EDITORIAL

Mahmut Nedim DORAL, M.D.
Editor

Dear Colleagues,

After an intense period of scientific meeting we’re here with newest NL; summer 2012. 15th ESSKA Congress was held in Geneva and 13th EFORT Congress was held in Berlin with succesfull EFOST Specialty days. It was a great opportunity to meet friends and share science again (photos below). I would like to congratulate all Board Members, especially President Dr. Kelberine and Programme Chairs for their great efforts. Now it’s time to concentrate forthcoming World Sports Trauma Congress and 7th EFOST Congress which will be organized after London 2012 Olympic Games. Thanks to Programme Committee and Organising Committee for their intense effort they show on preparing a perfect meeting and GCO (Global Conference Organisers) B.V. Hope to see your participation for London Meeting.

Prof. Mahmut Nedim DORAL, M.D.

EFOST Specialty Day Session at 12th EFORT Congress 2012, Berlin
GL Canata, B Pijnenburg, H Laprell, MN Doral, H Farouk, F Kelberine, G Felmet (on the left)

EFOST Board Meeting at 15th ESSKA Congress, Geneva
GL Canata, P Papadopoulos, J Huylebroek, MN Doral (on the right)
EDITORS NOTE

The Summer 2012 Issue of our Newsletter is now on the web. The Tenth Volume, has been designed to allow our members an insight to EFOST, to provide information on upcoming meetings and events, to spread the knowledge on available courses and fellowships and to access updated scientific information and reviews of current literature abstracts.

We are launching additional sections in our Newsletter: An interview with a leading person in our field, a clinical case with detailed debate and with key person opinions and shortly "Tip and Pearls" from our members.

Could we possibly encourage you, our faithful members, to send in interesting material of your own: Interesting arthroscopic or surgical pictures, surgical tips you use, an interesting case you have encountered or a solution you have discovered when a problem came up, and others may benefit from knowing it.

We, the EFOST Board and Newsletter Editorial, wish you a beautiful, peaceful and productive summer for 2012.

Prof. Gideon Mann, M.D.

Meir University Hospital Medical Center
Department of Orthopaedic Surgery
Service of Sports Injuries

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Dear EFOST Members, Dear Friends,

As you know, our Society bye-laws have been modified to bring new blood. And I would like first to express my gratefulness to all the board members (executive and at large) for their tireless support and their involvement in EFOST development and maturation. A large part of the tasks have been achieved so EFOST grew significantly to became more active, efficient and relevant.

This summer issue reports an overview of our expanding activities and a lot of informations about our upcoming bi annual meeting which will be combined with the 4th Word Sport Trauma Congress.

In 3 months, October 17th to 20th, the 7th EFOST meeting will be hold in London. This meeting is really focused on Sports injuries including prevention, epidemiology, trauma, treatment, rehabilitation and return to sport criteriae.

The Programme Committee chaired by Mike Carmont, Burt Klos and myself worked hard to propose an outstanding scientific content. Thanks a lot to BOSTAA and EFOST boards for their input.

We do expect this attractive programme will make this meeting a very successful one.

Have a look on Roger Hackney’s editorial, Co-President of the meeting and visit the congress web site www.wstc2012.com.
I would like to emphasize the very high quality of the faculty, worldwide famous in the Orthopaedic Sport Medicine field. They often represent other International Societies (ISAKOS, ICRS, AOSSM, APOSSM, EFSMA, ESTES, ESSKA, ECOSEP or UEFA).

Here are some non British participants: M.Cohen, P.Neyret, J.Bergfeld, N.Van Dijk, E.Arendt, T.Miniaci, J.Willems, N.Nakamura, M.Cooken, M.Maracci, B.Mandelbaum, B.Reider, P.Indelicato, E.Wojtys, J.Espregueira, J.Menetrey, G.Cerulli, J.Ekstrand,…and many others I do apologize as I can’t nominate all.

The British Faculty is similarly outstanding and I thank National Societies, EFOSF members, which will run their own session.

In this e-newsletter you’ll find also:
- an interview of Hans Passler, founding member and Past President of EFOSF, a legend in Knee Traumatology.
- the report of the fellows who performed the DJO Global-EFOSF team physician fellowship through US sport centers in March 2012.
- scientific contributions.
- Informations about the upcoming events.
- Informations about our free scientific e-Journal (MLTJ,) thanks to Nic Maffulli and about a special subscription rate to Sport Health.

I am proud and pleased we strengthened our links with National Societies and we welcome also new ones from Estonia (EASTS) and Sweden (STSS). We participate in National Sport Trauma meetings with, conversaly, an involvement of the National Societies members to our international activities. This is a major issue in order to grow simultaneously.

EFOSF and Burt Klos are organizing the European tour for 2 US fellows before our congress meeting. This DJO Global-EFOSF team physician fellowship will run through Portugal (H.Jones), Italy (GL Canata, Giuseppe Longo), Germany (G.Felmet), The Netherlands (B.Klos, B Pijnenburg) and EFOSF London meeting.

MLTJ, our official EFOSF publication is now at its fourth issue. The Editorial Board chaired by our Vice President Nicola Maffulli will get indexation next year.
You receive MLTJ by e-mail for free. Just click on the link to reach high quality articles and promote it by simple e-mail transfer.

Again, we strongly ask our members to submit their manuscripts to MLTJ.

Due to the efforts of my friends, EFOST Past Presidents, our society got a place on the international council. I talked about a cutting edge for EFOST development in my last editorial; I believe we moved beyond especially due to the new guidelines and the enlarged structure. And I am confident in the willingness of our next President, Nic Maffulli to continue this team work with the whole dynamic EFOST board supported by our Office GCO.

We are all available for any request or information coming from National Society or individual. Don’t hesitate to keep in touch!

Visit and use regularly our website: www.efost.org

I am quite excited to attend this meeting which will also conclude my President mandate. See you in London!

EFOSTly yours

François Kelberine M.D.

EFOST President
World Sports Trauma Congress

Roger Hackney

Preparation for the World Sports Trauma Congress is well under way. This major international meeting will be held in the Queen Elizabeth II Conference Centre, Westminster from 17-20 October 2012.

The programme includes sessions from many of the specialist societies of the British Orthopaedic Association. Speakers from around the world have accepted invitations to speak, ensuring the highest standards of education and learning. There are four parallel sessions running each day. There is plenty to attract orthopaedic surgeons of all interests. In addition to sports trauma, there will be ample opportunity to meet other sports medicine physicians and sports physiotherapists. There are top-level sessions on topics such as injections, extracorporeal shock wave therapy, core stability, tendinopathies and return to play which are as relevant to general orthopaedics as to a sport-specific practice.

Day 1 includes sessions dealing with the hip and groin pain, joint replacement and sport, ankle problems, knee pain, shin pain and the role of the orthopaedic surgeon in team care.

Day 2 consists of knee surgery, hand and wrist pain, Achilles tendon ruptures, back pain and upper limb problems. Cartilage repair is discussed with a guest session from the International Cartilage Repair Society.

Day 3 The upper limb is in greater focus, and there are impressive sessions on return to play. The knee sessions include presentations on ACL registries, and managing meniscal injury. There are guest sessions from the South American sports trauma association, RIM, the international federation of sports medicine and the UK Institute of Sports and Exercise medicine (IFSM).

Day 4 The international theme continues and of particular interest to all are sessions looking at the use of imaging at the London Olympic Games and the role on management. There are upper limb foot and ankle and return to play sessions.

Lunchtime workshops are planned from trade participants, as well as guest keynote lectures from internationally renowned speakers.


The call for free papers is out and papers are already being submitted. Please consider this major conference for presentation of your work. We intend to have free paper presentations and posters. Details of how to submit papers can be found on the congress website.
WORLD SPORTS TRAUMA CONGRESS & 7TH EFOSI CONGRESS 2012
17-20/10/2012
London, UK

Summer 2012 ... an exciting time in sport!
Autumn 2012 ... an exceptional EFOSI Congress!
Share in the aftermath of the Olympic Games and the Paralympics and be part of the
WORLD SPORTS TRAUMA CONGRESS 2012
EFOST London Highlights.....Meet your National Society there!

SIGASCOT - Società Italiana di Chirurgia del ginocchio, artrosocopia, sport, cartilagine e tecnologie ortopediche
/ Thursday 18th October 2012 / 16h45—17h45

SETRADE - Sociedad Española de Traumatología del deporte / Saturday 20th October 2012 / 14h30–16h00

More specialty sessions by:

ISAKOS session on “Muscle Tears” chaired by Joseph Lowe and Myles Coolican

AOSSM session on “Team physician sideline decision making” with Peter Indelicato, Bruce Reider, Robert Stanton and Ed Wojtys

ESSKA session chaired by Niek Van Dijck and Grzegorz Adamczyk

ICRS session chaired by Bert Mandelbaum and Wojcieh Widuchowski

UEFA session with Jan Ekstrand, Jose Huylebroek and Henrique Jones

FORTE session provided by the Federation of Orthopaedic Trainees in Europe

The TOP 5 learning take-aways....5 good reasons to be there!

1. Dedicated focused sessions on sports trauma
2. Intimate audience guarantees high level of interaction with KOLs
3. Advanced presentation opportunities for abstract presenters
4. Lectures from top-level athletes
5. Insight and analysis of the Olympic Games experience

As a member of EFOST, we look forward to welcoming you in London to this exceptional Congress!

Further information on www.wstc2012.com
The German physician Professor Dr. Hans H. Pässler is one of the leading specialists in knee surgery all over the world, with particular focus on cruciate ligament surgery and chondrocyte transplantation. From 1997 to 2010, Pässler was Medical Director of the ATOS Clinic Heidelberg. Pässler is a general surgeon and trauma surgeon who initiated the early functional therapy after ligament surgery at the knee joint (1972). He has assumed various functions in specialist organisations, such as Past-President of the European Federation of National Associations of Orthopaedic Sports Traumatology (EFOST), Vice President of the Collège Européenne de Traumatologie du Sport (CETS), and is a member of numerous international organisations. Pässler is an honorary member of the Royal College of Surgery in Edinburgh, the oldest medical society of the world (1505), of the Arthroscopy Association of North America and the Greek Association of Arthroscopy, Knee Surgery and Sports Injuries.
**GF:** Professor Paessler, you are an international well known German specialist in sports trauma and knee surgery - and you are one the founder and have been the third past President of EFOST. What have been the ideas and circumstances to found EFOST?

**HP:** Jean-Claude Imbert, St. Etienne, Wolfgang Pförringer, Munich, and me founded EFOST in 1992 in Munich. I was General Secretary for the first 3 years, than President for another 3 years. We founded EFOST, because we thought, that EFORT is a too general orthopaedic organization like the AAOS. The same happened years ago in the USA by founding in 1975 the AOSSM as a society focusing on sports injuries and sports pathology. We thought that we need also in Europe a specialised federation, representing all national societies of sports trauma in Europe to bring this field forward in science and in practical sports traumatology.

**GF:** How was the relationship of the European societies in the past?

**HP:** Not very good. ESKA (at that time this was the name, not yet ESSKA). We always had better relationship to the AOSSM due to personal relationships with their leaders.

**GF:** Did EFOST got influence to the European societies?

**HP:** Little by little. Our well organized biannual meetings with excellent speakers from Europe and USA made us with time to a respected scientific organization in Europe.

**GF:** Did EFOST got influence on the national and international guidelines for prevention and treatment in sports trauma - and how?

**HP:** I think in some way yes by our publications in international journals and our biannual meetings.
GF: What do you think is the difference between EFOST and other similar societies e.g. the EFORT?

HP: The main difference is, that we are a federation of specialized societies. The colleague, who is interested mainly in orthopaedic sports medicine, wants to go to meetings where he gets a concentration of sports related presentations. In a meeting of EFORT or AAOS this field plays only a very limited role and it is difficult to find the presentations which are of interest for a sports medicine specialist.

GF: What is the most important experience of your time as President of EFOST?

HP: The language problem. In countries like Spain, Italy and France we still needed expensive simultaneous translations for our congresses. I hope this will be not necessary anymore in the future.

GF: What do think are the main goals for EFOST in future?

HP: Get all European national societies in orthopaedic sports trauma into EFOST. Initiate the foundation for such national societies in countries, where this field is still a part of the national society of orthopaedics.

GF: Thank you Professor Paessler for the interview. I know you still busy in our field. Meet you in London to the WSTC-Congress!

Gernot Felmet, MD
Orthopedic Surgeon Clinical Director, ARTICO Sportklinik, Germany
The Official Journal of European Federation of National Associations of Orthopaedic Sports Traumatology (EFOST) and of the Italian Society of Muscles, Ligaments and Tendons (I.S.Mu.L.T)

MLTJ (http://www.mltj.org/) is an international open access quarterly peer reviewed journal, published in English. (Editor in Chief: Nicola Maffulli)
EFOST - DJO GLOBAL FELLOWSHIP

Team Physician Travelling Fellowship 2012 from Europe to USA

By Dror Lindner and Rocco Papallia

We were honored to be selected as Travelling Fellows of the European Federation of National Associations of Orthopaedic Sports Traumatology (EFOST). We are both young surgeons involved in team sports in our respective countries. Dror, an avid cyclist and triathlete, participated in many national events, and is involved in treating high level athletes in Israel. Rocco, with many publications is highly involved in treatment of high performance athletes.

The Fellowship is kindly sponsored by DJO Global and has been arranged by Francois Kelberine and Nicola Maffulli who arranged all the venues, selected for their academic excellence, involvement and expertise in team sports.

We started at the AAOS in San Francisco. We were amazed at the size of Convention Centre and even more from the number of participants in the event. As always, the AAOS is a great chance to listen key opinion leaders, learn new surgical techniques and meet colleagues. On our first evening we went to dinner with Francois Kelberine, Nicola Maffulli were we met Lutul Farrow, a past travelling fellow and one of our hosts in the Cleveland Clinic, he knew what lay ahead of us.

The AAOSM specialty day was the jewel on the crown, the hottest topics in sport medicine were discussed, from hip arthroscopy to ACL reconstruction and the final session: pediatric ACL reconstruction was fascinating and despite it being the last session of the convention there was a big crowd listening till the end. The only way to keep up to date is attending these conventions. The specialty day gave us the opportunity to meet most of our future hosts: Dr Boyd, Dr Amendola, Dr Bergfeld, Dr Fu and Dr McCarty.
Minnesota, TRIA Orthopaedic Center

Our first stop was the TRIA Orthopedic Center in Minnesota, where after a short stop in our hotel we were picked up for dinner which was prepared and hosted by Dr Fisher and his wife. The meal was based on local ingredients and produce. Dr Fisher is among the founders of TRIA and was team physician for the US 1992 “Dream Team” Basketball Team and for the Minnesota Vikings for 26 years, among his many other team coverage positions. At the dinner we met Dr Boyd, Dr Nelson and the TRIA sport fellows.
Next morning we attended a shoulder conference at the University Minnesota where in depth discussions were conducted. Our next stop was the TRIA Orthopaedic Center, Dr Boyd showed their impressive new facilities and took us to the OR, the clinics and the rehabilitation center.

