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OUTCOMES FOLLOWING SEVERE DISTAL TIBIA, ANKLE, AND/OR MID/HINDFOOT TRAUMA. COMPARISON OF LIMB SALVAGE AND TRANSTIBIAL AMPUTATION (OUTLET) http://dx.doi.org/10.2106/JBJS.20.01320

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Casual Analysis

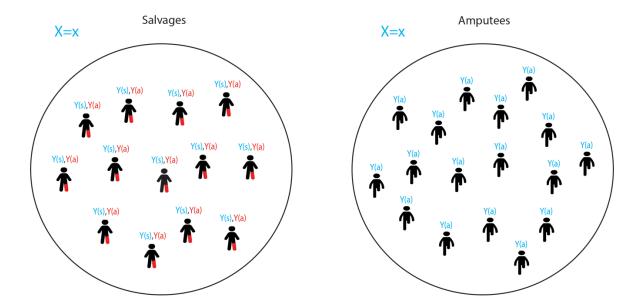
Casual Analysis used in this study requires conceptualizing potential outcomes that patients may have experienced had they received the alternative treatment that is contrary to what was actually received. This is known as the counterfactual. Our goal is to compare outcomes for salvage patients at 18 months to the outcomes these patients would have experienced, had they contrary to fact undergone early amputation. To understand our approach, consider the following thought experiment.

- Imagine stratifying salvage and amputees into strata based on a shared set of covariate information. In the figure below, we denote the covariate information by X and use the notation X=x to indicate that the salvages in the left circle and the amputees in the right circle share the same covariate information.
- Each salvage patient has an observable outcome, i.e., their outcome, under salvage. In addition, each salvage patient has an unobservable outcome representing their counterfactual outcome under amputation. In the left figure below, we use the notation Y(s) to denote the outcome under salvage and use the color blue to indicate that it is observable; we use the notation Y(a) to denote the counterfactual outcome under amputation and use the color red to indicate that it is not observable.
- Each salvage patient has an observable outcome, i.e., their outcome under salvage. We do not imagine their counterfactual outcome under salvage because the injury may not be salvageable. In the right figure below, we use the notation Y(a) to denote the outcome under amputation and use the color blue to indicate that it is observable; we do not introduce the notation Y(s) for amputees.

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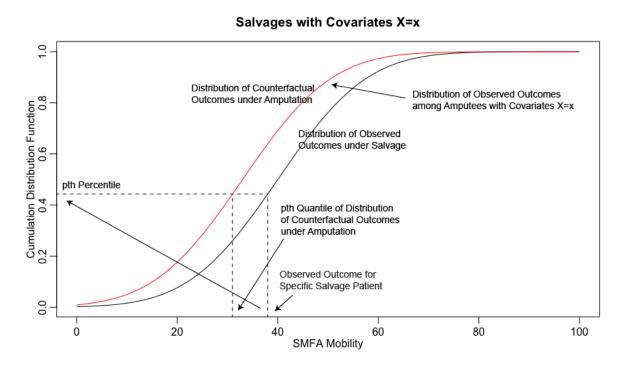


In order to draw inferences about the causal effect of interest, we need to impose assumptions. We assume that, within each stratum X=x, the observable distribution of the outcome among amputees Y(a) is the same as the *unobservable* distribution of the outcome for salvages had they been amputated Y(a) (amputation outcomes for the individuals in the left circle). This is equivalent to assuming that the amputation/salvage decision is independent of the outcome under amputation, within each stratum X=x.

In the figure below, the black line represents the cumulative distribution function for the outcome among patients with limb salvage with covariates X=x. This is based on observable Y(s) values on the left side of the figure above. The red line is the cumulative distribution function for the counterfactual outcome among patients with limb salvage had they been amputated. This is inferred based on the assumption described above from the observable Y(a) values on the right side of the figure above.

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To simulate the counterfactual outcomes, we use a statistical working device called "rank preservation". To understand this device, consider a salvage patient with covariates X=x: compute the percentile (p) of her observable outcome under salvage based on the cumulative distribution function of observable outcomes for salvage patients who share the same covariate values (i.e., black distribution in figure above). The device says that her counterfactual outcome under amputation can be simulated by the p^{th} quantile of the cumulative distribution function of the counterfactual outcomes under amputation (i.e., red distribution in figure above). Under the assumption above, this latter distribution is equal to the observable distribution of outcomes among amputees who share the same covariates X=x.

