



EUFLEXXA (1% sodium hyaluronate) is indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative nonpharmacologic therapy and simple analgesics (e.g., acetaminophen).

## IMPORTANT SAFETY INFORMATION

EUFLEXXA is contraindicated in patients who have a known hypersensitivity to hyaluronate preparations or who have knee joint infections, infections, or skin disease in the area of the injection site.

EUFLEXXA should not be administered through a needle previously used with medical solutions containing benzalkonium chloride. Do not use skin disinfectants for skin preparation that contain quaternary ammonium salts.

Do not inject intravascularly due to potential for systemic adverse events.

The safety and effectiveness of injection in conjunction with other intra-articular injectables, or into joints other than the knee have not been studied. Remove any joint effusion prior to injecting. Transient pain or swelling of the injected joint may occur after intra-articular injection with EUFLEXXA.

The most common adverse events related to EUFLEXXA injections reported in 12- and 26-week clinical studies were arthralgia, back pain, pain in extremity, musculoskeletal pain, and joint swelling. In an open-label extension of the 26-week clinical study with repeat series of injections, the most common adverse events related to EUFLEXXA at Week 52 were arthralgia and joint swelling.

\*In the 12-week trial, there was 1 joint effusion reported in the EUFLEXXA group (n=160) vs 13 joint effusions in the Synvisc group (n=161). $^1$ 

References: 1. Kirchner M, Marshall D. A double-blind randomized controlled trial comparing alternate forms of high molecular weight hyaluronan for the treatment of osteoarthritis of the knee. Osteoarthritis Cartilage. 2006;14:154-162. 2. EUFLEXXA [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; 2011.

Please see brief summary of Prescribing Information on the next page.







## BRIEF SUMMARY

Please consult package insert for full Prescribing Information.

## CONTRAINDICATIONS

Do not use EUFLEXXA to treat patients who have a known hypersensitivity to hyaluronan preparations; Do not use EUFLEXXA to treat patients with knee joint infections, infections or skin disease in the area of the injection site.

## WARNINGS

Mixing of quaternary ammonium salts such as benzalkonium chloride with hyaluronan solutions results in formation of a precipitate. EUFLEXXA should not be administered through a needle previously used with medical solutions containing benzalkonium chloride. Do not use disinfectants for skin preparation that contain quaternary ammonium salts: Do not inject intravascularly because intravascular injection may cause systemic adverse events.

## PRECAUTIONS

Patients having repeated exposure to EUFLEXXA have the potential for an immune response; however, this has not been assessed in humans; Safety and effectiveness of injection in conjunction with other intra-articular injectables, or into joints other than the knee has not been established; Remove any joint effusion before injecting, Transient pain or swelling of the injected joint may occur after intra-articular injection with EUFLEXXA; Do not use after expiration date; Protect from light; Do not re-use—dispose of the syringe after use; Do not use if the blister package is opened or damaged.

Provide patients with a copy of the Patient Information prior to use; Transient pain and/or swelling of the injected joint may occur after intra-articular injection of EUFLEXXA; As with any invasive joint procedure, it is recommended that the patient avoid any strenuous activities or prolonged (i.e., more than 1 hour) weight-bearing activities und as jogging or tennis within 48 hours following intra-articular injection; The safety of repeated treatment cycles of EUFLEXXA has been established up to 1 year.

## Use in Specific Populations

use in specific Populations

Pregnancy: The safety and effectiveness of EUFLEXXA have not been established in pregnant women.

Nursing Mothers: It is not known if EUFLEXXA is excreted in human milk. The safety and effectiveness of EUFLEXXA have not been established in lactating women. Children: The safety and effectiveness of EUFLEXXA have not been established in lactating women. Children: The safety and effectiveness of EUFLEXXA have not been demonstrated in children.

## ADVERSE REACTIONS

Adverse event information regarding the use of EUFLEXXA as a treatment for pain in OA of the knee was available from two sources; a 12 week multicenter clinical trial conducted in Germany, and a 26 week multicenter clinical trial conducted in the US.

Reported Device-Related Adverse Events
The most common adverse event related to EUFLEXXA injections reported in the clinical studies are the following: Afrhangia; Back pain; Pain in extremity; Musculoskeletal pain; Joint swelling. All adverse events related to EUFLEXXA injections reported in Tables 1, 2, 3 and 4.

## Potential Adverse Events

The following adverse events are among those that may occur in association with intra-articular injections: Arthralgia; Joint swelling; Joint effusion; Injection site pain; Arthritis

## 12 Week Multicenter Clinical Study

This clinical investigation was a prospective randomized, double-blinded, active control (commercially available hyaluronan product) study conducted at 10 centers. Three hundred twenty-one patients were randomized into groups of equal size to receive either EUFLEXXA(n=160) or the active control (n=161).

A total of 119 patients reported 196 adverse events: this number represents 54 (33.8%) of the EUFLEXXA group A total of 119 plateline reported 199 adverse events, ins luminer leptosesins 34 (33.5%) of the EUTLEXAX group and 65 (44.4%) of the active control group. There were no deaths reported during the study, incidences of each event were similar for both groups, except for knee joint effusion, which was reported by 9 patients in the active control group and one patient in the EUTLEXAX treatment group. Fifty-vadverse events were considered device-related. Table 1 lists the adverse events reported during this investigation.