The afternoon was dedicated to touring the sport centers, Dr Boyd shows us the football and basketball training courts and Dr Steubs took us to Target Field, the baseball stadium where we met the team’s general manager. That evening a private dinner, at the Seven Sushi Ultralounge, was sponsored by Don Joy.

The Next day started at the TRIA Community Conference with an interesting talk about “Adolescent Overuse Injury” followed by some more OR time observing ACL reconstruction and revision and RC repair. Lunch was dedicated to our talks, followed by some more OR time.
Dr. Boyd in action

That evening we attended the Minnesota Wild Hockey game vs. Anaheim Ducks, Dr Fisher and Dr Boyd presented us with the teams jersey with our names on it! Unfortunately the home team lost 2-1, but the atmosphere at the game was electrifying.

We left with mixed filling after having such a good experience we were sad to leave but looking forward for what our next visit hold.
University of Iowa Sports Medicine, Iowa

We were greeted at the airport by Paul Etre, the Personal Assistant of our host Prof Ned Amendola. We had little time to recuperate from the flight and whisked off to the OR where we saw Prof Amendola perform ACL reconstruction followed by ACL revision. Mr Etre showed us around the department, he was the personal assistance for Prof Ponseti who revolutionized the treatment of Club Foot and passed away a couple of years ago at the age of 95, and still working till his last days. That evening we attend the woman’s top 10 swimming match followed by dinner, we learned that University sport is big business in the US and in Iowa especially. UISM sends an Orthopaedic Surgeon and a Sports Physician to each game of the local University Basketball team.

7 AM : grand round meeting starts, an impressive number of attendance: interns, residents, fellows and others attending. We are presented with a case of complex post traumatic deformity of knee followed by our presentations. In the OR we had the opportunity to see Dr Wolf in action, reconstructing the UCL in the elbow and a shoulder scope. The day concluded in nice dinner with the UISM staff.

With Paul Etre, Ned Amendola and the staff in Iowa.

Next morning we knew that we were on a tight schedule but still managed to get some more OR time with Prof Amendola, performing meniscus transplant and revision ACL reconstruction, before Paul took us to the airport.
We said our good bye and were off to our next destination:

**The Cleveland Clinic, Cleveland**

After our first two stops we were looking forward to our next stop, in the US’s second largest private hospital, the Cleveland Clinic. The Cleveland Clinic receives patients from all over the world and many stay pre and post operation in the hotel which has special suites for Royalty and Presidents.

We were picked at the airport by Bret, one of the sport fellows, who informed us that the local Basketball team, the Cavs just lost to the Miami Heat, this was an emotional game because Lebron James who was the local hero, made the transfer from the Cavs to the Heat.

Saturday morning, the weekly academic meeting, many interesting and important talk: Waqas Hussain, one of the sport fellows managed to summarize Patello-femoral disorders in 45 minutes, Jim Rosneck, talked about Hip Impingement and Femoral Version, Lutul Farrow presented the Allograft ACL Outcomes, Morgan Jones explained about bone lose and shoulder instability and many more talks. We gave our presentations: Rocco about shoulder bone defects and Dror about Cycling injuries. The meeting was concluded with Dr Parker giving us some insight about the MOON group study and their results.
Before touring the sport clinic we sat down and had lunch with Dr Bergfeld, that was a great opportunity to listen to one of the icons of sports medicine, we wanted to continue this conversation for several more hours but we were on a tight schedule.

Dr Farrow showed us the clinics and later on took us to the Browns and the Cavs training facilities. The Cavs have a state of the art training center which is impressive even for the NBA standards. Dror was able to meet and talk to the only Israeli player in the NBA Omri Caspi who plays for the Cavs.

The day was concluded in the Shorby Club, which is a private club, Dr Bergfeld was gracious to invite us along with his fellows and staff to dinner.

Sunday morning started off with a typical American breakfast followed by a not so typical pass time activity: Clay Shooting. Dr Bergfeld took us to his Clay Shooting club, we got our ammunition and guns and headed off to shoot. After summarizing our points the winner by a LARGE margin was Dr Bergfeld.
The “Shooting Crew”: Dr Bergfeld, Rocco, Brett, Dror and Paul Saluan

After the excitement of shooting we needed some relaxation, we meet with Dr Farrow and headed to one of Cleveland’s iconic museums: The Rock and Roll Hall of Fame.

To top it all off Lutul took us to a Cavs game vs Sacramento Kings. We met Dr Parker who is the chairman off the Orthopedic department and the Cavs physician, we sat beside him, practically on the court. The game was very close and we were glad after the Cavs won by one point!

Our last day in Cleveland we went with Dr Farrow to the OR and saw him perform an ACL reconstruction, than a quick tour around the main OR, Biomechanics labs
and private suites. We engaged in conversation with Lutul in regards to first time shoulder dislocation and acute ACL reconstruction, finally when our drive arrived we were reluctant to go but we knew that interesting things lay ahead.

University of Pittsburg Sport Medicine, Pittsburg

A short two hour drive got us to Pittsburg, we were both very excited for the opportunity to meet Dr Fu again. Rocco was a research fellow in UPMC in 2006 and Dror has met Dr Fu when he came to perform live surgery in Israel. We arrived to the Inn on Negley had a very short time to get organized before Dr Fu and his wife Hilda came to pick us from our hotel and we were headed to Duquesne Club, which is a private club were we had a lovely dinner with Hilda and Dr Fu. We were already on a good start.

The next morning started off in the OR, Dr Fu had two ACL reconstructions and two revisions. Unfortunately none of them turned out to be a double bundle but watching Dr Fu in action was a privilege in itself. Besides us Dr Fu had fellows and physician from all over the world come to Pittsburg to observe him operate, Dr Fu has so much energy and is such a dedicated physician, it is no wonder why he is such respected figure.
With Dr Fu.

After surgery we had a tour of the local sport teams, both the professional and the college, the clinics and laboratories. Walking through the sport clinic and seeing all the top athletes that had been treated there makes you feel in awe.

The Fellows with Dr. Fu

After touring the labs and clinic we headed to the concussion clinical, head injuries are life threatening injuries and even ‘minor’ head injuries might have serious repercussions. The day ended with the annual Mardi Gras Gala, Hilda and Dr Fu were crowned last year as the queen and king of Mardi Gras and this year they crowned the new queen and king. This was a colorful event, for a good cause,
raising money for the Epilepsy foundation. We didn’t stay up late because 6 AM Sports Medicine Rounds begin!

Despite the early hour the number of people in the room was surprising. After our talks, we joined the Orthopaedic Grand Rounds where Col. Ficke gave a fascinating talk about war injuries and mangled extremities. The ground rounds were followed by the ACL study group meeting, which was a good example on how to conduct a research project, all the participants are dedicated to producing the best study possible and that is the reason that UPMC is such a leading force in Orthopedic research. Dinner was held in the Inn on Negley, this gave us the opportunity to talk to Dr Harner, Dr Fu and the rest of the staff exchanging ideas and listening to experienced Orthopedic surgeons is always a good way to spend an evening. Our flight was leaving early the next morning so we said our good byes and watched Dr Fu driving away in his sport car.

![Rocco in Dr Fu’s car](image)

**Denver University, Colorado**

This was our final stop in this tour and we didn’t know what to expect, the weather that greeted us, sunny with snow on the sides of the roads was mesmerizing and a good indication to our stay in Colorado. We were picked at the airport by Dr Mei-Dan and after a short stop to our hotel we headed to the OR where Dr Bravman did
an ACL reconstruction with medial meniscus suture.

Our schedule threw out the entire fellowship was very busy and Denver was going to be no different, after OR we met with Dr McCarty for dinner. The Denver Broncos were in the playoff and everyone was talking about Tim Tebow.

Dr McCarty’s group cover most of the college sport in the area, and as in Iowa, college sport is huge in Denver. To prove this we went to college basketball game on a Thursday evening, the stadium was packed, this is a different atmosphere than the professional games. Unfortunately the home team lost by a large margin.
Next morning 5:30 AM Dr McCarty picked us up from the hotel and took us to the football training facilities, while walking along the corridor the entire building started to shake, and only when we got to the weight room we figured out why the building was shaking: the football team was into their weight training, they were throwing down huge, unbelievably heavy dumbbells that was the reason the entire building was shaking. Dr McCarty a past football player himself was familiar with this and was not as impressed as we were.

Dr McCarty now and in his football days

Despite our early start to the day, there is no rest for the wicked and we continued on to the OR were we met with Dr Vidal and observed him perform a hip arthroscopy. After surgery we headed out to lunch with Dr Vidal and discussed several topics, every time we had the opportunity to have a discussion with one of our hosts, we took it. Those conversations were a big part of this fellowship, exchanging ideas and opinions.

Before heading off to a hockey game Dr McCarty took us to his house which is located in Boulder, the view from there is breathtaking. Before the game we went to dinner with Dr McCarty and his wife, the usual bad luck continued to haunt us and the home team lost, maybe we were the reason for all this bad luck?
Our last day of the fellowship, today we were going back home. It was a beautiful day and we took advantage of it by going hiking with Dr McCarty in the nearby area, the views were magnificent and we concluded our trip with a hearty breakfast. After that there was time to pack our suitcases have a short walk along the town of Boulder and head out to a lacrosse game. Before the game ended we had to leave to the airport to catch our flight back home.

The fellows with Dr McCarty

Summary

There is a wonderful alchemy that makes traveling fellowship an enchanted world where you forget the daily routine and dive into a surreal world of smiles, hugs and great professionalism. After an amazing three weeks we are back to daily routine, but we feel richer. The Fellowship had been an amazing experience and had surpassed even our highest expectations. We had seen some outstanding surgery, fantastic hospitals and amazing research facilities but most importantly we met exceptionally great physicians. The constant discussions and changing and sharing of ideas gives this fellowship its extra value. Each center we visited was different and this diversity allowed us to experience so many approaches and surgical techniques. We had seen the Sports Medicine care of all aspects of US sport from individual recreational athletes to professional sports teams. The combination of
great physicians, dedicated to the treatment of athletes and to research is what makes them centers of excellence. All the people we met, and the friendships we gained will follow us our entire lives. This was a life changing experience

Acknowledgements

There are many people we would like to thank. First of all we would like to thanks our hosts: Joel Boyd, Dave Fisher, Ned Amendola, Lutul Farrow, John Bergfeld, Freddie Fu, Eric McCarty for their superb hospitality. We would also like to thank their Surgical Colleagues and Fellows who all took time out of busy surgical schedules to look after us during our travels.

Rocco and Dror would like to express a special thank to their respective mentors, Prof Enzo Denaro and Prof Gabriel Agar for having supported their fellowship and their professional growth by allowing them to be away from daily practice in their Hospitals for 3 weeks.

We would like to thank Francois Kelberine, Nicola Maffulli and the EFOST committee for organising the Fellowship.

Finally we would like to thank DJO Global for sponsoring the EFOST Team Physician Travelling Fellowship.

This was an outstanding educational opportunity in which we have been very fortunate to participate. We now use the principles, skills and attitudes we saw on a daily basis and can only hope other surgeons have this chance in the future.
ARTICLE

REHABILITATION AFTER ACL RECONSTRUCTION USING A NOVEL, NITINOL BASED PROSTHESIS: INTERIM ANALYSIS

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Abstract

The new Knee-T-nol™ ACL Prosthesis developed by Tavor Medical is built of a standard implantable alloy. It is aimed to enhance healing and rehabilitation kinetics after ACL reconstruction. This clinical study of 14 patients was meant to explore its safety and efficacy.

The ACL prosthesis was used as a frank ACL replacement during conventional ACL reconstruction, performed on patients with ACL deficient knees. Literature data served as control. Safety and efficacy were assessed clinically and by a radiographic follow up.

One adverse event occurred during the study, and was deemed a result of surgical error, i.e. insufficient implantation depth, resulting in failure of the fixation device and subsequent removal of the prosthesis.

Healing kinetics and rehabilitation period were significantly enhanced in the study group. All patients returned to their pre-injury activity level within 3 months of implantation. In comparison, according to literature, return to pre-injury activity level after conventional ACL reconstruction (autograft or Allograft) can be expected after 6-9 month post-op.
Average Lysholm score at 3 and 6 months post-op was 92.8 and 95.3 accordingly, compared to 51.7 pre-op.

Operative time was reduced to 65.7 minutes on average compared to the standard autograft procedure time of 80-90 minutes.

**Background/Motivation**

ACL injuries are becoming more common, thus raising the need for effective ACL reconstructive surgeries. The internal/external rotation of the knee can be measured to determine the stability of the ACL. A reliable method for determining the internal/external rotation of the knee is essential for diagnosing a ruptured ACL or to evaluate how close reconstruction techniques are at restoring the function of the normal ACL. Many clinicians perform this test; For a device to be manufactured and distributed widely to standardize results of this procedure It should be accurate, simple, lightweight, and adjustable to differently sized patients.

One of the most common sports injuries is a torn ACL. According to the medical literature, about 700,000 cases of torn ACL occur each year in the U.S. alone.

Currently, the gold standard medical treatment involves a dual-procedure operation [CPT 29888]: first, harvesting a Hamstring or Patella tendon from the patient [ICD-9-CM 83.81], than, implanting the autograft instead of the torn ligament [ICD-9-CM 81.45]. This procedure is associated with loss of movement, pain, local morbidity and scaring of the harvested location. An alternative treatment can be conducted by using an allograft (harvesting a tendon from a cadaver). This procedure is less common due to lack of donors, risk of infection and a psychological barrier among patients.

Until today, several polymeric products made of natural polymers [silk] or artificial polymers [ePTFE, PET, CF or PP] have been used as a substitute ligament. These polymers are more elastic than metal, therefore were the natural choice for medical engineers in the past.
However, some of their long term mechanical features, such as fatigue and creep, as well as chemical effects such as leeching, did not last, thus causing those products to fail within a few years of usage. Their clinical success was limited and they were recalled. Today, some of them are approved only for cases in which the autograft implant has failed, and the only other option is knee replacement.

The need for a device that can be manufactured and distributed widely so as to standardize results of this procedure is well established. The device should be dependable, simple, and adjustable to differently sized patients.

Tavor Ltd. is focused at developing an artificial, intra articular implant as an ACL prosthesis, made of Nitinol.

Nitinol has been an accepted implant material for decades in various medical fields such as cardiovascular and muscoskeletal. In vitro, in vivo and clinical studies were conducted that evaluated systemic response of the human body to Nitinol was extensively studied. Muscle, bone, vascular and urethral response have been showing good biocompatibility. Further long term in vivo studies in a caprine models demonstrated the safety and efficacy of the prosthesis.

**Objectives:**

The objective of this study was to evaluate the long term safety and efficacy of implanting the ACL prosthesis in subjects with a ruptured ACL. The evaluation was performed by assessing: (a) improved healing kinetics; (b) Tegner Lysholm knee score and (c) major adverse treatment events (SAEs)

The safety of the tested implant was assessed as having no treatment-emergent SAEs, including Adverse Events of Interest (AEOI), 3 months post operation that include:

- Need for open surgical intervention
- Severe local hematomat
- Severe infection of the surgical site
- Severe swelling
- Uncharacteristic long lasting pain
The efficacy was evaluated by significantly improved healing kinetics of ACL deficient knee in favor of the experimental vs. literature, defined by post operation period [weeks] to successful rehabilitation phase healing kinetics were assessed by independent physiotherapy professionals as well as the investigators.

