

Muscle versus Nonmuscle Flaps in the Reconstruction of Chronic Osteomyelitis Defects

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Background: Surgical treatment of chronic osteomyelitis requires aggressive debridement followed by wound coverage and obliteration of dead space with vascularized tissue. Controversy remains as to the effectiveness of different tissue types in achieving these goals and in the eradication of disease.

Methods: Chronic osteomyelitis was induced in 26 goat tibias using *Staphylococcus aureus* as an infecting inoculum. In a single stage, debridement followed by reconstruction using either a muscle flap ($n = 13$) or a fasciocutaneous flap ($n = 13$) was performed. Flap donor sites were closed primarily and antibiotics were given for 5 days postoperatively. Daily clinical evaluation for 1 year was performed and monthly radiographs were obtained for 9 months and 1 year after the reconstruction.

Results: Twenty-five flaps survived completely, and one nonmuscle flap underwent partial flap loss following a period of venous congestion. There were no postoperative complications in the muscle flap group. Two goats (15 percent) in the nonmuscle group developed superficial wounds in the immediate postoperative period that resolved with conservative management. No limbs had recurrent osteomyelitis wounds at 1 year of clinical follow-up examination. Radiographic evidence of osteomyelitis was present in two goats (15 percent) in the muscle group and one goat (8 percent) in the nonmuscle group. There was no statistically significant difference in the incidence of recurrent osteomyelitis between the groups by clinical and radiographic assessment.

Conclusions: The findings in this study demonstrate that vascularized tissue flaps in the form of muscle or nonmuscle flaps provide viable options for wound coverage of osteomyelitis defects following adequate surgical debridement. (*Plast. Reconstr. Surg.* 118: 1401, 2006.)

The treatment of osteomyelitis, particularly after trauma, continues to pose significant reconstructive challenges. Surgical treatment of chronic osteomyelitis requires aggressive debridement of involved bony structures and soft tissues followed by definitive reconstruction using viable local, regional, or distant

flaps.^{1,2} Before the use of local or free muscle flaps, the options for resurfacing osteomyelitis defects following debridement included mainly primary closure (immediate or delayed) and skin grafting. Over the past three decades, reconstruction of these defects using pedicled and free muscle flaps has been performed extensively and has yielded excellent success rates in many published series.²⁻⁷ Nonmuscle flaps have also been used for the treatment of osteomyelitis defects and have been reported in limited numbers and with inconsistent outcomes.⁸⁻¹⁰ These clinical series demonstrating the effectiveness of muscle flaps and nonmuscle flaps in the treatment of osteomyelitis wounds have all lacked in providing consistency in the extent and severity of the bone infection and its correlation with recurrence of the osteomyelitis, which occurs in at least 15 percent of cases. The success of nonmuscle flaps in some published series has not

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been totally convincing to many who believe that muscle is necessary to provide bulk and superior blood supply and to aid in the healing of osteomyelitis defects.

Longstanding surgical dogma, based on previous experimental studies and a large volume of clinical evidence, has clearly demonstrated the effectiveness of muscle flaps in the treatment of osteomyelitis wounds. Although muscle flaps have been shown to be superior to nonmuscle flaps in bacterial growth inhibition and elimination, early increased skin oxygen tension has been found to be present to a larger degree in fasciocutaneous flaps.¹¹ Nevertheless, there are no controlled, randomized studies demonstrating the superiority of muscle flaps over nonmuscle flaps in the eradication of osteomyelitis following surgical debridement of infected bone. If a comparative study were to be performed in a clinical model, a significant flaw would be the inability to accurately quantify the degree of osteomyelitis or amount of infected bone, and therefore a true comparison would not be possible. The type of organism, its virulence, and its susceptibility to antibiotics are other variables that are uncontrollable in a clinical model, thus making an accurate comparative study between muscle and nonmuscle flaps not achievable. The Cierney-Mader model has been used to clinically stage osteomyelitis. It identifies four major factors influencing the treatment and prognosis of chronic osteomyelitis: (1) the degree of necrosis, (2) the condition of the host, (3) the site and extent of involvement, and (4) the disabling effects of the disease itself.¹² This model does not take into consideration the type of organism in the wound or its concentration. In a previous study at this institution,¹³ an animal model for chronic osteomyelitis was developed in a goat tibia using a known concentration of infecting inoculum. This model was then used for the purpose of this study; to evaluate the effectiveness of muscle versus nonmuscle flaps in the eradication of chronic osteomyelitis after surgical debridement.

