

Partnerships in Clinical Trials

ARANZ Medical’s Silhouette™ solution plays a key role in enabling KLOX Technologies to demonstrate the value of their Fluorescence Biomodulation (FB) system for treating chronic wounds.

In 2014, the KLOX team was preparing for a new study on the safety and efficacy of their FB system in patients with Venous Leg Ulcers. This was their first clinical trial that required images of the ulcers over the treatment period, and for those images to be associated with the clinical trial records.

KLOX were looking for an imaging system that not only took good images, but was also reliable, easy to use, robust, and would securely store the data they collected at different trial sites. After a 3-month search and evaluation period, they settled on Silhouette as their preferred imaging and documentation solution for their chronic wound studies.

KLOX chose Silhouette as their chronic wound documentation solution because it offered the most benefits of all the systems they investigated. Silhouette captures the key data they need to evaluate the ulcer healing rates of their subjects, provides good images and is easy to learn to use, as well as to teach others to use.

“Silhouette is a very good system for taking images, monitoring healing progress and providing accurate data on skin and wound healing. We evaluated a number of documentation systems before deciding to use Silhouette for our studies. Our decision to choose this system was primarily based on the accuracy and reliability of the data provided.”

Stéphane Fauverghe, Senior Director - Clinical and Medical Affairs, KLOX Technologies

Standardization is the Key to Success

Silhouette has enabled KLOX to standardize their wound measurement techniques across their trial sites. For all their chronic wound studies, KLOX is now able to train their site co-ordinators and nurses to trace and measure wounds in the same way using Silhouette. This consistency ensures that the measurements they collect at their sites can be compared and analysed together, and that their final results are accurate.

KLOX Studies Using Silhouette

Dates	Topic	Participants	Results
2016 - 2017	Investigating the efficacy, safety and quality of life associated with the use of FB system for venous leg ulcers, diabetic foot ulcers and pressure ulcers.	100 subjects in 12 wound centres in Italy.	The FB system was proven to be very effective in providing wound healing in hard-to-heal chronic wounds.
2016	Evaluating the Klox FB system in diabetic foot ulcers: A prospective case series.	10 subjects with diabetic foot ulcers.	The treatment showed potential as a new option for managing complex wounds. Confirmation of the excellent safety profile.
2014 - 2016	Evaluating the Klox FB system in venous leg ulcers: A prospective case series.	10 subjects with venous leg ulcers.	The FB system was shown to be safe and extremely well tolerated. It also showed potential for wound closure, wound surface area regression and wound bed preparation.