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Outcomes of Wound Healing and Limb Loss After Transmetatarsal Amputation in the Presence of Peripheral Vascular Disease

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A B S T R A C T

Transmetatarsal amputation (TMA) is the procedure of choice in treating forefoot gangrene and infection. Foot and ankle and vascular surgeons work closely together in limb salvage, but little is known about the timing of vascular intervention to achieve a healed amputation site. This study retrospectively looked at 153 patients with peripheral vascular disease who underwent TMA with a minimum of a 3-year follow-up. A total of 102 patients received vascular intervention: 79 endovascular and 23 open bypass. The primary focus of this study was to look at the timing of vascular intervention, incidence of wound healing, and incidence of limb loss. There was an overall 44% rate of limb loss. Patients who underwent open bypass did better than those who underwent endovascular intervention with a lower incidence of limb loss (87% compared with 51%), and quicker time to wound healing. The timing of vascular intervention, performed either before or after TMA, had no association with wound healing or limb loss. Similarly, the time interval between vascular intervention and TMA had no association with wound healing or limb loss. Comorbidities, including end-stage renal disease on hemodialysis, hyperlipidemia, and congestive heart failure, showed a significant association with TMA stump nonhealing and limb loss. Body mass index ≥30, end-stage renal disease on hemodialysis, and hyperlipidemia were all risk factors for limb loss.

Transmetatarsal amputation (TMA) was introduced by Leland McKittrick in 1949 as a method for partial foot preservation and limb salvage (1). Since then, it has become the procedure of choice in the treatment of forefoot gangrene and infection in diabetics and patients with peripheral vascular disease (PVD) (2–4). Unfortunately, a large proportion of patients who have TMA fail to heal and up to 29% have limb loss at 1 year (5–8). Despite suboptimal wound healing rates ranging from 40% to 70% and its unpredictable outcomes, TMA is still considered a reasonable level of amputation for limb salvage because it preserves ambulatory status and avoids the high mortality rates associated with below-knee and above-knee amputations (9). Although proximal amputations are a more definitive procedure with predictable healing rates, TMA is still advocated in patients who have good rehabilitation potential with favorable prospects for postoperative ambulation (9).

The vascular surgeon plays a critical role in limb preservation and improving outcomes after lower extremity amputation (10–13). Aggressive revascularization has been shown to significantly improve outcomes of limb preservation (14); however, it is still unclear at what point in the disease process vascular intervention would be most beneficial. Only 1 study by Sheahan et al (15) looked at the timing of revascularization in minor lower extremity amputations; they found that revascularization after amputation resulted in a worse prognosis for limb salvage compared with revascularization before amputation.

The goal of this study was to observe the impact of the timing of vascular intervention in patients undergoing TMAs. We hypothesized that revascularization before TMA would result in higher rates of wound healing, quicker time to wound healing, and lower rates of limb loss. Our primary aim was to measure the incidence of limb loss, defined by below- or above-knee amputation, within a 3-year period after TMA. Our secondary aim was to measure wound healing rates after TMA. We undertook a retrospective cohort study to compare outcomes in patients who underwent revascularization before and after TMA.

Patients and Methods

After obtaining institutional review board approval, a retrospective cohort study was performed by using electronic medical records from the Kaiser Permanente Northern

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California Healthcare System. The charts of all patients between January 2010 and December 2011 who received TMA were reviewed. Inclusion criteria were as follows: (1) patient age >18 years on the day of surgery, (2) PVD defined by nonpalpable pulses, and (3) postoperative follow-up until wound healing was achieved or proximal limb amputation. Exclusion criteria were as follows: (1) all patients who had TMA with palpable pulses, (2) amputation secondary to trauma, (3) patients who died before documented wound healing or limb loss, and (4) proximal limb amputation secondary to residual infection from TMA. All patients who met inclusion criteria were followed for a minimum of 3 years from their date of amputation until limb loss or healed TMA. Eligible patients were identified by searching the medical records using the Current Procedure Terminology code 84.12; 1257 charts were reviewed, and 153 patients met inclusion criteria.

