

Improving Pressure Ulcer Reconstruction: Our Protocol and the COP (Cone of Pressure) Flap

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Background: Surgical treatment of pressure ulcers is challenging for high recurrence rates. Deepithelialized flaps have been used previously with the aim to eliminate shearing forces and the cone of pressure (COP) effect. The goal of this study is to adopt a standardized protocol and evaluate if 2 different flap techniques affect outcomes.

Methods: The novel COP flap is illustrated. Twenty patients were prospectively treated with flap coverage over a 36-month period. According to the flap type, patients were assigned to 2 groups: group 1 with 11 patients treated with the COP flap and group 2 with 9 patients treated with conventional flap without anchoring technique. We adopted a standardized protocol of debridement, tissue cultures, and negative-pressure wound therapy. Rotation fasciocutaneous flaps were used for both groups and mean follow-up was 19 months. The COP flap is a large deepithelialized rotation flap inset with transcutaneous nonabsorbable bolster sutures. The 2 groups were comparable for demographics and ulcer location and size ($P < 0.05$). Five patients showed positive cultures and were treated with antibiotics and negative-pressure therapy before surgery.

Results: Recurrence rates were 12% in the COP flap group and 60% in the conventional flap coverage group ($P < 0.001$). Results were compared at 16-month follow-up.

Conclusions: The COP flap significantly reduces recurrences and eliminates shearing forces, suture ripping, and tension on superficial soft-tissue layers. The technique can be applied to both ischial and sacral pressure sores. The flap provides padding over bony prominence without jeopardizing flap vascularity. (*Plast Reconstr Surg Glob Open* 2017;5:e1234; doi: 10.1097/GOX.0000000000001234; Published online 30 March 2017.)

INTRODUCTION

Pressure ulcers are a common but preventable condition that often present in high-risk populations.¹ Each year, over 2.5 million patients develop pressure ulcers in the United States and the incidence continues to increase.² Depending on the clinical setting, the occurrence of pressure ulcers varies widely, ranging from 0.4% to 66%, with higher incidence in quadriplegia and femoral neck fractures.³ The treatment of pressure ulcers varies depending on ulcer depth, degree of undermining, concomitant infections, and associated complications.⁷ Stage

1 and 2 ulcers are generally managed with a conservative approach such as pressure off-loading, wound care, and improved nutritional status of the patient. Pressure ulcers in stages 3 and 4 may require surgical intervention such as serial debridement of the infected and necrotic tissues, osteotomy, and reconstruction of the soft-tissue defect over the bony prominence. Tissue damage occurs when the capillary beds are occluded, which occurs when external pressure exceeds 33 mm Hg.²¹ Occlusion of the capillary beds in conjunction for times greater than 2 hours will lead to irreversible tissue damage.²² The surgical outcomes of pressure ulcer treatment are often a challenge for the tendency to recur. Evidence-based data show that the most important factors influencing pressure ulcer pathophysiology are pressure, nutrition, and infection.⁸ The pressure exerted over bony prominences is a combination of vertical, shear, and friction pressures. The area of necrosis can be described as an “inverted ice cream” or “cone of pressure” (COP) with a 3-dimensional configuration

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resembling an iceberg. Underlying muscle has a higher metabolic activity than the overlying skin, making it more sensitive to prolonged ischemia (Fig. 1). In addition, if bone is exposed at the bottom of the pressure wound, an accompanying osteomyelitis could develop.

We hypothesize that the main contributors to pressure ulcer development and recurrence are the shearing forces over a bony prominence, the COP effect, and tissue undermining.

Deepithelialized flaps have been used in the past to obliterate dead spaces and reduce shearing forces.⁹⁻¹³ In this study, we present a protocol that addresses the multifactorial pathophysiology leading to the development of pressure ulcers. We also compare 2 groups of patients treated within the same protocol who underwent different methods of reconstruction such as “the conventional method” and the “COP” flap groups. Rationale for the use of the “COP flap” is to obliterate the dead spaces and soft-tissue undermining. In addition, the COP flap attempts to decrease the sheer forces between the overlying flap and underlying bone. The goal of our study is to demonstrate that surgical technique can influence outcomes in pressure ulcers when other parameters are kept constant.

