

# Validation of a diabetic foot surgery classification

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## ABSTRACT

The purpose of this project was to evaluate associations of increasing diabetic foot surgery stage with postoperative outcome. This project, designed as a retrospective cohort model, was conducted at three large, urban referral-based diabetic foot clinics. The investigators abstracted medical records from 180 patients with diabetes, 76.1% male, aged  $57.8 \pm 11.2$  years, falling equally into four classes of a previously reported diabetic foot surgery classification system. These classes included class 1 (elective), class 2 (prophylactic), class 3 (curative) and class 4 (emergency). There was a significant trend towards increasing risk of ulceration/reulceration ( $\chi^2_{\text{trend}} = 17.8, P = 0.0001$ ), peri-postoperative infection ( $\chi^2_{\text{trend}} = 96.9, P = 0.0001$ ), all-level amputation ( $\chi^2_{\text{trend}} = 41.7, P = 0.001$ ) and major amputation ( $\chi^2_{\text{trend}} = 8.6, P = 0.003$ ), with increasing class of foot surgery. The results of this study suggest that a non vascular foot surgery classification system including variables such as the presence or absence of neuropathy, an open wound and acute infection may be predictive of peri- and postoperative complications. This may assist the surgeon in better identifying risk when determining a rationale for and type of surgery in persons with diabetes.

**Key words:** Amputation • Classification • Risk • Surgery • Wound

## Key Points

- the purpose of this project was to evaluate the associations of increasing diabetic foot surgery with postoperative outcome
- this project, designed as a retrospective cohort model, was conducted at three large, urban referral based diabetic foot clinics
- medical records were abstracted from 180 patients with diabetes, 76.1% male, aged  $57.8 \pm$  who met the following criteria: 1) a diagnosis of diabetes by their primary care physician, 2) the ability to ambulate freely without the assistance of a wheelchair, 3) at least one year of reliable follow up information

## INTRODUCTION

Over the past decade, there have been numerous descriptive studies detailing various surgical techniques in the treatment of the high-risk diabetic foot (1–16). While there has been a relative dearth of studies evaluating specific procedures, relatively recent studies have suggested some potential benefit from judicious

intervention in this high-risk diabetic foot population (17–19).

In response to the increasing attention to this area of intervention and the lack of a concise nomenclature of indications, a diabetic foot surgery classification system was proposed in 2003 (20). This system divides non vascular diabetic foot surgery into four classes: elective, prophylactic, curative and emergency (Figure 1). There have been no studies in the medical literature evaluating the ability of this system to predict key outcomes (i.e. risk for amputation, peri/postoperative infection, ulceration). Therefore, the purpose of this project was to evaluate the associations of increasing diabetic foot surgery stage with postoperative outcome.

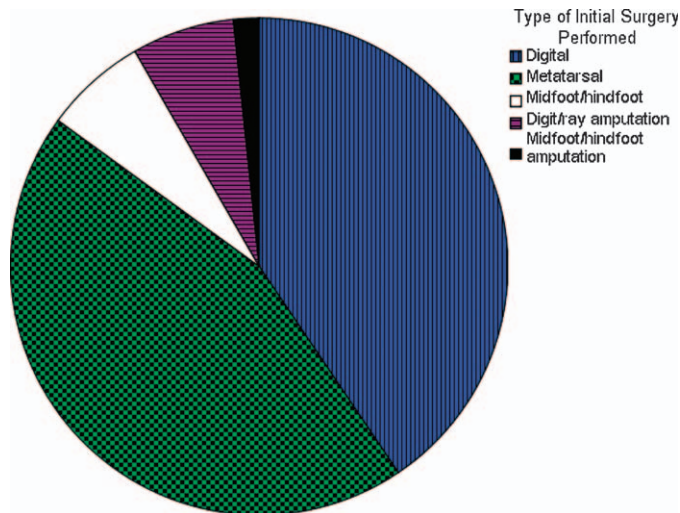
## METHODS

This project, designed as a retrospective cohort model, was conducted at three large, urban referral-based diabetic foot clinics. Medical records were abstracted from 180 patients with diabetes, 76.1% male, aged  $57.8 \pm 11.2$  years, who met the following criteria: 1) a diagnosis

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**Figure 1.** Types of initial surgery performed

of diabetes by their primary care physician, 2) the ability to ambulate freely without the assistance of a wheelchair and 3) at least 1 year of reliable follow-up information. All foot surgeries performed on patients were classified using the aforementioned diabetic foot surgery classification system (Table 1) (20). Of all the procedures done, 45 consecutive patients receiving foot surgery from each of the four classes of surgery who met the criteria for assignment into that specific surgery class in addition to the above-mentioned entry criteria were selected. These included class 1 (elective), class 2 (prophylactic), class 3 (curative) and class 4 (emergency). Data were abstracted over a 5-year period for procedures fitting the above criteria.

