





ABSTRACT

Purpose: To demonstrate the benefit of adding Microburst Insulin Infusion (MII) to conventional diabetic wound care to significantly decrease time to heal.

Methods: Five patients received MII treatment for significant peripheral diabetic ulceration after failing conventional wound care. MII is an adjunctive treatment to conventional diabetic therapy performed in an outpatient clinic setting. Oral glucose based on weight is administered followed by pulsatile intravenous insulin administered by the Bionica Microdose pump. The treatment is comprised of three 1 hour sessions and occurs up to five times a week. Five cases were treated from 4 independent MII clinics. Four of the wounds exceeded 6 cm² with one measuring 228.6 cm². Patient charts were reviewed and relevant data collected.

Results: A significant decrease in wound healing time was observed when utilizing MII. The mean time to complete healing was 84.2 days compared to 133 days in published literature.

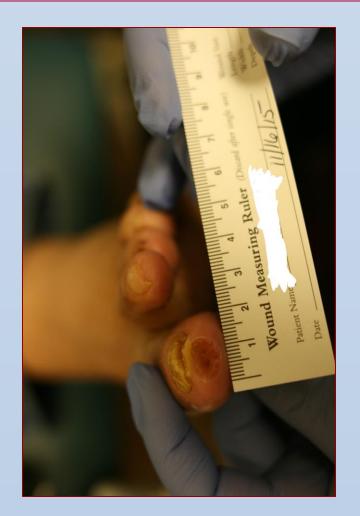
The patient with a foot wound measuring an amazing 228.6 cm² healed in 180 days and amputation was not necessary. There were no treatment failures in this small series. As a result of decreased healing time, there was an absence of infection and no amputations were necessary for these wounds.

Conclusion: The addition of MII therapy resulted in a shortening of the time to healing by 49 days (7 weeks) for patients with poor response to conventional wound care. This is a 37% reduction in time to heal thus reducing risk of infection and additional healthcare costs. The mechanism of action of MII is still unclear, but may involve an improved cellular metabolism, decreased inflammation and increased levels of Nitric oxide that enhance peripheral vascular supply and tissue healing.

CASE STUDY 1

67 y.o. Male, Type 1 DM





After 19 Treatments

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Healing of Peripheral Diabetic Ulcerations and Necrosis Utilizing Microburst Insulin Infusion (MII)

John Elliott, M.D.; Nardo Zaias, M.D.; Sandra Escovar, M.D.; Allison Cimler, FNP-C; Andrew Elliott, B.S.; G. Ford Gilbert, PhD

¹Diabetic Innovations, Scottsdale, AZ ²Trina Health, Sacramento, CA ³Telangana, India ⁴Trina Health of Florida, Miami, Florida