Initially, a successful rehabilitation period was defined by the ability of the patient to perform the following functional tests:

- 70% of single leg 1 Rep Max on leg press vs. uninvolved
- 10 single leg squats from 0-45° of flexion without loss of balance, muscle quivering, or varus/valgus moments (patella moving out of the sagittal plane)
- 30 consecutive forward step-and-holds from the uninvolved to involved leg without loss of balance, muscle quivering, or varus/valgus moments (patella moving out of the sagittal plane)

**Device Principle of Operation**

Nitinol is characterised by temperature-dependent austenitic-to-martensitic phase transformation on an atomic scale, which is also called thermo-elastic martensitic transformation. The thermo-elastic martensitic transformation causing the shape recovery is a result of the need of the crystal lattice structure to accommodate to the minimum energy state for a given temperature (Otsuka & Wayman 1998). In Nitinol, the relative symmetries between the two phases lead to a highly ordered transformation, where the displacements of individual atoms can be accurately predicted and eventually lead to a shape change on a macroscopic scale. The crystal structure of martensite is relatively less symmetric compared to that of the parent phase. If a single crystal of the parent phase is cooled below $M_r$, then martensite variants with a total of 24 crystallographically equivalent habit planes are generally created. There is, however, only one possible parent phase (austenite) orientation, and all martensitic configurations revert to that single defined structure and shape upon heating above $A_r$. The mechanism by which single martensite variants deforms is called twinning, and it can be described as a mirror symmetry displacement of atoms across a particular atom plane, the
twinning plane (Buehler et al. 1967, Andreasen et al. 1987). While most metals deform by slip or dislocation, Nitinol responds to stress by simply changing the orientation of its crystal structure through the movement of twin boundaries. A Nitinol specimen will deform until it consists only of the correspondence variant which produces maximum strain. However, deformation beyond this will result in classical plastic deformation by slip, which is irrecoverable and therefore has no “memory effect”. If the deformation is halted midway, the specimen will contain several different correspondence variants. If such a specimen is heated above Ar, a parent phase with an orientation identical to that existing prior to the deformation is created from the correspondence variants in accordance with the lattice correspondences between the original parent phase and each variant. The austenite crystal structure is a simple cubic structure, while martensite has a more complex rhombic structure. This phenomenon causes the specimen to revert completely to the shape it had before the deformation (Andreasen et al. 1987, Gil et al. 1998). This phenomenon is the basis of such special properties as the shape memory effect and super-elasticity.

Super-elasticity (or pseudo-elasticity) refers to the ability of Nitinol to return to its original shape upon unloading after a substantial deformation. This is based on stress-induced martensitic formation. The application of an outer stress causes martensite to form at temperatures higher than Ms. The macroscopic deformation is accommodated by the formation of martensite. When the stress is released, the martensite transforms back into austenite and the specimen returns back to its original shape. Super-elastic Nitinol can be strained several times more than ordinary metal alloys without being plastically deformed, which reflects its rubber like behaviour. It is, however, only observed over a specific temperature area. The highest temperature at which martensite can no longer stress induced is called Md. above Md Nitinol alloy is deformed like ordinary materials by slipping. Below As, the material is martensitic and does not recover. Thus, super-elasticity appears in a temperature range from near Ar and up to Md. The largest ability to recover occurs close to Af (Duerig et al. 1996). About 8% strain can be recovered by unloading and heating. Strain above the limiting value will remain as a permanent plastic deformation. The operating temperature for shape memory devices must not move significantly away from the transformation range, or else the shape memory characteristics may be altered.
For orthopaedic biomaterial applications, the two most important properties are strength (mechanical) and reactivity (chemical). The mechanical properties of Nitinol depend on its phase state at a certain temperature (Buehler et al. 1967, Van Humpback et al. 1998). Fully austenitic Nitinol material is generally considered as a suitable material for surgical implantation. ASTM F2063 specifies Nitinol alloy composition for medical devices and surgical implants.

**Device design**

The prosthetic ligament comprises of braided cables, where each cable of the braid comprises of superelastic Nitinol ASTM 2063 filaments twisted into a cable structure (fig. 1).

![Fig 1. The braid design](image-url)
This structure provides a prosthesis of which the mechanical properties are specifically suitable to replace a ruptured ACL.

Both the braid and the strands have a helical structure, but with different helix radii.

The braid has a relaxed radius of 9mm, corresponding with the width of the native ACL.

When tensioned, the braid helix unwinds until it can no longer do so. At this point, the strands begin unwinding. Since the ratio of radius to pitch of the strand helixes is smaller than that of the braid, the stiffness of the strands is larger than that of the braid. This corresponds with the uncrimping of the ligament fibrils. When both the braid and strands are fully unwound, the alloy starts to provide stiffness, which is larger than that of the strands. Since the alloy itself is superelastic at body temperature, the ensuing force/elongation is by itself non-linear, with different elastic modulii in the martensitic phase, transitional phase ("upper plateau"), and austenitic phase.
Another important trait of the aforementioned design is that its resistance to bending and twisting movements is very low as compared to its tensile resistance. This allows implanting the prosthesis as a replacement for an ACL (we believe that it would also apply to PCL, however, it was not tested yet), which undergo extensive twisting and bending during the flexion of the knee.

**Manufacturing of the Device**

The Tavor Prosthesis was designed by Tavor Ltd., a start-up company headquartered in Ashqelon, Israel, established in May 2008.

The actual manufacturing and quality control of the Tavor Prostheses used in this study was performed by Admedes Schussler GmbH, a Qualified and ISO 13485 certified subcontractor specializing in the manufacture of stents, with an experience and profound background in the field of medical device production. The devices were assembled and packaged by trained Tavor personnel at Rafimed Ltd., a qualified and ISO 13485 certified class 10,000 clean room services provider. The prostheses were then sterilized at Sorvan Ltd., an accredited gamma radiation sterilization service provider. Validation of the sterilization process and packaging was performed by AminoLabs Ltd., an accredited testing laboratory.

**Study Procedures**

**Subject Screening and Informed Consent**

The background and purpose of the proposed study and its potential risks and benefits were explained to the patients under the care of the investigator. They were then requested to sign the Informed Consent Form and screened for eligibility using the Inclusion/Exclusion Form.
Subject Enrolment Procedure

A Screening/Enrollment Log was maintained to document selected information about candidates who fail to meet the entry criteria. Due to the radiographic inclusion/exclusion criteria, not all subjects that consented were actually enrolled.

The participation of subjects who did not meet all of the eligibility requirements, was terminated.

As of the date of this report, the clinical investigation site enrolled a total of 15 patients, one patient (IL-01-002) has withdrawn from the study at the screening stage, but after signing an informed consent form, and a total of 14 patients were actually treated in the study arm.

Concomitant Medications

The generic names of the concomitant medications were recorded on the Case Report Form (CRF) from the time of the pre-procedure visit through post procedure visits.

Procedure

Pre-procedure

The following pre-procedure data was collected prior or on the day of the procedure for all subjects:

a) Medical history
b) Radiographs – X-ray/CT/MRI
c) Clinical examinations

The pre-procedure visit included an assessment of subject qualification for inclusion in the study, according to the protocol's inclusion/exclusion criteria.
Informed consent was signed by those subjects agreeing to participate. Key data collected included medical history. The first visit included Tegner-Lysholm and the FDA questionnaire (see appendix C), physical examination using the Lachman test or the pivot-shift test, as well as a range of motion examination to determine loss of extension by holding both heels clear of the table and comparing the extension of the injured knee against the uninjured knee. Joint line tenderness and McMurray test were performed to assess meniscal tears, followed by collateral ligament assessment by varus and valgus stress testing at 0° and 30°.

Assessment results were recorded in the CRF.

As per physician's discretion, radiographic, computed tomography (CT) or magnetic resonance imaging (MRI) were used to further diagnose the exact nature of the injury to the ligament as well as adjacent anatomies. Imaging results were attached to the CRF.

**Procedure**

NOTE: the following sections, other than implant passage and fixation, briefly describe standard textbook procedures, slightly modified to allow thinner tunnels. The surgeon was allowed to perform these stages differently according to his discretion and experience, taking into account the fact that the implant is thinner than a graft.

**EUA and documentation**

Time of start of procedure was registered on the CRF.

Anesthetization was administrated.

Lachman test, pivot shift test and collateral ligament examination were performed and the findings were registered in the CRF.
Diagnostic arthroscopy and meniscal repair/menisectomy

1. Anteromedial, anterolateral, and the accessory medial portals were established. (see picture 1)

![Picture 1. Establishing portals](image)

2. High lateral portal, at the corner of the patellar tendon and the patella was established
3. The knee was scanned with a W manoeuvre to examine the synovium, articular cartilage, medial aspect, articular surfaces of the femur and tibia, PCL, and popliteus tunnel.
4. The ACL was carefully examined and degree of tear assessed. If the tear was less than 50%, the need for reconstruction was reassessed. Results were registered in the CRF.
5. If needed meniscal repair or menisectomy was performed (at surgeon's discretion)

Stump debridement and notchplasty

1. The ACL stump was removed with a combination of a shaver and electrocautery
2. If needed, notchplasty was performed (at surgeon's discretion) taking into account that the prosthesis is only 4.5mm wide as compared to 8-10mm graft.
Tibial tunnel

1. A tibial guide was set to 55° and inserted through the anteriomedial portal.
2. The knee was flexed to 90°, so that the distal point of the guide was positioned 20mm medial to the tubercle and 40mm from the joint line.
3. The tip was placed in the midline between the spines and 7mm anterior to the PCL.
4. A K-wire was used to drill through the guide into the joint. When the wire hit the guide, it was loosened and allowed to advance until it just touched the leading edge of the PCL.
5. Reaming over the K-wire with a 4.5 mm drill bit was completed.
6. Both interior and exterior tunnel sites were cleaned.

Femoral tunnel

1. A femoral guide was placed through the tibial tunnel.
2. A guide passing wire was used to drill to the femoral tunnel through the tibial tunnel with the use of the femoral guide, aiming at 11 or 1 position.
3. A footprint was reamed over the wire with a 4.5mm drill bit on the condyle by drilling only half of the head of the drill bit into the bone. The footprint was examined to determine whether it is in the correct position, in which case the tunnel was drilled through (see picture 2).

Picture 2. Femoral tunnel drilling
**Inspection Prior to Use**

Prior to treatment, all equipment to be used during the procedure was carefully examined to ensure proper performance. Careful inspection the package prior to use for any breach of the sterile barrier or damage to the contents was done.

**Passage**

The implant is designed to be used like an autograft. As per physician discretion, femoral fixation was achieved with an Arthrex™ ACL tightrope® device which was also used to pass the implant into the tunnels.

The implant was passed through the tibial and femoral tunnels as with a hamstring autograft:

1. The implant was folded in half over a suture of the tightrope
2. A graft passing guide wire was used to pull the tightrope device through the tibial tunnel (see pic 3).

**Picture 3. Pulling the implant through the tibial tunnel using an Arthrex™ ACL tightrope® fixation device**
3. The knee was hyperflexed and the guide wire introduced through the low anteromedial portal and into the notch in the femoral tunnel.
4. The guide was used to pull the tightrope device into the femoral tunnel until it reached the cortical bone.
5. The sutures of the tightrope device were used to pull the implant into the femoral tunnel to a depth of 30mm, thus achieving femoral fixation (see picture 4)

![Picture 4. Pulling the implant through the femoral tunnel using an Arthrex™ ACL tightrope® fixation device](image)

**Picture 4. Pulling the implant through the femoral tunnel using an Arthrex™ ACL tightrope® fixation device**

**Tibial Fixation**

1. As per physician discretion, for all subjects, the implant was tensioned to 80N (measured by a force gauge) when the knee was at a flexion angle of 15° (see picture 5) and fixated in the tibial tunnel using a standard orthopaedic staple.

standard orthopaedic staple.
2. The ends of the implant were cut off.
3. X-ray was taken to ensure correct positioning of the implant (see picture 6)
Final inspection and measurements

Once arthroscopy was finished, a manual Lachman test was performed. The time of procedure end was registered on the CRF.

Post procedure

Assistive devices and pain medication were administered as per investigator discretion

Rehabilitation

Rehabilitation program was determined on a subject basis according to physician and physiotherapist discretion, based on a physiotherapy guidance protocol.
supplied by Tavor (see Appendix A). The aim of the rehabilitation program was to have full strength in the operated knee as in the opposite knee.

The full rehabilitation program, as well as subject's participation and progress, were registered on the CRF

**Follow-up Procedures**

The clinical evaluation was performed at the following stages:

- Pre-procedure
- Immediate post-procedure
- 7 days post-procedure
- 3, and 6 months post-procedure

**Procedure evaluation**

The following subject data was recorded immediately after the investigational procedure

- Final radiography
- All relevant information was recorded in the Case Report Forms (CRF's).

**Post-procedure Evaluation**

**7 days post-procedure**

- Clinical and physical examination of the knee
- Tegner-Lysholm assessment
- FDA questionnaire
- All adverse events (serious and non-serious)
• Tunnel width was assessed using a bone density scan (DXA)/CT scan/comparative radiography (with a 5mm diameter metal disk placed adjacent to the knee) or MRI, as per physician discretion, and registered in the CRF. The radiographs were attached.

3, and 6 months post-procedure

• Clinical and physical examination of the knee including Lachman Test.
• Tegner-Lysholm assessment
• FDA questionnaire
• All adverse events (serious and non-serious)
• Concomitant medications

In the three months post-procedure - tunnel width was assessed using a bone density scan (DXA)/CT scan/comparative radiography (with a 5mm diameter metal disk placed adjacent to the knee) or MRI, preferably with the same method as used at 7 day follow-up visit, and registered in the CRF. Radiographs were attached to the CRF.

