimately shifted the industry paradigm.

“Patient safety is a personal issue to me,” Joel reiterated. “It’s our responsibility to ensure it, and it’s also our responsibility to be proactive, take ownership, and make any corrections necessary if there is ever an issue. Zimmer Biomet has very robust patient safety systems in place, which we monitor continuously and about which we are extremely serious.”

Looking to the future, Joel sees even greater focus on patient safety than ever before for the medical devices industry, noting that the challenge for companies will be ensuring that they put their resources towards advancements that truly reflect the needs of the patients and make a difference in their health, while upholding the highest standards of safety. He believes Zimmer Biomet is well positioned for such a future.

“Zimmer Biomet has an unwavering dedication to the patients we serve, and their safety is first and foremost in every decision we make,” said Joel. “That commitment has always been, and will continue to be, non-negotiable.”

nSTRIDE APS FAQs

What differentiates/distinguishes Zimmer Biomet's nSTRIDE clinical research program?

nSTRIDE APS was developed through a Zimmer Biomet research program that is second to none and prioritizes patient safety. nSTRIDE APS Kit is a novel therapy, specifically designed to treat knee OA pain and slow the progression of cartilage degradation and destruction. It has been widely studied in preclinical trials, animal models, and human studies, and is clinically proven to treat pain and slow the progression of cartilage degradation and destruction in the knee for early and moderate OA patients.^{i,ii,iii}

How much of a global economic burden is knee OA?

Knee OA is a tremendous economic burden around the world. In the U.S. it is one of the top five leading causes of disability for non-institutionalized adults, resulting in more than 13 days of work missed per year, annual direct and indirect costs of \$5,700 per patient, and approximately \$3.4 to \$13.2 billion in job-related costs ever year.^{iv}

In Europe, depending on the country and treatment approach, knee OA results in direct and indirect costs of €1,330-€10,452 for every patient.^v Knee OA affects 3.8% of the global population,^{vi} and is a growing problem.

How severe is the current knee OA treatment gap?

Between conservative care and the more invasive implant solutions there are few well-researched, clinically-proven products that relieve knee OA pain and potentially delay the need for an implant. A significant need exists for newer therapies that address underlying disease processes and delay/preclude arthroplasty.

Although there are currently no approved disease-modifying treatments, increased understanding of OA pathophysiology at the molecular level means more targeted options. Since OA is tied to an increase in catabolic pro-inflammatory cytokines, which leads to cartilage matrix break-down,^{vii,viii,ix} targeting this pro-inflammatory/anti-inflammatory imbalance may offer hope.

Upcoming 2019 Events

- Meet the expert Meeting Early Intervention, Oslo, September 26th
- ICRS 15th World Congress- Vancouver, Canada, October 5-8th
- Meet the expert Meeting Early Intervention, Prague, October 9-10th
- DKOU- Berlin, Germany, October 22-25th
- AGA Conference- Mannheim, Germany, October 12-14th

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