Chronic osteomyelitis produces significant deficits in the involved limb; therefore, the curative procedure should bear extreme consideration to preservation of structures that provide function. Theoretically, if local and regional flaps are considered for use, nonmuscle flaps would offer the added advantage of preserving muscle function by sparing the muscle and its function at its potential donor site and would provide a more ideal donor flap, on the condi-

tion that it is as effective in treating the disease. Despite reports of clinical successes with skin flaps for the treatment of chronic osteomyelitis wounds, a controlled model is essential to clarify the true relationship between osteomyelitis wounds and vascularized tissue of various forms (muscle versus nonmuscle). The lack of a controlled experimental study provided the motivation for this investigation.

MATERIALS AND METHODS

Twenty-eight goats (*Capra hircus*) were used for this study. The experimental design and protocol were approved by the Department of Clinical Investigation's Institutional Animal Care and Use Committee at William Beaumont Army Medical Center, and all experiments were conducted in the animal surgical laboratories of this institution. The goats were obtained from farm flocks and were cared for in accordance with the Biological Research Service's Farm Animal Care Procedures. The animals were housed in the large-animal area of the Biological Research Service and were allowed free access to water. They were fed daily with a ruminant laboratory diet (Rumilab 5508; Purina Mills, Brentwood, Mo.), and were supplemented with fresh alfalfa under the nutritional guidance of the attending veterinarian (R.G.) to provide standard nutritional support. All animals were screened negative for brucellosis and Q-fever before enrollment in the study. Two goats were labeled as refinement goats and were used to ensure the success of the proposed muscle and nonmuscle flap harvest techniques. The average age of the animals was 2 years (range, 1 to 4 years) and the average weight was 34 kg (range, 25 to 45 kg.).

Anesthesia Protocol

For the radiographic procedures, xylazine (0.5 mg/kg intramuscularly) was administered for immobilization and yohimbine was used as a reversal agent (0.11 mg/kg intramuscularly). For the surgical procedures, the goats were induced using a combination of ketamine and diazepam. The goats were then intubated and a cephalic intravenous catheter was placed. General endotracheal anesthesia was maintained using an inhalation agent (isoflurane) administered using an animal-specific anesthetic system (Ohmeda Modulus anesthesia system; Ohmeda, Madison, Wis.). All animals had a fentanyl patch, 25 µg/hour, placed on the dorsum of their shaved necks approximately 12 hours before surgery and then changed at 72 hours postoperatively. If excessive pain was noted

on clinical examination by the veterinarian, another patch was placed in addition to the first. The fentanyl patch was discontinued after 1 week in both groups.

Creation of Osteomyelitis Model

A chronic osteomyelitis model was established in a goat tibia,¹³ with 4×10^9 *Staphylococcus aureus* isolated from human osteomyelitic bone (American Type Culture Collection no. 700260) and maintained in tryptic soy broth. The bacteria were streak-diluted on a brain-heart infusion agar plate and incubated overnight at 37°C. An isolated colony was transferred to a side-arm culture flask containing 50 ml of tryptic soy broth. The culture was incubated at 37°C until mid-log phase growth was reached as determined spectrophotometrically at 600 nm (Spectronic 20; Bausch & Lomb, Rochester, N.Y.). The mid-log suspension was diluted 1:1 with tryptic soy broth containing 20% glycerol and stored at -70°C until used. Standard growth curves were performed to quantitate *S. aureus* plaque-forming units. Frozen aliquots were rapidly thawed, transferred to flasks containing prewarmed tryptic soy broth, and incubated at 37°C. At 30-minute intervals, optical densities were measured with a spectrophotometer at 600 nm. Aliquots of 100 μ l were plated in triplicate on brain-heart infusion. After overnight incubation at 37°C, colony counts were performed and colony-forming units per milliliter was plotted against optical densities over time. All animals were infected with *S. aureus* grown from the frozen stock characterized with a standardized growth curve. At surgery, frozen *S. aureus* vials were rapidly thawed at 37°C, contents transferred to flasks of prewarmed tryptic soy broth, and incubated while shaking at 37°C until mid-log phase was reached. Twenty minutes before infection, optical density readings were made. Using these data, numbers of colony-forming units per milliliter were determined from the standardized growth curves. Appropriate volumes of culture (containing 4×10^9 colony-forming units) were centrifuged at 3000 rpm for 10 minutes at 4°C. Supernatant fluids were removed by aspiration and cell pellets resuspended in sufficient volumes of cold phosphate-buffered saline to achieve a concentration of 4×10^9 colony-forming units/ml. The *S. aureus* suspensions were immediately transported to the animal research facility and 1 ml of suspension was injected into previously prepared goat tibias.