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In the above figure, the observed outcome for the salvage patient M.W. is 38. This corresponds to the 44th percentile of the distribution among salvages who share the same covariates as M.W. The 44th quantile of the corresponding distribution of the counterfactual outcomes under amputation is 31. Thus, M.W.'s counterfactual outcome is simulated to be 31.

Within covariates X=x, the distribution of the simulated counterfactuals will be equal to distribution of counterfactual outcomes under amputation. We do not use the device to compare the observable outcome under salvage with the simulated counterfactual outcome under amputation for specific individuals. Rather we compare a feature (mean, median) of the distribution of observable outcome under salvage to the same feature of the distribution of the simulated counterfactual outcomes.

In our analysis, we use the following covariates (X): age, gender, race-ethnicity, education, work status pre-injury, insurance status, BMI, self-reported health pre-injury, tobacco use, major co-morbidities pre-injury, vigorous activity status pre-injury, injury severity score, contralateral injury and ipsilateral injury. We assume that injury characteristics below the level of amputation have no impact on the ultimate amputation outcome because the injury is removed with the amputation. That is, we assume we do not need to further stratify on these latter factors in the above thought experiment.

Because X has many levels, the number of individuals in any stratum will be very small. This is called the curse of dimensionality. To deal with this problem, we borrow information across strata through the use of regression models and a technique called Gestimation ^{23,24}. We characterize the uncertainty of our estimators using re-sampling (i.e., bootstrap) techniques.

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Table 1a. Characteristics Among Participants with Limb Salvage who did not Complete versus Completed an 18-month Study Visit

	Did not Complete an	Completed an	p value
	18m Visit	18m Visit	
	(n=96)	(n=392)	
Age, mean (SD)	34.6 (11.3)	38.4 (12.2)	0.005
Female (%)	22 (22.9)	156 (39.8)	0.002
Race-Ethnicity, n(%)		· ·	
White non-Hispanic	60 (62.5)	269 (68.6)	0.550
Non-White non-Hispanic	23 (24.0)	73 (18.6)	
Hispanic	13 (13.5)	45 (11.5)	
Other	0	4 (1.0)	
Missing	0	1 (0.26)	
Education, n (%)			
<high school<="" td=""><td>22 (23.0)</td><td>65 (16.6)</td><td>0.065</td></high>	22 (23.0)	65 (16.6)	0.065
High School/GED	36 (37.5)	115 (29.3)	
>High School	36 (37.5)	204 (52.9)	
Missing	2 (2.1)	6 (1.5)	
Working Pre-Injury, n (%)			
Yes	68 (70.8)	306 (78.1)	
No	26 (27.1)	81 (20.7)	0.492
Missing	2 (2.0)	5 (1.3)	
Active Duty Military, n (%)	2 (2.1)	5 (1.3)	0.551
Health Insurance, n (%)			
Medicaid	12 (12.5)	51 (13.0)	0.608
Other Insurance	59 (61.5)	259 (66.1)	
None	25 (26.0)	82 (20.9)	
Missing	0	0	
Body Mass Index, mean (SD)	29.2 (7.0)	30.5 (8.2)	0.157
Self-Reported Health, n (%)			
Excellent	24 (25.0)	117 (30.3)	0.821
Very Good	35 (36.5)	122 (31.1)	
Good	24 (25.0)	105 (26.8)	

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Fair/Poor	10 (10.4)	42 (10.7)	
Missing	3 (3.1)	6 (1.5)	
Tobacco Use, n (%)			
Never/Former smoker	52 (54.2)	241 (61.5)	0.449
Current Smoker	42 (43.8)	144 (36.7)	
Missing	2 (2.1)	7 (1.8)	
Major Comorbidity, n (%)			
None	58 (60.4)	220 (56.1)	0.624
1	20 (20.8)	100 (25.3)	
>=2	18 (18.8)	72 (18.2)	
Pre-Injury Participation in Vigorous	30 (31.9)	111 (28.8)	0.547
Activity [¶] , n (%)			
Injury Severity Score (ISS)			
<=17	87 (90.6)	337 (85.9)	0.316
>17	9 (9.4)	51 (13.0)	
Missing	0	4 (1.0)	
Contralateral Limb Injury, n (%)	21 (21.8)	90 (23.2)	0.783
Ipsilateral Limb Injury (above the zone of	8 (8.3)	65 (16.8)	0.039
injury), n (%)			

[¶]As determined by the Paffenbarger Physical Activity Questionnaire (PPAQ). Vigorous activity defined as reporting at least one leisure or recreational activity associated with a metabolic equivalent score (MET) of 6 or higher.