Results

Patient enrollment and demographics

As of Jan 2012, 15 patients were enrolled to the study.
<table>
<thead>
<tr>
<th>Subject</th>
<th>Date of Procedure</th>
<th>Date of Birth</th>
<th>Sex (m/f)</th>
<th>Operated Knee</th>
<th>Revision</th>
<th>Active Athlete</th>
<th>Type of Sports</th>
<th>Cause of Injury</th>
<th>Last Follow-up as of Data</th>
<th>Comment</th>
</tr>
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<td>IL01-001</td>
<td>23/02/2011</td>
<td>24/06/1977</td>
<td>m</td>
<td>R</td>
<td>no</td>
<td>yes</td>
<td>Rugby</td>
<td>knee</td>
<td>6 months</td>
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<td>IL01-002</td>
<td>NA</td>
<td>29/06/1988</td>
<td>m</td>
<td>NA</td>
<td>no</td>
<td>no</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>voluntary withdrawal before procedure, participation terminated</td>
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<tr>
<td>IL01-003</td>
<td>19/04/2011</td>
<td>26/04/1970</td>
<td>m</td>
<td>R</td>
<td>yes</td>
<td>yes</td>
<td>Soccer</td>
<td>Work accident</td>
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<td>Falling from bike</td>
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<td></td>
</tr>
<tr>
<td>IL01-005</td>
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<td>20/12/1982</td>
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<td>L</td>
<td>no</td>
<td>no</td>
<td>Soccer</td>
<td>Soccer</td>
<td>6 months</td>
<td></td>
</tr>
<tr>
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<td>29/04/1970</td>
<td>m</td>
<td>R</td>
<td>no</td>
<td>no</td>
<td>NA</td>
<td>6 months</td>
<td>6 months</td>
<td></td>
</tr>
<tr>
<td>IL01-008</td>
<td>19/07/2011</td>
<td>20/11/1989</td>
<td>f</td>
<td>L</td>
<td>no</td>
<td>no</td>
<td>Basketball</td>
<td>Sport accident</td>
<td>6 months</td>
<td></td>
</tr>
<tr>
<td>IL01-009</td>
<td>07/02/2011</td>
<td>22/11/1970</td>
<td>m</td>
<td>R</td>
<td>no</td>
<td>no</td>
<td>--</td>
<td>Field work</td>
<td>2 months</td>
<td>not an athlete but considered as participant by the PI due to his physical fitness work</td>
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<tr>
<td>IL01-010</td>
<td>06/01/2011</td>
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<td>m</td>
<td>L</td>
<td>no</td>
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<td>NA</td>
<td>NA</td>
<td>3 months</td>
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</tr>
<tr>
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<td>12/06/2011</td>
<td>10/06/1980</td>
<td>m</td>
<td>R</td>
<td>yes</td>
<td>no</td>
<td>Soccer</td>
<td>Soccer</td>
<td>3 months</td>
<td></td>
</tr>
<tr>
<td>IL01-012</td>
<td>30/03/2011</td>
<td>21/03/1989</td>
<td>m</td>
<td>R</td>
<td>no</td>
<td>no</td>
<td>Soccer</td>
<td>Soccer</td>
<td>3 months</td>
<td></td>
</tr>
<tr>
<td>IL01-013</td>
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<td>02/10/2010</td>
<td>m</td>
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<td>Soccer</td>
<td>Soccer</td>
<td>2 months</td>
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</tr>
<tr>
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<td>02/04/1980</td>
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<td>Soccer</td>
<td>Soccer</td>
<td>2 months</td>
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</tr>
<tr>
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<td>military training</td>
<td>2 months</td>
<td>not an athlete but considered as participant by the PI due to his physical fitness work</td>
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</table>
Procedure

Procedure time

Table 2 summarize the procedure time

<table>
<thead>
<tr>
<th>Patient No.</th>
<th>time in minutes</th>
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<td>IL-01-001</td>
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<td>IL-01-004</td>
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<td>IL-01-006</td>
<td>75</td>
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<td>IL-01-007</td>
<td>52</td>
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<tr>
<td>IL-01-008</td>
<td>90</td>
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<td>IL-01-009</td>
<td>63</td>
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<tr>
<td>IL-01-014</td>
<td>70</td>
</tr>
<tr>
<td>IL-01-015</td>
<td>72</td>
</tr>
</tbody>
</table>

Average procedure time: 65.7 minutes (Standard Deviation = 11.4 minutes)

Clinical outcomes

Knee stability, as measured by a KT-1000 Arthrometer or Lachman test immediately post operation

Table 3 summarizes the pre-procedure knee stability tests
At 3 and 6 months follow up, 13 out of 14 patients (except patient IL-01-004) have exhibited full stability (score 0) in all of the tests (Lachman test, Anterior Drawer, Neutral Rotation, Pivot Shift, Valgus Laxity, Varus Laxity, Posterior Drawer, Posterior sag).

Short and medium term Tegner knee score, 3 and 6 months post operation (respectively). Table 4 summarize Tegner scores.
Table 4: Tegner scores Short and medium term Lysholm knee score, 3 and 6 months post operation (respectively): Table 5 summarizes Lysholm knee score at 3 and 6 months FU.

<table>
<thead>
<tr>
<th>Patient No.</th>
<th>Pre Op</th>
<th>3 months</th>
<th>6 months</th>
</tr>
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<tbody>
<tr>
<td>IL-01-001</td>
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<td>100</td>
<td>100</td>
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<tr>
<td>IL-01-003</td>
<td>48</td>
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<td>100</td>
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<td>NA</td>
</tr>
<tr>
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<td>NA</td>
</tr>
<tr>
<td>IL-01-015</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Average</td>
<td>51.7</td>
<td>92.8</td>
<td>95.3</td>
</tr>
<tr>
<td>SD</td>
<td>17.9</td>
<td>7.6</td>
<td>8.3</td>
</tr>
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</table>

Table 5. Lysholm knee score at 3 and 6 months FU.

Table 6 summarize the Range of motion during the study.
<table>
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<tr>
<th></th>
<th>0° to 125°</th>
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<th>0° to 125°</th>
<th>0° to 125°</th>
</tr>
</thead>
<tbody>
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<td>0° to 125°</td>
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<tr>
<td>IL-01-003</td>
<td>0° to 145°</td>
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<td>IL-01-004</td>
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<td>0° to 100°</td>
<td>0° to 125°</td>
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<td>IL-01-005</td>
<td>0° to 140°</td>
<td>13° to 90°</td>
<td>0° to 125°</td>
<td>0° to 125°</td>
</tr>
<tr>
<td>IL-01-006</td>
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</tr>
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<td>0° to 120°</td>
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</tr>
<tr>
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<td>3° to 90°</td>
<td>0° to 125°</td>
<td>NA</td>
</tr>
<tr>
<td>IL-01-012</td>
<td>0° to 140°</td>
<td>2° to 90°</td>
<td>0° to 120°</td>
<td>NA</td>
</tr>
<tr>
<td>IL-01-013</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>IL-01-014</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>IL-01-015</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Average</td>
<td>0° to 131°</td>
<td>3 to 83</td>
<td>0 to 124.5</td>
<td>0 to 124</td>
</tr>
<tr>
<td>SD</td>
<td>9.7</td>
<td>18.6</td>
<td>5.8</td>
<td>1.8</td>
</tr>
</tbody>
</table>

**Safety**

All Adverse Events are registered in Table 7
<table>
<thead>
<tr>
<th>Patient No</th>
<th>AE Date</th>
<th>Name of Event</th>
<th>SAE FU obtained? (Yes/No)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>IL-01-001</td>
<td>9 May 2011 to 13 May 2011</td>
<td>Sensitivity in anterior scars of the knee of the arthroscopy.</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>IL-01-001</td>
<td>15 Jun 2011 to 16 Jun 2011</td>
<td>Sore throat (mild)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>IL-01-001</td>
<td>3 Sep 2011 to 12 Sep 2011</td>
<td>Sore throat</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>IL-01-003</td>
<td>5 Jun 2011 to 5 Jun 2011</td>
<td>Effusion</td>
<td>N/A</td>
<td>Aspiration performed</td>
</tr>
<tr>
<td>IL-01-003</td>
<td>30 Jun 2011 to 30 Jun 2011</td>
<td>Mild Effusion</td>
<td>N/A</td>
<td>Aspiration performed</td>
</tr>
<tr>
<td>IL-01-004</td>
<td>17 Sep 2011 to 18 Sep 2011</td>
<td>Mild Effusion</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>IL-01-004</td>
<td>26 Jun 2011 to 28 Jun 2011</td>
<td>Effusion</td>
<td>N/A</td>
<td>30cc aspiration performed</td>
</tr>
<tr>
<td>IL-01-004</td>
<td>22 Jul 2011 to 24 Jul 2011</td>
<td>Effusion</td>
<td>N/A</td>
<td>NSAID and Elastic band</td>
</tr>
<tr>
<td>IL-01-004</td>
<td>31 Jul 2011 to 4 Aug 2011</td>
<td>Break down of scar</td>
<td>Initial and FU</td>
<td>N/A</td>
</tr>
<tr>
<td>IL-01-004</td>
<td>21 Oct 2011 to 23 Oct 2011</td>
<td>Effusion</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>IL-01-004</td>
<td>7 Oct 2011 to 8 Oct 2011</td>
<td>Effusion</td>
<td>N/A</td>
<td>Disappeared spontaneously</td>
</tr>
<tr>
<td>IL-01-006</td>
<td>11 Jul 2011 to 12 Jul 2011</td>
<td>dizziness</td>
<td>N/A</td>
<td>Resolved</td>
</tr>
<tr>
<td>IL-01-007</td>
<td>28 Jul 2011 to 29 Jul 2011</td>
<td>Breakdown of scar</td>
<td>N/A</td>
<td>Band – oil</td>
</tr>
<tr>
<td>IL-01-008</td>
<td>29 Aug 2011 to 31 Aug 2011</td>
<td>Cold</td>
<td>N/A</td>
<td>Scheduled for surgery on 9 Aug, Surgery postponed to 5 Sep.</td>
</tr>
<tr>
<td>IL-01-008</td>
<td>6 Sep 2011 to 11 Sep 2011</td>
<td>Post op effusion</td>
<td>N/A</td>
<td>Aspiration of 30 cc</td>
</tr>
<tr>
<td>IL-01-009</td>
<td>6 Sep 2011 to 7 Sep 2011</td>
<td>38.9 °C fever</td>
<td>N/A</td>
<td>Analgesics</td>
</tr>
<tr>
<td>IL-01-010</td>
<td>19 Oct 2011</td>
<td>Tendonitis biceps</td>
<td>N/A</td>
<td>Voltaren</td>
</tr>
</tbody>
</table>
All Serious Adverse events are registered in table 8

<table>
<thead>
<tr>
<th>Patient No</th>
<th>SAE Date</th>
<th>Name of Event</th>
<th>SAE FU obtained?</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>IL-01-004</td>
<td>Oct 21 2011 to Nov 21 2011</td>
<td>revision arthroscopy due to suspected meniscus tear</td>
<td>Yes</td>
<td>Fixation device failure due to procedure malfunction discovered, decided to remove implant.</td>
</tr>
<tr>
<td>IL-01-005</td>
<td>27 Jun 2011 to 2 Jul 2011</td>
<td>Post spinal anesthesia low Back pain</td>
<td>N/A</td>
<td>analgesics</td>
</tr>
<tr>
<td>IL-01-006</td>
<td>20 Sep 2011 onwards</td>
<td>Suspected Tear of medial meniscus</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

**Discussion**

**Postoperative stability**

The primary criterion for any successful ACL reconstruction surgery has traditionally knee stability immediately postoperatively, as tested whether using Lachman test or an arthrometer such as a KT-1000 device. This allows assessing both the surgical technique as well as the strength and flexibility of the graft or prosthesis, regardless of the quality of the rehabilitation protocol, adherence of the patient to physiotherapy, or the remodeling process (see below)

As all operated knees exhibited perfect stability immediately post-op, the primary endpoint has been fully achieved. It is important to note that all operated knees were also stable at 3 and 6 months post-op, supporting the assumption that remodeling is not required (see below).

Primary safety endpoint: no treatment emergent SAEs, including AE of interest, 3 month post-op

Of the 14 patients treated, 3 patients had SAEs;
**Patient IL-01-004**

The patient is an avid extreme bicycle rider. had a deficient ACL and was implanted with a prosthesis. it was fixated with a tightrope system (Arthrex, Naples, Florida) in the femur and a staple at the tibia.

The patient returned to extensive sporting activity within a month after the implantation. 6 weeks after the implantation, he complained about pains in his operated knee. also reported a bicycle accident which was noted on the CRF. had repeated effusions and was suspected of having a medial meniscus tear. A revision Arthroscopy was performed during which it was discovered that the femoral fixation device failed, resulting in the prosthesis being fixated at the tibial side only, thus having no anatomic function. The prosthesis was explanted. The company has informed the hospital immediately and voluntarily halted the study until further data is available as to the cause of the failure.

An internal adverse event review committee was adjourned and reviewed the video of the original arthroscopy as well as the revision arthroscopy. The committee discovered that the prosthesis was implanted at a depth of 5mm in the femur instead of 20-25mm as required by the protocol. Further analysis of the post-op radiograph confirmed this assessment.

Picture 7 shows radiographs of the operated knee of patient IL-01-004, showing the inadequate depth of femoral fixation as compared to a patient with a normal fixation depth as required by the protocol, as shown in Picture 8 (patient IL-01-013). Specifically, in picture 8, a meander can be easily observed where the prosthesis enters the femoral tunnel, a meander which is absent in patient IL-01-004.
**Picture 7.** Postoperative radiograph of patient IL-01-004

**Picture 8.** Postoperative radiograph of patient IL-01-013
The committee has classified the SAE as a procedural malfunction, and not related to the studied device. The company has amended the protocol to include an intraoperative radiograph before tibial fixation to ensure proper implantation depth in all future patients, informed the hospital and resumed the study as planned. It is to be noted that such a procedural malfunction of shallow fixation depth may occur in standard ACLR procedures involving autograft or allograft as well, However, since the prosthesis is radiopaque compared to bone, whereas a graft is not, such an error can be easily mitigated with the use of the new prosthesis by maintaining a protocol of intraoperative radiography before final fixation.

**Patient IL-01-006**

Patient IL-01-006 suffered from lower back pains following the procedure. These pains were deemed a result of the anesthesia and not device related.

**Patient IL-01-007**

Patient IL-01-007 was suspected of having a tear in the medial meniscus and was scheduled for further examination. Results will be reported separately when available.

**Rehabilitation kinetics**

Functional outcome of the ACL reconstruction is extremely important to athletes who desire to return to their sport. However, it is also important for common people as well, for various clinical reasons as well as for the Quality of life.

Traditional rehabilitation programs following ACL reconstruction aim to return the athlete to sporting activity by 6 to 12 months postoperatively. Some athletes however, for whom accelerated rehabilitation is of utmost importance, use an accelerated rehabilitation program, these programs usually allow the patient to return to sporting activity at 4-6 months postoperatively, but these programs raise concerns about stability or compromise of the graft.
For an ACL reconstruction procedure to succeed, two integrated processes must occur; remodelling of the graft (particularly in the synovial compartment), as well as ossointegration of the graft, both in the femur and in the tibia. As the blood supply in the bones is much higher than in the synovial compartment, the latter usually occurs much faster than the former.

A common concern regarding accelerated rehabilitation programs, is the viability of the graft during the first 6 months post operatively. It is currently understood that a newly implanted graft will undergo a number of stages as it matures. A newly inserted graft initially undergoes Avascular necrosis (AVN), followed by a process of ligamentisation, whereby it revascularizes and remodels to resemble ACL tissue. In animals, this vascularization process has been shown not to reach its peak until 6 months postoperatively, suggesting the graft may be susceptible to compromise during the first 6 months.

These animal studies suggest increased demands on the graft 4-6 months postoperatively, may place the graft at risk of lengthening or rupture\(^7\).

