Leeds-Keio artificial ligament: a new concept for the anterior cruciate ligament reconstruction of the knee

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Abstract. The features of the Leeds-Keio artificial ligament, which was developed as a collaborative project between the University of Leeds in the UK and Keio University, are introduced. The ligament is made of polyester, and has a mesh structure. The diameter of the polyester fibers is 22 μm. The ligament has a tensile strength sufficient for anterior cruciate ligament (ACL) reconstruction, and fatigue tests have shown satisfactory durability of the ligament. The stiffness of the Leeds-Keio artificial ligament is about 200 N/mm, which is similar to the natural ACL. A combination of a bone plug and stapling is used for the bone fixation, taking into consideration the strength in both the initial mechanical fixation and the long term fixation. From an animal study, it was shown that fibrous tissue was induced around the artificial ligament, and the collagen fibers became aligned in the longitudinal direction of the ligament. For the clinical experience, one-hundred and thirty five cases were reviewed. The Lachaman sign disappeared in 87.4%, and the pivot shift sign disappeared in 88.1%. Side-to-side difference of anterior displacement of the knee, measured with a KT-2000 knee arthrometer at 30 degrees of flexion, was less than 3 mm in 85.9%. More than 90% of the patients experienced full range of motion. Thus, from the clinical results, it can be concluded that reasonable stability was obtained with the operation. If the Leeds-Keio artificial ligament may not be the perfect substitute for the ACL, both experimental and clinical studies indicate that it represents a major forward step in the history of knee ligament surgery. (Keio J Med 50 (3): 161–166, September 2001)

Key words: knee, ligament, reconstruction, anterior cruciate ligament, artificial ligament

Introduction

Knee ligament injury often impedes the sports activities of athletes. Injury of the anterior cruciate ligament (ACL), in particular, may sometimes even terminate their participation in sports. Therefore, an accurate diagnosis and prompt treatment are essential to allow athletes to resume their sports activities. Primary suture of the ligament in the acute phase used to be the standard treatment for ACL injury, but several reports concluded that this method failed to obtain satisfactory results. Primary reconstruction is now usually recommended for injuries to the ACL, even in the acute phase. Several materials have been developed for ACL reconstruction, including autogenous tissues, allografts and artificial materials, but each material has several weak points and the perfect substitute has not yet been developed.

The Leeds-Keio artificial ligament was developed in 1982 as a collaborative project between the Rheumatism Research Unit, University of Leeds in the United Kingdom and the Department of Orthopaedic Surgery, Keio University in Japan (Fig. 1).[1] It has been used clinically for knee ligament reconstruction, particularly for ACL reconstruction, and in the other types of reconstructive surgery for more than 19 years. In general, satisfactory results have been reported with this artificial ligament, although there are still some points of controversy.[2,3] In this paper, the features of the Leeds-Keio artificial ligament are introduced and the ex-

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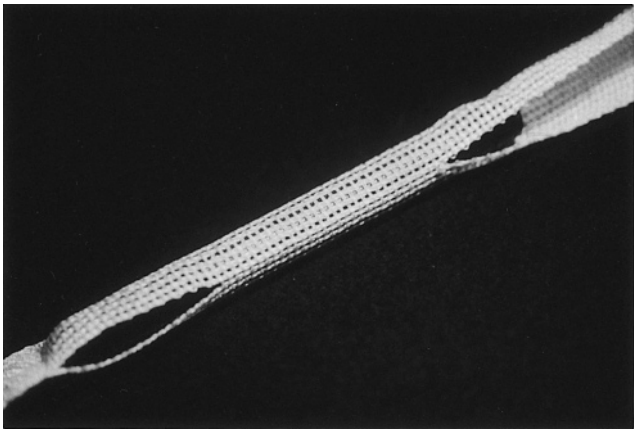

Fig. 1 The Leeds-Keio artificial ligament.

perimental and clinical studies on this ligament are reviewed.

