

TREATMENT

Bone and Tissue Transplantation

This guide to bone and tissue transplantation is provided by the American Academy of Orthopaedic Surgeons (AAOS) and the American Association of Tissue Banks (AATB).

Your physician has recommended that you have a surgical procedure in which a bone or other musculoskeletal tissue will be used.

The Importance of the Musculoskeletal System

The musculoskeletal system is a network of muscles, bones, joints, tendons, and ligaments that provide us with the ability to perform the tasks of daily living.

Musculoskeletal disorders and diseases significantly impact the quality of life. These disorders are the most frequently reported impairments in the United States. More than 100 million Americans have musculoskeletal conditions with limitations of function that are chronic and permanent.

The cost to our society for these conditions exceeds \$800 billion every year. The human cost, however, goes beyond dollars. Limitation of activity, nagging or severe pain, unsightly deformity, or the inability to function normally each have enormous impact on the quality of life.

Orthopaedic Surgery

Orthopaedics is a medical specialty that deals with the musculoskeletal system and uses medical, physical, and surgical methods to restore function lost as a result of injury or disease. An orthopaedist, also called an orthopaedic surgeon, is a highly skilled physician trained in a variety of medical and surgical techniques that will be used during your surgery. The lengthy educational process that is required to become an orthopaedic surgeon helps assure a high level of skill and competence.

What grafts are used in orthopaedic surgery?

Bone or tissue transplanted from one part of a person's body to another part is called an autograft.

Bone or tissue transplanted from the body of one person to another person is called an allograft.

The term graft is commonly used to refer to either an allograft or an autograft.

Where does allograft musculoskeletal tissue or bone come from?

As you may be aware, many people choose to donate their organs and tissues. These otherwise healthy people often become donors as the result of an unexpected death. Most allograft musculoskeletal tissue used comes from such donors. Occasionally though, allograft bone may come from a living patient.

How is the bone recovered from the donor?

A tissue bank is an organization that provides donor screening, recovery, processing, storage, and/or distribution of allograft tissue. Specialists trained in transplantation recover and process donated musculoskeletal tissues. These professionals are well trained and most have passed a rigorous examination that certifies them on the basis of their knowledge in all areas of tissue banking including decontamination techniques, quality assurance, quality control, product testing, labeling, and record keeping.

The American Association of Tissue Banks is the national standard-setting organization that provides this certification. Presently, not all tissue banks are AATB accredited. However, tissue banks may choose to undergo this voluntary accreditation.

What type of screening occurs?

Before donation, all potential donors must undergo strict screening scrutiny that includes physical examination, comprehensive medical history, and social risk review. A detailed medical history that includes social risk background and medical issues is obtained. The information collected on potential donors is compared against criteria established by the United States Public Health Service to identify and exclude individuals with high-risk behaviors. Furthermore, all tissue is held in quarantine until microbiological and blood tests are completed. These tests are required by the AATB and the U.S. Food & Drug Administration (FDA), and include analysis of infectious diseases including HIV, hepatitis B and C, and syphilis.

All of the information is evaluated by a team of medical specialists in the fields of infectious disease and tissue banking. No allograft can be released until the tissue bank's medical director determines the tissue to be safe after review of the screening and testing information.

How safe is it?

Preparing the tissue for transplant begins with the removal of debris and organic matter. The allograft is then soaked in various solutions to prevent the transmission of bacteria and viruses. Processing and packaging are performed using sterile techniques in clean room conditions to maintain biological integrity. On occasion, low dose radiation is used to aid in sterilization. Final processed tissues are tested for microbiological contamination in accordance with United States Pharmacopeia (USP) guidelines to ensure compliance with regulatory requirements. Although there is some theoretical risk for disease transmission, the use of allografts that have undergone rigorous donor screening, serological testing, and formal processing has significantly reduced this risk.

The FDA has regulated this field very closely since 1993 to ensure the safety of allograft transplant. Over the past decade, more than five million musculoskeletal allografts have been distributed to surgeons for transplant into patients with a remarkable record of safety.

What happens to the bone or tissue graft after transplantation?

Once the transplanted bone or soft tissue graft is accepted by the body, it is slowly converted into new living bone or soft tissue and incorporated into the body as a functional unit.

What are the costs?

It is illegal to buy or sell human organs or tissues. Costs for recovering organs and tissues for donation are never passed on to the donor or the donor family.

Many protocols are followed in tissue banks to ensure safety. Tissue banks insist on professional expertise in maintaining uniform and standardized donor screening, testing, quality control, and state-of-the-art applications of processing procedures. They also explore advancements in the areas of tissue sterilization and incorporation of bone grafts into the body. Tissue banks must also keep abreast of the development of new products, processing procedures, and FDA regulations regarding good manufacturing processes. All these efforts represent the costs of providing the utmost safety in allograft tissue. These expenses are then passed on to the hospital, surgeon, or recipient. Costs are kept at a minimum, but must cover personnel and services in the areas of acquiring, processing, and storage of the allograft.

What research is being done?

Some tissue that does not meet the criteria for transplantation for human use is directed to research projects in order to advance the science in musculoskeletal transplantation. Other selected tissue may go into programs of tissue engineering.

The American Association of Tissue Banks, organized in 1976, has been an accrediting agency since 1986. The FDA began providing significant oversight in 1993 with regard to tissue banks when it began formal regulation of tissue banking. The purpose of the AATB is to standardize the operations of participating tissue banks throughout the United States and to achieve nationally recognized uniform levels of safety and quality in allograft transplants. Accreditation status by AATB further ensures that a bank has met national standards for donor screening, procurement, processing, and storage of human tissue. Each bank voluntarily agrees to be inspected every three years to insure compliance in providing the safest tissues possible for transplantation. Only laboratories listed under Clinical Laboratories Improvement Act (CLIA) and only FDA-licensed tests can be used. AATB continues to work closely with the FDA to ensure an exemplary record of safety to the American public.

The American Academy of Orthopaedic Surgeons represents more than 34,000 members. The Academy is the world's largest and most influential medical organization of orthopaedic surgeons dedicated to providing the highest quality musculoskeletal care. The AAOS believes that musculoskeletal allografts provide beneficial treatment for appropriate patients.

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