

Newest SoftWave™ study on skin grafts in burn patients selected for publication; highlights Tissue Regeneration Technology's growth and development.

Woodstock, GA. – **Tissue Regeneration Technologies, LLC (TRT)**, a Woodstock, GA. based medical technology company, announced Tuesday the publication of a study on the effects of unfocused SoftWave™ therapy on skin graft treatments in the *Journal of the American College of Surgeons*. The treatment of a skin graft site with SoftWave technology was found to speed the skin healing and recovery process for burn patients. SoftWave technology and therapy uses TRT's proprietary unfocused acoustical pressure pulse device. This innovative device is based on an improved and patented redesign of traditional focused shockwave technology.

The study, titled "Prospective Randomized Trial of Accelerated Re-Epithelization of Skin Graft Donor Sites Using Extracorporeal Shock Wave Therapy," was chosen as a lead article in the journal and published July 14, 2010. It focused on the effect of SoftWave therapy on skin graft sites. Authored by Drs. Alexander Stojadinovic, Wolfgang Schaden, Richard Thiele, Christian Ottoman, Bernd Hartmann, Josh Tyler, and Heike Maier, the study found significant acceleration of donor site epithelization resulting from unfocused SoftWave treatment following skin graft harvest.

Subjects receiving SoftWave therapy had mean epithelization times of 13.9 ± 2.0 days while those subjects not receiving SoftWave therapy had mean times of 16.7 ± 2.0 days. This represents a 16.8 percent improvement in mean healing time after one treatment.

John Warlick, Chief Executive Officer of TRT, noted the significance of this peer-reviewed publication. "The percent reduction in healing time demonstrated in this randomized and controlled trial is highly significant both statistically and clinically," he said. "Burn patients suffer horribly and challenge a facility's medical staff to provide around the clock care," he continued. "Any reduction in healing time offers a huge advantage to patients, physicians and payors – TRT's foundational philosophy."

Warlick also elaborated on the effects such a study has on TRT. "TRT's proprietary SoftWave technology offers clear cost and effectiveness advantages over competitive platforms by improving healing rates while reducing dependence on costly necessities such as anesthesia," he said.

TRT was founded in 2005 to develop unfocused SoftWave technology in wound care and orthopedics and has since expanded its operations to the urology, cardiology, dental and neurological fields. Research has proven that unfocused SoftWave therapy has a strong regenerative effect on all avascular (scar) tissues by stimulating strong biologic responses. The biologic responses include production of growth factors, nitric oxide, and critical gene expressions, which results in angiogenesis and improve blood supply with strong antibacterial properties for treated areas. Conditions that benefit from shock wave treatment include acute and chronic wounds, non-healing bones, ischemic heart tissue, prostatitis and burns.

"A significant and clinically relevant modification of a well-established therapeutic modality, ESWT, has ushered into clinical medicine a safe and efficacious treatment for various wounds.

A Phase II study published in the Journal of Surgical research in 2007 demonstrated the safety and potential effectiveness of ESWT for the treatment of various acute and chronic, complicated wounds.

A Phase III trial recently published in the Journal of the American College of Surgeons shows the efficacy of a single application of low energy, defocused shock wave therapy at time of skin grafting to rapidly accelerate tissue repair in graft donor sites. Mean healing time was significantly shorter in the shock wave treated group than in the controls (13.9 ± 2.0 and 16.7 ± 2.0 days, respectively), which as highly statistically significant ($p=0.0001$).

Based on the findings of Phase II and Phase III trials, we are optimistic that unfocused, low-energy shock waves will represent a clinically important, transformational advance in wound care."

-TRT CEO John Warlick



The company currently sponsors U.S. Food and Drug Administration trials for its “Gold” product line, which is approved in Europe, Asia, Canada and South America. TRT is confident its technologies will dramatically improve patient care and reduce health care costs.

Notice: This press release contains forward-looking statements within the meaning of the federal security laws. Forward-looking statements are only predictions and not guarantees of performance. You should not place undue reliance on any forward-looking statements. TRT's SoftWave technology is undergoing investigational use in the United States and is not currently available for sale.