Intervention

Patients who met the inclusion criteria were then categorized based on whether vascular intervention was performed in association with TMA (Fig.), as defined by intervention within 1 year before or after TMA. The type of vascular intervention, based on the discretion of the attending vascular surgeon, fell into 1 of 2 categories: (1) endovascular approach involving stent placement in a minimum of 1 artery or (2) open surgical bypass. The timing of the vascular procedure was also noted, specifically if the procedure occurred before or after TMA, as well as the time interval between the date of the vascular procedure and the date of TMA. If multiple vascular procedures were performed, the procedure closest to the TMA date was determined to be the procedure associated with TMA. If both endovascular and open surgical bypass were performed, the bypass was determined to be the procedure associated with TMA. Documentation of surgical wound healing or limb loss was obtained from chart review by 2 of the authors (E.S., M.J.). Wound healing was defined by a healed incision at the TMA site after sutures were removed. Our primary aim was to measure the incidence of limb loss, defined by below- or above-knee amputation, within a 3-year period after TMA. We also measured the time to limb loss after TMA. Our secondary aim was to measure wound healing rates after TMA, specifically the rate of wound healing before and after 3 months.

Statistical Analysis

Several patient variables at the time of surgery were examined: age; smoking status (active smoker, nonsmoker, or quit smoking); and history of comorbidities including diabetes, obesity (set at body mass index [BMI] ≥30), end-stage renal disease (ESRD) on hemodialysis, congestive heart failure (CHF), hyperlipidemia, and coronary artery disease. Statistical tests including a categorized chi-square and *t* test were used to analyze the association between the type of vascular intervention, patient comorbidities, and timing of vascular intervention with limb loss and stump wound healing. Statistical significance was defined at the 5% ($p \leq .05$) level. Univariate and multivariate logistic regression analyses were used to assess risk for limb loss based on the type of vascular intervention, timing of vascular intervention, and patient comorbidities. Logistic regression analysis was used to assess predictor variables associated with healing.

Results

In our cohort of 153 patients with PVD, 67 (43.8%) patients lost their limb, regardless of whether vascular intervention was performed and regardless of the type of vascular intervention. We found a significant association between wound healing, limb loss, and type of vascular procedure (endovascular, open bypass, no intervention). Seventy-nine patients underwent endovascular intervention and 39 (49.4%) lost a limb compared with 23 patients who underwent open bypass, of whom only 3 (13.0%) lost a limb. Of the 51 patients who received no vascular intervention, 25 (49.0%) lost a limb (Table 1).

Of the 102 patients who underwent vascular intervention, 88 (86.3%) had TMA performed first. There was only 1 case of surgical bypass performed after TMA. Of the 79 patients who underwent endovascular intervention, 66 (83.5%) were performed before TMA and 13 (16.5%) were performed after TMA. The timing of endovascular intervention, either before or after TMA, had no significant association with wound healing or limb loss.

In the cohort of 66 patients who received pre-TMA endovascular intervention, we looked at the time interval between vascular intervention and TMA (Table 2). Thirty (45.5%) interventions occurred within 1 week before TMA; however, there was no significant association with the time interval and TMA healing or limb loss. Of the 20 patients who had a healed TMA after open bypass, 13 (65.0%) healed within 3 months. Fourteen (35.0%) of the 40 patients who received endovascular intervention healed within 3 months. Open bypass was a significant factor for wound healing <3 months.

Comorbidities including ESRD on hemodialysis ($p = .002$), hyperlipidemia ($p = .02$), and CHF ($p = .04$) all showed a significant association with TMA stump healing and limb loss (Table 3). BMI ≥30 ($p = .04$), ESRD on hemodialysis ($p < .001$), and hyperlipidemia ($p = .02$) were all risk factors for limb loss. The time to limb loss from TMA had a significant association with the type of vascular intervention. Of the 3 patients who lost a limb after open bypass, all delayed limb loss >6 months. On the contrary, of the 39 patients who lost a limb after endovascular intervention, 35 (89.7%) lost it within 6 months. From multivariate risk analysis calculations for risk for limb loss within a 3-year period, we found patient BMI ≥30, ESRD on hemodialysis, and hyperlipidemia to be risk factors for limb loss. Endovascular intervention compared with open

