Peter Simonian, M.D.

Peter T. Simonian received his medical degree from the University of Southern California School of Medicine, Los Angeles. He did a surgical internship in general surgery and completed his orthopaedic surgery residency at the University of Washington, School of Medicine, in Seattle. He spent a year at the Hospital for Special Surgery in New York as an orthopaedic surgery fellow specializing in sports medicine/knee and shoulder reconstruction.

Dr. Simonian is currently team physician and the orthopaedic coordinator for the University of Washington, Husky Intercollegiate Athletics. He is the attending surgeon at the University of Washington Medical Center, Harborview Medical Center, Children's Hospital and Medical Center and the Veterans Administration Hospital and Medical Center in Seattle, Washington.

Dr. Simonian is an Associate Professor of Orthopaedic Surgery, the Director of Sports Medicine Research and Chief of the Sports Medicine Clinic at the University of Washington School of Medicine.

Robert T. Burks, M.D.

Robert T. Burks, M.D. is a graduate of Southern Methodist University and St. Louis University Medical School. He completed his orthopaedic residency at the University of California San Diego and his Knee fellowship and sports medicine at Kaiser Permanente Hospital in San Diego.

Dr. Burks is the head team physician for the University of Utah, a Professor of Orthopaedic Surgery at the University and The Director of the University of Utah Sports Medicine Center.

Dr. Burks is the Co-Chairman for the Metcalf Memorial Meeting, Director of the Dunbar Sports Medicine Lecture Series and Director of the University of Utah Sports Medicine Fellowship Program.

John C. Richmond, M.D.

John C. Richmond, M.D. received a bachelor's degree in Marine Biology from the University of Pennsylvania and a medical degree from Tufts University School of Medicine in Boston. He did a surgical internship and one year of general surgical residency at the Hospital for the University of Pennsylvania, and then went on to complete his training in orthopaedic surgery at Tufts University Combined Orthopaedic Program in Boston. He followed that with a Travelling fellowship in Sports Medicine.

Dr. Richmond is an Associate Professor of Orthopaedic Surgery at Tufts University School of Medicine and Attending Orthopaedic Surgeon at New England Medical Center, where he has been in practice since 1981. He specializes in arthroscopic surgery and the treatment of sports related injuries.

At present, Dr. Richmond is the team physician for Tufts University Department of Athletics, Fellowship Director for the Tufts University Combined Sports Medicine Program, and Chairman of the Massachusetts Interscholastic Athletic Association Sports Medicine Committee.

David M. Lintner, M.D.

Dr. David Lintner is a Board Certified Orthopaedic Surgeon who is fellowship trained in Sports Medicine, and specializes in treatment of injuries of the knee and shoulder. He is a member of the Hopestar Orthopaedic Group and has practiced at the Baylor Sports Medicine Institute in Texas Medical Center for 7 years, and is on the faculty at Baylor College of Medicine. He is the Team Physician for the Houston Astros and the Houston Hotshots Professional Indoor Soccer team, Lee College, Texas Southern University, and many high schools in the greater Houston area. He now has an office in Baytown at the San Jacinto Methodist Professional Buildings.

Marc J. Friedman, M.D.

Marc J. Friedman, M.D. is a graduate of Princeton University and Cornell University Medical School. He completed his orthopaedic residency training at UCLA and spent a year at Lenox-Hill Hospital in New York City as a Sports Medicine Fellow. At the time he had primary responsibility for the New York Jets football and New York Knicks basketball teams. He is an Assistant Clinical Professor of Orthopaedics at UCLA. Dr. Friedman has organized the American Academy of Orthopaedic Surgeons annual instructional course on treatment of anterior cruciate ligament (ACL) injuries from 1992-1996. Also, Dr. Friedman was the Sports Medicine Fellowship Director at the Southern California Orthopaedic Institute.

Mitek® PRODUCTS

ETHICON a Johnson & Johnson company

Mitek Products, Division of ETHICON, Inc.
60 Glacier Drive, Westwood, Massachusetts 02090 • www.mitek.com

Intra*fix*

Tibial Fixation

A roundtable discussion on ACL reconstruction using Intrafix™ tibial fixation with soft tissue grafts.

