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NEW STUDY USING COMBINATION OF BIOENGINEERED SKIN AND STEM CELLS SHOWS PROMISE IN TREATMENT OF NON-HEALING WOUNDS

SAN FRANCISCO (March 5, 2009) – Scleroderma is an autoimmune disease that leads to thickening and severe scarring of skin as well as thickening and failure of internal organs, including the lungs, heart, kidneys and intestines. The disease – which the Scleroderma Foundation estimates affects approximately 300,000 Americans – can be fatal and there is no cure. A major and incapacitating complication of scleroderma is the development of ulcers on the patients’ fingers and toes that are very painful and difficult to heal. Now, researchers are studying the viability of administering stem cells topically to ulcerated fingers using bioengineered skin to help heal these wounds.

Speaking today at the 67th Annual Meeting of the American Academy of Dermatology (Academy), dermatologist Vincent Falanga, MD, FAAD, professor of dermatology and biochemistry at Boston University in Boston and chairman of the department of dermatology and skin surgery at Roger Williams Medical Center in Providence, R.I., presented his study findings in which cultured stem cells and bioengineered skin were used to successfully treat skin ulcers of three scleroderma patients and discussed how bioengineered skin plays a critical role in this procedure.

“The concept of using bioengineered skin to heal difficult wounds, such as leg and foot ulcers, previously has been shown to be effective for chronic wounds but, in our experience, has not by itself been consistently useful in healing scleroderma finger ulcers,” said Dr. Falanga. “Through our research, we learned that our combined approach of using stem cells with bioengineered skin may provide value by ‘instructing’ the stem cells on how to stimulate healing in a difficult wound.”

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As a source of stem cells, Dr. Falanga and his team of researchers focused on taking a small amount of bone marrow from the affected patients’ hip. This common procedure is performed to diagnose conditions affecting the blood or bone marrow, such as anemias and leukemia. From this sample, the intention was to grow a particular type of stem cells in the laboratory called mesenchymal stem cells, which are cells that can create other cell types, including those in skin and muscle, and are capable of repopulating damaged skin.

The delivery method used to apply stem cells to the wounds was a fibrin spray system that had not been used in humans prior to the research pioneered by Dr. Falanga and his team. Fibrin is a chemical by-product that occurs naturally in the body and helps clot blood. For each of the three scleroderma patients, up to three spray applications of stem cells were performed.

“For the first time in humans, the investigators used a fibrin spray system – which takes advantage of the immediate polymerization, or ‘gluing,’ of stem cells in fibrinogen when mixed with thrombin,” said Dr. Falanga. “Both fibrinogen and thrombin are naturally occurring substances in blood which, when mixed to form fibrin, are normally involved in the formation of a clot. In this case, the two substances, highly diluted, were used to deliver the cultured mesenchymal stem cells to the wounds of scleroderma patients in a fine transparent spray.”

After delivering the stem cells to the affected finger, the wound was covered and treated with the additional stimulus provided by bioengineered skin – a bi-layered, substitute skin that consists of living human keratinocytes (cells that make the upper skin layer) and fibroblasts (cells that make collagen) – derived from neonatal foreskin following a circumcision and preserved for medical research.

From this initial study, Dr. Falanga and his team were very encouraged by their early results. “Our combined approach resulted in dramatic healing of these extremely difficult-to-heal wounds, with new skin growth that blended in nicely with the surrounding skin,” said Dr. Falanga. “On follow-up examination, one patient who had painful and incurable finger ulcers for many years remained healed and free of pain from this
procedure. Importantly, the concept of ‘instructing’ stem cells with other interventions or biological agents is significant and could be applicable to other situations where the use of stem cells is being pursued.”

Headquartered in Schaumburg, Ill., the American Academy of Dermatology (Academy), founded in 1938, is the largest, most influential, and most representative of all dermatologic associations. With a membership of more than 15,000 physicians worldwide, the Academy is committed to: advancing the diagnosis and medical, surgical and cosmetic treatment of the skin, hair and nails; advocating high standards in clinical practice, education, and research in dermatology; and supporting and enhancing patient care for a lifetime of healthier skin, hair and nails. For more information, contact the Academy at 1-888-462-DERM (3376) or www.aad.org.

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