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Preliminary development of a diabetic foot ulcer database from a wound electronic medical record: A tool to decrease limb amputations

Michael S. Golinko, MD[1], **David J. Margolis, MD, PhD**[2,3], **Adit Tal, BS**[1], **Ole Hoffstad, MS**[2,3], **Andrew J. M. Boulton, MD**[4], and **Harold Brem, MD**[1]

[1]Department of Surgery, Division of Wound Healing and Regenerative Medicine, Helen & Martin Kimmel Wound Center, New York University School of Medicine, New York City, New York

[2]Division of Endocrinology, Department of Medicine, University of Miami School of Medicine, Miami, Florida

[3]University of Manchester, Manchester, UK

[4]Department of Dermatology and Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania School of Medicine, Philadelphia, Pennsylvania

Abstract

Our objective was to create a practical standardized database of clinically relevant variables in the care of patients with diabetes and foot ulcers. Numerical clinical variables such as age, baseline laboratory values, and wound area were extracted from the wound electronic medical record (WEMR). A coding system was developed to translate narrative data, culture, and pathology reports into discrete, quantifiable variables. Using data extracted from the WEMR, a diabetic foot ulcer-specific database incorporated the following tables: (1) demographics, medical history, and baseline laboratory values; (2) vascular testing data; (3) radiology data; (4) wound characteristics; and (5) wound debridement data including pathology, culture results, and amputation data. The database contains variables that can be easily exported for analysis. Amputation was studied in 146 patients who had at least two visits (e.g., two entries in the database). Analysis revealed that 19 (13%) patients underwent 32 amputations (nine major and 23 minor) in 23 limbs. There was a decreased risk of amputation, 0.87 (0.78, 1.00), using a proportional hazards model, associated with an increased number of visits and entries in the WEMR. Further analysis revealed no significant difference in age, gender, HbA1c%, cholesterol, white blood cell count, or prealbumin at baseline, whereas hemoglobin and albumin were significantly lower in the amputee group ($p < 0.05$) than the nonamputee group. Fifty-nine percent of amputees had histological osteomyelitis based on operating room biopsy vs. 45% of non-amputees. In conclusion, tracking patients with a WEMR is a tool that could potentially increase patient safety and quality of care, allowing clinicians to more easily identify a nonhealing wound and intervene. This report describes a method of capturing data relevant to clinical care of a patient with a diabetic foot ulcer, and may enable clinicians to adapt such a system to their own patient population.

Chronic wounds are defined by multiple physiological impairments to healing,[1] including inadequate angiogenesis,[2] impaired innervation,[3] direct pressure,[4] microcirculatory ischemia,[5] and impaired cellular migration,[6] all of which may contribute to extensive morbidity and

Reprint requests: Harold Brem, MD, Department of Surgery, Division of Wound Healing and Regenerative Medicine, Langone Medical Center, Helen & Martin Kimmel Wound Center, New York University, 301 East 17th Street, Room 1026, New York, NY 10003, USA. Tel: +1212 598 6500; Fax: +1212 598 6689; harold.brem@nyumc.org.

limb amputation. Foot ulcers are estimated to occur in 2–5% of those with diabetes per year, [7,8] and they are now the leading cause for hospitalization in patients with diabetes.[9] Patients with ulcers undergoing major amputation are also hospitalized longer, have a diminished quality of life,[10] as well as increased morbidity and mortality.[11] The lifetime risk of a person with diabetes developing a foot ulcer is as high as 25%,[12] and the presence of an ulcer increases the risk of lower extremity amputation by almost sixfold:[13] the 5-year survival rate of major amputees with diabetes is approximately 31%.[14]

A challenge in the management of foot ulcer patients is designing and executing appropriate treatment plan(s) that may include local care, systemic antibiotics,[15] debridement,[16,17] biological therapies,[18–20] and offloading.[8] The need and frequency of use of these agents often change over the course of therapy. Moreover, demographic information, laboratory values, radiology, pathology, microbiology results, and access to home care may all affect clinical decision making.