Patients were excluded if they had a diagnosis of clinically significant vascular disease.

**Table 1** Classification of non vascular diabetic foot surgery

Class	Type	Definition
1	Elective	Procedure performed on patient with protective sensation intact to eliminate pain or to improve function
2	Prophylactic	Procedure performed on patient with protective sensation absent but no open wound to reduce deformity and reduce occurrence/recurrence
3	Curative	Procedure performed on patient with an open wound with the goal of promoting healing and reducing risk for recurrence
4	Emergency	Procedure performed with goal of limiting the spread of limb- or life-threatening infection

Vascular status was evaluated by pedal pulse palpation. The diagnosis of ischaemia was standardised in the facilities where data were abstracted. This diagnosis was made by the absence of more than one foot pulse or a non audible signal on Doppler ultrasonography of the dorsalis pedis or posterior tibial pulses the affected extremity. This method of evaluation, while arguably not as sensitive as other non invasive methods such as transcutaneous oximetry, segmental extremity pressure studies or laser Doppler flowmetry, has the benefit of having been performed systematically on all patients in this study (21–24).

Soft tissue or bone infection was a clinical diagnosis made by the treating physician at the time of assessment. As per standard protocol, the diagnosis of infection was consistent with the current criteria described by the International Working Group on the Diabetic Foot (25). This includes the presence of purulence, advancing cellulitis or two or more other local signs of inflammation. Major versus minor amputation was defined as surgery performed above or below the ankle. The period of evaluation for infection included the period from time to surgery to wound healing or amputation.

Patients in all categories were treated in a standardised fashion per the protocol followed in the high-risk diabetic foot centres where treatment was rendered. All procedures were performed under local anaesthesia and monitored sedation. These procedures were performed by surgeons with similar training. Postoperative care for all patients was identical,

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- data was abstracted over a 5-year period
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- major versus minor amputation was defined as surgery performed above or below the ankle
- the period of evaluation for infection included the period from time to surgery to wound healing or amputation
- patients in all categories were treated in a standardised fashion per the protocol followed in the high-risk diabetic foot centres where treatment was rendered

### Key Points

- all healed subjects were assessed for appropriate footwear by the podiatrist/pedorthics team, as required
- patients were followed every 2 months following healing for foot examination and shoe gear checks
- to evaluate the differences in continuous variables among the four foot surgery groups, a Tukey range test for multiple comparisons was used
- analysis of variance suggested tendencies towards poorer outcomes based on increasing foot surgery class

with the first dressing change performed at 2 days postoperatively and weekly thereafter. Elective, prophylactic and curative postoperative wounds were dressed with moisture-retentive gauze and were not disturbed between weekly postoperative visits. On postoperative visit, three (at 2 weeks) sutures were removed, based on clinician's assessment. Patients were then switched to a daily dressing change regime until the wound healed. Patients were offloaded in a standard fashion using a DH pressure-relief walker or sandal (Royce Medical, Incorporated, Camarillo, CA, USA). These devices were converted into 'instant total contact casts' at the discretion of the attending clinician (26–28). Patients who underwent emergency (class 4) surgery received daily dressing changes during the immediate postoperative period.

Care following healing was according to the standardised protocols in place at the treating clinics. All healed subjects were assessed for appropriate footwear by the podiatrist and prosthetics/pedorthics team, as required. This footwear consisted of either comfort shoes or prescriptive-depth inlay shoes with sufficient room in the toebox to accommodate an accommodative pressure-reducing insole. Patients were followed-up every 2 months following healing for foot examination and shoe gear checks.

At the aforementioned 1-year period, several outcomes were analysed, including proportion of infections, reulceration and amputation at 1 year. Foot infection was defined clinically, by criteria consistent with the International Working Group guidelines (25) i.e. the presence of purulence or at least two local signs or symptoms of inflammation. These criteria were, in all cases, evaluated by the attending clinician.

Determination of the sample size to abstract was based on the data accumulated from postoperative infection rates of the previous studies of prophylactic and curative proce-

dures. These rates have ranged from 0 to 14% for prophylactic and up to 40% for curative procedures (3,18,29,30). Therefore, to identify a 35% difference in postoperative infection between prophylactic and curative procedures (classes 2 and 3), a sample size of 41 was required in each group, yielding a power (beta) exceeding 90% and an alpha of 5%. The authors therefore felt comfortable with abstracting data for 45 subjects in each group to allow for the considerable variation in previous reports.

To evaluate the differences in continuous variables among the four foot surgery groups, a Tukey range test for multiple comparisons was used. To evaluate the potential trends towards increasing prevalence of ulceration, infection and amputation based on increasing foot surgery class, a chi-squared test for trend ( $\chi^2_{\text{trend}}$ ) was used (31). All data were reported as mean  $\pm$  standard deviation unless otherwise stated. For all analyses, the alpha was set at 0.05.

