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SERENAGROUP NEWSLETTER

Building the Nation's Leading Wound Care Team

Industry Leader in Wound Care Studies

THOMAS SERENA, MD, CEO

SerenaGroup® Research Foundation is a global wound care cooperative group with a growing network of leading wound care research sites with a growing number of active clinical trials. We are an industry leader in implementing and managing wound care studies. Our experience in managing complex wound studies enables us to draw from proven strategies for addressing key operational considerations while maximizing both site and patient recruitment. We have implemented a dynamic process that optimizes results through active management based on a continuous, detailed stream of real-time information about enrollment progress.

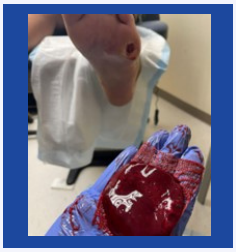
Data Support/Collection
A number of meaningful metrics are in place to analyze the effects of different practices, media and marketing efforts. Tracking enrollment metrics allows us to adjust our strategy continuously and allocate resources to the most productive approaches. This maximizes the number of patients, minimizes the number of screen failures and ensures high continuation rates.

SerenaGroup is an Industry Leader in Wound Care Studies.

SerenaGroup® Research Foundation is currently conducting a wide continuum of trials including a RCT using an autologous blood clot matrix, a randomized double-blind controlled clinical trial comparing a synergistic antimicrobial cleanser and gel to normal saline and an amorphous gel, a prospective ECM trial using porcine placenta, and the evaluation of a type 1 hydrolyzed collagen clinical trial.

RedDress ActiGraft™
Is a Multi-Center, Prospective, Randomized, Controlled Trial, Comparing the Safety and Efficacy of ActiGraft™ to Standard of Care in Patients with Chronic Neuropathic Diabetic Foot Ulcers. The RedDress ActiGraft System is an FDA cleared product, intended to be used at point-of-care for the safe and rapid preparation of Whole Blood Clot (WBC) gel from a small sample of a patient's own peripheral blood. The ActiGraft has been developed to address the need for cost effectiveness and clinical effectiveness of wound care.

There are several commercially available matrix or scaffold products. However, all of



these products are derived from foreign material: animal tissue or human donor skin. An autologous blood clot matrix should have no immunologic rejection or risks associated with the use of animal products. The ActiGraft is created by drawing the patient's blood with the use of citrate anticoagulant. The anticoagulant allows the clot to form later in a controlled fashion. Citrate is a widely used anticoagulant. The blood is then placed in the clotting tray (within few minutes) and the coagulation is facilitated by adding calcium and kaolin (insoluble aluminum silicate). The forming clot assumes the shape of the tray containing it, and can then be applied to the wound, and then covered with primary and secondary dressings.

BIAKŌS – Lower Extremity Ulcers

Across the United States many advanced wound care centers have adopted the practice of cleansing nonhealing wounds with Antimicrobials. However, some centers continue to use normal saline to clean wounds, citing a lack of clinical trial evidence for Antimicrobials.Commercially available Antimicrobials promote products based on laboratory or preclinical evidence rather than clinical trials in the wound clinic population. This study is designed to compare healing rates between normal saline wash and an amorphous hydrogel (NSS-HG) to the combination of a synergistic antimicrobial cleanser (AMC) and antimicrobial gel (AMG) in chronic lower extremity ulcers.

Triad:InnovaMatrix® AC Sterilized, Porcine

Placental Extracellular Matrix (ECM)

Our current study intends to investigate the effectiveness and safety of InnovaMatrix AC sterilized porcine placental ECM to treat chronic DFUs in a multi-center prospective trial. InnovaMatrix AC is a decellularized extracellular matrix (ECM) topical wound covering derived from harvested porcine placental tissue. Eligible patients will receive treatment over the course of 12 weeks.

HYCOL-Hydrolyzed Collagen is Type I

Diabetes is known to influence wound healing, specifically affecting collagen synthesis and degradation by prolonging the inflammatory phase and delaying proliferation and subsequent formation of granulation tissue. Diabetes affects the inflammatory process by altering the chemotaxis and phagocytosis of polymorphonuclear leukocytes (PMN). This results in a protracted inflammatory process. People with diabetes also have an increased susceptibility to infection. The presence of infection and defective leucocytes is likely to continue the cycle of inflammation preventing the transition to proliferation phase and the formation of collagen. If the proliferative phase does proceed, diabetes has a direct effect on fibroblasts causing their dysfunction thus preventing collagen deposition and remodeling. The balance of MMPs and TIMPs within this phase also appears to be altered by diabetes causing an increased proteolytic environment, reducing the formation of the extracellular matrix (Stojadinovic et al, 2012). The aim of this investigation is to evaluate the impact of a Type 1 Hydrolyzed Collagen wound dressing on the healing progression of recalcitrant diabetic foot ulcers.