No previous studies to our knowledge have described the COP technique and compared outcomes using different surgical techniques within a standardized protocol.

PATIENTS AND METHODS

With approval from the Institutional Review Board at Rhode Island Hospital, our prospective study reviews 20 sequential patients treated with flap coverage over a 36-month period from 2011 to 2014. The patients included in the study were hospitalized at a university institution with modern facilities, providing full postoperative rehabilitation. Inclusion criteria were patients with non-healing stage 4 pressure ulcers, and exclusion criteria were patients with comorbidities. Consent to participate in the study was signed. To study the effectiveness of COP flaps in the treatment of pressure ulcers, 11 patients were randomly assigned to the treatment group (COP flap) and 9 patients to the control group (conventional method without anchoring technique). At the time of

presentation, the patients were randomly assigned to either the conventional method or the COP flap group. All patients underwent the same optimization before undergoing either flap treatment to guarantee uniformity in both groups. To ensure that the patients of each group were at similar baseline status during the start of the treatment and to avoid selection bias, the following factors were addressed: nutritional status to an albumin > 3.0 g/dL, prealbumin > 20 mg/dL, and transferrin > 0.2 g/dL; control of muscle spasms; pressure control devices such as air mattress beds and turning protocols; and scheduled dressing changes to maintain wounds clean. Patients aged younger than 20 years and older than 70 years were excluded from the study. Patients with multiple comorbidities that would prevent optimal wound healing, such as diabetes, coronary vascular disease, and peripheral vascular disease, were not included in the study. The data analyzed were demographics, comorbidities, location and stage of ulcers, treatment history with outcomes, and laboratory findings.

Three surgeons performed the cases and results were evaluated at 16-month follow-up.

Group 1 (COP) included 11 patients (7 males and 4 females) with a mean age of 43.7 years. Eight ulcers were located at the ischium and 3 at sacrum (Table 1). The control or group 2 (conventional method) included 9 patients (7 males and 2 females) with a mean age of 47.1 years and 8 ulcers located at the ischium and 1 at the sacrum (Table 2).

Our protocol included debridement with Versajet (Smith&Nephew, St. Petersburg, Fla.), pressure relief on air mattresses (Clinitron, Hill-rom, Chicago, Ill.), optimization of nutrition with albumin >3g/dL, and infection control. All patients were treated with debridement, tissue cultures, and negative-pressure wound vacuum therapy before definitive surgical closure. Surgery with flap closure was performed only when tissue cultures were negative after debridement, wound vacuum therapy, and antibiotic therapy.

Deep tissue cultures were sterilely obtained intraoperatively with rongeur or osteotome to rule out subclinical osteomyelitis. Cultures, aerobic and anaerobic with Gram stain, were evaluated, and length of treatment was guided by sensitivity to antibiotics and infectious disease recommendation. Upon completion of the recommended antibiotic course, quantitative bacterial cultures were obtained during intraoperative debridement. This was continued until quantitative bacterial cultures were less than 10^5 colony-forming units per milliliter of wound exudate. After flap closure, the patients were kept for 3 weeks on flat bed rest followed by a graduated sitting protocol.¹⁴ After 3 weeks of bed rest, patients used the following perioperative protocol: First day: The patient began sitting for 15 minutes, 3 times per day. Second day: If there was no erythema of the flap or incisions, the patient increased sitting to 30 minutes, 3 times per day. Third day: The patient increased sitting to 45 minutes, 3 times per day. Fourth day: The patient increased sitting to 60 minutes, 3 times per day. Fifth day: The patient would keep advancing the amount of sitting time until the sitting time reaches 2 hours, 3 times per day.

