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ACFAS Clinical Consensus Statement

American College of Foot and Ankle Surgeons' Clinical Consensus Statement: Perioperative Prophylactic Antibiotic Use in Clean Elective Foot Surgery

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A R T I C L E I N F O

Keywords: antibiotic prophylaxis clinical consensus statement foot and ankle surgery

ABSTRACT

Some controversy exists regarding the use of antibiotic prophylaxis in elective foot and ankle surgery. A task force was appointed by the American College of Foot and Ankle Surgeons (ACFAS) to provide a clinical consensus statement on this topic. The panel members performed a literature search and identified 6 studies that met the inclusion criteria. They then developed a list of 13 questions about which they attempted to reach consensus using a modified Delphi method. The questions were grouped into 4 categories: indications for antibiotic prophylaxis relative to surgical procedure; antibiotic prophylaxis in high-risk patients; antibiotic selection; and timing of antibiotic prophylaxis. Consensus was reached for all 13 questions. The panel members found that studies pertaining specifically to elective foot and ankle surgeries that were not level I evidence generally did not recommend prophylaxis. They also found that multispecialty guidelines, which reflect data that are stronger, tended to recommend routine prophylaxis by surgeons. More high-level evidence is required to make a definitive determination about whether prophylaxis is necessary in elective foot and ankle surgery. Until that time, routine prophylaxis will likely be continued at most institutions, because few complications have been reported with the practice.

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This document was created to serve as a clinical consensus statement (CCS) of the American College of Foot and Ankle Surgeons (ACFAS). It is important to appreciate that consensus statements do not represent *clinical practice guidelines, formal evidence reviews, recommendations,* or *evidence-based guidelines.* Rather, a CCS reflects information synthesized from an organized group of experts based on the best available evidence, and it also may contain opinions, uncertainties, and minority viewpoints. A CCS should open the door to discussion on a topic, as opposed to attempting to provide definitive answers. Adherence to consensus statements will not ensure successful treatment in every clinical situation, and the physician should make the ultimate decision based on all available clinical information and circumstances with respect to the appropriate treatment of an individual patient.

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Although routine perioperative antibiotic prophylaxis is common practice, empirical evidence in support of this practice is generally lacking and somewhat inconclusive. This is specifically true in elective surgery of the foot and ankle. The discussion in this CCS includes not only questions regarding the timing, duration, dosage, and microbial coverage during the pre-, intra-, and postoperative periods but also regarding the necessity of any perioperative antibiotic administration. As with any medical intervention, the potential benefits of a therapy, such as a reduction in postoperative infection rates, must be weighed against the possible adverse consequences, including allergic or other inflammatory reactions, higher health care costs, specific medication adverse effects, and emergence of drug-resistant organisms.

Definition of Surgical Site Infection

The Centers for Disease Control and Prevention (CDC) has established criteria that define surgical site infections (SSIs), and this definition represents the current national standard (1,2). The CDC defines an *SSI* as any infection related to an operative procedure that occurs at or near the surgical incision or within an organ space within 30 days of

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Table	1
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Included studies involving prophylaxis and infection rates in foot and ankle surgery

Author	Level of Evidence	Surgery	Included Patients Preop Antibiotic/None	Infection Rates Preop Antibiotic/None	Conclusion
Zgonis et al (9)	III	Bone and soft tissue	306/249	1.6%/1.4%	Preop antibiotic not required
Paiement et al (10)	II	Ankle ORIF	60/62	1.67%/4.83%	Preop antibiotic not required
Reyes et al (11)	IV	Bone and soft tissue	233/226	0.43%/0.88%	Preop antibiotic may be necessary with implants
Miller et al (12)	IV	Bone and soft tissue	0/1841	NA/2.2%	No specific recommendation

Abbreviations: NA, not available; ORIF, open reduction internal fixation; Preop, preoperative.

the procedure or within 90 days if prosthetic material is implanted at surgery. The definition of *infection* is based on the presence of purulent exudate from the surgical incision and/or a surgical site that requires reopening. SSIs are further classified as either superficial or deep. *Superficial infections* involve only the skin and subcutaneous tissue, whereas *deep infections* involve deep tissue spaces or organs.