The care of individuals with chronic wounds may involve many different physicians and health care providers. The use of a database to help coordinate care and track clinical findings is important for a disease that requires multiple care givers. The Curative Health Services (CHS) [21] system was an example of one such database. This database was used during every patient encounter. Investigators were also able to use this database to correlate wound duration, ulcer size, and grade with healing rates and22 hospitalization with amputation in patients with DFUs. 23 Other databases have been used to identify diagnostic indicators of infection of foot ulcers, 24 codify leg ulcers,[25] and standardize care between wound centers of chronic wounds.[26] While statistical analyses of these large databases are invaluable, translation of their findings to patient care is yet to be elucidated in a concrete way.

The goal of this report is to illustrate the design and preliminary implementation of a diabetic foot ulcer database. In theory, information from *any* type of medical record, electronic or otherwise, can be extracted into the database described below and moreover adapted to suit particular practice needs. The variables included in the database are not exhaustive, but are rather representative of the variables utilized in published protocols,[27,28] which are both standards in the field and those that have been shown to impact clinical outcomes, e.g., change in wound area and/or amputation.

Materials and Methods

Patients and point of entry

Any patient with a diabetic foot ulcer seen at our dedicated wound service was eligible for inclusion in this study, which was approved by the Institutional Review Board. To implement standard guidelines[27,28] and protocols,[29] Microsoft Access® was used to design a wound electronic medical record (WEMR).

Clinical treatment protocol

The treatment protocol begins at the patient's initial visit, during which a thorough history and physical is performed and documented, with pertinent findings entered into the WEMR. Laboratory values such as complete blood cell count, basic metabolic panel, albumin, hemoglobin (HgB) A1C%, and lipid panel are drawn and sent. Blood cultures and swabs of the patient's nares and wound are sent before any treatment is initiated. The wound is photographed in a standardized way[30] and the area is recorded into the WEMR.

All patients have arterial evaluation with noninvasive flow studies, i.e., ankle-brachial indices (ABI) and pulse volume recording (PVR). Appropriate consultation is carried out with a dedicated vascular surgeon for any abnormal findings, such as ABI < 0.9 or suppressed

waveforms on the PVR. Any impaired arterial flow is corrected (when indicated) with minimally invasive techniques such as atherectomy.

All patients are offloaded with the assistance of a pedorthist, and the most commonly used devices are the CAM walker (AliMed, Dedham, MA) or Airboot.

Any patient with a diabetic foot ulcer presenting with cellulitis, increased drainage, and/or new or increased pain in their wound was treated with surgical debridement and antibiotics within 72 hours of presentation.

Topical wound therapy begins at the initial visit by maintaining a moist wound environment with either a triple antibiotic ointment, Cadexomer Iodine, or collagenase.

Principles of debridement included wide excision of all hyperkeratotic tissue to soft skin and deep debridement to a level with absence of osteomyelitis.[31,32] Moreover, all thickened nails were removed and common findings were resistant bacteria[33] and/or onchomycosis. After removal of clinically nonviable or infected tissue, the tissue left behind both at the edge and at the depth of the wound was sent for pathology and culture. Antibiotics were initiated based on culture results. If the wound did not decrease in area by 10% as recorded in the WEMR, at 2 weeks, additional debridement was performed and biological therapy was applied such as a bilayer of keratinocytes and fibro-blasts[34] or PDGF-BB. If the wound was not decreased by 20% at 4 weeks, additional wide and deep operative debridement was performed, new cultures and pathology were sent, and biological therapy was repeated.

In addition to a general surgeon who was the primary wound clinician, each patient had access to an orthopedic surgeon, a podiatrist, a diabetologist, and a social worker. Each specialist has real-time access to the wound's progress, as the WEMR is part of the patient's permanent medical record.

At each clinical encounter, all the relevant data were entered into the WEMR. A report function of the WEMR allowed the clinician to print on a single page a graphical trend in the wound area, two digital photographs of the wound, and a summary of variables including laboratory values, current medications, noninvasive flow study results, culture, and pathology results. This single printed sheet was part of the patients' permanent medical record.

To illustrate how relevant variables can be captured and quantified for diabetic foot ulcers, Access® queries were written and reports were exported into a Microsoft Excel® spreadsheet for easy manipulation.

