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Responsible Innovation

LARS™

A Q&A for patients

Important
Please be aware that the information and guidance provided within this booklet is general in nature and should not be considered as medical advice in any way. You should always seek detailed advice from a qualified medical practitioner.

Contents

Introduction

This booklet is designed to answer the many questions that you may have if you are considering LARS™. The information in this booklet is general in nature and it is not designed to replace advice from your physician or surgeon. Seek advice from a qualified medical practitioner to determine if LARS™ is suitable for you.

For further information, please visit our website:

www.larsligaments.com

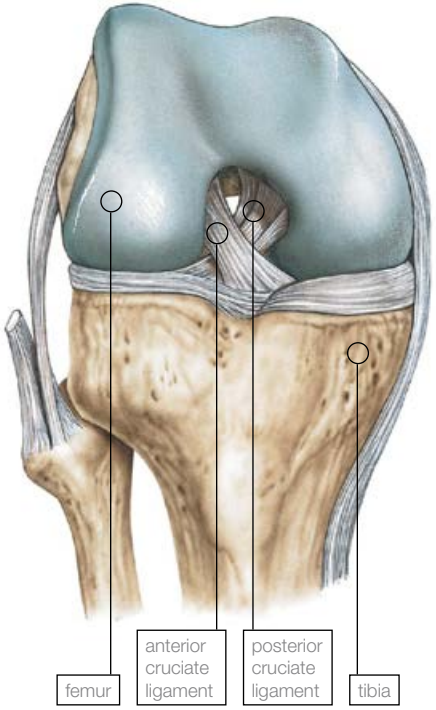
Your anatomy

The human body has close to two hundred ligaments and tendons that come in a variety of shapes and sizes depending on the surrounding anatomy and their purpose. Although tendons and ligaments are similar in structure they perform very different functions.

Ligaments provide strength and support to your joints. A ligament is a short band of tough, fibrous tissue that connects bone to bone. This connection allows for a normal range of movement within the joint but prevents excessive movement or movement in the wrong direction.

Tendons have a similar structure to ligaments, however they anchor muscle to bone. When your muscles contract the force is transmitted to your bones which enables your body to move.

Ligaments of the knee



Ligament and tendon Injury

Although your ligaments and tendons are very strong, excessive strain or force can result in injury. Injury sustained from a sporting incident, a motor vehicle accident or even during daily activity where excessive force has caused the joint to overstretch, can result in a tear of tendons or ligaments.

The severity of the injury is related to the extent of the tear in your ligament or tendon. This will determine the type of treatment you will receive. As tendons and ligaments have limited blood supply, these tissues are very slow to repair. If your injury has resulted in a severe or complete tear of the tissue, surgical intervention may be required to prevent permanent damage and/or impaired function.

Tendon and ligament reconstruction is usually performed to restore stability, range of movement and proper function. It may reduce the possibility of developing osteoarthritis in the injured joint. Osteoarthritis is a degenerative joint condition which is unfortunately commonly associated with ligament, meniscal and cartilage injury. It causes pain and swelling of the joint.

Restoring function as early as possible will allow you to return to your daily activities and active lifestyle, minimising pain and muscle wasting.

1. What is LARS™?

The LARS™ Ligament Augmentation and Reconstruction System is an artificial implant used to repair damaged ligaments and tendons. LARS™ is a versatile system designed to mimic the normal function and anatomy of the ligaments and tendons. LARS™ is available in a number of lengths and designs making it suitable for treating a wide variety of injuries.

LARS™ ligaments come in a variety of shapes, sizes and strengths to suit the many areas of the body. Made from specially selected high-strength polyethylene terephthalate (PET), they are designed as a permanent scaffold for your own healing tissue to grow into, rather like ivy growing up a tree. This particular PET has been specially selected because it is very well accepted by the body[1].

The LARS™ ligament provides mechanical support and stability to the joint while your own tissue is healing. This may allow you to go back to your occupation and sporting activities more quickly[2].

2. What are the surgical alternatives?

Your surgical options will vary depending on the nature, severity and location of your injury.

The surgical treatment commonly performed for anterior cruciate ligament (ACL) injuries is a tissue graft. An 'autograft' is tissue that is harvested from another part of your own body, usually from the knee cap tendon or the hamstring tendon (the muscle that runs at the back of the thigh). This may result in residual pain or reduced strength at the site where the graft was harvested for some years after surgery[3].