Table 1. Incidence of Adverse Events Reported by >1% of Patients

			Patients, n (%)		
Body System	ADE	EUFLEXXA	Active Control		
		(n = 160)	(n = 161)		
Gastrointestinal	Nausea	3 (1.88)	0		
disorders					
General disorders and	Fatigue	2 (1.25)	0		
administration site					
Infections and	Bronchitis	1 (0.63)	2 (1.24)		
infestations	Infection	2 (1.25)	0		
Investigations	Blood pressure	6 (3.75)	1 (0.62)		
	increased	1 ' '	, ,		
	Arthralgia	14 (8.75)	17 (10.6)		
	Arthrosis	2 (1.25)	0		
Musculoskeletal,	Back pain	8 (5.00)	11 (6.83)		
connective tissue	Joint disorder	2 (1.25)	2 (1.24)		
and bone	Joint effusion	1 (0.63)	13 (8.07)		
	Joint swelling	3 (1.88)	3 (1.86)		
	Pain in limb	2 (1.25)	0		
	Tendonitis	3 (1.88)	2 (1.24)		
Nervous system	Headache	1 (0.63)	3 (1.86)		
disorders	Paresthesia	2 (1.25)	1 (0.62)		
Respiratory, thoracic	Rhinitis	5 (3.13)	7 (4.35)		
and mediastinal		` ′	1 ' '		
Skin and subcutaneous	Erythema	0	2 (1.24)		
tissue disorders	Pruritus	0	3 (1.86)		
Vascular disorders	Phlebitis	0	2 (1.24) .		

Vascular discribers

A total of 160 patients received 478 injections of EUFLEXXA. There were 27 reported adverse events considered to be related to EUFLEXXA injections: arthralgia = 11 (6.9%); back pain = 1 (0.63%); blood pressure increase = 3 (1.88%); noint effusion = 1 (0.63%); joint swelling = 3 (1.88%); nausea = 1 (0.63%); paresthesia = 2 (1.25%); feeling of sickness of injection = 3 (1.88%); skin irritation = 1 (0.63%); brour adverse events were reported for the EUFLEXXA group that the relationship to treatment was considered to be unknown: fatigue = 3 (1.88%); nausea = 1 (0.63%).

Table 2. Relationship of Adverse Effects to Treatment Groups That Were Considered to Be Treatment Related

Adverse Event	(EUFLEXXA) (Number of Reports) n = 160	Commercially Available Hyaluronan Product (Number of Reports) n = 161
Arthralgia	11	9
Back pain	1	0
Baker's cyst	0	1
Blood pressure increase	3	0
Erythema	0	1
Inflammation localized	0	1
Joint effusion	1	9
Joint swelling	3	2
Nausea	1	0
Edema lower limb	0	1
Paresthesia	2	0
Pruritus	0	1
Sickness	3	0
Skin irritation	1	0
Tenderness	1	0
TOTAL	27	25

26 Week Multicenter Study
This was a multicenter, randomized, double-blind trial evaluating the efficacy and safety of EUFLEXXA, as compared with saline, in subjects with chronic osteoarthritis of the knee followed by an open labeled safety extension study. The intervention consisted of three (3) weekly injections of study device into the target knee, with scheduled follow-up evaluations during the 52 weeks following the first injection. In the extension phase subjects received three (3) weekly injections of EUFLEXXA into the target knee with follow-up evaluation up to 52 weeks. Table 3 shows the treatment-emergent adverse events by preferred term with an incidence of ≥ 2% among treatment groups.

Table 3: Treatment-Emergent Adverse Events (TEAEs) by Preferred Term with an Incidence of  $_{\rm 2}\,2\%$  among the Treatment Groups (Safety Population)

				Extension Study Repeat Injection for
	26 W	eek FLEXX Study		52 Weeks*
	All Treatments	Saline	EUFLEXXA	EUFLEXXA
System Organ Class	N = 588	N = 295	N = 293	N = 219
Preferred Term	n (%)	n (%)	n (%)	n (%)
Any TEAE	326 (55.4)	169 (57.3)	157 (53.6)	96 (43.8)
Musculoskeletal and connecti				
Arthralgia	62 (10.5)	35 (11.9)	27 (9.2)	19 (8.7)
Back pain	23 (3.9)	11 (3.7)	12 (4.1)	6 (2.7)
Pain in extremity	13 (2.2)	10 (3.4)	3 (1.0)	3 (1.4)
Musculoskeletal pain	10 (1.7)	4 (1.4)	6 (2.0)	2 (0.9)
Osteoarthritis	9 (1.5)	7 (2.4)	2 (0.7)	0
Joint swelling	8 (1.4)	4 (1.4)	4 (1.4)	6 (2.7)
Infections and infestations				
Upper respiratory	23 (3.9)	11 (3.7)	12 (4.1)	6 (2.7)
tract infection				
Nasopharyngitis	17 (2.9)	13 (4.4)	4 (1.4)	10 (4.6)
Sinusitis	16 (2.7)	10 (3.4)	6 (2.0)	5 (2.3)
Urinary tract infection	12 (2.0)	6 (2.0)	6 (2.0)	3 (1.4)
Injury, poisoning, and proced				
Injury	17 (2.9)	9 (3.1)	8 (2.7)	9 (4.1)
Nervous system disorders				
Headache	17 (2.9)	11 (3.7)	6 (2.0)	3 (1.4)
Gastrointestinal disorders				
Diarrhea	14 (2.4)	2 (0.7)	12 (4.1)	3 (1.4)
Nausea	12 (2.0)	7 (2.4)	5 (1.7)	4 (1.8)
Respiratory, thoracic, and me				
Cough	10 (1.7)	3 (1.0)	7 (2.4)	3 (1.4)
Vascular disorders				
Hypertension	18 (3.1)	5 (1.7)	13 (4.4)	1 (0.5)

\*Treatment group for repeat study are for subjects who received EUFLEXXA in both the core and extension

N = number of subjects in a given treatment group for the population analyzed; n = number of subjects reporting at least one adverse event within system organ class/preferred term; (%) = percentage of subjects based on N; TEAE = treatment-emergent adverse event.

