ARTHROSCOPY AFTER ANTERIOR CRUCIATE RECONSTRUCTION WITH THE LEEDS-KEIO LIGAMENT

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The healing of anterior cruciate ligaments reconstructed with the Leeds-Keio artificial ligament was observed by arthroscopy in 42 knees and biopsy in 19 knees at intervals from 3 to 24 months after implantation. By three months the implant was covered with immature new tissue, and a dense vascular network crossed its surface. At 12 months a new ligament had developed and matured, looking like the natural one in most cases. Histology at this stage showed abundant collagenous fibres running parallel and longitudinally, while the synovial membrane showed no more than very slight inflammatory changes.

By 18 to 24 months, the new ligament often had the arthroscopic appearance of a normal anterior cruciate ligament. These results suggest that this scaffold type of artificial ligament is effective for cruciate reconstruction, giving satisfactory healing without significant complications.

Injury of the anterior cruciate ligament (ACL) has been treated in many ways, ranging from conservative management to complex operations. Primary repair, augmentation or primary reconstruction have been used for fresh injuries, while different methods of reconstruction with autogenous tissue have been used for chronic cases. No procedure has given uniform success, and when reconstruction failed, the patient still had dysfunction of the knee and no more autogenous tissue was available for further reconstruction. This led to another solution, the use of synthetic implants for augmentation or reconstruction of the ACL. Recently, efforts have been made to develop an artificial ligament of sufficient strength to reconstruct the ACL without sacrifice of, or interference with, any autogenous tissue (Grood and Noyes 1976; Jenkins et al 1977; Jenkins 1978; James et al 1979; Alexander et al 1982; Fujikawa et al 1984; Fujikawa 1984; Bolton and Bruchman 1985; Goodship, Wilcock and Shah 1985; King and Bulstrode 1985; Neugebauer and Burri 1985; Park, Grana and Chitwood 1985; Strover and Firer 1985; Weiss et al 1985; Fujikawa 1988). A second aim has been to simplify operative procedures and ensure more consistent results.

Two types of artificial ligament have been developed. The first is a true prosthesis, a replacement ligament which aims to provide stability and support for the rest

of the patient's life. Since this may be 40 years or more, there must be some doubt about this solution. The second type of artificial ligament is one which will act as a scaffold for biological tissue which will eventually regenerate a new ligament. In the initial stage of tissue induction, the artificial ligament must act as the main tension-bearing element of the composite of artificial material and biological tissue. This stage lasts until the tissue ingrowth has matured and its fibres have become aligned along the direction of the tensile forces.

In time, the material of an artificial ligament may degrade chemically or mechanically by fatigue, losing some of its strength or even breaking down. In the ideal case, the ingrown tissue will progressively take over the tensile load. The success of this takeover of the function of load-bearing will depend on the presence and quality of well-aligned collagen fibres. Doubt has been cast on the quality of ingrowth that surrounds many such implants; some consider it as mere scar tissue with a

Fig. 1

Leeds-Keio artificial ligament.

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random immature collagen content. There is also some doubt as to adhesion of this tissue to the implant material; and therefore whether there can be a significant transfer of load from the fibres of the implant to the ingrown tissue. We have accordingly observed this important biological process over a period of time.

We now report the healing, maturation and remodelling in ACLs reconstructed with the Leeds-Keio artificial ligament, studied arthroscopically and histologically from small biopsies of the superficial layers of the new ligament.

The implant. The Leeds-Keio artificial ligament is both a strong, permanent implant and a scaffold-type device. It is made of polyester as an open weave mesh-like structure (Fig. 1), and is anchored to femur and tibia with bone plugs. These plugs unite with host bone through the mesh of the ligament and tissue ingrowth can occur into the intra-articular and extra-articular sections of the ligament.

Fig. 2

To show intra-articular reconstruction of the ACL and combined intra-articular and extra-articular repair.

The artificial ligament is tubular in its middle section with an 11 mm diameter. One end has a pouch for the insertion of one bone plug; the other is simply split open. The total length of the implant is 60 cm; this is sufficient for the combination technique of intra-articular reconstruction and extra-articular lateral stabilisation which we use for cases with excessive anterolateral rotatory instability (Fig. 2). The implant is completely flexible and has a maximum tensile strength of about 2 220 N, which is well above the average tensile strength (1 730 N) of the normal ACL of young adults (Noyes and Grood 1976).

The stiffness of the Leeds-Keio implant measured within soft grips (thus simulating the manner in which it is held in bone) is close to that of the natural ligament (Seedhom 1988). This is regarded as a vital feature of the design, since the comparable stiffness ensures that ingrown tissue will be subjected to some tensile strain during normal activities. These tensile strains cause the tissue to mature into collagen aligned parallel to the axis of the implant.

PATIENTS AND METHODS

Since 1982, more than 350 Leeds-Keio artificial ligaments have been implanted into knees with torn cruciate ligaments. These include 67 knees in which both ACL and PCL were ruptured, and 43 with both ACL and medial collateral ligament (MCL). In these cases, combined reconstruction of both torn ligaments was performed.

We report an arthroscopic study of 42 knees 3 to 24 months after reconstruction of the ACL or ACL and MCL, carried out with the informed consent of the patients. The patients' ages were 16 to 40 years (mean 23.5 years). The distributions of age, sex and follow-up period are given in Figure 3. Most patients had already returned to normal daily activities, with or without return to sport.

Age distribution (left) and period of follow-up (right) of 42 Leeds-Keio ligament replacements, showing the knees from which biopsies were taken.

