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Review Article

American College of Foot and Ankle Surgeons[®] Clinical Consensus Statement: Perioperative Management

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ABSTRACT

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Executive Statement

The following represents a clinical consensus statement sponsored by the American College of Foot and Ankle Surgeons[®] on the topic of perioperative management. A modified Delphi method was undertaken by a 5-member panel in an attempt to develop consensus on a series of 22 statements using not only the best available evidence, but also a degree of clinical experience and common sense.

The panel reached consensus that the following statements were "appropriate":

- Cigarette smoking should be considered a risk factor for the development of complications after foot and ankle surgical procedures
- Elevated glycated hemoglobin should be considered an independent risk factor for the development of complications after foot and ankle surgical procedures

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- Patients with open foot and ankle fractures should be treated with antibiotics
- The urgency of the treatment of open foot and ankle fractures is dependent on a variety of factors, including, but not limited to, time, anatomic location, and fracture grade and extent
- Perioperative management of diabetes medications warrants consideration before foot and ankle surgical procedures
- Perioperative management of rheumatoid arthritis medications warrants consideration before foot and ankle surgical procedures
- Perioperative management of anticoagulation medications warrants consideration before foot and ankle surgical procedures
- Tourniquets can be safely used for most patients undergoing foot and ankle surgical procedures
- Prophylactic antibiotic therapy should be considered for foot and ankle surgical procedures
- Prophylactic postoperative antithrombotic therapy should be considered for some patients after foot and ankle surgical procedures
- Foot and ankle surgeons should consider a multimodal approach to postoperative pain management
- Foot and ankle surgeons should be aware of objective measures of patient satisfaction and postoperative outcomes

The panel reached consensus that the following statement was "inappropriate":

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A wide range of factors contribute to the complexity of the management plan for an individual patient, and it is the surgeon's responsibility to consider the clinical variables and to guide the patient through the perioper-

ative period. In an effort to address a number of important variables, the American College of Foot and Ankle

Surgeons convened a panel of experts to derive a clinical consensus statement to address selected issues

associated with the perioperative management of foot and ankle surgical patients.





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 Foot and ankle surgeons should use routine postoperative radiographs in the absence of a clinical indication to assess osteotomy, fracture, and/or arthrodesis healing

The panel reached consensus that the following statements were "neither appropriate nor inappropriate":

- Foot and ankle surgical procedures should be considered a low perioperative risk
- Foot and ankle surgeons should use specific hair removal and preoperative skin bathing protocols before elective foot and ankle surgical procedures
- Preoperative methicillin-resistant Staphylococcus aureus decontamination protocols should be performed before elective foot and ankle surgical procedures
- An elevated body mass index should be considered a risk factor for the development of complications after foot and ankle surgical procedures
- A high preoperative blood glucose level should be considered a risk factor for the development of complications after foot and ankle surgical procedures
- Foot and ankle surgical procedures involving arthrodesis of the first ray should use a period of non-weightbearing immobilization
- Specific postoperative incisional care protocols should be used by foot and ankle surgeons

The panel was unable to reach consensus on the following statements:

- Vitamin D levels should be assessed before all foot and ankle arthrodesis procedures
- Foot and ankle surgeons should consider the use of bone stimulation in cases of delayed and nonunion

Introduction

This document was created to serve as one of a series of clinical consensus statements (CCSs) sponsored by the American College of Foot and Ankle Surgeons[®] (ACFAS) (1,2). It is important to appreciate that consensus statements do not represent clinical practice guidelines, formal evidence reviews, recommendations, or evidence-based guidelines. A CCS reflects information synthesized from an organized group of experts based on the best available evidence. However, it can also contain, and to some degree, embrace opinions, uncertainties, and minority viewpoints. A CCS should open the door to discussion on a topic, as opposed to attempting to provide definitive answers.

In 2003, Smith and Pell (3) reported what can only be described as a sarcastic systematic review of randomized controlled trials examining the effectiveness of parachutes in preventing death after jumping out of airplanes. Because they were unable to identify any level 1 evidence on the topic, their only possible conclusion within the modern paradigm of evidence-based practice was that parachutes could not be proved to prevent death after free fall. They even went so far as to encourage the proponents of evidence-based medicine to organize and participate in a double-blind, randomized, placebocontrolled, crossover trial of the parachute. Their broad point was that high-level evidence is not always available for all clinical situations and interventions; thus, some amount of common sense is important in contemporary medicine. We think this also represented our primary theme during the construction of this CCS: an attempt to develop consensus on a broad range of topics relevant to the clinical practice of foot and ankle surgeons using not only the best available evidence, but also a degree of clinical experience and common sense. Adherence to consensus statements will not ensure successful treatment in every clinical situation, and individual physicians should make their ultimate decisions using all available clinical information and circumstances with respect to the appropriate treatment of an individual patient. This CCS is on the general topic of perioperative management of the foot and ankle surgical patient, and its purpose is to address some of the preoperative, intraoperative, and post-operative considerations facing the foot and ankle surgeon in contemporary practice.

Materials and Methods

Creation of the Panel

Believing that the creation of CCSs would be beneficial to its members, the 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 to replace previous clinical practice guidelines (4-10). To move forward with this initiative, a formal consensus method process was undertaken. Seven experts in the field of foot and ankle surgery were initially sent an invitation by the ACFAS to participate on a panel to develop a CCS on "perioperative management." A 5-member panel was eventually convened and tasked with reviewing the published medical data and providing opinions about this topic. The panel was chaired by 1 member (A.J.M.) and assisted by ACFAS members and staff. During a several-month period, the panel members participated in an electronic mail dialog, conference calls, and a face-to-face meeting. The stated goal of the panel was to develop a series of CCS questions on the topic of perioperative management that might be of interest and value to foot and ankle surgeons, examine the current published data relating to these statement questions, and synthesize this information and our consensus opinions for ACFAS members and The Journal of Foot and Ankle Surgery® readers.

Development of CCS Questions

Our first task was the development of a series of CCS questions for inclusion. The topic of perioperative management is broad, and any number of subtopics and specific statement questions could be derived from it. Initially, through ACFAS member survey feedback, our collective clinical experience, and the results of an open discussion during an introductory conference call, we developed a preliminary list of approximately 35 to 40 specific topics within the realm of perioperative management to consider as consensus statement questions for inclusion in this CCS. The panel members subsequently performed preliminary data reviews and wrote brief synopses on these topics, attempting to answer the questions of (1) whether any guidelines exist on this topic; (2) whether any original investigations have been reported on this topic specific to the foot and ankle; and (3) whether any other original investigations have been reported on this topic specific to other medical specialties, but still potentially relevant. On a subsequent conference call, these initial reviews and synopses were discussed, and the panel made majority decisions resulting in the inclusion and development of 22 CCS questions (Table).

Formal Literature Review

Comprehensive reviews of the published data were then performed by the panel members and included searches of Medline[®], EMBASE[®], the Cochrane Database of Systematic Reviews, and manual searches of the references of the included articles. Although this was not a formal systematic review, each panel member conducted thorough literature searches using these databases in an attempt to answer specific questions on each topic. The data searches included at least all prospective clinical trials, retrospective clinical cohort analyses, and retrospective case series specifically involving foot and ankle surgery on the respective topics.

Consensus

A modified Delphi method was then used to attain consensus on the clinical questions by the members of the panel (11). The series of 22 statement questions was developed by the panel chairperson and sent to all panel members to review and answer. The answers were determined by the appropriateness of the statement question and were graded from 1 (extremely inappropriate) to 9 (extremely appropriate) using a Likert scale (12). Each panel member initially answered the questions anonymously, and the results were returned to the panel chairperson. The answers were reviewed, analyzed, and grouped from 1 to 3 (inappropriate), 4 to 6 (neither inappropriate nor appropriate), and 7 to 9 (appropriate). The results were summarized with basic descriptive statistics, kept anonymous, and distributed back to the panel members. At the face-to-face meeting, the questions and initial consensus results were reviewed and opened to discussion. Although an attempt was made to reach consensus

