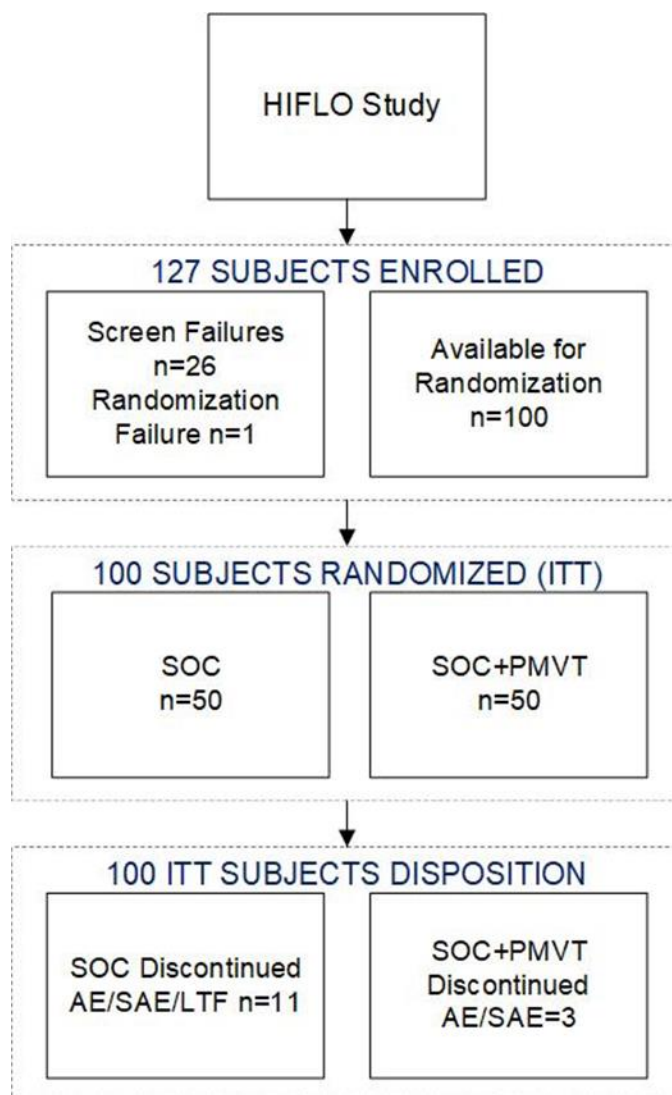


TITLE:

A Multi-center, Randomized Controlled Clinical Trial Evaluating the Effect of Allogenic Microvascular Tissue in the Treatment of Wagner one and two Diabetic Foot Ulcers

PARTICIPANT FLOW



BASELINE CHARACTERISTICS

Variable	SOC+mVASC	SOC	p Value
Age (years)	59.4 (SD 13.22)	61.2 (9.79)	0.43
Race			
Caucasian	44 (88)	46 (92)	0.74
African American	6 (12)	4 (8)	
Sex			
Male	32 (64)	34 (68)	0.67
Female	18 (36)	16 (32)	
BMI	34.3 (8.79)	32.5 (6.65)	0.54
Smoking Status			
Never	24 (48)	24 (48)	0.91
Former	19 (38)	18 (36)	
Current	7 (14)	6 (12)	
Hypertension	39 (78)	37 (74)	0.64
HbA1c			
Screening	8.1 (1.65)	7.4 (1.50)	0.0474
End of study	8.0 (1.88)	7.0 (1.57)	0.008
Creatinine	1.1 (0.36)	1.1 (0.39)	0.80
DFU History			
Significant deformities	12 (24)	14 (28)	0.65
Age first DFU appeared (years)	54.0 (14.3)	55.7 (11.09)	0.51
Prior number of DFUs	3.2 (4.35)	2.7 (2.48)	0.70
Amputations (study foot)	13 (26)	16 (32)	0.51
Amputation (contralateral foot)	6 (12)	11 (22)	0.18
Concurrent DFUs (screening)	6 (12)	12 (24)	0.12

