



LARS

Ligament Augmentation
& Reconstruction System



Patient Information Brochure

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Corin



Introduction

The Company LARS, (Laboratory for Applied Scientific Research) was founded in 1991 in Dijon, France. Its original objective was to improve the treatment of ligament and tendon injuries. These frequent and serious injuries often affecting young, active patients usually require surgical intervention, with a long period for rehabilitation before returning to pre-injury activities.

Originally other companies' synthetic ligament results had been disappointing, and this led to many surgeons globally refusing to use them again. However, they also demonstrated that the actual procedure was less complicated and time consuming. Just as osteo synthesis of fractures had allowed for shorter immobilization, surely we could apply this principle to ligament and tendon repair. LARS realised that an improvement could be made to the original principle of synthetic ligament reconstruction, and hence the LARS ligament and reconstruction system was born in 1991. Since then LARS has had unequivocal success with this system.

This has been LARS' main goal since its creation, supported by a competent and creative team, we co-operate with leading laboratories and international surgeons worldwide, to keep our innovation at the forefront of medical technology and innovation. This enables LARS to keep ahead of the latest medical advances and new indications for ligament and tendon repair and replacement. LARS enables patients to have a quicker return to work and sports than the majority of other medical techniques available. This is well supported by the wealth of clinical data supporting the implantation of LARS worldwide.

Product Qualities

LARS (Ligament Augmentation and Reconstruction System) is a range of synthetic ligaments used in many countries throughout the world (not yet in the USA) mainly for knee ligament reconstruction, ankle and shoulder repairs. Designed to mimic the normal anatomic ligament fibres, the intra-articular longitudinal fibres resist fatigue and torsion and allow fibroblastic ingrowth. The extra-articular woven fibres provide strength and resistance to elongation.

The biggest advancement in present day synthetic ligaments is that they encourage ingrowth from the surrounding tissues and ligaments, which then allows the patients' damaged ligaments to repair, while supporting the joint, and allowing early mobilisation.

Surgeons presently use one of two different types of tissue to repair ligaments:

- Autografts - functional tendons from around the injured knee, or the opposite knee. These can cause pain in the donor site, as well as temporarily reducing the function of the donor knee.
- Allografts - tissue from another donor, with a low risk of transmitted diseases. Both of these grafts need the same extended period of healing and revascularisation, 6 to 8 months, before normal function returns.
- LARS ligaments reduce surgery time considerably (no harvesting of grafts), and the patient can expect to return to full function 6 to 8 weeks following surgery, as the damaged ligament is allowed to heal.





Ligament Construction

The construction of the LARS ligament is the result of many years' detailed research into finding a suitable material for this application and the best way to apply the material to make the various ligaments available.

The material used is polyethylene terephthalate - an industrial-strength polyester fibre which has the ideal characteristics for ligament replacement applications. Each type of LARS ligament contains a specific number and length of fibres, depending on the intended use and size of patient.

The intra-articular portion of the LARS ligament is made of longitudinal fibres without transverse or crossing

components. The fibres are oriented to the ligament they are made for, to mimic the anatomic fibres. This patented structure allows a high resistance to fatigue, especially in flexion and torsion as well as providing a porosity encouraging fibroblastic ingrowth which then covers the synthetic fibres. In the extra-articular portion the same parallel fibres are kept united by a process of warp knitting. Biological and mechanical testing for resistance, fatigue and creep have shown that LARS ligaments are highly effective ligament reconstruction and augmentation devices, and long-term clinical results are excellent. The use of the LARS artificial ligaments require specific surgical techniques, for which dedicated LARS instruments are available.



Clinical History

LARS ligaments have been in clinical use for over 17 years, with no acute examples of synovitis reported after many thousands of operations. There are many studies and publications supporting the use of LARS for all indications.

Case Studies

Dimitra Dova: Professional Runner

Dimitra Dova is a 33-year-old Greek National. She is a professional sportswoman who competed in the 2004 Olympic Games 400m relay in Athens, after tearing her anterior cruciate ligament (ACL) one year beforehand, threatening her sporting career. She is also a 2nd Lieutenant in the Greek Air Force and has a variety of sporting interests including water and snow skiing.

In July 2003 Dimitra fell over and ruptured her right ACL. In August 2003 she had her ACL ligament reconstructed by Dr Stelios Maheras in Athens. Dr Maheras used a synthetic ligament to reconstruct Dimitra's torn ACL so that she could return to sport more quickly than if she had a conventional reconstruction using her own tissues. Conventional treatment would have seen her out of action for up to nine months and she would have missed competing in the 2004 Olympic Games.

Dimitra says, "I had some pain for the first two days after the operation, but I started physiotherapy and swimming after four days. I started running 30 days after the operation and three months later I was in a full Olympic Games roadwork programme. The following year (2004) I ran in the 400m women's relay at the Olympic Games in Athens. In 2005 I won the gold medal in the Mediterranean Games and bronze in Bruno Jaouli Golden League for the 400m.

"My operation was totally successful and with the physiotherapy programme that I followed I did not have a decrease in my speed times for the 400m, I actually had my personal best time the following year in Florence at the Super League, 51.89 seconds for 400m."



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Since the operation I have been able to participate in full sporting activities and now feel able to train to a high standard in karate again

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Phil Shufflebotham: Teacher and Athlete

Phil is a 32-year-old Business Studies teacher from the UK. He enjoys a number of different sporting activities but his main interest is karate where he is a 5th Dan black belt. Phil has been involved in karate since the age of 16 and has competed in international competitions.

