Introduction. Autogenous cancellous bone graft is often used to heal critical-size bone defects. Other treatment modalities may involve bone graft substitutes. These are mainly produced from biomedical ceramics, primarily hydroxyapatite, tricalcium phosphate and carbonated hydroxyapatite. Many commercial and experimental ceramic bone substitutes show generally excellent biocompatibility and are osteoconductive. The potential drawback of these materials may be associated with the fact that they occupy space in the fusion mass that would otherwise be filled with viable bone. In addition, ceramic bone substitutes may introduce stress concentration at the implantation site and impede vascularization. “Ideal” cancellous bone graft substitute should be biodegradable, porous with interconnected pores of adequate size; allow for the ingrowth of capillaries, perivascular tissues and osteoprogenitor cells; attract mesenchymal stem cells from the surrounding area and promote their differentiation into osteoblasts. Such bone substitutes should complex calcium ions from the body fluids allowing for the formation of calcium phosphate salts in regenerated bone and be radiolucent to permit the follow up of the healing process with a routine X-ray technique. Whether such a substitute should also be mechanically strong would depend on the intended application and the site of implantation. Candidate materials for such substitutes could be biodegradable polyurethanes, for example. Impregnation of such substitutes with autogenous bone marrow aspirates or platelet concentrate would add an osteoinductive potential to the implant. In previous studies, biodegradable polyurethane cancellous bone graft substitutes with varying hydrophilicity were implanted in monocortical defects in the ilium of healthy sheep and in bicortical defects in the ilium of estrogen-deficient sheep. In both cases the polyurethane bone substitute induced regeneration of new cancellous bone.

In this study bone substitutes from biodegradable polyurethanes with varying hydrophilicity were evaluated in critical-size segmental bone defects in the sheep tibiae.

Materials and Methods. Animal model: Swiss mountain sheep 23 years old, 50-60 kg body weight, critical-size 4 cm long segmental tibial defects, 2 experimental groups of 6 animals each. Group 1: polyurethane sponge with 70% of the hydrophobic component. Group 2: polyurethane sponge with 70% of the hydrophilic component. Implantation time was 6 months. Surgery: under general anaesthesia 4 cm long segments of the tibia with peristome were cut out of the mid-diaphysis using an oscillating saw (Swiss Federal Legislation, Approval No. GR 13/1998). The defects were fixed with modified intramedullary nails (UHN Synthes 462.919, O.D. 9.5 mm) interlocked statically (distally and proximally). Bone marrow was aspirated from the ilium with an 8G biopsy needle into heparinized syringes and injected into the sponges to ensure homogeneous impregnation (15 ml per sponge). All sponges were first soaked in Ringer solution before they were impregnated with marrow. Impregnated sponges were placed in the defects around the medullary nails, and then a muscle flap was wrapped around the entire implant. Wounds were closed in layers using Vicryl Ethicon V312H sutures. The affected extremity was wrapped with a fascia bandage and an elastic bandage. Radiographs were taken every second week until euthanasia at 4 months. Sections taken from explanted, operated tibiae were stained with giemsa/eosin for histological evaluation. Bone substitutes. Cylindrical porous sponges 28 x 42 mm with a central hole along the longitudinal axis were produced from experimental biodegradable polyurethanes having two different hydrophilic-to-

hydrophobic content ratios of 70-30% and 30-70%. Sponges were sterilized by a cold-cycle ethylene oxide process, followed by evacuation at 50°C and 3x10⁻¹ mbar for 10 hours.

Results. The polyurethane bone substitutes used in the study were porous with interconnected pores (Fig. 1A). The sponges with 70% of the hydrophobic component had an average pore size of 100 - 900 µm and a pore-to-volume ratio of 75% (Fig. 1B). The sponges with 70% of the hydrophilic component had an average pore size of 100 - 600 µm and a pore-to-volume ratio of 84% (Fig. 1C).

Discussion. The treatment of critical-size segmental defects with cancellous bone graft to promote healing is a gold standard. Harvesting of bone graft is traumatic and results in morbidity of the donor site. The use of a cancellous bone graft substitute with adequate biological properties instead of autogenic bone graft would be advantageous. The polyurethane sponges investigated in the study are potential candidates for bone substitutes. Their properties could be optimized by further fine tuning of their chemical composition, pore size and pore-to-volume ratio.

Conclusions. Resorbable porous sponges from biodegradable polyurethanes are promising candidates for cancellous bone graft substitutes. Sponges impregnated with autogenic bone marrow facilitate healing of critical-size segmental defects in the sheep tibiae.