Historical Background and Concept of the Leeds-Keio Artificial Ligament

The development of artificial ligaments has a long history, started in the field of veterinary surgery in the beginning of the 20th century and followed by the medical field. Silver wire, stainless wire, silk string, nylon string, polyethylene and other synthetic fibers were initially tried as the material for the artificial ligaments. However, most of these were abandoned at the stage of animal experiments and were not used clinically at all, since the implants tended to rupture at a very early stage after the operation. After these early experiments, there has been a long pause in the development of artificial ligaments.

The second wave in the development of artificial ligaments was started in the late 1970's. An artificial ligament using carbon fiber was developed by Jenkins in 1978,[4] and an artificial ligament made from Gore-Tex (polytetrafluoroethylene) was also developed in 1985.[5] Both were called artificial ligaments, but they differ in concept from each other. The Gore-Tex one is a so called prosthetic type, which means that the ligament is expected to work as a ligament by itself semi-permanently. On the other hand, the carbon fiber one is a so called scaffold-type, and is expected to work as a ligament until biological tissue is induced around the implant, which subsequently becomes ligamentous tissue and finally assumes the role of the original artificial ligament.

A knee ligament receives not only a tensile force but also a substantial bending force at its bone attachment when the knee is flexed or extended. In physiological knee ligaments, the tensile force is carried by the middle fibrous portion aligned in its longitudinal direction, and the bending force is carried by the cartilage portion at its bone attachments. Therefore, it is important for an artificial ligament to have sufficient strength against both the tensile and the bending forces. Since most of the artificial ligaments are made of synthetic fibers, it is relatively easy to provide the tensile strength, but it may be difficult to cope with the bending force. Breakage at the bone attachment had thus been a weak point of artificial ligaments. This weak point however can be overcome if the growth of a biological tissue (ideally cartiligenous tissue) is induced around the artificial ligament. Hence, the scaffold-type artificial ligament has a great advantage in that it can cope with the bending force exerted on it.

In fact, the Gore-Tex artificial ligament had an extremely high tensile strength, and, therefore, excellent stability was achieved immediately after the operation.[5] With these favorable short term results, this ligament was at one time widely used clinically. However, it was gradually recognized that this ligament was often ruptured within a certain period after the operation, possibly because the artificial ligament could not tolerate the bending force, in spite of its sufficient strength against the tensile force. Thus, the Gore-Tex artificial ligament has been completely abandoned in the field of knee surgery.

On the other hand, it was proved both experimentally and clinically that good tissue induction was observed around the carbon fiber artificial ligament.[4] It was widely used clinically all over the world, and it was thought that an ideal artificial ligament had been developed. However, the weak point of the carbon fiber, that is fragility, was gradually recognized after the ligament was first used clinically. It was reported that the carbon fiber artificial ligament tended to break up into many fragments which induced severe synovitis in the knee joint. The search for and development of an ideal artificial ligament was therefore restarted.

Material and Structure of the Leeds-Keio Artificial Ligament

There are several conditions imposed on the material from which an artificial ligament is constructed: 1) no toxicity; 2) biocompatibility; 3) mechanical strength; 4) easy handling; 5) low cost/benefit ratio, and 6) the ability to induce tissue (in case of the scaffold type). The Leeds-Keio artificial ligament is made of polyester, which has a long history in its use as material for artificial vessels in the human body, and has been proved to be successfully biocompatible in a number of studies. In addition, it has excellent mechanical properties (strength and stiffness) and the ability to induce tissue growth around it.[1]

As far as the structure of artificial ligaments is concerned, most of them are woven with bundles of synthetic fibers, and the method of weaving is also one of the important factors in a successful artificial ligament. There are some artificial ligaments which are woven like a shoe-lace, in which most of the fibers run obliquely to the long axis of the ligament, and repeated loading along the ligament may cause a longitudinal realignment of the fibers thus leading to a loosening of the ligament structure. The Leeds-Keio artificial ligament has a mesh structure woven with longitudinal bundles of polyester fibers and transverse bundles at right angles arranged at intervals of 2.5 mm. The advantage of this arrangement is that the load along the ligament can be transferred by only the longitudinal bundles, and structural loosening does not occur with this arrangement.