CASE STUDY 2

60 y.o. Female, Type 2 DM

After 20 Treatments

CASE STUDY 3

65 y.o. Female, Type 2 DM

CASE STUDY 4

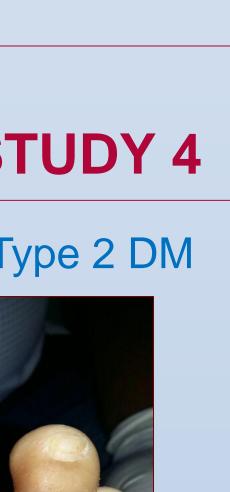
56 y.o. Male, Type 2 DM

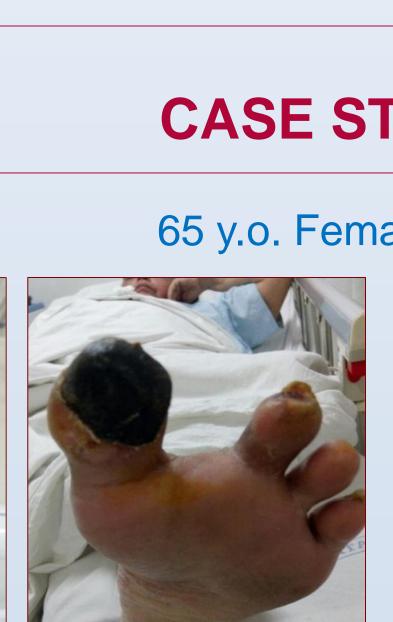






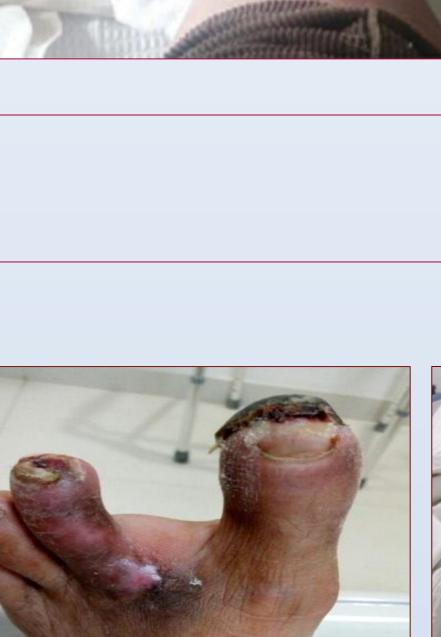








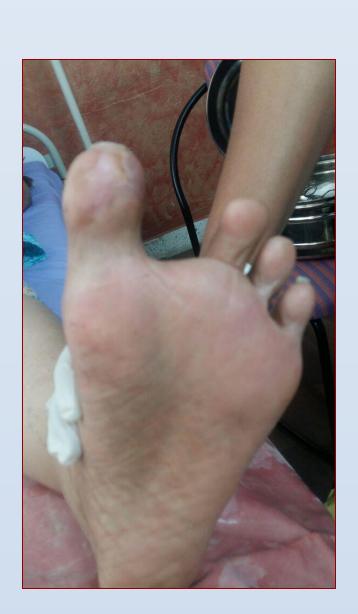












After 30 Treatments



Case Study #	Pre-MII Wound Area (CM ²)	Total # of MII Tx	Frequency of Tx per week	Time to Healing (Days)	Healed (Y/N)
1	1	19	1X	180	Y
2	228.6	20	2X	102	Y
3	3 rd Toe Great Toe 1 12	30	5X	36	Y/Y
4	6.4	38	5X	32	Y
5	18	19	2X	71	Y
Literature Comparison ¹	6.12	NA	2x	133	5Y/3N

Worldwide, every 30 seconds, a limb is lost to diabetes. Nearly 2 million people living in the US are living with limb loss².

Compared to data on wound healing by Zimny, 2002¹, MII therapy resulted in healing in 6 out of 6 wounds compared to 5/8 for standard therapy.

MII in addition to standard diabetic wound care has the potential to reduce amputations which result in death of 80% of patients within 5 years.²

The mechanism of action of MII is still unclear, but may involve an improved cellular metabolism, decreased inflammation and increased levels of Nitric oxide that enhance peripheral vascular supply and tissue healing.

The addition of MII therapy resulted in a shortening of the time to healing by 49 days (7 weeks) for patients with poor response to conventional wound care.

This is a 37% reduction in time to heal thus reducing risk of infection and additional healthcare costs.

(1) Zimny, Stefan, et al. "Determinants and Estimation of Healing Times in Diabetic Foot Ulcers." Journal of Diabetes and Its Complications, vol. 16, no. 5, 2002, pp. 327–332., doi:10.1016/s1056-8727(01)00217-3. (2) Hoffstad, Ole, et al. "Diabetes, Lower-Extremity Amputation, and Death." *Diabetes Care*, vol. 38, no. 10, 2015, pp. 1852–1857., doi:10.2337/dc15-0536.





CASE STUDY 5

77 y.o. Female, Type 2 DM

RESULTS

DISCUSSION

CONCLUSION