NSOSMC

Consensus Statement by Orthopaedic Surgeons
from the North Sydney Orthopaedic and Sports Medicine Centre
LARS Ligament and ACL Reconstruction

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There has recently been considerable interest in the use of the LARS ligament for reconstruction of the Anterior Cruciate ligament (ACL) in Australia. The knee surgeons of North Sydney Orthopaedic and Sports Medicine Centre have arguably performed the largest volume of ACL reconstructions of any practice in Australia. It was considered appropriate to summarize their collective experience, current opinion and the literature regarding the use of this ligament.

LITERATURE REVIEW

THE HISTORY OF ARTIFICIAL LIGAMENTS

Artificial ligaments for reconstruction of the ACL were introduced in the 1970s and 1980s and used for many years. The theoretical benefits of an artificial ligament over an autograft include their strength at implantation, lack of harvest site pathology, a technically easier surgical technique and faster rehabilitation period.

Carbon fibre and Gortex grafts were used initially but quickly abandoned due to significant complications arising from foreign body reactions and extremely high failure rates over the medium term. Dacron ligaments were introduced in 1989, made of polyester (polyethelene terephthalate) or PET, which is the same material as the LARS ligament[1]. Again early results were encouraging, but failure rates of 40-60% were soon reported [2-4], as well as inflammation of the joint lining (synovitis) in up to 20% of cases[5] and significant premature osteoarthritis[6].

Perhaps the most popular artificial ligament used to date is the Leeds-Keio ligament which has been used in over 50,000 cases worldwide[1]. Similar to the LARS ligament the Leeds-Keio is made of polyester PET and is designed as a "scaffold" type of prosthesis, which in theory encourages the formation of natural tissue around the artificial ligament. Again the early results were encouraging with relatively low failure rates of 8%[7] at 33 months, but results were inconsistent with others reporting failure of 38%[8] at 24 months. Inflammation of the joint lining (synovitis) was reported in 30%[9]. In a 10 to 16 year follow up instability was found in 66% and 100% had more osteoarthritis compared to the opposite knee[10]. The Leeds-Keio ligament is now considered unsuitable for ACL reconstruction.

In 2010 Ventura et al[11] report the longest follow up of 18 to 21 years in a series of 51 patients who received PET artificial ligaments. They report a failure rate of 27%, normal or nearly normal IKDC grade in only 24% and a positive Lachman test in 75%. Osteoarthritis on radiographs was found in 100% of patients.

The mechanism by which artificial ligaments induce osteoarthritis has been studied in animal models. Artificial ligaments will tend to form wear particles that cannot be absorbed by the body. Studies have shown that these wear particles induce an internal reaction within the knee that alters the cells within the knee to initiate breakdown of cartilage which may lead to the premature development of osteoarthritis[12].

THE LARS LIGAMENT

Despite the poor long term outcomes of artificial ligaments there has recently been resurgence in interest in the use of the synthetic LARS (Ligament Advanced Reinforement System) ligament for ACL reconstruction in Australia.

The LARS ligament is composed of a polyester material called called PET (polyethelene terephthalate). The same material was used in the Dacron and Leeds- Keio ligaments. However the manufacturers advocate the LARS design as superior due to the longitudinal alignment of the fibres to allow for tissue ingrowth around the synthetic ligament, and higher fatigue resistance.

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It is widely agreed that there is inadequate number and strength of studies examining the outcome of the LARS ligament for ACL reconstruction[1,13,14]. The current results are inconsistent with respect to outcomes and the length of follow up is relatively short. The latter is of significance as many of the previous artificial ligaments had good short term results but very poor long term outcomes. The current published studies are summarized below.

