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Original article

Prevention of postoperative surgical wound complications in ankle and distal tibia fractures: results of Incisional Negative Pressure Wound Therapy

Gianluca Canton, Roberto Fattori, Emanuele Pinzani, Luca Monticelli, Chiara Ratti, Luigi Murena

Orthopaedics and Traumatology Unit, Cattinara Hospital - ASUGI, Department of Medical, Surgical and Life Sciences, Trieste University, Trieste (Italy)

Abstract

Background and aim of the work: complications in surgical wound healing represent the main postoperative complication in ankle and distal tibia fractures. Whereas the use of Incisional Negative Pressure Wound Therapy (INPWT) is recognized to have a role in wound complications prevention in prosthetic surgery, literature about its use in trauma surgery is scarce. The aim of this study was to compare the effectiveness of INWPT with a conventional dressing in order to prevent surgical wound complications in ankle and distal tibia fractures. *Methods:* The study population included patients over 65 years as well as patients under 65 years considered at risk for wound complications (smokers, obese, affected by diabetes), who underwent ORIF for bi/tri-malleolar ankle fractures or distal tibia (pilon) fractures. After surgery, patients were randomized to receive a conventional dressing or INPWT. Complications in surgical wound healing were classified in major (requiring surgical intervention) and minor complications. *Results:* 65 patients were included in the study. The rate of minor and major complications between the two groups was not significantly different, although a positive trend towards a lower minor complications rate was noted in the INPWT group (12.6% vs 34.7%). No complications or complaints were reported for the INPWT device. Conclusions: INPWT proved to be safe, well-tolerated and showed promising results in preventing surgical wound complications in ankle and distal tibia fractures.

Key words: INPWT, negative pressure, wound complications, distal tibia fracture, ankle fracture

Introduction

Ankle fractures are one of the most frequent fractures in worldwide population[1,2], accounting 10% of all fractures, with an estimated incidence in US population around 75-208 cases/100000 people per year[1,3,4,5]. On the contrary, intra-articular distal tibia (pilon) fractures are very rare (0.4-0.7% of fractures)[1,2]. Nonetheless, they deserve clinical interest for the high level of complexity and the relevant complications rate

The literature shows a bimodal age distribution of these fractures, with younger patients involved in high-energy trauma and older patients involved in low-energy trauma such as simple fall[1,4,6].

Open reduction internal fixation (ORIF) is the gold standard of treatment [3,7,8] for these fractures. Although the surgical technique is consolidated, complications in surgical wound healing - such as local infection, dehiscence, skin necrosis - still remain the main postoperative complication[9,10,11,12]. The high

complications rate negatively affects clinical results and determines a significant increase in hospital management costs[13].

According to the literature, complications in surgical wound healing range from 7.2% to 30% in ankle fractures[9,10,11,12]. In pilon fractures these complications reach up to 36% of cases[14,15]. The complication rate increases in the elderly population and in people affected by comorbidities such as smoking, diabetes and obesity[16,17,18,19,20,21,22,23]. The latter are considered to be the most important intrinsic risk factors in surgical wound healing problems. Post-traumatic soft tissues compromise, which is often severe in these fractures, represents the other main risk factor for surgical wound healing[24,25].

Detailed analysis of the general conditions and comorbidities of the patient as well as a careful evaluation of soft tissues compromise are essential to plan the best individual operative and postoperative care in order to minimize the risk of complications.

The use of Incisional Negative Pressure Wound Therapy (INPWT) represents one of the solutions reported by the most recent literature in order to reduce the incidence of wound complications[26,27,28]. Early studies about INWPT in orthopedic elective surgery report encouraging results[29,30,31]. On the other hand, the literature about INWPT use in trauma surgery is scarce[29,32,33].

The aim of this study was to compare the effectiveness of INWPT with a conventional dressing in order to prevent surgical wound complications in ankle and distal tibia fractures.

Materials and methods

A prospective cohort study was conducted at the Orthopedics and Traumatology Unit – Cattinara Hospital – ASUGI, Trieste (Italy). All patients treated with ORIF for ankle fractures (bi-malleolar, tri-malleolar, fracture-dislocations) and distal tibia (pilon) fractures between March 2018 and April 2019 were considered.

Inclusion criteria for this study were at least one of the following risk factors for surgical wound healing: patients over 65 years old, patients under 65 years but smokers or/and obese (BMI > 30) and/or diabetics.

For the selected patients, anamnestic data, BMI, information related to the mechanism of injury, skin condition after trauma and during hospitalization, therapeutic strategy, timing between injury and definitive treatment and any complications were recorded.