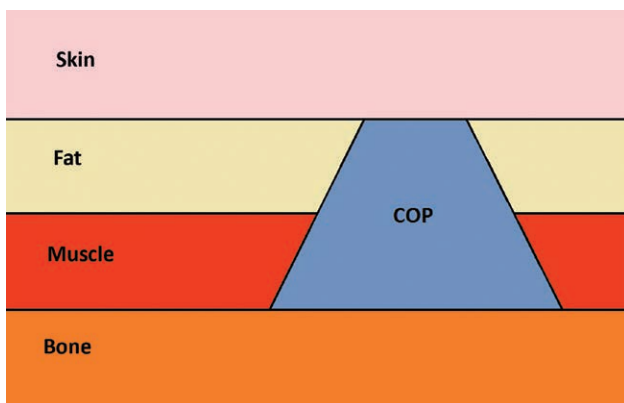


Fig. 1. The COP creates a wide undermining over bony prominences, often leaving the skin intact. This increases shearing forces.

Table 1. COP Flap Patient Demographics

| | Pt 1 | Pt 2 | Pt 3 | Pt 4 | Pt 5 | Pt 6 | Pt 7 | Pt 8 | Pt 9 | Pt 10 | Pt 11 |
|---------------|-------------------------|-------------------------|-------------------|--------------|-------------------------|-----------|--------------------------|--------------------------|--------------------------|-------------------------|-------------------------|
| Age | 27 | 54 | 67 | 55 | 69 | 41 | 42 | 38 | 31 | 35 | 22 |
| Injury | GSW; spinal cord injury | MVC; spinal cord injury | CVA; quadraplegic | Aneurysm ICA | MVC; spinal cord injury | GSW | Fall; spinal cord injury | MVC; central cord injury | Stab; spinal cord injury | GSW; spinal cord injury | Drug overdose; CVA; PVS |
| Comorbidities | Neurogenic bladder | HLD | HTN | None | HTN | None | HLD | None | None | Neurogenic bladder | None |
| Social | + Tobacco | ETOH | + Tobacco | None | None | + Tobacco | None | ETOH | None | None | Heroin |
| Location | R ischial | Sacral | Ischial | Ischial | Ishcial | Ischial | Sacral | Sacral | Ischial | Ischial | Ischial |
| Sex | Male | Male | Male | Male | Female | Male | Female | Female | | | |
| Ulcer stage | IV | IV | IV | IV | IV | IV | IV | IV | IV | IV | IV |

GSW, gun shot wound; MVC, motor vehicle accident; CVA, cerebral vascular accident; PVS, persistent vegetative state; HLD, hyperlipidemia; HTN, hypertension; ETOH, alcohol; R, right.

Table 2. Conventional Flap Patient Demographics

| | Pt 1 | Pt 2 | Pt 3 | Pt 4 | Pt 5 | Pt 6 | Pt 7 | Pt 8 | Pt 9 |
|---------------|-------------------------|--------------------|-------------------|---------------------------|---------|---------|----------------|-------------------------|-----------------|
| Age | 47 | 24 | 52 | 40 | 55 | 24 | 68 | 41 | 73 |
| Injury | MVC; spinal cord injury | Stab; quadriplegic | MVC; quadraplegic | Fall; central cord injury | GSW | Stab | Fall; SDH; DAI | GSW; spinal cord injury | MVC; paraplegic |
| Comorbidities | None | HLD | HTN | None | HTN | None | HLD | None | None |
| Social | None | None | ETOH | None | None | None | None | HLD | None |
| Location | Ischial | Sacral | Ischial | Ischial | Ischial | Ischial | Ischial | Ischial | Ischial |
| Sex | Male | Female | Male | Male | Female | Male | Male | Male | Male |
| Ulcer stage | IV | IV | IV | IV | IV | IV | IV | IV | IV |

MVC, motor vehicle accident; GSW, gun shot wound; SDH, subdural hematoma; DAI, diffuse axonal injury; HLD, hyperlipidemia; HTN, hypertension.

Fasciocutaneous flaps were used for both groups, the posterior thigh flap for ischial and the gluteal flap for sacral pressure ulcers. The parameters analyzed in the perioperative period were major complications requiring a new surgical intervention (hematomas or major dehiscence), minor complications not requiring operative intervention, patient compliance to positioning and other treatments, and complications not related to the surgery itself.

Statistical analyses were performed using the Fisher exact test method. A *P* value less than 0.05 was considered significant.