TEAL — Leading transplant adverse event.

Note: An adverse event was counted as a TEAE if it was either not present at baseline (prior to the first dose of double-blind study device) or present at baseline but increased in severity during the treatment period.

During the initial randomization/treatment phase, 326 (55.4%) subjects in the safety population experienced 742 TEAEs. The proportion of subjects reporting TEAEs was generally similar in the EUFLEXXA and saline groups (53.6% and 57.3%, respectively). The most common preferred term of TEAE was arthralgia (10.5% of all subjects). Thirty (51.5%) subjects experienced severe TEAEs, and the proportion with severe events was larger in the saline group (6.4%) than the EUFLEXXA group (3.8%). Overall, 10.4% of subjects had TEAEs considered related to study device, with comparable proportions in each treatment group (9.9% and 10.8% for EUFLEXXA and saline, respectively).

During the extension phase, 43.4% (188/43) of subjects reported 37 TTEAs. Of these 43.8% (96/219) subjects receiving repeated EUFLEXXA reported 199 TEAS. The most frequently reported preferred term in subjects formerly assigned to the core study EUFLEXXA group were arthralgia (8.7%), nasopharyngitis (4.6%), injury (4.1%), upper respiratory tract infections (2.7%), of int swelling (2.7%), back pain (2.7%), and sinustis (2.3%). Of these TEAS 9 (4.1%) subjects had study device related AEs classified as "Certain," "Probable," "Possible" or "Un-assessable." The most common related TEAS were arthralgia (2.3%) and joint swelling (1.4%). Table 4 shows the Study Device Related Treatment-Emergent Adverse Events by Preferred Term with an Incidence of > 1 among Treatment Groups (\*\*Certa) Provided (Safety Population)

Table 4: Study Device Related Treatment-Emergent Adverse Events by Preferred Term with an Incidence of

				Extension Study Repeat Injection for
		ek FLEXX Study (		52 Weeks*
	All Treatments	Saline	EUFLEXXA	EUFLEXXA
System Organ Class	N = 588	N = 295	N = 293	N = 219
Preferred Term	n (%)	n (%)	n (%)	n (%)
Any related TEAEs	61 (10.4)	32 (10.8)	29 (9.9)	9 (4.1)
Musculoskeletal and connec	ctive tissue disorders	•		
Arthralgia	23 (3.9)	13 (4.4)	10 (3.4)	5 (2.3)
Joint swelling	3 (0.5)	2 (0.7)	1 (0.3)	3 (1.4)
Pain in extremity	3 (0.5)	3 (1)	0	0
Skin and subcutaneous tissu	ie disorders			
Erythema	5 (0.9)	3 (1)	2 (0.7)	0

TEAEs are for subjects who received EUELEXXA in both the core and extension (219 out of 433).

N = number of subjects in a given treatment group for the population analyzed; n = number of subjects reporting at least 1 AE within system organ class/preferred term; (%) = percentage of subjects based on N; TEAE = treatment-emergent adverse event.

Note: Related AEs are AEs with study device relationship classified as "Certain," "Probable," "Possible" or

"Un-assessable.

Un-assessable. Twenty-three serious TEAEs were reported in 19 (3.2%) subjects during the study: 10 (3.4%) subjects in the EUFLEXXA group and 9 (3.1%) subjects in the saline group. One of these events was considered related to the study device (increased refenses of the left knee joint in the EUFLEXXA group. [girl (1.4%) subjects had 9 TEAEs leading to discontinuation: 3 (1.0%) subjects in the EUFLEXXA group and 5 (1.7%) subjects in the saline group. Twelve (2.8%) subjects reported 20 serious TEAEs during the extension phase. Six of these subjects had received EUFLEXXAduring the core study. None of the serious TEAEs was considered related to study device, and all resolved. Two (0.5%) subjects had TEAEs leading to discontinuation from the study, one of whom received EUFLEXXA during the core study, both subjects had events that were considered unrelated to study device.

Two subjects on saline experienced joint effusion. There were no reports of joint effusion among subjects receiving EUFLEXXAduring the core and extension phase.

Toll free number for providers and patients to call with questions: 1-(888)-FERRING (1-(888)-337-7464).

Or visit www.euflexxa.com



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## Welcome

**WELCOME TO** the second edition of Ocean Orthopedic Journal. We would like to take this opportunity for our patients to get to know us better. Ocean Orthopedic Associates is a collection of talented, highly trained Orthopedic Surgeons and staff dedicated to serving Ocean, Monmouth, and Middlesex counties. Ocean Orthopedic Associates was founded in 1969 by some of the original Orthopedic Surgeons to practice in Ocean County and their commitment to excellence and dedication to orthopedic care continues today.

Our Orthopedic Surgeons are Board-Certified by the American Academy of Orthopedic Surgeons specializing in sports medicine, total joint replacement, spine surgery, pain management and adult reconstructive surgery. Our goal is to provide a comprehensive team approach in order to offer patients a continuum of care from general orthopedics and fracture care to highly specialized spine and joint reconstruction.

