



Septic Arthritis Following Anterior Cruciate Ligament Reconstruction Using Tendon Allografts --- Florida and Louisiana, 2000

In the United States, approximately 50,000 knee surgeries are performed each year for repairing anterior cruciate ligament (ACL) injuries (1). Tissue allografts frequently are used for ACL reconstruction, and septic arthritis is a rare complication of such procedures. This report describes four patients who acquired postsurgical septic arthritis probably associated with contaminated bone-tendon-bone allografts used for ACL reconstruction. Effective sterilization methods that do not functionally alter musculoskeletal tissue are needed to prevent allograft-related infections.

Florida

On April 5, 2000, at a surgical center, a girl aged 16 years had ACL reconstruction using a bone-tendon-bone allograft. On April 21 at a local orthopedic clinic, she sought medical care for swelling and redness of the left knee. On examination, septic arthritis was diagnosed, and she was treated with joint irrigation, a 6-week course of intravenous antimicrobial therapy, and removal of the allograft and screw. Cultures from the left knee aspirate yielded *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Enterococcus faecalis*.

On April 7 at a surgical center, a man aged 40 years underwent ACL reconstruction using a bone-tendon-bone allograft. On April 24, he sought medical care for drainage from the knee. On examination, septic arthritis was diagnosed; his treatment was an 8-week course of antimicrobials and screw removal. *P. aeruginosa* was cultured from the surgical site.

The allografts used for the two patients were supplied by a Texas tissue bank (tissue bank A) and were harvested from a common donor. Both patients' initial ACL reconstruction procedures were performed on different days by different surgeons using different arthroscopic instruments but at the same surgical center. The local health department conducted an onsite investigation of the center and identified no breaches in infection-control procedures. At tissue bank A, the implicated allografts had been irradiated and processed using standard quality-control procedures. All other allografts used during the preceding 4 years at this surgical center had been supplied by a tissue bank other than tissue bank A; no postoperative infections were detected by orthopedic surgeons at follow-up visits among approximately 1,000 ACL reconstructions performed at this center during the 4-year period. *P. aeruginosa* isolates cultured from the surgical site infections of the two patients had genotypic patterns that were indistinguishable from each another by pulsed-field gel electrophoresis.

Florida and Louisiana

On October 9 at a surgical center in Florida, a woman aged 55 years had ACL reconstruction using a bone-tendon-bone allograft. On October 17, she was taken to

an orthopedic clinic for purulent drainage from the left knee. On examination, septic arthritis was diagnosed, and she was treated with joint irrigation and 12 weeks of antimicrobial therapy. On July 11, 2001, the patient required a total knee arthroplasty. *Citrobacter werkmanii/youngae* and group B beta hemolytic streptococci grew from the knee aspirate.

On October 19 in Louisiana, a woman aged 29 years had ACL reconstruction using a bone-tendon-bone allograft at a local surgical center. On November 7 at an orthopedic clinic, she presented with a temperature of 103° F (39.4° C) and septic arthritis. She was treated with joint irrigation and 13 weeks of antimicrobial therapy. *Klebsiella oxytoca* and *Hafnia alvei* were cultured from the knee aspirate.

Both patients received allografts from the same Florida tissue bank (tissue bank B), and the allografts were from a common donor. When tissue bank B conducted a trace-back investigation and reviewed quality-control procedures, the implicated allografts had not received terminal sterilization with gamma irradiation. The same species of organisms isolated from the two recipients and *Serratia liquefaciens* were cultured from the donor allografts during tissue processing; other donor tissues were culture negative. No isolates from the donor or recipients were available for additional testing.

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Editorial Note:

In the cases described in this report, clinicians suspected contaminated allografts because of the rarity of septic arthritis following arthroscopic interventions and the polymicrobial nature of these infections and worked with local public health authorities and tissue bank staff to link the infections to allografts of common donors. The epidemiologic and laboratory investigation related to tissue bank A indicated that the allografts were the source of the infection despite no apparent lapses in tissue processing. Cases related to tissue bank B were linked to allografts from a common donor that were released inadvertently before standard terminal sterilization procedures were conducted.

In 1999, U.S. tissue banks distributed approximately 750,000 allografts for transplantation (2). Transmission of infectious agents (e.g., fungi, bacteria, and human immuno-deficiency virus [HIV]) caused by contaminated allografts has been described (3--5). The number of persons who develop septic arthritis caused by bacterially contaminated allografts is unknown. In addition, tissue banks, donors, and recipients often are located in different states, complicating detection of bacterial infections associated with contaminated allografts. The Food and Drug Administration (FDA) requires screening of tissue donors for HIV, hepatitis B and C, and other bloodborne pathogens. Reporting of infections resulting from contaminated allografts is not required. FDA has proposed regulations that would require reporting adverse reactions that involve the transmission of communicable diseases if fatal, life threatening, or results in permanent impairment.

The American Association of Tissue Banks (AATB) publishes quality standards for procuring and processing tissue, and provides guidelines on donor screening, time limits for retrieval of soft tissues, and procedures for preservation (e.g., freezing or freeze-drying), sterilization, preparation, and evaluation, and labeling of tissue components (6). Gamma irradiation or ethylene oxide are used to sterilize allografts. Tissue banks use gamma irradiation for sterilization, but high doses of gamma irradiation may adversely affect the biomechanical properties of allografts (7). Ethylene oxide has limited ability to penetrate tissue and has been associated with adverse patient outcomes (8,9). Concern about possible sterilization-related complications has resulted in musculoskeletal tissues (e.g., bone-tendon-bone allografts) being processed aseptically but is not necessarily sterile. Although aseptic processing avoids contamination of tissue at the tissue bank, it does not eliminate contamination originating from the donor that might be inherent to the graft. AATB standards require that tissue banks establish a list of organisms which, when cultured from tissue, necessitate discarding, sterilization, or disinfection of harvested tissues (6). However, not all tissue is cultured, and AATB does not specify the organisms for which corrective actions should be taken (6).

According to the Office of the Inspector General, approximately 44% of tissue banks identified were not accredited by AATB or inspected by Florida or New York (the two states that require licensing and inspection of tissue banks) (2), and this probably represents an underestimate of the tissue banks that are unaccredited or unlicensed (10). Tissue banks that lack accreditation and licensure are not required to comply with external quality requirements beyond donor screening for HIV and hepatitis (2).

This report underscores the need for 1) standard practices for screening, disinfecting, sterilizing, or discarding potentially contaminated allografts; 2) mechanisms for certification and oversight of tissue banks and adherence to quality standards; 3) a system for reporting and investigating infections (bacterial, viral, or fungal) potentially transmitted through human tissues; and 4) the development of safe and effective sterilization methods for musculoskeletal tissue. When septic arthritis occurs after use of an allograft, allograft contamination should be suspected, especially when the infection is polymicrobial or associated with Gram-negative organisms. Clinicians should report infections involving allograft tissue to FDA's MedWatch system and through local and state health departments to CDC's Division of Healthcare Quality Promotion, National Center for Infectious Diseases, telephone 800-893-0485.

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