## RESULTS

Descriptive characteristics for this population are outlined in Table 2. The types of procedures performed are outlined in Figure 1. There was not a significant difference in age, gender or duration of diabetes between foot surgery classes 2–4. However, persons receiving class 1 procedures were younger than their higher risk counterparts ( $P = 0.001$  for all between-class associations). Additionally, persons receiving class 1 procedures had significantly lower glycosylated haemoglobin than did persons receiving either class 3 ( $P = 0.04$ ) or class 4 ( $P = 0.05$ ).

General outcomes associated with persons falling into the four foot surgery classes are outlined in Table 3 and Figure 2. Analysis of variance suggested tendencies towards poorer outcomes based on increasing foot surgery class. Using specific multiple comparisons between adjacent surgery classes, there was a significant difference in both infection and

**Table 2** Population descriptive statistics

	Class 1	Class 2	Class 3	Class 4	Total
N	45	45	45	45	180
Age (years)	50.9 $\pm$ 9.8	59.5 $\pm$ 11.3	59.7 $\pm$ 9.7	61.1 $\pm$ 11.4	57.8 $\pm$ 11.2
Gender (% male)	77.8	75.6	71.1	80.0	76.1
Glycosylated haemoglobin (%)	8.4 $\pm$ 1.0	8.6 $\pm$ 0.9	9.0 $\pm$ 1.0	9.0 $\pm$ 1.2	8.8 $\pm$ 1.1
Duration of diabetes mellitus (years)	11.2 $\pm$ 6.4	13.4 $\pm$ 6.4	12.1 $\pm$ 6.6	12.5 $\pm$ 6.3	12.3 $\pm$ 6.4

**Table 3** Peri- and postoperative outcome by diabetic foot surgery class

	Class 1	Class 2	Class 3	Class 4	Total
Ulceration/reulceration (%)	0	2.2	11.1	24.4	9.4
Postoperative infection (%)	2.2	6.7	20.0	100.0	32.2
Amputation (%)	0	2.2	6.7	48.9	14.4
Major amputation (%)	0	0	4.4	11.1	3.9
Major/minor amputation ratio	0	0	1.5	0.2	0.3

amputation between classes 3 and 4 ( $P = 0.001$  for both associations). Similar characteristics could be shown when specifically evaluating for trend. There was a significant trend towards increasing risk of ulceration/reulceration ( $\chi^2_{\text{trend}} = 17.8$ ,  $P = 0.0001$ ), peri-postoperative infection ( $\chi^2_{\text{trend}} = 96.9$ ,  $P = 0.0001$ ), all-level amputation ( $\chi^2_{\text{trend}} = 41.7$ ,  $P = 0.001$ ) and major amputation ( $\chi^2_{\text{trend}} = 8.6$ ,  $P = 0.003$ ) with increasing class of foot surgery.

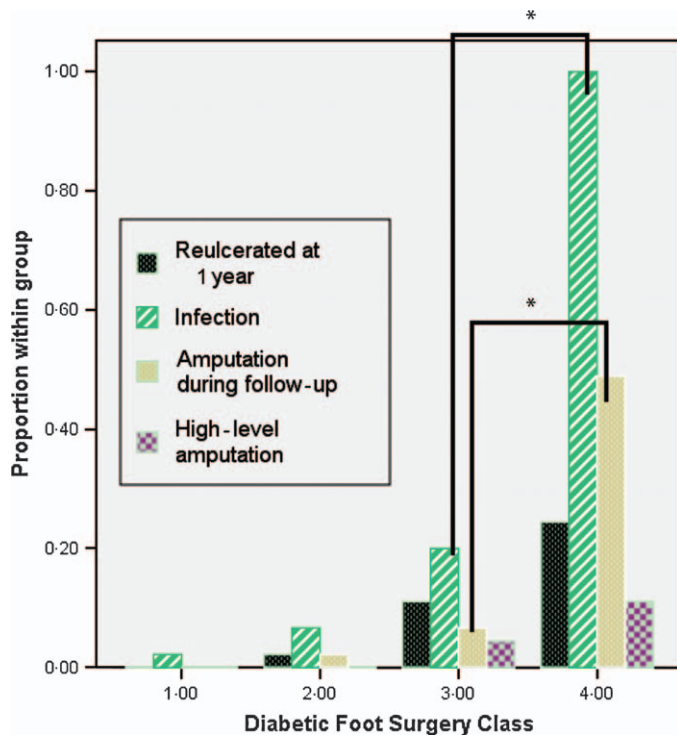
## DISCUSSION

The results of this study suggest that this diabetic foot surgery classification system may be predictive of postoperative complications. This may assist the surgeon in better assessing risk when determining a rationale for and type of surgery in persons with diabetes. It can further help the surgeon explain the risks of surgery and long-term complications associated with surgery to patients and their families. This classification systematically eliminated persons with severe peripheral vascular disease. It would therefore be inappropriate to generalise these results to the entire diabetic population.

