

Abstract

Background: Diabetic foot ulcer (DFU) is a complication of diabetes mellitus (DM) and the leading cause of nontraumatic lower limb amputations. The lifetime incidence of DFU formation in individuals with DM may be as high as 25%. In 2013, an estimated 384 million individuals suffered from DM. The etiology of DFU is multifactorial and primarily includes some combination of neuropathy, poor vascularity, and isolated or repeated trauma. Once a DFU has formed, the wound microenvironment is characterized by poor healing due to continued pressure and/or trauma, chronic infections, and displacement of the plantar fat pad. Current DFU treatments are laden with expense and unpredictable outcomes; however, emerging evidence indicates that autologous micro-sized fat tissue may be a safe and effective alternative to the current treatment options.

Methods: In this randomized controlled trial with two arms, 28 patients will be randomized to standard of care or to micro-sized adipose tissue injection prepared using the SyntrFuge™ System, which will output a minimally manipulated adipose tissue. Clinical outcomes were determined weekly up to 12 weeks and then 2-4 week post wound closure. Primary Endpoints is calculating the heal rates of the subjects treated with the adipose tissue processed with the SyntrFuge™ System versus Control (SOC). As well as obtaining the wound closure data at a 12-week timeframe. Secondary Endpoints will include Percent Area Reduction (PAR) at 4, 8 and 12 weeks, Safety in relation to the number of adverse events (all types) reported while the device is in use against the control group.

Preliminary Results: Initial recruitment for this study has followed 6 patients. Six patients have undergone the SyntrFuge Treatment arm of the study has completed healed and closed their wound on average of 4 ± 0.6 weeks. Six other patients in the SOC group have either healed or failed to heal at their respective Healing Confirmation Visits, with an average wound closure time of 11 ± 1.6 weeks. We will continue to study the patients and recruit more in the next few months. No treatment-related adverse events nor relapses were documented.

Preliminary Conclusion: With this first-in-human data, we understand that more data is needed. We believe that that over the course of the next 8 months we should complete a good portion if not all the patients needed for our 28-patient randomized controlled study. However, this initial human data showing complete wound closure at 4 ± 0.6 weeks post a single injection of micro-sized adipose tissue processed with the SyntrFuge system is very promising. The SyntrFuge system overcomes manual processing techniques related to the processing of adipose tissue, along with adding the benefits of standardization and automation of the process to output consistent micro-sized adipose tissue for the treatment of DFUs.