1. Only one randomised controlled trial has been performed by Nau et al[15] in 2002 comparing a LARS artificial ligament with a patellar tendon autograft in 53 patients over 2 years[15]. Review at 6 months revealed significantly greater laxity of the ACL in the LARS group compared to the patellar tendon group (p=0.01). Subjectively they reported better results in the LARS group at 6 and 12 months, but no difference was seen at 24 months.
2. Goa et al (2010) [16] recently reported the outcome of a series of 159 retrospectively reviewed patients receiving a LARS graft for ACL reconstruction in China at 3-5 years after surgery. The failure rate of the LARS graft was reported as 7 of 159 (4.4%). Obvious synovitis of the knee was found in one of the patients who ruptured their graft. They reported good subjective outcomes with a mean Lysholm of 95 postoperatively and normal or nearly normal IKDC grade in 92% of patients.
3. Lavoie et al[17] (2000) reported the results of a retrospective review of 47 patients who received a LARS graft for ACL reconstruction in Canada. At 8-45 months postoperatively 69% had more than 5mm laxity on Lachman testing and the average displacement on PA testing with Telos stress radiography was 7.3mm greater than the uninjured knee. They reported no evidence of synovitis and the mean subjective KOOS subscales were 74 to 93 postoperatively.
4. Huang et al[18] (2010) reported the outcome of ACL reconstruction with the LARS ligament in a series of 43 patients at a mean 29 months from surgery. They reported a mean Lysholm of 83 postoperatively; overall IKDC was normal or nearly normal in 95%. Despite including instrumented testing in the study design no report is made of the outcome of ligamentous evaluation or KT1000 testing in the ACL group in the published article.
5. Gäbler et al [19] (2006) report the results of a series of 26 patients at a minimum of 12 months after ACL reconstruction with a LARS graft and reported a complication rate of 69%, a reoperation rate of 42% and 15% incidence of objective laxity on Lachman testing.
6. Liu et al (2010)[20] reviewed 60 patients after reconstruction with either 4 strand hamstring tendon autograft or the LARS ligament at a mean 49 months after surgery. The study was retrospective and non randomised. They report a mean laxity of 2.4mm in the HT group and 1.2mm in the LARS group (p=0.01). No other significant differences were identified in subjective outcomes, activity level or overall IKDC grading.

CONCLUSIONS

It can be seen that the existing published literature on the outcome of the LARS ligament for ACL reconstruction is inconsistent. Similar inconsistencies were reported with the previous PET ligaments in the short term which was followed by more consistently poor outcomes over the longer term.

The LARS ligament has received considerable press over recent years after it was used in several high profile athletes. Anecdotally it appears that the short term results in these athletes are acceptable. However there is currently little evidence to suggest that the theoretical faster recovery associated with the LARS ligament will not come at the considerable cost of long term poor outcome with respect to failure rates and development of premature osteoarthritis. Unfortunately there is a long history of experimental techniques used in high profile athletes without scientific or practical evidence.

It is the consensus of the surgeons at the North Sydney Orthopaedic and Sports Medicine Centre that longer term outcome demonstrating equivalent results to human tissue grafts are required before the adoption of the LARS ligament should be considered for the general population.

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SURGEON OPINION– DR MERVYN CROSS, OAM

POSITION STATEMENT ON USE OF LARS LIGAMENT

Ever since commencing Orthopaedic practice and specialising in the knee since 1973, I have been up to date with all the attempts at introducing artificial ligaments for the human knee. There have been many artifical ligaments attempted and employed over the last 40 years and none of any intra-articular long standing success. There has been occasional use of an artificial ligament for extra-articular activities such as reinforcing medial and sometimes and the lateral ligaments. These ligaments which are extra-articular are surrounded by soft tissue and the artificial tissue can integrate in some cases in the extra-articular manner by creating a fibrous reaction.

The anterior cruciate ligament however travels across a space within the knee and therefore has great difficulty in being surrounded by connective tissue as it crosses the space.

The artificial ligaments that are used intra-articularly have all failed with time because of the stresses placed on an artificial tissue. Human anterior cruciate and posterior cruciate ligaments are continually being replaced with cellular ingrowth as the old cells die. This is because they have a blood supply which sustains their longevity.

The LARS ligament has been used for many years and when it was earlier introduced 20 years ago it was associated with a number of failures.

It has been brought to my attention recently that some Surgeons have attended a course where the founder and developer of the LARS ligament has attended and have recommended the use of the LARS ligament in fresh anterior cruciate ligament ruptures. The idea is that these elite sportsmen will return to full activity within three months. It has been my experience over the last 30 years, using conventional ligament transplants from the human, that is, autografts of the patellar tendon and hamstrings, that a top elite sportsman can return to full activities in twenty four weeks. This can give them a sustained career as well as the avoidance of arthritis in later years because the knee will be permanently stabilised.

The only advantage of a LARS ligament is that they can possibly return to playing in twelve weeks rather than twenty four weeks.

I do not believe that the extra twelve weeks is a difficult price to pay for a knee that returns to normal and will not ultimately fail. You only have to see the complications of a failed artificial ligament to understand the difficulties of reconstruction when that fails because of the large foreign body reaction within the knee.