Wound Classification for Surgical Patients

The National Academies of Science and the National Research Council define surgical wounds as follows (3):

- 1. *Clean wounds:* Uninfected operative wounds in which no inflammation is encountered and the wound is closed primarily
- 2. *Clean-contaminated wounds:* Operative wounds in which a viscus is entered under controlled conditions and without unusual contamination
- 3. *Contaminated wounds:* Open, fresh accidental wounds, operations with major breaks in sterile technique, or gross spillage from a viscus; wounds in which acute, purulent inflammation was encountered are also included in this category
- 4. *Dirty wounds:* Old traumatic wounds with retained devitalized tissue, foreign bodies, or fecal contamination, or wounds that involve existing clinical infection or perforated viscus

Although this classification scheme is widely used, in reality it is a poor predictor of overall risk of SSI. Other factors such as operative technique, length of surgery, and health of the surgical patient are as important as wound classification in predicting risk for SSI (4–7).

Current guidelines regarding the use of antibiotic prophylaxis in a variety of surgical procedures were proposed in a recent report by the American Society of Health-System Pharmacists (ASHP) (8). In addition, recommendations and guidelines set forth by the Surgical Care Improvement Project (SCIP) are widely accepted by regulatory agencies and are commonly part of health care system quality programs. The purpose of this CCS is to address the topic of prophylactic perioperative antibiotic use in clean elective foot and ankle surgery.

Materials and Methods

Creation of Panel

Table 2

Members of ACFAS suggested that clinical consensus statements would be useful; therefore, ACFAS enacted an initiative to create such documents for foot and ankle surgeons. This initiative was originally conceived to report on a variety of topics and take the place of previous clinical practice guidelines (CPGs). To move forward with this initiative, a formal consensus method (CM) process was undertaken. On April 18, 2014, experts in the field of foot and ankle surgery were sent an invitation by ACFAS to participate on a panel to develop a CCS on antibiotic usage. A 5-member panel was selected and tasked with providing opinions and suggestions about perioperative antibiotic usage. The panel was chaired by one of the authors (M.S.), and assisted by ACFAS members and staff. Over several months, panel members participated in e-mail dialog, several conference calls, and a face-to-face meeting. The panel's stated goal was to examine the current literature relating to the use of antibiotics in elective foot and ankle surgery and to compile this information to provide direction in antibiotic usage in the perioperative setting. Panel members acknowledged the inherently limited number of published studies on this subject and established criteria for inclusion of studies in their evaluation. A literature search was undertaken to identify published studies. In addition, the panel reached a consensus on a series of questions relating to the use of perioperative antibiotics.

Literature Review

The search terms used in the formal literature search were antibiotic prophylaxis, antimicrobial prophylaxis, surgical site infection, foot surgery, ankle surgery, podiatric surgery, orthopedic surgery, and bone and joint surgery in which AND and OR were the Boolean operators used. These terms were searched using the Cochrane Database of Systematic Reviews, Pubmed, OVID, EMBASE, and Google scholar. In addition, panel members conducted a manual search of the literature from 1990 to 2014 for the following journals: Journal of Bone and Joint Surgery, American Journal of Bone & Joint Surgery and British Journal of Bone & Joint Surgery (now Bone & Joint Surgery); Journal of Foot & Ankle Surgery; Foot and Ankle International; Journal of Pediatric Orthopaedics; Journal of the American Podiatric Medical Association; and Journal of Infectious Diseases. Inclusion criteria consisted of studies evaluating clean elective surgery (including non-emergent, open reduction, and internal fixation of closed ankle fractures) that were either prospective or retrospective in nature. Exclusion criteria consisted of studies examining emergency surgery, open fractures, and surgery to manage infection. Originally, 52 studies were compiled for possible inclusion based on the initial search. These articles were evaluated by the panel chair and agreed upon by the panel members for final inclusion. Ultimately, 6 studies were retained for review: 2 prospective randomized trials, 1 prospective study of bone concentration of antibiotics, and 3 retrospective reviews (Tables 1 and 2) (9-14).

Studies related t	o timing of antibiotio	c in LE surgery

Author	Level of Evidence	Type of Surgery	Antibiotic Before/After Tourniquet	Postop Infection	Conclusion
Akinyoola et al (13)	III	ORIF LE fracture	54/52	14.8%/3.9%	Antibiotic pre-tourniquet not better than post-tourniquet
Deacon et al (14)	II	Bunionectomy	25/0	NA	MIC90 in bone within 70 min of antibiotic infusion

Abbreviations: LE, lower extremity; MIC90, minimal inhibitory concentration that will inhibit growth of 90% of bacterial species in vitro; NA, not available; ORIF: open reduction internal fixation.