The diameter of the polyester fibers in the Leeds-Keio artificial ligament is 22 μm. The thickness of the fibers is also an important factor. Tissue induction is expected to occur around the scaffold type of artificial ligament which is initiated by the foreign body reaction to the artificial fibers. Therefore, the smaller the diameter of the artificial fibers is, the more tissue induction occurs. The surface area of the fibers is in an inverse proportion to the diameter, and, therefore, is one of the most important factors for the foreign body reaction. In addition, the smaller diameter has the mechanical advantage of reducing the bending deformity at the bone attachment when a bending torque is applied to each fiber.

There are different types of artificial ligaments for different purposes; the tubular type with a diameter of 10 mm (LKDT) which is usually used for the ACL reconstruction, and several tape-type ligaments from 10 mm to 60 mm in width (LK10–LK60) for other ligament reconstructions.

Mechanical Properties of the Leeds-Keio Artificial Ligament

Sufficient tensile strength is an important factor for an artificial ligament, but the ability to maintain the strength after implantation should be also considered. The tensile strength of the normal ACL is about 630 N in older persons, according to an experimental study by Kennedy,[6] and about 1730 N in the young according to a study by Noyes.[7] Therefore, artificial ligaments for ACL reconstruction should have a tensile strength equal to or greater than these figures. The mechanical properties (tensile strength and stiffness) of the Leeds-Keio artificial ligament were tested under the following conditions ($n = 170$):[1] LKDT (used for the ACL reconstruction) was used as ligament whose gauge length was 40 mm. Strain rate was 1%, 50% or 100% per second, and the media were room air at 20 °C or physiological saline at 37 °C.

The maximum tensile strength ranged from 2061 ± 31 N (preconditioned for 3 hours at 25 cycles under load of 50–500 N) to 2350 ± 28 N (non-preconditioned). The average stiffness ranged from 151 ± 91 N/mm (non-preconditioned) to 294 ± 26 N/mm (preconditioned for 3 hours at 25 cycles under load of 50–500 N). A fatigue test was also carried out under the following conditions ($n = 18$):[1] sinusoidal 500 N was loaded at a frequency of 25 cycles in room air at 20 °C or in saline at 37 °C.

None of the ligaments tested in these series ruptured. The average value of the residual strength was about 1700 N (77% of the original strength) after 10×10^6 cycles.

The Leeds-Keio artificial ligament was demonstrated to have sufficient tensile strength for ACL reconstruction, and the fatigue test showed satisfactory durability of the ligament.

The stiffness of the substitute material is also an important factor, particularly for the scaffold-type artificial ligament. If the stiffness is too low, the substitute cannot work as a constraint, and if it is too high, tissue induction around the artificial ligament is hindered by the stress shielding. Amis, *et al.* reconstructed sheep Achilles tendons, having an average stiffness of 46 N/mm, with polyester (40 N/mm in stiffness) or carbon fiber (600 N/mm in stiffness), and compared the pathological findings at 15 to 18 months after the operation.[8] The authors found that the biological reaction was stronger with carbon fiber but that the amount of collagen fibers induced was much higher with polyester fiber. In other words, tissue induction occurred as a reaction to the material but tissue maturation occurred when the induced tissue was under tension with less stiff material. Therefore, an artificial ligament with a stiffness similar to the natural ligament may offer great advantages for the tissue induction. The stiffness of the Leeds-Keio artificial ligament is about 200 N/mm, which is similar to the natural ACL, but further experimental studies are required to determine the ideal stiffness of the substitute.

Bone Fixation System of Leeds-Keio Artificial Ligament

There is no point in achieving the correct mechanical strength of an artificial ligament without also considering the strength of its fixation to the bone. Therefore, the mechanical strength of the bone fixation is an equally important factor for a good operative outcome. In the Leeds-Keio artificial ligament, a combination of a bone plug and stapling is used for the bone fixation (Fig. 2). The initial mechanical strength of the fixation is