Our services include digital x-ray technology, open MRI, physical therapy, canes, crutches, braces and other medical equipment, pain management including radiofrequency ablation, advanced fluoroscopic imaging and ultrasound. Ocean Orthopedic Associates team includes nine orthopedic surgeons, three physician assistants, five physical therapists, an on-staff radiologist, and a highly trained staff of medical assistants, nurses, radiology technicians, surgical technicians, case managers, surgical coordinators, paralegals, certified coders and various administrative personnel. Our nursing staff is outstanding, including certifications in advanced cardiac life support (ACLS) and pediatric advanced life support (PALS). We are proudly Joint Commission Accredited and NJ ambulatory care facility licensed, here for you, focused on providing the very best customer service. I hope you enjoy our Orthopedic Journal. Please share this with friends and family. We thank you for the opportunity to provide comprehensive orthopedic care to our community.

Warmest Regards,

Alex J. Sturzebecher, MBA Executive Director







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## Orthopedic ASSOCIATES

## Services





Pyramid MRI has an open MRI. This type of imaging provides more comfort for many patients than a closed MRI. The machine will be close to the part of the body it is scanning but the sides are open.

## **Digital X-Ray:**

This is new technology that allows for time efficiency by-passing the chemical processing and the ability to digitally transfer and enhance images.

## **Physical Therapy:**

The Physical Therapy Department prides itself in quality hands on care. Patients receive individual care that continues with in-house support directly from their doctor. Each individual receives a specific exercise program that is tailored to their rehab needs.

## **Pain Management:**

Our procedure room allows for our patients to get the relief they need in-house. We have nurses on staff to provide individual care to our patients.

Coming to the office for your epidurals and hip injections allows for less time taken out of your day and still get the same results as going to the surgery center.



Our office can provide the medical equipment your doctor might suggest at the time of your visit. Medical equipment that is on hand consists of canes, crutches, boots, wrist guards, back & knee braces. Any other medical equipment that is not on hand, we can direct you to Community Surgical with a script of what would need to be obtained.

## Med Legal:

On staff paralegals are here to assist your needs when it comes to obtaining your medical records. All inquiries for records and forms require a 48 hour turn around period to complete your request efficiency.



# Action Action

Advanced spine surgery returns NBA star Bill Walton and others struggling with back and leg pain to the game of life

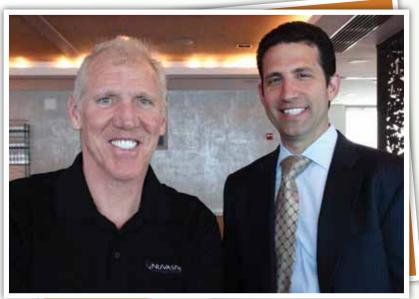
by Susan Bloom

n the face of things, NBA Hall of Famer Bill Walton seemed to have it all - recognition as one of the NBA's 50 Greatest Players of all time and, following his retirement from basketball, a promising career as an NBC sports commentator. Behind the scenes, however, Walton was struggling with an agonizing medical condition that threatened to derail him both personally and professionally. Though no stranger to injuries - the 6'11" star athlete, who played for the Portland Trailblazers and Boston Celtics in the 1970s-1980s, underwent the first of 37 orthopedic surgeries at age 14, the year before he was recruited to play for UCLA -- nothing prepared him for the agony of the incapacitating back pain he would suffer up until four years ago. "Until you've experienced spine issues, you have no idea how bad it can be - the frustration, desperation, loneliness, and hopelessness you feel," Walton, 60, said of the debilitating pain and near immobility that often left him confined to a wheelchair and led him to contemplate suicide. "When your spine doesn't work, everything falls apart."

For California resident Walton, who recounted his struggles with degenerative back pain during a seminar for medical professionals and other patients hosted by Ocean Orthopedic Associates at Avenue Restaurant in Long Branch, NJ on July 10th, 2013, the culprit was spinal stenosis, a degenerative narrowing of the spinal canal which results in pinched nerves in the back and can cause crippling pain and impaired functionality. The solution? A breakthrough and minimally-invasive procedure known as XLIF® (eXtreme Lateral Interbody Fusion), developed by San Diego-based medical device company NuVasive, which has allowed Walton and others suffering from chronic back or leg pain to resume a full life and which has been successfully performed by Justin Kubeck, M.D., an orthopedic surgeon at Ocean Orthopedic Associates in Toms River and Old Bridge thousands of times over the past five years.

## An Exciting New Procedure

"Years ago," Kubeck said, "if you needed a spinal fusion to fuse bones with a disc, the procedure required complex vascular surgery with large incisions in the front and a lengthy recovery process involving an up to five day hospital stay and rehab for up to a few weeks. However," shared



**Bill Walton** with **Justin Kubeck, M.D.**, an orthopedic surgeon at Ocean Orthopedic Associates in Toms River and Old Bridge who specializes in the unique XLIF procedure, at a seminar for medical professionals and other patients hosted by Ocean Orthopedic Associates in Long Branch, NJ

Kubeck, who trained in the unique procedure under Walton's west coast-based doctor, Steven Garfin, "the exciting new XLIF procedure developed in the last 5-10 years involves specialized implants and an advanced side-approach technique which is less traumatic to the muscle and tissue, involves a smaller incision, and results in a much speedier recovery."

According to Walton, a devoted husband and father of four and now a patient advocate and spokesperson for NuVasive since his successful XLIF surgery in 2009, there are no words to express how he feels about the opportunity to return to an active lifestyle, which includes his beloved 100-mile bike rides and the ability to counsel others nationwide living with the agony of chronic spinal issues. "I had no idea what life could be like without back pain, but now it's a miracle for me – I have no pain and no medication and there's so much for me to do," Walton shared. "I feel like the luckiest guy in the world to be able to play in the game of life again."