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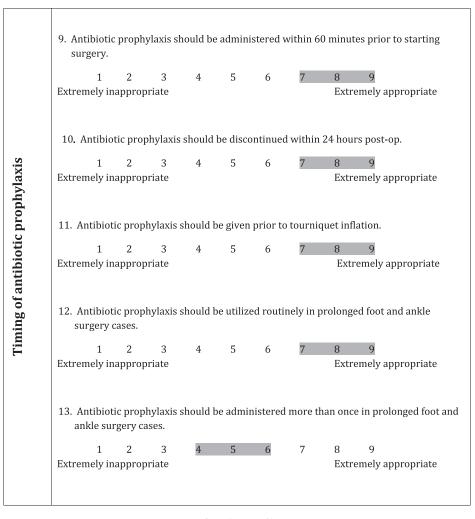
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Fig. 1. Clinical consensus statement questions. Highlighted answers indicate consensus reached by the panel. MRSA, methicillin-resistant Staphylococcus aureus (continued).

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Consensus

A modified Delphi method was used to attain consensus on several pertinent clinical questions by members of the panel (15). A series of 13 statement questions were developed by the panel chair (Fig. 1). These were sent to the rest of the panel to determine relevancy, inclusion, and categorization. Once the questions were finalized, they were sent to all panel members to review and answer. The answers were based on the appropriateness of the statement question and were graded from 1 (extremely inappropriate) to 9 (extremely appropriate) based on a Likert scale (Fig. 2) (16). Each panel member answered the questions anonymously, and the results were sent to the panel chair. The answers were reviewed, analyzed, and grouped from 1 to 3 (inappropriate), 4 to 6

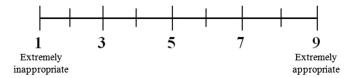


Fig. 2. The Likert scale was used to ascertain consensus on the 13 developed statements. The scale ranged from "1" (extremely inappropriate) to "9" (extremely appropriate). Anonymous panel member answers were reviewed and grouped as 1–3 (inappropriate), 4–6 (uncertain), and 7–9 (appropriate).

(uncertain), and 7 to 9 (appropriate). The results were summarized, kept anonymous, and distributed back to panel members, with the reasons for varying judgments included. This was left for review, and at the face-to-face meeting the questions were administered again in light of the explanations provided by other panel members. Panel members were able to change ratings based on group discussions. An attempt was made to reach consensus for all questions, although this was not a requirement. All panel members participated in creation of the CCS manuscript. The final draft was submitted to the ACFAS leadership for adoption.

Results and Discussion

The panel was able to reach consensus on all 13 questions (Fig. 1). It should be noted, however, that the consensus was largely based on much broader multispecialty prophylaxis guidelines for which the

Table 3

Level	Research Design
I	Randomized controlled trial
II	Cohort study
III	Case control study
IV	Case report or series
V	Animal, benchtop, or computer study

data were stronger and more compelling (8), as opposed to the panel's specific review of the foot and ankle literature on the topic. The available foot and ankle specific studies were limited in number and quality of evidence; therefore, these studies rarely had a significant influence on the panel's consensus.

Indications for Antibiotic Prophylaxis Relative to Surgical Procedure (Questions 1–4, Fig. 1)

Consensus statement: The panel reached consensus that it is appropriate for antibiotic prophylaxis to be routinely utilized in surgeries involving bone, hardware, and prosthetic joints. With regard to soft tissue surgery, the panel reached consensus that it was uncertain whether antibiotic prophylaxis should be utilized and would be considered procedure dependent.

For surgery involving bone, hardware, or prosthetic joints, the studies specific to foot and ankle surgery did not provide sufficient evidence to change our current clinical consensus (9-14). Of the 4 included studies relating to use of prophylactic antibiotics and incidence of infection (Table 1), the panel considered 2 studies to be level IV evidence, 1 study to be level III evidence, and 1 study to be level II (Table 3) (17). Only 1 of the studies (10) was prospective, but it had a small number of included subjects. No sample size calculation was performed to identify how many subjects were required to reach statistically significant results with appropriate power. Both Paiement et al (10) and Zgonis et al (9) concluded that antibiotic prophylaxis was unnecessary in elective foot and ankle surgery; however, neither investigation team provided level I evidence. Unfortunately, no highlevel evidence is available in the literature to corroborate these conclusions. The ASHP report supports prophylaxis in surgery involving prosthetic joints and generally accepts antibiotic prophylaxis for use in surgery where hardware is implanted (8).

