



The Wifl System for Threatened Limbs

Let's take a closer look at SVS' lower extremity threatened limb classification.

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Introduction

Classification systems typically rely on critical limb ischemia (CLI) as the primary criterion to deter-

mine the prognosis of threatened lower extremities, to lead clinical decision-making, and to define the disease burden from these condi-

tions.¹ However, existing classification systems, which rely heavily on critical limb ischemia criteria, are not sufficient in addressing all patient populations and presentations, such as patients with type II diabetes mellitus (T2DM). While perfusion is an important consideration, other components such as the presence and severity of infection must be assessed to adequately classify and stratify threatened lower extremities.

Current practices prioritize anatomic characteristics over disease severity. The Society for Vascular Surgery (SVS) Lower Extremity Guidelines Committee created a new framework that includes three main factors: Wound, Ischemia and Foot Infection (Wifl). This system incorporates perfusion along with wound extent and the severity of infection, because current major classification systems, such as the Wagner Grading System, do not include the degree of such characteristics (Figure 2). The Wifl system is not intended to be used as the sole decision-making tool; rather, it aids clinical decision-making by stratifying amputation risk.¹ In addition, this grading system allows for comparison between similar patient populations in order to determine the relative effectiveness of alternative therapies.²

Historically, traditional definitions of ischemia have not easily translated for patients with T2DM.¹

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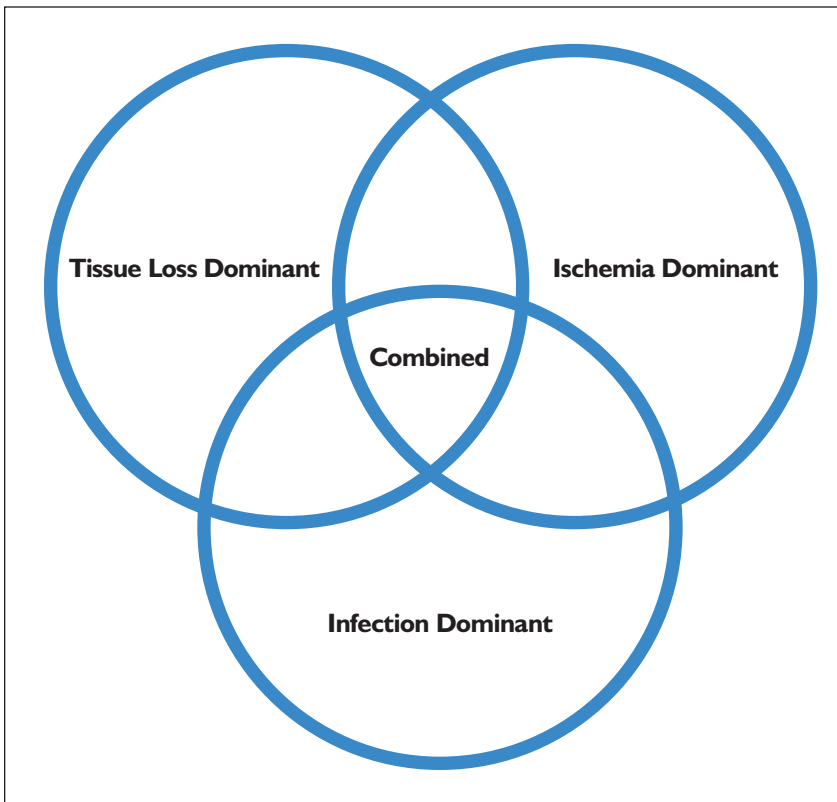


Figure 1: Ring of dominance to determine the patient's most pressing condition: infection, ischemia, tissue loss or a combination.



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The rising incidence of diabetes and associated complications call for a more standardized classification system that allows for the assessment of broader populations. Thus, the Wound, Ischemia and foot Infection (Wifl) system is a promising evaluative tool that provides a more comprehensive assessment than existing standards and has the potential of improving care for heterogeneous populations.

Methods

For all three categories, classification is based on a 0 to 3 scale where 0,1,2 and 3 represent none, mild, moderate and severe, respectively.¹ This is similar to the tumor, node, metastasis (TNM) system used in cancer screening. Overall, this classification system is able to provide a more holistic representation of a threatened limb and standardizes risk.

Based on the cumulative scores from each category, patients are stratified into one of four clinical stages. These stages correspond to the estimated risk of amputation of the threatened limb, with these

**FIGURE 2:
Wagner Grading System
for Diabetic Feet**

- 0 - Intact Skin
- 1 - Superficial ulcer of skin or subcutaneous tissue
- 2 - Ulcers extend into tendon, bone, or capsule
- 3 - Deep ulcer with osteomyelitis, or abscess
- 4 - Gangrene of toes or forefoot
- 5 - Midfoot or hindfoot gangrene

differing risks per stage having been derived from the consensus of an expert panel. In summary, Wifl grades determine a patient’s clinical stage in which the degree

which are assessed with Wifl are presented below.

