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

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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 INPWT 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 population1,2, accounting 10% of all fractures, with an estimated incidence in US population around 75–208 cases/100000 people per year3,5,8. On the contrary, intra-articular distal tibia (pilon) fractures are very rare (0.4–0.7% of fractures)3,8. Nonetheless, they deserve clinical interest for the high level of complexity and the relevant complications rate.
complications rate negatively affects clinical results and determines a significant increase in hospital management costs\textsuperscript{13}.

According to the literature, complications in surgical wound healing range from 7.2\% to 30\% in ankle fractures\textsuperscript{8,10,11,12}. In pilon fractures these complications reach up to 36\% of cases\textsuperscript{14,15}. The complication rate increases in the elderly population and in people affected by comorbidities such as smoking, diabetes and obesity\textsuperscript{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\textsuperscript{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 (INWPT) represents one of the solutions reported by the most recent literature in order to reduce the incidence of wound complications\textsuperscript{26,27,28}. Early studies about INWPT in orthopedic elective surgery report encouraging results\textsuperscript{29,30,31}. On the other hand, the literature about INWPT use in trauma surgery is scarce\textsuperscript{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 INWPT portable single-use device called PICO (Smith & Nephew medical, Hull, UK). \textsuperscript{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 INWPT device coverage.
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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 opportune 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 opportune 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 2 shows the complications in surgical wound healing recorded during follow-up.

There were 16 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 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                             |                  |                    |                      |         |
| Male                            | 43(66.2%)        | 6(37.5%)           | 16(32.7%)            | .766    |
| Female                          | 22(33.8%)        | 10(62.5%)          | 33(67.3%)            |         |
| Diagnosis                       |                  |                    |                      |         |
| BF                              | 18(27.7%)        | 3(18.8%)           | 15(30.6%)            | .010    |
| 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               |                  |                    |                      |         |
| On damaged skin                 | 12(18.5%)        | 4(25.0%)           | 8(16.3%)             | .470    |
| Days waited before surgery      | 4(2.0-8.0)       | 7.5(3.3-10.8)      | 3.0(2.0-7.0)         | .056    |
| (median, Q1-Q3)                 |                  |                    |                      |         |
| 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
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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.3,10,11,12,25.

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.3,5,8,11,12,13,14.

Moreover, according to the literature, surgical wound complications rate is even higher considering specific individual comorbidities – such as BMI ≥30 kg/m², 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 estimated 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 2. Complications In The General Population And In The Two Study Groups**

| Variable                        | Total (29.2%) | INPWT (12.5%) | Standard (34.7%) | p-value |
|---------------------------------|---------------|---------------|------------------|---------|
| Complications in surgical wound healing | 19            | 2             | 17               | .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)
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%) | >.999   |
| 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
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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 infections32,33.

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 surgery37.

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.

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                             |                                       |                                          |         |
| Male                            | 7(36.8%)                              | 15(32.6%)                               | .779    |
| Female                          | 12(63.2%)                             | 31(67.4%)                               |         |
| Diagnosis                       |                                       |                                          |         |
| 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
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.\textsuperscript{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\textsuperscript{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\textsuperscript{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\textsuperscript{> 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\textsuperscript{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)\textsuperscript{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\textsuperscript{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.\textsuperscript{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\textsuperscript{5, 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\(^6\). 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 patient, having the following risk factors for wound healing: tri-malleolar fracture-dislocation, uncontrolled diabetes, chronic kidney disease, NYHA2A chronic heart disease, peripheral arteriopathy.

According to Volgas and Stannard data\(^3\), 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)\(^3\).

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\(^6\) 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.

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