In comparison, when a frank replacement prosthesis is used to reconstruct a ruptured ACL, remodelling is not required, and the only process needed for a successful procedure is osseointegration of the prosthesis in the tibial and femoral tunnels. As mentioned earlier, this process occurs much faster than remodelling, allowing a much safer and faster rehabilitation for the patient. This assumption is supported by both scientific literature as well as by the fact that Lachman tests at 3 and 6 months post op for 13 out of 14 patients, exhibited no signs of loss of stability (excluding patient IL-01-004, for whom a procedural malfunction has occurred)

Rose et al. \(^4\) have reported the differences in the rehabilitation period following two methods of anterior cruciate ligament replacement: semitendinosus/gracilis tendon vs. ligamentum patellae, exhibiting the following results for lysholm scores (table 9), range of motion (table 10) and Tegner scores (Table 11)
**Table 9.** Lysholm scores after standard ACLR using autografts

<table>
<thead>
<tr>
<th>Time post procedure</th>
<th>Test</th>
<th>Angle</th>
<th>SG</th>
<th>LP</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Extension deficit</td>
<td>&lt;3</td>
<td>86%</td>
<td>92%</td>
</tr>
<tr>
<td>3 months</td>
<td>3-5</td>
<td>14%</td>
<td>8%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt;5</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Maximal flexion</td>
<td>&gt;120</td>
<td>84%</td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td>90-120</td>
<td>16%</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt;90</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>6 months</td>
<td>Extension deficit</td>
<td>&lt;3</td>
<td>84%</td>
<td>92%</td>
</tr>
<tr>
<td></td>
<td>3-5</td>
<td>14%</td>
<td>8%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt;5</td>
<td>2%</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Maximal flexion</td>
<td>&gt;120</td>
<td>84%</td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td>90-120</td>
<td>14%</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt;90</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

**Table 10.** Range of motion after standard ACLR using autografts

<table>
<thead>
<tr>
<th>Tegner score</th>
<th>SG</th>
<th>LP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-injury</td>
<td>5.3±2.0</td>
<td>4.8±1.9</td>
</tr>
<tr>
<td>3 months</td>
<td>2.1±1.3</td>
<td>1.5±1.2</td>
</tr>
<tr>
<td>6 months</td>
<td>3.2±1.6</td>
<td>3.3±1.8</td>
</tr>
<tr>
<td>12 months</td>
<td>4.3±2.2</td>
<td>4.0±2.1</td>
</tr>
</tbody>
</table>

**Table 11.** Tegner score after standard ACLR using autografts
**Conclusion**

Although the study results are very preliminary, with only partial outcomes available, interim results suggest that ACL reconstruction using the novel Nitinol prosthesis is a safe, effective and economic alternative to current surgical techniques using autografts or allografts, providing good clinical outcome, and faster rehabilitation.

**BIBLIOGRAPHY:**

There are numerous rehabilitation protocols for the Achilles tendon ruptures (1,2,3,4,5) while a few rehabilitation protocols are available after the Achilles tendon repair and they are controversial (6,7,8). As such in our previous study (9) (See Table), rehabilitation protocols are only part of the texts in all studies at above. There is no double-blind randomized controlled study to evaluate effects of the rehabilitation protocols after the percutaneously Achilles tendon repair in the literature. It is suggested that future studies might evaluate the effects of intensive rehabilitation protocols and look at the longer term follow-up of these patients.

Our new article revealed a significant difference in joint position sense at plantarflexion of the patients at least one year after percutaneous Achilles tendon surgery compared to their unaffected side and dominant side of healthy control (10). This is the first study to investigate proprioception by ankle joint position sense after percutaneous Achilles tendon repair.

The aim of this paper was to call clinician’s attention to proprioceptive deficit after Achilles tendon repair. The summary of our proprioception study was presented in this paper.

Proprioceptors are located within the muscles, tendons, ligaments and other soft tissues of the body. They are sensors which relay information to the brain about joint position, pressure and muscle stretch (11, 12, 13). In the case of the injury
or rupture, the proprioceptors of the Achilles tendon can be affected.

Although there is speculation as to whether proprioceptive deficits predispose an individual to injury (12), there have been no studies that have evaluated ankle proprioception following endoscopically guided percutaneous repair of a ruptured Achilles tendon. Nineteen male patients with percutaneous Achilles tendon surgery and age and sex matched 19 healthy controls were included in our Achilles proprioception study (10).

<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>0-3 weeks</strong></td>
<td>Range of motion: 20 PF &amp; 10 DF passively</td>
</tr>
<tr>
<td><strong>3-6 weeks</strong></td>
<td>Neuromuscular exercises with flexion and extension of the toes, full PF and DF of the ankle to neutral in a supine position. Extension of the knee in a sitting position. Flexion of the knee in a prone position. Extension of the hip in a prone position.</td>
</tr>
<tr>
<td><strong>6-10 weeks</strong></td>
<td>Resistance DF &amp; PF exercises, eversion and inversion of the ankles. Standing on the toes and heels. Ankle stretching exercises for calf, ankle and toes muscles. Balance and proprioception exercises on different surface progress from bilateral to unilateral. Controlled squats, lunges exercises. Controlled slow eccentrics versus body-weight.</td>
</tr>
<tr>
<td><strong>After 10 weeks</strong></td>
<td>Start training jogging/running, jumping and eccentric loading exercises, non-competitive sporting activities, sports-specific exercises, and return to physically demanding sports and/or work.</td>
</tr>
</tbody>
</table>

**How did we evaluate the ankle proprioception?** Before testing, each subject warmed up for 5 minutes on a stationary exercise cycle at a self-selected intensity. Ankle proprioception was defined as the ability to match reference ankle joint angles (the ‘target angle’) without visual feedback. Joint position sense was measured by Active Angle Reproduction (AAR) by using a Biodex System 3 Dynamometer (Biodex Corp., Shirley, NY, USA) (See **Figure**). The dynamometer was calibrated according to the manufacturer’s instructions prior to each testing session; data were read from the on-screen goniometer. Patients sat upright with the knee flexed to approximately 20°, the seat back tilted 100°, and their barefoot
in a neutral position. They were asked to close their eyes during testing to eliminate visual input (11, 13, 14). For each repetition the patients moved the limb to the target angle of either 10° for dorsiflexion or 15° for plantar flexion actively (15). These midrange angles were selected in an attempt to maximize sensory input from muscle proprioceptors (13). When patients felt they had reached the target angle they activated the stop button and were not permitted to correct the angle. The angle was recorded from the on-screen goniometer; this process was repeated six times for each target angle (16). A total of six readings were taken and the difference between the perceived angle and each of the target angles 10° for dorsiflexion or 15° for plantar flexion was noted as the absolute error and an average absolute error calculated for each trial.

![Fig. Joint position sense test positions](image)

| Joint position sense test position for dorsiflexion | Joint position sense test position for plantar-flexion |

Although there was an article focus on proprioception after Achilles tendon surgery (17) in the literature, there was no data about surgical technique (open or percutaneous) in text. Our search of the literature failed to identify any previous study of ankle proprioception following percutaneously Achilles tendon repair. Bressel et al evaluated proprioceptive level of the patients with unilateral Achilles tendon rupture that was surgically repaired at least one year from the day of
testing and compared healthy controls (17). Proprioception of the ankle of the twenty patients with unilateral Achilles tendon rupture and twenty healthy controls were evaluated using electrogoniometer in prone position. Target and estimated angles (from all ankle range of motion) were taken using electrogoniometer and twelve different angles were replicated. Proprioception absolute errors for the involved and uninvolved limbs of the experimental group were 27% and 31% greater respectively, than values for the control group (17). In our study, there was no difference in ankle joint position sense at 10° dorsiflexion while there was significantly difference at 15° plantarflexion. After the surgery there were no differences in muscle strength, functional level, range of motion, and ankle joint position sense at 10° dorsiflexion while there was still difference in ankle joint position sense at 15° plantarflexion (10). Bressel et al found poor proprioceptive sense both of ankle joint than healthy controls. Authors speculated unilateral proprioceptive deficit may result in bilateral deficit. Authors also explained bilaterally proprioceptive deficit with phenomena of cross education (17). The most important finding of our study was a significant difference in joint position sense at 15° plantarflexion between the affected and unaffected side. There were no other significant differences in hop and jump tests, joint position sense at 10° dorsiflexion, dorsi and plantar-flexor isokinetic muscle strength and dorsi and plantar-flexion range of motion between the affected and unaffected side of the patients. Joint position sense at 10° dorsiflexion and at 15° plantar flexion at affected side was poor in patients compared with the dominant side of the controls while there were no differences in joint position sense at 10° dorsiflexion and at 15° plantarflexion between the unaffected side of the patients and dominant side of the controls (10). Loss of the proprioception at plantar-flexion may due to these patients having poor level of proprioception before the injury and surgery at affected side. Although poor proprioception may predispose the Achilles tendon to rupture, this topic is not well understood. The result of the present study showed that proprioception at the unaffected side of the patients was nearly normal. We thought decreased proprioceptive sense after the injury may relate to Achilles tendon damage. Although proprioception exercises were started in the early phases of our rehabilitation program, proprioception deficit at plantarflexion still remained. Therefore we recommend that specific and intensive proprioceptive program should be started at an early stage of the treatment for patients with percutaneous
Achilles tendon surgery. It is suggested that future studies might evaluate the effects of intensive and specific proprioceptive exercises and look at the longer term follow-up of these patients. The muscle strength, functional level, and range of motion may be re-established as a normal ankle feature after surgical repair while tendon genetic feature cannot be changed. Inadequate sensory feedback from mechanoreceptors around the ankle joint distorts a patient's perception of foot position during movement and may increase the risk of an injurious oblique load to the Achilles tendon and trigger the tendon rupture (18). It is also suggested that future studies might evaluate the effects of calcaneal position for Achilles tendon rupture and on proprioception, and look at the longer term follow-up of these patients. The results of our study suggest that while this time period may be sufficient for connective tissue remodeling to occur, re-establishing non-impaired psycho-neuromotor properties may take longer to achieve. In addition to achieving standard post-operative goals of alleviating pain, eliminating ROM and strength impairments, and functional limitations, clinicians need to increase their attention on the neuromechanical aspects of patient recovery especially proprioceptive sense after Achilles tendon repair.

As a conclusion, increased proprioceptive level may prevent re-rupture, provide extensive connection between the brain, joint and ground. The proprioceptive training should not be neglected. Isolated proprioceptive exercises should be included in the rehabilitation programme for Achilles tendon repair.

REFERENCES


REHABILITATION AFTER MUSCLE INJURY

Joseph Lowe*, Gabriel Agar**

* Unit of Sports Medicine, Hadassah University Hospital, The Hebrew University, Jerusalem, Israel, ** Department of Orthopaedics, Asaf Harofeh Medical Center, Tel-Aviv University, Tel-Aviv, Israel

**INTRODUCTION:**

The goals of rehabilitation programs following muscle injury are to promote the tissue healing response in the shortest possible time, to return the athlete to sport as soon as possible, and to prevent re injury.

There is a lack of consensus in the literature on the effectiveness of rehabilitation protocols for muscle injuries, with little evidence based data. The available published studies tend to deal more with hamstring tears than with other muscle injuries.

Rehabilitating a muscle injury needs to address the two competing processes which are occurring concurrently i.e. muscle healing and regeneration on the one hand, and scar tissue formation on the other.

In addition, application of rehabilitation protocols require an appreciation of the natural healing response relative to the severity of the injury, and to the time since the injury occurred.

The severity of the muscle injury has been graded, for example according to Clanton, as Grade I (tear of a few fibers, minimal swelling, minimal loss of function), Grade II (partial tear, swelling, loss of strength), Grade III (complete tear, total loss of muscle strength).
The stage of the healing has been divided by Clanton into five phases i.e. Acute (1-7 days), Subacute (7-21 days), Remodelling (1-6 weeks), Functional (2weeks-6 months) and Return to competition phase (1-6 months). These vary according to the severity of the injury.

Discussion of the rehabilitation of muscles that have been injured assumes an understanding of some of the risk factors associated with muscle injuries:

Bi-articular muscle groups such as hamstrings, biceps, gastrocnemius and rectus femoris, are said to be more prone to muscle injury, because of the rapidly alternating more forceful eccentric and less forceful concentric contractions involved during running or throwing.³

Regarding hamstring injuries, a strength imbalance of 10% or more between right and left leg muscles, or a flexor/extensor ratio of 0.6 or less are said to increase the likelihood of muscle injury. This needs to be corrected to normal values in a properly constructed rehabilitation program. The caveat is that these ratios are not absolute. They decrease with increased speed of isokinetic testing, and vary between males and females, between participants in different sports, and between playing positions in the same sport.

**FACTORS WHICH INFLUENCE THE RISK OF INJURY:**

The following modifiable and non modifiable factors may put the athlete at greater risk of muscle injury, and need to be addressed in a properly constructed rehabilitation program:

Non modifiable risk factors:

Aging athletes,⁴ Aboriginal and Black sports people.⁵

Modifiable risk factors:

Imbalance of muscular strength between agonist and antagonists, i. e. low hamstring/quadriceps ratio in hamstring injuries⁶,⁷, Muscle fatigue⁸,⁹, Hamstring tightness¹⁰,¹¹,¹², Insufficient warm up¹¹,¹³, Previous injury⁴,¹⁴.
**TREATMENT:**

Worrell stressed that rehabilitation protocols should assume that muscle tears are due to an interaction of all of the above factors 15. Devlin suggested that there is a threshold involved above which a combination of the above factors could lead to muscle injury 13.

**Rehabilitation Protocol:**

The following issues in treatment protocols may be relevant to the rehabilitation of muscle injuries:

In the early phase after muscle injuries there is consensus that RICE is the accepted method to control pain and hemorrhage. However, simple analgesia for pain management in the first week may be preferable to NSAID’s, as initial suppression of the inflammatory response may delay the healing and rehabilitation process 2. Optimal immobilization time in the early phase of muscle healing should be brief, no more than one week according to Jarvinen 16. Longer immobilization may lead to atrophy and stiffness delaying rehabilitation. Immediate mobilization without rest could lead to dense fibrosis which would impair rehabilitation. The injured muscle should be immobilized in the fully stretched position.

Early controlled mobilization after the brief rest period is said to be critical to restoration of the mechanical properties of the injured muscle, and to shortening the rehabilitation time 17. Submaximal isometric muscle contractions at multiple joint angles within the pain free range have been advised at this early stage 15. Walking in a pool and stationary biking allow pain free motion and controlled resistance exercises in the early rehabilitation period when walking on land may still be painful.

As pain resolves and motion improves in the subacute healing phase, isometric contractions should be replaced with light graded isotonic exercises, using concentric and avoiding eccentric activity. The force of eccentric contractions performed too early could damage healing muscle in the subacute stage.
Initiating a high speed low resistance isokinetic program in the pain free range has been advised as the healing reaches the remodeling phase, with light eccentric exercises started at this stage. Muscle stretching and eccentric strengthening should be in the pain free range in the remodeling phase, but must be avoided if they cause pain, as this may lead to rehabilitation induced re injury.

In the more advanced stages of the remodeling phase, and in to the functional healing phase, slow progression has been advised to a higher resistance slower speed isokinetic protocol. Walking, jogging and running could be initiated at this stage, guided by the results of isokinetic testing (improving muscle torque compared to baseline measurements, and improving agonist/anagonist ratios). All activities should be performed pain free.

