Biodegradable film reduces surgical scarring

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A new, biodegradable film designed to reduce the severity of scarring following open heart surgery in young children appears to be safe and effective, according to researchers attending the annual meeting of the Society of Thoracic Surgeons in Ft. Lauderdale.

Scarring is a normal response to surgery, but it can be troublesome in children born with congenital heart defects because many need multiple surgeries to correct or treat their problems. “Often the scarring is severe enough that when we perform a second surgery, we find the heart is stuck to the sternum,” says Dr. Andrew Lodge, a pediatric cardiothoracic surgeon at Duke University Medical Center and study leader.

Lodge says widespread scarring, or adhesions, can mean higher risk for the patient, more time in surgery and more difficult work for the surgeons. “With adhesions, we have to cut through tough, fibrous tissue in very delicate areas – not just between the heart and the sternum, but also in other areas between vessels and cardiac chambers. This increases the amount of time a patient has to be under anesthesia and potentially could involve more bleeding and the need for transfusion or other blood products,” says Lodge. “So we are very interested in anything that can keep scarring to a minimum.”

Biomedical engineers have searched years for a solution, but so far, nothing has worked very well, says Lodge. “Right now, if we use anything we usually use a non-absorbable membrane made of Gore-Tex that we place between the heart and the sternum, but it’s not ideal.” He says anything foreign that’s left in the body can provoke an inflammatory

response or invite infection and “that’s why the idea of an absorbable film is so attractive.”

Researchers at 15 institutions around the U.S. evaluated the new barrier film, called Repel-CV® Adhesion Barrier, in 103 infants undergoing open-heart surgery who were expected to undergo a second procedure. Roughly half were randomized into the treatment group and the others served as controls. Using a graded scale of none, mild, moderate or severe, physicians evaluated the extent of adhesions during the children’s second surgery, from two to three months later.

They found that use of the Repel-CV® dramatically reduced the incidence of severe scarring, with only 30 per cent of those receiving the barrier film experiencing severe scarring, compared to 71 percent of the patients in the control group. They also found that patients who underwent cardiopulmonary bypass or a Norwood procedure, as well as patients whose incisions were closed after some delay, were at higher risk of developing dense scarring in the chest, but that Repel-CV® was effective in reducing adhesions in these patients as well.

Investigators did not note any side effects from use of the new film. The product has not yet been approved by the FDA, although an application for approval has been accepted.

Source: Duke University