It is therefore my practice not to recommend to any patient, whether they be elite or not to undergo an artifical ligament when autografts give rise to a better and a long standing result.

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SURGEON OPINION –ASSOCIATE PROFESSOR LEO PINCZEWSKI

There has been considerable recent media interest on the LARS ligament for reconstruction of the anterior cruciate ligament (ACL). This is of concern as all prior attempts to reconstruct the ACL with artificial ligaments and Ligament Augmentation Devices have failed with poor medium and long term outcomes for the patient. The Surgeons at the North Sydney Orthopaedic & Sports Medicine Centre consider it appropriate to summarise their collective experience, the current evidence and provide an opinion regarding the use of the LARS and other artificial ligaments.

THE HISTORY OF ARTIFICIAL LIGAMENTS

Artificial ligaments for reconstruction of the ACL were introduced in the 1970's. In 1992 the International Knee Society reviewed artificial ligaments. They noted uniformly poor clinical outcomes and recommended cessation of their use. A recent resurgence in Australia is related to a new generation of surgeons who have not shared this experience and to a marketing push with no new clinical evidence provided. Their marketing strategy is to emphasise the theoretical benefits over using autograft (the patient's own tissue, patella tendon or hamstring tendon). These include artificial ligament's early strength at implantation, the lack of harvest site morbidity and a technically easier surgical technique for the surgeon (with a potentially faster rehabilitation for the patient). There is no question that our early experience with artificial ligaments showed that they were successful in restoring knee stability in the short term. However, all man-made materials suffer from fatigue fracture of the fibres and, with time, they all ultimately wear and fail. This process is accelerated in poorly positioned ligaments, however, even when ligaments are well placed, the expected survival is only 7-10 years.

The most popular artificial ligament used to date is the Leeds-Keio ligament which has been used in over 50,000 cases worldwide[1]. It is made of a similar polyester material as that of the LARS ligament. Early results were very encouraging with failure rates of less than 10% at 3 years[2]. With increasing time however, inflammation of the synovial lining of the joint due to fragments of polyester has been reported as well as increasing instability with 66% of patients at 10 years having unstable joints. Also of great concern is that 100% of patients had developed osteoarthritis at 10 years post operatively. The best results were reported by Ventura[3] in 2010 with an 18-21 year follow up. Ventura showed that only 25% of patients considered their knee normal, with 75% demonstrating laxity on clinical testing and 100% of patients having signs of osteoarthritis. The mechanism for this osteoarthritis has been studied[4]. Artificial ligaments form wear particles that cannot be absorbed by the body. These particles produce an inflammatory reaction which alters the cartilage cells initiating a breakdown of articular cartilage leading to osteoarthritis.

THE LARS LIGAMENT

The LARS ligament is advocated by the Corin Company and the surgeons who use it, as having a superior design to previous polyester ligaments. It has been recommended to be used as a stent through the native anterior cruciate ligament to prevent the polyester particles from entering the joint. Unfortunately the nature of ACL injury rarely allows enough tissue to cover the stent even if surgery is carried out immediately. Whilst this coverage might prevent polyester wear particles from entering the joint should the native cruciate ligament heal, the native ligament tissue is stress shielded by the stent and when finally the stent fails, the stress shielded tissue is unable to support knee stability resulting in rupture, laxity and exposing the joint to polyester particles.

The LARS ligament has received considerable press since being used in several high profile athletes. If the surgery is performed technically correctly, a good short term outcome is to be expected with a return to sport appearing possible at 3 months rather than the 5 or 6 months with the use of the patients own tissue. However, whilst such a quick return to sport may be indicated in the professional athlete reaching the end of his career, for the younger professional athlete or the general population, the inevitable failure of the

ligament leading to the need for further surgery to stabilise the joint and the markedly increased risk of premature osteoarthritis makes their use unacceptable.

On current evidence the LARS ligament should only be used in ethically based clinical trials in a research setting with informed consent of the patient regarding known failure rates and osteoarthritic outcomes at the 10-15 year post operative mark.

The LARS ligament has been used and licensed in France for over 25 years for repair and augmentation of the posterior cruciate ligament. However French surgeons have reported a high failure rate of this ligament and inevitable osteoarthritis after posterior cruciate ligament reconstruction with LARS. These results, and the difficulty in covering the artificial ligament with soft tissue in ACL reconstruction, suggest a similar poor outcome.