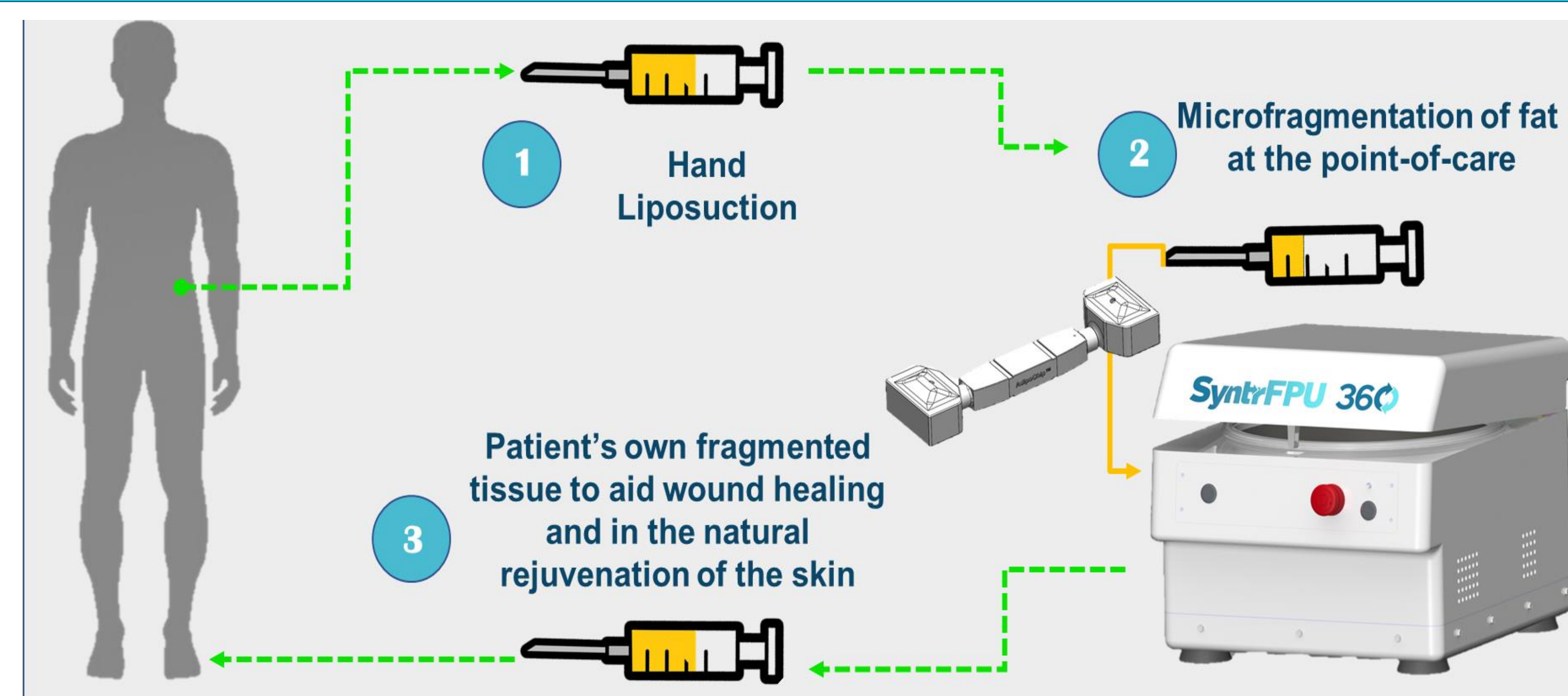
Solution

Syntr Health Technologies, Inc. has developed a point-of-care, autologous, and affordable adipose tissue therapeutic. Through minimal manipulation the SyntrFuge™ system can utilize the structural and supportive properties of human fat tissue to aid in wound healing.