Boxma et al (18) performed a prospective, double-blind, randomized, placebo-controlled trial comparing the incidence of superficial and deep wound infection in subjects undergoing open reduction and internal fixation (ORIF) of closed limb fractures. Patients were randomized to receive either 1 dose of intravenous preoperative antibiotic (ceftriaxone) or placebo. Among the 2195 patients enrolled, the incidence rate for superficial and deep infection was 8.3% in the placebo group and 3.6% in the ceftriaxone group. The rates for nosocomial infection within 30 days of the procedure were 10.2% in the placebo group and 2.3% in the ceftriaxone group. The authors concluded that single-dose administration of antibiotic prophylaxis reduces the rate of surgical site and nosocomial infection in patients undergoing surgical treatment of closed limb fractures.

Gillespie and Walenkamp (19) performed a systematic review of randomized and quasi-randomized controlled trials evaluating any regimen of preoperative antibiotic use compared with placebo, no prophylaxis, or a regimen of different duration in patients undergoing ORIF of closed proximal femoral or other long bone fractures. They identified 23 studies and pooled data from 8447 subjects and found that single-dose antibiotic prophylaxis significantly reduced the risk of deep and superficial SSIs in addition to urinary and respiratory infections postoperatively. They concluded that single-dose antibiotic prophylaxis should be offered to patients undergoing ORIF of proximal femoral and other closed long bone fractures.

AlBuhairan et al (20) performed a meta-analysis of 7 studies (3065 subjects) that evaluated antibiotic prophylaxis and SSI in total hip and knee arthroplasty. They found that the absolute risk of wound infection was reduced by 8% and the relative risk was reduced by 81% in patients who were administered antibiotic prophylaxis compared with those who did not receive prophylaxis. The authors concluded that antibiotic prophylaxis should be used routinely in joint replacement procedures.

For procedures strictly involving soft tissue, the literature is unclear regarding the use of antibiotic prophylaxis. Despite this, the panel agreed that, in cases of extensive soft tissue dissection, lengthy procedures, tissue transplantation, or high-risk patients, prophylaxis would be a consideration.

Formaini et al (21) retrospectively evaluated 2330 pediatric patients who underwent minimally invasive orthopedic procedures with (1087) or without (1243) preoperative antibiotics. The procedures included knee arthroscopy, closed reduction with percutaneous fixation, excision of soft tissue or bony masses, soft tissue releases, and hardware removal. Only 1 patient in the no prophylaxis group required a return to surgery within 30 days to treat an SSI. None of the patients in the prophylaxis group required a return to surgery related to infection within 30 days of the index procedure. The authors concluded that antibiotic prophylaxis may not be required for minimally invasive procedures performed in low-risk pediatric patients.

Tosti et al (22) performed a multicenter retrospective review of 600 elective soft tissue hand procedures in which 212 patients received antibiotic prophylaxis and 388 subjects received no prophylaxis. The SSI rate within 30 days of the procedure was reported as 0.47% for those who received prophylaxis and 0.77% for those who did not. The difference in results was not statistically significant. All infections were considered to be superficial and did not require a return to surgery.

Although the aforementioned studies are not specific to foot and ankle surgery, they do provide some evidence that antibiotic prophylaxis may not be required in soft tissue procedures of short duration with minimal dissection when performed on low-risk patients. The surgeon should determine on a case-by-case basis which procedures and patients might warrant the use of antibiotic prophylaxis.

Antibiotic Prophylaxis in High-Risk Patients (Questions 5 and 6, Fig. 1)

Consensus statement: The panel reached consensus that antibiotic prophylaxis is appropriate in patients who may be at increased risk for infection including those with diabetes, those who are immunocompromised, and those at risk for endocarditis. The panel noted that patient factors may more strongly drive the decision to use antibiotic prophylaxis than type of procedure performed.

Ehrenkranz (23) performed a 5-year prospective study evaluating SSI rates in clean, elective operations. The subjects included 9108 community hospital patients undergoing various types of elective surgery. He found that the patients at highest risk for infection were those with diabetes, those with remote infections from the surgical site, and those undergoing procedures of 4 hours or longer in duration. Wound infection rates in this high-risk population ranged from 1.7% to 7.9% by type of procedure. Infection rates in patients without these risk factors ranged from 0.8% to 2.8%. Due to the increased rate of SSI in a high-risk population, antibiotic prophylaxis may need to be considered for these patients.