With 15 year follow-up of patella tendon and hamstring tendon grafts for ACL reconstruction, the long term results of this surgery have been shown to provide long standing ligamentous stable joints that allow full participation in sport at the highest level without damage to the menisci due to instability and the subsequent development of osteoarthritis.

SUMMARY

Whilst an argument can be made for the implantation of a LARS or any other artificial ligament into a professional sportsperson who is reaching the end of his/her career in the hope, of a few more seasons, the known risks from artificial ligament failure, the need for further surgical procedures and the subsequent osteoarthritis are rarely appreciated or emphasised to the patient.

The current evidence is that artificial ligaments will have good short term results over 5-7 years but will have an inevitably higher risk of revision surgery for increasing laxity and inflammatory synovitis secondary to artificial ligament particle debris resulting in premature osteoarthritis. Accordingly, it cannot be ethically recommended to our patients.

A/ PROF LEO PINCZEWSKI

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SURGEON OPINION – DR SAM SORRENTI

I have been looking at the literature in regards to the LARS ligament. Most of the information available which is available to the LARS ligament basically comes from the Company. There have not been many studies. There was one randomised clinical trial in The Journal of Bone and Joint Surgery by T. Nau British Editorial 2002 84 B page 356 - 360 it is a randomised trial but it is only a 2 year follow up and the final conclusion is that follow up at 24 months of the LARS ligament seems to be a satisfactory treatment option especially when early return to high level activities is demanded. Most of the other studies do not go past 2 years and the ones that do again do not show any major changes and they do not establish the fact there is any major advantages.

The only other study is from China which is in Clinical Medicine Journal 2010: 123(2): 160-164 by Jian-ming Huang this is 81 cases looking at various ligaments and again their conclusion follow up at 10 - 49 months the clinical results are satisfactory in the short term.

Therefore the major problem at this stage with advising anyone to have a LARS ligament is there is nothing to indicate that long term it produces the type of effect and result which people want. Most of the follow up is only in the 2 year period therefore my advise at this stage is to wait and see.

Kind regards

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SURGEON OPINION – DR DAVID WOOD

Rupture of the Anterior Cruciate Ligament is a common knee injury, which causes ongoing instability of the knee, affecting the ability to undertake pivoting exercises. This injury requires operative reconstruction to avoid instability and the risk of further injury to the structures of the knee, which may ultimately increase the risk of osteoarthritis.

The gold standard treatment for this condition is reconstruction with autograft (tissue taken from the patient) using either hamstring or patella tendon. There are pros and cons for preferring patella-tendon or hamstring, but in general terms, the outcome is very good and similar between the two groups(1)(2).

Recently there has been interest shown in artificial grafts for the reconstruction of the ACL. This has been advocated in order to avoid the problems associated with autograft harvest (knee pain, or slight reduction in hamstring strength), and to allow earlier return to sport.

As yet the LARS ligament has only been available for about ten years, and so the longterm outcome of its use is not fully understood. In the literature, there is only one randomised controlled trial following the ligaments up to 2 years postoperatively (3), which showed an earlier return to sport, but no difference in function after 2 years. This was published in 2002, and no further results from this group of patients has been published. It is therefore difficult to know what happened to those grafts in the long term. In 2006 a study of problems associated with the LARS ligament graft was published(4), which showed a 69% rate of postoperative problems and complications., including stiffness, laxity and 42% reoperation rate. There are also reports of marked synovitis associated with using synthetic materials within the knee. Any artificial graft cannot repair itself like normal human tissue, and so is vulnerable to fatiguing and ultimately failure, as it is stressed.

Artificial grafts are not new, but have frequently been brought to the market with theoretical advantages, which have often not been found in practice. At this stage there is not enough longterm data available for the use of the LARS ligament to advocate is use routinely over the gold standard autograft option. There are situations, where it might currently have its place, such as an elite athlete who injures their ACL a few months before an important event (Olympics, or World Cup), or as part of an ongoing trial of its longterm results.

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SURGEON OPINION – DR JUSTIN ROE

Synthetic grafts have been around for many years and their history has been quite checkered. All synthetic grafts have shown early promise but mechanical failures have occurred with the resultant graft wear debris causing major synovitis. Subsequently the majority of synthetic grafts have been abandoned. Synovitis has been a major issue in addition to mechanical failure. Articular cartilage damage is a flow-on effect from this.

The LARS Ligament is a synthetic graft that is being marketing as an "internal stent". The Company and Surgeons promoting its use advise the surgery to be done on a knee with a "good ACL stump". The technique, however, is unclear and the preservation of this "good ACL stump" technically, is difficult.