## A New Lease

The XLIF procedure has been similarly miraculous for Lanoka Harbor, NJ-based Mark Zieniuk, a 62-year-old lifelong hiker and backpacker who first learned that he had degenerative disc disease and spinal stenosis four years ago, after receiving an MRI for a sports-related injury in 2009. By 2010, "I had lower back, leg, and hamstring pain on my right side as well as occasional bouts of numbness in both legs," the retired librarian shared. "It came on slowly, but by 2011, I was concerned because the pain just continued to get worse. I had to cut back on many activities and was afraid I was going to lose my ability to walk." In fact,

during a trip to New York City at the time with son Gregory, Zieniuk recalls struggling through the five-block walk from the car to their destination and having to stop every half-block due to the pain in his back and leg. "With that kind of unbearable pain and limited mobility, you get irritable and frustrated and you wonder, 'is the rest of my life going to be like this?' I was afraid my next stop would be a wheelchair," he said.

In October 2012, Zieniuk consulted with Dr. Kubeck and the following month had the XLIF procedure on three levels, which involved the placement of three spacers in his back between vertebra L2-L5 in his lumbar spine. "I had an overnight hospital stay and the next day I didn't feel any pain other than from the operation itself," Zieniuk said of his post-surgery experience. "Then I walked around the hospital with the physical therapist and was cleared to go home. The pain was gone and I couldn't believe it was possible."

"I had an overnight hospital stay and the next day I didn't feel any pain other than from the operation itself," Zieniuk said of his post-surgery experience. "Then I walked around the hospital with the physical therapist and was cleared to go home. The pain was gone and I couldn't believe it was possible."



Mark Zieniuk, his wife Micheline, and Bill Walton celebrated a pain-free life at the Ocean Orthopedics-sponsored seminar in Long Branch, NJ

Since then, "I feel really good," Zieniuk confirmed. After returning to work for the final few months until his retirement this past June, "I walk in the park whenever I can, am back working out at the gym, and even took a trip to the Adirondacks to go hiking." The best part? "After my surgery, my wife and I went back to New York City and took that same trip I'd taken with my son – this time, I walked 5 blocks with no issues and then 35 more," he smiled. "A year ago, that trip would never have been possible for me." And though it's never an easy decision to make, he acknowledged of his surgery, "you get to a point where anything is preferable to the way you're feeling.

Dr. Kubeck and his staff were outstanding and I was blown away by the high-tech procedure, which involved no stitches," he said. "Today, I look forward to continuing to enjoy a pain-free life."

## A Pain-Free Life

"People have traditionally been scared to have back surgery, but it's a new day in the field and people don't have to live with chronic back pain as they get older any longer," Kubeck said. "These new options can get people back up again and greatly improve their quality of life in a minimally-disruptive way. Technology and surgical techniques have changed, enabling great outcomes with quicker recoveries," Kubeck concluded. "With a proper evaluation, there's more hope for people dealing with back and leg pain than ever before and people suffering with these conditions should definitely look into their options."

Returned to a full and active life *6 months* following his XLIF surgery in 2012, **Mark Zieniuk** enjoyed a hiking trip to the Adirondacks in the summer of 2013

With New Jersey locations in Toms River, Whiting, and Old Bridge, **Ocean Orthopedic Associates** can be reached at (732) 349-8454 or by visiting www.oceanortho.com

## Common Problems Seen in

## The Female Athlete

ver the past fifty years, the number of women participating in sports has grown exponentially. As more women begin to compete in sporting activities, doctors have found particular injuries that affect female athletes more so than their male counterparts. Beyond the anatomic differences between the sexes; hormonal and neuromuscular differences are believed to play a greater role in the higher prevalence of certain injuries seen in females, especially anterior cruciate ligament (ACL) tears, patellofemoral pain, osteoporosis, and stress fractures.

Anterior cruciate ligament (ACL) tears of the knee have been shown to be more prevalent in female athletes. The ACL is a main central stabilizing ligament in the knee which is frequently torn during noncontact injuries, such as making a sudden stop, cutting to maneuver or landing from a jump. Several studies have confirmed that female athletes are anywhere from two to



Jess G. Alcid, M.D.,
Sports Medicine

by Jess G. Alcid, M.D.

ten times more likely to tear their ACL when compared to male athletes. This is a season ending injury that usually requires reconstructive surgery and months of physical therapy to get the athlete back into competition.

Varying studies have looked at limb alignment, joint laxity, hormonal influences and ACL thickness, but none have shown definitive correlation to ACL tears. Biomechanical studies have shown that women land and

pivot differently from men, in a manner that leads to more injuries. Specialized neuromuscular training programs have been developed for female athletes emphasizing flexed hips and knees when landing and using the balls of the feet to pivot. Studies have shown that these special exercises decrease the rate of ACL tears in female participants. In an effort to avoid ACL injuries in female athletes, preventative training is now becoming part of regular professional and collegiate athletic programs.

Another common issue with the female athlete's knees is patellofemoral joint problems that commonly presents as pain or grinding behind the kneecap. When compared to men, the average woman is of shorter stature, with shorter limbs and smaller joints. Women are also wider in the pelvis than men, making the alignment of their knees and kneecaps more prone to maltracking thereby giving them more pain. Typically the pain is felt behind the kneecap, especially with sitting, squatting and stair-climbing activities. Most cases can be treated conservatively with physical therapy (concentrating on quadriceps strength) and taping/bracing techniques to help realign the patella on the knee. A small percentage of severe cases may require surgical intervention to help realign the patella.

