

Association Between Foot Surgery Type and Subsequent Healing in Veterans With Moderate-to-Severe Diabetic Foot Infections

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Background. Diabetic foot infections are a common precursor to lower extremity amputations. The treatment of diabetic foot infections involves both medical and surgical management, of which limb-sparing surgeries are increasingly preferred over amputations at or above the ankle to preserve mobility and quality of life. The outcomes following these limb-sparing surgeries are not well described.

Methods. This was a single-center, retrospective cohort study of 90 Veterans with moderate-to-severe diabetic foot infections between 2017 and 2019 from the Veterans Affairs Maryland Health Care System. The exposure was foot surgery with bone resection (ie, toe amputation, metatarsal resection, transmetatarsal amputation) vs debridement alone. The outcome was healing within 1 year. We used log-binomial regression to assess the association between foot surgery type and healing, stratify by infection location, and evaluate potential confounding variables.

Results. The cumulative incidence of healing after foot surgery with bone resection was greater than that following debridement (risk ratio [RR], 1.80 [95% confidence interval {CI}, 1.17–2.77]). This association was modified by infection location and greater for toe infections (RR, 4.52 [95% CI, 1.30–15.7]) than other foot infections (RR, 1.19 [95% CI, .69–2.02]). We found no evidence of confounding by comorbidities or infection severity.

Conclusions. For patients with toe infections, foot surgery with bone resection was associated with better healing than debridement alone. The multiple specialties caring for patients with diabetic foot infections need a stronger common knowledge base—from studies like this and future studies—to better counsel patients about their treatment and prognosis.

Keywords. amputation; debridement; diabetic foot infection; retrospective cohort study; surgery.

Diabetes is one of the most prevalent chronic diseases, affecting 1 in 10 adults in the United States, and increasing the risk for diabetic foot complications such as ulcers, infections, and amputations [1]. The lifetime incidence of diabetic foot ulcers among patients with diabetes is >20% [2]. Over half of diabetic foot ulcers become infected, and 20% of moderate-to-severe diabetic foot infections ultimately progress to amputation [3–5]. More than 70 000 diabetic foot amputations are performed in the United States annually [3]. Diabetic foot infections are

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often what prompt patients with foot complications to seek medical care and usually require a combination of medical (eg, antibiotics, wound care) and surgical management. While the medical management of patients with diabetic foot infections is critical, the surgical management of these infections is as important, or more important, as surgery achieves source control [6-8]. Patients favor limb-sparing foot surgeries (eg, toe amputations, transmetatarsal amputations, metatarsal resections, and debridement procedures) over amputations at or above the ankle because they perceive that these limb-sparing surgeries preserve mobility and quality of life, though the truth of this perception is debatable [9-11]. Additionally, the clinical course and outcomes of these foot surgeries are not well described; while previous work has compared surgery to no surgery [6, 12, 13] and above- vs below-the-ankle amputations [14], few studies have rigorously examined foot surgery type as the primary exposure of interest [15, 16].

As the prevalence of diabetes among Veterans is about 25%, the treatment of diabetic foot complications is an important problem to the Veterans Health Administration [17].

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The purpose of this study was to understand the relationship between the type of foot surgery and subsequent healing in Veterans with diabetic foot infections, and to determine how this relationship varies with infection location. We hypothesized that the 1-year cumulative incidence of healing in Veterans undergoing foot surgery with bone resection would be greater than that of those undergoing foot surgery with debridement alone because the former would achieve better source control. We also hypothesized that the association between foot surgery and healing would be stronger for toe infections than for other foot infections since toe surgery requires a relatively smaller incision. Findings from this study can be used to better understand the clinical course following diabetic foot infections, which will allow providers to better counsel and care for these patients.

METHODS

Study Design, Setting, and Data Sources

This was a retrospective cohort study of 90 Veterans with moderate-to-severe diabetic foot infections [3] from the Veterans Affairs (VA) Maryland Health Care System from 1 January 2017 through 31 December 2019. The VA Maryland Health Care System provides both inpatient and ambulatory care to many of its Veterans, including all of the Veterans in this cohort. At this center, inpatient care for diabetic foot infections typically involves internal medicine as the primary provider with podiatry, infectious diseases, and vascular surgery as consultants. Podiatry consultants obtain a deep foot culture after debridement or incision and drainage for almost all moderateto-severe diabetic foot infections. In the outpatient setting, podiatry follows these patients in a high-risk clinic until healed (ie, months to years), and infectious diseases follows these patients for the duration of antibiotic therapy (ie, weeks to months).