With the history of synthetic grafts and the renewed interest in the LARS Ligament, it is essential that the Company and Surgeons using and promoting the LARS provide us with good evidence based medicine in favour of this device. There are very few medium to long term published results in peer reviewed journals. Before considering clinical results, we also have to consider scientific results using animal models and mechanical testing models. These data are also scanty.

The current debate is based around patients wanting to get back from injury and surgery quicker. In addition to this, all Surgeons would like better results from their surgery and for their patients. Both Surgeon and patient want to avoid re-injury and the instinctual thinking is that a "stronger graft" will avoid re-injury. The fundamental principle in medicine however is "to first do no harm".

When considering a quicker recovery, we must remember that an injury to the anterior cruciate ligament reflects an injury to the whole knee. This injury and the subsequent surgery that takes place requires a period of time to recover. The duration of this recovery period is not known exactly. It is based on clinical experience as well as the knowledge of physiology. Currently this recovery period following ACL injury and surgery can extend from 4 months through to 18 months. Clinical studies have shown that there is a higher re-injury rate in the first 24 months following ACL surgery. Clinical studies have not shown reproducibly that the LARS Ligament reduces this time-period with confidence.

When considering the desire for better results following ACL surgery the literature has not shown that the LARS Ligament provides this outcome. With respect to the higher re-injury rate in younger patients, peer reviewed studies have not shown that the LARS Ligament deals with this issue any better than the current techniques. When the small problem of graft-site morbidity is considered, the LARS Ligament does deal with this issue. The question is, however, does this benefit outweigh the unknown risks?

The behaviour of the LARS Ligament when it fails is still not clear. With successful surgery and the ideal outcome of returning patients to normal, there is always the risk that re-injury will occur. Biological grafts have a predictable behaviour when they fail but synthetic grafts have a poor history when they fail. This requires further investigation therefore, to make sure that no harm results to the knee when they do actually fail.

In summary, therefore, due to the poor track record of synthetic grafts it should be a requirement of those Surgeons who are using them in to follow their patients closely and report early complications. Patients should be fully informed of the evidence available for their use such that an informed decision can be made when undergoing this type of surgery.

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SURGEON OPINION – DR TIM MUSGROVE
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New Knee or News

The stethoscope and the arthroscope are the symbols of the physician and (orthopaedic) surgeon. They are the ears and the eyes reminding the surgeon to listen and look. New products and techniques are assessed, as would a new patient, with history (listen) and examination (look).

Patients should be aware of the experience or the experiment of their proposed surgery. Surgeons should not " try one" because the patient would "buy one". No longer, "see one, do one, teach one".

Throughout this decade, orthopaedics has seen chondrocyte implantation and computer navigation introduced and unicompartmental knee replacement revisited, with many as willing to adopt and then drop the procedures.

Dr Tim Musgrove

Currently, a wave of popularity, driven by newsworthiness, is evident in surgery for reconstruction of the anterior cruciate ligament. Sports headlines herald the success of the synthetic artificial ligament for treatment of the "stars ". Surgeons and patients caught in the headlights may trial the surgical "antidote" based on the anecdote.

Reminded, however, of basic surgical training, LISTEN to history and LOOK at the literature.

Artificial ligaments for reconstruction of the anterior cruciate ligament were introduced in the 1970s with the theoretical benefits of strength at implantation, lack of harvest site morbidity, a technically easier operation and a faster rehabilitation period.

Polyester (polyethylene terephthalate) or PET grafts were introduced in 1989 with early encouraging results reported, but high failure rates, synovitis and premature arthritis evident in the available long term reviews.

Peer and published opinion, support the use of an auto graft (hamstring tendon or patella tendon), positioned anatomically and rehabilitated appropriately, to deliver a functionally stable knee with a predictable return to sport within 6 – 9 months.

What is old (PET), is new again, reintroduced with proposed superior design and biology. The media and marketing emphasise an earlier return to sport. The potential short term WIN. The size and strength of papers remain limited in support. The potential long term LOSS. A professional athlete may be motivated by "show me the money ", however the surgeon should be governed by "show me the studies ".

An amateur athlete armed with newspapers and net knowledge, brochures and blogs may shop, and the surgeon may sell on the hype, not the history. The leap from basic science to clinical application is in randomised controlled trials. While sport is a game, surgery is not a gamble, so listen and look.

Dr Tim Musgrove
Regional Committee Executive Member &
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