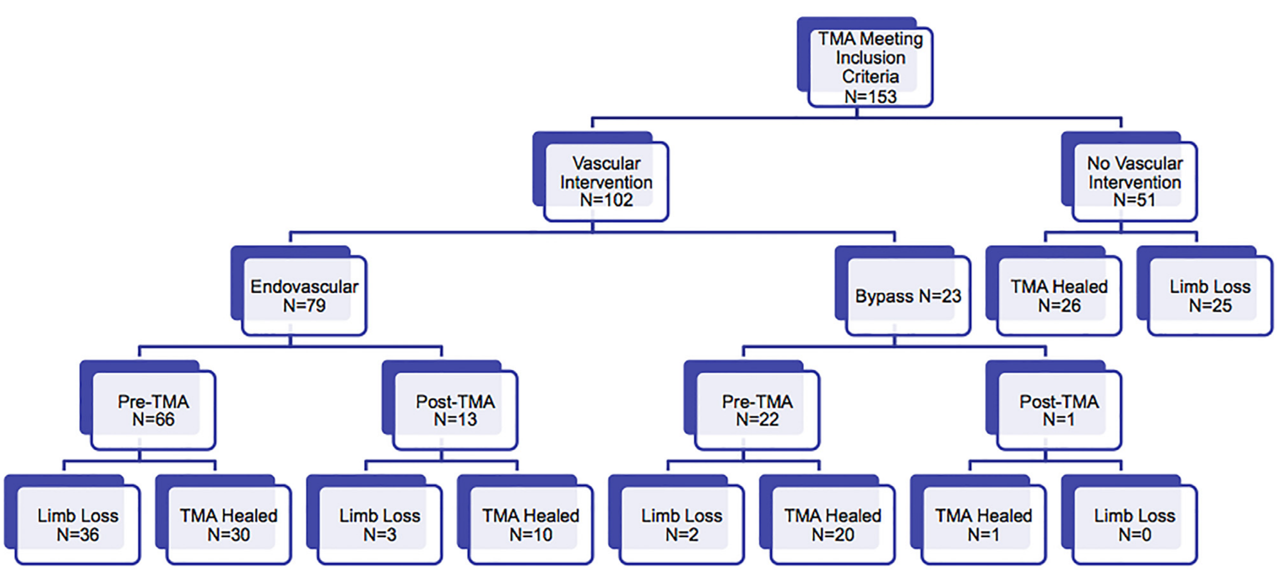

Fig. Flowchart of the intervention that took place and the postoperative outcomes for the 153 patients that met inclusion criteria. TMA, transmetatarsal amputation.

Table 1
Outcomes of wound healing and limb loss based on vascular intervention and patient characteristics

Type of Vascular Intervention*	Limb Loss Time to Limb Loss From TMA Date* <1 mo, N (%)	1–6 mo, N (%)	>6 mo, N (%)	Limb Loss Total, N (%)	TMA Healed Time to TMA Healed From TMA Date* TMA Healed <3 mo, N (%)	TMA Healed >3 mo, N (%)	TMA Healed Total, N (%)
Endovascular (n = 79)	17 (21.5)	18 (22.8)	4 (5.1)	39 (49.4)	13 (16.5)	27 (34.2)	40 (50.6)
Bypass (n =2 3)	0 (0)	0 (0)	3 (13.0)	3 (13.0)	13 (56.5)	7 (30.4)	20 (87.0)
No intervention (n = 51)	25 (49.0)				10 (19.6)	16 (31.4)	26 (51.0)
Total (n = 153)	67 (43.8)				36 (23.5)	50 (32.7)	86 (56.2)

Patient Characteristics	Limb Loss (n = 67) N (%)	TMA Healed (n = 86) N (%)
DM1 or DM2	65 (97)	76 (88.4)
CAD	34 (50.7)	29 (33.7)
ESRD on hemodialysis*	28 (41.8)	14 (16.3)
CHF*	37 (55.2)	30 (34.9)
Hyperlipidemia*	66 (98.5)	68 (79.1)
Smoking status		
Active smoker	6 (9.0)	12 (14.0)
Nonsmoker	20 (29.9)	31 (36.0)
Quit smoking	41 (61.2)	43 (50.0)
Total (n = 153)	67 (43.8)	86 (56.2)

Timing of Endovascular Intervention	Limb Loss (n = 39) N (%)	TMA Healed (n = 40) N (%)
Pre-TMA	36 (92.3)	30 (75.0)
Post-TMA	3 (7.7)	10 (25.0)
Total (n = 79)	39 (49.4)	40 (50.6)

Abbreviations: CAD, coronary artery disease; CHF, congestive heart failure; DM1, type 1 diabetes; DM2, type 2 diabetes; ESRD, end-stage renal disease; TMA, transmetatarsal amputation.
* $p \leq .05$. *p* Values for continuous variables calculated using the *t* test or analysis of variance test; *p* values for categorical variables calculated using the chi-square or Fisher's exact test.

