First introduced in 1992, LARS ligaments are gaining popularity as an internal fixation device providing a scaffold for natural tissue in-growth. Incorporating a patented ‘pre-twisted parallel fibre’ concept, LARS has been designed and processed to avoid the problems faced with synthetic ligaments in the past.

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a) How long have LARS ligaments been available?

Commercially available since 1992, LARS ligaments have been in use in countries such as the UK, France, Germany, Canada and Australia. Regulatory approval has been granted for LARS use in all countries where it has been sought. In countries where LARS is not available (e.g. the USA), it is because Corin has not yet commenced the often complex and costly regulatory procedures to secure approval in that country.

b) What data does LARS have regarding ACL reconstruction?

There are currently 22 published papers regarding LARS use in knee ligament reconstruction, with the bulk of these being in ACL and PCL. The 22 peer-reviewed studies/case series include one randomised controlled trial (level I evidence), three retrospective comparative studies (level III evidence), eleven case series (level IV evidence) and seven expert reviews (level V evidence). Many more congress abstracts and non-peer reviewed online papers are available. Each of these studies, with the exception of the Gäbler study, observed excellent functional outcomes, minimal complications and high levels of patient satisfaction after a follow-up period of up to five years.

In addition, nine-year unpublished data on LARS has been presented at various congresses. While there is a lack of published long-term data for LARS ligaments, research is continuing.

Please contact Corin’s LARS product management team for more information on LARS published and unpublished data.

c) Aren’t all synthetic ligaments the same? I have had previous failures with other polyethylene terephthalate (PET), polypropylene (PP), polytetrafluoroethylene (PTFE) or carbon fibre ligaments.

All synthetic ligaments are not created equal. They are designed for different purposes, with different materials and different structures. A ligament for permanent replacement of the ACL will have no requirement for in-growth of ACL tissue and must take the full load of a normal ACL. A scaffold ligament however, will require porous fibres for fibroblastic in-growth and its function will eventually be overtaken by the newly formed collagen. With this in mind, a valid like-for-like comparison cannot be made between different types of synthetic ligaments.

The same can be said for comparing synthetic ligaments of different structures and materials. Due to the differing material properties, it cannot be said that a ligament made from PET, with the same structure as a ligament made from PTFE, will perform in a similar manner with regards to mechanical performance or biocompatibility. LARS is made from PET and is the only synthetic ligament to have undergone a vigorous torsion/flexion-extension fatigue test.

Even within a particular material, structural differences will have a huge impact on the wear resistance, porosity and fibroblastic in-growth potential of a synthetic ligament. LARS incorporates a patented ‘pre-twisted parallel fibre’ design, unique to its philosophy and different from previous synthetic ligament designs. An independent in-house study, performed by the Institute National de Recherche Appliquée (INRA), in France, confirmed braided and woven ligaments are far more susceptible to wear from the natural torsion in the ACL during...
knee movement\textsuperscript{8,9} when compared with a ‘pre-twisted parallel fibre’
design.

Indeed, even the treatment of synthetic fibres post-manufacture can affect fibroblastic in-growth. LARS is chemically treated to remove an emulsion of fat enzymes that are used as a process aid during the carding and spinning of the strands which constitute the synthetic fibre. This emulsion can provoke pathological reactions in-vivo, such as synovitis and immuno-responses. This unique and thorough treatment of PET fibres is pivotal in the success of healing ACL tissue. This process has been shown to have great effect on fibroblastic proliferation surrounding the synthetic filaments, increasing fibroblastic growth by greater than 20 fold\textsuperscript{8,9}. In side-by-side comparison in the laboratory, LARS ligaments supported over three times the fibroblastic culture of other previously-used PET ligaments\textsuperscript{8,9}.

d) Is the technique for reconstruction using a LARS ACL ligament the same as for an autograft?

The technique for successful LARS ligament implantation is dependent upon the following criteria:

i. The ligament should not be over-tensioned, should be positioned appropriately and range of motion should be checked before fixation.

