

Exposed Subcutaneous Implantable Devices: An Operative Protocol for Management and Salvage

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Background: Implantable venous and electrical devices are prone to exposure and infection. Indications for management are controversial, but—especially if infected—exposed devices are often removed and an additional operation is needed to replace the device, causing a delay in chemotherapy and prolonging healing time. We present our protocol for device salvage, on which limited literature is available.

Methods: Between 2007 and 2013, 17 patients were treated (12 venous access ports, 3 cardiac pacemakers, and 2 subcutaneous neural stimulators). Most patients were operated within 7 days from exposure. All patients received only a single perioperative dose of prophylactic antibiotic. In cases of gross infection ($n = 1$), the device was immediately replaced. In the absence of clinical signs of infection:

Complete capsulectomy and aggressive cleaning with an *n*-acetylcysteine solution and saline solution.

Primary exposure of venous ports with sufficient skin coverage ($n = 10$): the device was covered with local skin flaps.

Recurrent cases, cases with insufficient skin coverage or big devices ($n = 7$): the device was moved to a subpectoral pocket.

Mean follow-up was 19 months.

Results: Sixteen devices were saved. Only one grossly infected pacemaker was removed and replaced immediately. Only in 1 case, exposure of a venous port recurred after 18 months and was successfully moved to a subpectoral pocket. Chemotherapy was always restarted as scheduled and electrical devices remained functional.

Conclusions: This protocol allows—with a straightforward operation and simple measures—to save exposed devices even several days after exposure. Submuscular placement or immediate replacement is indicated only in selected cases. (*Plast Reconstr Surg Glob Open* 2015;3:e343; doi:10.1097/GOX.0000000000000303; Published online 30 March 2015.)

Exposure of implantable venous and electrical devices is a relatively common event, mainly caused by inadequate tissue coverage. Bacterial con-

tamination and subsequent infection follow exposure. Limited literature is available on exposure management, with contrasting recommendations, with removal and replacement in a secondary operation several months later^{1,2} often being advocated for pacemakers.

Venous access ports are implanted in cancer patients for IV chemotherapy delivery, and up to 11% of them require removal during treatment due to pocket infection or pressure necrosis³; subcutaneous electrical devices are also prone to exposure.⁴ Secondary replacement of a removed device is responsible for significant patient discomfort, treatment delays or interruptions, and direct and indirect costs.

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Recently, there is a tendency toward aggressive cleaning and salvage of exposed implants in breast surgery,^{5,6} which suggests that a conservative treatment might also be possible for subcutaneous implantable devices. Several authors have suggested device salvage and coverage if no gross infection is present, but many reports only include small groups, and different techniques have been reported.^{2,7-9}

We present our protocol for salvage of exposed subcutaneous implantable devices and propose it as a tool to speed healing time and avoid treatment delays.

MATERIALS AND METHODS

Between 2007 and 2013, 17 patients with exposed devices were treated at a single institution. Among exposed devices, there were 12 venous access ports, 3 cardiac pacemakers, and 2 subcutaneous neural stimulators. Most patients were operated within 7 days (range, 2–27). All patients were operated under local anesthesia and received only a single preoperative dose of cefazoline (2g) as antibiotic prophylaxis.¹⁰

The following protocol was applied to all cases:

- Gross infection: removal and immediate replacement.
- No signs of infection.

A complete capsulectomy was performed for every type of device. The device and the surgical field were then washed with an *n*-acetylcysteine solution and later irrigated with saline solution (500ml). Then, a different strategy was adopted for venous ports and for bigger devices:

Venous ports (primary cases): Primary cases with adequate local tissue were covered with random flaps, propeller perforator flaps, or perforator-based flaps. The flap was deepithelialized and partially buried under the skin or folded on itself to provide additional coverage for the device.

Recurrent cases, big device (cardiac pacemakers, neural stimulators) or cases with insufficient skin coverage (thin or debilitated patients): The device was moved to a subpectoral pocket and anchored to the surrounding tissues to avoid displacement and reduce patients' discomfort.

The wound was closed with buried, monofilament absorbable sutures to minimize risks of bacterial colonization. Mean follow-up was 19 months (range, 6–50). Data on healing time, postoperative

infection, recurrent exposure, and other complications were recorded.

According to Italian rules (art. 13, DLgs n. 196/03), this study did not require authorization by the Institutional Review Board.

RESULTS

There were 11 primary exposures of venous ports, 10 of which were maintained in a subcutaneous pocket: 4 were covered with a random flap, 2 with a propeller perforator flap, and 4 with a perforator-based flap; only in 1 case of a debilitated patient with very thin skin, submuscular placement was needed. There were 5 primary exposures of electrical devices: a cardiac pacemaker, in the presence of gross infection, was immediately replaced; all 5 devices were moved to a subpectoral pocket. One recurrent exposure of a venous access port was treated with placement in a subpectoral pocket.

The protocol allowed salvage of all but one device (16 of 17), which was immediately replaced. All patients healed uneventfully within 15 days. No patients developed a postoperative infection at a minimum follow-up of 6 months. One patient with a venous device had a reexposure 18 months after coverage. The device was saved again and moved to a subpectoral pocket. Submuscular placement caused early postoperative discomfort, which solved spontaneously within 1 month. Chemotherapy was always restarted as scheduled (7–21 days), and electrical devices remained functional.