The fractures were immobilized in a cast in emergency room after clinical and radiological evaluation. In case of open fracture or non-reducible fracture-dislocation, patients underwent immediate temporary external fixation. The definitive treatment was planned after daily skin evaluation. All patients received enoxaparin prophylaxis during hospitalization and antibiotic prophylaxis before surgery. After definitive surgical treatment, the leg was immobilized in a short leg cast.

Afterwards, included patients were divided in two groups. One group was treated with a conventional standard dressing with sterile gauze and cotton bandage until suture removal.

The other group was treated with an INPWT portable single-use device called PICO (Smith & Nephew medical, Hull, UK). [31,34]. The post-operative cast and medications were modified in order to avoid covering of the device, as suggested by the producer to allow its proper function (fig.1).

This device applies continuous negative pressure of 80 mmHg for seven days. After this time (the working life of the device), the INWPT device was removed and a standard sterile dressing applied until suture removal.

Figure 1. Clinical picture showing the properly modified post-operative cast to avoid the INPWT device coverage

After hospital discharge, participants underwent regular clinical and radiological follow-up. During follow-up surgical wound healing was recorded. The surgical wound was considered healed in case of a well-consolidated wound, in absence of secretions and redness, with all sutures removed. Any delay or complication regarding wound healing was also recorded. Any device malfunction, incompatibility or conflict with the opportunely modified cast where recorded. Moreover, patients' compliance in terms of pain, discomfort, intolerance, rash, itching and blisters were registered at the first clinical follow-up after seven days from PICO positioning.

Surgical wound dehiscence, wound edge necrosis and surgical site infection were considered as complications (fig. 2).

Based on the need for further surgery, complications were classified as major (requiring surgical treatment) and minor complications.

Each group was first individually analyzed considering the major and minor wound complications recorded. Then the two groups were compared each other on the basis of the respective complications recorded.

Furthermore, demographic data (age and sex) and risk factors for wound healing complications (BMI, diabetes, smoking, days between trauma and surgery, presence of skin suffering) were compared between patients who developed and who did not develop complications.

Figure 2. Superficial surgical wound infection (minor complication) in a patient treated with a standard dressing. The patients received oral antibiotic therapy and multiple medications until surgical wound healed more than 1 month after surgery

Statistical analysis was conducted with IBM SPSS Statistics Software.

The continuous variables have been reported as median (Q1-Q3) and the groups were compared through non-parametric analyzes using the Mann-Whitney U test.

Categorical variables have been reported as numbers and proportions. Between-group differences in categorical variables were compared with Fisher's exact test and Chi-Square Test.

A p-value <0.05 was considered statistically significant.

Results

According to inclusion criteria, 65 patients were included in the present study. There were 43 females (66.2%) and 22 males (33.8%), with a median age of 66.0 years (56.0-73.5) and a median BMI of 26 (23-29). There were 20 (30.7%) smokers, 15 patients (23.1%) with BMI> 30, 6 diabetics (9.2%) and 37 patients over 65 (56.9%).

After surgery, 16 patients were treated with INPWT device (24.6%) whereas 49 patients (75.4%) were treated with standard dressing.

Table 1 shows the characteristics of the two populations.

Comparing the two groups, tri-malleolar fractures were significantly more frequent in the standard dressing group (p-value=0.013). Conversely, tri-malleolar fracture-dislocations were significantly more frequent in the INPWT group (p-value=0.034).

There were no statistically significant differences between the two groups with respect to demographic data, risk factors for wound healing complications and time to definitive treatment.

No device malfunction, incompatibility or conflict with the opportunely modified cast were recorded. None of the patients reported pain, discomfort, intolerance, rash, itching and blisters at the first clinical follow-up after seven days from PICO positioning.

In the population study, 19 patients (29.2%) reported one or more surgical wound complications during follow-up.

Table 1. Demographic Data, Fracture Types and Risk Factors In The General Population and in The Two Study Groups