Over-tensioning an implanted ligament, either synthetic or autogenous, can reduce range of motion in the knee\textsuperscript{10}. Over-tightening will not only increase the likelihood of premature failure, but can result in excessive compressive forces on the knee, accelerating often pre-existing arthritic changes. Over-tightening of
the LARS ligament will also take mechanical load from the ACL, leading to stress shielding and a neoligament of poor tissue quality. It is important to ensure that the ligament will have minimal demand for elasticity during movement; the aim being to minimise fatigue. The avoidance of intra-articular elongation, by considering the functional anatomy of the knee\(^8\), will lead to a longer lifespan.

Correct positioning of the free fibres within the joint will also decrease the risk of wear\(^8\). By ensuring that the free fibres are unhindered in the intra-articular space and by positioning the woven intra-osseous section 1-2mm into the intra-articular space, shearing forces on free fibres will be reduced.

\textit{ii. A viable ACL stump.}

The ACL has the potential for cell proliferation and healing\(^12,13,14,15,16,17,18\). Studies have demonstrated that the placement of a substitute provisional scaffold in the wound site of the ACL injury initiates healing of the ruptured ligament after primary repair\(^15\). Retaining the native ACL has many other potential advantages, such as preserving the complex ACL attachments and innervation of these structures, thereby retaining the mechano-receptive and proprioceptive function of these tissues\(^15,19,20,21,22\), even up to 42 months after injury\(^22\). Yu et al\(^23\) reported good fibrotic tissue in-growth where the LARS ligament was covered by sufficient ACL stump in rabbits. Seitz et al\(^24\) showed fibroblastic in-vivo in-growth into PET ligaments after implantation in sheep. Gao et al\(^25\) also demonstrated native tissue encapsulation in three patients when LARS ligaments were revised.

Overlooking any of these key criteria can greatly reduce the probability for a successful LARS graft.
e) Do LARS ACL ligaments cause synovitis?

The ACL is subject not only to extension and contraction, but also to shearing and torsion. The presence of transverse fibres when ligaments are subjected to torsion may create free micro-particles, or wear particles. Most early synthetic ligaments were either braided or woven in the intra-articular region; by the nature of their construction these were not designed to cope with such forces and therefore produced wear particles. It has been hypothesised that this is the primary mechanism for synovitis in the knee with synthetic ligaments\(^{23,26,27}\). This is believed to be due to the formation of free micro-particles during the normal motion of the knee.

The LARS ligament is designed to have free longitudinal fibres in the intra-articular portion of the knee to minimise these shearing forces. In addition, LARS ligaments should be aligned so that 1-2mm of woven (intra-osseous) section should be visible from the end of the femoral tunnel. This placement protects the free fibres from shearing without compromising functionality in movement.

To date, only one patient in one study has shown an incidence of synovitis. Gao et al\(^{25}\) reported that one of three patients who had a reported rupture, in 159 cases, demonstrated development of synovitis at three to five years. This can be contrasted against many other synthetic ligaments and their documented increased rates of synovitis, previously reported to be as high as 48%\(^{28,29,30}\).

f) Do LARS ACL ligaments increase the risk of early onset osteoarthritis?

Early onset osteoarthritis has been associated with ACL reconstruction, regardless of the nature of the graft, for quite some time\(^{31,32}\).

Rates of radiographically observed osteoarthritis in ACL reconstructed knees with autografts vary widely and in some studies are reported to be in excess of 70%\(^{33,34}\). In fact it has been noted that the reconstruction of the ACL did not appear to provide protection from degenerative change in the knee and high levels of osteoarthritis occur regardless of whether surgical intervention is undertaken.

Some authors have tried to demonstrate a relationship between the body’s inflammatory response to synthetic ligament wear particles and osteoarthritis\(^{35}\). Olsen\(^{26}\) evaluated the effects of injecting wear particles from six different types of ligaments, diluted in saline, into rabbit knees and found the results to be dependent on dose and particle size. He also noted that surgical technique needed to be evaluated. Although two of the ligaments were PET-based, neither shared similar design characteristics (woven vs free fibres) with the LARS ligament.

