

DEHYDRATED AMNION MEMBRANE ALLOGRAFT (DAMA)* THERAPY FOR PLANTAR DIABETIC FOOT ULCERS: COMBINING PLACENTAL ALLOGRAFT WITH OPTIMAL OFF-LOADING



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OBJECTIVE

Adequate pressure off-loading of plantar diabetic foot ulcers (DFUs) is known to be the Gold Standard of care, and total contact casting (TCC) is recognized as the modality that best reduces this pressure. The objective of this case series is to demonstrate the results of adding DAMA to the Roll on TCC System with the goal of identifying any increased benefit of combination therapy.

METHODS

A three patient case series of diabetic patients with plantar ulcers, adequate perfusion to heal, previous failed therapies, and orthopedic abnormalities in the affected foot. The Roll on TCC System™ was placed approximately weekly, and the primary dressing, DAMA, was placed approximately every two weeks. Patient #1 had a severely supinated ankle since childhood with exposure of joint capsule and history of MRSA; Patient #2 had Charcot changes with mid-foot collapse and an acute Jones fracture; Patient #3 had a rocker-bottom foot, exposure of tendon, and history of *Pseudomonas*. Previous therapies included applying a cast (on and off) without an advanced ulcer dressing under the cast for approximately 4 years.

RESULTS

Patient #1 had a days-to-healed (DTH) of 42 since the first treatment, and required 3 applications of DAMA. Patient #2, DTH of 42 requiring 3 applications of DAMA, and Pt# 3, DTH of 72 requiring 5 applications of DAMA. One new ulcer from the cast occurred during treatment, in Pt# 3 which was treated and healed prior to the index ulcer healing. The average DTH was 52, with the average number of grafts being 3.7.

DISCUSSION

Results compare very favorably with current treatment regimens, and show a favorable DTH with these complex patients. These results suggest that combining DAMA with the Roll on TCC System should be considered in patients with this type of diabetic ulcer, in the ongoing effort to achieve healing in the shortest time possible.

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TCC LT is a registered trademark Derma Sciences Inc, Princeton, NJ USA
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References: Cavanagh PR, Owens TM. Nonsurgical strategies for healing and preventing recurrence of diabetic foot ulcers. Foot and Ankle clinic N Am 11:735-743, 2006. Armstrong DG, et al. Off-loading the diabetic foot wound. Diabetes Care 24:1019-1022, 2001. Mueller NJ, et al. Effect of Achilles tendon lengthening on neurotrophic plantar ulcers. Journal of Bone and Joint Surgery 85A:1438-1445, 2003. Katz JA, et al. A randomized trial of two removable off-loading devices in the management of plantar neuropathic diabetic foot ulcers. Diabetes Care 28:555-559, 2005. Puggioni A, et al. An off-the-shelf instant contact casting device for the management of diabetic foot ulcers. Diabetes Care 28:595-599, 2005. Mueller NJ, et al. Total contact casting in treatment of diabetic plantar ulcers. Controlled clinical trial. Diabetes Care 12:384-388, 1989. Caravaggio C, et al. Effectiveness and safety of a nonremovable fiberoptic off-loading cast versus a therapeutic shoe in the treatment of neuropathic foot ulcers. Diabetes Care 23:1746-1751, 2000. Armstrong DG, et al. Evaluation of removable and immovable cast walkers in the healing of diabetic foot wounds. Diabetes Care 28:551-554, 2005.

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CASE 1

68 yo Hispanic male stepped on a nail. He had surgical ID with wash out and MRSA treated with IV antibiotics in hospital and po at home.

History: DM, HTN, Neuropathy, Severe Supination of Lt. foot. Went to the OR May 18th and seen in WCC 1 month later. Saline W to D dressings with Iodasorb gel used prior to DAMA and Roll on TCC System.

Results: DAMA and Roll on TCC System started 6/19/14 and patient was healed on 7/31/14.



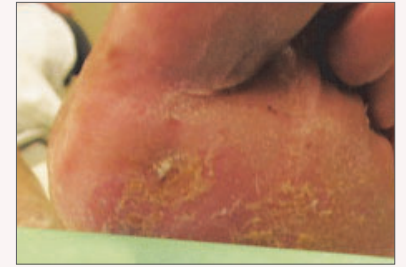
6/19/14 – Prior to 1st application of DAMA and Roll on TCC system



7/10/14 – Prior to 2nd application of DAMA and Roll on TCC System



7/17/14 – 1 week after 2nd application of DAMA and Roll on TCC System



7/31/14 – Wound is healed

CASE 2

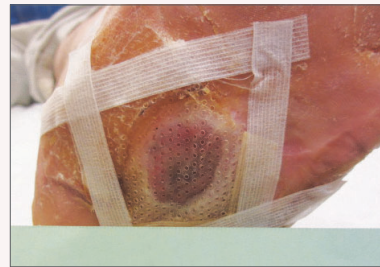
67 yo female wound present for the previous year.

History: DM, Neuropathy, and Charcot foot. Prior wound care: Betadine/Neosporin/Iodasorb gel and gauze. This patient fell and had a Jones fracture of the foot with the wound.

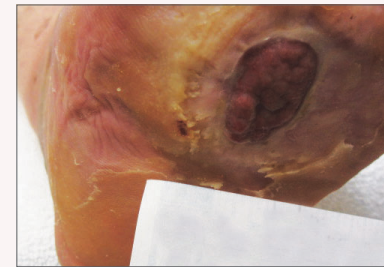
Results: DAMA and Roll on TCC System were started on 8/14/14 and the wound healed by 9/25/14.



8/14/14 – Prior to 1st application of DAMA and Roll on TCC system



8/26/14 – 2nd application of DAMA and Roll on TCC system



9/10/14 – 3rd application of DAMA and Roll on TCC system



9/25/14 – Wound is healed

CASE 3

72 yo male with wound present for 4 years, previously treated with NS W/D gauze and Antimicrobial Alginate Dressings.

History: DM, CHF, HTN, Neuropathy, and Chronic Renal Failure. Pt had a normal floral culture. Early Charcot and used the Charcot boot.

Results: DAMA and Roll on TCC System started 7/18/14 and patient was healed by 10/17/14.



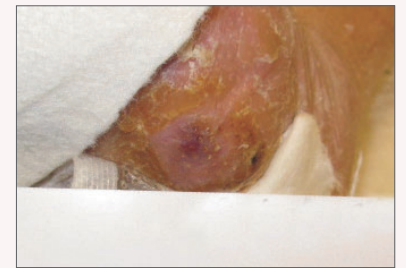
7/18/14 – Prior to 1st application of DAMA and Roll on TCC system



9/11/14 – 2nd application of DAMA and Roll on TCC system



9/25/14 – 3rd application of DAMA and Roll on TCC system



10/17/14 – Wound is healed