**Core Stability:**

The importance of stabilization by core muscle and proprioceptive exercises has been stressed. In their literature review of evidence based prevention of hamstring injuries in sport, Peterson et al found only one prospective, randomized controlled study in the English literature that investigated the effectiveness of different rehabilitation protocols for the treatment of acute hamstring strains. In this study Sherry and Best compared two different rehabilitation programs. They showed that progressive agility and trunk stabilization programs were better than static stretching and isolated progressive hamstring resistance exercises in rehabilitating the injured muscle and in preventing re injury.

**RE-INJURY:**

The possibility of re injury of the healed muscle following return to sport could be avoided by rehabilitation programs that concentrate upon maintaining flexibility, increasing muscle strength utilizing concentric/eccentric isokinetic protocols, emphasizing pre-competition warm-up, and minimizing the fatigue factor in competition.
Heiser et al. in their retrospective study of the rehabilitation of hamstring injuries in football players, concluded that isokinetic testing and rehabilitation of muscle imbalances could prevent hamstring injury. They applied high speed isokinetic workouts from the third post injury day in their experimental group, allowing jogging when peak hamstring torque equaled 70% of the baseline score and the H/Q ratio was 0.55 or more. The control group did not receive the isokinetic program and returned to sport 2 weeks after injury. There were 13 recurrences in the control group and none in the experimental group. They concluded that injured muscle healed with higher tensile strength and less likelihood of recurrence following early application of an isokinetic rehabilitation program.

**FURTHER DEVELOPMENT:**

Despite the fact that muscle injuries are so common in the athletic population, there is little sound evidence based research in the literature upon which to offer recommendations regarding rehabilitation following these injuries. There is a need for much further research, preferably in the form of randomized controlled trials.

**BIBLIOGRAPHY:**


A retrospective comparison of four plate constructs for first metatarsophalangeal joint fusion: static plate, static plate with lag screw, locked plate, and locked plate with lag screw.

Hyer CF, Scott RT, Swiatek M.


**Abstract.** The primary treatment for progressive first metatarsophalangeal (MTP) joint arthritis is arthrodesis. Multiple fixation types have been used to accomplish fusion including plating. There have been no published articles reporting the outcomes of these 4 plate and/or screw constructs. We present our experience with 138 first MTP joint fusions using these constructs. A retrospective comparison and radiographic chart review of 132 patients (138 feet) was performed to compare different constructs in regards to successful union and time to fusion. All operations were performed by 4 fellowship-trained foot and ankle surgeons. The radiographs were independently read by 2 authors not involved in the index procedures. Radiographic fusion was determined by bridging cortices across the joint line. The mean time to union (in days) and rate of fusion were static plate: 59, 95%, static plate with lag screw: 56, 86%, locked plate: 66, 92%, and locked plate with lag screw: 53, 96%. There was not a statistically significant difference between the groups in regards to patient age, time to weight bearing, time to fusion, or rate of fusion. We report on the results of fusion comparing 4 different plate and/or screw constructs for first MTP joint fusion. The data reveal no significant difference in time to fusion or rate of fusion between static and locked plates, with or without a lag screw.
Comparison of Motion Changes and Clinical Outcomes between Cervical Disc Replacement and Anterior Cervical Discectomy and Fusion in Single Level Cervical Degenerative Disease: Retrospective Analysis

Sang-DEOK Kim, Jung-Kil Lee, Jae-Won Jang, Hyung-Sik Moon, Soo-Han Kim, Dae-Yong Kim

Objective. Cervical Total Disc Replacement (CTDR) has recently been developed as an alternative to Anterior Cervical Discectomy and Fusion (ACDF) in cervical degenerative disease to preserve the motion at the treated level. The aim of this study is to investigate the safety and efficacy of CTDR by comparing it with ACDF in the treatment of single-level cervical degenerative disease, retrospectively.

Methods. This study included 61 patients, who underwent either stand-alone single-level ACDF (n = 33) or single level CTDR (Bryan cervical artificial disc, n = 28) at C3 to C7 for degenerative cervical disease between June 2007 and December 2009. Cervical radiographs were obtained to measure overall and regional cervical angle and Range of Motion (ROM). For evaluation for patient’s pain, visual analogue scale and Japanese Orthopedic Association score was measured.

Results. The changes of the overall Cervical Sagittal Angle (CSA) were not significantly different between the two groups. The Segmental Angle (SA) was maintained at a significantly higher in the CTDR group compared to the ACDF group during the follow-up period (p < 0.05). The ROM of the upper adjacent segment was significantly increased in the ACDF group compared to the CTDR group.

Conclusions. Clinically, CTDR is at least as efficient as ACDF. CTDR using a Bryan artificial disc provided a significant maintenance of the SA and the ROM at the treated level, and prevented the hyper-mobility at the upper adjacent segment compared to the ACDF. In the Future, prospective, randomized, long-term follow-up study with large-number will be required to clarify the efficacy of CTDR.
The incidence of thromboembolic events in surgically treated ankle fracture.

Pelet S, Roger ME, Belzile EL, Bouchard M.


**Background.** Thromboembolic events occur following musculoskeletal injury, and some have serious sequelae, including death. The purpose of this study was to determine the incidence of thromboembolic events and its relationship with risk factors in ambulatory patients with ankle fracture requiring open reduction and internal fixation.

**Methods.** We conducted a retrospective chart review of 2478 patients who underwent open reduction and internal fixation of an ankle fracture at any one of three university hospitals between January 1, 1997, and April 30, 2005. One thousand five hundred and forty patients meeting the inclusion criteria and with complete records (minimum follow-up, six months) were identified. The median age of the patients at the time of surgery was forty-six years, and there was an equal proportion of male and female patients. Fracture types included 45% unimalleolar fractures, 31% bimalleolar, and 24% trimalleolar. Charts were reviewed to identify thromboembolic events, risk factors (neoplasia, hormone use, pregnancy, blood dyscrasia, history of a previous thromboembolic event, a current history of smoking, obesity, dyslipidemia, atherosclerotic vascular disease, or paralysis), and use of thromboprophylactic agents. A thromboembolic event was defined as symptomatic when deep venous thrombosis was confirmed with use of Doppler ultrasonography or when pulmonary embolism was confirmed with use of ventilation and perfusion scintigraphy or helical computed tomography.

**Results.** The incidence of thromboembolic events was 2.99% (forty-six patients), with 2.66% (forty-one patients) involving a deep venous thrombosis and 0.32% (five patients) involving a nonfatal pulmonary embolism. There were no fatal pulmonary emboli recorded. The incidence did not differ among hospitals. Of the 1540 patients, 16.43% received thromboprophylaxis during their hospital stay and
for six weeks (for the 10.78% taking low-molecular-weight heparin) or three months (for the 5.65% taking warfarin) after discharge without significantly modifying the incidence of thromboembolic events (2.56% vs. 2.37%, relative risk = 0.91). However patients with one or more risk factors had a greater risk of a thromboembolic event than did patients with no risk factors (3.59% vs. 2.38%, respectively; relative risk = 0.66). The use of thromboprophylaxis had no apparent impact on the occurrence of thromboembolic events in patients who did or did not have risk factors (3.68% vs. 3.55%, respectively; relative risk = 0.96). No significant correlation could be identified between the occurrence of thromboembolic events and fracture types, age, or sex.

Conclusions. Clinically detectable thromboembolic events after surgical treatment of ankle fractures are uncommon and do not appear to be influenced by the use of thromboprophylaxis. Patients with risk factors appear to be at higher risk for these events, but there is a need for prospective studies to determine the efficacy of thromboprophylaxis after surgical treatment of ankle fractures.

The Importance of Image Guidance during Epidural Injections: Rates of Incorrect Needle Placement during Non-Image Guided Epidural Injections

Joshua H. Levin, Ryan Wetzel and Matthew W. Smuck

Background. Epidural steroid injections are commonly-performed procedures used to treat several spinal conditions. Traditionally, these procedures have been performed without image guidance. However, a large number of blindly-performed injections are inaccurate with needle placement outside the epidural space. The purpose of the current article was to review the data on inaccuracy rates of non-image guided epidural injections.

Results and Conclusions. 9-52% of non-image guided caudal epidural injections are outside the epidural space. 7-30% on non-image guided lumbar interlaminar epidural injections is outside the epidural space.
Serum and synovial fluid analysis for diagnosing chronic periprosthetic infection in patients with inflammatory arthritis.

Cipriano CA, Brown NM, Michael AM, Moric M, Sporer SM, Della Valle CJ.


**Background.** The serum erythrocyte sedimentation rate and C-reactive protein level, as well as the synovial fluid white blood-cell count with differential, are commonly used tests for the diagnosis of periprosthetic joint infection; however, their utility for the diagnosis of periprosthetic joint infection in patients with inflammatory arthritis is unknown.

**Methods.** Eight hundred and three patients undergoing 871 consecutive hip and knee arthroplasties (including sixty-one in patients with inflammatory arthritis and 810 in patients with noninflammatory arthritis) were prospectively evaluated for periprosthetic joint infection. The erythrocyte sedimentation rate, C-reactive protein level, and synovial fluid white blood-cell count with differential were obtained routinely. Receiver operating characteristic curves were used to establish optimal thresholds for the diagnosis of periprosthetic joint infection, and the area under the curve was calculated to determine the overall accuracy of these tests for patients with inflammatory compared with noninflammatory arthritis.

**Results.** The utility of all serum and synovial tests for predicting chronic periprosthetic joint infection was similar for patients with noninflammatory and inflammatory arthritis. The optimal cutoffs in patients with noninflammatory and inflammatory arthritis were 32 and 30 mm/hr, respectively, for the erythrocyte sedimentation rate; 15 and 17 mg/L, respectively, for the C-reactive protein level; 3450/µL and 3444/µL, respectively, for the synovial fluid white blood-cell count; and 78% and 75%, respectively, for the differential. The areas under the curves were similar for the two groups (84.9% and 85.0%, respectively, for the erythrocyte sedimentation rate; 88.5% and 85.1%, respectively, for the C-reactive protein level; 94.5% and 93.8%, respectively, for the synovial fluid white blood-
cell count, and 95.0% and 93.6%, respectively, for the differential). Finally, the sensitivities, specificities, negative predictive values, and positive predictive values for all tests were also comparable in both groups. The rate of periprosthetic joint infection was significantly higher following procedures in patients with inflammatory arthritis than following procedures in patients with noninflammatory arthritis (31% compared with 18%; \( p = 0.013 \)).

**Conclusions.** The erythrocyte sedimentation rate, C-reactive protein level, and synovial fluid white blood-cell count with differential are useful for diagnosing periprosthetic joint infection in patients with inflammatory as well as noninflammatory arthritis, with similar optimal cutoff values and overall testing performance. The synovial fluid white blood-cell count and differential performed the best for the diagnosis of periprosthetic joint infection. Physicians evaluating patients with a failed or painful total hip or knee arthroplasty should not assume that elevation of the erythrocyte sedimentation rate, C-reactive protein level, and synovial fluid white blood-cell count with differential is secondary to inflammatory arthropathy; rather, elevation of these markers may indicate periprosthetic joint infection, and further evaluation for infection is warranted.

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**Management of calcaneal tuberosity fractures.**

**Banerjee R, Chao JC, Taylor R, Siddiqui A.**

**Abstract.** Fractures of the calcaneal tuberosity are relatively uncommon and are seen most frequently in elderly and diabetic patients. These injuries are typically avulsion fractures caused by concentric contraction of the gastrocnemius-soleus muscle complex. Displacement of these fractures can compromise the skin over the posterior aspect of the heel; therefore, early recognition and management are imperative. Surgical management of calcaneal tuberosity fractures requires reduction and stable fixation of the displaced fragment. When the patient has preexisting tightness of the gastrocnemius-soleus complex, successful management must also address this pathology to improve outcome.
Proximal humeral malunion treated with reverse shoulder arthroplasty.

Willis M, Min W, Brooks JP, Mulieri P, Walker M, Pupello D, Frankle M.


**Background.** The purpose of this study was to determine the outcomes of patients with proximal humeral malunions treated with reverse shoulder arthroplasty (RSA).

**Materials and Methods.** Sixteen patients were treated with RSA for sequelae of a proximal humeral fracture with a malunion. Clinical outcomes (American Shoulder and Elbow Surgeons [ASES] score, Simple Shoulder Test, visual analog scale [VAS] score for pain and function, range of motion, and patient satisfaction) and radiographs were evaluated at a minimum follow-up of 2 years. Wilcoxon signed-rank tests were used to analyze preoperative and postoperative data.

**Results.** All patients required alteration of humeral preparation with increased retroversion of greater than 30°. The total ASES score improved from 28 to 63 (P = .001), ASES pain score from 15 to 35 (P = .003), ASES functional score from 15 to 27 (P = .015), VAS pain score from 7 to 3 (P = .003), VAS function score from 0 to 5 (P = .001), and Simple Shoulder Test score from 1 to 4 (P = .0015). Forward flexion improved from 53° to 105° (P = .002), abduction from 48° to 105° (P = .002), external rotation from 5° to 30° (P = .015), and internal rotation from S1 to L3 (P = .005). There were no major complications reported. Postoperative radiographic evaluation showed 2 patients with evidence of notching and 1 patient with proximal humeral bone resorption.

**Conclusion.** RSA is indicated for treating the most severe types of proximal humeral fracture sequelae. The results of RSA for proximal humeral malunions with altered surgical technique yield satisfactory outcomes in this difficult patient population.
Operative versus nonoperative care of displaced midshaft clavicular fractures: a meta-analysis of randomized clinical trials.

McKee RC, Whelan DB, Schemitsch EH, McKee MD.


**Background.** Recent studies have suggested benefits following primary operative fixation of substantially displaced midshaft fractures of the clavicle. We reviewed randomized clinical trials of operative versus nonoperative treatment of these fractures, and pooled the functional outcome and complication rates to arrive at summary estimates of these outcomes.

**Methods.** A systematic review of the literature was performed to identify studies of randomized clinical trials comparing operative versus nonoperative care for displaced midshaft clavicular fractures.

**Results.** Six studies (n = 412 patients, mean Detsky score = 15.3) were included. The nonunion rate was higher in the nonoperatively treated patients (twenty-nine of 200) than it was in patients treated operatively (three of 212) (p = 0.001). The rate of symptomatic malunion was higher in the nonoperative group (seventeen of 200) than it was in the operative group (0 of 212) (p < 0.001).

**Conclusions.** Operative treatment provided a significantly lower rate of nonunion and symptomatic malunion and an earlier functional return compared with nonoperative treatment. However, there is little evidence at present to show that the long-term functional outcome of operative intervention is significantly superior to nonoperative care.
Sliding hip screw versus the TargonPF nail in the treatment of trochanteric fractures of the hip: a randomised trial of 600 fractures.

Parker MJ, Bowers TR, Pryor GA.