As the intensity of competition has risen over the years, so has the intensity of training, which has led to a problem known as the "female athlete triad." The triad involves a complex relationship between amenorrhea (lack or loss of menses), anorexia/bulimia and osteoporosis often seen in endurance and performance athletes like long distance runners and professional ballet dancers or figure skaters. Intense athletes often lack sufficient caloric intake, whether it be from starving themselves to keep

thin or from not taking in enough calories to keep up with the intense exercise regimen. The lack of adequate calories and physical stress can lead to loss of normal menses. Prolonged amenorrhea can in turn lead to an overall loss of bone mineral density, causing softening of the bones or osteoporosis.

Osteoporosis is usually thought of as an older woman's disease, but bone loss in an amenorrheic athlete can approach that of a postmenopausal woman. This makes them more prone to bony injuries like fractures and stress fractures. Stress fractures are tiny cracks in the bone (usually involving the hip, leg or foot) that develop with repetitive weight bearing exercise and do not show up on regular X-rays. Up to seventy percent of bone mass is obtained by the age of 20. Therefore it is important to stress to adolescent females (who are often influenced by fad diets to keep their weight down) to take appropriate calories and calcium intake daily (i.e. 1300mg of calcium with Vitamin D daily). Treatment of female athletes thought to have the "female athlete triad" should involve parents, trainers, coaches and even nutritionists and psychiatrists in some cases to break the deleterious cycle.

The female athlete's anatomy, physiology, biomechanics and hormonal variations all play a role in the types of injuries they tend to get. Anyone experiencing the symptoms noted above should talk to their primary physician or gynecologist. Musculoskeletal or sports injuries can be further discussed with an orthopedic surgeon.





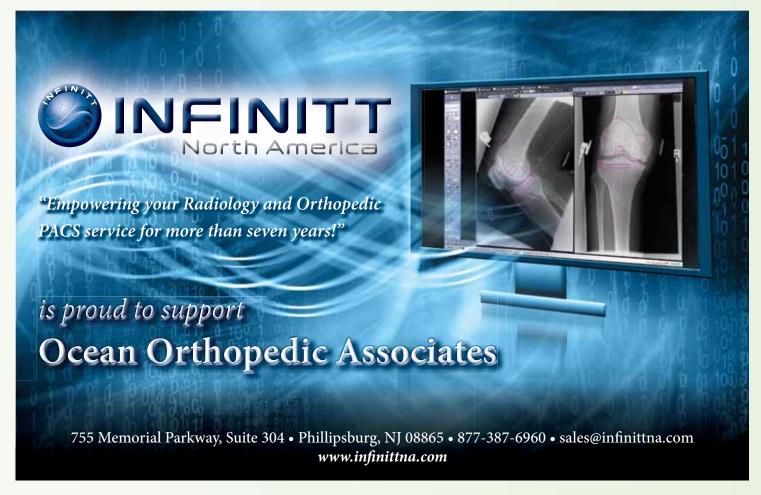
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# On the Fast Track

New 'direct anterior' approach to hip replacement procedure offers patients speedy recovery

by Susan Bloom

oms River, NJ resident Jerry Balestro was never one to sit around - the active 78-year old, a retired cook and army veteran, loved to garden and was a regular fixture at the gym, where he worked out on the treadmill four mornings a week. Until late 2011, that is, when a growing pain in his left hip began to impair his routine. "I would get up from a chair and I couldn't walk - I had to wait 2-3 minutes to take a step," Balestro shared of his declining condition. "It felt like a knot in my left hip and I couldn't find a comfortable position to sleep." Several months and a variety of unsuccessful chiropractic and steroid treatments later, the pain continued to worsen and Balestro's activity level became increasingly restricted. "Eventually, I couldn't garden or go to the gym at all," he said, nor could he keep up with the part-time cooking job he enjoyed in nearby Seaside Park. "It really started affecting my life and I realized that I couldn't keep going on like this."

When he was told to pursue a hip replacement by his doctor, Robert Closkey, M.D., a specialist in joint replacement and revision surgery at Ocean Orthopedic Associates in Toms River, Balestro was happy to comply. "I try to take a lot of things in stride, so I wasn't nervous," said Balestro, who proceeded to undergo a successful hip replacement on his left side in May 2012. And after a disciplined regimen of physical therapy and a standard recovery period, "it felt good," Balestro confirmed. Until the same condition began affecting his right side, necessitating the need for another hip replacement in October 2013.

The difference this time? Closkey was able to offer his patient a choice of options for his



second hip replacement surgery – either the standard 'posterior approach" to surgery, which was the method used on his left hip 18 months earlier, or a new 'direct anterior approach,' which would significantly reduce his recovery time. Balestro was game.

## Cause and Effect

"Over time, many people experience a degeneration of the ball and socket within the hip joint, which can be exacerbated by trauma but is most often the result of osteoarthritis caused by the aging process," Closkey said. "This wearing out of the cartilage, or the lower protective bone of the ball and socket in the hip joint, can cause pain in the groin while walking, a grinding sensation, or a sense of stiffness, and can greatly limit activity, making it hard to bend at the hip to put your socks on or tie your shoes,"

Robert Closkey, M.D., a specialist in joint replacement and revision surgery at Ocean Orthopedic Associates in Toms River

he said of the condition, which typically affects individuals between the ages of 60 and 80 and causes a progressive loss of mobility and tremendous pain. "The pain can be anywhere from annoying and nagging – requiring you to stop, sit down, and rest often – to excruciating," he confirmed. "At its end stage, the hip is in a complete frozen state and is extremely stiff. Through the hip replacement procedure, however, an implant resurfaces the ball attached to the stem on the femur side and mimics the outer coating of the ball and socket so that they're brand new."