Before surgery, food and water were withheld for 24 hours. Preoperatively, the animals were shaved from the mid trunk distally. Surgical access to the left proximal tibial metaphysis marrow cavity was achieved through a 2.0-cm skin incision approximately 2.0 cm distal to the tibial tuberosity. The periosteum was incised and elevated over an area approximately 2.0 cm². A unicortical drill hole with a diameter of 3.0 mm was made through the medial proximal cortex of the tibia until the marrow cavity was reached. Bone wax (Ethicon; Johnson & Johnson, Somerville, N.J.) was used to seal the drill hole. An 18-gauge angiocatheter was introduced through the bone wax into the marrow cavity. Using a 5-cc syringe, 1 cc of 5% sodium morrhuate solution was slowly injected as a sclerosing agent. Ten minutes later, cefazolin-sensitive *S. aureus* (4×10^9 colony-forming units) suspended in 1 cc of brain-heart infusion broth in a 1-cc tuberculin syringe was slowly injected using a separate 18-gauge angiocatheter. The entry hole was again sealed with bone wax and the wound closed in one layer with 2-0 Prolene (Ethicon). Animals were given a postoperative dose of cefazolin intravenously 1 hour after the operation to prevent fatal sepsis.

Twenty-six goats treated with inoculation of the tibia as above were followed clinically and radiographically for the next 12 to 16 weeks. Radiographs were obtained of each of the inoculated tibias at 2, 6, and 12 to 14 weeks after inoculation. All radiographs were analyzed in a blinded fashion by our hospital radiologist for the presence of lucency, periosteal reaction, sclerosis, and sequestrum (radiographic evidence of osteomyelitis).

Tissue samples for culture and histology were taken at the time of single-stage reconstruction. Deep cultures of the medullary cavity were obtained using a culture swab that was directly plated onto culture plates with antibiotic disks, to confirm the recovery of the identical infecting strain that was present in all specimens. These culture plates were evaluated by a microbiologist at 24 and 72 hours for colony growth and recorded. A hospital pathologist examined all specimens for evidence of acute and chronic osteomyelitis, with attention to the presence of inflammatory cells, osseous destruction, and fibrosis. All 26 study animals developed both radiographic and histologic evidence of acute and chronic inflammation (osteolysis and clusters of bacteria, with occasional necrotic fragments of bone within areas of fibrosis) (Fig. 1).

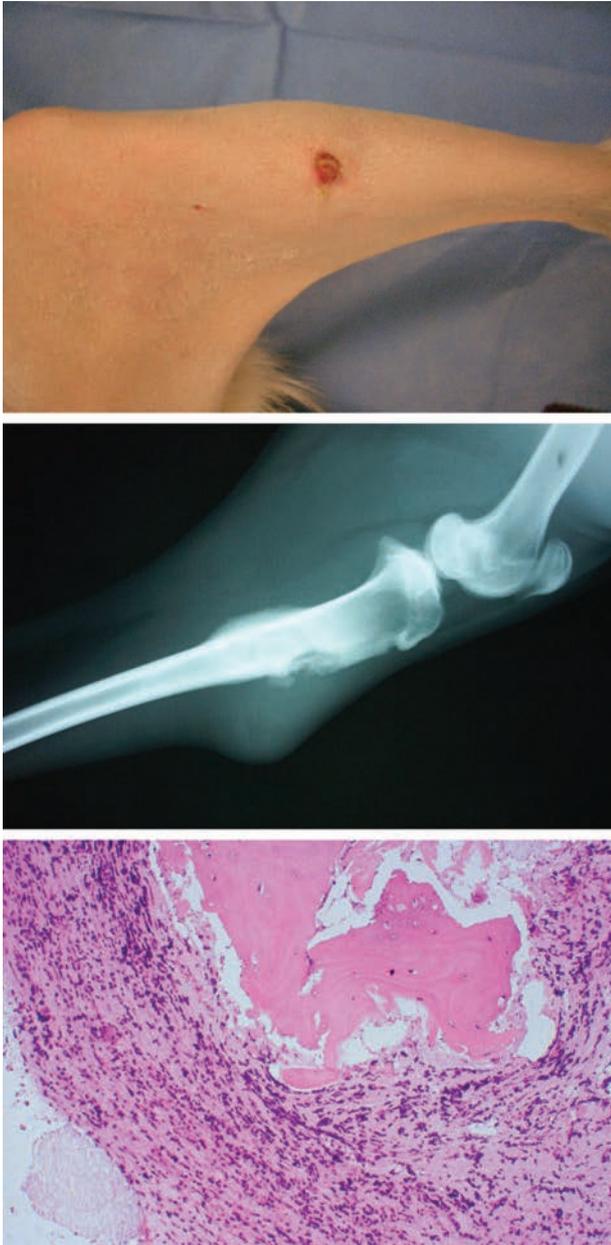


Fig. 1. (Above) Anterior view of goat hind limb before single-stage reconstruction. (Center) Lateral radiograph of the tibia of the goat before single-stage reconstruction. Note the degree of soft-tissue swelling, radiolucency, and periosteal reaction in the proximal tibia. (Below) Bone specimen histopathologic examination after surgical debridement showing remnants of viable lamellar bone with associated fibrosis and extensive chronic inflammation, findings that are consistent with chronic osteomyelitis (hematoxylin and eosin; original magnification, $\times 200$).