We identified potential subjects using culture data from TheraDoc (Premier Inc, Charlotte, North Carolina), a clinical surveillance system commonly used by hospital epidemiology and infection control programs for healthcare-associated infection surveillance. Additional inclusion and exclusion criteria were applied by review of the Computerized Patient Record System (CPRS), the electronic medical record for both inpatient and ambulatory encounters at the VA Maryland Health Care System and VA facilities across the country. This study was approved by the Research and Development Office of the VA Maryland Health Care System and determined exempt by the Institutional Review Board of the University of Maryland, Baltimore.

Study Population

Our inclusion criteria were diabetes and a deep foot culture (eg, bone, soft tissue, abscess), meeting criteria for moderate or severe diabetic foot infection as defined by the Infectious Diseases Society of America and the International Working Group on the Diabetic Foot, excluding superficial swabs and foot cultures unrelated to diabetes (eg, hardware removal, cancer biopsy) [3, 18, 19]. Diabetes was defined by a diagnosis code of diabetes from at least 2 primary care encounters in CPRS during the year prior to baseline. We did not distinguish between type 1 and type 2 diabetes because their complications tend manifest similarly. The date of foot culture defined entry into the cohort (ie, baseline). We stopped enrollment on 31 December 2019 to allow for at least 1 year of follow-up (ie, through 31 December 2020) for the entire cohort.

Of the 157 Veterans with moderate-to-severe diabetic foot infections during the study period, we excluded subjects with a foot culture obtained in the 3 months (n = 9) before baseline to restrict the cohort to incident infections, as well as infections resulting in amputations at or above the ankle within 1 month before or after baseline to restrict the cohort to foot surgeries only (n = 5). We excluded subjects who died during the 1 month following baseline so that the exposure could be ascertained in all subjects (n = 3). We also excluded subjects with calcaneal infections (n = 7), a past transmetatarsal amputation on the infected foot (n = 6), and gangrene (n = 37), as there was no variation in foot surgery type (eg, all subjects with calcaneal infections and a history of transmetatarsal amputation underwent foot surgery with debridement alone, almost all subjects with gangrene underwent foot surgery with bone resection). This left us with a final study population of 90.

Exposure, Outcome, and Covariates

We defined the exposure as any foot surgery occurring up to 1 month after baseline. Foot surgeries were categorized as with bone resection (ie, toe amputation, metatarsal resection, and transmetatarsal amputation) or with debridement only. The primary outcome of interest was healing (ie, complete epithelialization of the wound as documented by serial follow-up examinations) within 1 year of baseline. Those with recurrent ulcers or infection after initial healing and those who required a subsequent foot surgery related to the initial infection were classified as not healing. There were no losses to follow-up in this cohort, as all subjects had documentation in CPRS of healing, death, or otherwise survival beyond a year of follow-up. We used the following covariates, collected from CPRS and TheraDoc: age, sex, race, hemoglobin A1c (HbA1c), chronic kidney disease (CKD), peripheral arterial disease (PAD), successful revascularization during follow-up, osteomyelitis of the foot, systemic inflammatory response syndrome (SIRS), fever or leukocytosis, and antibiotic duration. Specific criteria for these covariates are provided in Table 1.

Statistical Analysis

We examined the frequency of categorical variables, distribution of continuous variables, and missingness of all variables

Table 1.	Definitions of Covariates for Patients With Moderate-to-	Severe Diabetic Foot Infections, Vete	erans Affairs Maryland Health Care System, 2017–2019