An 'allograft' is a similar concept, but the tendon used to make the repair is harvested from a deceased donor. As they are not your own tissue, allografts pose a small risk of disease transmission and/or tissue rejection[4]. With an allograft, you will not incur further injury from harvesting your tendons from your already injured knee.

Both of these grafting procedures require an extended period of healing to allow the return of blood supply to the tendon post-surgery. It is usually six to twelve months before full sporting activity can be resumed[5].

You should discuss all potential treatment options with your surgeon so you can decide what is best for you.

LARS™

LARS™ is designed and manufactured in France in conformity to very high quality standards (ISO 90002 EN 460001 and compliant to directive 93/42/CEE).

3. What are the risks?

Before you undergo any surgery you should inform yourself of the potential risks involved.

Bleeding and infection are risks common to any surgical procedure. Breathing difficulties or allergic reactions can sometimes be triggered from anaesthetic.

Other risks from surgery include:

- Stiffness or reduced range of movement
- Irritation/inflammation
- Loosening of screws or sutures
- Pain and swelling

These risks are common to any soft tissue surgery.

A LARS™ surgical procedure requires the surgeon to have undergone specialist training to increase the chances of a successful outcome. Please ask your surgeon whether he or she has experience implanting the LARS™ ligament and has undergone specialist training.

The specific risk for any tendon or ligament reconstruction is re-injury, particularly if engaging in high demand occupational or sporting activities. Your reconstructed ligament may fail under excessive force or strain.

As a result of your injury you may be at increased risk of developing osteoarthritis which is a degenerative joint condition, causing pain, swelling and cartilage damage. Restoring stability to the knee through ACL reconstruction does not eliminate your chance of developing osteoarthritis[6]. Up to 13% of patients show some sign of osteoarthritis after sustaining an ACL injury, this risk is increased if you have also sustained damage to the meniscus or cartilage[7]. There is no evidence to suggest that LARS™ further increases the risk of developing osteoarthritis.

There is a low risk of developing synovitis[8]. This is a swelling of the joint capsule that surrounds the joint, which can cause pain. There are many causes of synovitis: injury, genetic conditions and osteoarthritis. The treatment of this condition will vary depending on the cause.

4. When should LARS™ NOT be used?

If you suspect you have an infection you must tell your doctor immediately as your surgery may need to be rescheduled. Any infection should be treated and resolved prior to surgery to prevent infection from spreading and affecting your new ligament. The success of LARS™ surgery requires that the injured tissue has a good blood supply, from which new tendon or ligament can grow.

If the injured tissue is badly degraded, scarred or missing, LARS™ should be used in combination with your own tissue (autograft) to allow tissue re-growth.

Your surgeon will assess the treatment best suited for your injury.

5. Preparing for surgery

Remaining active while you are waiting for your surgery is important and may improve recovery[9]. Moderate exercise such as walking or swimming can help prevent muscle wasting or weakening.

If you are a smoker, you should try to quit at least six weeks before the operation to help reduce the risk of complications. You must inform your surgeon if you suspect you have an infection as your surgery may need to be rescheduled.

