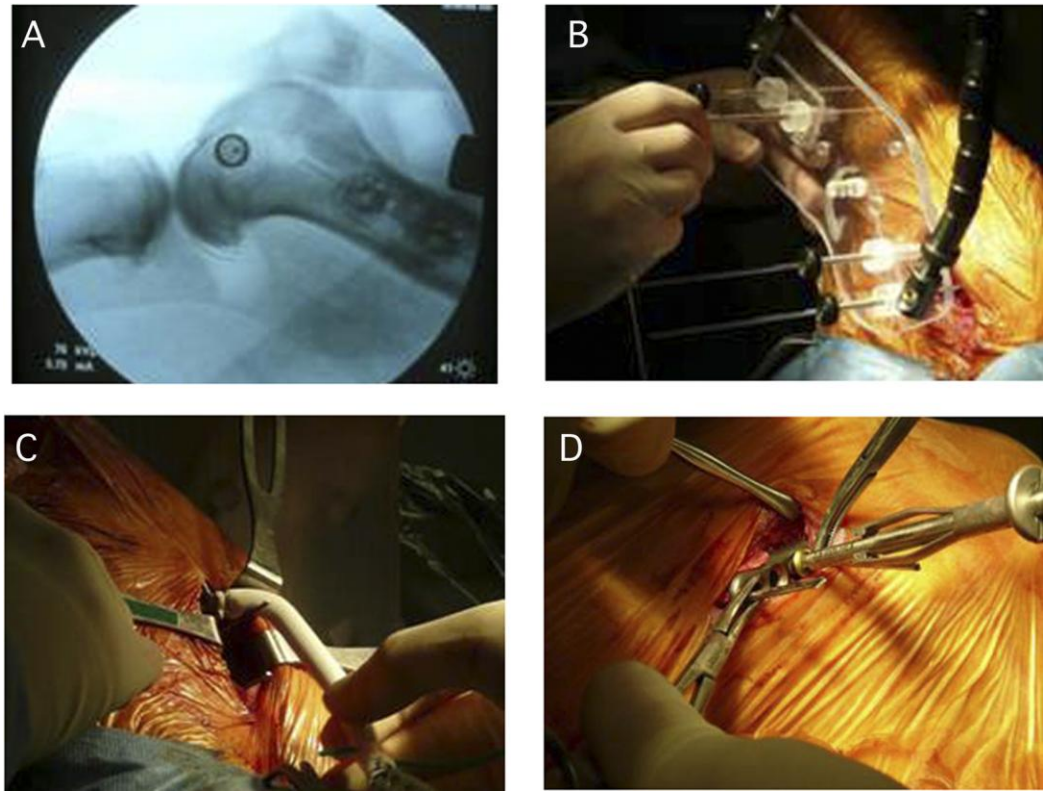

Fig. E-1

Key steps in KineSpring System implantation. Acrylic plastic aiming guide used to locate the desired femoral base position (**Figs. E-1A and E-1B**). KineSpring System (with sheath visible as white covering) passing through a subcutaneous tunnel between the femur and tibia (**Fig. E-1C**). Tibial base is secured to the tibia with 3.5-mm cortical bone screws (**Fig. E-1D**).