Covariate	Time Frame	Comments
Age	At baseline ^a	Categories: ≥65 years, <65 years
Sex	At baseline	Categories: male, female
Race	At baseline	Categories: Black, White, or other
Hemoglobin A1c	<1 year before or after baseline	Categories: ≥8%, <8%
CKD	 Before admission (inpatients) or <1 month before base- line (outpatients) for creatinine At baseline for dialysis 	Present if creatinine >2 mg/dL or on dialysis
PAD	Before (ever) baseline	Present if ankle brachial index <0.9, >1.4, or noncompressible; or if Doppler waveform not triphasic
Successful revascularization	<1 year after baseline	Present if peripheral vascular surgery or angiography with stent
Osteomyelitis	 Before surgery or baseline for imaging Date of admission to baseline (inpatients) or most recent podiatry office visit before baseline (outpatients) for probe to bone At baseline for pathology 	Present if imaging (X-ray, computed tomography, or magnetic resonance imaging), probe to bone, or pathology (acute or chronic osteomyelitis) were positive
SIRS	 At admission (inpatients) or most recent podiatry office visit before baseline (outpatients) for vitals Date of admission to baseline (inpatients) or <1 month before baseline (outpatients) for white count 	 Present if 2 or more of fever (>38°C) or hypothermia (<36°C), tachycardia (>90 beats/min) tachypnea (>20 breaths/min), and leukocytosis (>12 000 cells/µL) or leuko- penia (<4000 cells/µL) Patients seen in clinic without documentation of vitals or labs were categorized as not having SIRS
Fever or leukocytosis	 At admission (inpatients) or most recent podiatry office visit before baseline (outpatients) for temperature Date of admission to baseline (inpatients) or <1 month before baseline (outpatients) for white count 	Present if fever or leukocytosis
Antibiotic duration	<4 weeks before or after baseline	 Categories: >28 days, ≤28 days Antibiotic duration was defined as the minimum of: start date to stop date, start date to date of subsequent surgery, date of exposure to stop date, date of exposure to date of subsequent surgery, baseline to date of subsequent surgery^b Included both intravenous and oral antibiotics

Abbreviations: CKD, chronic kidney disease; PAD, peripheral arterial disease; SIRS, systemic inflammatory response syndrome.

^aDate of first deep foot culture (ie, bone, soft tissue, or abscess) collected between 1 January 2017 and 31 December 2019 defined entry into this cohort.

^bAssuming that surgery, if performed, defines the start of a new antibiotic course

by univariate analysis. By bivariate analysis, we determined the crude associations between the exposure and outcome, covariates and exposure, and covariates and outcome. We compared the medians of continuous variables using the Wilcoxon rank-sum test and the proportions of categorical variables using Pearson χ^2 or Fisher exact test as appropriate. We assessed whether infection location modified the association between foot surgery type and healing by inspection of stratified risk ratios (RRs). We interpreted stratified RRs that were markedly different from each other as evidence for effect modification. We assessed the following covariates as potential confounders, based on both biological plausibility from a causal diagram and a review of the literature: HbA1c, CKD, PAD, osteomyelitis, SIRS, and fever or leukocytosis [20]. We then assessed each potential confounder individually using the change-in-estimate approach (ie, in order for a covariate to be a confounder, the adjusted RR and crude RR had to differ by >10%) [21]. We did not assess antibiotic duration or successful revascularization as confounders because these occurred after the initial foot surgery.

As a secondary analysis, we estimated the rate ratio of healing after foot surgery with bone resection vs foot surgery with debridement using the method of Fine and Gray to account for competing risks [22, 23]. In this analysis, healing was the event of interest, and subsequent foot surgery or death were competing events. Subjects who neither healed nor experienced a competing event at the end of the follow-up period were censored. The stratified analysis and assessment of confounding were conducted similarly to the primary analysis. We assessed the proportional hazards assumption of the unadjusted and adjusted models using time-dependent covariates (ie, *P* value for interaction < .05 of a covariate-log[person-time] interaction term is inconsistent with the proportional hazards assumption). We used SAS Studio 3.8 software (SAS Institute, Cary, North Carolina) for all statistical analyses.

RESULTS

Demographic and clinical characteristics by foot surgery type are given in Table 2. The median age was approximately 65 years, 95% of participants were male, and 57% were Black. The median HbA1c was about 8%, the median creatinine level was 1.2 mg/dL, and 85% had evidence of at least mild PAD by

Table 2. Demographic and Clinical Characteristics of Patients With Moderate-to-Severe Diabetic Foot Infections by Foot Surgery Type, Veterans Affairs Maryland Health Care System, 2017–2019