Variable	Total n=65(100%)	INPWT n=16(24.6%)	Standard n=49(85.4%)	p-value
Age (median, Q1-Q3)	66.0(56.0-73.5)	63.5(52.3-71.8)	66.0(59.0-74.0)	.256
Sex				.766
Male	22(33.8%)	6(37.5%)	16(32.7%)	
Female	43(66.2%)	10(62.5%)	33(67.3%)	
Diagnosis				**.010**
BF	18(27.7%)	3(18.8%)	15(30.6%)	.523
BFD	9(13.8%)	4(25.0%)	5(10.2%)	.207
TF	21(32.3%)	1(6.3%)	20(40.8%)	**.013**
TFD	9(13.8%)	5(31.3%)	4(8.2%)	**.034**
PF	4(6.2%)	2(12.5%)	2(4.1%)	.252
PF+LMF	4(6.2%)	1(6.3%)	3(6.1%)	>.999
BMI (median, Q1-Q3)	26.0(23.0-29.0)	28.5(23.5-31.0)	26.0(23.0-28.5)	.110
Obesity	15(23.1%)	6(37.5%)	9(18.4%)	.170
Diabetes	6(9.2%)	2(12.5%)	4(8.2%)	.631
Smokers	20(30.7%)	5(31.3%)	15(30.6%)	>.999
Over 65	37(56.9%)	8(50.0%)	29(59.2%)	.570
External Fixation	12(18.5%)	4(25.0%)	8(16.3%)	.470
On damaged skin	8(12.3%)	3(18.8%)	5(10.2%)	>.999
Days waited before surgery (median, Q1-Q3)	4(2.0-8.0)	7.5(3.3-10.8)	3.0(2.0-7.0)	.056
Damaged skin before surgery	36(55.4%)	7(43.8%)	29(59.2%)	.387

BF: bimalleolar fracture; BFD: bimalleolar fracture-dislocation; TF: trimalleolar fracture; TFD: trimalleolar fracture-dislocation; PF: pilon fracture; PF+LMF: pilon fracture + lateral malleolus fracture

Table 2 shows the complications in surgical wound healing recorded during follow-up.

There were16 cases of surgical wound dehiscence (24.6%), 9 cases of wound edge necrosis (13.8%) and 4 cases of surgical site infection (6.2%). In 9 cases (13.8%) more than one complication was seen in a single patient. In 16 patients (24.6%) complications did not require surgery (minor complications), while in 3 (4.6%) surgery was necessary to manage the complication (major complication).

In INWPT study group, two out of 15 patients (12.6%) reported complications in surgical wound healing. One patient had a minor complication (6.3%) and one patient a major complication (6.3%) (fig. 3).

In the conventional dressing study group, 17 of 49 patients (34.7%) had surgical wound complications. There were 15 cases (30.6%) of minor complication and 2 cases (4.1%) of major complication.

There were no statistically significant differences between the two groups comparing both all complications and single specific complications (Table 2).

The difference in terms of minor and major complications between the two groups was not statistically significant. However, a clear trend towards a lower incidence of minor complications was noted in the INPWT group (30.6% vs 6.3%, *p-value* 0.091). Conversely, major complications incidence was comparable (4.1% vs 6.3%).

Table 2. Complications In The General Population And In The Two Study Groups

Variable	Total	INPWT	Standard	p-value
Complications in surgical wound healing	19(29.2%)	2(12.5%)	17(34.7%)	.119
Wound dehiscence	16(24.6%)	2(12.5%)	14(28.6%)	.318
Wound edge necrosis	9(13.8%)	1(6.3%)	8(16.3%)	.433
Infection	4(6.2%)	0(0.0%)	4(8.2%)	.565
Major complication	3(4.6%)	1(6.3%)	2(4.1%)	>.999
Minor complication	16(24.6%)	1(6.3%)	15(30.6%)	.091

Figure 3. Wound edge necrosis with hardware exposure in over 65 years old patient with severe and multiple comorbidities treated with PICO device. Surgical debridement and hardware removal was required (major complication)

Stratifying the outcomes of patients treated with INPWT dressing and those treated with standard dressing based on the type of fracture, no difference appeared statistically significant (Table 3).

Comparing the demographic data and risk factors of patients who developed wound complications and patients who did not have complications, there were no were statistically differences between the two groups (Table 4).

Discussion

Wound healing complications can be a relevant problem for the trauma surgeon in clinical practice, especially in high risk areas such as the foot and ankle. In these areas, delayed surgical wound healing or complications are very likely to occur, leading to prolonged therapies and repeated medications up to surgery for hardware removal[9,10,11,12,25].

Although open reduction and internal fixation still remains the gold standard technique for ankle and distal tibia fractures treatment[3,7,8], the range of surgical wound complications ranges from 7.2% to 30% for ankle fractures and from 20% to 35% for distal tibia fractures[9,10,11,12,13,14].

Moreover, according to the literature, surgical wound complications rate is even higher considering specific individual comorbidities - such as BMI ≥30 kg/m, age> 65 years, diabetes mellitus, smoking - or trauma related complications as soft tissues impairment after trauma and prolonged surgical time[15-24].