Types and constraints of clinical variables

Discrete variables such as sex, race, and presence or absence of a medical condition such as neuropathy as assessed using a 10-g Semmes–Weinstein monofilament were entered into the database.

The following narrative reports were available for clinical review.

Microbiology reports

Three levels of cultures were taken and recorded: (1) a nasal culture at enrollment for infection control to identify community-acquired Methicillin resistant *Staphylococcus aureus* (MRSA); (2) a superficial wound swab; and (3) a culture taken after sharp debridement that reflected the tissue left behind after removal of clinically nonviable and/or infected tissue. All cultures were immediately processed by the microbiology laboratory.

Pathology reports

Pathology from any patient sharp debridement at the bedside or operating room was entered into the database. Specimens for pathological analysis were typically taken from four areas of the diabetic foot ulcer: the skin edge (proximal to the open wound and distal, toward normal skin) and the wound bed (nonviable or tissue appearing infected, and deeper tissue left behind after debridement). All pathology specimens were sent for routine hematoxylin and eosin staining.

Radiology

Results from X-ray, MRI, bone scan, or, if available, Tc-99 leukocyte scan, were assessed for evidence of osteomyelitis and entered into the database.

Additional information was also available for review and entry into the database:

Nutritional markers—Prealbumin ± 7 days from enrollment date and albumin ± 30 days from the enrollment date.

Glycemic control—HbA1c ± 2 months from the enrollment date.

Lipid profile—total cholesterol, HDL, and LDL ± 3 months of the enrollment date.

Hematology—complete blood count, white blood cell count (WBC), HgB, hematocrit ± 7 days of the enrollment date.

Wound measurements—A digital photograph of the wound is uploaded to a computer. The resulting digital image is traced by the user and measured with a Wound Imager (Med Data Systems, Cherry Hill, NJ). All areas are reported in cm^2.

Anatomic depth—Depth can be measured directly (in cm) or assigned a University of Texas stage and grade.[35,36]

Vascular insufficiency—ABI were recorded in both extremities, toe-brachial indices or percutaneous oximetry, in mmHg. In addition to these continuous variables, angiographic evidence of peripheral arterial disease (PAD) was noted, as was revascularization (open or endovascular) within 1 month of the enrollment date.

Amputation data

The date of amputation was recorded as well as one of the following levels. Minor: toe, transmetatarsal, or foot (or Syme) and major: below the knee (BKA) and above the knee (AKA); the number of days was calculated from the time of presentation to initial debridement. All patients were seen for care following their amputation as needed.

Data structure methodology

For ease of clinical use, the variables from WEMR were extracted into five separate spreadsheets; it is important to emphasize that each row in the database *must* have the wound ID or patient ID, depending on the level of analysis. This will allow easy importation into a statistical package that relates each covariate to a particular outcome measure. Narrative data included variables that appeared in sentence or paragraph form in the medical record. A coding system for narrative data was developed to abstract the data into a quantifiable form.

Each variable field in the WEMR constitutes a column heading in MS Excel. The enumerated variables were organized into the following five spreadsheets:

1. Demographics, medical history, & baseline laboratory values.
2. Vascular data.
3. Radiology data.
4. Wound characteristics (location, length, width, area).
5. Wound debridement (culture, pathology data).

Examples of the codes used to quantify pathology and culture data were:

Tissue codes	Microorganism codes	Pathology codes
E=Epidermis	A=Acinetobacter	A=Abscess
D=Dermis	BF=*Bacteroides fragilis*	F=Fibrosis
S=Subcutaneous tissue	C=*Candida* species	G=Gangrene
F=Fascia	EF=*Entercoccus faecalis*	GT=Granulation tissue
T=Tendon	GBS=Group beta hemolytic *Streptococcus*	K=Hyperkeratosis
M=Muscle	KP=*Klebsiella pneumoniae*	N=Necrosis
B=Bone	MRSA=Methicillin-resistant *Staphylococcus aureus*	O=Osteomyelitis
N=Nasal	NG=No growth PA=*Pseudomonas aeruginosa* VRE=Vancomycin-resistant *Enterococcus*	

Although all elements of the data structure and database could not be displayed, Table 1 shows representative data columns for a patient with bilateral ulcers.

