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LETTER TO THE EDITOR

Ossicle Homografts Revisited

Dear Editor:

For the last 40 years, good functional results at low cost have made ossicle homografts the most widely used material for reconstruction of severely damaged middle ears.[1,2] During all this time, no disease transmission associated with ossicle–homograft implants has been described in the literature.[3] Ossicle homografts are still ranked second in the United States for use in middle ear reconstruction, according to a recent survey.[4] On the other hand, the general discussion on human immunodeficiency virus (HIV) and prion-associated Creutzfeldt-Jakob disease (CJD) transmission has led to an almost complete ban on use of homograft ossicles in many countries such as Great Britain, France, and Germany. Insufficiently inactivated living transplant or dead implant material involves a risk of viral, bacterial, and/or prion disease transmission from donor to recipient. This has been confirmed by bone-associated but not by ossicle allograft–associated HIV, hepatitis, and tuberculosis transmission, according to the literature.[5] Moreover, two ear surgery–associated case reports using untreated non-ossicle material, such as lyodura and pericard, describe a putative CJD transmission.[6,7] The World Health Organization (WHO) classification for spongiform encephalopathies[8] grades human ossicles as risk class 4 (nondetectable). Implant material for elective surgery such as ossicle homografts must undergo safe and effective treatments to inactivate all types of infection agents and yet maintain optimal preservation to be eligible for implantation. Today, the most widely (until recently) used formaldehyde/cialit disinfection/preservation procedure is obsolete; apparently, it is not only ineffective in preventing the sensitive HIV but even commonly thought to propagate CJD infections.[9] Based on guidelines dealing with infections, the recommended sterilizing or inactivating procedures that also inactivate the more resilient germs, such as the nucleotide-free putative infectious prions causing CJD, include autoclaving and NaOH treatment.[10] We have developed[11] and been using the SHIP protocol for *s*election, *h*arvesting, *i*nactivation, and *p*reservation of human ossicles for ossicle implant purposes since 1998 (Table I). According to our in vitro[12] and in vivo[13] results after the combined NaOH/autoclaving inactivation procedure, homografts keep their biomechanical and clinical properties to an amount comparable to the formerly used formalin/cialit procedure. No local or systemic adverse effects or homograft extrusion has been observed during the operation or during follow-up. The described protocol is simple, inexpensive, practical for routine use, and is not ototoxic. For the surgeon and the nurse, such inactivated ossicles imply no changes in surgical technique or ossicle handling.

Compared with the successful four-decade record of ossicle homografts, artificial implants still remain uncertain alternatives with a maximum clinical time horizon of less than 20 years. Mostly biomechanically completely different from ossicles, they are not so rarely extruded from the middle ear in comparison to the proven long-term suitability of ossicular implants.[14] Moreover, artificial implants cost hundreds of dollars per piece and thus are affordable only for patients in industrialized countries with billion-dollar health care systems.[15] How can we provide otological help to thousands of patients in developing countries, when the price for the implant alone exceeds several years' salary of the patient? An apparent economic conflict of interest is documented by the vast choice of artificial middle ear implants emerging on the market since homografts have been banned.

In conclusion, there is no scientific or clinical evidence that ossicle homograft implants have been responsible for disease transmission during the last 40 years. The literature and daily practice over a period of decades evidence the validity of ossicle homografting in middle ear reconstruction. The guidelines for homografting to be respected compulsorily include a certified organ donor program at the hospital, a defined uncomplicated transcanal-

TABLE I.
Ossicle Selection-Harvesting-Inactivation-Preservation Protocol.

Donor selection	A certified organ donor program guarantees appropriate donor selection according to established actual guidelines.
Ossicle harvesting	Human incus and malleus are removed from the intact middle ear by transcanalicular tympanotomy. Patients with disease or traumatic temporal bone pathology are not eligible for the procedure. Neither may isolated temporal bones used for ossicle harvesting. The ossicles may be kept frozen at −20°C for several weeks.
Ossicle inactivation procedure	Complete ossicle immersion in 1N NaOH for 60 minutes at room temperature. Ossicle rinsing in 1000 mL 0.9% sterile NaCl solution overnight at room temperature. Ossicle autoclaving for 8 minutes at 134°C.
Ossicle preservation	Ossicles packed under sterile conditions may be kept shelved for several months.

icular harvesting process from an intact middle ear, and a state-of-the-art inactivation/preservation procedure.

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