Some older generation synthetic ligaments have shown increased rates of osteoarthritis. Ventura\(^{36}\) showed a rate of osteoarthritis of 100% when using the Trevira ligament. The Ventura study however, differed from LARS implantation in a number of ways:

- The Trevira ligament is a woven PET design
- The Trevira ligament does not undergo the same chemical treatment before implantation
- The Trevira ligament was used either as a permanent
replacement for the ACL or as an augment to an autograft as opposed to a scaffold

There was a likely absence of a sufficient ACL stump (all chronic cases) and subsequent in-growth

To date, no reports of increased rates of osteoarthritis have been described specifically after using a LARS ligament.

g) What is the failure rate for the LARS ACL ligament and how does this compare with hamstring and patella tendon failure rates?

Hamstring and patella autograft failure rates vary – recent meta-analyses demonstrate that ACL reconstructions can deliver good to excellent results in as low as 60% and in as high as 95% of patients

Shen et al also stated “as many as 20% to 30% of athletes fail to achieve their previous level of performance, suggesting that there is room for improvement” with traditional hamstrings and patella tendon reconstructions.

A number of studies reported very low failure rates for the LARS ligament in ACL reconstruction. Gao et al reported 94% (146/156) of patients had good to excellent results at three to five years follow-up. Huang et al reported 95% (41/43) of patients had good to excellent results at 10-49 months follow-up. Liu et al reported 93% (26/28) of patients had good to excellent results at greater than four years follow-up. Cerulli et al reported positive results in greater than 95% (24/25) at five year follow-up by an independent examiner. Nau et al reported 4% (1/26) failure in the LARS arm of his comparative study.

This is in contrast with other synthetic ligament designs over a similar follow-up period. Richmond et al and Barrett et al reported failure rates of 37.1% and 47.5% respectively in studies of Dacron reconstructions with mean long-term follow-ups of 50 and 48 months. Likewise, Schroven et al reported failure rates of 47.1% at five years follow-up and Dandy et al reported 40% of patients had an unsatisfactory outcome six years after reconstruction with Leeds-Keio ligaments.

h) One study produced high failure rates – this seems to be at odds with the rest of the data, what happened?

Gäbler et al reported a revision rate of 42% and post-operative problems of 69% in his study of 26 patients. The author cited a number of issues in this study including use by nine different surgeons, with varying levels of ACL experience and expertise (from 1 to 40 ACL reconstructions per year).

Furthermore, technique issues were also highlighted in the study. Despite quoting that procedures were performed in accordance with LARS recommended methods which specify no ligament over-tensioning and fixation in full extension; the tibial fixation was made under manual tension and in 20° flexion. There is a possibility that this fixation technique could have increased the tensile stress on the ligament and may have led to an over-constrained knee, thereby resulting in premature failure or poor subjective results.
i) What other complications arise with LARS and how do these compare with autografts?

As with autografts, allografts and other synthetic ligaments, some complications with LARS ligaments have been reported. The most common complications have been loosening of femoral or tibial screws and associated pain, limited flexion and/or extension, rupture and superficial infection. With the exception of Gäbler’s study, reports of these complications have been remarkably low.

High levels of ligament laxity (69% had >5mm Lachmann) has been reported in LARS patients in a study by Lavoie et al. Patients in this study reported high levels of satisfaction and no obvious ruptures were noted by the observers. Other studies have reported that where marked laxity was observed, readjustment of femoral or tibial fixation resolved laxity issues. The LARS group has also demonstrated significantly less anterior displacement than the four-strand hamstring graft in the study by Liu et al.

In comparison, patella tendon autograft recipients have been reported to experience anterior knee pain, extensor mechanism deficits, loss of sensitivity and the loss of extension. Hamstring graft recipients often experience loss of knee flexor strength, rotational strength, increased laxity, habitual muscle injuries and weak re-grown hamstring tendons.

Regardless of graft type, a degree of morbidity can be seen following autograft harvest which can affect recovery after ACL reconstruction. Over the longer term, Von Porat demonstrated that ACL rupture, whether treated surgically or not, is clearly associated with an increase in osteoarthritis.
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