Statistical methods

Amputation was the primary outcome measure. Covariates were studied using a Cox's-proportional hazards model, specifically the number of entries in the database before amputation or at last visit, initial wound area, area at 4 weeks, area at the last visit, and the mean treatment time. Other variables at baseline that were compared between the amputee and the nonamputee group were male (%), age, HbA1C%, total cholesterol, HDL, LDL, WBC count HgB, prealbumin, and albumin. A Student *t*-test was used when indicated and Fisher's exact test was used to compare the percentages of a positive finding between two groups, i.e., percentage of osteomyelitis.

Results

Clinical outcomes with the DFU database

Amputation as an outcome was studied in 146 patients who had at least two visits (e.g., two entries in the database). Analysis revealed that 19 (13%) patients underwent 32 amputations (nine major and 23 minor) in 23 limbs. Patient characteristics are given in Table 2 and revealed no significant difference in age, gender, HbA1c%, cholesterol, WBC count, or prealbumin at the time of enrollment, whereas HgB and albumin were significantly lower in the amputee group ($p < 0.05$) than the nonamputee group.

Analysis of covariates with respect to amputation

Using a proportional hazards ratio, there was a slightly decreased risk of amputation, 0.87 (0.78, 1.00), associated with an increased number of visits, i.e., entries into the WEMR The

initial wound area, area at 4 weeks, and number of days of protocolized treatment did not differ significantly between the nonamputee and the amputee group; see Table 3 for *p* values. The presence of PAD was evaluated by either an ABI < 0.9, revascularization in the last 6 weeks prior to enrollment or positive findings on angiogram or magentic resonance angiography. Fifty-seven percent of amputee limbs had evidence of PAD vs. 48% of nonamputee limbs.

Analysis of narrative data: osteomyelitis

Osteomyelitis was characterized and quantified. Patients routinely underwent a radiographic evaluation for osteomyelitis. If a patient did not have bone debridement, then the diagnosis was solely based on these radiographic findings. Radiology data revealed that 55% of the amputee limbs showed the presence of osteomyelitis compared with 38% of the limbs of nonamputees (p=0.39). Using the coding methodology described, 59% of amputees showed pathologic evidence of osteomyelitis vs. 45% of nonamputees (p=0.82). The incidences of select microorganisms grown from bone are shown in Table 4; among the most commonly reported organisms in amputees wounds were *Entercoccus faecalis* and *Pseudomonas aeruginosa*.

Analysis of amputation: major vs. minor

Nineteen patients underwent 32 amputations (nine major and 23 minor) in 23 limbs. Seven patients underwent nine major amputations, seven BKA, and two AKA. Twelve patients underwent 16 (70%) toe amputations and seven (30%) underwent transmetatarsal or foot-level amputations. Two patients who underwent a minor amputation went on to have a one major amputation each. Eight patients had bilateral wounds and 50% of these patients (n=4) underwent bilateral amputations. There were no statistically significant differences in the mean area of the wound that led to amputation nor the mean number of WEMR entries (i.e., visits). No significant difference was observed in the percentage of limbs with PAD or evidence of osteomyelitis, as demonstrated by either pathology or bone scan or MRI (See Table 5).

Discussion

The description of the DFU database described illustrates (1) how clinical variables are abstracted from the medical record (in this case the WEMR) and tracked longitudinally, (2) how data may be structured to relate covariates to an outcome measure such as amputation, and (3) how such a database may be used a research tool to study new variables. Use of the WEMR resulted in an amputation rate of 13% for persons with diabetic foot ulcers in a tertiary referral practice. Further using the WEMR may decrease minor and major amputations.

How can one measure and improve patient outcomes using a database?

Without the use of a comprehensive database, tracking of variables shown to increase or decrease the risk of amputation becomes cumbersome. For the treatment of a chronic wound, the first description of a leg ulcer database[25] presented the variables used and preliminary results but was not specific on how the data were captured and quantified. In this report, we described an approach on how a database was constructed to capture diverse clinical information such as laboratory values and results from operative debridement and relate them to outcome measures such as amputation. The German Wound Net[26] has been successful in this regard and has been used to establish that a 50% reduction in the wound area at 4 weeks after treatment is a reliable indicator of healing.[37] The change in the wound area over time is a well-established indication of the effectiveness of the treatment and the long-term ability of the wound to heal.[38–41] Construction of a DFU database allows prospective tracking of the wound area and correlation to other variables such as neuropathy[42] and PAD,[43] thus allowing the clinician to identify patients at risk for amputation and to ensure that the wound area is decreasing.

