

Soft Tissue and Skin Reinforcement with Acellular Dermal Matrix to Protect Implanted Cardioverters/Defibrillators and Pacemakers

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Summary: Cardiac pacemakers and implantable cardioverters/defibrillators are often placed in older patients with thin skin and scanty subcutaneous tissue. These devices and cardiac leads are at risk for progressive skin erosion and exposure leading to infection. To prevent this severe complication, we developed a reinforcing insertion of acellular dermal matrix. Twenty-two of 24 patients had successful implantation with long-term avoidance of skin erosion (*Plast Reconstr Surg Glob Open* 2018;6:e1866; doi: 10.1097/GOX.0000000000001866; Published online 13 July 2018.)

INTRODUCTION

Thin-skinned older patients with minimal subcutaneous fat are at risk for progressive erosion of subcutaneous pacemakers (PM), implantable cardioverters/defibrillators, and cardiac leads through the skin. Capsular contraction can occur around the implants, which can lead to skin thinning and exposure.¹ Exposure can lead to infection, and infected devices must be removed; infected cardiac leads may need to be removed from myocardium, which has caused deaths. Prevention of impending skin erosion has required device replacement in another anatomic area, or extensive flap reconstruction, both posing significant risks in this fragile population with significant heart disease.²⁻⁷ To prevent this severe problem with minimally invasive surgery, we implanted acellular dermal matrix (ADM) for soft tissue and skin reinforcement. Replacement in a nearby location as suggested by some authors²⁻⁶ would avoid the cost of ADM, but would not increase the tissue thickness over the devices, and progressive tissue thinning could reoccur.

PATIENT POPULATION

This study was approved by the Scripps Clinic Institutional Review Board and was Health Insurance Portability and Accountability Act compliant.

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All 24 patients, who had 14 PMs and 10 ICDs, were referred from cardiology. Twenty were referred with primary concern for device erosion and exposure, 3 of whom were at risk for immediate skin breakdown because of severe progressive skin discoloration or lack of skin mobility, both predictive of skin breakdown and erosion per cardiology experience. Ten of the 24 patients complained of pressure and tenderness, all of whom had concern for erosion, as did 1 patient who complained of deformity due to visibility of device and wires. None of the cardiac devices were already exposed at the time of surgery.

The study duration was 2004–2016. Patient age range was 60–92 with mean of 80 years. By definition, all patients had significant cardiac disease. Patients with PMs were predominantly affected with conducting system disease, that is, sick sinus syndrome and were paced because of bradyarrhythmias or heart block. Patients with defibrillators often had complex disease with coronary artery disease, congestive heart failure, significant valvular disease, and potentially lethal ventricular rhythm disturbances.

METHODS

Surgery to prevent device skin erosion and exposure by reinforcing the subcutaneous tissue and skin was performed in these 24 consecutive patients.

Cardiologists were immediately available during surgery. With general or local anesthesia with anesthesiology monitoring, the prior device placement scar was incised and limited dissection done to expose the superficial cardiac leads and devices (Fig. 1). Compromised skin if present was excised. Subcutaneous dissection created a space on top of the devices and the leads, without any need to manipulate the PMs or ICDs.

Disclosure: Dr. Rudolph and Dr. Curtis were both one-day consultants to St. Jude Inc., manufacturer of pacemakers and cardioverter/defibrillators. The Article Processing Charge was paid for by the authors.



Fig. 1. Cardiac leads visible superficially in PM pocket after dissection. Note protruding bend of lead, prone to overlying skin thinning and erosion, on the right side. The subcutaneous PM is immediately inferior to the incision.

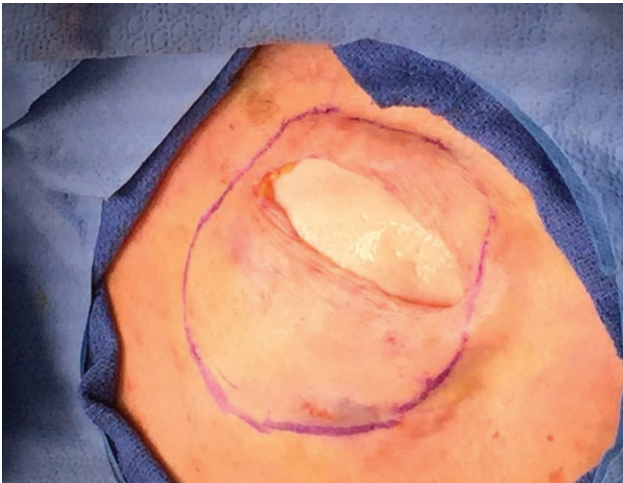


Fig. 2. Acellular dermis inserted over PM and cardiac leads, from below clavicle to inferior border of the PM case.

