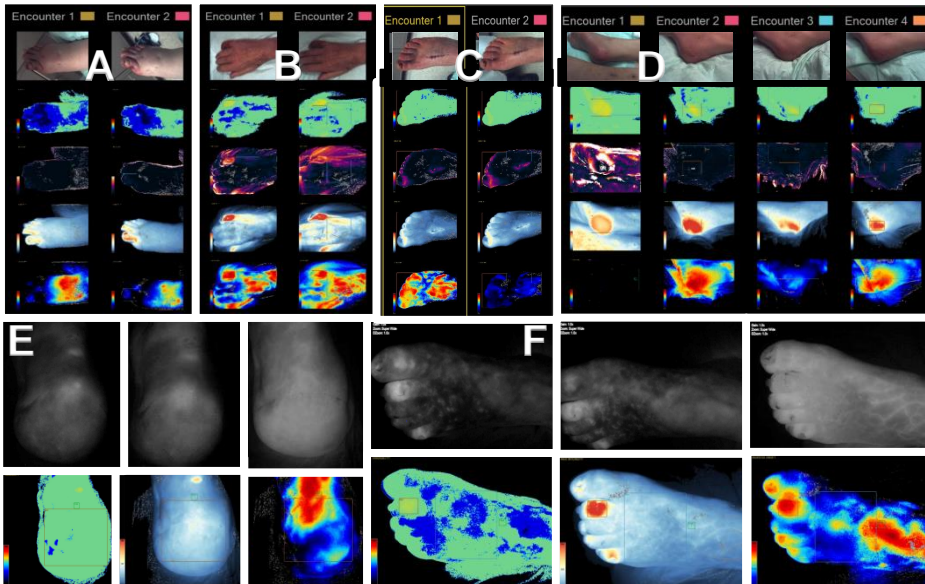


The Rooke® Boot: Providing Offloading Protection and Enhanced Skin Perfusion

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INTRODUCTION

Changes in cutaneous circulation in response to local and whole body heat stresses have been reported to occur due to a combination of local and neurally mediated vasodilation of the cutaneous vascular system. These mechanisms are predominantly mediated by temperature changes and result in shunting of blood from the core to the periphery at upwards of 7-8L/min in cases of where profound heat stresses are applied. The ability of local heat stress applied to increase cutaneous circulation may be of benefit in the extremity affected by an acute or chronic wound in the presence of peripheral arterial disease. The Rooke® Boot is designed to protect the limb for additional trauma, insulate the limb to reduce the effects of heat loss and offload the limb to assist in wound healing. It was hypothesized that the effect of heat retention may also result in increased local skin perfusion. Six subjects with extremity wounds in various locations were studied prior to and following application of a Rooke® boot device for 60 minutes and some additional days or weeks after daily use. All six patients exhibited signs of increased warmth and local cutaneous perfusion as documented with fluorescence angiography. Fluorescence angiography was also able to document shunting of this increase cutaneous blood flow to the area of the wound. This may result in healing of wound that might not heal due to the presence of peripheral arterial disease.



LEGEND: A – Critical limb ischemia with tissue loss, largest wound on the medial hallux, pre-Rooke boot (Encounter 1) and post-Rooke boot application for 60 minutes (Encounter 2), blood flow is preferentially shunted to the hallux; B – Steal Syndrome and calciphylaxis, pre-modified Rooke boot (Encounter 1) and post-modified Rooke boot application for 60 minutes (Encounter 2), blood flow is preferentially shunted to the third and fourth digits which had the least amount of flow prior to modified Rooke boot use; C – Normal noninvasive studies and pain to distal tips of digits, pre-Rooke boot (Encounter 1) and post-Rooke boot application for 60 minutes (Encounter 2), note shunting of blood to the distal digits; D – Pain to left heel with no visible changes to skin on physical examination, Initial imaging (Encounter 1), pre-Rooke boot (Encounter 2), post-Rooke boot application for 60 minutes (Encounter 3) and 4 days after daily use (Encounter 4), note area of reduced fluorescence as bottom of heel in Encounter 2 and 3 and resolution in Encounter 4 signifying reduced pressure and inflammation to the area; E – Critical limb ischemia and BKA, pre-modified Rooke sleeve (top, left), post-modified Rooke sleeve application for 60 minutes (top, middle), and two weeks after daily use (top, right) with associated color map analysis (bottom row), note increased fluorescence signal from left to right, Ingress Onset Map (bottom row, right) reveals onset of signal at anterior proximal tibia; F – Critical limb ischemia and tissue loss to dorsum of digits 2-5, pre-Rooke boot (top, left), post-Rooke boot application for 60 minutes (top, middle), and after four days of daily use (top, right) with associated color map analysis (bottom row), note increased fluorescence signal from left to right, Ingress Onset Map (bottom row, right) reveals onset of signal along course of dorsalis pedis artery