A clinical tool

First and foremost, the DFU database was created as a clinical tool to distill and consolidate the vast amount of information needed to make a decision during the clinical encounter. Using the database in real time allows the user to discern clinically relevant variables from clinically irrelevant ones. Without viewing all of the variables together, it may be easy to focus on only one abnormal variable and "treat the lab value"; however, the DFU database allows for reporting of trends in any particular variable and, moreover, relates that trend to the wound area.

In the first 146 patients entered into this database, we found that certain variables were significantly different between the patients who went on to amputation and those who did not, e.g., serum albumin was lower in the amputee group, while others such as HgA1c% or initial wound area did not differ significantly.

Although this study was not designed to determine whether or not use of the WEMR or the DFU database may decrease amputations, the observation that patients with fewer visits were more likely to be amputated merits further discussion. This finding may simply indicate that patients who underwent an amputation presented late, e.g., with advanced soft tissue or bone infection. The amputee group had fewer entries into the database in a similar time period, though, indicating that this group was seen less regularly than the nonamputee group. Our interpretation of this finding is that if a patient proved to be refractory (i.e., no decrease in wound area < 2 weeks) to simultaneous treatment (i.e., IV antiobiotics, deep tissue debridement, offloading, and biological therapy), then early amputation was indicated. It was not uncommon for patients who eventually underwent an amputation to stop coming to the clinic at some point during treatment if they thought their wound "looked good." However, when these patients did return, the window of opportunity for simultaneous treatment had been missed because significant bacterial resistance or osteomyelitis may have developed in the wound and amputation was the only viable option. Using what was learned from this study, we implemented a patient callback system and so a call was made from the wound center and documented in the chart, reminding the patient to return to the clinic the following week. Our preliminary observations using this system suggest that we can reduce the amputation rate even further. Future versions of the WEMR will include an alert system that will send a notification to the appropriate clinician via a mobile device if a wound is not healing.

The majority of amputees showed evidence of osteomyelitis in their wound before amputation, whereas the non-amputees did not. Whether osteomyelitis is diagnosed with bone biopsy (the gold standard), radiological exams, bone culture, or any combination thereof, the DFU database provides a standardized structured way to capture this information that allows for corrective action. Moreover, because evidence of osteomyelitis may be recorded at different time points, resolution of infection can be recorded.

Although the sample size was too small for a definitive statistical comparison, we can make the following observations regarding the analysis of minor vs. major amputations. With regard to the number of WEMR entries, although there was a statistical significance between amputation and nonamputation (p=0.023), this difference was less pronounced when analyzed at the level of amputation, i.e., minor vs. major (p=0.07). Most strikingly, patients who underwent a major amputation had fewer visits and hence fewer WEMR entries. Although this difference was not statistically significant (p=0.07), it is clinically significant because had these patients presented earlier and been entered into the WEMR, signs of clinical deterioration could have been recognized more easily. Because the WEMR datasheet trends the wound area since the initial visit, a clinician can identify even subtle changes in area. Although our data did not reveal a statistically significant difference in the baseline area, the difference was clinically significant and may be a baseline predictor of amputation when studied in a larger population.

Because the WEMR datasheet displays all the relevant clinical variables, including pathology, culture, radiology, and lab values, the clinician has a mechanism to discern why the wound may be deteriorating and may intervene. This heightened surveillance, indicated by more frequent visits, may be a factor in preventing major amputation, although patients may still require a minor amputation. Clearly, a subsequent study of the WEMR with sufficient power to detect a statistical difference needs to be completed.