Operative Techniques

We compared 2 surgical techniques of pressure ulcer closure that differ in their ability to obliterate dead spaces. In both groups, rotation fasciocutaneous flaps were used for ischial (posterior thigh flap) and sacral (gluteus flap) pressure ulcers.

In one group (control), we used the conventional method. In this group, the flap was sutured only at the superficial layers, such as the subcutaneous layer, the dermis, and the skin. This method does not obliterate completely the undermined areas and does not decrease the overlying shear forces between the flap and the underlying bone.

In the second group, we used the COP flap. This technique is a modification of rotation fasciocutaneous flap in which a large portion of its tip is deepithelialized and inset to obliterate the undermined ulcer.

All patients were positioned prone on the operating table. After debridement with Versajet and bursectomy,

the rotation fasciocutaneous flap was harvested “a la demande” and rotated to fill the undermined area. The extent of the back cut was determined depending on the amount of flap tip required to fill the dead spaces. For all patients, flaps that were needed to fill the dead space were outlined for deepithelialization. In the conventional group, the deepithelialized area was placed within the dead space. For the COP flaps, xeroform gauze was used to bolster the 2-0 prolene mattress sutures that inset the deepithelialized flap. The bolsters were inset at least 2cm away from the wound edge to improve circulation at the suture line. A straight needle was inserted at the deepest point of the undermined area and then passed in horizontal mattress fashion through the tip of the flap and back to the normal tissues and the xeroform gauze. The stitch is tightened without excessive tension on the tissues to avoid skin necrosis. The remaining layers of the flaps of all patients were closed in the same fashion with reapproximation of Scarpa’s fascia, deep dermal, and subcutaneous layers. Patients from each group received comparable postoperative care. All the patients were placed on turning schedules with standard pressure ulcer precautions. Klinatron beds were continued for all patients for the 8 weeks during the postoperative course. The bolster sutures were left in place for 2 weeks (Figs. 2–5).

RESULTS

The 2 groups had similar demographics, nutritional status, ulcer location, and ulcer size. Before intraoperative treatment, the ulcers were similar in each group and

F2-F5



Fig. 2. Clinical case of ischial pressure ulcer. Rotational flap and obliterated space is outlined.



Fig. 3. Rotation of flap performed with deepithelialization of flap edge.



Fig. 4. Deepithelialized edge inset and sutured into place with bolsters to prevent skin necrosis.



Fig. 5. One-month postoperative result.

similar preoperative treatment was provided. In the COP group, 2 ischium ulcer patients and 1 sacral ulcer patient had local rotational skin flaps performed at community

hospitals before their transfer to our institution. In the conventional group, 2 ischium ulcer patients were treated at community hospital with local rotation skin flaps be-

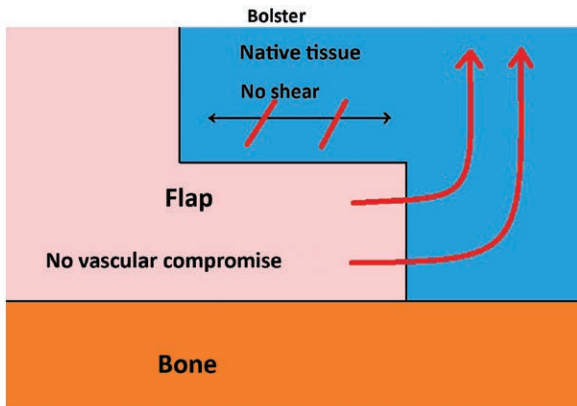


Fig. 6. The COP flap uses bolster sutures and this allows obliteration of undermined areas and reduction of shearing forces. Vascular supply is not jeopardized, and there are no foreign materials once the bolsters are removed after 2 weeks.

fore their transfer to our institution. In the COP group, the average size of the ischium ulcer was 6 cm × 2 cm or 12 cm² and the sacral ulcer was an average of 5 cm × 3 cm or 15 cm². Furthermore, the average size of the inset deepithelialized flap was 15 cm × 6 cm or 90 cm². The conventional ulcer size was 4 cm × 3 cm or 12 cm² and 4.5 cm × 3.5 cm or 15.75 cm² averaged.