Table

Clinical consensus statement questions and results

Preoperative Cons	iderations							
1. Foot and ankle	surgical procedures s	should be considered	l low perioperative ri	sk.				
1 Extremely inappropriate	2	3	4	5	6	7	8	9 Extremely appropriate
2. Foot and ankle : 1 Extremely	surgeons should use 2	specific hair remova 3	l and preoperative sk 4	kin bathing protocols 5	s before elective foot 6	and ankle surgical p 7	procedures. 8	9 Extremely
inappropriate								appropriate
3. Preoperative mo 1 Extremely inappropriate	ethicillin-resistant <i>S</i> . 2	<i>aureus</i> decontaminal 3	tion protocols should 4	l be performed befor 5	re elective foot and a 6	nkle surgical proced 7	ures. 8	9 Extremely appropriate
4. Cigarette smoki 1 Extremely inappropriate	ng should be conside 2	ered a risk factor for 3	the development of a 4	complication followi 5	ng foot and ankle su 6	rgical procedures. 7	8	9 Extremely appropriate
5. An elevated bod	ly mass index should	l be considered a risl	k factor for the devel	opment of complicat	tions following foot a	and ankle surgical pr	ocedures.	
1 Extremely inappropriate	2	3	4	5	6	7	8	9 Extremely appropriate
6. Elevated glycate	ed hemoglobin shoul	d be considered an i	ndependent risk facto	or for the developm	ent of complications	following foot and a	nkle surgical proced	ures.
1 Extremely inappropriate	2	3	4	5	6	7	8	9 Extremely appropriate
7. A high preopera	ntive blood glucose le	evel should be consid	lered a risk factor for	the development of	f complications after	foot and ankle surgi	cal procedures.	0
Extremely inappropriate	2	,	-	5	0	,	0	Extremely appropriate
8. Vitamin D level	s should be assessed	before all foot and a	nkle arthrodesis pro	cedures (No consens	us).			
1 Extremely	2	3	4	5	6	7	8	9 Extremely
inappropriate								appropriate
Direct Perioperativ	ve Considerations							
9. Patients with op	oen foot and ankle fr	actures should be tre	eated with antibiotics	5.				
1 Extremely	2	3	4	5	6	7	8	9 Extremely
inappropriate								appropriate
 The urgency of extent. 	the treatment of op	en foot and ankle fra	ctures is dependent o	on a variety of factors	s including, but not li	mited to, time, anato	omic location, and fra	cture grade and
1 Extremely inappropriate	2	3	4	5	6	7	8	9 Extremely appropriate
11. Perioperative 1	nanagement of diab	etes medications war	rrants consideration	before foot and ankl	e surgical procedures	s.		
1 Extremely inappropriate	2	3	4	5	6	7	8	9 Extremely appropriate
12. Perioperative 1	management of rheu	matoid arthritis med	lications warrants co	nsideration before fo	oot and ankle surgica	l procedures.		
1 Extremely inappropriate	2	3	4	5	6	7	8	9 Extremely appropriate
13. Perioperative 1	nanagement of antic	oagulation medicatio	ons warrants conside	ration before foot a	nd ankle surgical pro	cedures.		
1 Extremely inappropriate	2	3	4	5	6	7	8	9 Extremely appropriate
14. Tourniquets ca	n be safely used for	most patients under	going foot and ankle	surgical procedures.				
1 Extremely inappropriate	2	3	4	5	6	7	8	9 Extremely appropriate
							(continu	ed on next page)

Direct Perioperative Considerations										
15. Prophylactic antibiotic therapy should be considered for foot and ankle surgical procedures.										
1 Extremely inappropriate	2	3	4	5	6	7	8	9 Extremely appropriate		
Postoperative Con	siderations									
16. Prophylactic po	ostoperative antit	hrombotic thera	py should be conside	ered for some patier	nts after foot and ank	de surgical procedure	es.			
1 Extremely inappropriate	2	3	4	5	6	7	8	9 Extremely appropriate		
17. Foot and ankle	surgeons should	consider a mult	imodal approach to p	ostoperative pain n	nanagement.					
1 Extremely inappropriate	2	3	4	5	6	7	8	9 Extremely appropriate		
18. Foot and ankle	surgical procedu	res involving ar	throdesis of the first i	ray should use a per	riod of non-weightbe	earing immobilization	L.			
1 Extremely inappropriate	2	3	4	5	6	7	8	9 Extremely appropriate		
19. Foot and ankle	surgeons should	use routine pos	toperative radiograph	ns in the absence of	a clinical indication	to assess osteotomy,	fracture, and/or arth	rodesis healing.		
1 Extremely inappropriate	2	3	4	5	6	7	8	9 Extremely appropriate		
20. Specific postop	erative incisional	l care protocols :	should be used by foo	ot and ankle surgeor	15.					
1 Extremely inappropriate	2	3	4	5	6	7	8	9 Extremely appropriate		
21. Foot and ankle	surgeons should	consider the us	e of bone stimulation	in cases of delaved	union and nonunior	n (No consensus).				
1 Extremely inappropriate	2	3	4	5	6	7	8	9 Extremely appropriate		
22. Foot and ankle	surgeons should	be aware of obj	ective measures of pa	atient satisfaction ar	nd postoperative out	comes.				
1 Extremely inappropriate	2	3	4	5	6	7	8	9 Extremely appropriate		

Values in bold indicate the consensus of the 5-member panel.

for all questions, it was not a requirement, and, in fact, contrary opinions were encouraged. All panel members participated in the creation of the CCS manuscript, the final draft of which was subsequently submitted to the ACFAS leadership for adoption and to *The Journal of Foot and Ankle Surgery*[®] for publication.

Results and Discussion

Preoperative Considerations

Consensus statement: The panel reached consensus that the statement "Foot and ankle surgical procedures should be considered low perioperative risk" was <u>neither appropriate nor inappropriate</u>.

Although it is likely that most foot and ankle surgical procedures should be considered low perioperative risk, for a number of situations our panel concluded that perioperative risk could increase to an elevated risk category.

Patient perioperative risk is traditionally thought of in objective terms as the development of a major adverse cardiac event (MACE) and, unsurprisingly, determining this risk is a complex and multi-factorial process. Recent guidelines published by the American College of Cardiology and the American Heart Association defined a "low risk" procedure as one in which the risk of a MACE is <1%, and an

"elevated risk" procedure is one in which the risk of MACE is $\geq 1\%$ (13). Note that the terms "moderate risk" and "high risk" were not used, and, instead, the term "elevated risk" was used to describe any procedure with risk of a MACE of > 1%.

Determining this risk is both patient and procedure dependent. In terms of procedure-specific considerations, surgeries have conventionally been categorized into "high-risk procedures" (including but not limited to intrathoracic procedures, intraperitoneal procedures, and some peripheral vascular surgeries), "intermediate-risk procedures" (including, but not limited to, head and neck surgery, major neurologic surgery, major orthopedic surgery, endovascular procedures, pulmonary procedures, major urologic procedures, and so forth), and "low-risk procedures" (including minor orthopedic procedures, dental procedures, breast procedures, minor urologic procedures, and so forth) (14). These categories carry a corresponding estimated risk of a MACE of approximately >5%, 1% to 5%, and <1% (14). Although no clear objective definition of the difference between a "major" and "minor" orthopedic procedure is available, as a reference, total hip and knee arthroplasty procedures are generally considered "major" (15). It is likely that most osseous foot and ankle specific procedures would be considered "minor orthopedic surgery"; however, several procedures (i.e., tibiotalocalcaneal arthrodesis with intramedullary reaming, total ankle arthroplasty, Charcot reconstruction) could be argued to rise to the level of "major orthopedic surgery." Furthermore,

foot and ankle limb preservation procedures can be performed in conjunction with higher risk endovascular procedures or open arterial bypass. The specific type of anesthetic technique used would also be expected to influence the procedure-dependent risk.

In terms of patient-specific considerations, several classification systems can be used to assist physicians in objectifying risk. Perhaps the most common is the American Society of Anesthesiologists (ASA) physical status (PS) classification, which defines normal healthy patients as type 1, patients with mild systemic disease as type 2, patients with severe systemic disease as type 3, patients with severe systemic disease that is a constant threat to life as type 4, moribund patients who are not expected to survive the operation as type 5, and patients who have been declared brain dead but undergoing organ harvest as type 6 (16). The ASA PS also includes a type E prefix for patients undergoing emergency procedures. A degree of subjectivity exists between type 2 "mild systemic disease" and type 3 "severe systemic disease." Conventionally "mild" conditions are "well-controlled" and "severe" conditions are "uncontrolled" (16). This might be most applicable with respect to the foot and ankle when considering the diagnoses of diabetes mellitus and hypertension. Although it is not uncommon for published case series to include ASA PS information within the patient demographic data, we identified 1 study specific to the foot and ankle that had evaluated the "safety" of an anesthetic technique (17). Their review examined 110 consecutive ASA PS level 3 and 4 patients undergoing limb preservation surgery, which speaks to the potential scenario of performing foot and ankle surgery on relatively high ASA PS patients.

Although the ASA PS classification is widely recognized and used, several other systems might offer a greater degree of specificity. The American College of Surgeons National Surgical Quality Improvement Program has developed a risk calculator with an online component (available at: http://riskcalculator.facs.org/). This risk calculator takes into account the type of procedure (using the Current Procedural Terminology code) and a number of patient factors, including age, functional status, ASA class, steroid use, systemic sepsis within 48 hours of surgery, the presence of diabetes, the presence of hypertension requiring medication, previous cardiac event, the presence of congestive heart failure, the presence of dyspnea, smoking history, a history of chronic obstructive pulmonary disease, the need for dialysis, the presence of acute renal failure, and body mass index (BMI) (18). The calculator then produces an objective number for the estimated risk of a serious complication, any complication, pneumonia development, a cardiac complication, a surgical site infection (SSI), a urinary tract infection, venous thromboembolism, renal failure, a return to the operating room, death, discharge to a rehabilitation facility, and the predicted length of stay. For example, a 65-year-old male with a history of insulindependent diabetes, hypertension, smoking, and obesity undergoing an emergency bimalleolar ankle fracture with open reduction and internal fixation (ORIF) carries a 10.0% risk of a serious complication, a 12.1% risk of any complication, a 1.3% risk of a cardiac complication, and a 0.8% risk of death. This, again, at least speaks to the potential for foot and ankle surgery to carry an elevated risk. Another resource with an online calculator is the revised cardiac risk index (available at: http://www.mdcalc.com/revised-cardiac-riskindex-for-pre-operative-risk/). This also provides an objective measurement of estimated cardiac risk by accounting for high-risk versus intermediate- or low-risk procedures, a history of ischemic cardiac disease, a history of congestive heart failure, a history of cerebrovascular disease, creatinine level, and preoperative treatment with insulin (19). Both of these tools emphasize the broader point that the term "medical clearance" for the operating room is a misnomer. All surgeries are associated with some perioperative risk, and the goal of a preoperative medical evaluation should be to objectify the risk, with the understanding that the risk can never be completely eliminated.

If it is accepted that a "low-risk" procedure is one in which the incidence of a MACE is <1%, we can conclude that most, but not all, foot and ankle surgical procedures are likely to be low risk.