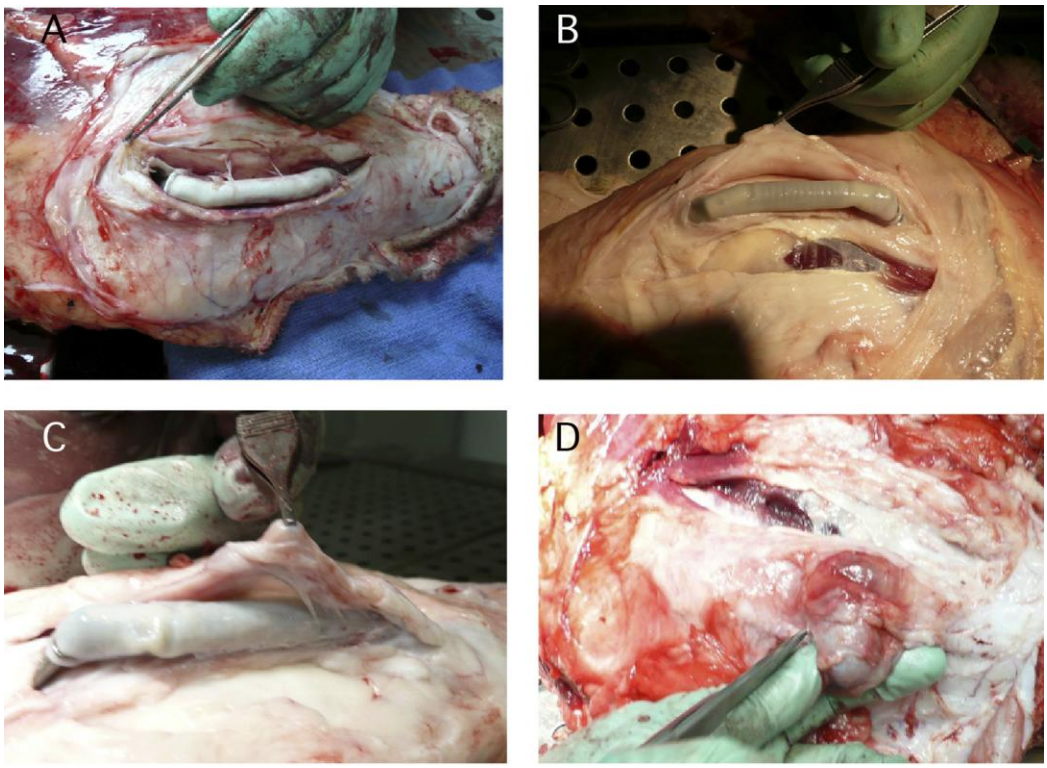

Fig. E-2

Gross necropsy findings from around the absorber sheath harvested at four weeks (**Fig. E-2A**; sheep 1037), twelve weeks (**Fig. E-2B**; sheep 1038), and fifty-two weeks (**Fig. E-2C**; sheep 1033). Note the resolution of the acute inflammatory response and the smooth pseudosynovial lining that can be seen around the device at twelve weeks (**Fig. E-2B**). In sheep 1041 (fifty-two weeks), there was a prominent cystic structure adjacent to the device (**Fig. E-2D**).

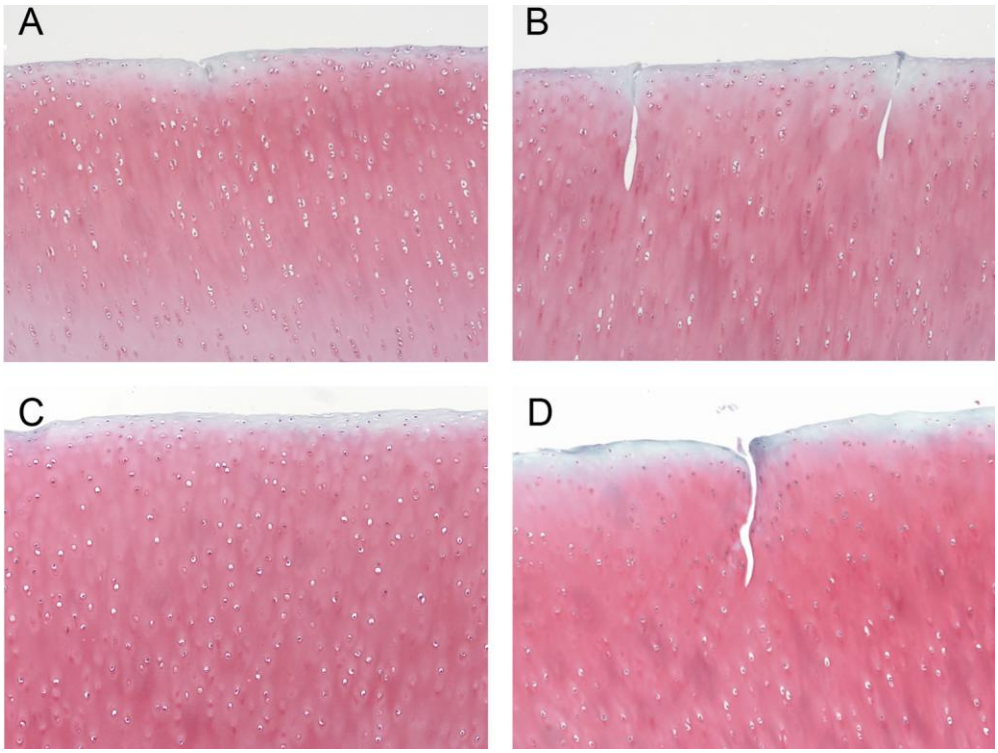

Fig. E-3

Histological images of the articular cartilage and subchondral bone from the lateral femoral condyle of a stifle joint treated with a medially applied KineSpring system for fifty-two weeks (**Fig. E-3A**) and the contralateral control (no operation) stifle joint (**Fig. E-3B**). There was no evidence of device-related changes in cartilage integrity or cellularity. Similar findings were observed in the medial compartment when comparisons were made between the joint treated with KineSpring (**Fig. E-3C**) and the control joint (**Fig. E-3D**). Sections stained with safranin O-fast green (original magnification, ×100).

TABLE E-1 Allocation of Implants and Surface Treatments Within the Eleven Experimental Subjects

Sheep Identification Number	Time Point *(wk)*	KineSpring System (TPS-HA or uncoated)	Uncoated Washers	Coated Washers (TPS-HA Coating)
1029	52	TPS-HA	Tibia	Tibia
1031	52	TPS-HA	Femur	Femur
1033	52	TPS-HA	Tibia	Tibia
1034	4	TPS-HA	Tibia	Tibia
1037	4	TPS-HA	Femur	Femur
1038	12	TPS-HA	Femur	Femur
1039	4	TPS-HA	Tibia	Tibia
1040	52	TPS-HA	Femur	Femur
1041	52	TPS-HA	Tibia	Tibia
1000	26	Uncoated	NA	NA
2416	12	Uncoated	NA	NA

KineSpring System implants with the plasma-sprayed titanium-hydroxyapatite (TPS-HA) coating were implanted in nine sheep; in these sheep TPS-HA coated washers were implanted in the contralateral femur and tibia. KineSpring System implants with uncoated femoral and tibial base components were implanted in two study animals; these animals were not implanted with washers (NA = not applicable).

