Patient Information

Department of Trauma & Orthopaedics

Knee Reconstruction using Osteochondral Allografts

Introduction

This information is provided for patients who are due to undergo or who have been considered for the operation procedure of OsteoChondral Allograft reconstruction in their knee.

It describes the nature of the procedure and the risks and benefits, and has been produced by the knee team at UHCW NHS Trust

Background information

Allografting or, to give its full name, 'fresh osteochondral allograft transplantation (OCA)' is an operation in which a damaged or diseased area of a joint is reconstructed using a bone and articular cartilage transplant. The cartilage cells can survive the transplantation only if the tissue is 'fresh', which means it has not been exposed to radiation or prolonged freezing.

OCA was pioneered at the beginning of the 20th century, and has had a long and successful history. It is becoming increasingly popular as a treatment for large injuries caused by trauma, osteochondritis dissecans (growth abnormality of bone and joint), and bone death (osteonecrosis) resulting from lack of blood flow to the bone supporting the joint cartilage.

The scientific basis of OCA is the transplantation of fully developed or mature hyaline (joint) cartilage containing living cartilage cells ('chondrocytes') that survive the transplant and support the production of the cartilage matrix indefinitely. Theoretically, this maintains the tissue balance ('homeostasis') of the joint cartilage. Studies have shown chondrocytes living as long as 29 years after transplant. The graft often includes a portion of bone to help restore missing bone.

The most common reasons for performing OCA are:

- A focal cartilage lesion greater than 2 cm^2
- Re-treatment (revision or salvage) of previous cartilage surgery, such as microfracture, autologousosteochondral transfer (OAT) or autologous chondrocyte transplantation (ACI)

- Severe (type III or IV) osteochondritis dissecans
- Osteonecrosis (bone death)
- Joint reconstruction after a fracture, known as post-traumatic reconstruction

The surgery itself is fairly straightforward, but the patient should understand that they will receive living human tissue that has been donated. Fortunately, patients do not need to take anti-rejection drugs after surgery, as the immune response from these grafts is, in the majority of cases, mild or non-existent.

However, the tissue being donated means it is often difficult to predict availability and patients must therefore be prepared for surgery with a few days' notice.

Prior to surgery

There are very specific indications for OCA and it is important that full evaluation is undertaken. Decisions are based on careful history and clinical examination, and the size and type of the lesion, or defect, within the joint is documented. This involves either a photo or video taken during diagnostic arthroscopy, or an MRI (magnetic resonance imaging), along with plain X-rays. At this point, if the patient is a candidate for OCA, the size of the joint is measured. The patient is then placed on the hospital surgery waiting list.

Donor tissue is obtained from an accredited tissue bank that specialises in the complex process of recovering and preparing fresh, living osteochondral (bone and cartilage) tissue. No tissue-type matching is performed because the allograft causes a minimal immune reaction. This is because the graft is considered to be relatively 'immuno-privileged'. This means that cartilage is not fed by blood vessels, and the cartilage cells ('chondrocytes') are protected from surveillance by the immune system.

Donor–recipient matching is primarily by size to ensure the best fit of the graft. When a donor becomes available and is matched to the appropriate recipient, the patient is contacted and scheduled for surgery, ideally within the subsequent week or two. The tissue is transplanted fresh (within 28 days of being taken from the donor), and is not processed like other tissue grafts. This allows the cartilage cells to survive. However, the tissue may be frozen before transplanting, as the cells within the tissue are still viable after thawing.

At UHCW the allograft will be provided by a company in the United States called JRF Ortho. In accordance with American Association of Tissue Banks (AATB) standards and FDA requirements, JRF Ortho and its recovery and processing partners utilize extensive evaluation criteria to identify and qualify suitable donors. To ensure the safety of each allograft produced, all recovered tissue is quarantined until donor eligibility has been established. Further information on the donor evaluation process is provided by JRF Ortho and can be supplied on request.

Because fresh tissue is being transplanted, and the availability of a matching graft cannot be predicted, patients must be prepared for surgery with a few days' notice.

Surgery

A diagram showing an illustration of the surgery can be found on page 4.

