MTS: Shock wave technology for the therapy of diabetic foot ulcer

Almost 15 percent of an estimated seven million diabetes mellitus patients in Germany suffer from diabetic foot syndrome (DFS). It is associated with damage to the foot nerves and blood vessels as well as the presence of chronic wounds, which in thousands of cases every year precede lower leg amputations. The Konstanz-based company MTS Medical has developed a shock wave therapy system that has the potential to considerably reduce the number of amputations in the foreseeable future. The application of high-energy, acoustic shock waves actively stimulates biological regeneration processes and the patient’s ability to produce growth factors like the enzyme eNOS and the VEGF signalling molecule. The innovative technology therefore enables a quicker and permanent regeneration of chronic foot wounds.

Over the last few years, diabetes has become an illness of epidemic proportions. The incidence of diabetic foot syndrome (DFS), which is a major complication arising from diabetes mellitus, has therefore also increased. Around 230,000 new patients are diagnosed with DFS in Germany every year (Hochlenert et al., 2009). DFS develops gradually over many years in people with a raised blood glucose level that occurs as a consequence of long-term insulin deficiency. This results in damage to the foot nerves and blood vessels, which results in a delayed sensation of pain in the feet. Minor injuries are therefore recognised at a late stage, lesions may heal badly or not all. In the worst cases, chronic foot ulcers develop, requiring the affected limb to be amputated.

According to recent figures published by the Diabetic Foot Workgroup of the German Diabetes Association (DDG), around 50,000 amputations per year in Germany can be attributed to DFS. The current standard of care of chronic wounds resulting from DFS comprises moist dressings and the application of hyperbaric oxygen therapy. No regenerative therapeutic options are yet available to support the costly and time-consuming treatment of the wounds. Medical doctors have been desperately waiting for a tool or method that is able to permanently regenerate the chronic wounds of DFS patients. MTS Medical’s innovative spark wave technology now has the potential to remedy the situation.

Stimulation through acoustic waves
The Konstanz-based company MTS Medical has spent many years assessing the efficacy of spark waves for treating DFS. Numerous scientific studies have also demonstrated that the technology has a positive effect on the treatment of food ulcers. “We have been able to show that spark waves stimulate the body’s own production of growth factors in the treated areas, which in turn induces the growth of new blood vessels, resulting in improved blood flow,” said Nikolaus Hopfenzitz of MTS Medical. The spark waves are generated according to what is known as the electrohydraulic concept, i.e. they are generated by means of a spark gap triggered in a body of water. “Spark waves are high-energy acoustic waves with a very short pulse duration,” explained Nikolaus Hopfenzitz.

MTS Medical has redefined the electrohydraulic spark wave technology and added unique performance characteristics. “Our patented Advanced Electrohydraulic Spark Wave Technology (AEHT) reduces the rise time and the negative pressure phase of the spark waves to a minimum. Spark waves generally consist of a pressure pulse and a tensile wave portion. The lower the tensile pressure, the better the spark wave quality,” said Nikolaus Hopfenzitz summarising the major
aspects of AEHT. Spark waves induce biological regeneration processes in the human body, including the release of angiogenic growth factors. “For example, the vascular endothelial growth factor (VEGF) and the endothelial nitrogen monoxide synthase (eNOS) enzyme are growth factors,” said Nikolaus Hopfenzitz.

Several “spark wave” treatments lead to a considerable improvement in wound healing. Left: wound prior to treatment; right: wound after spark wave treatment. © MTS Medical

The proteins VEGF and eNOS induce wound healing

VEGF is a signalling molecule that induces the development of embryonic blood circulation and the growth of new blood vessels. It mainly stimulates the vascular endothelium, i.e. the thin layer of cells that lines the inner surface of lymphatic and blood vessels. In addition, VEGF also has certain effects on other cells, including the stimulation of monocyte and macrophage migration. In vitro, VEGF induces the division and migration of endothelial cells in which the enzyme eNOS is produced. eNOS catalyses the formation of nitric oxide from the amino acid L-arginine. Nitric oxide (NO) is a signalling molecule that plays a vital role in vascular protection and in maintaining blood vessel function.

Molecular biology analyses carried out in clinical studies have shown that the application of spark waves led to the upregulation of VEGF. In addition, a considerable improvement in blood flow was observed immediately after the application of spark waves, which in turn had a positive effect on wound healing (Schaden and Mittermayr, 2011). It was also observed that VEGF and eNOS, which elevates blood flow, had a reciprocal effect on one another. In addition, spark wave treatment was found to lead to the attachment of larger numbers of stem cells and precursor cells to the site of chronic wound healing disorder, which in turn has a positive effect on the wound being treated. In general, the application of spark waves leads to changes in the extracellular tissue matrix. “In addition to inducing the formation of new blood vessels, the spark wave therapy also has a bactericidal effect, which additionally supports the recovery of the wound area from inflammation,” Nikolaus Hopfenzitz said.

Scientific evidence for positive effect of spark waves
The efficiency of extracorporeal shock wave therapy (ESWT) for the treatment of chronic wounds and wounds that heal slowly has been assessed in clinical and experimental studies. In 2007, Edelmann et al. conducted animal experiments to assess the promotion of cell differentiation as a result of neovascularisation and the release of angiogenic growth factors upon application of the spark wave therapy (Edelmann et al., 2007). 16 rats were divided into two groups; one group was treated with spark waves, while the other group was used as a control. “The researchers observed that the necrotic area surrounding the wound was on average much smaller (around 3.8 cm²) in the spark wave group than in the control group (an average size of 11.7 cm²),” Nikolaus Hopfenzitz
Wang et al. (2009) performed a study of 72 patients with chronic diabetic food ulcers and confirmed the effectiveness of spark wave therapy, which led to improved local blood flow, as well as higher cell concentration and activity in the wound area. The scientific studies conducted to investigate the biological mechanism of action of spark wave technology used MTS Medical devices and all came up with excellent results. “This method provides long-term successful therapy possibilities for diabetic foot ulcers and the long-term regeneration of the foot. New blood vessels form and the patient’s tissue functionality improves,” said Nikolaus Hopfenzitz summarising the positive effects of his company’s spark wave technology.

**Treatment only takes 10 minutes**

Treatment involving the MTS devices only lasts ten minutes and is repeated every two weeks as long as necessary. “Our devices are equipped with an unfocused applicator, which makes the treatment painless and well tolerated by patients,” Nikolaus Hopfenzitz added. Before spark waves are applied to the affected area, the wound is cleaned and sterile ultrasound gel is applied directly onto the wound, which is then covered with a sterile foil. Further ultrasound gel is applied to the sterile foil, so that the spark waves can be applied to the wound safely and without problems. The number of spark waves applied depends on type and size of the wound. After the 10-minute treatment, the wound is covered with a standard dressing. “There are no known side effects,” pointed out Nikolaus Hopfenzitz.

The Konstanz-based company hopes that their technology will soon be used all over Germany. “I believe that politicians should be highly interested in new treatment methods, as the cost of amputations and medical aftercare is extremely high, making it a huge financial burden on the health system,” Nikolaus Hopfenzitz said. According to information from the Diabetic Foot Workgroup of the German Diabetes Association (DDG), amputations and aftercare treatment cost around six billion euros per year. The use of the spark wave therapy therefore not only has the potential to successfully treat chronic wound ulcers, but is also able to relieve the burden on the health system. At present, therapy approaches for diabetic foot ulcers concentrate on preventive measures such as optimal insulin adjustment and professional foot care, aimed at reducing the number of amputations,” stated Nikolaus Hopfenzitz.

**Further information:**

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