Anderson et al.[16] analyzed 71 patients who underwent ORIF after ankle fracture and demonstrated a 40% incidence of surgical wound complications in the elderly (age> 65 years), while only 10% of under 65-patients developed surgical wound complications.

It is also well known that smoking has a dramatic negative effect on wound healing. Nasell et al.[35] extimated that wound healing complications ratio is six times higher in smokers compared with non-smokers that underwent ORIF for ankle fractures.

In another RCT, the same authors even showed the possibilities of preventing surgical wound healing complications when smoking abstension was undertaken.

Instead, Wukich et al.[36] compared in their study patients with well-controlled diabetes versus patients with complicated diabetes, both treated with ORIF for ankle fracture, recording an incidence of surgical site

Table 3. Outcomes stratified according to the fracture type

Variable	Total	INPWT	Standard	p-value
Complications in surgical wound healing				
BF	6(33.3%)	0(0.0%)	6(40.0%)	.515
BFD	3(33.3%)	1(25.0%)	2(40.0%)	>.999
TF	5(23.8%)	0(0.0%)	5(25.0%)	>.999
TFD	2(10.5%)	1(20.0%)	1(25.0%)	>.999
PF	2(10.5%)	0(0.0%)	2(100.0%)	.333
PF+LMF	1(25.0%)	0(0.0%)	1(33.3%)	>.999
Wound dehiscence				
BF	4(22.2%)	0(0.0%)	4(26.7%)	>.999
BFD	3(33.3%)	1(25.0%)	2(40.0%)	>.999
TF	4(19.0%)	0(0.0%)	4(20.0%)	>.999
TFD	2(22.2%)	1(20.0%)	1(25.0%)	>.999
PF	2(66.7%)	0(0.0%)	2(100.0%)	.333
PF+LMF	1(25.0%)	0(0.0%)	1(33.3%)	>.999
Wound edge necrosis				
BF	3(16.7%)	0(0.0%)	3(20.0%)	>.999
BFD	1(11.1%)	0(0.0%)	1(20.0%)	>.999
TF	1(4.8%)	0(0.0%)	1(5.0%)	>.999
TFD	2(22.2%)	1(20.0%)	1(25.0%)	>.999
PF	1(33.3%)	0(0.0%)	1(50.0%)	>.999
PF+PMF	1(25.0%)	0(0.0%)	1(33.3%)	>.999
Infection				
BFD	1(20.0%)	0(0.0%)	1(20.0%)	>.999
TF	2(9.5%)	2(10.0%)	0(0.0%)	>.999
PF	2(66.7%)	0(0.0%)	1(33.3%)	.333
Major complication				
BF	1(5.3%)	0(0.0%)	1(6.7%)	>.999
BFD	1(11.1%)	0(0.0%)	1(20.0%)	>.999
TFD	1(12.5%)	1(20.0%)	0(0.0%)	>.999
Minor complication				
BF	5(27.8%)	0(0.0%)	5(33.3%)	.522
BFD	2(22.2%)	1(25.0%)	1(20.0%)	>.999
TF	5(23.8%)	0(0.0%)	5(25.0%)	>.999
TFD	1(11.1%)	0(0.0%)	1(25.0%)	.444
PF	2(66.7%)	0(0.0%)	2(100.0%)	.333
PF+LMF	1(25.0%)	0(0.0%)	1(33.3%)	>.999

BF: bimalleolar fracture; BFD: bimalleolar fracture-dislocation; TF: trimalleolar fracture; TFD: trimalleolar fracture-dislocation; PF: pilon fracture; PF+LMF: pilon fracture + lateral malleolus fracture

Table 4. Outcomes in patients with and without surgical complications

Variable	Patients with wound complications n=19	Patients without wound complications n=46	p-value
Age (median, Q1-Q3)	65.0(58.0-74.0)	66.0(54.8-73.0)	.619
Sex			.779
Male	7(36.8%)	15(32.6%)	
Female	12(63.2%)	31(67.4%)	
Diagnosis			.899
BF	6(31.6%)	12(26.1%)	.762
BDF	3(15.8%)	6(13.0%)	.714
TF	5(26.3%)	16(34.8%)	.572
TFD	2(10.5%)	7(15.2%)	>.999
PF	2(10.5%)	2(4.3%)	.574
PF+LMF	1(5.3%)	3(6.5%)	>.999
BMI (median, Q1-Q3)	26.0(24.0-29.0)	26.0(23.0-29.3)	.971
Obesity	4(21.1%)	11(23.9%)	>.999
Diabetes	1(5.3%)	5(10.9%)	.662
Smoking	7(36.8%)	13(28.3%)	.560
Over 65	11(57.9%)	26(56.5%)	>.999
External fixation	2(10.5%)	10(21.7%)	.484
Suffering soft tissue	1(5.3%)	7(15.2%)	>.999
Days before surgery (median, Q1-Q3)	4(3.0-8.0)	4(2.0-8.5)	.902
Soft tissue suffering before surgery	10(52.6%)	26(56.5%)	.791