Moderator

Peter Simonian, M.D.
Seattle, Washington

Panelists

John C. Richmond, M.D.
Boston, Massachusetts

Marc J. Friedman
Van Nuys, California

Robert T. Burks, M.D.
Salt Lake City, Utah

David M. Lintner, M.D.
Houston, Texas

Intrafix was released in October 1999 to address the challenges associated with fixating hamstring grafts in soft tibial bone.

Intrafix was designed and patented to provide strong and stiff intra-tunnel fixation. The system maximizes bone ingrowth by exposing 360 degrees of the bone tunnel to the soft tissue graft. Intrafix is a two-part polyethylene system with a screw and expandable sheath. The sheath separates and holds the graft strands in place as the screw expands the sheath. The system provides expansion and compression fixation to maximize tissue to bone contact. Intrafix provides confident intra-tunnel tibial fixation.

The roundtable discussion that follows, moderated by Peter Simonian, presents the experience of several leading orthopaedic surgeons with first hand experience using Intrafix.

Intrafix Tibial Fixation Roundtable Discussion

Simonian

As we all know, hamstring grafts are gaining popularity around the world. Lets start by describing your indications for hamstring grafts vs. bone patellar tendon grafts.

Richmond

In my practice, I do approximately 40% hamstring grafts, 40% BTB, with the last 20% being allograft. My indications for a BTB graft are in the high performance, demanding athlete, or the patient with chronic instability who had developed appreciable excess laxity. For most acute ACL tears in the recreational athlete, I rely on the hamstring graft as my graft of choice. I also tend to use hamstring grafts in the older population, or those patients who have avocations or occupations that require them to kneel on a regular basis.

Friedman

I do about 70% hamstrings, 20% allograft, and 10% BTB. I have a community orthopaedic practice so I feel comfortable using hamstring grafts on most of my patients. I save BTB for young, heavy, high level athletes with excess laxity.

Simonian

I perform about 80% hamstring versus 20% BTB. I present the options to the patient and let them make the decision. I think both grafts perform extremely well in recreational athletes. I think the advantage of using a hamstring graft is that donor site morbidity seems significantly less than with patellar tendon grafts. The disadvantage is that the recovery time is a bit longer. I do not allow patients to return to full cutting sports until about nine months after hamstring reconstruction versus six months with the BTB reconstruction. Interestingly, I have a group of patients who have had a hamstring graft on one side and a BTB graft on the other and nearly all of them like their hamstring graft subjectively better than their BTB graft. Patients also like the small incision associated with the hamstring graft.

Burks

I have a similar breakdown with 80% of my cases being performed with hamstring grafts, 20% with bone tendon bone and a few allografts.

Lintner

I used to prefer BTB, but I now use hamstrings on approximately 95% of my primary ACLR. I will use BTB if the patient prefers, but I typically use hamstring grafts even on football players. There is some evidence that some sports are hamstring dependent (i.e. collegiate wrestling, skating, etc.) and for those I would consider a patellar tendon.

Simonian

There is a lot of discussion surrounding bioabsorbable implants. What are your thoughts on bioabsorbable implants. Do you mind that Intrafix is plastic?

Lintner

Since most bioabsorbable implants turn into fibrous tissue rather than bone, leaving defects in the bone comparable to that left behind after screw removal, I am not a large proponent of bioabsorbable implants. The Intrafix has superior strength and fixation close to the joint line, the fact that it is not bioabsorbable is insignificant. I have had to remove one Intrafix eight weeks postoperatively because of an automobile versus pedestrian accident that disrupted the ACL graft. The screw and sheath were quite easy to remove and left no debris.

Friedman

I personally have no problem with plastic on the tibia. I wouldn't mind Intrafix as a bioabsorbable implant if the mechanics are unchanged. The only theoretical concern would be cystic formation on resorption. We know it does not appear to effect the clinical results with BTB but this is bone-bone healing.

Simonian

I am truly concerned about bio-degradable implants, especially when they constitute a very large mass. I think the jury is out whether bioabsorbable implants will cause problems down the road primarily because of the fact that it takes so long for them to degrade and the bigger they are the slower their degradation is. I think the fact that the Intrafix is plastic is important. It is an inert material that minimizes the chances of it having any type of foreign body reaction. At the same time, if you were unable to remove the device in whole you can drill directly through it for revision cases, something you can not do with a metallic device.