Although major amputations are thought to be primarily due to arterial inflow and minor due to bone infection, we observed a similar percentage of osteomyelitis in the wounds that preceded a minor or a major amputation. Although the sample size is too small to draw a definitive conclusion, this finding indicates that regardless of blood flow to the affected limb, infection in the bone had not been eradicated by the time of amputation. The larger percentage of PAD present in limbs that underwent a major amputation was not surprising. Taken together, we recommend early recognition and entry into a system such as the WEMR for diabetic foot ulcers of any size or grade with systematic, objective surveillance regardless of how "good" the wound looks.

A research tool

Tracking wound area over time will indicate that the wound is not healing, but not *why*. A database structured such as the one described herein allows the clinician to investigate patterns in clinical variables and relate them to outcome. With more physiologic impairments under investigation such as specific bacteria[44] or matrix-metal-loproteinases,[45] a database allows the clinician–researcher to capture data on the variable of interest. Although this study did not have adequate power to discern whether certain bacteria may be a risk factor for amputation, the database structure allows for such analysis with a sufficient sample size. These variables or any other of interest can be built into a database such as the one described here, simply by adding another column in the appropriate spreadsheet. In addition, other outcome measures of interest such as wound closure or percentage healing at 4 weeks or health-related quality of life may also be added and related to the covariates.

Study limitations

This database is not without limitations and may not be practical to implement in all healthcare settings or by all clinicians. Moreover, further study is needed to determine the precise amount of time saved by maintaining such a database in addition to an electronic medical record. Construction of the spreadsheet column headings varies depending on the number of variables used, but time can be saved by using the coding system described here as opposed to entering narrative data. Although the times may vary with software aptitude, 10 minutes per patient is required to fully enter the data into the WEMR, code pathology, culture and radiology data and enter into the spreadsheets. Undoubtedly, extra time must be taken to extract data from the WEMR, e.g., code narrative data such as pathology reports and then enter it into a spreadsheet. However, even though this may take longer for the individual at the onset, the clinician and patient ultimately benefit because a longitudinal record of their treatment course distilled into relevant variables such as wound area, debridement dates, and pathology data can be viewed at a glance, on a single page, and subsequently analyzed by a statistician.

This report is meant to be taken as a starting point to stimulate dialogue about how best to capture clinical data with the aim of coordinating patient care, enhance communication between health care providers, and most importantly, preventing amputations. Further formal study is underway at multiple centers to determine whether such a database improves clinician decision making and can decease amputations in patients with diabetic foot ulcers.

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Table 1

Representative table of data extracted from WEMR into DFU database

										Pathology Codes		
Wound ID#	**Patient ID#**	**HgA1C (%)**	**Side**	**Loc**	**Wound date**	**Area (cm^2)**	**Amp level**	**Interval day**	**Swab**	**EK**	**DG**	**BO**
59	123456	7	R	Pa	2/6/08	7.31		0	NG	1	1	Null
59	123456		R	Pa	2/13/08	7.97		7				
59	123456		R	Pa	3/17/08	4.81		39				
60	123456	7	R	Pb	2/6/08	2.3		0	D	1	1	0
60	123456		R	Pb	2/13/08	0.7		7				
61	123456	7	L	T1	2/6/08	1.1		0	MRSA	1	0	0
61	123456		L	T1	2/13/08	1.5		7				
61	123456		L	T1	3/17/08	3.78		39	MRSA	1	0	1
61	123456		L	T1	3/24/08	2.35		46				

This table records the tracks the data for a patient with two plantar wounds on the right foot and a large toe ulcer on the left foot. The two right foot ulcers were decreasing in area over the treatment period and one wound had no growth (NG) in culture from a wound swab at baseline, though initial debridement showed hyperkeratosis in the skin edge of the wound (EK), and granulation tissue in the dermis (DG). Although bone biopsy was taken no mention was made of osteomyelitis (BO)=null. The second wound on the plantar surface was growing *Diptheroids* (D) and had similar skin edge pathology to first plantar wound (Pa), with the exception of absence of osteomyelitis in the bone.

The contra-lateral wound on the large toe was initially seen at the same time and grew MRSA. Although the wound edge, typically callus, contained hyperkeratosis, indicated abnormal keratinocyte function, no granulation tissue nor osteomyelitis was reported from routine H&E pathology.