BF: bimalleolar fracture; BFD: bimalleolar fracture-dislocation; TF: trimalleolar fracture; TFD: trimalleolar fracture-dislocation; PF: pilon fracture; PF+LMF: pilon fracture + lateral malleolus fracture

infection of 17% in uncomplicated diabetes and 30.4% in complicated diabetes respectively.

Because of the negative impact of these complications a prevention strategy should be implemented.[25].

Over the past three decades, surgeons have successfully used NPWT to treat chronic non-healing wounds or complications such as dehiscence and infections[32,33].

Several studies have documented that NPWT, when applied either on healthy or damaged skin, increases microvascular flow and stimulates edema absorption, granulation tissue formation and infectious material removal.

In 2009 Stannard at al. proposed INPWT as an option for the prophylactic management of high-risk surgical wounds in orthopedic surgery[37].

As a result, several studies suggested the use of INPWT in elective joint replacement surgery to be able to prevent wound complications and reduce healthcare costs compared to conventional dressings.

Nherera et al.[38] estimated healthcare costs related to wound complication management in hip and knee arthroplasty surgery to range from 1132 Pounds to 7955 Pounds, which would suggest the cost-efficacy application of INPWT in elective joint replacement

surgery assuming an initial price of the INPWT device of approximately 220 Pounds.

As far as trauma surgery is concerned, the major contribution to the literature comes from Stannard et al.[32, 33], who published in 2012 a RCT analyzing the INPWT role for prophylactic management of surgical wound healing in tibial plateau, tibial pilon and calcaneus fractures surgery.

The same authors in 2009 proposed a classification system to stratify patients who could have requested INPWT in consideration of their comorbidities[37]. In addition, in 2016 an international multidisciplinary consensus recommendation was published to better define the opportunity to use INPWT in order to reduce the incidence of surgical site infections[31].

The latter studies agree that the use of INPWT is recommended in patients with at least one of the following intrinsic risk factors: diabetes, ASA score> 3, advanced age, obesity, smoking, peripheral arterial disease, hypoalbuminemia, corticosteroid use, alcoholism, chronic kidney disease, chronic obstructive pulmonary disease. Other risk factors are represented by skin suffering, soft tissue damage, wound contamination, prolonged surgical time.

These recommendations have recently been validated for orthopedic trauma surgery in the meta-analysis conducted by Wang et al. in 2019[39]. The high incidence (34.7%) of wound complications in the conventional dressing group of the present study, which includes only high-risk patients, seem to confirm the validity of these recommendations.

The INPWT device used in the present study was the PICO system (Smith&Nephew medical, Hull, UK), a portable single-use device that applies continuous negative pressure of 80 mmHg for seven days. At our knowledge, there are no data available in literature neither on the use of the PICO system in orthopedic trauma surgery nor about the compatibility of this device with casts or braces.

The PICO system is cheap, safe, portable, easy to apply and manage, and its use might be considered instead of traditional INPWT systems to prevent surgical wound complications in orthopedic trauma surgery. The results of the present study demonstrate the PICO device to be safe and tolerable for the patient. Moreover, an opportunely modified cast does not affect the device efficacy.

Analyzing the population in the present study, no statistically significant differences in terms of individual risk factors for surgical wound healing between the two groups (INPWT vs standard dressing) were noted. Nonetheless, a statistically significant prevalence (p-value = 0.034) of tri-malleolar fracture-dislocation (31% vs 8.2%) in the INPWT group versus control group was noted. Some authors report that tri-malleolar fracture-dislocation pattern has the highest incidence of wound healing complications among all types of ankle fractures and fracture-dislocations (excluding tibial pilon fracture)[40,41].

Thus, there was a theoretically higher risk of developing surgical wound complications in the INPWT group. This selection bias must be considered one of the main limitations of this study and might have actually influenced the results on the effectiveness of PICO in terms of preventing surgical wound complications. However, in the present study no statistically significant differences in complications rates were found concerning fracture type. These data seem to be not aligned to other literature studies. In detail, Shao[12] et al. found a doubled-up risk of surgical site infection for unstable ankle fractures compared with stable ones. Dodson et al. established a 14.26 OR for wound complications following tri-malleolar fracture surgery, when compared to bi-malleolar fracture. Lavini et al.[41] reported surgical wound complications rate of 20% in a cohort of patients who underwent ORIF after bridging external fixation for tibial pilon fracture, according to damage control principles. These inconsistence with literature findings might be due to the small sample size. Moreover, in high risk patients affected only by unstable fracture types these differences might become more subtle.