A video showing an animation of the surgery can be found at the following web address:

http://cartilage.org/patient/video/

The procedure takes approximately 1–2 hours and consists, essentially, of replacing the damaged surface of the joint with a carefully fitted graft from a donor joint. A summary of the surgical technique is as follows:

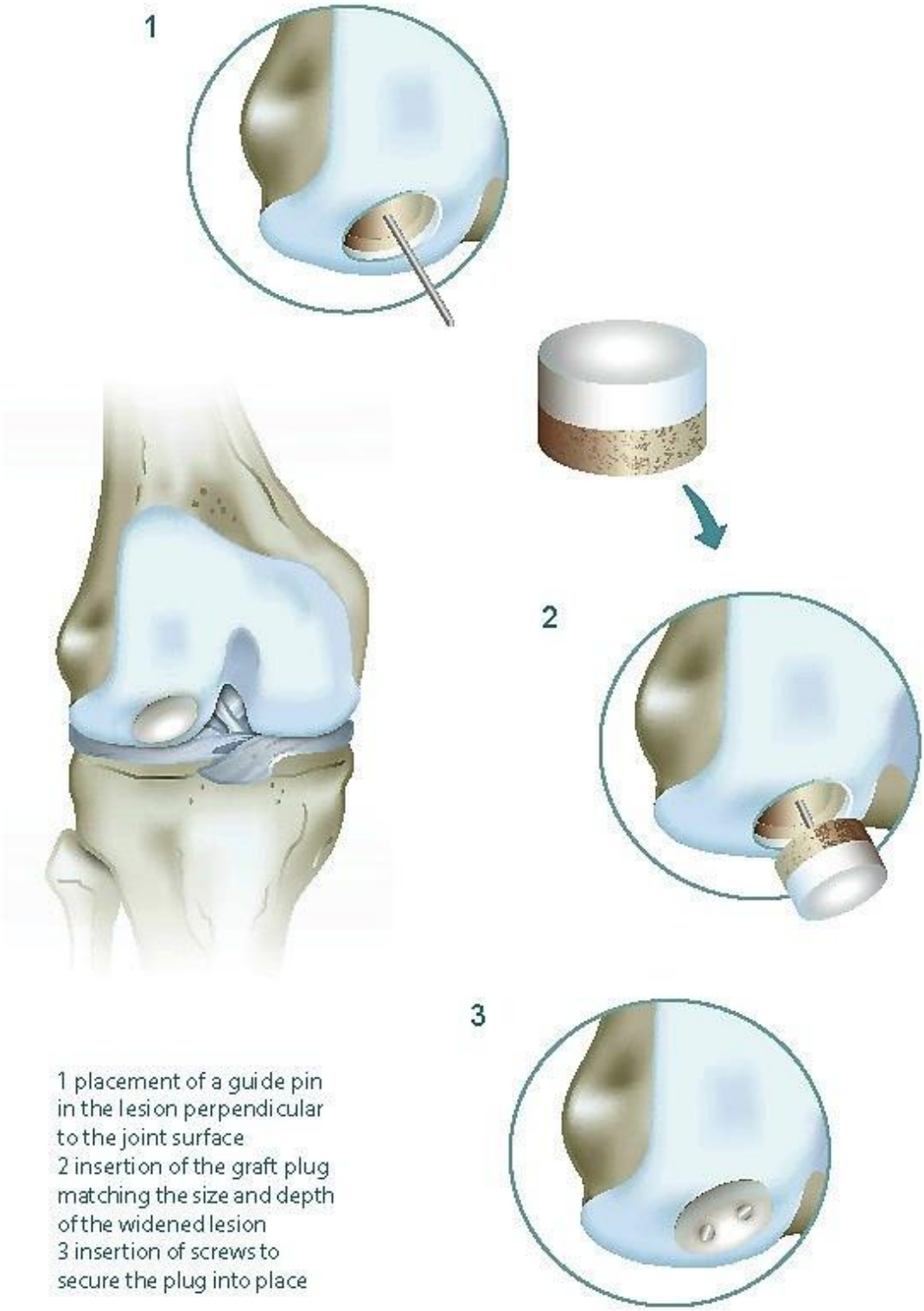
- The defect is exposed and measured, and a guide pin placed through the centre of the lesion, perpendicular (90º, or at a right angle) to the surface of the joint
- The lesion is widened (reamed) to a modest depth to remove the diseased cartilage and a small (3–6 mm) amount of bone.
- Depth measurements are taken from the prepared site where the transplant will be placed
- A ‘graft plug’ is removed from the donor tissue using a special tool called a coring reamer
- Depth measurements are marked on the plug and any excess bone removed, creating an graft matching the size and depth of the prepared site
- The graft is washed to remove blood and debris, and the bony edges are trimmed to help insertion
- The graft is gently inserted either with a special device or simply by moving the joint, which compresses it
- Loose grafts are then fixed with absorbable pins or screws, if necessary.