Other insurance included private, Medicare, Tricare, or any other form of public insurance.

Major comorbidities included diabetes, cardiac disease, vascular disease, pulmonary disease or psychiatric conditions.

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Table 1b. Principal Injury Characteristics of Patients with Limb Salvage who did not Complete versus Completed an 18-month Study Visit (restricted to OUTLET Study Participants)

	Did not Complete an	Completed an 18m Visit	p value
	18m Visit	(n=392)	
	(n=96)		
Principal Study Injury, n (%)			
Type III Pilon/ IIIB Ankle	34 (35.4)	162 (41.3)	0.457
Type III Talus/Calcaneus	29 (30.2)	97 (24.7)	
Other foot Injury	33 (34.4)	133 (33.9)	
Traumatic Amputation	0	0	
Gustilo Type, n (%)			
Open/Closed Crush/Blast	12 (12.5)	53 (13.5)	0.949
IIIA	54 (56.3)	228 (58.2)	
IIIB	21 (21.9)	79 (20.2)	
IIIC	0	0	
Closed	9 (9.4)	32 (8.2)	
Missing (Traumatic Amputation)	0	0	
Heel Pad Degloving, n (%)	11 (11.5)	43 (10.9)	0.891
Injuries with Flap, Severe Articular	67 (69.8)	290 (73.9)	0.407
Fracture, and/or Severe Bone Loss			
Open OTA Classification (only for	N=87	N=347	
open injuries)			
Contamination, n (%)			
None/Minimal	29 (33.3)	94 (27.3)	0.407
Surface	42 (48.3)	169 (48.9)	
Imbedded	16 (18.4)	82 (23.8)	
Missing	0	2 (0.6)	
Skin Damage, n (%)			
Can be approximated	49 (56.3)	220 (63.4)	0.120
Cannot be approximated	21 (24.1)	63 (18.2)	
Degloving	16 (18.4)	64 (18.4)	
Missing	1(1)	0	
Muscle Damage, n (%)			

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None/Minimal	46 (52.8)	152 (43.9)	0.299
Damaged but functional	34 (39.1)	155 (44.8)	
Damaged and not functional	7 (8.1)	39 (11.3)	
Missing	0	1 (0.3)	
Bone Loss, n (%)			
None	35 (40.7)	121 (34.9)	0.297
Some contact	43 (50.0)	171 (49.3)	
<=2cm	5 (5.8)	22 (6.3)	
>2cm	3 (3.5)	33 (9.5)	
Missing	1 (1)	0	
Arterial Damage, n (%)			
No Injury	70 (81.4)	266 (76.6)	0.641
Without Ischemia	14 (16.3)	71 (20.5)	
With Ischemia	2 (2.3)	10 (2.9)	
Missing	1 (1)	0	

^{**}Articular injuries were defined as OTA 43B orC, 81B or C, or 82 B or C fractures

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Table 2a. Characteristics Among Participants with Amputation who did not Complete versus Completed an 18-month Study Visit

	Did not Complete an	Completed an	p value
	18m Visit	18m Visit	
	(n=37)	(n=114)	
Age, mean (SD)	40.1 (14.2)	40.8 (12.4)	0.791
Female (%)	21.6	16.7	0.494
Race-Ethnicity, n (%)			
White non-Hispanic	27 (72.9)	84 (73.7)	0.925
Non-White non-Hispanic	7 (18.9)	19 (16.7)	
Hispanic	3 (8.1)	11 (9.7)	
Other	0	0	
Missing	0	0	
Education, n (%)			
<high school<="" td=""><td>5 (13.5)</td><td>17 (14.9)</td><td>0.878</td></high>	5 (13.5)	17 (14.9)	0.878
High School/GED	18 (48.7)	50 (43.9)	
>High School	14 (37.8)	47 (41.2)	
Missing	0	0	
Working Pre-Injury, n (%)			
Yes	32 (86.5)	93 (81.6)	0.492
No	5 (15.5)	21 (18.4)	
Missing	0	0	
Active Duty Military, n (%)	2 (5.4)	2 (1.8)	0.230
Health Insurance, n (%)			
Medicaid	5 (13.5)	7 (6.14)	0.171
Other Insurance	23 (62.2)	88 (77.2)	
None	8 (21.6)	19 (16.7)	
Missing	0	0	
Body Mass Index, mean (SD)	28.9 (6.2)	29.0 (5.6)	0.962
Self-Reported Health, n (%)			
Excellent	12 (32.4)	33 (28.9)	0.565
Very Good	15 (40.5)	47 (41.2)	
Good	8 (21.6)	21 (18.4)	