Table 2
Time interval between vascular intervention and transmetatarsal amputation

Time Between Vascular Intervention and TMA, wk	Endovascular Pre-TMA ($p = .996$)* Limb Loss, N (%) N = 36	TMA Healed, N (%) N = 30	Total, N (%) N = 66	Endovascular Post-TMA ($p = .894$)* Limb Loss, N (%) N = 3	TMA Healed, N (%) N = 10	Total, N (%) N = 13	Bypass Pre-TMA ($p = .792$)* Limb Loss, N (%) N = 2	TMA Healed, N (%) N = 20	Total, N (%) N = 22
0 to 1	17 (47.2)	13 (43.3)	30 (45.5)	1 (33.3)	5 (50.0)	6 (46.2)	2 (66.7)	10 (50.0)	12 (54.5)
1 to 2	6 (16.7)	5 (16.7)	11 (16.2)	0 (0)	2 (20.0)	2 (15.4)	0 (0)	3 (15.0)	4 (18.2)
2 to 4	4 (11.1)	4 (13.3)	8 (12.1)	1 (33.3)	3 (30.0)	4 (30.8)	0 (0)	2 (10.0)	2 (9.1)
4 to 8	5 (13.9)	4 (13.3)	9 (13.6)	1 (33.3)	0 (0)	1 (7.7)	0 (0)	2 (10.0)	2 (9.1)
>8	4 (11.1)	8 (12.1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (15.0)	3 (9.1)

Abbreviations: TMA, transmetatarsal amputation.
* *p* Values for continuous variables calculated using the *t* test or analysis of variance test; *p* values for categorical variables calculated using the chi-square or Fisher's exact test.

Table 3
Multivariate risk analysis for limb loss (N = 102 patients)

Predictor Variables Type of Vascular Intervention	Multivariate risk analysis for limb loss* HR (95% CI)	*p* Value
Endovascular (Ref: bypass)	0.545 (0.07 to 4.0)	.5520
Timing of Vascular Intervention		
Post-TMA (Ref: pre-TMA)	1.583 (0.2 to 12.0)	.6586
Patient Characteristics		
Age ≥60 y (Ref: <60 y)	1.079 (0.5 to 2.2)	.8388
BMI ≥30 (Ref: <30)	0.419 (0.2 to 1.0)	.04
ESRD on hemodialysis	3.147 (1.6 to 6.1)	<.001
Hyperlipidemia	5.924 (1.4 to 25.7)	.02

Abbreviations: BMI, body mass index; CI, confidence interval; ESRD, end-stage renal disease; HR, hazard ratio; ref, reference value; TMA, transmetatarsal amputation.
* Variables chosen for multivariable analysis, based on multivariate $p < .05$ and model fit statistics.

bypass was not a risk factor for limb loss. Vascular intervention post-TMA compared with pre-TMA was not a risk factor for limb loss.

Discussion

Diabetic limb salvage continues to challenge foot and ankle surgeons. TMA outcomes in the diabetic patient with PVD and microvascular disease are uncertain and unpredictable. The choice of a "definitive" level of amputation is complicated and depends on a variety of patient-specific factors. Readmission rates within 2 months after diabetic lower extremity amputations occur in 10% to 19% of the cases (14,16). Of these readmissions, 94% required reamputation and 64% of them lost a limb (16). A systematic review by Thorud et al (17) found a 33% rate of limb loss in a cohort of 1146 TMAs**.** Despite these statistics, TMA is still an acceptable level of amputation to preserve the function of the foot in ambulation.

Much work has been done to find predictors of wound healing following TMA. The difficulty with this task is that many variables contribute to wound healing. Abnormalities in laboratory values such as leukocyte count, hemoglobin, lymphocyte count, and albumin can delay wound healing (5). Younger et al (16) found that elevated hemoglobin A1c and the need for repeat debridement were significant factors in predicting TMA failure. Several other studies have found that patients with ESRD on hemodialysis have the worst outcomes for wound healing and the greatest risk for loss of limb and death (18). Landry et al (9) looked at 62 TMAs for forefoot gangrene to find factors to predict wound healing. They looked at patient demographics, comorbidities, and preoperative vascular status and found no measures that were able to predict which patients would go on to heal their amputations. They even found that patients who had TMA without revascularization had similar healing rates as patients who were revascularized. Despite an overall low TMA healing rate of 53% and a 35% incidence of limb loss, the authors still advocated for TMA in the patients with a higher likelihood of continued ambulation.