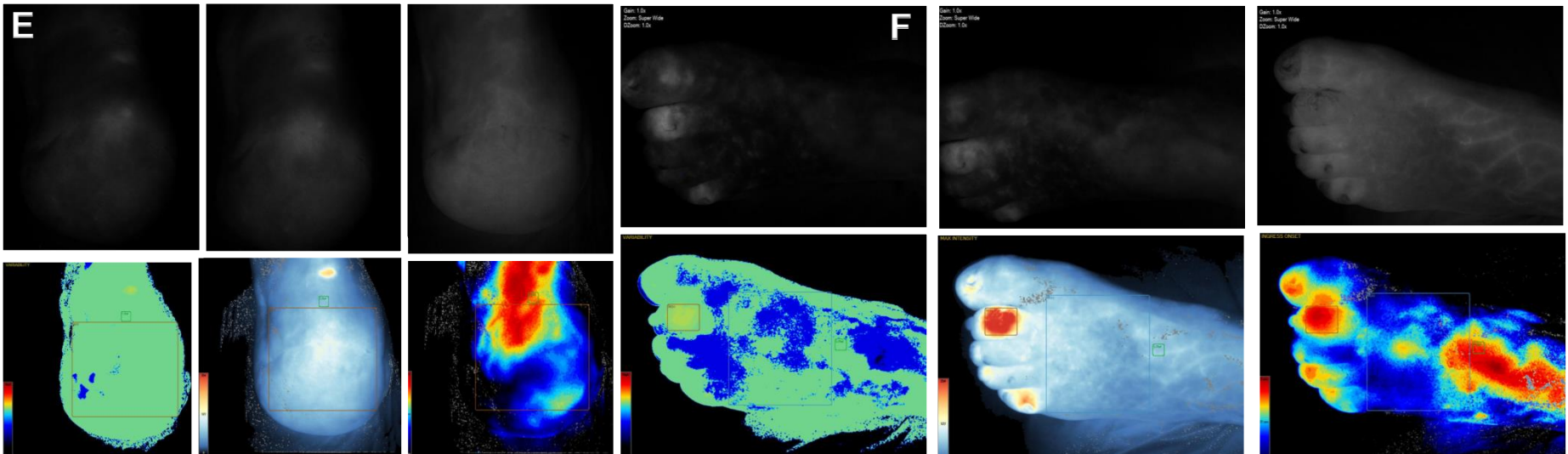
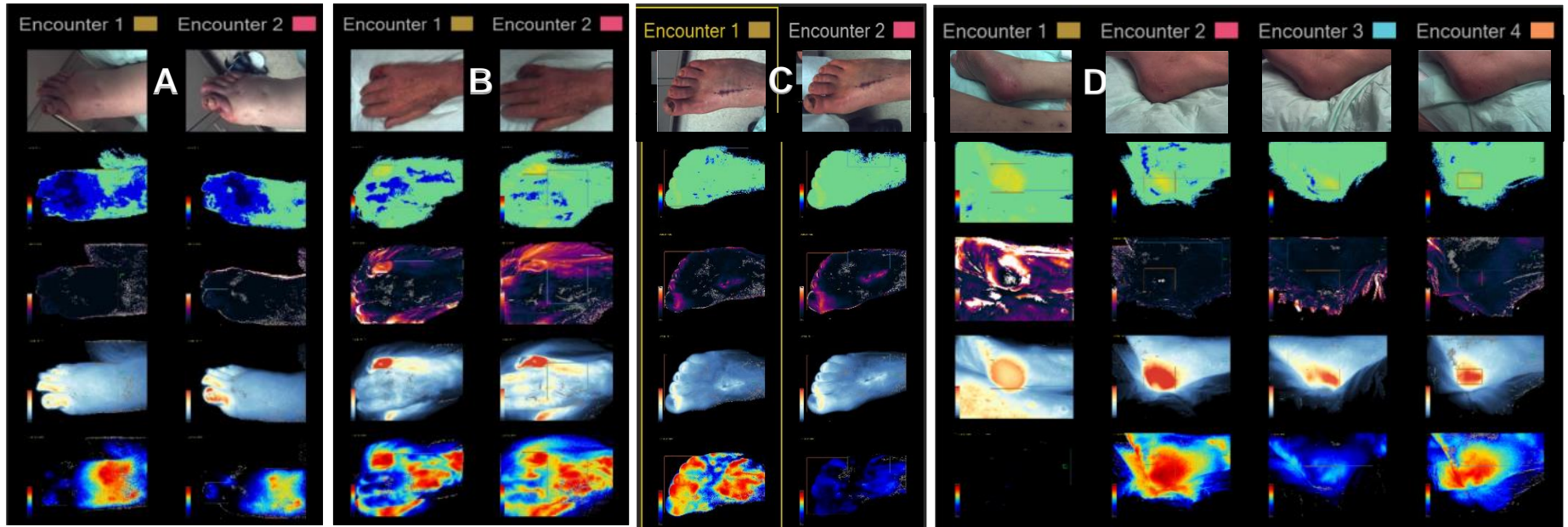
Subject	M/F	Age	Location of Wound	Time of NIR angiography in relation to Rooke Boot Use	Body Temp °F	Local Skin Temp °F	ROI 1 IR	ROI 1 ER	ROI 2 IR	ROI 2 ER
A	M	79	Right foot dorsal digits	Pre	97.3	85.7	0.8	0.1	2.5	0.2
				60 minutes post	97.3	88.0	0.5	0.0	3.4	0.3
B	M	69	Right hand	Pre	98.5	82.8	15.4	3.9	3.0	0.2
				60 minutes post	98.3	85.0	14.5	4.8	4.8	0.4
C	M	56	Right distal hallux	Pre	NR	NR	2.5	0.1	0.4	0.0
				60 minutes post	NR	NR	3.5	0.2	0.7	0.1
D	M	84	Left heel *no open wound	Baseline	99.7	NR	12.9	1.3	4.0	0.3
				Pre	97.8	96.1	10.4	0.3	3.4	0.2
				60 minutes post	98.0	96.9	9.4	0.3	3.2	0.2
				4 days post	97.8	NR	11.5	0.9	2.9	0.2
E	M	69	Distal left BKA	Pre	98.6	82.8	NA	NA	NA	NA
				60 minutes post	98.0	85.0	NA	NA	NA	NA
				2 weeks post	98.2	97.5	1.8	0.2	1.7	0.1
F	M	75	Left foot toes	Pre	97.5	79.1	NA	NA	NA	NA
				60 minutes post	96.4	81.3	NA	NA	NA	NA
				4 days post	97.1	98.1	12.5	1.9	1.7	0.1

LEGEND: ER – Egress Rate, decrease in fluorescence signal intensity from peak to baseline/seconds; F – female; IR – Ingress Rate, increase in fluorescence signal intensity from baseline to peak/seconds; M – male; NR – not recorded

CONCLUSION

Use of the Rooke® Boot provides effective protection, offloading and insulation of the extremity. This study supports the additional benefit of increasing skin perfusion as an adjunct to healing wounds in the ischemic extremities.

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