TABLE E-2 Components of the KineSpring System

Part	Material Selection
Bases (femoral and tibial)	Ti6Al4V per ASTM F136
Coating: TPS-HA	Plasma-sprayed Ti onto Ti6Al4V base substrate with subsequent overcoating of plasma-sprayed HA
Sockets (upper and lower caps)	Co-Cr alloy per ASTM F1537 alloy #1
Arbor	Co-Cr alloy per ASTM F1537 alloy #1
Piston	Co-Cr alloy per ASTM F1537 alloy #1
#4-40 fastener (screws)	Ti6Al4V per ASTM F136
1/16 dowel	Ti6Al4V per ASTM F136
Spring	Co-Cr alloy per ASTM F1058 grade 1
Sheath	ePTFE

Ti6Al4V = titanium alloy; ASTM = American Society for Testing and Materials; Co-Cr = cobalt-chromium; ePTFE = expanded polytetrafluoroethylene; TPS = titanium plasma-sprayed; HA = hydroxyapatite.

e-Appendix

Surgical Implants

The implants used in this sheep study were developed specifically for the sheep but incorporated the same materials and design principles as the human KineSpring System (see Table E-2 for specific details). The absorber is contained within an expanded polytetrafluoroethylene (ePTFE; Bard Peripheral Vascular, Tempe, Arizona) sheath that is designed to isolate the articulating components from the surrounding soft tissues. The ePTFE sheath has a diameter of 8 mm, an internodal distance (a measure of porosity) of 10 to 40 μm, and a wall thickness of 0.7 mm.

The absorber-base rotations at the ball and socket articulations at each end of the absorber unit allowed 110° of motion in the sagittal plane, while the average flexion-extension excursion for the normal sheep stifle joint during walking is 34°[18]. These articulations allow the device to accommodate normal motions of the knee while limiting motions to only axial displacements (length changes) within the absorber itself. When the absorber length shortens to cause spring compression, the device is active and carries load, and when the absorber elongation is such that the spring is uncompressed, the device is passive.

Surgical Procedure

Sheep were sedated with an intramuscular injection of xylazine (0.22 mg/kg), and anesthesia was induced with an intravenous injection of ketamine (11 mg/kg). After intubation, animals were maintained on inhaled isoflurane (1% to 3% in oxygen). Preoperative doses of antibiotics (ampicillin, 20 mg\kg) and analgesics (buprenorphine, 0.01 mg/kg intramuscularly) were administered and the surgical sites were clipped, scrubbed, and isolated with sterile drapes. A straight incision (approximately 8 cm in length) was made over the medial aspect of the distal part of the femur. After sharp dissection of subcutaneous tissues, the distal one-third of the medial femoral shaft was exposed by blunt dissection between the bellies of the vastus medialis muscle cranially and the sartorius muscle caudally. Accurate positioning of the femoral and tibial bases was accomplished through the use of a sterile acrylic plastic aiming guide used under fluoroscopic guidance (Fig. E-1A and E-1B). Once the location of the femoral base had been identified, the skin over the medial aspect of the proximal part of the tibia was incised and a subcutaneous tunnel was created between the tibial incision distally and the femoral incision proximally. The KineSpring System was introduced into the femoral incision, and the tibial base was pushed through the subcutaneous tunnel until it was located over its intended location on the tibia (Fig. E-1C). The femoral and tibial bases were secured to the adjacent bone with titanium cortical bone screws (Fig. E-1D). The sleeve and enclosed absorber unit were located extra-articularly in the subcutaneous tissues medial to the stifle joint. Fluoroscopy was used to confirm that the movement of

the components was consistent with what would be expected in a functioning implant system. The subcutaneous tissues were then closed with resorbable suture, and the skin incisions were apposed with monofilament nylon sutures.

Postoperatively, animals were administered antibiotics (ampicillin, 20 mg/kg intramuscularly) and opiate analgesics (buprenorphine, 0.01 mg/kg intramuscularly twice daily) for three days and an anti-inflammatory agent (flunixin meglumine, 1.1 mg/kg intramuscularly once daily) for three to five days. No restrictions were placed on the animals' activity levels following surgery. Sheep were examined daily for evidence of pain, distress, or lameness. Skin sutures were removed ten to fourteen days after surgery.

Gross Necropsy Findings

Representative photographs of the gross pathology are presented in Figure E-2. (See figure legend and article text for more detail.)

Microscopic Pathology

Representative photomicrographs of the histology from the femoral and tibial articular cartilage in KineSpring-implanted and contralateral (control) stifle joints are presented as Figure E-3. (See figure legend and article text for more detail.)