Current Safety Sterilization and Tissue Banking Issues for Soft Tissue Allografts

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KEYWORDS

• Allograft • Tissue bank • Processing • Graft • Safety

The number of recent grafts harvested and *implanted* in the United States has steadily increased. According to the American Association of Tissue Banks (AATB), the number of grafts distributed increased from 500,000 in 1998 to 1,300,000 in 2003.[1] This trend has been seen in other countries as well.[2–4] Although they are used in other specialties, allografts are used predominantly in orthopedic sports medicine and reconstructive procedures. Orthopedic surgeons more often make daily decisions on the use and implantation of these tissue grafts. Many surgeons do not have a great understanding about allograft tissue and tissue banking. According to a recent survey by the American Orthopaedic Society for Sports Medicine (AOSSM), over 85% reported using allografts and over half of those surveyed did not know whether their grafts were sterilized or the specific sterilization process used.[5,6]

The public is concerned regarding the safety of allografts and transmission of disease.[7] As complications from allograft contamination have occurred, so has oversight from government agencies such as the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC).

REGULATION ISSUES

Oversight of tissue processors is mandated by state and federal regulations and has greatly improved in the last decade. Human cells or tissues intended for another human recipient are classified as ''human cell, tissue, and cellular and tissue-based products'' (HCT/P). The federal code established in 2004 mandated the FDA Center for Biologics Evaluation and Research (CBER) to regulate HCT/P.[8] These regulations required tissue banks to register and list their HCT/P with the FDA, to screen and test

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donors to reduce the transmission of communicable diseases, and to keep detailed records documenting the type of tissue processed, tests performed, results, and destination of the tissue.

Federal and state governments are not the only entities who have oversight of the tissue banks. The Joint Commission (JC), formerly known as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), is a regulatory entity independent of the FDA. In 2007, the JC released the latest version of Tissue Storage and Issuance Standards.[9] These standards apply to implantable and transplantable products that are human or cellular based. The JC requires hospitals, critical access hospitals, ambulatory office-based surgery, and outpatient centers to develop procedures to address the critical areas of tissue recovery and storage, record-keeping and tracking, and adverse events/infection follow-up. These written procedures are required to describe protocols for tissue ordering, receipt, temperature-monitored storage, tissue handling, preparation for use, tracking the graft from receipt to implantation, and investigation/reporting of adverse events or possible infections. According to these guidelines, hospitals and surgery centers should be able to trace any tissue bidirectionally to report potential disease transmission to the recipient when notified by the tissue bank as well as report to the donor facility any adverse reactions. This improves record-keeping and adverse event monitoring. They have power of accreditation over hospitals and tissue banks, which, without these entities, would have difficulty billing state and private insurance companies, providing further new quality controls for current allograft tissue.

An organization critical to the regulation of tissue banks is the AATB. Founded in 1976, the AATB is a nonprofit organization to spread voluntary safety standards and ensure that human tissues intended for transplantation are safe and free of infectious disease, are of uniform high quality, and are available in quantities sufficient to meet national needs.

The AATB first published its Standard for Tissue Banking in 1984. Since then, it has been updated and revised, with the 12th edition released in 2008.[10] Two years after the release of the Standard for Tissue Banking, the AATB began an accreditation program for institutions. This was followed 2 years later by a certification program for individuals. Accreditation is renewed every 3 years and is based on compliance with its standards. In addition, the AATB may perform surprise inspections to ensure compliance.[11]

The AATB standards are stringent. Specifically, the AATB required nucleic acid testing (NAT) for human immunodeficiency virus (HIV) and hepatitis C virus (HCV) in March 2005. NAT reduces the window period, which is the time between infection and when the virus is detectable. The FDA later required this testing in August 2007.

The AATB is also strict regarding culture results. It requires that any processed allograft that tests positive for *Clostridium* or *Streptococcus pyogenes* be discarded.[6,12] Furthermore, the AATB requires that a graft with positive final culture be discarded if there is no validated protocol to eliminate the identified organism.

Currently, the AATB has 106 accredited tissue banks, and it has been estimated that AATB-accredited tissue banks distribute 90% of musculoskeletal tissues in the United States.[12] Membership in the AATB is voluntary, and the AATB does not have any formal disciplinary powers outside of restriction or removal of AATB accreditation. The ''committee on biological implants tissue work group'' of the American Academy of Orthopaedic Surgeons have urged the orthopedic surgeons to work with AATB tissue banks and ''know their tissue banker.''[13] Other authors have stated that a tissue bank not accredited by the AATB should be ''a red flag''[14] with respect to quality.