Single-Stage Reconstruction (Muscle versus Nonmuscle Flaps)

All study animals ($n = 26$) underwent extensive debridement, which consisted of excision of

all the necrotic bone and devitalized soft tissues overlying it, using a knife, rongeur, and rotating burr. The wounds were then irrigated with 250 ml of an antibiotic solution containing 1 g of cefazolin diluted in normal saline. Aerobic and anaerobic cultures of the wounds were performed by swabbing the subcutaneous tissues and bone before and after debridement and irrigation. In the same stage, the resultant soft tissue and osseous defects were resurfaced with a pedicled muscle flap [superficial digital flexor muscle ($n = 13$)] or a pedicled fasciocutaneous flap [saphenous artery flap ($n = 13$)]. The flaps were randomly chosen to be a skin or a muscle flap at the time of reconstruction. The donor defects were closed primarily in two layers over a rubber Penrose drain, and 1 g of cefazolin was given to all animals perioperatively and continued daily until postoperative day 5. Radiographs were obtained monthly for the first 6 months after reconstruction, and then at 9 and 12 months. The radiographs were evaluated by a radiologist, blinded to the reconstructive procedure, for the evaluation of periosteal elevation, radiographic lucency, and the presence or absence of sequestrum. Daily observation of all animals by the attending veterinarian was performed to detect clinical evidence of persistent or recurrent osteomyelitis (guarding of the involved limb, tenderness, or the development of an external wound with or without a draining sinus). In addition, the animal's ability to regain full ambulation and weight bearing on the operated limb was recorded.

Muscle Flap (Superficial Digital Flexor Muscle)

The superficial digital flexor muscle is one of the flexors of the digits and extensors of the tarsus in addition to the gastrocnemius muscle in the goat hind limb. The muscle originates from the caudal surface of the femur and proximal tibia. Its tendon combines with the tendon of the gastrocnemius muscle and inserts into the tuber calcanei. The dominant vascular pedicle to the muscle arises from the posterior tibial artery, and the main nerve supply to the muscle is from the tibial nerve, which originates mainly from the S1 and S2 divisions of the sacral plexus. The incision for flap harvest is made with the intention of providing a skin bridge between the flap harvest site and the recipient osseous defect. Using a medial approach, the distal tendon of the superficial digital flexor muscle is separated from that of the conjoined gastrocnemius muscle's tendon and is raised cranially. The superficial digital flexor mus-

cle lies just deep to the gastrocnemius muscle because the soleus muscle is a vestigial muscle in the goat. Flexor function of the digits and extensor function of the tarsus is preserved by means of the gastrocnemius muscle.

The muscle is then pedicled under the skin bridge to fill the defect and is secured to the surrounding tissue with absorbable suture. The incision for harvest of the donor muscle is then closed primarily in two layers over a Penrose drain that is left in place for 48 hours to aid in preventing seroma formation. The superficial digital flexor muscle is then covered with local tissue after adequate undermining (Fig. 2).

Nonmuscle Flap Harvest (Saphenous Artery Fasciocutaneous Flap)

Two animals were designated as “refinement animals” and were used to assess the viability and reliability of this fasciocutaneous flap. A cut-down



Fig. 2. (Above) The superficial digital flexor muscle is elevated and ready to be inset into the debrided proximal tibia bone. (Below) The muscle flap after inset into the osseous defect. The wound was then covered with local skin after undermining.

technique was used to access and cannulate the femoral artery with an 18-gauge angiocatheter. Nonionic contrast was used to inject the vessel and the femoral artery, and all of its major branches were visualized using fluoroscopy techniques. A branch arising at the midlevel of the femur was noted to be of significant size (approximately 3 mm at its origin), with a long course along the medial aspect of the thigh, knee, and distally until the junction between the proximal and middle segments of the lower hind limb. Doppler ultrasonography using a portable Doppler probe was used to confirm the presence of an arterial signal along the medial aspect of the goat hind limb.