Follow-up

Patients will stay in hospital for up to 3 days, depending on circumstances. Crutches are used for protected weight bearing for 10–12 weeks and physiotherapy is started immediately. Patients are encouraged to complete a rehabilitation program, including range of motion and muscle exercises, which begin immediately after surgery. Follow-ups are scheduled for 4–6 weeks, 3 months, 6 months and yearly. Outcome questionnaire forms are required at each annual evaluation to monitor outcome and results.

X-rays are taken to check graft healing. If the graft appears to be functioning and incorporating into the joint, then a progressive weight-bearing program is started. At 4–6 months, if there is good healing then return to more strenuous activity and light sports are allowed.

Most patients feel they have not completed their full recovery until up to a year after surgery. Transplant patients are followed on a routine basis every year indefinitely. This is important, as the long-term outcome of OCA procedures is not completely known.



1 placement of a guide pin in the lesion perpendicular to the joint surface
2 insertion of the graft plug matching the size and depth of the widened lesion
3 insertion of screws to secure the plug into place

Benefits

OCA replaces the missing bone and cartilage with living donor cells capable of producing new bone and cartilage. Furthermore, the transplanted bone and cartilage provide a scaffold into which the recipient's own cells can theoretically make new bone and cartilage indefinitely.

Replacing the bone and cartilage is undertaken with the aim of reducing pain and improving the function of the knee. It may help to reduce the rate of damage to the area of cartilage surrounding the defect.

In the largest series of patients who had undergone OCA to the femoral condyle, fewer than one in five required removal of the OCA or conversion to knee replacement at ten years after OCA.

One proposed advantage of OCA is that it should not affect the surgical difficulty or outcome after a total knee replacement.

Risks

It is important to recognise that the success of the OCA depends on it being implanted into a knee in which the following conditions are favourable: alignment of the knee; stability of the knee ligaments; and load distribution provided by the meniscal ("shock-absorber") cartilage.

If any one of the above factors are unfavourable, additional surgery would be required prior to, or at the time of, OCA. Incorrect alignment would require osteotomy (breaking and resetting the femur or tibia). Instability would require ligament reconstruction. A deficient meniscus might require a meniscal transplant. While these additional procedures improve survival of the OCA, they may increase the need for additional future keyhole surgery.

The OCA procedure cannot be performed through keyhole incisions and will require a vertical incision over the front of the knee. The procedure therefore carries risks common to all other kinds of knee surgery, including: wound complications; infection; blood clots; and numbness around the scar.

OCA tends to perform better in some parts of the knee than others. OCA may not last as long when used on the knee-cap or if OCA is required on both the femur and tibia. OCA tends to last longer in younger patients and those with smaller areas of missing bone and cartilage.

Alternatives

Some patients may prefer not to undergo surgery. They might find they can manage their symptoms by reducing or avoiding the activities they find painful, using a brace to off-load the damaged area, and by use of medication or occasional injections.

Alternative surgical solutions to replace missing cartilage include microfracture, mosaicplasty, and osteochondral allograft transposition. All these procedures also require favourable alignment, ligament stability and meniscal cushioning. However, they tend to be less successful when used to treat the larger defects for which OCA is typically recommended.

An osteotomy in isolation may help to redistribute the load in the knee away from the deficient cartilage.

The deficient area can be replaced with a metal surface. This could be a small resurfacing button limited to the affected area (currently known as the Episurf procedure), a partial or a total knee replacement. A disadvantage of knee replacements in young patients is that the procedure may have to be repeated once or more during their lifetime, which each replacement potentially more difficult and yielding a less good outcome than the last.

