Infrared Eyes(iREyes)-Thermal Indexing to Quantify Wound Healing

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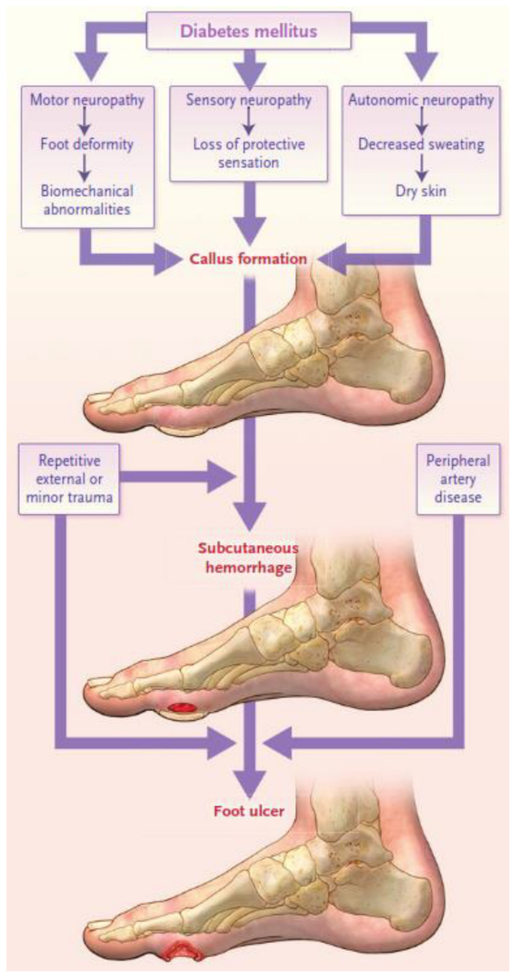
The Problem

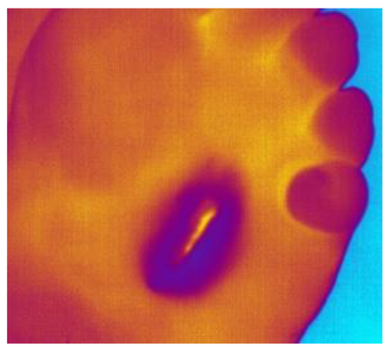
Common Pathway of Diabetic Foot Ulcer Occurrence and Recurrence



Key Facts-

- 9.1 to 26.1 million diabetic foot ulcers develop per year worldwide[1]
- 785 million outpatient visits(between 2007 and 2013) due to DFU and infection[2]
- $176 billion per year in US for diabetic direct costs[3]
- 40% DFU reoccurrence within 1 year(60% within 3 years[4]
- Strongest predictor of DFU is previous ulcer[5]
- Key Factors- early signs of skin damage(callus, blistering, or hemorrhage), repetitive shear stress, loss of sensation
- Early recognition is a key to preventive care(temperature ID-inflammation, callus(assess potential to hemorrhage), degree of redness, limit patient activity, education
- ***Key Strategy***- to detect inflammation as thermal map[6] and it's relationship with morphological factors(i.e. callus formation, degree of swelling, isotherm pattern (contour lines, temperature gradient-increasing/decreasing, isotherm density-spacing between lines, area of, stack shape)), hot or cold spot(occlusion or blood flow)

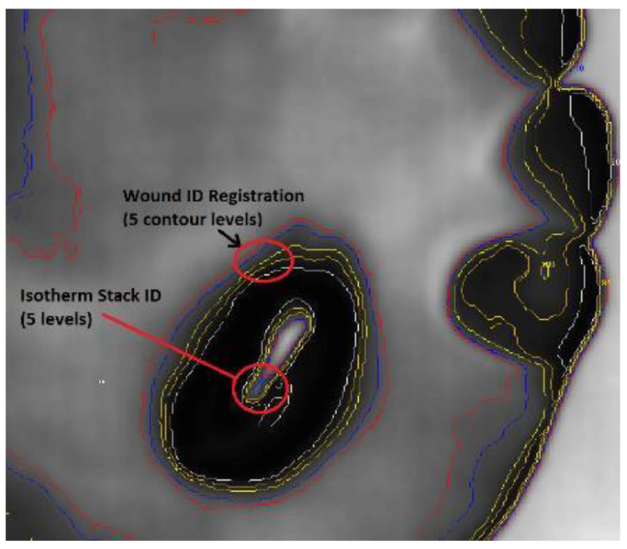
Case Study-Thermal Indexing



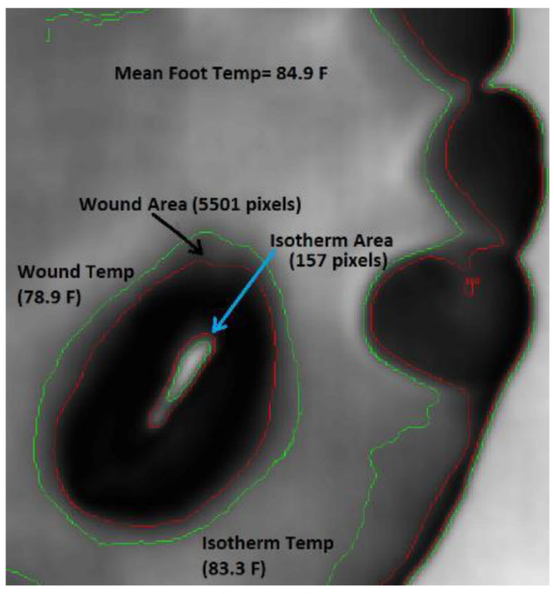
Mid Left Plantar Wound

Visual Image

A 33 year old male with mid left plantar ulcer during our Phase 1 SBIR Study . He is a type 2 diabetic with neuropathy. He has osteomyelitis, depression, bipolar (Type 1 disorder) condition, and existing left distal hallux wound as risk factors. Wound ID- His wound was treated over a 17 week period and 10 visits. Wound edges were thickened and macerated. A light amount of serous fluid existed.