The medial saphenous artery arises from the superficial femoral artery. Its concomitant veins drain directly into the superficial femoral vein at the level of the mid femur. The vessels lie under the caudal aspect of the head of the sartorius and enter the superficial fascia at the level of the distal femur. At the level of the proximal tibia, the medial saphenous artery and accompanying veins branch into cranial and caudal branches and course distally down the medial aspect of the tibia. Numerous cutaneous branches of the medial saphenous artery perfuse the skin overlying the medial aspect of the femorotibial area and provide the blood supply to the skin island of this flap. The skin paddle is marked over the course of the artery (detected by Doppler imaging) and measured to be 1 cm longer and wider than the defect to be reconstructed. The flap design maintains a skin bridge between the debrided soft-tissue/osseous defects and the donor sites. The anterior incision is made to the subfascial level and the dissection is performed posteriorly under loupe magnification until the flap vessels are clearly visualized. The saphenous artery and its concomitant veins are ligated at the distal aspect of the flap and the posterior incision is then made to the subfascial level. Anterior dissection is performed until the vessels are visualized, and then the flap is raised from distal to proximal until the arc of rotation of the flap is adequate to reach the defect. The flap is then transferred as an island flap into the defect and secured in place. Confirmation of flap vascularity is made by clearly visualizing continuous bleeding at the flap edges after harvest and before transfer. The donor site is closed primarily in two layers over a rubber Penrose drain that is left in place for 48 hours (Fig. 3).

Study Endpoints/Statistical Analysis

The animals were observed daily for clinical symptoms and signs of persistent or recurrent os-



Fig. 3. (Above) Marking and design of the saphenous artery skin flap. A Doppler probe was used to mark the course of the saphenous artery, and the skin island was drawn centered over the course of the vessel. (Center) The axial-pattern, saphenous artery fasciocutaneous flap after harvest and before inset into the debrided tibia osteomyelitis wound. (Below) The saphenous artery fasciocutaneous flap after inset rotation and inset into the tibia defect. The donor-site wound was closed primarily.

teomyelitis (guarding of the involved limb, tenderness, or an external wound with or without a draining sinus) and for identification of surgical

complications. Radiographs were obtained monthly for the first 6 months after reconstruction and at 9 months and 1 year after reconstruction to detect persistent or recurrent disease. Films were evaluated by a radiologist blinded to the reconstructive procedure for the resolution of periosteal elevation, lucency, and sequestrum. The animal's ability to regain full ambulation and weight bearing on the operated limb was recorded and a comparison was made between the two groups. Fisher's exact test was used for statistical analysis of wound complications and the chi-square test was used for repeated binary measurements (i.e., generalized estimating equations). Analysis for the presence or absence of repeated measurements was used to detect a significant difference between treatment groups. In addition, a Mann-Whitney test for the month when the osteomyelitis disappeared among treatment groups was also performed.

RESULTS

Thirteen superficial digital flexor muscle flaps and 13 axial-pattern, pedicled fasciocutaneous flaps based on the saphenous artery and vein were performed in 26 goats. Predebridement cultures were positive for the original infecting bacteria strain and postdebridement cultures were negative in all animals in both groups.

All flaps survived. There was one partial flap loss in the nonmuscle group because of venous congestion noted at postoperative day 5. Two goats in the nonmuscle group developed seromas at the recipient site that resolved after needle aspiration. A limp was noted in all goats, which disappeared after an average of 6 days in the nonmuscle group and 6.2 days in the muscle group. One goat in the nonmuscle group sustained an iatrogenic injury to the posterior tibial nerve during reconstruction that resulted in a significant limp that completely resolved at 70 days. This goat was not included in the average time to ambulation portion of our evaluation.

During the follow-up period of 1 year, no goats developed wounds in the muscle group, and superficial wounds were noted in two goats in the nonmuscle group, one of which was the animal with a partial flap loss. Both wounds resolved with local care in both goats, showing no significant difference between groups using Fisher's exact test (Table 1).

A radiologist blinded to the reconstructive procedure evaluated all tibia radiographs for the resolution of periosteal elevation, lucency, and sequestrum that was present on preoperative films. Osteomyelitis was present radiographically

Table 1. Fisher's Exact Tests Comparing the Effectiveness of the Nonmuscle Flaps to Muscle Flaps, Showing No Significant Differences in Complications

Complications	Nonmuscle Group (<i>n</i> = 13)	Muscle Group (<i>n</i> = 13)	Fisher's Exact Test <i>p</i>
Partial flap loss caused by venous congestion	1	0	1.0000*
Seromas at the recipient site	2	0	0.4800*
Developed wounds/recurrent wounds	2	0	0.4800*

*Not significant at the 0.05 level of significance.

in two of 13 (15 percent) goats in the muscle group and in one of 13 (8 percent) goats in the nonmuscle group at 1 year postoperatively. Using chi-square statistical analysis for repeated binary measurements, there was no statistically significant difference between the muscle and nonmuscle flap groups regarding the presence of osteomyelitis based on monthly radiologic evaluation of the tibia after single-stage reconstruction (chi-square test = 1.31, $p = 0.25$). A Mann-Whitney test showed no statistically significant difference between groups and the month when the osteomyelitis disappeared ($p = 0.2498$). In addition, at 1 year postoperatively, there were no clinical signs of osteomyelitis in either group (Figs. 4 through 6).