6. What is involved in LARS™ surgery?

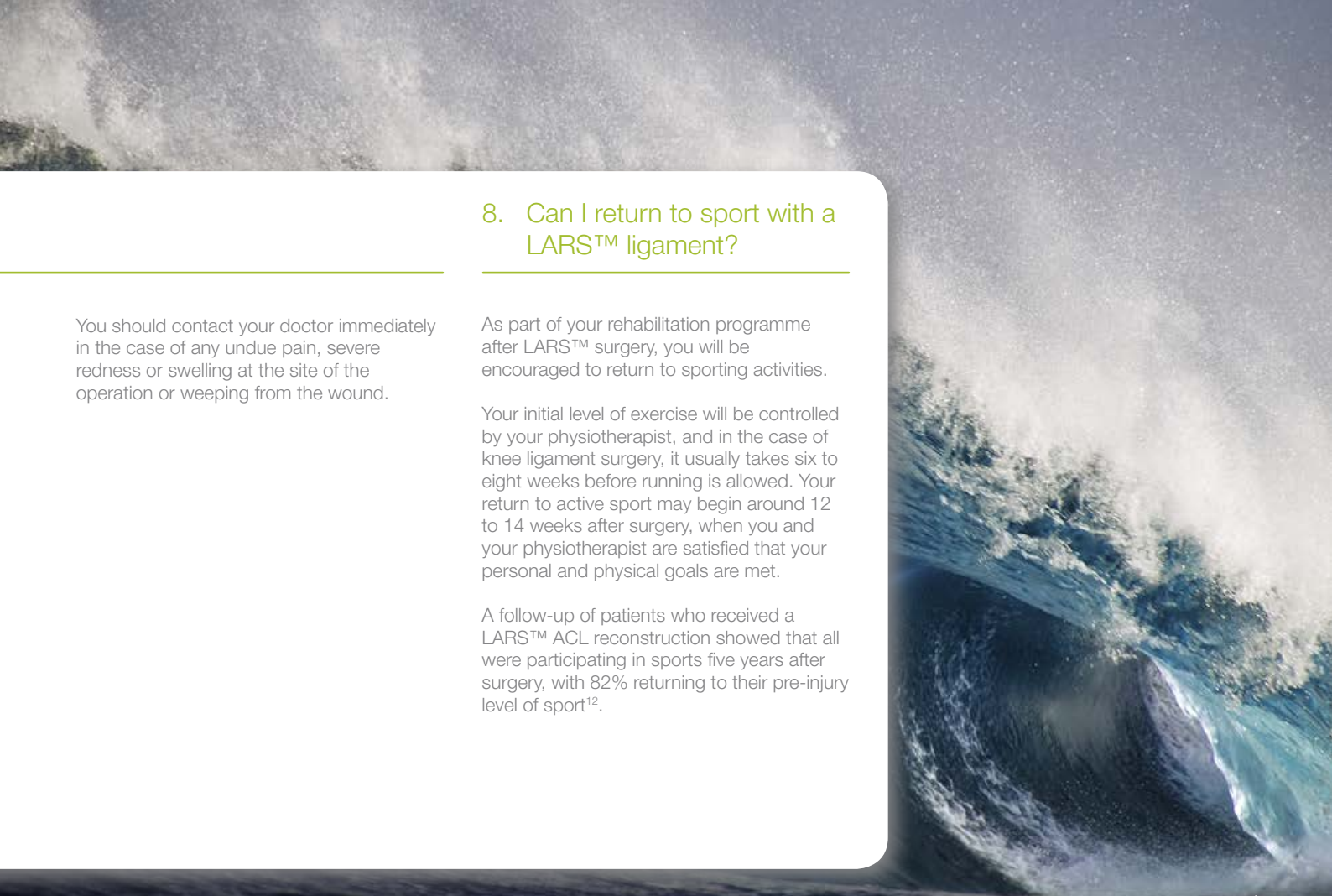
If your surgeon recommends LARS™ for your reconstruction, you will need to have an operation, usually performed under general anaesthetic. Most procedures use arthroscopy or minimally invasive techniques to implant LARS™ ligaments. Your surgeon will provide specific information about your type of surgery.

If your surgeon is able to repair your torn tendon or ligament remnants in conjunction with the LARS™, you may have a shorter recovery time[2]. If you need to have a graft of your own tissue taken, for example from your hamstring tendon, you may take longer to recover[10].

7. What to expect after surgery?

To manage your own expectations about how quickly you will be 'back on your feet', it is important to understand what will happen both immediately after your surgery and in the months that follow. Normal recovery from any operation varies from patient to patient and is partly dependent on pre-operative health. Post-operative rehabilitation regimes also vary, your surgeon will advise you about this.

You may see a physiotherapist during your hospital stay and he/she will help you with exercises to strengthen your muscles. The exercises recommended by your physiotherapist are a crucial part of your recovery, so it is essential that you continue to do them when you return home. It has been shown that adhering to your rehabilitation programme may be a significant indicator of positive outcome after reconstructive surgery[11].



You should contact your doctor immediately in the case of any undue pain, severe redness or swelling at the site of the operation or weeping from the wound.

8. Can I return to sport with a LARS™ ligament?

As part of your rehabilitation programme after LARS™ surgery, you will be encouraged to return to sporting activities.

Your initial level of exercise will be controlled by your physiotherapist, and in the case of knee ligament surgery, it usually takes six to eight weeks before running is allowed. Your return to active sport may begin around 12 to 14 weeks after surgery, when you and your physiotherapist are satisfied that your personal and physical goals are met.

A follow-up of patients who received a LARS™ ACL reconstruction showed that all were participating in sports five years after surgery, with 82% returning to their pre-injury level of sport[12].