A prospective study was performed by Wukich et al (24) comparing SSIs in 2060 patients who underwent foot and ankle surgery. The patients were categorized into 4 groups:

- 1. Those without diabetes or neuropathy
- 2. Those with neuropathy but no diabetes
- 3. Those with diabetes without complications
- 4. Those with diabetes and at least 1 complication

The results showed that patients with complicated diabetes had a 7.25 times greater risk of SSI than patients without diabetes or neuropathy. The subjects with complicated diabetes also had a 3.72 times greater risk of postoperative infection than those with uncomplicated diabetes. Patients without diabetes but with neuropathy had a 4.72

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times greater risk of SSI than subjects without diabetes or neuropathy. Complicated diabetes and neuropathy both appear to increase the risk of SSI; therefore, patients with these comorbidities might be considered for antibiotic prophylaxis irrespective of the planned surgical procedure.

Rheumatoid arthritis (RA) also has been demonstrated to increase SSI risk in patients undergoing total joint replacement. Somayaji et al (25) performed a retrospective study evaluating RA patients who underwent total hip or knee arthroplasty over a 10-year period, looking at rates of SSI. They found increased infection rates among patients who received more than 15 mg of prednisone daily. Patients who were underweight or who had coronary artery disease in addition to RA also had increased risk of infection.

Ravi et al (26) performed a retrospective study looking at infection rates as well as dislocation rates after total hip and total knee arthroplasty in RA patients compared with osteoarthritis (OA) patients. They found higher rates of infection after total knee arthroplasty and higher rates of dislocation after total hip arthroplasty in RA patients relative to OA patients.

There is controversy in the literature regarding the effectiveness of antibiotic prophylaxis among patients at risk for endocarditis. Some experts still recommend prophylaxis in patients with high-risk cardiac conditions who undergo oral procedures, but others recommend discontinuing the use of prophylaxis altogether (27). Some articles have discussed placing nonspecific hygiene measures above antibiotic prophylaxis (28). The American Heart Association guidelines for prevention of infective endocarditis suggest that a limited subset of patients may benefit from antibiotic prophylaxis to prevent endocarditis (29). The question of whether the potential harm of prophylaxis outweighs the benefit relating to patients at risk of endocarditis as well as to the risk of SSI based on the type of procedure needs to be considered on a case-by-case basis by the surgeon.

Antibiotic Selection (Questions 7 and 8, Fig. 1)

Consensus statement: The panel reached consensus that narrow spectrum antibiotics covering Staphylococcus aureus should be utilized for prophylaxis in patients without a history of resistant infection. The panel reached consensus that it was not appropriate to routinely perform preoperative nasal swabs to check for methicillin-resistant Staphylococcus aureus (MRSA) colonization.

The preponderance of literature indicates that *Staphylococcus aureus* is the most common infecting organism in postoperative infections (30-32). The literature also supports the use of narrow spectrum antibiotics covering *S. aureus* for routine antibiotic prophylaxis. The ASHP report provides no recommendations regarding antibiotic agents for clean operations of the foot that do not involve implantation of foreign materials. However, the report does recommend cefazolin as the agent of choice when implantation of internal fixation is performed; clindamycin or vancomycin are recommended for patients with beta-lactam allergy. The evidence cited for these recommendations was based on expert opinion (8).

There are no specific data regarding routine MRSA surveillance and decolonization in foot and ankle surgery. Chen et al (33) performed a systematic review looking at screening for MRSA and decolonization protocols with relation to reduction in SSI as well as cost-effectiveness. Their review was based on level I through level IV studies and would be considered to be level IV evidence. The studies included elective surgery (total joints, spine surgery, and repair of sports injuries) as well as trauma. Each of these 19 studies demonstrated reduced SSI rates after administering a screening and decolonization protocol that was deemed to be cost-effective due to the reduction of postoperative complications.

A systematic review by Schweizer et al (34) looked at nasal decolonization, glycopeptide prophylaxis, or both with respect to reduction of Gram-positive SSI. The review included 39 randomized controlled trials, quasi-experimental studies, and cohort studies with subjects who underwent total joint replacement or cardiac procedures. The investigators found reduced rates of *S. aureus* SSI when all patients or only *S. aureus* carriers underwent decolonization. There was a benefit to using glycopeptide prophylaxis versus beta-lactam antibiotics to prevent MRSA infections.