Postoperative complications included positive cultures, hematomas, ulcer recurrence, and wound dehiscence. Five patients showed positive cultures (3 in the COP group and 2 in the conventional group), treated with antibiotics and negative-pressure wound therapy. Recurrences were evaluated at 16-month follow-up. Recurrence rates were 9% for the COP flap group and 60% for the conventional flap coverage group (P value < 0.001). Hematomas were the only major complication that occurred in the COP group (2 cases) and in the conventional group (1 case). Minor complications, defined as delayed healing and wound dehiscence that did not require surgical intervention, have been comparable between the 2 groups. There were similar occurrences of minor complications.

DISCUSSION

Pressure ulcers have a multifactorial pathophysiology, and the critical duration of ischemia that leads to pressure injury is variable depending on the tolerance of the tissue, ischemia, and individual predisposition.¹⁵ Importantly, in addition to the vertical pressure forces, shear forces contribute to ulcer development and recurrence. Flap selection should follow the guidelines of designing a flap as large as possible and placing the suture line away from the area of direct pressure.¹⁶ The flap should not violate adjacent flap territories so as to preserve options for coverage in the event subsequent breakdown or recurrence dictates further reconstruction.¹⁷ Fasciocutaneous flaps have been demonstrated to be as advantageous as muscle flaps in pressure ulcer reconstruction, with minor residual morbidity.^{7,17–20} Flap design and pattern of flap movement are both important and aim not to “burn bridges” for future reconstructions.¹⁹ Rotation fasciocuta-

neous flaps offer the advantage to be readvanced in case of recurrence without jeopardizing another vascular supply.¹⁶ Conventional methods of wound closure usually address the superficial soft-tissue closure, leaving shearing forces to act over the bony prominence to enlarge the undermined area. Deepithelialized flaps have been used previously for pressure ulcers, demonstrating decreased recurrence rates.^{9–13} Anchoring the flap over ischial tissues can be difficult, and bone anchors have been advocated for this purpose.¹⁰

Compared with previously described techniques, our innovative technique avoids foreign bodies with removal of bolster sutures. These sutures secure and inset the flap that eliminates shearing forces, suture ripping, and tension on superficial sutures. Also, our technique does not cause vascular compromise at the juxtaposed tissues by avoiding strangulating sutures. The COP flap can be applied to both ischial and sacral pressure ulcers, which provides padding over bony prominences without jeopardizing vascularity (Fig. 6).

Although recent publications have tried to delineate evidence-based treatment guidelines, they often lack decision-making algorithms on selecting a flap according to size and location of the ulcer.⁷ We present a new surgical technique and a defined protocol for the management of pressure ulcers. To provide the best environment for flap survival, the infection should be first controlled in the ulcer. The choice of flap should be oriented toward a large deepithelialized rotation fasciocutaneous flap because this will obliterate the dead spaces and shearing forces and can be reused in case of recurrence. The posterior thigh flap for the ischial and the gluteal flap for the sacral pressure ulcers should be the first choice in the plastic surgeon armamentarium for the treatment of these pressure ulcers.

Limitations of the study include the limited number of patients, duration of each patient’s pressure ulcer, and prior operative ulcer treatments. We found that the defect size is not a limitation to the use of the flap because big rotation flaps allow wide range of motion, recruiting enough tissue to fill the undermined areas. Another limitation is the sample size and loss of follow-up for some of our patients.

Our study demonstrates that a defined protocol to decrease bacterial overload and filling the dead spaces with the COP flap significantly reduces recurrence rates. Anchoring the flap over ischial tissues can be difficult with deep sutures and bone anchor. Our technique eliminates this difficulty. Compared with other techniques, our innovations avoid foreign bodies with removal of bolster sutures and the secured, inset flap eliminates the shearing forces, suture ripping, and tension on superficial sutures and tissues. The technique can be applied to both ischial and sacral pressure ulcers, providing padding over bony prominence without jeopardizing flap vascularity.

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