Consensus statement: The panel reached consensus that the statement "Foot and ankle surgeons should use specific hair removal and preoperative skin bathing protocols before elective foot and ankle surgical procedures" was <u>neither appropriate</u> nor inappropriate.

We identified no consensus within our panel for a clear benefit or detriment to specific hair removal and/or bathing protocols before elective foot and ankle surgery. The panel did not conclude that these techniques were inappropriate; rather, we did not identify a clear positive or negative effect to support consistent implementation of specific preoperative measures.

The preoperative removal of hair from the surgical field is a practice that has been used for many years as a method to decrease the potential for surgical site contamination and, therefore, SSIs. However, contemporary debate has ensued over the effectiveness of hair removal in decreasing SSIs and an increasing body of evidence of some possible negative effects that hair removal might have as it relates to postoperative complications. Evidence on this topic has primarily been derived from other surgical specialties and not specifically from the foot and ankle specialty. A 2011 Cochrane review on preoperative hair removal found "no statistically significant effect on surgical site infection rates" (20). In another meta-analysis of 19 randomized controlled trials, shaving with a razor was significantly associated with a more frequent occurrence of SSIs compared with clipping, chemical depilation, or no hair removal (21). Another comparative analysis evaluated patients undergoing general surgery procedures, specifically comparing hair removed with a razor to hair removed with a depilatory cream and found a significant difference in postoperative infection rates (12.8% versus 2.5%, respectfully) (22). An increasing number of opponents to using a razor for hair removal have argued that it disrupts the normal skin flora homeostasis, can disrupt the bacteria present in hair follicles, and that the use of contaminated razors could lead to postoperative infection (23). We concluded that hair can likely be safely removed preoperatively, although preferably with a clipper or depilation cream and not a razor.

Similarly, the practice of preoperative bathing or skin cleansing before the formal surgical preparation is a commonly performed practice that does not appear to have clear supporting evidence of a substantial benefit. A prospective cohort study was reported within the foot and ankle literature evaluating the effects of a single preoperative chlorhexidine foot bath 20 minutes before elective foot surgery and revealed a decrease in positive culture results but no difference in the incidence of SSIs between the control and intervention groups (24). Another Cochrane review of 10,157 participants did not demonstrate substantial evidence for preoperative showering or bathing with chlorhexidine compared with other products such as soap to reduce the incidence of SSIs (25). Additionally, a separate meta-analysis reviewed 16 trials with 17,932 patients and found that chlorhexidine bathing did not reduce the incidence of SSIs compared with detergent, soap, placebo, or no bathing protocol (26).

Consensus statement: The panel reached consensus that the statement "Preoperative methicillin-resistant *Staphylococcus aureus* decontamination protocols should be performed before elective foot and ankle surgical procedures" was <u>neither appropriate nor inappropriate</u>.

Although a fair amount of clinical evidence supports preoperative methicillin-resistant *Staphylococcus aureus* (MRSA) decontamination

protocols before elective surgery, our panel did not reach consensus that this was universally appropriate for the foot and ankle. The panel did not conclude that these techniques were inappropriate but also did not identify a clear positive or negative effect of consistently implementing this specific preoperative measure.

This is a topic that on the surface would appear to make intuitive sense. Several sources, including the Centers for Disease Control and Prevention have recognized that preoperative colonization with S. aureus (SA) is a risk factor for the development of a SSI (27–29), and this might be even more applicable for those colonized with MRSA. Kalra et al (30) found that rates of MRSA SSI development were significantly greater in those preoperatively colonized with MRSA compared with those not colonized (1.86% versus 0.20%; p < .0001). Both Kalra et al (30) and Gupta et al (31) found an approximate 9 times greater odds of developing a MRSA SSI in those preoperatively colonized with MRSA. Furthermore, a substantial percentage of patients undergoing lower extremity orthopedic surgery are likely to be colonized with either SA and/or MRSA. An investigation by Price et al (32) of 284 patients undergoing orthopedic surgery, including the foot and ankle, found that 86 (30%) were colonized with either SA or MRSA. Although 30% is a substantial proportion of patients, we believe it is important to note that this still represents a minority of patients.

However, despite knowledge that some of our patients might be colonized with SA and MRSA and that this might increase the risk of a postoperative infection, preoperative decolonization protocols might not have a significant preventative effect on the development of a SSI. In the study by Price et al (32), low rates of SSI were observed whether or not the patients were colonized and whether or not the patients underwent decolonization. Additionally, the investigators did not identify a specific risk with procedures involving the foot and ankle. In another study of patients undergoing elective orthopedic surgery, Kim et al (33) did not find a significant difference between SSI rates among noncarriers (0.14%) and MSSA carriers (0.19%). In another prospective study of patients undergoing cardiac, hip, or knee surgery, no significant differences were noted in SSI rates among patients who had undergone a decontamination process (0.20% rate of infection) compared with those not undergoing decontamination (0.35% rate of infection) (34).

In contrast, other studies seem to point toward a positive effect of screening and decontamination protocols. Hacek et al (35) studied 912 patients who were screened before hip or knee replacement, 75% of whom were negative for SA colonization and demonstrated a 0.6% rate of infection. The 25% of patients who were SA carriers and underwent decontamination before surgery had a 1.3% rate of infection. The SSI rate for the patients who were neither screened nor treated was 1.7%. Chen et al (36,37) in 2013 recommended decolonization for patients undergoing total joint replacement because of the significant reduction in MRSA infection after decontamination (4.6% decreased to 0%).

Although studies have advocated the use of decontamination in cardiac, spinal, and total joint replacement procedures, little conclusive evidence is available to support the universal use of such practices in general or for the foot and ankle specifically. Certainly, some reduction in postoperative infection rates might occur when SA or MRSA carriers undergo decontamination; however, this might not always be statistically or clinically significant. Moreover, in our review of the published data, decontamination protocols often varied considerably among practices and hospitals. Many of the protocols recommended the use of intranasal mupirocin twice daily for 5 days, with chlorhexidine showers for 5 days before surgery (33,34,36–40). Other protocols involved used mupirocin for 5 days, but chlorhexidine bathing was used for 1 day before surgery (41). We did not identify a specific "standard of care" decontamination protocol and it would

likely be difficult to develop one owing to the variations in patient populations and microbiologic demographics.

Consensus statement: The panel reached consensus that the statement "Cigarette smoking should be considered a risk factor for the development of complications after foot and ankle surgical procedures" was appropriate.

The numerous negative effects of cigarette smoking on the physiology of the human body, in addition to the increased perioperative risks of patients who smoke, have been well documented (42–48). This is primarily due to the effects of nicotine and carbon monoxide resulting in vasoconstriction, decreased microperfusion, decreased tissue oxygenation, endothelial damage, increased blood viscosity, and hypercoagulation (42). We reached consensus that tobacco use in the form of cigarette smoking should be considered a risk factor for the development of complications after foot and ankle surgical procedures and that patients who smoke should be educated on the potential complications of this activity before undergoing foot and ankle surgery.

We identified several investigations examining foot and ankle surgical outcomes in relation to cigarette smoking. Krannitz et al (49) found that in active smokers, a distal first metatarsal osteotomy for the surgical correction of hallux abductovalgus required 1.73 times longer to radiographically heal compared with nonsmokers. In another investigation examining elective forefoot surgery, smokers were 4.3 times as likely to develop any complication and demonstrated greater rates of delayed union, infection, delayed wound healing, and persistent postoperative pain compared with nonsmokers (50). Furthermore, increased rates of wound complications and infection have been associated with smoking in patients after ORIF of calcaneal fractures (51) and ankle fractures (52,53). Greater nonunion rates in smokers were also observed after subtalar arthrodesis (54).

What might be less certain is the effect of preoperative smoking reduction or cessation on surgical outcomes. A study evaluating patients undergoing general surgery and total joint arthroplasty demonstrated that smoking cessation 4 weeks before surgery and extending for 4 weeks after surgery resulted in an overall decrease in complications by 20% (55). Another study evaluating patients undergoing hip and knee arthroplasty revealed a decrease in all postoperative complications by 34% and a decrease in wound-related complications by 26% after a 6- to 8-week preoperative smoking cessation protocol (56). In an investigation evaluating incisional healing after cutaneous biopsy, smoking cessation 4 weeks before the procedure significantly decreased the rate of infection (57). That study also suggested that the duration of smoking cessation of 4, 8, or 12 weeks did not show any significant difference in terms of the occurrence of postoperative infection. Additionally, a study of colorectal patients showed no effect on the postoperative complication rate when the smoking cessation programs were initiated <4 weeks in advance (58).

We concluded that substantial evidence exists that cigarette smoking is associated with postoperative complications after foot and ankle surgery and that, as a profession, we should relay these risks to our patients. A survey of the British Orthopaedic Foot and Ankle Society revealed that only 9% of surgeons documented the smoking habits of their patients on consent forms and warned them of the risk of potential complications and only 23% reported taking any preventative perioperative measures (59). Although we cannot conclude that a smoking history is an absolute contraindication to a specific foot and ankle surgery, our consensus is that tobacco use should be considered a relative risk factor for the development of complications. Patients should be educated regarding the specific risks of tobacco use, and, when possible, smoking should be stopped at least several weeks before the performance of elective foot and ankle surgical procedures.

Consensus statement: The panel reached consensus that the statement "Elevated body mass index should be considered a risk factor for the development of complications after foot and ankle surgical procedures" was <u>neither appropriate nor</u> inappropriate.