Levy et al (35) performed a meta-analysis looking at nasal decolonization of MRSA and rates of SSI after orthopedic surgery. They found that positive MRSA colonization did increase SSI rates in orthopedic patients. However, the numbers were not adequate to determine a statistically significant reduction in orthopedic SSIs in colonized patients who underwent decolonization protocols preoperatively. The authors recommended that the risk versus benefit of surveillance and decolonization be weighed on a case-by-case basis. Routine decolonization without surveillance could lead to increased resistance and is not considered appropriate.

Based on the panel's review of the literature, there is no compelling benefit to performing routine surveillance or decolonization specifically with regard to foot and ankle surgery. If the patient has a history of MRSA or is in a high-risk group, such as a nursing home patient, consideration of appropriate surveillance, decolonization, and prophylaxis might be entertained.

Timing of Antibiotic Prophylaxis (Questions 9–13, Fig. 1)

Consensus statement: The panel reached consensus that in cases where prophylaxis is used it is appropriate for the antibiotics to be administered within 60 minutes prior to surgery, discontinued within 24 hours after surgery, given prior to tourniquet inflation, and utilized routinely in prolonged foot and ankle surgery cases. The panel reached consensus that it is uncertain whether prophylaxis should be performed more than once in prolonged foot and ankle surgery cases.

A prospective study by Classen et al (36) examined postoperative infection rates in relationship to timing of antibiotic prophylaxis. The investigators evaluated 2847 patients who underwent various clean or clean-contaminated procedures in which antibiotic prophylaxis was administered 2 to 24 hours before incision, within 2 hours prior to incision, within 3 hours after incision, or within 3 to 24 hours after incision. Patients who received antibiotic prophylaxis within 2 hours prior to incision had the lowest incidence of SSIs. Several articles advocate administration of antibiotic prophylaxis within 60 minutes prior to surgery (37–39).

Deacon et al (14) looked at the minimal inhibitory concentration of cefazolin in the bone of the first metatarsal head resected during bunionectomy procedures. They found that administration of 1 g of cefazolin 1 hour prior to tourniquet inflation leads to adequate levels of the drug in bone to inhibit colonization of *S. aureus*.

Akinyoola et al (13) examined the effects of antibiotic administration before and after tourniquet inflation and found more postoperative infections in patients who had antibiotics administered prior to inflation. However, the panel concluded that the methodology of this study was flawed and had an insufficient sample size to provide valid results. Moreover, the findings were influenced by administering 3 doses of intravenous antibiotics postoperatively to all subjects. Therefore, the panel continues to agree that administration of prophylactic antibiotics before tourniquet inflation is appropriate.

In some areas it is common practice for patients to continue receiving antibiotics for several days after clean elective surgery. Although no studies have addressed the optimal duration for postoperative antibiotic prophylaxis, the literature does not demonstrate any benefit to the patient by continuing antibiotics longer than 24 hours postoperatively, and many studies do not show any benefit to administering antibiotics postoperatively at all (40–42). Longer administration may lead to increased bacterial resistance (43,44).

More complicated cases involving extensive dissection, multiple incisions, and prolonged operative time may have a higher potential for postoperative infection. In such cases, prophylactic antibiotics may be more strongly indicated (45). With regard to multiple dosing of prophylactic antibiotics in prolonged foot and ankle surgery, there are no clear data to indicate how frequently to re-dose. Some consideration could be given to re-dosing if the surgery lasts longer than 2 half-lives of the antibiotic used. Increased or multiple dosages also can be considered for obese patients to ensure proper tissue penetration (8). Consideration may be given to deflating the tourniquet, if used, prior to re-administration of antibiotics.

In conclusion, in many ways, the topic of prophylactic antibiotics in elective foot and ankle surgery is an unusual one, in that a relative divide exists between empirical science and common practice. Although there may not be a preponderance of evidence in support of this intervention, it is nevertheless widely used and, in fact, it is a requirement of most hospital systems. One way to view this is that physicians are routinely performing a relatively futile intervention that may be of little or no benefit to our patients. Another way to view it, however, is that this is an intervention without significant risk. The 6 studies specific to elective foot and ankle surgery that the panel identified as meeting our inclusion criteria did not demonstrate significant benefit in terms of infection prophylaxis, but at the same time they did not result in a single adverse event or complication from the intervention in more than 1000 patients studied. We will need to await more high-level research on this topic to determine whether a change in the use of antibiotic prophylaxis in elective foot and ankle surgery is warranted.

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