DISCUSSION

Chronic osteomyelitis is a recalcitrant condition in which symptoms have been present for longer than 3 months or in which an initial therapeutic regimen has failed. This disease has been treated in a variety of forms, both medically and surgically, with variable results. The purpose of this investigation was to evaluate and compare the effectiveness of muscle flaps and nonmuscle flaps in the eradication of chronic osteomyelitis following adequate debridement and resurfacing with vascularized tissue. This topic has been one of significant controversy for many years and has stimulated many discussions and clinical studies that have been extremely worthwhile though not decisively convincing. This is evident by the fact that muscle flaps have been advocated over nonmuscle flaps by most surgeons treating osteomyelitis defects despite a lack of clinical evidence demonstrating a clear superiority of one over the other. In fact, several clinical studies have advocated the use of nonmuscle flaps for reconstruction of osteomyelitis defects, citing the decrease in donor-site morbidity attributable to the preservation of functional muscle tissue. These clinical studies have confidently and appropriately reported outcomes of both types of flaps but have been unable to control many of the variables

present in the wounds, including the type and concentration of organisms, the extent of the wounds, and the antibiotic susceptibility of the organisms. A controlled, reproducible animal model of osteomyelitis was necessary to provide an unambiguous comparison of the two types of flaps.

Although muscle flaps have been demonstrated in many previous studies to be successful in the eradication of osteomyelitis after adequate debridement of diseased tissues,^{2-4,6} their associated functional donor morbidity has encouraged the search for alternate reconstructive options. Commonly used muscle flaps include the latissimus dorsi and rectus abdominis. These flaps are typically used for these problematic wounds and can be harvested in a variety of forms and tissue combinations. With advances in reconstructive techniques, efforts have been directed toward refinements in flap harvest and preservation of function at flap donor sites and achieving equal or superior reconstructive outcomes.

Osteomyelitis has been classified by Waldvogel and colleagues¹⁴ as hematogenous osteomyelitis, contiguous focus osteomyelitis, osteomyelitis associated with vascular disease, and chronic osteomyelitis. Chronic osteomyelitis was then classified anatomically by Cierney and Mader as medullary, superficial, localized, and diffuse.¹² In the animal experiment presented in this article, the type of osteomyelitis evaluated was of the localized type of chronic osteomyelitis. Clinically, this type of osteomyelitis presents following a traumatic injury and often has the combined features of medullary and superficial osteomyelitis resulting from an extension of either of the two entities. Although classification and staging systems for osteomyelitis have been proposed and used for clinical and experimental purposes,¹⁵ they have not taken into account specific variables such as the pathogenic organism, its antibiotic sensitivity, and the anatomical location of the disease, all of which are necessary to study, comparatively, different treatment methods and algorithms.

The goat was chosen for the purpose of this study because of its large size, its tolerance to the



Fig. 4. (Above) Lateral radiograph of a goat hind limb exhibiting extensive osteomyelitis before single-stage reconstruction with a superficial digital flexor muscle flap. (Center) Lateral radiograph of a goat hind limb 6 months after successful single-stage debridement and reconstruction with a superficial digital flexor muscle flap of the infected tibia with chronic osteomyelitis. (Below) A goat hind limb 6 months after successful single-stage reconstruction of the left tibia with a superficial digital flexor muscle flap.

