

## Post-operative seroma volume was significantly reduced in the PICO<sup>®</sup> group compared to patients in the standard care group

Results of a clinical study of patients with spinal fracture undergoing open reduction and internal fixation (ORIF) treated with a PICO single-use Negative Pressure Wound Therapy (NPWT) system or standard care



### Evidence

- Level 1 evidence
- Prospective, parallel group, randomised controlled trial (RCT) in spinal fracture with ORIF
- PICO (used for 5 days) versus standard care in a total of 20 patients



### Seroma volume under the spinal surgical wound was significantly reduced in those treated with PICO compared to standard care

- Mean seroma volume measured at day 5: PICO group 0 ml ; standard care group 1.9 ml  
*Statistically significant p=0.0007*
- Mean seroma volume measured at day 10: PICO group 0.5 ml ; standard care group 1.6 ml  
*Statistically significant p=0.024*



### Patients treated with PICO had significantly fewer dressing changes than the standard care patients

- Mean dressing changes per patient: PICO group 4.8 ; standard care group 7.9  
*Statistically significant p<0.0001*
- Mean wound care time per patient: PICO group 13.8 min ; standard care group 31 min  
*Statistically significant p=0.0005*



### Wound secretion was measured

- Wound secretion into Redon drains was similar between the 2 groups  
*Not statistically significant p=0.16*
- Wound secretion occurred for a shorter duration in the PICO group compared to the standard care group  
*Statistically significant p=0.0055*

### S.M.A.\* COMMENTS:

Seroma is a pooling of plasma or lymph fluid under a wound and is a key risk factor for surgical site infection as it collects in a “dead space”.

In this study, seroma volume was measured by ultrasound which is a high sensitivity imaging method so that even in this small study population (n=20) a statistically significant effect was found, although whether this small reduction in seroma volume is clinically relevant is unknown.

This clinical group have previously performed similar sized studies with the same endpoints in orthopaedic hip surgery to also demonstrate an impact of other NPWT devices on reduction of post-operative seroma formation.<sup>1,2</sup>

This is an example of how NPWT can affect the tissue beneath the closed incision. Previous evidence suggests that improved lymphatic drainage may be a key mechanism of action to reduce seroma formation.<sup>3</sup>

Spinal fracture with open reduction and internal fixation produces large surgical incisions with substantial manipulation of soft tissues in a wide area and large PICO dressings were used in this study. There is a recommendation to use a PICO dressing to cover the entire manipulated zone of tissue injury – not just the closed incision (suture line). The term ‘Treat the Zone of Injury’ is often used.<sup>4</sup>

Authors:	Matthias Nordmeyer, Pauser, Biber, Jantsch, Lehl, Kopschina, Rapke, Bail, Forst, Brem
Title:	Negative Pressure Wound Therapy for seroma prevention and surgical incision treatment in spinal fracture care
Aim of the study:	To evaluate the impact of NPWT on wound healing, particularly seroma formation in the wound area, in surgical internal fixation of spinal fractures compared to standard care
Study Type:	RCT
Wound Type:	Closed Surgical Incision
Speciality/Indication:	Orthopaedic Surgery – Spinal Fracture
Products:	PICO
Number of patients:	20 patients: (PICO n=10; Standard Care n=10)
Reference:	International Wound Journal (2015)   doi: 10.1111/iwj.12436   Article first published online 30 APRIL 2015
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1. Pauser *et al.* 2014. Incisional NPWT after hemiarthroplasty for femoral neck fracture – reduction of wound complications. *Int Wound J* Aug 14; 2. Pachowsky *et al.* 2012. NPWT to prevent seromas and treat surgical incisions after total hip arthroplasty. *Int Orthop Trauma* 36: 719-722; 3. Kilpadi & Cunningham 2011. Evaluation of closed incision management with Negative Pressure Wound Therapy (CIM): hematoma/seroma and involvement of the lymphatic system. *Wound Rep Regen* 19: 588-596; 4. World Union of Wound Healing Societies (WUWHS) Consensus Document. *Closed surgical incision management: understanding the role of NPWT*. Wounds International, 2016  
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