Thick or extra thick ADM of surface area sufficient to cover the entire leads and device, from immediately below the clavicle to inferior to the device metal case was then inserted (Fig. 2). Five patients had double layers of ADM placed early in the series, with extra thick single layer placed in later patients. Alloderm (LifeCell Corp, Branchburg, N.J.) was selected for its softness to reinforce the soft tissue and skin: most likely other ADMs could instead be used. The ADM was sutured around the periphery, and the incisions closed after insertion of small suction drains.

RESULTS

Of the 24 ADM insertion procedures, 1 was aborted intraoperatively because of profuse bleeding; 23 patients had successful completion of the surgery.

Two patients early in the study, at the time of cardiologically necessary PM or ICD replacement, had insertion of

another layer of ADM for further reinforcement. One of these, after the first surgery, had had antibiotic treatment of possible minor infection (suggested by increasing skin redness) with resolution and negative culture at the second procedure. One other patient had extra thick ADM placed when repeat device surgery was required because of pain and device displacement after trauma.

Thus, 3 patients had secondary ADM placement only because PM or ICD revision was needed.

Another patient developed a pin-point incision opening, treated by antibiotic pocket irrigation and immediate ADM replacement with uncomplicated healing; culture was negative at the second procedure.

The only failure in the completed 23 procedures was in a patient who had recurrent capsular contraction around his PM with exposure and infection, requiring PM removal and replacement.

In summary, 22 of 24 operated patients had long-term prevention of PM and ICD erosion, infection, and device removal. Mean follow-up was 37 months, a long duration in this group of older sick patients.

During the 12 years of this study, 9 patients died of intrinsic cardiovascular or pulmonary disease, or malignancy; no deaths occurred as a result of the ADM implant surgery.

DISCUSSION

Over 10,000,000 PM and implantable cardioverters/defibrillators have been implanted since introduction in 1958. Skin erosion and device exposure has been estimated in 0.8% to as high as 12.6% (in early studies) of implantations.^{1,3} Thus, a minimum of 80,000 erosions leading to infection may have occurred, and possibly more. This dire cardiologic complication can lead to infection and need for extensive surgery,^{1,2} and deaths have occurred. Prevention before erosion and exposure is a highly sought-after goal. In a previous study,⁷ we used live autogenous dermis to close open wounds after skin erosion and began to use ADM as well in a limited number of patients.

Utilizing principles from extensive breast reconstruction, we inserted subcutaneous ADM with minimal dissection, avoiding device manipulation. The ADM softens the visual deformity of the subcutaneous devices, which many patients find desirable. Having used multiple combinations of ADM thicknesses, and layers, we now recommend single layer extra thick ADM. ADM may help to prevent capsular contraction around cardiac devices, as has been suggested with breast implants.⁸ ADM placement could be considered at the time of first device placement in very thin patients with minimal subcutaneous tissue; we have not yet done this.

Subpectoral implantation has been suggested as an alternative solution. However, many cardiologists prefer subcutaneous placement, as the rigid device metal case can cause pressure and pain under an active muscle, as opposed to soft pliable breast implants.

In summary, with ADM placement, 22 of 24 patients had successful long-term avoidance of PC and ICD erosion, infection, and need for more extensive surgery.

Neurosurgeons at Scripps Clinic have adopted this novel technique to protect implanted subcutaneous nerve stimulators, with promising results.

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REFERENCES

1. Rudolph R, Utley JR, Woodward M. Contractile fibroblasts (myofibroblasts) in a painful pacemaker pocket. *Ann Thorac Surg.* 1981;31:373–376.
2. Kolker AR, Redstone JS, Tutela JP. Salvage of exposed implantable cardiac electrical devices and lead systems with pocket change and local flap coverage. *Plast Reconstr Surg.* 2007;59:26–29.
3. Griffith MJ, Mounsey JP, Bexton RS, et al. Mechanical, but not infective, pacemaker erosion may be successfully managed by re-implantation of pacemakers. *Br Heart J.* 1994;71:202–205.
4. Jung CY, Kim TG, Kim SE, et al. Safe and simplified salvage technique for exposed implantable cardiac electronic devices under local anesthesia. *Arch Plast Surg.* 2017;44:42–47.
5. Toia F, D’Arpa S, Cordova A, et al. Exposed subcutaneous implantable devices: an operative protocol for management and salvage. *Plast Reconstr Surg Glob Open.* 2015;3:e343.
6. Harcombe AA, Newell SA, Ludman PF, et al. Late complications following permanent pacemaker implantation or elective unit replacement. *Heart.* 1998;80:240–244.
7. Rudolph R, Smith MR, Curtis GP. Salvage of pacemakers and automatic implantable cardioverter-defibrillators using dermis grafts. *Ann Thorac Surg.* 2011;91:452–456.
8. Mofid MM. Acellular dermal matrix in cosmetic breast procedures and capsular contracture. *Aesthet Surg J.* 2011;31:77S–84S.