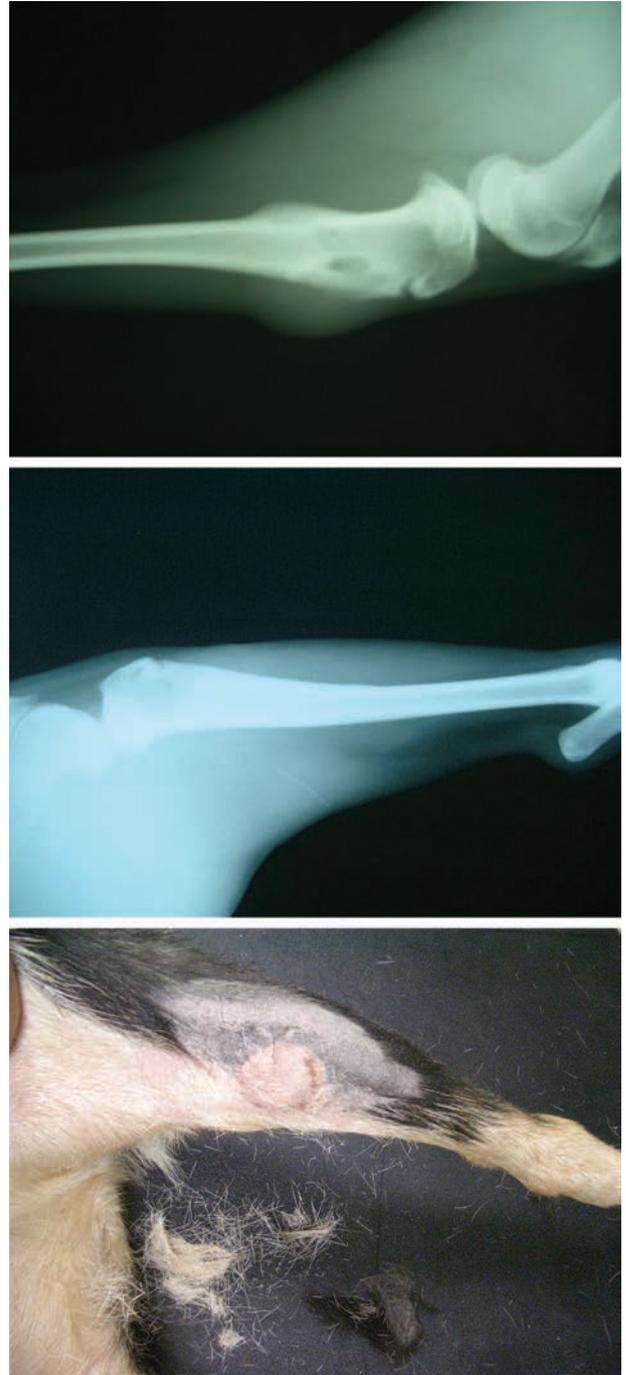


Fig. 5. (Above) Lateral radiograph of a goat hind limb exhibiting extensive osteomyelitis before single-stage reconstruction with an axial-pattern saphenous artery fasciocutaneous flap. (Center) Lateral radiograph of a goat hind limb 6 months after successful single-stage reconstruction of left tibia osteomyelitis with an axial-pattern saphenous artery fasciocutaneous flap. (Below) Goat hind limb 6 months after successful single-stage reconstruction of the left tibia with an axial-pattern saphenous artery fasciocutaneous flap.



Fig. 6. (Above) Lateral radiograph of a goat hind limb before single-stage muscle flap reconstruction. (Below) Lateral radiograph of a goat hind limb 6 months after single-stage muscle flap reconstruction demonstrating persistent osteomyelitis.

toxic effects of antibiotics, and its availability for experimental research in the authors' regional location. Other large-animal models exist and have been used for the study of osteomyelitis; however, the goat provided a more inexpensive large-animal model that was shown to be as reliable as other large-animal models for the establishment of osteomyelitis.^{16,17} In this experimental study, comparing two different treatment options for a specific disease entity, the investigators were able to control the defect location, size, subject size, body habitus, nutritional status, and the amount and type of bacterial organism causing the infection. In addition, all bacteria present had the same antibiotic sensitivity, creating a simple, reproducible, and accurate method with which to evaluate one variable only, the type of surgical reconstruction performed, muscle versus nonmuscle flaps. The design of the experiment was made with the intention of providing a comparison between mus-

cle and nonmuscle flaps for the treatment of chronic osteomyelitis in a single-stage reconstruction. The options for flap coverage, therefore, had to meet a set of criteria. Both flap types had to be supported by a set of vessels that provided a reliable blood supply with branches feeding the majority of the tissues included in the flap, they had to be able to be transferred in a reliable fashion to fill the defect, and technical variabilities with possible technical setbacks were to be minimized. The flaps were chosen from locations nearby the defect to make the operative procedures simpler. The superficial long digital flexor muscle and the saphenous artery fasciocutaneous flap fit these criteria and were used for the purpose of this study. Both of these flaps were developed in the goat based on previous designs in other large-animal models.¹⁸ The authors studied the anatomy of the goat and other animals in the same genus, such as the sheep, and evaluated the arterial anatomy of the goat hind limb using conventional arterial angiography. The superficial digital flexor muscle has a dominant vascular pedicle that arises from the posterior tibial artery and minor pedicles that arise along the length of the muscle (Mathes and Nahai type II).¹⁹ The saphenous artery flap is an axial-pattern fasciocutaneous flap with a clear arterial and venous system that has visible skin vessels arising from it. The initial experimental design included a third study group consisting of random-pattern skin flap coverage (local skin undermining and closure); however, after an extensive literature review, peer discussions, and Institutional Animal Care and Use Committee review, it was deemed that random-pattern skin flaps for this purpose have been clearly demonstrated to be less reliable for the purpose of complex wound coverage. Mathes and colleagues² demonstrated the superiority of muscle flaps over random-pattern skin flaps in the treatment of osteomyelitis wounds. In a previous study by Richards and colleagues,²⁰ a comparison was made between the results achieved following coverage of bony defects with random-pattern skin flaps versus muscle flaps. Their conclusions, based on the strength of union of bone that was achieved and the presence of infection after devascularization of a segment of canine tibia, showed muscle flap coverage to be superior to coverage with local skin alone. Based on these findings, the institutional review committee felt strongly that an attempt to include this third study group would be unjustifiable considering previous data demonstrating suboptimal outcomes of local, random-pattern skin flaps for the treatment of osteomyelitis defects. Therefore,

the design of this study was made to compare muscle flaps and fasciocutaneous flaps only, in the treatment of osteomyelitis defects following debridement.