9. Can a LARS™ fail and what happens if it does?

Regardless of the reconstruction method your surgeon chooses, the risk for any tendon or ligament reconstruction is re-injury, particularly if engaging in high demand occupational or sporting activities. In a similar way to your original injury, your reconstructed ligament may tear or the grafted ligament may 'slip' out of position if excessive force is placed on the joint.

If a LARS™ ligament fails, it can be removed and another reconstruction performed. LARS™ can be revised with another LARS™, allograft or autograft. Your options for reoperation will depend on the previous surgical treatments you have received for your injury.

10. What clinical evidence exists for LARS™?

LARS™ has over 20 years of clinical use. During this time LARS™ reconstructions have been clinically proven to be reliable procedures[2,7,8,12,13,14]. Developed in France in the 1980s by a French orthopaedic surgeon, Professor Jacques-Philippe Laboureau, the first implant took place in 1992 in Dijon, France. LARS™ is now widely used and accepted throughout Europe, the United Kingdom, Canada and Australia. Approval to use LARS™ in the USA has not been sought to date.

Since 1992 more than 60,000 LARS™ ligaments have been implanted worldwide, with more than 30,000 used for ACL alone. LARS™ has been used with great success[8] and with very high patient satisfaction[13] in a large number of applications including, but not limited to, knee reconstructions involving the anterior cruciate ligament (ACL); posterior cruciate ligament (PCL); posterolateral corner (PLC); medial collateral ligament (MCL); and/or lateral collateral ligament (LCL) structures; patella realignments; gluteal repairs; as well as acromioclavicular joint and rotator cuff repairs in the shoulder. Studies report 'good' to 'excellent' outcomes in greater than 95% of LARS™ recipients[12].

Clinical studies have shown:

- High patient satisfaction in terms of pain, range of movement, stability, swelling and activity levels[13].
- High implant survival rate of 92.9% after more than 10 years for LARS™ ACL reconstruction[14]
- Comparable medium-term results (4 year follow-up after surgery) for ACL reconstruction compared to patellar tendon autograft reconstruction[8].
- An earlier return to normal activity, usually within 3-6 months[2]
- Low complication rate[13]

11. What are the similarities and differences between LARS™ ACL reconstruction and traditional ACL (autograft/allograft) reconstruction?

The intention of any reconstructive surgery is to return stability and restore range of movement to the knee.

A LARS™ ligament offers:

- Immediate stability to the joint allowing rehabilitation to commence within a few days post-surgery. This may allow a quicker return to a normal lifestyle and even to sporting activity[2].
- Healthy tissue does not have to be removed from your tendons for use as a graft, avoiding the problems that can sometimes occur around the harvest site[10].
- No tissue is implanted into your body from another person, avoiding any potential problems caused by your body rejecting the donor tissue or possible disease transmission[4].

Traditional techniques (autograft and allograft) for ACL reconstruction have a long clinical history, however medium-term results for LARS™ are comparable to results of autograft reconstruction.

12. What are the indications for using LARS™?

LARS™ may be used in various orthopaedic procedures to replace or repair a missing or damaged ligamentous structure in order to restore natural function.

LARS™ ligaments are intended for the intra- and extra-articular reconstruction of:

1. Ruptured ligaments such as the cruciate ligaments, the knee collaterals, posterolateral corner reconstructions, medial patellofemoral ligament, acromioclavicular dislocations, medial and lateral ankle ligament repairs, etc.
2. Various tendons such as patellar tendon, quadriceps tendon, hamstrings tendon, major rotator cuff tears, biceps, triceps tendons, acute or chronic achilles tendon repairs, muscular reinforcement and posterior capsule reinforcement during revision of an unstable hip replacement.
3. Muscular reinforcement and extensor mechanism reconstructions
4. As a bare prosthesis following major traumatic incidences or tumour surgery.
5. In the context of anterior cruciate ligament (ACL) repair, LARS™ should be utilised only after non-synthetic alternatives (allografts and autografts) have been considered as possible treatment options by the treating clinician and patient. LARS™ ACL repair should only be used in the presence of viable tissue remnants. In the absence of viable tissue remnants, LARS™ should be used as an augmentation or reinforcement alongside an autograft or allograft. Regardless of treatment method, acute phase post-ACL injuries should be treated with caution.

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Corin

The Corinium Centre
Cirencester, GL7 1YJ
t: +44 (0)1285 659 866
f: +44 (0)1285 658 960
e: info@coringroup.com

www.coringroup.com