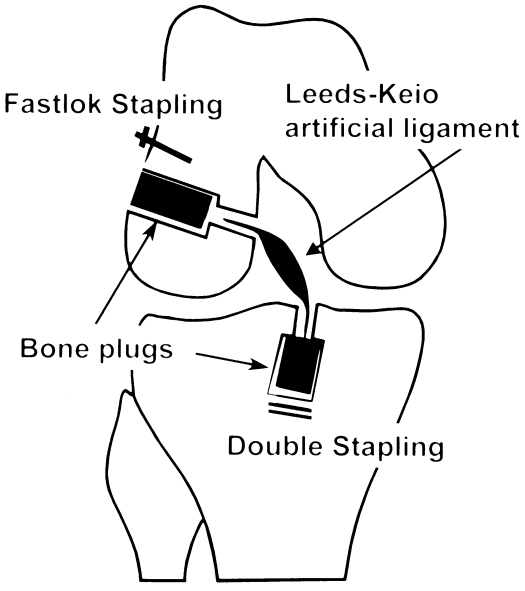

Fig. 2 Bone fixation system. A combination of a bone plug and stapling is used for the bone fixation.

expected to be carried out by the stapling and the long term fixation is expected to be performed by the biological osseointegration between the plug and the tunnel. A double stapling method is used for the tibial fixation, and Fastlok stapling, which is a staple with buckle, for the femoral fixation. It was revealed from an experimental study that the double stapling method has more than double the tensile strength (647 $\pm$ 25 N) compared with that of the single stapling method (253 $\pm$ 68 N).[9] Fastlok stapling works by pinching the artificial ligament between the staple and the buckle when the tension is applied to the artificial ligament. The mechanical strength of the Fastlok stapling is twice compared to that of the double stapling (1035–1223 N, 1113 N on average). In addition, fatigue testing, in which the mechanical strength of the Fastlok stapling was examined after 1.5 million cycles of loading (between 50 and 400 N), revealed that the residual strength of the stapling was sufficient (852 N on average).[1]

The bone plug fixation is a method of fixing the artificial ligament both mechanically and biologically and is achieved by making a double bone tunnel with different diameters (11 mm and 6 mm). A bone plug with diameter of 11 mm is taken from the extra-articular exit of the bone tunnel using a special reamer. The tunnel is then continued on through to the intra-articular side (the original site of the ligament attachment) with another reamer of 6 mm in diameter. After the artificial ligament is passed through this double bone tunnel, the bone plug is replaced in the tunnel. With this method, the artificial ligament is fixed to the bone tunnel both mechanically and biologically when bone union occurs between the tunnel and the plug after the operation.

Tissue Induction of the Leeds-Keio Artificial Ligament

As previously described, it is important for the scaffold-type artificial ligament to induce biological tissue. Tissue induction and remodeling around the Leeds-Keio artificial ligament were examined experimentally using 16 dogs.[10,11] The ACL was replaced with the artificial ligament under tension in 13 of the 16 dogs and without tension in the remaining 3 dogs in order to examine the effect of tension on tissue remodeling. Fixation of the artificial ligament was achieved by the use of bone screws and washers, taking the size of the animal into consideration. The animals were sacrificed at different postoperative intervals between 8 and 36 weeks. After macroscopic observation, microangiography was carried out using a blue acrylic dye and the vascularization of the induced tissue was observed through a binocular microscope. Histological samples were then prepared from the materials and were also examined microscopically.

From the macroscopic observation, proliferation of the fibrous tissue with a rich blood supply was observed around the artificial ligament at 8 weeks after the operation (Fig. 3). The fibrous tissue occupied the whole intercondylar space in some cases. This proliferation of the fibrous tissue was similar to the foreign body reaction. The proliferated fibrous tissue was, however, found only in a limited area around the artificial ligament at 12 to 16 weeks after the operation, and the vascularity was also reduced. The induced fibrous tissue resembled the natural ACL at 24 to 36 weeks after the operation, and vessels were observed only at the femoral and tibial insertions of the induced ACL (Fig. 4).