The trend analysis in this classification for the outcomes of ulceration, infection and amputation is driven by the first and last categories. As expected, there was little or no morbidity associated with risk group 1, elective surgery, and a very high rate of ulceration, infection and amputation in risk group 4, emergency surgery. However, the reulceration rate was at the low end of what other specialty foot centres have reported in high-risk patients. The lower incidence of recurrent

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**Figure 2.** Outcomes by foot surgery classification. There was a significant trend towards reulceration, infection, amputation and high-level amputation for all classes of surgery ( $P < 0.05$  for all associations). Using specific comparisons between adjacent surgery classes, there was a significant difference in both infection and amputation between classes 3 and 4 ( $P = 0.0001$ ). \* $P = 0.0001$

### Key Points

- there were a number of limitations to the current model. This was a retrospective design and is thus subject to various methodological biases unique to the model
- future studies should enhance operational definitions while also considering variability factors among clinicians of various disciplines
- the highlight of the diabetic foot surgery classification is that presence of ulcer and infection seems to affect risk for amputation when patients undergo surgery
- this information when collated can better help the clinician identify and communicate risk to his or her patient

ulceration may be partly a result of eliminating severe peripheral vascular disease from the risk pool or because of a very high level of preventive care including therapeutic shoe, education and frequent access to podiatry care.

The reulceration and amputation rates in risk group 3 were very low compared with those reported in published results (32,33). The reulceration rates in other published reports range from 19 (34) to 63% (32) in 12–18 months. In the last decade, there has been a growing focus on Achilles tendon lengthening as both an adjunctive and a primary procedure to facilitate ulcer healing (19,35,36). The reulceration rate in several published reports at tendo achilles lengthening (TAL) was similar to our findings.

From published studies, postoperative infection rates for prophylactic and curative procedures (risk groups 2 and 3) range from 0 to 14% and up to 40%, respectively (3,18,29,30). Data from this project fall squarely in the middle of the existing work. The prevalence of bone and soft tissue infection in an open diabetic foot ulcer exceeds 50% over the life cycle of a wound (37). Balanced against the prevalence of infection resulting from an open ulceration, infection rates in surgery classes 2 and 3 were much better. Based on the little knowledge of the natural history of ulceration and the risk of recidivism, the short-term benefits of surgery in appropriately selected high-risk groups 2 and 3 seem to improve clinical outcomes.

In this study, persons receiving class 1 procedures had significantly lower glycosylated haemoglobin than did persons receiving either class 3 ( $P = 0.04$ ) or class 4 ( $P = 0.05$ ). This is an interesting finding as glycosylated haemoglobin levels have not been previously identified as a significant predictor in ulceration risk. Rigid glycaemic control (38) has been shown to be of fundamental importance to help delay the onset and slow the progression of complications associated with diabetes. Future studies may provide insight into the relationship between elevated glycosylated haemoglobin levels and surgical prognosis in this specific population.

There were a number of limitations to the current model. This was a retrospective design and is thus subject to various methodological biases unique to the model. Additionally, it was not possible to assess inter- or intrarater variability

through this model. Certainly, the definitions of neuropathy, deformity, infection and an open wound are subject to some degree of interpretation. This has been a feature similarly affecting most other classification systems in this milieu. That being said, the application of those definitions as assessed by the clinicians using the classification system nonetheless appeared to lead to an association with poorer outcome based on increasing surgery class. Future studies should continue to enhance operational definitions while also considering variability factors among clinicians of various disciplines.

As mentioned above, there was a trend towards poorer outcomes based on increasing foot surgery class. This trend corresponds well to the foot risk classification system promoted by the International Working Group on the Diabetic Foot (25) as well as similar classification systems described by Rith-Najarian and coworkers (39,40) and Armstrong *et al.* (41). Additional studies by Peters and Lavery (42) and Mayfield *et al.* (43) seem to corroborate this general line of assessment; that the presence of neuropathy and history of ulcerations are predictors of poor outcomes. The diabetic foot surgery classification is predictive of postoperative complications, whereas the foot-risk classification systems previously described are predictive of ulcer formation. Despite differences in focus, the trends inferred by these classification systems coincide well and may ultimately prove useful in tandem. The highlight of the diabetic foot surgery classification is that presence of ulcer and infection seems to affect risk for amputation when patients undergo surgery. It is this information that, when collated, can better help the clinician identify and communicate risk to his or her patient.

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