Covariate	Foot Surgery With Bone Resection, No. (%) (n = 48)	Foot Surgery With Debridement Only, No. (%) ($n = 42$)	<i>P</i> Value ^a
Age, years ^b	65.9 (15.1)	64.7 (13.7)	.76
Age ≥65 years	25 (52)	20 (48)	.67
Male sex	44 (92)	41 (98)	.37
Race			.21
White	23 (48)	14 (33)	
Black	24 (50)	28 (67)	
Other	1 (2)	O (O)	
Hemoglobin A1c, %	8.0 (2.5)	8.2 (2.5)	.57
Hemoglobin A1c >8%	24 (50)	22 (52)	.82
Creatinine, mg/dL	1.19 (0.62)	1.25 (0.98)	.47
Dialysis	2 (4)	1 (2)	1.00
Chronic kidney disease ^c	6 (13)	8 (19)	.39
Ankle brachial index	1.11 (0.22) ^d	1.10 (0.38) ^e	.37
PAD measured by:			
Ankle brachial index ^f	9 (23) ^d	13 (46) ⁹	.04
Doppler waveform ^h	31 (79) ^d	26 (93) ⁹	.17
Successful revascularization ⁱ	3 (6)	5 (12)	.47
Osteomyelitis ⁱ	38 (79)	23 (55)	.01
SIRS ^k	8 (17)	13 (31)	.11
Fever or leukocytosis ^l	11 (23)	19 (45)	.03
Toe infection ^m	21 (44)	10 (24)	.05
Antibiotic duration, days	15 (41)	17 (30)	.19
Antibiotic duration >28 days	18 (38)	18 (43)	.60

Abbreviations: PAD, peripheral arterial disease; SIRS, systemic inflammatory response syndrome.

^aPearson χ^2 or Fisher exact test for categorical variables; Wilcoxon rank-sum test for continuous variables.

^bMedian (interquartile range) for continuous variables.

^cCreatinine >2 mg/dL or dialysis.

^dn = 39.

^en = 27.

^fAbnormal if <0.9, >1.4, or noncompressible.

^gn = 28.

^hAbnormal if nontriphasic.

ⁱDuring follow-up, by peripheral vascular surgery or angiography with stenting.

^jBy imaging, pathology, or probe to bone.

^kTwo or more of temperature <36°C or >38°C, heart rate >90 beats/min, respiratory rate >20 breaths/min, and white blood cell count <4000 cells/µL or >12000 cells/µL.

Temperature >38°C or white blood cell count <4000 cells/uL or >12000 cells/uL.

^mVersus foot infection.

Doppler waveforms, though 23 subjects did not have an ankle brachial index study on record. Those with bone resection were more likely to have osteomyelitis (79% vs 55%) and a toe infection (44% vs 24%) but less likely to have a fever or elevated white blood cell count (23% vs 45%) than those with foot surgery with debridement only. For other covariates, the groups were relatively similar. Demographic and clinical characteristics by healing are given in Table 3. Those who healed were more likely to have a toe infection (43% vs 24%) but less likely to have an elevated HbA1c (43% vs 61%) or require >28 days of antibiotics (29% vs 54%) than those who did not heal. For other covariates, the groups were relatively similar.

The outcomes among the bone resection vs debridement groups are summarized in Figure 1. The cumulative incidence of healing after 1 year of follow-up in those undergoing foot surgery with bone resection (33/48 [69%]) was greater than in those undergoing foot surgery with debridement (16/42 [38%]) with an RR of 1.80 (95% confidence interval [CI], 1.17–2.77). As summarized in Table 4, the association between foot surgery type and healing was stronger for toe infections (RR, 4.52 [95% CI, 1.30–15.7]) compared to other infection locations such as the metatarsal head or the midfoot (RR, 1.19 [95% CI .69–2.02]). Additionally, the foot surgery with bone resection group in the toe stratum experienced better healing than the debridement group in the foot stratum (RR, 2.07 [95% CI, 1.36–3.14]). None of the covariates tested as confounders met criteria and were hence not adjusted for in the final analysis.

The results of the secondary analysis are summarized in Supplementary Figure 1. The rate of healing was greater in the bone resection than the debridement group with a rate ratio of 2.34 (95% CI, 1.29–4.23). The rate ratio was greater for toe

Table 3. Demographic and Clinical Characteristics of Patients With Moderate-to-Severe Diabetic Foot Infections by Healing, Veterans Affairs Maryland Health Care System, 2017–2019