DISCUSSION

The results of this study show that most devices can be saved if treated before gross infection develops, and only a minority needs removal and immediate replacement. The protocol we propose allows salvage of exposed devices in most cases, with a single straightforward operation and no risk for patients' health. It avoids the need for secondary repositioning, thus preventing deleterious delays in treatment and unnecessary morbidity. Removal and immediate replacement is indicated only for grossly infected cases and seems effective in controlling infection if the above-mentioned measures are adopted.

Literature on salvage of exposed subcutaneous devices is limited and mainly concerns pacemakers.^{2,4,7-9} When a clinical infection is evident, removal and delayed replacement is advocated,^{11,12} although some authors suggest immediate replacement for exposed devices in the absence of gross infection.^{7,8}

Removal and delayed replacement, which can appear as a safer approach, is not devoid of complications. For venous ports, it delays chemotherapy, pro-

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longs healing, and can impair prognosis, whereas for pacemaker, removal of leads from the endocardium can lead to acute cardiac problems; also, it requires the use of temporary or external pacing device.⁴

Based on recent trends in breast and orthopedic surgery, we propose that a salvage attempt can be performed also for these devices.

It is generally agreed that coverage should be as early as possible, "within 48 hours of identification of exposure when possible,"⁴ and we recommend treatment even for impending exposure. However, in our series, 3 patients with an exposed venous port were referred between 13 and 27 days following exposure, and were successfully treated, suggesting that also devices with late referral and no clinical sign of infection deserve a salvage attempt.

Several measures may be adopted to salvage exposed devices and minimize risks of infection or reexposure. As a small number of pathogens is necessary for developing an infection on an implant, complete capsulectomy and accurate cleaning of the pocket are mandatory. We routinely irrigate the pocket with an *n*-acetylcysteine solution. *n*-Acetylcysteine is a glutathione precursor, which has shown to be effective in destroying bacterial biofilms and inhibiting their formation.^{13,14} Its clinical use is still limited, but existing experimental and clinical results are very promising, also on difficult bacteria as *Pseudomonas aeruginosa*. Following irrigation with *n*-acetylcysteine, we do recommend a thorough mechanical washing of the pocket with a minimum of 500 ml of saline solution, a strategy that has shown to be effective in the salvage of exposed breast implant.⁶ As for clean-contaminated surgery, a single dose of preoperative prophylactic antibiotic was administered.¹⁰ There is contrasting evidence in the literature with regard to the need for antibiotic therapy^{4,8}; however, it has been shown that even a positive culture in an exposed but clinically noninfected device does not correlate with reexposure.⁴ In our series, after irriga-

tion and without postoperative antibiotics, no infection was observed, despite no use of postoperative antibiotics.

Several authors recommend pocket change and subpectoral placement,^{8,9} but there is no general agreement and different techniques have been suggested.^{2,7-9} Bonawitz,⁴ in their series of 16 patients with exposed pacemakers, report no difference in reexposure rate for submuscular or subfascial placement, the latter having become their preferred choice. For pacemakers or other voluminous electrical devices, we do prefer submuscular placement because exposure in the absence of infection is often due to an imbalance between skin thickness and pressure exerted by the device; thus, once the primary cause of exposure is not eliminated, reexposure is more likely to happen. Also, submuscular placement of the pacemaker allows for a more pleasant aesthetic outcome and has been proposed as first choice even for primary pacemaker placement.¹⁵ In our series, subpectoral placement was associated with early discomfort and spasm, but it always solved within 1 month, as also reported by Bonawitz⁴ and Fayman et al.⁹

Smaller devices, such as venous ports, can be left subcutaneously in most cases. These devices need an external access for their use, which is easier in case of subcutaneous placement. Thus, submuscular placement should be limited to selected cases. When there is adequate local tissue, the port can be moved to a subcutaneous pocket in anatomical continuity with the previous one. However, skin is often thin in cancer patients (often debilitated) with a venous access port. To obtain thicker skin coverage, a local skin flap can be deepithelialized and partially buried under the skin overlying the device (Fig. 1) or deepithelialized and folded on itself. A random or a perforator-based flap can be used in case of sufficient skin laxity; a propeller perforator flap is preferred when an increased freedom in design and movement is required.¹⁶



Fig. 1. A, Exposed venous access port. A perforator-based flap was planned for reconstruction. B, Following capsulectomy and aggressive cleaning of the pocket, the flap was deepithelialized and buried under the skin to provide additional coverage. C, One-year postoperative result. The venous access port is still in place.

Although the numbers are relatively small, they are comparable to all the other series previously published. Considering that the results of this study are promising and that large prospective studies are unlikely to be performed, we propose the application of our protocol for device management in the hope that it will be a useful tool for other plastic surgeons and that it could ultimately be validated by evaluation on a larger number of patients.

CONCLUSION

The protocol we propose allows—with a straightforward operation and simple measures—saving of exposed devices even several days after exposure. Submuscular placement or immediate replacement is indicated only in selected cases.

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