BASELINE WOUND CHARACTERISTICS

Variable	SOC+mVASC	SOC	p Value
Wound are (cm ²) (randomization)	3.1 (3.42) Median: 2; IQR: 2.6	3.5 (2.3) Median: 2.8; IQR: 3.4	0.081
Initial Depth (mm) (screening)			
<1	14 (28)	10 (20)	0.024
1	27 (54)	19 (38)	
2	5 (10)	12 (24)	
>2	4 (8)	9 (18)	
Wound Age (weeks) (screening)	15.2 (10.41) Median: 9; IQR: 13	15.6 (10.75) Median: 8; IQR: 10	0.71
Wagner Grade			
Wagner 1	26 (52)	17 (34)	0.069
Wagner 2	24 (48)	33 (66)	
Plantar Location	41 (82)	35 (70)	0.16
Wound Position			
Lateral	24 (48)	21 (42)	0.55
Medial	26 (52)	29 (58)	
Wound Location			
Toe	13 (26)	7 (14)	0.044
Forefoot	17 (34)	14 (28)	
Midfoot	10 (20)	13 (26)	
Hindfoot	1 (2)	2 (4)	
Heel	8 (16)	8 (16)	
Ankle	1 (2)	6 (12)	
Mean Percent Time Wound Offloaded During Study	82.1 (11.14)	81.1 (9.10)	0.88
Mean Offloading Duration at Screening (weeks)	16.0 (14.78)	14.0 (11.38)	0.51

OUTCOME MEASURES

Primary Endpoint	Results
Percentage of index ulcers healed at 12 weeks	The unadjusted results for the SOC+mVASC group are 37/50 (74%) healed and the SOC group 19/50 (38%) healed, in 12 week's, p=0.00029.

Secondary Endpoints	Results		
Time to heal within 6 and 12 weeks	For the SOC+MVASC group: mean: 53.5 days (95%CI: 46.0-60.9); median: 56 days (95%CI: 40.7-71.3). For the SOC group: mean: 64.3 days (95%CI: 56.5-72.1); it was not possible to calculate median values for the SOC group. p=0.009.		
Percent Area Reduction (PAR) at 6 and 12 weeks	Week	MVASC + SOC	SOC
	4	48.7 (104.17)	19.4 (164.41)
	6	68.9 (56.92)	24.4 (164.93)
	8	71.4 (61.32)	31.3 (167.55)
	12	76.0 (68.83)	23.5 (175.18)
Changes in peripheral neuropathy	For the SOC+MVASC group: baseline, mean: 1.1 (SD: 2.01); end of study, mean: 2.4 (3.25); difference in scores, mean: 1.3 (SD: 2.71). For the SOC group: baseline, mean: 1.8 (SD: 2.76); end of study, mean: 2.0 (SD: 2.93); difference in scores, mean: 0.2 (SD: 1.31). The difference between groups was statistically significant, p=0.028.		
Difference in cellulitis and/or infection at 12 weeks	No differences.		

ADVERSE EVENTS

There was no treatment (product) or procedure related adverse events (AE) or serious adverse events (SAE) in any study subjects.

All AE/SAE that occurred in study subjects are typical of this patient population. See table below that identifies the number and type of event by study group and whether or not it was associated with the study wound.

Type of AE/SAE	SOC+mVASC	SOC
Study Wound	1 SAE (dermatitis) 2 AE (swelling -1, infection-1)	4 SAE (amputation-1, infection 2, osteomyelitis-1) 4 AE (wound worsened-1, infection-1, cellulitis-1, bursitis-1)
Total Study Wound	3 (SAE-1, AE-2)	8 (SAE-4, AE-4)
Non-Study Wound – Disease Related	3 SAE (amputation-1, biopsy-1, skin graft-1) 2 AE (cellulitis-1, blister-1)	3 SAE (infection-1, swelling-1, PVD-1) 7 AE (new wound/infection-4, skin graft-1, cellulitis-1, osteomyelitis-1)
Total Non-Study Wound	5 (SAE-3, AE-2)	10 (SAE-3, AE-7)
TOTAL DFU	8 (SAE-4, AE-4)	18 (SAE-7, AE-11)

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