Obesity has been described as a global epidemic, and its effect on the development of some foot and ankle pathologic features is well established (60-72). However, the specific effect of obesity on complications after foot and ankle surgical procedures is less certain. We identified little evidence of an absolute contraindication to foot and ankle surgery in the setting of patient obesity or a BMI threshold over which specific foot and ankle surgical procedures should not be performed. However, the conclusion of our panel was that the presence of an elevated preoperative BMI is likely to carry at least some degree of risk for the development of some postoperative complications, including a thrombotic event, postoperative infection, and postoperative wound healing complications. This increased risk should be recognized and appreciated by both the surgeon and the patient.

Although many investigations have evaluated the association of BMI and surgical complications in their secondary analyses (51,73-84), we identified 20 studies with hypotheses specifically addressing the effect of obesity on lower extremity surgery (85-104). These included studies on total ankle arthroplasty, pilon fracture ORIF, ankle fracture ORIF, calcaneal fracture ORIF, ankle arthrodesis, Achilles tendon repair, ankle arthroscopy, flatfoot reconstruction, and elective forefoot reconstruction. Interestingly, 9 of these studies showed an association of obesity with the development of postoperative complications, including postoperative wound complication, postoperative infection, the need for revision surgery, the loss of articular reduction, an increased operative time, longer healing times, implant failure, decreased implant survival, venous thromboembolism, an increased length of stay, and general medical complications (including pulmonary embolism, myocardial infarction, respiratory failure, cerebral vascular event, pneumonia, acute renal failure, cholecystitis) (85-93), but the remaining 11 investigations did not show such an association (94-104).

Several of these studies involved database analyses with relatively large cohorts, and we observed that those larger studies tended to show the development of postoperative complications in the obese. Burrus et al (87) reviewed 18,948 patients undergoing Achilles tendon repair. Of those, 2962 were obese. The study found a greater rate of postoperative wound complication, postoperative infection, and other medical complications in the obese group. Werner et al (89) reviewed 23,029 patients undergoing total ankle arthroplasty or ankle arthrodesis and found that obese patients were more likely to experience postoperative infection, postoperative stiffness, and a range of medical complications. Bostman et al (93) found that a greater BMI was associated with a loss of reduction requiring reoperation in 3061 patients undergoing ankle ORIF. Chen et al (88) observed that obese patients were more likely to require revision hallux abductovalgus surgery in a series of 452 participants. In contrast, however, Stewart et al (94) found no difference in outcomes associated with obesity in a series of 633 forefoot surgeries.

This is an area in which our profession will likely learn more in the future and appears to be of contemporary interest to investigators, because most studies we identified specifically examining the effect of obesity on surgical outcomes have been published within the past 5 years. We also believe that it is important to note that although it is possible that obesity has a direct effect on surgical outcomes, it is also possible that obesity simply serves as a surrogate for other confounding factors.

Consensus statement: The panel reached consensus that the statement "An elevated glycated hemoglobin should be considered an independent risk factor for the development of complications after foot and ankle surgical procedures" was <u>appropriate</u>.

The association between hyperglycemia and postoperative complications has been well documented after many types of surgical procedures (105–115). Poor long-term glucose control, as measured by glycated hemoglobin, has been recognized as a risk factor for the development of adverse outcomes after major surgeries, such as vascular and coronary artery procedures (105,106,109,114). In the foot and ankle specifically, poorly controlled and complicated diabetes has also been shown to be significant risk factors for both postoperative soft tissue and bone healing complications (112-114,116-121). Surgeons should be aware of this when recommending and performing foot and ankle surgery, and our patients should also be made aware that this increases the potential for postoperative complications. We also recommend that foot and ankle surgeons perform glycated hemoglobin measurement before performing elective surgery. It should be noted that this is in contrast to a random glucose measurement, which might be influenced by a variety of preoperative stresses and other factors.

Myers et al (116) have shown an association between an elevated glycated hemoglobin level and postoperative infection after hindfoot and/or ankle arthrodesis. Younger et al (120) also found that the most significant factor associated with successful transmetatarsal amputation in diabetic patients was blood glucose control measured by the glycated hemoglobin. They compared the mean glycated hemoglobin levels between a failed and successful group in their retrospective study of 42 patients. The mean level in the failed group was 10.6% and that of the successfully healed group was 7.8%. Lepore et al (122) evaluated patients admitted to the hospital for foot ulceration. In their cohort study, patients who had undergone major amputation, minor amputation, and no amputation were compared in terms of glycated hemoglobin level. They found that patients who had undergone amputation had a significantly greater glycated hemoglobin level than did those who had not undergone amputation. In particular, those who had undergone major amputation had a mean glycated hemoglobin level of 10% and those with minor amputation or no amputation had a mean glycated hemoglobin level of 9% and 8%, respectively. Humphers et al (123) investigated whether the glycated hemoglobin level was independently associated with postoperative complications in a retrospective cohort study. After adjusting for other covariates, they found that the glycated hemoglobin level was independently associated with postoperative soft tissue complication, including infection and wound dehiscence. Jupiter et al (124) assessed the relationship between the glycated hemoglobin levels and the rate of postoperative infection in the foot and ankle. They explored the general trends relating to the infection rates and preoperative glycated hemoglobin levels (124). Their preliminary analysis indicated that infection rates increased as the glycated hemoglobin level increased to 7.3% but increased rapidly with glycated hemoglobin values of 7.3% to 9.8% before leveling off.

The incidence of bone healing complications in diabetic patients is also high after foot and ankle surgeries (117,125–131). Although this association of hyperglycemia has been well documented (117,132–140), little clinical information is available regarding which diabetes-related comorbidities directly affect bone healing at a biochemical level. Shibuya et al (141) showed that approximately 1 of 4 diabetic patients had \geq 1 bone healing complications. A bone healing complication was defined as \geq 1 of nonunion, malunion, delayed union, or surgical- or trauma-induced Charcot neuroarthropathy. They found that a patient with a glycated hemoglobin level >7% had roughly 3 times greater odds of developing a bone healing complication than those with a glycated hemoglobin level <7%.

Most often in studies assessing the effect of long-term glycemic control on postoperative outcomes, the glycated hemoglobin level is used as the metric for control. Comparing well-controlled versus poorly controlled diabetics, many use a cutoff level of 7% to categorize good versus poor control, based on the American Diabetes Association recommendation. The American Diabetes Association recommendation is derived from several studies assessing intensive glycemic control therapy in reducing the long-term complications associated with diabetes, including the Diabetic Control and Complications Trial Research Group (DCCT), UK Prospective Diabetes Study (UKPDS), Action in Diabetes and Vascular Disease: Preterax and Diamicron Modified Release Controlled Evaluation (ADVANCE), Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial, and Veterans Affairs Diabetes Trial (VADT) (142-147). Summarizing these findings, the benefits of lowering the glycated hemoglobin level in patients with diabetes in terms of the reduction of diabetes-related macro- and microvascular complications appear to be substantial. However, in decreasing the glycated hemoglobin level to <7%, the benefits seem to diminish, and a risk also exists of adverse events (including death, weight gain, and hypoglycemic episodes) in this range. It should also be noted that intensive glycemic control could be a risk itself, especially in a chronically uncontrolled diabetic patient population. Caution should be taken when attempting aggressive preoperative hyperglycemic control.

As recommended by many, including the American Diabetes Association, a glycated hemoglobin threshold of 7% is known to be a relatively good reference point, at least in terms of general health (148). However, definite evidence on foot and ankle-specific surgical procedures is still lacking. Furthermore, we believe it is important to note that an absolute threshold line might also depend on the type of procedure to be performed. Our panel concluded that elevated glycated hemoglobin values should be considered a risk factor for the development of complications after foot and ankle surgical procedures, that foot and ankle surgeons should check the glycated hemoglobin value before recommending and performing elective surgery in patients with diabetes, and that patients with an elevated glycated hemoglobin level should be made aware of their specific perioperative risks. However, we do not recommend a specific glycated hemoglobin threshold for the performance of elective foot and ankle surgical procedures.

Consensus statement: The panel reached consensus that the statement "A high preoperative blood glucose level should be considered a risk factor for the development of complications after foot and ankle surgical procedures" was <u>neither appropriate</u> nor inappropriate.

Although exceedingly abnormal preoperative serum glucose levels are a general contraindication for elective surgery, little evidence is available to support that it has a consistent and direct effect on foot and ankle surgical outcomes. The reason that it might not be as robust a predictor as the glycated hemoglobin value might be because serum glucose levels can be affected by multiple factors, such as nil per os (or "nothing by mouth") status, surgical stress, and other day of surgery medications (149,150). It should also be noted that an attempt to rapidly decrease an elevated serum glucose level on the day of surgery could result in hypoglycemia and increased cardiovascular risk (151,152). In general, intensive glucose control and a low serum glucose level could be more harmful than a moderately elevated serum glucose level on the day of the surgery in diabetic patients (153–155).

We recognize that several studies have demonstrated an increased occurrence of SSIs associated with high preoperative serum glucose levels (111,156–158) but concluded that high serum glucose levels on the day of surgery might primarily be a confounder for poor longterm glycemic control. Therefore, one should understand that although the perioperative glucose level is unstable, sensitive, and easily affected by many factors on the day of surgery, it should primarily raise a concern regarding the patient's long-term glucose control and other underlying medical conditions. We identified no definitive evidence of a threshold value for the serum glucose level over which foot and ankle surgical procedures should not be performed.

Additionally, some emergency situations exist in which the risk of delaying surgery outweighs the risk of performing the operation with a high preoperative serum glucose level. In the management of abscess and cellulitis, for example, the elevated glucose level might be due to the infection itself; thus, the serum glucose level cannot be easily managed without surgical debridement, incision, and drainage. The anesthesia and surgical risks should be discussed among the surgical team in these situations.