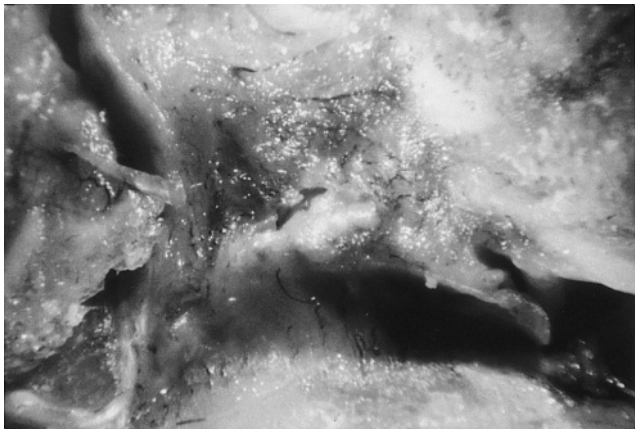

Fig. 3 Macroscopic findings at 8 weeks after the ACL reconstruction (from the canine experiment). Proliferation of fibrous tissue was found around the artificial ligament.

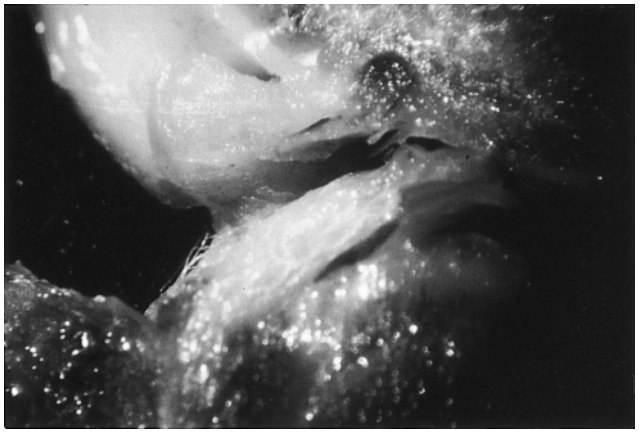

Fig. 4 Macroscopic findings at 24 weeks after the ACL reconstruction (from the canine experiment). The induced fibrous tissue resembled to the natural ACL and the vessels were observed only at the femoral and tibial insertion of the ACL.

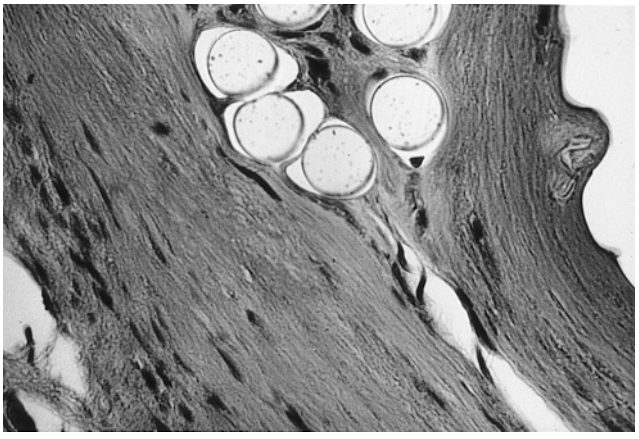

Fig. 6 Histological findings at 36 weeks after the ACL reconstruction (from the canine experiment). The fibrocytes became spindle shaped and their number was much reduced, with dense collagen fibers aligned in the direction of the longitudinal fibers of the artificial ligament.

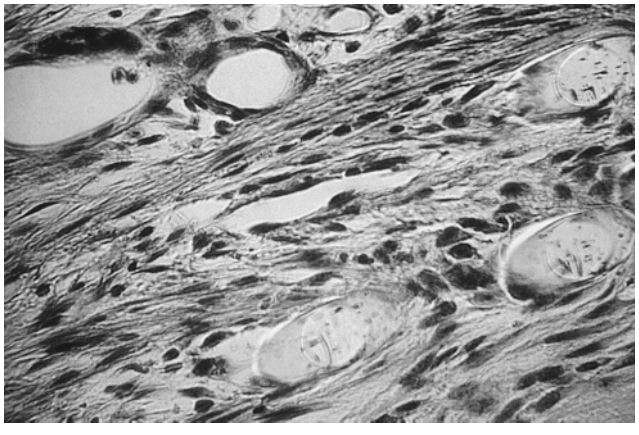

Fig. 5 Histological findings at 8 weeks after the ACL reconstruction (from the canine experiment). Proliferation of immature round fibrocytes is combined with the appearance of foreign body giant cells, with coarse and randomly oriented collagen fibers.