## The History on Hip Replacements

According to Closkey, "hip replacements first began in the 1960s and hit their 'modern era' in the late 1970s and early 1980s, when patients started enjoying long-term success rates." Back then, he explained, the procedure involved fixation of the prosthesis to the bone, with doctors cementing both the socket and stem side of the hip joint; in time, that procedure evolved to cementing of just the stem side and press-fitting of the socket, while today it's become standard to press-fit both the stem and the socket on the implant side. Such advances in technique, along with improvements in the design of and materials used to make implants, have increased the lifespan of implants from 10-20 years back in the 1970s to over 30 years

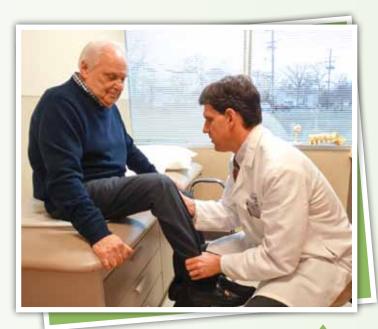
today "and have resulted in many fewer revision surgeries than ever before," Closkey said.

But the evolution has continued beyond that. "Up to now, a 'posterior approach' to hip replacement surgery, which involves the positioning of the patient on his side with the affected hip up, has been the proven gold standard," said Closkey, who has performed hundreds of successful posterior procedures in his decade-plus in the field. However, a relatively new 'direct anterior approach' – in which the patient undergoes the procedure lying on his back – has proven to be a viable alternative and is gaining ground in the U.S. based on its range of demonstrated benefits.

"Both approaches involve a small incision about four inches in length, which minimizes trauma to the tissue, though in a posterior approach the incision is made on the lower backside, while in the anterior approach it's located down from the pelvis," Closkey said of the procedure he's specialized in at Ocean Orthopedic Associates since June 2013. "While both approaches are excellent, we've found that the anterior approach limits complications on the surgical side because it goes around the muscle rather than through it, allowing patients to experience fewer restrictions in the post-operative period." For example, he said, "patients can drive as soon as they feel safe, they don't require the extended use of a pillow between their legs to help their muscles heal, and they typically need only four weeks of rehab instead of the standard eight associated with the posterior approach."

## True Believers

While Balestro enjoyed a successful outcome from the posterior approach used during his hip replacement surgery in 2012, he was sur-



**Robert Closkey, M.D.**, a specialist in joint replacement and revision surgery at Ocean Orthopedic Associates in Toms River, checks the mobility of patient **Jerry Balestro**'s hip following his hip replacement surgeries in 2012 and 2013



Toms River resident **Jerry Balestro** is all smiles as he demonstrates his pain-free mobility to **Dr. Robert Closkey**, who performed Balestro's successful hip replacement surgeries in 2012 and 2013

prised and delighted by the results of the new anterior approach used in his hip replacement surgery the following year. "It was an easier surgery and I was amazed by the difference in recovery from one hip to the other," Balestro said. "After the first day, I didn't even need pain pills; it was unbelievable. I can walk without a walker now."

Currently seeing Balestro annually, Closkey is thrilled by his patient's success and says that Balestro's experience with the anterior procedure has been typical. "He was very comfortable in the hospital after the surgery and was done with his physical therapy in four weeks." As for his prognosis, "Jerry has no limitations," Closkey said.

Following his two procedures, Balestro, too, believes the sky's the limit. "The way I felt, I could hardly walk, but I would definitely recommend the procedure to others," he said. "People in pain should go for a hip replacement, especially one involving the anterior method, which had a much shorter recovery. Now I can kneel down and get up and it's 100% better," the 54-year married father of two children and grandfather of four shared. "I feel great and I look forward to doing all my favorite things again."

"There's help out there for people who are challenged by hip pain, and the new anterior method is a great option," Closkey concluded. "It's a quick recovery and a return to a better life faster, more comfortably, and with fewer restrictions."

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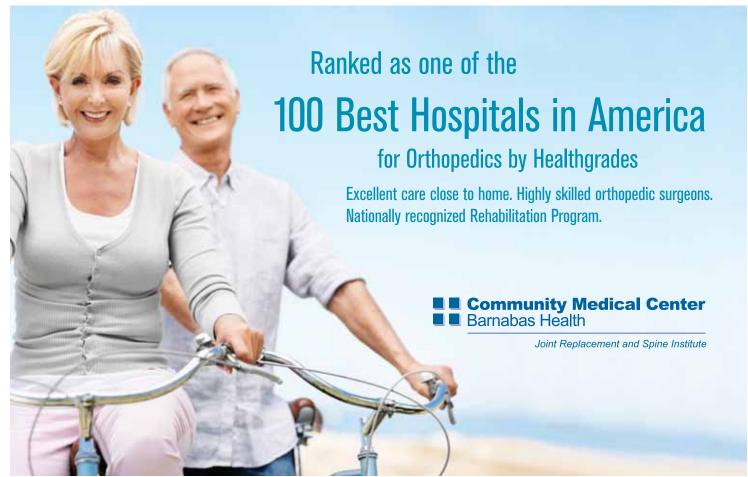
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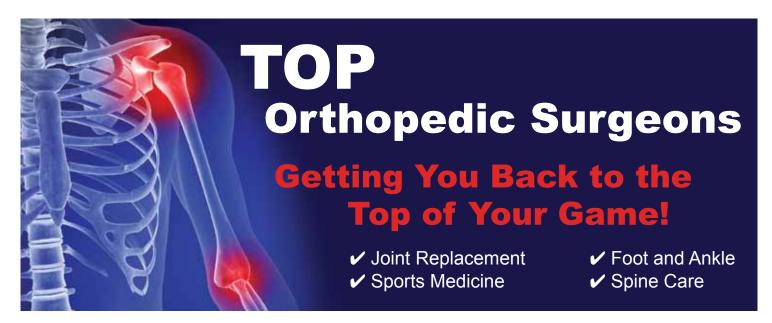
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Robert F. Closkey, Jr., M.D. Revision Specialist