Information Concerning the Tissue Bank: JRF Ortho

This information that follows is taken from information provided by JRF ortho and helps give reassurance to the processing that is required for allograft donor tissue.

JRF Ortho

JRF Ortho specializes in providing orthopaedic surgeons with the highest viability, most widely available cartilage solutions in the industry. Their unique member relationship with AlloSource® and Community Tissue Services® (CTS) enables them to offer the largest selection of specialized high-viability fresh osteochondral grafts, tendons and menisci in the industry. Through innovation and a commitment to clinical results and positive outcomes, JRF Ortho is redefining the standard for allograft joint repair. JRF Ortho is headquartered in Centennial, CO. For more information, please visit JRFORTHO.org.

JRF Ortho makes every effort to ensure the quality and safety of our grafts. Cleaning, processing and preservation procedures for frozen allograft tissues are designed to provide safe, high quality allografts.

Processing and Sterilization

To minimize potential contamination from the donor, environment, personnel or equipment, all tissue is processed in ISO Class 5 clean rooms. Processing is performed utilizing aseptic conditions and graft sterilization is achieved through validated processes which ensure the absence of bacteria in accordance with the United States Pharmacopeia (USP) and provides a Sterility Assurance Level (SAL) of 10-6.

- Rigorous donor screening that includes complete medical social history and physical examination
- Rigid recovery procedures performed by highly trained surgical technicians using aseptic technique in a controlled environment
- Extensive donor testing in accordance with AATB and FDA guidelines
- Highly trained processing technicians
- Aseptic environment and processing techniques
- Robust cleansing process reduces or eliminates bacteria, marrow elements and lipids
- Includes a series of disinfecting and cleansing rinses, centrifugation and sonication

- Employs a combination of detergents and traditional treatments such as alcohol, hydrogen peroxide and antibiotics
- Ultra-low dose gamma irradiation (0.9 – 1.5Mrads) in final packaging at low temperature to achieve tissue sterility without impairing the biomechanical integrity of the grafts
- Sterile tissue has an SAL of 10-6
- No donor pooling or batching
- Packaging is clearly labelled with expiration date and storage instructions

Microbiological Testing

- Laboratories that perform testing on behalf of the JRF Ortho are CLIA-certified.
- Testing includes microbiological evaluations during processing and final packaging, as well as environmental and water quality monitoring.
- Donated bone and tissue are cultured either at the time of recovery or during processing.
- Swab cultures are obtained from each tissue prior to exposure of the tissue to antibiotics, disinfectants or cleansing agents.
- Cultures are incubated in two types of media at two temperatures for a minimum of 7 days.
- Destructive and fluid extraction cultures may be taken and incubated for up to 14 days.
- If any of the cultures demonstrate microbial growth, the tissue is sterilized or not released for transplant.
- Any aerobic or anaerobic bacteria detected are identified to the Genus level.

Environmental Monitoring

- Our environmental monitoring program utilizes a combination of RODAC touch plates, viable air particle counts, non-viable air particle counts and settle plates.

Water Quality Monitoring

- All water used in processing is routinely monitored for microbial content, water quality changes, conductivity and total organic carbon content.

Preservation and Storage

- Frozen allograft tissues are frozen in ultra-low temperature freezers set at -80°C. Allografts are packaged in peel pouches and maintain a five year shelf life when stored at or below -40°C. Frozen allografts may be stored between -40°C and -20°C for up to six months.

Frequently Asked Questions

1. What are the chances that my body will reject the donated tissue? Do I need to take medication to prevent rejection?

Unlike live organ transplants (heart, lung, liver, kidney), tissue rejection is not a concern with bone and cartilage transplantation; therefore, you will not need to take anti-rejection medication.

2. How safe is it? Can I catch a disease?

There are extremely strict criteria for tissue donation including a thorough review of the donor's medical records and social history to maximize the tissue quality and minimize risk to recipients. Once the donor background check has been approved, the tissues are tested for diseases including HIV (AIDS), hepatitis, etc. Also, all tissues are tested for bacterial and microbial contamination and the graft you receive has been cleared for transplantation by a Medical Director. This testing process takes 2 weeks to complete. JRF Ortho has never had an incident of disease transmission.

Further Information

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