Consensus statement: The panel was <u>unable to reach consensus</u> on the statement "Vitamin D levels should be assessed before all foot and ankle arthrodesis procedures."

The panel was unable to reach consensus on the routine assessment of vitamin D levels before elective foot and ankle arthrodeses. The members of the panel who believed this was an inappropriate practice pointed to evidence demonstrating a high prevalence of hypovitaminosis D in acute fractures and other cohorts of otherwise "normal" individuals (159-163). Although the positive effects of vitamin D combined with calcium supplementation in fracture prevention in an elderly population has been well established (164–166), the effect of vitamin D on bone healing after injury or surgical intervention has not been as extensively studied. Although some studies have indicated a high incidence of vitamin D deficiency in patients with nonunion, these studies have often lacked a control group for comparison (162,167). Even less evidence is available to show that normalization of serum vitamin D in a deficient patient can assist in the prevention or treatment of nonunion. Therefore, it is uncertain whether a routine preoperative serum vitamin D evaluation is indicated before foot and ankle surgical procedures for assessment of bone healing potential and prevention of nonunion.

Further evidence has been provided by Haining et al (168), who compared the vitamin D levels in 15 patients with nonunion with 15 age- and gender-matched controls. The serum 25-hydroxyvitamin D, 1,25-dihydroxyvitamin D₃, and 24,25-dihydroxyvitamin D₃ levels were compared between these 2 groups (168). They did not show any difference in the vitamin D levels between the nonunion and the matched control groups (168). Boszczyk et al (169) conducted a casecontrolled, cross-sectional study comparing the prevalence of vitamin D deficiency between patients with an idiopathic fracture healing impairment versus patients without such a complication. A total of 35 patients from each group were enrolled in their retrospective study. No differences were observed in the prevalence of vitamin D deficiency between the 2 groups. The overall prevalence of hypovitaminosis D was 86% in their cohort. Pourfeizi et al (170) compared the serum vitamin D levels in tibial nonunion cases and normal union cases. Their case-control study enrolled the control group from normal union patients matched by treatment type, age, gender, and BMI. They were considered vitamin D deficient when the serum 25hydroxyvitamin D level was <23 nmol/L. They found that the prevalence of vitamin D deficiency was 30% in the matched control group and was 60% in the nonunion group. Ravindra et al (171) in their longitudinal study of 133 elective spinal fusions in the United States showed no association between vitamin D deficiency (serum 25dihydroxyvitamin D level <20 ng/mL) and nonunion on bivariate analysis. However, it became an independent factor (odds ratio 3.5) for nonunion after adjusting for age, fusion length, and gender in a multiple regression analysis. In their cohort, 21 of the 133 patients (16%) were patients with nonunion. Nine of the 21 patients in this group had a vitamin D deficiency. They also showed that the median time to union was significantly longer in the vitamin D-deficient group on Kaplan-Meier survival analysis. Doetsch et al (172) in a randomized clinical trial examined the effect of vitamin D and calcium supplementation (oral 800 IU of vitamin D₃ and 1 g of calcium) on osteoporotic proximal humerus fracture healing. They found that the mineral density of the shoulder in the group with vitamin D and calcium supplementation was significantly greater statistically at 6 weeks. No difference was found at other time points (0, 2, and 12 weeks).

Because many patients in the control groups of these and other investigations have vitamin D deficiency, the incidence of this deficiency is also believed to be high in the normal population (173). Because of this, the results have been mixed in assessing the association of vitamin D deficiency and bone healing complications in the available case-control studies. Furthermore, no substantial evidence is available that supplementation of vitamin D positively affects bone healing after foot and ankle surgery. Further still, vitamin D deficiency is known to confound with many factors, such as older age, BMI, smoking, and heart and vascular diseases (162,173–175). The casecontrol studies accounted for some of these factors; however, it is difficult to control for all the variables without randomization.

The members of the panel who believed this was an appropriate practice argued that vitamin D deficiency could also affect aspects of postoperative outcomes other than bone healing (176–180). Warner et al (176) showed significantly lower clinical outcomes, as evidenced by the Foot and Ankle Outcome Score, after ORIF of ankle fractures in those patients with a preoperative vitamin D level <20 ng/mL. Lee et al (177) found that more patients experienced moderate to severe pain after knee arthroplasty when deficient in vitamin D.

Additionally, evidence has shown an association of vitamin D and bone healing in the published data (167,172,181–186). Vitamin D is crucial for ideal bone formation and metabolism and overall health (172,181,182). Vitamin D deficiency has been linked to several health issues, including cardiovascular disease, cancer, autoimmune diseases, diabetes mellitus, hypertension, and multiple sclerosis (186– 188). In addition, vitamin D deficiency has been associated with specific bone metabolic diseases, including osteoporosis, osteomalacia, and poor bone growth. Vitamin D deficiency has also been cited as a common cause of stress fracture development and poor fracture healing (181,183,184).

During the past 2 decades, interest has been renewed in vitamin D and its role in bone and fracture healing, and it has been clearly established that the prevalence of hypovitaminosis D in the general population is high (167,185,189–191). The Centers for Disease Control and Prevention conducted a study identifying a prevalence rate of approximately 67% using a serum 25-hydroxyvitamin D concentration of <30 ng/mL as a threshold. Another study of young adults found a hypovitaminosis D prevalence rate of 51% (<30 ng/mL) (191). Several studies have evaluated vitamin D levels in patients undergoing orthopedic procedures. One study identified a vitamin D deficiency rate of 57% in patients who experienced nonunion after surgery (160). Smith et al (162) revealed a hypovitaminosis D prevalence rate of 47% in patients with low-energy ankle fractures.

Although we did not reach consensus that it is directly related to the postoperative outcome of foot and ankle arthrodeses, measurement of the preoperative vitamin D level might provide both the patient and the physician with an unrecognized component of the patient's overall health.

Direct Perioperative Considerations

Consensus statement: The panel reached consensus that the statement "Patients with open foot and ankle fractures should be treated with antibiotics" was appropriate.

Our panel reached consensus that the immediate use of intravenous antibiotics, in conjunction with appropriate fracture debridement and stabilization, has been shown to be a primary key in reducing infection rates after lower extremity open fractures. This general treatment recommendation with respect to open fractures has been relatively unchanged since the 1970s, when Gustilo and Anderson (192) demonstrated greater rates of deep infection in grade 3 fractures when no antibiotics were used compared with those who received antibiotics. In the same decade, Patzakis et al (193) reported a significant infection rate of 14% in patients without antibiotic treatment versus 2.3% when intravenous antibiotics were used.

Most evidence and recommendations have pointed to the immediate initiation of intravenous antibiotics, with continuation extending approximately 48 to 72 hours after wound closure (194–199). In cases in which the wound cannot be closed primarily, the recommendation is to continue with intravenous antibiotics for 24 to 48 hours after eventual wound closure (194–196,199). The use of antibiotics for >72 hours after closure has not been found to provide additional benefit. In a study by Al-Arabi et al (200), the length of antibiotic therapy did not appear to have a significant effect on postoperative infection; rather, the fracture grade and degree of soft tissue injury were the most significant factors associated with the occurrence of infection. This finding has been supported by the results of other studies (195,201–203). Many contemporary studies have reported on the use of cefazolin for grade 1 and 2, with the addition of gentamicin for grade 3 open fractures (192,195,204–207).

Consensus statement: The panel reached consensus that the statement "The urgency of the treatment of open foot and ankle fractures is dependent on a variety of factors including, but not limited to, time, anatomic location, and fracture grade and extent" was <u>appropriate</u>.

A review of the contemporary data indicated that most open foot and ankle fractures are likely not an emergent surgical situation but rather should be considered an urgent condition. A study by Skaggs et al (208) found that the rate of postoperative infection for pediatric patients undergoing debridement within 6 hours of the injury was 2.5%. However, patients who underwent debridement after 6 hours actually had a lower rate of infection at 1.6%, although this difference was not statistically significant (208). Another study by Harley et al (209) also failed to demonstrate that the time to debridement was a factor associated with development of a postoperative infection. The strongest predictors for deep infection in their study were fracture grade and lower extremity fracture location. The interval to formal debridement among the 215 patients in the study by Harley et al (209) ranged from 1 hour and 35 minutes to 30 hours and 40 minutes. Similar results of higher infection rates with lower extremity open fractures were observed by Malhotra et al (195) compared with upper extremity fractures. A similar study by Al-Arabi et al (200) noted that the only factor associated with incidence of postoperative infection was the fracture grade. Among their 237 patients, the infection rate was 7.8% for those who underwent debridement within 6 hours versus 9.6% if the debridement occurred after 6 hours. In 2008, Tripuraneni et al (210) showed similar infection rates, regardless of the interval to debridement. The patients who underwent debridement within 6 hours had an infection rate of 10.8%, and those who waited 6 to 12 hours before debridement had an infection rate of 9.5%. Counterintuitively, the patients who had undergone debridement >12 hours after the injury had an even lower infection rate of 5.6%. The investigators concluded that in the absence of gross contamination, early informal irrigation should be performed on an urgent basis, along with the initiation of intravenous antibiotics, and that formal debridement can wait until later (210). Several studies have further supported the idea that the degree and severity of injury has a greater impact on postoperative infection development than the interval to formal debridement (195,202,206,211–214).

Our panel reached consensus that the treatment of open fractures in the foot and ankle always represents an urgent surgical matter but not necessarily an emergent one. We identified little clinical evidence in support of the so-called 6-hour "golden window." Certainly, open fractures warrant immediate antibiotic administration, bedside irrigation, and fracture stabilization; however, the timing of formal irrigation in an operating room might not have significant impact on the development of postoperative infections.