Histological examination showed proliferation of immature round fibrocytes combined with the appearance of foreign body giant cells at 8 weeks after the operation, and the collagen fibers were rough with a random orientation (Fig. 5). The number of the fibrocytes was reduced at 12 to 16 weeks after the operation, although the foreign body giant cells were still observed. The collagen fibers became denser than those observed at 8 weeks post-operatively. The fibrocytes became spindle-shaped and the number of the cells was much reduced at 24 to 36 weeks after the operation. The dense collagen fibers were aligned in the direction of the longitudinal fibers of the artificial ligament (Fig. 6), although the foreign body giant cells were still observed at this stage. In addition, cells similar to chondrocytes were observed at the bone insertion of the ligament.

From these results, it was found that the tissue induction around the artificial ligament was initialized by the foreign body reaction, which subsequently brought about prolific neocollagenesis. The proliferation subsided once the artificial ligament was covered with tissue, and then remodeling occurred, in which the collagen fibers gradually became aligned in the longitudinal direction of the artificial ligament, if the repeated tension was applied to the induced tissue by first replacing the ligament under tension.

Operative Procedures

The operation is usually carried out arthroscopically. Intra-articular conditions are examined carefully, and combined meniscal or cartilaginous injuries, if any, are treated before starting the ACL reconstruction. A skin incision (about 30 mm in length) is made at the anterior surface of the tibia and the tibial bone surface is exposed. The reamer guide is fixed from the center of the physiological ACL insertion of the tibia intra-articularly to the exposed tibial anterior surface. The distal half of the bone tunnel is made by taking a bone plug with a diameter of 11 mm from the tibial surface using a reamer. The tunnel is then continued on through into the intra-articular side with another reamer of 6 mm in diameter. Another skin incision is made at the lateral side of the femur, the iliotibial tract is split, and the distal part of the femoral shaft is exposed. The reamer guide is fixed from the postero-lateral corner of the physiological ACL insertion of the femur to the exposed femoral shaft, and the same procedure as for

the tibial bone tunnel is repeated on the femur. The Leeds-Keio artificial ligament (LKDT-LK30) is passed through the tunnels as far as possible under the remnant of the ACL. The artificial ligament at the tibial side is fixed to the tibia with the double stapling method, and at the femoral side it is fixed with Fastlok stapling after the ligament has been manually tightened. A notchplasty is carried out if narrowing of the notch exists. After confirming full range of motion, sufficient stability and no notch impingement, the joint is washed with saline, a suction drainage is left in the joint and the wound is closed.[2,3]

Clinical Experiences

More than 1000 cases have been operated on since 1982. However, since the operative procedure was changed several times, this paper reviews 135 cases in which the above-described procedure of the ACL reconstruction was carried out, and those have been followed up for five years or more.[1,2] Preoperatively, all cases showed remarkable giving way subjectively and at least 1+ Lachman sign and pivot shift sign. The Lachman sign disappeared in 87.4%, scored a trace in 4.4%, was mildly positive in 5.2% and was gross positive in 3.0%. Pivot shift sign disappeared in 88.1%, scored a trace in 5.2%, was mildly positive in 3.0% and was gross positive in 3.7%. Side-to-side difference of anterior displacement of the knee, measured with a KT-2000 knee arthrometer at 30 degrees of flexion, was less than 3 mm in 85.9%. No significant difference in anterior terminal stiffness between the operated side and the contralateral side was found in 77.0%. More than 90% of the patients experienced a full range of motion. Thus, from these clinical results, it can be concluded that reasonable stability was obtained by the operation with the Leeds-Keio artificial ligament.

Conclusion

The Leeds-Keio artificial ligament was developed as a new device for the ACL reconstruction, and reasonable clinical results have been obtained with it. Although it may not be the perfect substitute for the ACL, this ligament represents a forward step in the history of knee ligament surgery.

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