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Fair/Poor	2 (5.4)	13 (11.4)	
Missing	0	0	
Tobacco Use, n (%)			
Never/Former smoker	20 (54.1)	58 (50.9)	0.309
Current smoker	17 (45.9)	56 (49.1)	
Missing	0	0	
Major Comorbidity, n (%)			
None	23 (62.2)	61 (53.5)	0.283
1	10 (27.0)	27 (23.7)	
>=2	4 (10.8)	26 (22.8)	
Pre-Injury Participation in Vigorous	13 (36.1)	35 (30.7)	0.544
Activity [¶] , n (%)			
Injury Severity Score (ISS)			
<=17	32 (86.5)	103 (90.4)	0.465
>17	1 (2.7)	7 (6.1)	
Missing	4 (10.8)	4 (3.5)	
Contralateral Limb Injury, n (%)	10 (30.3)	27 (24.6)	0.508
Ipsilateral Limb Injury (above the zone of injury),n (%)	3 (9.1)	13 (11.8)	0.663

[¶]As determined by the Paffenbarger Physical Activity Questionnaire (PPAQ). Vigorous activity defined as reporting at least one leisure or recreational activity associated with a metabolic equivalent score (MET) of 6 or higher.

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Major comorbidities included diabetes, cardiac disease, vascular disease, pulmonary disease or psychiatric conditions.

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Table 2b. Principal Injury Characteristics among Amputees who did not Complete versus Completed an 18-month Study Visit (restricted to OUTLET Study Participants)

	Did not Complete an 18m	Completed an 18m Visit	p value
	Visit	(n=73)	-
	(n=20)		
Principal Study Injury, n (%)			
Type III Pilon/ IIIB Ankle	7 (35.0)	18 (24.7)	0.524
Type III Talus/Calcaneus	4 (20.0)	11 (15.1)	
Other foot Injury	9 (45.0)	40 (54.8)	
Traumatic Amputation	0	4 (5.5)	
Gustilo Type, n (%)			
Open/Closed Crush/Blast	3 (15)	19 (26)	0.197
IIÎA	6 (30)	8 (11)	
IIIB	9 (45)	26 (35.6)	
IIIC	2 (10)	14 (19.2)	
Closed	0	2 (2.7)	
Missing	0	4 (5.5)	
Heel Pad Degloving, n (%)	11 (55)	40 (54.8)	0.987
Open OTA Classification (only for			
open injuries)			
Contamination, n (%)			
None/Minimal	3 (15)	8 (10.9)	0.161
Surface	11 (55)	22 (30.1)	
Imbedded	6 (30)	35 (47.9)	
Missing	0	8 (10.9)	
Skin Damage, n (%)			
Can be approximated	8 (40.0)	14 (19.2)	0.056
Cannot be approximated	7 (35.0)	15 (20.5)	
Degloving	5 (25.0)	36 (49.3)	
Missing	0	8 (10.9)	
Muscle Damage, n (%)			
None/Minimal	4 (20.0)	6 (8.2)	0.164
Damaged but functional	7 (35.0)	15 (20.5)	

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Damaged and not functional	9 (45.0)	44 (60.3)	
Missing	0	8 (10.9)	
Bone Loss, n (%)			
None	7 (35.0)	15 (20.5)	0.448
Some contact	6 (30.0)	20 (27.4)	
<=2cm	3 (15.0)	6 (8.2)	
>2cm	4 (20.0)	24 (32.9)	
Missing	0	8 (10.9)	
Arterial Damage, n (%)			
No Injury	12 (60.0)	30 (41.1)	0.460
Without Ischemia	4 (20.0)	13 (17.8)	
With Ischemia	4 (20.0)	22 (30.1)	
Missing	0	8 (10.9)	

^{**}Articular injuries were defined as OTA 43B orC, 81B or C, or 82 B or C fractures

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Table 3. Observed Short Musculoskeletal Function Assessment (SMFA) & Brief Pain Inventory (BPI) Scores 18 months following injury

