

FREQUENTLY ASKED QUESTIONS

Are Bone Allografts from Living Donors Safer or of Higher Quality?

Allografts are commonly recovered from deceased donors with consent for transplantation. However, there are many examples of allografts being provided from living donors including kidney, blood, and bone marrow donations as well as dermis from weight loss surgery and amniotic tissues from live birth placentas.

Additionally, bone, such as femoral heads, from amputations and other orthopedic procedures are also available for transplantation. In these Living Donor cases, an orthopedist may directly interview the potential donor patient prior to surgery to gain consent for donation. They would also screen the patient for potential risk factors by direct questioning or examination of medical records. In addition, a serological sample would be taken to test for transmissible diseases. It may be postulated that Living Donor tissue may have safety advantages due to more accurate patient history or being recovered and processed more quickly. However, there is nothing to suggest that these factors are actually advantages, and here we will consider a comparison between deceased and living donor tissue. This discussion will be limited to bone.

Does Living Donor Tissue have an Inherently Lower Risk of Disease Transmission?

Deceased donors: Tissue banks certified by the AATB will gather as much risk factor data as reasonably possible before making a decision to perform a tissue recovery, as approved by a Medical Director. This screening includes higher risk behavior such as recent tattoos, time in prison, sexual activity, etc. This information is typically gained from a close family member or friend as a donor historian and using a set list of questions with all answers recorded. This, in addition to available medical records, can be used to defer or accept a donor for tissue recovery.

Living donors: Likewise, a living donor can provide similar medical/social history to help make the decision whether to recover tissue for potential transplantation. While a living donor could be a better historian for their own potential donation, the reliability of this information is dependent not only on their memory, but also their honesty. It is possible that a living donor faced with the potential stress of going through an orthopedic surgical procedure at or around the time of their consent may not recall all of their history. They may also fail to be fully forthcoming about high risk behavior when questioned in person by the surgeon performing their procedure. Finally, since an orthopedic surgeon conducts the interview, it is unclear if there is a prescribed list of questions, and if so, how strictly a busy surgeon would adhere to this time-consuming process.

Discussion: Note that regardless of whether the donor is deceased or living, the Medical/Social screening is only a first step in the process to prevent disease transmission by AATB-accredited tissue banks.

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Conclusions: There is nothing to suggest that a Living Donor would yield tissue with lower risk of disease transmission based solely on their living status at the time of donation. In fact, the thoroughness and accuracy of information obtained by the orthopedist interviewing a patient before surgery is questionable.

Is Tissue from a Living Donor of Higher Quality?

Deceased donors: Tissue from deceased donors are only acceptable for distribution from AATB-certified tissue banks if the donor records suggest there is no reasonable cause for concern for disease transmission or poor tissue quality. In addition, processing steps are taken to not only disinfect the tissues but also to note any tissue quality issues through visual inspection.

Living donors: It is unclear what inspection steps living donor tissue undergoes and how that might be different from an AATB-certified tissue bank. Regarding the source of the tissue, note that is common for these grafts to be manufactured from **femoral heads** (during hip arthroplasty surgery). Since this type of procedure is often necessitated by complications from arthritis, fracture, avascular necrosis, or genetic bone diseases, the quality of the tissue may be inferior (Leung et al. 2010). Furthermore, this potential for poor quality of femoral heads from living donors can lead to concerns about the suitability of these grafts for cases that require graft strength (Moucha et al. 2007; Siddiqui et al. 2004).

Conclusions: Multiple studies in the literature can raise concerns about the quality of tissue from living donors (Leung et al. 2010; Moucha et al. 2007; Siddiqui et al. 2004) since these tissues are typically being obtained from an anatomical site adjacent to an area of bone or joint malfunction. This raises questions about the quality of this particular living donor bone.

Is Tissue from a Living Donor Processed to Yield Tissue of Greater Sterility or Quality?

Deceased donors: Allowash XG processed bone allografts provided by LifeNet Health are processed using cleaning and disinfection treatments including debridement, washing, and the use of solutions including isopropyl alcohol, hydrogen peroxide, and antibiotics. Depending on the surgical application and graft type, tissue may be preserved in a frozen or freeze-dried state or at room temperature in a patented glycerol solution in a process referred to as Preservon[®]. Finally, the tissue is packaged, placed into a container in a specific load configuration and gamma irradiated at dry ice temperatures to achieve a validated Sterility Assurance Level (SAL) of 10⁻⁶.

Living donors: Some banks describe various treatment processes that may include debridement, milling, washing, and the use of chemical solvents such as ethanol, chloroform, hydrogen peroxide, and sodium hypochlorite. Additionally, the tissue may be freeze-dried and gamma

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irradiated for sterilization. While several of these processing steps are similar to those used in Allowash XG, validation information is not available regarding impact of processing the biomechanical and clinically relevant properties of the grafts nor a validated Sterility Assurance Level. It is incumbent upon the surgeon to ask and confirm whether or not the tissue is sterile with appropriate SAL.

Conclusions: There is nothing to suggest that a Living Donor would yield tissue with greater sterility or quality. LifeNet Health provides information regarding the properties of Allowash XG treated tissue as well as published clinical studies, benchtop data, and a validated SAL of 10^{-6} .

Summary:

While tissues sourced from living donors have the potential to be clinically useful and with a low risk of disease transmission, there are numerous concerns including quality of bone, the reliability of donor information, and whether the processes used to treat these tissues are validated or thoroughly studied.

In favorable contrast, LifeNet Health provides tissues from deceased donors using well validated processes with established clinical efficacy document in numerous published clinical results. Since introducing the industry-standard Allowash processing technology in 1995, LifeNet Health has distributed over 5 million bio-implants processed with no incidence of disease transmission. The Allowash XG process is validated to yield tissue with an SAL = 10^{-6} , which is recommended for an implantable medical device. In support, there are over 100 publications that describe the successful clinical use of allografts produced by LifeNet Health (Representative Clinical Reports: 68-20-081, 68-20-083, 68-20-085, 68-20-143, 68-20-165, 68-20-174).

References

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