The wound complication rate in the present study population was 29.2%, which is consistent with the incidence reported in the literature for ankle (7.2% -30%) and pilon fracture (20-36%) in the overall population[9-14]. However, being the present study population at high risk for wound complications, it should be better compared to studies specifically addressing these type of patients, that report complication rates

from 30% to 50% of cases[36]. This difference might at least in part be due to the application of the PICO device. In fact, despite there were no statistically significant difference (p-value = 0.091), INPWT group showed a considerably lower rate of minor wound complication (6.3%) compared to standard dressing group (30.6%). It is reasonable to assume the absence of statistical significance to be due to the small sample size of our cohort, as well as to the already described selection bias.

Considering major complications, there were no statistically significant differences comparing INPWT and standard dressing groups, with a rate of 6.3% and 4.1% respectively.

To be noted, the only patient (6.3%) of the INPWT group who underwent surgery for hardware removal was an extremely high-risk patients, having the following risk factors for wound healing: trimalleolar fracture-dislocation, uncontrolled diabetes, chronic kidney disease, NYHA2A chronic heart disease, peripheral arteriopathy.

According to Volgas and Stannard datas[33], in patients with risk factor for wound complications INPWT may be effective in preventing minor complications of wound healing, while it does not affect the development of major complications in ankle and pilon fractures. The present study data seem to confirm this statement.

Analyzing the surgical site dehiscence rate and infection rate as separate outcomes, surgical site infection rates of 0% in the INPWT group and 10.2% in the standard dressing group were found, while the dehiscence rate was 12.5% for the INPWT group and 28.6% for the standard dressing group. Although these differences did not result to be statistically significant, they represent a clear trend towards a better result with INPWT in these cases. Comparable findings were reported by Stannard et al., who recorded surgical site infection rate of 9.9% in the INPWT group and 18.9% in the standard dressing group (p value = 0.049), while the dehiscence rates were 8.6% and 16.5% respectively (p-value = 0.044)[33].

Although neither the present nor other studies have quantified and compared the costs between patients receiving INPWT and patients receiving standard dressing, Mullins et al[42] estimated a potential health cost savings of 5338 dollars for infections and 1586 dollars for dehiscence applying INPWT in high-risk cases

Conclusions

There are still insufficient evidences to quantify the real benefits of INPWT.

Despite no statistically significant differences were detected, we can assume that INPWT - and PICO system specifically - has shown to be a safe, well-tolerated device and a reliable option for minor wound complications prevention in patients undergoing surgery for ankle or tibial pilon fractures. Larger RCT are needed to confirm these findings and to better define individual and fracture-related inclusion criteria to recommend application of INPWT in orthopedic trauma surgery.

Conflict of interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article

References

1. Court-Brown CM, Caesar B. Epidemiology of adult fractures: A review. *Injury*. 2006;37(8):691-697. doi:10.1016/j.injury.2006.04.130
2. Court-Brown CM, Clement ND, Duckworth AD, Biant LC, McQueen MM. The changing epidemiology of fall-related fractures in adults. *Injury*. 2017;48(4):819-824. doi:10.1016/j.injury.2017.02.021
3. Court-Brown CM, Clement ND, Duckworth AD, Aitken S, Biant LC, McQueen MM. The spectrum of fractures in the elderly. *Bone Jt J*. 2014;96 B(3):366-372. doi:10.1302/0301-620X.96B3
4. Curtis EM, van der Velde R, Moon RJ, et al. Epidemiology of fractures in the United Kingdom 1988-2012: Variation with age, sex, geography, ethnicity and socioeconomic status. *Bone*. 2016;87:19-26. doi:10.1016/j.bone.2016.03.006
5. Elsoe R, Ostgaard SE, Larsen P. Population-based epidemiology of 9767 ankle fractures. *Foot Ankle Surg*. 2018;24(1):34-39. doi:10.1016/j.fas.2016.11.002
6. Beerekamp MSH, de Muinck Keizer RJO, Schep NWL, Ubbink DT, Panneman MJM, Goslings JC. Epidemiology of extremity fractures in the Netherlands. *Injury*. 2017;48(7):1355-1362. doi:10.1016/j.injury.2017.04.047