Consensus statement: The panel reached consensus that the statement "Perioperative management of diabetes medications warrants consideration before foot and ankle surgical procedures" was <u>appropriate</u>.

The panel reached consensus that foot and ankle surgeons should consider and be cognizant of the medications prescribed for the treatment of diabetes mellitus in the perioperative period. However, the panel also concluded that this specific management was probably best deferred to the patient's primary care physician or endocrinologist when possible. Because patients with diabetes have an increased risk of morbidity and mortality during the perioperative period, maintaining appropriate glycemic control can minimize many of the consequences of hypoglycemia and hyperglycemia associated with surgery (149,151,215,216). The overall goal of the outpatient treatment of the diabetic patient should be focused on maintaining steady blood glucose levels and avoiding hypoglycemia, hyperglycemia, and other diabetes-related complications.

If lacking in specific consensus, some general themes were found in terms of the perioperative management of diabetes medications. Regarding insulin, the general recommendations include withholding short- or rapid-acting insulin and reducing intermediate- or longacting basal insulin by 50% to 75% on the morning of surgery (148,149,151,215,217,218). Most oral glycemic agents such as thiazolidinediones and sulfonylureas can also be discontinued on the morning of surgery (149,217). Also, some have proposed withholding metformin 1 to 2 days before surgery owing to concerns of possible lactic acidosis (149,215,217). We found that evidence-based recommendations for the perioperative management of diabetic medications were somewhat limited (217–221).

Consensus statement: The panel reached consensus that the statement "Perioperative management of rheumatoid arthritis medications warrants consideration before foot and ankle surgical procedures" was appropriate.

The panel reached consensus that foot and ankle surgeons should consider and be cognizant of the medications prescribed for the treatment of rheumatoid arthritis in the perioperative period but also concluded that this specific management was probably best deferred to the patient's primary care physician or rheumatologist when possible. The obvious concern is that the medications prescribed for the management of rheumatoid arthritis (including tumor necrosis factor [TNF]- α inhibitors, disease-modifying antirheumatic drugs, nonsteroidal anti-inflammatory drugs, and steroids) aim to suppress immune and inflammatory function and that this could result in an increased risk for the development of healing complications and postoperative infection.

Although many investigations have specifically examined foot and ankle surgery in the presence of rheumatoid arthritis, few have performed a comparative analysis or specifically examined the effect of perioperative medication management on patient outcomes (222-236). In 2003, Bibbo et al (222) retrospectively reviewed 725 foot and ankle procedures in 104 patients by dividing the cohort into those who had developed a postoperative complication (n = 33) and those who had not (n = 71). They observed no differences between the 2 groups with respect to medications. Bibbo and Goldberg (223) subsequently evaluated 2 groups of patients with rheumatoid arthritis undergoing elective foot and ankle surgery. One group was prescribed TNF- α inhibitor medications and continued these as originally prescribed throughout the perioperative course and another group did not receive TNF- α inhibitors (223). They observed no differences in healing or infectious complications between the 2 groups and concluded that these "agents may be safely administered in the perioperative period in the usual fashion" (223). Although 2 other studies identified delayed healing complications in 18% and 20.8% of rheumatoid arthritis patients undergoing forefoot surgery, this was only found to be associated with the duration of rheumatoid arthritis and longer operating times and not with medication use (224,225).

Several other review studies have addressed the need for stress dosing of prednisone and maintenance versus discontinuation of medications, including TNF- α inhibitors, disease-modifying anti-rheumatic drugs, nonsteroidal anti-inflammatory drugs, and steroids (237–243). Bibbo (237) has suggested a specific algorithm such that patients can continue regular dosing unless they have a documented history of wound healing complications, are undergoing surgery for an active infection, or develop an infection in the postoperative period. Our panel was in general agreement with these recommendations for most patients with rheumatoid arthritis.

Consensus statement: The panel reached consensus that the statement "Perioperative management of anticoagulation medications warrants consideration before foot and ankle surgical procedures" was appropriate.

The panel reached consensus that foot and ankle surgeons should consider and be cognizant of anticoagulation medications in the perioperative period but also concluded that this specific management was probably best deferred to the patient's primary care physician, cardiologist, or vascular surgeon when possible. This includes management of both vitamin K antagonists and antiplatelet therapies.

The American College of Chest Physicians (ACCP) has published guidelines for the perioperative management of antithrombotic therapy, with the most recent edition published in 2012 (244). We recommend that foot and ankle surgeons familiarize themselves with these guidelines. We have provided a short summary of their recommendations. When considering elective outpatient foot and ankle surgical procedures, these guidelines recommend stopping vitamin K antagonists 5 days before surgery and resuming the antagonist 12 to 24 hours after surgery when hemostasis has been achieved. Bridging anticoagulation is recommended for patients at high risk of thromboembolism. This includes those with a mechanical heart valve, atrial fibrillation, or a history of venous thromboembolism. In patients with a relatively low risk of thromboembolism, bridging was not recommended. For patients taking aspirin and undergoing minor procedures, it was recommended that the aspirin should be continued around the time of surgery rather than discontinuing it for 7 to 10 days before the procedure. In patients with a coronary stent who require surgery, it is recommended that surgical intervention should be delayed 6 weeks after bare metal stent placement and 6 months after drug-eluting stent placement. If surgery is required during those periods, it is recommended that the antithrombotic therapy be continued through the surgery rather than stopping the therapy (244).

However, some recent investigations of which foot and ankle surgeons should be aware have challenged these guidelines. In a review of patients undergoing total knee and total hip arthroplasty, major surgical bleeding was noted in 12 of 13 patients who had received perioperative antithrombotic bridging (245). Of the bridging patients, 69% developed a hematoma (compared with only 10.2% of the control group). Also, 54% of the bridging patients required transfusion (compared with 8.3% of the control group) (245). Both of these differences were statistically significant. A second study evaluating total hip and knee arthroplasty patients revealed that patients who received anticoagulant bridging experienced a significantly greater bleeding-related complication rate and a significantly lower postoperative serum hemoglobin level compared with those who received prophylaxis (246). We identified no foot and ankle studies that evaluated perioperative complications secondary to the ACCP guidelines. We also could not identify studies that investigated the bleeding risk of foot and ankle surgery performed while maintaining antithrombotic therapy through the perioperative period.

Consensus statement: The panel reached consensus that the statement "Tourniquets can be safely used for most patients undergoing foot and ankle surgical procedures" was appropriate.

A number of studies in the literature support the use of tourniquets in foot and ankle surgery, and our panel reached consensus that this is an appropriate practice for most patients. Surgeons should be aware, however, that although major adverse events are rare and the technique is generally considered to be safe (247–249), a few studies have noted increased postoperative pain and swelling in patients undergoing foot and ankle surgery with tourniquet use (250–252).

What might be a more clinically relevant discussion on this topic are the varying opinions on the appropriate tourniquet pressures used for foot and ankle surgery. Although we identified no comparative studies on different pressure levels, some interesting data are worth reviewing. Massey et al (253) have made recommendations for the appropriate tourniquet pressure using the mean arterial occlusion pressure. Using a handheld Doppler device, they determined that the average tourniquet pressure required to provide a bloodless field was 161.7 mm Hg for ankle tourniquets (253). In their study, the mean systolic pressure of the 50 healthy volunteers was 119.8 mm Hg (253). Thus, the investigators recommended that the lower extremity effective tourniquet pressure is approximately 230 to 250 mm Hg or 75 mm Hg greater than the systolic pressure. This might be in contrast to contemporary clinical practice. In a survey of 317 podiatric physicians, the most commonly used pressure was 301 to 350 mm Hg for the thigh and 201 to 250 mm Hg for the ankle and calf (254). Similar findings by the same group of investigators were reported in a survey sent to orthopedic physicians (255).

Another topic of potential debate is the concept of the "breathing period" with tourniquet use. We observed a lack of substantial evidence and considerable variance among the recommendations with respect to the ideal breathing period. For example, the recommendations for the breathing time ranged from a 30-minute interval after 2 hours of use, to a 10-minute deflation after 90 minutes of use, to 20 minutes after 1 hour of use, with upper limits of 3 hours (256–258). An animal study using rabbits reviewed the perfusion and degree of muscular ischemia after the prolonged use of tourniquets (259). Tourniquets were placed for 2 or 4 hours on the rabbit hind limbs, and the degree of skeletal muscle injury was identified using a technetium-99m scan. At 350 mm Hg of tourniquet pressure, muscle reperfusion was significantly reduced after 2 hours compared with 1 hour of cuff inflation.

In a study by Derner and Buckholz (260) using an ankle pressure of 325 mm Hg and thigh pressure of 400 mm Hg, 5 tourniquet-related

postoperative complications were identified among 3027 patients. The investigators recommended deflating the tourniquet at 2 hours with a breathing time of 10 minutes (260). In another study by Reyes et al (248), 11% of 454 tourniquet cases exceeded 2 hours of total inflation time. The investigators reported no complications in these extended cases (248). Wakai et al (261) measured the creatine phosphokinase levels in patients undergoing surgery using an ankle tourniquet. The creatine phosphokinase levels did not increase after 1 hour of tourniquet use. Thus, they suggested limiting the ischemia time to 90 minutes, with a recommendation of 30 minutes of breathing time after 2 hours of tourniquet use (261). Given this variability, our panel did not reach consensus regarding breathing time intervals. This could represent an interesting avenue for future investigation within our profession.