In January 2005 Phil took a bad fall during training which caused severe disruption of the acromioclavicular joint in his shoulder. He attended his local Accident and Emergency department immediately, where he was put under the care of two orthopaedic surgeons. Due to the severity of the injury, surgical correction was necessary and a LARS synthetic ligament was used to reduce and correct the damage to the joint.

“My recovery was a slow process in the beginning due to the nature of the operation and the associated pain that came with it. My shoulder was kept in a sling for six weeks to minimise any movement of the shoulder. I was advised that it would be six months before I could get back to karate again.

“Some weeks later I was able to return to work and drive again. My sling came off approximately five weeks after the operation when I started to regain full use of my right arm. Movement and strength were restricted initially, but I soon gained the confidence to use it again and I was back teaching at school and at my karate classes as though I had not been away.

“Since the operation I have been able to participate in full sporting activities and now feel able to train to a high standard in karate again, which I thought I would not be able to do. I am able to drive, cycle, play squash, swim and play golf and I can do everything that I did before my operation. Without this operation I would not be able to lead my life to the full and enjoy participating in sport which to me is a major part of my life. In late 2005 I was able to lead an association karate team to win the SSU World Cup in France, a feat I never dreamed possible at the start of the year.”

Efi Sfyri: Olympic Beach Volleyball Player

Efi Sfyri competed in the 2000 Sydney and 2004 Athens Olympic Games in beach volleyball after overcoming an injury that had threatened to end her sporting career.

Efi is a 35-year-old coastal policewoman in Greece and also a professional beach volleyball player. She was seeded 6th at the 2004 Athens Olympic Games. In her spare time she plays squash and tennis. Efi had no previous history of ligament damage prior to her injury.

At the beginning of 2000 she tore her right ACL in a sporting accident; she was operated on by Mr Greg Papadopoulos in Athens. He reinforced her torn ACL with an artificial ligament (LARS) so that the torn

ACL could heal and be as strong, if not stronger than before the operation. Efi left the hospital walking and not in a brace. The surgery allowed Efi to compete six months later at the World Open Tour in Brazil in beach volleyball.

Conventional surgery would have seen her out of action for at least nine months.

Efi describes how after the operation she walked on the first day, was driving within one week and on the eighth day she returned to the gym. She started with slow careful exercises to keep her knee safe, but also to maintain her fitness levels. Efi said that the first month after the operation her life as a professional player was obviously slower and more limited, but after six months she was back to pre-injury fitness levels.

“The operation was really important for the future of my career - 11 months after the operation I became the European Champion. I won the gold medal in beach volleyball in Italy 2001 and had great success the following year, winning a bronze medal in Rhodes 2002. Without the operation this would have never been possible.”

In total, in 2001 Efi competed in 12 major volleyball tournaments, some of which resulted in medal positions.



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Orthoula Papadakos: TV Host and Retired Pro Basketball Player

Orthoula Papadakos is 36 years old and was born in Toronto, Canada. From a young age she was involved in competitive sports, and wanted to become a professional basketball player. She played for the Canadian National Team in both soccer and basketball and was offered scholarships for both sports in the USA. However she decided to become a professional athlete instead, signing at the age of 17 with Panathinaikos, a professional basketball team in Greece.

Her first injury occurred in 1988 at the age of 18, when she tore her ACL during a match. She was operated on immediately and returned after one year to play at the same level.

In 2002, she again tore her ACL in a basketball match and was operated on by Dr Papagianopoulos from Greece. He reinforced her torn ACL with an artificial ligament (LARS). This method gave her the confidence that her knee would be stronger than before, and allowed her to compete again a lot sooner than if she had undergone conventional surgery.

Orthoula compared both methods used on her ACL and describes the conventional method as being very painful, needing months of rehabilitation, and keeping her out of athletic competition for ten months.

The artificial LARS ligament used in her second operation allowed her to walk the same day, drive within the week and start rehabilitation (pool and gym) within ten days. Devoting all her time and effort towards her rehabilitation, she started playing basketball professionally again after 75 days to the surprise of her doctors and physiotherapists.

Orthoula feels that the operation allowed her to continue her professional career without the loss of any strength or speed. She can participate in any sport she chooses without any pain, and the only thing to remind her of the operation is the scar on her knee.

Orthoula is now a TV host and celebrity in Greece after her participation in a TV reality show 'Survivor' in 2002-2003.

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LARS[®]
Ligament Augmentation
& Reconstruction System



Post-Operative Care and Physiotherapy Therapy for the Knee

- No post-op bracing or immobilisation
- Full weight bearing and mobilisation to be started the day following surgery
- Isometric quad exercises to be started the day following surgery to recover full extension
- 90° of flexion should be obtained after 7-10 days
- Return to driving should be at the patient's and surgeon's discretion
- Return to work will depend on the type of work, and the individual patient's recovery time
- Return to sports (jogging) after approximately 2-3 weeks
- Return to full contact sports once proprioception has returned
- Competitive training after approximately 5 weeks
- No limits to full motion
- Isokinetic closed chain rehab.

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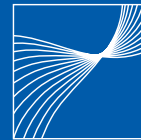
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This information is intended as an overview only, and does not replace
physicians' recommendations or consultations.

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