HYCOL Hydrolyzed Collagen is Type I bovine hydrolyzed collagen and contains no additives. The powder is hydrolyzed collagen, and the gel is approximately 65% hydrolyzed collagen and 35% purified water. HYCOL Hydrolyzed Collagen is much smaller than native collagen. As a result, HYCOL Hydrolyzed Collagen is not broken down by the patient and is immediately available to support the healing process.

Interested in hearing more about our revolutionary clinical research trials? Reach out to Laura Serena, Chief Research Officer, lserena@serenagroups.com.

ANOTHER YEAR, ANOTHER AUDIT AND ANOTHER DISAPPOINTING RESULT

Matt Schweyer, CCO

In August of 2021, the Center for Medicare and Medicaid Services announced that Target Probe and Educate would be restarting.One year later, the results for wound care are coming in and there are some concerning trends relative to documentation, goals, and medical necessity.

Medicare Administrative Contractors (MAC) to which we provide services have reported. Wisconsin Physician Services (WPS) released audit finding September 20, 2022.Their data demonstrates CPT 11042 has a trending claim error rate of 43%. The top reason for denial, documentation did not contain initial wound measurements. Novitas, likewise, released information for first quarter 2022, and, while they tallied differently, the messaging is very similar. Of the audit claims computed: 90% had minor, 8% had moderate and 2% major issues. While they did not comment on minor or major issues, what they stated is concerning. Initial measurements, documentation support, medical necessity and goals are either not there or have not been updated. Another audit wound care centers need to listen up for is Surgical Dressing Supplies being conducted on Durable Medical Equipment (DME) companies. This audit has an indirect impact on your center(s). Surgical supply dressings are the benefit that affords patients the ability to receive wound care supplies from CMS. And, Noridian Health Care Solutions' audits found approximately a 64% overpayment for those surgical supplies. From a compliance perspective, I would anticipate your DME companies are pushing for better clinical documentation to support them in sending supplies to the patient.

The meaning: audits by the governments and insurance companies will continue and potentially with increasingly severe results. As a company, we will continue to create, implement, and recommend templates for documentation, continue, and strengthen our SG internal audit program, review medical records, and provide timely feedback to all parties.

I would be remiss if I did not mention our concerns: goals have been discussed and lectured on. If your Provider(s) are not implementing them on the first visit and periodically updating the goals; the others are SG templates. The provider(s) must use and ensure they are inputting the information and removing the prompts.

Why? When the auditor sees the bold, italicized, or underlined language, it infers cloning of a medical record. Moving forward, either of these will lead to a failure of the internal audit, and increased focus on your facility.

We have success with our programs, and that is typically found when we go through an audit. A HUGE shout-out goes to Fairview Medical Center, and Jamie Hanson, RN, BS, CWCN for completing and passing a TPE (Target Probe Educate) audit, that felt more like a PPR (Post Payment Review). Passing 39/40 patient encounters and the one that failed was for a minor indiscretion. Why did they pass? Because Jamie, and Fairview Hospital have hardwired all the resources available to the medical center. Congratulations Jamie!

2022 SerenaGroup Educational Courses

40hr Intro to HBO
Nov 3-6, 2022 | Wichita KS
Jan 12-15, 2023 | Omaha NE
Nov 9-12, 2023 | West Palm Beach FL

Tri-Certification
October 14-15 | Minneapolis MN

SerenaGroup Leadership Meeting
October 5-8 | New Orleans LA

Education is one of many key benefits to partnering with SerenaGroup.

SerenaGroup recognizes that the key to continued success with positive clinical outcomes is education. Education is provided through different platforms to ensure the tools are available to our centers.

SerenaGroup Blue Star Winner

Emily Metzger

RN, Clinical Coordinator

"Emily has made a huge impact in her short time here. She spearheaded our transition into Epic which started her second week here."

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