Fig. 4a

Fig. 4b

Fig. 4c

Fig. 4d

Fig. 4e

Arthroscopic appearance of reconstructed anterior cruciate ligament at three (a), four (b), seven (c), 12 (d) and 18 months (e) after implantation.

Fig. 5a

Fig. 5b

Fig. 5c

Histological findings after reconstruction. Figure 5a -- At six months, showing an early stage of tissue maturation. Figure 5b -- By 12 months after reconstruction the orientation of the fibres is longitudinal and parallel. Figure 5c -- At 18 months, abundant mature collagen fibres are running longitudinally and parallel, but some hypercellularity is seen.

A Dyonics arthroscope was introduced by a lateral infrapatellar approach. The whole joint cavity was inspected and tissue ingrowth around the implant was examined by probing. The new ligament was observed throughout the range of knee flexion to decide whether it was tense or slack and the condition of the synovial membrane was recorded.

In 19 cases, biopsies were obtained from the newly-

Fig. 6

Histology of synovial membrane at 18 months. There are no marked inflammatory changes.

formed ligament and from the synovial membrane for histological study (Fig. 3). Sections were stained with haematoxylin-eosin and toluidine blue for ligament and haematoxylin-eosin for synovial membrane. Only one biopsy was taken from each ligament, to avoid damaging its function.

RESULTS

Morphology. In a few cases, especially early after operation, it was difficult to obtain a good view because of overgrowth of fibrous tissue in the intercondylar area.

Three to four months after surgery (Figs 4a and 4b), the artificial ligament had been already covered with newly-formed tissue, though this was still immature and fibrotic. An extensive vascular network was seen crisscrossing the surface of the ligament. In a few cases, the front of the femoral part of the substitute was still visible through the limited amount of tissue ingrowth in that region.

At six to seven months (Fig. 4c), probing confirmed that induced tissue was firmly adherent to the implant. A vascular network was still visible on its surface. In most cases, synovial cords, some slack and others tight, ran along the new ligament appearing to originate mainly from the infrapatellar adiposynovial fringe.

By eight months, the tibial insertion seemed to have remodelled and become broader and fan-shaped. When the knee was flexed and extended, the new ligament appeared to be tense throughout the range of movement.

At 12 months after reconstruction (Fig. 4d), the new ligament had developed and matured; it appeared like the natural one in both shape and thickness. This suggested that genuine remodelling had taken place. The vascular network on the surface had already begun to reduce.

At 18 to 24 months (Fig. 4e), in some knees, the newly-formed ligament could easily be mistaken for a normal ligament.

Most of the 42 arthroscoped cases conformed with this course, except in five cases. Two knees at five months, two at nine months and one at 12 months showed poor tissue induction and/or poor maturation of new tissue on the substitute ligament. In two of these cases (one at nine months, the other at 12 months) the implant was found to be slack and the new tissue had partially flaked away from its surface. In no case was there any inflammatory or reactive findings such as oedema, thickening, hypervascularity or foreign body reaction on the synovial membrane.

Histology

Ligament. After reflection of the synovial sheath of the new ligament, biopsies were taken from the front part of 19 ligaments during the arthroscopic investigation at 3, 6, 12 and 18 months as shown in Figure 3.

At three months the induced tissue covering the artificial ligament was fibrotic, immature and very cellular. No orientation of the fibres could be seen; they appeared to be randomly arranged.

At six months (Fig. 5a), abundant newly-formed tissue covered the artificial ligament. Histology showed early maturation, in that fibres at a distance from the implant, where new tissue would be expected to take some of the tensile load, showed alignment in a longitudinal direction. However, fibres close to the implant were still immature and randomly orientated. The new tissue was still hypercellular.

By 12 to 18 months, the induced tissue had become aligned; it contained large quantities of parallel collagenous fibres running in the direction of loading (Fig. 5b). However, more cells were present than would be found in normal ligamentous tissue. After this period, the cell component reduced gradually and some tissue obtained at 18 months showed a profuse array of collagen fibres (Fig. 5c). Some regions of the new ligament at this stage proved difficult to distinguish histologically from natural ligamentous tissue, except for some hypercellularity.

In the cases which had shown poor tissue induction and maturation on arthroscopic examination, histology at 12 months after implantation showed that induced tissue was still immature and fibrotic, with random direction of the fibres.

Synovial membrane. Specimens showed no more than very slight inflammation at 6, 12 (Fig. 6) and 18 months postoperatively.

DISCUSSION

Polyester, the material of the Leeds-Keio artificial ligament, has been confirmed as a suitable biomaterial experimentally and clinically in cardiovascular surgery. It is non-toxic, can induce natural tissue around itself, and maintain a considerable portion of its original strength for a long time after implantation.

Our arthroscopic study showed that this artificial ligament could induce new tissue which appeared to originate from the synovial membrane. Once the implant was wholly covered, induction of new tissue began to subside but vascularisation was still profuse. As time advanced, the new tissue developed a ligamentous structure both in shape and histological nature.

It must be strongly emphasised that it is important that the implant is kept under tension during knee movement, so that the induced tissue will mature and align parallel to the axis of the implant, and so form an adequate neoligament. This has been confirmed not only in this study but also in our experimental work with animals.

There was poor tissue induction and poor maturation in a few cases even 6 to 12 months after implantation. Some of our recent animal experiments, have shown that tissue induction and maturation are much quicker and more abundant when some of the infrapatellar adiposynovial tissue is transferred and sutured to the substitute. This method has been used in some recent clinical cases.

Our results to date suggest that the scaffold type of artificial ligament is effective in the reconstruction of the cruciates, and gives good results with no significant complications.

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