A key factor to wound healing in patients with osteomyelitis is debridement. This procedure, an endeavor strongly dependent on the operator, when performed properly, rids the soft tissue and bone in the wound of a large bulk of the bacterial inoculum and any nonviable tissue that could harbor further bacterial growth. The criteria for debridement were strict and were based on recommendations and standards set forth by Attinger and Bulan in 2001.²¹ Aerobic and anaerobic cultures were performed on the wounds before and immediately after debridement. The cultures were performed by the same laboratory and under the same conditions. In all animals, the predebridement cultures demonstrated the presence of similar concentrations of the original infecting organism in all wounds. Postdebridement cultures in all animals were either negative or demonstrated insignificant growth at 48 hours. Although clinical evaluation of the wounds was the major criterion for adequacy of surgical debridement, the lack of significant growth found in postdebridement culture swabs of the wounds allowed the authors to feel more confident that the wounds, before coverage, were similar in nature, allowing for a more fair comparison of the different study groups.

Plain radiography is the most commonly used method of evaluating bone disease and is both inexpensive and universally available. For the detection of acute osteomyelitis, the sensitivity is less than 5 percent at presentation and approximately 33 percent at 1 week; however, the sensitivity is 90 percent 3 to 4 weeks after presentation. For the detection of chronic osteomyelitis, the sensitivity of plain radiography is high.^{22,23} Evaluation of the radiographs was performed by the same radiologist, blinded to the reconstructive procedure. All goats in this study, following the introduction of the bacterial inoculum, had marked radiographic evidence of osteomyelitis. Correlation between radiographic evidence of osteomyelitis and the presence of disease in the bone histopathologically was 100 percent in this study. Radiographic evaluation was performed on all goats after debridement and reconstruction on a monthly basis for the first 6 months and then at 9 and 12 months. As expected, the initial two to three monthly radiographs in all goats showed radiolucency because the osseous defect, without the presence of periosteal reaction or sequestrum; however, the radiologist could not

definitively rule out osteomyelitis in any of these initial films. After 3 months, most of the osseous defects had healed and the radiolucencies resolved. In three goats, evidence of osteomyelitis persisted in the proximal tibia until the end of the study period. Two of these goats had undergone reconstruction with a muscle flap and one with a nonmuscle flap, a difference that was statistically insignificant. Interestingly, we have found that with this type of experiment, there is no clear benefit to obtaining monthly radiographs before the third month because, radiographically, the presence of osteomyelitis was not distinguishable from the osseous defect caused by debridement.

This experiment demonstrates that muscle flaps and nonmuscle flaps are viable reconstructive options for the treatment of osteomyelitis wounds following debridement. All wounds had in common the absence of foreign material, an added burden that may complicate the issue of which reconstructive option is more suitable. Considering the difficulty of performing as extensive a debridement in patients with retained hardware, the bacterial count may remain high in the wounds following the debridement effort. The data from this study are not necessarily valid for wounds with the added factor of retained hardware. Calderon and colleagues¹¹ documented a decrease in bacterial concentration in wounds covered with muscle flaps when compared with fasciocutaneous flaps. This, in addition to the fact that muscle flaps may conform better to a wound with retained hardware, may argue favorably for the essentiality of provision of muscle flap coverage for treatment of these complex wounds. Are nonmuscle flaps able to provide enough vascularity to treat indolent wound infections with retained hardware or prosthetic grafts? Would nonmuscle flaps be equally as effective? These questions remain subjects for future investigation. Muscle flaps have been proven to be effective in the treatment of infected vascular grafts.²⁴

CONCLUSIONS

Although the common knee-jerk response for muscle flap coverage of osteomyelitis wounds has been challenged by recent studies,²⁵ a lack of a controlled study has led most centers to persist in the use of muscle flap coverage for these wounds. This experimental study confirms the fact that adequate debridement and obliteration of the residual dead space remains the most critical factor in achieving success with any method of reconstruction and, although the lack of a significant difference does not prove equivalence, this study

does provide strong evidence that both muscle flaps and nonmuscle flaps are effective in providing coverage for bone defects with chronic osteomyelitis following adequate debridement.

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DISCLOSURE

None of the authors of this article have any commercial associations that might pose or create a conflict of interest with the information presented in the submitted manuscript. This includes consultancies, stock ownership or other equity interests, patent licensing arrangements, and payments for conducting or publicizing the study described in the article.

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