Tuble 5. Observed b		Limb Salvage					
	All Limb Salvage ^a	Type III Pilon/ IIIB Ankle ^b	Type III Talus/Calcaneus ^c	Other Foot Injuries ^d	Without Flap, Severe Articular Fracture, and/or Severe Bone Losse	Flap, Severe Articular Fracture, and/or Severe Bone Loss ^f	Amputation
SMFA							
Bother	28.3 (21.7)	32.2 (23.1)	26.5 (18.9)	24.8 (21.2)	23.4 (19.6)	29.9 (22.1)	26.4 (23.5)
Dysfunction	28.8 (17.5)	32.3 (17.8)	27.3 (16.3)	25.6 (17.4)	25.0 (17.1)	30.1 (17.5)	25.5 (19.3)
Mobility	38.6 (21.8)	42.5 (21.2)	38.1 (21.7)	34.3 (21.9)	33.5 (22.2)	40.4 (21.4)	31.3 (22.0)
Daily Activities	33.9 (24.6)	39.2 (24.6)	31.5 (23.1)	29.2 (24.5)	28.7 (24.5)	35.7 (24.4)	30.3 (26.4)
Emotional	37.2 (22.8)	40.2 (23.8)	35.4 (21.9)	34.9 (22.1)	34.1 (21.4)	28.3 (23.2)	33.4 (24.0)
Arm/Hand	4.0 (8.1)	5.4 (9.8)	2.7 (5.4)	3.3 (7.4)	3.0 (6.4)	4.4 (8.7)	5.7 (11.0)
Pain Scores							
Pain Severity, mean (SD)	3.58 (2.4)	3.89 (2.5)	3.26 (2.2)	3.44 (2.4)	3.38 (2.5)	3.65 (2.4)	2.96 (4.5)
Pain Interference, mean (SD)	3.83 (2.9)	4.31 (3.0)	3.29 (2.5)	3.65 (2.9)	3.16 (2.7)	4.07 (2.9)	3.18 (3.1)

^a SMFA Bother: Salvage n=387; Amputation n=113; Dysfunction: Salvage s n= 390; Amputation n=112; Mobility: Salvage n=390; amputes n=114; Daily Activities: Salvage n=390; Amputation n=112; Emotional: Salvage n=390; Amputation n=112; Pain severity: Salvage n=390; Amputation n=115; Pain interference: Salvage n=388; Amputation n=112

^b SMFA Bother: Salvage n= 160; Dysfunction: Salvage n=161; Mobility: Salvage n=161; Daily Activities: Salvage n=161; Emotional: Salvage n=161; Pain severity: Salvage n=160; Pain interference: Salvage n=159

^e SMFA Bother: Salvage n= 97; Dysfunction: Salvage n=97; Mobility: Salvage n=97; Daily Activities: Salvage n=97; Emotional: Salvage n=97; Pain severity: Salvage n=97; Pain interference: Salvage n=96

^d SMFA Bother: salvages n= 130; Dysfunction: Salvage n=132; Mobility: Salvage n=132; Daily Activities: Salvage n=132; Emotional: Salvage n=132; Pain severity: Salvage n=133; Pain interference: Salvage n=133

^e SMFA Bother: Salvage n= 99; Dysfunction: Salvage n=101; Mobility: Salvage n=101; Daily Activities: Salvage n=101; Emotional: Salvage n=101; Pain severity: Salvage n=102; Pain interference: Salvage n=102

f SMFA Bother: Salvage n= 288; Dysfunction: Salvage n=289; Mobility: Salvage n=289; Daily Activities: Salvage n=289; Emotional: Salvage n=289; Pain severity: Salvage n=288; Pain interference: Salvage n=286

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Table 4. Status of Physical Performance Assessment among Individuals who Completed an 18-month Study Visit