Covariate	Healing, No. (%) (n = 49)	No Healing, No. (%) (n = 41)	<i>P</i> Value ^a
Age, years ^b	64.7 (12.9)	65.9 (13.5)	.77
Age ≥65 years	23 (47)	22 (54)	.53
Male sex	46 (94)	39 (95)	1.00
Race			.59
White	21 (43)	16 (39)	
Black	27 (55)	25 (61)	
Other	1 (2)	O (O)	
Hemoglobin A1c, %	7.6 (2.6)	8.3 (1.8)	.05
Hemoglobin A1c >8%	21 (43)	25 (61)	.09
Creatinine, mg/dL	1.15 (0.63)	1.26 (0.75)	.37
Dialysis	3 (6)	O (O)	.25
Chronic kidney disease ^c	8 (16)	6 (15)	.83
Ankle brachial index	1.10 (0.24) ^d	1.10 (0.24) ^e	.97
PAD measured by:			
Ankle brachial index ^f	11 (32) ^g	11 (33) ^e	.93
Doppler waveform ^h	28 (82) ^f	29 (88) ^e	.73
Successful revascularization ⁱ	3 (6)	5 (12)	.46
Osteomyelitis ^j	31 (63)	30 (73)	.32
SIRS ^k	10 (20)	11 (27)	.47
Fever or leukocytosis ^l	15 (31)	15 (37)	.55
Toe infection ^m	21 (43)	10 (24)	.07
Antibiotic duration, days	11 (35)	29 (36)	<.01
Antibiotic duration >28 days	14 (29)	22 (54)	.02

Abbreviations: PAD, peripheral arterial disease; SIRS, systemic inflammatory response syndrome.

 $^a\text{Pearson}\,\chi^2$ or Fisher exact for categorical variables; Wilcoxon rank-sum test for continuous variables.

^bMedian (interquartile range) for continuous variables.

^cCreatinine >2 mg/dL or dialysis.

^dn = 33.

^en = 33.

^fAbnormal if <0.9, >1.4, or noncompressible.

^gn = 33.

^hAbnormal if nontriphasic.

ⁱDuring follow-up, by peripheral vascular surgery or angiography with stenting.

ⁱBy imaging, pathology, or probe to bone.

^kTwo or more of temperature <36°C or >38°C, heart rate >90 beats/min, respiratory rate >20 breaths/min, and white blood cell count <4000 cells/µL or >12000 cells/µL.

Temperature >38°C or white blood cell count <4000 cells/uL or >12000 cells/uL.

^mVersus foot infection.

infections (8.86 [95% CI, 1.94–40.4]) than in other infection locations (1.19 [95% CI, .58–2.46]). Both osteomyelitis and PAD met criteria as confounders; the adjusted rate ratios are also given in Supplementary Figure 1. The proportional hazards assumption held for both the unadjusted and adjusted models using time-dependent covariates, with P values for interactions of .61 and .95, respectively.

DISCUSSION

We have shown that among Veterans with moderate-to-severe diabetic foot infections involving the toe, the cumulative incidence of healing after 1 year was significantly greater in those with foot surgery with bone resection compared to debridement alone. However, among those with other infection locations (eg, midfoot), healing after 1 year was similar regardless of the type of foot surgery. This makes intuitive sense, as toe surgery tends to result in a smaller wound than foot surgery (eg, transmetatarsal amputation), and subsequent healing of the latter is slower with a greater risk of dehiscence and development of a chronic wound due to greater challenges with adherence to offloading [24]. We also suspect that better healing in the bone resection group could be attributed to better source control after more extensive removal of the infectious focus, while worse healing in the debridement group could conversely be attributed to insufficient source control.

Our study is unique in that we examined associations of both foot surgery type and infection location on subsequent healing, while most prior work has focused on one or the other. Tan and colleagues reported that the proportions of patients requiring amputations at or above the ankle or dying after initially undergoing debridement compared to localized

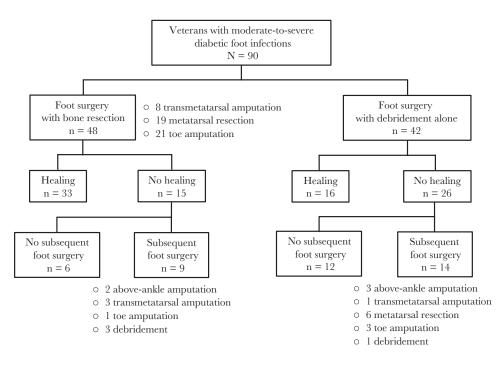


Figure 1. Outcomes after 1 year among Veterans with moderate-to-severe diabetic foot infections, Veterans Affairs Maryland Health Care System, 2017–2019 (n = number of patients).

amputation were not significantly different, though these results were not stratified by infection location and the type of foot surgery was not the primary exposure of interest [6]. Armstrong and colleagues reported that subsequent amputations and postoperative infections were significantly more common after surgery done for infection compared to surgery done for a chronic wound. However, their cohort included subjects with and without a diabetic foot infection, and they did not account for the extent or depth of surgery or for anatomical differences [25, 26]. Nehler and colleagues compared toe amputations to amputations through the metatarsal head and metatarsal shaft and found that the risk of a subsequent foot amputation for toe amputations were significantly less than that of amputations through the metatarsal head or shaft [15]. However, other studies have yielded differing results [27, 28]. Notably, outcomes following debridement alone were not examined in any of these studies.