**Abstract.** In a randomised trial involving 598 patients with 600 trochanteric fractures of the hip, the fractures were treated with either a sliding hip screw (n = 300) or a TargonPF intramedullary nail (n = 300). The mean age of the patients was 82 years (26 to 104). All surviving patients were reviewed at one year with functional outcome assessed by a research nurse blinded to the treatment used. The intramedullary nail was found to have a slightly increased mean operative time (46 minutes (sd 12.3) versus 49 minutes (sd 12.7), *p* < 0.001) and an increased mean radiological screening time (0.3 minutes (sd 0.2) versus 0.5 minutes (sd 0.3), *p* < 0.001). Operative difficulties were more common with the intramedullary nail. There was no statistically significant difference between implants for wound healing complications (*p* = 1), or need for post-operative blood transfusion (*p* = 1), and medical complications were similarly distributed in both groups. There was a tendency to fewer revisions of fixation or conversion to an arthroplasty in the nail group, although the difference was not statistically significant (nine versus three cases, *p* = 0.14). The extent of shortening, loss of hip flexion, mortality and degree of residual pain were similar in both groups. The recovery of mobility was superior for those treated with the intramedullary nails (*p* = 0.01 at one year from injury). In summary, both implants produced comparable results but there was a tendency to better return of mobility for those treated with the intramedullary nail.
Efficacy of autologous platelet-rich plasma use for orthopaedic indications: a meta-analysis.

Sheth U, Simunovic N, Klein G, Fu F, Einhorn TA, Schemitsch E, Ayeni OR, Bhandari M.


Background. The recent emergence of autologous blood concentrates, such as platelet-rich plasma, as a treatment option for patients with orthopaedic injuries has led to an extensive debate about their clinical benefit. We conducted a systematic review and meta-analysis to determine the efficacy of autologous blood concentrates in decreasing pain and improving healing and function in patients with orthopaedic bone and soft-tissue injuries.

Methods. We searched MEDLINE and Embase for randomized controlled trials or prospective cohort studies that compared autologous blood concentrates with a control therapy in patients with an orthopaedic injury. We identified additional studies by searching through the bibliographies of eligible studies as well as the archives of orthopaedic conferences and meetings.

Results. Twenty-three randomized trials and ten prospective cohort studies were identified. There was a lack of consistency in outcome measures across all studies. In six randomized controlled trials (n = 358) and three prospective cohort studies (n = 88), the authors reported visual analog scale (VAS) scores when comparing platelet-rich plasma with a control therapy across injuries to the acromion, rotator cuff, lateral humeral epicondyle, anterior cruciate ligament, patella, tibia, and spine. The use of platelet-rich plasma provided no significant benefit up to (and including) twenty-four months across the randomized trials (standardized mean difference, -0.34; 95% confidence interval [CI], -0.75 to 0.06) or the prospective cohort studies (standardized mean difference, -0.20; 95% CI, -0.64 to 0.23). Both point estimates suggested a small trend favoring platelet-rich plasma, but the associated wide confidence intervals were consistent with nonsignificant effects.
**Conclusions.** The current literature is complicated by a lack of standardization of study protocols, platelet-separation techniques, and outcome measures. As a result, there is uncertainty about the evidence to support the increasing clinical use of platelet-rich plasma and autologous blood concentrates as a treatment modality for orthopaedic bone and soft-tissue injuries.

Detection of total hip prostheses at airport security checkpoints: how has heightened security affected patients?

Johnson AJ, Naziri Q, Hooper HA, Mont MA.


**Background.** The sensitivity of airport security screening measures has increased substantially during the past decade, but few reports have examined how this affects patients who have undergone hip arthroplasty. The purpose of this study was to determine the experiences of patients who had hip prostheses and who passed through airport security screenings.

**Methods.** A consecutive series of 250 patients who presented to the office of a high-volume surgeon were asked whether they had had a hip prosthesis for at least one year and, if so, whether they had flown on a commercial airline within the past year. Patients who responded affirmatively to both questions were asked to complete a written survey that included questions about which joint(s) had been replaced, the number of encounters with airport security, the frequency and location of metal detector activation, any additional screening procedures that were utilized, whether security officials requested documentation regarding the prosthesis, the degree of inconvenience, and other relevant information.

**Results.** Of the 143 patients with hip replacements who traveled by air, 120 (84%) reported triggering the alarm and required wanding with a handheld
detector. Twenty-five of these patients reported subsequently having to undergo further inspection, including additional wanding, being patted down, and in two cases having to undress in a private room to show the incision. Ninety-nine (69%) of the 143 patients reported that the prosthetic joint caused an inconvenience while traveling.

Conclusions. This study provides interesting and critical information that allows physicians to understand the real-world implications of implanted orthopaedic devices for patients who are traveling where there has been heightened security since September 11, 2001. Patients should be counseled that they should expect delays and be prepared for such inconveniences, but that these are often only momentary. This information could relieve some anxiety and concerns that patients may have prior to traveling.

Return of motor function after segmental nerve loss in a rat model: comparison of autogenous nerve graft, collagen conduit, and processed allograft (AxoGen).

Giusti G, Willems WF, Kremer T, Friedrich PF, Bishop AT, Shin AY.


Background. An effective alternative to nerve autograft is needed to minimize morbidity and solve limited-availability issues. We hypothesized that the use of processed allografts and collagen conduits would allow recovery of motor function that is equivalent to that seen after the use of autografts.

Methods. Sixty-five Lewis rats were divided into three experimental groups. In each group, a unilateral 10-mm sciatic nerve defect was repaired with nerve autograft, allograft treated by AxoGen Laboratories, or a 2.0-mm-inner-diameter collagen conduit. The animals were studied at twelve and sixteen weeks postoperatively. Evaluation included bilateral measurement of the tibialis anterior
muscle force and muscle weight, electrophysiology, assessment of ankle contracture, and peroneal nerve histomorphometry. Muscle force was measured with use of our previously described and validated method. Results were expressed as a percentage of the values on the contralateral side. Two-way analysis of variance (ANOVA) corrected by the Ryan-Einot-Gabriel-Welsch multiple range test was used for statistical investigation (α = 0.05).

**Results.** At twelve weeks, the mean muscle force (and standard deviation), as compared with that on the contralateral (control) side, was 45.2% ± 15.0% in the autograft group, 43.4% ± 18.0% in the allograft group, and 7.0% ± 9.2% in the collagen group. After sixteen weeks, the recovered muscle force was 65.5% ± 14.1% in the autograft group, 36.3% ± 15.7% in the allograft group, and 12.1% ± 16.0% in the collagen group. Autograft was statistically superior to allograft and the collagen conduit at sixteen weeks with regard to all parameters except histomorphometric characteristics (p < 0.05). The collagen-group results were inferior. All autograft-group outcomes improved from twelve to sixteen weeks, with the increase in muscle force being significant.

**Conclusions.** The use of autograft resulted in better motor recovery than did the use of allograft or a collagen conduit for a short nerve gap in rats. A longer evaluation time of sixteen weeks after segmental nerve injuries in rats would be beneficial as more substantial muscle recovery was seen at that time.

**Clinical results and risk factors for reinjury 15 years after anterior cruciate ligament reconstruction: a prospective study of hamstring and patellar tendon grafts.**

*Leys T, Salmon L, Waller A, Linklater J, Pinczewski L.*


**Background.** There is a lack of prospective studies comparing the long-term
outcome of endoscopic anterior cruciate ligament (ACL) reconstruction with either a patellar tendon or hamstring tendon autograft.

**Purpose.** This prospective longitudinal study compared the results of isolated endoscopic ACL reconstruction utilizing a 4-strand hamstring tendon (HT) or patellar tendon (PT) autograft over a 15-year period with respect to reinjury, clinical outcomes, and the development of osteoarthritis.

**Study Design.** Cohort study; Level of evidence, 2.

**Methods.** Ninety consecutive patients with isolated ACL rupture were reconstructed with a PT autograft, and 90 patients received an HT autograft, with an identical surgical technique. Patients were assessed at 2, 5, 7, 10, and 15 years. Assessment included the International Knee Documentation Committee (IKDC) knee ligament evaluation including radiographic evaluation, KT-1000 arthrometer testing, and Lysholm knee score.

**Results.** Patients who received the PT graft had significantly worse outcomes compared with those who received the HT graft at 15 years for the variables of radiologically detectable osteoarthritis (grade A: 46% in PT and 69% in HT; P = .04), motion loss (extension deficit <3°: 79% in PT and 94% in HT; P = .03), single-legged hop test (grade A: 65% in PT and 92% in HT; P = .001), participation in strenuous activity (very strenuous or strenuous: 62% of PT and 77% of HT; P = .04), and kneeling pain (moderate or greater pain: 42% of PT and 26% of HT; P = .04). There was no significant difference between the HT and PT groups in overall IKDC grade (grade A: 47% of PT and 57% of HT; P = .35). An ACL graft rupture occurred in 17% of the HT group and 8% of the PT group (P = .07). An ACL graft rupture was associated with nonideal tunnel position (odds ratio [OR], 5.0) and male sex (OR, 3.2). Contralateral ACL rupture occurred in significantly more PT patients (26%) than HT patients (12%) (P = .02) and was associated with age ≤18 years (OR, 4.1) and the PT graft (OR, 2.6).

**Conclusion.** Anterior cruciate ligament reconstruction using ipsilateral autograft continues to show excellent results in terms of patient satisfaction, symptoms, function, activity level, and stability. The use of HT autograft does, however, show
better outcomes than the PT autograft in all of these outcome measures. Additionally, at 15 years, the HT graft-reconstructed ACLs have shown a lower rate of radiological osteoarthritis.

**In vivo analysis of the isolated posterior cruciate ligament-deficient knee during functional activities.**


**Background.** Most patients with isolated posterior cruciate ligament (PCL) injuries have minimal symptoms, and nonoperative treatment is recommended. However, over time, these patients can develop significant degenerative changes in their knees. Historically, PCL laxity is graded by nonweightbearing anteroposterior measuring techniques that do not reproduce the true, dynamic weightbearing conditions in the injured knee. The purpose of this study was to determine the patholaxity in patients with isolated PCL deficiency during functional weightbearing activities (running, walking, and stair ascent).

**Hypothesis.** Patients with unilateral, isolated PCL deficiency will demonstrate dynamic anteroposterior and rotational instability in their affected knees during functional activities of level running and stair ascent compared with their unaffected, contralateral knees.

**Study Design.** Controlled laboratory study.

**Methods.** Nine asymptomatic patients with isolated grade II PCL injury underwent Dynamic Stereo X-Ray (DSX) of both knees during level running and stair ascent. Three-dimensional reconstructions of the patients’ bilateral distal femurs and proximal tibias were created from high-resolution computed tomography (CT) scans. Three-dimensional joint kinematics were determined using a model-based tracking approach to align the radiographic images with CT-derived bone models. The resulting tibiofemoral rotations and translations for the PCL-deficient and PCL-
intact knees were then compared.

**Results.** During level running, the tibia of the PCL-deficient knee was approximately 2 mm posteriorly subluxated and had an anterior velocity relative to the femur approximately 40 mm/s greater than the contralateral, uninjured knee; however, this was only during the swing phase. No significant differences were found during the stance phase of running. During stair ascent, the tibia of the PCL-deficient knee was approximately 4 mm posteriorly subluxated compared with the intact limb during the terminal swing phase and early stance phase. Between foot strike and the time of peak ground-reaction force (GRF), the tibia of the PCL-deficient knee translated anteriorly relative to the femur with velocities 3 to 4 times greater than in the intact limb. Level walking was also evaluated in 3 patients, but no differences were seen, and it was not tested in the remaining 6 patients.

**Conclusion.** Changes in knee kinematics due to isolated PCL injuries were highly activity dependent. During running, small differences were identified only during the swing phase when the knee was unloaded. However, during stair ascent, significant differences extended from the late swing into early stance phase. During the swing phase of stair ascent, the tibia in the PCL-deficient joint subluxated posteriorly. Then, as load was transferred to the ascending limb, the tibia reduced anteriorly with high velocity relative to the femur. The resulting shear motion may expose the loaded joint to abnormal and potentially damaging forces.

**Clinical Relevance.** During functional activities, patients with isolated PCL injuries experience significant knee instability that cannot be identified by standard nonweightbearing static laxity measurements. The finding that different activities create different degrees of instability may have important implications for rehabilitation and activity limitations for PCL-deficient individuals.
Early radial head excision for displaced and comminuted radial head fractures: considerations and concerns at long-term follow-up.


**Objectives.** The aim of this study is to retrospectively review the outcomes of patients with comminuted radial head fractures surgically treated with early radial head excision.

**Design.** Retrospective follow-up study.

**Setting.** University orthopaedic trauma center.

**Patients.** Forty-two patients with unilateral, isolated, closed, displaced, or comminuted radial head fracture (Mason type 2-10, Type 3-32).

**Intervention.** Early radial head excision.

**Main Outcome Measurements.** Patients were clinically and radiographically evaluated at an average follow-up of 18 years. The uninjured contralateral limb was used as a comparison. Clinical evaluation was rated using the Broberg and Morrey system, the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire, and the visual analog scale (VAS) for pain.

**Results.** At last follow-up, 36 patients had no complaints, whereas six admitted to occasional pain. The mean Broberg and Morrey score was 91.2 ± 6.3, and the mean Disabilities of the Arm, Shoulder and Hand score was 10.1 ± 8.8.

**Conclusion.** Early radial head excision represents a viable option in case of displaced and comminuted fractures. According to the results of this study, it demonstrated a high rate of good results and patient satisfaction, a quick recovery after surgery, and a low rate of complications with durable results at long-term follow-up.
**Level of Evidence.** Therapeutic Level IV. See Instructions for Authors for a complete description of levels of evidence.

The surgical treatment of isolated mason type2 fractures of the radial head in adults: comparison between radial head resection and open reduction and internal fixation.


**Objectives.** To compare the outcomes of two different surgical treatments for the management of isolated closed Mason Type2 radial head fractures.

**Design.** Retrospective study. The Student t test and McPearson chi-square test were used to evaluate whether there was a significance difference between the groups.

**Patients.** Fifty-nine patients with isolated Mason Type2 radial head fractures.

**Intervention.** Twenty-four patients treated with radial head excision (Group I) and 35 treated with open reduction and internal fixation (Group II).

**Main Outcome Measurements.** Clinical outcomes were assessed using the Broberg and Morrey functional rating scores and the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire. Orthogonal radiographs were performed on both the elbow and the wrist; these were assessed for the presence of arthritis, heterotopic ossification, and the degree of proximal radial migration.

**Results.** The length of postoperative follow-up was 157 ± 61.84 months (Group I) and 125 ± 39.09 months (Group II). The Broberg and Morrey functional rating score was 86.21 ± 6.10 points and 95.09 ± 4.78 points, respectively. The DASH score was 21.82 ± 6.01 points and 2.81 ± 2.73 points, respectively. Radiologically
moderate or severe osteoarthritis was present in the elbows of nine patients in Group I and only two patients in Group II.

**Conclusions.** Patients with isolated Mason Type2 radial head fractures treated by open reduction and internal fixation (Group II) had less residual pain, greater range of motion, and better strength than patients treated by radial head excision (Group I). Additionally, Group II had a lower incidence of severe posttraumatic arthritis, which contributed to improved DASH and Broberg and Morrey functional scores. These results support open reduction and internal fixation as the treatment of choice for these fractures.

**Level of Evidence.** Therapeutic Level III. See Instructions for Authors for a complete description of levels of evidence

**Hemiarthroplasty of the hip with and without cement: a randomized clinical trial.**

Taylor F, Wright M, Zhu M.