We also recognize that some relative contraindications to tourniquet use exist. Some suggested contraindications include the presence of peripheral vascular disease, a prosthetic vascular graft or previous arterial bypass, extensive soft tissue injury, sickle cell disease, and a history of deep vein thrombosis (DVT) (254,255,257). However, few studies supporting such statements are available.

Most complications associated with the use of ankle or thigh tourniquets include postoperative pain and edema. A survey of foot and ankle surgeons reported complications such as strike-through bleeding or an inability to occlude at normal cuff pressures (39%), nerve injuries (28%), and skin injuries (26%) associated with ankle tourniquet use (254). Similar findings were reported in patients with thigh cuff use. Konrad et al (251) compared the complications observed in patients who had undergone an ankle fracture surgery with and without the use of a tourniquet. The investigators noted a greater postoperative complication rate among patients who had had a tourniquet used during their operation. Wound dehiscence (2 patients versus 1 patient), postoperative infection (2 patients versus 1 patient), and DVT (1 patient versus 0 patients) were seen more frequently in the group using tourniquets (251). Other listed, but not as well supported, complications include postoperative compression neuropraxia, hematoma, infection, compartment syndrome, thrombotic event, breakthrough bleeding, and skin injuries (262,263).

Consensus statement: The panel reached consensus that the statement "Prophylactic antibiotic therapy should be considered for foot and ankle surgical procedures" was appropriate.

In 2015, the first ACFAS CCS addressed the topic of perioperative prophylactic antibiotic use in clean elective foot surgery (1). This CCS identified 6 investigations that produced original data on perioperative antibiosis in foot and ankle surgery (248,264-268) and relied heavily on 2 previously published guidelines by other medical societies (269,270). Although that panel generally produced consensus in favor of prophylactic preoperative antibiotic therapy in elective foot and ankle surgical procedures, they conceded that little to no empiric evidence was available in support of such practices. Their conclusion was that "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 a significant benefit in terms of infection prophylaxis, but at the same time they did not result in the reporting of a single adverse event or complication from the intervention in more than 1000 patients studied" (1).

The present panel identified no other published studies directly evaluating prophylactic antibiosis in foot and ankle surgery and reached the same consensus. Despite a lack of objective evidence, given hospital regulations and common practice, we agree that it is not inappropriate to give preoperative antibiosis. This might be more appropriate in cases of longer duration and those involving the implementation of surgical hardware and less necessary (although not necessarily less appropriate) in cases not involving surgical hardware implementation.

Postoperative Considerations

Consensus statement: The panel reached consensus that the statement "Prophylactic postoperative antithrombotic therapy should be considered for some patients after foot and ankle surgical procedures" was <u>appropriate</u>.

In 2015, a second ACFAS CCS addressed the topic of venous thromboembolism use in foot and ankle surgical procedures and in situations of prolonged immobilization (2). The panel suggested that the use of routine chemical prophylaxis in foot and ankle surgery is not justified. However, the panel also reported that use of chemical prophylaxis in foot and ankle surgery was appropriate in some situations depending on patient-specific risk factors. The factors they identified as resulting in the greatest risk included a personal history of venous thromboembolism, a history of malignancy, a hypercoagulable state, and situations of prolonged lower extremity immobilization. Other factors discussed in published studies that should be considered include a family history of thromboembolism, oral contraceptive use, hormone replacement therapy, advanced age, obesity, smoking, diabetes mellitus, and air travel (271-282). Our panel also concluded that although the routine use of pharmacologic prophylaxis is not necessary after foot and ankle surgery, the use of prophylaxis should be considered for some patients at high risk of venous thromboembolism development.

This is a challenging topic and one that remains of interest within the contemporary medical literature. As the risk of venous thromboembolism after major orthopedic surgery is well documented for patients undergoing procedures such as total joint arthroplasty and hip fracture, these patients are commonly treated with prophylactic antithrombotic therapy (283–289). However, the incidence of venous thromboembolism after foot and ankle surgery is relatively low. In a prospective multicenter study, Mizel et al (272) reported on 2733 patients after foot and ankle surgery and found an incidence of 0.22% for DVT and 0.15% for nonfatal pulmonary embolus (PE). In 2008, Wukich and Waters (271) reported an incidence rate of 0.4% for DVT and 0.3% for nonfatal PE in 1000 patients after foot and ankle surgery. Slaybaugh et al (273) in a retrospective review evaluated 1821 patients after foot and ankle surgery. The investigators demonstrated a 0.5% and 0.16% incidence rate for DVT and nonfatal PE, respectively (273).

In contrast, other studies have reported greater rates of venous thromboembolism after foot and ankle surgery, possibly related to patient-specific risk factors. A study by Solis and Saxby (274) involving 201 patients who underwent foot and ankle surgery found a prevalence of DVT of 3.5%. These investigators performed Doppler ultrasound examinations on the first postoperative visit of all patients, regardless of symptoms. Lassen et al (288), in a prospective, double-blind, placebo-controlled study, evaluated 440 patients who required immobilization after lower extremity fracture or Achilles tendon rupture. The incidence of DVT was found to be 19%. The investigators concluded that DVT is common with immobilization and that DVT prophylaxis is warranted and effective (288). In 2007,

Lapidus et al (290) conducted a study of 105 foot and ankle surgery patients who had been surgically treated for Achilles tendon ruptures. They reported a DVT incidence of 36% (290).

In 2012, the ACCP published their most recent guidelines for the management of antithrombotic therapy in orthopedic surgery patients (291). In patients undergoing major orthopedic surgery, the ACCP recommends the administration of pharmacologic prophylaxis or an intermittent pneumatic compression device. In addition, the group suggested no pharmacologic prophylaxis for patients with isolated lower extremity injuries requiring immobilization. This is likely a topic and discussion that will continue to evolve as more evidence with respect to patient-specific factors is produced.

Consensus statement: The panel reached consensus that the statement "Foot and ankle surgeons should consider a multimodal approach to postoperative pain management" was <u>appropriate</u>.

The appropriate use of pain management can affect the overall outcome after foot and ankle surgery, including improved recovery, a reduction in postoperative complications, and increased levels of patient satisfaction (291). Traditionally, pain control after surgery has been achieved with the use of opioid analgesics and other narcotics. However, these agents are clearly associated with several negative effects, including respiratory depression, sedation, nausea, vomiting, and physical dependence (292). In an effort to provide more effective pain relief and reduce the occurrence of these side effects, a multimodal approach to postoperative pain management has been widely advocated (293–295). The use of several analgesic techniques simultaneously might accomplish a synergistic effect and might provide more effective pain management compared with single-modality methods.

A substantial portion of the published orthopedic-related research on the multimodal approach to postoperative pain management has focused on total hip and knee arthroplasty (294–300), although some investigations have specifically studied the foot and ankle (301–305). Additionally, other clinical practice guidelines have discussed this topic in the general perioperative setting (306,307). Effective multimodal analgesic approaches for orthopedic surgery have included the use of opioids, nonsteroidal anti-inflammatory drugs, acetaminophen, alpha-2-delta ligands (i.e., gabapentin, pregabalin), regional anesthesia, peripheral nerve blocks, periarticular injections, and intra-articular infusions (294–300,302,303,305,306). Although many agree with respect to the use of a multimodal approach, little consensus has been reached with respect to which combination of specific interventions should be used for specific clinical situations.

Several broad considerations that foot and ankle surgeons should consider include preoperative education with respect to post-operative expectations (306,308), the preoperative administration of agents, including nonsteroidal anti-inflammatory drugs and alpha-2-delta ligands (301,304,307,309–314), and maximization of long-term agents with regional anesthesia (302,303,305,310,311).

Another challenging aspect of postoperative pain management is the duration of opioid use. Although this has been a topic of contemporary interest within the medical literature and national media, these concerns primarily relate to the long-term prescription of narcotics for chronic pain and not the treatment of acute postoperative pain (315–317). Most would consider that narcotic use should be short-term after acute surgical intervention, although no universal definition of "short term" has been identified. It is often difficult to balance this with patient expectations, and it is likely that it is a decision that should be made on an individual basis with clear open lines of physician–patient communication.

Consensus statement: The panel reached consensus that the statement "Foot and ankle surgical procedures involving arthrodesis of the first ray should use a period of non-weightbearing immobilization" was <u>neither appropriate nor inappropriate</u>.

Arthrodesis procedures involving the first ray (first metatarsalphalangeal joint and first metatarsal-medial cuneiform joint) have traditionally involved a period of postoperative non-weightbearing cast immobilization until some radiographic evidence of osseous consolidation has been observed at the fusion site (318–322). In addition to limiting the indication of these procedures to patients able to withstand this protocol, prolonged immobilization inherently has concerns for muscular atrophy and the development of venous thromboembolism. After a review of the contemporary data, our panel reached consensus that it is likely that early weightbearing can be allowed safely for some patients after these procedures.

With respect to first metatarsal-phalangeal joint arthrodesis, we identified a series of investigations that specifically evaluated some form of immediate or early weightbearing (323–331). Lampe et al (323) performed a prospective and randomized study of 61 participants undergoing first metatarsal-phalangeal joint arthrodesis with full weightbearing in a cast at 2 to 4 days versus non-weightbearing in a cast for 4 weeks. No differences in primary healing rates were observed. Storts and Camasta (324) completed a retrospective cohort study comparing buried Kirschner wire fixation and crossed screws, with both groups bearing immediate weight in a surgical shoe postoperatively. Although no comparative statistical analysis was performed, both groups demonstrated union rates >95%. We additionally identified 7 other retrospective case series of early weightbearing, with union rates ranging from 87.5% to 100.0% (325-331). We did not identify any study that concluded a negative effect of early weightbearing on outcomes after first metatarsal-phalangeal joint arthrodesis.