Region of Interest(ROI)

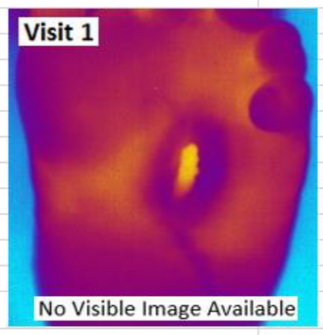


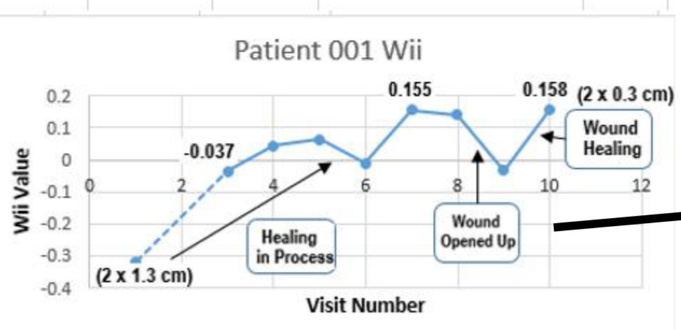
Isotherm Details

Storyboard

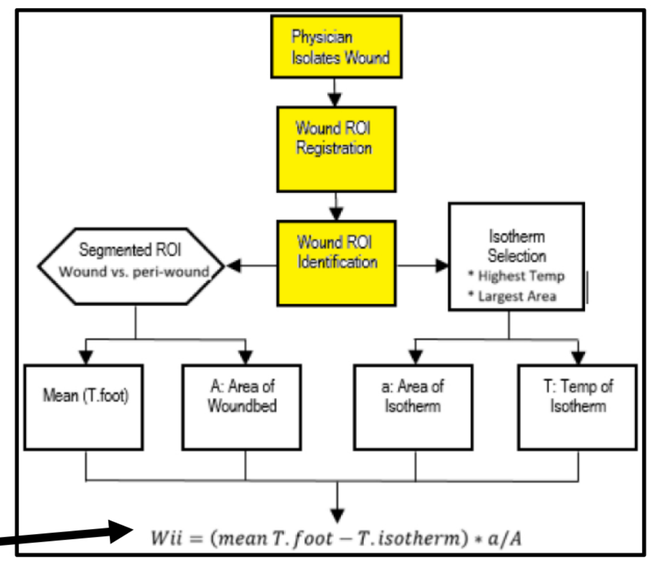
Subject ID	Age	Gender	Diabetes Type	Ethnicity	Year Diagnosed	Neuropathy	Foot	Location of Ulcer
001	33	Male	Type 2	Not specified	Not Specified	Yes	Left	Mid Left Plantar

Visit Number	File	Date	Average Temp	Isotherm Area	Isotherm Temp	Woundbed Area	Woundbed Temp	Delta T	Wii Calc	Isotherm
1	623	9/27/2016	83.1	593	86	5476	81.3	-2.93	-0.318	warm
2	-	10/4/2016	no data	no data	no data	no data	no data	-	-	-
3	339	10/25/2016	89.3	361	89.8	4353	87.7	-0.444	-0.0368	warm
4	327	11/18/2016	84.7	298	83.7	7151	79.4	1.05	0.044	cold
5	215	12/2/2016	87.9	115	87	1531	86.5	0.841	0.063	cold
6	203	12/28/2016	90.4	253	90.7	5635	88.4	-0.245	-0.011	warm
7	207	1/5/2017	87.5	352	85.4	4830	86.2	2.126	0.155	cold
8	319	1/13/2017	86.7	191	83.6	4261	81.6	3.146	0.141	cold
9	207	1/20/2017	88.2	205	89.6	9177	86.3	-1.487	-0.033	warm
10	543	2/3/2017	91.1	189	88.2	3400	85.8	2.844	0.158	cold





Wound Index-Wii



Isotherm Criteria-

- ***Highest Temperature***
- ***Largest Area***

Key Isotherm Map Parameters-

- *Contour Lines(thermal profile)*
- *Thermal Gradient*
- *Isotherm Density*
- *Area of Isotherm*
- *Isotherm Stack Shape*

Conclusions

- Thermal Indexing- is a powerful diagnostic method for assessing wound healing and ulceration reoccurrence risk
- Key criteria for assessment of wounds- highest/lowest temperature and largest isotherm area
- Two types of wound healing patterns observed to date- a negative-to-positive index and a positive-to-negative index with both patterns trending to a final index value of zero as healing was occurring. The index trending may indicate have the potential of delayed healing due to existing ischemic conditions

Acknowledgements

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