**Background.** Controversy exists regarding the use of cement for hemiarthroplasty to treat a displaced subcapital femoral neck fracture in elderly patients. The primary hypothesis of this study was that use of cement would provide better visual analog pain scores following this procedure in an elderly patient population.

**Methods.** Elderly patients (at least seventy years of age) without severe cardiopulmonary compromise who presented to one institution with a displaced subcapital femoral neck fracture were offered inclusion in the study. One hundred and sixty patients (mean age, eighty-five years) with an acute displaced femoral neck fracture were randomly allocated to hemiarthroplasty with either a cemented Exeter or an uncemented Zweymüller Alloclassic component. Clinical and
radiographic follow-up was performed for two years and the outcomes were recorded by a blinded assessor. The main clinical outcome measures were pain, mortality, mobility, complications, reoperations, and quality of life measured with use of validated instruments.

**Results.** The mean visual analog pain score at rest did not differ significantly between the groups. The total number of complications was greater in the uncemented group (sixty-three compared with twenty-eight in the cemented group). Subsidence was significantly more common in the uncemented group (eighteen compared with one in the cemented group). Intraoperative or postoperative fracture was also significantly more common in the uncemented group (eighteen compared with one in the cemented group). The mortality rate did not differ significantly between the groups at any time point (thirty-five deaths in the uncemented group compared with thirty-two in the cemented group at two years). The Oxford hip score was significantly poorer in the uncemented group at six weeks (38.8 compared with 35.7 in the cemented group), and it was also poorer or similar at later follow-up time points although the differences were not significant. There was also a trend toward poorer mobility and greater dependence on walking aids in the cemented group. The postoperative Short Musculoskeletal Function Assessment and Mini-Mental State Examination scores did not differ significantly between the groups.

**Conclusions.** In elderly patients (seventy years or older) without severe cardiopulmonary compromise who were treated with hemiarthroplasty for a displaced femoral neck fracture, use of a cemented Exeter implant and use of an uncemented Alloclassic implant provided a comparable outcome with regard to pain. However, implant-related complication rates were significantly lower in the group treated with a cemented implant. Trends toward better function and better mobility in the cemented group were observed. These trends reached significance in particular functional scores at some postoperative time points.

**Level of Evidence.** Therapeutic Level II. See Instructions for Authors for a complete description of levels of evidence.


Background. The purpose of this study was to evaluate the relationship between walking ability, as determined with use of the Gross Motor Function Classification System (GMFCS), and the outcome of hip adductor surgery used to prevent hip displacement in children with cerebral palsy.

Methods. We performed a retrospective review of the records of all children with cerebral palsy whose index surgery, performed between January 1994 and December 2004 at one tertiary-level pediatric hospital, was bilateral hip adductor releases. All children had a hip migration percentage of >30% in at least one hip prior to the adductor surgery, and the minimum duration of follow-up was twenty-four months. Kaplan-Meier survivorship curves were generated by determining the time from the index surgery to "failure," defined as either the need for subsequent surgical procedures or a migration percentage of ≥50% in either hip. Hazard ratios were calculated for sex, migration percentage at the time of the index surgery, age at the time of the index surgery, and GMFCS level.

Results. Three hundred and thirty children were included in the study; 73% (242) were nonambulatory (GMFCS level IV or V). The mean age at the time of the index surgery was 4.2 years, the mean migration percentage was 43%, and the mean duration of postoperative follow-up was 7.1 years. Surgery consisted of open lengthening of the adductor longus and gracilis muscles in all children, with additional procedures as deemed necessary. "Success" was defined as the absence of subsequent surgical procedures during the study period and a migration percentage of <50% in both hips at the time of follow-up. One hundred and six children (32%) met these criteria for success. The success rate was 94% (thirty-one of thirty-three) in children at a GMFCS level of II, 49% (twenty-seven of fifty-
five) in children at a level of III, 27% (twenty-eight of 103) in children at a level of IV, and 14% (twenty of 139) in children at a level of V.

**Conclusions.** Walking ability, as defined with use of the GMFCS level, is a strong predictor of success or failure after hip adductor surgery in children with cerebral palsy. The paradox of hip adductor surgery for children with cerebral palsy is that the children who are most severely affected and need the surgery the most have the poorest results.

**Complications of supracondylar osteotomies for cubitus varus.**

Raney EM, Thielen Z, Gregory S, Sobralske M.


**Background.** Humeral osteotomies for cubitus varus have a notoriously high complication rate. Pitfalls of this difficult procedure are highlighted.

**Methods.** A 50-year experience of 68 consecutive surgeries was reviewed. Factors such as surgical approach and fixation technique were compared for complication incidence and type.

**Results.** Seventeen patients (25%) had 23 (34%) clinically remarkable complications. Nine postoperative nerve palsies occurred in 8 patients. Loss of reduction requiring revision or manipulation was seen in 3 patients. The following complications were noted in 2 patients each: nonunion, loss of flexion, lateral prominence, and unsatisfactory scar. Growth arrest, osteomyelitis, and under-correction requiring revision each occurred once. A lateral, triceps-sparing approach was associated with an overall prevalence of complications of 24% (5 of 21) equivalent to the posterior, triceps splitting approach of 24% (10 of 42). An olecranon osteotomy was used in 2 patients both with complications. No nerve
injuries occurred in patients who underwent a lateral approach, whereas nerve palsies occurred in 14% (6 of 42) of the patients where a posterior approach was used. An olecranon osteotomy was used in 2 patients with nerve injury occurring in both. A medial approach in 2 patients and a combined medial-lateral approach in 1 patient were used with no complications. Plate and screw fixation was implemented in 29 cases with complications occurring in 6 of them; pin fixation, in 30 cases, 7 of which had complications. There was a higher incidence of under-correction requiring additional surgery with plate fixation (1 of 29) compared with pin fixation which had no under correction but had loss of fixation in 2 of 30. The average correction obtained was similar in the group with complications (32 degrees) versus those without (27 degrees).

**Conclusions.** Supracondylar humeral osteotomy is a technically demanding procedure fraught with complications. Plate fixation and pin fixation techniques resulted in similar complication rates, but the surgical approach used appeared to make a difference. The posterior, triceps splitting, approach resulted in a high incidence of nerve palsies versus none with the lateral, triceps-sparing approach.

**Level of Evidence.** This is a retrospective case series, Level IV.

**A randomized, controlled, multicenter study on the effectiveness of Traumeel (ointment and gel) in terms of pain reduction and function improvement compared with diclofenac gel in acute ankle sprain**

**De Vega CG, González J**

**on behalf of Traumeel Acute Ankle Sprain Spain (TAASS) Study**

**Background.** Acute lateral ankle sprain is generally accepted as the most common ligamentous sports and daily exercise injury associated with acute inflammation.
When left untreated, these injuries can lead to joint instability and a limited range of motion.

**Objectives.** To demonstrate that Traumeel (ointment and gel) is non-inferior to diclofenac gel 1% in the treatment of acute ankle sprain.

**Methods.** In this multicenter study, 449 physically active patients (18–40 years) with unilateral ankle sprain were randomized blinded to receive 2 g of Traumeel ointment (n=152) or Traumeel gel (n=150) or diclofenac gel (n=147) administered topically three times a day for 14 days, with 6-weeks follow-up. Primary endpoints were patients’ assessment on a 0–100 mm Visual Analogue Scale (VAS) ankle pain and on the Activities of Daily Living (ADL, 0–100) subscale of the Foot and Ankle Ability Measurement (FAAM) on Day 7.

**Results.** On Day 7, median percentage reductions in VAS pain score were demonstrated by all groups: Traumeel ointment, 60.6% (median: baseline 52.6 mm; change -33.0); Traumeel gel, 71.1% (median: baseline 53.1 mm; change -37.1); and diclofenac, 68.9% (median: baseline 55.7 mm; change -37.1). Total pain relief was reported by 8.5%, 5.0% and 5.9% of patients in each group, respectively. Mann-Whitney (MW) effect sizes and lower bound of the confidence intervals (LBCI; predefined benchmark 0.4) for Traumeel ointment and gel combined vs. diclofenac (MW=0.4910; LBCI=0.4321), Traumeel ointment vs. diclofenac (MW=0.4682; LBCI=0.4004) and Traumeel gel vs. diclofenac (MW=0.5142; LBCI=0.4464) demonstrated non-inferiority of both the Traumeel preparations vs. diclofenac for reducing pain. On Day 14, median percentage reductions in VAS pain score were 94.3%, 93.4% and 94.8% (median changes -46.4, -50.5 and -50.5 mm) for Traumeel ointment, Traumeel gel and diclofenac groups, respectively. On day 7, median improvements in FAAM ADL score were 26.2, 26.2 and 25.0 points (median baseline 51.2, 56.0 and 51.2 points) for Traumeel ointment, Traumeel gel and diclofenac groups, respectively. MW effect sizes and LBCI for Traumeel ointment and gel combined vs. diclofenac (MW=0.5260; LBCI=0.4656), Traumeel ointment vs. diclofenac (MW=0.5169; LBCI=0.4485) and Traumeel gel vs. diclofenac (MW=0.5352; LBCI=0.4666) demonstrated non-inferiority of both Traumeel preparations vs. diclofenac for
functional improvement. On Day 14, median improvements in FAAM ADL score were 41.7, 40.5 and 41.7 points for Traumeel ointment, Traumeel gel and diclofenac groups, respectively. At 6 weeks, all patients reported total pain relief and normal functioning. Median time to normal function was 19.09, 19.35 and 19.39 days for Traumeel ointment, Traumeel gel and diclofenac groups, respectively. Adverse events (n=43) were reported by 31/447 patients (6.9%). Events were mostly mild or moderate in severity, none was serious and all treatments were equally well tolerated.

**Conclusions.** In this large scale trial, Traumeel ointment and gel decreased pain and improved joint function to the same extent as diclofenac gel in acute ankle sprain, with a good tolerability profile. Trial ID: NCT01066520
In recent years, research studies into sports injuries have provided healthcare professionals with a better understanding of their etiology and natural history. On this basis, novel concepts in the diagnosis and management of these conditions are now being explored. This timely book offers a complete guide to the latest knowledge on the diagnosis and treatment of the full range of possible sports injuries. Individual sections are devoted to biomechanics, injury prevention, and the still emerging treatment role of growth factors, which foster more rapid tissue healing. Sports injuries of each body region are then examined in detail, with special attention to diagnostic issues and the most modern treatment techniques. In addition, pediatric sports injuries, extreme sports injuries, the role of physiotherapy, and future developments are extensively discussed. All who are involved in the care of patients with sports injuries will find this textbook to be an invaluable, comprehensive, and up-to-date reference.
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<td>ICRS Focus Meeting - Foot &amp; Ankle</td>
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Call for Abstracts

ONLINE ABSTRACT SUBMISSION
The International Society of Arthroscopy, Knee Surgery and Orthopaedic Sports Medicine (ISAKOS) is pleased to announce the Call for Abstracts for the 2013 Congress.

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Abstract Submission Deadline: September 1, 2012
TiGenix focuses on applying regenerative medicine to damaged and diseased joints with the goal of developing durable treatments, validated through controlled clinical trials.

ChondroCelect®, the company's lead product for cartilage repair in the knee, received the European Marketing Authorisation on October 5, 2009 as the first centrally authorised Advanced Therapy Medicinal Product (ATMP). The product is a suspension of characterised viable autologous cartilage cells expanded ex-vivo and expressing specific marker proteins.

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NAME OF THE MEDICINAL PRODUCT: ChondroCelect 10,000 cells/microlitre implantation suspension. QUALITATIVE AND QUANTITATIVE COMPOSITION: General description: Characterized viable autologous cartilage cells expanded ex vivo expressing specific marker proteins. Qualitative and quantitative composition: Each vial of product contains 4 million autologous human cartilage cells in 0.4 ml cell suspension, corresponding to a concentration of 10,000 cells/microlitre. PHARMACEUTICAL FORM: Implantation suspension. Before re-suspension the cells are settled to the bottom of the container forming an off-white layer and the excipient is a clear colourless liquid. Therapeutic indications: Repair of single symptomatic cartilage defects of the femoral condyle of the knee (International Cartilage Repair Society [ICRS] grade III or IV) in adults. Concomitant asymptomatic cartilage lesions (ICRS grade I or II) might be present. Demonstration of efficacy is based on a randomized controlled trial evaluating the efficacy of ChondroCelect in patients with lesions between 1-5cm².

Posology and method of administration: ChondroCelect must be administered by an appropriately qualified surgeon and is restricted to hospital use only. ChondroCelect is solely intended for autologous use and should be administered in conjunction with debridement (preparation of the defect bed), a physical seal of the lesion (placement of a biological membrane, preferentially a collagen membrane) and rehabilitation. Posology: The amount of cells to be administered is dependent on the size (surface in cm²) of the cartilage defect. Each product contains an individual treatment dose with sufficient number of cells to treat the pre-defined lesion size, as measured at biopsy procurement. The recommended dose of ChondroCelect is 0.8 to 1 million cells/cm², corresponding with 80 to 100 microlitre of product/cm² of defect. Method of administration: ChondroCelect is intended solely for use in autologous cartilage repair and is administered to patients in an Autologous Chondrocyte Implantation procedure (ACI). The implantation should be followed by an appropriate rehabilitation schedule for approximately one year, as recommended by the physician. Contraindications: Hypersensitivity to any of the excipients or to bovine serum. ChondroCelect must not be used in case of advanced osteoarthritis of the knee.

Undesirable effects: In a randomized, controlled study in the target population, 51 patients were treated with ChondroCelect. In these patients, a periosteal flap was used to secure the implant. Adverse reactions occurred in 78.4% of the patients over a 36-months postoperative follow-up period. The most common adverse reactions were arthralgia (47.1%), cartilage hypertrophy (27.4%), joint crepitation (17.6%) and joint swelling (13.7%). Adverse reactions collected from 370 patients included in a Compassionate Use Program are similar to those reported in the target population. Most of the reported adverse reactions were expected as related to the open-knee surgical procedure. The most frequently occurring reactions reported immediately after surgery include joint swelling, arthralgia and pyrexia. These were generally mild and disappeared in the weeks following surgery. Adverse reactions of special interest: Arthrofibrosis: In the compassionate use patients, a higher incidence of arthrofibrosis and decreased joint range of motion was observed in a subgroup of patients with a patellar lesion (8.2% and 13.1% respectively) compared to non-patellar lesions (0.6% and 2.6% respectively). Cartilage hypertrophy: In the majority of the 370 patients included in the Compassionate Use Program, a collagen membrane instead of a periosteal flap was used to seal the defect. According to current literature the incidence of cartilage hypertrophy can be reduced by using a collagen membrane to cover the lesion site instead of using a periosteal flap (Gooding et al., 2006; Niemeyer et al., 2008). When a collagen membrane was used to seal the lesion site after application of ChondroCelect, the incidence of cartilage hypertrophy was reported to be 1.8% compared to 25% in the randomized, controlled trial alone.

Name of the MA holder: TiGenix NV, Romeinse straat 12/2, B-3001 LEUVEN, Belgium. Product authorization number: EU/1/09/563/001. Medicinal product to restricted medical prescription – restricted to hospital use only.
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