With respect to the first metatarsal-medial cuneiform joint arthrodesis, we identified a series of investigations that specifically incorporated early weightbearing into the study design (332-345). The reported arthrodesis union rates observed in these investigations ranged from 90.2% to 100.0%. Although most were case series, 3 studies implemented a comparative design. Prissel et al (332) performed a nonrandomized retrospective cohort analysis of >300 procedures comparing early (<21 days) and late (>21 days) weightbearing and did not observe a statistically significant difference in union rates. Basile et al (333) compared the arthrodesis performed with 2 crossed screws, an intermetatarsal pin, and immediate weightbearing (n = 24) to arthrodesis performed with 2 crossed screws and 4 to 6 weeks of non-weightbearing (n = 17) and found no nonunions or revision procedures in either group. Gutteck et al (334) prospectively grouped 34 patients into either immediate or delayed weightbearing and did not observe differences between the groups. Again, we did not identify any study that concluded a negative effect of early weightbearing on outcome after first metatarsal-medial cuneiform arthrodesis.

We think it is important to note, however, that these studies had some limitations for answering the question of early weightbearing. First, the studies varied substantially in terms of the fixation constructs used, the definition of "early weightbearing" (varying from immediately postoperative to up to several weeks), and the immobilization devices used (including surgical shoes, walking boots, and weightbearing casts). Second, little standardization was present in defining radiographic union. Finally, as a group, these studies were at risk of confirmation bias because most were retrospective case series performed by either a single surgeon or a small group of surgeons. Recognizing these limitations, we reached consensus that early weightbearing was not inappropriate and could be considered appropriate in some situations.

Consensus statement: The panel reached consensus that the statement "Foot and ankle surgeons should use routine post-operative radiographs in the absence of a clinical indication to assess osteotomy, fracture, and/or arthrodesis healing" was inappropriate.

The panel reached consensus that it was inappropriate to use routine or serial postoperative radiographs in the absence of a specific clinical indication. This consensus does not refer to dedicated postoperative plain film radiographs and/or final intraoperative fluoroscopic imaging or radiographs taken at a postoperative clinical decision point (i.e., the initiation of weightbearing). It instead refers to radiographs performed without a specific indication and which are unlikely to result in a change in the treatment of a patient.

We identified several studies specific to the foot and ankle that provide evidence against routine postoperative radiographic assessment. Murphy and Blundell (346) performed a retrospective review of >250 consecutive scarf-type osteotomies for the surgical correction of the hallux abductovalgus deformity in which >1 "routine" postoperative radiograph was taken in the absence of a specific indication. A change in patient treatment occurred in only 2 of these cases—1 for broken fixation and 1 for recurrence. Several other investigators have studied the use of routine radiographs after ORIF of ankle fractures (347-350). Three studies with >500 ankles compared final intraoperative fluoroscopic images to either a dedicated postoperative plain film radiograph or a plain film radiograph on the first postoperative visit, and none resulted in a change in patient treatment (347–349). Similarly, McDonald et al (350) performed a retrospective review of 1411 ankle fractures comparing early (defined as 7 to 21 days) or late (defined as 22 to 120 days) initial postoperative radiographs. No differences were observed in the complication rates between the 2 groups.

These studies are consistent with other orthopedic studies examining routine postoperative radiographs after total knee arthroplasty, total hip arthroplasty, fixation of femur fractures, and spinal arthrodeses (351–359). We identified no study in the orthopedic literature that purported that the potential benefits of routine radiographic assessment in the absence of a specific clinical indication (i.e., identifying a complication that would result in a change in management) outweigh the risks (primarily cost and cumulative radiation exposure) (347,358–360).

We believe it is important to note that this consensus would not be expected to interfere with the requirements for foot and ankle surgery board certification. The American Board of Foot and Ankle Surgery requires "initial postoperative images" (defined as within 1 week of surgery and/or intraoperative images) and "final outcome images" (defined as \geq 4 weeks postoperatively and demonstrating radiographic osseous union). Radiographs between these 2 time points are not specifically required (361).

Consensus statement: The panel reached consensus that the statement "Specific postoperative incisional care protocols should be used by foot and ankle surgeons" was <u>neither</u> appropriate nor inappropriate.

Many potential benefits result from an appropriately applied postoperative surgical dressing, in particular, within the first 48 hours of the procedure (362,363). These include insulation and protection from outside debris, organisms, and temperature changes, absorption of excessive bleeding and drainage, compression against edema and hematoma formation, and minimization of pain, postoperative infection, and wound healing complications (364–367). With that said,

however, evidence is lacking that any specific postoperative dressing protocol is superior to another when considering foot and ankle surgery (368). In contrast, in fact, it is likely that incisional care is multifaceted and decisions should be made based on a variety of factors, including the type of procedure, underlying medical conditions of the patient, postoperative follow-up and specific weightbearing protocols, the patient's home situation, and the use of adjunct modalities.

Underlying medical conditions that might affect dressing choices can include, but are not limited to, vascular diseases, coagulopathies, neuropathies, the use of tobacco products, allergies, and hypersensitivities. Adjunctive devices, such as drains, negative pressure-assisted wound dressings, cryotherapy, and gradual compression devices have been shown to be effective but can also alter the state of the surgical incision (369,370). A surgeon might therefore need to apply more or fewer compression or dressing materials or change the type of dressing, duration of coverage, and immobilization protocol depending on these medical and physical factors. Particular caution should be taken to protect the skin under a tube from a drain or negative pressureassisted device, hard or sharp casting material, and excessive cold or heat. This is especially true when a patient has underlying neurovascular issues.

Postoperative compression might be clearly beneficial for hemostasis to reduce hematoma formation and blood loss and to reduce edema to control pain and wound healing (365,371–375). However, excessive compression can result in nerve palsy, blistering, pressure sore development, and even necrosis (366,376,377). Because the compression force is not easily measureable and the ideal force varies among individuals, a patient's feedback is important to avoid these complications. Similarly, the use of cryotherapy should be individualized because it depends on many medical and physical factors.

Consensus statement: The panel was <u>unable to reach consensus</u> on the statement "Foot and ankle surgeons should consider the use of bone stimulation in cases of delayed and nonunion."

The panel was unable to reach consensus with respect to the relative appropriateness of bone stimulator use in cases of delayed and nonunion of the foot and ankle. Although it might be argued that little risk is associated with bone stimulator use (aside primarily from patient time and financial costs), contradictory evidence is available with respect to its efficacy in the foot and ankle for this indication. The group reached consensus that such treatment is not "inappropriate" but could not reach consensus on whether it was "appropriate" or "neither appropriate nor inappropriate." We concluded that the use of bone stimulators should likely be considered by foot and ankle surgeons for some, but not all, situations of delayed union and nonunion but that the specific indications are not currently evident to the point of consensus.

One of the complicating factors influencing this discussion is the inherent limitations of investigations into bone stimulator technology. It is rare that the bone stimulator is the only variable studied, and in fact, nearly always other confounding variables are present to consider. For example, we identified a small series of studies considering bone stimulator use with foot and ankle arthrodesis procedures (378–381). Jones et al (378) and Midis and Conti (379) implemented bone stimulator use in conjunction with revision arthrodesis surgery, but, of course, this also involved revision surgery. It would be difficult for these investigators to draw conclusions on the effect of the bone stimulator independent of the surgical procedure. Interestingly, Saltzman et al (380) reported on a series of 19 delayed foot and ankle arthrodeses initially treated with a pulsed electromagnetic field stimulator. Of these 19 patients, 5 healed with the stimulator use alone, but the others required revision surgery or refused further treatment.

Furthermore, even the original comparative studies of this technology comparing actual and sham units involved some form of immobilization and a component of time (382–390). This is a difficult topic as time also represents a confounding variable to consider because all fractures, osteotomies, and arthrodesis sites might be expected to demonstrate some progression toward healing given enough time with proper immobilization.

A Cochrane review was one of a number of reviews we identified that concluded the potential for, but less than definitive, beneficial effect (391–396). Griffen et al (391) specifically concluded with respect to delayed union or nonunion of long bone fractures that it "may offer some benefit....but is inconclusive and insufficient to inform clinical practice."

Consensus statement: The panel reached consensus that the statement "Foot and ankle surgeons should be aware of objective measures of patient satisfaction and postoperative outcome" was <u>appropriate</u>.

Although the specifics might not as yet be clear, it is evident that US health care centers, hospitals, and third party payers are working toward value-based and outcome-based reimbursement strategies. We did not identify any investigation on this topic specific to the foot and ankle but did find a number of published reviews that have examined this as it relates to orthopedics and other surgery-based specialties (397–401). Walijee and Nellans (400) reported that with respect to extremity orthopedic surgery, this might be best thought of in terms of safety, outcomes, satisfaction, and cost. Of these, perhaps the most modifiable in terms of individual physicians and their practices are patient satisfaction and outcomes measurement. The strongest predictor of patient satisfaction has been identified as physician-patient communication; however, other important factors include the amount of time physicians spend with patients, patient waiting time for physicians, and physicians' ability to acknowledge risk and uncertainty with respect to patient care (400,402-404). Outcomes measurement might be relatively more difficult. Andrawis et al (401) criticized that orthopedic specialties lag behind other specialties on this topic because of a lack of accepted definitions, undefined indications for surgical intervention, and the use of too many outcome measures all evaluating similar factors. This is likely an area in which our national organizations can potentially work together toward standardization and physician education on a topic that is likely to affect the way we all practice during the coming decades. We reached consensus that it is appropriate for foot and ankle surgeons to at least begin to consider these measures within their practices.

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