7. Y Asloum , B Bedin, T Roger, J-L Charissoux, J-P Arnaud, C Mabit - Internal fixation of the fibula in ankle fractures: a prospective, randomized and comparative study: plating versus nailing; Orthop Traumatol Surg Res. 2014 Jun;100(4 Suppl):S255-9.
8. OdedCoifman, Jason T.Bariteau, NachshonShazar, Shay A.Tenenbaum - Lateral malleolus closed reduction and internal fixation with intramedullary fibular rod using minimal invasive approach for the treatment of ankle fractures; Foot and Ankle Surgery Volume 25, Issue 1, February 2019, Pages 79-83
9. SooHoo NF, Krenek L, Eagan MJ, Gurbani B, Ko CY, Zingmond DS. Complication rates following open reduction and internal fixation of ankle fractures. *J Bone Jt Surg - Ser A*. 2009. doi:10.2106/JBJS.H.00653
10. White TO, Bugler KE, Appleton P, Will E, McQueen MM, Court-Brown CM. A prospective randomised controlled trial of the fibular nail versus standard open reduction and internal fixation for fixation of ankle fractures in elderly patients. *Bone Jt J*. 2016;98-B(9):1248-1252. doi:10.1302/0301-620X.98B9.35837
11. Schepers T, Lieshout EMM Van, Vries MR De, Van Der Elst M. Increased rates of wound complications with locking plates
12. Shao J, Zhang H, Yin B, Li J, Zhu Y, Zhang Y. Risk factors for surgical site infection following operative treatment of ankle fractures: A systematic review and meta-analysis. *Int J Surg*. 2018;56:124-132
13. Sam Peeperkorn, Stefaan Nijs, Harm Hoekstra - Why Fibular Nailing Can Be an Efficient Treatment Strategy for AO Type 44-B Ankle Fractures in the Elderly; The Journal of Foot & Ankle Surgery 57 (2018) 961–966
14. Dillin L, Slabaugh P. Delayed wound healing, infection, and nonunion following open reduction and internal fixation of tibial plafond fractures. *J Trauma*. 1986;26:1116-1119.
15. Wyrsch B, McFerran M, McAndrew M, et al. Operative treatment of fractures of the tibial plafond. A randomized, prospective study. *J Bone Jt Surg*. 1996:1646-1657.
16. Holt DR, Kirk SJ, Regan MC, Hurson M, Lindblad WJ, Barbul A. Effect of age on wound healing in healthy human beings. *Surgery*. 1992;112(2):293-297; discussion 297-8. http://www.ncbi.nlm.nih.gov/pubmed/1641768.
17. Anderson SA, Li X, Franklin P, Wixted JJ. Ankle Fractures in the Elderly: Initial and Long-Term Outcomes. *Foot Foot Ankle Int. 2009;29(12):1184-1188.*
18. Shivarathre DG, Chandran P, Platt SR. Operative Fixation of Unstable Ankle Fractures in Patients Aged over 80 Years. *Foot Ankle Int*. 2011;32(6):599-602
19. Varenne Y, Curado J, Asloum Y, Salle de Chou E, Colin F, Gouin F. Analysis of risk factors of the postoperative complications of surgical treatment of ankle fractures in the elderly: A series of 477 patients. *Orthop Traumatol Surg Res*. 2016;102(4):S245-S248
20. Yosipovitch G, DeVore A, Dawn A. Obesity and the skin: skin physiology and skin manifestations of obesity,. *J Am Acad Dermatol*. 2007;56(6):901-916.
21. Lanzetti RM, Lupariello D, Venditto T, et al. The role of diabetes mellitus and BMI in the surgical treatment of ankle fractures. *Diabetes Metab Res Rev*. 2018;34(2). doi:10.1002/dmrr.2954
22. Çeçen GS, Gülabi D, Yanik E, Pehlivanoğlu G, Bekler H, Elmali N. Effect of BMI on the clinical and radiological outcomes of pilon fractures. *Acta Orthop Traumatol Turc*. 2014;48(5):570-575. doi:10.3944/AOTT.2014.14.0073
23. Martin ET, Kaye KS, Knott C, et al. Diabetes and risk of surgical site infection: A systematic review and meta-analysis. *Infect Control Hosp Epidemiol*. 2016;37(1):88-99. doi:10.1017/ice.2015.249
24. Strauss EJ, Petrucelli G, Bong M, Koval KJ, Egol KA. Blisters associated with lower-extremity fracture: Results of a prospective treatment protocol. *J Orthop Trauma*. 2006;20(9):618-622. doi:10.1097/01.bot.0000249420.30736.91
25. Sirkin M, Sanders R, DiPasquale T, Herscovici JD. A staged protocol for soft tissue management in the treatment of complex pilon fractures. *J Orthop Trauma*. 2004;18(8):32-38.
26. Banwell PE, Musgrave M. Topical negative pressure therapy: Mechanisms and indications. *Int Wound J*. 2004;1(2):95-106.
27. Banwell P. Topical negative pressure therapy in wound care. *J Wound Care*. 1999;8(2).
28. Cooper HJ, Bas MA. Closed-Incision Negative-Pressure Therapy Versus Antimicrobial Dressings After Revision Hip and Knee Surgery: A Comparative Study. *J Arthroplasty*. 2016;31(5):1047-1052. doi:10.1016/j.arth.2015.11.010
29. Strugala V, Martin R. Meta-Analysis of Comparative Trials Evaluating a Prophylactic Single-Use Negative Pressure Wound Therapy System for the Prevention of Surgical Site Complications. *Surg Infect (Larchmt)*. 2017;18(7):810-819
30. Cooper HJ, Bas MA. Closed-Incision Negative-Pressure Therapy Versus Antimicrobial Dressings After Revision Hip and Knee Surgery: A Comparative Study. *J Arthroplasty*. 2016;31(5):1047-1052
31. Karlakki SL, Hamad AK, Whittall C, Graham NM, Banerjee RD, Kuiper JH. Incisional negative pressure wound therapy dressings (iNPWTd) in routine primary hip and knee arthroplasties: A randomised controlled trial. *Bone Joint Res*. 2016;
32. Volgas DA, Stannard JP, Obremskey W, et al. Incisional Negative Pressure Wound Therapy After High-Risk Lower Extremity Fractures. *J Orthop Trauma*. 2011;26(1):37-42.
33. Cooper HJ, Roc GC, Bas MA, et al. Closed incision negative pressure therapy decreases complications after periprosthetic fracture surgery around the hip and knee. *Injury*. 2018;49(2):386-391. doi:10.1016/j.injury.2017.
34. Helito CP, Bueno DK, Giglio PN, Bonadio MB, Pécora JR, Demange MK. Negative-Pressure Wound Therapy in the Treatment of Complex Injuries After Total Knee Arthroplasty. *Acta Ortopédica Bras*. 2017;25(2):85-88.
35. Nåsell H, Ottosson C, Törnqvist H, Lindé J, Ponzer S. The impact of smoking on complications after operatively