In our cohort of 153 patients with PVD, 67 (43.8%) lost a limb after TMA. This value is higher than that reported in a meta-analysis performed by Thorud et al (17), who found a 30.2% incidence of limb loss after all TMAs and higher than the findings of Landry et al (9), who found a 35% limb loss rate in cases of forefoot gangrene. We found several areas where open bypass improved patient outcomes compared with endovascular intervention. More patients who underwent bypass healed the TMA stump and avoided limb loss (87%) compared with those who underwent endovascular intervention (51%). This was consistent with the findings by Causey et al (19), who found a 95% limb salvage rate with open bypass and a 68% rate with endovascular intervention. We also found that compared with endovascular intervention, open bypass decreases time to wound healing and delays time to limb loss. Comorbidities including ESRD on hemodialysis, hyperlipidemia, and CHF all showed a significant association with TMA stump healing and limb loss. BMI $\geq$30, ESRD on hemodialysis, and hyperlipidemia were all risk factors for limb loss. These risk factors were consistent with those reported in prior literature (5,9,16,18–20).

Revascularization in any foot with nonpalpable pulses plays a critical role in limb preservation and improving outcomes after lower extremity amputation (10–14). Aggressive revascularization has been shown to significantly improve outcomes of limb preservation (14); however, it is still unclear at what point in the disease process vascular intervention would be most beneficial. One of the main goals of this study was to observe the effect of the timing of vascular intervention on wound healing and limb loss. Sheahan et al (15) were the only authors to look at the timing of revascularization among patients who underwent open surgical bypass; they found a greater incidence of limb loss in patients who received postamputation revascularization compared with those who were revascularized before amputation. They looked at 920 interphalangeal joint, ray, and transmetatarsal amputations and found that surgical bypass after amputation resulted in worse prognosis for limb salvage compared with surgical bypass before amputation. Similar to our study, only patients with ischemic feet defined as nonpalpable pulses were included in the study. Unlike our study, only open bypass revascularizations were performed. Of the 75% of patients who underwent vascular intervention, 1-year limb salvage rates were 91% in the preamputation group and 23% in the postamputation group. The authors concluded that revascularization after amputation results in significant rates of limb loss.

The drawback of the Sheahan et al (15) study was that it did not address the timing of endovascular intervention. In our study, 78% of those who received revascularization underwent endovascular intervention. We found a small percentage (14%) of patients who received vascular intervention after TMA. Of the patients who received endovascular intervention, there was no association with wound healing or limb loss with timing of the vascular procedure. We could not draw the same conclusions for bypass because only 1 patient in our cohort received bypass post-TMA. We also looked at the time interval between vascular intervention and TMA. In the pre-TMA endovascular intervention group, the majority of interventions occurred within 1 week before TMA (46%); however, there was no significant association between the time interval and TMA healing. Vascular intervention closer to the date of TMA in an attempt to "maximize" the effects of the revascularization does not improve wound healing or decrease limb loss.

There is still much debate in the vascular surgery literature regarding the outcomes of open bypass and endovascular intervention for critical limb ischemia. A study by O'Brien-Irr et al (21) looked at 106 endovascular interventions for tissue loss and found wound healing within 4 months in only 21% of cases. Similar to our study, they found that patients with a combination of diabetes and CHF were at risk for developing a nonhealing wound. Nicoloff et al (22) looked at 112 cases of open bypass and found wound healing at an average of 4 months. On the contrary, a study by Varela et al (23) found similar rates of ulcer and limb salvage between open bypass and endovascular intervention groups.

This study has several limitations. First, we did not take into account at the amount of blood flow that was available to the foot at the time of amputation. The quality of the revascularization varied in regard to the number of vessels and amount of blood flow to the foot after vascular procedure. The success of a revascularization was left to the discretion of the treating vascular surgeon in terms of whether it would be sufficient to heal an amputation. Second, given the retrospective nature of the study, there was no standardization as to which patients received an open bypass versus endovascular intervention. Third, an exclusion criterion of this study was if the patient died before wound healing. We did not track what type of vascular intervention these excluded patients received. We do not believe that this would have caused any selection bias. A final limitation would be the small cohort of patients who underwent open bypass, which composed only 23% of all revascularization cases included in the study.

In conclusion, we found an overall 44% rate of limb loss after TMA in patients with PVD. Patients who underwent open bypass experienced a better outcome than those who underwent endovascular intervention, including a lower rate of limb loss and quicker time to wound healing. The timing of vascular intervention and the time interval between vascular intervention and TMA had no association with wound healing or limb loss. Additional research is needed to identify the quantity of blood flow sufficient to heal an amputation site to better guide clinicians in determining a more definitive level of amputation.

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