The major strength of this study is the quality of the data, which were collected by detailed chart review—rather than

relying on diagnosis codes-from a center with a podiatry service experienced in the care of diabetic foot complications. By carefully reviewing operative and clinic notes, we were able to ensure that the exposure, outcome, and covariates were accurately captured and less prone to errors or bias. Limitations of this study include its small size and retrospective nature and that it was derived from a single center. Importantly, our results may not be generalizable to non-Veterans, mild diabetic foot infections, infections involving the heel, infections in patients with a past transmetatarsal amputation, or infections with gangrene. While our outcome variable of healing is important to patients, we were unable to capture other important patient-centered outcomes (eg, mobility, psychological health, or quality of life) from the medical record; these would be valuable to ascertain in a future study. We found no evidence of confounding by HbA1c, CKD, PAD, osteomyelitis, and abnormal vital signs on presentation.

Our effect estimate could still be biased by residual confounding, since these data were derived from the medical record,

Table 4. Association Between Foot Surgery Type and Healing, Stratified by Infection Location, Veterans Affairs Maryland Health Care System, 2017–2019

	Foot Surgery Type		
	Bone Resection	Debridement Only	
Infection Location	Healing/No Healing	Healing/No Healing	RR (95% CI) for Healing Associated With Foot Surgery Type Stratified by Infection Location
Foot	14/13	14/18	1.19 (.69–2.02)
Тое	19/2	2/8	4.52 (1.30-15.7)

Ratio of stratified RRs, 3.82 (95% Cl, .98–14.8); P = .05Abbreviations: Cl, confidence interval; RR, risk ratio. which may have had errors or been incomplete. However, we imposed strict inclusion and exclusion criteria such that participants would be more similar, regardless of whether they had foot surgery with bone resection or debridement only, which reduces the threat of residual confounding. One concern is that we were unable to ascertain information about the clinical decision-making process, specifically whether the provider recommended a specific surgical procedure, or performed the procedure because the patient refused more extensive treatment (eg, with bone resection). However, the findings presented in Figure 1 suggest that this decision might not have been straightforward, as only about half of these subjects required a subsequent surgery, the majority of which were limb-sparing procedures rather than major above-the-ankle amputations. We thus have less reason to suspect that potential residual confounding would be differential with respect to foot surgery type.

Diabetic foot infections are increasingly commonplace and will continue to demand the attention of multiple specialties including infectious diseases. In the future, high-quality prospective cohort studies would enable us to study factors of importance to patients such as mobility, psychological health, and quality of life. However, we will also need clinical trials to better account for confounding. Much of the infectious diseases literature has assessed outcomes of diabetic foot infections as a function of antibiotic selection [29, 30] and duration [31]. Our study has demonstrated that type of foot surgery and infection location are also important determinants of healing, though these are often unfamiliar to nonsurgical specialties including infectious diseases. Professional guidance appropriately emphasizes the need for multidisciplinary care in managing diabetic foot infections, though patients often correctly perceive this care to be fragmented and ineffective [32]. Studies such as this could empower providers to remedy this perception. For example, in addition to providing counseling on antibiotic side effects, an infectious diseases provider could help reinforce to patients that they are likely to require months of follow-up for wound care after completing antibiotics following midfoot debridement. On the other hand, patients who undergo a toe amputation might be reassured that their wound is likely to heal within a year. The ability of providers from multiple disciplines to deliver a more cohesive message to patients based on a more comprehensive knowledge base about treatment and prognosis is essential for providing better care to patients with these complex disease processes.

Supplementary Data

Supplementary materials are available at *Open Forum Infectious Diseases* online. Consisting of data provided by the authors to benefit the reader, the posted materials are not copyedited and are the sole responsibility of the authors, so questions or comments should be addressed to the corresponding author.

Notes

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Patient consent. This retrospective study was approved by the Research and Development Office of the Veterans Affairs Maryland Health Care System and determined exempt by the Institutional Review Board of the University of Maryland, Baltimore and thus did not require patient consent.

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Potential conflicts of interest. All authors: No reported conflicts of interest.

All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.

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