The patient had a gap in care between February and March and returned with larger toe wound and more invasive infection as evidenced by osteomyelitis the bone. After that, debridement and treatment with antibiotics the wound started to decrease in area.

Table 2

Patient characteristics and baseline laboratory values

Patient characteristics	Amputee patients (*n*=19)	Non amputee patients (*n*=127)	Student *t*-test
Demographics			
Male (%)	12 (63%)	85 (67%)	*p*=0.74
Age mean ± SD, median (years)	58.4 ± 17.6, 60	59.5 ± 14.3, 59	*p*=0.97
Laboratory values ± SD, median			
HbA1C (%)	9.1 ± 2.4	8.6 ± 2.3, 8	*p*=0.37
Cholesterol (mg/dL)	169.1 ± 50.8, 157	165.2 ± 46.2, 164	*p*=0.36
HDL (mg/dL)	40.1 ± 11.6, 38	41.9 ± 12.9, 39	*p*=0.38
LDL (mg/dL)	95.6 ± 40.7, 96	94.1 ± 37.7, 88	*p*=0.87
WBC (cell/L)	10.0 ± 4.3, 9	8.4 ± 3.4	*p*=0.077
HgB (g/dL)	10.8 ± 1.6, 10	11.9 ± 3.3, 12	*p*=0.007
Prealbumin (mg/dL)	21.1 ± 5.4, 23	20.8 ± 7.5, 22	*p*=0.91
Albumin (mg/dL)	3.5 ± 0.6, 4	3.9 ± 1.1,4	*p*=0.02

Table 3

Wound characteristics covariate analysis

Wound characteristics ± SD, median	**Amputee wounds (*n*=23)**	**Nonamputee wounds (*n*=145)**	**Hazard ratio [95% CI]**	**Student *t*-test**
# database entries (visits) until last visit or amputation	4.6 ± 3.6, 3.0	6.7 ± 6.3, 4	0.87 [0.78,1.00]; *p*=0.046	*p*=0.023
Initial area (cm^2)	15.2 ± 22.3, 5.4	6.8 ± 9.1, 3.1		*p*=0.084
Area at 4 weeks (cm^2)	17.8 ± 23.4, 5.9	6.7 ± 9.6, 2.7		*p*=0.064
Area at last visit (cm^2)	18.2 ± 25.9, 5.6	4.8 ± 8.3, 1.1	1.06 [1.03,1.09]; $p <$ 0.0009	0.020
Treatment time (days)	93.4 ± 110.6, 53	131.4 ± 168, 66		*p*=0.167

Table 4

Analysis of osteomyelitis from the DFU database

Pathology (*n*) % of all reports	**Amputee wounds**	**Nonamputee wounds**	***p*-value**
Total reports mentioning bone	17	53	
Positive for Osteomyelitis	10 (59%)	28 (45%)	0.82
Radiology Osteomyelitis per limb	**Limbs=23**	**Limbs=145**	
Total (Radiology)	20	132	
Positive for osteomyelitis *n* (%)	11 (55%)	50 (38%)	0.39
Microbiology of bone			
# patient culture reports mentioning bone	9	40	
Incidence of microorganism in bone			
A=Acinetobacter	1	19	
BF=*Bacteroides fragilis*	1	2	
C=*Candida species*	0	0	
EF=*Entercoccus faecalis*	3	5	
GBS=group β hemolytic *Streptococcus*	1	1	
KP=*Klebsiella pneumoniae*	0	1	
MRSA=*methicillin-resistant Staphylococcus aureus*	2	4	
N=No growth	1	18	
PA=*Pseudomonas aeurginoasa*	3	1	
VRE=*vancomycin-resistant Enterococcus*	1	0	

Table 5

Analysis of variables: minor vs. major amputation

	Minor	Major	*p* value
Patients	12.00	7.00	
Amputations	23.00	9.00	
Initial area ± SD (cm^2)	7.50 ± 8.4	33.00 ± 33.3	0.09
% Osteomyelitis*	75.00	71.00	
% PAD	31.00	50.00	
Mean visits (WEMR entries)	5.30	3.00	0.07

*Pathology (bone biopsy) present in 60% of cases for both minor and major categories.