treated ankle fractures-a follow-up study of 906 patients. *J Orthop Trauma*. 2011;25(12):748-755.
36. Wukich DK, Joseph A, Ramirez C, Irrgang JJ, Ryan M. Outcomes of Ankle Fractures in Patients with Uncomplicated versus Complicated Diabetes. *Foot Ankle Int*. 2011;32(2):120-130
37. Stannard JP, Atkins BZ, O'Malley D, et al. Use of negative pressure therapy on closed surgical incisions: a case series. *Ostomy Wound Manage*. 2009;55(8):58-66
38. Nherera LM, Trueman P, Karlakki SL. Cost-effectiveness analysis of single-use negative pressure wound therapy dressings (sNPWT) to reduce surgical site complications (SSC) in routine primary hip and knee replacements. *Wound Repair Regen*. 2017;25(3):474-482
39. Wang, C., Zhang, Y., & Qu, H. (2019). Negative pressure wound therapy for closed incisions in orthopedic trauma surgery: a meta-analysis. Journal of Orthopaedic Surgery and Research, 14(1).
40. Dodson NB, Ross AJ, Mendicino RW, Catanzariti AR. Factors Affecting Healing of Ankle Fractures. *J Foot Ankle Surg*. 2013;52(1):2-5
41. Lavini F, Dall'Oca C, Mezzari S, et al. Temporary bridging external fixation in distal tibial fracture. *Injury*. 2014;45(S6):S58-S63. doi:10.1016/j.injury.2014.10.025
42. Mullins A, Paulos M. Cost effectiveness model: comparison of closed incision management using negative pressure and standard of care over clean closed incisions based on a 2012 randomized controlled trial. Value Health. 2012;15(4):A68

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Correspondence:
Roberto Fattori,
Orthopaedics and Traumatology Unit, Cattinara Hospital – ASUGI, Department of Medical, Surgical and Life Sciences, Trieste University, Strada di Fiume 447, 34149, Trieste (Italy).
Phone number: +39 0403994730
Fax number: +39 0403994544.
E-mail address: roberto.fattori@hotmail.com