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Clinical trial shows 'stress shield' device reduces appearance of revised scars

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A small clinical trial of a device invented by researchers at the School of Medicine has shown that it can help reduce the size of existing scars when used after scar-revision surgery.

The same device was previously shown to minimize the development of scars after surgery, but this is the first time it has been tested as part of a procedure for reducing old scars.

"This is exciting because there are a lot of scars out there and a lot of people are bothered by them," said Michael Longaker, MD MBA, the Deane P. and Louise Mitchell Professor at the School of Medicine and a senior author of the study. The results of the study were published Jan. 28 in *Plastic and Reconstructive Surgery*.

Longaker estimates that every year in the United States there are 80-100 million surgical incisions and 5-12 million accidental lacerations, all of which heal with a scar of some sort. "We don't know how many people are really bothered by scars, but we do know that every year 300,000 to 400,000 Americans approach their doctors to get their scars reduced," he said.

Scar formation has long been of interest to Longaker and the other senior author of the paper, Geoffrey Gurtner, MD, professor and associate chair of surgery. Previously, while at UC-San Francisco, Longaker studied how babies in the womb are able to heal without any scarring after fetal surgery. At Massachusetts General Hospital, Gurtner

studied how mechanical pressure reduced scarring in burn healing.

Scar tissue is much tougher than normal skin, making it less susceptible to reinjury. But scars are also less flexible, they don't have the pores that are essential to regulating heat in our bodies, and many people feel their scars are unsightly. Extensive scarring can be much more than a cosmetic problem; scarring can make certain movements and activities difficult or painful.

Longaker and Gurtner's device is what they call a "stress shield." As cuts and injuries heal, normal tension in the skin pulls the edges of the wound away from each other, which widens the scar as it forms. The device precisely pulls together the skin around the wound to reduce that tension at the injury site.

"Doctors try to take off these mechanical forces using steri-strips or other bandaging, but most don't do this with any degree of precision," Gurtner said. "They either pull too much, which creates blistering in the skin, or don't pull enough, and the scar then tends to grow during healing."

The device, which is manufactured by the Menlo Park, Calif., company Neodyne Biosciences Inc., has received clearance for marketing by the Food and Drug Administration, according to Bill Beasly, Neodyne's president. Longaker and Gurtner have a financial stake in the company but did not perform any of the surgeries in the clinical trial, which was funded by Neodyne. The surgeries were done by an independent surgical center in Palo Alto, Calif.

Currently, scar revision surgery does not work very well. Scars are cut out, the edges of the incision are closed, and surgeons work to make the new scar less obtrusive than the old one. But the revision surgery using current methods doesn't work very well, Longaker said. "Most of the

time, after a year the patient feels that the scar is just as bad as it ever was," he says.

In this clinical trial, surgeons cut out old scars on each of 10 patients and then placed the scar-reduction device over half of the incision; the other half they closed using traditional methods. After the study, patients were offered the chance to have the traditionally revised section of the scar closed using either of the two methods so that the two sides matched.

Six months after surgery, photos of the two halves of the scar were compared by four independent surgeons who did not know which sides of the scars had been treated with the device. Using a visual scoring system, the judges determined that the scar on the side treated with the scar-reduction device was significantly smaller. "It was pretty obvious," Longaker said. "It was not even subtle."

"This is the first demonstration of a new therapy that affects this very ubiquitous problem, and the beginning of a new class of therapy that works against fibrotic disease," Longaker says.

More information: "The Embrace Device Significantly Decreases Scarring Following Scar Revision Surgery in a Randomized Controlled Trial." Lim, Angeline F.; Weintraub, Jennifer; Kaplan, Ernest N.; Januszyk, Michael; Cowley, Christy; McLaughlin, Peggy; Beasley, Bill; Gurtner, Geoffrey C.; Longaker, Michael T. *Plastic & Reconstructive Surgery*. 133(2):398-405, February 2014. DOI: 10.1097/01.prs.0000436526.64046.d0

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