Wound Grades

Classification from 0 to 3 depends on the size, depth, severity and wound-healing ability. Grade 0 indicates lack of wounds. Grades from 1 to 3 are assigned by increasing level of tissue loss as well as increased complexity of the treatment procedure required. Grade 1 includes small ulcers with no indication of

gangrene, while grade 3 includes extensive ulcers and gangrene. Gangrene cases that would prevent salvage of limbs are excluded from this classification.¹

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of amputation increases by stage: clinical stage 1 (very low), clinical stage 2 (low), clinical stage 3 (moderate), clinical stage 4 (high).² A brief summary of the three grading components of the threatened limb

Ischemia Grades

Grading for ischemia is based on the ankle-brachial index (ABI). Patients with ABI > 0.8 would be considered grade 0 for ischemia. Patients

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**TABLE I:
The University of Texas Classification Combines
Grades and Stages for Wounds**

	0	I	II	III
A	areas of pressure which are sometimes called pre-ulcerative lesion	superficial ulcer not including tendon, capsula or bone	deep ulcer including tendon, capsula but not bone	deep ulcer including bone and articulation
B	infection	infection	infection	infection
C	ischemia	ischemia	ischemia	ischemia
D	infection + ischemia	infection + ischemia	infection + ischemia	infection + ischemia



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with ABI < 0.4 would be considered grade 3. Grades 1 and 2 are reserved for patients with intermediate perfusion deficits (between 0.4 and 0.8). TP or TcPO₂ measurements may also be used when ABI may not be reliable such as with diabetics or the elderly.¹



Figure 3: Example of non-infected wound.

Infection Grades

Grades for infection severity would be based on clinical observations where grade 3 refers to infections causing systemic or metabolic toxicity.¹ Figure 3 provides an example of a non-infected wound, whereas Figure 4 provides an example of a wound with both infection and ischemia. One



Figure 4: Example of foot wound with infection and ischemia present.

accepted classification system that outlines such ischemia and infection grades is the University of Texas Classification System (Table 1).

Results

The goal of the Wifi classification system has been to define a more accurate representation of disease conditions, through assigned grades and stages, in order to better inform patient care decisions.¹ A variety of studies have evaluated the Wifi criteria and clinical stages since the system's development to assess its correlation with relevant clinical mark-

threatened limbs including risk of major amputation, wound healing time (WHT), and one-year amputation free survival (AFS) rate.

found that Wifi stages are predictive of one-year limb amputation and confirmed that Wifi grades assessing wound size, the degree of ischemia, and the extent of infection correlate with actual wound healing and the likelihood of a limb being salvaged. A similar study evaluated 201 patients stratified by Wifi clinical stages to compare outcomes; the study found that as the clinical stage progresses, the risk of a major amputation increases, the one-year AFS rate decreases, and WHT is prolonged.⁴ These two studies confirmed that the Wifi clinical stage predictions parallel the outcomes of the actual patients.

A final clinical study stratified limbs according to Wifi stage and concluded with the following results. The percentage of limbs un-

A number of studies have sought to determine if the Wifi system is predictive of and correlates with major clinical outcomes, such as limb amputation and WHT.

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ers and its predictive ability for major outcomes; thus far, a majority of studies have affirmed and validated the Wifi classification system as an effective and precise tool for assessing many aspects of lower extremity

with major clinical outcomes, such as limb amputation and WHT. One study evaluated 139 patients presenting with foot wounds, and calculated Wifi grades and stages for each of these patients.³ The study

dergoing any revascularization procedures and the percentage of limbs undergoing minor amputation increased significantly with each increasing Wifi stage; more specifically, the use of endovascular and open revascularization procedures increased significantly by stage in addition to the mean number of minor amputation procedures required per limb.⁵ Moreover, the percentage of limbs which achieved complete wound healing decreased significantly with each increasing Wifi clinical stage, highlighting a decreased rate of healing and an increase in Wifi stage.

This study also performed Kaplan-Meier analyses of the one-

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year limb salvage rates and found significant differences between the stages (Stage 1: 96%, stage 2: 84%, stage 3: 90% and stage 4: 78%). Finally, an increased Wifl stage was associated with a decreased one-year AFS rate

Numerous studies have demonstrated that Wifl is able to effectively stratify heterogeneous patient populations with limb-threatening conditions and predict major clinical outcomes in a standardized fashion.

(Stage 1: 84%, stage 2: 75%, stage 3: 80%, and stage 4: 69%). Thus, this study affirmed that the different Wifl clinical stages correlate with distinctions in patient outcomes, including limb treatment procedures and the likelihood of limb salvage.

Discussion

An analysis of the Wifl system and review of recent literature assessing its merits strongly demonstrate that the tool is both effective at predicting major outcomes and correlates with relevant clinical outcomes. Numerous studies have demonstrated that Wifl is able to effectively stratify heterogeneous patient populations with limb-threatening conditions and predict major clinical outcomes in a standardized fashion.^{2,3,4}

Early studies also indicate that the Wifl system may correlate with more patient-centered outcomes including ambulatory status, independent living status, and the likelihood of complete wound healing.⁵ Ultimately, these studies support Wifl as a promising tool not only for use in clinical decision-making to guide treatment decisions but also as a new framework to analyze clinical outcomes. This suggests that Wifl can and should be used for comparing different treatment and therapy options in clinical trials as this tool could facilitate the development of new therapies and analyses of existing treatments. Thus, the Wifl classification is uniquely poised to provide more comprehensive assessments of lower extremity threatened limbs and to address the current gaps in clinical tools available for broad, diverse patient populations, including those with T2DM. **PM**

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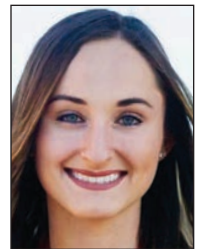
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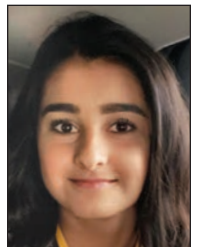
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