

**Prophylactic Closed-Incision Negative Pressure Wound Therapy (ciNPWT) in Breast Surgery:  
A Pilot Study on the Prevention of Surgical Site Complications**

Marco Yusef<sup>1-3</sup>, Luca Improta<sup>3</sup>, Augusto Lombardi<sup>1-3</sup>, Valeria Vitale<sup>3</sup>, Gianluca Stanzani<sup>3</sup>,  
Francesco Maria Carrano<sup>1</sup>, Virginia Di Donato<sup>2</sup>, Gianfranco Silecchia<sup>1</sup>

<sup>1</sup>Department of Medical-Surgical Sciences and Translational Medicine, Faculty of Medicine and  
Psychology, Sant'Andrea University Hospital, Sapienza University of Rome, Rome, Italy

<sup>2</sup>General Surgery Residency Program, Faculty of Medicine and Psychology, Sapienza University, Rome  
Italy

<sup>3</sup>Breast Unit, Sant'Andrea University Hospital, Rome, Italy

**Abstract**

*Aim:* Surgical wound complications remain a relevant issue in breast surgery, particularly in patients with risk factors such as obesity. Closed-incision negative pressure wound therapy (ciNPWT) has been proposed as a strategy to reduce postoperative complications, including seroma formation. However, evidence in mastectomy without immediate reconstruction remains limited.

*Methods:* A prospective observational single-center pilot study was conducted at Sant'Andrea University Hospital (Rome). Twenty-two consecutive patients undergoing mastectomy for oncologic indications were treated with ciNPWT (PICO device) and compared with a historical cohort of 40 patients managed with standard dressings. Each breast was considered an independent unit of analysis. The primary endpoint was postoperative seroma, assessed clinically and quantified in milliliters. Secondary endpoints included hematoma, skin necrosis, ecchymosis, postoperative bleeding, reintervention, and device compliance. Follow-up was performed at 7 and 14 days postoperatively.

*Results:* A total of 70 mastectomy units from 65 patients were analyzed (22 ciNPWT vs 48 controls). The ciNPWT group was significantly older ( $74.09 \pm 9.51$  vs  $65.71 \pm 14.12$  years;  $p = 0.014$ ) and had a higher proportion of axillary dissections. At 7 days, mean aspirated seroma volume was lower in the ciNPWT group ( $33.41 \pm 59.83$  mL vs  $44.58 \pm 96.49$  mL;  $p = 0.619$ ), although not statistically significant. At 14 days, the ciNPWT group showed a significantly higher seroma volume ( $59.55 \pm 78.95$  mL vs  $17.02 \pm 40.17$  mL;  $p = 0.025$ ). Secondary complication rates were comparable between groups. No skin necrosis was observed. Device compliance was 100%.

*Conclusions:* ciNPWT using the PICO device demonstrated excellent safety and tolerability. While an early trend toward reduced seroma was observed, a significant increase at 14 days suggests a possible rebound effect after device removal. Due to methodological limitations, definitive conclusions on efficacy cannot be drawn. These findings support the need for larger prospective randomized multicenter studies to clarify the role and optimal duration of ciNPWT in mastectomy patients.

**Keywords:** breast surgery, ciNPWT, PICO, mastectomy, seroma, surgical site complications