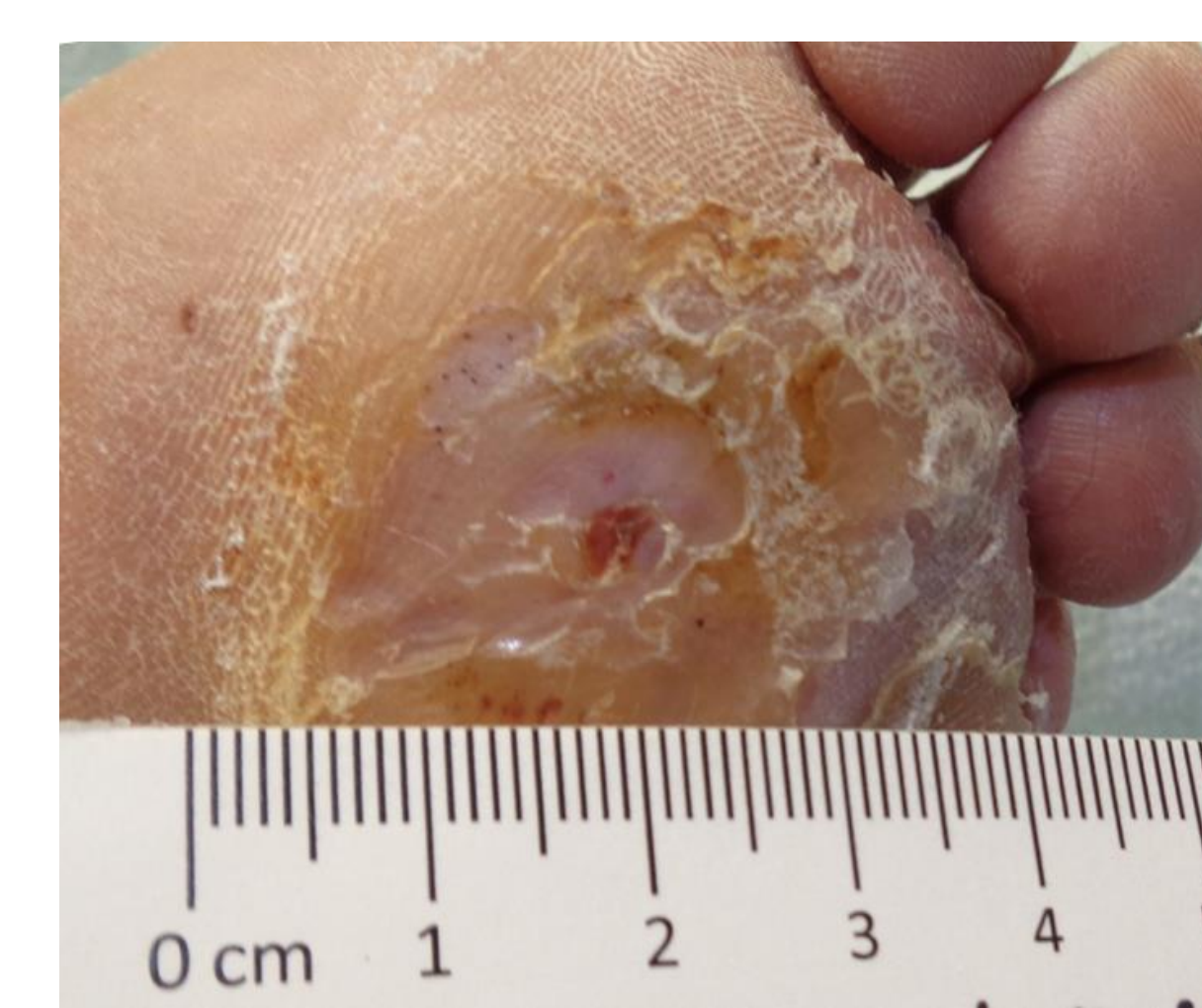
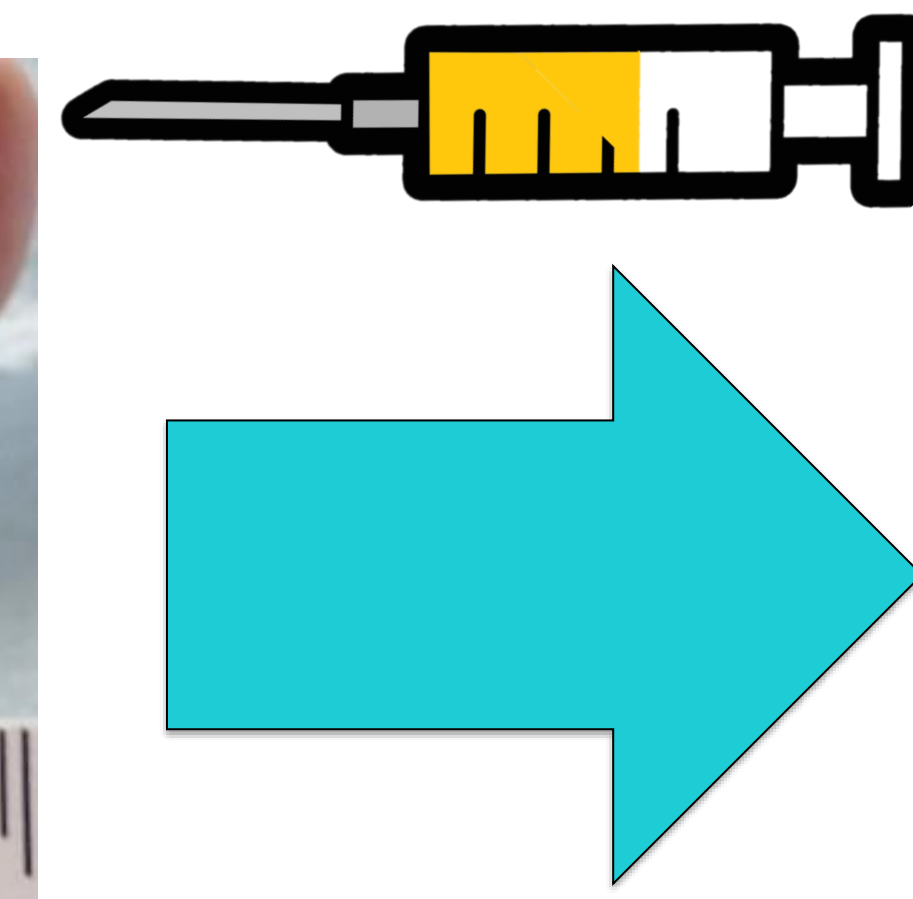
By means of mechanical stress, our device processes fat tissue to produce a high-quality fat graft. The entire process involves three steps:

1. Harvest of a small 15cc sample of fat tissue via minimally invasive liposuction.
2. Process the sample with the SyntrFuge™ system in the SyntrFPU 360™ device.
3. Inject the processed fat graft in the affected area to aid in tissue regeneration.

Cases



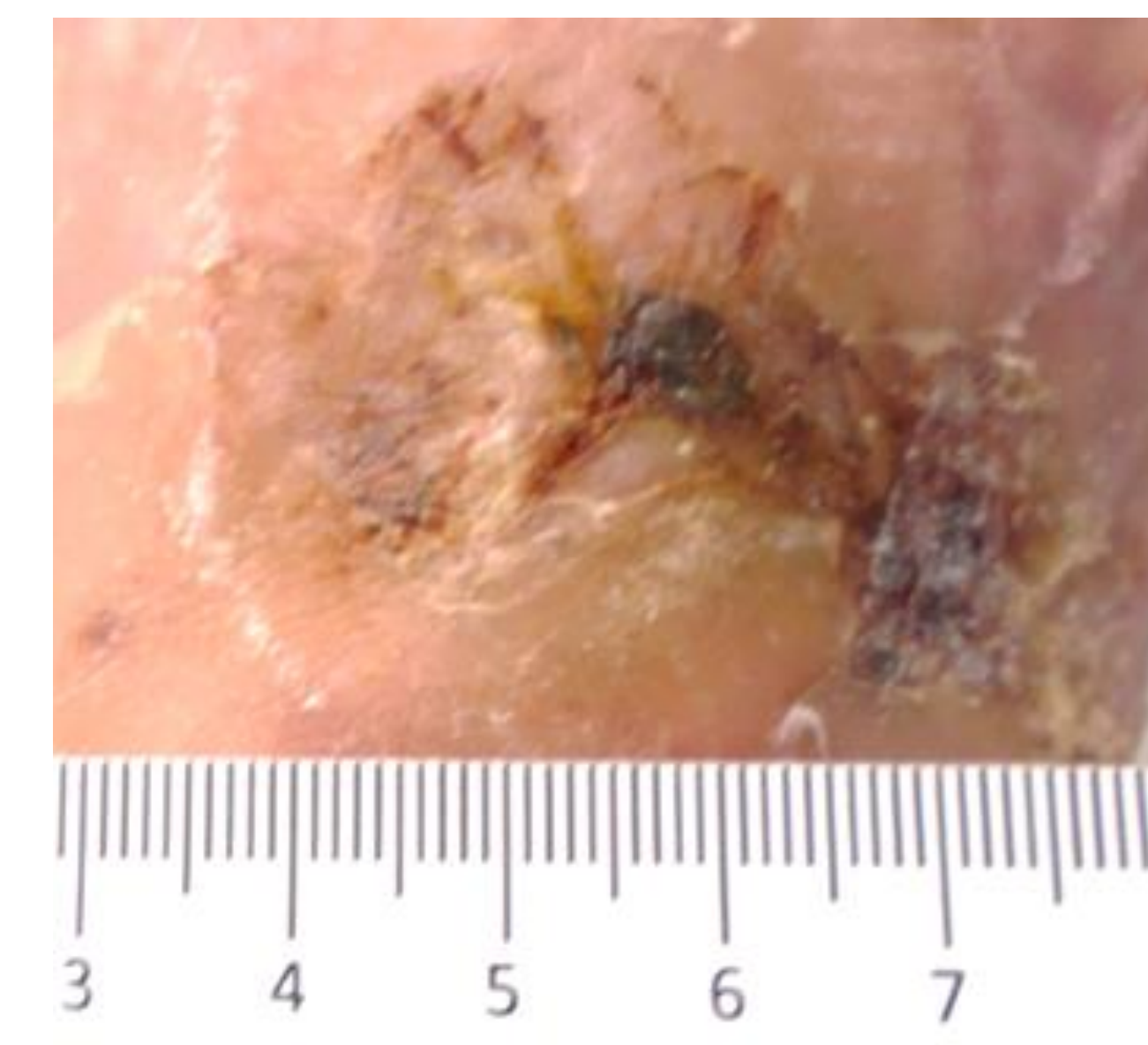
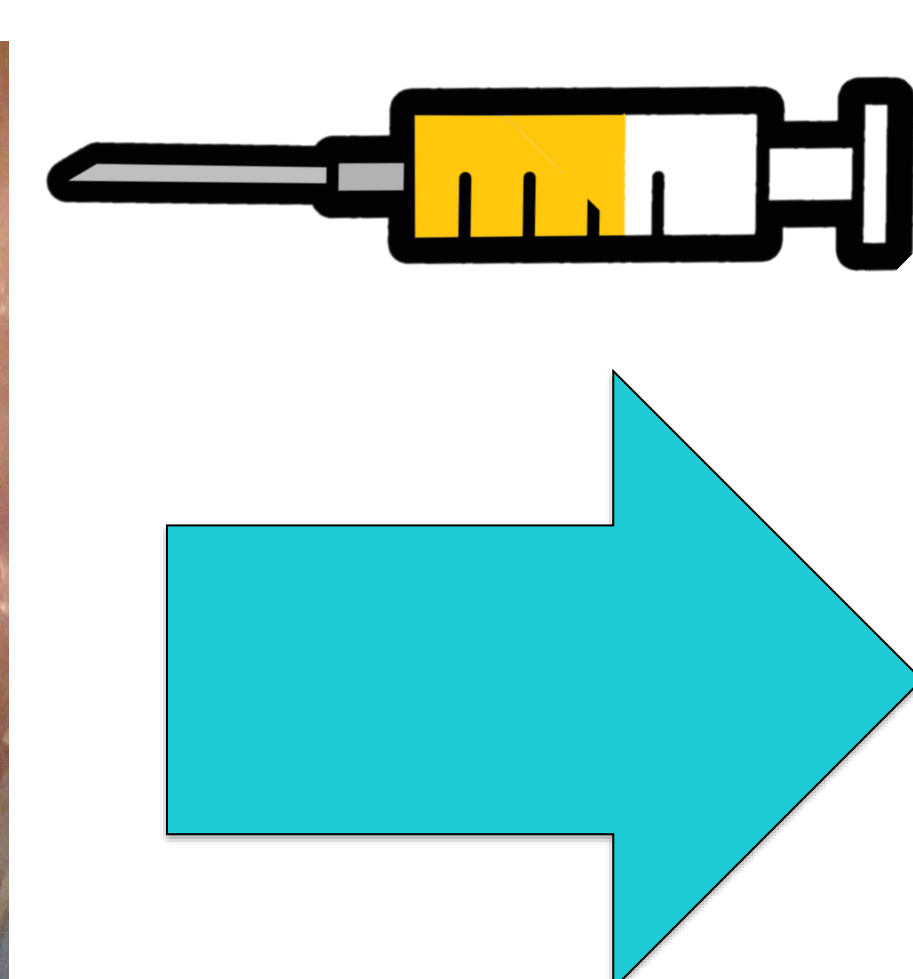
Baseline