Sripad H. Dhawlikar, M.D.

Spine Specialist

Mark T. Kasper, M.D. Joint Replacement

Justin P. Kubeck, M.D. Spine Specialist

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# Strike Out!

he crack of the bat, smell of the leather mitt and running of the bases are a few of the things players love about baseball and softball. More than 33 million Americans play organized baseball and softball each year, with nearly 6 million of these players being children from 5 to 14 years old. According to the U.S. Consumer Product Safety Commission, in 2003 more than 200,000 of these kids were treated in hospitals, doctors' offices, clinics, ambulatory surgery centers and hospital emergency rooms for baseball-related injuries. That is why the American Academy of Orthopaedic Surgeons recommends that children use caution when partaking in youth baseball, particularly year-round.

"We have seen a tremendous increase in the number of youth baseball injuries over the last five years. The reason is that kids are now playing 12 months out of the year and are overusing their bodies during the season," explained James Andrews, MD, orthopaedic surgeon, founding member of the Alabama Sports Medicine and Orthopedic Center (ASMOC) and chairman and medical director of the American Sports Medicine Institute (ASMI) in Birmingham, Alabama and AAOS fellow. "Children involved in overhead throwing and hitting sports should actively rest from such activities for two to three months out of the year.

It is also important that children cross-train and change sports throughout the year to prevent one area from becoming overworked and stressed."

The American Academy of Orthopaedic Surgeons offers the following tips to help keep your child off the injured list:

• Always take time to warm up and stretch before and after play. Research studies have shown that cold muscles are more prone to injury.

- If a child is pitching, he should concentrate on stretching his arm and back muscles.
- If a child is catching, the focus should be on the legs and back.
- Children should not be encouraged to play through pain. It is important that they take breaks if tired.
- Limit the number of teams your child is playing on in one season. Kids who play on more than one team are especially at risk for overuse injuries.
- Equipment should fit each player properly and be worn correctly.
- A batting helmet should be worn at the plate, when waiting a turn at bat and when running bases.
- Facial protection devices that are attached to batting helmets should be worn by children, when available. These devices can help reduce the risk of a serious facial injury if you get hit by a ball.
- Players should wear molded baseball shoes with cleats that fit comfortably.
- Children need to wear the appropriate mitt in each position.
- Catchers should always wear a helmet, face mask, throat guard, long-model chest protector, protective supporter, a catcher's mitt and shin guards.
- Inspect the playing field for holes, glass and other debris.
- Drink plenty of fluids.
- Supervising adults should be prepared for emergency situations and have a plan to reach medical personnel to treat injuries such as concussions, dislocations, elbow contusions, wrist or finger sprains, and fractures.
- To prevent sliding injuries, install breakaway bases in the playing fields and an extra large first base to avoid the runner stepping on the first baseman's foot.

While there is no concrete guideline for the number of pitches allowed, reasonable limits are 80 to 100 pitches in a game and 30 to 40 pitches in a single practice session, depending on the child's skeletal maturity, muscle strength and pitching techniques. Additional pitching recommendations for young baseball players include:



Players should wear molded baseball shoes with cleats that fit comfortably.

- 8-10 year olds should only throw from 37 to 67 pitches in approximately 1.4 to 2.6 games per week.
- 11-12 year olds should only throw from 50 to 86 pitches in approximately 1.4 to 2.6 games per week.
- 13-14 year olds should only throw from 60 to 92 pitches in approximately 1.6 to 2.4 games per week.
- 15-16 year olds should only throw from 75 to 107 pitches in approximately 1.4 to 2.6 games per week.
- 17-18 year olds should only throw from 90 to 122 pitches in approximately 1.4 to 2.6 games per week.

Source:



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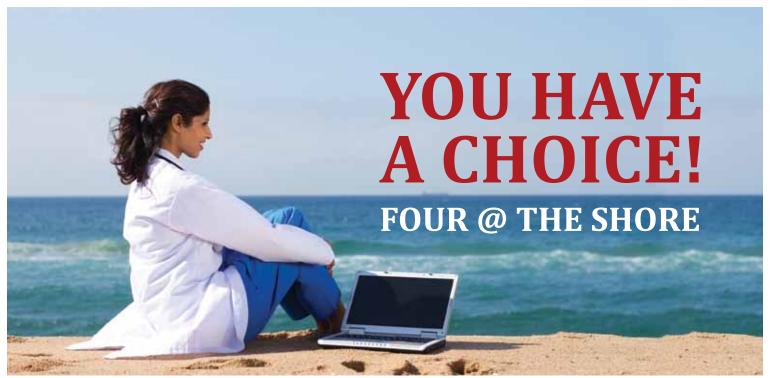
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