Richmond

I agree with Dr. Simonian, it has been my experience with large absorbable implants that they absorb at best slowly, if at all. I have revised several patients more than 2 years out from ACL or PCL reconstruction that were performed with bioabsorbable screws and these showed no signs of dissolving at that point. I suspect that they stay around for such a long time that if they are replaced it is only with scar. The benefit I see for Intrafix being plastic is that there is not likely to be any distortion of future MRI images by the implant. Therefore we will have a better opportunity for imaging if there is further injury to the reconstructed knee. I have no problems with it not being absorbable.

Burks

I agree with my colleagues, bioabsorbable implants take years to go away, Intrafix is radiolucent and can be drilled out in a revision case.

Simonian

What were you using for tibial fixation prior to Intrafix? What made you switch to Intrafix?

Richmond

Prior to my use of Intrafix, I used a bioabsorbable screw and backed this up by tying the sutures around a screw as a post. I switched to Intrafix so that I could eliminate the second fixation point in most of my patients. This eliminates a point of potentially painful hardware. I do continue to use a backup screw as a post for the Intrafix whenever there is a concern over the quality of the tibial bone. I routinely dilate the tibial tunnel 1mm, but still in those patients who have relatively soft tibial bone, I rely on the backup system.

Burks

I also used a belt and suspenders approach and switched to Intrafix for the superior fixation.

Friedman

I used a staple and belt buckle combination. I eventually had to remove 5%. I switched based on the biomechanical data especially on cyclic loading. I also think it is significant to be able to individually tension each strand of the construct.

Lintner

I was using metal or absorbable interference screws advanced to the tibial plateau and backed up by a staple. I switched to Intrafix because of the superior strength, the ability to obtain equal tension on all four strands and circumferential fill of the tunnel.

Simonian

I used belt and suspenders. I like the idea that the interference screw decreased the point of fixation distance, however I think the interference screw alone allows for significant graft slippage especially on the tibial side where the bone density is less than that of a femur. This combination fixation is expensive and despite using a very low profile screw and washer I still had to remove about ten percent for prominence. The Intrafix is a single device that allows for secure intratunnel fixation on its own and therefore shortens the points of fixation at the same time does not require a back-up device.

Simonian

I know we can be slow to change systems, how would you describe the learning curve for Intrafix.

Burks

Quick, two or three cases and I hit my comfort zone.

Friedman

The learning curve was easy. I found it was important to aggressively debride the tibial tunnel to improve visualization.

Richmond

I agree.

Lintner

At first the tensioner appeared cumbersome to use, in fact after a few cases it becomes quite simple. I teach residents and fellows how to use the device and implant and usually within a few cases they have it down. I have made a real time video of Intrafix placement for our residents, which shows that it takes approximately four minutes to tie the sutures, tension the graft, and place the implant.

Simonian

I found the learning curve to be steep. There are a couple of key points. If you are going to use the tensioning device you have to have proper suture length knots from the ends of the graft. The suture length knot has to be about 4 to 5 inches to allow use of the tensioning device. I recommend using a simple knot that can easily be untied to ease the learning curve. Another important point is putting the sheath in far enough so there is no prominence. As Dr. Friedman mentioned, debriding the entrance to the tibial tunnel greatly improves the visualization.

Simonian

Now that you have changed systems, are you happy with your results?

Richmond

Although I am early in my use of Intrafix (less than 2 years), I feel that it has given me results at least equal to if not better than prior bioabsorbable screws with secondary suture fixation around the post, while eliminating hardware problems as a postop complication requiring screw removal.

Burks

I feel that my early KT-1000 results with Intrafix are about 1mm on average better than without the Intrafix.

Lintner

I have been using Intrafix for over one year and other than my traumatic rupture mentioned earlier, I have had no failures. KT-1000 tests done at six months and beyond as well as functional tests show excellent results. Results even in elite athletes' performance have been outstanding. There have been no problems with prominent hardware either.

Friedman

I'm in the process of evaluating my first 20 cases with KT 1000's.

Simonian

I have been using the device for 6 months so my results are not complete but to date based on KT-1000 data as well as physical examination, performance is excellent.

Simonian

Final Comments

Richmond

Intrafix gives very high fixation strength with limited creep, while obtaining aperture fixation for the soft tissue graft on the tibial side. It has markedly reduced the need for secondary fixation.

Simonian

Tibial fixation with soft tissue grafts has been problematic. I think Intrafix goes a long way to solving these problems.