3 weeks post single Injection



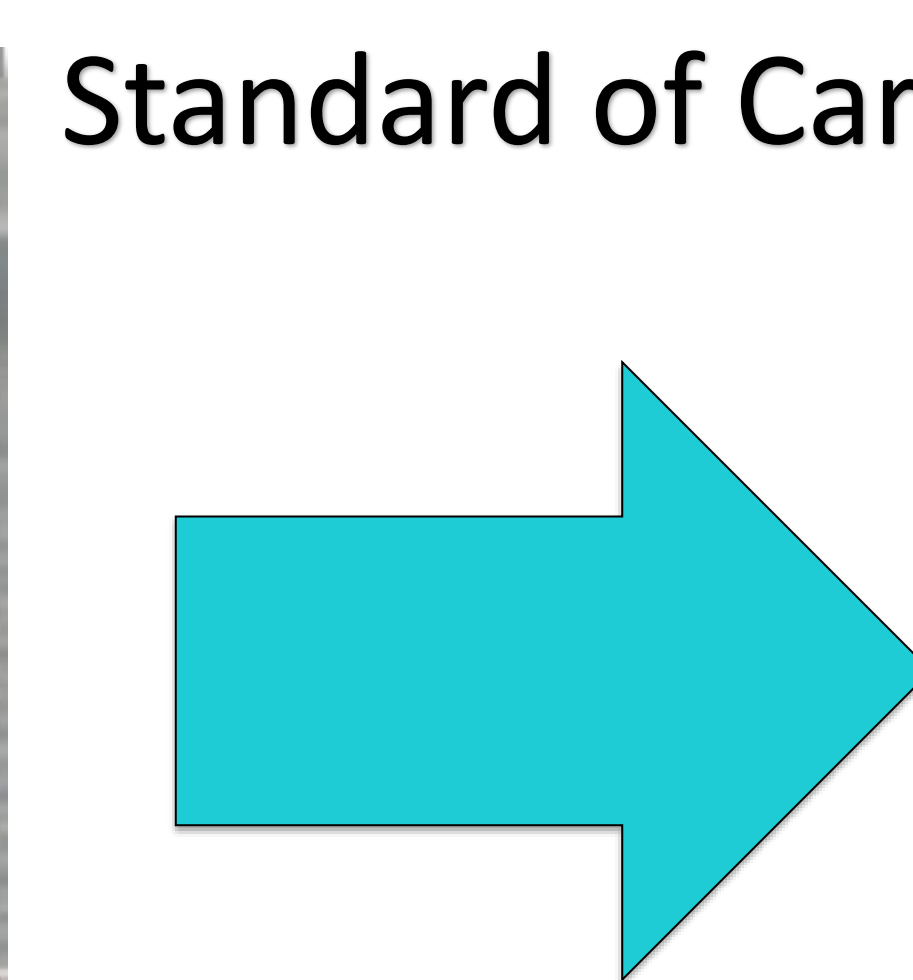
Baseline



1 week post single Injection



Baseline



14 weeks SOC

Results

In this randomized controlled trial so far 12 patients have been recruited. 6 out of 12 patients have been randomized to the SyntrFuge Autologous Processed Fat Group (Microsize Adipose Tissue (MAT)). The average wound closure time is currently at 4 ± 0.6 weeks. 6 out of 12 patients have been recruited to Standard of Care. The average wound closure time is currently 11 ± 1.6 weeks. No adverse events were noted in patients treated with autologous fat tissue processed with the SyntrFuge System.

Discussion

The SyntrFuge™ system offers a device that produces an affordable therapeutic that utilizes microfragmentation of adipose tissue to harness the tissue's intrinsic structural and supportive properties to aid in wound healing for chronic wounds such as DFU. With the easily accessible and abundant source of fat tissue this therapy can pave the way for a new and quicker treatment modality.