Preliminary study of ethylene oxide sterilization of full-thickness cortical allografts used in segmental femoral fracture repair

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SUMMARY

Full-thickness canine cortical allografts were cleanly harvested, sterilized with ethylene oxide, and stored at room temperature. The allografts were incorporated into canine segmental femoral fracture repairs and compared clinically, radiographically, and morphologically with control femoral cortical autografts for function of the limb, graft acceptance, and bone union. Sterility was maintained and the cortical allografts were well accepted by the host animals, resulting in full use of the limb which was subjected to surgical operation. The allografts showed healing patterns similar to those of the autografts, as determined by radiographic, gross, and histologic evaluation of the proximal and distal host-graft interfaces. Evaluations were made monthly. The host-graft interfaces of the allografts and autograft were filled with woven bone with adjacent vascular invasion and remodeling of the graft at the final 4th-month evaluation.

Comminuted midshaft diaphyseal long-bone fractures in the dog and cat present a challenge to the veterinary orthopedic surgeon. Segmental full-thickness cortical allografts may be used in selected animals in which the diaphysis is so severely comminuted that it precludes the reconstruction and rigid fixation of the fracture by conventional methods.[1-6]

Recommended procedures for harvesting cortical allografts include careful donor selection and aseptic operating room conditions during bone harvesting.[1-3,7,8] Aseptic conditions must be strictly maintained to prevent the possibility of infection at the fracture site and subsequent rejection of the bone graft.[1,2,7,8] Cortical allografts are usually subjected to treatment designed to destroy or reduce antigenicity before implantation to minimize recipient rejection of the graft.[1,3,7-9] Treatments advocated for reducing antigenicity have included boiling, chemically treating, irradiating, freezing, and freeze drying the bone allografts.[7,8,10,11] Freezing and freeze drying are presently the most widely accepted procedures for clinical use, because these methods of treatment reduce antigenicity and retain the structural characteristics of the bone necessary for fracture reconstruction.[7-9,11]

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An alternative to aseptic cortical allograft collection and freezer storage is the use of ethylene oxide (EO) sterilization of bone graft material and room temperature storage.[12,13] Gas sterilization reduces the need for rigid donor screening with regard to systemic illness and strict asepsis at harvesting.[12] The purpose of the present study is to evaluate EO-sterilized cortical allografts incorporated in femoral fracture repair in the dog for evidence of surgical infection, host acceptance of the graft, clinical use of the limb, bone healing, and graft remodeling.

Materials and Methods

Fourteen dogs of mixed breeding (between 12 and 20 kg) from the surgical teaching laboratory were euthanatized. The femurs were harvested cleanly, but not aseptically, and the surrounding soft tissues, including periosteum, were removed. The epiphyses were resected, allowing access for cleansing of the marrow cavity with a bottle brush and tap water. The femoral diaphyses were individually wrapped in a polyethylene tubing,[a] sterilized with 12% EO[b] at 43.3 C for 2 hours, and placed in an aeration cabinet[c] for 8 hours. The grafts were labeled, radiographed, and stored at 24 C for 1 to 2 months.

Sixteen healthy dogs of mixed breeding (between 12 and 20 kg) were radiographed to document normal femoral anatomy, skeletal maturity, and bone size. The dogs were divided into 4 equal groups. Each dog was anesthetized with thiobarbital[d] induction and intubated anesthetically; anesthesia was maintained with halothane[e] and oxygen. Ampicillin[f] (500 mg) was administered IV and continued by oral administration every 8 hours for 48 hours postoperatively. One pelvic limb was randomly selected and prepared for surgical operation. An appropriate graft was selected by matching host and graft radiographs. A middiaphyseal segment (2.5 cm) was removed with an oscillating saw cooled with sterile saline solution. The defect was replaced with a cortical allograft segment (2.5 cm) in 3 dogs of each group. The 4th dog received its own ostectomized bone segment after removal of soft tissues and marrow, functioning as a cortical autograft control. The fractures were stabilized, and the graft was compressed with an 8-hole 3.5-mm dynamic compression plate and eight 3.5-mm cortex bone screws.[g] Postoperative radiographs were taken after dogs recovered from anesthesia (to document graft and implant position).

The dogs were confined to individual runs for the duration of the study. Radiographs of the femurs which were subjected to surgical operation were obtained at 2 and 4 weeks postoperatively and then once a month. Radiographs were evaluated for

[a] Steri-Lok, 3M Co, St Paul, Minn.
[b] Ethylene oxide Freon mixture, AGA Gas Inc, Secaucus, NJ.
[c] Steri-Vac, 3M Co, St Paul, Minn.
[d] Biotal, Bio-Ceutic, St Joseph, Mo.
[e] Fluothane, Fort Dodge Laboratories Inc, Fort Dodge, Iowa.
[f] Ampicillin, Med-Tech Inc, Elwood, Kan.
[g] Synthes, Wayne, Pa.