			Limb S	alvage			
	All Limb Salvage ^a	Type III Pilon/ IIIB Ankle ^b	Type III Talus/Calcaneus ^c	Other Foot Injuries ^d	Without Flap, Severe Articular Fracture, and/or Severe Bone Loss ^e	Flap, Severe Articular Fracture, and/or Severe Bone Loss ^f	Amputation
FSST Missing	54 (14%)	23 (14.2%)	14 (14.3%)	17 (12.8%)	15 (14.6%)	39 (13.5%)	17 (15%)
Impaired Completed Mean time (min-max)	64 (16%) 275 (70%) 13.1 (4-106)	32 (19.8%) 107 (66.1%) 15.4 (4-106)	15 (15.3%) 69 (70.4%) 11.6 (5.5-30)	17 (12.8%) 99 (74.4%) 11.6 (4-51)	14 (13.6%) 74 (71.8%) 10.9 (4.5-36)	50 (17.2%) 201 (69.3%) 13.9 (4-106)	16 (14%) 83 (72%) 13.1 (4-44.5)
IAT Missing	100 (25%)	43 (26.5%)	26 (26.5%)	31 (23.3%)	27 (26.2%)	73 (25.2%)	31 (27%)
Impaired Completed Mean time (min-max)	98 (25%) 195 (49.6%) 48.1 (10-136)	48 (29.6%) 71 (43.8%) 48.9 (12.5-136)	24 (24.5%) 48 (49%) 48.9 (20-95)	26 (19.6%) 76 (57.1%) 46.9 (10-117)	23 (22.3%) 53 (51.5%) 46.7 (10-103)	75 (25.9%) 142 (48.8%) 46.7 (12.5-136)	23 (20%) 62 (53%) 43.7 (11-111)
STS Missing	54 (14%)	23 (14.2%)	14 (14.3%)	17 (12.8%)	15 (14.7%)	39 (13.5%)	16 (14%)
Impaired Completed Mean time (min-max)	60 (15.5%) 279 (71%) 14.5 (5-48.5)	34 (21.0%) 105 (64.8%) 14.7 (6-48.5)	12 (12.4%) 72 (73.5%) 14.5 (5-35)	14 (10.5%) 102 (76.7%) 14.4 (5.5-46.5)	11 (10.7%) 77 (74.8%) 14.6 (5-46.5)	49 (16.9%) 202 (70.0%) 14.5 (6-48.5)	22 (19%) 78 (67%) 14.1 (6.5-44)

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TSA Missing Impaired Completed Mean time (min-max)	59 (15%) 	25 (15.4% 	16 (16.3%) 	18 (13.5%) 	17 (16.5%) 12 (11.7%) 74 (71.8%) 8.2 (2-41)	42 (14.5%) 	21 (18%)
	All Limb Salvage ^a	Type III Pilon/ IIIB Ankle ^b	Type III Talus/Calcaneus ^c	Other Foot Injuries ^d	Without Flap, Severe Articular Fracture, and/or Severe Bone Loss ^e	Flap, Severe Articular Fracture, and/or Severe Bone Loss ^f	Amputation
SHR Missing	64 (16%)	31 (19.1%)	16 (16.3%)	17 (12.8%)	15 (14.5%)	49 (16.9%)	19 (16.4%)
Impaired Completed Mean rate m/s (min-max)	79 (20%) 249 (63.6%) 1.46 (0.39-4.5)	40 (24.7% 91 (56.2%) 1.4 (0.41-3.11)	17 (17.4%) 65 (66.3%) 1.4 (0.52-3.4)	22 (16.5%) 94 (70.1%) 1.6 (0.39-4.53)	19 (18.5%) 69 (67.0%) 1.6 (0.54-4.5)	60 (20.7%) 181 (62.4%) 1.40 (0.39-3.35)	23 (19.8%) 74 (63.8%) 1.54 (0.35-3.35)

^aFSST: Salvage n=339; Amputation n=99; IAT: Salvage n=293; Amputation n=85; STS: Salvage n=339; Amputation n=100; TSA: Salvage n=334; Amputation n=95; SHR: Salvage n=329; Amputation n=97

Missing includes participants who completed an interview over the phone and did not return to clinic for assessment, or patients that refused to complete the performance test due to time constraints or other reasons unrelated to the study injury.

Impaired includes participants who were unable to complete the test due to their injury.

^b FSST: Salvage n=139; IAT: Salvage n=119; STS: Salvage n=139; TSA: Salvage n=137; SHR: Salvage n=131

^e FSST: Salvage n=84; IAT: Salvage n=72; STS: Salvage n=84; TSA: Salvage n=82; SHR: Salvage n=82

^d FSST: Salvage n=116; IAT: Salvage n=102; STS: Salvage n=116; TSA: Salvage n=115; SHR: Salvage n=116

 $[^]e\ FSST:\ Salvage\ n=88;\ TSA:\ Salvage\ n=86;\ SHR:\ Salvage\ n=88$

^f FSST: Salvage n=251; IAT: Salvage n=217; STS: Salvage n=251; TSA: Salvage n=248; SHR: Salvage n=241